Quo Vadis?

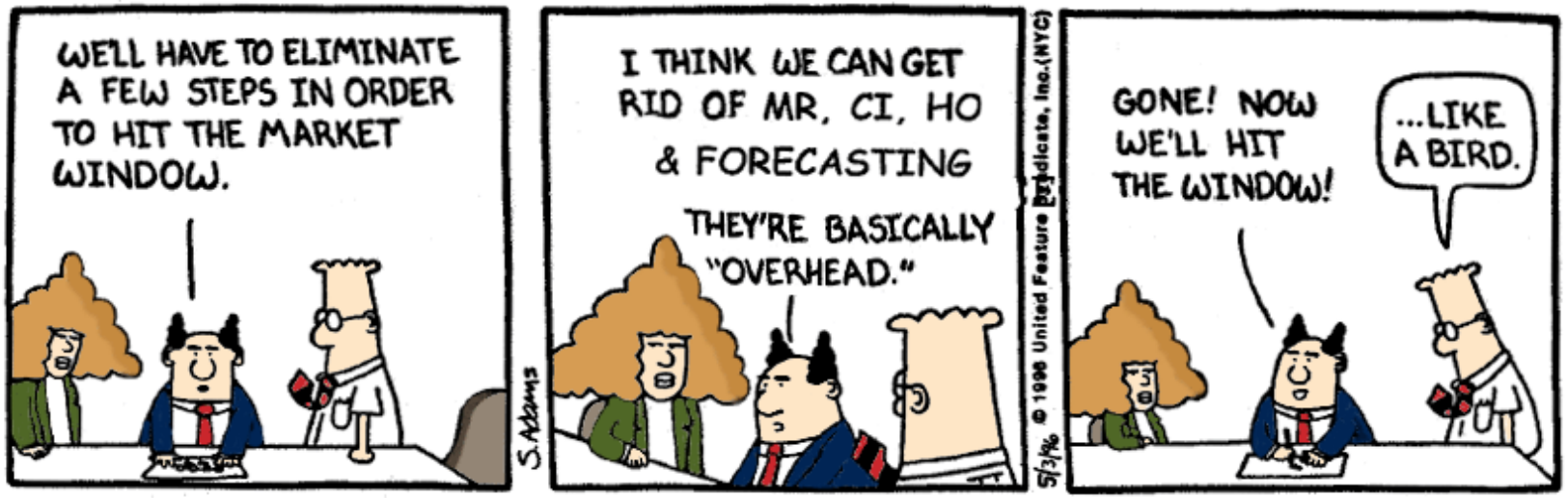
Healthcare Reform in the USA

Charlotte Sibley and Daniel Hoffman

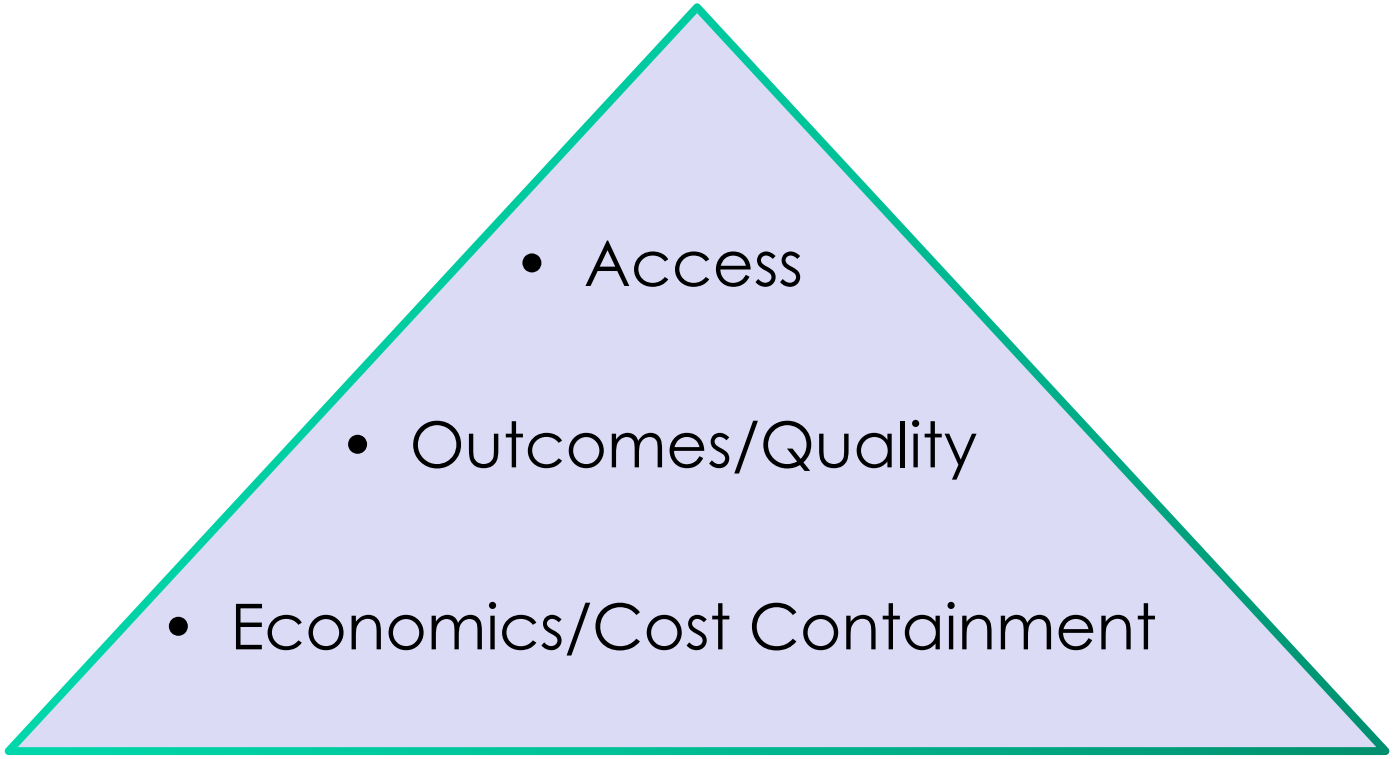
June 2011

Why Do We Exist?

- Bring clarity to issues
- Define the issue
- Provide objectivity
- Be the VOC (Voice of the Customer)
- Develop event-based strategic forecasts
- Minimize surprises
- Provide objective assessments of opportunities
- Deliver actionable recommendations
- Reduce the risk around decisions


WE'LL HAVE TO ELIMINATE A FEW STEPS IN ORDER TO HIT THE MARKET WINDOW.
I THINK WE CAN GET RID OF MR, CI, HO & FORECASTING
THEY'RE BASICALLY "OVERHEAD."
S.Adams
5/3/96 © 1996 United Feature Syndicate, Inc.(NYC)
GONE! NOW WE'LL HIT THE WINDOW!
...LIKE A BIRD.

Key Goals of Any Healthcare System



These constitute the *Triangle* of healthcare

How does the U.S. perform?
….. on Access? *Grade = D*

- **Health insurance is 100% voluntary**
  - 46% insured through employers
  - 25% Medicare/Medicaid
  - 11% insured independently
- **52 million Americans lack health coverage = 1 in 6**
  - 1 in 3 in some states
  - 9 million lost coverage in the recent recession
  - ~ 5 million are one paycheck away from losing coverage
  - Health care traditionally seen in USA as a "privilege", not a right
  - Number *and %* uninsured have been increasing for years
- **20% of Americans report barriers to care**
- **1 in 5 Americans has no "family doctor"**

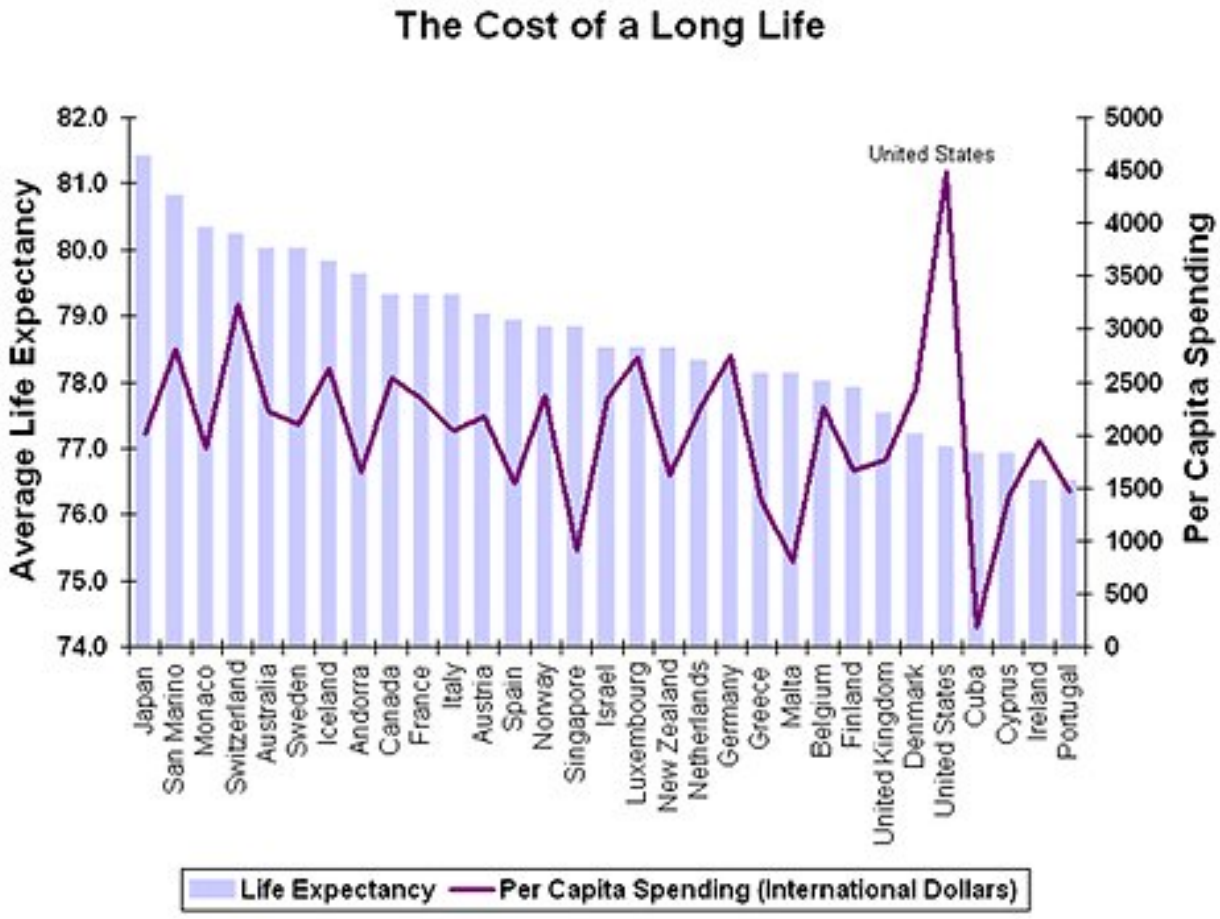
..... on Outcomes and Quality? *Grade = D*

- WHO ranks the U.S. as 37th, reflecting:
  - Infant mortality: rank 29th
  - Life expectancy: rank 34th, just ahead of Cuba
- Wide variation in quality of care across the U.S.
- 30% of spend is for useless or potentially harmful care
- We have the highest number of deaths that could have been prevented by good healthcare
- We are the heaviest people on the planet!!
- And, here come the Boomers!!
  - 16% of population will be over 65 in 2020 vs. 7% in India
  - Boomers expect and will demand the best

….. on COST? *Grade = F!*

- The U.S. spent ~$2.5 trillion in 2009
  - Drugs represent ~10%
  - Biotech drugs estimated to be 50% of drug budget in 2020
- Healthcare spend accounts for 18% of GDP
  - And increasing faster than the CPI
  - At current rate, will consume 100% of GDP by 2060!
- The U.S. spends 2-3X more per capita than any other country (~$8,100) – especially at end of life
- Ranks 54th in fairness of financial contribution to the healthcare system (WHO World Health Report, 2000)
- Rising healthcare costs helped destroy the auto industry
  - GM was a healthcare company that made cars
- And has resulted in flat wages since the 1980s

….. COST: *Grade = F! (cont'd)*



EphMRA
www.ephmra.org

Stepping it up

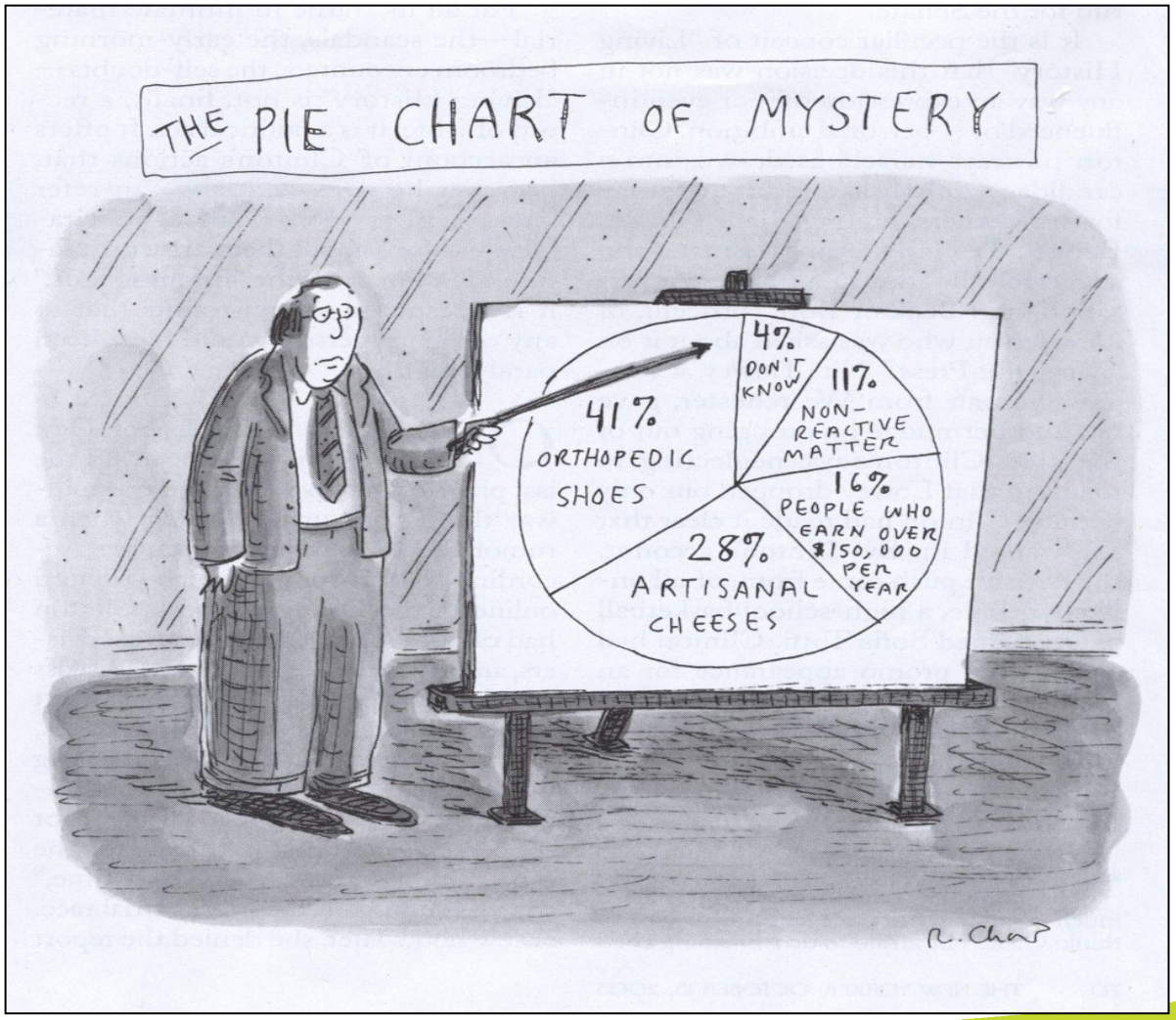
What is the U.S. Doing to Improve?

Patient Protection and Affordable Care Act (ACA) of 2010: Key Provisions

- Requires everyone to buy health insurance from private carriers
- No one can be excluded for pre-existing conditions
- No limits on lifetime benefits
- Medicaid / Children's health coverage expanded
- Money for electronic medical records (EMRs)
- "Wellness" and "Prevention" enter the lexicon
- Accountable Care Organizations (ACOs)
  - "The Decider"

Status of Reform Today

- It will not be repealed
- But there are challenges
  - Republicans will try to change or eliminate some provisions
    - Eliminate Medicare?
  - Understanding: 22% think it has already been repealed
  - Acceptance: 46% want it repealed
  - "Greedy Geezers" seniors are very opposed …and they vote
- Expanding Medicaid will cost the States ~$120 billion over 10 years
  - And many states are broke!!
- Democrats may want ACA to fail
  - So we can start all over


THE PIE CHART OF MYSTERY
41% ORTHOPEDIC SHOES
4% DON'T KNOW
11% NON-REACTIVE MATTER
16% PEOPLE WHO EARN OVER $150,000 PER YEAR
28% ARTISANAL CHEESES
R. Chast

Projected Effects on Costs

- Certain to increase costs
  - Estimated $1 trillion over 10 years
- Insurers receive **gift** of captive market with no constraints on premiums
  - Must insure people with pre-existing conditions but no limits on differentially higher premiums...and will there be exemptions??
- Same or smaller supply of providers but increased demand from >30 million new patients
- ~ 50% of Americans are insured through employers
  - Premiums to employers will increase...and more cost shifting to employees, i.e., higher employee premium contributions and co-pays

➔**LAW OF SUPPLY AND DEMAND**

Projected Effects on Quality

- Quality disparities likely to be exacerbated
  - Existing variations in procedural approaches by region and population likely to increase
- Focus on quality *may* improve adherence
- Comparative Effectiveness …is still in the future
- Integrated Electronic Medical Records .. are still in the future
- We might get serious about “wellness” and “prevention”

Projected Effects on Access

- Medicaid and employers' contracts with private insurers will contain:
  - More restricted drug options
  - More restrictions on devices, extended care
- 50 million more people demanding primary care services from the same supply of "providers"
  - Many will refuse or be unable to accept new patients
- Where we get our healthcare may change
  - Wal-Mart; MinuteClinics ("You're sick? We're quick!)
  - Insurance-operated clinics
- And from whom

Results???

- Cost issues

➔NOT ADEQUATELY ADDRESSED!!!

- Quality issues

➔NOT ADEQUATELY ADDRESSED!!!

- Access issues

➔NOT ADEQUATELY ADDRESSED!!!

*"The federal government is now an insurance company with an army" **

*Ezra Klein, *Washington Post* blogger

Where Have All the Doctors Gone?

- Estimated shortage of MDs: 60,000
- Further decline in number of primary care physicians (PCPs) due to:
  - Lifestyle choices/Work-life balance
  - Income
  - No desire to manage the *business* of healthcare
- PCPs moving into:
  - Larger group practices
  - Managed care organizations
  - Closed-loop systems (Mayo, Geisinger)
  - Outpatient clinics, "Doc-in-a-Box"
  - Hospital-managed groups
- More care from "mid-levels" (Nurse Practitioners, PAs)

Key Trend: Practice Consolidation

- Small medical practices consolidating into larger practices, outpatient chains and especially…
- Acquisition by hospital-based, Integrated Delivery Networks (IDNs) to gain leverage over private payors for negotiating reimbursement contracts
  - Hospital systems now employ 16% of all US practicing physicians
  - ~ 55% coming out of residency go to work for an IDN

IDN Chief Executive to Private Payor:
"Try getting an interventional cardiologist in this town without us. They all work for us."

Effects of Hospital-Dominated Provider System

- IDNs will drive more cost *increases* as hospital admissions and ER visits increase
  - Trend foretold by experience of UK's NHS, resulting in recent "any willing provider" reform
  - **Inherent conflict...**
    - Outpatient care contains costs by keeping people out of hospital
    - But: outpatient services are a key profit center for hospitals

      versus
    - Privately-owned hospitals that derive revenue from increasing demand for their services
- Over the past 18 months, some IDNs have won 60-70% increases from private payors on contract rates

Effects of these Trends on Pharma and Biotech Companies

1. Individual Docs No Longer Make Drug Selection

- As more physicians become employees, discretion over development, selection and use of protocols and **formularies will shift from individual physicians to business-influenced committees**

  ➔ **Pharma's entire customer base will change**

- Universal adoption of Electronic Medical Records (EMRs) by 2015 is driving top-down rationalization and control of practice patterns

  –Medicare requires practicing physicians to use EMRs by 2015 or face substantial reimbursement impact

  –EMRs permit provider organizations and payors to develop databases that indicate the most cost-effective treatment patterns, based on real-world experience

2. Dueling Databases Will Drive Drug Selection & Usage

- Prospectively-designed, primary clinical trials will exert less influence because...
  - Recent scandals make pharma-sponsored trials less credible
  - Inherent conflict of interest: product's maker sponsors study
  - Increasing % of trials sited in eastern Europe & Asia-Pacific
  - Networks and payors increasingly recognize that trials' efficacy not necessarily borne out in practice
- EMRs will permit payors and IDNs to mine their own databases to develop optimal protocols and formularies
- Dynamic will be whether database of **IDN or payor or manufacturer** will prevail

3. Dueling Databases Will Create World of Small, Niche Products

- Pharma company will submit its retrospective, outcomes analysis…
- Payors and providers will run them against their own databases
- The most common response by payor and provider organizations:

*"Your product is good and we think first-line (or second-line or third-line) preference over the generic is warranted-- **in 4% of patients**."*

4. *Requietem in pacis*: Blockbuster Model

- The final nail in the coffin of the mega-company, blockbuster business model
- With 4-5% shares, **pharmas will need to prosper on smaller, niche products**
  - Can't manage quarterly earnings/ROI growth for $120 billion company with small products
  - How many "niche-busters" does it take to replace a blockbuster?
- And the industry will need to develop truly superior products
  - And link them with a diagnostic/biomarker

5. Hooray for Hollywood!

- Oracle CEO Larry Ellison predicted several years ago pharma would have to go the way of the Hollywood movie studios
  - In 1948, the U.S. Supreme Court forced movie studios to divest downstream distribution holdings, e.g., movie theater chains
  - Retrenched to core competencies
    - Each major studio ceased producing 50 films each year and limited production schedule to 6
    - Production now mainly done by small, independent producers
    - Studios contribute to financing, take a portion of equity, compete even on films where they hold such interest to provide production facilities, compete to provide distribution, marketing and advertising

6. Pharma ≠ Drug Development

- Pharma is failing at its historic mission of developing NMEs to advance standards of care

7. Pharma's Communication Channels Seriously Challenged

- Many academic medical centers banning reps; other facilities limiting rep access
- Medical journals, in wake of ghost writing scandals, demanding more transparency regarding authorship and pharma involvement
- FDA developing *Sentinel* Initiative: database of 100 million patients

  ➔ **Will limit pharma's ability to differentiate its products**
- ***Pharma can no longer rely on the asymmetry of information historically enjoyed for promoting products***

How is Pharma Responding to the Emerging Environment?

1a. Senior Management: Denial

- CEOs know they cannot meet investors' quarterly goals with small, niche products
  - Can only meet such goals by divesting substantial chunks of their companies
  - Problem: Executives seldom receive higher compensation for managing smaller companies
- Most CEOs still paid on the basis of revenue
  - Only 12% of incentive plans include any "innovation/new drug" metrics
- Leadership: "IBG/YBG"
  - Played the myopic "Washington insider card" to limit exposure to Medicare Part D price negotiation
  - Instead of showing leadership and shaping the agenda

1b. Line Marketing Managers: Denial and Resistance

- Prefer to ignore the realities and pretend it's still 1995 because their familiar tools (office reps, conventions, dinner meetings, seeding studies, others) won't work
  - The new marketing & selling will be high-level, business-to-business
  - Pharma doesn't even know what good BTB selling looks like
  - A lot of discussion about BTB/KAMs -- but not a lot of real change
- "W&H" that increased lives covered will be the saviour
  - But Medicaid rebates will reduce revenue gain
  - And there will be even more generic prescribing

2. Cut R&D

Annual R&D Spend, Billions US $

	2008	2009	2010	2011	2012
Pfizer	7.51	7.72	9.41	8.40	7.01
AstraZeneca	4.95	4.33	4.22	4.05	3.85
GSK		3.95	3.96	3.89	3.49
Lilly			4.88	4.85	4.75
Sanofi-Aventis		4.58	4.40	4.28	4.18

2009-2012: Pfizer ↓9.2%; AZ ↓11%; GSK ↓ 11.6%; S-A ↓ 8.7%

- New product development through R&D represents branded pharma's historical basis for existence. Do we cut our way to success?
- Reorganization into smaller Centers of Excellence (COEs) may…or may not…work

3. Cut SG&A, Principally Headcount

- In 2010, pharma led all U.S. commercial sectors in absolute numbers of layoffs*
  - Exceeded only by combined total for government and nonprofits

Sector	*2010*
Government & Nonprofit	142,255
Pharmaceuticals	53,636
Retail	38,751
Health Care/Products	28,058
Industrial Goods	26,487

*Challenger Gray & Christmas, January 5, 2011

4. Let Finance Run Operations

- Finance, through its Myrmidons in purchasing, seeks to commodify all vendor services (including marketing research, manufacturing and others) and pursue volume discounts over insight or quality
- Some results:
  - Johnson & Johnson has sustained weekly recalls through 2010 and 2011 in numerous operating companies across pharma, consumer, diagnostics and devices
  - GSK fined $750 million for poor manufacturing quality at Puerto Rico drug manufacturing facility
  - Business researchers privately complain they're obliged to work with only large suppliers, operating on thin margins, using junior, low-paid analysts, providing minimal insight

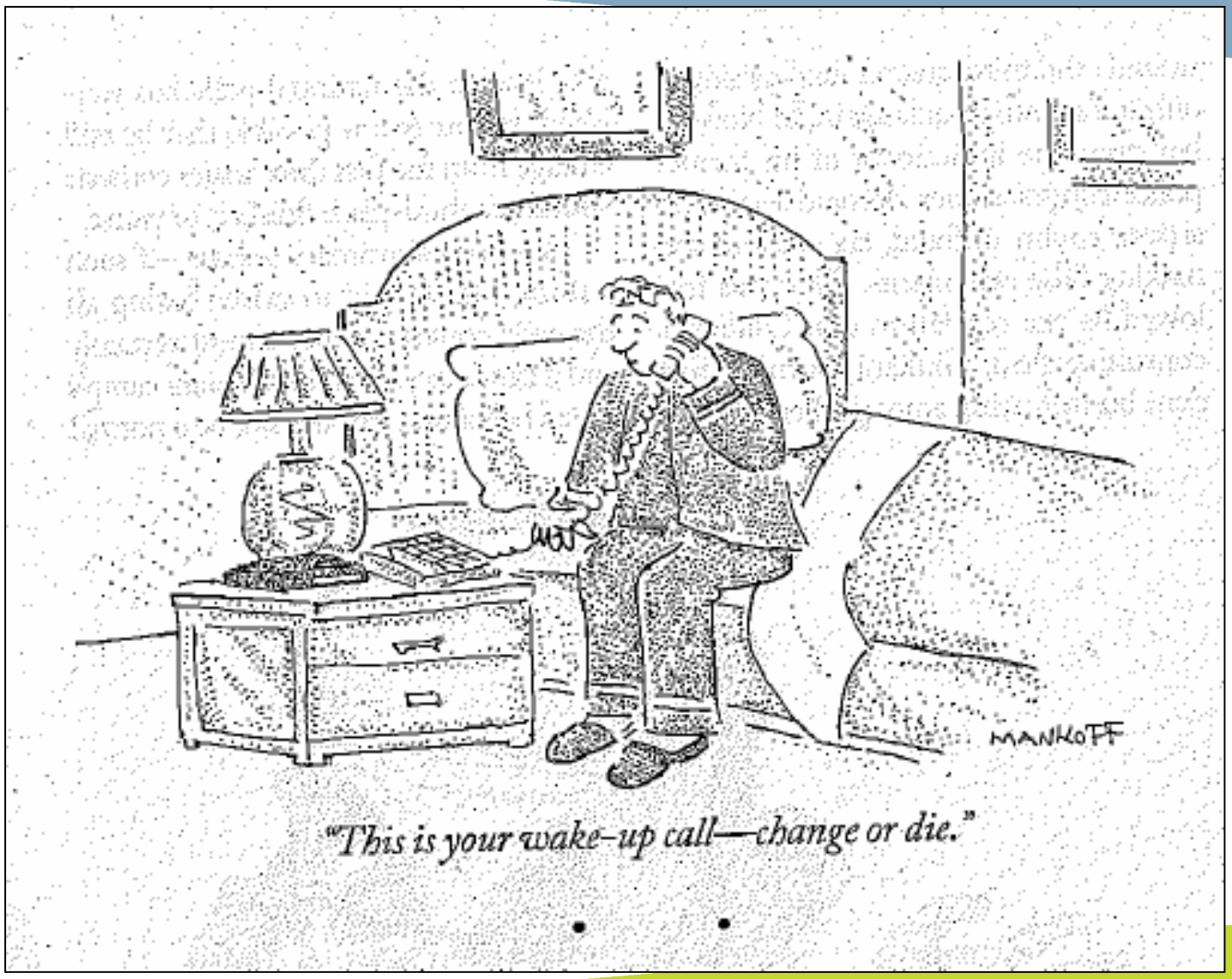
5. Adopt Orphan-Level Pricing for All New Products

- With the demise of blockbusters, pharma is trying to make more money from fewer units
  - Prices of $38K-$200K per patient per year
- May work for Gaucher or Fabry (10K total patients in U.S.), but not a solution for 1 of the 4 major tumor types
  - Payors make patients pay 20%, *i.e.*, up to $40K per year
  - Try charging that for breast cancer
    - 100,000 women will march on Congress demanding **patent-busting compulsory licensing (like HIV meds)**
  - Pushback for Novartis' Gilenya (MS) and KV's Modena
- And biosimilars are here!

6. For All Questions, China is the Answer

- A pabulum for investors but….
- While absolute revenues and share of total pharma revenues from developing countries will grow steadily, the margins are not there ...and may never be
  - Most revenue growth will be from generics, branded generics, and OTCs – ***not branded drugs***
  - Health care "reform" in China, ostensibly to bring more care to rural areas, explicitly favors local manufacturers, gives provinces greater pricing leverage
  - And they just cut prices 21% on 1,200 drugs
  - In Russia, Putin recently decreed he will seek to empower local drugs to effectively compete in Russia with those from the West

What Can You Do?


MANKOFF
"This is your wake-up call—change or die."

Questions About the Facts of Life

1. Pharma is not as effective at pursuing its historic mission of developing NMEs to advance the standards of care

   ➔ **What else can the industry do to earn returns on capital?**

2. Given the large proportion of marketing research devoted to testing and monitoring communications, **what else can MR do to justify its existence** when customers proactively seek to shut down pharma's communication channels?

   - **Current focus on products and physicians is shortsighted**

3. Start thinking about how your job would change if you were working for a consumer products company with a pharma subsidiary – or for Google!

New Goals for Marketing Research

- Assess and recommend opportunities for your company to grow and survive
- Pharma's declining ability to develop NMEs that improve outcomes requires learning to make money from the drug business in other ways
  - Investors, financiers, suppliers of marketing services
  - Getting smaller
  - Embracing generics and branded generics
  - Drug/device/diagnostic intersection

New Goals for Marketing Research

- The pharma industry has lost $1 trillion of capitalization between 2000 and 2010
- Understand what you must do to remain part of the company – and the industry

➔ **Your ship is taking on water and there are no places for you on the lifeboats**

How Do We Get to *The Promised Land?*

1. Drop the "we're special" parochialism and learn from other industries
2. Ask strategic questions and work on strategic research issues
   - Who are the real customers? Are you talking to ACOs?
   - What do they *really* need?
3. Make sure management hears from you!
   - Remember the **hidden power of MR:** everything you study has the potential to reveal bad decisions
   - **You are the Voice of the Customer!!!**
4. **Work outside the boundaries of conventional MR**

"We're not sure, but we think Foy just disappeared into the bureaucracy."