

Speaking Notes for

**Dawn Graham
President
Merck Frosst Canada Ltd.**

Address to the Canadian Club of Montréal

***Biopharmaceutical Research:
Health and Wealth for All Canadians***

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Check Against Delivery

Thank you very much. Good afternoon, ladies and gentlemen.

I want to begin by thanking the Canadian Club of Montréal for this kind invitation.

It is an honor and a privilege for me to be here at such a prestigious venue with such an impressive history, stretching back more than 100 years. I am delighted to stand here today representing an organization that also enjoys a long association with this great city, Montreal, and whose history is also proud and illustrious.

Merck Frosst can trace its origins back to 1899, with the creation of the Charles E. Frosst & Company.

In 1910, Frosst developed a first painkiller. The next year, the firm established a plant here in Montréal. Frosst was an innovative company which developed many pharmaceutical products that became household names at the time. Many of you would recall a song by Pauline Julien about her 222s...

In 1965, Merck acquired Frosst, and this new firm embarked on a journey of discovery that continues to this day.

But I'm not here today to look back only on the achievements of the past — although these are important.

I'm here to talk about the future – about the promise of new medicines, both in terms of health care and economic growth, and the role that my firm intends to play in this promising new era.

Healthcare is a top-of-mind issue everywhere in the world as it is here in Québec and Canada. A month ago, the Healthcare in Canada survey demonstrated that the Canadian public now believes that wait times and the shortage of doctors are the two most important health issues, with an aging population coming in at a distant third.

Three weeks ago, the Castonguay report generated a lot of controversy in the media and among stakeholders for its favourable opening to more private healthcare interventions in Québec. We all saw how fast some of these recommendations were put aside. I mention this because it allows you to understand the environment in which we at Merck Frosst do business everyday as an important member of one of the few private industries providing health services in a public system. Even the title of my talk today may appear controversial to some since many believe that it's wrong to generate wealth in the field of health. Not that I'm a contrarian but I am here today to demonstrate that we can all gain from the progress derived from health research.

If you go see your physician today, he or she will be able to offer you four basic types of intervention:

- Diagnosis such as observation, tests, scan, etc.;
- counselling, ranging from a discussion on lifestyle changes such as "exercise more or eat better" all the way to psychotherapy;
- there can be surgery;
- or pharmaceutical treatment.

Prescribing a pharmaceutical treatment is the most frequent intervention performed by physicians and they do this because it's in the best interest of their patients. Merck Frosst and the pharmaceutical industry are proud to partner with physicians by providing them with the tools that empower them to offer the best care to their patients.

In fact, new drugs in large part have been responsible for dramatic drops in hospitalization rates. For example, between 1983 and 2001, reductions in hospitalization rates were 75% for ulcers, 71% for HIV/AIDS, and 44% for diabetes and respiratory diseases.

Death rates were also reduced for HIV/AIDS by 70% and by 63% for heart attacks. I like to think that innovations brought forward by Merck Frosst and the pharmaceutical industry have played a large role in these astonishing numbers. Merck was first in developing protease inhibitors for HIV, one of the pillars of tri-therapy. Another pillar of HIV/AIDS tri-therapy is 3TC which was discovered in Laval by Biochem Pharma. And just last year, Merck Frosst came back with a new type of treatment called an integrase inhibitor which, frankly, is a revolution for HIV/AIDS patients who do not respond anymore to traditional treatment.

Merck was also first to develop statins which have completely changed the way physicians can now prevent heart attacks by lowering cholesterol.

And I've not yet spoken about vaccines, a field where Merck is one of the few companies still doing research. Many of the products we market ensure that your children do not get life threatening diseases such as measles, mumps, meningitis, hepatitis, rabies or pneumonia.

And two years ago, Merck introduced GARDASIL, the first vaccine to prevent cervical cancer and genital warts! As a woman, I could not be more proud of an innovation which will save thousands of women's lives in years to come.

And not that we are trying to outdo our Canadian heroes Banting and Best who discovered the properties of insulin for the treatment of diabetes but Merck Frosst just launched a novel treatment for type-2 diabetes here in Canada.

And you don't have to be a physician or a patient to benefit from health research. All Canadians benefit if research is going on in their communities. The local economy gains employment opportunities and investments. According to Statistics Canada, one job in research leads to the creation of two more jobs in the economy. The innovative pharmaceutical community invests more than \$1 billion dollars in research in Canada

each year, second only to the telecommunications sector in terms of research and development. And much of this research is done right here in Montréal.

But this success does not come easy. Let me quickly remind you how pharmaceutical research and development works. The first step is basic research, such as that performed by Merck Frosst at our Montreal research laboratory where we have 300 scientists. This is where we will develop chemical entities on the research bench. Once our scientists believe that they have a good molecule, they pass it on to their colleagues in formulation who must turn this molecule into a form of pharmaceutical dosage. Once we have this experimental drug, we must test it through three phases of clinical research in humans to ensure that it works and that it's safe.

Results of these clinical studies are used by regulatory agencies such as the FDA or Health Canada to grant authorization to bring a product to market.

The whole development cycle lasts on average twelve years and costs approximately \$1 billion per new drug. Only one in 10,000 molecules makes it to the market. Then it would be no surprise to you that without patent protection, it becomes simply impossible to carry on such risky and costly research.

Given the success of medical innovation in new medicines, governments at both the federal and provincial levels have recognized the importance of the biopharmaceutical, or life sciences sector.

I had the pleasure to be invited last year to the release of the Government of Canada's new Science and Technology Strategy. The sector "Health and related life sciences and technologies" was recognized as one of the four key areas the government will focus on in the years ahead.

In October 2006, the Federal Government strengthened intellectual property protection for new medicines by ensuring that new drugs are not copied for at least 8 years in order to harmonize with the rest of the developed world. This was an important move that signalled the Federal Government's recognition of the need to encourage new drug innovation.

At the provincial level, there is the recently announced \$150 million that the Ontario government has set aside to encourage pharmaceutical firms to do more research and manufacturing in that province.

And then, of course, there is the Québec government's long-established recognition of the importance of the bio-pharmaceutical sector to the province of Québec.

This was underlined most recently last year, with the Québec government's newly released "politique du médicament". It stated quite clearly that, quote, "Le maintien

d'une industrie biopharmaceutique dynamique au Québec" is one of the key elements of this new policy.

This support for the bio-pharmaceutical sector is certainly understandable, when you stop to consider some of the statistics associated with the industry.

Take Merck Frosst as an example!...

In this province we are responsible for 1,166 full-time jobs. The average salary is more than \$83,000 a year. And 3/4 of our workforce has a university diploma.

We also support the training of more than 70 students per year through our various internship programs.

In essence, this sector is a symbol of the "high-skills, high-wage" economy all governments say they want to build.

And our contribution goes well beyond the great jobs we create within our own company.

Merck Frosst is responsible for purchases of roughly \$115 million per year from more than 2,000 suppliers. In the past ten years, we have invested more than \$550 million in our Québec facilities.

If we can do all these things, it is due in no small part to the fact that the conditions for innovation success are, to a large extent, in place, here in Québec and in Canada.

Those conditions are very straightforward. They are:

- The presence of leading research centres and institutes dedicated to the development of the sector. Université de Montréal and McGill come to mind instantly of course in the health sector;
- A large pool of talent and a highly qualified work force;
- Good access to a diversified range of funding, notably in venture capital;
- Promising interrelations among the various players in the sector's value chain;
- Favourable scientific and business environments, notably with respect to regulations and reimbursement of innovative drugs by both public and private payers.

Now, I say that these conditions are in place "to a large extent" because there are some inconsistencies, and these keep the biopharmaceutical industry from doing all that it could for Canadians.

The primary challenges the industry faces at present are the lengthy approval process our products must undergo, and the patchwork of mounting regulations we are subject to in different jurisdictions across the country related to access and reimbursement.

The fact is, we're in a very demanding field. Our sector has the longest product development cycle, as I said, with more than 10 years as the average in R&D.

And this cycle has grown in the past decade as a result of the increased complexity of R&D projects. To put it simply, remaining diseases such as cancer, Alzheimer's, Parkinson's disease, etc. are more complex than those we are currently treating and that difference can be seen in the lab, among other places, as it takes longer and costs more to address these complex targets.

At the same time, while it takes a very long time to research and develop new medicines and vaccines to address these diseases, our sector is also subject to one of the strictest regulatory regimes of any in the economy.

Every step of the way, from clinical trials to market approval, to access to patents, and then post-marketing surveillance, there are many checkpoints we must pass, and safeguards that must be respected.

And looking ahead, I can tell you that regulations are becoming even tighter, both to reduce potential adverse effects, but also to contain the growth of health costs.

On that last point, at least, Canada has to be careful. The fact is that various drug therapies when used appropriately help reduce health care costs, by enabling patients to leave hospitals earlier, and to stay in their homes longer. Brand-name prescription medicines account for less than 10 cents of every dollar invested in health care in Canada. Every dollar invested in new medicines saves seven dollars elsewhere in the health-care system by reducing hospitalization and surgeries.

If governments want to reduce health care costs, which is an understandable goal that we all agree with, there are other tools that can be used instead of regulations that reduce access to reimbursement by provincial payers which prevent patients from receiving the treatments they need. This current approach places a needless burden on a sector that has contributed a great deal both to the advancement of medical science, and to finding economies in the system.

Now I'd like to take a few moments to speak about some of the accomplishments that we are proud of at Merck Frosst and that relate back to our proud heritage here in Montreal. Our scientists in Montreal discovered the asthma therapy SINGULAIR[®], currently Merck's number one product with expected worldwide sales in 2008 of \$4.8 billion.

Other successes for Merck Frosst are the discovery of the cardiovascular drug BLOCADREN[®], the muscle relaxant FLEXERIL[®] and TIMOPTIC[®] for glaucoma.

Our research colleagues also deserve recognition for their recent work on CORDAPTIVE for the treatment of elevated cholesterol, currently awaiting FDA approval in the United States.

After CORDAPTIVE, the next one in line is MK-0822, which is being evaluated for the treatment of osteoporosis.

And it doesn't stop there. Looking at the recently publicly disclosed global Merck Research Laboratory pipeline, no less than six molecules originate from our Merck Frosst Research Labs in Montreal. In fact, our research lab is one of the most productive within Merck globally.

We hope to have more successes like these in the years ahead. As I've demonstrated, they're good for the economy of Québec and Canada, and they contribute directly to the quality of life, not only Canadians, but for people around the world.

But those successes are going to be harder to come by, because international competition for research and scientists is so fierce. And while Canada is a leader and pioneer in biotechnology research, other countries are racing to catch up. Consider a few of these examples:

China now has 2500 biotech companies, and is adding about 100 new firms every year. They have 200 laboratories funded by their government, with more than 20,000 employees.

In Malaysia, there is a Biotechnology Implementation Council chaired by the Prime Minister. Tax incentive programs include a 100 percent tax exemption for 10 years beginning from the first year a company realizes profit, or an Investment Tax Allowance of 100 percent on qualifying capital expenditure incurred within 5 years.

And these are just two examples of the emerging competition that we are facing in Canada. The fact is that countries around the globe are marshalling their resources to carve out a place for themselves in the "bio-economy". Currently and for the foreseeable future, they are able to do R&D at a fraction of the cost that we can in a country like Canada.

Before I returned to Merck Frosst as President in 2006, I had the pleasure to hold the position of Vice-President, Asia Pacific for Merck & Co. Inc. and spent a lot of time in Southeast Asia and mainland China. So I saw first hand how these developing countries are focusing their efforts in building this new economy. And believe me – they are determined to win. The perspective that the Chinese government is currently taking with respect to attracting R&D investments from our sector is the following – and I have seen this in a number of meetings in which I've participated in China.

The perspective of the government of China begins with a 100 year horizon into the future. This is their mindset. 100 years to China is a drop in a bucket. I think you would agree with me that this is a little different than the 2-4 year mindset that governments tend to have in Canada, the U.S. or Europe.

Well, you might say — within this 100 year lens, there's nothing to worry about in the short to mid-term. Well, this is flawed thinking. When the Chinese pick the sectors for their 100 year plan, it means that they play to win in these sectors and are willing to invest heavily upfront to ensure success over the long term. This is formidable competition.

So the perspective they bring to the table related to bio-pharmaceuticals is what can we do to create a win-win-win situation for patients, industry and government over the span of 100 years? A win for Chinese patients is that they have access to innovative medicines. A win for industry is that we have a low cost source of R&D and that we can have access to new markets in which to sell our medicines. And the win for the Chinese government is that the industry invests in R&D in China versus in Canada, Western Europe, Japan or the U.S.

Now let's think about the Chinese market for a moment. China's population is 1.3 billion people (roughly 20% of the people on the planet). There is an emerging middle-class in China as we speak. Even if this emerging middle-class grows to 30% of the total population of China, our industry would have access to a market of new consumers that would be roughly the same size as the U.S.

And this new emerging middle-class in China is brand-loyal. They want and are willing to pay for Crest toothpaste, Nike running shoes and brand name pharmaceuticals.

So access to the Chinese market is a terrific opportunity for a global pharmaceutical company.

So, as Canadians, how do we compete against this? How do I, as the President of the Canadian subsidiary of Merck & Co., compete internally within my own global company to maintain and to grow Merck R&D investments in Canada?

Can we compete against India and China on cost? Not in my lifetime. However, there are two areas where we can compete and we have to protect these market forces with a vengeance. The first is the quality of our science and the productivity of our scientists. And the second is our policy environment.

Currently, the policy environment in China and other developing countries is not supportive of innovation since patent protection legislation is still lagging. But they're working hard on improving this and have no doubt that they will close the gap. So we need a sense of urgency here to ensure that Canada remains competitive from a policy environment with respect to Intellectual Property protection and regulations that give access and reimbursement for medicines.

If Canada merely rests on its laurels, if we say “we’re doing great” I believe that without any doubt we will lose significant ground to this emerging competition.

And if we fall behind in this race, we could find our firms and our scientists seeking out better opportunities abroad.

And so as a Canadian industry, what we do expect is that we will be able to work in partnership with governments so that policies are developed to reflect the new competitive realities of the 21st century that are already here.

Bureaucracy for the sake of bureaucracy is what kills innovation.

Unreasonable process and paperwork can strangle investment, and send firms in search of jurisdictions with more progressive regulatory regimes.

What we need is a regulatory regime in Canada that makes sense, that is leading-edge and that puts the safety of Canadians at the forefront while still encouraging innovation.

I sincerely believe that our governments in Ottawa and Québec City “get it” on a philosophical level.

Now we must ensure that all governments and their officials recognize that embracing innovation in the health care system is an important contributor to both our collective well-being from a health perspective, but also to the well-being of our industry, which is a growing and important piece of the emerging knowledge economy.

In short, new medicines and vaccines contribute to a healthy population and to a healthy economy – the best of both worlds!

Thank you very much.