

# ***Producing and Incorporating Innovation***

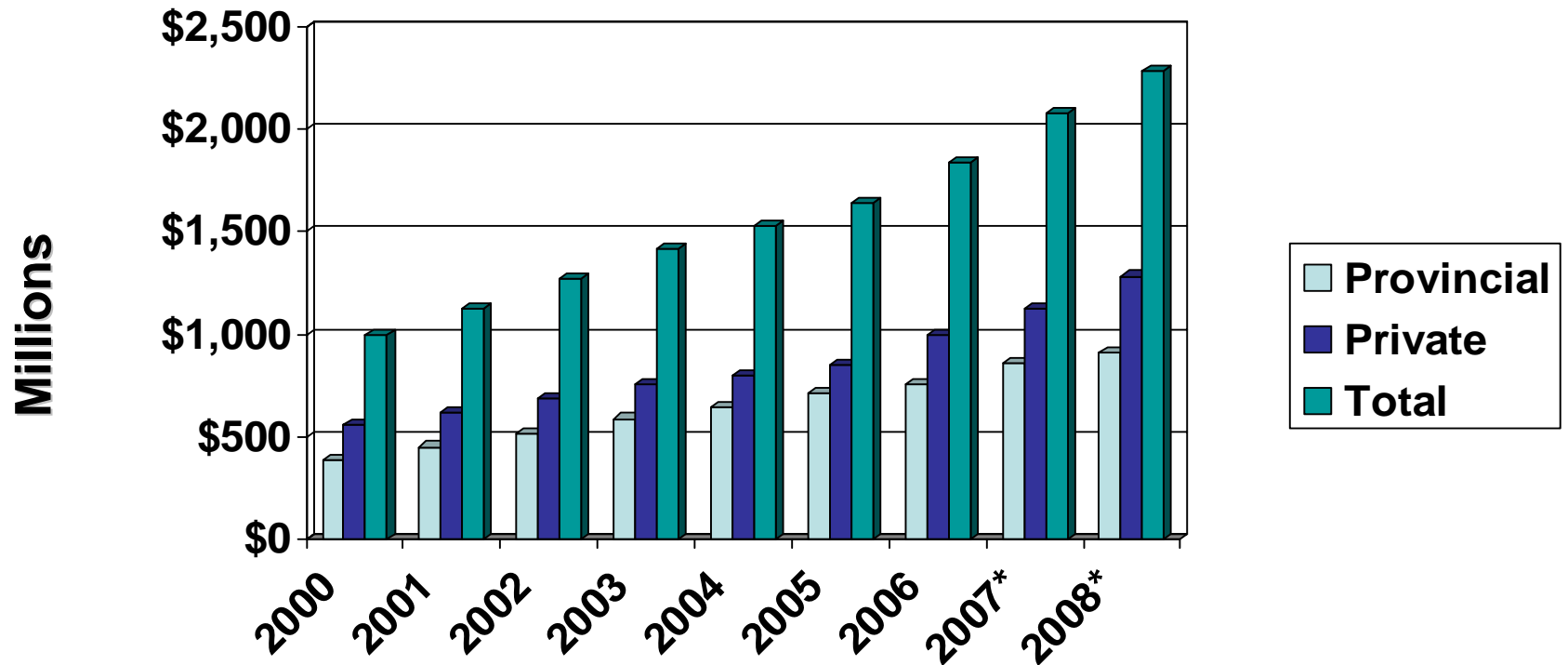


**Gregg Szabo**  
**IHE Innovation Forum II**  
**May 25, 2009**

# Overview

- **Cost** – *the lens through which innovation is seen*
- **Risk assessment** – *by companies, and its impact on producing new products*
- **Principles** – *for how innovative products may be incorporated into the system*

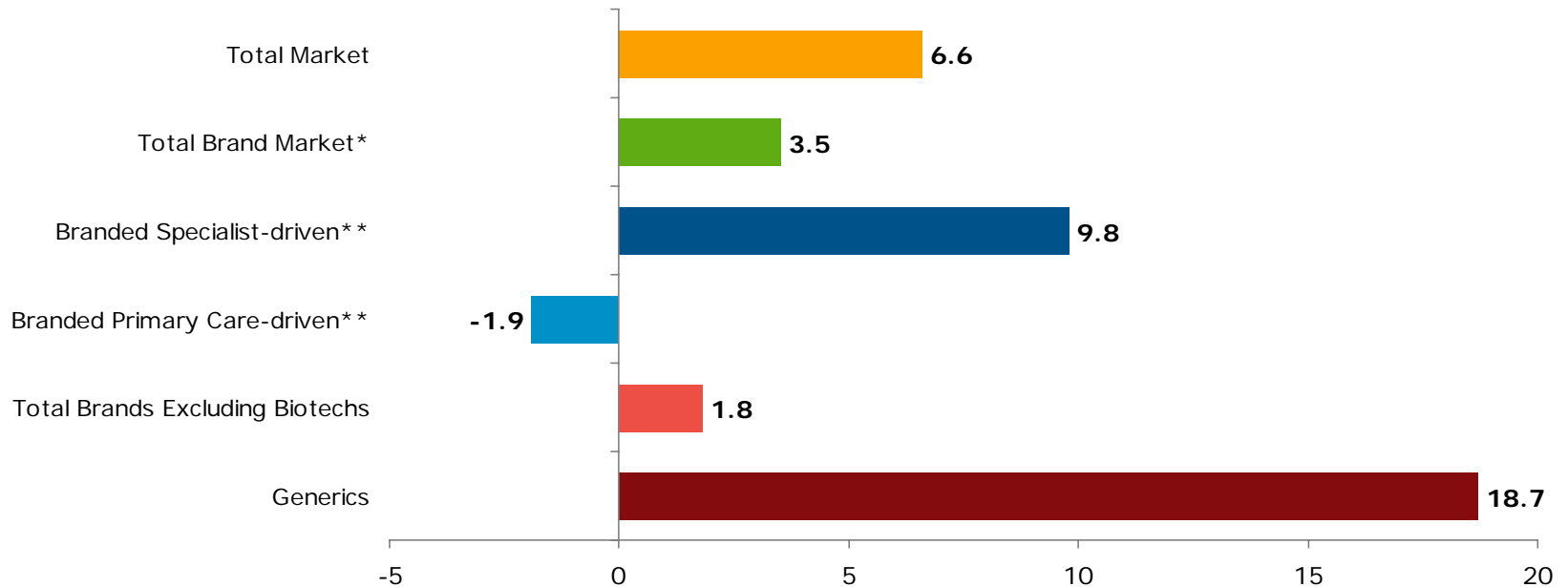
# Alberta Prescription Drug Expenditures: Provincial, Private, Total



\*Estimated

Source: CIHI, Drug Expenditure in Canada, 1885 to 2008, 2009

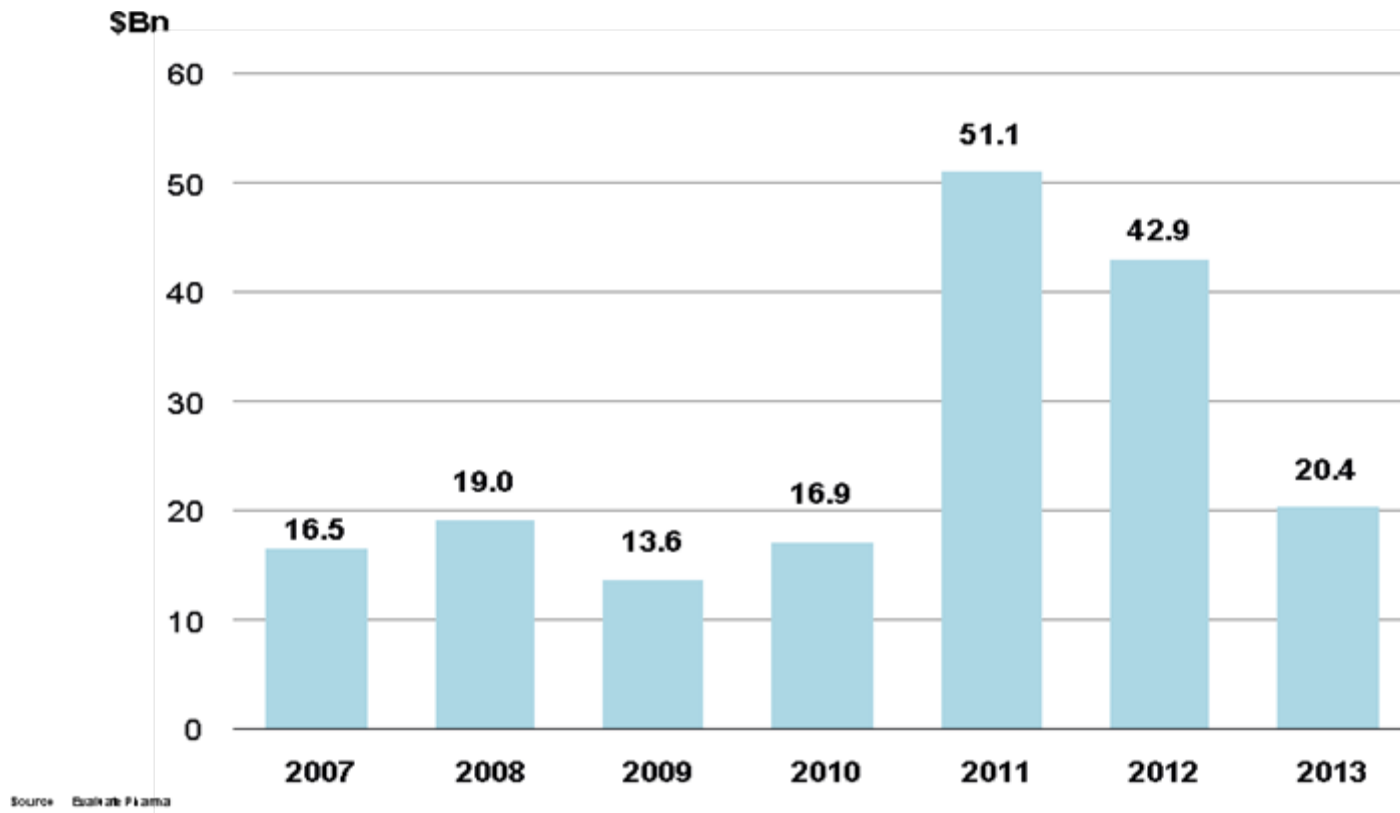
# Market Performance Varies by Segment MAT December 2008



\*Brand market segment definition includes biotech and oncology segments

\*\*Branded Specialist-driven and Primary Care-driven Growth Rates are from Midas, MAT December 2008

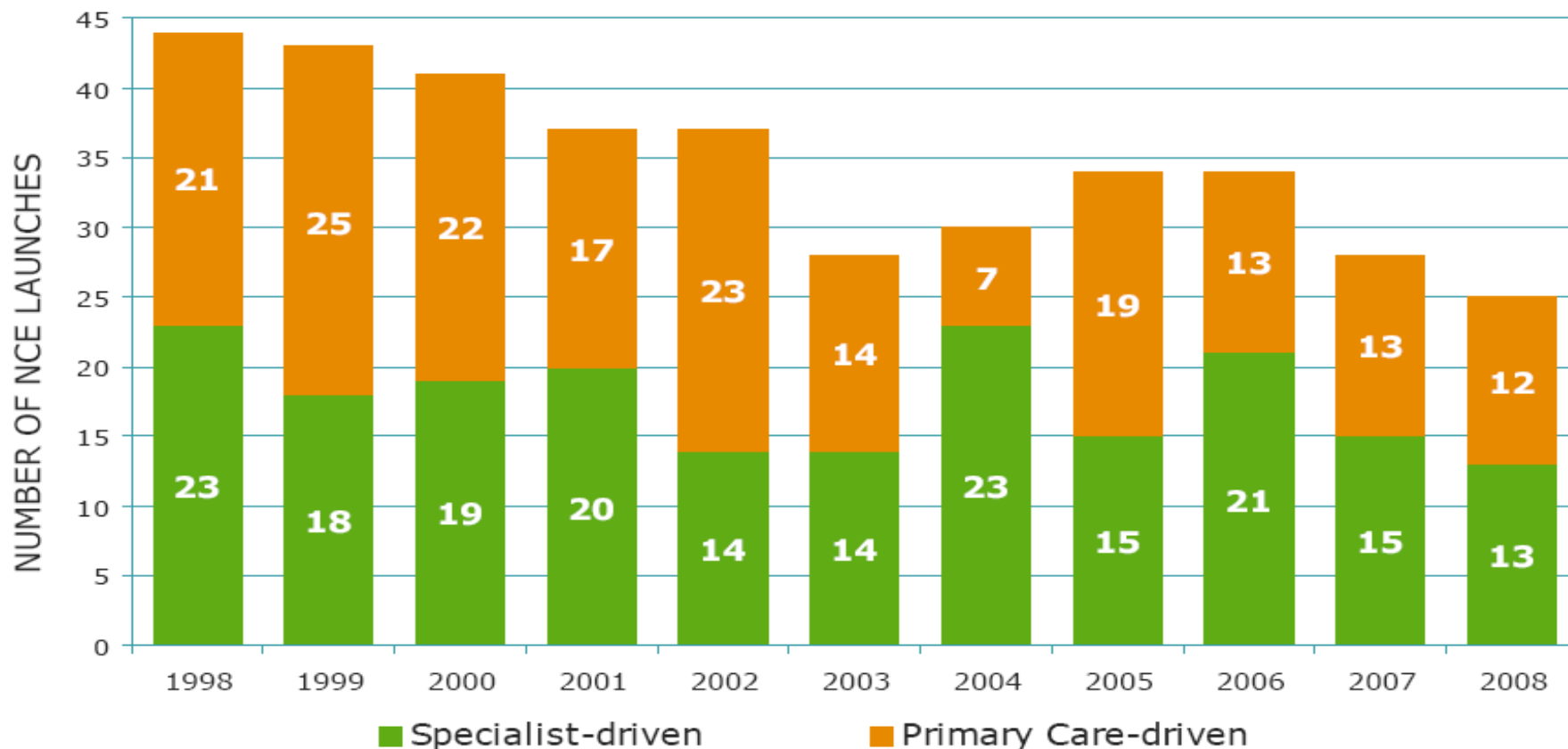
# Large Cap Pharma Patent Expirations by Year



**Source: Evaluate Pharma** (Includes Abbott, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, J&J, Merck, Novartis, Pfizer, Roche, Sanofi, Schering-Plough, and Wyeth. Revenue lost calculated as last full year of estimated sales prior to normally scheduled expiration)

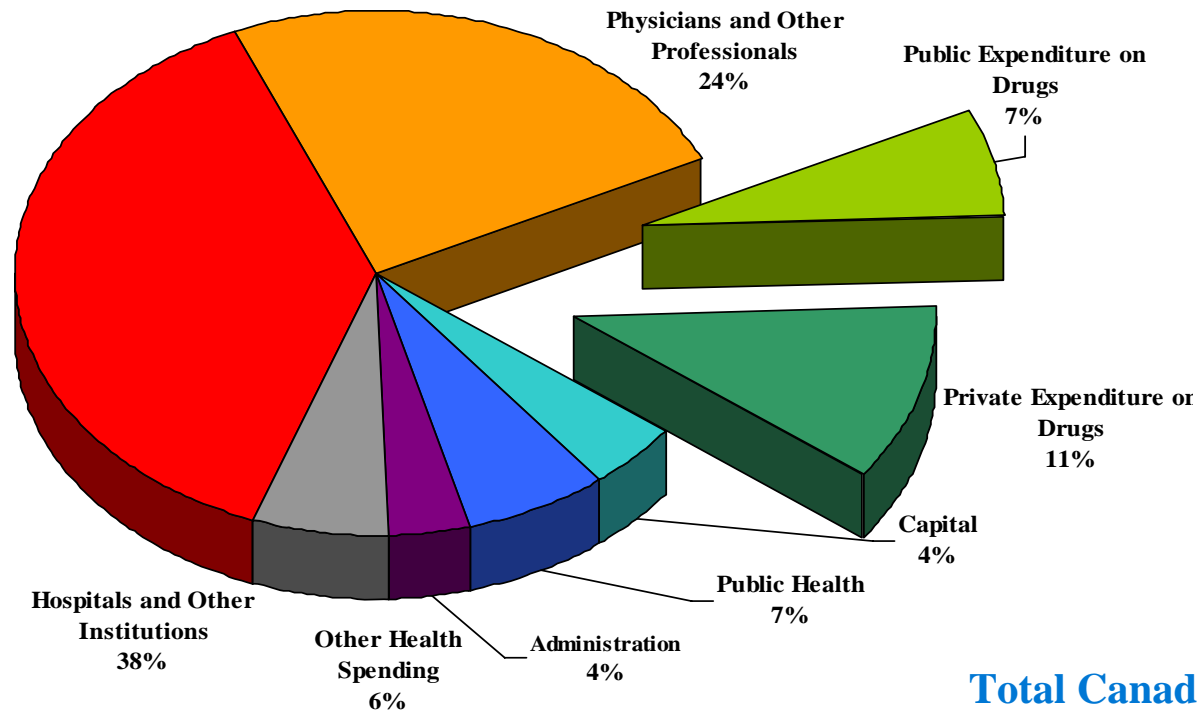
# With only 25 NCE launches, 2008 marks the lowest point since 1983

## Global NCE launches 1998-2008



Source: IMS Health. Market Insights Team Analysis. 2008.

# Assessment of Health Care Expenditures



Total expenditure on prescription and non-prescription drugs is forecasted to reach \$29.8 billion in 2008. This can be further divided into public (~\$11 B) and private (~\$18 B) expenditures.

**Total Canadian Health Expenditures  
\$171.91 Billion (2008 Forecast)**

Source: National Health Expenditure Database (NHEX).1987-2008. Canadian Institute of Health Information (CIHI). May 15, 2008.

Canadian Investment in Pharmaceuticals. 2007. Brogan Inc. Health Care Data. *Prepared for Rx&D.*

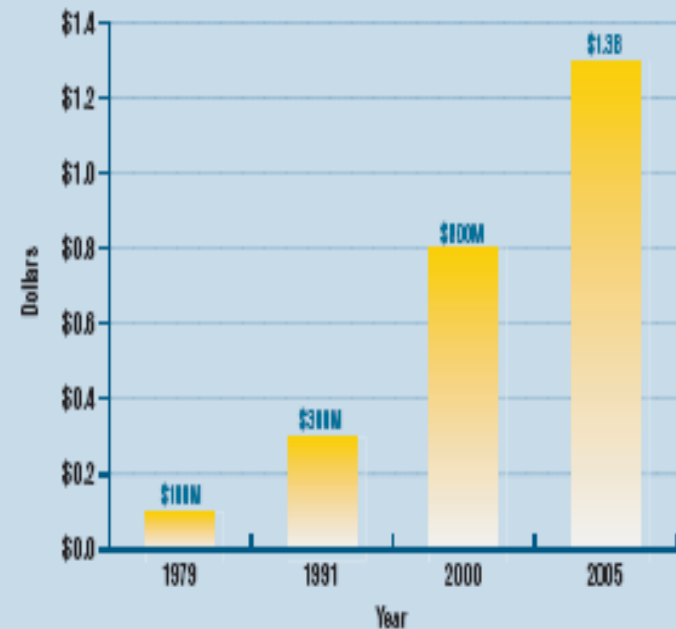
# Pharmaceutical R&D “Hurdles”: Safety, Efficacy, Quality

- Long process – 10 -15 yrs.
- Complex (pre-discovery, discovery, preclinical, clinical, HC review/approval, manufacturing, post-approval research)
- Highly competitive
- Increasing costs - \$1.3B US
- Depending on few products to support future R&D

**Requires analyses of future needs, potential value (patients, system, internal), competition, and assessment of risk**

- Evidence-based
- Pressure to “Get It Right”
- Safety, Efficacy, Quality

FIGURE 13: Cost to Develop One New Drug



SOURCES: J. A. DiMasi and H. G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics* 28, no. 4-5 (2007): 489-479; J. A. DiMasi, et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003): 151-185.

# Pharmaceutical R&D: “Additional Hurdles”

The Fourth: Value for money

Demanded by payers

The Fifth: Affordability

Societal restrictions for patient access to medicines are determined by the ability of a society to pay

# Embracing the new commercial realities with new thinking and business models is a necessity

## Implementing New Commercial Models

- Revising the nature of selling
- Moving to regional/local structures
- Aligning to changes in decision-makers

## Adjusting the cost base

- Adapting to the future portfolio
- Reflecting the new reality
- Outsourcing non-strategic functions

## Strengthening the Value of Medicines

- Framing benefits and risks
- Adopting payer mindset to define value
- Communicating to all stakeholders

## Adopting patient-centric approach

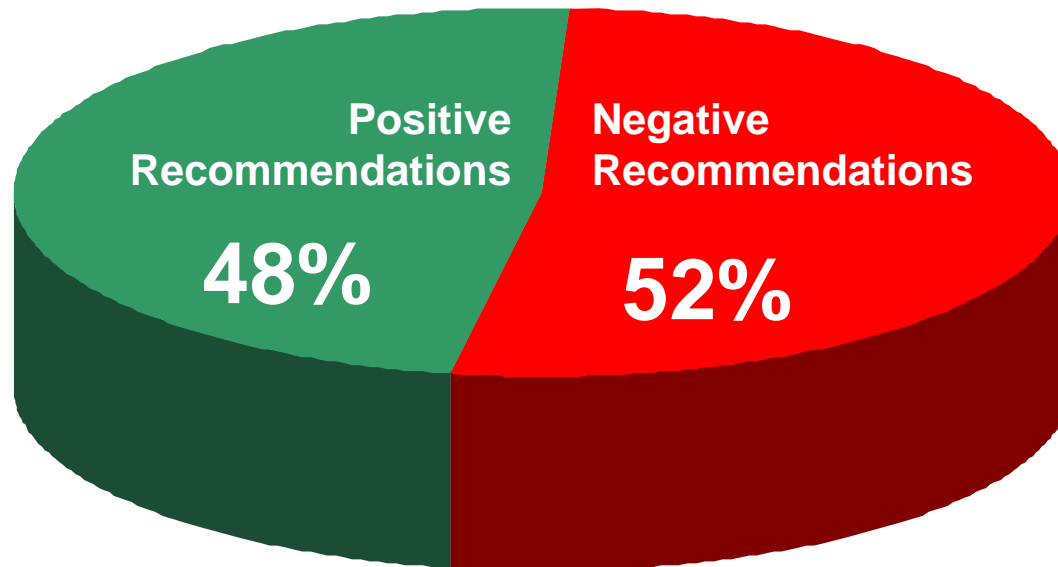
- Focusing on patient flows
- Supporting compliance and persistency
- Defining results in patient terms

## Pursuing growth in emerging markets

- Aligning product portfolio
- Adapting business model and leadership
- Establishing local presence

Source: IMS Health, Thought Leadership Research, Dec 2008

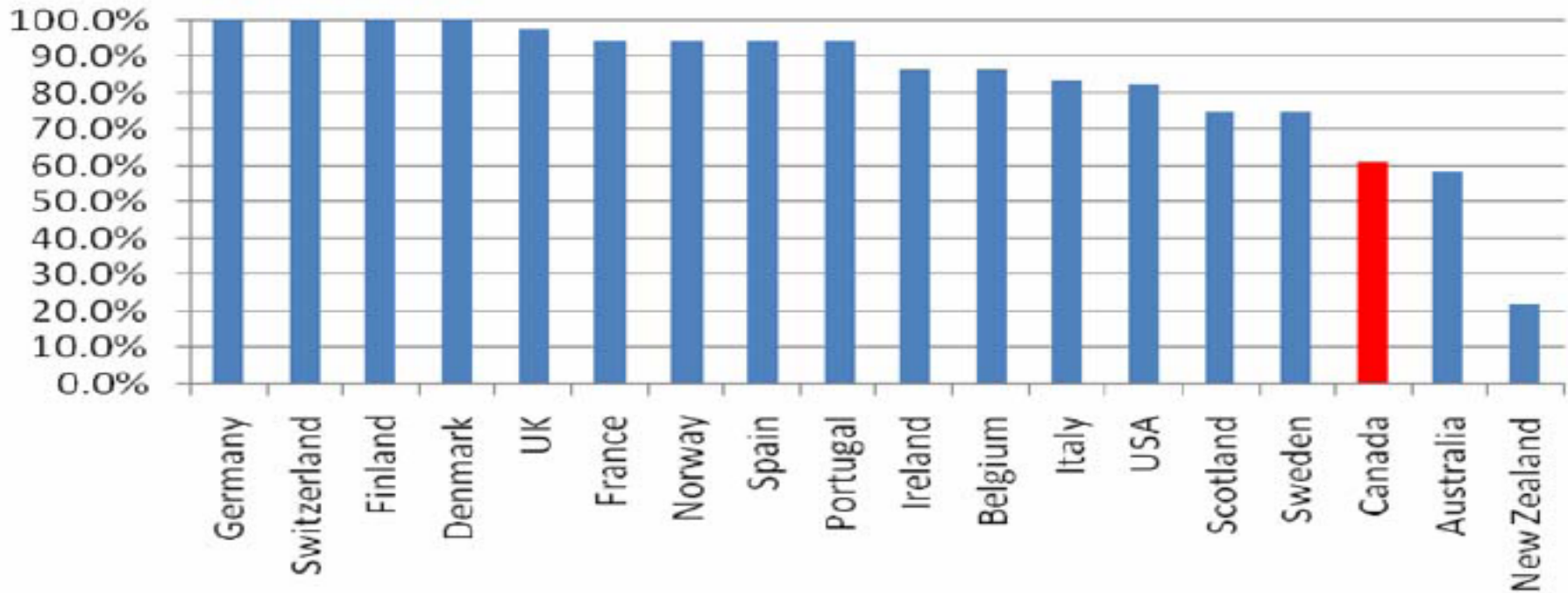
# 125 CDR Recommendations (as of March 27, 2009)



**\*Denote drugs with multiple recommendations due to resubmission or submission under a new indication.**

# International Comparative Listing Recommendations (for public plans)

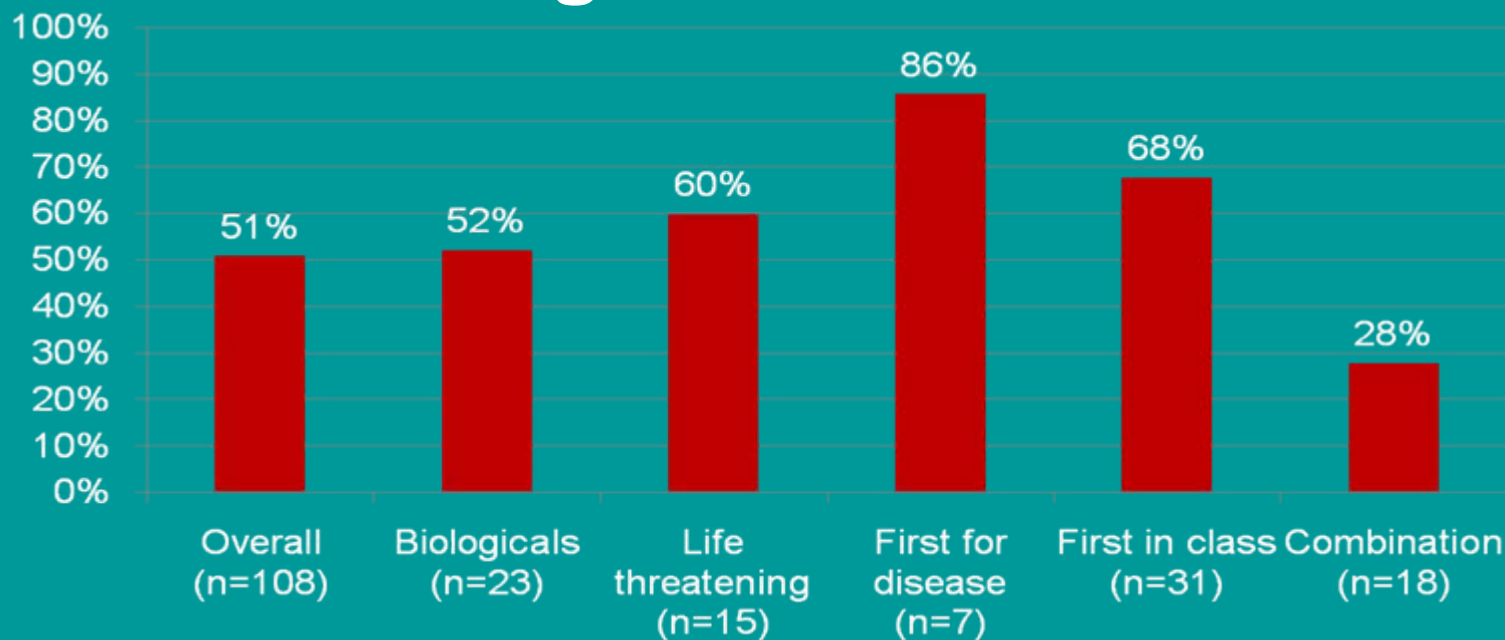
Percent Drugs Recommended / Reimbursed by Country



\* Analysis of 36 CDR reviewed innovative medicines submitted to above jurisdictions ( to April 30, 2008)

Source: Wyatt Health Management, *Access to Innovative Pharmaceuticals: How Do Countries Compare?*, 2008

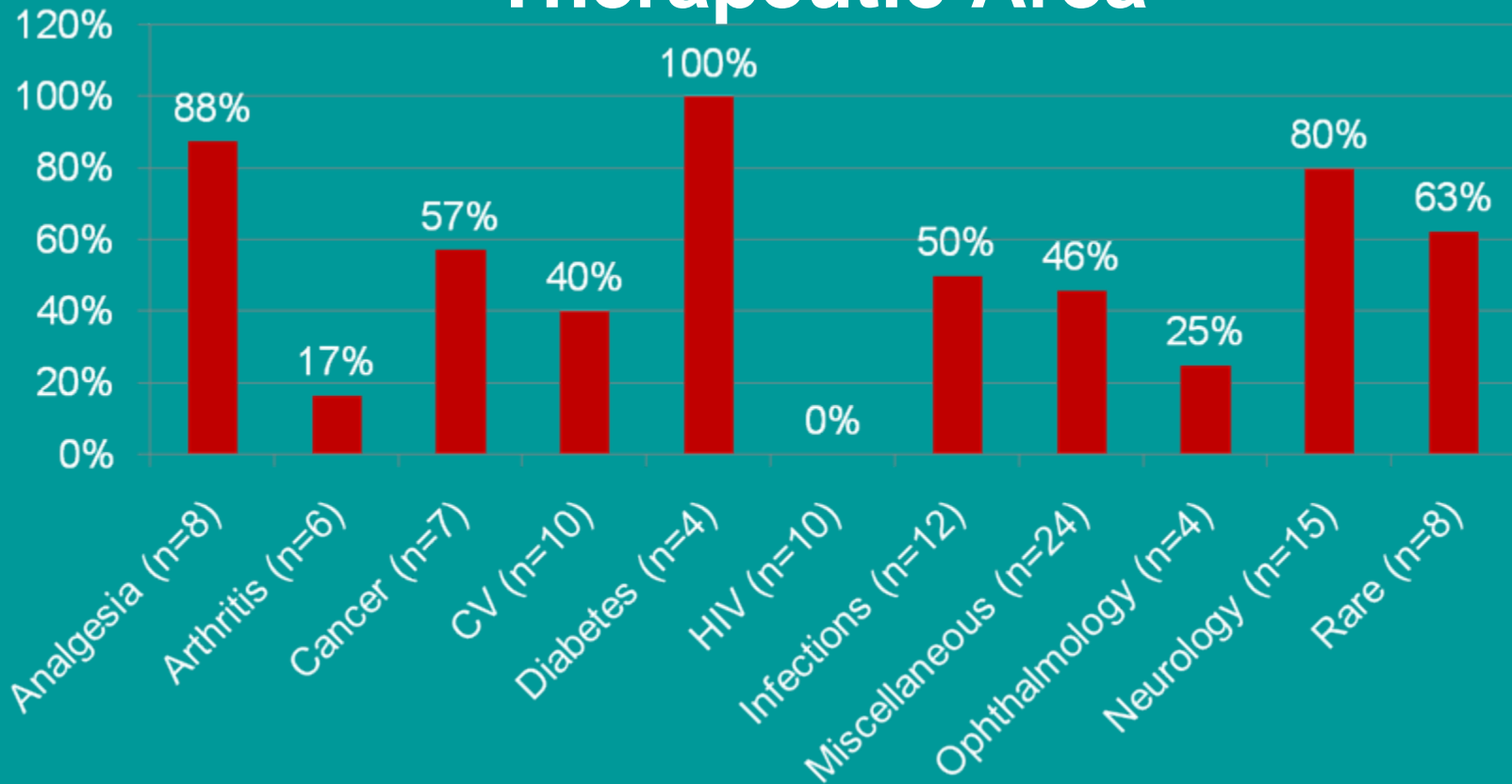
# CDR “Do Not List” Recommendations\*: Drug Attributes



\* Based on CDR recommendations between Sept. 2003 and Sept 2008

Source: Axia Research Inc, (presented at CADTH Symposium, 2009)

# CDR “Do Not List” Recommendations\*: Therapeutic Area



\* Based on CDR recommendations between Sept. 2003 and Sept 2008

Source: Axia Research Inc, (presented at CADTH Symposium, 2009)

# Everyone wants to avoid:

- Over-use and under-use of medicines;
- Wrong choice of medicine;
- Adverse reaction with other medicines;
- Duplication of prescriptions;
- Adverse reaction due to pre-existing known/unknown condition;
- Lack of patient monitoring and/or follow-up

List partially excerpted from Presentation by Johanne Monette, MD, FRCPC, MSc, Solidage, Groupe de Recherche Université de Montréal/Université McGill sur les services intégrés pour les personnes âgées, Centre d'Épidémiologie Clinique et de la Recherche en Santé Publique, Division de Gériatrie, Hôpital général juif, Université McGill; presented at *Symposium sur l'utilisation optimale du médicament*, May 20 and 21, 2004, Québec.

# Principles for Incorporating Innovation

- Focus on the patient (access, outcomes, choice, involvement)
- Be pragmatic
- Ensure optimal use (and outcomes measurement)
- Be transparent and accountable – Shared vision of “value”
- Streamline processes, apply in a uniform, consistent manner, and build in effective dialogue and appeal mechanisms
- Adopt a systemic approach to health care budgeting
- Allow for a fair and equitable patient contribution
- Promote innovation integration (both “breakthrough” and “incremental”) and align policies with innovation goals
- Adopt partnership approach for future planning

“ We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear.”

*George W. Merck*

*Dec 1950*