

# **Costs of Colorectal Cancer Treatment: The Big Picture Context**

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# **Health Care Costs: The Big Picture**

- **Health care spending 17% of US GDP in 2006**
- **Premiums rising much faster than inflation and are higher for both workers and employers**
- **48 million Americans are uninsured**
- **50% of personal bankruptcy ~ Medical expenses**
- **Health care costs impact on ability of US firms to compete in the global economy**

# Health Care Costs Threaten US Industry

- Delta Air in bankruptcy: cuts health insurance
- General Motors Corporation: Near bankrupt



**2006 GM's Health Care Costs are \$5.6 billion (1.1m people)**

**American workers health care costs add \$1500/new car**

**Canadian workers health care costs add \$120/new car**

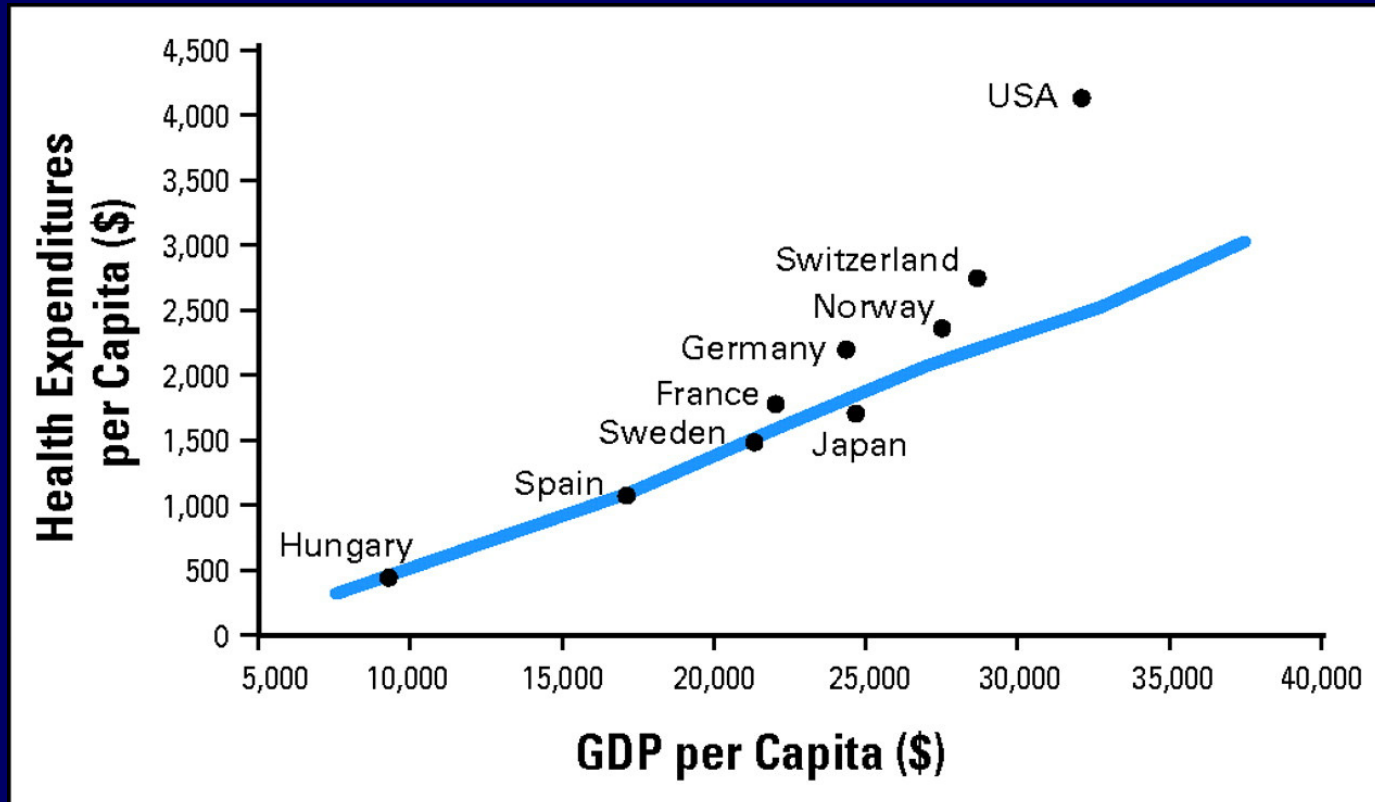
**“The worst part of all this is that these very high costs don't necessarily but the best health” Rick Wagoner Chairman and CEO, General Motors**

# Multiple Perspectives on a Complex Issue

It depends on the stakeholder:

- Patients
- Doctors
- Employers
- Insurers
- Hospitals
- Drug, diagnostic, and device manufacturers
- Societies

# Health Expenditures and GDP Worldwide



Adapted from Bodenheimer, T. *Ann Intern Med* 2005; Reproduced in Meropol and Schulman, *J Clin Oncol*, 2007

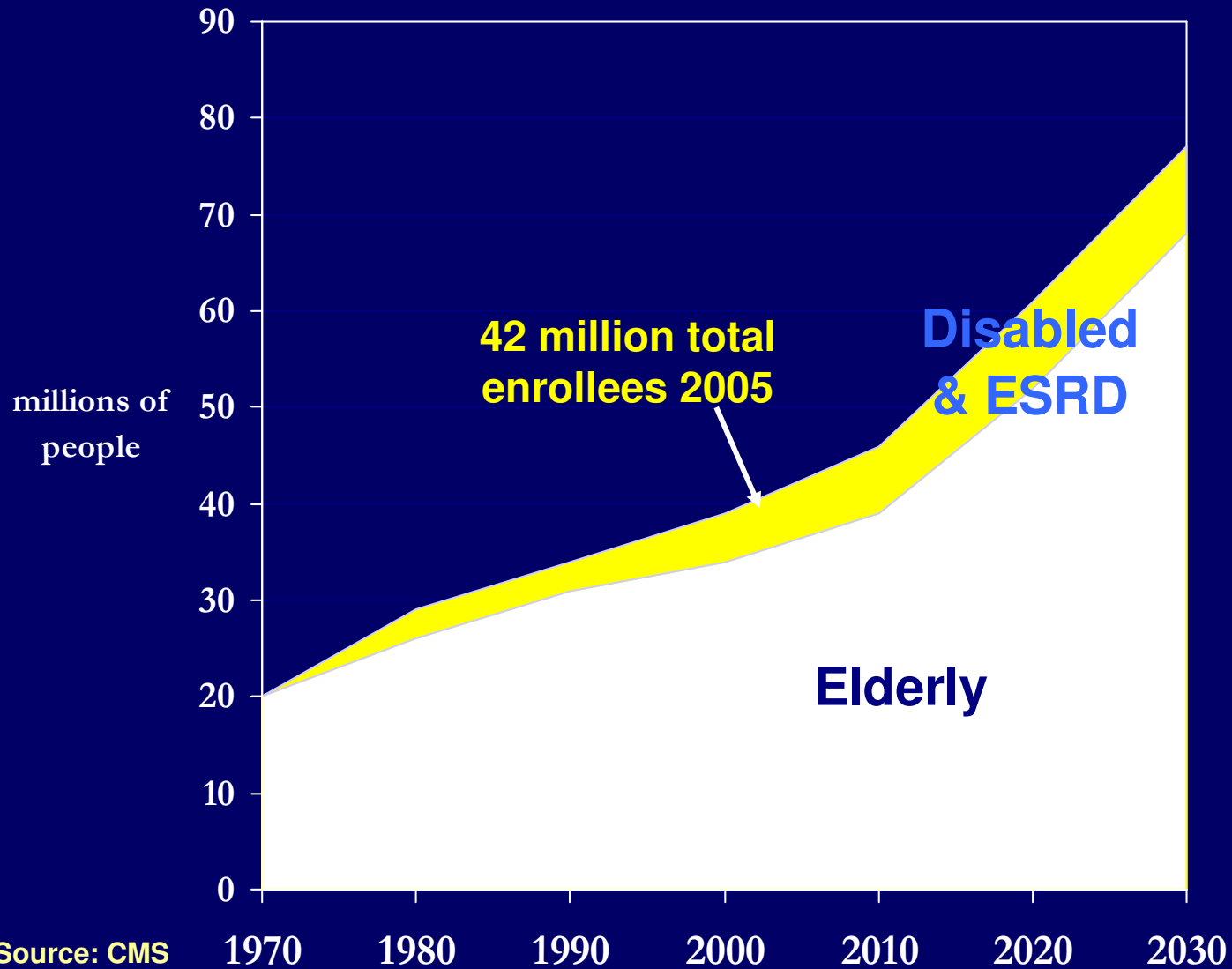
# More spending $\neq$ Better health

**Table 1.** Life Expectancy and Health Expenditures Worldwide<sup>3</sup>

Country	Life Expectancy (female-years)	Total Expense per Person (US \$)	% of GDP
Australia	83	2,519	9.5
Canada	83	2,669	9.9
Ireland	81	2,860	7.3
Japan	86	2,662	7.9
Monaco	85	4,587	9.7
Singapore	82	964	4.5
Spain	83	1,541	7.7
Switzerland	83	5,035	11.5
United Kingdom	81	2,428	8.0
United States	80	5,711	15.2

Abbreviation: GDP, gross domestic product.

# Actual and Projected Growth of the Medicare Population



Source: CMS

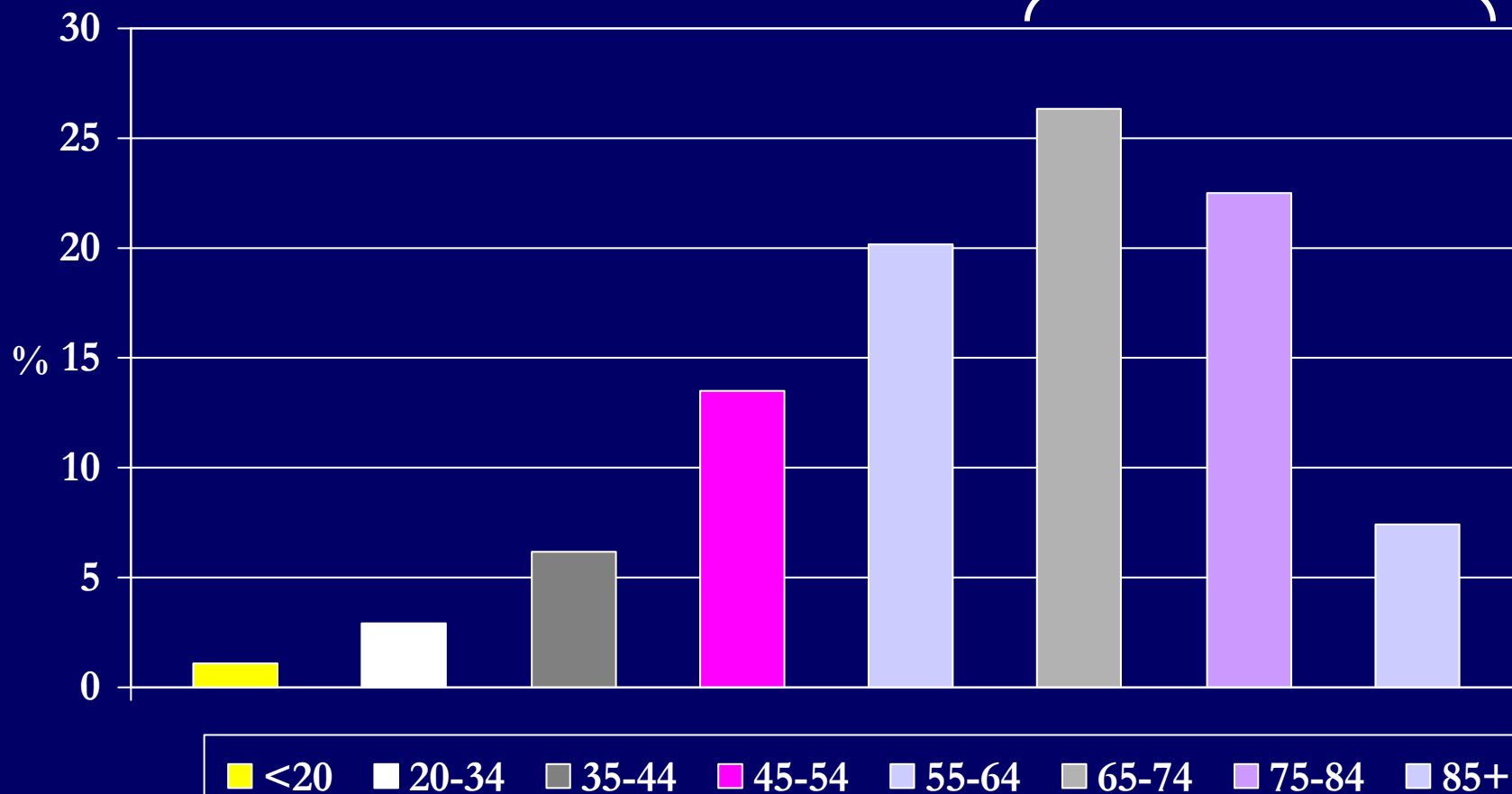
# Income for the US Population >65

- ❖ The 2005 median income for people over 65:
  - ❖ Men: \$21,542
  - ❖ Women: \$12,765
- ❖ For one-third of Americans over 65, Social Security benefits constitute 90% of income
- ❖ Roughly 3.8 million people over 65 (10.6%) were below the poverty level in 2005
- ❖ Another 2.4 million elderly (6.8%) had incomes between 100% and 125% of the poverty level

# Age at Diagnosis for Patients with All Cancers, 1999-2002

Over half of all malignancies occur in patients 65 and older.

56.2%

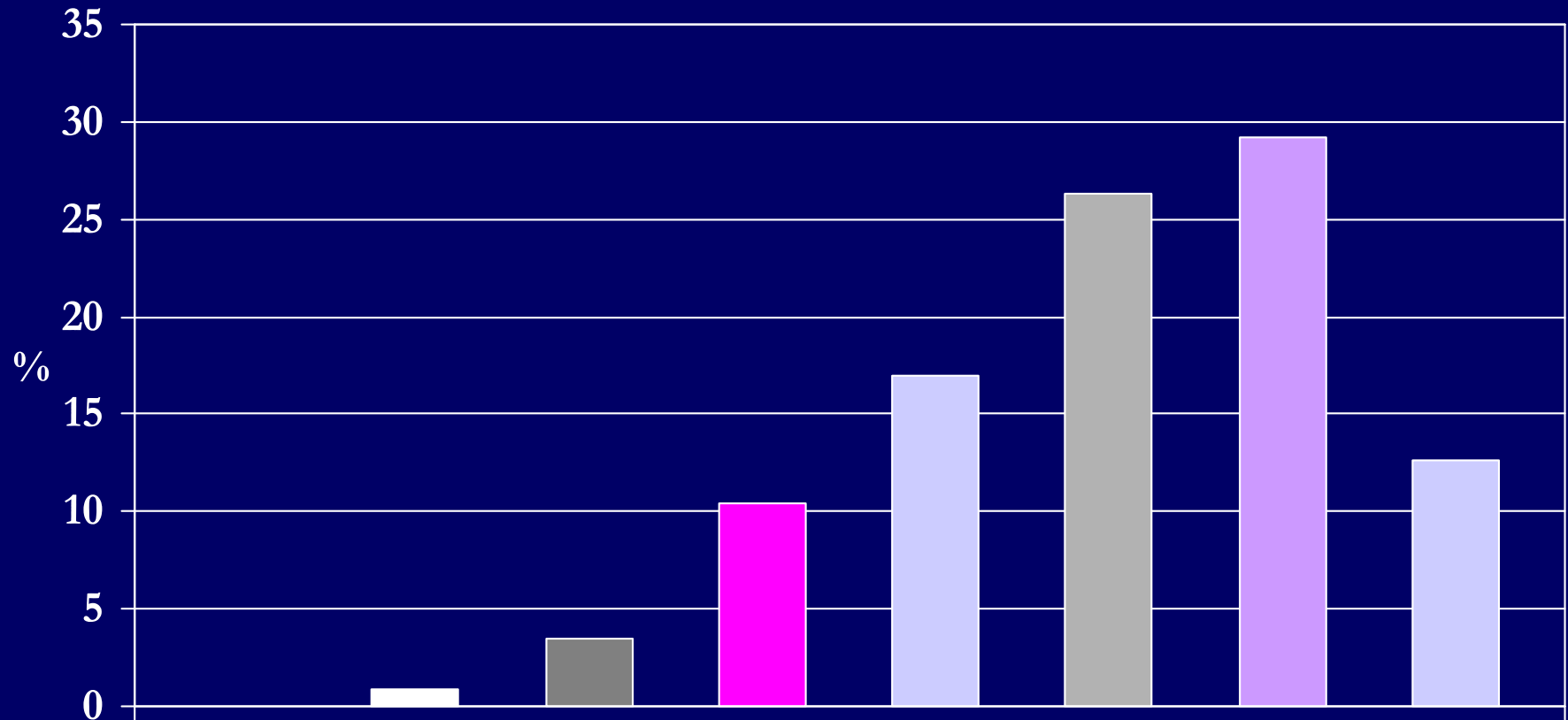


Source: SEER

# Colorectal Cancer

Between 1998 and 2002, the median age for CRC was 72.

68.1%



Source: SEER

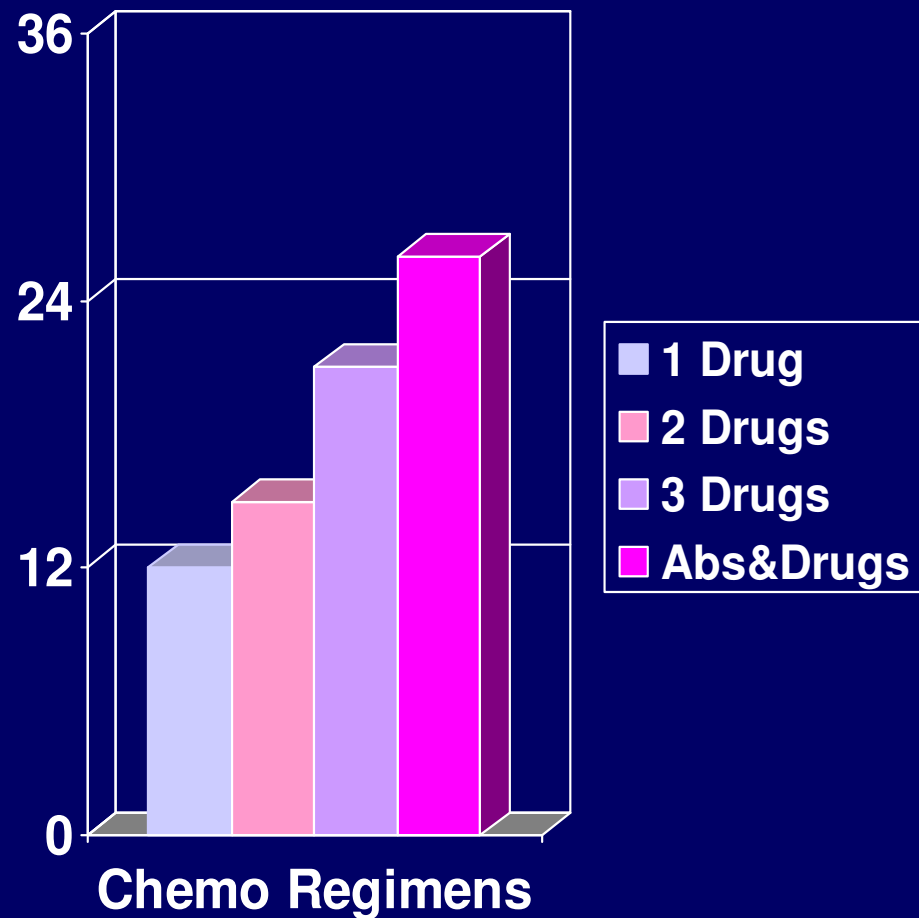
■ <20 ■ 20-34 ■ 35-44 ■ 45-54 ■ 55-64 ■ 65-74 ■ 75-84 ■ 85+

# Costs of Colorectal Cancer

- Second most common cancer in US men and women
- ~150,000 cases per year in the US
- New FDA approved treatment options
  - Irinotecan 1996
  - Oxaliplatin 2002
  - Bevacizumab 2004
  - Cetuximab 2004
- Prevalence of disease among Medicare beneficiaries makes Medicare cost data a good source for obtaining estimates of treatment

# New Drugs Have Improved Colon Cancer Survival!!

- Median Survival has improved and has broken the 2 year barrier
- Tail on survival curve is yet unknown
- Are we delaying or preventing death?



# Costs of Colorectal Cancer Chemotherapy Regimens

**Table 4.** Cost of Colorectal Cancer Treatment

Regimen	Cost per 6 Months (\$)
FU/LV daily for 5 days, monthly	96
Infusional FU/LV every 2 weeks	352
Capecitabine for 14 days, every 3 weeks	11,648
Irinotecan every 3 weeks	30,100
Irinotecan weekly for 4 weeks, every 6 weeks	21,500
FOLFIRI every 2 weeks	23,572
FOLFOX every 2 weeks	29,989
Bevacizumab (alone) every 2 weeks	23,897
Cetuximab monotherapy weekly	52,131
Panitumumab	44,720

Meropol and Schulman, *J Clin Oncol*, 2007

# Estimating the Costs of Colon Cancer Therapy

- No companion cost-effectiveness studies or resource utilization conducted for recent trials
- Crude analysis: assume only change is the cost of the new drugs
  - No added complications
  - No added visits or monitoring
  - No dose reduction or delay
  - Compare 8 weeks of each regimen for average person
  - Analyses assume BSA=1.81, Weight =70kg

# Estimated Lifetime Chemotherapy Drug Costs for Metastatic CRC

Regimen	Typical Duration	ASP+6% For person with BSA=1.8, 70Kg
FOLFOX/Bevacizumab	4 months	\$44,280
Irinotecan Monotherapy	3 months	\$19,992
Irinotecan/Cetuximab	2 months	\$37,307
Total Chemo Costs		<b>\$101,580</b>

~50,000 persons per year in the US have metastatic CRC

# Projected Drug Only Costs: Second line FOLFOX/Bevacizumab:

	FOLFOX	FOLFOX Bevacizumab 10mg/kg
N Per Arm	289	290
Mean # of cycles	7	10
Median Survival	10.7	12.5
Cost per month	\$6,258	\$15,882
Costs/Mean # of Cycles	\$21,901	\$79,412

# Intergroup Study for Metastatic Disease:

## Monthly Drug Costs

R  
A  
N  
D  
O  
M  
I  
Z  
A  
T  
I  
O  
N

FOLFOX with Cetuximab  
\$18,247

FOLFOX with Bevacizumab  
\$11,070

FOLFOX with Bevacizumab & Cetuximab  
\$23,059

# NIH Estimates for Cancer Costs in the United States: 2006

Total costs: \$206.3 billion

- \$78.2 billion for direct medical costs
- \$17.9 billion for indirect morbidity costs (lost productivity)
- \$110.2 billion for indirect mortality (loss of productivity due to premature death)

# Medicare Payments for Part B Oncology Drugs 2004

- \$5.3 billion total
- \$2.3 billion chemotherapy
- \$1.5 billion erythroid growth factors

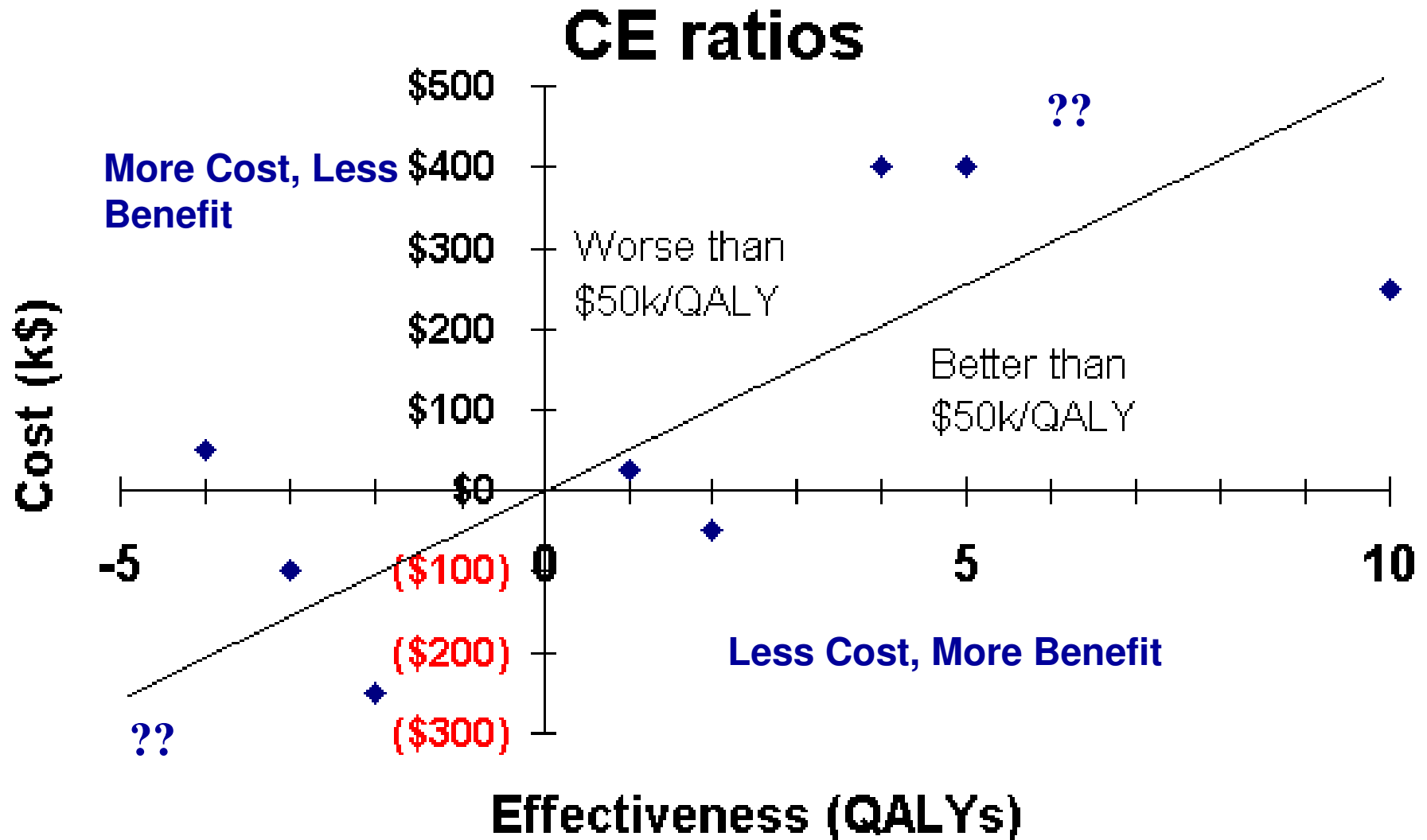
Drugs prescribed by oncologists account for more than 40% of Medicare drug spending

**Are these costs justified?**

# Cost-Effectiveness Ratios

- The recommended measure for cost-effectiveness is the quality-adjusted life year, a common unit for comparison.
- $QALYs = \sum (\text{time in state} * \text{utility of state})$ 
  - 1 year of life in perfect health is as good as 2 years of life in 0.5 utility health.
- $< \$100,000/QALY$  is regarded as “cost-effective” threshold for US health care interventions
- Thresholds are context dependent
- The richer the society, the higher the threshold

# The Cost-Effectiveness Plane



**Table 1. Cost-Effectiveness and Use of Selected Interventions in the Medicare Population.\***

Intervention	Cost-Effectiveness (Cost/QALY)†	Implementation
Influenza vaccine	Cost saving <sup>24,25</sup>	40–70% <sup>26-28</sup>
Pneumococcal vaccine	Cost saving <sup>29</sup>	55–65% <sup>26</sup>
Beta-blockers after myocardial infarction	<\$10,000 <sup>30</sup>	85% <sup>29,30</sup>
Mammographic screening	\$10,000–\$25,000 <sup>31</sup>	50–70% <sup>26,28,32,33</sup>
Colon-cancer screening	\$10,000–\$25,000 <sup>24,31</sup>	20–40% <sup>26,27,32</sup>
Osteoporosis screening	\$10,000–\$25,000 <sup>31</sup>	35% <sup>34,35</sup>
Management of antidepressant medication	Cost saving up to \$30,000 <sup>31</sup>	40–55% <sup>33</sup>
Hypertension medication (DBP >105 mm Hg)	\$10,000–\$60,000 <sup>31</sup>	35% <sup>33</sup>
Cholesterol management, as secondary prevention	\$10,000–\$50,000 <sup>36,37</sup>	30% <sup>38</sup>
Implantable cardioverter–defibrillator	\$30,000–\$85,000 <sup>10,39-41</sup>	100,000 cases per year <sup>10,40</sup>
Dialysis in end-stage renal disease	\$50,000–\$100,000 <sup>10,42</sup>	90% <sup>43</sup>
Lung-volume–reduction surgery	\$100,000–\$300,000 <sup>44</sup>	10,000–20,000 cases per year <sup>10</sup>
Left ventricular assist devices	\$500,000–\$1.4 million <sup>10,45</sup>	5000–100,000 cases per year <sup>10</sup>
Positron-emission tomography in Alzheimer's disease	Dominated <sup>46</sup> ‡	50,000 cases per year <sup>47,48</sup>

\* Ranges are provided, rather than point estimates, because the actual cost-effectiveness will vary according to the target populations and the strategies used. Additional data on the cost-effectiveness ratios associated with public health interventions and medical interventions can also be found at the Harvard Center for Risk Analysis Cost-Effectiveness Registry (at [www.hsph.harvard.edu/cearegistry](http://www.hsph.harvard.edu/cearegistry)). QALY denotes quality-adjusted life-year, and DBP diastolic blood pressure.

† The calculation was based on 2002 dollars.

‡ With the use of this intervention, benefits are lower and costs are higher than with the use of the standard workup.

# Crude Threshold Analyses: Incremental Cost Effectiveness for Metastatic Colon Cancer Regimens

Incremental Cost-Effectiveness	Cost Difference for 4 Months of therapy	Threshold Gain Necessary for CE Ratio <\$100K/Life Year
FOLFO/Bev/ Cetux  versus  FOLFOX	\$67,207	0.67 Life Year = 8 months
FOLFOX/Bev/Cetux  versus  FOLFOX/Bev	\$47,957	0.48 Life Year = 5.8 months

# How is Coverage for Chemotherapy Decided?

- So goes Medicare.....so goes the nation...
- “Reasonable and necessary” clause of the Social Security Act
  - Subject to interpretation
  - Cost is explicitly not a consideration
- Discretion previously left to local carriers
  - Cumbersome administrative process
  - Wiggle room for interpretation of “reasonable and necessary”
  - Meant regional variation
- Efforts to develop national regulations defining reasonableness and necessity abandoned in 2003

# Medicare Determination of Chemotherapy Coverage

- Medicare provides coverage for FDA-approved indications for anticancer chemotherapeutic agents and for other indications that are listed in specific approved compendia
- Uses not approved by the FDA and listed as not indicated in one or more of the cited compendia are generally non-covered
- Medicare contractors, based on guidance provided by CMS, may determine local coverage policy for off-label indications for an FDA-approved anticancer chemotherapeutic agent if they find supporting clinical evidence in peer-reviewed medical literature.

# Medicare is Changing

- Congress mandates increased transparency
- Increasing reliance on National Coverage Decisions  
New CRC drugs are approved on this basis
- Medicare as a vehicle for data collection
  - Coverage “under protocol”
  - Coverage with “evidence development”
  - Coverage with “data collection requirements”

We'll pay, but we are going to scrutinize this closely....

2006 Medicare demonstration project

Claims reveal: drug, cancer, MD, patient

Demo project obtains: disease context, evidence base

# The FDA and Post-Marketing Studies

- The FDA may stipulate post-marketing studies of “fast-tracked” drugs
  - Between 1993-1994-FDA asked for:
    - 91 studies on 42 products.
  - As of 2005:
    - 46 studies were not done
    - 21 not started
- BUT, it has done very little to enforce these requirements
- Increasing scrutiny may result in more post-approval studies

# Coping with High Drug Costs: The Patient Perspective

- Very little is known about how patients prefer that cost issues be discussed
- Very uncomfortable topic
- “Cost shouldn’t be a consideration”
- Anger at “the system”---insurers and industry
- Viewpoints differ based on vantage point
  - Time horizon and curative potential
- Hard to be rational when you are sick—harder still if life threateningly sick

# Moral Hazard

Without  
Insurance

Cost

\$1

Value

\$1 or more

With  
Insurance

Cost

\$1.00

- 0.80

0.20

Value

\$0.20 or more



**We purchase lower value services through insurance**

**Adapted from Schulman, KA. Can Society Afford State-of-the-Art Cancer Treatment? ASCO 2005.**

# RAND Experiment

- 1971-1982
- 2750 families, 7700 individuals, < 65 years old
- Randomized to HMO; or fee for service with 0, 25%, 50%, or 95% coinsurance
- Out-of-pocket capped at \$1000 per year
- Results
  - Coinsurance associated with less resource utilization
  - Reduced use resulted primarily from not initiating care
  - Health outcomes similar between groups, *except* for the poor and sick

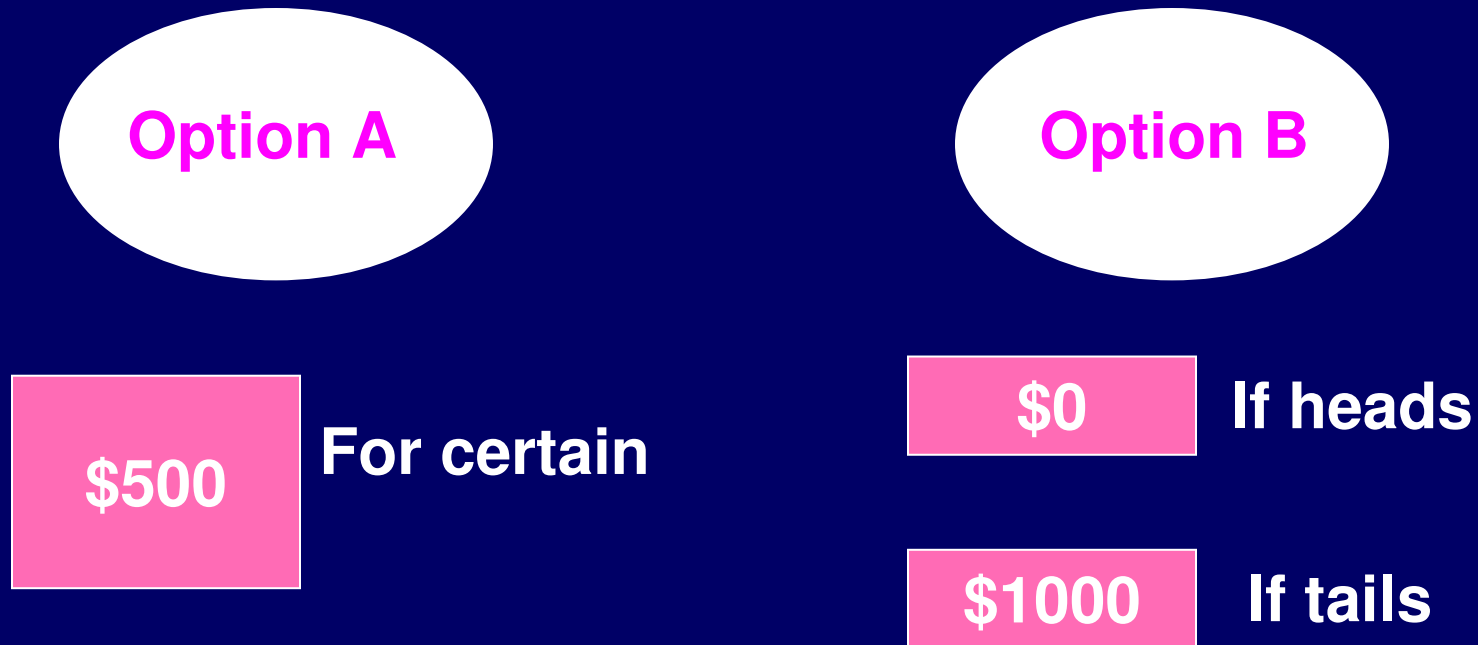
# RAND Results

Coinsurance	Visit Rates	Admission Rates	Spending (2003\$)
0 (free care)	4.55	0.128	1377
25%	3.33	0.105	1116
50%	3.03	0.092	1032
95%	2.73	0.099	946

Newhouse, *Health Affairs* 2004

# Prospect Theory: How Patients Make Choices

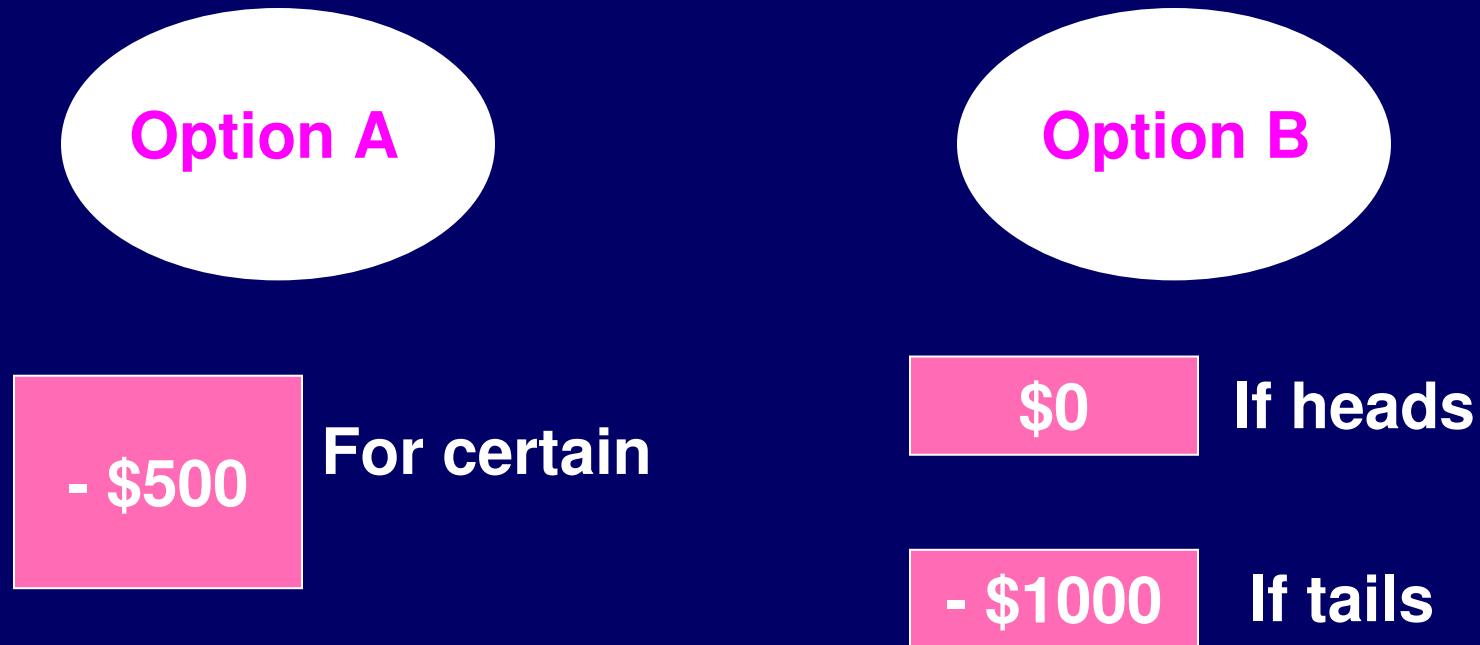
- ❖ First game: Choose between \$500 for certain and an equally-weighted gamble of either \$1000 or \$0.



Adapted from Schulman, KA. Can Society Afford State-of-the-Art Cancer Treatment? ASCO 2005.

# Prospect Theory: How Patients Make Choices

- ❖ Second game: Choose between *losing* \$500 for certain and an equally-weighted gamble of losing either \$1000 or \$0.



Adapted from Schulman, KA. Can Society Afford State-of-the-Art Cancer Treatment? ASCO 2005.

# Prospect Theory and Cancer Treatment: Kahnemann (and Tversky) Nobel Prize 2002

- We tend to value a gain that is certain more than a gain that is less than certain, even when the expected value of each is the same
- The opposite is even more true for losses: we will clutch at straws to avoid a certain loss, even if it means taking even greater risks
- “We have an irrational tendency to be less willing to gamble with profits than with losses”—framing matters
- Why is this relevant for understanding high costs of cancer rx?
- In face of great loss, patients may gamble for even small upside

# Phase I Trial Participant Attitudes

**Table 5.** Patient Considerations of Adverse Effects in Trial Participation

Potential Adverse Effect	Would Still Participate in the Research Trial (%)
Total hair loss	96
Nausea	89
Fatigue	96
10% chance of death	91
Laboratory tests twice a week	90
Bone marrow biopsy	92
Weight gain of 20 pounds	95
Overnight hospitalization	99
Impaired ability to think	76
Cytostatic not cytotoxic experimental treatment	99

# The Physician Vantage Point

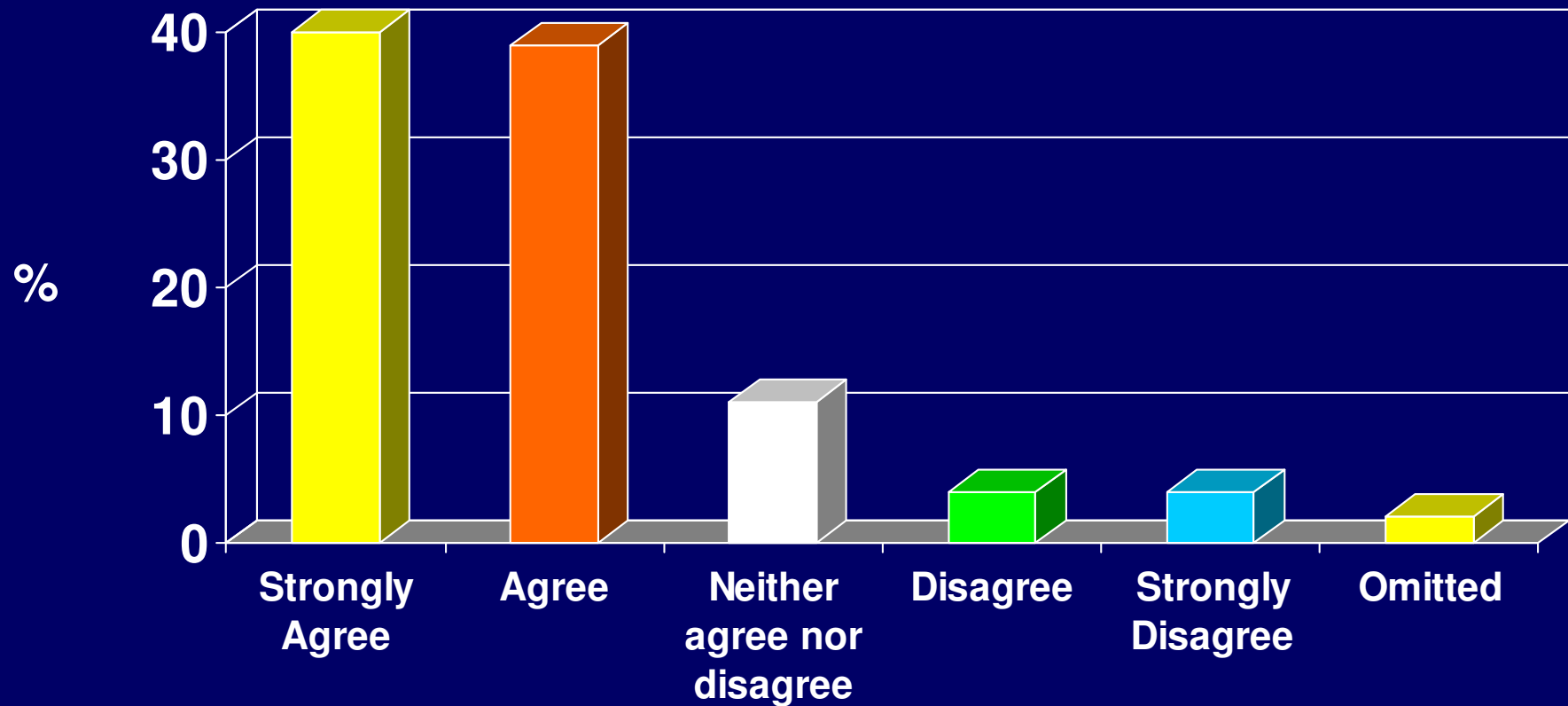
- We make recommendations and often the decisions about chemotherapy administration
- We counsel patients about whether or not to receive drugs
- We choose to use or not use new drugs
  - We want to help our patients
  - We are hopeful by nature
  - We are bombarded by marketing
  - We have economic incentives to administer therapy
- We do not typically view our role as economic advisors
- How do oncologists perceive and interpret their role as advocates for patients confronting high costs of chemotherapy?

# Physician Survey:

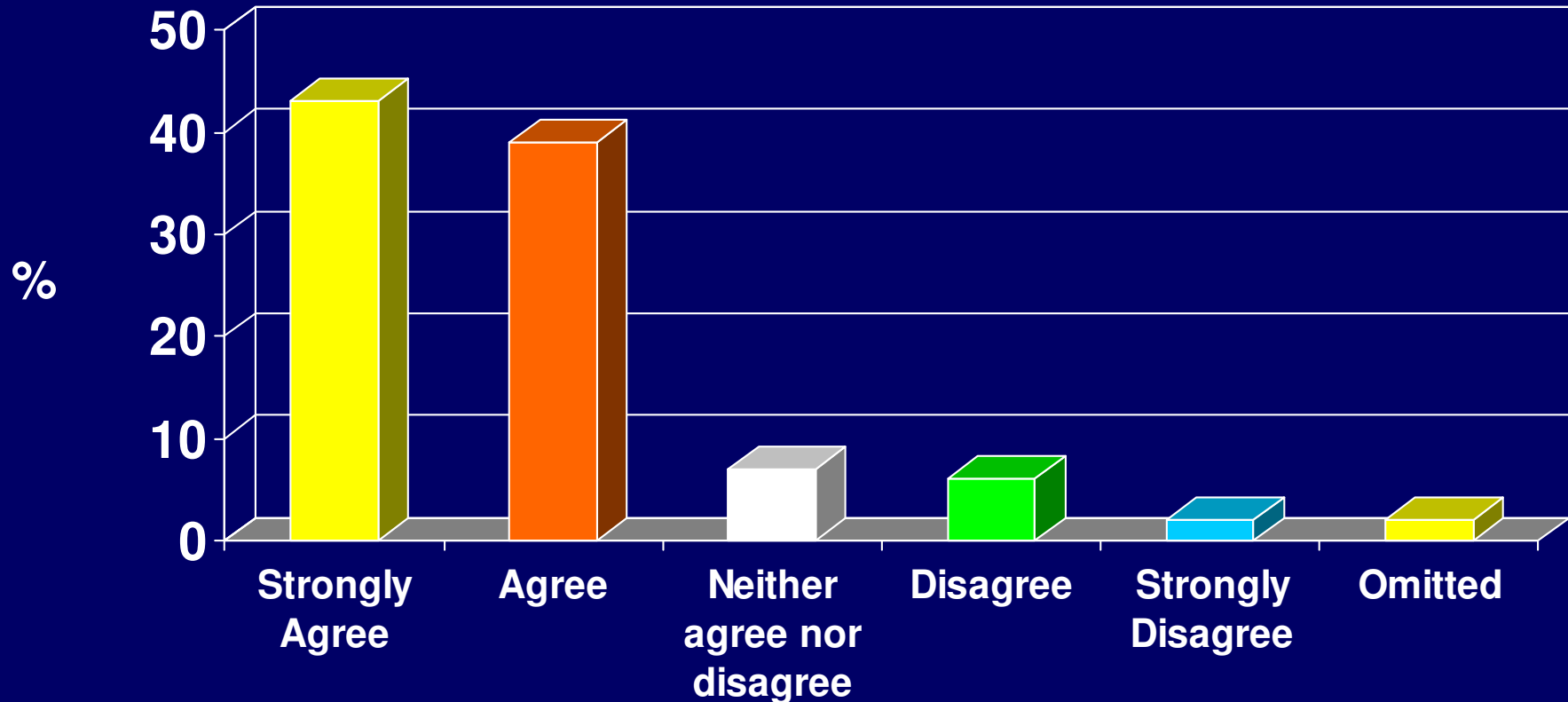
## Discussing treatment costs with patients

- Almost no information on the extent to which \$\$\$ is discussed
- Mailed survey (March 2006) to understand physician attitudes towards discussing costs with patients
- Random sample of ASCO members from 50 states
- 340 mailed surveys
- 31% response rate
- Respondent Characteristics
  - 68% community MDS
  - 21% academic practice
  - 11% fellows, administrators, researchers

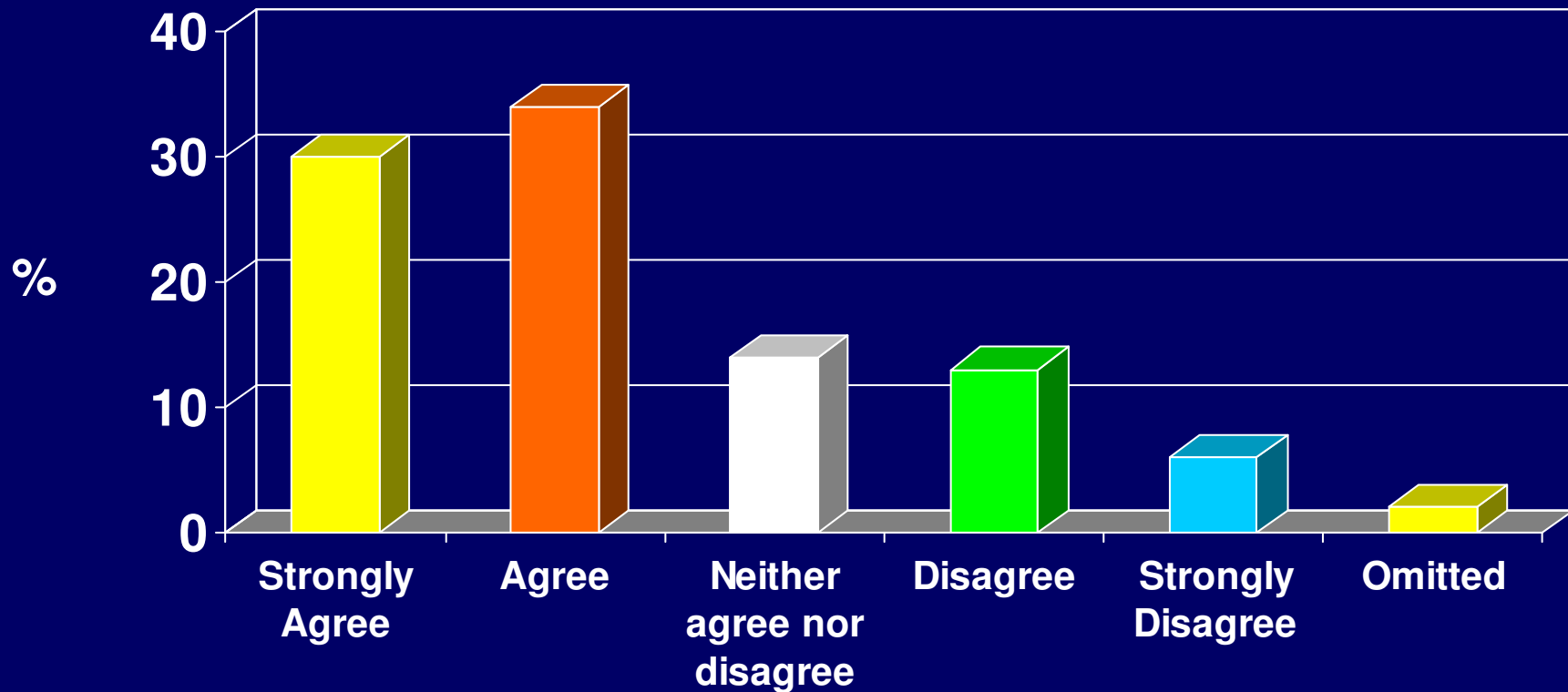
**It is important to be explicit with patients about the financial impact of their treatment preferences.**



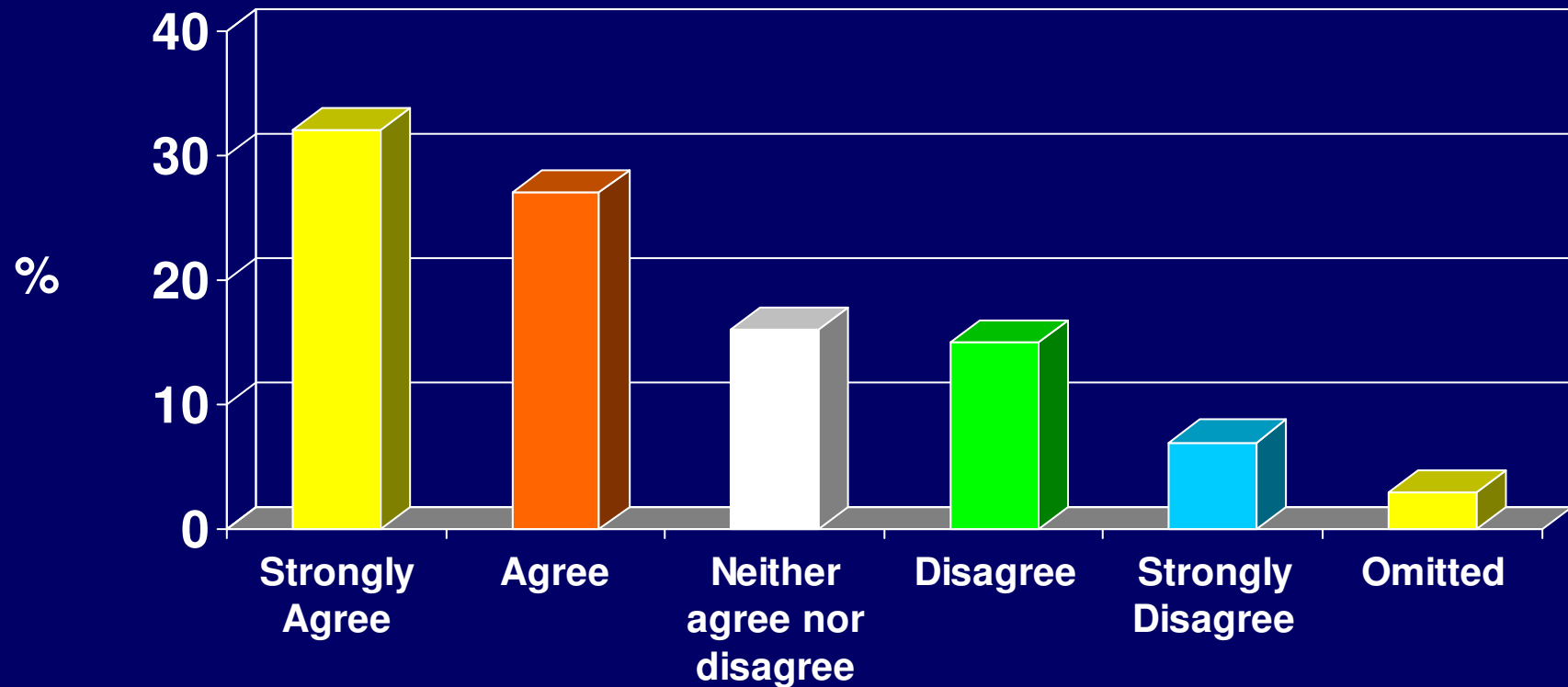
# Oncologists have a responsibility to consider the impact that treatment decisions may have on the patients' financial well-being.



**Part of the oncologist's role is to consider the overall cost-effectiveness of treatments when making recommendations to the patient.**



**When recommending expensive cancer treatments with limited efficacy, oncologists have a responsibility to balance the well-being of the patient with the use of society's resources.**



# Solutions:

## The Patient-Physician Interface

- Patient and family advance planning
- Develop strategies to address this uncomfortable issue
- Elicit patients' preferences and help make choices explicit
- Identify supportive resources for patients
- Understand how life threatening illness may influence decision-making
- Recognize that reform regarding cost issues will not happen at the level of the patient-doctor interaction

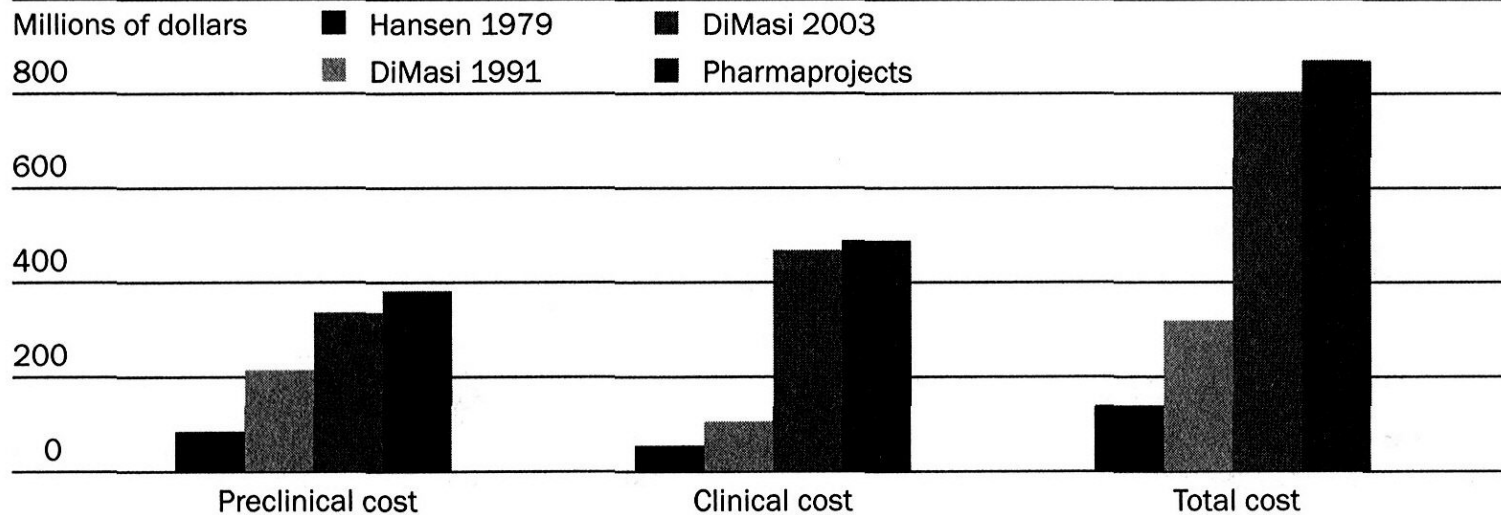
# **Coping with the High Costs of Chemotherapy: The Pharmaceutical Industry Vantage Point**

- **Rationale for Astronomical Expense:**
  - Products are valued
  - Development is expensive
  - Risks are high
  - High profits are necessary to drive innovation

# What does it cost to develop a cancer treatment?

## EXHIBIT 3

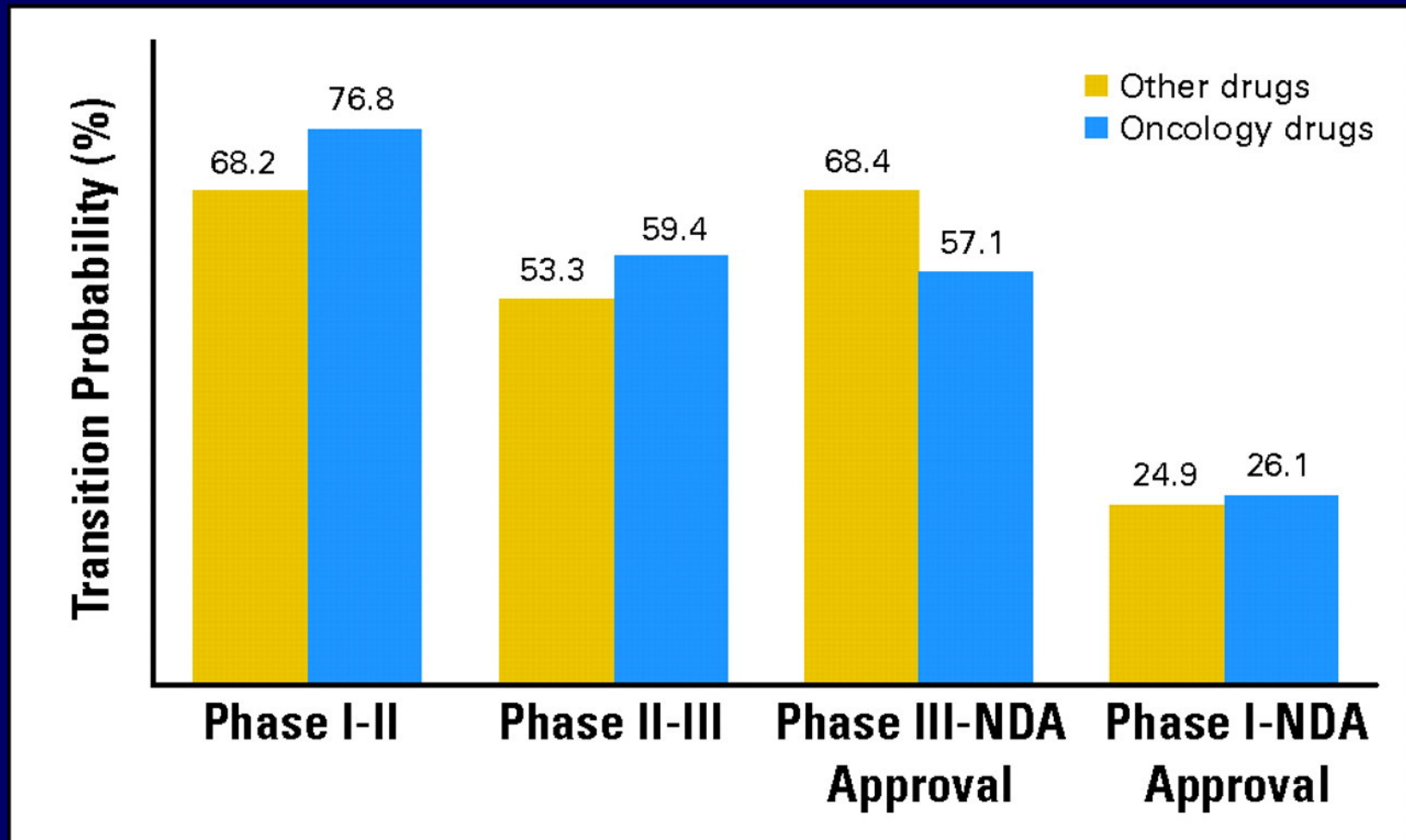
### Capitalized Preclinical, Clinical, And Total Cost Per New Drug, In Millions Of 2000 Dollars



**SOURCES:** R.W. Hansen, "The Pharmaceutical Development Process: Estimates of Current Development Costs and Times and the Effects of Regulatory Changes," in *Issues in Pharmaceutical Economics*, ed. R.I. Chien (Lexington, Mass.: Lexington Books, 1979), 151-187; J.A. DiMasi et al., "Cost of Innovation in the Pharmaceutical Industry," *Journal of Health Economics* 10, no. 2 (1991): 107-142; J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, no. 2 (2003): 151-185; and data from Pharmaprojects.

Adams and Brantner. Health Affairs, 2006

# Clinical Phase Transition Probabilities:



DiMasi and Grabowski, JCO, 2007

# Cancer drugs are a good investment

- 68 oncology drugs FDA-approved 1990-2005
- Regulatory approval time shorter than other agents, but
- Clinical development longer than other agents

**Table 2.** Regulatory Characteristics of New Therapeutic Oncology and Other Drugs Approved in the United States, 1990-2005

Characteristic	%	
	Oncology Drugs	Other Drugs
FDA priority rating*	70.9	40.2
Orphan drug designation	48.5	18.5
Expedited access†	47.1	13.4

DiMasi and Grabowski, JCO, 2007

# Justifying the High Costs of Treatment

- Problems with Justification of Great Expense:
  - Strong patent protection keeps costs high
  - Development costs shared by public and private sectors
  - Profitability is astronomical
  - Expenditures for non R&D items are high
  - US market bears unequal share of cost burden
  - Its not a free market! ---Its illegal for the biggest purchaser (CMS) to negotiate over price ( an amazing clause buried in the MMA)
  - The government (CMS) cannot negotiate bulk prices with manufacturers. Instead, each individual provider, such as health plans and pharmacy benefits companies, must negotiate separately

# Public and Private Sector Share Costs of Drug Development:

- NIH spends \$484 million on research related to the drug paclitaxel (Taxol)
- BMS receives license to commercialize in 1991
- Says it spent ~\$1 billion to develop
  - all trials were NIH sponsored
  - FDA approved and marketed starting in 1993
- BMS has over \$9 billion in sales in 2002
- 
- NIH receives a TOTAL of \$35 million in royalty payments (<0.5%)

**“Now, because NIH didn’t use its power to get a better deal for taxpayers and patients, Medicare has paid more than a half-billion taxpayer dollars to buy a taxpayer-funded drug for the taxpayers who funded it”**

**—Sen Ron Wyden based on 2003 Report from General Accounting Office**

# Estimated Drug Cost for 8 Weeks of CRC Chemo: UK vs Germany vs. US in 2005 US\$

Regimen	US	United Kingdom		Germany	
	Drug Costs	Drug Costs	Drug Costs Relative to U.S. (PPP)	Drug Costs	Drug Costs Relative to U.S. (PPP)
<b>Regimens containing fluorouracil</b>					
Mayo Clinic	\$32	\$349	967%	\$268	717%
Roswell Park	\$153	\$2,682	1555%	\$3,437	1921%
LV5FU2	\$134	\$1,363	903%	\$1,818	1160%
<b>Regimens containing irinotecan and oxaliplatin</b>					
CPT	\$8,534	\$3,195	33%	\$4,730	47%
IFL	\$8,556	\$3,423	36%	\$4,896	49%
FOLFIRI	\$8,327	\$4,900	52%	\$6,469	66%
<b>FOLFOX6</b>	<b>\$10,567</b>	<b>\$5,510</b>	<b>46%</b>	<b>\$6,483</b>	<b>52%</b>
<b>Regimens containing bevacizumab and cetuximab</b>					
CPT/C225	\$27,830	\$12,813	41%	\$17,330	53%
FOLFIRI with bevacizumab	\$16,305	\$10,788	59%	\$13,222	69%
FOLFOX6 with bevacizumab	\$18,545	\$11,398	55%	\$13,237	61%
FOLFOX6 with bevacizumab and cetuximab	\$37,841	\$21,016	49%	\$25,837	58%

# **Solutions: The Societal Level**

- **Political Reform**
  - **Single payor systems for catastrophic illness**
  - **Tax reform ---incentivize health savings accounts**
  - **Patent reform**
  - **Permit CMS to negotiate with pharma for bulk pricing**
  - **Ensure that financial rewards from publicly sponsored research are returned to the public**
  - **Greater dialogue and awareness about these issues**

# **Solutions: Reform in Research and Health Care Delivery**

- **Build and maintain the evidence base**
- **Consider cost data in approval process-CEA**
- **Mandatory post- FDA approval clinical trials**
- **Invest in systems to track and record outcomes**
- **Greater Reliance on “guidelines”**
- **CMS Explicit coverage decisions**
  - **National coverage decisions vs. local carriers**
  - **Transparent processes for coverage determinations**
- **Reimburse oncologists for care not chemotherapy**
- **Dialogue between MDs and CMS/FDA/Private payors about these complex issues**

- QUESTIONS
- Extra Material

# EXTRA INFORMATION

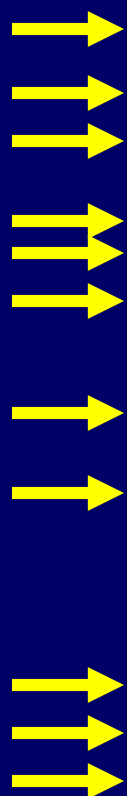
# Top 15 Hospital Drug Expenditures

Drug	Total 2004 Expenditures (\$ Thousands)	Percentage of Total 2004 Nonfederal Hospital Expenditures	Percent Increase over 2003
→ Epoetin alfa (Procrit, Epogen)	1,178,462	4.8	-13.2
→ Enoxaparin (Lovenox)	806,156	3.3	15.1
→ Darbepoetin (Aranesp)	379,864	1.5	68.5
→ Pegfilgrastim (Neulasta)	426,804	1.7	44.0
→ Infliximab (Remicade)	521,449	2.1	2.6
→ Ondansetron (Zofran)	497,174	2.0	7.6
→ Rituximab (Rituxan)	451,023	1.8	7.5
Pipercillin-tazobactam (Zosyn)	396,940	1.6	24.3
Propofol (Diprivan, generics)	470,571	1.9	3.5
Ceftriaxone (Rocephin)	444,471	1.8	-0.8
→ Filgrastim (Neupogen)	335,413	1.4	-2.6
Iohexol (Omnipaque)	344,644	1.4	20.8
Sevoflurane (Ultane)	267,090	1.1	15.0
Nesiritide (Natrecor)	372,662	1.5	63.9
Eptifibatide (Integrilin)	312,588	1.3	5.1

JM Hoffman et al. Am J Health-Syst Pharm, 2006

# Top 15 Clinic Drug Expenditures

Drug	Total 2004 Expenditures (\$ Thousands)	Percentage of Total 2004 Clinic Expenditures	Percent Increase over 2003
Epoetin alfa (Procrit, Epogen)	3,901,126	17.7	-0.05
Darbepoetin (Aranesp)	1,214,297	5.5	83.8
Pegfilgrastim (Neulasta)	1,160,429	5.3	45.8
Infliximab (Remicade)	1,269,004	5.8	25.1
Rituximab (Rituxan)	950,981	4.3	12.1
Oxaliplatin (Eloxatin)	541,014	2.5	71.8
Docetaxol (Taxotere)	635,990	2.9	-0.4
Zoledronic acid (Zometa)	466,887	2.1	10.6
Trastuzumab (Herceptin)	364,762	1.7	33.9
Gemcitabine (Gemzar)	420,510	1.9	16.6
Paricalcitol (Zemlar)	349,728	1.6	23.7
Pneumococcal vaccine, diphtheria conjugate (Prevnar)	349,836	1.6	-16
Irinotecan (Camptosar)	327,023	1.5	-14.9
Filgrastim (Neupogen)	227,999	1.0	-7.1
Carboplatin (Paraplatin)	317,603	1.4	-30.5



JM Hoffman et al. Am J Health-Syst Pharm, 2006

# Total Hospital Spending on Cancer Drugs

Drug Class	Total 2004 Expenditures (\$ Thousands)	Percentage of Total 2004 Nonfederal Hospital Expenditures	Percent Increase over 2003	2005 Expenditures (through Sep 2005) (\$ Thousands)	Percent Increase, Year-to-Date Sep 2005 versus Year-to-Date Sep 2004
Systemic antiinfectives	2,930,815	11.9	9.0	2,398,920	11.1
Hemostatic modifiers	2,745,314	11.1	9.5	2,214,756	8.5
Antineoplastic agents	2,581,121	10.4	12.9	2,042,241	5.8
Blood growth factors	2,457,858	10.0	4.4	1,955,227	6.3
Diagnostic aids	1,588,784	6.4	15.5	1,283,333	2.5
Hospital solutions	1,250,071	5.1	13.1	954,768	4.5
Anesthetics	1,107,746	4.5	5.0	889,748	9.1
Psychotherapeutics	1,114,133	4.5	5.3	845,740	1.0
Biologicals	859,399	3.5	5.7	773,072	21.8
Gastrointestinal agents	956,735	3.9	6.6	711,563	-2.4

Antineoplastics    \$2.6 B    10.4%    12.9%    \$2.0 B    5.8%

JM Hoffman et al. Am J Health-Syst Pharm, 2006

# What do these numbers mean?

Payment for Part B oncology drugs billed to Medicare in 2004: \$5.3 billion

Domestic cigarette advertising in 2003 by 5 major manufacturers: \$15.2 billion

Medicare budget 2004: \$265 billion (estimate \$340B 2006)

[www.medpac.gov/publications/congressional\\_reports/june03\\_ch9.pdf](http://www.medpac.gov/publications/congressional_reports/june03_ch9.pdf)

[www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf](http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf)

FTC Cigarette Report for 2003, issued 2005

<http://www.whitehouse.gov/omb/budget/fy2006/hhs.html>

# Medicare Part B vs. Part D

- Part B
  - Oral drugs with IV equivalent
  - 20% copay, small deductible
  - No limit
- Part D
  - All other oral drugs
  - Copay and deductible varies by plan
  - E.g. \$250 deductible, 25% coinsurance until \$2250; 100% cost until \$3600 (donut hole)
  - 5% coinsurance after \$5100 in a year

# National Survey of Households Affected by Cancer

- Conducted by USA Today, Kaiser Family Foundation, Harvard School of Public Health
- 930 adults
- Household affected by cancer in past 5 years
  - 46% of respondents were cancer patients
- Nationally representative sample
- Telephone survey
- Questions asked about the person in the family with cancer
- Results reported 11/06

National Survey of Households Affected by Cancer, USA Today, Kaiser Family Foundation, Harvard School of Public Health, 2006.  
<http://www.kff.org/kaiserpolls/7590.cfm>

# Financial Burden of Cancer

- Burden of costs on the family – 17% major burden (28% if < 50 years old)
- 25% used up all or most of savings
- 13% borrowed from relatives
- 11% sought charity
- 8% delayed or did not get care because of cost (27% if ever uninsured)

National Survey of Households Affected by Cancer, USA Today, Kaiser Family Foundation, Harvard School of Public Health, 2006.  
<http://www.kff.org/kaiserpolls/7590.cfm>

# In pursuit of innovation

- Biotechnology/oncology is an attractive realm for investment
- Patients benefit from new drugs
- However,
  - Potential for profit-driven inefficiencies in drug development
  - Incentives for marginally better treatments
  - Potential disincentive for identification of predictive markers

# The Problem of the Uninsured (2005)

Overall	15.9%
Non-Hispanic White	11.3%
Non-Hispanic Black	19.6%
Hispanic	32.7%
Income <\$25,000	24.4%
\$25,000-\$49,999	20.6%
\$50,000-\$74,999	14.1%
\$75,000+	8.5%

<http://www.census.gov/prod/2006pubs/p60-231.pdf>

# The Challenge

To ensure:

1. continued innovation, new therapies and diagnostics
2. access to high quality care for all patients

# Solutions?

- Societal
  - Consider costs and benefits
  - Ensure value for each dollar spent
  - Reward appropriate use; align incentives
    - e.g. tiered copays, incentives for use/development of generics, pay for performance
- Physician
  - Promote evidence-based practice
  - Support trials/research to improve evidence
  - Balance allegiance patient/society

# European Approaches

- Public-integrated
  - Government as insurer and provider
- Public-contract
  - Government or centralized social insurer purchases services from private providers
- Central authority has leverage over providers
- Central authority can set price and budgets
- Discrete drug budgets
- Economic data considered in approval decisions
  
- *Contrast U.S.: Private insurance/provider*
  - *Private insurers purchase services from private providers*

# Evaluating Costs of Cancer Care

## Why not explicitly determine value?

- Cost-Effectiveness not routine in the US
- Not mandatory for drug approval
- CMS may not consider cost data
- True costs hard to obtain in multi-payor system
  - Which costs?
    - Direct medical costs
    - Direct non-medical costs
    - Indirect medical costs
  - Billing reflects charges not costs
  - Itemizing resources is challenging