

Hope or Hype: The Conflict Between Science and Profit in Health Care

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Nelene Fox, 38 yo from California

- Mother of 3, diagnosed with breast cancer age 38
- Bilateral mastectomies, chemotherapy
- Developed bony metastases
- Doctors: only chance for survival is high dose chemo and autologous bone marrow transplant

Nelene Fox: Subsequent Care

- HMO (Health Net) refused to cover procedure (\$140,000) on basis that it was experimental
- Husband launched fundraising effort, raised \$212,000
- Received transplant, died 8 mos later
- Fox's brother attorney sued HMO, won \$89 million in damages
- Many similar lawsuits, several huge

Nelene Fox: Media, Political Responses

- Irresistible David and Goliath conflict: reporting focused on access; effectiveness presumed
- Story and verdict widely publicized
- *60 minutes*: story critical of insurers
- In face of coverage and lobbying, state legislatures passed laws requiring coverage
- Insurers facing suits and bad publicity

Other Developments

- Financial windfall for doctors, hospitals; new hospital wings built

BUT:

- Fraudulent research from S. Africa
- Long delayed RCT's: no more effective than standard chemotherapy; more toxic
- 42,000 women treated

Cost: \$3.4 billion

The Conflict Between Science and Profit in Health Care

- Other examples of new technology that decreased quality and increased costs
- The growth of industry-sponsored research: Getting the “right” results
- Suppressing the “wrong” results
- Some policy implications for election yr

Example: Drug Safety Problem

- Vioxx recalled after ~140,000 avoidable heart attacks
- Most who took it would have done as well with ibuprofen.
- Cost: \$2.5 billion each year on market

Dai C et al. Arch Int Med 2005; 165: 171

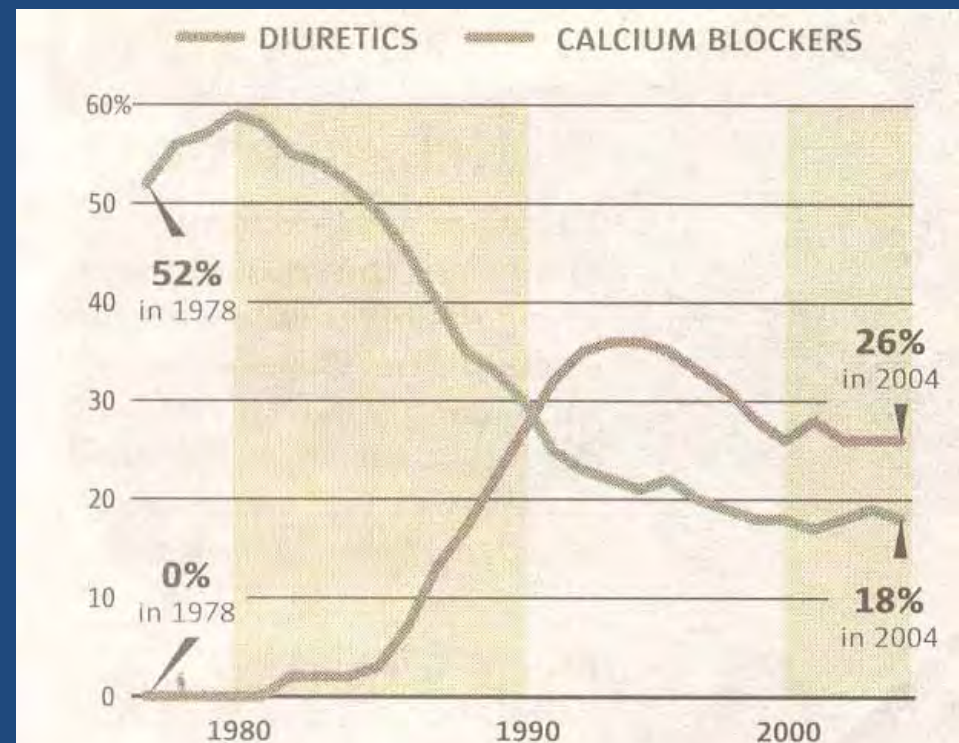
Example: Ineffective Arthroscopic Surgery

- Arthroscopic Knee debridement and lavage for osteoarthritis
- No more effective than sham surgery
- Cost: \$3 billion/yr.

Moseley JB et al:

Example: Hypertensive Drug Efficacy

- ALLHAT: thiazides > than newer drugs at preventing hypertension complications.
- Use ↓ in favor of newer drugs at 15x higher cost.
- ↑ use of diuretics: might prevent 70,000 MI's/year
Cost: \$1.2 billion/yr.



Source: IMS Health; Dr. Curt Furberg, Wake Forest University; Seattle Times research; National Institutes of Health

Consequences of Using Expensive, Marginal Treatments

- Treatments widely used before full evaluation; no comparison with competing treatments
- Expensive new treatments sometimes less effective or safe than alternatives; *after* avoidable harm or unnecessary expense
- Costs soaring; fewer can afford insurance
- Health policy makers not tackling the main reason for rising costs: new technology
- Marketing, politics, media, advocacy often trump the best science
- Hard to practice Evidence-Based Medicine

“Why Olanzapine beats Risperidone, Risperidone Beats Quetiapine, and Quetiapine Beats Olanzapine”*

Number of Reports Favoring:

	<u>Zyprexa</u>	<u>Risperdal</u>
Lilly (Zyprexa)	5	0
Janssen (Risperdal)	1	3

- Of 33 studies, 90% favored the sponsor's drug
- NIH study: none of 5 newer antipsychotics offered meaningful advantage over older generic drugs

Strategies for Making Research Results as Favorable as Possible

- Unfair comparisons
- Selective reporting of subgroups, side effects, outcome measures
- Publish favorable results multiple times
- Use guest authors, ghostwriters
- Withhold (or suppress) unfavorable results

Burying Bad News: University Research

- Carnegie-Mellon study of university-industry agreements:
 - 35% allowed sponsors to delete information from publications
 - 53% allowed publications to be delayed
 - 30% allowed both.

Another Strategy: Harassment & Intimidation of Independent Researchers



Bruce Psaty:
UW internist and
CHS
investigator

Bruce Psaty: Start of a Controversy

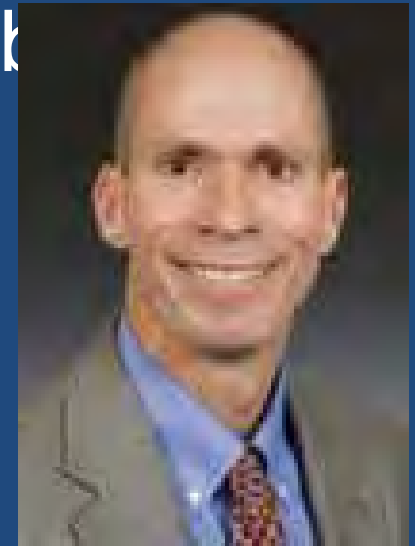
- Short-acting Ca^{++} Channel drugs for HTN: higher risk of MI than older, cheaper drugs
- 1995: Paper at Epi/Prevention Council of AHA
- Blindsided with faxes, calls; recommend JNC guides
- Fax to Med School Dean from Pfizer; call to Public Health Dean from state legislator
- Blistering “Dear Doctor” letter distributed nationally; Bayer not identified as sponsor
- Pressure on public health Dean not to publish
- FOI request from Pfizer: “all records, reports, data, analyses, correspondence, and any other documentation...”

Bruce Psaty: The Denouement

- Subsequent work confirmed initial case-control study, including RCT's, meta-analyses
- Silver lining: “Pfizer did more to promote the findings of our unwanted study than I could ever have done on my own. And maybe Bayer too. I don't want to give Pfizer all the credit.”

Greg Simon: Multiple Chemical Sensitivity

- Studied immune function in pts with “multiple chemical sensitivity” at Boeing plant; cast doubt on value of immunological tests
- Attacked by immunological testing lab advocacy organizations, plaintiff’s attorneys, expert witnesses
- Accusations of fraud & conspiracy to UW and GHC, federal Office of Research Integrity, licensing board
- 5 separate inquiries, 13 months: no basis for investigation; yet accusations continued



Eliminate Funding Agencies: Spine Fusion Surgery and the AHCPR

- Fastest rising back operation
- “Pedicle screws”: add \$13,000 per operation; \$4 billion/yr
- Literature synthesis:
 - few validated indications
 - Admin. Data: high costs, complications
 - Recommended RCT's

AHCPR-Sponsored Guidelines

- Congressional Mandate
- 23 panel members; 4 surgeons
- Non-surgical Rx for most acute problems

Opponents to Research, Guidelines

- *North American Spine Society* (NASS): letter-writing campaign
- *Center for Patient Advocacy* (founded by ortho surgeon on NASS board): eliminate AHCPR, curtail FDA
- *Sofamor Danek*: injunction to block guidelines

Consequences of Attacks

- 1996 House bill with \$0 for AHCPR
- Agency restored by Senate after intense lobbying in support by prof. societies
- Intimidation led AHCPR to end guideline work
- 25% budget cut: no new starts for years
- Today: companies under investigation for alleged kickbacks to surgeons; Sofamor Danek: \$40 million fine

Consequences of Suppressing Results

- Expose patients to unnecessary risks
- Discourage research in controversial areas: most in need of good science
- Vested interests determine acceptable questions, results
- Eliminating public peer-reviewed funding: slow new knowledge, push investigators to funding with conflicts of interest
- Increase cost without increasing quality – important to health care reform

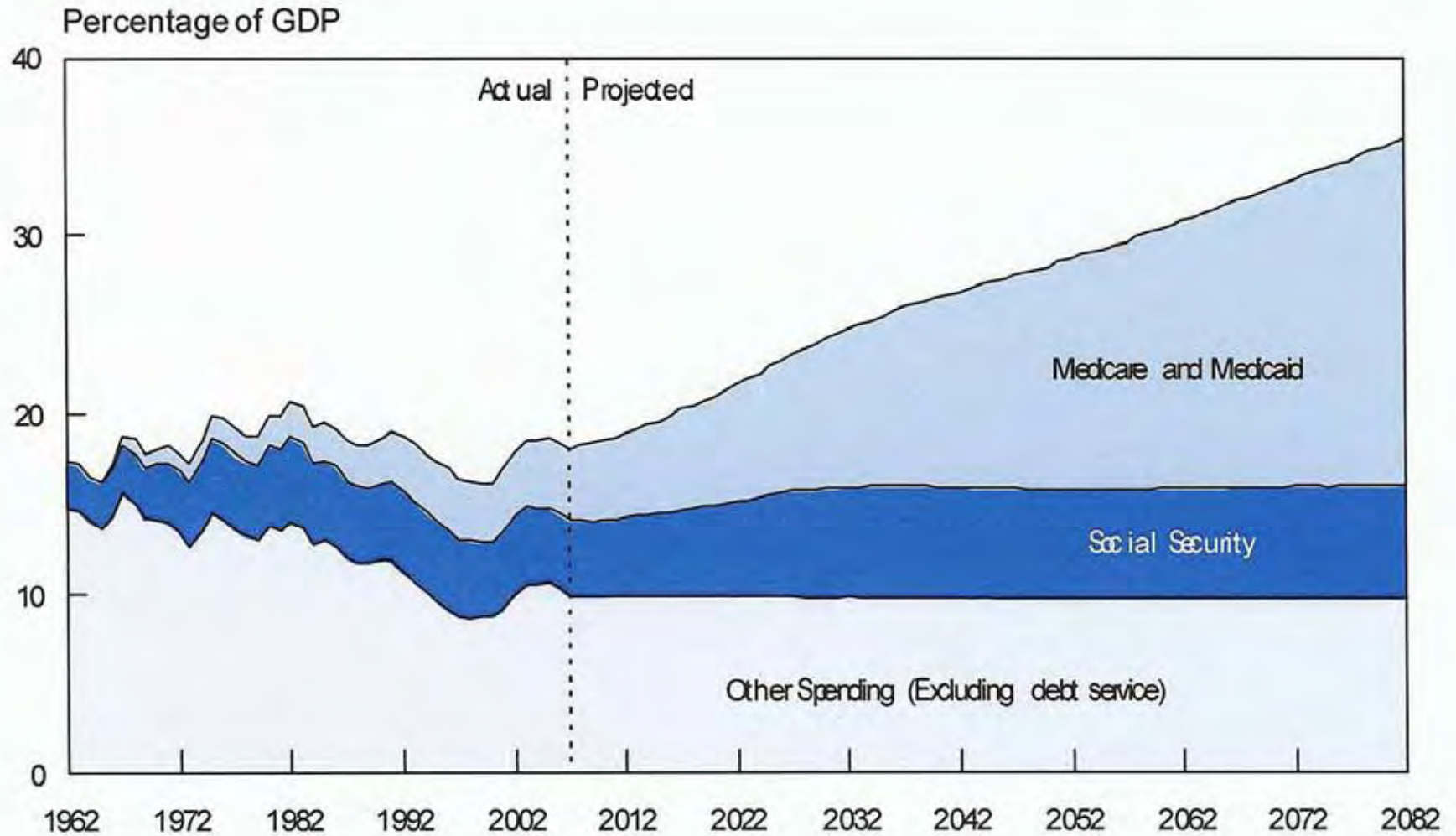
Estimated Contributions of Selected Factors to Growth in Per Capita Health Care Spending, 1940-1990

	Smith, Heffler & Freeland, 1999	Cutler, 1999	Newhouse, 1992
Aging of Population	2	2	2
Changes in 3 rd party payment	10	13	10
Personal income growth	11-18	5	<23
Prices in health care sector	11-22	19	Not est.
Administrative costs	3-10	13	Not est.
Defensive Medicine & Supplier-Induced Demand	0	Not est.	0
Technology-related changes in Medical Practice	38-62	49	>65



Federal Spending Under CBO's Alternative Fiscal Scenario

Source: Peter Orszag, CBO



Conclusions: Conflict between Science and Profit in Health Care

- Technology is major reason for rapid increases in health care costs; need comparative effectiveness
- Perverse financial incentives drive development and dissemination of new products
- Need to protect independent researchers, data, funding sources, peer review processes
- Need more rigorous approval process, better surveillance of new products
- Need more realistic public expectations