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WORLDWIDE GOVERNMENT AFFAIRS & POLICY

ECOSYSTEMS FOR SUSTAINABLE INNOVATION

AMCHAM Healthcare Innovation Seminar
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ECOSYSTEMS FOR SUSTAINABLE INNOVATION

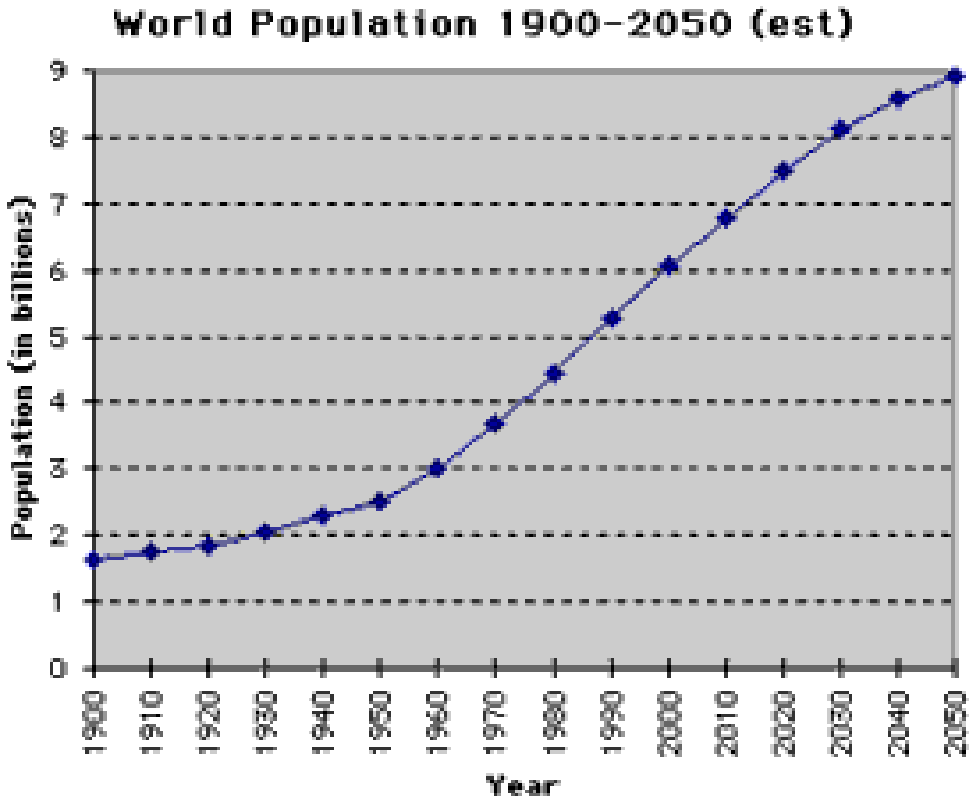
- **Objectives of Presentation:**

  - To identify the elements of ecosystems that support innovation in healthcare and health technologies

  - To showcase some examples:
    - –Positive – Ireland, United States
    - –Negative – New Zealand
    - –Middle of the road – Canada

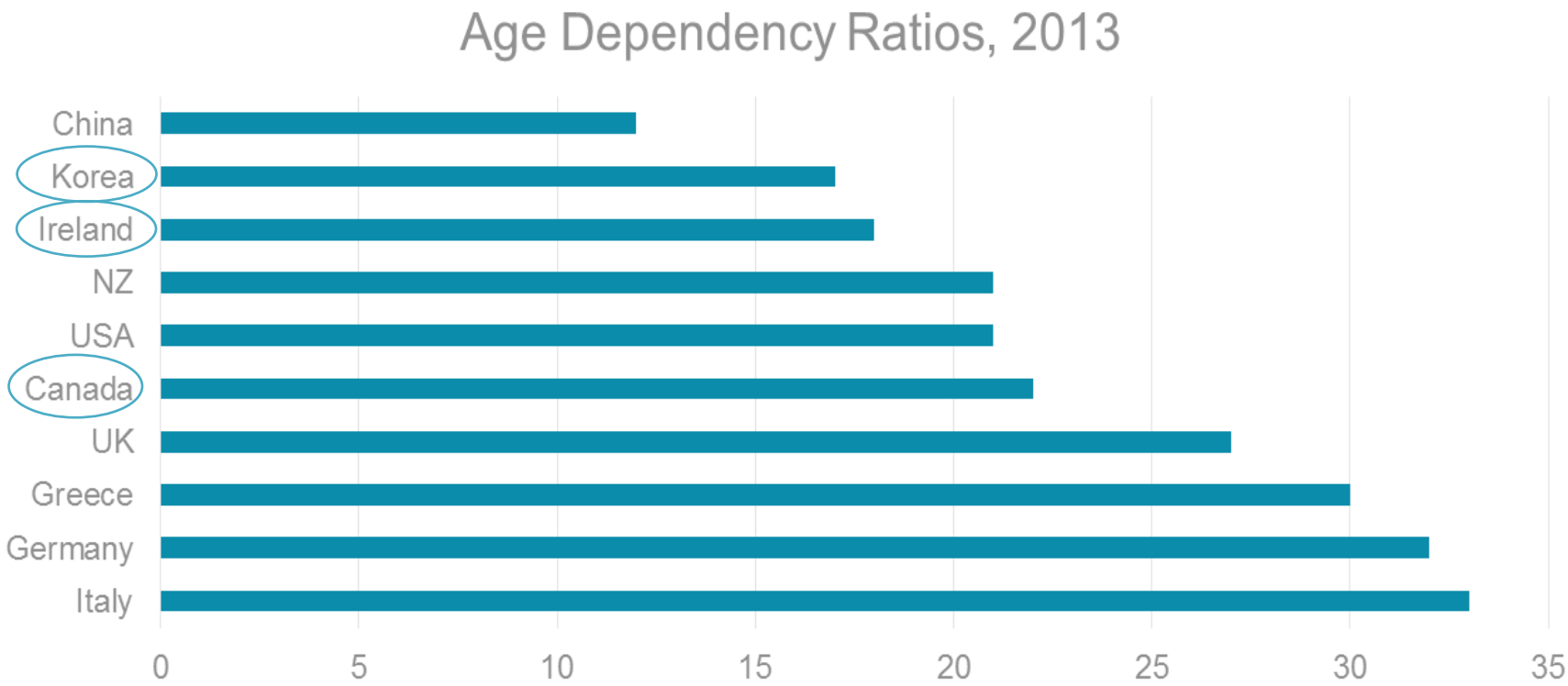
The Global Environment - Demographics

- In the space of a century, the world population will more than triple
  From < 3 billion in 1950 to > 9 billion in 2050



The Global Environment - Demographics

- **At the same time, the population is aging**



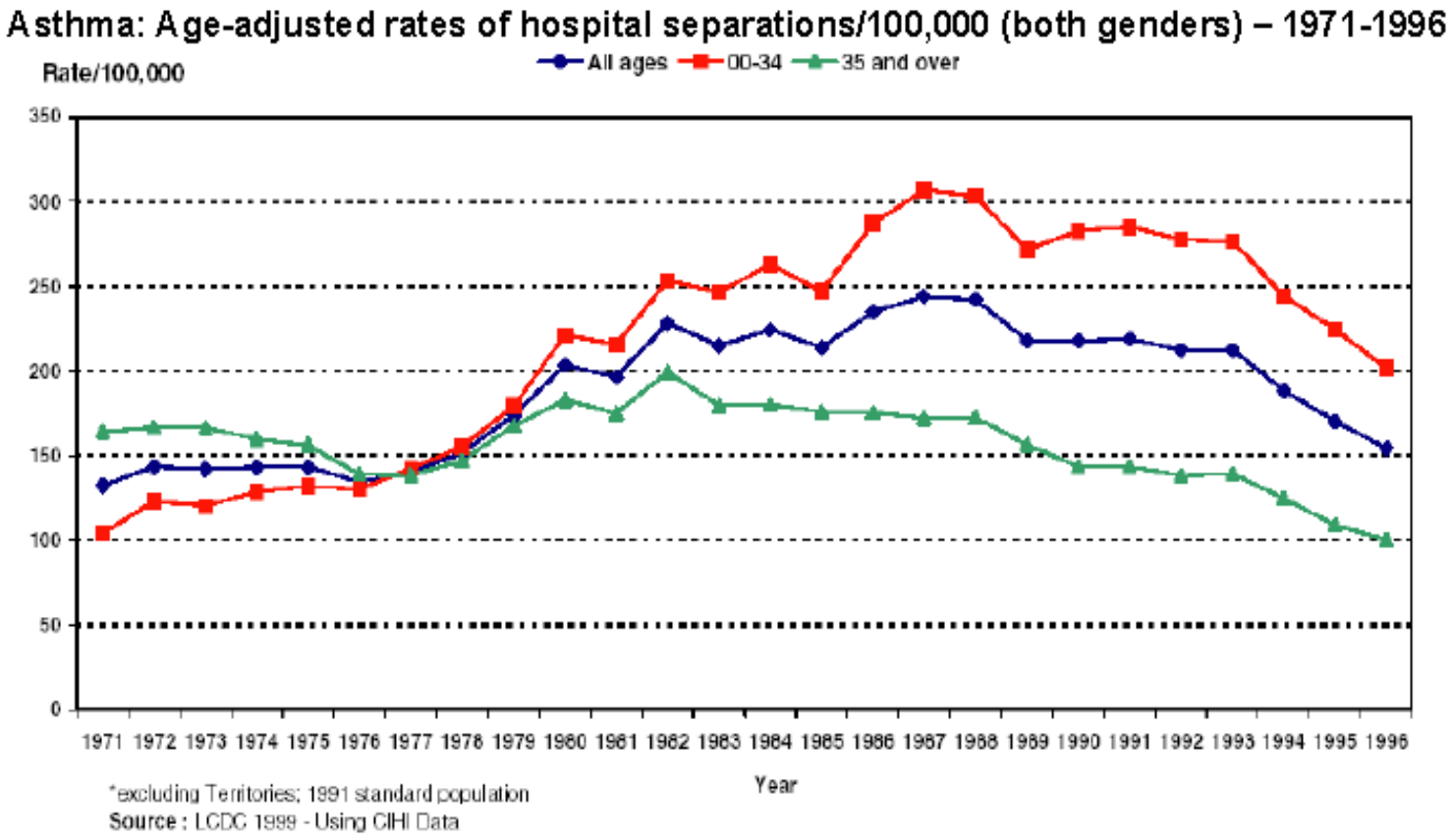
Innovation in Health Care

- **Dramatic strides in innovation over the past century**
  - Technological change has accelerated the pace of new discoveries and dispersion
  - Advances in genomics have created new potential for targeted research and treatments
  - Most common diseases have now been addressed, and in some cases eradicated
  - Research now focuses on:
    - More complex diseases and conditions, such as cancer and Alzheimer's
    - Drugs for rare diseases

- **Health care challenges**
  - Emerging new diseases – Ebola, MERS, antibiotic resistant bacteria
  - Chronic disease – aging population

Medicines Impact on Asthma

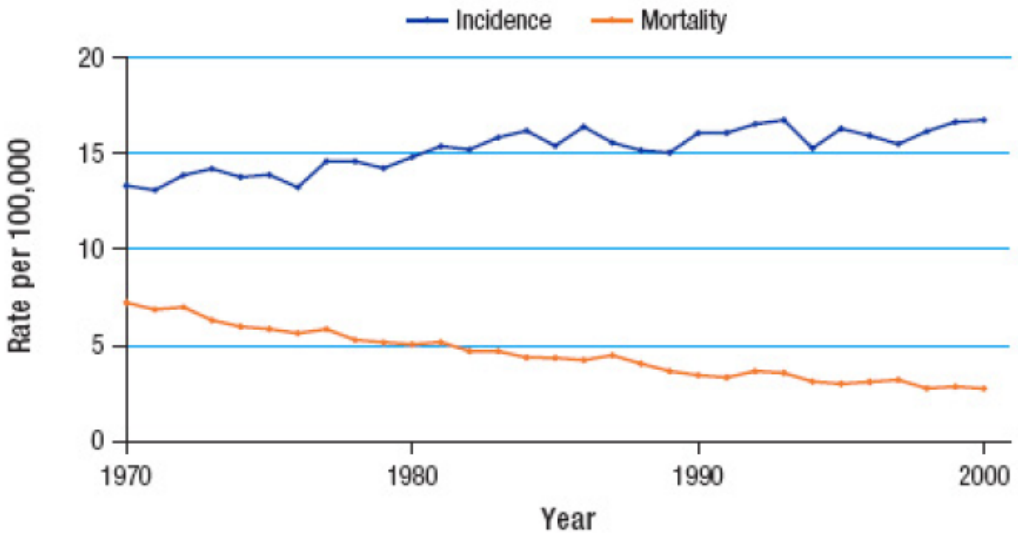
- The decrease in hospitalization for asthma over the last 20 years is a result of better education and the availability of effective medications



Cancer Mortality in Children

- **Sharp decline in childhood cancer mortality over the last 30 years. Studies indicate that 80% of children with leukemia are still alive five years after diagnosis, while in the early 1970s, only a minority of children survived leukemia**

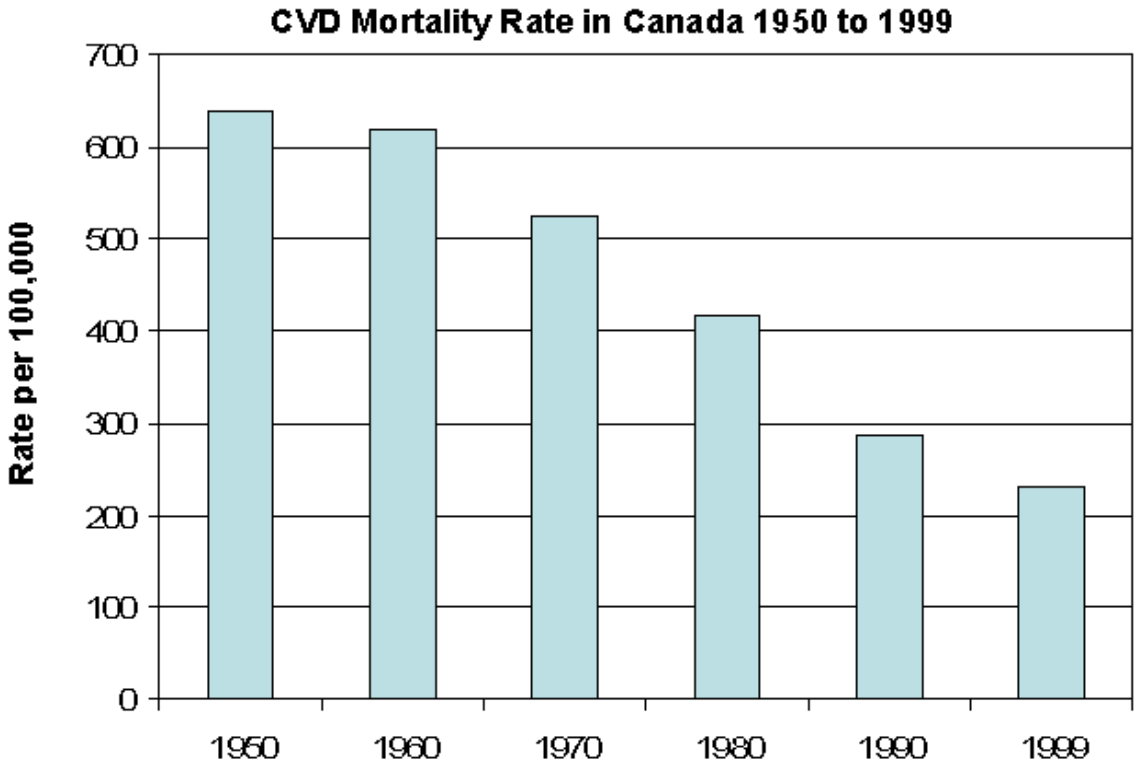
Age-standardized incidence and mortality rates for all cancers in children and youth, ages 0 – 19 years, Canada, 1970-2000



Source: Progress Report on Cancer Control in Canada. Public Health Agency of Canada: http://www.phac-aspc.gc.ca/publicat/prccc-relccc/chap_2-eng.php

Impact on CVD Death Rate

- Research leading to better prevention, diagnosis and treatment has resulted in a dramatic decline in the CVD death rate and hospitalization rate in Canada over the past 50 years



Source: Health Canada Cardiovascular Disease Surveillance On-Line

Challenges to Health System Sustainability

- **The aging population and the growing incidence of chronic disease combine to increase demands for health care**

- **New treatments for diseases that were not adequately treated in the past add to health care costs**

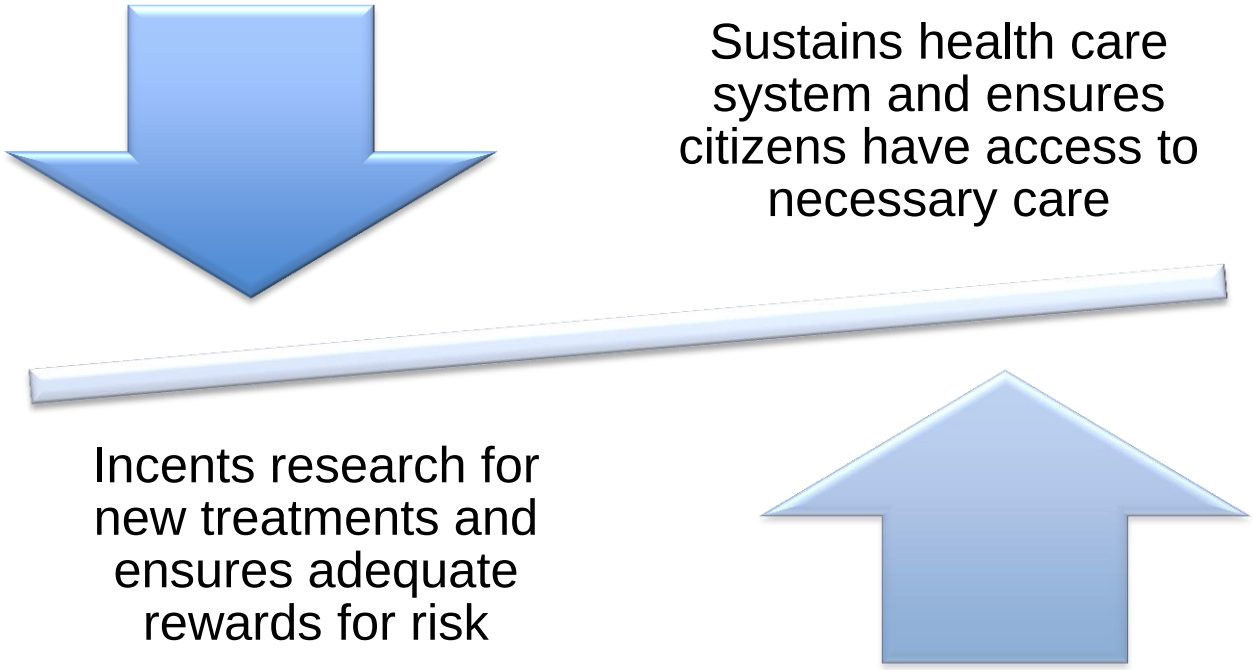
- **Increasing complexity, risk, and cost of research**

- **Targeted treatments for small populations**
  - On one hand, a challenge in that there is only a small patient base to recover high research investment
  - But also a benefit as advances support more incremental advances for treatments for o ther diseases

Challenges to Health System Sustainability

Bottom Line:

- **Challenge for modern societies to develop and maintain a healthcare ecosystem that:**



Key Elements for Sustainable Innovation

Political and Economic Environment

- Stable environment creates market certainty

Positive Research Environment

- Support for research and reward for innovation
- Partnerships available and encouraged

Industrial Policy

- Stable, predictable IP regime
- Tax and other policies
- Support for international trade agreements/policies

Regulatory System

- Quality and timely
- International standards

Pricing and Reimbursement

- Aligned with industrial policy; predictable, not a barrier

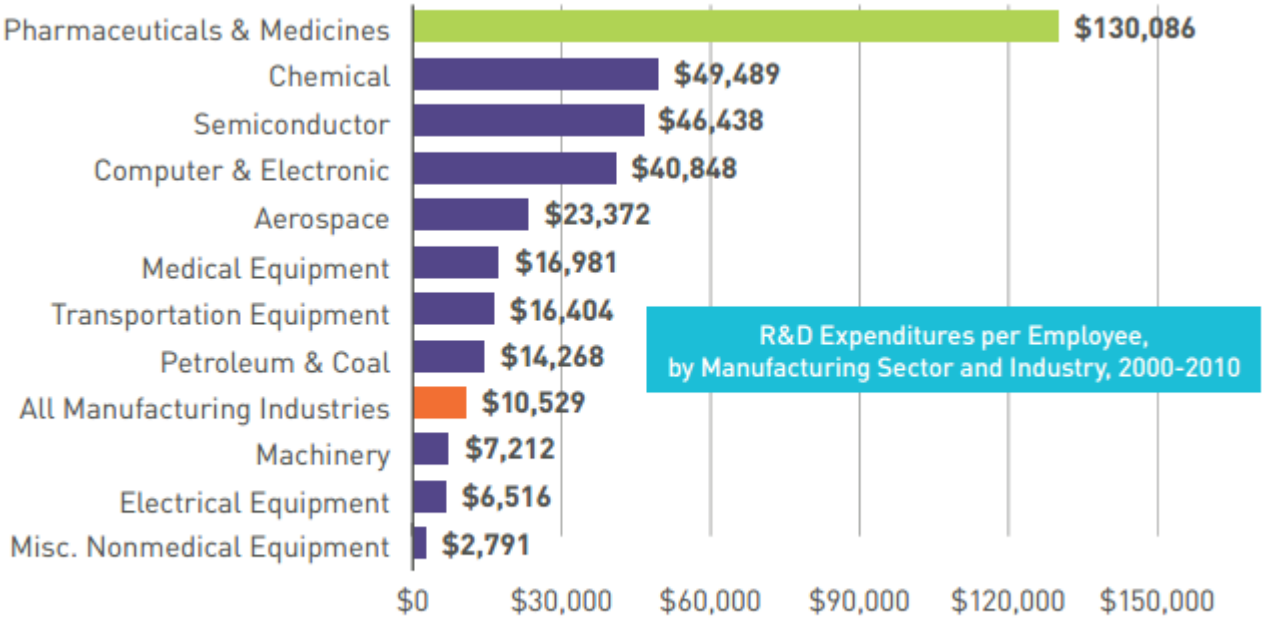
US an International Leader in Health Innovation

- **Prescription medicines continue to yield important advances, helping patients live longer and healthier lives**
  - Since peaking in the 1990s, cancer death rates have declined nearly 22 percent.
  - Approximately 83% of survival gains in cancer are attributable to new treatments, including medicines
  - Today treatments for hepatitis C have a nearly 90% cure rate for patients
  - The development of a new treatment that delays the onset of Alzheimer's could reduce Medicare and Medicaid spending on patients with Alzheimer's by more than $400 billion annually by 2050

- **Robust intellectual property protection encourages biopharma innovation**
  - Patent protection: 20 years + 5 years patent term restoration
  - Data protection: 12 years for biologics; 5 years for chemical + 3 year extension for new indications

Pharma Sector Among the Most R&D Intensive

- PhRMA member companies invested an estimated **$51.2 billion** globally in biopharmaceutical research and development (R&D) in 2014
- Biopharmaceutical companies invested more than **12 times** the amount of R&D per employee than manufacturing industries overall



Source: Pham N. IP-intensive manufacturing industries: driving US economic growth. Washington, DC: NDP Analytics; 2015. http://www.ndpanalytics.com/ip-intensive-manufacturing-industries-driving-us-economic-growth-2015. Accessed March 2015

Source: PhRMA

US FDA is the Gold-Standard Regulator

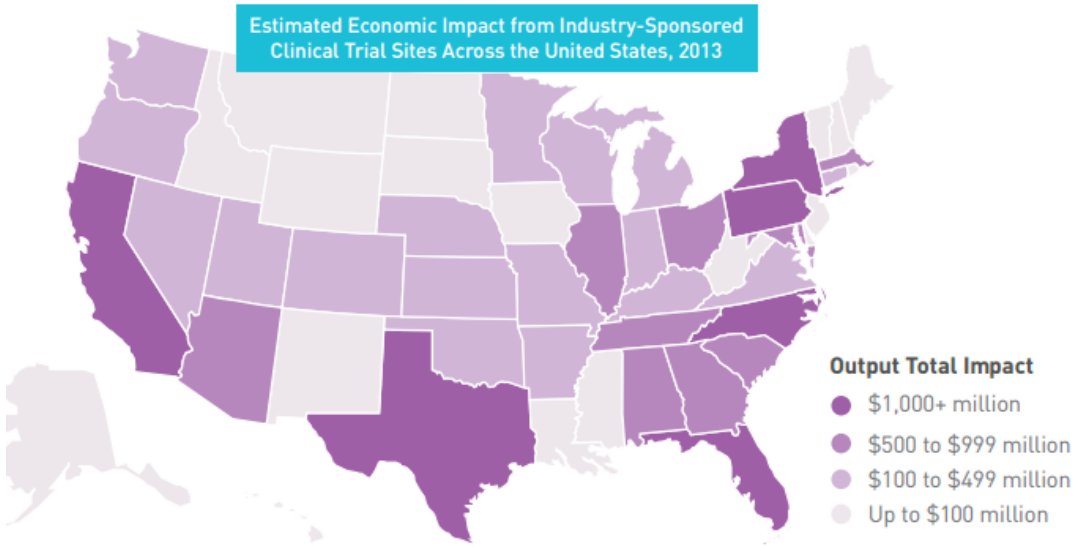
- **FDA highly skilled workforce: healthcare professionals; scientists; engineers; etc.**

- **Predictable review process, timelines, and regulatory expectations**
  - FDA accountability for meeting review and other process goals, and transparency regarding performance metrics

- **Excellent approach to engagement / collaboration**
  - Industry engagement in the creation of processes and timelines
  - Opportunities for sponsors to obtain input and feedback during product development, through meetings and occasionally correspondence
  - FDA internal training that includes inviting industry to present new science

Market-based Approach to Health Care

- **No reliance on a centralized HTA or price setting approaches**
  - Uses tools like cost sharing, prior authorization
- **Heavy reliance on generics (which are very low-cost in the US)**
  - 86% of prescriptions dispensed are generics
- **Market-based approach helps to attract clinical trial research:**
  - Major economic and health impact on local economies
  - 6,199 clinical trials of medicines in the United States, involving a total of 1.1 million volunteer participants and supporting a total of $25 billion in economic activity



Source: PhRMA

Ireland on the Move

- **Set to remain the fastest-growing EU economy**
- **One of the fastest growing manufacturing sectors globally**
- **Record levels of employment**
- **Record breaking 2014 for FDI (⬆20% # of investments)**
  - **9 of the top 10** global pharmaceutical companies have invested in Ireland
  - **17 of the top 25** medical devices companies have invested in Ireland

Source: IDA Ireland

Why Ireland Works

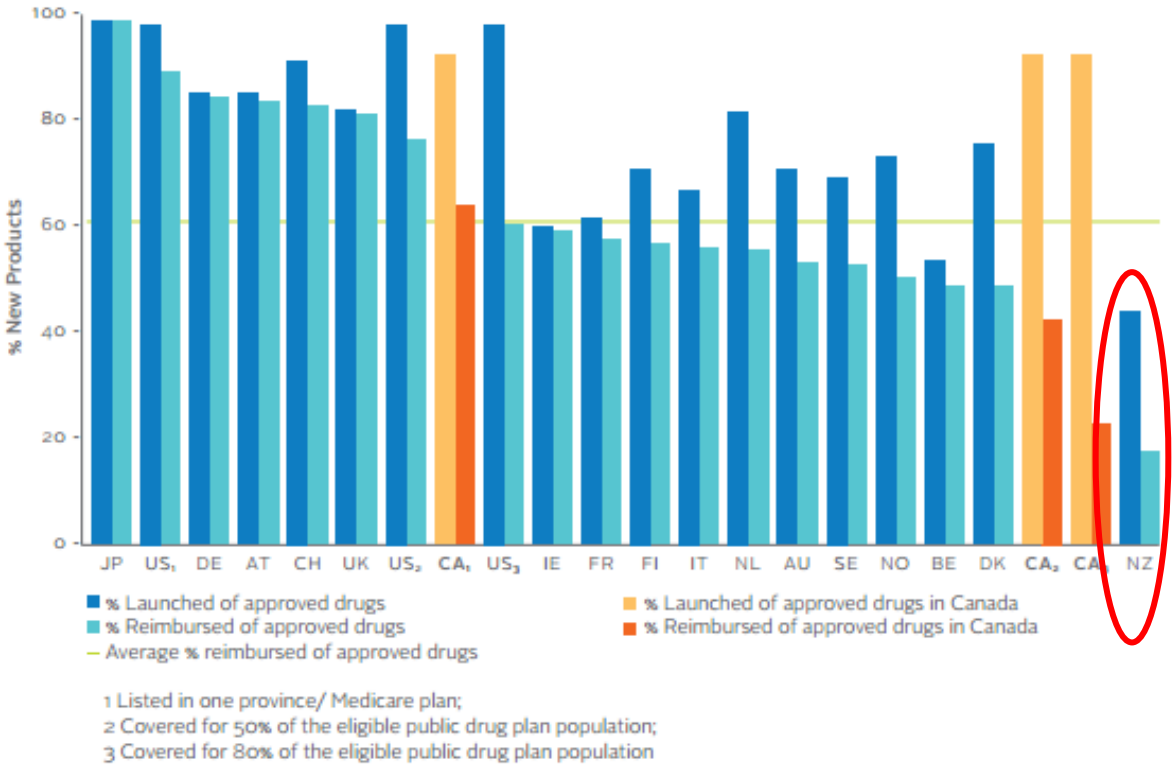
- **Coherent Strategy**
  - Mandate to attract foreign direct investment
  - Focuses on research-based, innovative industries
  - Consultation process to develop Irish "Knowledge Development Box" and enhance existing IP regime underway
- **Favourable tax rates and benefits:**
  - Commitment to maintain 12.5% corporate tax rate
  - Support for businesses accessing foreign export markets through special tax regime
  - Incentives for early stage business investment
- **Labour costs lower than many EU countries**
  - Ranks 4th in business efficiency
- **Education policy responsive to growth sectors**
  - Ranks 1st in EU in attaining third level education

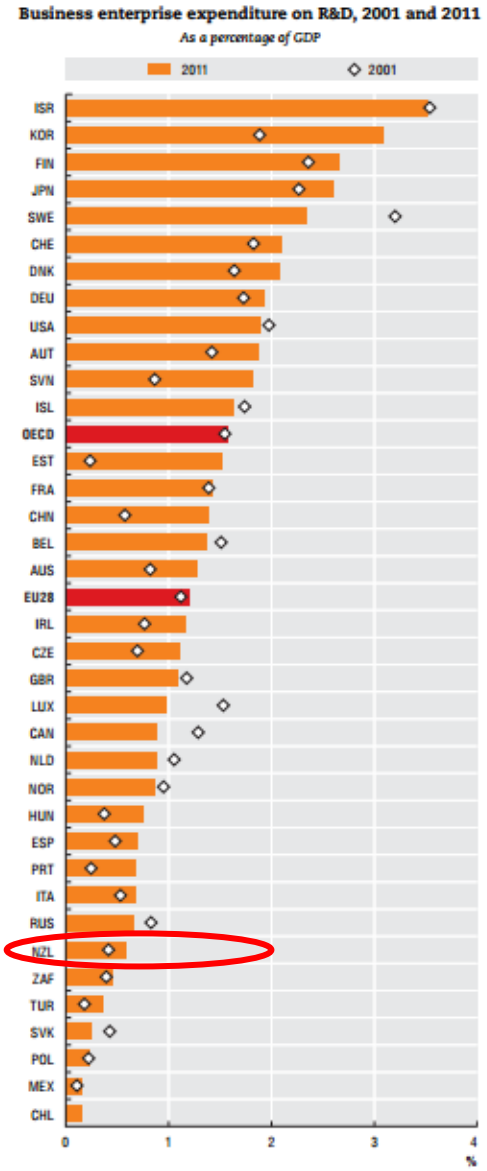
  Strong knowledge sector cluster with over 83 active Pharma companies

Source: IDA Ireland

New Zealand Lags: Access to New Medicines, Business R&D

Percentage of new medicines launched and publicly reimbursed by country





Source: Rx&D; OECD

New Zealand Lags: Global R&D Ranking, Government Procurement Ranking

- PHARMAC one of the most restrictive purchasing regimes internationally
- Uses therapeutic reference pricing (linking the price of new medicines to price of old medicines)
- Abolished many tax incentives for R&D
- Exodus of pharma investment

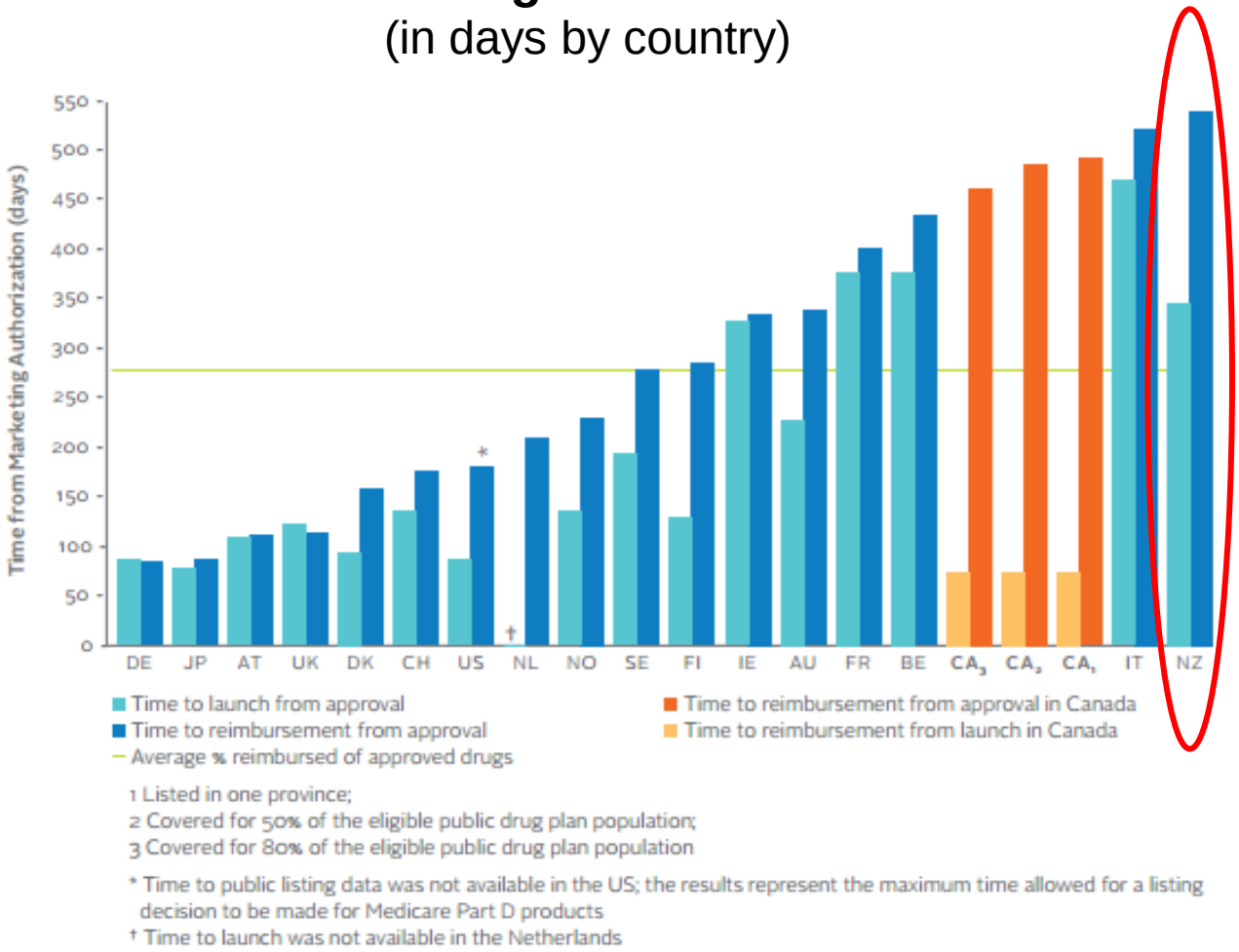
	2014-15 Global Rank: Company spending on R&D	2014-15 Global Rank: Government Procurement of advanced technology products
United States	4th	8th
Korea	20th	20th
Canada	27th	48th
New Zealand	29th	71st

Source: OECD; World Economic Forum, Global Competitiveness Rankings

New Zealand Lags: Time to Government Funding

Average time to launch and time to reimbursement from marketing authorization

(in days by country)

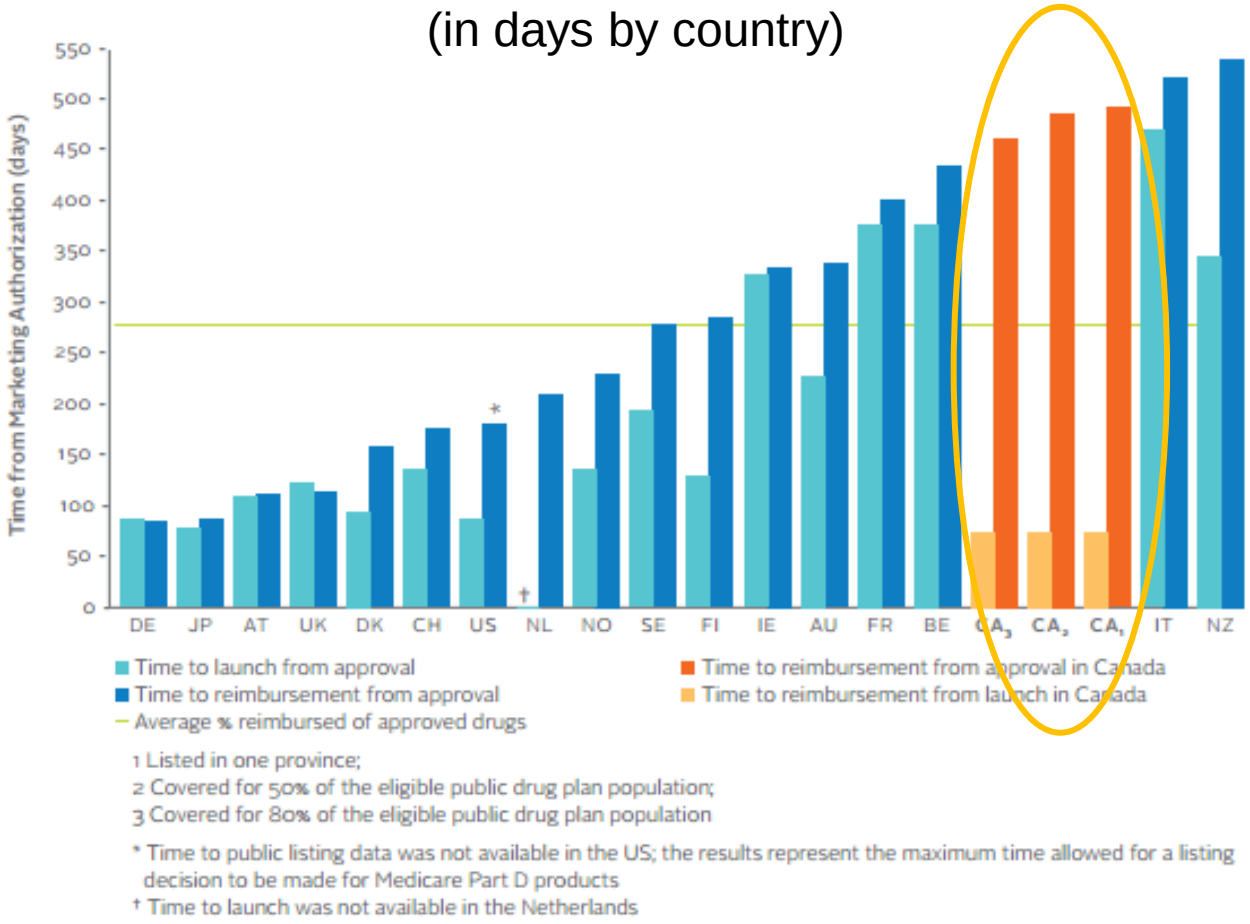


Source: Rx&D

Canada: Room for Improvement

Average time to launch and time to reimbursement from marketing authorization

(in days by country)



Source: Rx&D

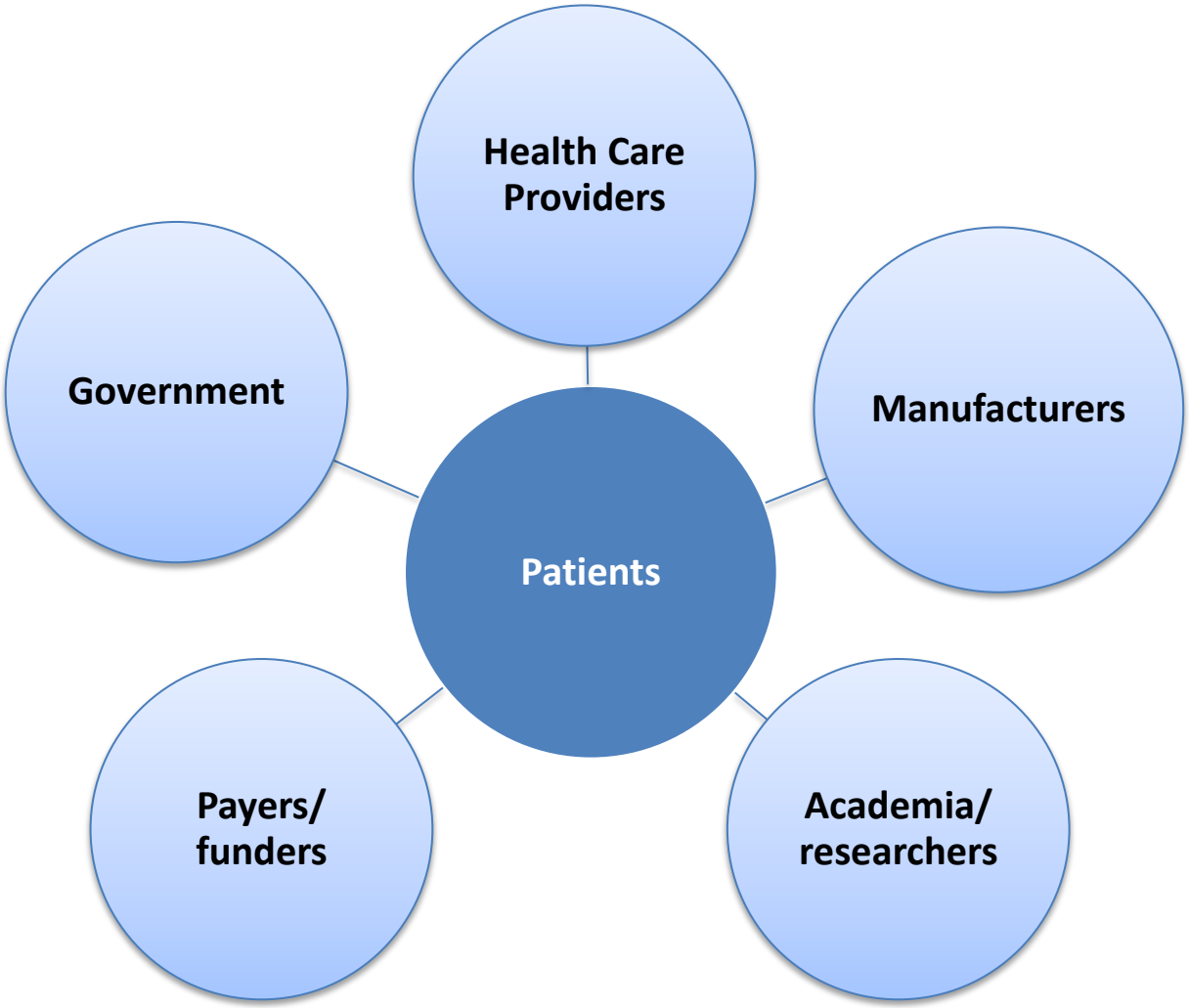
Canada: Room for Improvement

- **IP is good, but could be better**
  - 20 years patent protection
  - 8-8.5 years data protection
  - Patent term restoration: promised under CETA, not yet implemented
- **No orphan drug regulation (yet) and commitment to incentives for orphan drug development**
- **HTA used as barrier to coverage; Canada ranks well behind most other countries in funding of new drugs**
- **Complex pricing and reimbursement mechanisms:**
  - PMPRB
  - HTA
  - Joint price negotiation

Canada: Positive Elements

- **Public support for research – Canadian Institutes for Health Research**
  - Approximately $1 billion in support for health research in 2015-16
    - $703 million to support Investigator-Initiated Health Research
    - $295 million on Priority-Driven Health Research
- **Low corporate tax rates and some R&D supports**
  - Federal corporate tax rate is 15%; combined corporate tax rate 26.5% (Ontario)
  - Scientific Research and Experimental Development tax credit
- **International trade expansion**
  - Federal government has concluded 7 free trade pacts with 37 countries since 2007
  - High Priority: Trans-Pacific Partnership, Canada-European Union, Canada-Korea
- **Regulatory modernization**
  - Aim for comparable international standards
  - Canada-United States Regulatory Cooperation Council

Collaboration – A Critical Success Factor



Achieving Collaboration

Shared Vision

- Need for all parties to recognize the diverse interests and objectives of others
- But also identify the common interests!

Trust

- A huge challenge
- Does government trust industry?

Overcoming Barriers to Collaboration

- Relationship building
- Partnerships / collaboration in research
- Evaluate / recognize success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