



Canada's voice for biotechnology  
Le porte-parole canadien de la biotechnologie

## Health Biotechnology and Bill C-51

**Philip Schwab**  
**CAPRA Symposium**  
**October 6, 2008**

# BIOTECCanada

BIOTECCanada is the national industry-funded association with over 230 members representing the broad spectrum of biotech constituents including emerging and established companies in the health, industrial, and agricultural sectors, as well as academic and research institutions and other related organizations.

## MISSION

*BIOTECCanada is dedicated to the sustainable commercial development of biotechnology in Canada.*

## GOAL

*Inspire the domestic and international community on the value of biotechnology in Canada and provide solutions to the challenges our constituents face.*



**Canadians Value Biotech:**

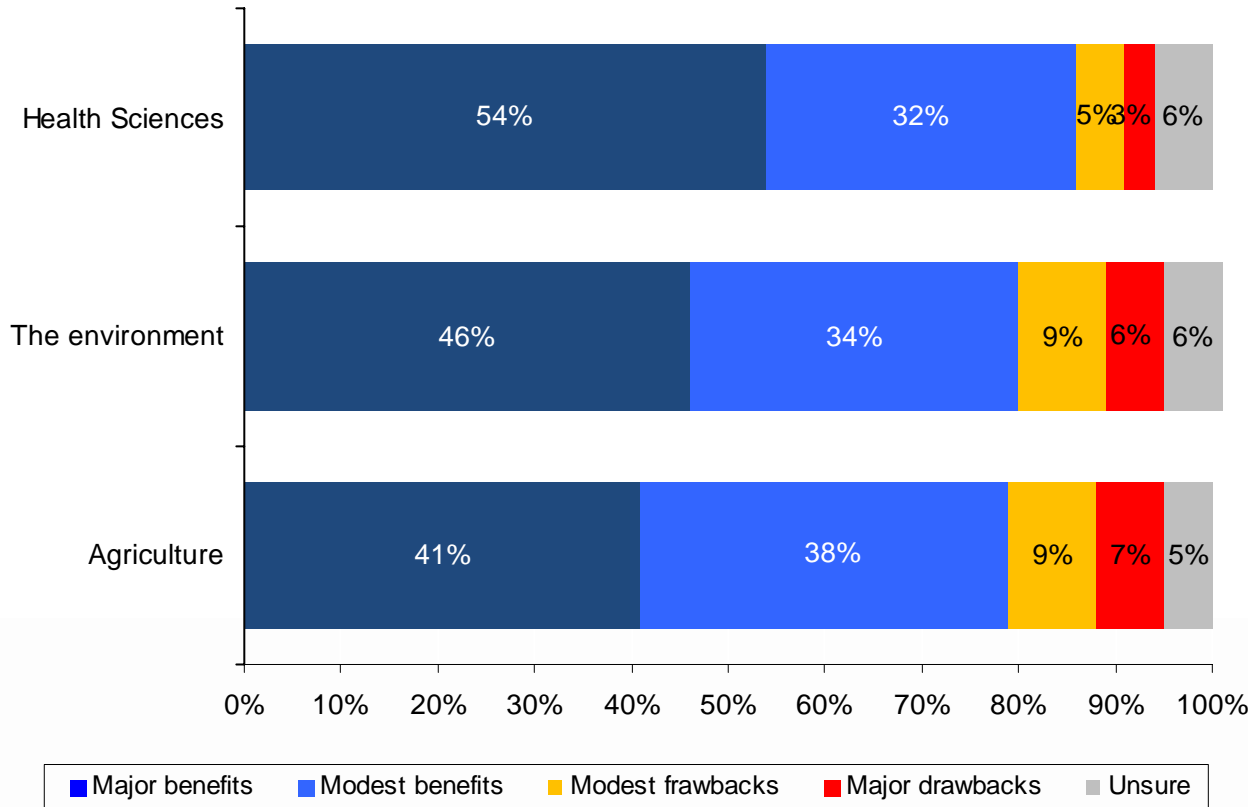
**BIOTECCanada Annual Opinion Polling-  
Results Overview 2008**



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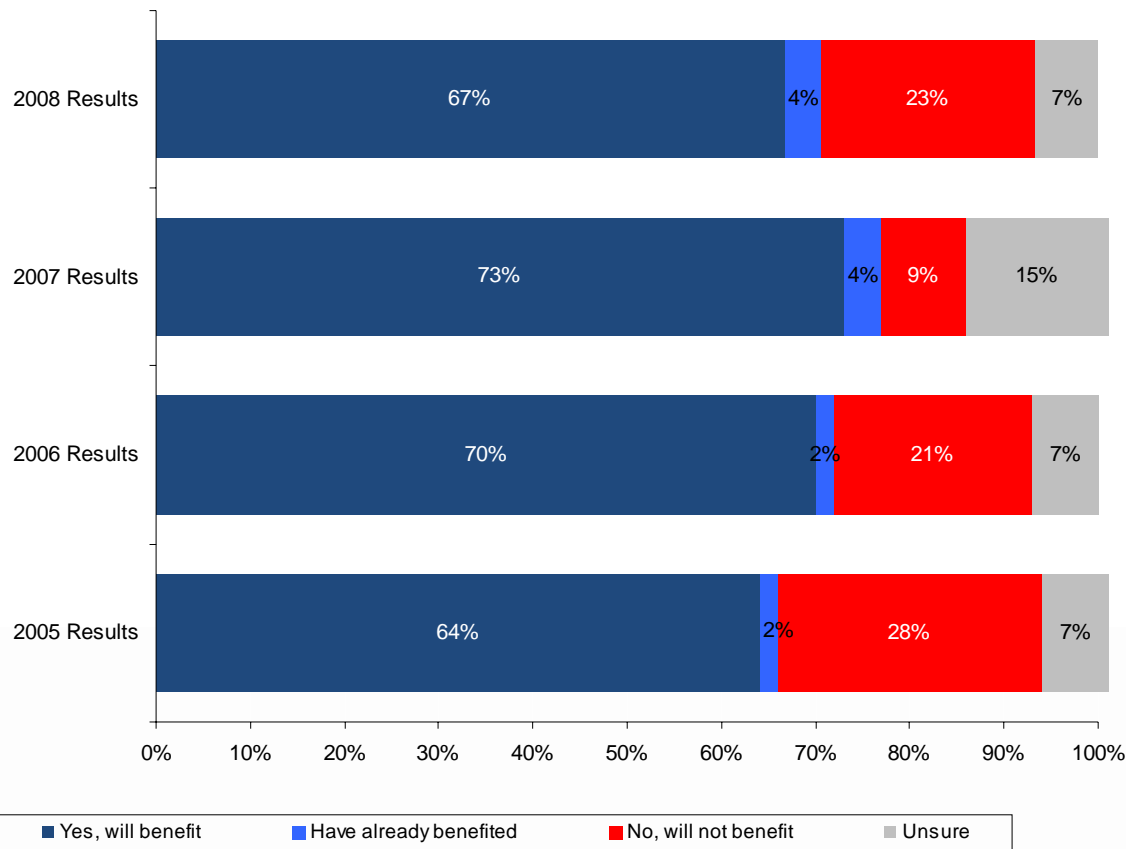
# 8 out of 10 Canadians see benefits in all aspects of biotechnology



**Do you believe that, overall, biotechnology will bring major benefits, modest benefits, modest drawbacks or major drawbacks in each of the following areas?**  
 (Source: Nanos Research, August 2008)



# 7 out of 10 Canadians expect to benefit from biotechnology



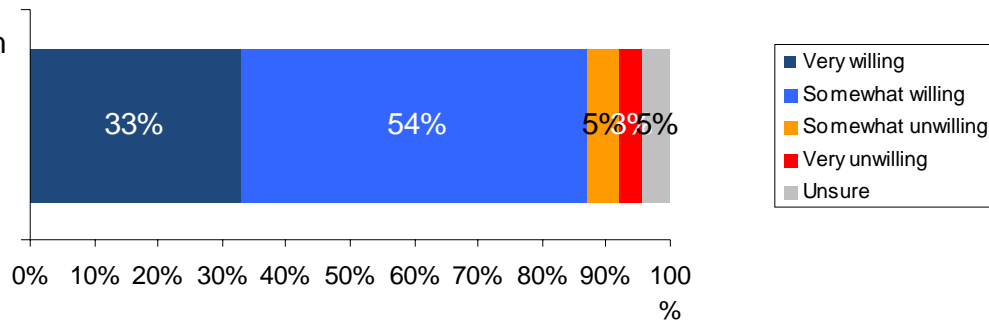
**Do you believe that you will personally benefit or not benefit from advances in biotechnology in your lifetime?**  
 (Source: Nanos Research, August 2008)



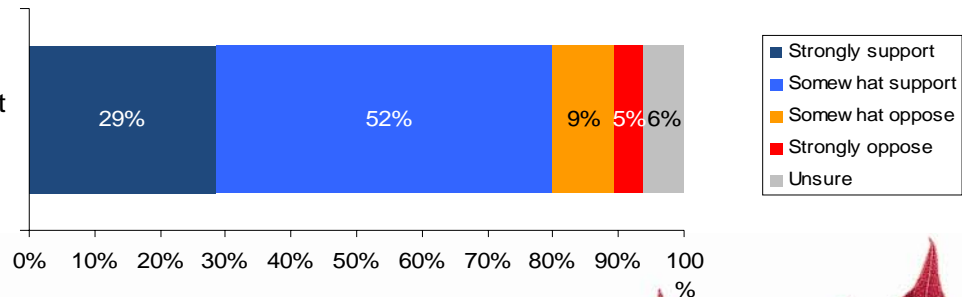
# Canadians want their governments to support biotechnology

To what extent should Canada's healthcare system be willing or unwilling to pay more for advances in new health biotechnologies?

Should they be very willing, somewhat willing, somewhat unwilling, or very unwilling?



As you may know, governments periodically encourage innovation through financial incentives to target industries. Do you strongly support, somewhat support, somewhat oppose or strongly oppose government encouraging innovation in the biotechnology industry?



(Source: Nanos Research, August 2008)

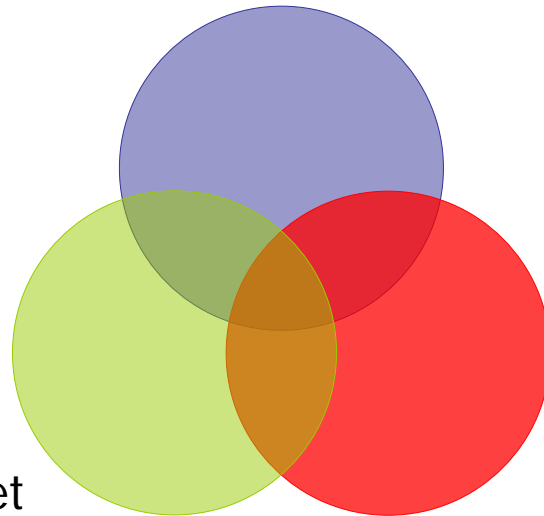


# Health Canada Renewal ?

- Blueprint for Renewal
- Progressive Licensing Framework
- Bills C-51/52
- Bill C-54
- Cost-Recovery
- CDR/JODR
- PMPRB Guidelines Review
- Parliamentary Review of CDR/Post-Market
- What next?

# Pillars of Biotech Success

Intellectual Property & Protection



Access to market

Financing





# Canadian Innovation

- Canadian Biotechs Fill Global Pipelines
  - Anormed – Genzyme
  - ID Biomedical – GSK
  - Arius – Roche
  - BioMS - Lilly
- Canadian Biotechs Develop Innovations
  - Cardiome
  - Oncolytics Biotechnology
  - YM Biosciences
  - Angiotech

# Positive Modernization

- Transparent Consultation Process with Industry
- Represents an alignment with regulatory process being implemented with major trading partners
- Sets a High Standard for Patient Safety
- Risk/Benefit Approach for Approvals
- Ability to Manage Scientific Uncertainty

# Items of General Concern

- Disclosure of Confidential Business Information
- Powers to Compel Trials
- Resources to Implement New Powers and Procedures
- Mandatory Periodic Product Review?
- Creation of Final Regulations



# Orphan Products

- A TRUE *Modernization* Opportunity
- 25<sup>th</sup> Anniversary of US Orphan Drug Act in 2008
- Over 30 Canadian Developed Products have received FDA Orphan Status
- Growing Consensus for Action
  - Cost-Recovery Panel
  - House of Commons Motion M-426
- C-51 should create an orphan drug definition
  - Orphan Diseases defined as fewer than 1 in 2000 patients in Canada.

# PLF Intersects with Many Initiatives

- PMPRB Guidelines Revisions
  - Will life-cycle approach affect “re-benching” ?
- Common Drug Review/JODR
  - How will provincial reimbursement authorities interpret the “life cycle” approach?
  - Will reimbursement decisions be delayed while waiting for “more data”
- Cost-Recovery
- National Pharmaceutical Strategy

# Post-Market Surveillance

- Biologics Already Subject to Extensive Post-Market Surveillance
  - Periodic Safety Updates
  - Extensive Reporting for Manufacturing Changes
- Global Safety Monitoring
- Patient Registries
  - Federal, Provincial, Industry?
- Ensure effective use of existing techniques and information before imposing new requirements

# Modernization of Vaccine Regulatory Framework

- Forward looking and flexible approaches are needed to adapt to the rapid advancement of vaccine technology, including combination and therapeutic vaccines.
- Reflect modern vaccine products and manufacturing processes. Antiquated sections should be removed, amended or replaced with guidance.
  - storage temperature and expiry date are now defined within the NOC process.
- Lot testing should reflect international standards.
- New Guidance Documents are needed
  - Requirements regarding inspection of finished products (e.g. vials, syringes, ampoules, large volume vs. small volume).
  - Biomarkers for Vaccine Efficacy (and their validation) and use as surrogate endpoints.

# Summary

- Many important opportunities for modernization exist that will encourage innovation.
- Need coordination of many individual processes underway.
- Consultation with sponsors is key as regulations are developed.
- Careful and clear communication with provinces will be necessary.
- A lot of work ahead!