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Chair

Mrs. Joy Smith

Standing Committee on Health

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● (1530)

[*English*]

The Chair (Mrs. Joy Smith (Kildonan—St. Paul, CPC)): Good afternoon, everyone. Welcome to the health committee today. I'm so glad everyone could be here.

I would like to welcome the Public Health Agency of Canada. Of course, Dr. Butler-Jones is no stranger to this committee. I understand Robert Pless, program director, is with him as well today.

I understand, Dr. Butler-Jones, you can stay until five o'clock. Is that correct?

Dr. David Butler-Jones (Chief Public Health Officer, Public Health Agency of Canada): Shortly before.

The Chair: Thank you.

Then we have the Department of Health, Elwyn Griffiths, director general. Welcome.

We also have from GlaxoSmithKline Canada, Paul Lucas. Welcome, Paul. I'm so glad you could come to our committee.

We also have two more. From Sanofi Pasteur, we have Rob Van Exan, the director of immunization policy; and we're going to have a video conference from Vancouver with Susan Fletcher, who's with the Vaccination Risk Awareness Network. Welcome to all of you.

Having said that, we're going to have five minutes for a presentation from each person, then we'll go into the regular questions and answers for seven minutes. That allows our committee to ask some more questions.

Dr. Butler-Jones, could you begin, please.

Dr. David Butler-Jones: Certainly. Thank you, Madam Chair.

Good afternoon, Madam Chair and members of the committee.

[*Translation*]

It's a pleasure to be here today to explain our plans for the H1N1 vaccine campaign for the fall flu season.

[*English*]

The second wave of H1N1 flu is here. We have worked hard together preparing for this wave, but our plans will only succeed if Canadians realize they and their families need to be vaccinated and take steps to do so. It's clear to me that vaccination is the most effective way of preventing the spread of any kind of flu, including this strain.

We know that Canadians have a lot of questions about the vaccine. Here are just a few examples: they want to know whether it's safe, whether it's been properly tested, whether it will work, and if the vaccine can give them the flu.

[*Translation*]

Those are good questions and we have good answers.

[*English*]

To begin, on Wednesday last week we made a very important announcement: we announced that the H1N1 vaccine has performed as we expected it would in clinical testing and that it is safe and effective. This announcement meant that we can start administering the millions of doses of this vaccine that have already been shipped to every province and territory. Now the provinces and territories can start administering the vaccine according to the plans for their own jurisdictions; in fact, the vast majority of the provinces are starting today.

Even though the H1N1 vaccine has been authorized, we don't expect the questions about its safety to stop. But the more Canadians know, the more they will trust the vaccine and see the merits of being immunized. It isn't easy to get that message across while battling the many myths out there. Over the last two weeks I've travelled with the minister, and we have met with Canadians and heard their concerns about the vaccine, about this disease, and we've answered their questions.

[*Translation*]

The average Canadian has to be reassured that the vaccine is safe or they won't be in line to be vaccinated when the program starts in their community.

● (1535)

[*English*]

We have ordered enough vaccine for every resident of Canada, but they have to be persuaded they need to get it. They have to understand that a vaccine will not only keep them from getting sick, but it will also prevent them from spreading it someone else, who will then spread it to yet another person.

Because this is a new strain, there's very little immunity to it, and we know that in some people it can be fatal. Already 86 people who have contracted this virus have died from it, and hundreds more have required intensive care.

We've been preparing for a pandemic influenza outbreak for several years. A contract has been in place with GlaxoSmithKline to ensure that every Canadian has access to a safe and effective vaccine. The Government of Canada facilitated the bulk purchase of the vaccine on behalf of the provinces and territories. Production began immediately after seasonal flu production runs were complete. That strategy was recommended by the WHO, the World Health Organization.

A handful of countries may have had access to H1N1 vaccines for some of their citizens before us. However, our bulk purchase means that we will be able to secure enough vaccine for every Canadian who needs and wants it—and few countries can say that. As I mentioned earlier, millions of doses have already been shipped to about 80 locations in the east, west, and northern parts of the country.

As you know, on the recommendation of the WHO, most of the vaccine being produced contains an adjuvant. The adjuvant boosts the immune system's response and makes it more effective, especially if the virus mutates during the fall flu season or into the spring. The adjuvant also allows faster production because it uses less of the antigen, the material that gives us the immunity.

The adjuvant's safety and efficacy have been proven. It has been used in Canada's H1N1 vaccine and it's made of natural products: oil, vitamin E, and water. This adjuvant has been safely tested on 45,000 people worldwide, and similar adjuvants have been used in millions of people. Adjuvant has been used since the 1920s and is included in such common vaccines as tetanus, hepatitis A and B, and diphtheria vaccines. Adjuvanted vaccine is the type of the vaccine we recommend for the vast majority of our population, and it is the vaccine that's available now.

The unadjuvanted vaccine is what we generally recommend for pregnant women until we have more clinical data. In the meantime, before the unadjuvanted vaccine is available, women more than 20 weeks pregnant and women in earlier stages of pregnancy with risk factors for severe disease should consider getting the adjuvanted vaccine.

While the order for 1.8 million does of unadjuvanted vaccine being produced by GSK is still on target for early November, we felt that given the increase in cases of H1N1 across the country, it would be prudent to offer pregnant women earlier access to an unadjuvanted vaccine. Today the Minister of Health announced that we had secured an additional supply of 200,000 doses of vaccine from Australia.

This vaccine has been approved for use by health regulators in Australia and the United States. Barring any distribution delays, this additional supply that's manufactured by CSL Australia will be available to the provinces and territories next week.

The fact that it comes from the southern hemisphere is an important point. While we in the northern part of the world were dealing with H1N1 over the summer in small amounts, the southern hemisphere was in the midst of its winter flu season. Australia was therefore one of the first countries in the world to offer the vaccine to the general population. We've learned a great deal from their efforts and about this vaccine.

Following the immediate distribution of the vaccine, Health Canada and the Public Health Agency of Canada will monitor the safety and effectiveness of the vaccine on an ongoing basis to help ensure the safety of pregnant women. It's important to note that some 600,000 people have already received this vaccine in Australia.

It is crucial that pregnant women consider the benefits of being immunized. The safety of the vaccine is of the utmost importance. So we will keep monitoring the vaccines for adverse events.

[*Translation*]

The Public Health Agency of Canada and Health Canada continue to monitor vaccines after they are authorized for use, with an eye to their future use .

[*English*]

We have comprehensive mechanisms in place to allow for rapid reporting of adverse events following immunization. In addition to existing surveillance systems, a pan-Canadian surveillance and risk management plan will be implemented to provide even more accurate reporting of adverse events.

We've also invested in the Pan-Canadian Research Network, a joint initiative between the Public Health Agency and the Canadian Institutes of Health Research, which links some 80 scientists in 30 institutions across Canada. This network will strengthen Canada's capacity to help evaluate the safety and effectiveness of the H1N1 campaign and programs.

Through the national immunization strategy, the Public Health Agency of Canada continues to work with provinces and territories to monitor and evaluate the immunization programs and to assess the need for any actions or additions or changes to the existing national strategy.

This is the largest immunization campaign in Canadian history. So it's important that we maintain our communication with all Canadians. The government has been working with the provinces and territories to assist with their public information campaigns and to ensure consistent delivery of information and resources across Canada. That collaboration also helped us develop the *Your H1N1 Preparedness Guide*, a comprehensive guide to information about this virus.

● (1540)

[*Translation*]

The guide is available online and it is being distributed through Canada Post outlets and can be ordered through 1-800-O-Canada.

[*English*]

We have been collaborating with key public health stakeholders, such as the Society of Obstetricians and Gynaecologists of Canada, the Canadian Paediatric Society, and other key stakeholders to develop fact sheets and immunization promotion materials to encourage immunization among at-risk populations. We have often said that knowledge is the best defence against this virus.

[*Translation*]

One of our most important tasks now is to share that knowledge.

[*English*]

Thank you, Madam Chair.

I look forward to answering all of the questions.

The Chair: Thank you, Dr. Butler-Jones.

Now we'll go to the Department of Health and Elwyn Griffiths, director general.

Dr. Elwyn Griffiths (Director General, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Department of Health): Thank you very much for this opportunity to speak to the committee.

As you've already heard from Dr. Butler-Jones, Health Canada authorized Arepanrix on October 21. This is the adjuvanted vaccine manufactured by GSK, GlaxoSmithKline, for use against the H1N1 flu virus. This authorization was made under an interim order.

An interim order is issued by the Minister of Health under the authority of the Food and Drugs Act in rare situations when the minister believes that immediate action is required to deal with a significant risk, direct or indirect, to human health, to public safety, or the environment. This interim order enabled Health Canada to authorize the vaccine based on human clinical data available at the current time. Based on Health Canada's review of the available data on quality, safety, and efficacy—in this case, its immunogenicity—and given the World Health Organization's declaration of an influenza pandemic and its risk to human health, Health Canada considers the benefit-risk profile of the vaccine as favourable for immunization against a pandemic strain.

Canada, like many other countries worldwide, exercises tight regulatory oversight over all vaccines, because they're usually given to very large numbers of healthy individuals. All vaccines made available to Canadians are subject to a strict authorization process conducted by Health Canada, the regulatory authority in Canada. In order to fulfill its mandate, Health Canada—which is the regulator, as I said—works in collaboration with the Public Health Agency of Canada, which itself provides health advice to Canadians.

To put the regulatory system into perspective, I'll very briefly describe some of Health Canada's activities on the vaccine side, activities that apply to a whole range of different vaccines, not just to the pandemic one. This is for the child and adult populations.

Prior to the approval of a new vaccine, the manufacturer must file a submission with scientific and clinical evidence demonstrating that the vaccine's health benefits outweigh the risks and that the vaccine is effective and suitable for use in Canadians.

Clinical trials that take place in Canada must also be approved by the regulator before their commencement. However—and I think this is quite important—it is not necessary for trials to be conducted in Canada in order for a vaccine to be eventually authorized here. Adherence to internationally accepted standards of good clinical practice helps ensure that clinical trials conducted in other countries meet the same high standards of evidence needed to support authorization in Canada. With clinical trials, the issue is the quality of the science, not where the science has been done.

All clinical data, regardless of where the trials are conducted, will be evaluated with data from laboratory and animal studies as well. Furthermore, as part of the overall approval processes, Health Canada conducts an evaluation of the manufacturer's facilities to assess the quality of the vaccine manufacturing process and determines the manufacturer's ability to carry out the necessary quality control studies on the vaccine. The manufacturer must also provide samples of the vaccine for testing by Health Canada.

Once the evaluation is completed, and if the conclusion is that the benefits of a vaccine outweigh any potential risks, then the vaccine is granted market authorization and can be sold in Canada. After approval, however, Health Canada continues its regulatory oversight by conducting its own independent testing as part of a lot release program before each lot is released onto the market. An inspection of the manufacturer's facilities is also conducted regularly—at least every two years—to make sure they're following the very best practices for drug manufacturing.

Potential adverse events with the vaccine are also monitored, this time by the Public Health Agency of Canada through active and passive surveillance. However, there are unique challenges associated with the development and regulatory evaluation of influenza vaccines. Each year the influenza vaccine must be remade to reflect the strain of the virus the WHO believes will be circulating that year. The time between the completion of the manufacturing and the need to get the vaccine into the arms of Canadians to provide immediate protection is always short. Health Canada works closely, therefore, with manufacturers to help minimize any delays.

While challenges are the norm in dealing with influenza vaccine regulation, these are magnified in a pandemic situation considerably. Influenza pandemics are actually caused by novel strains that have not previously circulated. A key challenge the regulatory authorities worldwide have had to deal with—this is not peculiar to Canada—is how to conduct clinical evaluation for safety and efficacy of a vaccine in the absence of disease and prior to the start of a pandemic. You cannot just manufacture or test a vaccine against a disease that doesn't yet exist.

● (1545)

For this reason, both Health Canada and the Public Health Agency of Canada have been proactively preparing for a pandemic for several years. The Canadian pandemic influenza plan has built in a balance between the need to provide access to a pandemic vaccine in a timely manner and the need to gather as much information as we can on vaccine quality, safety, and effectiveness.

A key component of this preparatory work has been close collaboration with the contract vaccine manufacturer GSK to complete as much of the process as necessary for the evaluation of a pandemic vaccine in advance of the declaration of a real pandemic. In this period, what you might call the pre-pandemic period, Health Canada evaluated potential pandemic or mock H5N1 avian vaccine that was produced by the manufacturer, and this enabled Health Canada to inspect the vaccine manufacturing facilities and review results from both animal and human studies with the mock vaccine. These activities were performed to assess the quality, safety, and efficacy of the vaccine, which all contribute, really, to the overall safety of the product. The idea was that the development of a regulatory evaluation of the prototype vaccine would facilitate the approval of a pandemic vaccine once the pandemic stream was identified and production started.

The GSK adjuvanted vaccine consists, as we've already heard, of two components, an antigen and the adjuvant. The antigen is the active component, an ingredient in the vaccine, or the immunizing part, which provides protection against the virus. The adjuvant is a substance added to the vaccine to boost the immune response. Adjuvanted vaccines may also provide broader cross-protection against mutating flu virus strains. Adding the adjuvant contributes also to what is called dose sparing, which allows for larger amounts of the vaccine to be produced because less antigen is used.

During the pre-pandemic period, the safety and effectiveness of the adjuvant to be used with the vaccine was assessed by both Health Canada and other regulatory agencies worldwide. Clinical trials on the adjuvant were conducted in the United States, Canada, Europe, and so on, and included over 13,000 patients. Data from additional trials conducted by GSK in Europe, which combined this same adjuvant with a seasonal influenza vaccine, were also assessed. Now overall, this adjuvant has been evaluated in around 40,000 to 45,000 individuals worldwide. No serious safety concerns regarding the use of the adjuvant have been detected.

A similar adjuvant has been used safely in Europe since 1999 in an influenza vaccine manufactured by the company Novartis, which is a licensed vaccine. Furthermore, the World Health Organization held a consultation early in June, from all the world regulators, on the safety of the adjuvanted vaccine, the conclusion of which was that there were no significant safety concerns or barriers to the use of adjuvanted vaccines in the current H1N1 virus situation.

In Canada, the pandemic vaccine file is what's called a rolling submission, which means that Health Canada has been reviewing data on an ongoing basis—as it becomes available, essentially—and it will continue to do so and review any additional information from the ongoing studies immediately upon receipt.

Quality, which means the chemistry and manufacturing of the vaccine, are the data that are used to indicate that the vaccine is produced with the H1N1 strain and it has been manufactured in accordance with the usual high standards expected of vaccines in Canada. Safety information for the H1N1 vaccine has been reviewed from studies in animals as well as clinical studies in around 900 individuals, to ensure that the vaccine has an acceptable safety profile for use in humans, and that the vaccine produced is an adequate immune response.

Both the safety of the antigen and adjuvant were considered. However, because it was recognized that the vaccine would need to be made available before extensive safety studies could be completed, additional studies and surveillance will continue post-market in order to detect any change in the incidence of adverse events or special interests, such as Guillain-Barré syndrome or any other rare adverse events. GSK's clinical development plan includes trials across Europe, the United States, and Canada, and it will also include resulting safety and effectiveness data in a further 10,000 people, approximately.

Data from clinical trials have become available globally during the authorization process. Using similar or related pandemic vaccines was also considered in this period. Clinical trial results from the United States, Europe, Australia, and China supported vaccine safety and effectiveness, and with no serious adverse events—we looked at all those as well. Canadian clinical trials of the GSK H1N1 pandemic vaccine are under way, and promising early results have already started to come in to us.

● (1550)

As you have already heard, a non-adjuvanted H1N1 pandemic vaccine is also being manufactured by GSK as part of its contract with the Government of Canada. Health Canada is also reviewing available data to support the quality, safety, and efficacy of this non-adjuvanted version as it becomes available.

Now, maximizing the quality, safety, and efficacy of vaccines is well recognized as really an essential component of any successful immunization program. Vaccines have an excellent safety record. However, we all know that rare adverse events cannot be detected until the vaccines are given to very large numbers of individuals. And these occur even when the very best regulatory controls are in place. There are instances where adverse events may occur following immunization. So further investigation is key, really, to determining if the reaction was directly or causally, as we say, related to the vaccine or not. This is an important way of investigating this.

Due to the uniqueness of the pandemic situation, all of the safety and clinical effectiveness data regularly required were not available at the time of licensure. This is the case in Canada and in all other jurisdictions. Major regulatory agencies, including Health Canada, have developed review processes specifically as part of their pandemic planning. As a result, a carefully designed post-market surveillance plan is a critical component in order for Health Canada and the Public Health Agency to monitor the safety and effectiveness of the vaccine and to communicate any adverse events following immunization in a very timely manner.

Now, a pandemic is a global issue that requires collaborative international response. It's not peculiar to Canada. As noted previously, Health Canada and the Public Health Agency, in close collaboration with other national regulatory and public health authorities, have been preparing for many years to deal with this situation. So between 2006 and 2007, Health Canada initiated and hosted regulatory preparedness workshops with the U.S. Food and Drug Administration and the World Health Organization. These workshops resulted in the development of what is now called the WHO guidelines on regulatory preparedness for human pandemic influenza vaccines and the creation of a global network of about 10 influenza vaccine regulators. These are the key global regulators.

Since the H1N1 virus emerged, the WHO has been hosting biweekly telephone conferences with this vaccine regulators network. In addition, Health Canada has been participating in biweekly multilateral discussions with the USFDA, the European Medicines Agency, the Australian Therapeutic Goods Administration—the regulator in Australia—and Japan to discuss clinical development plans and pharmaco-vigilance of the H1N1 vaccines.

Most importantly, there is a global commitment amongst this group to share clinical and safety data on the H1N1 vaccines in real time. This enables countries to maximize the amount of data available to support vaccine approval and rapidly share information on potential adverse events following immunization. This has already started and will continue to inform vaccine policy decisions worldwide as time progresses.

Vaccines are only authorized if the benefits outweigh any risks, be they real or theoretical. In the case of the H1N1 pandemic vaccine, as part of the authorization the manufacturer is required to submit and adhere to a risk management plan. The plan includes a list of adverse events of special interest, such as Guillain-Barré syndrome, which would develop by consensus between the WHO and major regulatory authorities around the world, and these adverse events will be monitored when the vaccine is rolled out.

The manufacturer will also be required to continue conducting clinical studies and to submit monthly safety reports to the government. The continued clinical trials will focus on assessing vaccine safety and effectiveness especially in specific population groups. And all lots of pandemic vaccine will be tested in Health Canada laboratories before they are released for the Canadian market.

Let me conclude by saying that the regulator has not really cut corners in the regulatory process here to verify the safety and effectiveness of this vaccine. A lot of work has gone into evaluating this vaccine.

Thank you very much.

● (1555)

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

Now we will go to Paul Lucas, who is the president and chief executive officer of GSK.

Mr. Lucas.

Mr. Paul Lucas (President and Chief Executive Officer, GlaxoSmithKline Canada): Thank you, Madam Chair. Thank you for the opportunity to appear today to share with you GlaxoSmithKline's update on H1N1. I'd like to make two key points.

First, we are fortunate in Canada to be home to a world-class vaccine production facility in Sainte-Foy, Quebec, as it provides a domestic and secure supply of H1N1 vaccine. All vaccines supplied by GSK in Canada will be manufactured here at our facility in Quebec.

Second, as a result, GSK's H1N1 vaccine production is on schedule and will meet the timeline set out in our Government of Canada contract, and Canada will be one of the first countries in the world to secure enough pandemic vaccine to cover its entire population.

[*Translation*]

Canada will be one of the first countries in the world to have enough vaccine against the flu pandemic to immunize its entire population.

[*English*]

GSK is a long-standing partner with governments across Canada and around the world in delivering life-saving medicines and vaccines. Our presence here goes back more than one hundred years. We are a top 15 contributor to R and D, investing more than $156 million in 2008 alone. We have facilities in several provinces, and we employ more than 3,000 people across the country.

GSK is the largest bio-pharmaceutical employer in Canada and the only company in Canada with a full influenza portfolio of pandemic vaccine, pre-pandemic vaccine, seasonal vaccine, and antivirals.

GSK began planning for pandemic production as far back as the nineties. Today we're applying our extensive global knowledge—again, from years of research, innovation, and investment—to the development of a safe and effective H1N1 vaccine. Over the past four years, GSK has invested globally approximately $5 billion in developing technologies and in increasing the capacity at our manufacturing sites.

[*Translation*]

Since acquiring ID Biomedical in 2005, GSK continued investing here in Canada and it invested $200 million in the centre at Sainte-Foy to triple production capacity and almost double the filling capacity, and nearly $50 million at Laval for research and development for North America.

[*English*]

As Canadians, we're fortunate to be assured this domestic security of supply, which, as I said earlier, will come from GSK's Quebec facility. Let me assure you that we take this responsibility seriously. Dedicated people across our Canadian and global organizations are collaborating with the Canadian government to provide a safe and effective supply of H1N1 vaccine in Canada and around the world.

While our initial focus is on the Canadian population, GSK has also allocated 20% of production in Canada to developing countries, including an intended donation of 50 million doses to the WHO. GSK's dedicated pursuit of innovation in this area put us on the leading edge when the H1N1 virus emerged. An example is GSK's ASO3 adjuvant technology.

Adjuvants enhance protection against challenging pathogens like H1N1. An adjuvanted vaccine can help to protect against the risk of a virus changing during a pandemic. It is also possible to produce more doses of vaccine faster, which ensures that more people around the world get access, all key elements to a successful global pandemic response.

In short, influenza is our business and our expertise. GSK's H1N1 vaccine production is on schedule, and Canada will be one of the first countries in the world to secure enough pandemic vaccine to cover its entire population.

GSK has been working closely with industry experts and government since the WHO first identified in late April the pandemic potential of the H1N1 virus. We began H1N1 vaccine development in late May upon receipt of the seed strain from the WHO. Production of H1N1 began following completion of our seasonal vaccine, as per guidance issued by the WHO and SAGE. Since then, GSK has initiated clinical trials at more than 150 sites around the world. To date, more than 2,600 people have received GSK's H1N1 vaccine in global clinical trials.

Canada's program began this month. More than 2,000 Canadian volunteers will be vaccinated, including healthy adults, the elderly, and children, including infants.

The adjuvant system in our influenza vaccine has been tested in more than 40,000 people globally in pandemic and seasonal influenza programs. GSK strongly supports the WHO's call for post-marketing surveillance of the highest quality, and we are sharing information from safety and effectiveness studies with the appropriate regulatory authorities on a regular basis.

Now that regulatory approval is achieved, dissemination of the H1N1 vaccine to Canadians will require continued collaboration. GSK will continue to support governments, public health, and health care providers who will administer the vaccine to ensure the success of the largest mass vaccination program in our history. I'd like to acknowledge the challenging and excellent work done by all involved, including the planning by the Canadian government as far back as 2001.

In closing, I want to assure members that GSK has embraced the responsibility entrusted in it. We take it very seriously and are committed to delivering to Canadians through their governments.

Thank you. I welcome your questions.

● (1600)

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

We'll now go to Sanofi Pasteur, Mr. Rob Van Exan, on immunization policy.

Please proceed.

Mr. Rob Van Exan (Director, Immunization Policy, Sanofi Pasteur): Thank you, Madam Chair and members of the committee, for your invitation to Sanofi Pasteur to be at your proceedings today. I am honoured to represent the 1,100 employees of Sanofi Pasteur who research, develop, and manufacture vaccines in Canada.

Our company's commitment to public health dates back to 1914 in this country. As Connaught Laboratories, a name many of you may remember, our company has played an integral role in many Canadian breakthroughs, including the first production of insulin in 1921, a significant role in the development of Salk vaccine during the outbreaks and epidemics of the mid-1950s, and in the global eradication of smallpox.

Our experience over the years with public health threats suggests the key to dealing with infectious disease threats is collaboration, and it's collaboration among governments, industry, non-governmental organizations, and academia. And having world-class facilities located in this country enhances the ability of this government to collaborate.

We are now part of the sanofi-aventis Group, a global pharmaceutical company with leadership in vaccines. Our Connaught campus in Toronto develops and manufactures vaccines for Canadians and the world. Each year we invest approximately $100 million in vaccine R and D alone, and a total of $200 million in research in Canada, making us one of the largest investors in research in this country.

Sanofi Pasteur's Connaught campus in Toronto currently manufactures 10 vaccines, all of which were researched and developed right here in this country. The Toronto site has a global mandate for these products and exports close to half a billion dollars' worth of vaccine each year. Sanofi Pasteur has invested over $350 million dollars in its production and R and D facilities at the Toronto campus in the last decade, and this includes a new $100 million R and D facility, which is under construction as we speak.

I appreciate your calling on Sanofi Pasteur's knowledge of immunization and vaccines in your committee's research and I would like to acknowledge, on behalf of Sanofi Pasteur, the successful milestone announced last week by the Canadian government and GlaxoSmithKline. The successful regulatory release in Canada of the first lots of pandemic H1N1 vaccine is a significant step forward in providing Canadians with protection from the H1N1 virus, which is currently circulating in this country.

Sanofi Pasteur is the world's largest influenza vaccine manufacturer, producing an estimated 40% of the total world demand for seasonal flu vaccine at our facilities in the U.S. and in France. We are playing a lead role as a pandemic supplier in the U.S. and many European countries and have committed to donating 100 million doses of H1N1 vaccine to the WHO for emergency use in developing countries. Our company is not currently supplying pandemic vaccine in Canada, although we have supplied annual inter-pandemic vaccines for decades.

Influenza vaccine is unlike other products our company makes. It is the only vaccine that changes every year in response to changes in the circulating virus. Some influenza strains are much harder to produce than others. Unpredictability in both the capacity and the timing of influenza vaccine supply from year to year and manufacturer to manufacturer is part of the nature of making influenza vaccine.

Because new vaccine production adaptations and strain formulation must be undertaken each year to meet the needs of regular annual influenza programs, influenza vaccine supply has a greater degree of unpredictability than the supply of any other vaccine. For this reason, our company has always advocated having two sources of supply of influenza vaccine to ensure production back-up capacity should one supplier experience production delays or difficulties and to ensure delivery of initial doses of vaccine in a timely manner to maximize program effectiveness.

● (1605)

Having access to more than one source of supply can likewise be important in a pandemic situation. Canada has chosen to focus on a single Canadian supplier of pandemic vaccine as a means of enhancing security of vaccine supply during a pandemic. Canada should also consider having a second supplier, with global expertise and capacity for influenza vaccine manufacturing outside of Canada, with a strong manufacturing, filling and packaging capacity inside Canada. This would provide Canada with the best of both worlds and would maximize pandemic vaccine security of supply. Strong public health policy for immunization in general should recognize the critical strategic importance of its Canadian-based manufacturers to the safety and security of its people when it comes to disease prevention and secure access to vaccines.

According to the WHO, existing and emerging infectious diseases are a threat to national and global security. Canadian policies that foster an environment that strengthens Canadian vaccine innovation and encourages investment in vaccine manufacturing capacity in Canada will go a long way to increasing the safety and security of its people by ensuring timely access to vaccines against existing and emerging diseases.

Thank you very much. I'd be pleased to respond to any questions you may have about Sanofi Pasteur's operations.

The Chair: Thank you very much for your presentation, Mr. Van Exan.

We'll now go to video conference via Vancouver. We're presenting now Ms. Susan Fletcher from the Vaccination Risk Awareness Network.

Good afternoon, Susan. Can you hear me?

Ms. Susan Fletcher (Researcher and Board Member, Vaccination Risk Awareness Network Inc.): Can you hear me now?

The Chair: My greetings to you. Please start with your presentation.

Susan, you must have muted your microphone.

Ms. Susan Fletcher: Hello? Can you hear me now?

The Chair: We can hear you now.

Welcome to the committee. We're so glad you're alive and well; just don't press any buttons.

Thank you.

Ms. Susan Fletcher: I'm new to this, as you might imagine.

The Chair: Susan, we have five minutes for your presentation, then you'll be a part of our question and answer session. It's a seven-minute round, and people can direct questions to you after your presentation. First, give us a five-minute presentation, and then we'll go into our round.

Can you start now?

● (1610)

Ms. Susan Fletcher: Thank you for the invitation.

In six months, 80 Canadian deaths have been linked to swine flu, also known as H1N1. During that time, almost 20,000 have been linked to diabetes. Immunologist Bart Classen, MD, MBA, provides evidence that vaccines may cause or contribute to both type 1 and type 2 diabetes. Even if vaccines were the source of only 1% of all diabetes cases, they would be much more lethal than H1N1 has been. Unsurprisingly, most of those who have been seriously ill or died from the swine flu have had underlying conditions like diabetes. VRAN contends that it would have been logical to focus most resources on the underlying conditions rather than the virus.

Categories of people highly recommended to have the vaccine include infants, pregnant women, and those with immune-suppressing health conditions. In his article, “Swine Flu: To Vaccinate or Not?”, Marc Girard, MSc, MD, consultant in drug monitoring and pharmaco-epidemiology, declares this to be criminal nonsense. Those are exactly the categories that are most likely to experience vaccine adverse events.

The Public Health Agency of Canada has reassured the public that the vaccine will be safe, when it cannot possibly know that this is true. This summer Dr. Elwyn Griffiths, director general of the biologies and genetic therapies directorate, revealed that a vaccine trial of a mere 100 to 200 Canadians would be enough to allow approval of the vaccine. I don't care what Dr. Griffiths says; I think Canadians need to be trialed, not somebody from Europe, Australia, or wherever. In fact, the trials had just begun the week the vaccine was approved, the week immediately before the first dose might be injected.

The GSK adjuvant ASO3 is the most worrisome ingredient in the vaccine. The book *Vaccine-A*, by award-winning journalist Gary Matsumoto, discusses oil-based adjuvants, especially squalene. Referring to 1970s UCLA research, he reveals that “rats injected with either squalene or squalane all developed experimental encephalomyelitis, an MS-like disease”.

ASO3 contains squalene. This month physicians and advisers of the German military have nixed the approved H1N1 vaccines containing squalene and thimerosal, which is also a concern. Perhaps the powerful immune stimulation from squalene was on the mind of microbiologist Karl Weiss when he was interviewed for an article in the September 25th edition of the *Montreal Gazette*. Aaron Derfel reported that Weiss was certain that "For those who have been confirmed to have been infected by H1N1, getting the vaccine would not be a good idea. That's because their immune systems could overreact horribly." This raises the question of how many Canadians would be at risk from the vaccine because they've already become infected with the virus, many without confirmation by testing or without realizing that they had an infection.

In his article, "How Vaccines Can Damage Your Brain", retired neurosurgeon Russell Blaylock, M.D., CCN, declares same-day multiple injections criminal. He warns of research showing that a priming effect on brain immune cells by an initial vaccination may be followed by an extreme overreaction of these cells if a second vaccination is administered up to a year later. How much more overreaction will Canadians' brain cells suffer with the addition of yet another vaccine to the recommended schedules?

The aims of VRAN are threefold: fully informed consent to vaccination, an easily accessible and unbiased vaccine adverse event monitoring or event reporting system, and a national no-fault compensation plan. IMPACT, Immunization Monitoring Program ACTive, is conflicted by its sponsorship from a profession that earns wages through administration of vaccines and by its monitoring of opportunities to introduce new vaccines.

● (1615)

To Canada's shame, it's one of only a few developed countries without a national compensation plan. The excellent no-fault compensation report drafted many years ago by the Manitoba Law Reform Commission serves only to gather dust.

The Chair: Thank you very much, Susan.

Now we're going to go to our first round of seven minutes of questions and answers.

We'll ask Dr. Duncan to begin.

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

Good afternoon, everyone. Thank you for being here and for your time and effort.

I don't know whether I'm allowed to ask this, but on what date was the vaccine ordered? Am I allowed to ask that?

The Chair: You can ask anything you want, Dr. Duncan.

Ms. Kirsty Duncan: Thank you.

Dr. David Butler-Jones: We signed the contract with the predecessor to GSK some eight or nine years ago.

Ms. Kirsty Duncan: For H1N1.

Dr. David Butler-Jones: That was for any pandemic vaccine.

As soon as the seed strain was available and the seasonal was done, GSK started producing vaccine. It didn't matter when we ordered it; we already had a contract for all of the first doses.

I can't remember what the date was, but it doesn't matter. It was August or—

Ms. Kirsty Duncan: Was it August 6?

Dr. David Butler-Jones: I can't remember.

Paul, do you remember?

Mr. Paul Lucas: That would be approximately right.

Ms. Kirsty Duncan: When was the order date for the non-adjuvanted vaccine?

Dr. David Butler-Jones: It was later that month.

Ms. Kirsty Duncan: It was later in August.

Did we have data for how the H1 adjuvanted vaccine would impact pregnant women?

Dr. David Butler-Jones: When will we have data—

Ms. Kirsty Duncan: No, did we have data for how the H1N1 vaccine with the adjuvant might impact pregnant women?

Dr. David Butler-Jones: There have been no clinical trials for pregnancy. You don't normally do that.

Ms. Kirsty Duncan: I'm aware.

I'm struggling with the fact that we know pregnant women have fared poorly during past pandemics and I'm wondering why a non-adjuvanted vaccine was ordered at a later date.

Dr. David Butler-Jones: Basically the only reason we ordered a non-adjuvanted vaccine was because of the recommendation in July from the advisory committee at WHO. They recommended to offer non-adjuvanted vaccine if you have it available. They also recommended that if you don't have non-adjuvanted to use adjuvanted. Many European countries are only using adjuvanted vaccine.

We have no concerns about the vaccine or the adjuvant itself.

Ms. Kirsty Duncan: I guess I'm struggling, and I know pregnant women are struggling, with being told to take the unadjuvanted vaccine unless the cases of H1N1 are increasing in their communities and the unadjuvanted vaccine is unavailable.

I've had e-mails all weekend on this, including from a friend who worked in pandemic preparedness for many years. She's 21 weeks pregnant—she's over that 20 weeks by one week—and she's agonizing over whether to take the adjuvanted vaccine or wait for the unadjuvanted vaccine. The minister has said it's up to Canadians to get the facts on the vaccines. She has done her research. She's spoken to six obstetricians, and she doesn't know what to do.

Dr. David Butler-Jones: Both we, from an epidemiological standpoint, and the Society of Obstetricians would suggest that she get the vaccine.

Ms. Kirsty Duncan: She should take the adjuvanted vaccine?

Dr. David Butler-Jones: That she be offered the adjuvanted vaccine.

Ms. Kirsty Duncan: She has to make the decision.

Dr. David Butler-Jones: Obviously a vaccination is a voluntary act in this country.

Ms. Kirsty Duncan: Right.

When will the non-adjuvanted vaccine be available?

Dr. David Butler-Jones: It should be available next week, barring some distribution problems.

Ms. Kirsty Duncan: So it should be in the provinces by next week?

Dr. David Butler-Jones: Correct.

Ms. Kirsty Duncan: The PHAC website says that people should not take the vaccine if they've had a previous anaphylactic reaction to any element of the vaccine or a hypersensitivity to eggs. How are people expected to know the components of the vaccine?

● (1620)

Dr. David Butler-Jones: They are told about the vaccine at the time they get it. That is part of it. Most people will be asked if they have had a severe allergy. They will be asked if they've ever reacted to an influenza vaccine or to thimerosal.

Now, the unadjuvanted vaccine we've ordered from CSL also has antibiotics in it: neomycin and garamycin. They are not in the other vaccines but they are in this one. So they would also be asked about an allergy to those antibiotics.

Ms. Kirsty Duncan: Is there concern about the adjuvant having fish oil?

Dr. David Butler-Jones: No. If you're wondering about the issue of allergy, adjuvants with fish oil in them have been used in millions of people without that being a concern.

Ms. Kirsty Duncan: I met with people this past Friday. They were public health officials. I asked the question specifically around allergy and the paperwork that's required to roll the vaccines out. I had one answer from one group and another answer from another group. I think that speaks to the confusion that still exists.

Dr. David Butler-Jones: What was the advice you were given that was different?

Ms. Kirsty Duncan: One group of health officials was actually surprised that there was fish oil in the adjuvant. They didn't know. The other group—

Dr. David Butler-Jones: Well, they will. It will be in the materials they receive that have been rolling out through the provinces in terms of the product monograph, etc. They would be expected to read those materials before they actually immunize anybody. I'm surprised. Perhaps they don't watch the news.

There are materials that will be going with the product that nurses and others will read. I don't know if these are officials who actually give immunizations or just people who are working in public health. The materials are there. The materials will be there.

Public health units, every year, do immunization against influenza. This is another influenza vaccine. The only difference is the addition of the adjuvant that improves immunity. There are not issues with allergies with this adjuvant.

Ms. Kirsty Duncan: I have one other concern. The adjuvant—

The Chair: Dr. Duncan, your time is up.

We'll go to Mr. Malo right now.

[*Translation*]

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

My question is addressed to Mr. Griffiths. The vaccine was authorized for distribution and administration in Canada after studies that were done in Europe. We know that the Europeans began to vaccinate their population well before we did. Consequently, I wonder what the guideline followed by Health Canada was when it authorized the vaccine on the basis of studies done in Europe although it waited, nonetheless, later than Europe to begin distributing the vaccine.

[*English*]

Mr. Elwyn Griffiths: The issue with authorizing on data generated in Europe is not quite true. It's a whole package of data, which I tried to express. The data from Europe was really on the efficacy of the H1N1; that was the early data coming in. The safety package was primarily from the H5N1, which has been tested in Europe and the United States and in Canada as well.

So the data are coming in, to start with from Europe, but there are data from Canada. There are safety data coming in from Canada as well. It's the same vaccine. So you cannot wait to get the data from Canada as well; you already have the data from European studies.

I think that's what you're asking.

● (1625)

[*Translation*]

Mr. Luc Malo: Are you telling me that the vaccine administered in Canada is exactly the same as the vaccine being administered in Europe? This does not match the information that I received. Mr. Lucas, could you tell me if it's really the same vaccine?

[*English*]

Mr. Paul Lucas: With respect to the vaccine in Canada, the vaccine is basically the same as the one GSK makes in Europe. The only small difference is a slight difference in the manufacturing process, but for all intents and purposes it's the same vaccine.

[*Translation*]

Mr. Luc Malo: Ms. Fletcher put a number of questions regarding the adjuvant, and regarding comments made by Mr. Griffiths on the number of candidates who were tested. Would you like to clarify the statements made by Ms. Fletcher?

[*English*]

Mr. Elwyn Griffiths: Could I answer that one?

I think she was referring to a group trial of 130 in Europe. It's bigger than that; there are two trials there. It's actually double that. I think the figures may have been mixed up somewhere. It's not just 130. There are two studies done in Europe with slightly different concentrations of the adjuvant and the antigen, essentially, so the numbers are not quite correct.

On the safety side, as I did explain originally, there is a whole safety database. For adjuvanted vaccines, it's H5N1, and then you switch over to the H1N1 virus for the actual efficacy part.

I think Paul wants to add to that.

Mr. Paul Lucas: As for the safety of the H1N1 adjuvanted vaccines, you would anticipate it to be the same as the H5N1 adjuvanted vaccine that has been approved in Europe. When you look at all of the adjuvanted vaccines, H5N1, H1N1, and adjuvanted seasonal vaccines, there are over 40,000 people who have been vaccinated with that adjuvant.

Mr. Elwyn Griffiths: With the annual seasonal flu vaccine, which is licensed, all that happens every year is that there's a strain change. There is a small clinical study of the same size that takes place. Some of them are in Europe, some of them are in Canada. Every year, it's the same. It's following the same pattern. There's nothing special about this.

[*Translation*]

Mr. Luc Malo: We heard comments from officials of the agency last week who said that pregnant women could, up to a certain stage, use the vaccine with the adjuvant. I simply wonder why 200,000 doses of vaccine without adjuvant were ordered from the Australian company CSL.

It does not seem clear to me. I feel that contradictory messages are being sent out from one week to the next. I think that it would be important to have one single clear message.

Dr. David Butler-Jones: It is the same message. The vaccine without the adjuvant is preferable because we have less data about the vaccine with the adjuvant during pregnancy. This is an option for women. This week and last week, the recommendation was the same, i.e. less than 20 weeks. The risk for pregnant women is the same as for other women of the same age group. However, after 20 weeks of pregnancy, the risks go up almost four-fold. If the illness is present in the community, the risk is greater than the theoretical risk of the vaccine.

[*English*]

The Chair: Thank you, Dr. Butler-Jones.

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

● (1630)

Ms. Judy Wasylycia-Leis (Winnipeg North, NDP): Thank you, Madam Chair, and thanks to all of you for your appearance here today.

I think the overriding purpose of this meeting is to get some clarity around testing and surveillance. If we are trying to get more Canadians interested and committed to taking the vaccine, then we have to be able to answer those questions. The more transparent and open we can be about what tests have been done and where, the better. I think obviously there was a change in the federal government, Health Canada, and the Public Health Agency's strategy vis-à-vis release of the vaccine, because it was on October 6 that your own handout suggested:

> Because the current H1N1 strain has not been a component of any previous influenza vaccine, it presents unknown factors that could require changes to the standard manufacturing process for vaccines. Tests will be conducted to confirm basic information on the vaccine. A small clinical study with humans will also be conducted to establish the safety of the vaccine.

Based on that, the minister said repeatedly in the House that it would probably not be until November 1 that she would be able to authorize the vaccines, depending on those studies. Clearly, some shortcuts were taken and a decision was made to actually approve the vaccine without some of the studies that were indicated in this handout that went out publicly. I'd like to know how the normal regulatory process has been short-cutted and modified.

What clinical studies, what preclinical trials, can you tell us about today that have been done in Canada or internationally, separate and apart and independent from the company GSK, which is producing the actual vaccine?

Mr. Elwyn Griffiths: Could I first clarify the point about the timing?

I think the idea was—and Dr. Butler-Jones can help me with this one—that we didn't want to say we were going to be able to have a vaccine available in mid-October when we weren't really sure we would be. The conservative approach was to say November. However, the data that we were waiting for—some quality data and some early data in terms of the actual efficacy—came in early from GSK, so we could actually look at those data early on, much earlier than we had expected. There was no point, then, in waiting another month or so to move forward. Basically, the data were in early, we could evaluate those data, and everything looked fine.

As to the data you're asking for on the safety, as with all vaccines and all drugs, usually the manufacturer conducts all these activities. There are other activities now going to take place with already licensed vaccines, and the Public Health Agency will be doing some of these studies. Usually these are not done prior. It's usually the manufacturer that does these particular studies, because it's not a publicly available product, essentially.

Do you want to comment on that, Paul?

Ms. Judy Wasylycia-Leis: While you're commenting on that, let me just make the comment that the original document from the government said, in the section that I read, this testing will take approximately six weeks. So for it to be modified to one or two weeks is quite a significant leap.

Besides what you can tell us about your testing, I'm still curious to know what steps have been left out and why, and what studies have been done independent of GSK. In fact, that's the hallmark of our health protection model in Canada. We have prided ourselves in the past that the precautionary principle will prevail. I know we're talking about a risk management model here, and we understand that, and I'm not trying to dissuade anyone from taking the vaccine, but I think we'll have a fuller uptake if people fully understand what studies have been done and what risks are involved.

Mr. Paul Lucas: I can comment, first of all, on the clinical trials that we're doing on H1N1. We're doing 16 clinical trials around the world.

Just to the point about studies being done in Canada, those 16 trials will include over 10,000 subjects, and 2,000 of those will be Canadian—

Ms. Judy Wasylycia-Leis: Could I interrupt for a second? I appreciate this and I'd love to get it, but my time is limited. Mainly what I'm asking for is what studies have been done independent of the company, because I don't know how otherwise we can actually measure it. I take GSK's word for it, but I think we've always based our conclusions on independent scientific surveillance of existing drugs or vaccines.

● (1635)

Mr. Elwyn Griffiths: Not really. When products are licensed in Canada, the data from the manufacturer is usually assessed. It's not an independent assessment. It may involve independent investigators, which is a different issue, but it's all manufacturers' data.

Dr. David Butler-Jones: There are independent researchers who are contracted to do the research, but it is from the company. But it is transparent; the regulator sees all the data, good or bad, with it. So that's not an issue.

We are doing additional trials, and again, to be clear in terms of when we were talking before about what was planned, that has not changed. Nothing has been short-cut. But what we found is that after one dose there was good immunity. The six weeks would be required for two doses and the results of two doses before you'd know.

In Canada we have said, and I've been saying from the beginning, that we were working to have it available as soon as possible in terms of safe and effective vaccine, confident about the beginning of November. Nothing was shorted. The only additional thing the regulator might look for is immunity data following the second dose, etc., which would not change the decision about when to immunize.

Ms. Judy Wasylycia-Leis: Can I ask, then, how you make decisions about dosage for, say, young children less than three years of age, when GSK's own report says there is no data, no experience in children less than three years of age, and also with respect to elderly people? And I could go through the list.

In regard to pregnant women, "No data have been generated in pregnant women with Arepanrix™ H1N1 nor with the prototype ASO3 adjuvanted H5N1 vaccine."

The Chair: Dr. Butler-Jones will have to answer your question, Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: I'd just like some answers to those questions.

Dr. David Butler-Jones: Those trials are coming in, and it really relates to dose. The recommendation from our expert committee, because of seasonal flu, was that normally children who are under the age of 10 need two half doses in order to produce immunity. From the initial trials, it looks like maybe one dose will be sufficient. So that's actually good news, but you shouldn't wait to start protecting people until you know whether you need one or two doses. If you know you need at least one, you start with that, and then you make the decision about a second dose when you have that information, which is starting to come in now.

The Chair: Thank you, Dr. Butler-Jones.

I'm sorry, did you want to add something?

Mr. Elwyn Griffiths: Could I add on to that?

There were data also from the prototype vaccine in the younger age groups coming in as well.There were half doses there, so we did have an idea coming in for that. The reason we went forward so quickly was that we could see from this first dose that there was sufficient immunity to go on; otherwise, we would have had to wait until November to get the results of the final study.

The Chair: Thank you for adding that, Dr. Griffiths.

We'll now go to Ms. McLeod.

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

Certainly it always strikes me that the older we are the better memories we have of significant diseases from our past that have impacted our families and communities. I think sometimes we forget how important these developments have been, and we tend to lose sight of what happens without immunization, the haemophilus being one that I clearly remember—very grave.

What Dr. Kumar said here a week or two ago when he talked about seeing a couple of young people in his intensive care unit with preventable diseases struck home to me. In a way, his image was very powerful. I think we forget about herd immunity and how well people are protected by the majority taking the vaccine.

Having said that, my first question would be for Dr. Griffiths. Could you elaborate a little bit further in terms of the process for our authorization? Of course, we Canadians, I've noted, in the media have compared ourselves with the United States and said they're earlier. Perhaps you could talk a little bit about the different processes between Canada and the United States.

Mr. Elwyn Griffiths: The process is not much different. They went forward in the United States; they decided to go for an unadjuvanted vaccine. I can't speak to the details they have. The manufacturers clearly had provided them with sufficient information for them to make a strain change from their seasonal vaccine into their pandemic vaccine, and so that enabled them to license early. But licensing is quite a different thing from actually producing sufficient vaccine for general use. The fact that they can license something doesn't necessarily mean that they have enough material to produce.

In Canada, though, we were actually going for this. We can only work on the data that are submitted to us. The regulator has to wait for data to come in from the manufacturer. As we've just discussed a few minutes ago, we were waiting for data to come in before we could actually license this product.

If there were a situation in Canada, for example, where this disease got really severe in September, then an emergency use order would likely have been instigated, run into an order. You really have to balance the absolute need for the product, in this case for the pandemic early on, versus waiting for data. I think you judge it by how much information you really need, and then you balance what the need is for the vaccine and move forward.

● (1640)

Mrs. Cathy McLeod: Dr. Butler-Jones, would you care to comment about the differences between the two countries, the U.S. and Canada?

Dr. David Butler-Jones: Each country, really every country in the world, is trying to address this as best they can with the tools at hand. The Americans chose to go with an unadjuvanted vaccine. We, along with most of the Europeans, chose an adjuvanted vaccine. In our view, it has greater prospects for better immunity, as well as making additional vaccine available internationally as a result of that.

To get back to your thing, immunization has transformed the face of childhood. When I was a kid, hospitals were full of kids with the complications of measles, whooping cough, and polio, etc. We've essentially wiped that out.

In the context of this disease that we're facing now, basically there are only two ways to stop the pandemic: either we're not immunized, and so all of us who are susceptible get it—so potentially 10 million of us—or we're immunized. There have been concerns, because back in 1976 there was not actually a pandemic but a large number of Americans were immunized. So you were facing a non-disease and there were about 12 per million people immunized who developed Guillain-Barré. That is set against a background of 10 to 20 per million every single year who get Guillain-Barré from some other cause, mostly campylobacter and other infections, and we have not seen that since. It's not clear whether it was even related to the vaccine of the day, given that it's pretty much the background rate.

If we don't immunize, we will see between 400 and 700 cases of Guillain-Barré from disease, from influenza, because the rates are 40 to 70 per million, not the one per million of severe risk, plus 100,000 in hospital, thousands dead, etc. So the risk ratio in terms of vaccine is very simple: the risk of not being immunized is huge.

Mrs. Cathy McLeod: Of course we have the adjuvanted vaccine, and as you look at it, it seems like very innocent kinds of ingredients. I'm sure it would require a lot of technical talk, but what is it about rose oil or fish oil and water and oil that create that? Again, it might be a little too technical.

Dr. David Butler-Jones: Oh no, it's just go figure.

Manufacturers of vaccines have been using adjuvants since the 1920s. A common one has been alum. Partly it's recognizing it and trying different things and finding that it actually increases a person's immunity with a smaller dose. So in terms of the trade-offs, you actually need less virus to produce a vaccine that allows us to develop immunity and protection against it.

I don't know whether you can speak to how it was discovered, but they're constantly trying different things so we can actually improve immunity.There are other things that can improve immunity, which people do, but in a vaccine that's actually our best strategy.

Mr. Paul Lucas: That captures it pretty well. It's like drug discovery and vaccine discovery. It's a lot of trial and error and a little bit of design, but eventually you find something that actually works.

Dr. David Butler-Jones: Actually, the discovery of vaccination in the first place, you might remember, was for smallpox, and it was the recognition that women working as milkmaids seemed to be protected against smallpox, having had cowpox. They tried infecting people with a bit of cowpox virus and the funny thing was that those people didn't get smallpox. So it really is exploring nature for hints as to things that can make a difference.

● (1645)

The Chair: Thank you so much, Dr. Butler-Jones.

We'll now go into our second round, which is five minutes with questions and answers.

We'll begin with Mr. Oliphant.

Mr. Robert Oliphant (Don Valley West, Lib.): Thank you to all of you for being here with us today. There seems to be so much intelligence at that end of the room I'm surprised it's not on a 45-degree angle.

My goal today will be to get the intelligence that's in here out into the public. You may explain this to us at great length, but it seems to me there is increasing, as opposed to decreasing, confusion in the public that is of great concern to me.

I listened to *Cross Country Checkup*, and on that program I heard a number of people calling yet again to raise the same issues: pregnant women at different periods in their pregnancy, people facing autoimmune disorders as well as people facing immunodeficiency disorders, people with quite different problems.

Dr. Gardam, from Ontario's public health agency, was quite successful at answering some people's questions. But as we follow the public opinion polls, actually seemingly less take-up of the vaccination is going to happen than more.

So I have concern that the information you have and are sharing with us is somehow not getting out to the public. My concern on that is what I would consider a relatively passive approach to the public campaign that we're doing. I think you've worked well. Anything in medical research involves probabilities. Anything in medical research and public health has to do with "our best guess at this time is for people to do such-and-such", based on history and probability and medical research, etc. I'm not trying to say that research hasn't been done well enough. I am hoping it has been.

What I am concerned about is the fact that the public is less and less inclined to take this vaccination. And I want to point out two difficulties I'd like comments on.

One concern is that when it says that things are available to be distributed online or at Canada Post outlets or through a 1-800 number, that to me is a passive approach. Unlike the government's economic action plan, which is in every household, every day, all the time on the television, I am not seeing this activity.

For instance, in Britain, "Catch it, Bin it, Kill it" is a very simple approach. I didn't know I was supposed to throw out my tissue right away. I've been using this one for half an hour. I just saw this. I now know that I should throw this out. It's not a prop. It really has been used.

The Chair: Excuse me, Mr. Oliphant. You might have to prove that.

Mr. Robert Oliphant: This is an active campaign. I think we're missing something about the way we need to tackle this problem.

So that would be the first question I have, which is a concern that either Health Canada or the agency is not getting this out actively, simply, and appropriately.

The second part of that is that I have a great fear that your concern with at-risk populations is actually counterproductive, because at-risk populations are at risk from someone like me, who is not at risk. If I don't get vaccinated because I think I'm not going to get really sick because I'm not at risk, then I am putting in jeopardy the health of someone else with whom I am going to come in contact.

The Chair: Might the doctor answer some of your questions, because you have about a minute and a half left.

Mr. Robert Oliphant: Okay. My concern is the passive and at-risk populations.

Dr. David Butler-Jones: First of all, it's far from passive. The minister and I have been out several times a week now. Any newspaper you pick up.... I just picked up one of the local *Metro* papers, and there are two ads in there, one from Ontario and one from us. We are coordinating with the provinces. There are materials out there. Friends are telling me that they're getting tired of waking up to my voice on the radio or seeing me—and provincial medical officers and others, as well—on television.

We printed 1.2 million preparedness guides, and 885,000 have already been distributed. We're printing another two million. The fightflu.ca website is currently getting one hundred hits a second.

You will see more ads rolling out over the next while as we move into the immunization campaign. It's hard to avoid us, actually. It has not been a passive campaign in any way.

Mr. Robert Oliphant: But the take-up is going down.

● (1650)

Dr. David Butler-Jones: No. There is a survey that suggests that it is 51%. Surveys in the summer suggested that as few as 30% were going to be immunized. It depends on the day. That survey was done before we started ramping up and before the vaccine was actually available.

On your point about those who are not at risk putting others at risk, whether it's health care workers or individuals who are healthy, the priority is to get them in early in terms of the highest risk of severe disease. But at the end of the day, we have vaccine available for every single Canadian to protect not only themselves but those around them.

The Chair: Thank you.

We'll go to Mr. Uppal.

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

Last week I actually asked a question of Health Canada about information, because information is so important, especially when we're talking about confidence in the vaccine itself. People need to know. I asked them about information getting to different cultural communities in different languages. I was pleased to hear that they understood that provinces were doing that. They were translating literature into different languages. Municipalities were also doing that. I was actually more pleased to hear that Minister Aglukkaq and, I believe, Dr. Butler-Jones will be on a conference call with various ethnic media outlets later this week. Something is being arranged. I'm pleased that this is going ahead so that different languages will have the benefit of getting that information directly from the minister and you.

Dr. Griffiths, have you been working with the provinces and territories on your pandemic plan from the beginning?

Mr. Elwyn Griffiths: Yes, we've been working for many years, right from 2001 or even before that, with the Public Health Agencies and with the provinces. This is not new. The idea that a pandemic was going to come sometime was well known. So there has been preparation all along.

Mr. Tim Uppal: That's very good. Thank you.

Dr. Butler-Jones, I notice that you made public the pandemic preparedness kits last week. What are your plans to ensure that they're received by Canadians across the country?

Dr. David Butler-Jones: There's a range of distribution methods available. All the ads talk about where people can get that information and how they can get it. They don't have to go to the website themselves. They can phone the number and have the information mailed out to them.

We're taking the advice of communications experts. I'm not an expert on that; I know how to talk, but I wouldn't claim to be a communications expert. We've been following their advice as to timing to get things out so that people have and retain the information they need at the point when they need to make decisions. Before having the vaccine, it was important to know about coughing into sleeves, avoiding other people, and so on. That's been the focus of the messaging.

As I think I've said before the committee before, people tell me that they can tell the Canadians in international airports, because they sneeze or cough into their sleeves, whereas that's not true elsewhere. In fact, the British and others have asked us for our materials and what we've been using so they can modify it. We're learning from each other as we go.

Mr. Tim Uppal: I was very interested to hear that Australia has already gone through its flu season. What have we learned from Australia?

Dr. David Butler-Jones: There are a few things, not just from Australia but from other countries in the southern hemisphere. Their first wave coincided, essentially, with their normal flu season. They saw a real burden on their ICUs, for example. They saw a similar pattern of disease. In other words, there was a large percentage of disease in the very young and there was the impact that has. We've not seen a change in the virus yet. Influenza is unpredictable. We don't know when the virus might mutate into a slightly different strain. Again, that's one of the reasons we have an adjuvanted vaccine, primarily, in Canada that potentially can protect against changes in the virus itself.

Mr. Elwyn Griffiths: On the issue of the virus changing, mutating, changes have been detected recently in the Netherlands, but they're not affecting the antigenicity at the moment. The vaccine is working okay, but I think things are moving in the virus. We don't know where it will take us. Maybe it won't change too much, but they're already detecting some changes in the virus.

The Chair: Dr. Butler-Jones, you have to leave.

Dr. David Butler-Jones: I do apologize. I suspect I will be back.

I thank you all for your questions and participation.

The Chair: Thank you for being here.

Please continue. You have about 45 seconds.

● (1655)

Mr. Tim Uppal: There has been some controversy with respect to the seasonal flu shot. Do you advise people to get it before or after the H1N1 shot?

Mr. Elwyn Griffiths: There are no data to say that you shouldn't have it. The idea would be that if you're going to have it at the same time, have it on different arms. There's no real data to say that you shouldn't have it at the same time.

Mr. Tim Uppal: So you can get both.

Mr. Elwyn Griffiths: Yes, you can get both.

The Chair: Thank you, Dr. Griffiths.

We'll now go to Monsieur Dufour.

[*Translation*]

Mr. Nicolas Dufour (Repentigny, BQ): Thank you very much, Madam Chair. I thank all the witnesses for having come here today.

I found what Mr. Oliphant was saying just now extremely interesting regarding the interest in the vaccine and the advertising campaign. We heard a lot about the very good work done by Health Canada—there is no doubt about that—but at the same time, we see that people are very reluctant to get the vaccine. I must say that I participated in several activities in my riding during the weekend and many people are still afraid of getting vaccinated.

Each side has its arguments, and we hear contradictory arguments from health professionals who do not exactly agree on the vaccine as such and on the need for vaccination. Ms. Fletcher mentioned this a while ago.

I would like to know, Mr. Lucas, how to answer that question and what you think of Ms. Fletcher's arguments with regard to vaccination.

[*English*]

The Chair: Who did you direct that to?

[*Translation*]

Mr. Nicolas Dufour: My question is addressed to Mr. Lucas.

[*English*]

The Chair: Please go ahead, Mr. Lucas.

Mr. Paul Lucas: First of all, I can say that I'm going to get vaccinated. As Dr. Butler-Jones explained, the benefits far outweigh the theoretical risks of getting vaccinated. I'm not a physician, so it would probably not be appropriate for me to take that answer any further.

Perhaps Dr. Griffiths could comment.

Mr. Elwyn Griffiths: I think there's no question of the benefits of immunization here in relation to the risks. Regarding the risks of a pandemic influenza, we don't know how it's going to develop. At the moment it's been fairly quiet in the first round. The second round could be much worse. We don't know how it's going to go.

It's a very unpredictable virus that's coming. We do know that it's not behaving like seasonal flu virus. People think it's just like the seasonal flu. In humans it's actually affecting deep in the lungs, in younger people. This has been mimicked, incidentally, for those of you who are interested in models. The ferret is the model for flu. It's doing the same thing in ferrets. This virus damages the lungs considerably. It's a nasty virus. We don't know why it's behaving this way.

This is the problem. We're really seeing a virus evolving, and we don't know which way it's going to go. Yes, the benefits far outweigh the risks here.

To your point from earlier about people forgetting, nowadays we don't have diphtheria or tuberculosis. I gave a talk six or seven months ago to a public audience, and I started my talk by showing a picture of my grandfather and a photograph of my aunt, my mother's sister. I never knew either of them. My grandfather died of tuberculosis before I was born, and my aunt died of diphtheria. You don't hear of that so much now.

We were talking about polio earlier on. Somebody in the audience came out and said they were working on polio with Connaught, which is quite interesting. People forget that these diseases do have devastating effects on communities when they roll out. They're preventable diseases.

I think when you roll out with large populations of millions, there will be some instances where somebody thinks the vaccine has caused some damage, an allergy or something. It's very important to investigate those and make sure they're not causally related. It may be embarrassing, but we need to know. It's all planned that we look at these things and build up the confidence as we roll out.

The Chair: Ms. Fletcher, you can intercede at any time.

Ms. Susan Fletcher: I didn't know that.

● (1700)

The Chair: Please go ahead.

Ms. Susan Fletcher: I'll talk to you about Dr. Girard's paper, which I have added to this. Dr. Mark Girard is a drug monitoring expert. He talks about the seasonal flu in Canada. Over the years FluWatch has shown that only about 10% of all virus samples submitted were actually influenza. Did you know that? That's for the seasonal flu.

On page 11 of Mark's article he says:

> Here is the appalling illogicality of vaccine development: whereas these drugs are supposed to exert their beneficial immunological effects on a very long term, they are never conscientiously suspected (and, in any case, never conscientiously assessed) regarding their potential to exert adverse immunological effects within the same long term.

The Chair: Thank you, Ms. Fletcher.

We'll go to Dr. Carrie.

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

I want to thank all the witnesses for taking the time to be with us here today. I want to thank Ms. Fletcher for being here on video conference.

This is something I'm reading about in the papers daily. I think there's a lot of information out there. I was in Washington this past week at a convention with a lot of International physicians and they were talking about what a good job we were doing on the economy and on H1N1. So it's nice to hear these compliments. Sometimes you have to go outside the country to hear them.

I want to talk a little more about the contradictory reports and the hesitation of Canadians to get the vaccine. I think I read today in the Ottawa paper that 51% do not think they will get the vaccine.

I wonder if Dr. Griffiths could comment a little more on the safety aspect of things. Then maybe Ms. Fletcher would like to comment too.

The Chair: Dr. Griffiths.

Mr. Elwyn Griffiths: On the safety aspect, this adjuvant type of vaccine has been used in up to 40,000 people without any significant effect. With a vaccine like Prevnar, which is the pneumococcal vaccine, virtually all the trials were done in the United States and Africa. In the United States trial there were about 37,000 individuals, and Prevnar is licensed in Canada and many other countries. That's a large study. These studies take a long time to do.

The Menactra study involved only about 10,000 to 12,000 individuals. That's the meningitis vaccine. The figures we have for this type of vaccine—the H5N1, which is the mock vaccine—plus data now being generated on the H1N1 vaccine are now getting into the same ballpark on safety and efficacy as you normally see for a vaccine. So although we say we're moving forward, this is what has happened.

In Europe and the United States there are questions about not just the adjuvant but the antigen as well. In 1976, as we heard from Dr. Butler-Jones, they came out with an H1N1 vaccine—the swine flu saga—but at that time they didn't have a real pandemic.

So it's a balance as you go forward. I think the safety margin is considerable now for moving forward with these vaccines.

Paul Lucas might have a comment on that as well.

Mr. Paul Lucas: Yes, I'm just commenting on the adjuvant.

It has three elements in it. They're all kind of natural ingredients. Squalene is the first, and it appears naturally in plants, animals, and humans. This isn't something that the human isn't used to. It also includes tocopherol, which is vitamin E, and most people are familiar with it. The third ingredient is polysorbate, which is an emulsifier that is actually put in ice cream. So these are three elements that are pretty common types of chemicals.

One shouldn't suspect that you're going to have a problem, and the H5N1 studies that we have done and the 40,000 patients that we've had this adjuvant in have seen no unusual side effects.

● (1705)

Mr. Colin Carrie: Ms. Fletcher, you seem to be the odd man out. I read in your presentation that squalene seems to be a problem, or thimerosal, and I've heard of that before in regard to autism. You don't seem to be looking at the same science as these other gentlemen, and I was wondering why you think it is not safe.

Ms. Susan Fletcher: I have here Gary Matsumoto's list, and you can get this on his website. I have the website listed in my references to our presentation, if you have it there. It lists 30 peer-reviewed studies—these are animal studies, mind you—showing that squalene produces autoimmune disease. This is the other thing about safety testing. Autoimmune disease, like MS, typically takes a long time to develop. My question is how long have these safety tests been carried out?

According to the Arepanrix product information leaflet that I looked at quickly on the weekend, the longest period I could see was six months. Now, MS can take a lot longer than six months. Diabetes can take up to 10 years. That's one aspect of this safety testing. The other—

Mr. Colin Carrie: Is Mr. Matsumoto a researcher?

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

We'll now go to Dr. Bennett. She can continue that if she chooses.

Hon. Carolyn Bennett (St. Paul's, Lib.): Maybe, Mr. Pless, you could tell us what your responsibility is in terms of the Canadian field epidemiology program.

Dr. Robert Pless (Program Director, Canadian Field Epidemiology Program, Public Health Agency of Canada): Madam Chair, given that the agency has increased the number of staff who are working on the pandemic file, I have a history in vaccine safety and so I was asked to come and help out with the vaccine safety section. Unfortunately, Dr. Barbara Law, who is the head of the section, was out of the country and couldn't make it.

Hon. Carolyn Bennett: Is it your responsibility to now track what's happening with the vaccine in terms of safety and efficacy?

Dr. Robert Pless: Yes. It's the vaccine safety section within the Public Health Agency that is going to be looking after the post-market surveillance of vaccine as it's rolled out.

Hon. Carolyn Bennett: The European Union said this week about the data from GSK and Novartis that the adjuvanted ones were too limited to warrant recommending a single dose schedule, but added that one dose might be sufficient in adults. How are we going to track that? How are we going to find out if people really are protected after one dose? When will that decision get made? And will you then have to remount a campaign for those for whom a second dose is being recommended?

Dr. Robert Pless: I can speak a little bit to vaccine efficacy, in terms of studies that are going to get under way to look at that very question, and perhaps Mr. Griffiths can elaborate on those. But there are plans in place to conduct additional studies to look at populations and their immunogenicity to the vaccine.

Mr. Elwyn Griffiths: I think this has been the big issue. Trials have been done so far in an age group from the middle group, if you like. There's a top end, where we're not really sure what the dose should be. Yes, these have to be tracked. They've got to be going off with one dose, but they will be doing immunogenicity studies on small subgroups here. This is important not just for Canada; the data will be shared globally. It would be the data from Europe, and that would be shared with us as well.

This is the advantage. It has never happened before on the regulator's side. This is something unusual.

● (1710)

Hon. Carolyn Bennett: But you'll have to do two studies—on the adjuvanted and the non-adjuvanted.

Mr. Elwyn Griffiths: That's right. Everybody is pooling their data from all the different countries, and that has never happened before on the regulatory side. It has always been confidentiality and this sort of thing. So we are all sharing. So you can imagine that from a safety point of view you have a much larger database than from the Canadian population.

Hon. Carolyn Bennett: My concern is that in the groups we've been advising to be careful, would somebody who is worried about fish oil not take it now, as they know it's in there? Would they be entitled to get the non-adjuvanted vaccine?

Mr. Elwyn Griffiths: Dr. Butler-Jones should answer that one.

Hon. Carolyn Bennett: We'll get him back on Wednesday.

I guess, Dr. Griffiths, because you're the regulator you probably can't answer the question on vaccine injury compensation. Maybe Mr. Lucas or Rob could. I know Quebec had a vaccine injury compensation package, as does the U.S. A lot of people feel that if the compensation package is still with regular tort law and the burden of proof is on the victim, they have to go to court and do all of that, and it just isn't as effective as what I think Ms. Fletcher was describing as a no-fault approach.

Is there a reason why the government didn't go straight to no-fault and has done this middle ground that worries people even more?

Mr. Paul Lucas: I can't speak on behalf of the government on that one, sorry.

Hon. Carolyn Bennett: It sounds as if other countries have no-fault as opposed to this business where you'd have to sue the government, and who on earth is going to have pockets deep enough to do that?

Mr. Rob Van Exan: A number of countries have no-fault insurance. My understanding is that they're all a bit different and a lot of different things need to be considered in developing that. Quebec has had a policy for some years and there was some discussion, and I believe some research was started on no-fault insurance this year through CIHR. The challenge is that it's such a complex issue it's not something you can just pull together in the middle of a pandemic.

The other concern, having talked with some of the experts in the field, is that rolling it out in the middle of a pandemic is a way to create more confusion and concern than is already there.

Hon. Carolyn Bennett: Dr. Griffiths, I just want one question about patients with AIDS—

The Chair: Ms. Davidson, you are next.

Hon. Carolyn Bennett: Maybe Ms. Davidson would ask my question then.

The Chair: Maybe she would.

Hon. Carolyn Bennett: I think some special groups from *Cross Country Checkup* that really want to know that if they've got MS, AIDS, had cancer chemotherapy.... Can you tell us what you are recommending to these people—

Mrs. Patricia Davidson (Sarnia—Lambton, CPC): Yes, that's not my question.

The Chair: That's not your question. I'm sorry, Ms. Bennett.

Go ahead, Ms. Davidson, please.

Mrs. Patricia Davidson: Thank you very much, Madam Chair. Thank you for being here and presenting to us today.

I think we have been in a long learning curve in this committee, and what you have added here today has certainly helped us.

We've had a fair amount of discussion today about adjuvanted and non-adjuvanted. I would ask Dr. Griffiths to make some further comments about safety for pregnant women.

In your presentation you talked about how adjuvanted vaccines may also provide broader cross-protection across mutating flu virus strains. I think Mr. Lucas referred to that, as well as Dr. Butler-Jones. I would like you to speak to that mutation and try to explain it to a layperson here—and also, what the ramifications of immunization or non-immunization will have with this mutation, if there is any relationship.

● (1715)

Mr. Elwyn Griffiths: I'll deal with the pregnant women, to start with. This vaccine isn't contraindicated for pregnancy. We're not saying it should not be used in pregnant women. The regulators are saying that we don't.... No clinical trials were carried out in pregnant women, so therefore we cannot say you can't use it. It's left open to assess the severity of the epidemiological situation. It's a "use" situation at this stage . So the use of the non-adjuvanted has been a public health issue, really.

Mrs. Patricia Davidson: But both will be available?

Mr. Elwyn Griffiths: Both will be available; that's right.

On this issue of the mutations, as you know, seasonal flu is mutating all the time. This particular virus is fairly stable, strangely enough. It hasn't mutated very much. As I mentioned earlier on, changes have now been detected in the Netherlands, but they haven't affected what is called the antigenicity of the virus. That means when you have a vaccine for a seasonal flu, it recognizes a particular virus, and if a small change comes along, then it doesn't match very well. You're doing a best-case scenario to match. And every year the World Health Organization has a meeting in February and they do a little bit of crystal ball gazing. I used to be part of the group that is involved there. They look at the serology—that is, what antibodies are circulating in people's blood. They look also at what viruses are circulating and whether they are changing, and they try to match them up. And if they see the virus moving ahead and they don't match very well, then they say, well, this virus is going to be circulating in the next season. And it has worked quite well. So they make a recommendation of what the new vaccine should be.

This means a lot of work, basically. And it looks as if these small changes do weaken the.... If you've been immunized and there's a changed virus, then your resistance is not as good as it was for the original virus.

With these adjuvants present, it's been shown at least in the H5N1 data.... This is where we do our work, on this prototype, if I can put it that way, because the H1 hasn't changed yet. It did seem that the immune response that came from the adjuvanted vaccine did cross-react. It's called cross-reaction. It recognizes these changed types, essentially, so it would give you protection against these other varieties as well.

So during the season as this pandemic progresses, you would not have to change your vaccine, essentially. That's the idea. Otherwise, by the second wave and by the time you get to the third wave, you might have to change. We don't know that with the H1, but that's the prediction, that it would be giving you a broader cross-protection, as they call it. There's some evidence of that coming from the mock, which we did all our work on originally.

Does that help?

Mrs. Patricia Davidson: Yes, thank you very much. That's very good. But that's something we haven't seen in other seasonal flu immunizations?

Mr. Elwyn Griffiths: Yes, the seasonal flu is changing every year. That is changing. That is why you have to have a new vaccine every year. So this meeting that takes place for the northern hemisphere takes place in Geneva. The southern hemisphere does the same. It takes place in September. They decide what the new strains are. This is the reason, because these strains are drifting, they call it. They drift.

With a pandemic strain, it's slightly different. It's a completely new strain. Everybody is naive. There's no immunity there at all for these new stains. That's why they move around so fast. And this has been helped, of course, by air travel.

The Chair: I think Mr. Lucas wanted to make some comments on this.

Mr. Paul Lucas: Yes. I was just going to make the point that we are studying the same adjuvant in the seasonal flu vaccine. So you could anticipate that in a couple of years or so. You'll potentially see a seasonal flu vaccine with the adjuvant in it because of the benefits Dr. Griffiths is talking about. So that's coming along.

The Chair: Thank you.

Ms. Wasylycia-Leis.

Ms. Judy Wasylycia-Leis: Thank you.

Let me ask a question of Dr. Van Exan.

In your paper and in your presentation, you mentioned that you believe there should always be two sources of supply for the flu vaccine. Here we have a case where one company, GSK, has the total production, I believe, for the flu vaccine and for the H1N1. And maybe the government or somebody needs to answer this, not you, but you can all comment. Why did you get everything, and what do you say about that, Dr. Van Exan?

● (1720)

Mr. Rob Van Exan: My comments were based on the fact that we have had a two-supplier process in Canada for the regular seasonal vaccines since 1992, which predates GSK's involvement in this. I've been with Connaught for 30 years, so I remember this. In fact, Connaught was one of the ones that instigated and negotiated the two-supplier system because of the dangers inherent in having only one supplier.

This is a much trickier vaccine to produce on a seasonal basis than any other. The concerns are not only with the virus changing. What about the source of eggs, and what about viruses getting into the eggs or into the chickens? There are so many places for something to go wrong. At the time, in 1992, we suggested—and the government fully backed—the concept of having two suppliers for seasonal vaccine.

When we came to looking at a pandemic vaccine, another element was introduced in 2001. That was the concern about an embargo, a shortage worldwide of this pandemic vaccine. What if we couldn't get it in Canada? So we should have a company in Canada that makes the vaccine. As a result, all other manufacturers were excluded from participating in that contract.

While that may be a valid concern and may be the reason Canada did what it did, I find it hard to separate out the fact that having two suppliers is viewed as being very critical to security of supply on the regular seasonal vaccine and somehow isn't important when it comes to a pandemic. So our position, in terms of talking about safety of the Canadian population, was to talk about safety in respect to security of supply and the fact that Canada would benefit from having multiple suppliers—definitely have one that's manufacturing in Canada, but also add on one that has manufacturing capability outside of Canada and other capabilities inside. For example, our plant in Toronto is labelling and packaging flu vaccine for the U.S. market as we speak. We have the capacity to do that kind of work in Toronto, even though we do not make the box. And we have the capacity to fill vaccine in Toronto.

I'm just saying there's more to this vaccine than what we have with other vaccines, and from a strategic position, we feel Canada would be well served to have two suppliers.

Ms. Judy Wasylycia-Leis: Yes, go ahead and comment. Dr. Griffiths, can you speak for the government on this?

Mr. Elwyn Griffiths: Not on the purchasing side. That's the Public Health Agency. We regulate whatever vaccine comes to us, let's say. But it's a Public Health Agency issue. It's the supply part.

Ms. Judy Wasylycia-Leis: Give us your take.

Mr. Paul Lucas: For seasonal vaccines, that's correct. We do split the supply for Canada. I wasn't involved with the company when we first purchased it. This company and the plants that are making this were owned by previous companies.

It's a tricky question on a tricky issue. The driving factor here was that Public Health wanted a secure source of domestic supply, not knowing what would happen in a pandemic around borders shutting down.

The Chair: The time is almost up. I know Ms. Fletcher also wants to say a couple of words.

Ms. Fletcher, quickly.

Ms. Susan Fletcher: Thank you.

I have here, from the year 2000, the U.S. national vaccine injury compensation program and vaccine injury table. It talks about vaccines for DPT, MMR, hepatitis B—all kinds of different vaccines. Each one says that any acute illness, disability, injury, or condition covered includes “any acute complication or sequela (including death)”.

In Canada, death is not recognized as an adverse vaccine event. Why is that? Why is it that it can happen in the States and not here?

● (1725)

The Chair: Thank you, Ms. Fletcher.

We'll now go to Mr. Brown.

Mr. Patrick Brown (Barrie, CPC): Thank you, Madam Chair.

I have a few questions to ask and hope you can answer within the time.

Ms. Fletcher made a comment a little while back about the vaccine potentially affecting autoimmune diseases. I thought maybe we'd get Mr. Griffiths' response to that, because we didn't have time allotted in that questioning for it. Second, could you expand upon the encouraging signs we've heard about from Australia with the H1N1 there?

I want to touch a little bit more upon domestic production. I've heard the comments about how there needs to be a second supplier. Would that production be 100% domestic as well? Could you also expand upon why the GSK has viewed that as important and could they handle all the production with a border shutdown?

Mr. Paul Lucas: Do you want to start with that one?

Mr. Elwyn Griffiths: There's a lot in there, but very briefly on autoimmune disease—Guillain-Barré syndrome, for example, could be an autoimmune disease—these are so rare you'd really have to look at the big picture here. You would not see these until you actually roll out into millions.

As Dr. Butler-Jones explained earlier on, I think it's one in a million with the seasonal flu vaccine, if that is really the link. We don't know. Many of these are brought up as potential theoretical risks, which are sometimes very difficult to prove. They're rare, extremely rare, so the issue here is that you have to balance the risk of a real threat to health and to the lives of individuals against this theoretical risk.

I didn't quite follow your point about Australia, but I can simply say that whatever is happening in Australia...we're in very close contact with the regulator in Australia, because we have these routine teleconferences, not only with them but with the U.S. and with Europe, and we discuss all these issues that come up, so we will know if anything comes up.

Mr. Patrick Brown: Aren't reports suggesting that the flu season in Australia was not as bad as it was here?

Mr. Elwyn Griffiths: Oh sorry, the H1N1. Yes, it was fairly mild, but that was their first wave. They expect the second wave in spring for us—our spring, essentially.

Mr. Patrick Brown: Mr. Lucas?

The Chair: Would you like to comment?

Mr. Paul Lucas: On the production side, all I can say is the strategy has worked in having a sole supplier domestically located, in this pandemic anyway. We are on track. We are on schedule in terms of producing the vaccine. We are one of the only countries in the world that will basically have enough vaccine to vaccinate its whole population with one dose by Christmas. We are in a strong position in Canada as a result of that strategy.

Mr. Elwyn Griffiths: Could I add a point there? I think you have to remember we're not making Aspirin or Coca-Cola, or something, when you're making vaccine. When you make a vaccine, there are biologics that are very difficult to make. You can have policy based on the best science that's available, but then biology often confounds issues.

Let's take the issue of supply—and this is where I was going to comment here. I'm sure you're all aware that the U.S. is now having difficulty with the supply of vaccines, although I think they have four or five manufacturers supplying. I think with all the best will in the world, the manufacturers predicted that they would be supplying 130 million doses to the U.S., or whatever. But the reality was....

Let me put it this way. We think we're dealing with a flu virus, as if it's sort of the same thing, you know. They change slightly every year. Somebody mentioned earlier on that there are very subtle changes in these viruses, and how they behave is very different. This particular virus, it turns out, grows very, very poorly. That wasn't predicted when they started to make these vaccines, and that really has caused a huge problem with the supply.

So I think you have to balance the best science you have to make the policy, but on top of that, you have to bear in mind that we're dealing with biology here as well.

Mr. Patrick Brown: On domestic production, Mr. Van Exan.

Mr. Rob Van Exan: Yes, only a comment.

In fact, on October 22 at the ACIP meeting in the U.S., the U.S. experts actually came out and said, “Thank God we have multiple suppliers.” There are five suppliers in the U.S., and they were able to get their first deliveries of vaccines starting on September 29. This really speaks to the idea of having multiple suppliers. If one is a little slower, another one will come.

In terms of domestic supply, the benefit of having two suppliers, one domestic and one not domestic, is that you don't have all your eggs in one basket. Pardon the pun, but if you were to have flocks in Canada infected, you would still have flocks in some other part of the world—

● (1730)

The Chair: Excuse me, Mr. Van Exan, we're running out of time. Thank you for your comments.

We have about 30 seconds or so left, and I'm wondering if I can ask a question. Okay.

I don't know if you can answer this, Dr. Griffiths, or if I need to ask Public Health. For people who have compromised immune systems because they have HIV, cancer, bone marrow transplants, or rheumatoid arthritis, what kind of vaccine is recommended? Is it the one with the adjuvant in it? What is the recommended dose for someone like that?

Mr. Elwyn Griffiths: I think Dr. Butler-Jones should be speaking to this.

The Chair: I know.

Mr. Elwyn Griffiths: The recommendation is to use the adjuvanted vaccine because they usually respond very poorly. But those data are not available yet. We are moving forward here, but there are still these special groups that we need to study. Do we need one or two doses of the vaccine? It's an ongoing dilemma on how to deal with those people, but I think the recommendation is to use two doses of the adjuvanted vaccine.

The Chair: Okay. When Dr. Butler-Jones returns, we'll probably ask him.

I want to thank the committee very much for coming.

I want to thank our guests especially for being here today. Your comments were very insightful.

As you know, the Subcommittee on Neurological Disease will be meeting on Wednesday.

The committee is adjourned.

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