

Speaking Notes for  
Paul Lucas, President and CEO  
GlaxoSmithKline Inc.  
Chairman, Rx&D – Canada's Research Based  
Pharmaceutical Companies  
Mississauga Board of Trade  
April 27, 2006

April 27, 2006  
Check against delivery

Ladies and gentlemen, it is a great pleasure to be here with you today. First, I would like to thank Mayor Hazel McCallion for her kind introduction. She is a great friend to our industry and a tireless advocate for the City of Mississauga. Under her leadership, the life sciences sector in our city has grown to include over 400 companies. It is as a direct result of the work of the Mayor, and a group of dedicated members of the community, that Mississauga has become the home of Canada's **third largest** life sciences cluster. Thank you Mayor McCallion for your tireless support.

I am also pleased to see so many people here from the University of Toronto at Mississauga, patient groups and local hospitals.

The last time I addressed the Mississauga Board of Trade, I outlined some policy initiatives that I thought were necessary

to help stimulate a robust life sciences sector in Ontario, new innovations in health care and quality jobs for our children. Today, I **planned** to speak about the National Pharmaceuticals Strategy or NPS -- a Federal/Provincial/Territorial initiative to drive cost-containment in pharmaceutical management. If implemented, NPS will pose a threat: to patient access to innovative medicines right across the country; to investments in R&D; and, to jobs in this sector. This initiative was scheduled to be discussed at the June meeting of the Health Ministers.

But, earlier this month, the Ontario government jumped ahead and introduced legislation that is consistent with the principles of the NPS and represents a major threat to the bio-pharmaceutical industry in our city, and to patients' ability to access the medicines they require to improve their health. As a result of that announcement, I changed my focus somewhat today to address what I see as a policy that will severely thwart innovation in life sciences in Mississauga, the Province, and Canada.

Let me begin by focusing on innovation. Research and innovation in health sciences contribute not only to a vibrant economic environment that we all enjoy, but more importantly, innovation in this sector saves lives and saves money in the health care system. The evidence is irrefutable: in 1900, life expectancy in developed countries was 40 years. In 2001, it was 78 years. This increase can be attributed to three things:

1. improvements in public health
2. the ability to prevent and better manage disease, and
3. the discovery and introduction of new and innovative medicines and vaccines.

In fact, death rates for most diseases have been reduced primarily due to innovative medicines: deaths associated with AIDS have been reduced by 56% and those from cardiovascular events by 48%. Medicines are not only effective – they're **cost** effective. Improved access to medicines creates savings in other parts of the health care system. For every \$1 spent on innovative medicines, \$7 are saved in other parts of the system. Between 1983 and 2001:

- hospitalization rates for the treatment of ulcers dropped by 75%,
- respiratory diseases such as asthma and COPD by 44%,
- diabetes by 44%, and
- chronic diseases of the liver by 31%.

And between 1993 and 2001, HIV/AIDS hospitalizations dropped by 71%.

Decreases in hospitalization rates mean savings to the bottom line -- savings that can be reinvested in the health care system and ongoing innovation.

It is important to recognize that innovation most often occurs in increments – not by breakthroughs. Rarely does a scientist discover a new cure overnight. The truth is that the vast majority of clinically important drugs developed over the last 50 years have resulted, not from big breakthroughs, but from an evolutionary process involving multiple small, successive improvements.

Unfortunately, most government health departments today do not understand the concept of incremental innovation; and maintain that there is no value in having a selection of therapies for a disease that can be tailored to a specific patient's needs. The aviation industry did not leap straight from Kitty Hawk to a Mars landing. There were many incremental steps in between. And each innovation typically costs more. It is the same with pharmaceutical innovation. If this incremental innovation is not valued, not funded and not supported, ongoing research and development will be discouraged; the creation of new bio-pharmaceutical companies will be stifled; and new therapies for patients will not be invented.

These improvements occur because innovative companies invest in research and development. The quest for innovation is an extremely expensive and risky business and must never be taken for granted. Today it requires, on average, approximately \$1 billion to discover and develop a new medicine.

The innovative bio-pharmaceutical industry in Canada invested over \$1.14 billion dollars in 2004 on R&D, creating high value jobs, inside and outside of the bio-pharmaceutical industry. That's a 1,000% increase since 1986. That increase is due to the vision of the Mulroney government which in 1987, and again in 1992, improved Canada's patent laws for pharmaceuticals to be competitive with the rest of the world.

Although the changes led to moderate increases in the cost of medicines, they also transformed the Canadian R&D landscape and the impact on the economy and patient care has been dramatic, far outweighing the additional costs. The sector is now the second largest investor in R&D in the country, and generates the highest level of productivity growth of all sectors at a time when Canada's productivity is lagging. With the right environment, one which stimulates and supports R&D, we are ready, willing and able to do more.

I have worked in the innovative pharmaceutical industry for my entire career, spending the last 20 years at GlaxoSmithKline. My professional life has been dedicated to building our industry in Canada, and I am very proud of the great things that we have accomplished.

When I started in the industry, there was little R&D performed, and very few science-based career opportunities in the health industries. In the intervening years; however, in addition to the increases in R&D, we have seen some very exciting changes, in Canada, Ontario and right here in Mississauga:

- GSK's manufacturing facility in Mississauga is a direct result of the changes in the patent laws and now ships more than 25% of Canada's pharmaceutical exports;
- The introduction into the global marketplace of innovative medicines, discovered right here in Canada have given patients new hope. Medicines such as **3TC**<sup>®</sup> still the world's largest medicine for the treatment of HIV; **Lamivudine**, for hepatitis B, the best-selling medicine in China, **Singulair**<sup>®</sup> for asthma; **Visudyne**<sup>®</sup> for macular degeneration; and pandemic flu vaccine, currently under development;

- Partnership with the UTM has lead to innovative programs such as the M.Biotech program allowing young graduates to study and work in the life sciences field here in Ontario, rather than being forced to move to pursue their careers;
- *Members of Canada's Research-Based Pharmaceutical Companies* (Rx&D) now directly employ 9,000 Ontarians – many of them in Mississauga - and are responsible for generating 25,000 additional indirect jobs. Our companies invested \$360 million in research and development in the province last year - \$50 million of which went to universities and hospitals.

So, it was with great excitement that I, along with Premier Dalton McGuinty and Mayor McCallion, announced on September 29, 2005, a \$23 million expansion of our manufacturing facility in Mississauga, new jobs, and an investment of \$1 million in the MaRS Discovery District. During his visit to GSK, the Premier stated, and I quote: "Research and innovation is vital to Ontario's future prosperity - jurisdictions that tap the creativity of their people will be home to the most rewarding jobs, the strongest economies and the best quality of life. That's why we've created the new Ministry of Research and Innovation. Our government is committed to doing its part and we need more companies like GlaxoSmithKline making this kind of commitment to innovation."

Then, in early April, at the BIO 2006 conference in Chicago, Premier McGuinty stated, and I quote: “Places that invest in innovation will be home to the most rewarding jobs, the strongest economies and the best quality of life.”

Now, based on these two quotes by the Premier, you’re probably left with little doubt that this provincial government is absolutely committed to innovation for all Ontarians. I was too. So you can imagine our disappointment on April 13, 2006. That’s the day the Minister of Health and Long-Term Care rose in the Legislature, at almost the same moment that the Premier was speaking in Chicago, and ushered in potentially the most anti-pharmaceutical innovation policy in North America. It is a move that has already reverberated around the world. Global headquarters have taken note and are seriously concerned. If this proposed legislation -- designed to re-structure the pharmaceutical market -- passes, our industry believes it will eventually:

- Vastly reduce the amount of R&D performed in the province;
- Force companies to outsource clinical trials to less costly markets – thus denying patients early access to new therapies;
- Affect our ability to support hospitals, universities, community programs and charitable causes; and,
- Make it very difficult for start-up bio-pharmaceutical companies to bring products to market.

Simply put, the legislation, known as Bill 102, is inconsistent with the laudable goal of Ontario becoming a leader in innovation and research and development. On one hand you have a newly created Ministry of Research and Innovation that envisions Ontario taking a global leadership role in innovation and R&D. On the other hand, the Ministry of Health and Long-Term Care, focusing on cost containment

in the drug budget with policies which discourage innovation. The two strategies are inconsistent and incompatible. This focus on cost containment is to the detriment of investment and economic growth. It has failed many times in the past. It will fail again.

History is a great predictor of the future. Here are some examples:

- First, the story of the Avro Arrow. A great example of Canadian innovation. But because the government of the day lacked the strategic foresight to see the Arrow for what it was -- the most advanced tactical fighter jet of the time -- and instead focused on the cost, we'll never know the whole story of this innovation's potential. In the end, with the cost deemed to be too high, the Arrow was scrapped; the company folded; the industry disappeared; and Canada's aerospace scientists -- more specifically **Mississauga's** aerospace scientists -- left this city and this country to put a man on the moon for the U.S. and build the Concorde for Europe. I lived in what is now Mississauga at the time. My father lost his job at Avro and we moved to Quebec City.

- Secondly, in 1968 Prime Minister Trudeau eliminated patent protection for pharmaceuticals in order to reduce costs. The result was the closing of manufacturing plants, research centres and the loss of some of our best pharmaceutical scientists. Patents were restored in 1987, but we lost 20 years of research and innovation.
- Next -- New Zealand implemented a very restrictive pharmaceutical policy a number of years ago to contain costs. The country is now a pharmaceutical waste land for investment, and health care costs for many diseases are higher than in Canada. The pharmaceutical policy proposed for Ontario is very similar to the model in New Zealand.

- And finally -- Canadian government policy decisions in health care based solely on costs have resulted in hospital closures, lengthy wait times, doctor shortages, nursing cutbacks, and an unacceptable quality of care. The evidence is overwhelming. Policy decisions based on cost containment alone don't serve the best interest of patients. Cost containment was the goal in reducing physician and specialist training and closing hospitals. Now we have critical shortages of physicians and a construction boom in hospital building to fix past mistakes. Cost containment was the goal in limiting nursing spaces and the introduction of new technologies. Now we have a nursing shortage, and those left in the profession face increasing workloads. And we all know that obtaining an **early** diagnostic test is difficult.

All in all, cost containment alone is a losing strategy for Ontario.

I won't get into all the details of the proposed Ontario legislation, but I'm going to cover four key areas of concern:

1. **Therapeutic substitution**. The legislation is unclear on its position on this issue. Professionals in health care and patients should be concerned. We believe the physician relationship with the patient is critical to achieving positive health outcomes. When you and your doctor decide what medicine is best for you, that decision should be honoured. We need to ensure that Bill 102 protects the integrity of the patient/physician relationship, rather than allowing the government to alter the prescribing decisions based on cost. This type of substitution is not good for patients and is a clear signal that incremental innovations are not valued.

2. A continuation of the **price freeze** on the provincial formulary which has been in place since 1994, and a roll back of any price increases taken in the private market. No one likes to see price increases but inflation has increased by at least 25% over that period of time and Canadian prices are already 9% below the international median for pharmaceutical prices. Price freezes impact investment, innovation and quality. A recent example you are all familiar with was the blackout - a direct result of hydro rate price freezes. In addition, as many of you here today can attest, the regulation of tuition (sometimes a freeze) in Ontario over the years has negatively affected the quality of post-secondary education by keeping salaries down, reducing the number of professors, and increasing class sizes.

3. **Off-Formulary Interchangeability or OFI.**

This component of the Bill will allow generic substitution of medicines that were never paid for by the government plan.

They maintain that this will reduce drug costs for employers in the private sector. And while we would welcome reforms resulting in employer cost-savings, there is currently no evidence indicating that OFI, as outlined in Bill 102, will achieve those savings. In fact, since the prices of generic drugs outside the provincial formulary are not regulated, there is no guarantee that patients or payors will receive lower prices. It is more probable that the money will be absorbed into the distribution channel.

4. And finally, **access to breakthrough drugs**. Despite the promise of rapid access to innovative, breakthrough drugs, as far as we can tell, the plan calls for an investment of \$30 million to fund them. While this sounds like a lot of money, it represents less than 1% of the overall drug budget of \$3.5 billion. As a patient, I am anxious to see a clear definition of what breakthrough means.

Let me give you an example of a drug that the government of Canada did **not** consider to be breakthrough.

Over 15 years ago, GlaxoSmithKline developed a drug called **Zofran**<sup>®</sup>, which is used to treat nausea and vomiting associated with chemotherapy. Prior to the introduction of **Zofran**, cancer patients were hospitalized and could not go home or back to work because of the nausea and vomiting associated with their therapy. With the introduction of **Zofran**, patients' quality of life drastically improved.

If you were to ask a panel of oncologists what the top 3 breakthroughs in oncology have been in the past 20 years, almost all of them would include **Zofran**. This drug allows patients who cannot tolerate the side effects of life-saving chemotherapy to receive treatment, better manage their disease, and thus live longer. Still, to this day, many cancer patients must first go through – and often suffer through – less effective treatments until they can have **Zofran**. To me,

that exemplifies the challenge we face and why we fight for better access to innovative new drugs.

Incredibly, the government of Canada did not view this drug as a breakthrough. Begging the question: what **does** qualify as a breakthrough? Will this be just another tactic to limit access to new medicines?

We have shared with the Ontario government our concerns regarding these four key issues and we are frustrated with their preliminary reaction.

We believe it is the government's perspective that our industry will continue to invest in Ontario **despite** anti-innovation policies and the resulting financial setbacks. How **can** we continue to invest when more than \$1.5 billion will be eliminated from the life sciences industry over the next three years because of Bill 102?

In 2005, the Ontario and Federal governments jointly funded a \$1 billion subsidy to the automotive industry – another truly innovative sector. I find it interesting that the government **selectively** supports innovation. **Other** sectors are recognized for their innovation – why not one as **critical** as the life sciences and health care sector? All we are looking for is a supportive environment – not subsidies.

Many other governments value our industry's contributions. Indeed, many countries are now actively competing to attract the innovative pharmaceutical industry and its R&D. Countries like the U.S., Singapore, Ireland, India, and China and the province of Quebec. With policies like the one proposed in Ontario, we will not be able to effectively compete. And as we all know, knowledge-based jobs are highly mobile

In a province that claims to embrace innovation, cost containment instruments should be replaced with innovative approaches to pharmaceutical care that:

- Invite the industry to be a partner in health care as opposed to treating us as a supplier of commodity medicines -- no different than suppliers of pencils and toothpaste.
- Focus on the prevention of disease. We are prepared to work with government on disease prevention programs.
- Stop managing health care costs in silos and start managing diseases by striving for improved clinical outcomes for patients, effectively leveraging medical and pharmaceutical technology; and,
- Look at spending on medicines not just as a problem but as an opportunity. An opportunity to leverage the spending on pharmaceuticals to drive economic growth and improve access for the medicines patients need.

In Mississauga, we have all worked very hard to attract R&D and quality jobs to our city. Along with Mayor McCallion, and the local government, we have built a successful life sciences sector -- a sector that employs over 20,000 highly educated, well-paid people in over 400 companies. Patients have early access to new medicines; local doctors lead life saving clinical trials; and, students at UTM have access to good quality science based jobs. Our industry and the local community have worked together to create the country's **only** Masters in Biotechnology program, and the Western GTA Convergence Centre.

Unfortunately, I believe that all of the hard work that went into building the sector in this city could be undermined. This won't happen overnight. You may not even read about it in the newspaper. But make no mistake, if the Ministry's policy moves forward unchanged, over time, "Pill Hill" will deteriorate. In 10 or 15 years, you **won't** be hearing about the wonderful R&D successes in Mississauga, you **will** be hearing about these discoveries happening in other countries.

The government now has a very clear choice to make. We'd like them to stand with us on the side of innovation, as they so often claim to do. Or, they can regress to short-term cost containment which will have a detrimental impact on the health of patients.

Some components of the Bill are helpful to patients, for example: the more prominent role for pharmacy in community care, and the reduction of paper work for physicians in the prescribing process. There are ways to improve the legislation. With a stronger focus on patients' needs, the government can achieve some cost savings, and at the same time support innovation and research.

I am very concerned about the future of the life sciences sector in our city and the well-being of patients across the province. We, along with other stakeholders, are ready to discuss solutions. We need a more balanced policy to benefit all Ontarians. This legislation is moving forward quickly. Too quickly.

I encourage the government to take the time to consult, in a meaningful and open way, with patient groups, pharmacists, medical professionals, municipal governments and our industry. The provincial government needs to hear from **more** of us that components of this Bill will have a devastating impact on the health of Ontarians and the economy.

If getting Ontario's drug policy right matters to you, please, make sure your voice is heard. I encourage you to contact your local MPP and tell them that you support the innovative life sciences sector in Mississauga, and that you want **them** to speak on your behalf.

The next time I speak to the Mississauga Board of Trade I hope to celebrate the positive outcome of this debate including: unrestricted access to medicines for patients, an environment that supports continued innovation, and a thriving bio-pharmaceutical industry.

Thank you for your support.