The Industry-Physician Relationship:
Flaws and Solutions

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Beth Israel Deaconess Medical Center
Harvard Medical School, Boston
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

LoGerfo, FW, Circulation, 2007;116:1596-1601
**STENTS vs SURGERY**
Randomized clinical trials
Rates of Stroke + Death

<table>
<thead>
<tr>
<th>STUDY</th>
<th>CAS (STENT)</th>
<th>CEA (SURGERY)</th>
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<tbody>
<tr>
<td>EvS</td>
<td>11.1%</td>
<td>6.2%</td>
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<tr>
<td>SPACE</td>
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<td>7.8%</td>
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<td>4.9%</td>
</tr>
<tr>
<td>CREST (USA)</td>
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</table>
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
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

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 X 25000/procedure = 17.5 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
Register before June 4!

MEET Official Dinner
Saturday, June 16 20.00 - 00.30
On the Martinez Hotel private beach: "Z Plage"

Join the Sandy Party
Seated buffet dinner & live music entertainment
featuring the trio jazz band "Marylin".

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