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The Year 2020

What Will Regulatory Affairs Look Like in Canada?

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The Year 2020

- What will the Healthcare Market look like?
- Who will the Patient be?
- What Treatment Modalities will be under development?
- What will the Payer be doing?
- How will Regulators be doing their job?
- What will the Regulatory Affairs Professional be doing?

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The Healthcare Market

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The New Pharma Market

- Total Market – more than double to US$1.3 Trillion
  - US
  - Japan
  - China
  - EU
  - India
  - Vietnam
  - Middle East

- Canada
- Australia

- What about Africa and South America?
- What about the Cayman Islands?

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The New Pharma Market

- Expanding market with larger customer base
  - Wider access to health care
  - Growing populations in emerging markets
- Health care will shift in focus from treatment to prevention.
- Pharmaceutical companies will provide total health care packages.
- The traditional blockbuster sales model will disappear.
- The supply chain function will become revenue generating as it becomes integral to the health care package and enables access to new channels.
- More sophisticated direct-to-consumer distribution channels will diminish the role of wholesalers.

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The New Pharma Market

- Chronic disease is soaring
- Healthcare policy makers and payers are increasingly mandating what doctors can prescribe
- Pay-for-performance is on the rise
- The boundaries between different forms of healthcare are blurring
- The markets of the developing world, where demand for medicines is likely to grow most rapidly over the next 10 years, are highly varied
- Governments are beginning to focus on prevention rather than treatment
- Regulators are becoming more risk-averse

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Marketing

- In order to be successful, companies will need to stop the aggressive marketing focusing only on the product of the current model and:
  - Recognise the interdependence of the payer, provider and pharmaceutical value chains
  - Invest in developing medicines the market wants to buy
  - Adopt a more flexible approach to pricing
  - Develop plans for marketing and selling specialist therapies
  - Manage multi-country launches and live licensing
  - Form a web of alliances to offer supporting services
  - Create cultures that are suitable for marketing specialist healthcare packages
  - Develop marketing and sales functions that are fit for the future and a knowledge based commercial organisation

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The New Pharma Market

- Small molecules
  - Across all molecules
  - More focus on sub-populations
  - Fewer “me too” products
  - Move away from blockbusters
- Biotech
  - Personalized medicine
  - Biomarkers
- Generic Products
  - Huge growth in market
  - Division between innovative and generic companies will blur
- Biosimilars
  - Will become much more routine
  - Huge growth
- Medical Devices
  - Division between drugs and devices will blur
  - Drug delivery, biomarker diagnostics, outcome based promise linked with drugs

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Who will the Patient be?

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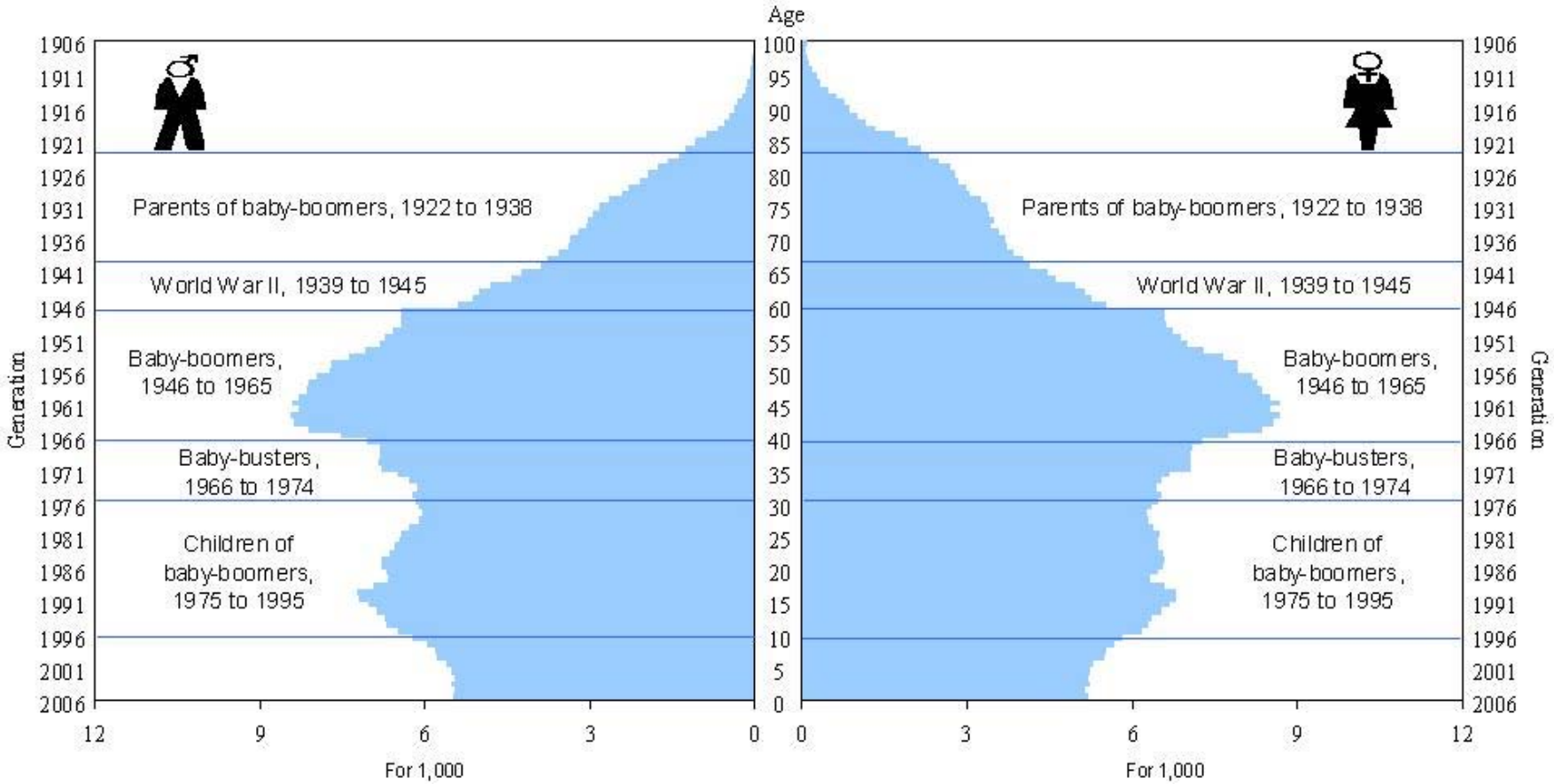
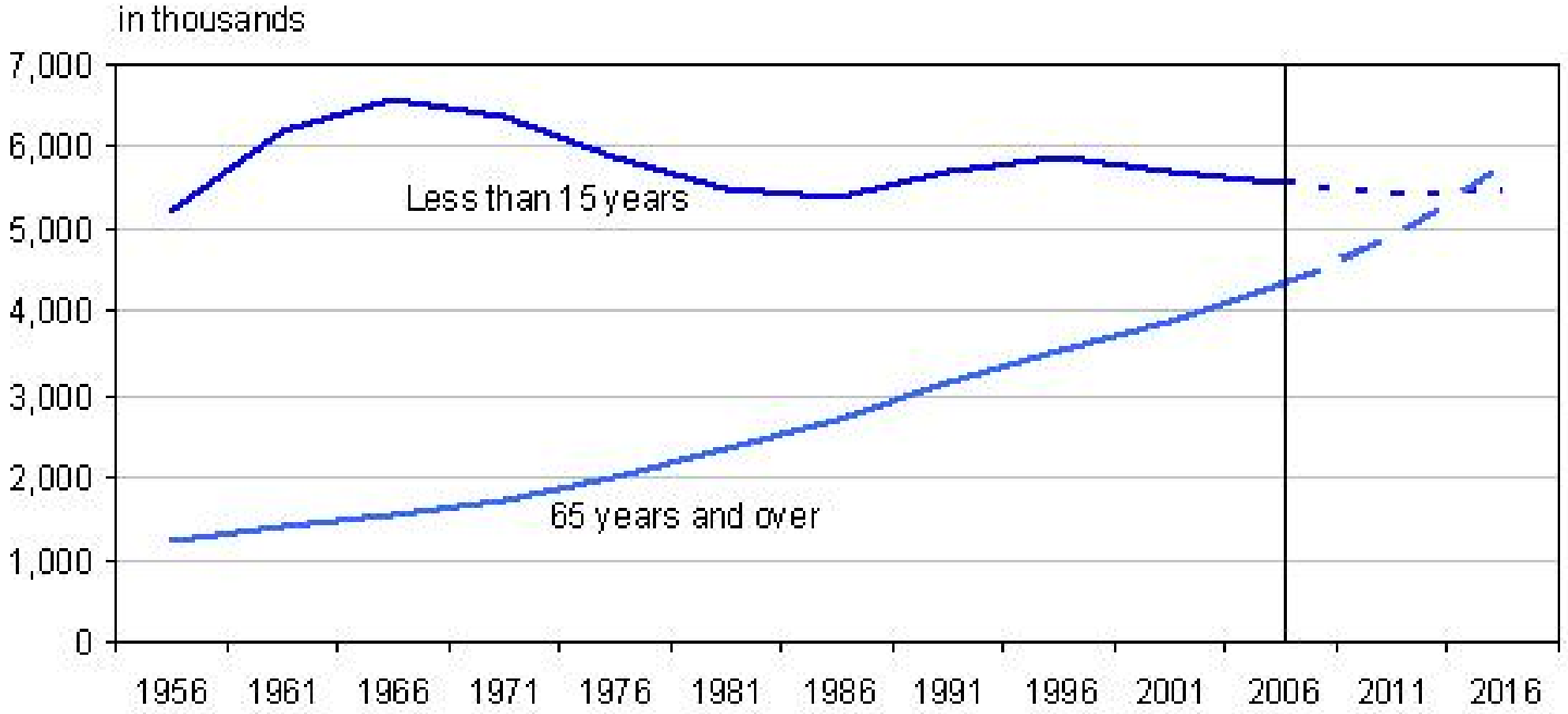
Different cohorts among the age pyramid of the Canadian population in 2006





Sources: Statistics Canada, censuses of population, 1956 to 2006; and Alain Bélanger, Laurent Martel and Éric Caron-Malenfant. 2005. ***Population Projections for Canada, Provinces and Territories 2005-2031***, Statistics Canada Catalogue no. 91-520, scenario 3.

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Who Will The Patient Be?

- People are living longer
  - Average life expectancy rose from 47.3 in 1900 to 76.9 in 2000
- Heart disease, malignant neoplasms and cerebrovascular disease are leading causes of death
- 80% of seniors have at least one chronic health condition
  - 50% have 2
- Arthritis, hypertension, heart disease, diabetes and respiratory disorders – leading causes of activity limitations among older people
- Disability among older population is declining.
- Older people are more highly educated now than at any time in the past

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What Will Be Implications of This Population

- The size and longevity of this group will trigger debate about changes to Old Age Security, Healthcare, retirement benefits.
- Older population will be healthier, more educated and wealthier than at any time in the past.
- Research on genetic, biological and physiological aspects of aging is likely to change the future for this population.
- Chronic diseases such as Alzheimer's Disease and osteoporosis will be prevalent.
- Young vs old.

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What About Other Populations

- India, Middle East, China
  - More young persons
  - Different health care needs

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What Treatment Modalities Will Be Under Development?

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New Technologies Will Drive R&D

- Genetic-based diagnostics in the development of personalized medicines
  - shortened R&D cycle for those products.
- Further research into the human genome
  - will open up a new world of opportunities in molecular science and targets.
- Improved understanding of diseases, including links genomic and clinical data.
- The development of molecular delivery platforms
  - speed the development of new products.
- The convergence of therapeutics and medical devices
  - become increasingly sophisticated,
  - improve efficacy
  - reduce the risk profile of many existing therapeutic agents.

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New Technologies Will Drive R&D

- The current linear R&D process will give way to in-life testing and live licensing.
  - The current R&D model, Involves phase I, II III and IV clinical trials that typically end in submission for a drug license and market approval
  - Replaced by collaborative in-life testing and 'live license' issued contingent on the ongoing performance of the drug over its lifecycle.
  - The industry will conduct smaller, more focused clinical trials, continuously sharing results with regulators.
  - If testing confirms that a medicine is safe and effective, a live license will be issued, permitting the company to market the drug on a restricted basis.
  - Further in-life testing will extend the license to cover a larger number of patients or a different patient population.

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New Technologies Will Drive R&D

- Our understanding of the underlying biology of the human body and its diseases will deepen.
  - Computer modelling will increase
- R&D Process will shorten significantly.
  - Attrition rates will decrease
  - Costs of clinical trials will reduce.
- World will be more connected and demanding
- Greater collaboration with regulators and health care providers about pricing, demonstrating efficacy, outcome benefit and value for money,

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Other Drivers of R&D

- Global Warming
  - Increase in malaria, cholera and respiratory illnesses.
  - Spread of insect born illnesses
- Pandemic concerns as the world shrinks
- Focus on Blockbusters disappears
  - Many fewer “me too” drugs
- Focus on prevention
  - Merge of functional foods, devices, drugs, natural health products
- Greater focus on Patient Reported Outcomes and Quality of Life.
- Deep involvement of patients, payers and healthcare providers in determining research goals.

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The Result of Changing Research

- Faster time to market for more limited market.
- More sophisticated products.
- Integration of device technology and pharm/biotech.
- Prevention packages of products.
- Outcome / cost based solutions.

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How Will The Regulators Be Doing Their Job?

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Greater International Regulatory Cooperation

- Already, several national and regional regulators have begun to collaborate by sharing safety and efficacy data.
- There may well be one global regulatory system by 2020, administered by national or federal agencies responsible for ensuring that new treatments meet the needs of the patient populations within their respective domains.
- Such a system would help to reduce the spiraling costs of regulatory compliance and reduce time to market.

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Harmonization of Development Requirements

- We are already familiar with ICH
- Pharmacopoeia are already being harmonized
- GHTF for devices
  - 510K's going away
  - PMA's towards Caterogries
- Biosimilars following ICH
- Drug safety, including postmarketing, harmonized

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Harmonized Does Not Mean Same Decision

- Different social environments
  - Viagra, Botox
- Different financial situations
  - Third world vs modernized country
- Different political systems
  - Far east vs US
- Different legal systems
  - Euthanasia, marihuana

- But in Canada we are used to the Common Drug Review

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Regulatory Science Initiative

- *regulatory science: the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.*
  - Tools we use today will be different in 10 years
    - Consider Acute Toxicity
    - As we learn more about the human genome, our understanding of clincial and nonclinical studies will increase
      - We may be able to do more with computers
      - We may learn more from epidemiology

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Universities

- Regulatory Science belongs in colleges.
- Apart from the University of Montreal, Canadian universities do not buy the concept.
- Regulatory Science and Drug Development will merge

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The Regulatory Professional

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What Will All of This Mean for Us?

- Regional regulatory professional will continue to exist.
  - Labelling
  - Regional specific interpretation of information
  - Regional political issues
  - However there will be fewer of these generalist regulatory individuals
- Strategic Role that is regional specific will develop merging
  - Regulatory
  - Pricing
  - Epidemiology
  - Safety

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What Will this Mean for Us?

- Subcategories of regulatory personnel will continue to emerge
  - Drug Safety/Pharmacovigilance
  - Postmarketing – REMS; Advertising
  - GXP – GCPs; GLPs; GMPs
  - These individuals will need to be a part of a Global Regulatory Team
- Globalization of Regulatory
  - Canada will be a very small player
  - We will need to live in a world more like Europe but without harmonized decision making
- Prehistoric Paper

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What Will This Mean For Us?

- Much more crossing of regulator / business / academic personnel.
  - Probably want to spend some time of your career in all three places.
- What about the regulatory CRO?
  - What could this mean for us in Canada?
- Professional Associations
  - What is the future of CAPRA?

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What Will This Mean for Us?

- Certification of Regulatory Professionals
  - RAC
    - Canadian, US, Europe, Japan, International
    - Entry level certification
- Consider certification of engineers in Mtl
  - Each has a piece of a failed bridge in their ring
  - Constant reminder of what they do
- What could remind us when Regulatory Science fails?

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Summary

- We have considered the changing market and environment, the patient needs in 10 years time, how regulators will adapt to cover this, and how we as regulatory professionals will also need to adapt.
- Regulatory jobs will continue and will grow.
- Academic training will heighten
- Regional regulatory will merge with payers and post marketing safety / epidemiology.
- Global regulatory players in subcategories of excellence will emerge
- For many of us in Canadian regulatory, CROs may signal a new career path.