

Decentralization in pharmaceutical reimbursement decisions: Canada's experience

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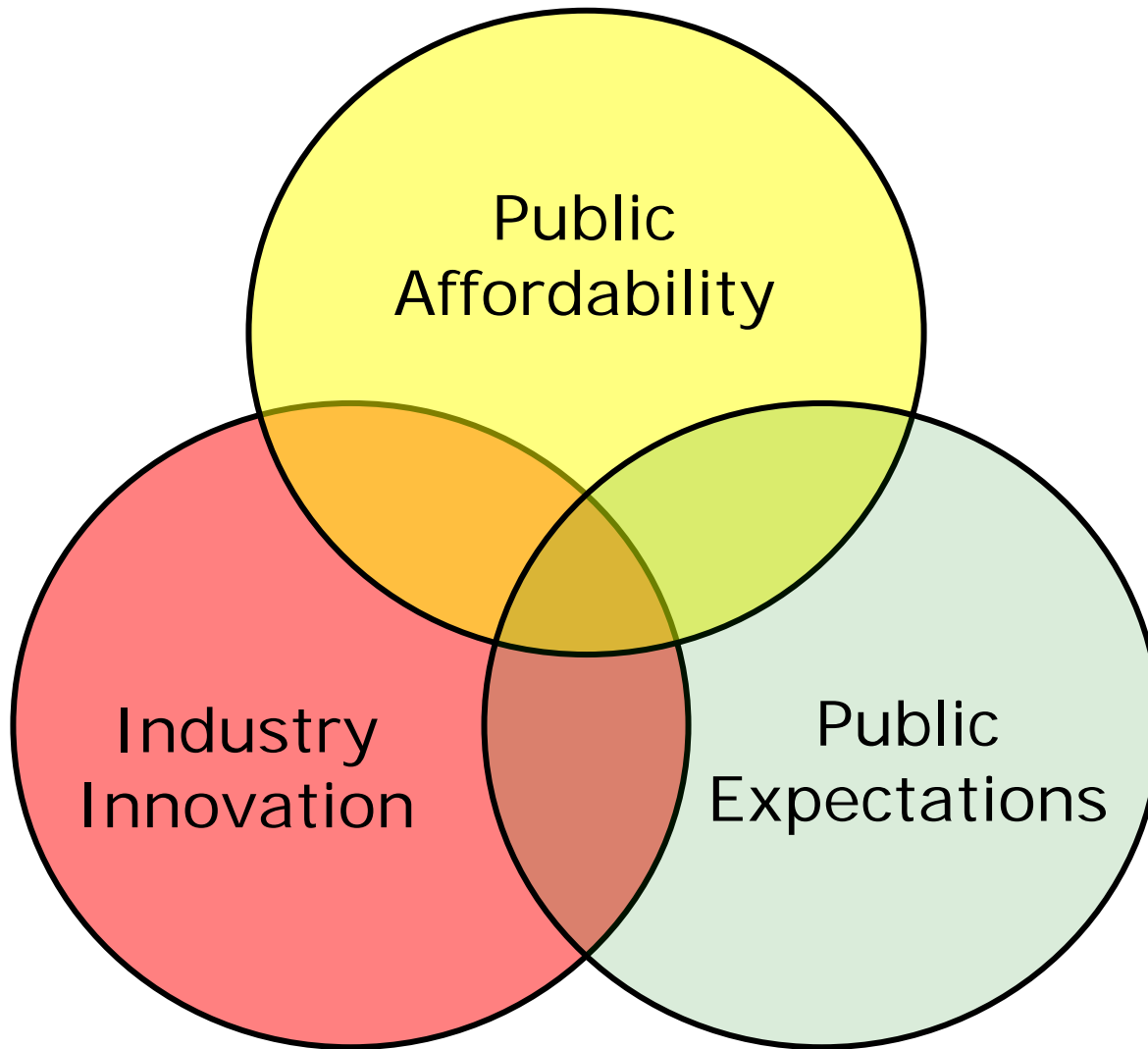
Outline

- Describe the Canadian approach to drug reimbursement decision-making
- Recent development of
 - The Canadian Common Drug Review
 - Canadian Joint Oncology Drug Review
- Discuss the pros and cons of centralized vs. decentralized decision making
- Discuss proposed methods for making better reimbursement decisions

My Perspective

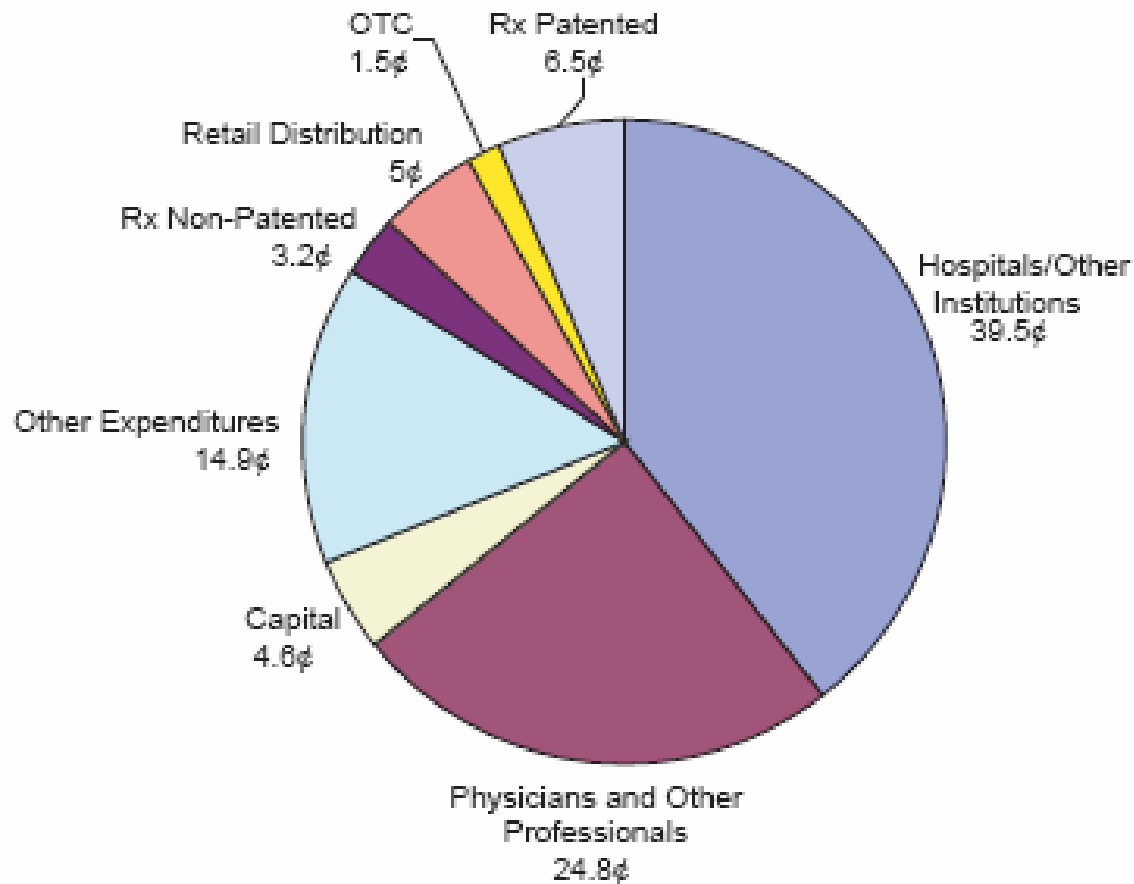
- Drug Policy Advisor
 - Chair of CED
 - Member of CED-CCO Subcommittee
 - Member of hospital-based P&T committee
- Clinician
 - Academic, hospital-based internal medicine & infectious disease
- Researcher
 - Clinical pharmacoeconomics “guy”

The Pressures on Drug Reimbursement

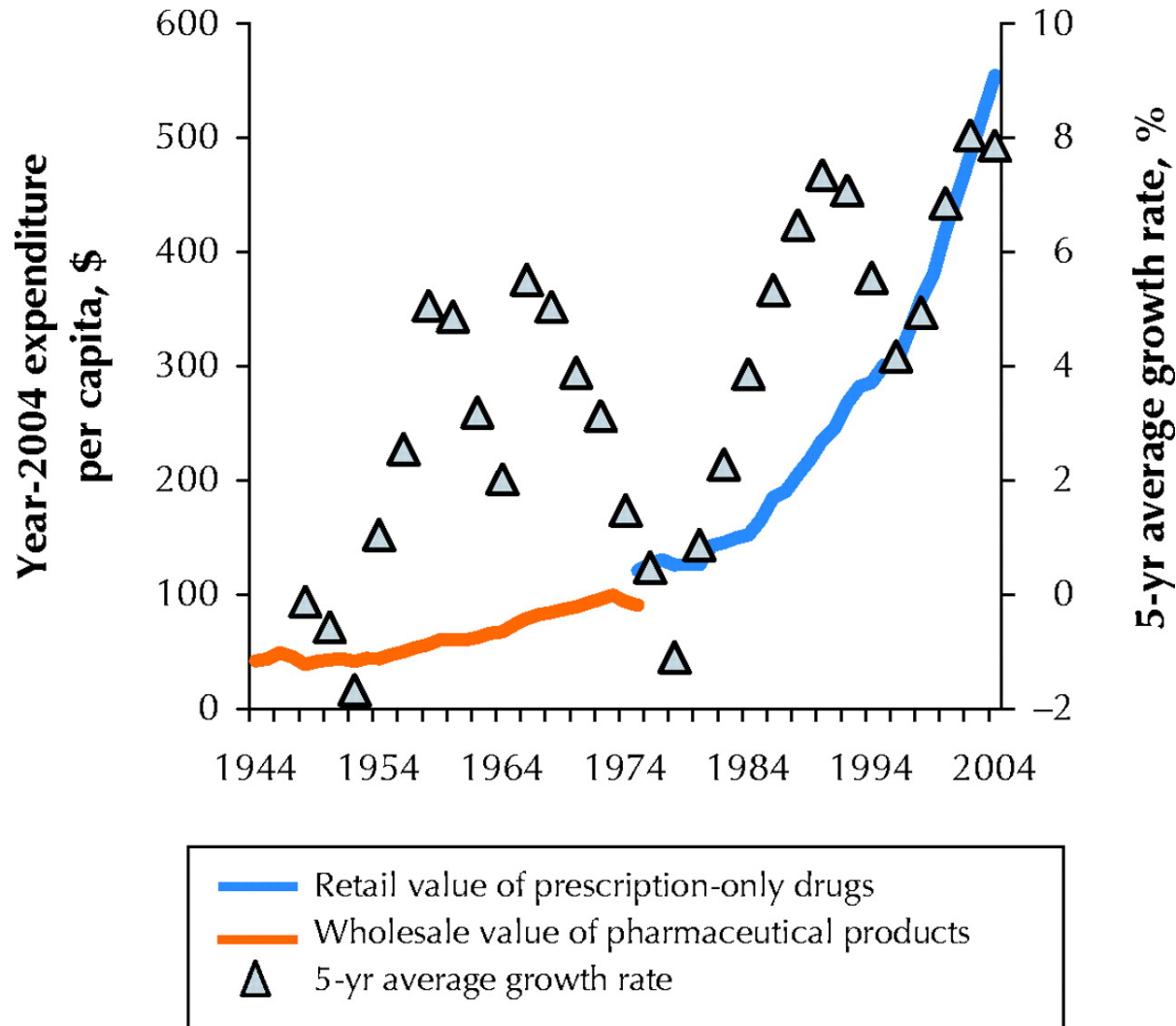


Health Expenditures in Canada

Source: CIHI National Health Expenditure Trends 1975-2003,
PMPRB Annual Report 2002, Brogan Inc., Rx&D Files



Trends in expenditures on pharmaceutical products from 1944 to 2004



Canadian Provinces & Territories



**Yukon
Territory**

**Northwest
Territory**

**Nunavut
Territory**

**British
Columbia**

Alberta

**Saskat-
chewan**

Manitoba

Ontario

Quebec

**Newfoundland
& Labrador**

PEI

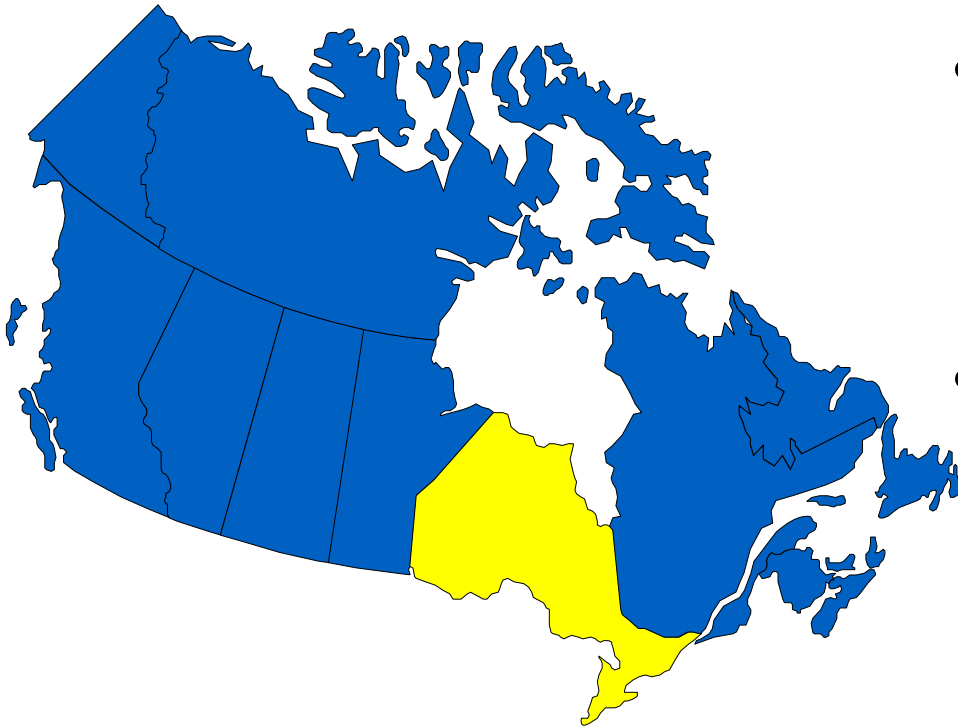
**Nova
Scotia**

**New
Brunswick**

Canadian Health Care Jurisdictions

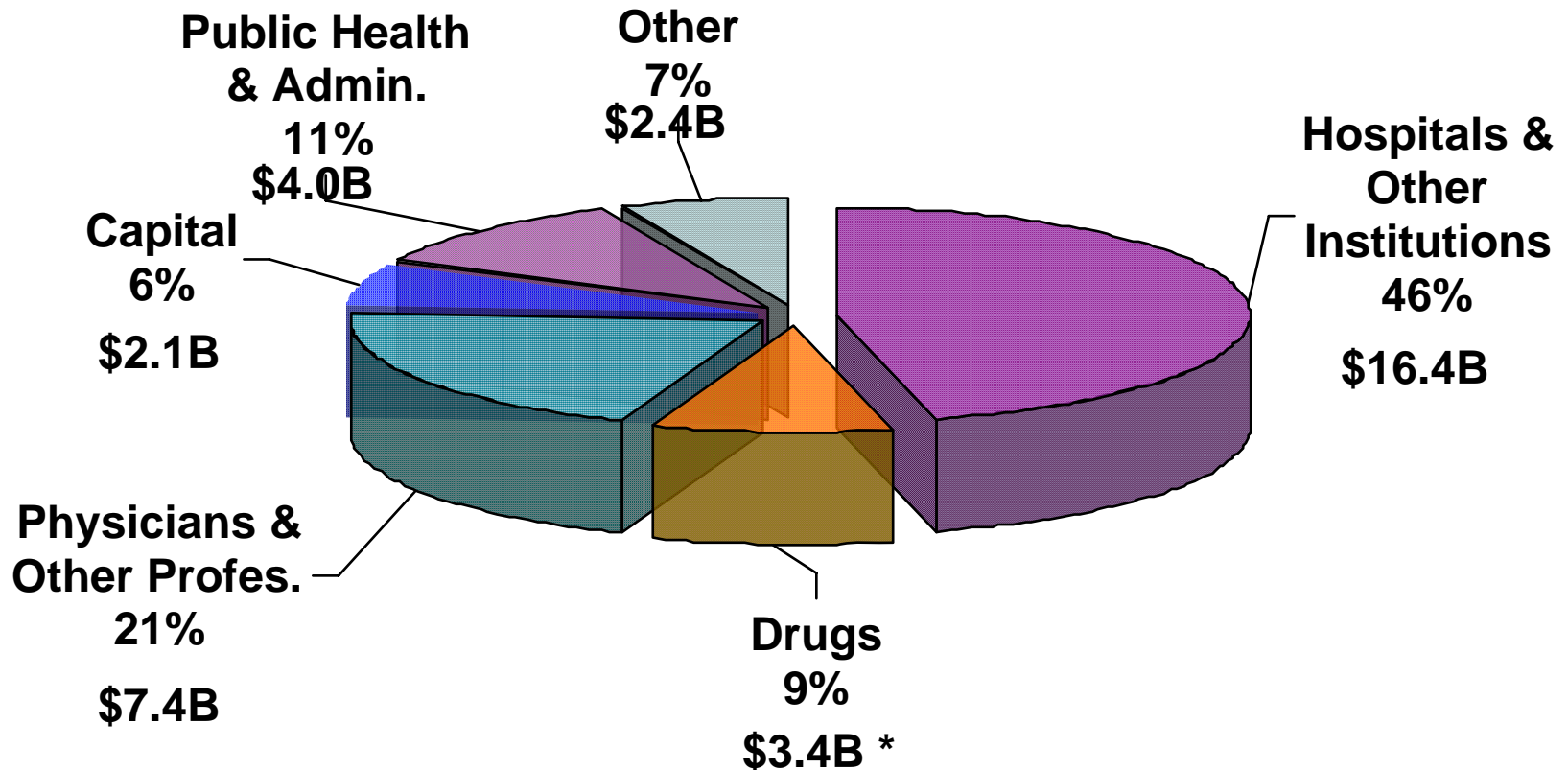
- National/Federal
 - Health policy legislation governing the all aspects of the universality of access to health care for Canadians
 - Approval process for licensing and approving drugs for sale in Canada
- Provincial
 - Expenditures on health for hospital care, physicians, public health and drug costs
 - Approval process for drug reimbursement by public payment plans

Province of Ontario



- Most populous province in Canada
 - 12,541,400 (2005 estimate)
- Public spending on drugs approx. \$3.4 billion dollars (2005-06 estimate)

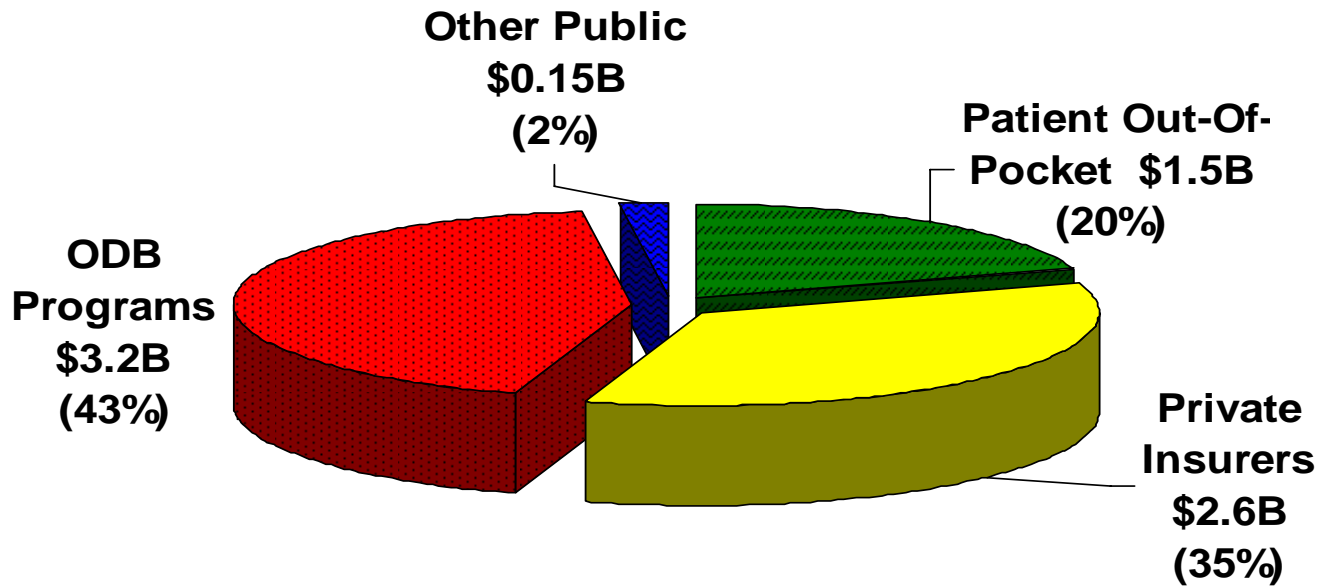
Provincial Health Expenditures - Total \$35.7 Billion, Ontario 2004



Source: Forecast from the Canadian Institute for Health Information, 2005

* Includes ODB Programs (\$3.2B) + Other Public Programs (\$0.15B)

Ontario 2004 Drug Costs - Total \$7.4 Billion Public, Private & Beneficiary Costs



Source: Canadian Institute for Health Information (CIHI)

Note: Other Public Programs include NIHB, Veteran's programs, and misc. Federal Programs (e.g. RCMP, etc.)

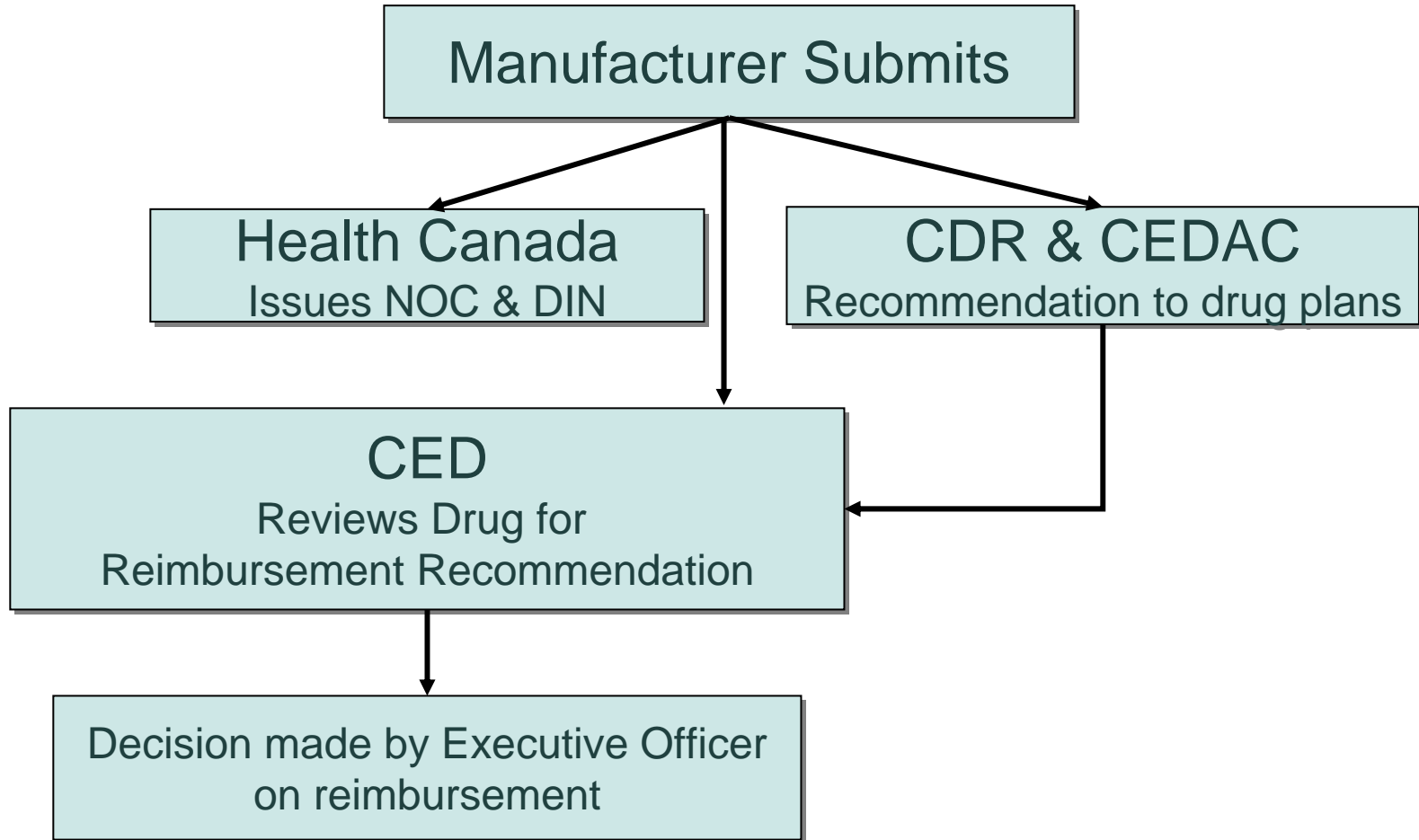
What is the Committee to Evaluate Drugs?

- The Ontario Ministry of Health and Long-term Care's expert advisory committee on drug therapy
 - Previously known as the DQTC
- Systematically evaluates new [and increasingly] older drugs in comparison to currently available therapies to treat the same disease
- Performs a comprehensive assessment, based on a thorough review of the scientific evidence available for a new drug compared to what we know about the drugs that we already fund

Committee to Evaluate Drugs

- Members appointed by Order-in-Council
- 16 members plus Chair
 - Medicine
 - Pharmacy
 - Pharmacology/
Pharmacokinetics
 - Epidemiology
 - Health Economics
 - Two Patients as Persons
- Over 150 active reviewers
 - Specialists
 - Generalists
 - Economic reviewers
 - Identities not revealed
- May also participate in Individual Clinical Review process

Ontario Drug Review / Reimbursement Process



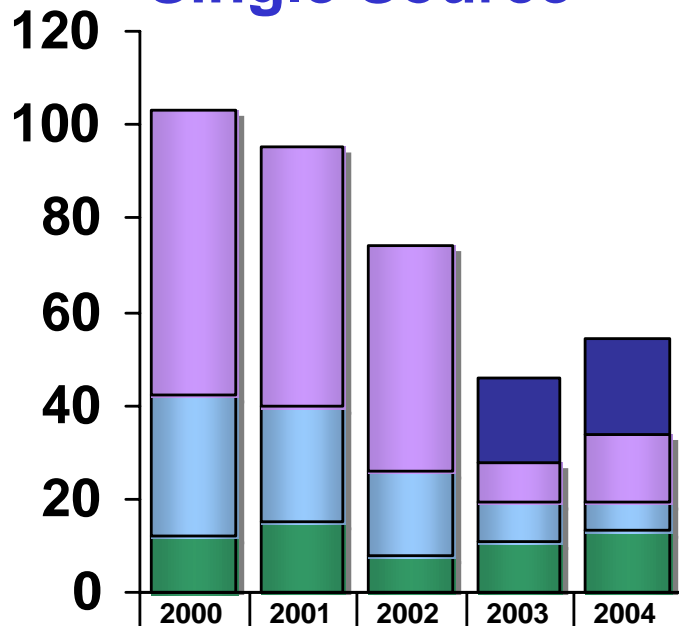
CED Recommendations

- Formulary
 - General Benefit listing
 - Conditional listing
 - Exceptional Access listing
 - Individual Clinical Review mechanism
 - Criteria for internal review
 - External review on a case-by-case basis
 - No reimbursement
- Special Drugs Program

DQTC(CED) Recommendations

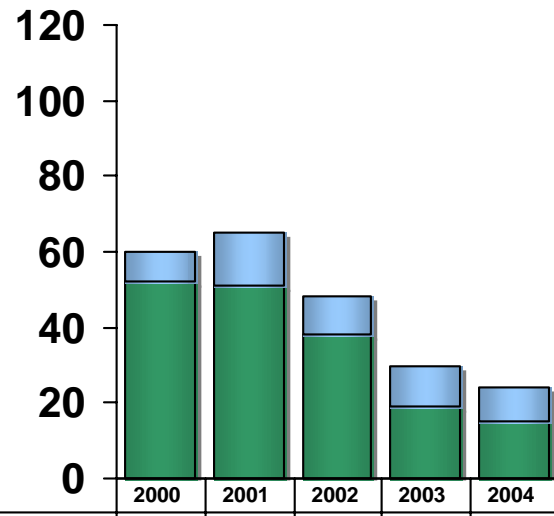
Submissions for First Review, 1999-2004

Single Source



| | | | | | |
|---------------------|----|----|----|----|----|
| ■ No Reimbursement* | - | - | - | 18 | 20 |
| ■ ICR* | 61 | 55 | 48 | 9 | 15 |
| ■ Limited Use | 30 | 25 | 18 | 8 | 6 |
| ■ General Benefit | 12 | 15 | 8 | 11 | 13 |

Multiple Source



| | | | | | |
|-------------------|----|----|----|----|----|
| ■ Rejected | 8 | 14 | 10 | 11 | 9 |
| ■ Interchangeable | 52 | 51 | 38 | 19 | 15 |

Note: Reviews of oral solid dosage forms were streamlined starting in 2002 and no longer require DQTC review.

* Negative listing recommendations prior to 2003 were not broken down into ICR and no reimbursement.

The Impact of the Ontario Formulary

- *“In addition, ... Ontario’s formulary, ... has an impact on all other sales in the province as other formularies and prescribing physicians often follow its lead. While other payers and prescribing physicians may have the ability to gain access to newer drugs, once approved by Health Canada, many take their lead from the Ontario formulary.”*

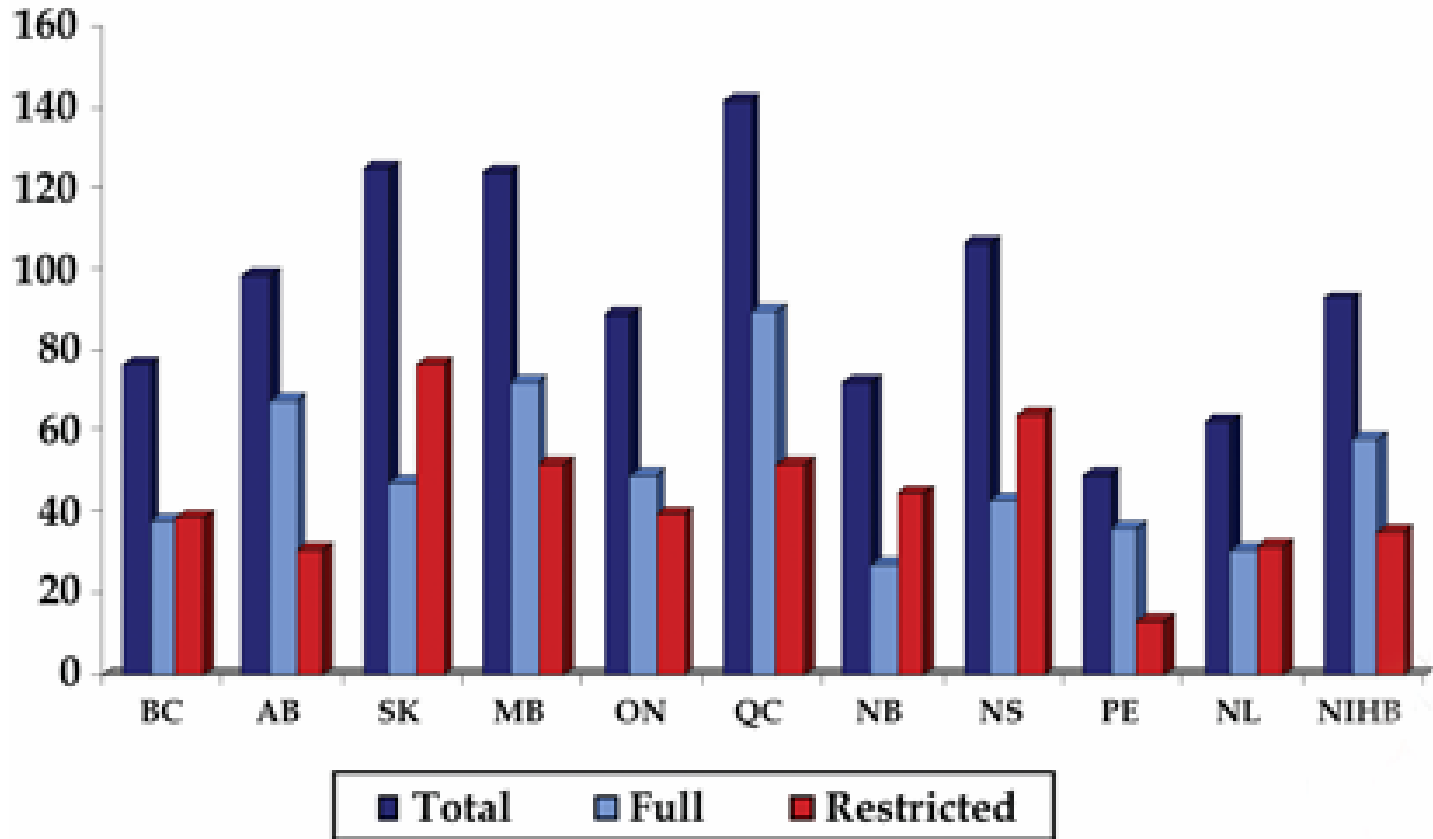
Atlantic Institute for Market Studies President Brian Lee Crowley

Provincial Drug Review Committees



| BC | AB | SK | MB | ON | QC | NB | NS | PEI | NF | YK | NT | NV |
|-----|-----|----|-----|-----|-----|----|-----|-----|----|----|----|----|
| Yes | Yes | No | Yes | Yes | Yes | No | Yes | No | No | No | No | No |

Provincial Listings for Single-Source Products Launched Between June 1, 1999 and May 31, 2004



Source: Provincial Reimbursement Advisor – August 2004

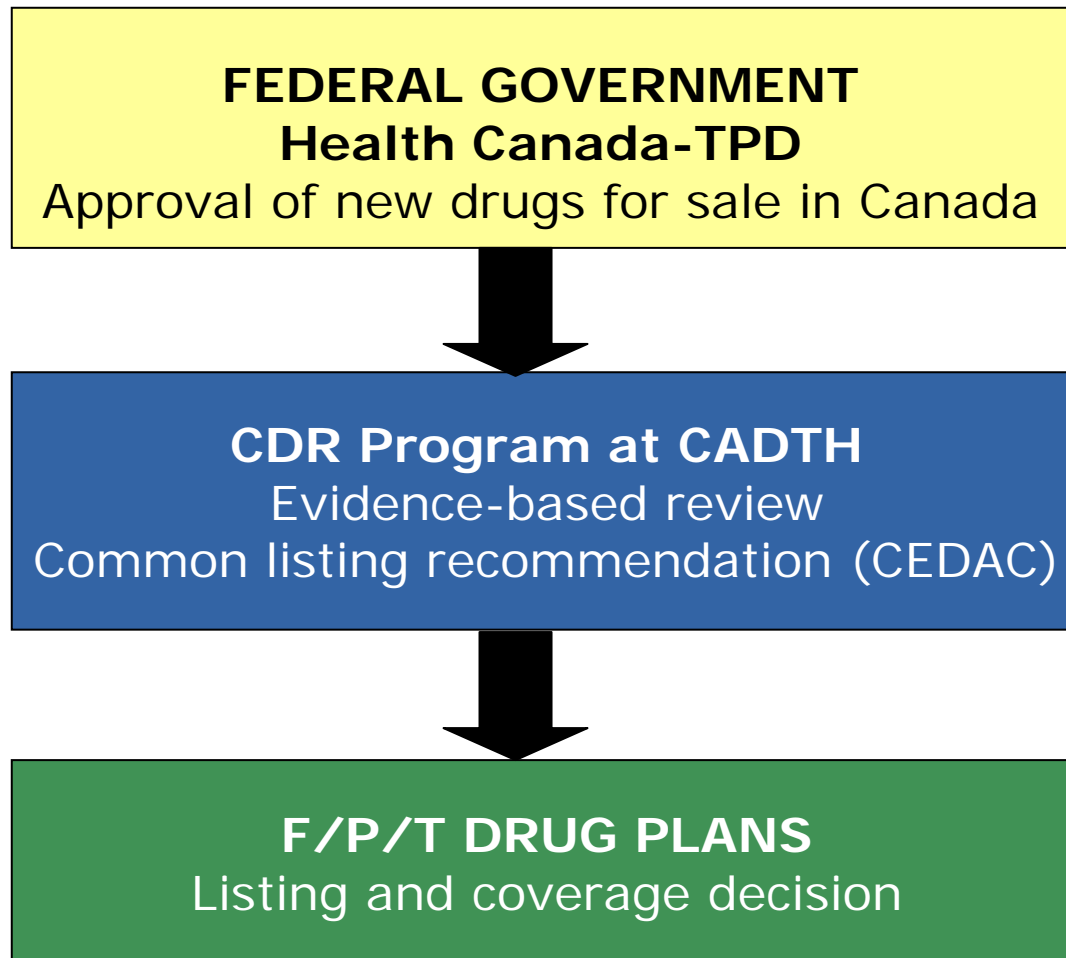
Diversity in Provincial Drug Reimbursement

- By 2001, it was evident that provinces were making different decisions regarding funding for similar drugs
- Perceived inequities around drug funding between provinces spilled into the political arena engendering discussion about a single, national process
- The Common Drug Review (CDR) was born

What is the Canadian Common Drug Review?

- Started in September 2003
 - Modeled on the Ontario DQTC (now CED)
- A single process for:
 - Conducting objective, rigorous reviews of the clinical and economic evidence for new drugs, and
 - Providing formulary listing recommendations to the publicly funded drug plans in Canada (except Quebec)
- Formulary decisions are made by the drug plans
 - Based on CDR recommendation, and plan mandates, priorities, resources

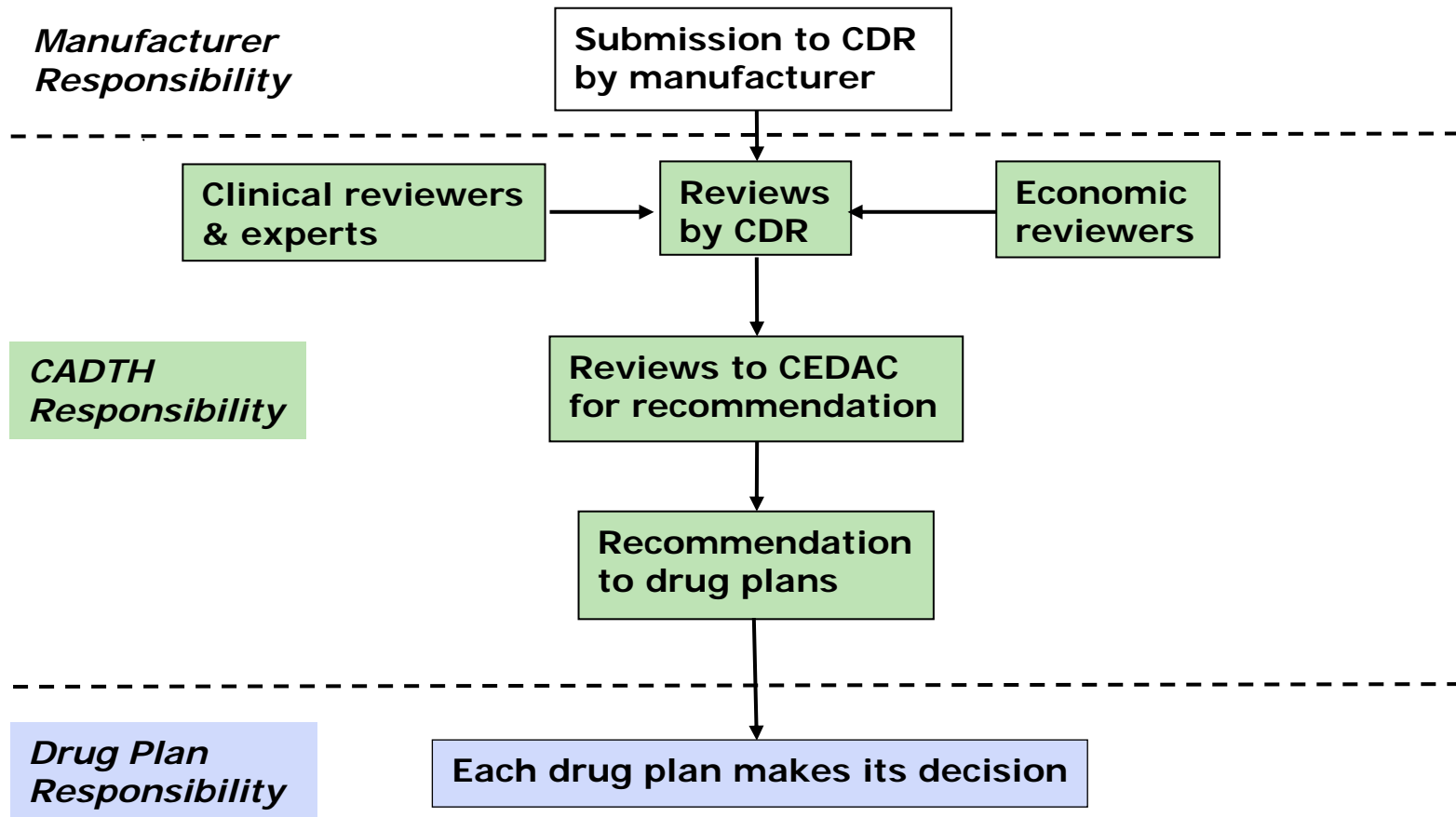
Who Does What – CDR's Role



What Does CDR Review?

- CDR was initially limited to new drugs
 - Excludes hospital-only drugs, most injectable oncology drugs
 - Includes any drug that would potentially be covered by the participating plans
- Submission to CDR = a submission to all participating plans
 - Typically made by the drug manufacturer
 - Drug plans may also initiate a CDR submission

CDR Process



CDR Timelines

- Total process takes 20-26 weeks from submission to CEDAC recommendation
 - 1 week to review submission
 - 9 weeks to prepare reviews
 - 3 weeks for manufacturer's comments and CDR response
 - 3-8 weeks to schedule for CEDAC
 - 1 week to prepare recommendation
 - 2 weeks when recommendation is embargoed
 - 1 week to issue final recommendation

CDR Activity to January 15, 2007

| | |
|--|-------|
| Number of submissions | 90 |
| Number of priority reviews requested/granted | 25/10 |
| Number of final recommendations issued | 62 |
| Number of recommendations to “list” | 30 |
| Number of recommendations to “not list” | 32 |

Program Success to Date

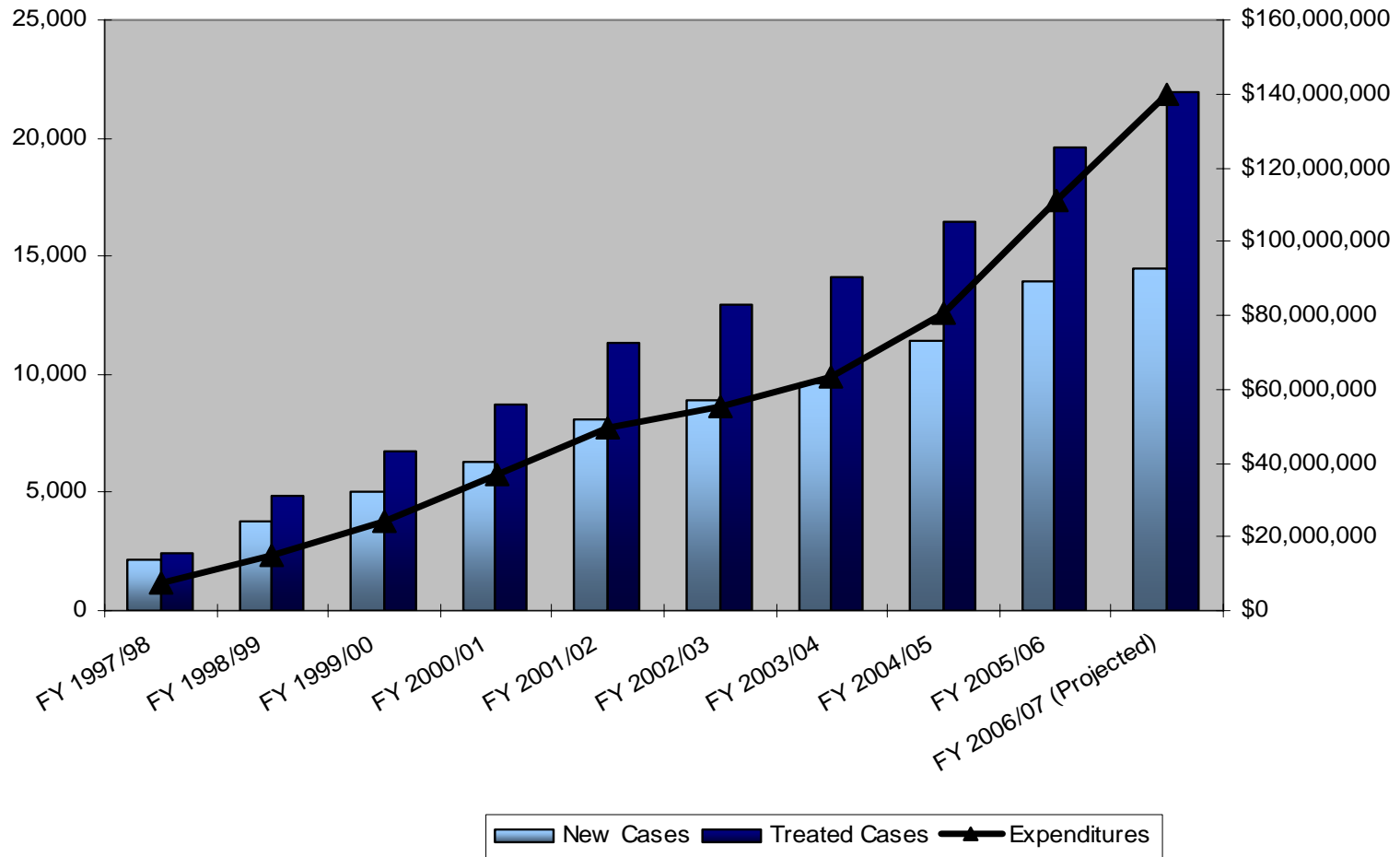
- Incorporated 18 processes into one
- Have met targeted timeframes >90% of time
- ~90% agreement between CEDAC recommendations and drug plan decisions
- High quality systematic reviews of published and unpublished trials
- Publicly available reasons for recommendations
- Stakeholder consultations, including formal evaluation of CDR
- Ongoing process improvements

The “C” Word

...the scariest word in pharmaceutical reimbursement decision-making!

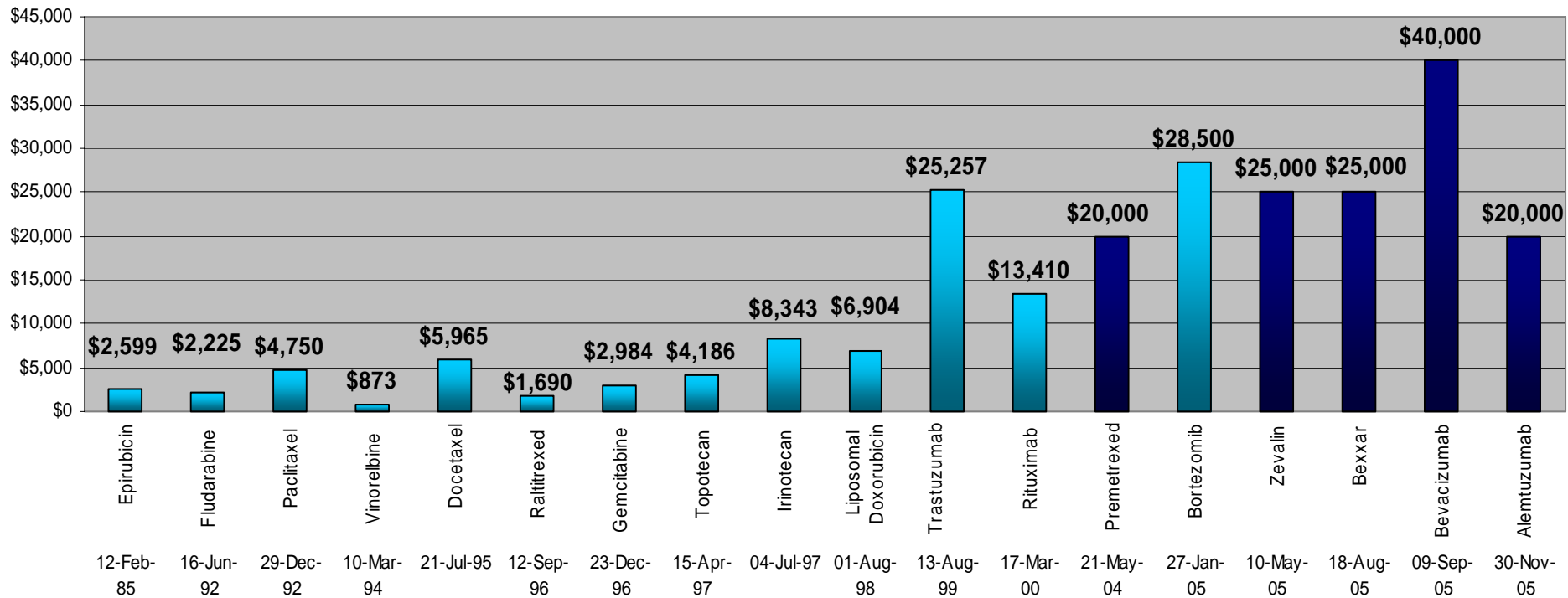
Affordability/Ability to Pay – Cancer Therapies

New Drug Funding Program (NDFP) - Expenditures



Affordability/Ability to Pay – Cancer

Avg. Cost Per Treated Case

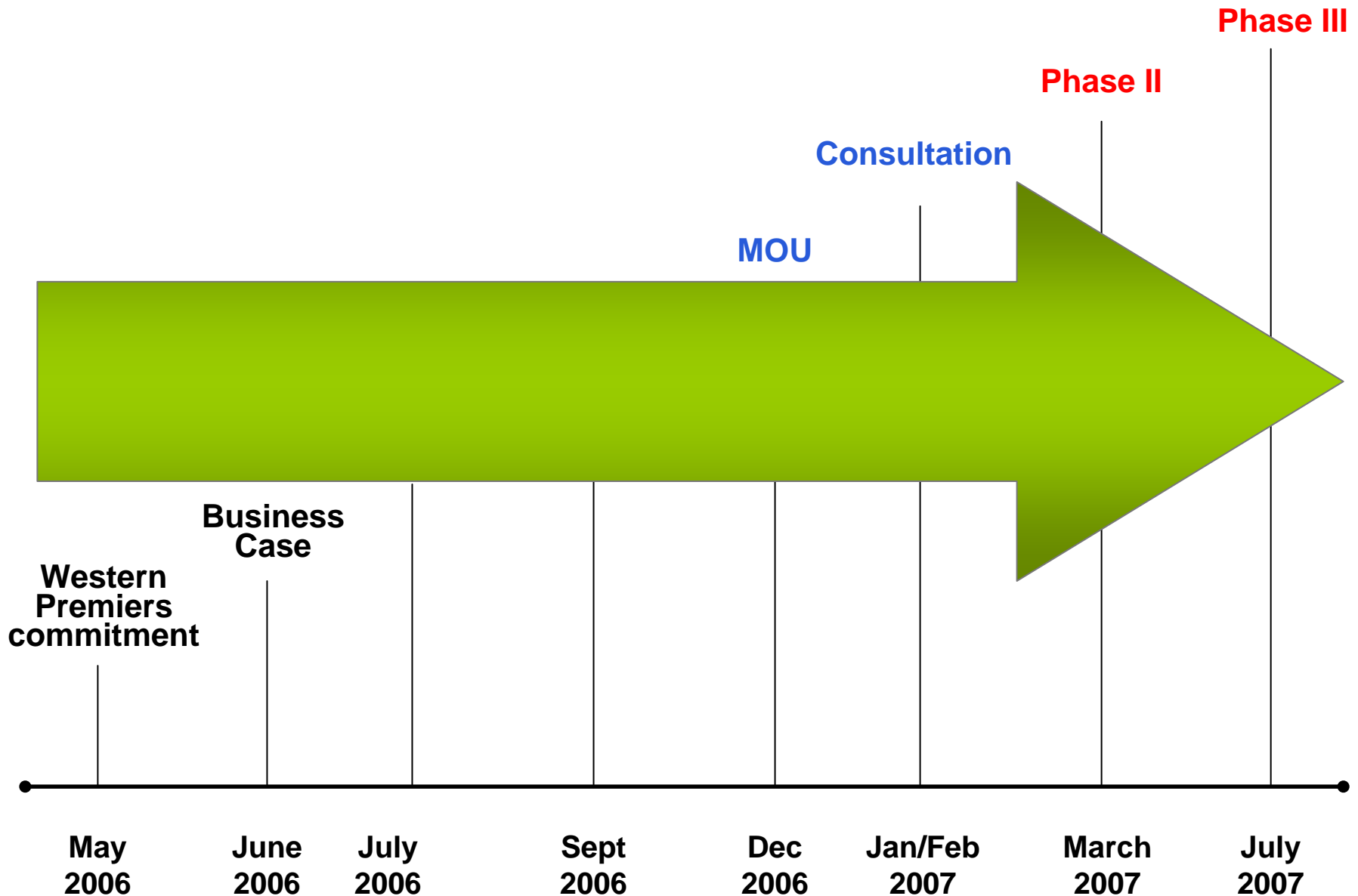


Reference: NDFP Microstrategy iPort April, 2007 (exception: premetrexed, bortezomib, Zevalin, Bexxar, bevacizumab, and alemtuzumab are estimated values, paclitaxel, pamidronate, irinotecan, vinorelbine – pre-generic pricing)

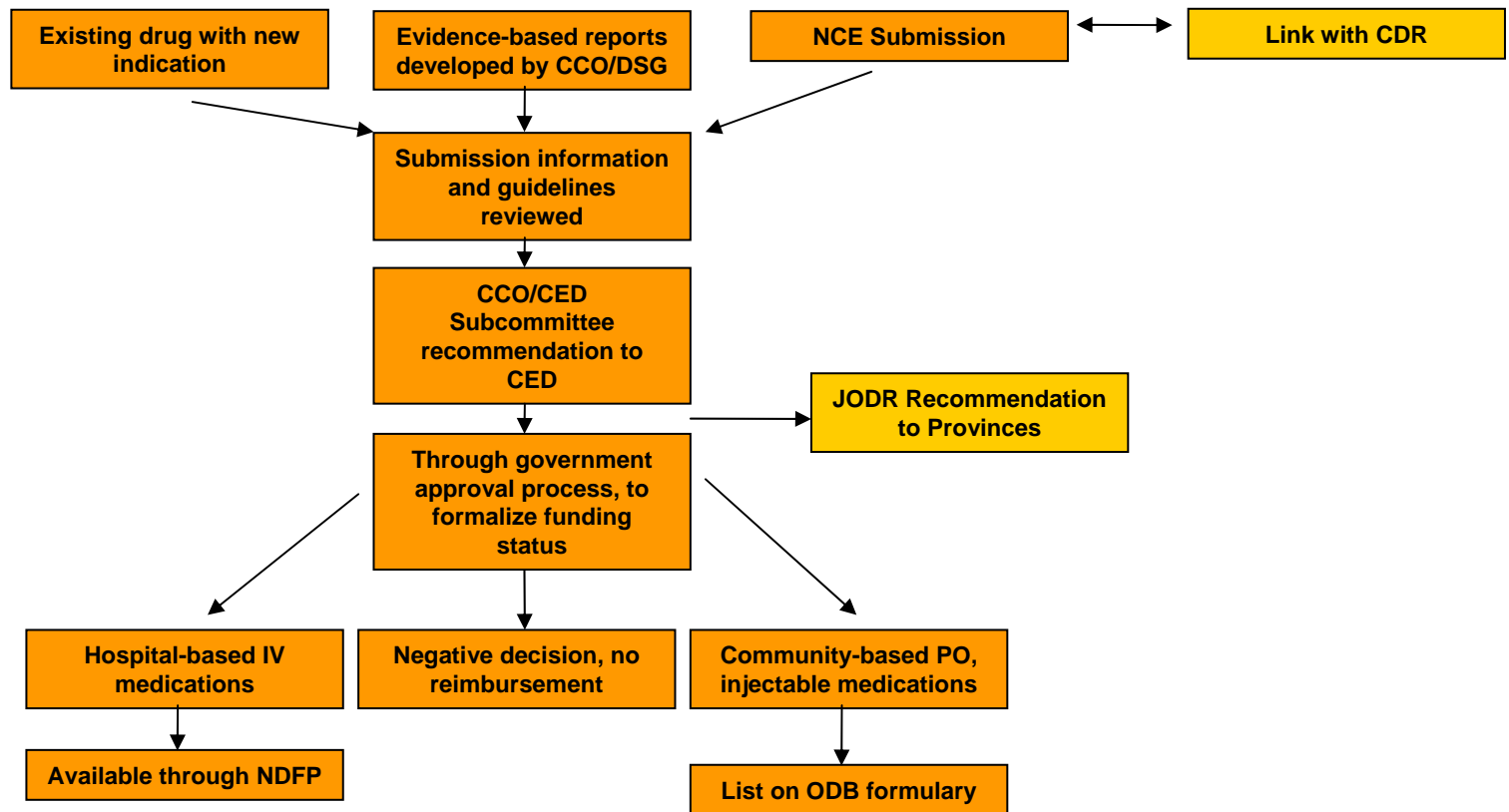
Why a Joint Oncology Drug Review Process?

- Cost
 - Oncology drug expenditures have risen 20-25% per year in recent years (roughly 2x the rate of other drugs)
 - Growing numbers of oral therapies for cancer
- Consistency
 - Differing drug approval mechanisms based on province
 - CDR process (2003) mandate did not include IV oncology drugs
 - Growing variations and inconsistency in coverage/criteria across jurisdictions despite review of a single body of clinical evidence
 - Patient concerns regarding inequitable access
- Pharmacoeconomics not considered in all jurisdictions

Joint Oncology Drug Review Chronology



JODR – CED/CCO Review Process



DSG – disease site group

NCE – New Chemical entity

CED – Committee to Evaluate drugs

Canadian Drug Reimbursement: Questions

- A decentralized system evolving into a more centralized one?
- Which is best?
- Has it adversely affected pharmaceutical investment nationally or regionally?
- Will provinces ever give spending decisions over to a centralized one?

Centralized vs. Decentralized: The Pros

Centralized

- Access to all relevant information from central agency
- Reduction in filing submissions and documentation
- Ability to include pharmacoeconomic data into licensing decision

Decentralized

- Fine-tune decisions based on unique population demographics or economics
- Introduces a “check and balance” into system
- Potential for diversity of investment to different regions

Centralized vs. Decentralized: The Cons

Centralized

- A negative decision allows for little chance to obtain reimbursement in all jurisdictions
- Only reviewed by a single group of reviewers, e.g. opportunity for bias in data review
- Inconsistent application of positive recommendations

Decentralized

- More expensive
- Duplicative
- Perceived asymmetry in recommendation decisions for reimbursement
- Impact of different decisions on access to drugs
- Potential for jurisdictions to undermine each other in negotiations to list

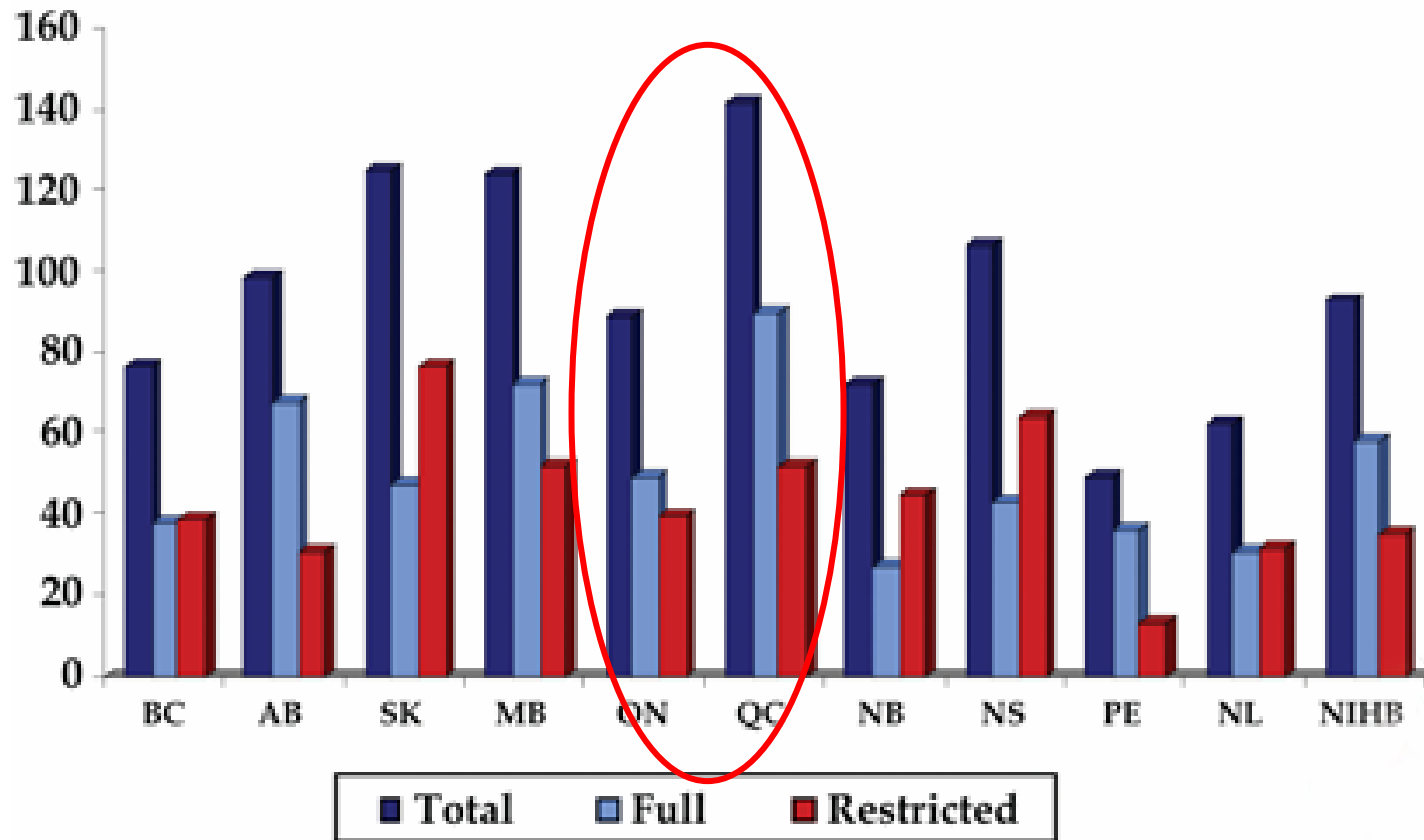
Pharmaceutical Investment in Canada

- Over the past 17 years in Canada, \$11.8 billion has been invested in R&D
 - \$2.1 billion has been spent in universities and hospitals
- Since 1988, spending in R&D has increased by 605%
- In 2004, spending in Canada amounted to \$1.17 billion

Pharmaceutical Pricing in Canada

- The prices of patented medicines in Canada are approximately 9% below the international median (US, UK, France & Sweden)
- Canadian patients pay on average 30% more for generic medicines than the international median

Provincial Listings for Single-Source Products Launched Between June 1, 1999 and May 31, 2004



Source: Provincial Reimbursement Advisor – August 2004

Pharmaceutical Investment in Ontario 2006

- R&D investment has increased by 751% since 1988 to \$537.2 million in 2003
- Pharmaceutical companies have \$718.4 million invested in land, facilities and equipment in Ontario

Pharmaceutical Investment in Quebec 2005

- Quebec attracts more than 50% of all investments in pharmaceutical research in Canada
- More than \$2 billion invested directly in the economy of Quebec
- \$450 million invested in research and development
- Of this total, more than \$30 million are allocated to universities and hospitals

The Canadian Drug Reimbursement System

Strengths

- Well established
- Objective
- Process driven
- Allows for some regional differences
- Rigorous use of pharmacoeconomics

Weaknesses

- Too diverse
- Potential for inequity
- Duplicative
- Lack of transparency
- Tied to provincial expenditures

How can we improve drug reimbursement decision-making?

- Real-world randomized trials
- Pharmacosurveillance
 - Post-marketing assessment of drug use, compliance and association of drug use with projected outcomes
 - Observational studies using administrative databases
- Primary data collection using drug registries

Conclusions

- Canada maintains a decentralized drug reimbursement system with decisions made at the provincial level
- Two national processes have been developed to address the perceived inequities in drug funding; the CDR and the JODR
- As to whether these processes can successfully resolve the regional disparities remains to be seen

PHARMACY

CLASSICS

BEST-SELLERS

NEW RELEASES

