Value for Money: Cost Containment In An Uncertain Era

Comparative Effectiveness, Personalized Medicine, End-of-Life Care, & Rationing

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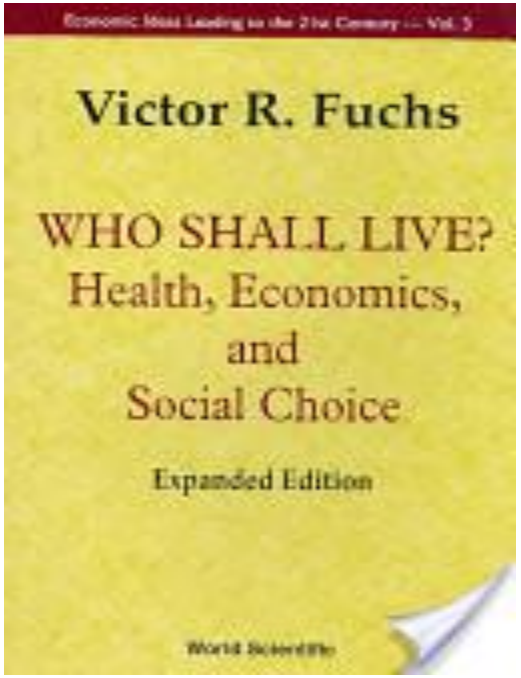
Presentation Roadmap

A. Health Care Reform
B. The Big Unknown
C. Cost Basics
D. Cost Containment Possibilities
    1. Comparative Effectiveness Studies
    2. Personalized (genomic) medicine
        a) Designer Drugs
    3. End-of-life Care
        a) Advance Directives & Futile Care
        b) Palliative care
        c) Provider-assisted Suicide
    4. Payment reform

Victor Fuchs on Health Spending:

- **"If we solve our health care spending problems, practically all our fiscal problems go away."**

And if we don't?

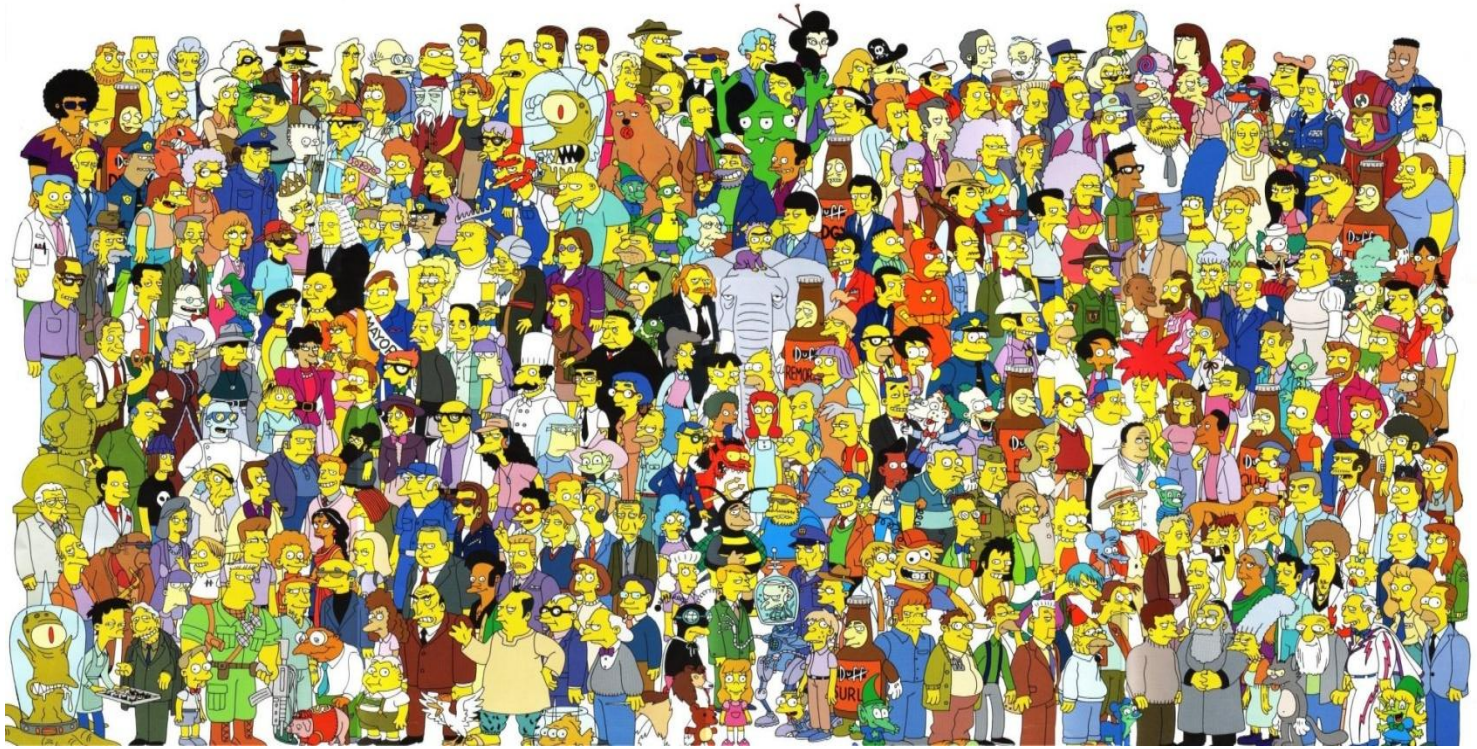


- **"Then almost nothing else we do will solve our fiscal problems."**

- Victor Fuchs, Stanford Health Economist, NYTimes, March 5, `12

Primary Problem Addressed by Reforms:

- About 18% of US Population = uninsured
  - As a result, US ranked #37 in WHO World Health Systems Ranking



Reforms E-x-p-a-n-d Health Ins Coverage for 34M Uninsureds

Medicaid eligibility increased (by 17 M) +

Health ins exchanges set up so low income people can afford coverage (16+ M)

Uwe Reinhart's 3-legged Stool re Expanding Coverage

1. Everyone must be in the risk pool
2. Insurers must accept all comers
3. Subsidize those who can't afford ins

The Uninsured Are Getting (at least some) Care Now Anyway

- Most of the uninsured receive health care (mostly in ERs) within each year regardless, &
- Almost all do so within five years (EMTALA)

- **When they do, 2/3 of the cost = already borne by others**

Uninsured Are Getting (inefficient) Care *Now*

- **These economic free riders already add an average $1,000/yr to the cost of everyone else's health insurance premiums**

The Big Unknown

- **Fate of the Obama health reforms**

The Big Unknown (cont.)

"If the Supreme Court hews to established law, **the only question it must answer in this case is modest:**

Did Congress have a rational basis for concluding that the economic effects of a broken health care system warranted a national solution?

The answer is incontrovertibly yes."

– NYT editorial, 3/27/2012

The Big Unknown (cont.)

If the Supreme Court does *not* hew to established precedent & strikes down the mandate

The cost containment issue will survive . . .

but most likely become exacerbated

Health Care Markets *Are* Different

"You can reason (about health care) from principle, but you also have to reason from facts, and messy reality."

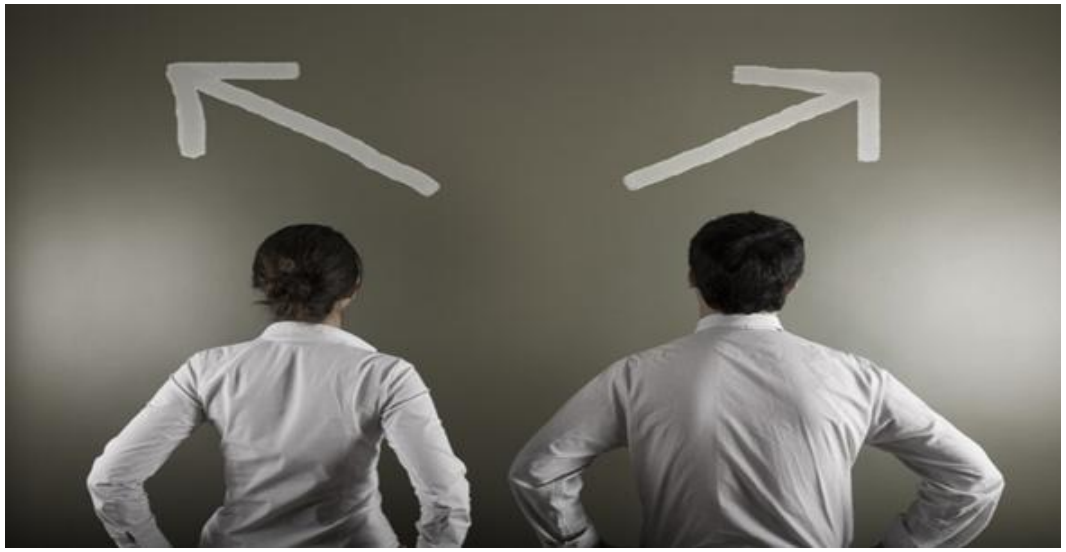
– **Fareed Zachariah, Editor at Large, *Time Magazine,* CNN host**

We Already "Ration" Care

- We just do it subliminally by pricing people out of an extremely complex health care delivery system

Subliminal Rationing

- **We're very good at making either/or (*allocation*) decisions**



- **But we avoid like the plague making outright yes/no (*rationing*) decisions**

The High-Altitude View

US spent about $2.7 *trillion* on health care in '11

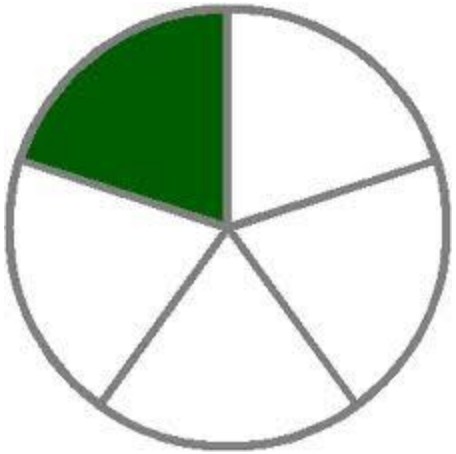
- **That's almost 18% of GDP**
- **= to $8700/*person* in the US**
  (twice the amt. spent in most European countries)

"We're # 37" in WHO rankings, *see* http://www.youtube.com/watch?v=yVgOl3cETb4

The High-Altitude View (cont.)

US health spending expected to grow @ 5.8% avg. annual rate thru 2020

- **1.1% faster than expected annual GDP growth**
- **By 2020 US health care spending expected to be about <u>1/5 of total economic output</u>**



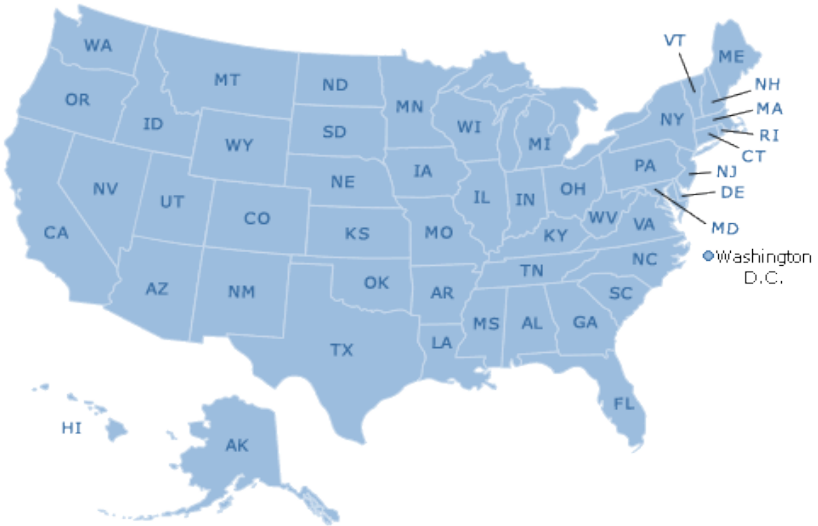
This Can’t Go On

“Edwina, we can’t go on propping each other up like this.”

Why Are We Spending So Much for So Little Health Improvement Return?

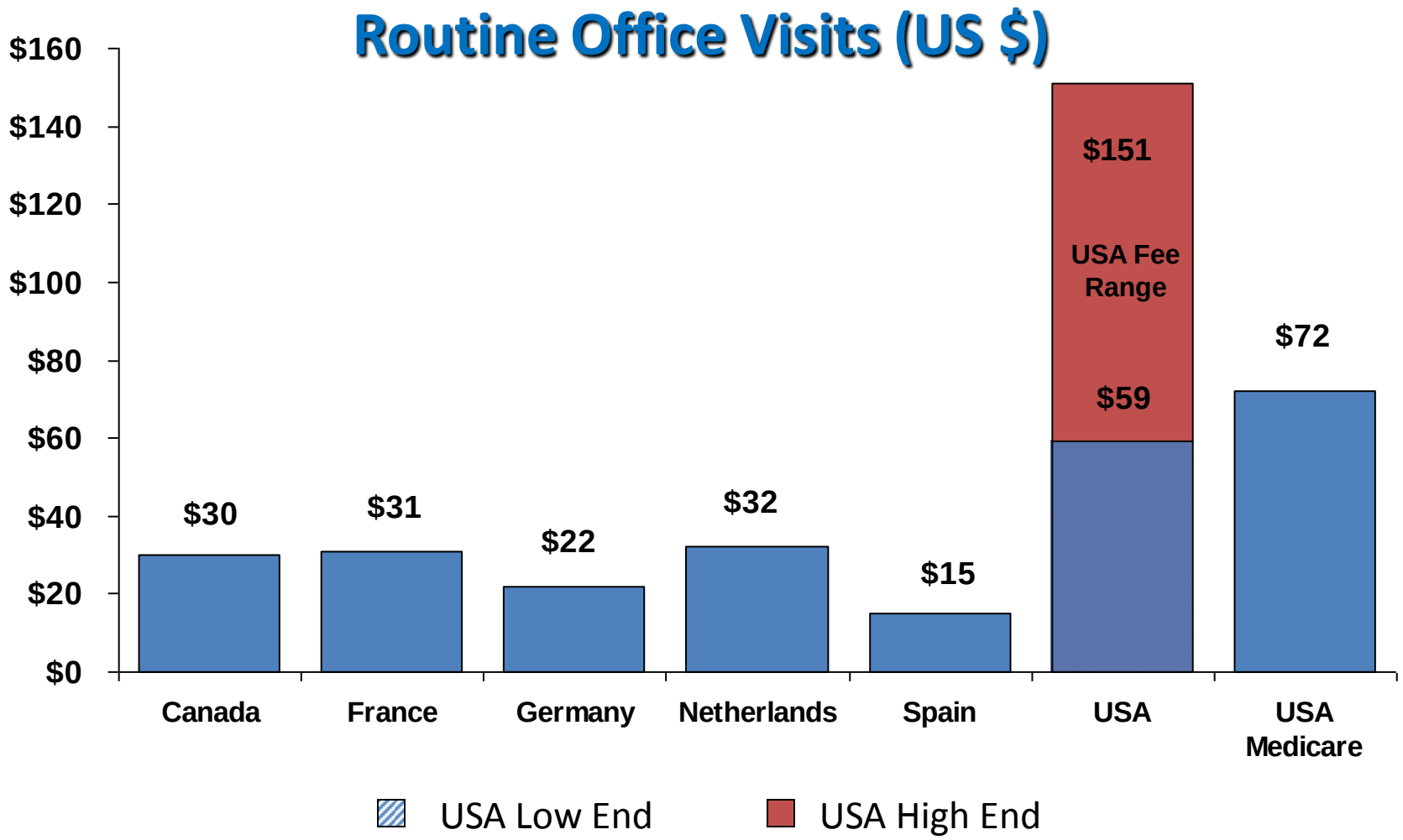
- Excess Utilization? Not really
- Expensive Technology? Yes
- Administrative Costs of Private Ins? Yes
- Medical Service Pricing? Yes

How Do US Medical Service Prices Compare With Canada & Western Europe?



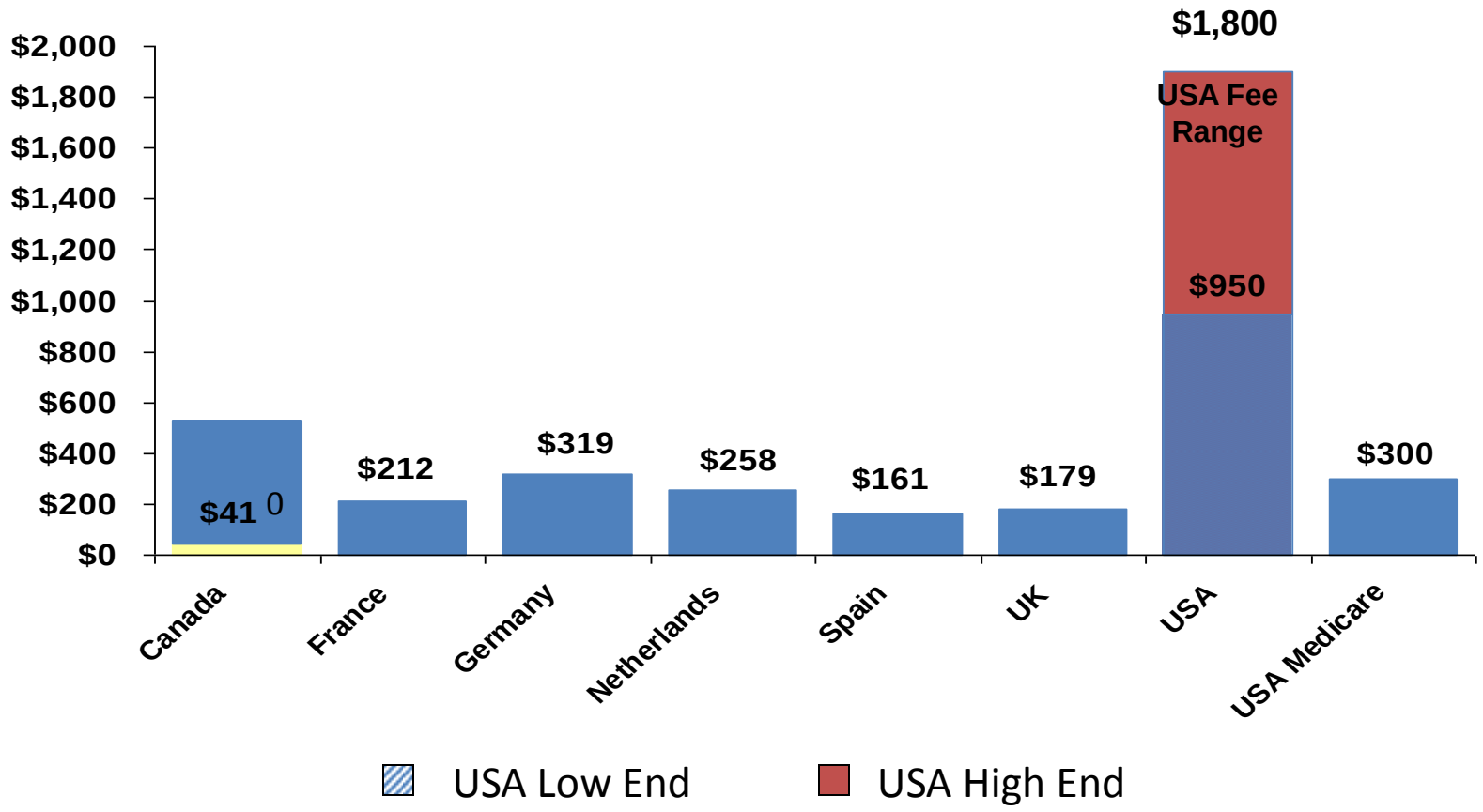
Source for next 5 slides: Internat'l Federation of Health Plans: Fee Report – Europe, Canada & USA

Physician Fees



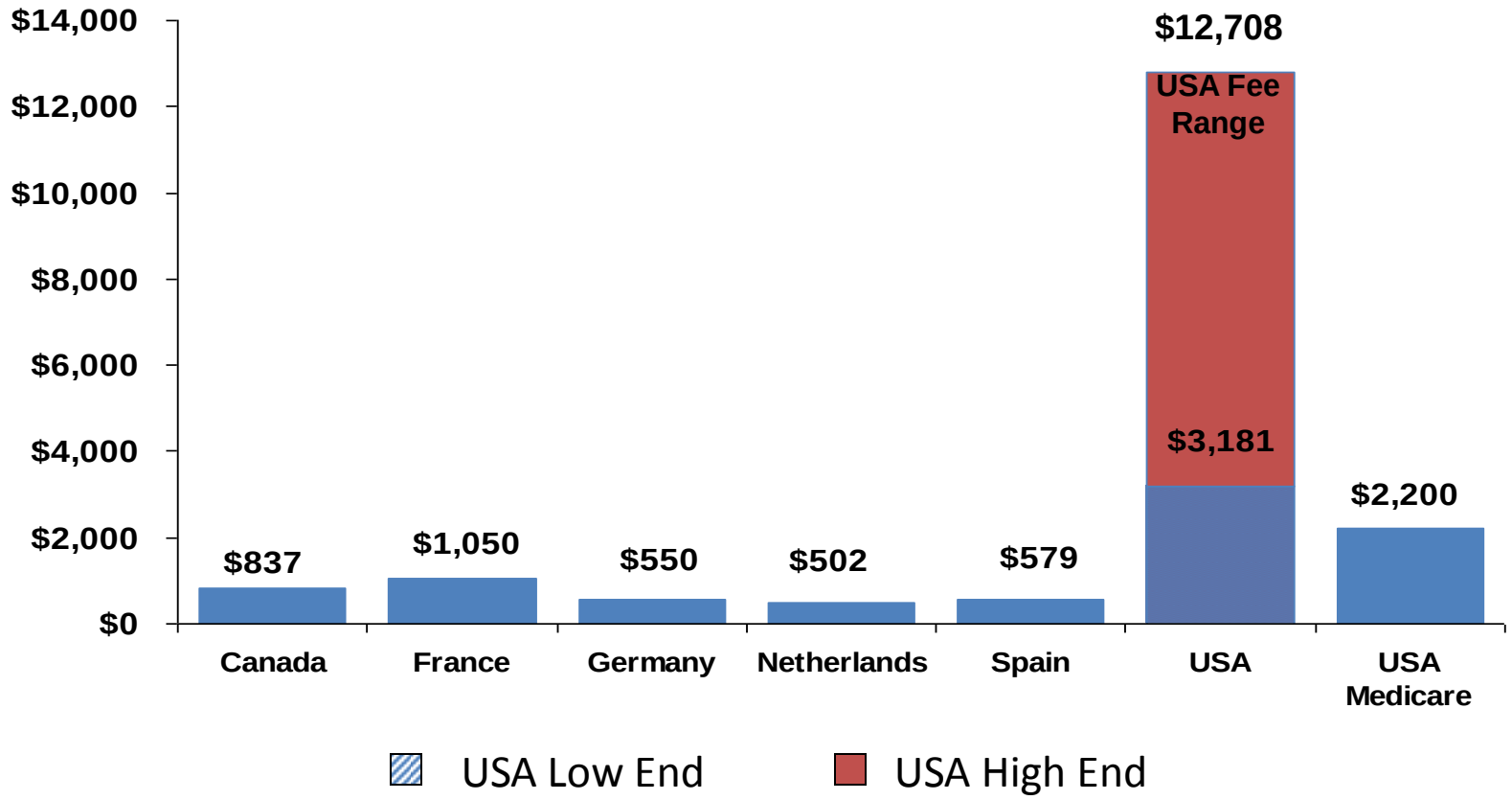
Scans and Imaging

CT Scan: Head (US $)



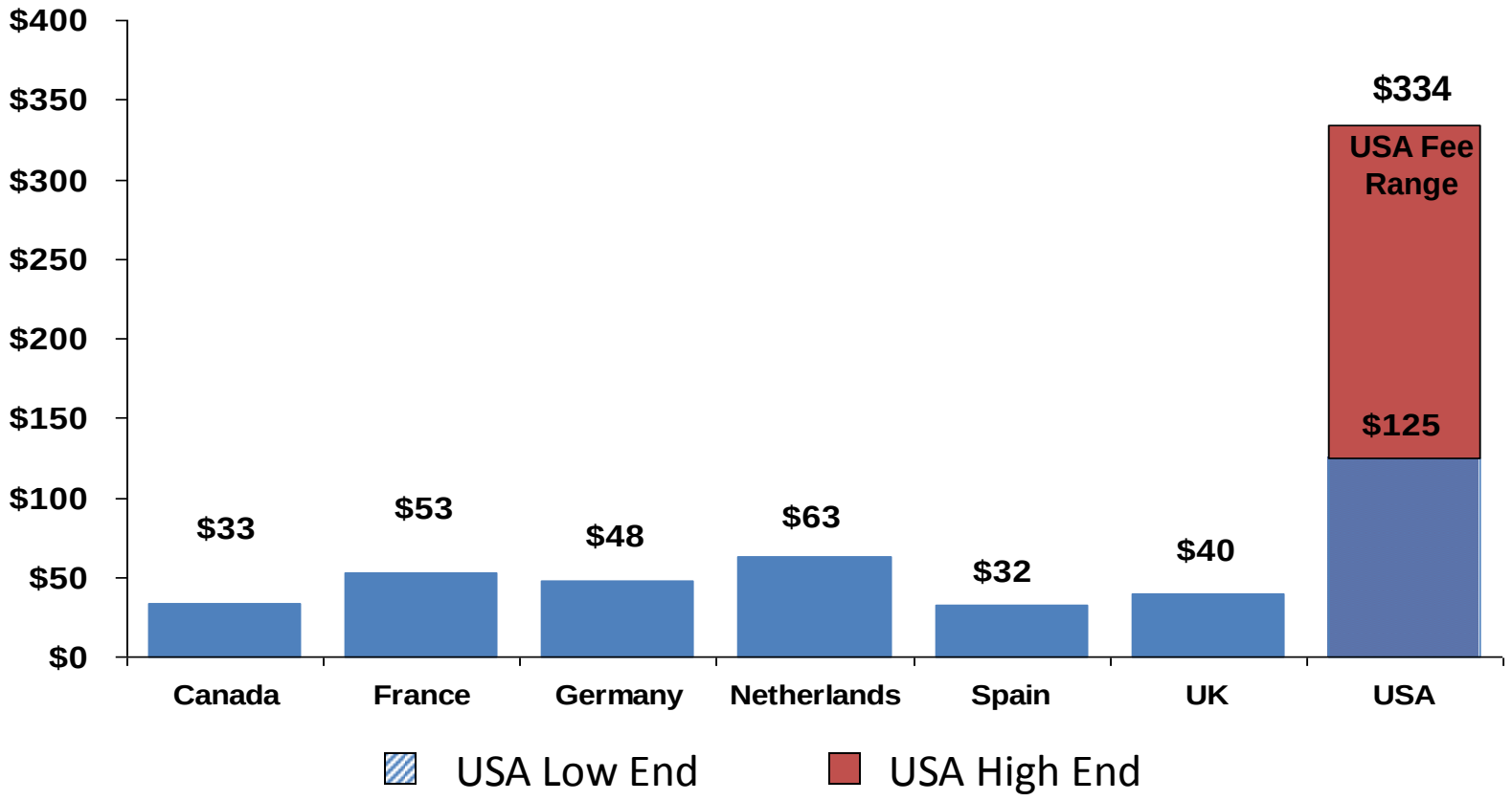
Hospital Charges

Average Cost Per Hospital Day (US $)



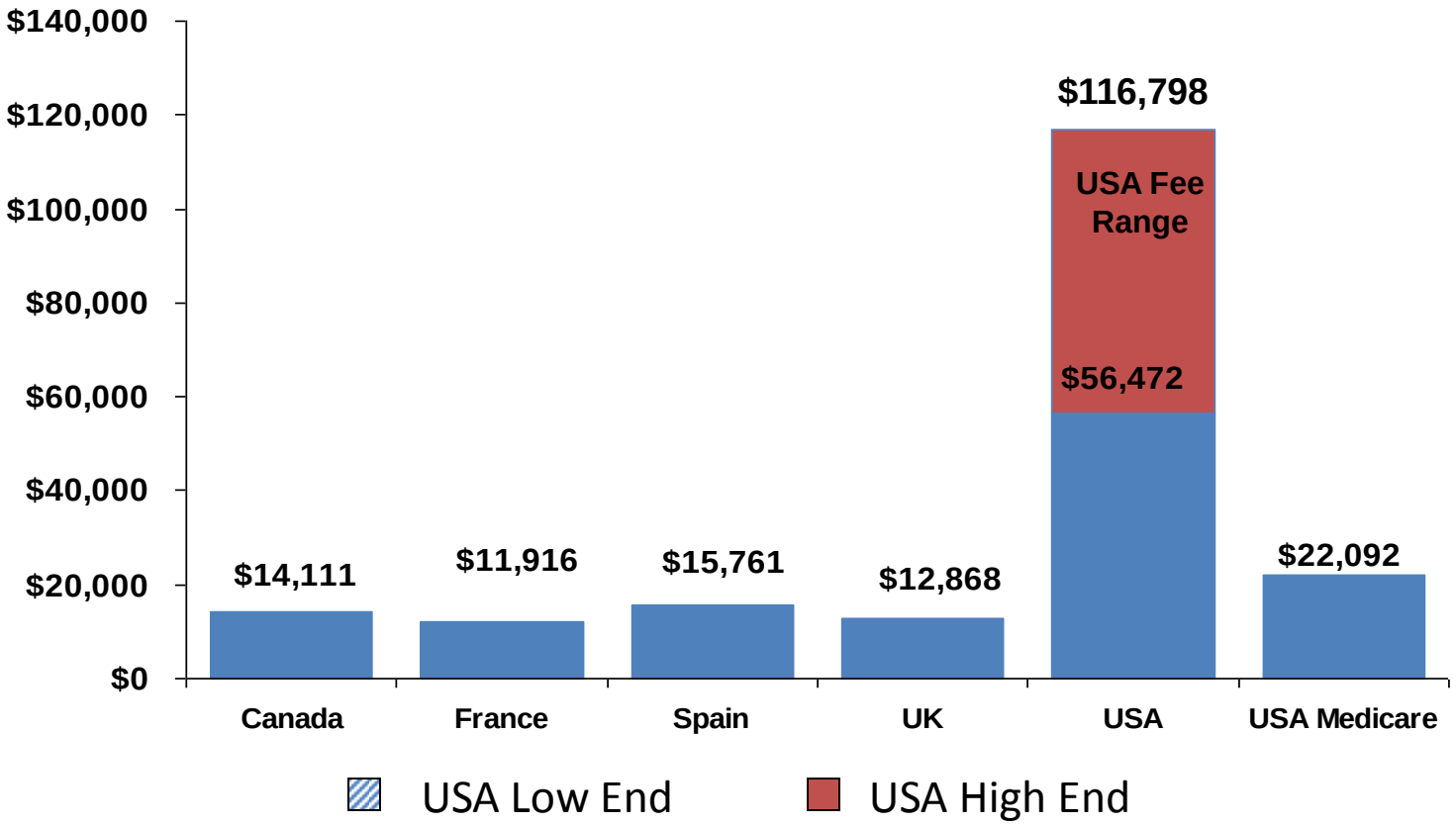
Drug Prices

Lipitor (US $ - before patent expired last fall)



Total Hospital & Physician Costs

Bypass Surgery (US $)



Why Are Prices So Much Higher In U.S.?

- Everyone In Health Care Earns More In U.S.
- Drugs and Devices More Expensive
- Administrative Costs of Mixed Public/Private System Much More Expensive
- Costs of Defensive Medicine
- Costs of Tighter Regulation
- Newer & More Expensive Delivery System
- Other???

So What Are We Doing About Health Care Spending?

1. Comparative Effectiveness
2. Personalized Medicine
3. Death & Dying
4. Payment Reforms

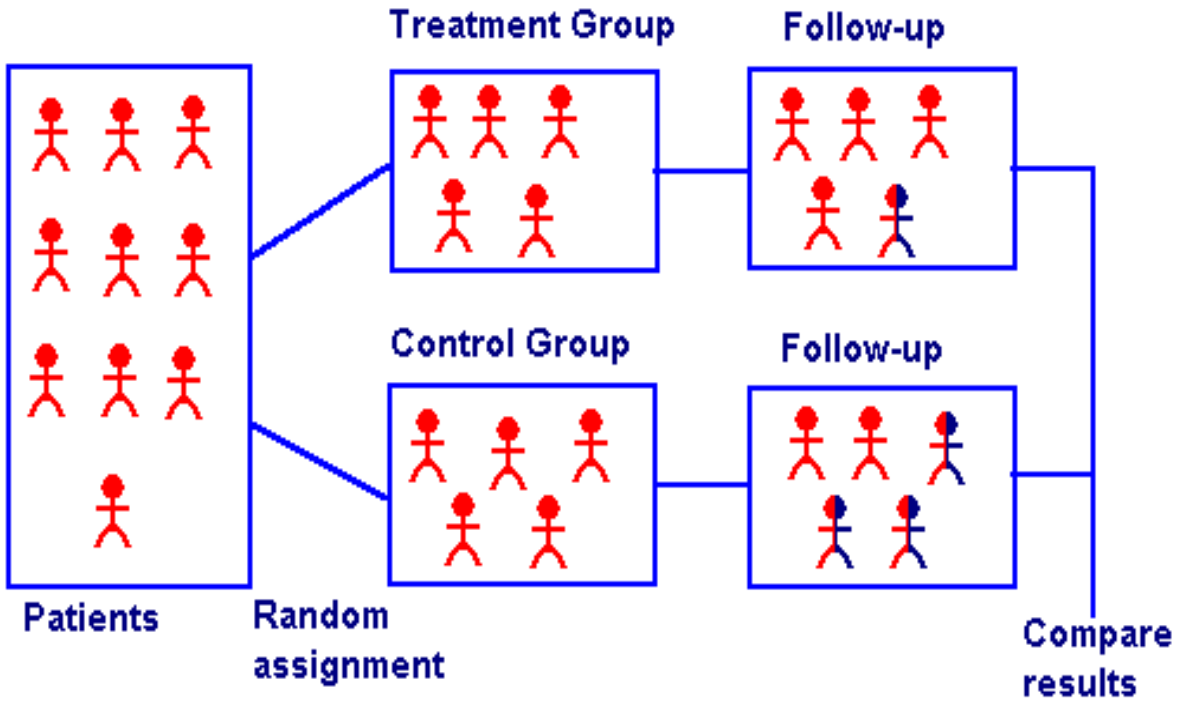
Donald Berwick, M.D.*

- **". . . All improvement is change, and human systems resist change . . . [I]mprovement requires a source of tension, discomfort with the *status quo,* sufficient to overcome this inertia."**

*** Former head of CMS**

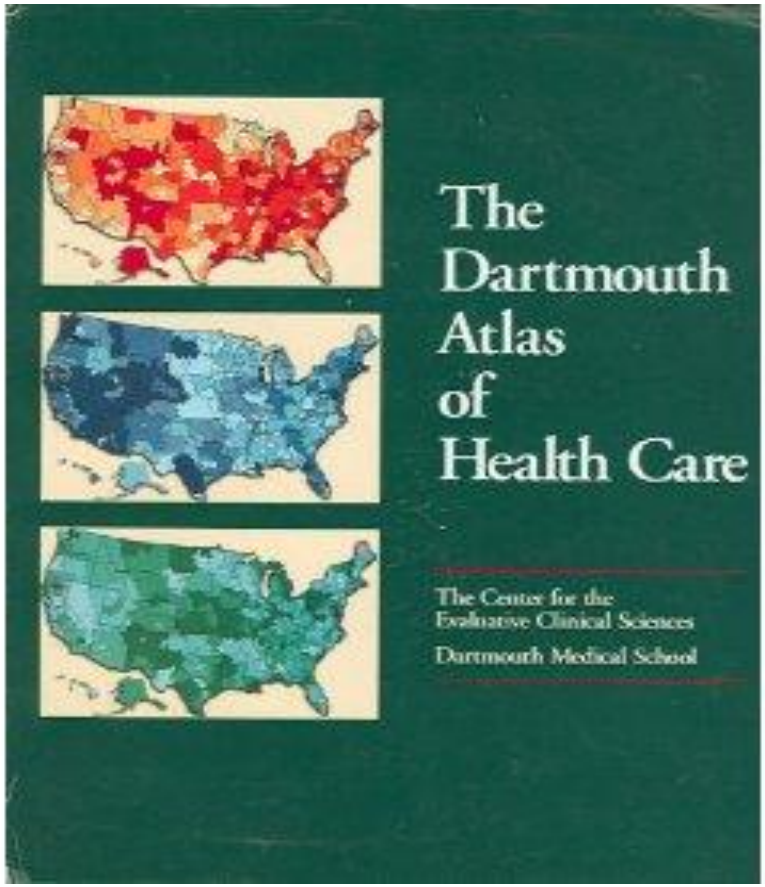
1. Comparative Effectiveness

- **Institute of Medicine estimates sound scientific studies support < 1/2 of current medical treatment**



Comparative Effectiveness

As a result, clinical practice varies widely, &



- **Providers may unknowingly deliver costly, ineffective & unnecessarily dangerous care**

Comparative Effectiveness Research

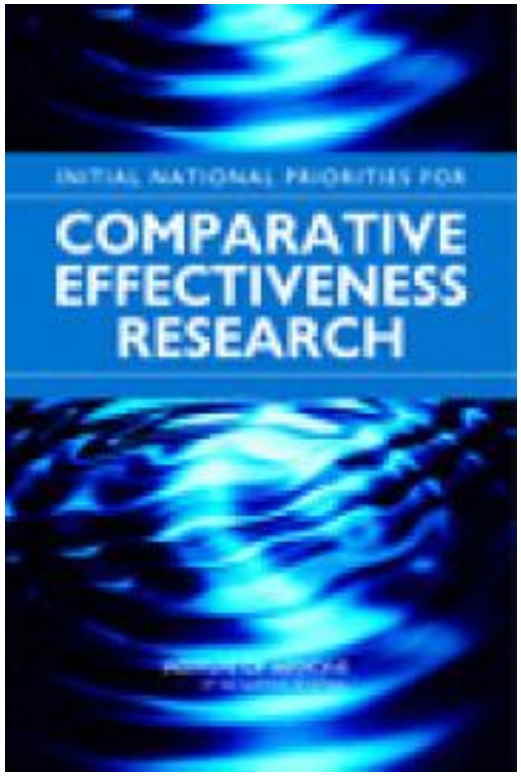
CER compares the effectiveness of *competing* health interventions

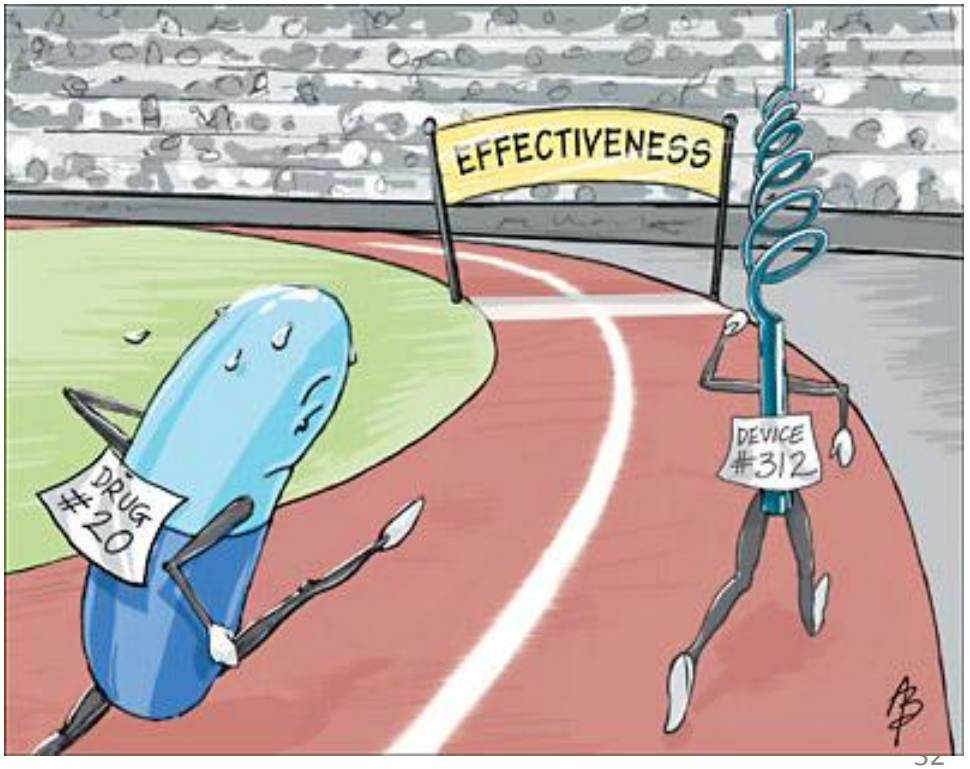
- **Evaluates the way different treatments fare *relative to each other***
- **Asks, "is this better than that?"**

Comparative Effectiveness: Excellent Overview in Oct. '10 Health Affairs

Patient Care Act:
Comparative Effectiveness Study Funding

- Established non-profit Patient-Centered Outcomes Research Institute to compare clinical effectiveness of medical treatments - $1.1 billion to fund studies





Comparative Effectiveness Research

Term has been a lightning rod for controversy

Easy to confuse with *cost* effectiveness

Which raises spectre of the R-word

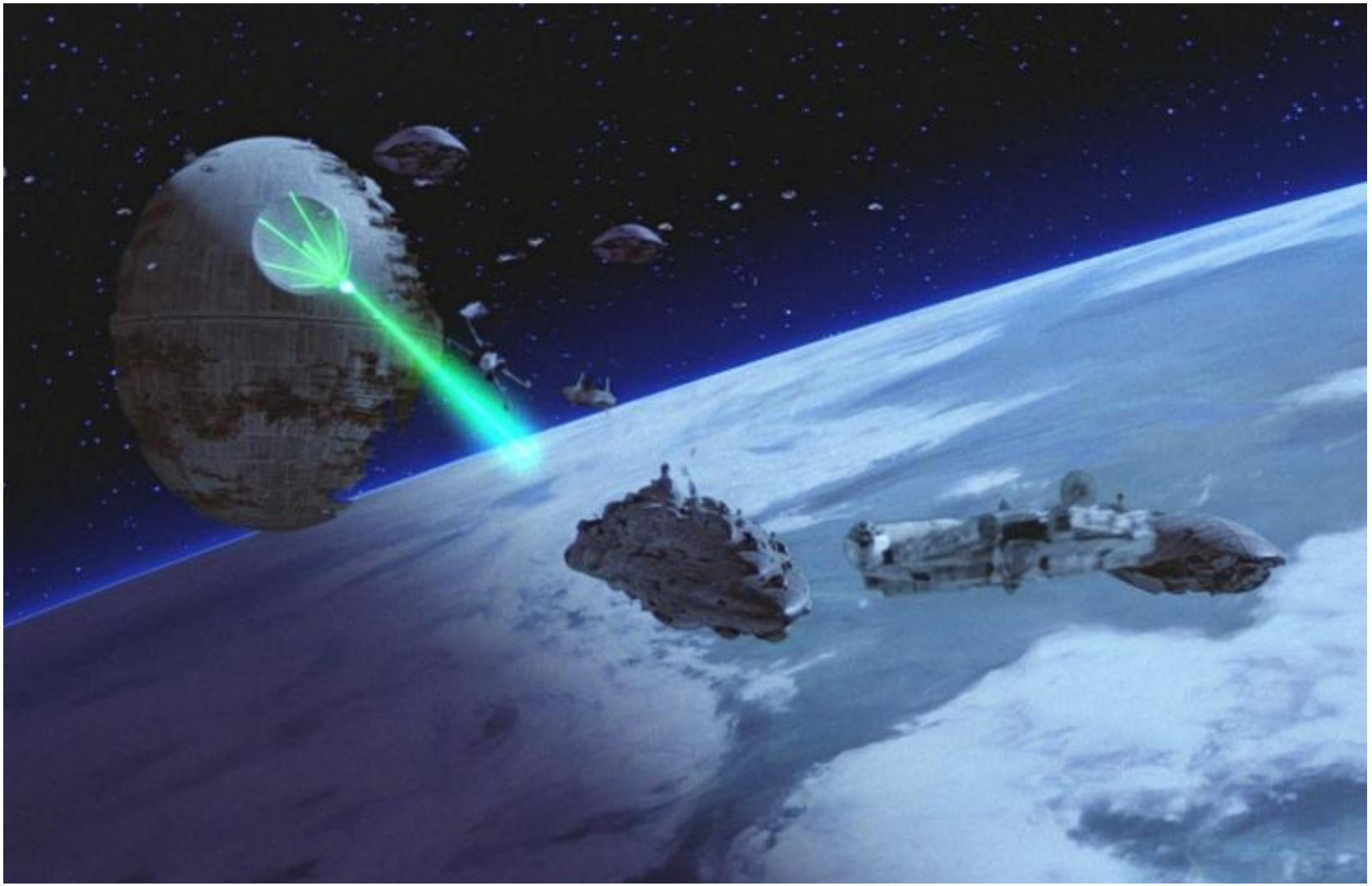
But PCA specifically prohibits Medicare from making coverage decisions "solely on the basis" of CER

To Keep the Debate Rational

Take proactive stance re getting value for $

- Shows "what works" (& what doesn't)
- Demonstrate cost saving potential
  - Emphasize: ***patient-centered medicine + effectiveness data = better care for individuals***

Proton Beam Therapy - the Death Star of American Medicine



Proton Beam Therapy (cont.)

One machine can generate up to $50M in annual revenue

Proton Beam Therapy (cont.)

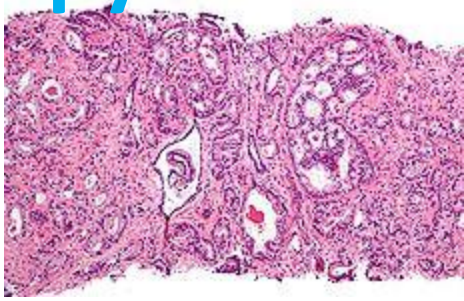
- **Uses narrowly focused proton beams to deliver precisely targeted radiation blasts**
- **Particle beams are delivered by 500-ton machines in facilities costing from $100 to $200M apiece**

Proton Beam Therapy (cont.)

- 10 facilities in operation now
- 7 more in construction & development
- Health care supply tends to create its own demand (information inequality)

Proton Beam Therapy (cont.)

- **Marketed now as prostate CA therapy**
  - **240,000 new cases dx'd/year**
  - **Claimed benefit = fewer side effects**



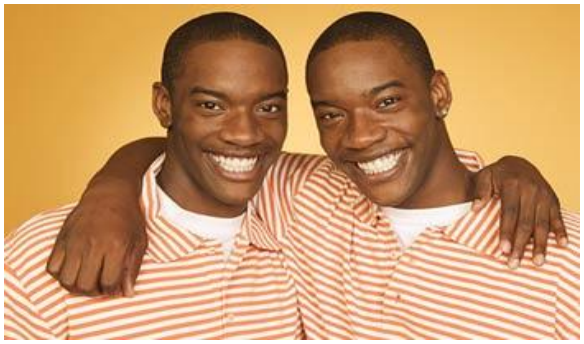
- **Typical treatment costs about $50,000**
  - **twice as much as traditional radiation therapy**
  - **usually covered by Medicare or private insurance**

Proton Beam Therapy (cont.)

U.S. Agency for Healthcare Research & Quality

2009 report on 243 pub. articles concluded:

- only a handful of studies compared proton therapy to standard treatment, &
- "no trial reported significant differences in overall or cancer-specific survival, or in total serious adverse events."



- *See also* Jacobs, et al, *Growth of High-Cost Intensity-Modulated Radiotherapy for Prostate Cancer Raises Concerns About Overuse,* Health Affairs, April 2012, 31:4

"Issues In Cancer Care: Value, Costs & Quality."

- **Excellent overview in hot-off-the-press April 2012 issue of *Health Affairs,* incl:**

- **'Swinging For The Fences' Versus Striking Out On Cancer**
- **An Analysis Of Whether Higher Health Care Spending In The United States Versus Europe Is 'Worth It' In The Case Of Cancer**
- **Patients Value Metastatic Cancer Therapy More Highly Than Is Typically Shown Through Traditional Estimates**
- **Therapies For Advanced Cancers Pose A Special Challenge For Health Technology Assessment Organizations In Many Countries**
- **In A Survey, Marked Inconsistency In How Oncologists Judged Value Of High-Cost Cancer Drugs In Relation To Gains In Survival**
- **Appropriate And Inappropriate Imaging Rates For Prostate Cancer Go Hand In Hand By Region, As If Set By Thermostat**
- **Growth Of High-Cost Intensity-Modulated Radiotherapy For Prostate Cancer Raises Concerns About Overuse**
- **End-Of-Life Care For Medicare Beneficiaries With Cancer Is Highly Intensive Overall And Varies Widely**
- **Changing Physician Incentives For Cancer Care To Reward Better Patient Outcomes Instead Of Use Of More Costly Drugs**

2. Personalized Medicine

Most prescription drugs are effective in only about 60% of pts

But science can now define individuals "at a more granular and molecular level than ever before imaginable."

Personalized Medicine, cont.

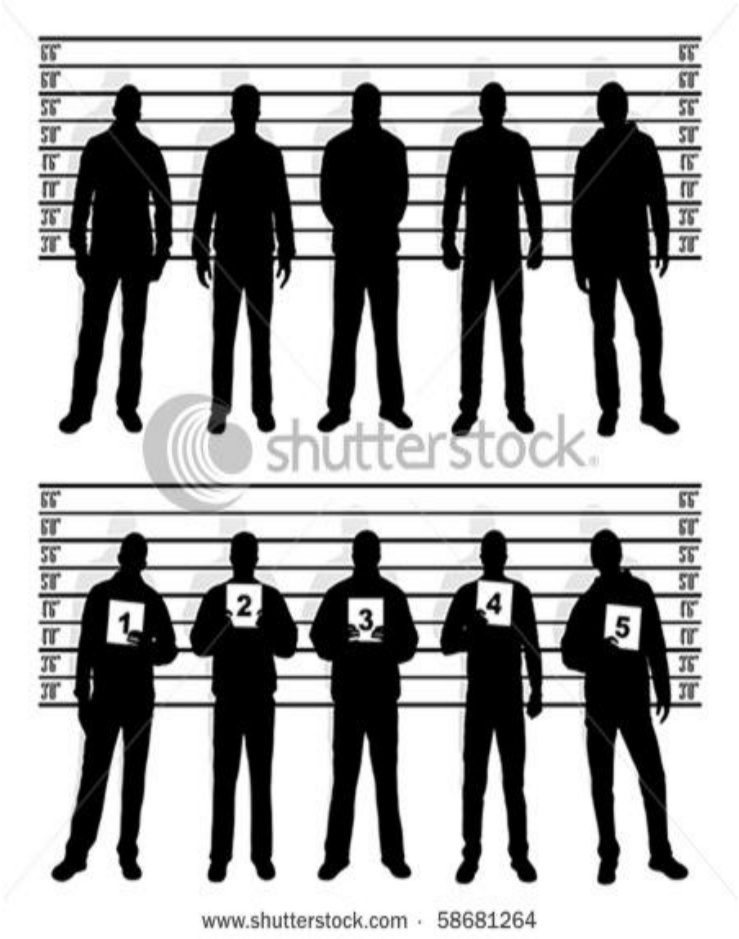
Pharmacogenetics (Pgx) = study of way genes cause different drug responses

- **Human Genome Project finished a decade ago**
- **As more genomes scanned, scientists "drowning in data"**

Genetic Testing

PGx tests can identify (some) individuals:

1. for whom a drug may be most efficacious
2. who are most at risk for adverse events
3. who are unlikely to benefit from treatment
4. whose genes indicate dosing modifications



Personalized Medicine

- → designer drugs, fewer one-size-fits-all pharmaceuticals?

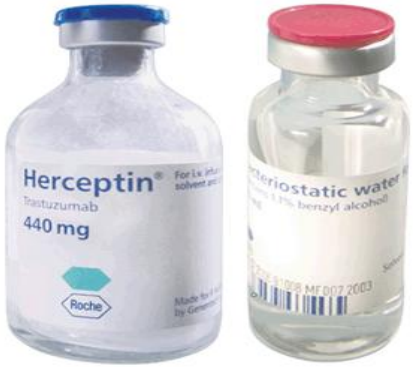
- **Goal: "The right drug for the right person at the right time"[1]**

[1] http://mobile.reuters.com/article/healthNews/idUSTRE65N2WK20100624

Personalized Medicine - Genetic Testing

FDA approves genetic tests for labeling of 95+ drugs

- **Some drugs work specifically with certain genotypes**
  - **Herceptin - breast cancer = only drug where genetic test now *required* before Rx**



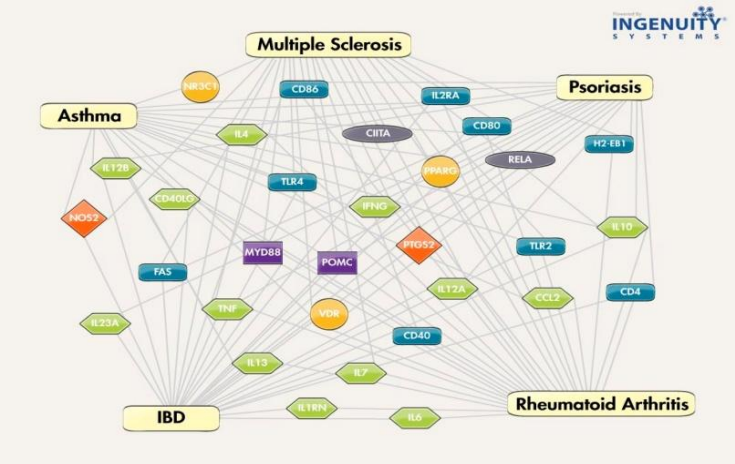
  - **Abacavir - AIDS, genetic test recommended, *but not req*, before Rx.**

Personalized Medicine - Genetic Testing

Other drugs employ genetic tests to improve dosing

–Warfarin (anti-coagulant)

- Most drug labeling just *mentions* heredity or genetic pathways with which drug interacts, but no “advice”



Personalized Medicine: Pharmacogenetics

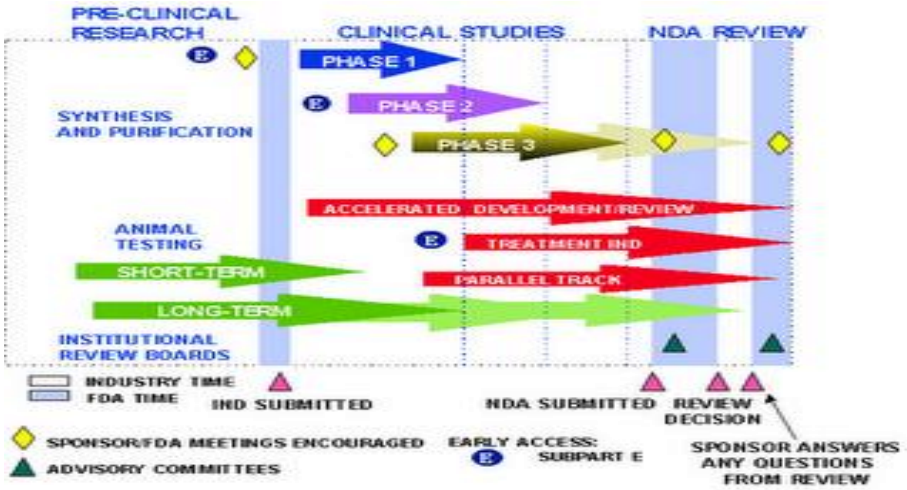
Feb. 2012 FDA approved Kalydeco,

- Treats cystic fibrosis patients > 6 yrs old
- With genetic mutation G551D
- 4% of cystic fibrosis pts have it = 1200 people in US
- Costs $294,000/year/patient = $360 *million*/yr

kalydeco™
(ivacaftor) tablets

Impact of FDA Drug Approval

NDA = pre-requisite for marketing (reasonable safety & efficacy)



But NDA not a guarantee of reimbursement* (medically necessary)

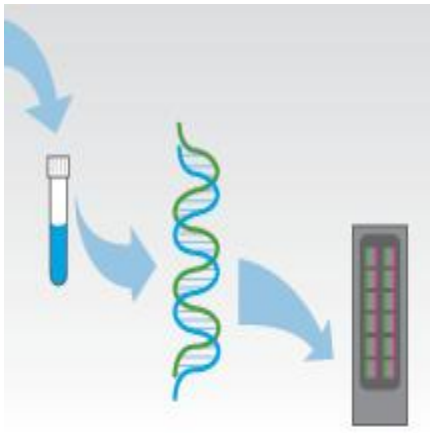
* *See* DA Messner & SR Tunis, *Current and Future State of FDA-CMS Parallel Reviews,* 91 Clinical Pharmacology & Therapeutics, March 2012

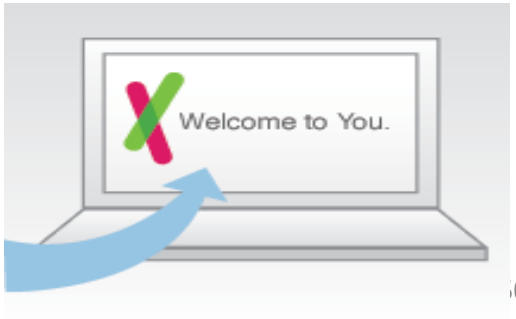
Direct-to-Consumer Genetic Testing (Q: DIY DNA to what end?)

23andMe

"Here's what you do:

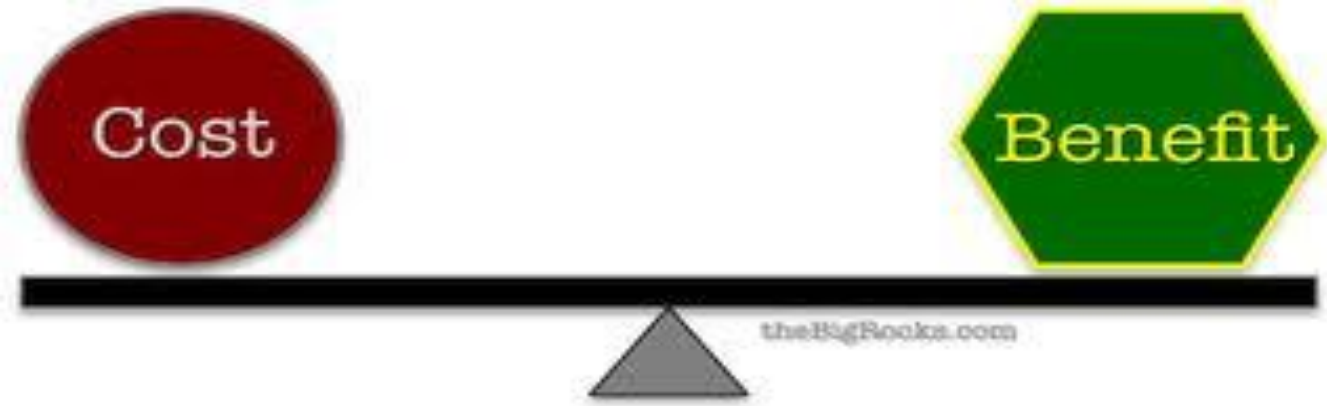
- 1. Order a kit from our online store. ($99)
- 2. Register your kit, spit into the tube, and send it to the lab.
- 3. Our CLIA-certified lab analyzes your DNA in 6-8 weeks.
- 4. Log in and start exploring your genome."





Personalized Medicine, cont.

- **The big (implicit) Q:**
  - **Are Pgx cost-effective enough yet to be marketed and/or reimbursed?**

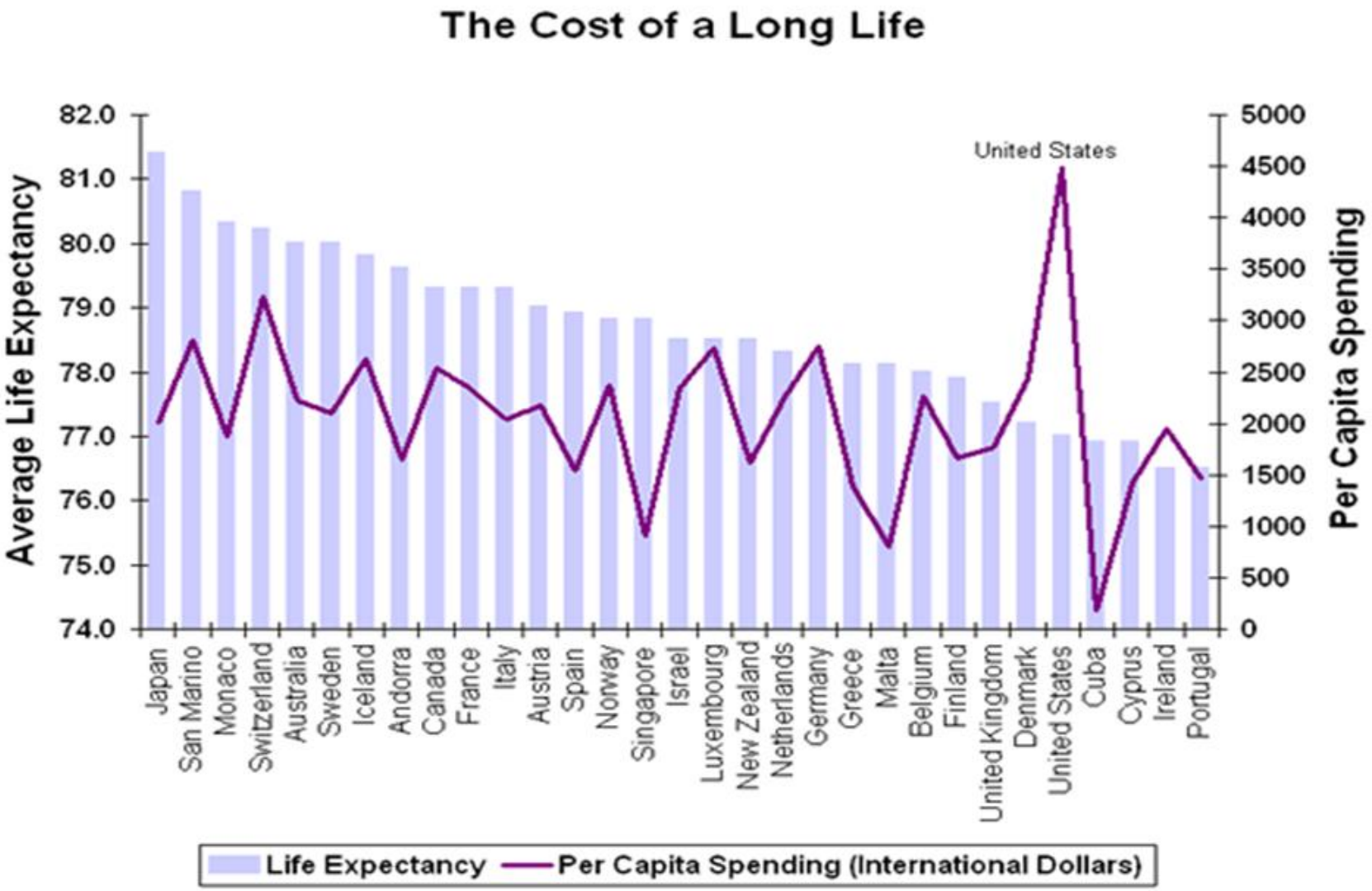


This May Help

Supreme Court March 20 ruling (9-0) that medical tests relying on correlations between drug dosages & treatment are *not* eligible for patent protection

-Mayo v Prometheus Labs, _ US _ (2012)

3. End-of-Life Care

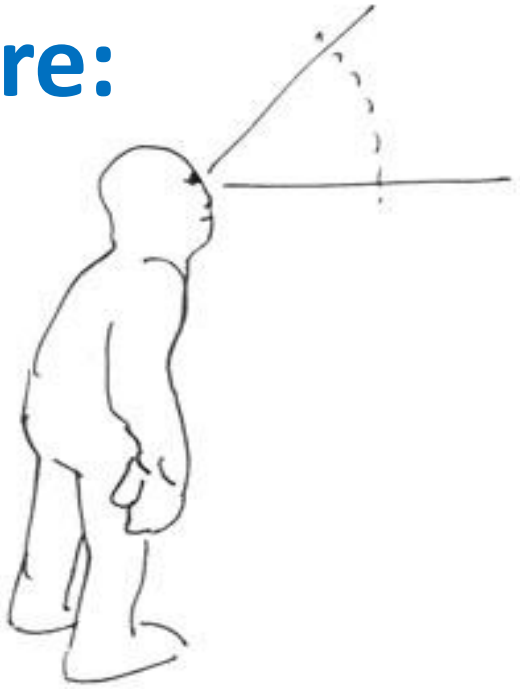


End-of-Life-Care

- 1/3 of Medicare budget = spent on end-of-life care
- 1/3 of that amt = spent in last 1-2 mos of life
- **Medicare population projected to grow by 1/3 in next 10 yrs.**

End-of-Life-Care: The Big Question

- **When is it appropriate to shift the focus of medical care:**



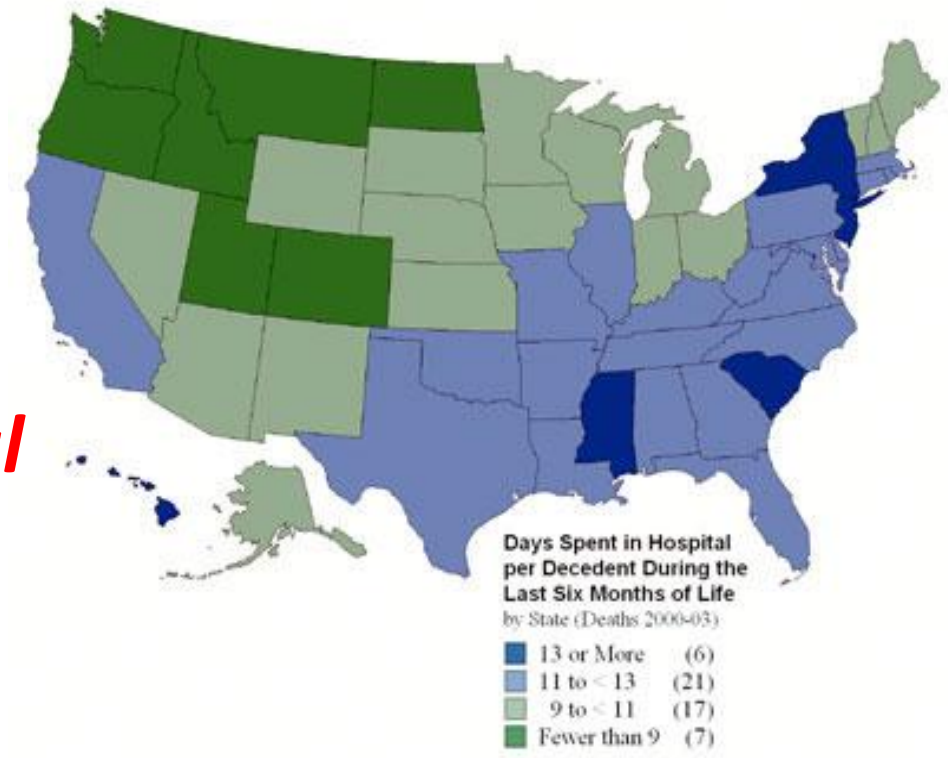
  - **from prolonging *dying***
  - **to protecting the quality of the dying process?**

Patient Preferences re End-of-Life Care

"Average patients confronted with poor survival chances prefer spending as much time as possible in home-like setting with good pain control"*

But only 54% of cohort received *any* hospice care in last month of life

And 55% died *in hospital*



*Morden, *et al, End-of-Life Care for Medicare Beneficiaries w Cancer Is Highly Intensive Overall and Varies Widely, Health Affairs 31, No. 4, 2012*

Patient Preferences re End-of-Life Care

Patients often prefer more conservative end-of-life care than they actually get, &

Understanding the following measures can improve their situation

- Advance Directives
- Medically futile treatment
- Palliative sedation
- Physician-assisted suicide

Advance Healthcare Directives*

- **Allow people to give instructions re health decisions when unable to make their own**

  - **Including directions to apply, continue, withhold or withdraw artificial food & hydration**
  - ***See* Hawaii's Uniform Health-Care Decisions Act (1999)**

Advance Healthcare Directives*

- **Allow people to name *someone else* to make health decisions for them**

  - **Including decisions to apply, continue, withhold or withdraw artificial food & hydration**

***See* Hawaii's Uniform Health-Care Decisions Act (1999)**

Medical Futility: Definition

Medical treatment that:

1. **has no realistic chance of providing therapeutic benefit patient can perceive or appreciate; or**
2. **has no realistic chance of returning patient to survival without acute care; or**
3. **has no realistic chance of meeting patient's own goals***

*** Evidenced by advance directive or other clear & convincing evidence**

Palliative Sedation

- **Pain relief = comfort measure for the dying**

Legitimate, humane, end-of-life care

Physician Assisted Suicide

- **No slippery slope discernible in 3 states which allow PAS**
  - **Oregon***
  - **Washington**
  - **Montana**
- **Georgia joined their ranks in Feb**

- **Steady 1/5 of 1% of Oregon deaths for past 15 years were PAS**

4. Payment Reforms

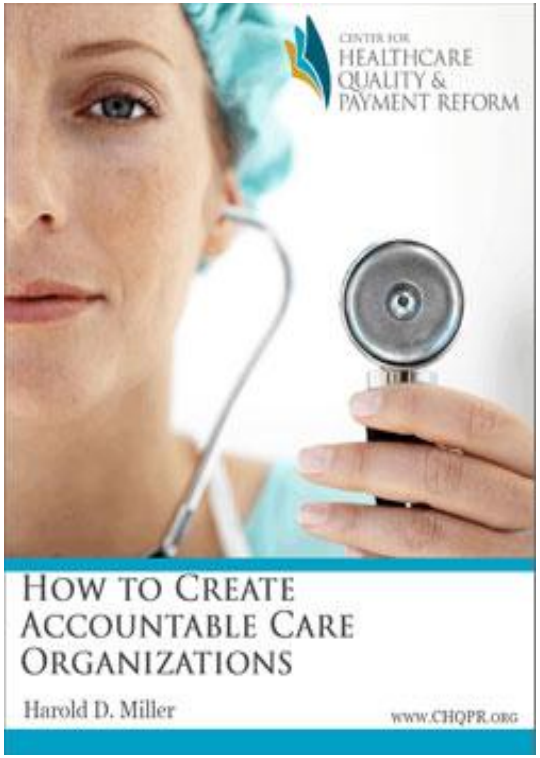
- Pay for Performance (P4P)
- Global budgeting
- Accountable Care Organizations (ACOs)
- Independent Payment Advisory Board

Pay for Performance

- Leapfrog Group
- Never Events
- Quality Metrics
- Incentives

Accountable Care Organizations

- Patient-centered care
- Greater accountability for patient outcomes
- Require paradigm shifts in management style
- Require ⇧ investment in health information technology



Global Budgeting

- Provider autonomy

- Is it any more than capitation in drag?

Independent Payment Advisory Board

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

The Independent Payment Advisory Board

Timothy Stoltzfus Jost, J.D.

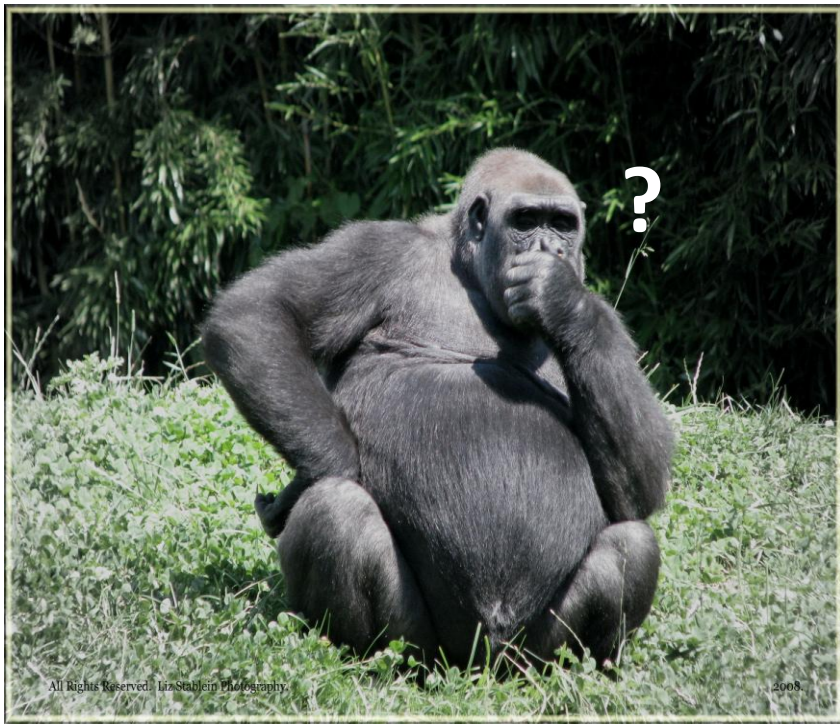
A common theme in the health care reform debate in recent years has been the need for a board of impartial experts to oversee the health care system. Market forces alone, it is argued, cannot control health care costs, and Congress is too driven by special-interest politics and too limited in expertise and vision to control costs.

Provisions of the Patient Protection and Affordable Care Act (now being referred to as the Affordable Care Act, or ACA) create an Independent Payment Advisory Board (IPAB) to meet the need to oversee health care system costs.[1] The legislation establishes specific target growth rates for Medicare and charges the IPAB with ensuring that Medicare expenditures stay within these limits. The IPAB must also make recommendations to Congress as to how to control health care costs more generally.

The IPAB will have 15 members appointed by the President for 6-year terms, supplemented by 3 officials representing the Department of Health and Human Services (DHHS). IPAB members are supposed to be nationally recognized experts in health finance, payment, economics, actuarial science, or health facility and health plan management and to represent providers, consumers, and payers. Service on the IPAB is a full-time job. Members will be compensated at a rate equal to the annual rate prescribed for level III of the executive schedule (for highly ranked appointed positions in the government's executive branch), which is currently $165,300.[2]

The board is charged with developing specific detailed proposals to reduce per capita Medicare spending in years when spending is expected to exceed target levels, beginning with 2015. The DHHS must implement these proposals unless Congress adopts equally effective alternatives. The board is also charged with submitting to Congress annual detailed reports on health care costs, access, quality, and utilization. Finally, the IPAB must submit to Congress recommendations regarding ways of slowing the growth in private national health care expenditures.

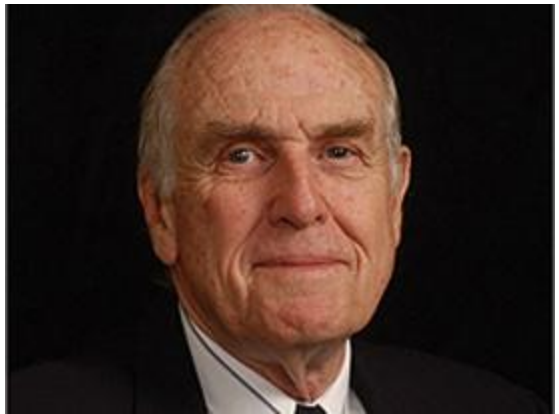
Each year, beginning April 30, 2013, the chief actuary of the Centers for Medicare and Medicaid Services (CMS) will make a determination as to whether the projected average Medicare growth rate for the 5-year period ending 2 years later will exceed the target growth rate for the year ending that period. For years before 2018, the target growth rate is the projected 5-year average of



Too Little, Too Late?

- **"We cannot expect change will be generated within the system; there is not enough desire for change, as opposed to desire on the part of too many stakeholders not to change.**

- **Because we are reaching a crisis and the only thing that will solve it is enormous change, we will have enormous change."**



- Victor Fuchs, Stanford Health Economist

Is Hawaii Ready for Single Payer?

- March 2009 Hawaii Medical Ass'n resolution supports single payer

- Dec. 2011 Hawaii Health Authority report to Gov & Legis proposed principles for cost-effective health care + strategic plan for comprehensive, universal health program
- http://hawaii.gov/budget/hha-1

Alexis de Tocqueville on American Progress

"In the United States things move from the impossible to the inevitable, never stopping at the probable."

Q: Is that still true?