

The Industry-Physician Relationship: Flaws and Solutions

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Disclosures:

None



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Industry-Physician Collaboration: A Track Record of Innovation.

Cardiopulmonary bypass

Organ preservation

Bypass grafts

Joint replacements

Recombinant proteins

Antihypertensives

Antibiotics

Radiation therapy

Imaging

Vaccines

Industry-Physician Collaboration: There is a Problem!

Kassirer: *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*

Angell: *The Truth About Drug Companies and How They Deceive Us*

Hawthorne: *Inside the FDA*

AAMC: *Industry Funding of medical education*

CBO: *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role 2007*

Industry-Physician Relationship: Common Practices.

Direct payments to physicians, consultancies,
directorships

Gifts

Travel, CME

Speakers bureaus

Ghost writing of mega analysis reviews

Research grants

Industry-Physician Relationship: Common Practices; Ghost Writing

Half of 75 review articles did not disclose sponsor

Many experts recruited as 'authors' with honoraria

Review article becomes a 'scientifically validated'
commercial

JAMA 2008,299:1800-1812

Industry-Physician Collaboration: There is a Problem!

Physician complicity is an essential ingredient.

Money and prestige are influential

Physicians are increasingly susceptible

Pressures come from many directions

No corner of American Medicine is free of
influence

Industry-Physician Collaboration: Is there a Problem!

Carotid Stents: Unleashed, Unproven

- Study design and leadership
- Institutional Review Board
- Journal review, disclosure
- FDA Waivers of COI, PUFA
- Failure of interagency communication or policy

STENTS vs SURGERY

Randomized clinical trials

Rates of Stroke + Death

STUDY	CAS (STENT)	CEA (SURGERY)
EvS	11.1%	6.2%
SPACE	9.4%	7.8%
ICSS	9.8%	4.9%
CREST (USA)	4.1%	2.3%

Industry fights back

WSJ 2/27: “Study Boosts Stents in Stroke Prevention”

LAT 2/26: “Stroke study puts 2 procedures on equal footing”

NYT 2/27: “Study finds stents as effective as surgery”

356 related articles

Industry fights back

Myocardial infarction rate with surgery was 2.3%,
with stents only 1.2%.

MI = stroke=death

But death rate was slightly higher with stents!

MI is a subjective, probably irrelevant endpoint.

No evidence of any consequence in this study

Industry-Physician Relationship: Comparative effectiveness.

Coronary Stents as initial treatment for stable
angina: No benefit over optimal medical therapy

Only 30% subsequently receive stent with equal
survival and freedom from heart attack

N Engl J Med 2007;356:1503-16
J Am Coll Cardiol 2008;52:905-7

Industry-Physician Relationship: Comparative effectiveness.

Medical therapy as the initial treatment

30% of 1 million = 700000

$700000 \times 25000/\text{procedure} = 17.5 \text{ billion}$

Annual health care for 4 million individuals @
4000 + per year.

Industry-Physician
Relationship:
Comparative effectiveness.

PRIMUM NON NOCERE

“First, do no harm”

Industry-Physician Relationship: Points of Intervention.

Increasing emphasis on dollar value of disclosure.
Society Officers will have to suspend relationships
Penalties for failure to disclose
Standards for Clinical Studies
Financing of studies
Financing of the FDA
Separation of powers NIH, FDA, CMS
Comparative Effectiveness Institute

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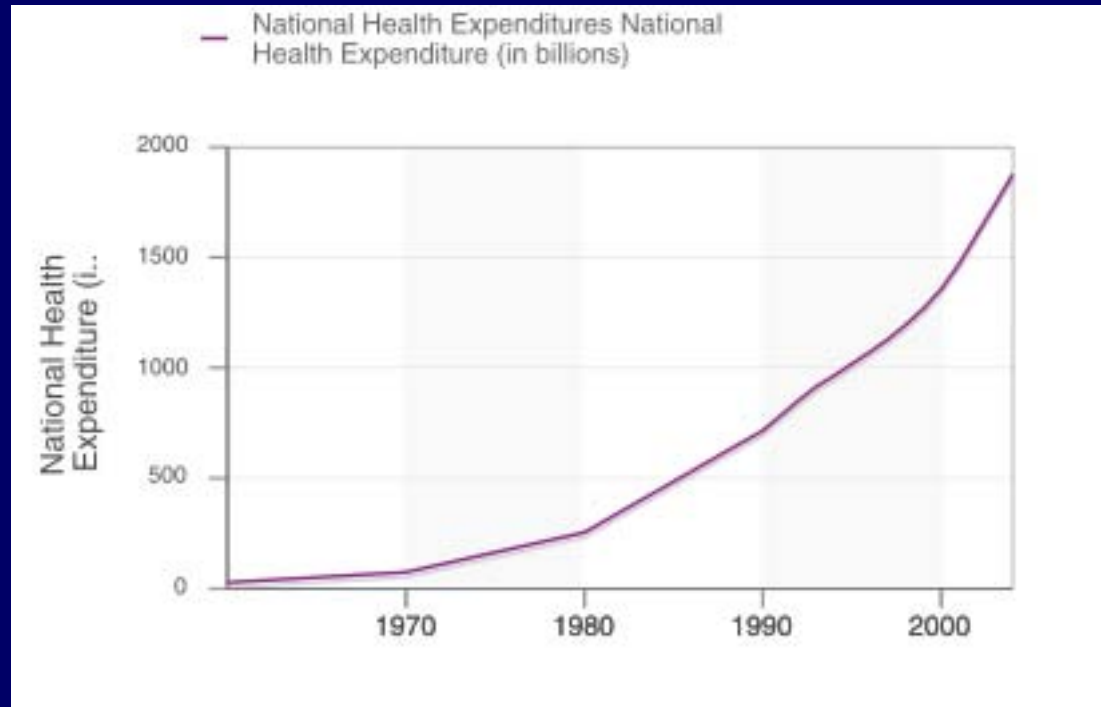
Participation fee is 50 €.

Make sure to register and present your invitation
at the entrance.

Informations at the registration desk.



- Once we lose public confidence in our ability to put the interests of patients first, we lose control of medical practice.



CBO: Research on Comparative effectiveness of Medical Treatments

(www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf)

Industry-Physician Collaboration: Other Flaws.

FDA funding by industry (PUFA)

FDA waiver of conflicts

CMS influence –Congress

Interagency communication

Industry-Physician Relationship: Some Negative Outcomes.

Commercialized Clinical 'Science'

DTC advertising

Misguided, ineffective, harmful 'care'

Industry-Physician Relationship: Commercialized Science.

Patent protection —————> generic

Modify drug A to create drug B

Compare B with placebo (not with drug A)

Market B

Industry-Physician Relationship: Commercialized Science.

A Device is invented

The Inventor's Institution owns the license

The Device is licensed to an Industry Sponsor
who, in turn, funds a clinical trial at the Inventor's
Institution

The Inventor participates in design of the trial,
data analysis, and is first author of the publication
in a prestigious journal.

Industry-Physician Relationship: Commercialized Science.

Once an industry is created it is extremely difficult to remove a device or medication.

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