



# **Core Competencies in Pharmacoeconomics**

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## **Recent Trends in Pharmacoeconomics: Needs and Unmet Needs**

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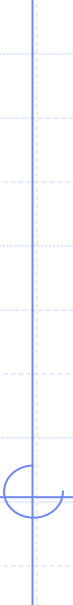
**19<sup>th</sup> Helsinki Drug Research Conference**

**10:30 – 11:15, June 9, 2008**

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**Biomedicum, Helsinki, Finland**

**June 9, 2008**



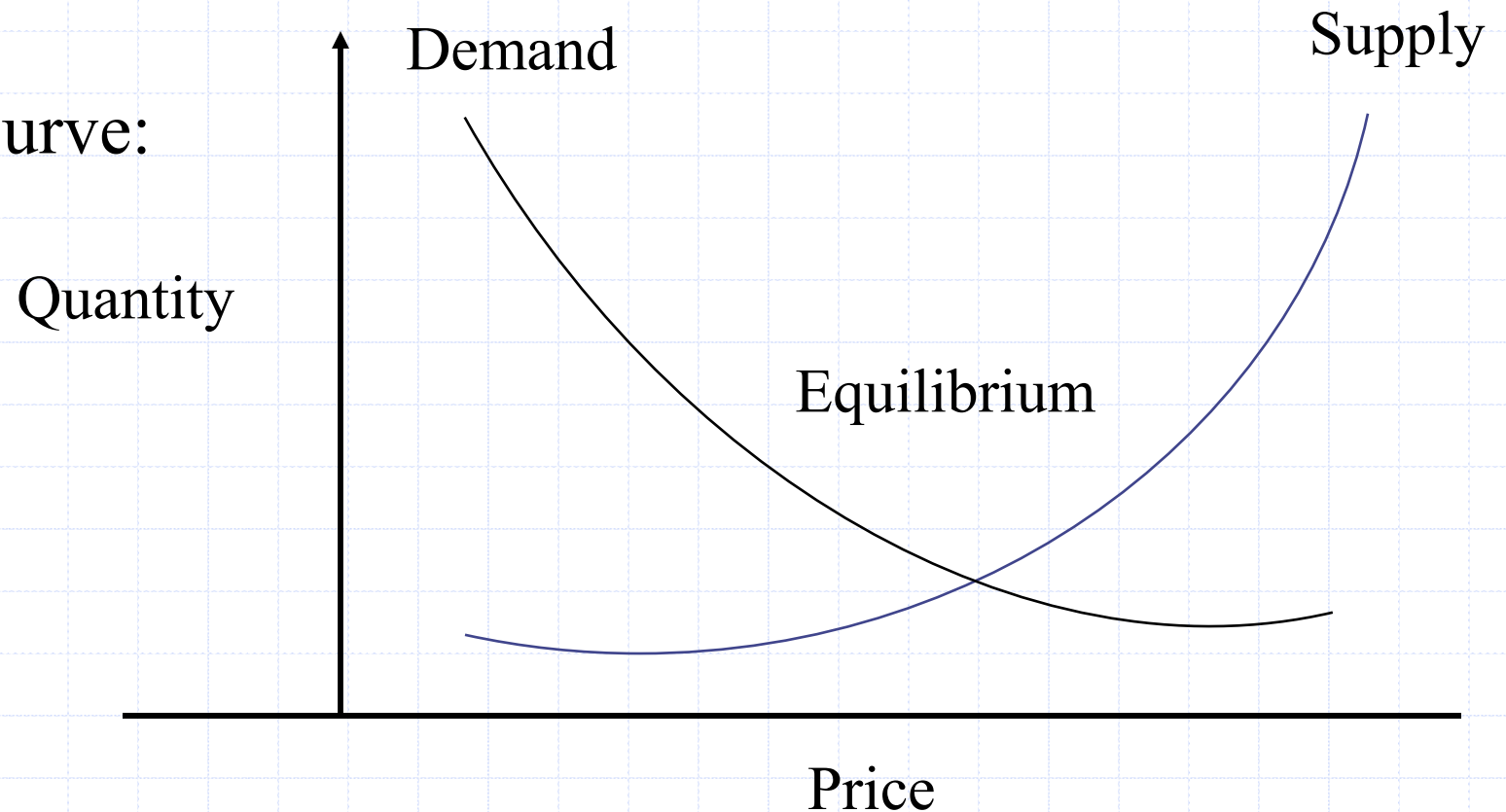
**“The right context  
is worth 50 IQ points.”**

**- Alan Kay**

**Inventor of Object Oriented Programming  
Visionary: Laptop Computer**

# Basic Ideas from Economics

Supply &  
Demand Curve:



**But note: Mullins CD. Rising Copayments and the Kinked Demand Curve.**  
*Clinical Therapeutics* 2003;25(12):3144-3146.

# Pharmacoeconomics<sup>1</sup>

**“ ... identifies, measures, and compares the costs and consequences of pharmaceutical products and **services.**”**

<sup>1</sup>Bootman JL, Townsend RJ, McGhan WF, eds. Introduction to Pharmacoeconomics. In: *Principles of Pharmacoeconomics*. 3<sup>rd</sup> ed. Cincinnati, Ohio. Harvey Whitney Books. 2004. ISBN 0929375270

# Pharmacoeconomic Analysis

“Pharmacoeconomics is a discipline that researches the **costs** of pharmaceutical products and drug therapy to society, health care systems and individuals, and **compares** these costs to the **benefits** of drug therapy.”

Faculty of Social Pharmacy,  
University of Helsinki

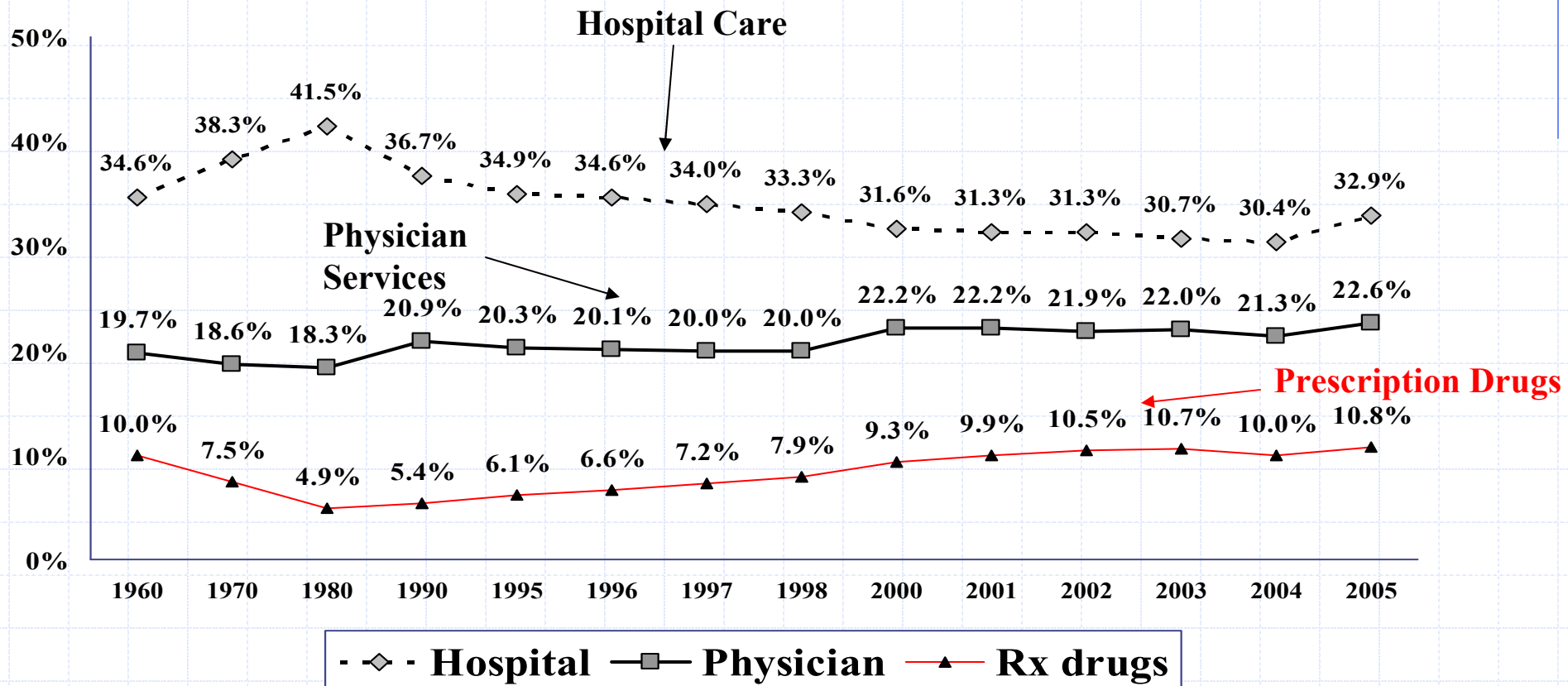
# Pharmacoeconomic Considerations

- What are the relevant costs?
- What are the relevant benefits?
- Compared to what?
- From whose perspective?
- Under what arrangements?
- What makes the results credible?

# Relevant Trends, Developments and Unmet Needs

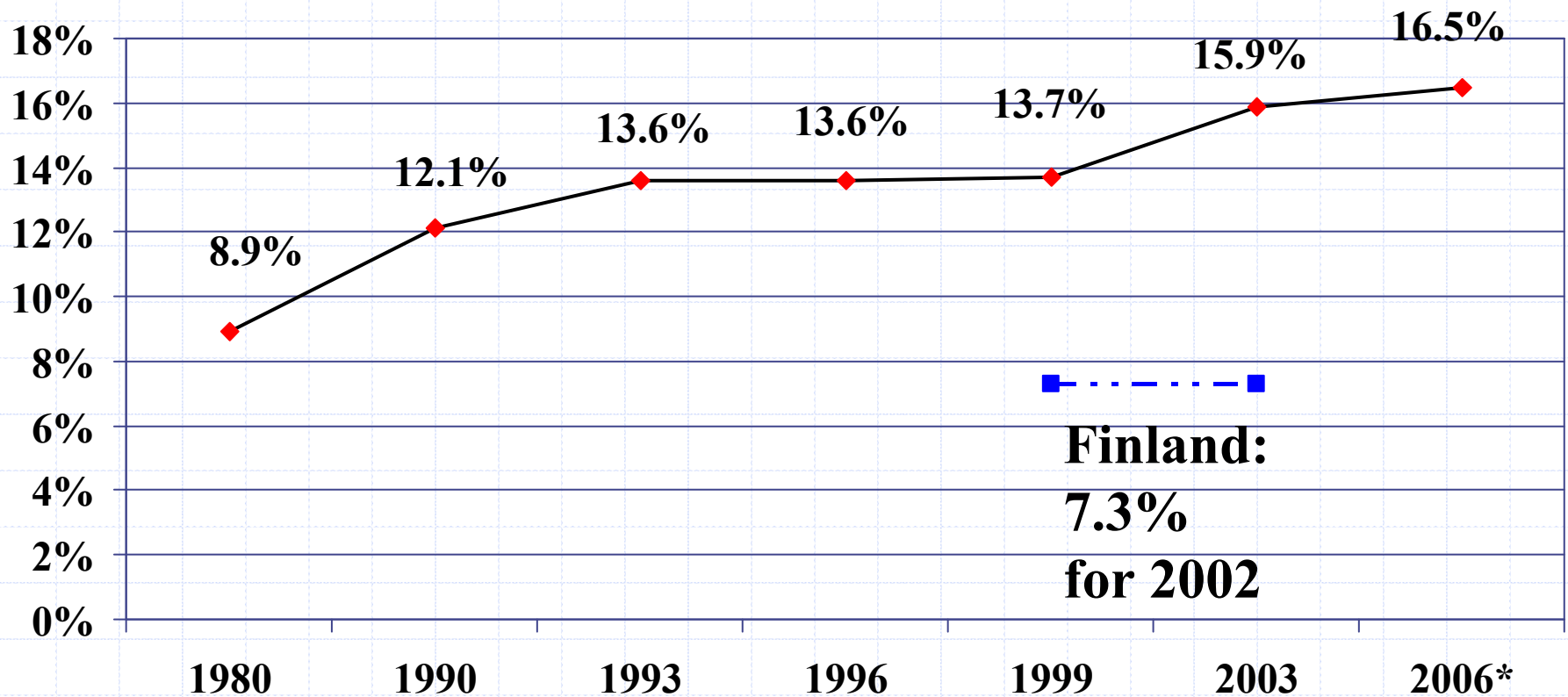
1. ↑ Demand
2. ↑ Methodological & Statistical Advances
3. ↑ Data, but need for more integrated clinical and economic data
4. Patient Reported Outcomes (PROs)
5. Services Evaluation
6. Competencies
  - Training and Diffusion
  - Embedded within the Formulary process
7. Application to Scientific Advances
  - Pharmacogenomics
  - Biologicals and Biosimilars
  - Pharmaceuticals
  - Diagnosics
  - Bundled products
8. Dissemination of Results
  - Peer reviewed
  - Managed COI
  - Transparency
9. National and International Organizations

# National Health Care Expenditure Cost Components, United States, 1960-2005



Sources: K. Levit et al., Health Spending Rebound Continues in 2002 *Health Affairs* 2004;23(1):147-159.; Smith C, et al. Health Spending Growth Slows in 2003. *Health Affairs* 2005;24(1):185-194; Smith C, et al. National Health Spending in 2003: Recent Slowdown Led By Prescription Drug Spending. *Health Affairs* 2006;25(1):186-196; Catlin A, et al. National Health Spending in 2005: The Slowdown Continues. *Health Affairs* 2007;26(1):142-153.

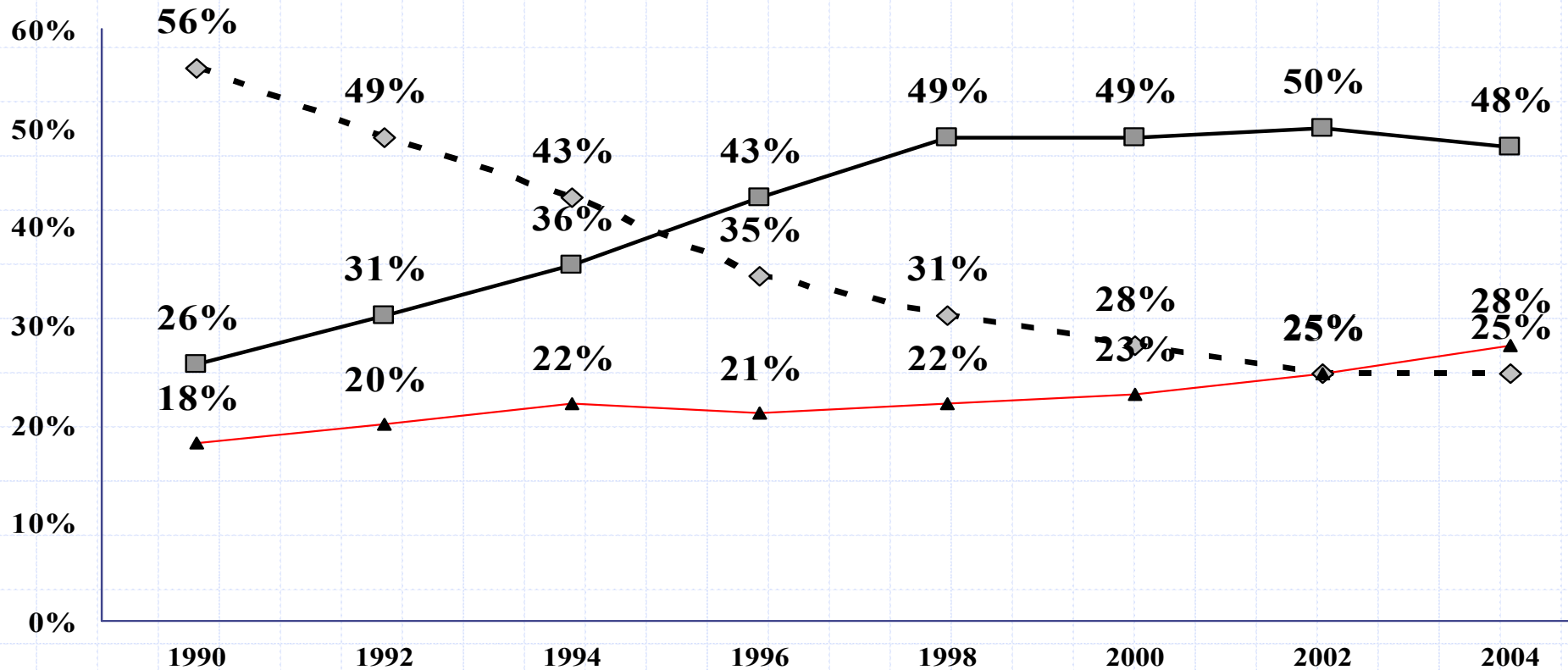
# National Health Expenditures as % Gross Domestic Product (GDP)



Source: 1965 – 1993 = <http://www.cbo.gov/showdoc.cfm?index=2&sequence=13>

1996 – 2006 = <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2005.pdf>

# Percent of Total National Prescription Drug Expenditures by Type of Payer, 1990-2004



- ◇ - Out-of-Pocket —■— Pvt Health Insurance —▲— Government

**Source:** Kaiser Family Foundation calculations using National Health Expenditures data from Centers for Medicare & Medicaid Services, at <http://www.cms.hhs.gov/NationalHealthExpendData/>. <http://www.kff.org/rxdrugs/upload/3057-05.pdf> 10

# National Health Accounts (2004)\*

<b>%</b>	<b>USA</b>	<b>France</b>	<b>Finland</b>	<b>Germany</b>	<b>Canada</b>	<b>UK</b>	<b>Spain</b>
Health expenditures as % GDP	15.4	10.5	7.4	10.6	9.8	8.1	8.1
Government expenditures as % Health expenditures	44.7	78.4	77.2	76.9	69.8	86.3	70.9
Private expenditures as % Health expenditures	55.3	21.6	22.8	23.1	30.2	13.7	29.1
Government health exp as % All Government expenditures	18.9	15.4	11.3	17.3	17.1	15.9	14.7

\* Source: World Health Organization, <http://www.who.int/nha/country/en/index.html>

# Pricing

- **“Price is what you pay, value is what you get.”**  
– **Warren Buffett**
- **Patient price sensitivity:** RAND Health Insurance Experiment with differential insurance benefits, cost-sharing\*
- **Demand influences:**
  - Marginal therapeutic gain
  - Cost & number of rival products
  - Relevant market

**+ Promotion**

Willaims SJ and Torrens PR. Introduction to Health Services (5th edn.)

•Leibowitz a, Manning WG & Newhouse JP.. The Demand for Prescription Drugs as a Function of Cost-Sharing. *Soc Sci Med* 1985;21(10):1063-1069.; Hillman AL, Pauly MV, Escarce JJ, et al. Financial Incentives & Drug Spending in Managed Care. *Health Affairs* 1999;18(2):189-200.

IMMIGRATION (P. 35) | MILLER TIME (P. 64) | P&G's BUZZ MOMS (P. 32)

The McGraw-Hill Companies

# BusinessWeek

MAY 23, 2004

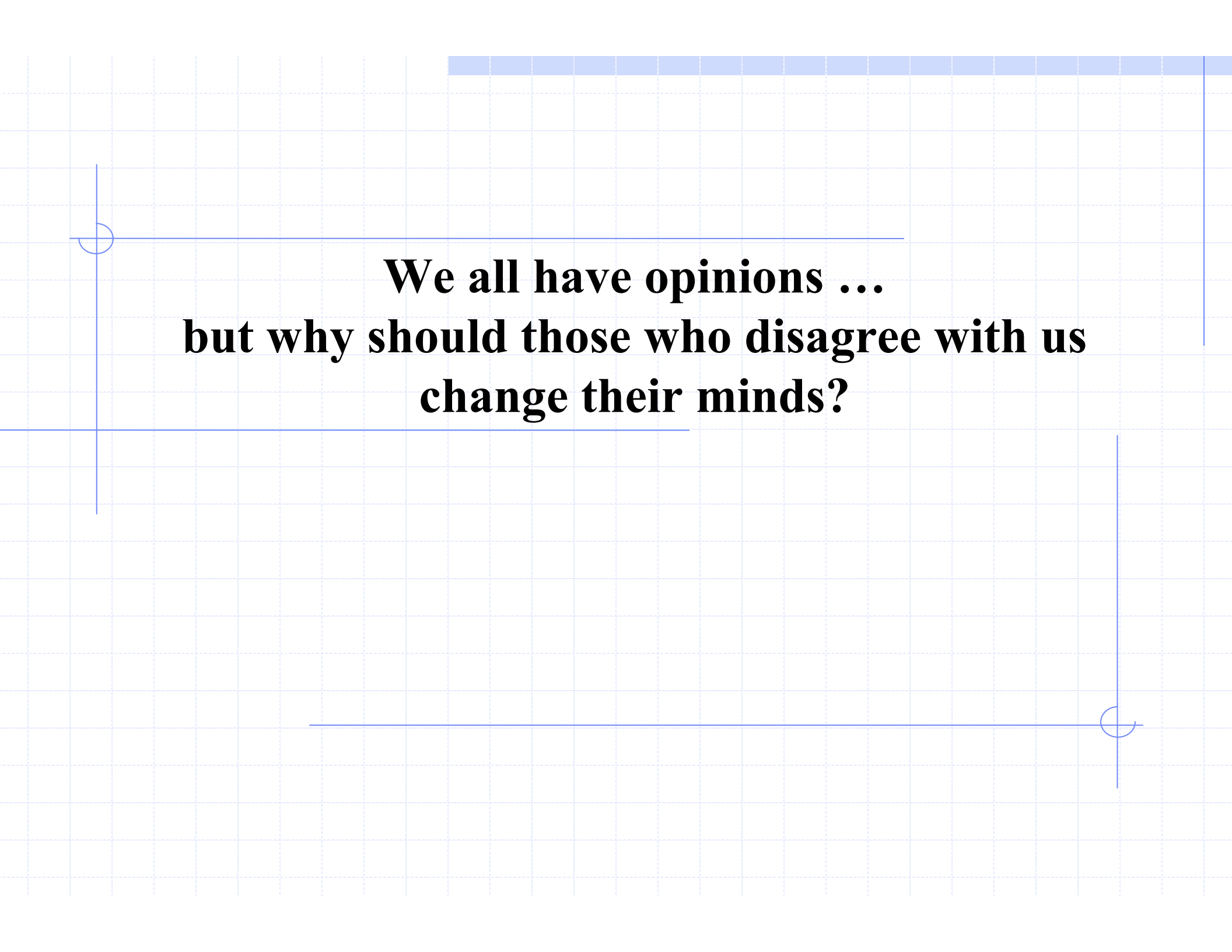

www.businessweek.com

## Medical Guesswork



From heart surgery to prostate care, the medical industry knows little about which treatments really work

BY JOHN CAREY (P. 72)





**We all have opinions ...  
but why should those who disagree with us  
change their minds?**



# The ECHO Model: Anticipated Impact Directions

- Economic
- Clinical
- Humanistic [Quality of Life]

# Patient Reported Outcomes<sup>2</sup>

Outcomes that the patient must provide, such as:<sup>1</sup>

- \* symptom severity,
- \* perception of daily functioning,
- \* feelings of well being,
- \* global impressions of the impact of treatment on daily life,
- \* satisfaction with treatment, and
- \* health-related quality of life.

<sup>1</sup> <http://www.ispor.org/meetings/va0502/symposium.asp>

Also, <http://www.ispor.org/taskforces/proinstrumentsuse.asp>

And: **PRO Task Force: Changing Mode of Administration of Instruments/ePRO**  
<http://www.ispor.org/TaskForces/ePROTF.asp>

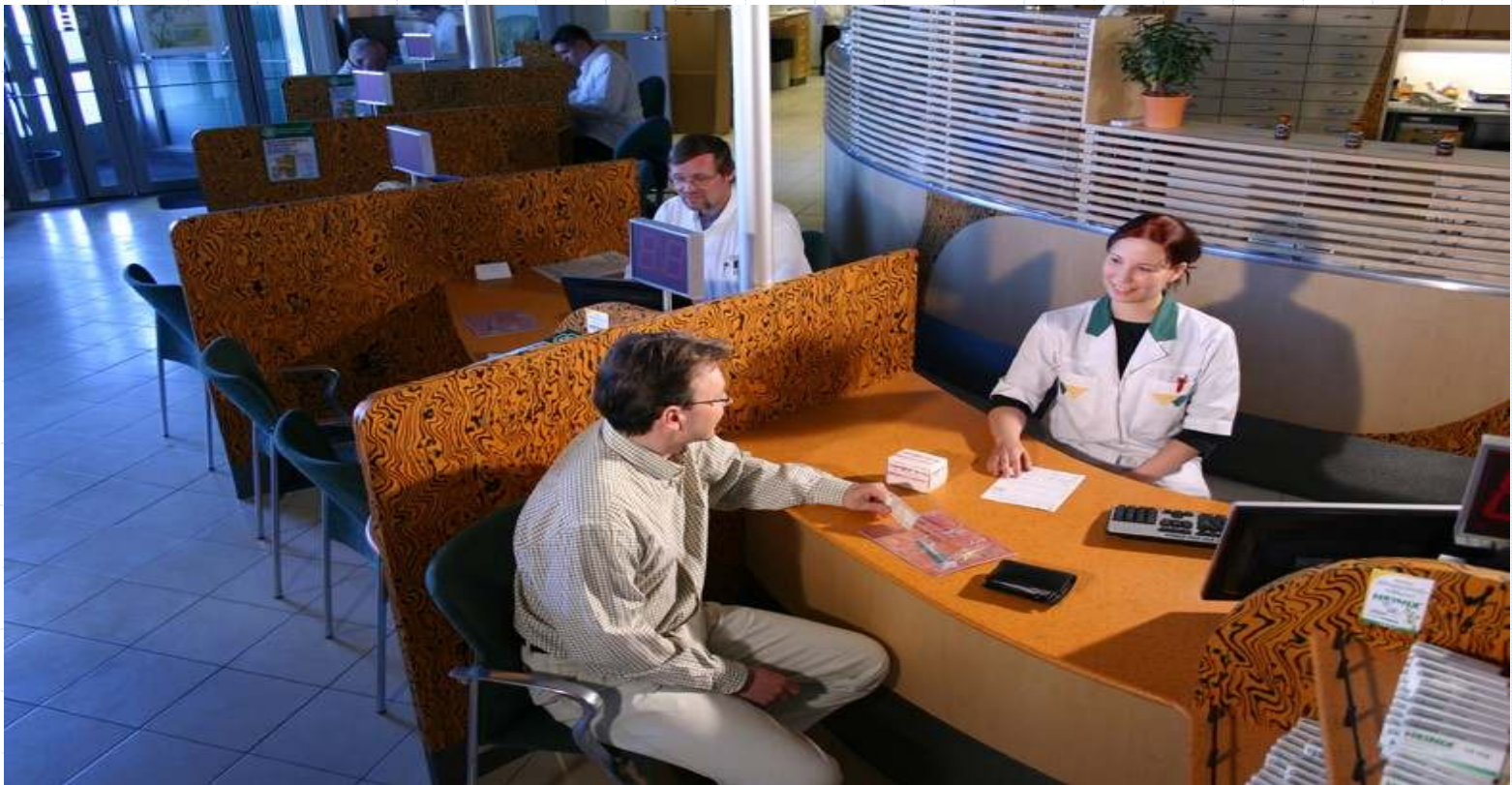
<sup>2</sup> [http://www.ispor.org/research\\_initiatives/qol\\_initiatives.asp](http://www.ispor.org/research_initiatives/qol_initiatives.asp)

# Commercial Features of Placebo and Therapeutic Efficacy<sup>1</sup>

- Price and patient reported analgesia from differently priced tablets: “Regular price of \$2.50” vs “Discounted to \$0.10”
- **Both** placebo tablets
- Significant pain relief
  - Regular price group: 85%
  - Discounted price group: 61%

<sup>1</sup> Rebecca L. Waber; Baba Shiv; Ziv Carmon; Dan Ariely. *JAMA*. 2008;299(9):1016-1017.

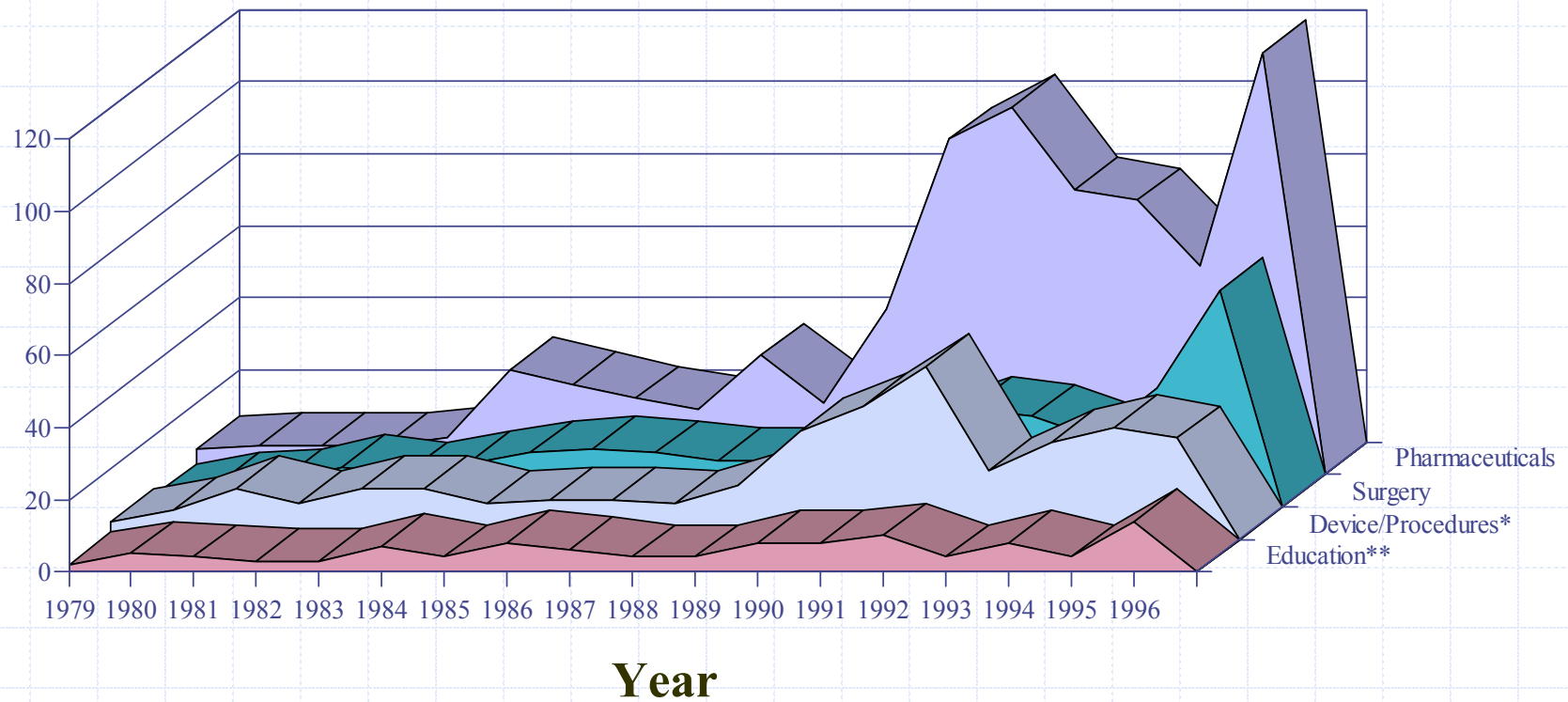
# COMMUNITY PHARMACIES IN FINLAND



**Source:** Professor Marja Airaksinen

# Frequency of Economic Impact Studies

## Number of Studies



\* Devices and procedures

\*\* Education, behavior, other

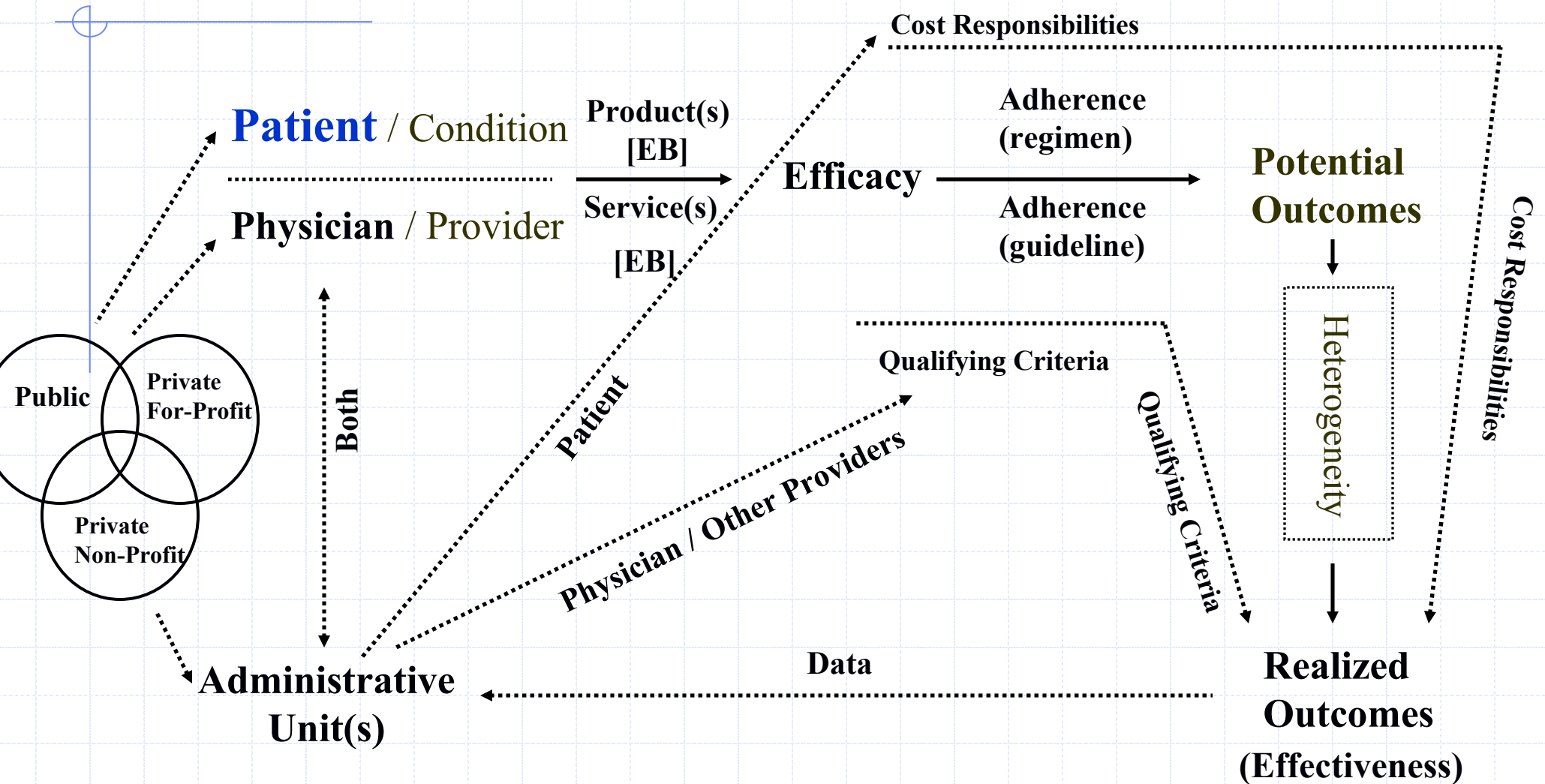
# The Efficacy-Effectiveness Gap

**Efficacy:** How well does a treatment work under optimal conditions?

**Effectiveness:** How well does a treatment work in usual practice?

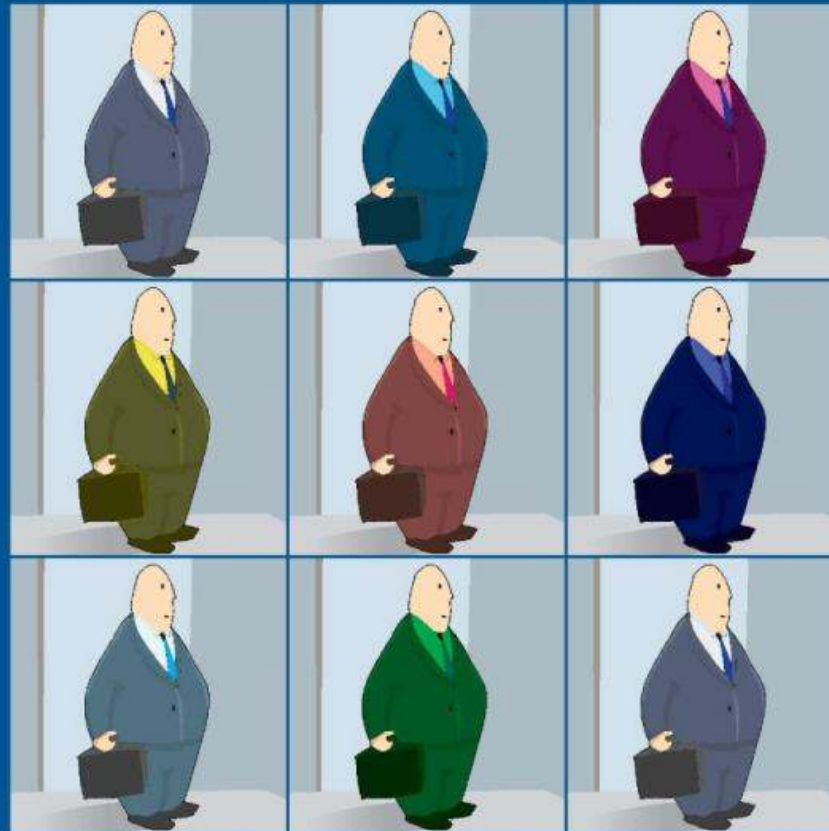
The effects that pharmaceuticals (treatments) have under optimal research conditions (**efficacy**) overestimate the effects that the same medications will have in usual practice (**effectiveness**).

# Outcomes Variation from Efficacy to Effectiveness of Pharmacotherapy (OVERxTx<sup>©</sup>): A Post-Marketing Systems Perspective





# Obesity, Business and Public Policy



Edited by **Zoltan J. Acs and Alan Lyles**

With a Foreword by Michael Huckabee

# Main Pharmacoeconomic Methodologies

- **Cost-of-illness**
- **Cost - minimization analysis**
- **Cost-benefit**
- **Cost-utility**
- **Cost-effectiveness**

Bootman JL, Townsend RJ & McGhan WF [editors]. Principles of Pharmacoeconomics, 2<sup>nd</sup> edn. Harvey Whitney Books, 1996.

# Prescription Drug Use

**Total Drug Cost =**

$$\text{(Ingredient Cost + Dispensing Fee - Co-pay) * Rxs}$$

## a) Ingredient Cost

- max generic substitution
- MAC for generic reimbursement
- formulary

“a dynamic, comprehensive list of drugs designed to direct physicians to prescribe the most C/E medications”

? Decision Processes

- rebates

## c) Co-pay

- Tiers

## b) Dispensing Fee

- generic diff<sup>1</sup>
- Network competition
- incentives

## d) Number of Rxs

- identify & notify outlier Rxers
- prior authorization
- step - therapy
- disease management

# What is a '*Cost*'?

- Charge
- Price
- Accounting Cost =
- Economic Cost =

“**accounting costs** (*explicit costs*) vs. **economic costs**: The real (*economic*) costs of production usually exceed the accounting (*bookkeeping*) costs of production because economic costs include both explicit accounting costs and implicit costs – **the value of the personal resources the owners of a firm make available (e.g., their labor and capital)**. “<sup>1</sup>

## Wal-Mart expanding its low-priced drug program

NEW YORK (Reuters) - [Wal-Mart Stores Inc](#) expanded its low-priced drug program, saying on Monday that it is now offering more than 1,000 over-the-counter items for \$4 or less **and selling some 90-day generic prescriptions for \$10...**

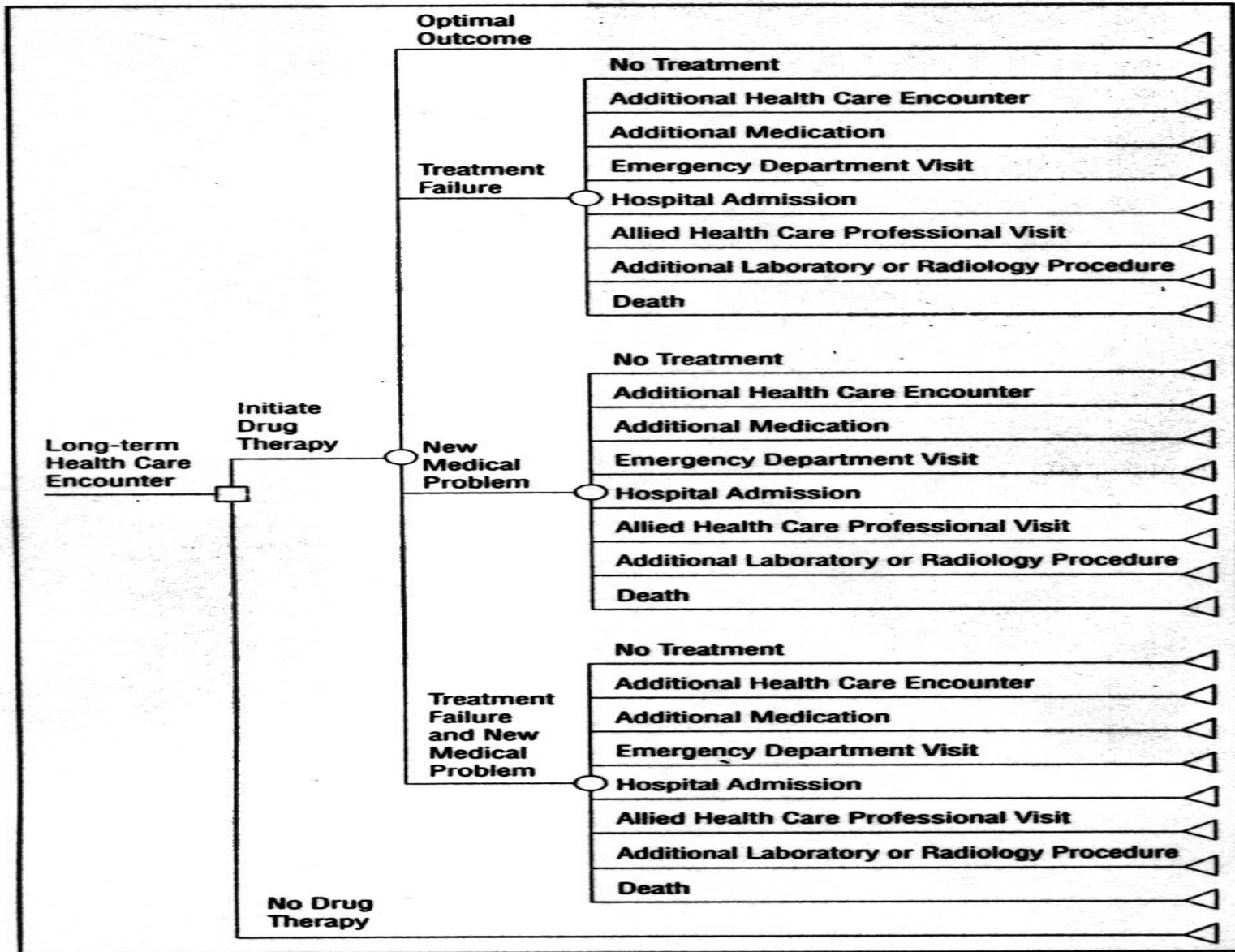
[Reuters, Boston.com, 05MAY2008]

What is the  
“true” cost?

To whom?

What about  
others who pay  
a different price?

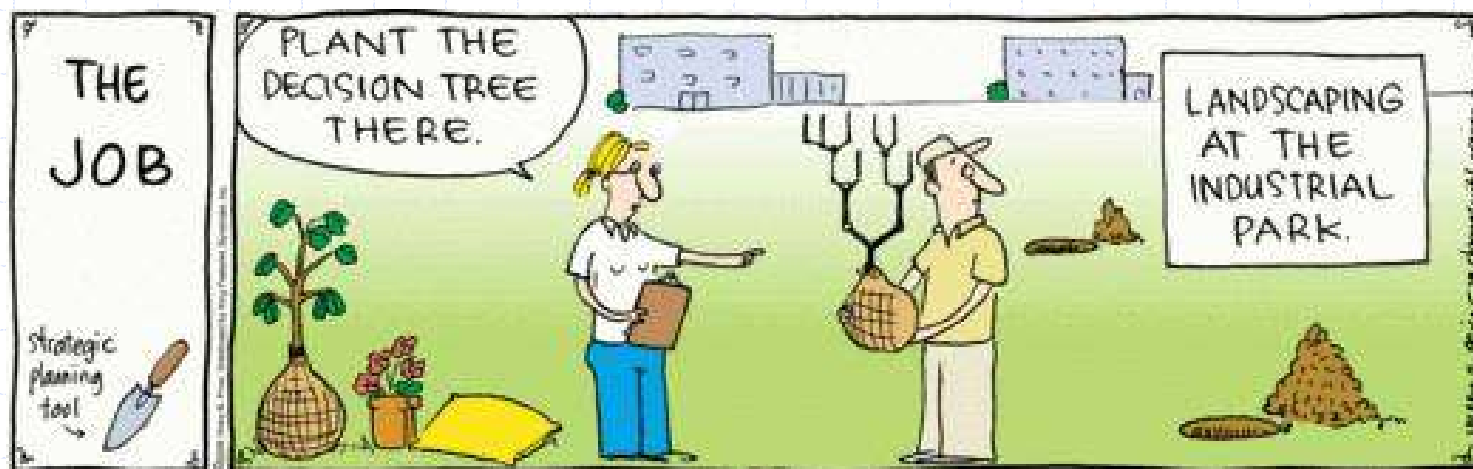




*Probability pathway model for drug-related morbidity and mortality in nursing facilities.*

# Pharmacoeconomic Calculation: Recipient Competence

Decisions based solely on numbers do not solve problems.  
Such decisions have only solved equations.\*



\* Ashley, Garland O. A Declaration of Independence from the Statistical Method. *Air University Review* March/April 1964, pages 83-84. ; Lyles A. Decision-Makers' Use of Pharmacoeconomics: What Does the Research Tell Us? *Expert Review of Pharmacoeconomics & Outcomes Research* 2001;1(2):133-144. ; Lyles CA and Luce BR and Rentz A. Managed Care Pharmacy, Socioeconomic Assessments and Drug Adoption Decisions. *Social Science and Medicine* 45 (4):511-521; 1997.

# Pharmacoeconomics (an Alternate Definition)

**“ ... a pseudodiscipline ... conjured into existence by the magic of money.”**

**- Evans RG.**

**Manufacturing consensus, marketing truth: Guidelines for economic evaluation. Ann Intern Med 1995;123:59-60.**

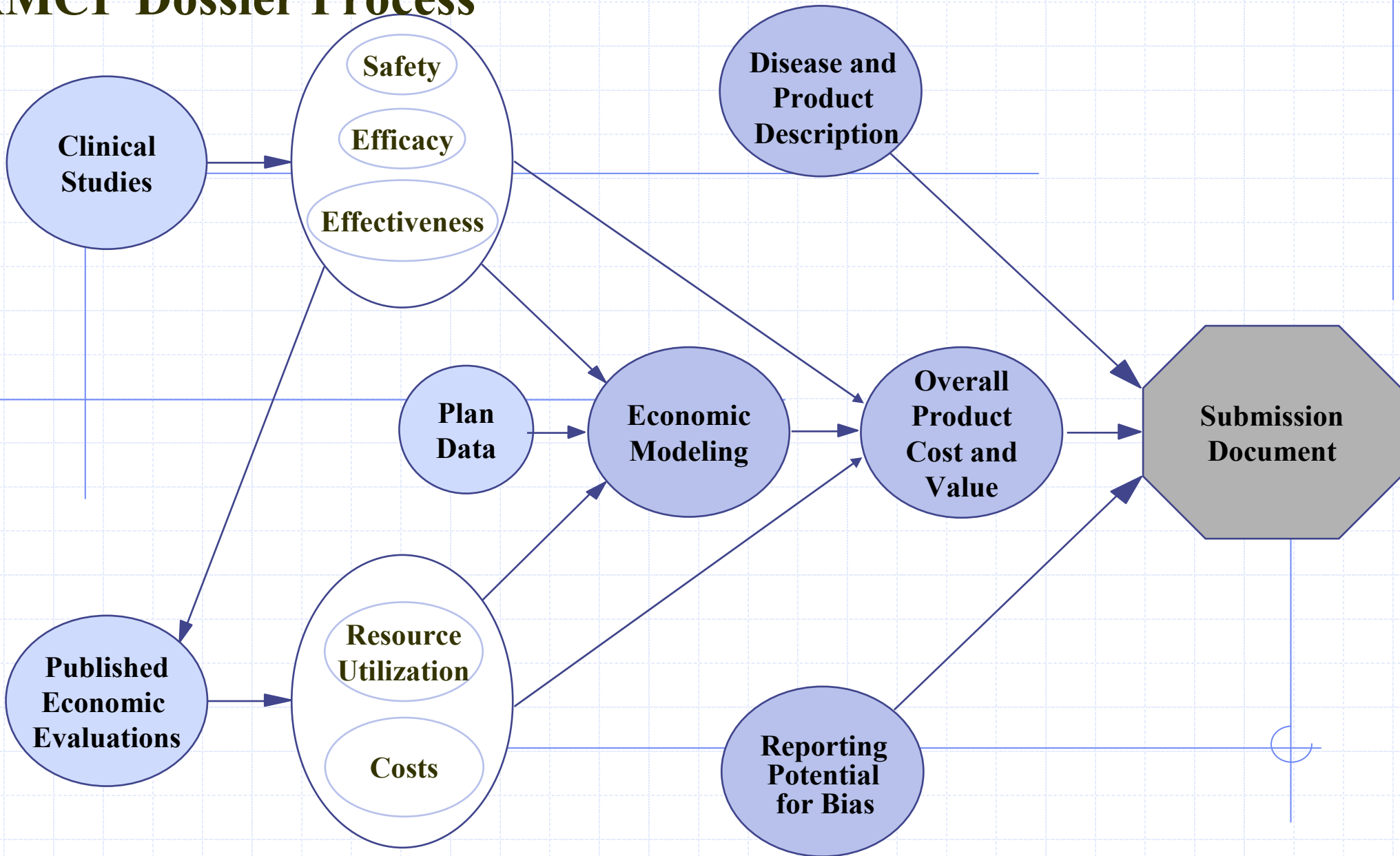
# Number-Needed-to-Treat (NNT) is *not* Cost-Effectiveness<sup>1</sup>

1. **NNT:** i. reciprocal of the absolute risk reduction; ii. The average number of patients who must undergo a therapy over a specified time period to observe one less adverse event at the end of the same or different time period<sup>2</sup>
2. **(NNT \* Mean treatment cost) ≠ est. cost per event avoided**
3. **CE > NNT:** it is comparative, continuous over a given time period, includes both clinical and economic aspects, estimates value by ICER.
4. **NNT alone** does not consider: outcome severity, changes over time, cost trade-offs.
5. **Comparing NNTs:** validity threats if differing baseline rate of event of interest, population or sub-populations of interest, specific time periods on which each is based.
6. **Evidence-Based Medicine:** the systematic identification, appraisal and synthesis of clinical studies, particularly RCTs<sup>2</sup>
  - > Strength of effectiveness evidence, **does \*not\* assess cost(s)**
  - > David Eddy: 2-stage model ⇒ 1 = scientific judgments about outcomes [EBM] ; 2 = identify preferences based on value judgments about acceptable amounts for treating specific conditions or populations.<sup>3</sup>

<sup>1</sup>Lyles A. Influenza Chemoprophylaxis: The Relative Utility of Number Needed to Treat and Cost-Effectiveness Analysis. *Clinical Therapeutics* 2007;29(8):1577-1578; <sup>2</sup>Chong CA, et al. An unadjusted NNT as a Moderately Good Predictor of Health Benefit. *J Clin*

*Epidemiol* 2006;59:224-233 ; <sup>2</sup>Ellrodt G, Cook DJ, Lee J, et al. Evidence-based disease management. *JAMA* 1997;278:1687-1692. ; <sup>3</sup>Tunis S. Reflections on Science, Judgment and Value in Evidence-Based Decision Making: A Conversation with David Eddy. *Health Affairs*

# AMCP Dossier Process



Graphic Courtesy of Sean Sullivan, PhD

**“...Remicade represents a pipeline in a product”\***

- Thomas F. Schaible, Centocor's Vice President of Medical Affairs

### **Compliance / Adherence:**

- **By Indication.**

**“When a product is to be used in the treatment of more than one disease, its impact should be modeled for each approved indication, unless a reasonable case can be made for a single model. Because of the complexity involved in constructing a model that simultaneously addresses several indications, we recommend using a separate model for each condition.”**

[AMCP Format v 1.2, page 12]

\*George J. Centocor seeks to extend profits with new Products. *Philadelphia Business Journal*. Nov 9, 2007.

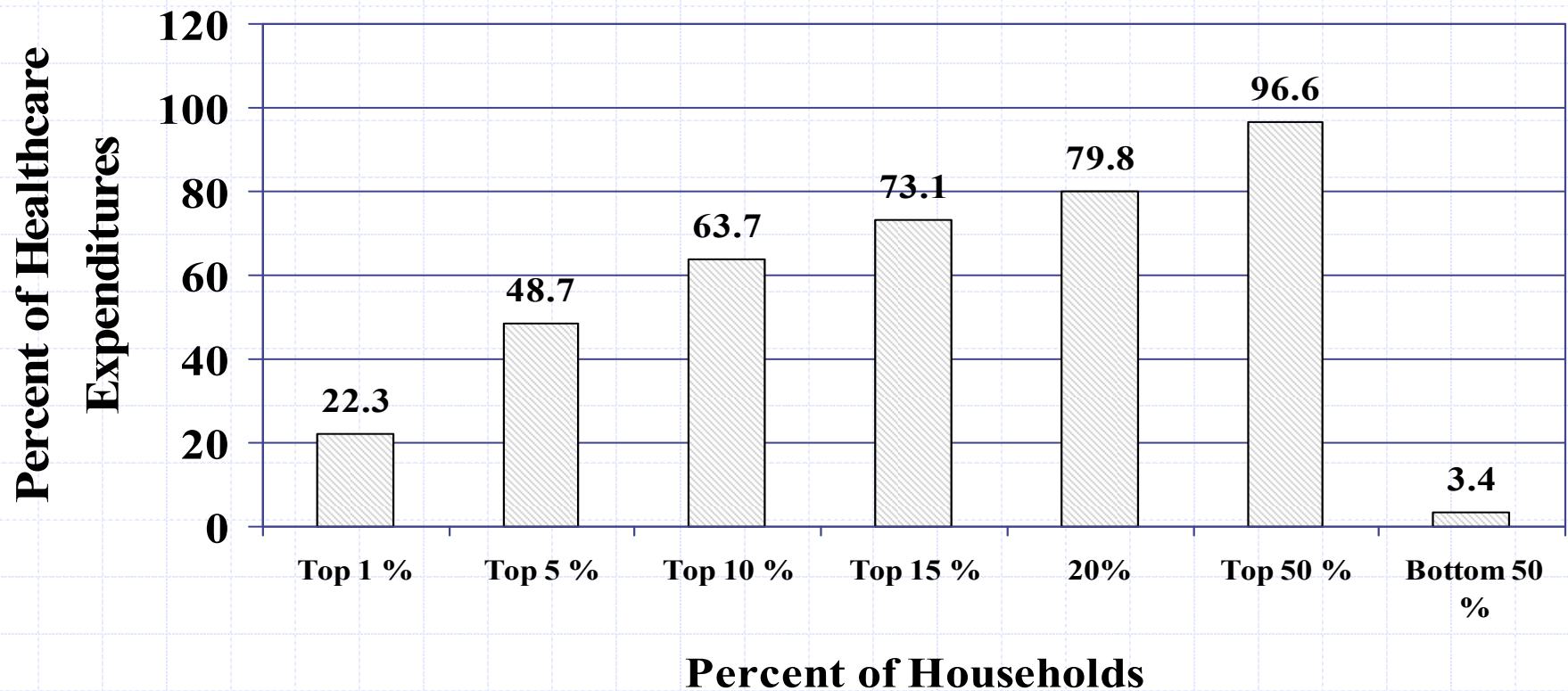
\*\* [http://www.fmcenet.org/data/resource/Format~Version\\_2\\_1~Final\\_Final.pdf](http://www.fmcenet.org/data/resource/Format~Version_2_1~Final_Final.pdf)



# Data Sources:

Availability  
Strengths  
Limitations

# Concentration of Health Spending in the Total U.S. and Family Populations, 2002\*



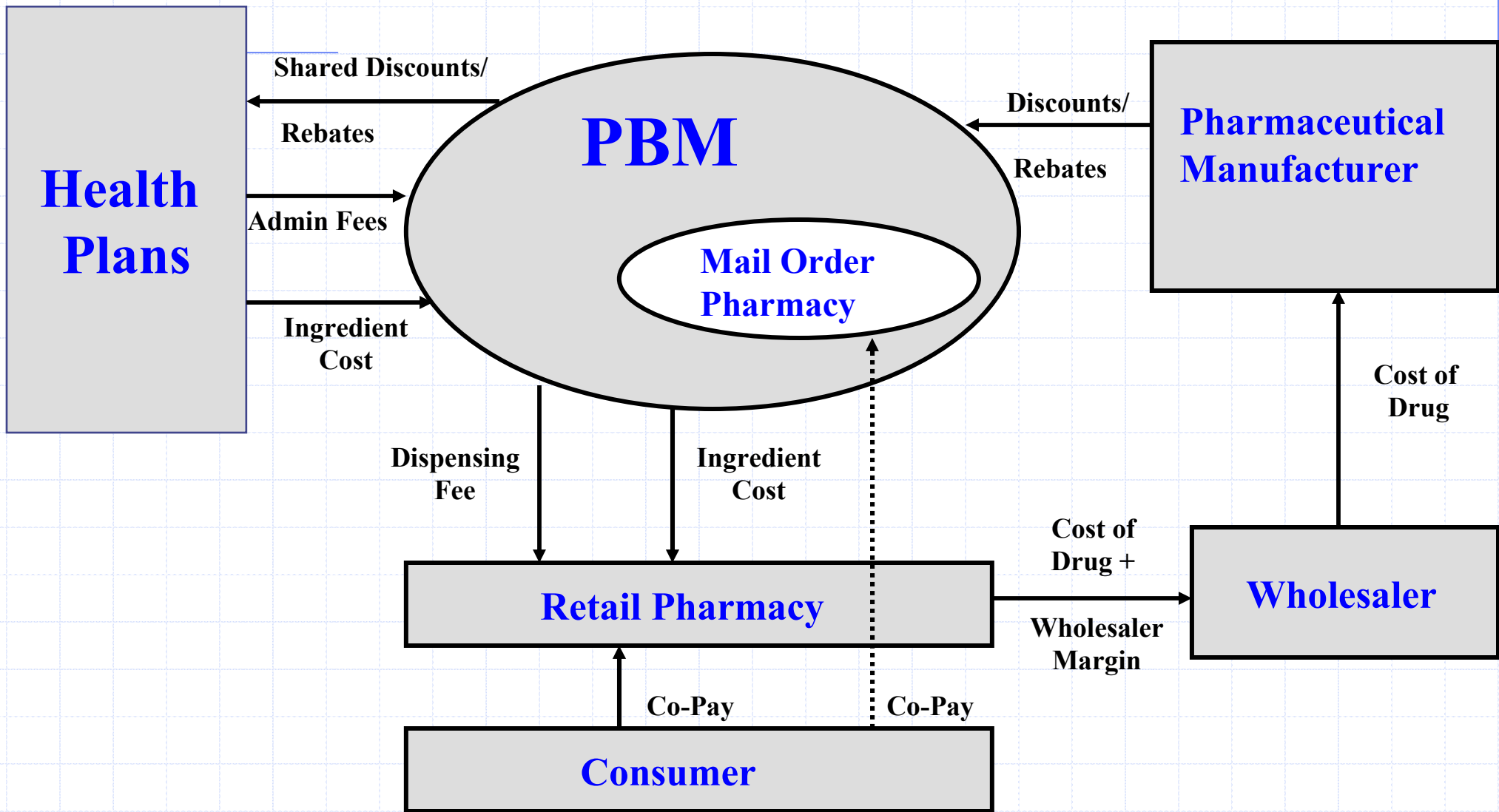
# Administrative Database Studies

## Discussion

(See 'Health Plan Data'

<http://www.hcfo.net/pdf/healthplan.pdf> )

# Money Flow in The Pharmaceutical Distribution Chain\*



\*Source: CMS, Office of Research, Development & Information

# Practice Research Networks

- Grasela Jr TH, et al. A clinical pharmacy-oriented drug surveillance network: II. Results of a pilot project. *Drug Intell Clin Pharm.* 1987 Nov;21(11):909-14.  
111 pharmacists = drug surveillance network, antibiotic use survey
- Psychiatry (Zarin, et al. Practice-based research in psychiatry. *Am J Psychiatry.* 1997 Sep;154(9):1199-208.): APA Practice Research Network
  - National initiative
  - Target 1, 000 practitioners
  - Goal: timely, practice-relevant information to inform policy, financing and service delivery decisions
- Community Pharmacy Safety Network (C-PATH):  
<http://www.c-path.org/>

# Guidelines Regarding Potential or Perception of Conflict of Interest

## Meta-analyses<sup>1</sup>:

?Funding sources linked to favorable findings

**NEJM<sup>2</sup>:** Due to the ‘discretionary nature of the methods’ used in CEA & its potential importance, additional requirements for submitted manuscripts:

- Industry support must be in the form of a grant to a nonprofit organization, not to an individual or a group,
- Written assurance of the author’s independence in design, interpretation, writing & submission ...
- The manuscript must provide sufficient detail ... to permit assessment & replication.

# Confidentiality & Research

“Accumulating Scientific Knowledge”

- Rely tampon linked to toxic shock, Proctor and Gamble withdrew it from the market Sept 1980.
- Company subpoenaed the list of names of women in the study, claiming it was *crucial to its defense*. The Court denied the motion, explaining that that would violate state privacy laws.

# Confidentiality & Peer Review\*

- Litigation involving a pharmaceutical company. The company's attorneys issued subpoenas that "sought all documents regarding the decision to accept or reject manuscripts, copies of rejected manuscripts, the identities of peer reviewers and the manuscripts they reviewed, and the comments by and among peer reviewers and editors regarding manuscripts, revisions, and publication decisions."
- The court ruled that "Especially given the strong policy behind preserving confidentiality in the peer review process, the Court finds any probative value would be outweighed by the burden imposed on the Journals in invading the sanctity of that process."

\* DeAngelis CD and Thornton JP. Preserving Confidentiality in the Peer Review Process. *Journal of the American Medical Association* 2008;299(16):1956.

# Guest Authorship and Ghostwriting in Publications Related to Rofecoxib

## A Case Study of Industry Documents From Rofecoxib Litigation

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Joseph S. Ross, MD, MHS

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Kevin P. Hill, MD, MHS

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David S. Egilman, MD, MPH

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Harlan M. Krumholz, MD, SM

**Context** Authorship in biomedical publication provides recognition and establishes accountability and responsibility. Recent litigation related to rofecoxib provided a unique opportunity to examine guest authorship and ghostwriting, practices that have been suspected in biomedical publication but for which there is little documentation.

**Objective** To characterize different types and the extent of guest authorship and

\* Ross et al. *JAMA* 2008;299(15):1800-1812.

**Context** Authorship in biomedical publication provides recognition and establishes accountability and responsibility. Recent litigation related to rofecoxib provided a unique opportunity to examine guest authorship and ghostwriting, practices that have been suspected in biomedical publication but for which there is little documentation.

**Objective** To characterize different types and the extent of guest authorship and ghostwriting in 1 case study.

**Data Sources** Court documents originally obtained during litigation related to rofecoxib against Merck & Co Inc. Documents were created predominantly between 1996 and 2004. In addition, publicly available articles related to rofecoxib identified via MEDLINE.

**Data Extraction** All documents were reviewed by one author, with selected review by coauthors, using an iterative process of review, discussion, and rereview of documents to identify information related to guest authorship or ghostwriting.

**Data Synthesis** Approximately 250 documents were relevant to our review. For the publication of clinical trials, documents were found describing Merck employees working either independently or in collaboration with medical publishing companies to prepare manuscripts and subsequently recruiting external, academically affiliated investigators to be authors. Recruited authors were frequently placed in the first and second positions of the authorship list. For the publication of scientific review papers, documents were found describing Merck marketing employees developing plans for manuscripts, contracting with medical publishing companies to ghostwrite manuscripts, and recruiting external, academically affiliated investigators to be authors. Recruited authors were commonly the sole author on the manuscript and offered honoraria for their participation. Among 96 relevant published articles, we found that 92% (22 of 24) of clinical trial articles published a disclosure of Merck's financial support, but only 50% (36 of 72) of review articles published either a disclosure of Merck sponsorship or a disclosure of whether the author had received any financial compensation from the company.

**Conclusions** This case-study review of industry documents demonstrates that clinical trial manuscripts related to rofecoxib were authored by sponsor employees but often attributed first authorship to academically affiliated investigators who did not always disclose industry financial support. Review manuscripts were often prepared by unacknowledged authors and subsequently attributed authorship to academically affiliated investigators who often did not disclose industry financial support.

*JAMA*. 2008;299(15):1800-1812

[www.jama.com](http://www.jama.com)

\* Ross et al. *JAMA* 2008;299(15):1800-1812.

## Unreported Financial Disclosures

To the Editor: We wish to notify you and the *JAMA* readers of undisclosed potential conflicts of interest with respect to an article that we published in *JAMA* in 2006<sup>1</sup> and a letter to the editor we published in *JAMA* in 2007.<sup>2</sup>

From 2000 to 2007, the Cornell Research Foundation Inc (CRF), a subsidiary of Cornell University, filed patent applications that cover a variety of computer-aided diagnostic methods, including measurement of nodules. These applications are for general diagnostic use. We are listed as co-inventors, among others. Starting in 2001, the CRF licensed certain of these technologies to General Electric and has received royalties. The license agreement was between General Electric and Cornell, the institution listed on the title page. A portion of the royalties are distributed to both of us and to the other co-inventors pursuant to Cornell policy, which in turn is consistent with the Bayh-Dole Act. One patent was issued on September 25, 2007, relating to measuring change in an object in any organ of a mammal using any type of imaging technique.

The *JAMA* article<sup>1</sup> examined lung-cancer susceptibility and lung cancer survival in women as compared with men. This

not disclose these financial relationships (published below). We apologize for any misperceptions that may have resulted.

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Department of Radiology  
Weill Medical College of Cornell University  
New York, New York

**Published Online:** March 24, 2008 (doi:10.1001/jama.299.15.jle80054).

**Financial Disclosures:** Drs Henschke and Yankelevitz reported being listed as co-inventors for the following patent and patent applications: US Patent No. 7,274,810, "System and Method for Three-Dimensional Image Rendering and Analysis" (patent issued to CRF September 25, 2007); US Patent Application No. 10/245,782, "System, Method and Apparatus for Small Pulmonary Nodule Computer Aided Diagnosis from Computed Tomography Scans" (CRF pending patent application); US Patent Application No. 11/827,985, "System and Method for Three-Dimensional Image Rendering and Analysis" (CRF pending divisional application); US Patent Application No. 11/827,994, "System and Method for Three-Dimensional Image Rendering and Analysis" (CRF pending divisional application); US Patent Application No. 10/688,267, "System, Method and Apparatus for Small Pulmonary Nodule Computer Aided Diagnosis from Computed Tomography Scans" (CRF pending patent application); US Patent Application No. 10/901,316, "System and Method for Providing Remote Analysis of Medical Data" (CRF pending patent application); US Patent Application No. 10/932,443, "System and Method for Analyzing Medical Data to Determine Diagnosis and Treatment" (CRF pending patent application); US Patent Application No. 10/901,362, "System and Method for Conducting a Clinical Trial Study" (CRF pending patent application); US Patent Application No. 11/688,980, "Medical Imaging Visibility Index System and Method for Cancer Lesions" (CRF patent cooperation treaty application also pending); US Patent Application No. 11/377,031, "Method for Expanding the Domain of Imaging Software in a Diagnostic Workup" (CRF pending

# Relevant Trends, Developments and Unmet Needs

1. ↑ Demand
2. ↑ Methodological & Statistical Advances
3. ↑ Data, but need for more integrated clinical and economic data
4. Patient Reported Outcomes (PROs)
5. Services Evaluation
6. Competencies
  - Training and Diffusion
  - Embedded within the Formulary process
7. Application to Scientific Advances
  - Pharmacogenomics
  - Biologicals and Biosimilars
  - Pharmaceuticals
  - Diagnosics
  - Bundled products
8. Dissemination of Results
  - Peer reviewed
  - Managed COI
  - Transparency
9. National and International Organizations

# ISPOR ([www.ispor.org](http://www.ispor.org))

- Annual International Meeting
- Annual European Congress
- Consortium
- Local Chapters
- Interest Groups
- Task Forces
- Student Chapters

# Finland: Finnohta

(<http://groups.stakes.fi/FIO/EN/enFinnohta.htm>)

- **Finnish Office for Health Technology Assessment (Finnohta)**
- Finnohta is the Finnish Office for Health Technology Assessment operating at the National Research and Development Centre for Welfare and Health (STAKES).
- Finnohta promotes the use of proper, evidence-based health technology in order to enhance the effectiveness and impact of health care.

Drive Thru  
Pharmacy

Drive Thru Pharmacy

🔄 Pick Up

Drop Off 🔄

18 15:54



# **Supplementary Material**

# Core Competencies in Pharmacoeconomics

12.00-14.15 Lunch & Posters

Chair: Alan Lyles, ScD, MPH, RPh,  
University of Baltimore

Short views about situation in Finland:

(14.15) **Suvi-Anne Siimes, Executive Director** (Pharma Industry Finland) Sui generis or sustainable solutions – What does a small country and its national policy look like from the industry perspective?

(14.30) **Akseli Kivioja, Chief Pharmaceutical Officer** (Pharmaceuticals Pricing Board, Finland) The role of pharmacoeconomics in Pharmaceuticals Pricing Board decision-making

(14.45) **Teija Kotomäki, Outcomes Research Manager** (Pfizer, Finland) Pharmacoeconomics in a pharmaceutical company in Finland

(15.00) **Heikki Bothas, Executive Director** (Finnish Generic Pharmaceutical Association) Generic pharmaceutical market in Finland

15.15-15.45 Coffee

# Core Competencies in Pharmacoeconomics

- **Suvi-Anne Siimes**  
Executive Director, Pharmacy Industry Finland  
[http://www.laaketietokeskus.fi/page.php?page\\_id=140](http://www.laaketietokeskus.fi/page.php?page_id=140)
- **Akseli Kivioja**  
Chief Pharmaceuticals Officer, Pharmaceuticals Pricing Board, Finland  
<http://www.stm.fi/Resource.phx/eng/orgis/board/pharmaboard/english.htx>
- **Teija Kotomäki**  
Outcomes Research Manager, Pfizer Finland  
<http://www.pfizer.fi/frontpage.html>
- **Heikki Bothas**  
Executive Director, Finnish Generic Pharmaceutical Association  
<http://www.rinnakkaislaaketeollisuus.fi/>

# Resources

- Rascati K. *Essentials of Pharmacoeconomics*. Lippincott Williams & Wilkins. 2008. ISBN 0781765447
- ME Drummond, M Sculpher, B O'Brien, G Stoddart, and GW Torrance, *Methods for the Economic Evaluation of Health Care Programmes*, 3rd ed., Oxford University Press, 2005 (ISBN 13: 978-0198529453).
- Bootman JL, et al. *Principles of Pharmacoeconomics*. Harvey Whitney Books Company ISBN 978-0929375175
- International Society for Pharmacoeconomics and Outcomes Research (ISPOR): [www.ispor.org](http://www.ispor.org)
- National Institute for Clinical Excellence: <http://www.nice.org.uk/>
- Canadian Agency for Drugs and Technology in Health (CCOHTA): <http://www.cadth.ca/index.php/en/home>
- Australian Pharmaceutical Benefits Scheme: <http://www.health.gov.au/pbs>
- European Medicines Agency (EMA): <http://www.emea.europa.eu/>

# Selected Pharmacy Issues

- Data access: Cost versus charge
- Line item versus global impact assessments
- Multidisciplinary teams
- Payment for cognitive services
- Strategies to influence use of medications
- Automatic / mandatory switching

## 5. Cost-effectiveness

An analytic tool in which costs and effects of a program and at least one alternative are calculated and presented in a ratio of *incremental cost* to incremental effect. Effects are health outcomes such as cases of a disease prevented, years of life gained, or QALYs, rather than monetary measures as in CBA

**NOTE: C/E does not mean cheapest!**

# HTAi

(<http://www.htai.org/>)

International Society for the Promotion of Health  
Technology Assessment

# UK: NIHCE

(<http://www.nice.org.uk/guidance/order/publicationslist/heatechassrep.jsp>)

National Institute for Health and Clinical Excellence  
Health Technology Assessment Reports

# Canada: CADTH

(<http://www.cadth.ca/index.php/en/home>)

Canadian Agency for Drugs and Technologies in Health

# Australia: PBS

([http://www.medicareaustralia.gov.au/providers/programs\\_services/about\\_pbs.shtml](http://www.medicareaustralia.gov.au/providers/programs_services/about_pbs.shtml))

Australian Pharmaceutical Benefits Scheme

Therapeutic Goods Administration:  
comparisons with EU guidelines:

<http://www.tga.gov.au/docs/html/euguideh.htm>

# The Fleetwood Model: An Enhanced Method of Pharmacist Consultation

- **Model:**
  - Prospective review
  - High risk assessment
  - **Direct Physician contact**
  - **Patient assessment**
- **Past Practice:** DRR judged by reduced prescription drug costs
- **Phase I:** Bootman = model of total costs avoided
- **Phase II:** Pilot test the implementation feasibility;  
describe global impact
- **Phase III:** Multi-center project

**Source:** Harms SL, Garrard J. The Fleetwood Model: an enhanced method of pharmacist consultation. *Consultant Pharmacist* 1998;13:1350-5.

# Types of Costs:

## Identify Examples – Which are Relevant?

- Direct
- Indirect
- Medical
- Non-medical
- Intangible costs: negative subjective experiences
- Other costs
  - Productivity costs
  - Non-health sector

# Published Article(s): Suggestions

1. Do you know what was measured & how?
2. What was included? Why?
3. What was excluded? Why?
4. What is the perspective of the analysis? Based on this,
  - a. which costs are relevant (direct & indirect)
  - b. which benefits are relevant (direct & indirect)

# Considerations When Reporting Analyses

- (Statistical) Power Calculations
- Point Estimates
- Confidence Intervals
- Sensitivity Analyses
  - Deterministic
  - Stochastic

# AAN Criteria for Rating Evidence Levels

Feature	Class I	Class II	Class III	Class IV
Prospective	√	√		
Independent Outcome Assessment	√	√	√	
Masked assessments	√	√		
Control Group, Representative Population	√	√	√	
Randomized*	√			
Clinical Trial	√			
Cohort Study		√		
Other Controlled Trial			√	
Uncontrolled Studies, Case Series, case reports, expert opinion				√

\*Also defines (1) Primary outcomes, (2) Exclusion/'Inclusion criteria,  
(3) Handling of drop outs, (4) Baseline characteristics of groups.

Goodin, Frohman, et al.  
*Neurology*. 2002;58:169-178.

# AAN Criteria for Rating Recommendations

Level of Evidence	A	B	C
≥ 1 Class I Study	√		
≥ 2 Class II Studies	√		
≥ 1 Class II Study		√	
≥ 3 Class III Studies		√	
≥ 2 Class III Studies			√

In the specified population,

**A** = Established as effective, ineffective or harmful

**B** = Probably effective, ineffective or harmful

**C** = Possibly effective, ineffective or harmful

**U** = Data are inadequate or conflicting. Tx is unproven

# Cost-Effectiveness Grid

