

**ARCC**

Canadian Centre  
for Applied Research  
in Cancer Control

# Cancer Drugs: Challenges and Opportunities for Applied Cancer Research

Dr. Peter Bach

Ms. Danica Wasney

Dr. Craig Earle



**BC Cancer Agency**  
CARE & RESEARCH  
An agency of the Provincial Health Services Authority



a place of mind



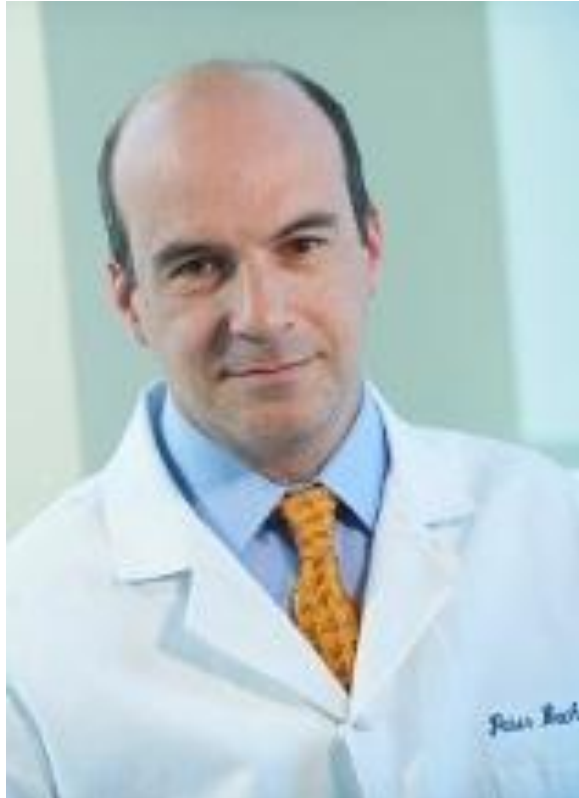
Canadian  
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**Action Cancer Ontario**



## Dr. Peter Bach, MD, MAPP

Director at the Center for Health Policy and Outcomes, Memorial Sloan-Kettering Cancer Centre

# Reforming the Oncology Payment System

Peter B. Bach, MD, MAPP

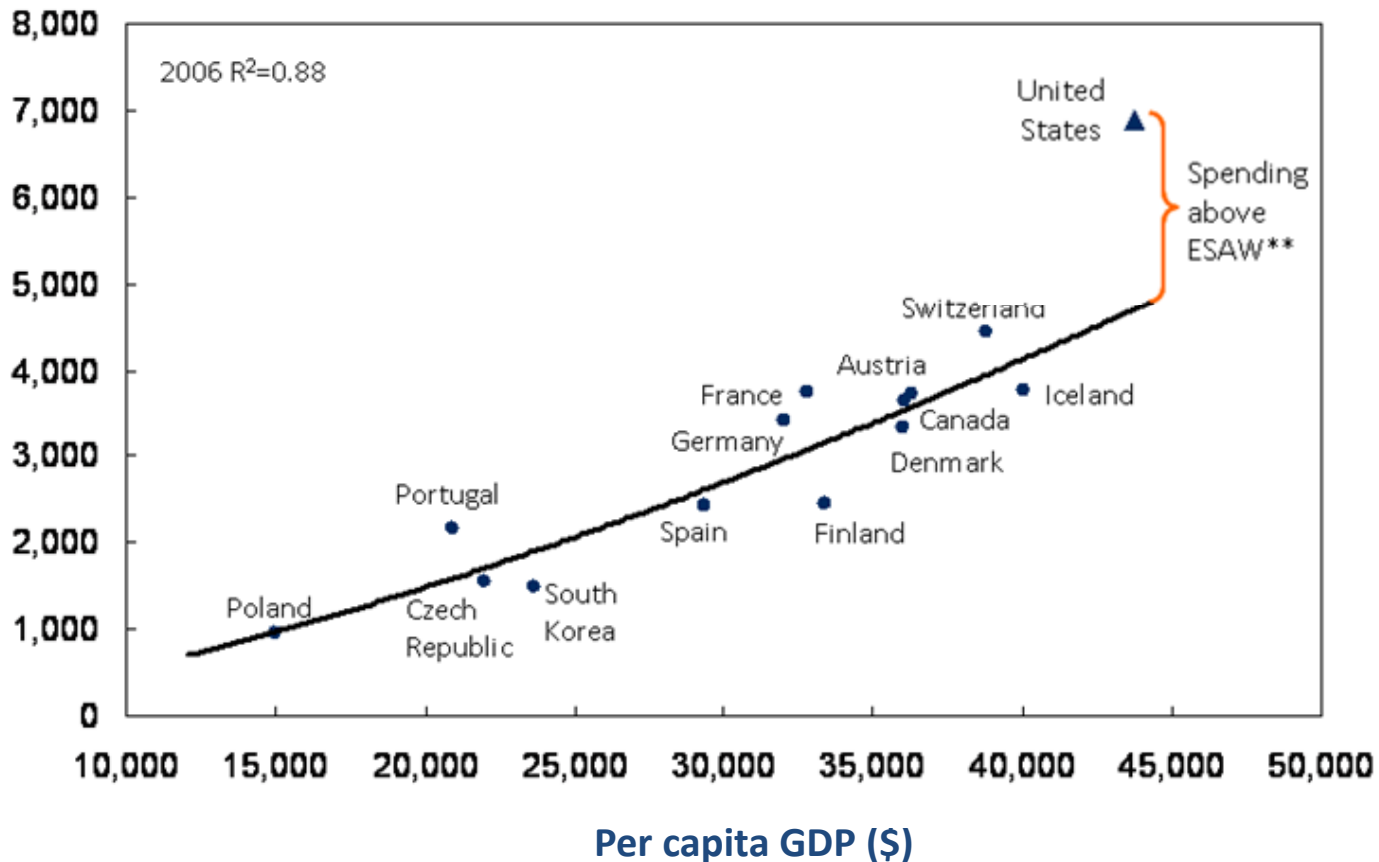
Director, Center for Health Policy and  
Outcomes

Memorial Sloan-Kettering Cancer Center

# US Spending vs. Other Countries

## Per capita health care spending, 2006

\$ at PPP\*



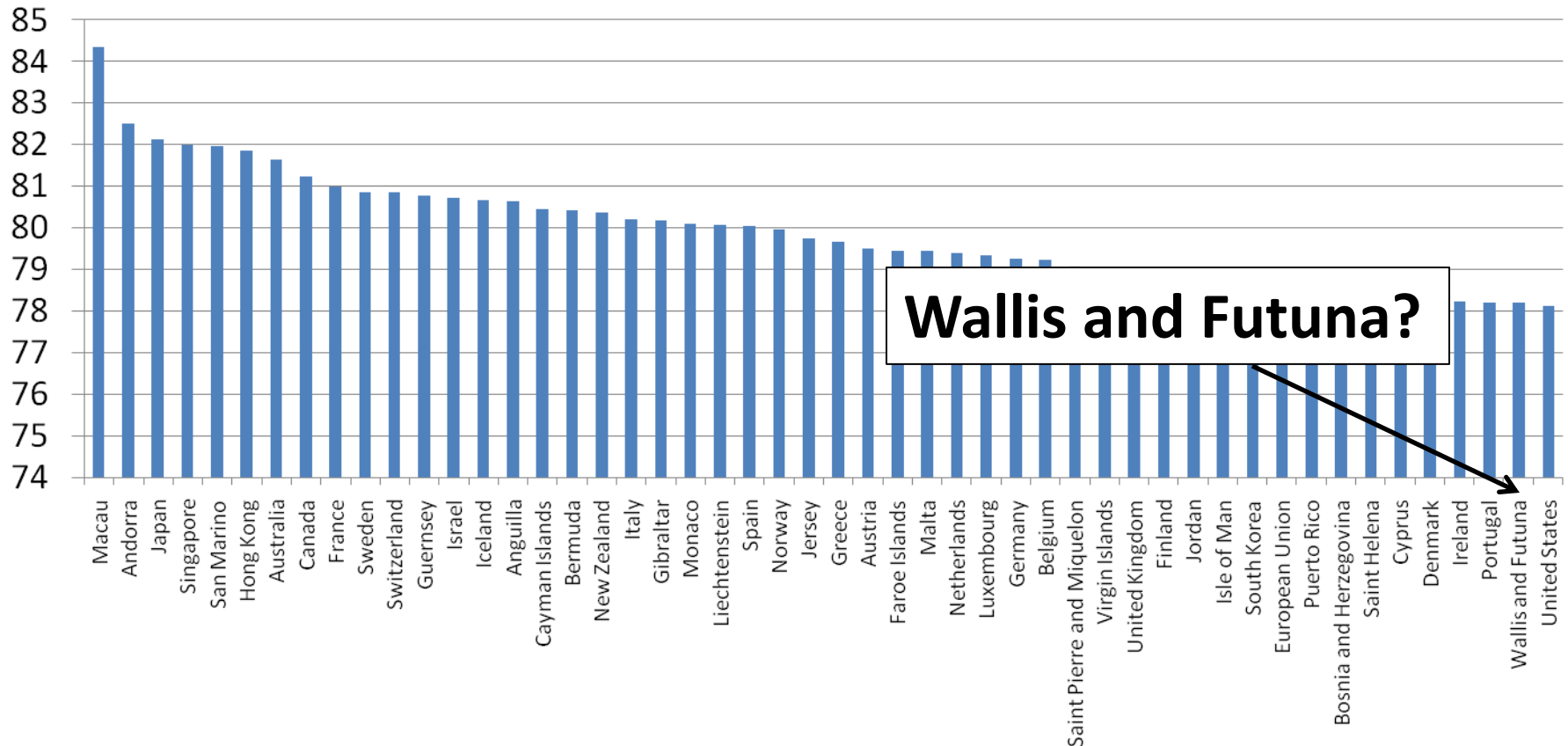
\* Purchasing power parity.

\*\* Estimated Spending According to Wealth.

Source: Organization for Economic Co-operation and Development (OECD)

# Overall Quality: Life Expectancy

The US is 50<sup>th</sup> in the world for life expectancy at birth.





Location of Wallis and Futuna



# Two views of spending: P or Q

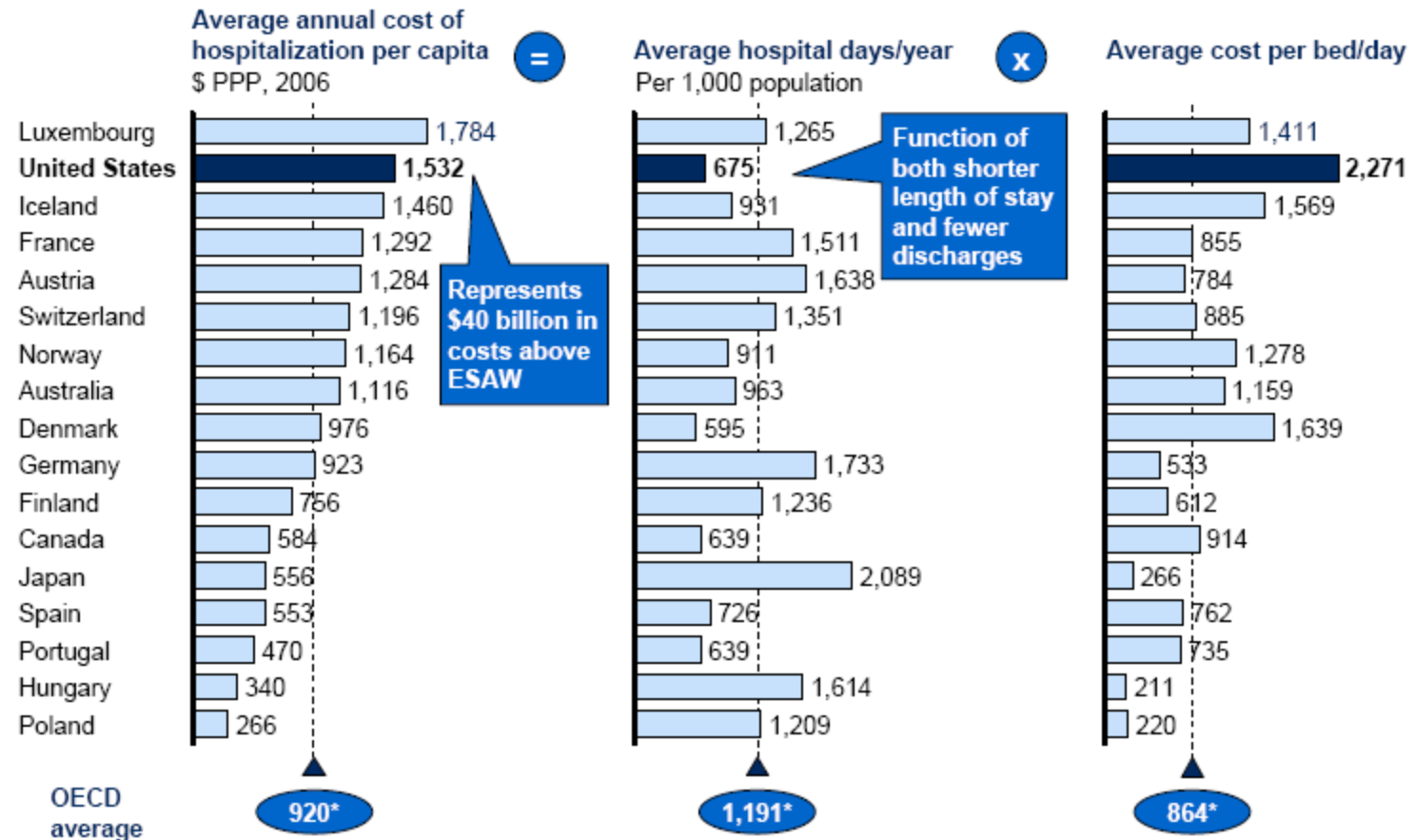
## Higher utilization (Q)

- Services are wasted, repeated, overdone, harmful
- Gawande: “Come on,” the general surgeon finally said. “We all know these arguments are bullshit. There is overutilization here, pure and simple.” Doctors, he said, were racking up charges with extra tests, services, and procedures.

## Higher prices (P)

- We just pay more for most (every) component of healthcare.
- Glied et al. “Higher health care prices in the United States are a crucial reason that the nation’s health spending is so much higher than that of other countries.”

## Lower US hospital admissions and shorter stays are offset by significantly higher costs per bed day



\* Excludes United States.

Note: Numbers may not sum due to rounding.

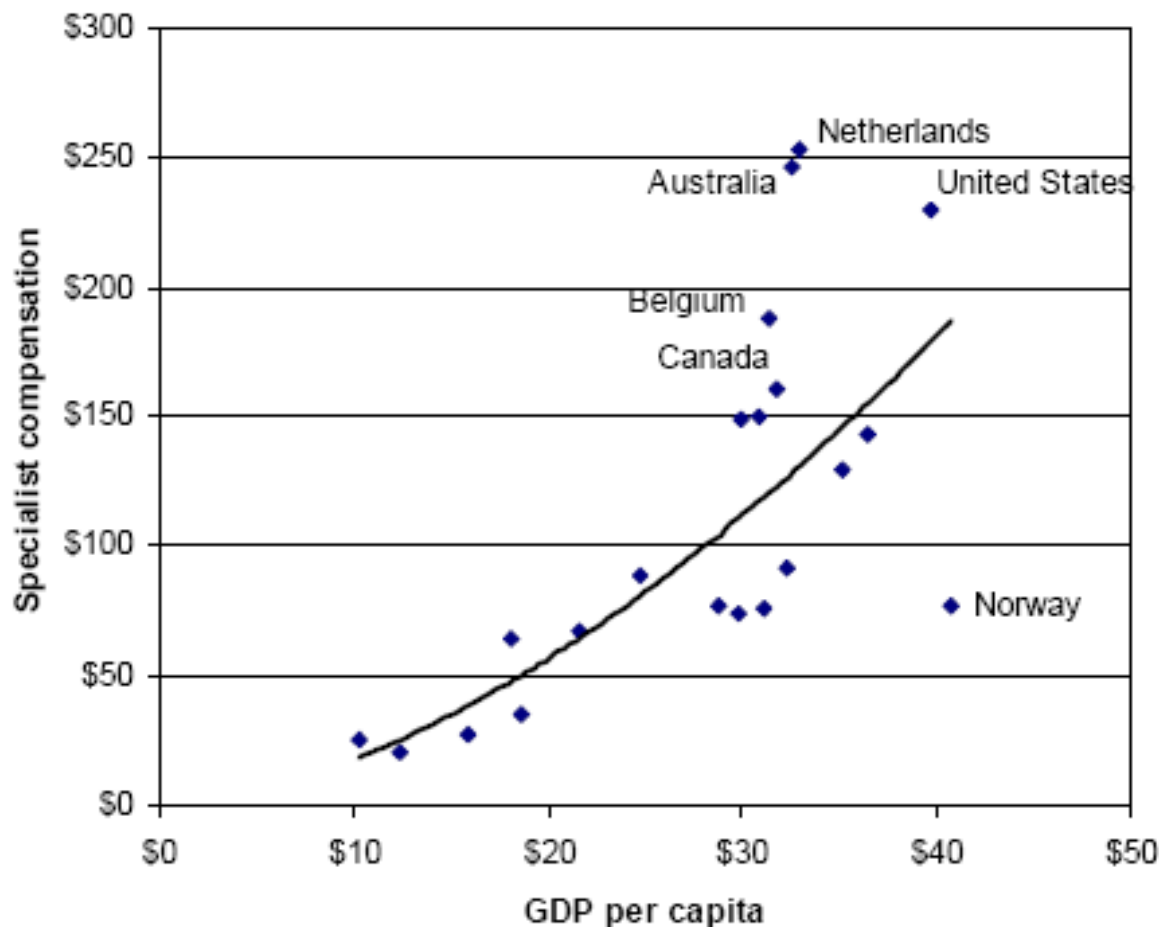
Source: OECD; McKinsey Global Institute analysis

## Primary Care and Orthopedic Surgery and Fees in Six Countries, 2008

Country	Primary Care		Orthopedic Surgery	
	Public payer fee for office visits (\$)	Private payer fee for office visits (\$)	Public payer fee for hip replacement (\$)	Private payer fee for hip replacement (\$)
Australia	34	45	1,046	1,943
Canada	59	—	652	—
France	32	34	674	1,340
Germany	46	104	1,251	—
United Kingdom	66	129	1,181	2,160
United States	60	133	1,634	3,996

Source: Adapted from M. J. Laugesen and S. A. Glied, "Higher Fees Paid to U.S. Physicians Drive Higher Spending for Physician Services Compared to Other Countries," *Health Affairs*, Sept. 2011 30(9):1647–56.

**Figure 14. Specialist Compensation and GDP per Capita  
(in U.S. \$1,000s), 2004**



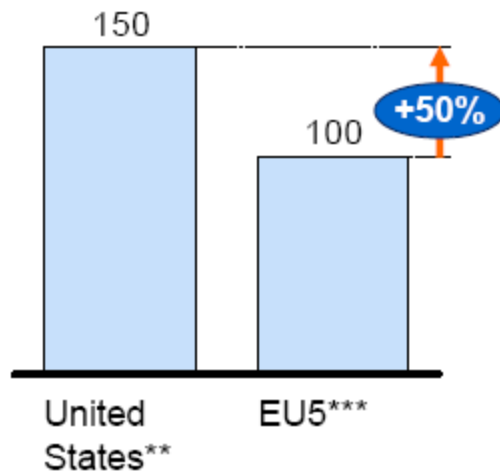
Source: Congressional Research Service (CRS) analysis of Remuneration of Health Professions, OECD Health Data 2006 (October 2006), available at [<http://www.ecosante.fr/OCDEENG/70.html>].

## Drug prices in the United States are 50 percent higher for comparable products; average price gap is nearly 120 percent due to usage patterns

**For comparable drugs, US prices are 50 percent higher than in other developed countries . . .**

**Average price\* difference for the same drug**

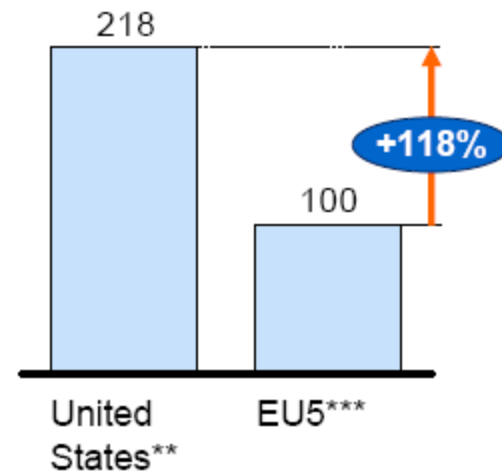
\$/pill indexed: EU5\*\*\* price = 100



**. . . and the use of a more expensive mix of drugs in the United States increases average prices even more**

**Overall average price\***

\$/pill indexed: EU5\*\*\* price = 100



\* Manufacturer price.

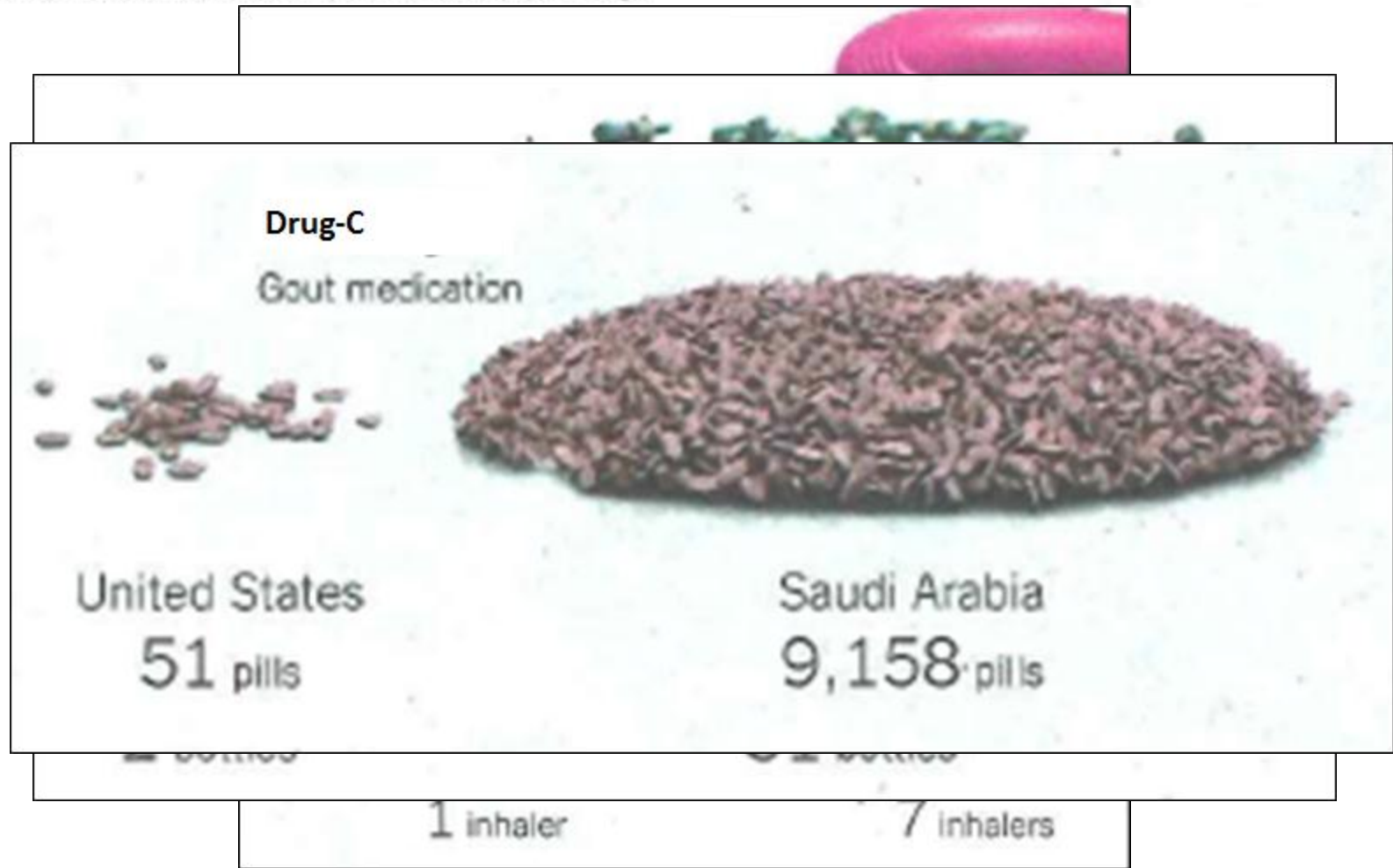
\*\* Assumes 15 percent rebates from manufacturers to payers and Pharmacy Benefit Managers (PBMs).

\*\*\* Average of the United Kingdom, Germany, Italy, France, and Spain.

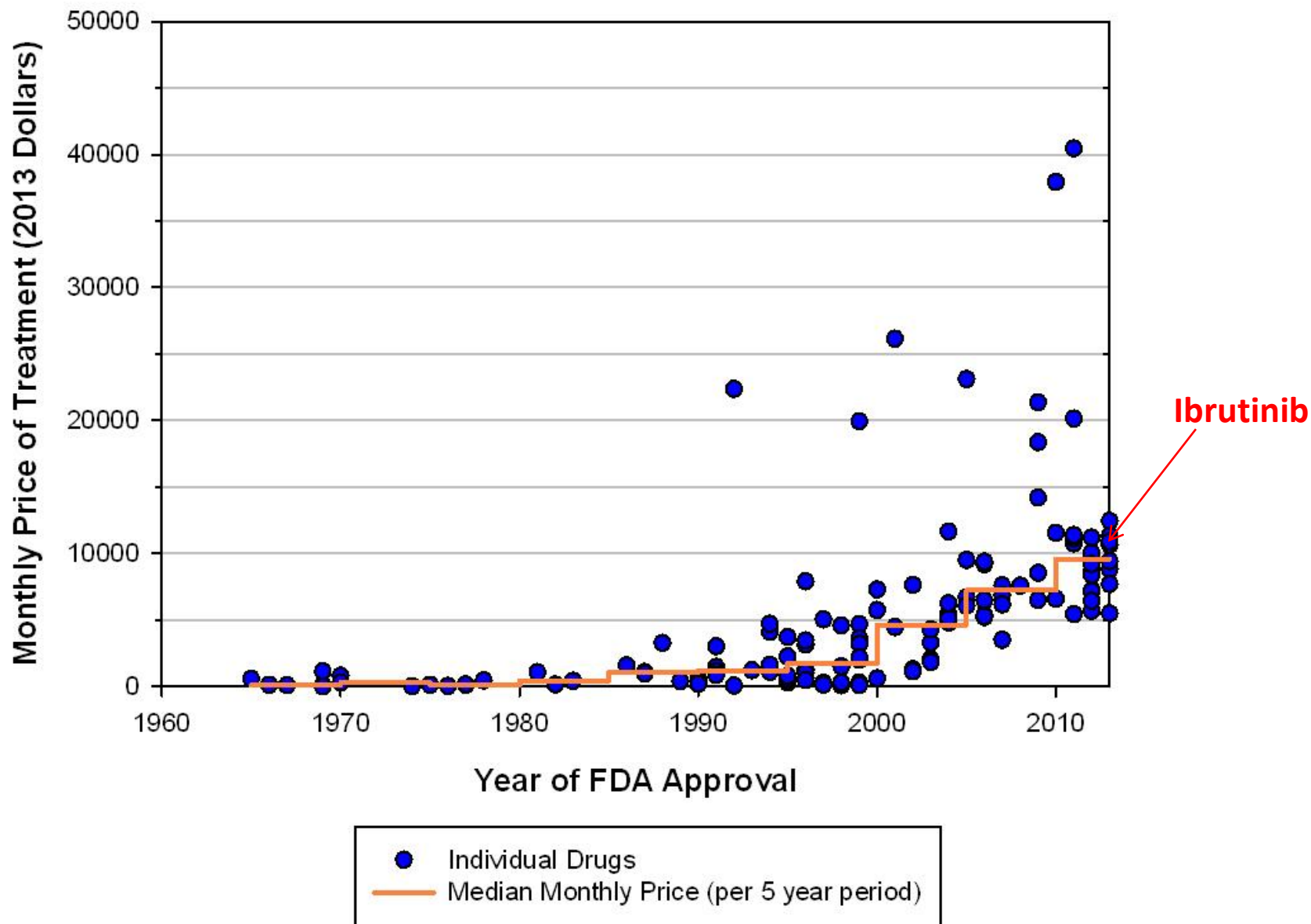
Source: IMS Health; McKinsey Global Institute analysis

## What \$250 of Prescription Drugs Looks Like

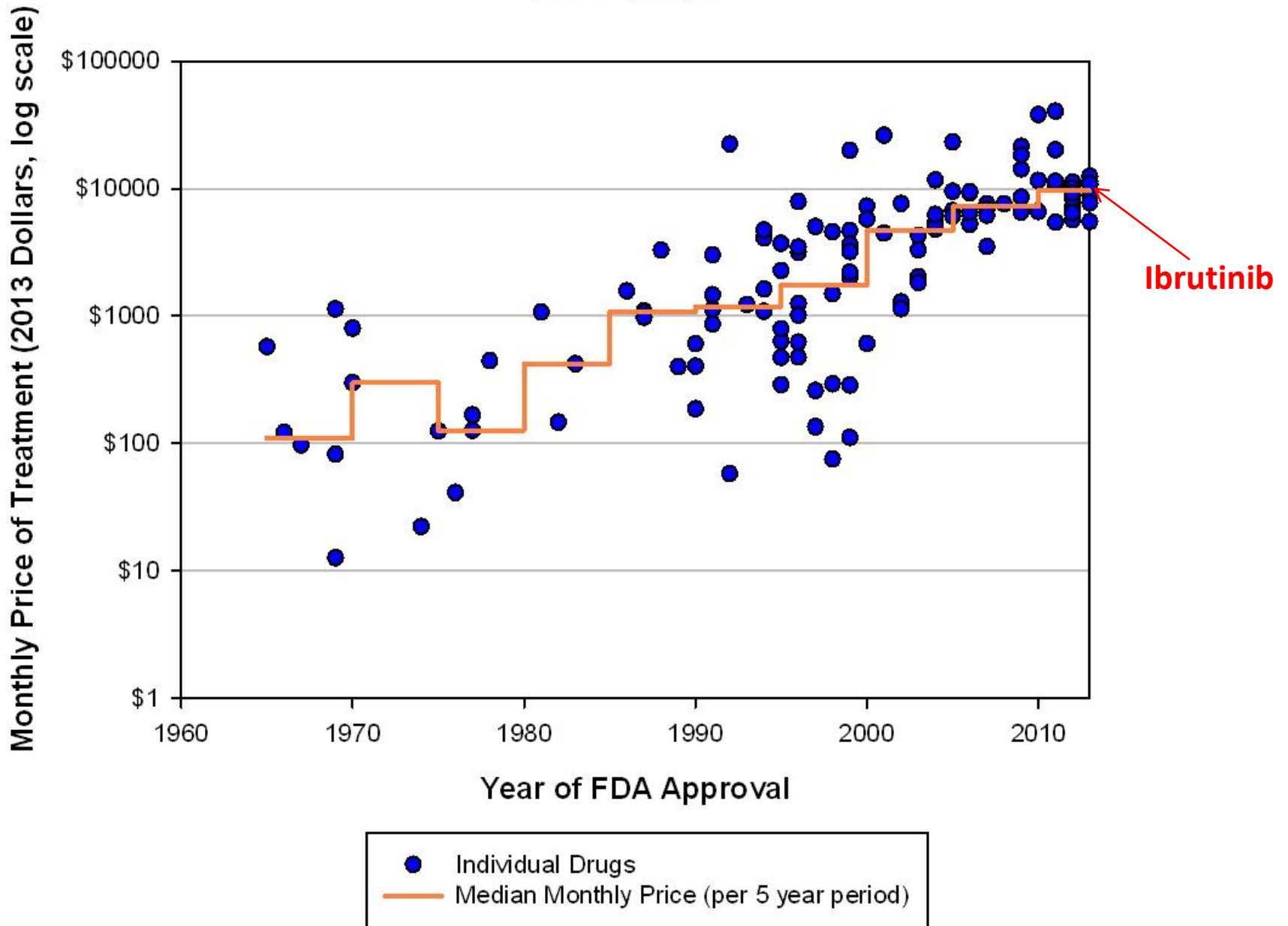
Drug makers often charge many times more for medications in the United States than they do in other countries. Below, a cost comparison of three popular drugs.



# Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965 - 2013



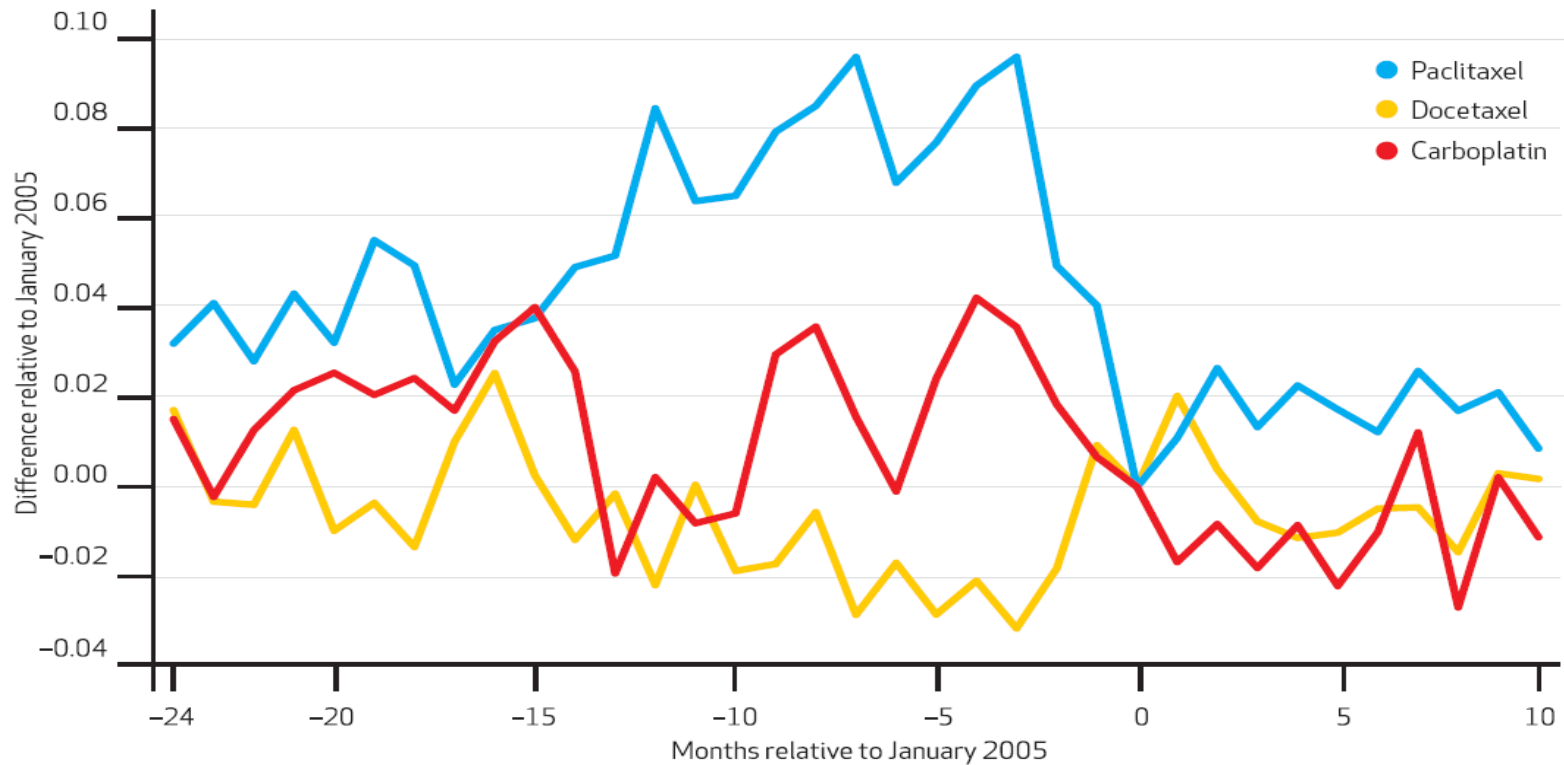
# Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965 - 2013



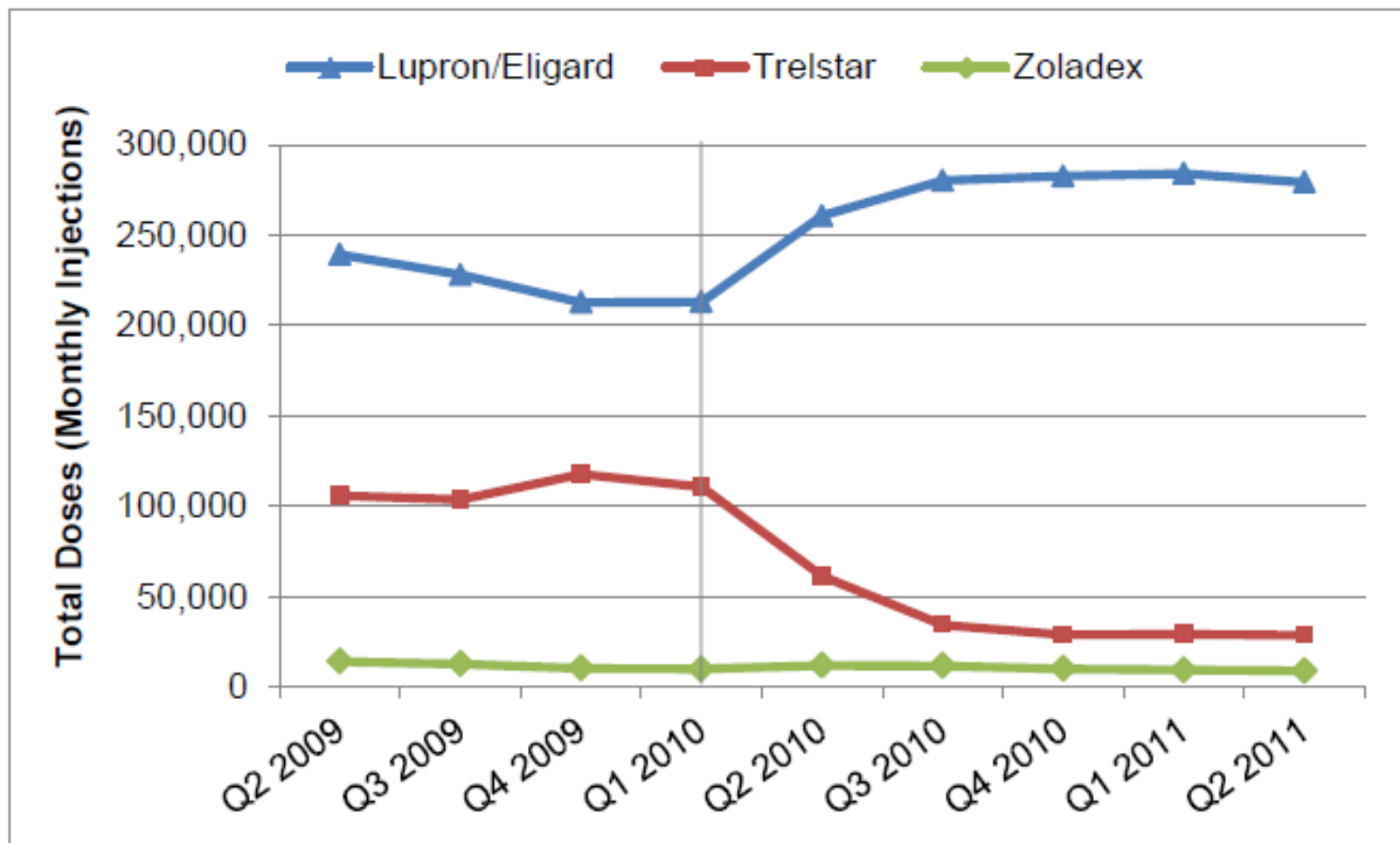
# How we pay matters

## EXHIBIT 4

Change In The Use Of Paclitaxel, Docetaxel, And Carboplatin, By Month Of Diagnosis Relative To The January 2005 Payment Change



**Figure 1: Utilization of Monthly Injections Before and After Removal of LCA Policies**



Note: Data points for each quarter represent the total utilization as of the end of that quarter. The vertical line distinguishes utilization under LCA policies from utilization after LCA policies were removed.  
Source: OIG analysis of Medicare Part B claims data, 2012.

# Metastatic Non-Small Cell Lung Cancer

Name	<h2>The Varied Costs of Chemo</h2> <p>Cancer doctors can choose among eight treatments for a type of lung cancer, but the therapies range widely in cost.</p>	Total Cost (12 Weeks)	Monthly Cost
Pemetrexed/Cisplatin	<p><b>Average cost per month to Medicare</b></p> <p>Pemetrexed \$7,092</p>	91 \$19,594.13	\$7,073.69
Gemcitabine/Cisplatin	<p>Gemcitabine 4,821</p>	85 \$13,303.24	\$4,802.61
Docetaxel/Cisplatin	<p>Docetaxel 4,506</p>	00 \$11,647.20	\$4,204.77
Irinotecan/Cisplatin	<p>Irinotecan 2,910</p>	40 \$7,984.63	\$2,882.54
Vinorelbine/Cisplatin	<p>Vinorelbine 1,809</p>	53 \$4,929.03	\$1,779.43
Etoposide/Cisplatin	<p>Etoposide 1,626</p>	86 \$4,453.86	\$1,607.89
Vinblastine/Cisplatin	<p>Vinblastine 1,380</p>	41 \$3,741.38	\$1,350.68
Paclitaxel/Cisplatin	<p>Paclitaxel 1,322</p>	17 \$3,578.70	\$1,291.95
<p><sup>1</sup> National Comprehensive Health Services, <sup>5</sup> Australia (NICE)</p>	<p>Each chemotherapy drug is combined with Carboplatin</p> <p>Source: Dr. Peter B. Bach (Memorial Sloan-Kettering Cancer Center)</p>	<p>Cancer Care Ontario (CCO), <sup>4</sup> Alberta for Health and Clinical Excellence</p>	
<p>The New York Times</p>			

# Third party buy and bill



## COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS<sup>[307]</sup>

SEC. 1847B. [42 U.S.C. 1395w-3b] (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION. —

(1) IMPLEMENTATION OF PROGRAM. —

(A) IN GENERAL. —The Secretary shall establish and implement a competitive acquisition program under which—

(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1847A; and

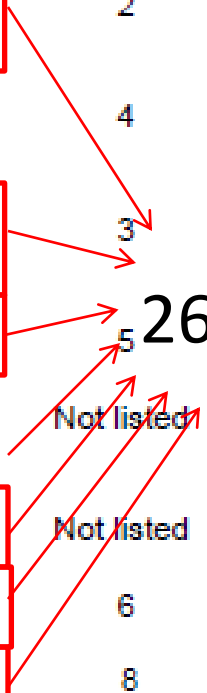
(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part. This section shall not apply in the case of a physician who elects section 1847A to apply.

**Chart 10-2. Top 10 Part B drugs administered in physicians' offices or furnished by suppliers, by share of expenditures, 2011**

Drug name	Clinical indications	Allowed charges (in millions)	Competition	Percent of spending	Rank in 2010
Ranibizumab	Age-related macular degeneration	\$1,366	Sole source	10.7%	1
Rituximab	Lymphoma, leukemia, rheumatoid arthritis	\$885	Sole source	6.9	2
Infliximab	Rheumatoid arthritis, Crohn's disease	\$669	Sole source	5.2	4
Bevacizumab	Cancer	\$526	Sole source	5.2	3
Pegfilgrastim	Neutropenia	\$490	Sole source	4.9	5
Immune globulin	Multiple (e.g., immunodeficiency, neuropathy)	\$326	Multisource biologic	2.5	Not listed
Oxaliplatin	Cancer	\$310	Sole source	2.4	Not listed
Darbepoetin alfa	Anemia	\$308	Sole source	2.4	6
Pemetrexed	Cancer	\$281	Sole source	2.2	8
Epoetin alfa	Anemia	\$273	Multisource biologic	2.1	7

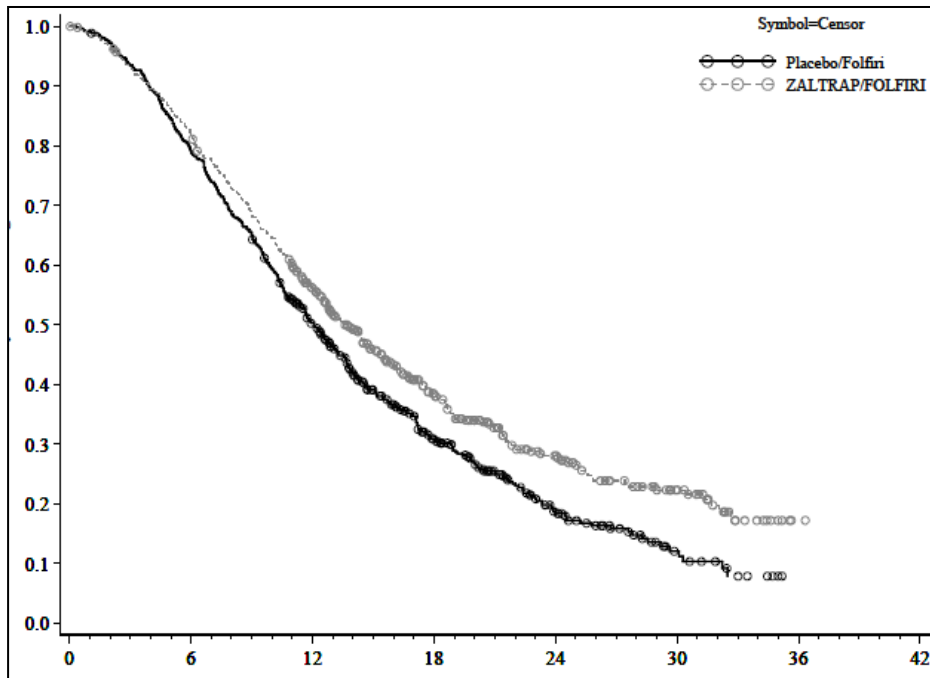
**Top 20 drugs: 75%**

**26.1%**



# The Zaltrap story

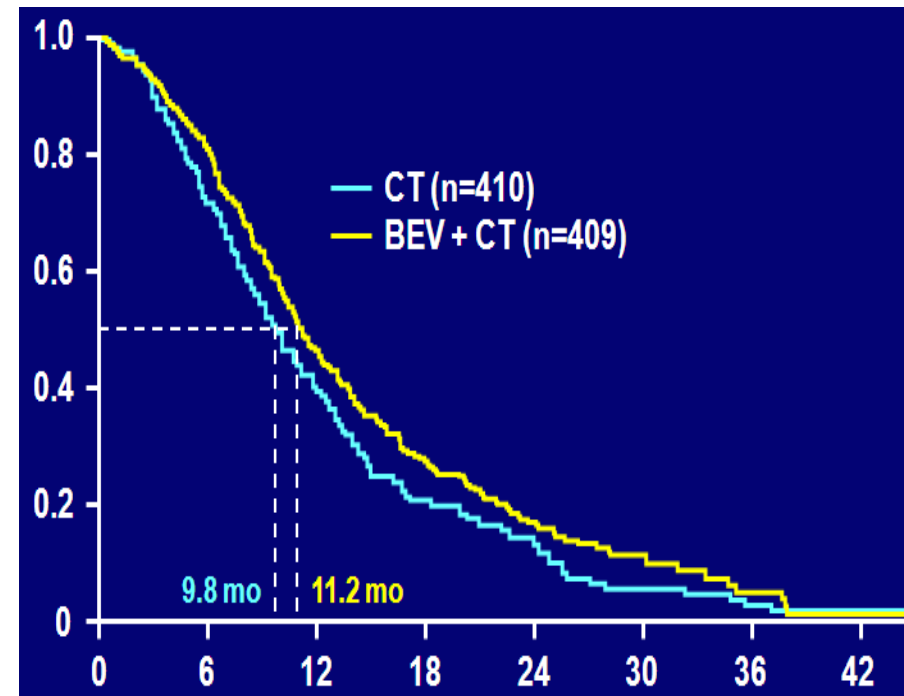
## Zaltrap



**Median survival benefit: 1.4 months**

**Cost per QALY gained: \$585,200**

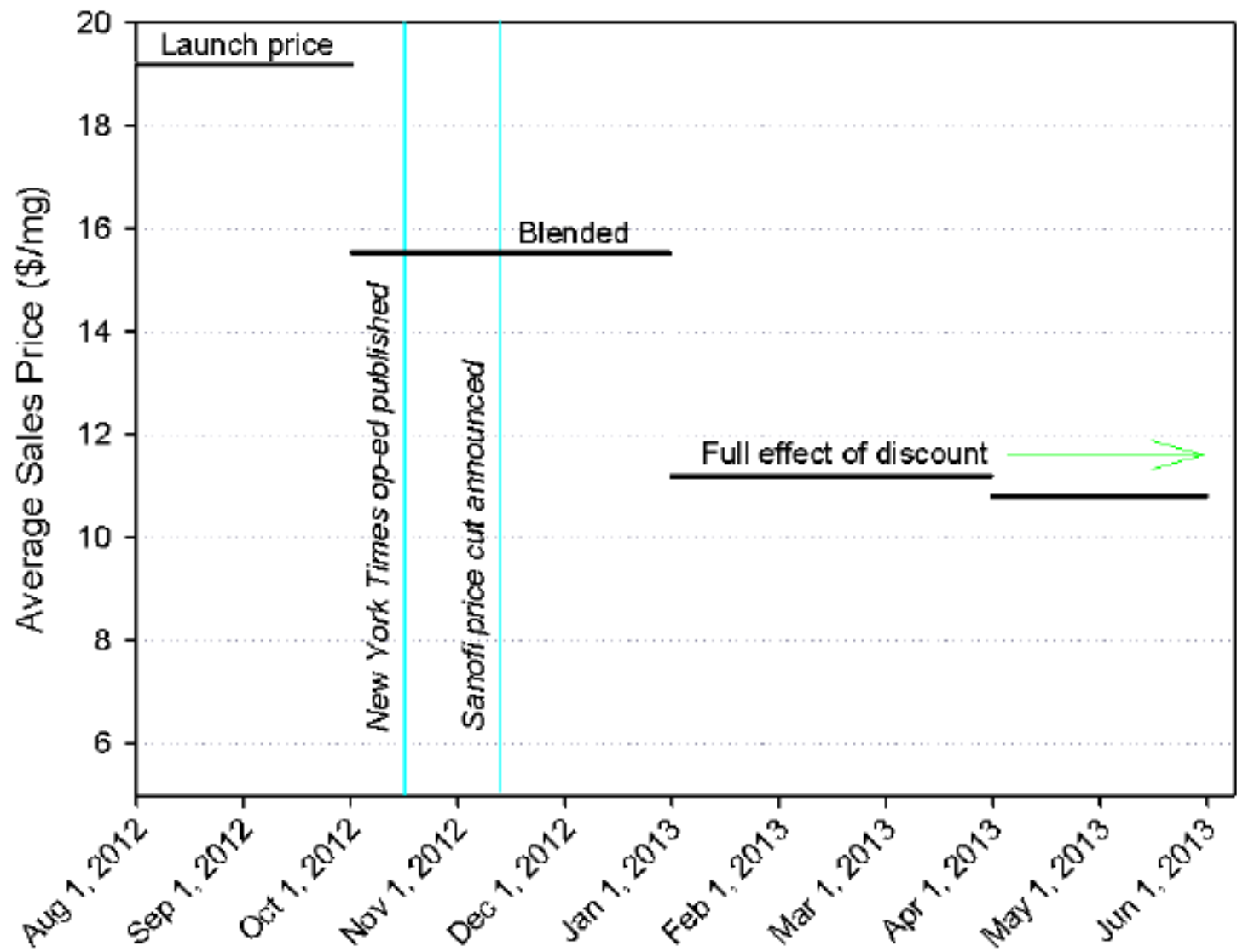
## Avastin



**Median survival benefit: 1.4 months**

# Zaltrap

## Quarterly Average Price



The New York Times  
October 14, 2012  
In Case  
By PETER B  
The New York Times  
November 8, 2012  
Sand  
Zaltrap  
By ANDREW  
The New York Times  
November 12, 2012  
Incredible Prices for Cancer Drugs

# The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts

Experts in Chronic Myeloid Leukemia

**Table 1. Annual price estimates, by region, of drugs approved for the treatment of CML**

Country	Price in thousands of US dollars (rounded to nearest \$0.5 thousand)		
	Imatinib	Nilotinib	Dasatinib
United States	92	115.5	123.5
Germany*	54	60	90
United Kingdom	33.5	33.5	48.5
Canada	46.5	48	62.5
Norway	50.5	61	82.5
France	40	51.5	71
Italy	31	43	54
South Korea	28.5	26	22
Mexico	29	39	49.5
Argentina	52	73.5	80
Australia	46.5	53.5	60
Japan	43	55	72
China	46.5	75	61.5
Russia	24	48.5	56.5
South Africa	43	28	54.5

# ASCO Value Initiative

A screenshot of the top portion of a New York Times article. The header includes a navigation bar with 'SECTIONS', 'HOME', and 'SEARCH' options, followed by the 'The New York Times' logo. Below this is a 'BUSINESS DAY' section indicator. The main headline is 'Cost of Treatment May Influence Doctors' in a large, bold, serif font. Underneath the headline, the author 'By ANDREW POLLACK' and the date 'APRIL 17, 2014' are listed.

SECTIONS HOME SEARCH The New York Times

BUSINESS DAY

***Cost of Treatment May Influence Doctors***

By ANDREW POLLACK APRIL 17, 2014

The society of oncologists, alarmed by the escalating prices of cancer medicines, is developing a scorecard to evaluate drugs based on their cost and value, as well as their efficacy and side effects. It is expected to be ready by this fall.

**Bloomberg News**

# **Express Scripts Plans Price War for Gilead Hepatitis C Drug (2)**

By Drew Armstrong | December 10, 2013

The biggest U.S. drug benefits manager plans to start a price war over a new generation of hepatitis C treatments that will cost \$1,000 a pill, in a bid to drive down spending on the medicines.

## Pricing for Orphan Drugs Will the Market Bear What Society Cannot?

come to market.<sup>2</sup> Ironically, the patients who assumed the risks of participating in the clinical trials necessary to bring this drug to market and who devoted countless hours to raising money for the CF Foundation to underwrite early work are now being asked to pay, most often through their insurers, an exorbitant price for the product that resulted from their efforts.

# Two Similar Drugs for Lung Cancer (ALK fusion)

	 Approved 2011	 Approved 2014
Approval required RCT	NO	NO
Sample size in pivotal trial(s)	136 and 119	163
Proof of concept approval	NO	YES
Time to complete trial	1.5 years	3.5 years
Name hard to pronounce	YES	YES
Which should cost more?		---
Cost (per month of treatment)	\$11,000	\$13,500

Thank you

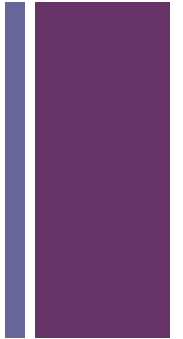


**Ms. Danica Wasney**

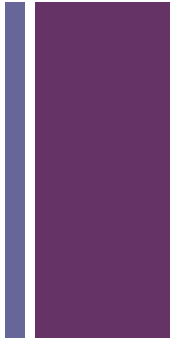
Clinical Pharmacist at the Provincial Oncology  
Drug Program, CancerCare Manitoba

# + DISCLAIMER

- I am a pharmacist



# + Objectives



- Cancer drugs and the conflicted clinician
  - Spotlight on the pharmacist's role and perspective
- Observed Opportunities and Successes – Manitoba and Canada
- A Clinical Case Study – Cancer drug cost is not always the issue

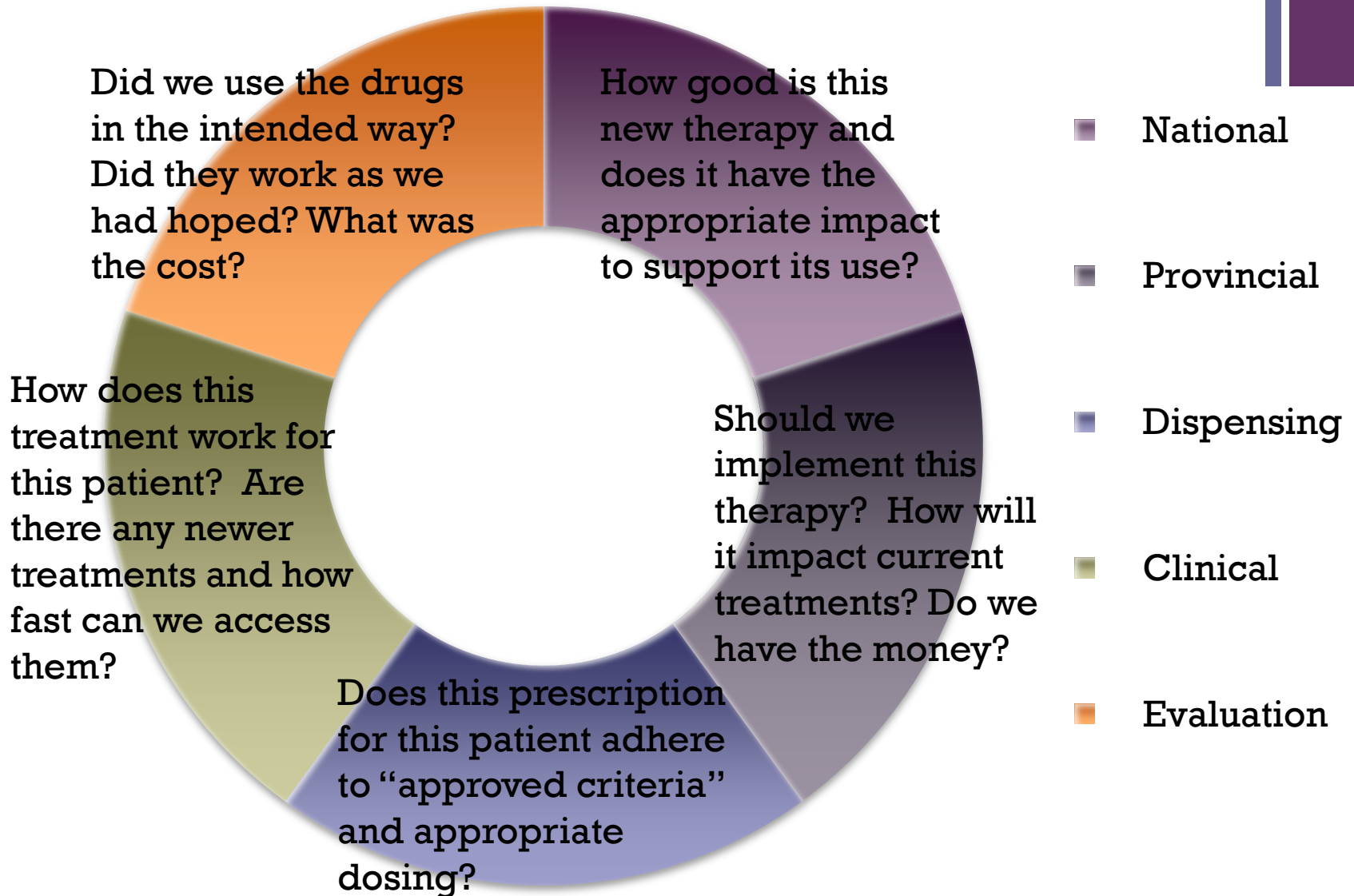
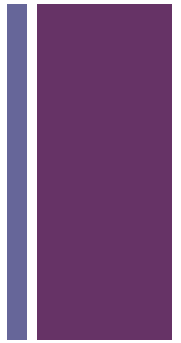


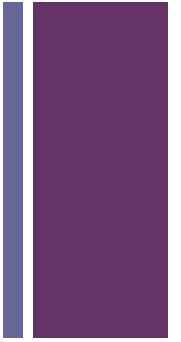
# A Pharmacist's Perspective



- Oncology Pharmacist's potential roles:
  - Preparation and dispensing of anticancer drugs
  - Evaluation of potential drug interactions between existing medications and anticancer drugs
  - Participation in multidisciplinary patient care teams
  - Provision of education and tools to patients and families regarding anticancer drugs
  - Navigation of access to drug coverage for patients (e.g. public, private)
  - Participation on drug review committees to evaluate the potential role of new anticancer therapy
    - Provincial: "P & T Committee"
    - National: pCODR
  - Involvement in initiatives to optimize appropriate anticancer drug use
  - Participation in research related to anticancer drugs (drug development, drug utilization evaluation, clinical outcomes)

# + “Complementary Yet Competing Roles”



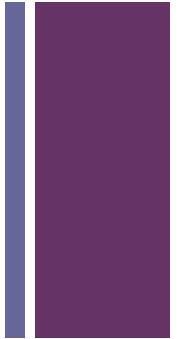


# + The Manitoba Experience

- A Drug Request Process was implemented in 2005 for all \$\$ drugs that were approved “with restrictions” – process facilitated through the pharmacy department
- A Provincial Oncology Drug Budget for parenteral therapies was established in 2006 (amalgamation of regional budgets)
- Computerized Physician Order Entry has been implemented since 2006 (ongoing)
  - Broader development of electronic protocols
  - Generation of electronic drug dose recording data
- Provincial Oncology Drug Formulary was revamped to provide more detail regarding status of drugs and clinical criteria
- Interested clinicians formed a working group (*ad hoc*): “Manitoba Oncology Drug Utilization and Clinical Outcomes Working Group” – “*MODUCO*”

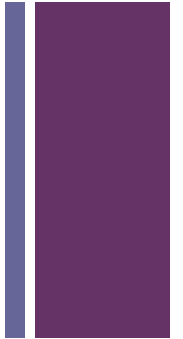
# + Opportunities from Progress – The Manitoba Experience

- The Drug Request Process, and companion database, managed by Pharmacy department
  - Helps to ensure optimum drug use and adherence to approved clinical criteria for use
  - Tracks information for statistics and future budget projections
  - Inadvertently “pre-populated” patient cohorts to assist with projects identified for evaluation:
    - Trastuzumab for HER2 + early stage breast cancer (drug funded in 2005; drug request process and CPOE initiated in 2005)
    - Best source of patient cohort data (Cancer Registry data also used as cross-reference)
- CPOE drug data provides “in house” electronic drug data for parenteral therapies
- Formation of MODUCO has provided more formalized research connections within the organization



# + Challenges – The Manitoba Experience

- Reliability of electronic drug utilization data; requires validation and ongoing education for CPOE users
- Electronic Health Record missing key elements of information required (e.g. radiographic imaging; “hybrid” chart) – manual chart review still required to some degree
- Oral cancer drugs are not dispensed and tracked in the same way as parenteral therapies (no “in house” data)
- Limited patient numbers due to small provincial population
  - few events observed during study time frame
- Ongoing funding/support/time for research
  - Cancer drug funding arrangements do not systematically include infrastructure to support ongoing evaluation and outcomes research



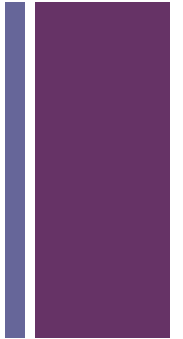
# + Opportunities from Progress – The National Experience



- The pan-Canadian Oncology Drug Review
  - Evidence-based, cancer drug review process launched in 2011
  - [www.pcodr.ca](http://www.pcodr.ca)
    - *“consistency and clarity to the assessment of cancer drugs by reviewing clinical evidence, cost-effectiveness, and patient perspectives, and using this information to make recommendations to Canada's provinces and territories (except Quebec) in guiding their drug funding decisions.”*
- Provides a thorough, transparent review process
- Aims to avoid replication of similar work at a provincial/territorial level
- Aims to reduce variability in access to cancer drugs across Canada
- Aims for consistency amongst its recommendations

# + Challenges – The National Experience

- Jurisdictional variability remains:
- \$\$\$\$
  - Funding decisions and drug budgets remain at the Provincial and Territorial level
  - Affordability and prioritization of cancer drugs varies amongst jurisdictions
- Interpretation and implementation of national recommendations may vary:
  - Jurisdictional variation in applicability of the drug reviewed
  - Study design may not provide clarity for incorporation into current treatment algorithms



# + Opportunities for Prospective Evaluation

- *“This study didn’t use the ‘right’ comparator.”*
  - Results available after standard of care has already changed
  - Jurisdictional variability in current standard of care
  - E.g. Axitinib for pre-treated renal cell carcinoma (vs. Sorafenib; Everolimus vs. placebo)
- *“This patient population doesn’t really exist anymore.”*
  - Inclusion criteria for the trial did not account for a line of therapy that has since been implemented
  - Do we exclude patients who have received this therapy or give the benefit of the doubt
  - E.g. Enzalutamide for pre-treated castrate resistant prostate cancer (post-docetaxel; no prior abiraterone, now likely to be given pre-docetaxel)

# + Opportunities for Prospective Evaluation

- *“This is a small patient population and a non-randomized trial. Can we believe these results?”*
  - Randomized trial unlikely due to rare diagnosis/small patient population
  - Uncertainty over magnitude of benefit
  - E.g. Brentuximab for relapsed Hodgkin lymphoma
- Many opportunities for institutional, provincial/territorial, cross-jurisdictional, or national data collection and analysis to address uncertainties with funding of cancer drugs
- Clinicians have the interest, but not always the resources to pursue

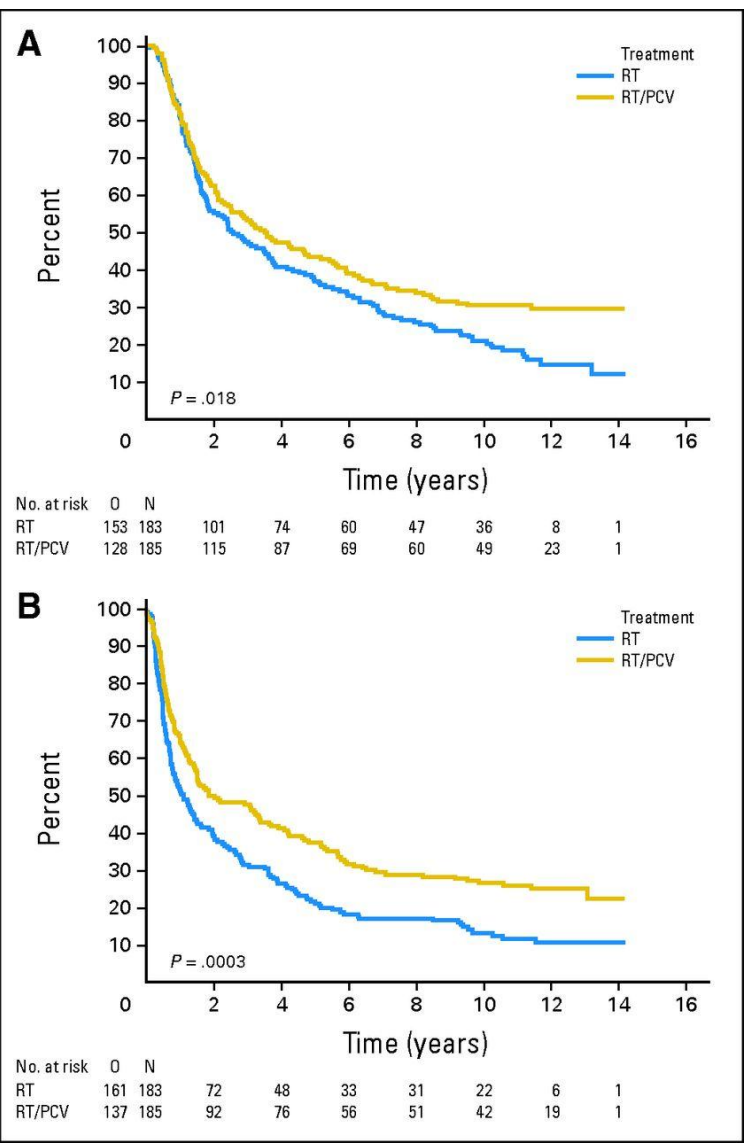




# Case Study – PCV for Oligodendroglioma



- 2012:
  - Standard of care extrapolated from more aggressive brain tumours (e.g. glioblastoma multiforme)
  - Patients offered Radiation (RT) plus Temozolomide (TMZ) at diagnosis, then proceed to Temozolomide for 6-12 months
  
- Then....
  - Long term follow-up of trials conducted between 1996-2002 were reported (EORTC 26951, RTOG 9402)
    - Median PFS and OS strongly favoured RT plus PCV regimen (Procarbazine, Lomustine, Vincristine) vs. RT alone
      - Temozolomide comparator not included (was not available/widely used at time of study)



After median follow-up of 140 months:

Median OS:

RT plus PCV: 42.3 months

RT alone: 30.6 months

(HR, 0.75; 95% CI, 0.60 to 0.95)

Median PFS:

RT plus PCV: 24.3 months

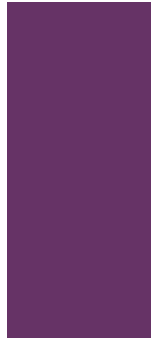
RT alone: 13.2 months

(HR, 0.66; 95% CI, 0.52 to 0.83)

EORTC 26951

van den Bent et al. *J Clin Oncol* 2006

van den Bent et al. *J Clin Oncol* 2013



# + Preplanned Subgroup Analysis: 1p/19q co-deleted tumours



Median OS: (n=80):

Median PFS: (n=80):

PCV/RT: Not reached (after median 140 months)

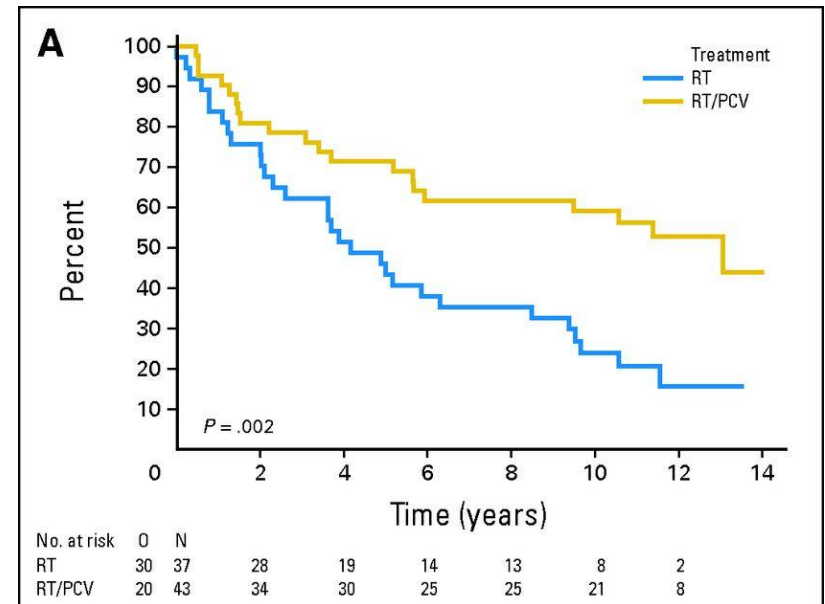
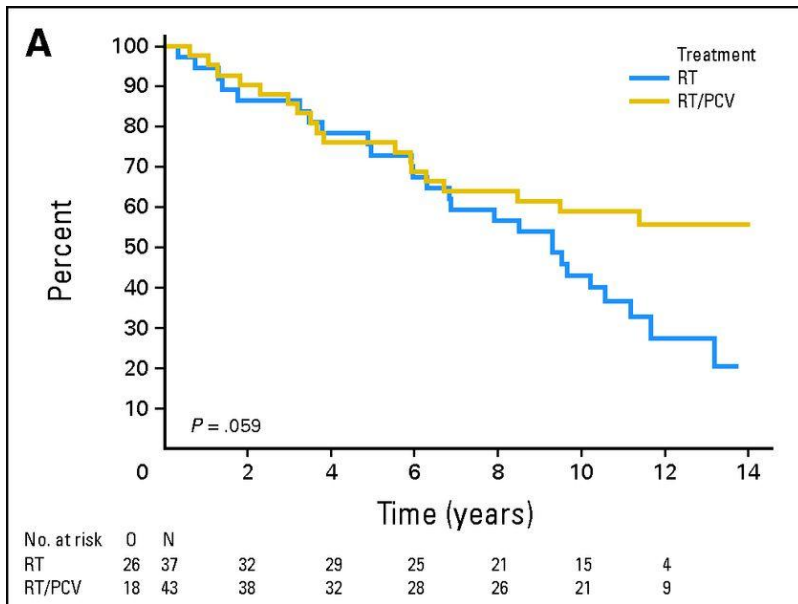
PCV/RT: 157 months

RT alone: 112 months

RT alone: 50 months

HR: 0.56, 95% CI (0.31-1.03)

HR: 0.42, 95% CI (0.24-0.74)



# + PCV Delivery

- Treatment plan: PCV regimen q42days x 6 cycles
- Median number of PCV cycles: 3 (5 cycles: 37%; 6 cycles: 30%)
  - Reasons for discontinuation
    - Hematologic toxicity: 33%
    - Tumour progression: 24%
    - Non-Hematologic Toxicity: 5%
    - Patient refusal: 5%
- Dose intensity considerably lower than intended (% not reported)
- Of patients on the RT alone arm, at disease progression, over 80% of patients went onto receive chemotherapy (65% being PCV regimen)

# + Case Study – PCV for Oligodendroglioma

- Change in local practice for patients with anaplastic oligodendroglioma or oligoastrocytoma
- A rare example of potentially significant incremental benefit for negligible incremental cost (vs. current TMZ)
- “Old Drugs, New Tricks”
  - Multiple Issues anticipated:
    - Poor tolerability versus currently used temozolomide
    - Multiple drug interactions between procarbazine and anti-seizure medications
    - Multiple interactions between procarbazine and tyramine-containing foods
    - Studies conducted when currently used supportive care agents not available – no data to guide practice, dose selection, etc.
    - Complicated dosing regimen for patients – both oral and IV medications
- January 2013 – first patient started onto the PCV regimen at CCMB



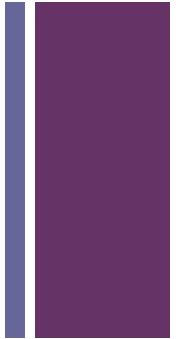
# Case Study – PCV for Oligodendroglioma



- PCV regimen was not widely adopted at other Canadian centres
- One study (RTOG 9402) had been conducted in Canadian centres
  - Hands on experience with the PCV regimen (and its difficulties)
- Need for prospective data to compare TMZ to PCV
  - NCIC CEC.2 design: AO patients with 1p/19q deletions – RT vs. TMZ-RT vs TMZ
    - No PCV arm when designed...



# Case Study – PCV for Oligodendroglioma



- “In-House” protocol approved to prospectively evaluate patients receiving PCV in the “contemporary era”
  - Data collection:
    - Pathology and 1p/19q deletion status
    - Requirement for:
      - Dose delay/reduction
      - Growth factor support
      - Change in anti-seizure drug therapy due to interactions with procarbazine
    - Safety/tolerability
    - PFS, OS
- As of February 2014, n = 14 (7 males, 7 females) have been started onto PCV regimen
- Of the 55 completed cycles, 37 (67.2%) required dose reductions or delays because of cytopenias
- Data collection and analysis ongoing

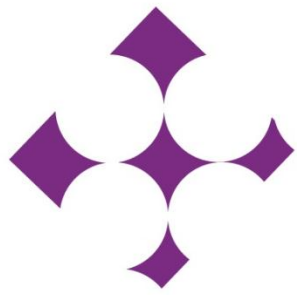


Thank you



## Dr. Craig Earle

Director of Health Services Research, Ontario  
Institute for Cancer Research and Cancer Care  
Ontario



**ARCC**

Canadian Centre  
for Applied Research  
in Cancer Control

# How applied research can help with oncology drug reimbursement decisions at the provincial level

Craig Earle, MD MSc FRCPC



**BC Cancer Agency**  
CARE & RESEARCH  
An agency of the Provincial Health Services Authority



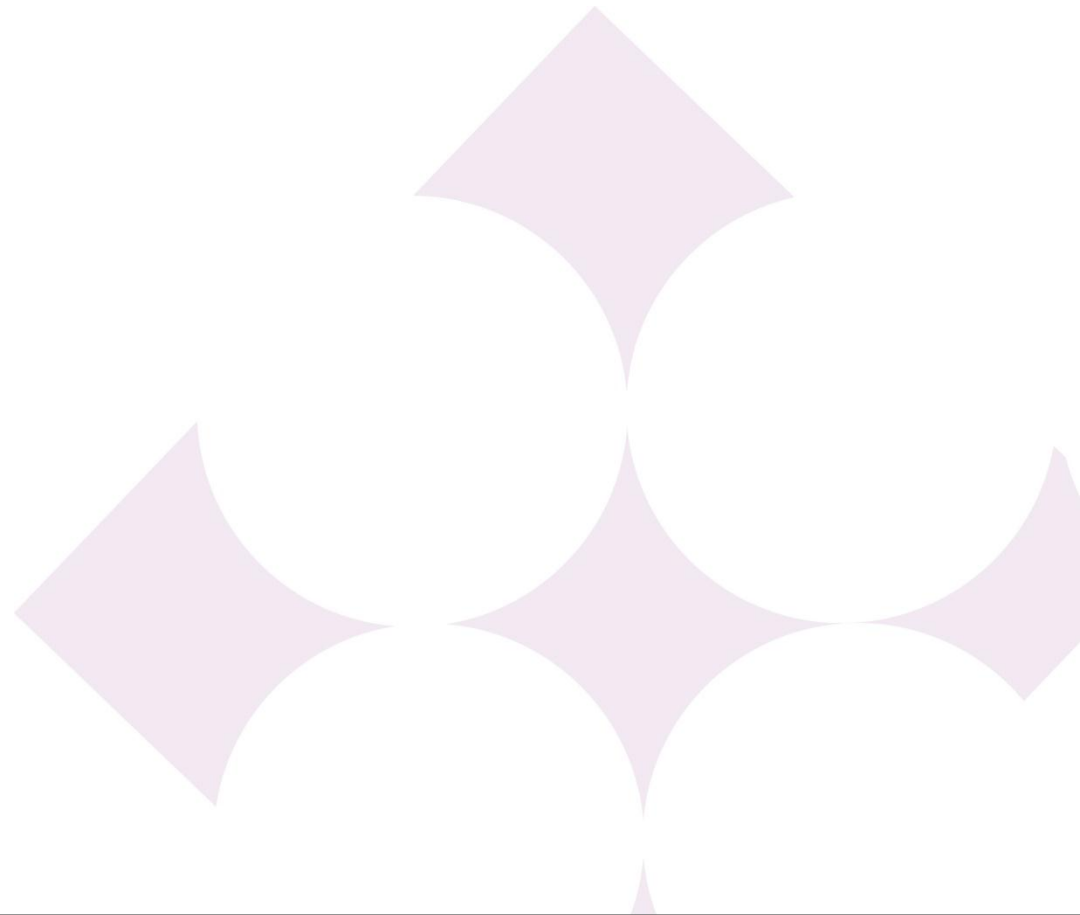
Canadian  
Cancer  
Society

Société  
canadienne  
du cancer



**Cancer Care Ontario**  
**Action Cancer Ontario**

**DISCLAIMER**



# Perception vs. Reality



A screenshot of a tweet from Will Ferrell (@Will\_\_Ferrell). The tweet text reads: "The Canadian version of Breaking Bad is kind of lame. It ends after he gets cancer and his treatment is totally paid for by the government." The tweet has 3,214 retweets and 980 favorites. The interaction bar includes icons for Reply, Retweet, Favorite, Buffer, and More. The avatars of users who interacted with the tweet are visible at the bottom, including a Pilsener beer can.

**Will Ferrell**  
@Will\_\_Ferrell

[Follow](#)

The Canadian version of Breaking Bad is kind of lame. It ends after he gets cancer and his treatment is totally paid for by the government.

[Reply](#) [Retweet](#) [Favorite](#) [Buffer](#) [More](#)

**3,214** RETWEETS    **980** FAVORITES



Courtesy Scott Gavura, Director, Provincial Drug Reimbursement Programs at Cancer Care Ontario

# Canada

## Political Regions



	Eligibility for Public Drug Plan	Specific High Drug Cost Program	Gaps in Eligibility
BC	All	N/A	
AB	All	N/A	
SK	All	N/A	
MB	All	N/A	
ON	Seniors Social assistance	All others	
QC	All	N/A	
NB	Low income seniors Social assistance	Limited*	Working families without private coverage. Moderate and high income seniors**
PE	Seniors Social assistance	Specific cancer drugs***	Working families without private coverage. High income families
NS	Seniors, social assistance and low income families	Cancer drugs for low-income residents	Average and high income families without private insurance
NL	Seniors, social assistance and low income families	All others	
YT	All	N/A	
NT	All	N/A	
NU	All	N/A	
Federal	Registered First Nations and Inuit, military, RCMP, inmates, refugees	N/A	

\* NB residents may apply to the Department of Social Development for "Health Card Only" benefits which provide 100% coverage for drugs listed on the public formulary. Eligibility for this benefit requires that applicants have high medical expenses relative to income and that they exhaust their personal assets first.

\*\* NB seniors who do not qualify for the public drug plan may purchase drug insurance through the Medavie Blue Cross Seniors' Prescription Drug Program.

\*\*\* All PEI residents with net household incomes less than \$150,000 per year are eligible to receive some assistance with payments for a selected list of oral cancer drugs.

## An example of public drug coverage variability across Canada: Bortezomib (Velcade) for pre- and post-transplant

Drug	Eligibility	AB	BC	SK	MB	ON	NS	NB	NL	PEI
Velcade (bortezomib)	Induction therapy pre-Autologous Stem Cell Transplant	Funded	Funded	Funded	Funded	Funded	Funded	Under consideration	Under consideration	Under consideration
	Maintenance therapy post-Autologous Stem Cell Transplant	Funded	Not funded	Not funded	Under consideration	Not funded	Under consideration	Under consideration	Under consideration	Under consideration

Funded	Not funded	Under consideration
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# Public drug funding pathway

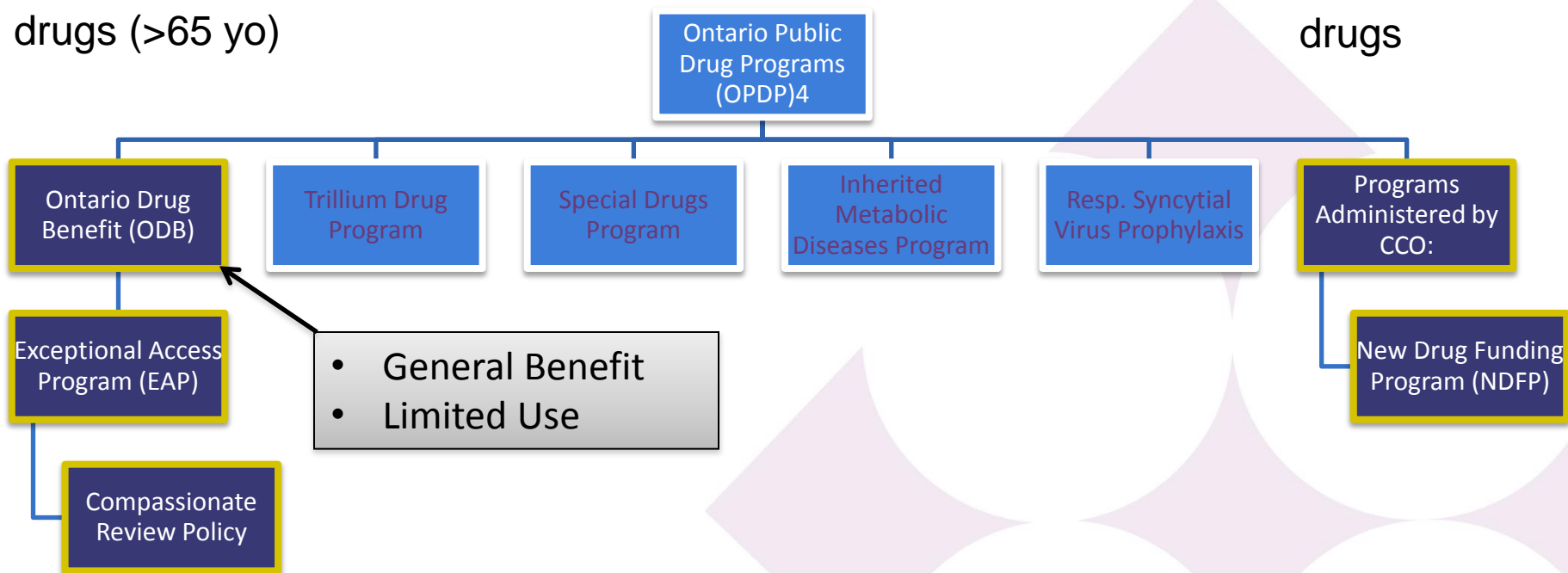
Requirement	Agency/Body	Output
1. Safety, Efficacy, Quality	Health Canada	Market authorization
2. List price	Patented Medicines Pricing Review Board (PMPRB)	Maximum price
3. Value (Health Technology Assessment)	Canadian Agency for Drugs & Technologies in Health(CADTH) • CDR / pCODR	Reimbursement recommendation to provinces
4. Value & Affordability	Provincial drug plans / Private insurers	Reimbursement decision
5. Reimbursed price	<ul style="list-style-type: none"> <li>• Pan-Canadian Drug Pricing Alliance</li> <li>• Product Listing Agreements</li> </ul>	Best reimbursement price



# How it's been done in Ontario

Oral cancer  
drugs (>65 yo)

IV cancer  
drugs





## Ontario Health Minister won't help mom get breast-cancer drug

**LISA PRIEST AND KAREN HOWLETT**

The Globe and Mail

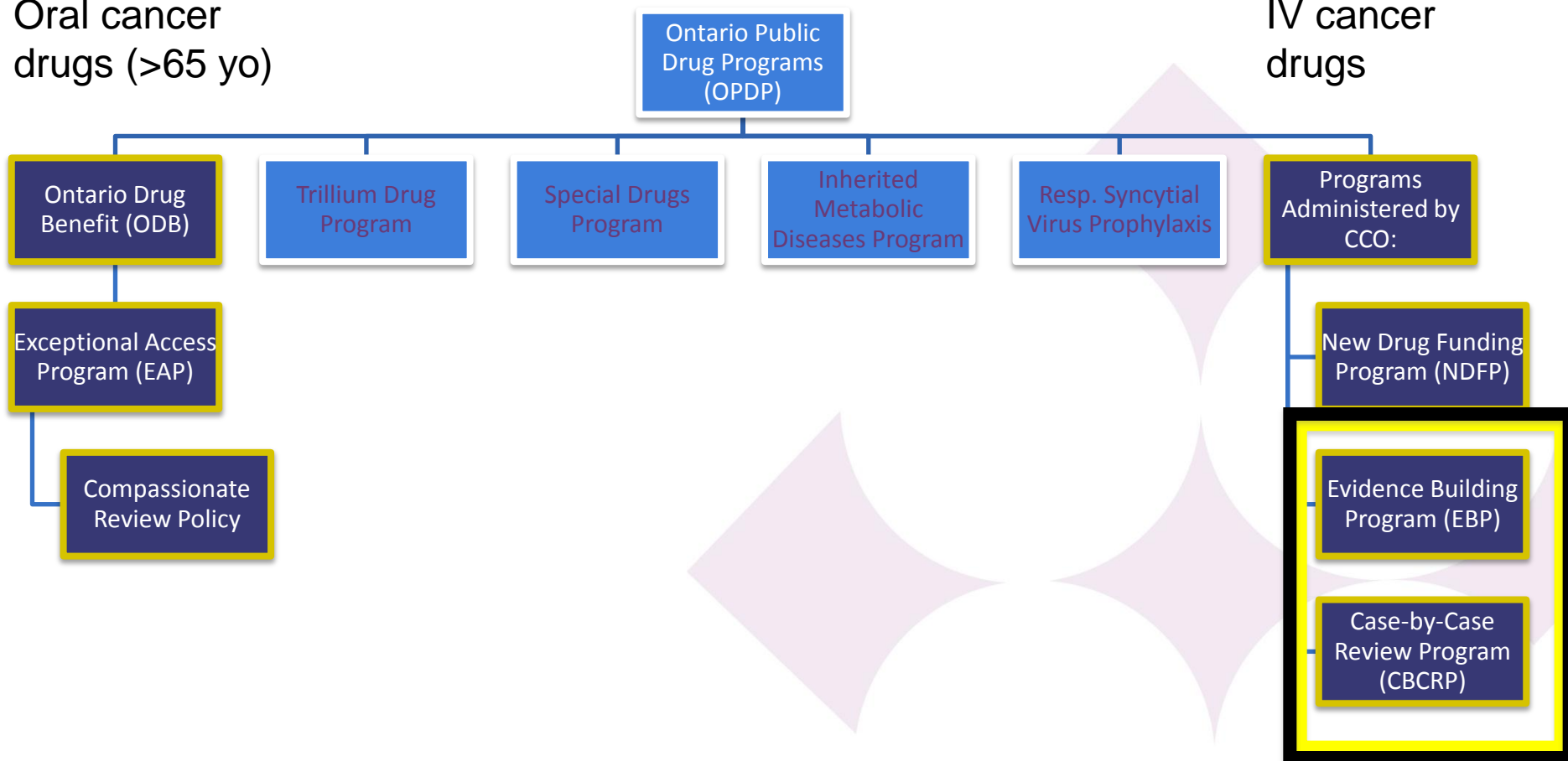
Published Wednesday, Mar. 09 2011, 12:42 AM EST

Last updated Thursday, Aug. 23 2012, 4:56 PM EDT

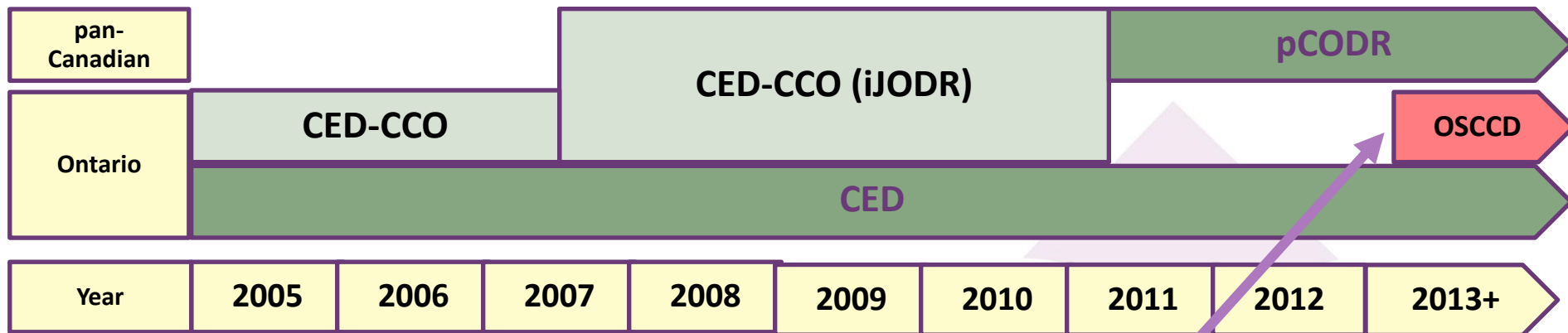
# How it's now done in Ontario

Oral cancer drugs (>65 yo)

IV cancer drugs



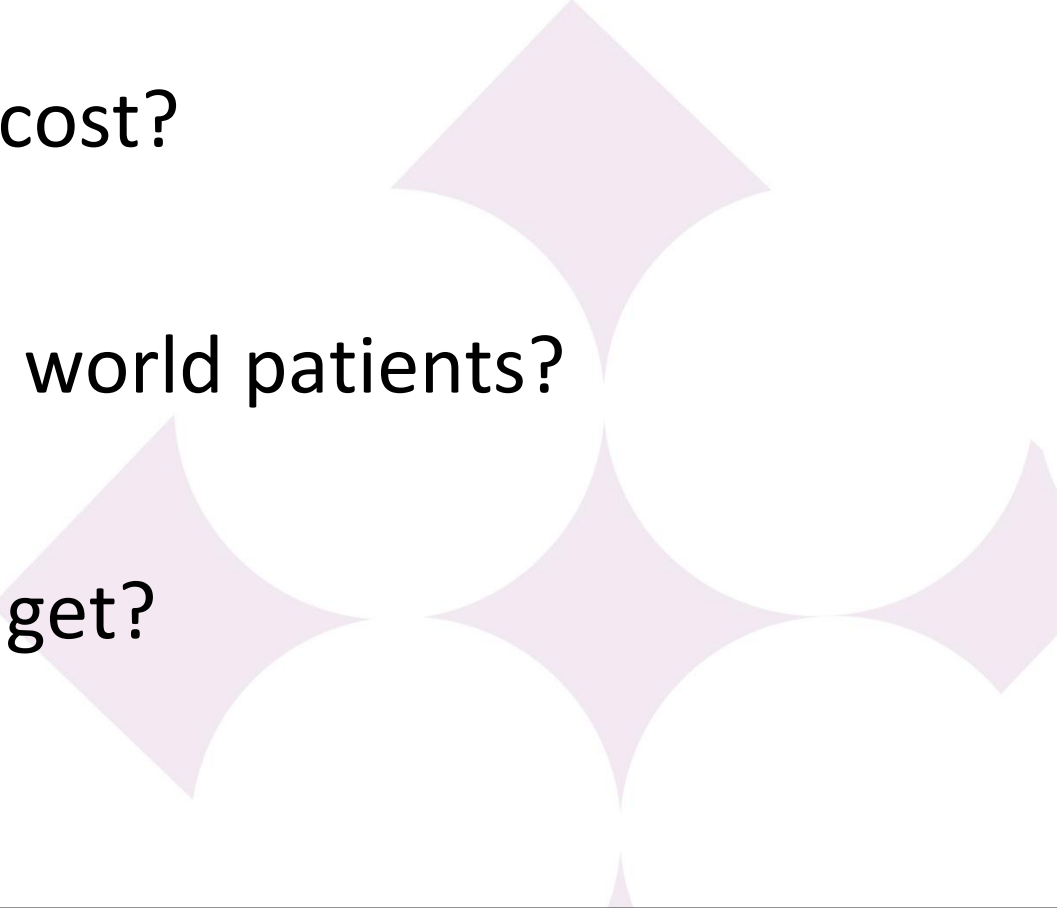
# Ontario Steering Committee for Cancer Drug Programs



To deal with Ontario-specific funding and policy issues

- Criteria management
- New evidence/resubmission
- Radiopharmaceuticals
- Evidence-building program
- ...

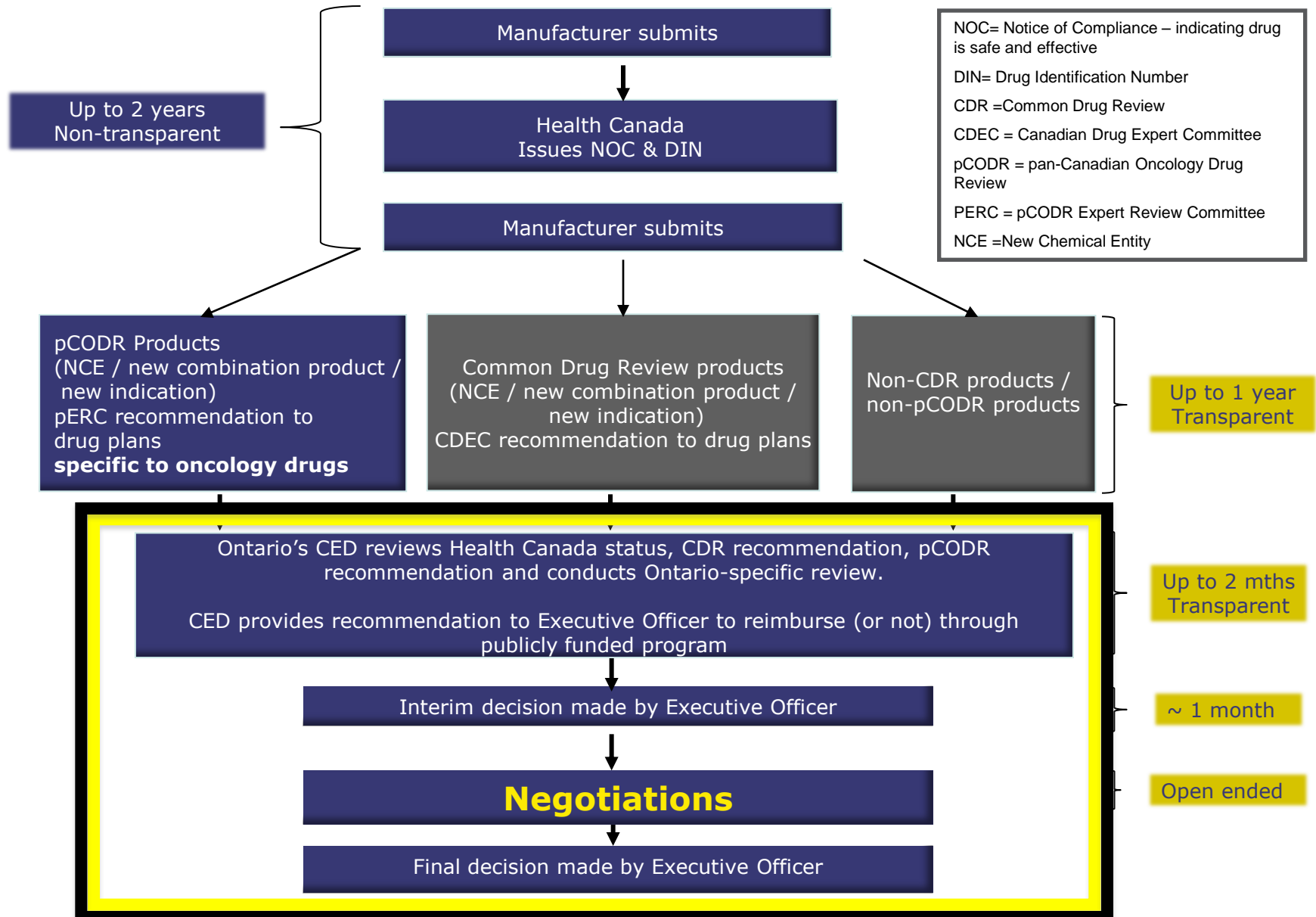
# At the provincial level we need to know

- What does it really cost?
  - Is it effective in real world patients?
  - Will it blow the budget?
- 



**WHAT DOES IT REALLY COST?**

# Drug Funding Process



# Product/Conditional Listing Agreements

Government negotiates with the drug company to:

- Obtain a lower price outright
- Commit to utilization reviews → cap or discount if:
  - budget impact
  - per-patient cost
  - per-patient volume is exceeded
- Commit to providing additional data as it becomes available
- Pay for results, rebate, or discount if health outcomes not achieved
- Finance disease management programs, targeted educational initiatives, etc.

# Such agreements may increase access in the short-term, but...

They're confidential

⇒ The list price for 'reference pricing' remains high

⇒ Prices remain high for everyone

# Pan-Canadian Drug Pricing Alliance

- August 2010
- Led by Ontario and Nova Scotia
  - (Quebec and Nunavut not participating)
- Use increased leverage to achieve:
  - Lower drug prices
  - More consistent drug prices

=> More consistent availability

# Pan-Canadian Drug Pricing Alliance

As of April 30, 2014

There are 9 negotiations **currently underway** for the following drug products:

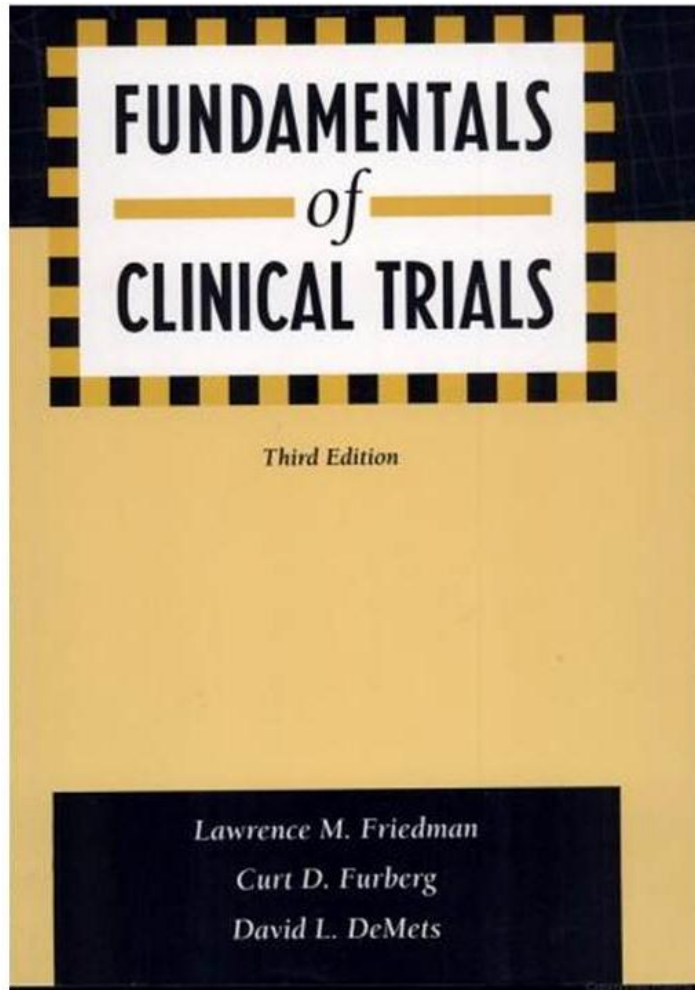
Drug Product Brand Name (Generic Name)	Indication/Use
Fibristal (ulipristal acetate)	Used to treat uterine fibroids
Jetrea (ocriplasmin)	Used to treat symptomatic vitreomacular adhesion
Kalydeco (ivacaftor)	Used to treat cystic fibrosis
Mekinist (trametinib)	Used to treat metastatic melanoma
Onglyza (saxagliptan)	Used to treat Type 2 diabetes mellitus
Orencia (abatacept)	Used to treat rheumatoid arthritis
Rebif (interferon beta-1a)	Used for clinically isolated syndrome
Revlimid (lenalidomide)	Used for maintenance treatment in multiple myeloma after a stem cell transplant
Tafinlar (darafenib)	Used to treat metastatic melanoma

No new drug products since last update of April 1, 2014.



**IS IT EFFECTIVE IN REAL WORLD  
PATIENTS?**

# Trial inclusion criteria $\neq$ Funding criteria



*“In selecting subjects to be studied...the investigator...wants to choose people in whom there is a high likelihood that he can detect the hypothesized results of the intervention...people with a high expected event rate.”*

# Criteria Management Scenarios

- Patients excluded from trials who would be expected to benefit
  - Low risk, poor PS, brain mets
- Uncommon diseases ‘treated as’ a common disease
  - Appendiceal adenocarcinoma, small bowel cancer
- A new funding policy changes the treatment algorithm
  - Line of therapy
- Unique clinical circumstances
  - Treatment stopped for toxicity, not progression

pCODR won't deal with these



**WILL IT BLOW THE BUDGET?**

# Budget Impact Assessment

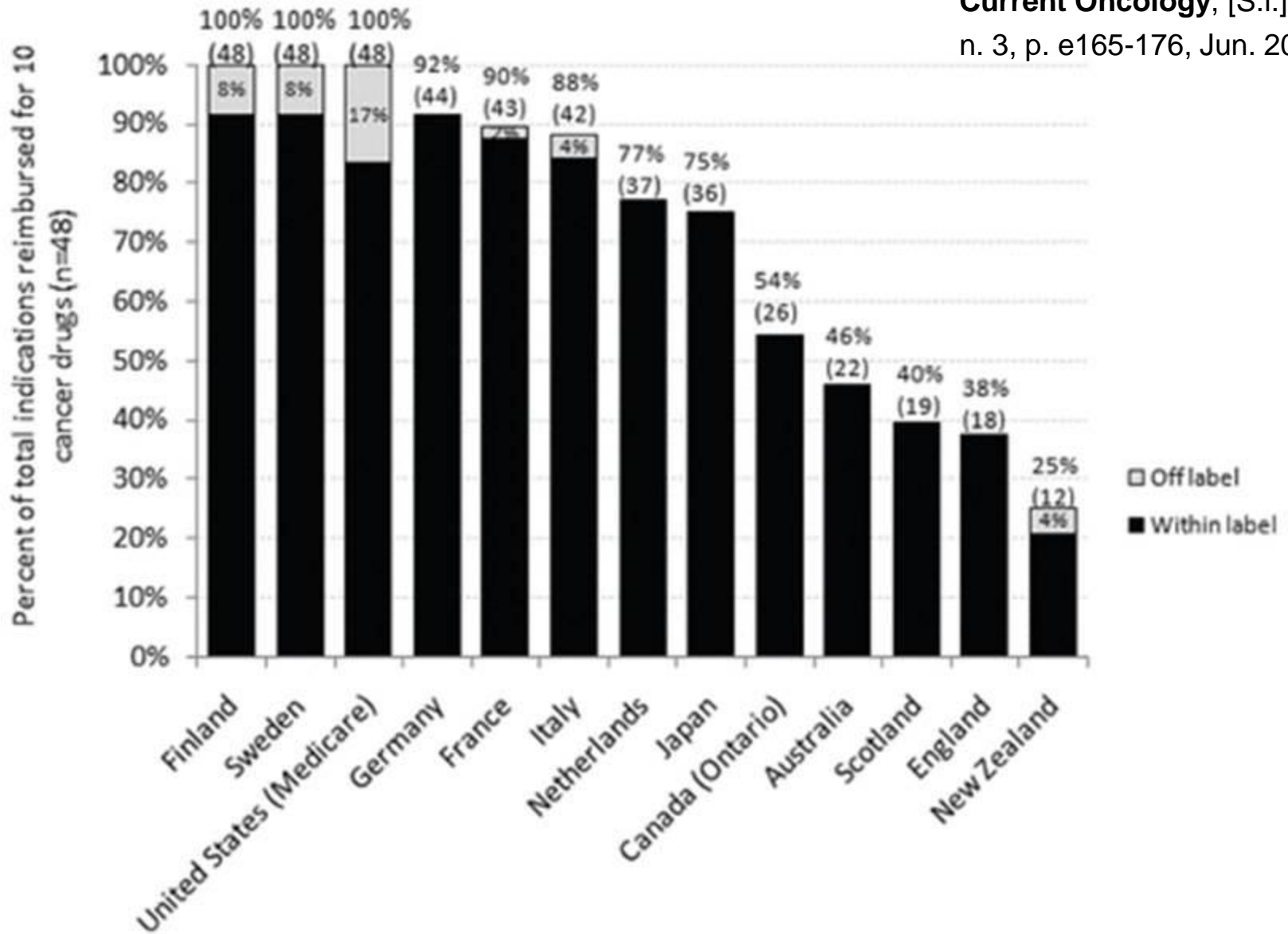
- Patient numbers in Ontario
- Likely uptake
- How long will they be on treatment?
- What is the cost of providing the drug (including ancillary costs: provider resources, genomic testing...)
- What's the patent situation?
- Are there offsets?
- Downstream effects on the treatment algorithm
- How are other jurisdictions managing?

**ISPOR Guidelines:** *Value in Health* 17(2014) 5-14



A VAST  
INJUSTICE

Investigation into the Ministry of Health  
and Long-Term Care's decision-making  
concerning the funding of Avastin for  
colorectal cancer patients



**FIGURE 1** Percentage of all licensed indications ( n = 48) reimbursed for 10 cancer drugs as of February 28, 2010

# The Timing of Drug Funding Announcements Relative to Elections: A Case Study Involving Dementia Medications

Sudeep S. Gill<sup>1,2\*</sup>, Neeraj Gupta<sup>1</sup>, Chaim M. Bell<sup>2,3,4</sup>, Paula A. Rochon<sup>2,3,5</sup>, Peter C. Austin<sup>2,3</sup>, Andreas Laupacis<sup>2,3,6</sup>

**1** Department of Medicine, Queen's University, Kingston, Ontario, Canada, **2** Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada, **3** Department of Medicine and Institute of Health Policy, Management, and Evaluation, University of Toronto, Toronto, Ontario, Canada, **4** Department of Medicine, Mount Sinai Hospital, Toronto, Ontario, Canada, **5** Women's College Research Institute at Women's College Hospital, Toronto, Ontario, Canada, **6** Keenan Research Centre, Li Ka Shing Knowledge Institute of St. Michael's Hospital, Toronto, Ontario, Canada

## Abstract

**Conclusions:** Impending elections appeared to affect the timing of drug funding announcements

disease and related dementias, were compared to the dates of provincial elections. Medical journal articles, media reports, and proceedings from provincial legislatures were reviewed to assemble information on the chronology of events. We tested whether there was a statistically significant increase in the probability of drug funding announcements within the 60-day intervals preceding provincial elections.

**Results:** Decisions to fund the cholinesterase inhibitors were made over a nine-year span from 1999 to 2007 in the ten provinces. In four of ten provinces, the drugs were added to formularies in a time period closely preceding a provincial election ( $P=0.032$ ); funding announcements in these provinces were made between 2 and 47 days prior to elections. Statements made in provincial legislatures highlight the key role of political pressures in these funding announcements.

**Conclusions:** Impending elections appeared to affect the timing of drug funding announcements in this case study. Despite an established structure for evidence-based decision-making, drug funding remains a complex process open to influence from many sources. Awareness of such influences is critical to maintain effective drug policy and public health decision-making.

# Question Period



Canadian  
Cancer  
Society    Société  
canadienne  
du cancer



**Cancer Care Ontario**  
**Action Cancer Ontario**