Life Sciences Ontario Annual Policy Forum November 27th, 2018



Achieving Policy Impact in a Transformed Political Landscape

Report & Recommendations

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Life Sciences Ontario: Achieving Policy Impact in a Transformed Political Landscape

This year the focus of our Annual Policy Forum was around engaging the new Ontario Progressive Conservative Government with the life sciences sector. After 15 years of a liberal government, the province of Ontario made a significant shift towards a Progressive Conservative regime.

The Life Sciences sector transcends political affiliation, it is non-partisan by its very nature, and as a sector we value economic and social prosperity for Ontario. Our goal with this forum was to discuss how our sector can work with this new government and how we can align with the goals and priorities of the government for the people. Specifically, how can we as a sector help achieve the government's priorities in ending hallway medicine, creating high-quality jobs, reducing red tape and regulations, and creating an Ontario that is truly Open for Business.

Ontario is now producing world leading life sciences innovation and we need to act now to ensure that we are capturing the full potential of this timely opportunity. Industry and government must come together to achieve the goal of a made-in-Ontario global biotech success story. The challenge we face in achieving this goal is that collectively we must identify what the barriers are and the solutions needed to overcome them.

The news of General Motors underlines that our reliance on the traditional sectors is not without peril and that life sciences truly has the most potential for this province, in terms of company formation, job creation and driving economic growth. We have clear alignment and a thriving commitment of the sector, we have the LSO Blueprint, we have the report from the provincial life sciences working group with input from across the sector, we have the Federal government and the recommendations for a health and bioscience economic strategy and we have a new provincial government, members of the legislatures (from all parties) and we have a Premier, that for the first time are listening.

At our Queen's Park day, our Blueprint for a coordinated life sciences strategy was very well received by representatives from all parties. We have consensus – among industry, academia and across government, that this is a much needed plan – the time is now.



To read the full text of the Blueprint, visit: <u>https://bit.ly/2DiJyEG</u>



Life Sciences Policy Under the New Ontario Government

Life Sciences remains Ontario's greatest untapped opportunity for economic growth and social prosperity. How we approach life science policy in the coming months and years will have a profound, long-term impact on our province and Canada as a whole. With a new government in place, what is emerging in terms of policy directions and priorities for our life sciences sector? How can we work together and build bridges to accelerate our success?



Ella Korets-Smith, CEO, TO Health!



Tom Blackwell, Senior National Reporter, National Post



Ashley Challinor, Vice President, Policy, Ontario Chamber of Commerce



Jason Lietaer, President, Enterprise



Michelle Noble, Executive Director, Council of Academic Hospitals of Ontario

Key takeaways:

- We have a government that is committed to reducing spending and bringing the province's finances under control, while getting out of the way of businesses in a market driven economy.
- The Government is committed to reducing regulation and red tape positive for our industry which is so heavily regulated.
- The Premier has repeatedly talked about the importance of using technology and innovation to drive efficiencies. He has appointed Rueben Devlin to be the head of his health policy task force.
- The Conservative government uses simple language in their communications and they expect stakeholders to talk to them in the kinds of languages that will be accessible to the general public.
- This government is a government for the people and as such they are very in tune with public opinion.
- Life Sciences is a sector that isn't entirely contained within the City of Toronto or the GTA, it is truly a pan-provincial sector and it's a sector that is quite key to regional economic development.
- The Ministry of Research, Innovation and Science no longer exists, its functions have been absorbed into the new Ministry of Economic Development, Job Creation and Trade – where does innovation, science and research fit within their mandate and focus remains to be established.



- Sector messages must be aligned with the government's priorities significant progress could be achieved under the Open for Business banner.
- Stakeholders must present a narrative that will help fix some of the government's problems the biggest one being health care system reform.
- The sector should continue to push this message: The life sciences strategy is based on the fact that there is no new spending required, it's all there and it exists in different ministries. It just needs a coordinated approached that is cross-ministerial.







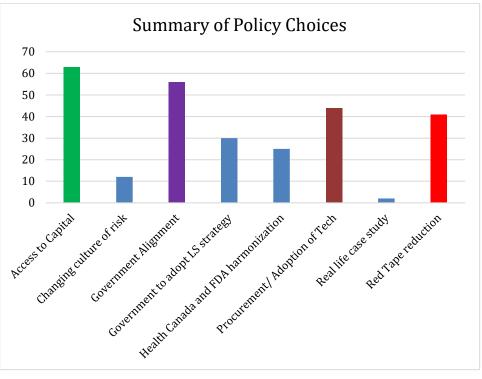
Audience Engagement Session

In this hour-long session, we'll be interacting with members of our audience directly to solicit their views on key policies and/or initiatives that would support the ultimate goal of a made-in-Ontario biotech success story. The session will include structured discussion with facilitators present at each table, and will conclude with live audience polling.



Lauren Fischer,

Vice President of Corporate Affairs, Eli Lilly Canada Inc



Top 3 Choices from Audience Participation (92 participants)

| Policy Solutions | Votes |
|---------------------------------------|-------|
| Private sector tax incentives | 25 |
| Leverage private investment | 20 |
| Flow through shares | 17 |
| Encourage individual investment | 1 |
| Changing culture of risk | 12 |
| Alignment across ministries | 47 |
| Clinical trials as an example of silo | 9 |
| busting | |
| Government to adopt life sciences | 30 |
| strategy | |

| Health Canada and FDA harmonization | 25 |
|--|----|
| Simplify procurement and data access | 16 |
| Ontario first adopter | 14 |
| Multi-Ministry procurement | 7 |
| Early adoption | 7 |
| Journey mapping for red tape reduction | 26 |
| Ontario as a leader in regulatory | 15 |
| reduction | |
| Real life case study | 2 |





Ryan Wiley, President, Shift Health



Giles Gherson, Deputy Minister, Red Tape and Regulatory Burden Reduction, Cabinet Office

Wendy Cukier, Professor, Entrepreneurship and Strategy, Ted Rogers School of Management, Director, Diversity Institute, Ryerson University



Huda Idrees, Founder & CEO, Dot Health

What are the primary issues we should focus on going forward? How can government and the private sector play an active role in this transformation?

Fireside Chat

- 1. Alignment across ministries
- 2. Technology/Innovation adoption
- 3. Adoption of a life sciences strategy
- 4. Journey mapping to support red tape reduction
- 5. FDA + Health Canada Harmonization
- 6. Tax incentives to encourage private sector investments

Key Takeaways:

- Journey mapping is hugely insightful, the government has already launched 5 journey maps in other sectors.
- The issue is not just about approval, innovation is not about making new stuff or even getting it approved innovation is about using things to drive change. A lot of the barriers to developing markets for technologies and innovations are massive, and that's why start-ups end up going to other jurisdictions to get their first customer, because navigating the procurement process at hospitals is a real problem. The provincial government has a very important role in driving innovations. The cross-ministerial strategy is a good idea.
- The office of the Red Tape and Regulatory Burden Reduction has gone to the government with a two-year action plan that aims to reduce regulatory burden by 25% over the two years. They plan on having a series of semi-annual packages of burden reduction measures, both legislative and regulatory. Ministries and the Red Tape and Regulatory Burden office are talking to stakeholders and trying to understand the most challenging regulatory barriers.
- Our healthcare system does not operate like a system, it is incredibly fragmented. The government funding models provide absolutely no incentives to innovate because of the way in which they are structured.



- The sector needs to define what it actually means when a government adopts a life sciences strategy.
- Tackle it at a systems level. In the same way you talk about journey mapping through the government, you have to think about journey mapping through markets in order to get adoption in healthcare. There is a lack of attention on markets and the processes that are required to break into the markets.
- In order to persuade policy makers that the life sciences sector is going to be a driver of wealth and prosperity in Ontario, the sector must frame the policy as an investment not just to grow the industry and create jobs but also to transform healthcare, provide better access, better quality and better service.
- Finding ways to disrupt systems requires people working together; it requires evidence not just a strategy but real targets, real accountability and real transparency. Alignment across ministries and having an integrated strategy has to be coupled with real accountability.





Access to Health Innovation Panel

Health innovation is an integral component of our success and sustainability as a province and a nation. However, we are failing to capitalize on our investments within this sector and deliver these innovations to patients. With so many stakeholders involved – including innovators, regulators, purchasers, and insurers – how do we work together to balance cost and access to innovations? As key policies are being developed regarding drug pricing and national Pharmacare, how will access to innovations potentially be impacted?



Wayne Critchley, Senior Associate with Global Public Affairs; Chair of the Board, Canadian Organization for Rare Disorders



William Charnetski, Ontario's first Chief Health Innovation Strategist



Tammy Moore, CEO, ALS Society of Canada; Chair, Health Charities Coalition of Canada (HCCC)



Helen Stevenson, Founder & CEO, Reformulary Group Inc.



Gamze Yüceland, General Manager, Takeda Canada

Key Takeaways:

- Value-based procurement in support of value based care. If we are going to have a sustainable health system, we need to find a different way to not just deliver beds and staffing, but have innovation an integral part of the offering.
- Value-based healthcare is related to outcome-based healthcare and there is a big opportunity but there is also a big gap - as it relates to the way we measure outcomes.
- The prospect of national pharma care could fill the gap in terms of coverage for people, however, it won't come anywhere near filling the gap with respect to outcome-based care and really being able to measure that.
- Areas such as rare diseases could really benefit from outcome based care, especially if it's done on a national scale.
- A study by Pollera found that Canadians put health care <u>generally</u> first as the most top of mind issue, not pharma care, not coverage and not universal coverage.
- The value definition is not the same for each and every stakeholder, therefore, we do not have a common understanding of value.
- Regulatory modernization process at Health Canada concrete steps to introduce an aligned process between Health Canada and CADTH to speed up the time to list for drugs.
- If the regulatory process isn't easy to navigate, we risk closing the door for manufacturers to make products available for Canadians.



- *Real World Evidence (RWE) is the key to create value.*
- The health systems need to articulate what their priorities are because then it opens up a discussion about whether the solution is being provided.
- Need to build the system for the future, not the present.
- There is a new initiative coming out of the three provinces heading up the expensive drugs and rare disease study looking at how to implement risk sharing type approaches in order to facilitate access to the more expensive, new, high-tech therapies, especially drugs in rare diseases. That is an opportunity for the life sciences sector to step up and participate and help make that approach and that system work.
- Patient reporting needs to be based on clinical metrics that we can interpret, in terms of how people are benefiting and their clinical outcomes.





Investment Panel

Ontario's life sciences sector is rapidly becoming known for its incredible innovations. But too often, we are losing our most promising companies to acquisition outside our borders. How can we amplify our competitiveness as a destination for global capital, while growing and scaling our companies here at home? What steps must both government and the private sector take to anchor our foothold within the global innovation marketplace?



Peter van der Velden, Managing General Partner, Lumira Ventures



Dominic Jaikaran, President and CEO Bright Angel Therapeutics



Alison Nankivell, Vice President, Fund Investments and Global Scaling, BDC Capital



Steve Romanyshyn, President & CEO, Ontario Venture Capital Growth Corp.



Cathy Steiner, Principal, Origin Merchant Partners

Key Takeaways:

- Current US administration provides opportunity for Canadian companies to attract foreign investment.
- There are a limited number of institutional investors who actually invest in life sciences because:
 - Not an area where institutional investors have a depth of expertise within their investment entities to be making the right decision
 - It is a challenge within the Canadian ecosystem to confirm that there is a company being formed as opposed to a project or an initiative that might be then acquired.
- Not enough early stage capital but easier now than five years ago.
- Canada is missing the "grand daddies", the homemade biotech success stories to get critical mass.
- Seed investment needs to change in Canada consider that phase III results are so far down the line
 use this to your capital raising advantage.
- Health IT is a huge opportunity not just about biotech
- Canadian investors are not necessarily risk adverse, they lack understanding of how value in health companies is created along the pathway to commercialization.
- Canada is great at basic research but not so much at translational research.

- We need a compelling narrative to get on the global investment market radar
- We need to incentivize investors through programs and policy (such as an angel tax credit or flowthrough shares)
- We need to educate investors on how value is created along the commercialization pathway of health companies



Federal Economic Strategy Table Panel



Jennifer Chan, Vice-President, Policy and External Affairs, Merck Canada Inc.

> Andrea Palmer, CEO and Founder, Awake Labs



Key Actions:

- **1.** Accelerate innovation adoption by employing value-based procurement within Canada's health systems and establishing a procurement innovation agency.
 - In order for the best life changing health innovations to gain adoptions in our health system we need a systemic shift towards a procurement approach that moves beyond price.
 - The Federal government could look at adopting value-based procurement in their areas of responsibilities.
 - New or potentially existing health organization be given a joint health and economic mandate, essentially be established as a health procurement innovation agency.
- 2. Create a modern agile regulatory system by adopting international best practices and eliminating duplications across jurisdictions and decreasing review times.
 - A high performing regulatory system should be predictable, efficient, consistent and transparent so it's not to present barriers to business investment, foreign direct investment, innovation and ultimately economic growth and improve patient outcomes.
 - Create a regulatory council with the objective of seeking harmonization and reducing red tape across our federal, provincial and territorial systems to enable and facilitate easier entry of innovative products into the Canadian market.
- **3.** Harness potential of digital technology by creating a national digital health strategy featuring an interoperable digital health platform.
 - The national strategy is needed in order to guide federal investments in digital health to unify the provincial and territorial partners among the common goal of delivering and leveraging digital technology to improve care and advance economic growth.
 - The key to success for this plan is to implement a pilot of a fully interoperable digital health system platform across two or more jurisdictions to demonstrate what success looks like before rolling it out nationally.
 - The access to high speed internet across the country is critical as to not create a digital divide and have that be a barrier to access healthcare.



- 4. Develop and attract world class talent by equipping Canadians for highly skilled jobs, eliminating hiring barriers and streamlining government skills programs.
 - The government of Canada, the health/bioscience sector, academia, the provinces and the territorial governments work together to establish an empowered, accountable hub to drive the necessary changes to the skills and talent program and to equip Canadians for highly-skilled jobs in the sector.
 - Streamlining the federally funded programs for skills development and training through a single body to manage outcomes and reduce duplications and overlap.
- 5. Drive the creation of anchor firms by mobilizing late-stage capital, scaling-up high potential firms, and broadening research and development tax incentives.
 - Creation (within the VCCI initiative) that would support and invest in the creation and development of later-stage venture capital and private equity funds that specifically focus on life sciences.

Key Takeaways:

- This process with the economic strategy table has been an unprecedented opportunity for industry leaders to come together and make recommendations to the government.
- One of the recommendations moving forward from this first phase is moving to phase two of implementation the recommendation that an FPT table be convened to be able to catalyze some of the recommendations and take concrete pilot projects and sandboxes from an FPT perspectives and move those forward into the next phase.
- Impactful Look at end to end agile regulatory system that ensures that health and innovation policies point in the same direction and help to accelerate innovation adoption.
- Was anything left out? Incentives for the provinces and the territories to implement these recommendations, how can we convince the provinces that this is an important initiative to take on within their own world and to do it in a comprehensive way that is consistent across the country?







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Organizing Committee

Ryan Wiley, (Committee Co-Chair), Shift Health

> Jason Field, President & CEO, Life Sciences Ontario

> > Ramy Ayad, Life Sciences Ontario

Jennifer Chan, Merck Canada Inc

Jeff Graham, Borden Ladner Gervais

> John Kelly, KeliRo Company

Ella Korets-Smith, TO Health! Lauren Fischer (Committee Co-Chair), Eli Lilly Canada

> Mark Smithyes Labtician Théa

Andrew Retfalvi, Global Public Affairs

Beni Rovinski, Lumira Ventures

Sue Munro, First Stage Enterprises

Brian Craig, First Stage Enterprises

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