You Get What You Pay For

The Unintended Consequences of "Buy and Bill" in Oncology

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Definitions

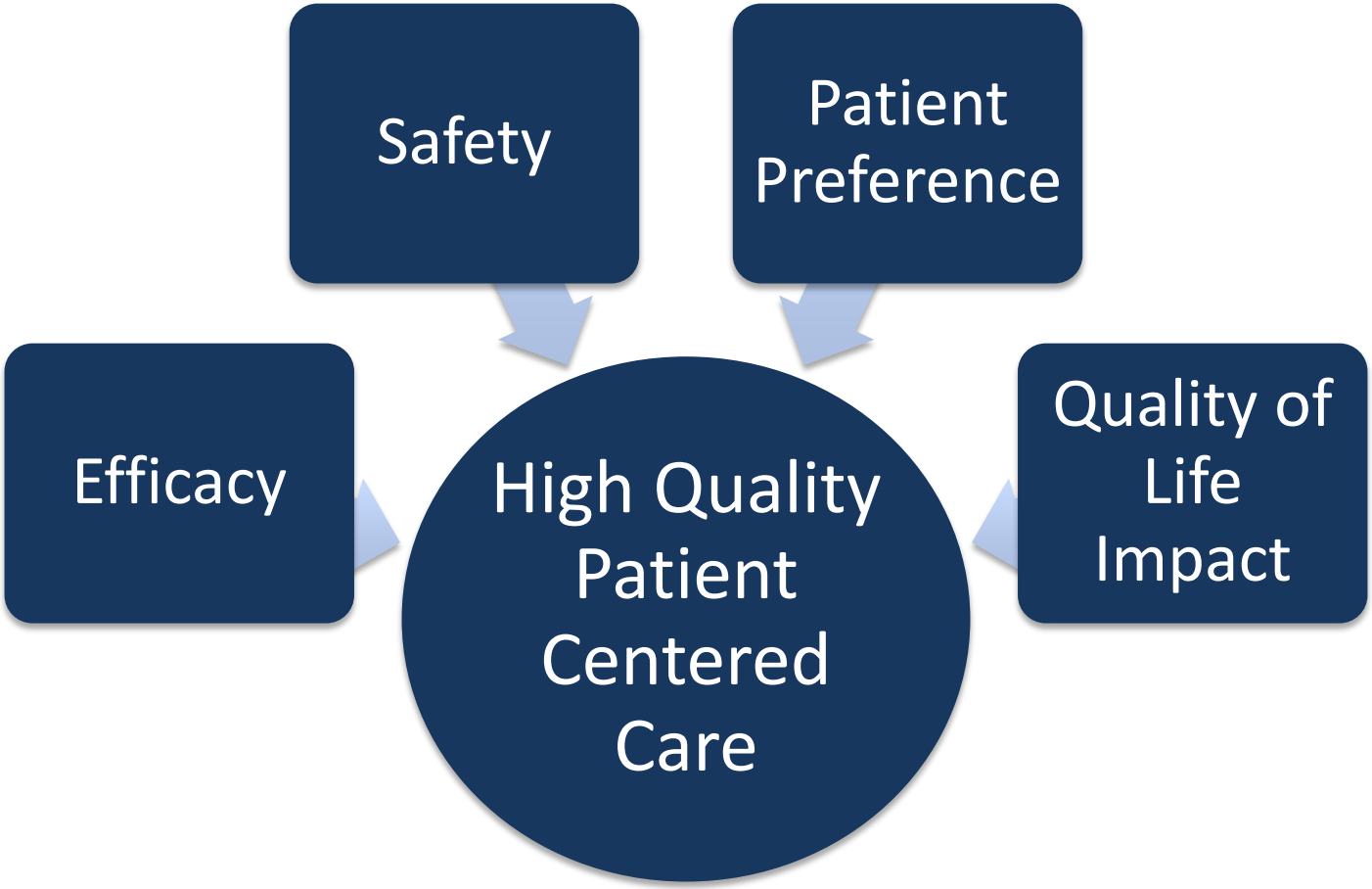
- Branded Drugs:
  - Novel drugs approved by the FDA
  - Produced by a “pioneer” manufacturer
  - exclusive production for patent duration

- Generics Drugs:
  - Approved drugs following patent expiration
  - Can be produced by multiple manufacturers
  - Based on active ingredient, bioequivalence, strict production standards

Societal Goals

- Incentivize New Drug Development
- Guarantee patient access to beneficial therapy
- Save money through use of generic drugs when possible
  - Incentivize manufacturers of generics
  - Encourage patient and physician use of generics
  - Avoid disincentives to use of generics…..

How SHOULD Medical Decisions be made?



How SHOULD Medical Decisions be made?

Efficacy

Beneficence

Patient Preference

Autonomy

Safety

Non-Maleficence

(DO NO HARM)

Efficiency and Equity

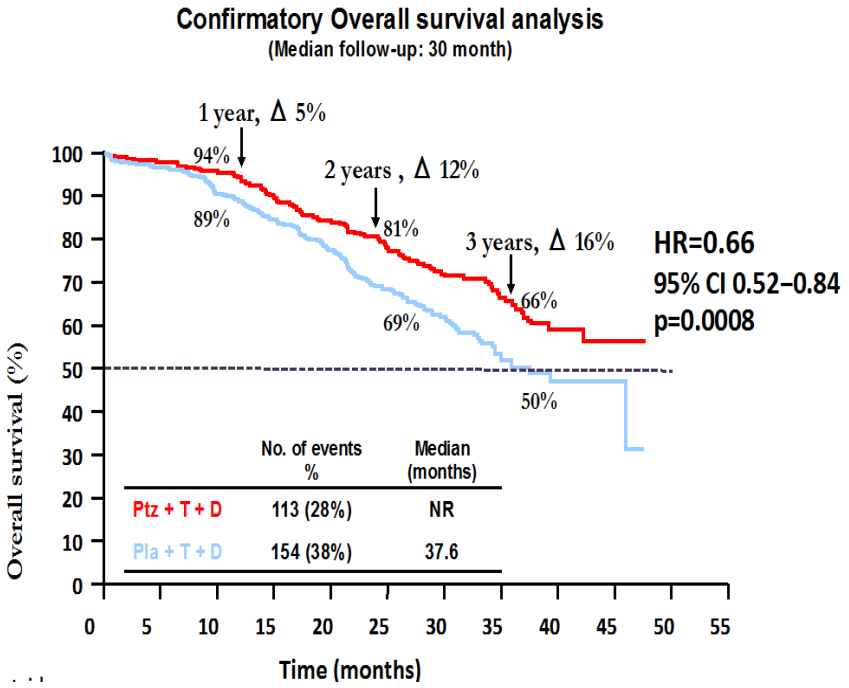
Justice

Case

- 45 yo woman presents with metastatic Her2 positive breast cancer. Previously treated with adjuvant Adriamycin and Cytoxan.
- Guidelines recommend Her2 targeted therapy.
- Use the novel drug pertuzumab??

DATA

- Phase III RCT with > 800 patients randomized to first line therapy with trastuzumab + taxane vs. trastuzumab + pertuzumab + taxane
- Pertuzumab arm superior for:
  - PFS: 18.5 vs. 12.4 months
  - Overall Survival median not reached
  - 3 year survival = 66% vs. 50%



Cost of Pertuzumab

- Trastuzumab plus Docetaxel = $124,000*

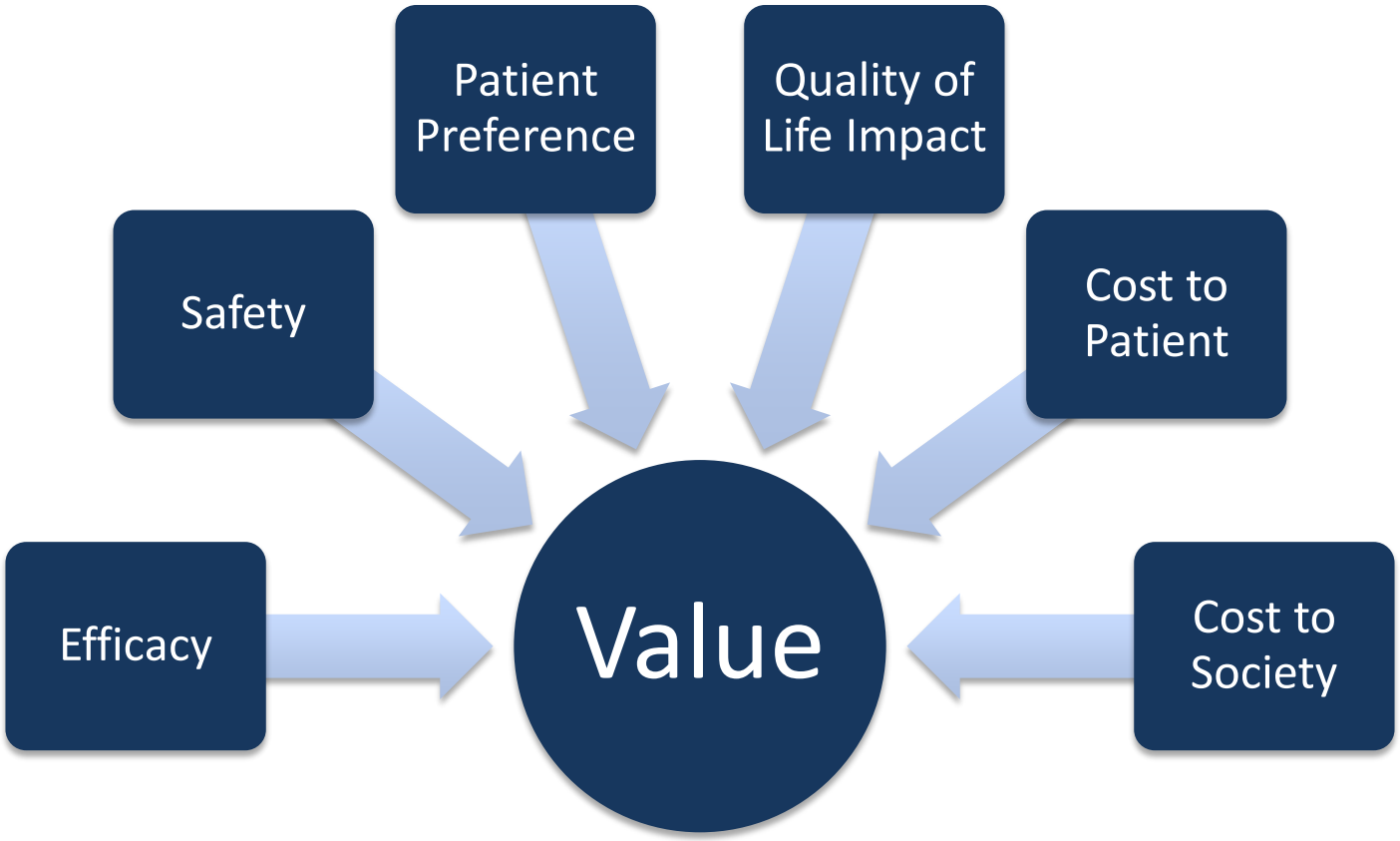
Babigumira, J Clin Oncol 32:5s, 2014 (suppl; abstr 642)

- Pertuzumab = $71,000

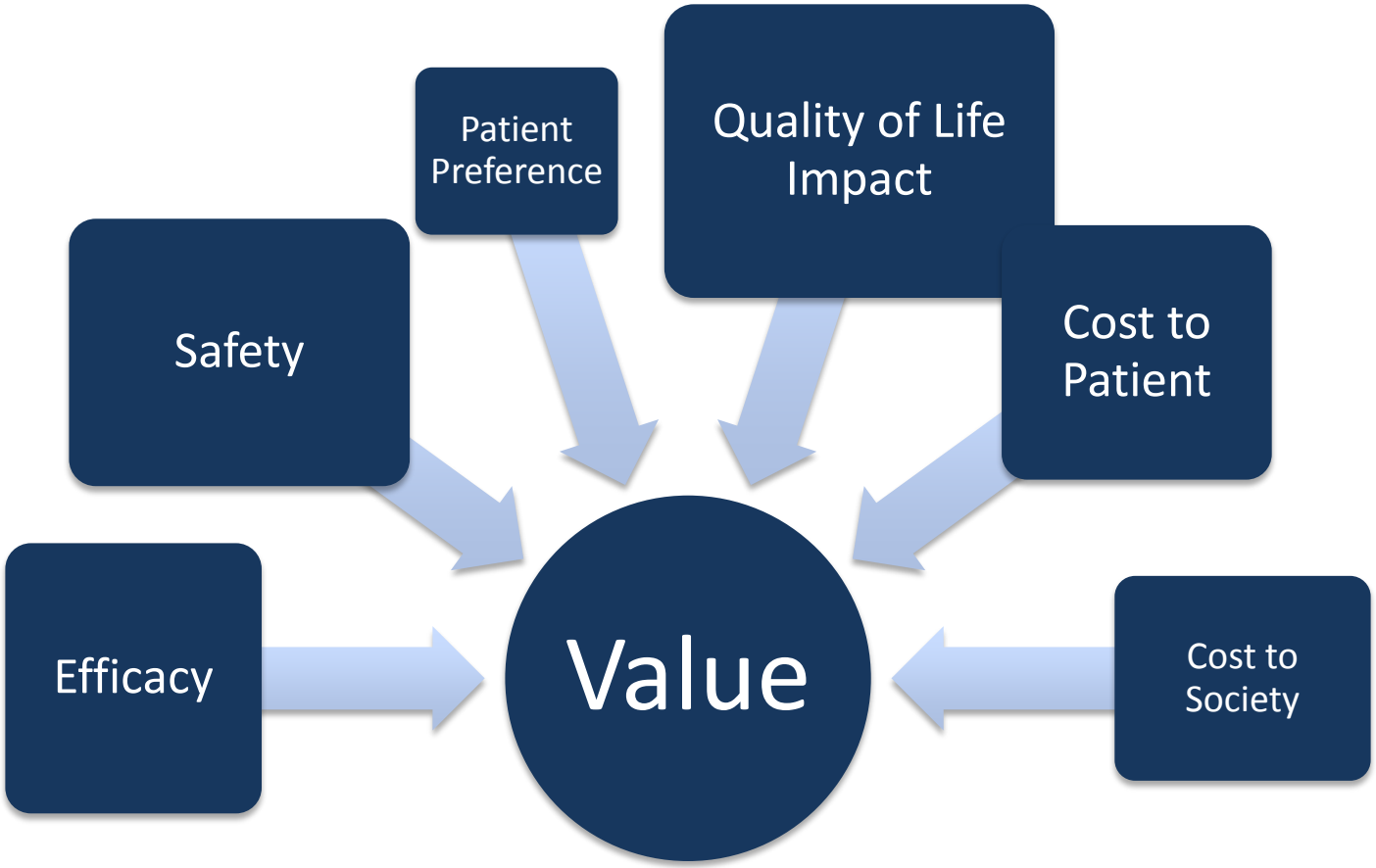
- Total cost = $195,000/year

* varies with duration of chemo and choice of taxane,
trastuzumab alone = $50,000 - $70,000/year

How SHOULD Medical Decisions be made? 2.0



How SHOULD Medical Decisions be made? 2.0

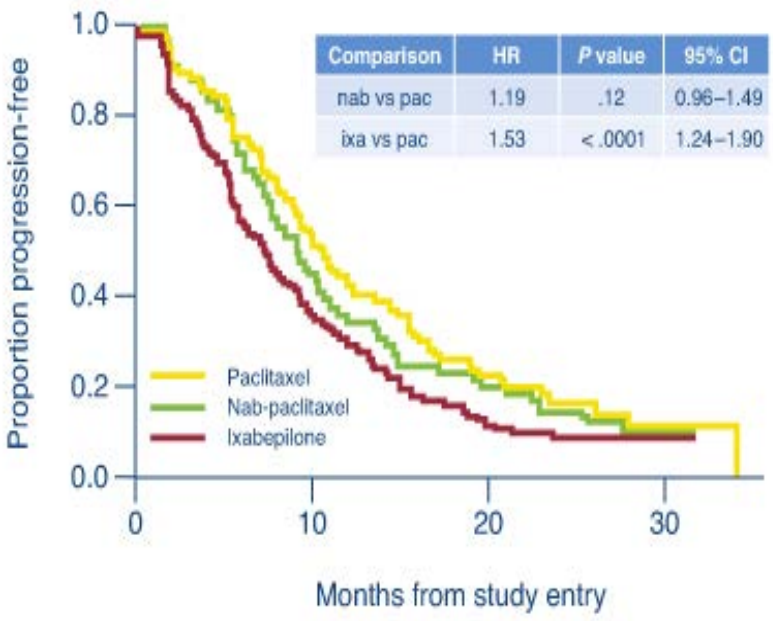


Case

- 45 yo woman presents with metastatic triple negative breast cancer. Previously treated with adjuvant Adriamycin and Cytoxan.
- Guidelines recommend taxane chemotherapy.
- Use generic paclitaxel (taxol) or nab-paclitaxel (abraxane)??

DATA

- 2005 trial = improved response (33% vs. 19%) and TTP (23 weeks vs 19), not survival, for q 3 week nab-paclitaxel vs. paclitaxel (Gradishar, JCO, 2005)
- 2008 trial = improved response (42% vs. 29%) and TTP (9 vs. 5 months), and improved survival, for weekly paclitaxel vs. q 3 week paclitaxel. (Seideman, JCO 2008)
- 2012 trial = no difference for weekly nab-paclitaxel vs. weekly paclitaxel (Rugo, ASCO 2012)



Which would you chose?

Paclitaxel

- Generally well tolerated
- Higher risk of allergic reaction
- Higher risk of neutropenia

- Generic

Nab-Paclitaxel

- Generally well tolerated
- Quicker infusion time
- Higher risk of neuropathy

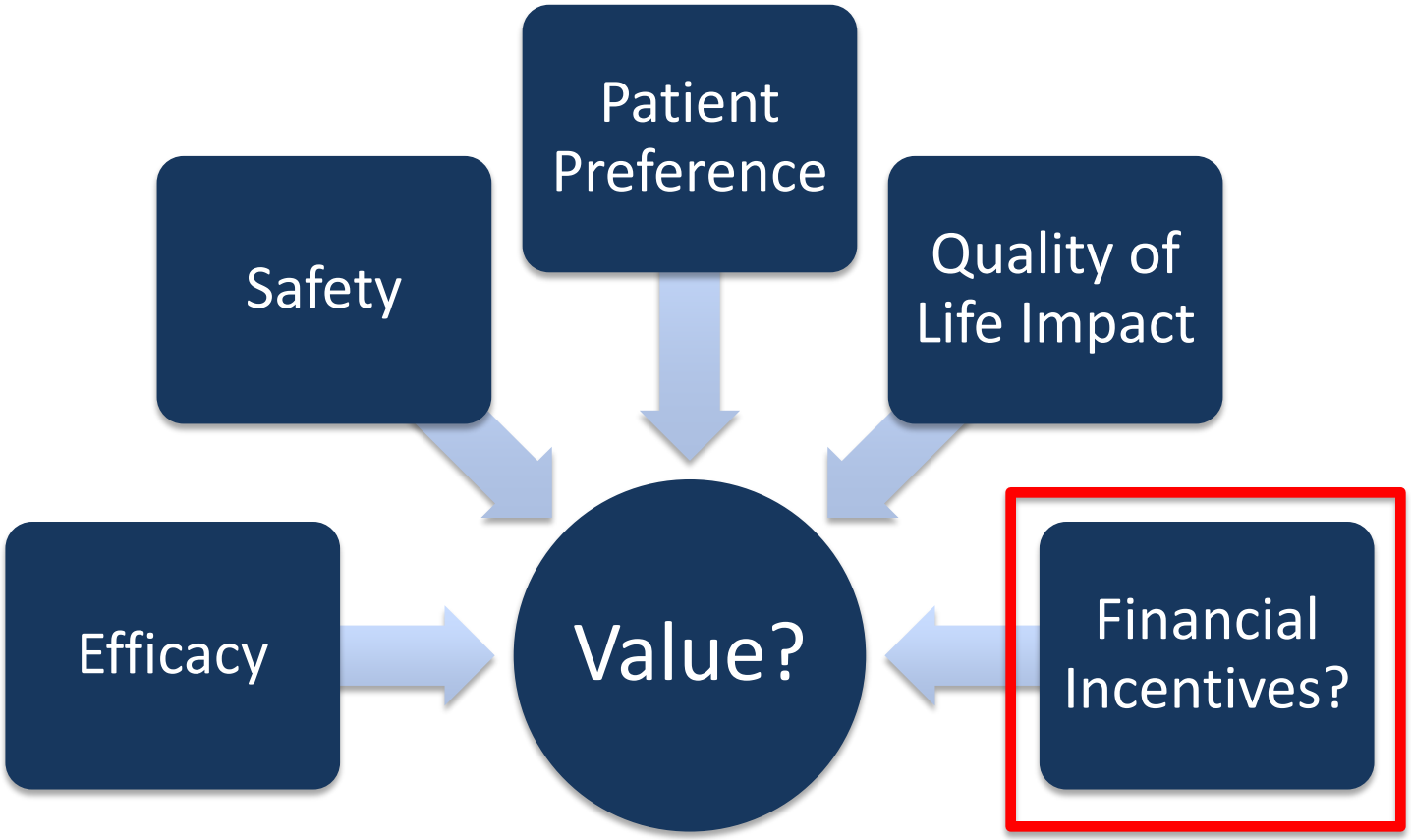
- On-Patent through 2024

Which is bigger?

$336

$2795

How ARE Medical Decisions be made?



How did we get here?

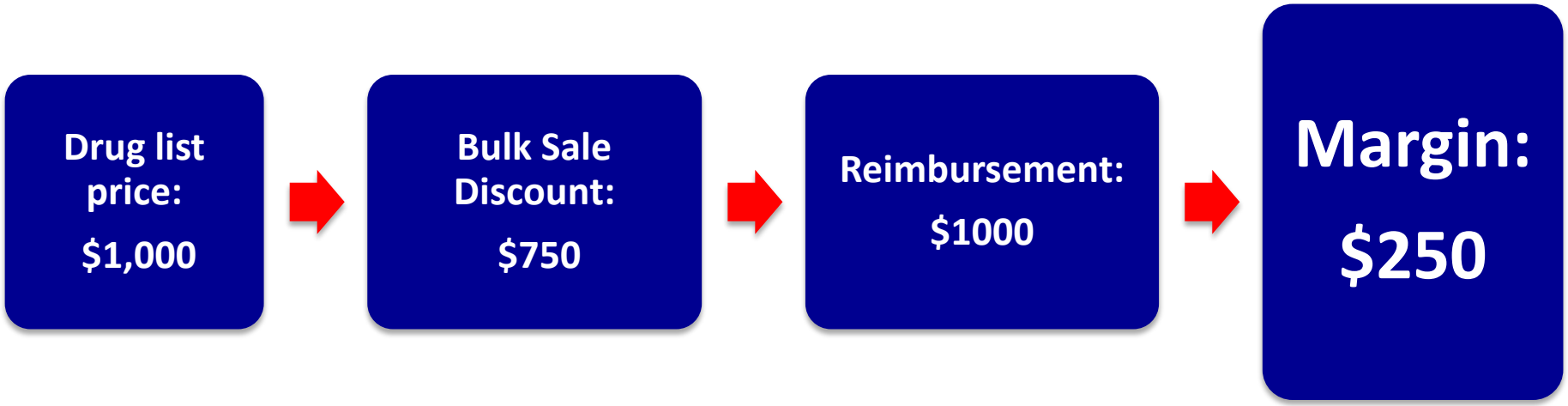
Pre-1998 Drug Reimbursement

Most chemotherapy drugs administered by the clinic

Most oncology care in private practice

Practice reimbursed 100% of Price of Drug

Jacobsen, Health Affairs, 2006

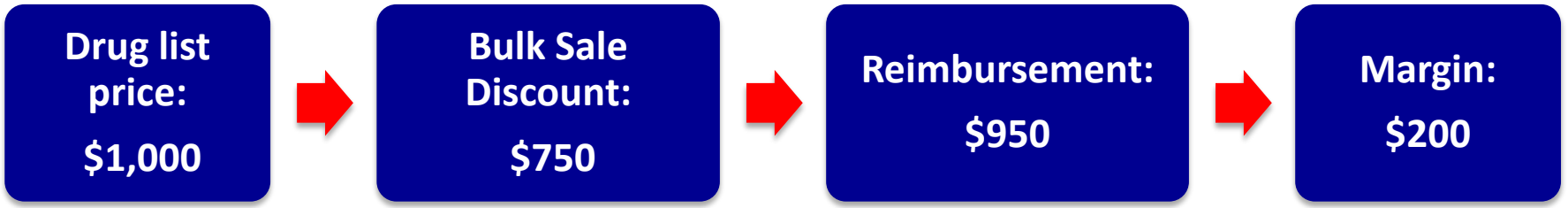


Balanced Budget Act of 1997

Effective January 1, 1998:

Medicare payment for drugs based on the lower of: actual charge on the Medicare claim or 95% of average wholesale price (AWP)

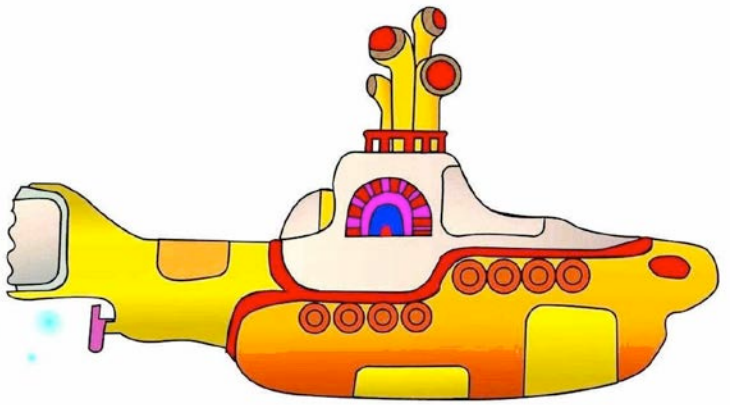
- CMS.gov Historical Part B Drug Pricing Files CMS accessed 03/23/2012



- Blamed for excessive government spending on cancer care and inflation in drug prices

Medicare Prescription Drug and Modernization Act of 2003

- Goal: reimbursement = purchase price + administration costs
- As of 2005, 106% of Average Sales Price (ASP + 6)
  - Manufacturers required to calculate ASP and submit quarterly to CMS
- Accomplishment: Saves Money (800 million?) MedPAC report
- Problems:
  - 1. Still incentivizes use of more expensive drugs
  - 2. For some practices cost > reimbursement (Underwater)
    - Practice does not get discount
    - ASP not up to date
    - Patients unable to pay copays
    - Administration costs not covered
      - (storage, safe handling, staff)
  - SEQUESTER: April 2013: ASP + 4.3%

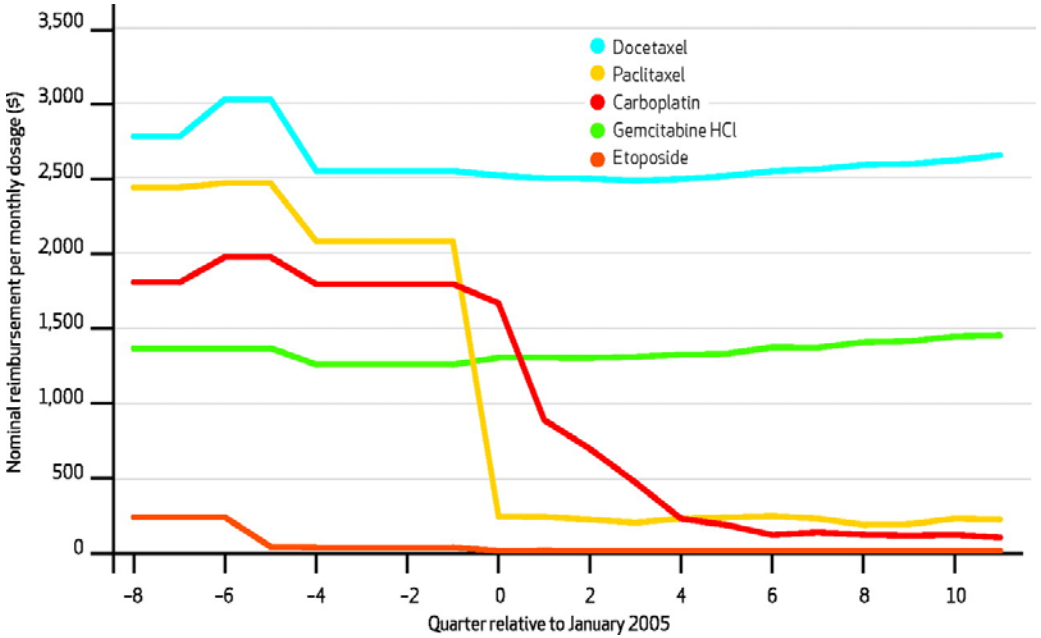


Societal Goals

- Incentivize New Drug Development ✔
- Guarantee patient access to beneficial therapy ?
- Save money through use of generic drugs when possible X

Do Financial Incentives impact Oncology Practice?

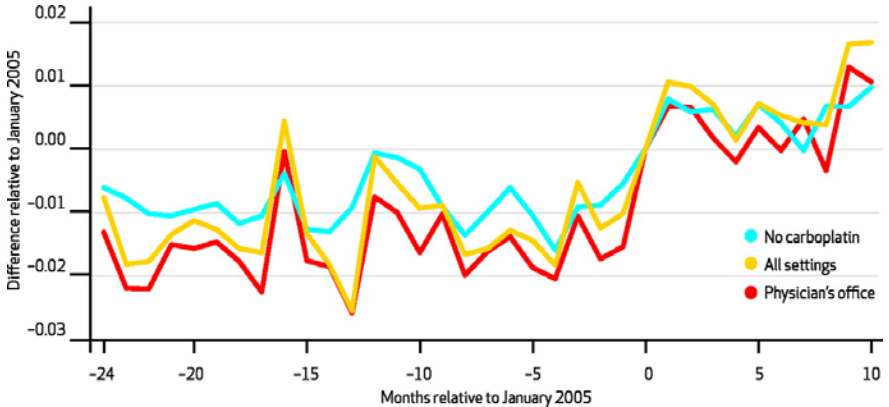
Jacobsen, Health Affairs 2010



Among patients with stage 4 lung cancer:

- As Reimbursement per patient drops, more chemo is used
- Use shifts from generic paclitaxel to brand doctexal

Coloectal: ~18 % decline in use of Irinotecan vs. oxaliplatin following generic in 2008 Conti et al. Am J Man. Care 2012

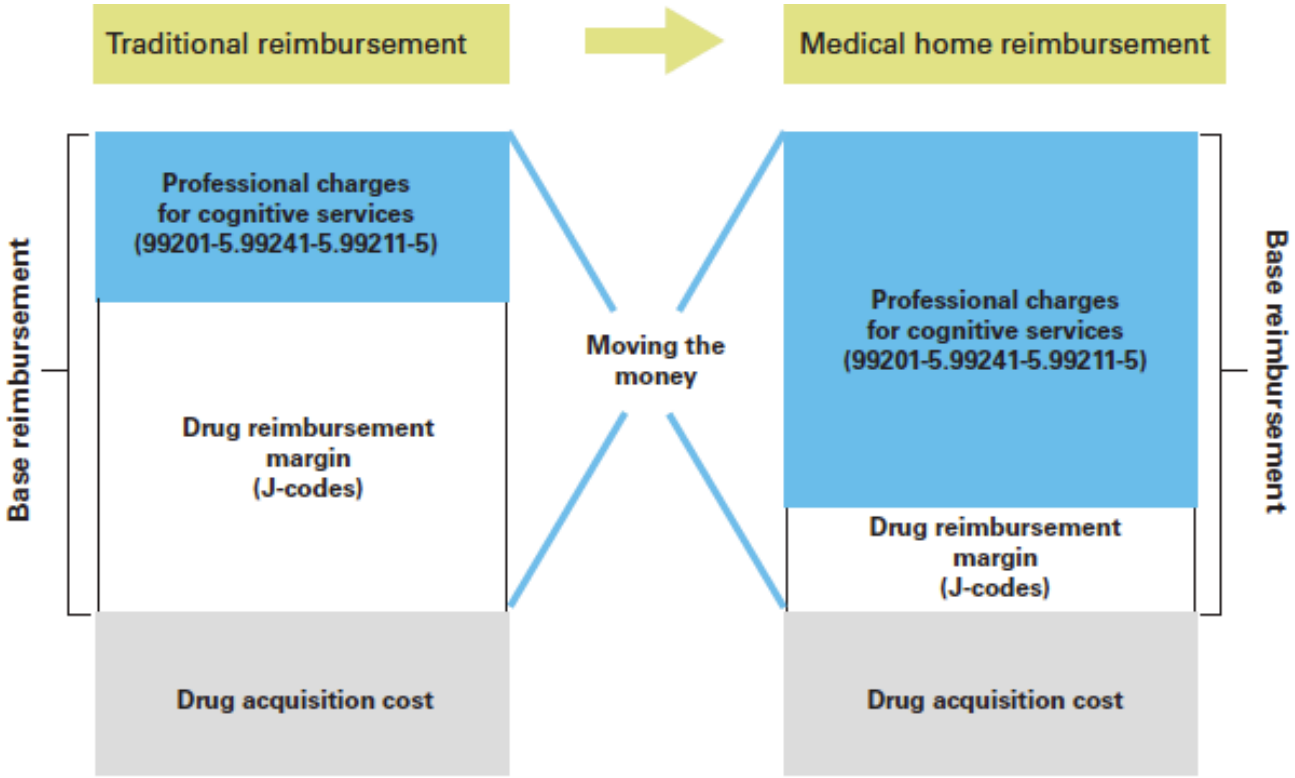


Is it GREED?

Do Financial Incentives impact Oncology Practice?

- Oncology Medical Home pathway program.

– Feinberg Am J Man Care April 2014



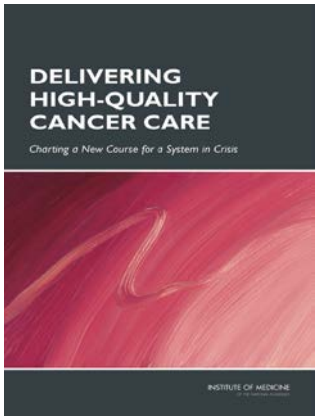
- Did not change MD behavior:
- type or frequency of chemotherapy
- Established or new patient visits.
- No change in use of generic drugs

Principles to Guide the Evolution of Health Care Payment Systems that Support High-Quality, High-Value Cancer Care

A Joint Statement by the Community Oncology Alliance and the American Society of Clinical Oncology

ASCO.org , Jan 2014

- "Traditional reimbursement models provide inadequate support for care coordination and complex disease management required for high quality cancer care"
- "ASP + 6 is inadequate to cover costs and risks for purchasing and maintaining expensive cancer drugs with specialized storage requirements"



Patient Education

Survivorship Care Planning

Navigation

Palliative Care

Discussing Costs of Care

Nutrition

Palliative Care

Symptom Management

Shared Decision Making

Other Unintended Consequences: Generic Drug Shortages

- Generic drugs have lower price, but lower profit margin for manufactures also contributes to supply problems

- Shortages have multiple factors

- ASP + 6 blunts normal response to shortage (↑Price → ↑ Supply)

- 2004 58 drug shortages reported
- 2005 ASP + 6 Begins…..
- 2010 211 drug shortages
    - (including noncancer drugs) – Emmanuel, NYT, Aug 6th , 2011

Biosimilars

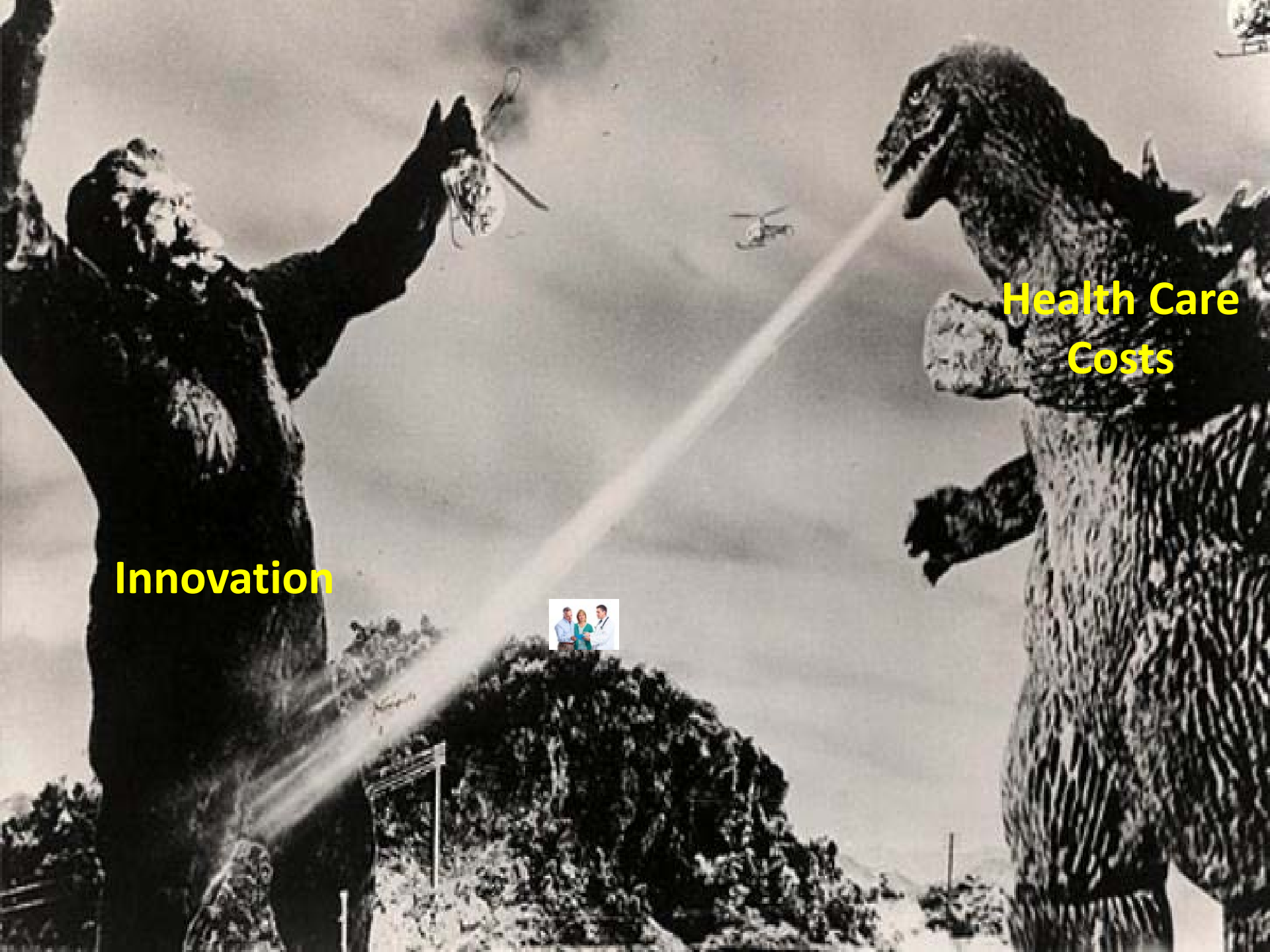
- Will we get cost savings as biologicals, antibody, immunotherapy patents expire?

- Harder to produce
- Less competition
- Unclear how generics will be priced or if there will be savings from generics

Clinical Oncology News May 2012

Solutions?

- Pay more for generic drugs?
  - ASP + 30? (Emmanuel, NYT)
- Pay chemo admin fee distinct from drug costs?
- Pay for what the oncologist actually does?
  - symptom management, cognitive aspects of care…
  - P4P, Bundled Payments, Capitation – Necomber, JOP, May 2014
  - United Reimbursement Pilot Program
    - Problem: not UNIVERSAL, multiple payers, Medicare dominates
- Pay less for branded drugs?


Health Care Costs
Innovation

Replacing Buy and Bill?

- Buy and bill is irrational and unsustainable
- BUT….other aspects of care WONT be compensated
  - detriment to patients? (and well as oncologists)

Conclusion:
You get what you pay for …

- When you pay for doctors to give a more expensive drug, regardless of medical need for that particular drug, you get use of more expensive drugs and higher spending

- We also want to support innovation and patient centered community based cancer care.

Find the balance