

PLATFORMS, PATHWAYS & PIONEERS: OREGON'S BIOSCIENCE PROGRESS.



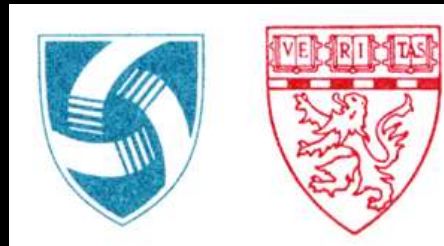
September 28, 2011



“CHALLENGES AND OPPORTUNITIES WITH PHYSICIAN-INDUSTRY COLLABORATIONS”

Tom Stossel

**Brigham & Women's
Hospital**



**Harvard Medical
School**



**cCENTER FOR MEDICAL INNOVATION
IN THE TRANSLATIONAL MEDICINE UNIT**



MY GAME PLAN

**EXPOSE *UNNECESSARY* CHALLENGES
TO PHYSICIAN - INDUSTRY
COLLABORATION: THE EMPEROR'S NEW
CLOTHES**



**Hans Christian Andersen
1805 - 1875**



**POLICIES NOW MANDATE MASSIVE
CONFESSION & *PROPHYLACTIC* RULES
REGARDING ALL ASPECTS OF MEDICINE**

All corporate payments to physicians disclosed.

Peer-to-peer speaking curtailed. Relationships preclude editorials, journal review articles, or service on guideline or FDA review panels.

No gifts, however trivial; heavily restricted payments for meals & travel. Samples & detailing prohibited or limited.

Rewards for *VALUE* eliminated or limited.

“EVIDENCE” INVOKED TO JUSTIFY THIS MASSIVE REGULATION

Industry’s profits exceed value added, and its marketing is fundamentally deceptive.

Industry relationships degrade research integrity and cause physicians unwittingly to promote or prescribe unnecessarily expensive products that harm patients.

Payments to physicians for time or work erode public trust.

SAYS WHO AND ON WHAT BASIS?

THE EMPEROR'S TAILORS.

The logo consists of the letters 'PG' in a bold, white, sans-serif font, centered within a blue rounded square. The entire logo is set against a white background with a black border.

PG

**Parental guidance
advised**

THE "CONFLICT OF INTEREST" MANIA

Articles per Year Concerning "Conflict of Interest"



**101 JAMA, LANCET & NEW ENGLAND
 JOURNAL OF MEDICINE PAPERS CONCERNING
 PHYSICIAN-INDUSTRY RELATIONSHIPS (1989 – 2009)**

Emphasis:	Relationship risks	Relationship benefits
	96%	4%
Provided evidence	44%	100%
Drew inferences about patient outcomes	76%	0%
Acknowledged alternative viewpoint	43%	100%
Critiqued alternative viewpoint	3%	100%

FLAWED *PROCESS*



Sudden concern about a problem often is a result of *conformity*, not real deliberative engagement to debate complex issues.

Information “*availability*” promotes conformity.

***Absence of dissent* promotes group polarization and encourages discrimination against demonized out groups.**

Sunstein, CR: Deliberative Trouble? Why Groups Go to Extremes. *Yale L J* 110: 71, 2000; Conformity & Dissent. *Chicago Law & Economics Working Paper* 164, 2002; Hazardous Heuristics. *Univ Chicago, L Rev* 70 : 751, 2003; *The Laws of Fear*, Cambridge University Press, 2005.

FLAWED CONTENT

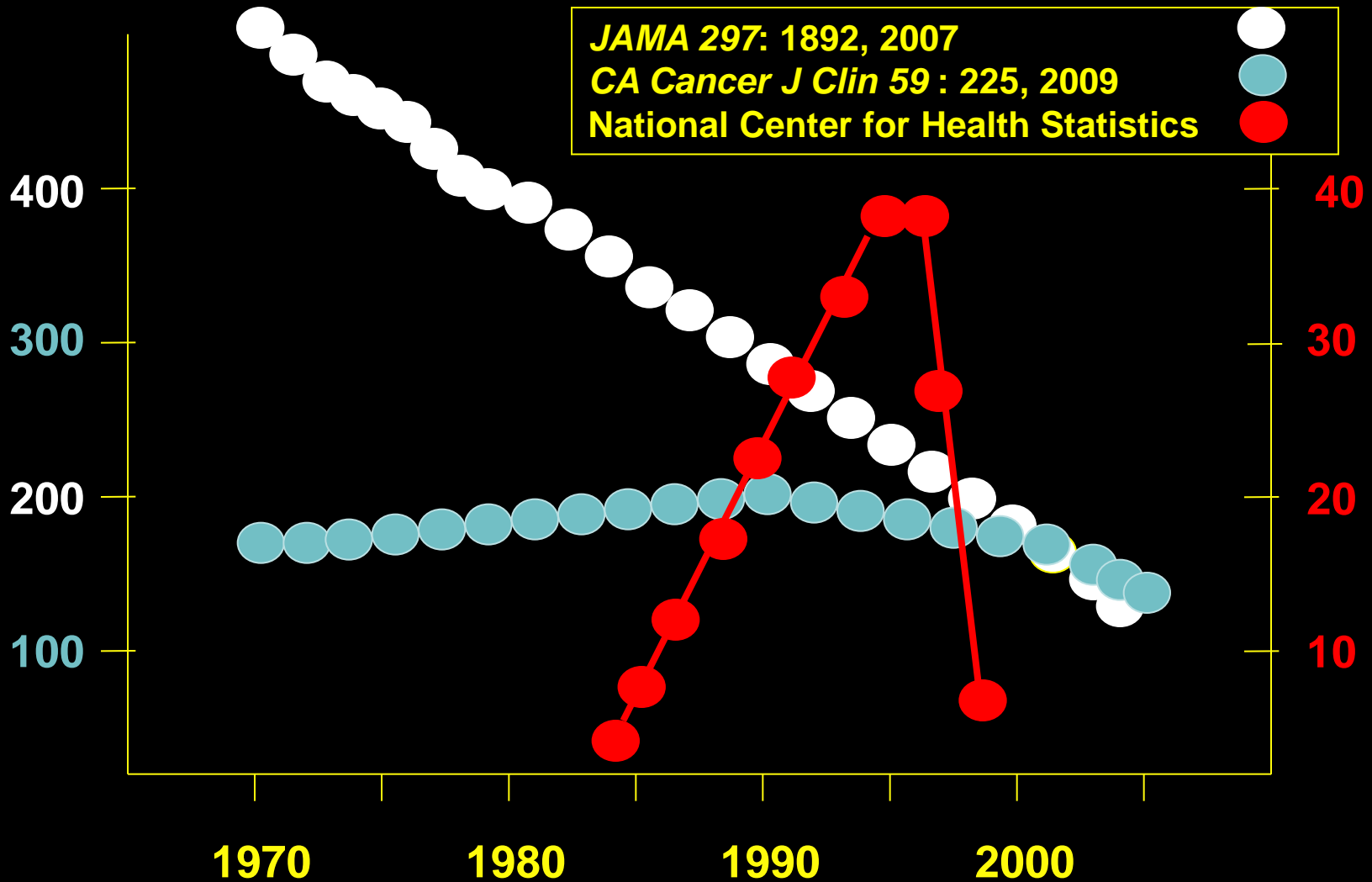
Dismissal of industry value and difficulty of its attainment represent economic illiteracy.

Adverse event narration to emphasize risk neglects the benefit denominator & exaggerates damages.

Claims that commercialism degrades research, “biases” CME, dupes physicians, compromises public trust and harms patients are *false*.

VALUE FROM RELATIONSHIPS

Heart Attack (●) Cancer (●), & HIV (●) Deaths (per 100K persons)



WHY GETTING TO VALUE IS CURRENTLY BARELY WORTH THE EFFORT

1 of 8000 compounds reach the clinic after 16 years elapsed and \$1.3 billion spent. Since 1960, development costs increased 100X. Biotech profitability is only slightly > zero. The main reason is more regulation.

Short cuts (“-omics,” screening gimmicks, “rational design,” mergers) rarely deliver as promised.

Academic “research” is not medical innovation.

Academic and industry bureaucrats “*talk the talk*” about “translation,” but their *actions* stifle it.

ADVERSE NON-EVENTS

The number of adverse events ascribed to physician-industry relationships is strikingly small, especially considering the value denominator.

The damages associated with these incidents are negligible (e.g. disclosure lapses).

Most reported incidents are not as advertised.

BOGUS EVIDENCE FOR PATIENT HARM

Health Industry Practices That Create Conflicts of Interest

JAMA 295 : 429, 2006

A Policy Proposal for Academic Medical Centers



Troyen A. Brennan, MD, MPH

David J. Rothman, PhD

Linda Blank

David Blumenthal, MD, MPP

Susan C. Chimonas, PhD

Jordan J. Cohen, MD

Janlori Goldman, JD

Jerome P. Kassirer, MD

Harry Kimball, MD

James Naughton, MD

Neil Smelser, PhD

“The systematic review of the medical literature on (industry) gifting by Wazana found that an overwhelming majority of interactions had negative results on clinical care.”

“THE WAZANA SYSTEMATIC REVIEW”

Physicians and the Pharmaceutical Industry Is a Gift Ever Just a Gift?

Ashley Wazana, MD



JAMA 283: 373, 2000

A review of 29 articles concerning “the relationship between physicians and the pharmaceutical industry and its representatives and its impact on the knowledge, attitudes and behavior of physicians.”

UNTRUE

“an overwhelming majority of interactions had negative results on clinical care”

WHAT WAZANA ACTUALLY SAID:

“NO STUDY USED PATIENT OUTCOME MEASURES.”

JAMA 283 : 273, 2000

EVIDENCE : WAZANA'S CONCLUSIONS ON DETAILING AND GIFTING OUTCOMES

POSITIVE OUTCOMES

Improved ability to identify the treatment for complicated illnesses.

“NEGATIVE” OUTCOMES

Non-rational prescribing.

Increased prescribing & formulary requests for promoted meds.

Fast new drug prescribing.

Positive attitude toward drug reps.

DEMONIZATION OF “MARKETING”

ACADEMIC “EDUCATION” VERSUS INDUSTRY “MARKETING”



“Marketing personnel...provide no direct educational benefit to our students...and are not necessary to the academic environment.”

**J. Flier, Dean, Harvard Medical School
2009 – 2010 Report on Conflicts of Interest and
Commitment.**

DISRESPECT

**“Positive Attitude Toward Drug Reps”
“Marketing personnel provide no direct
educational benefit.”**



Naturally, it works.™

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www.tomsofmaine.com



HYPOCRISY? WHO'S ALLOWED TO "MARKET" -- BASED ON WHAT EVIDENCE?

effects is impotence. Which can be devastating
y relationship. But with Robotic Assisted
oscopic Prostatectomy at Mount Sinai, that risk
greatly reduced. Our newest prostate specialist,
David Samadi, has pioneered a minimally invasive

MOUNT
SINAI

coupled with lowered risks of side effects,
while prostate cancer can undoubtedly change
Dr. Samadi can keep those lives from char
1-800-MD-SINAI • www.mountsinai.org
Another day. another breakthrough.

New York Times Magazine

PROSTATE

CANCER SURGERY SO EFFECTIVE,

EVEN WOMEN CAN

FEEL THE DIFFERENCE.



We're advancing the treatments in gynecology.
with the confidence of the women who need them.

UPMC

INDUSTRY-SUPPORTED CME IS UNDER FIRE

STAY ABOVE THE FRAY.

**EARN YOUR CME CREDITS WITHOUT
THE TAIN OF INDUSTRY BIAS.**

**TAKE THE MEDICAL LETTER
COMPREHENSIVE CME PROGRAM**



**COST OF REGULATION:
ARBITRARY CENSURE OF FACTORS
PROMOTING GOOD PATIENT CARE**

Peer-to-peer speaking.

Professional medical writing.

Product samples.

Expertise.

COSTS OF “TRANSPARENCY:”

PURPOSELESS RESOURCE DIVERSION

Redundant industry, health center, state and impending federal (“sunshine act”) payment disclosure registries are:

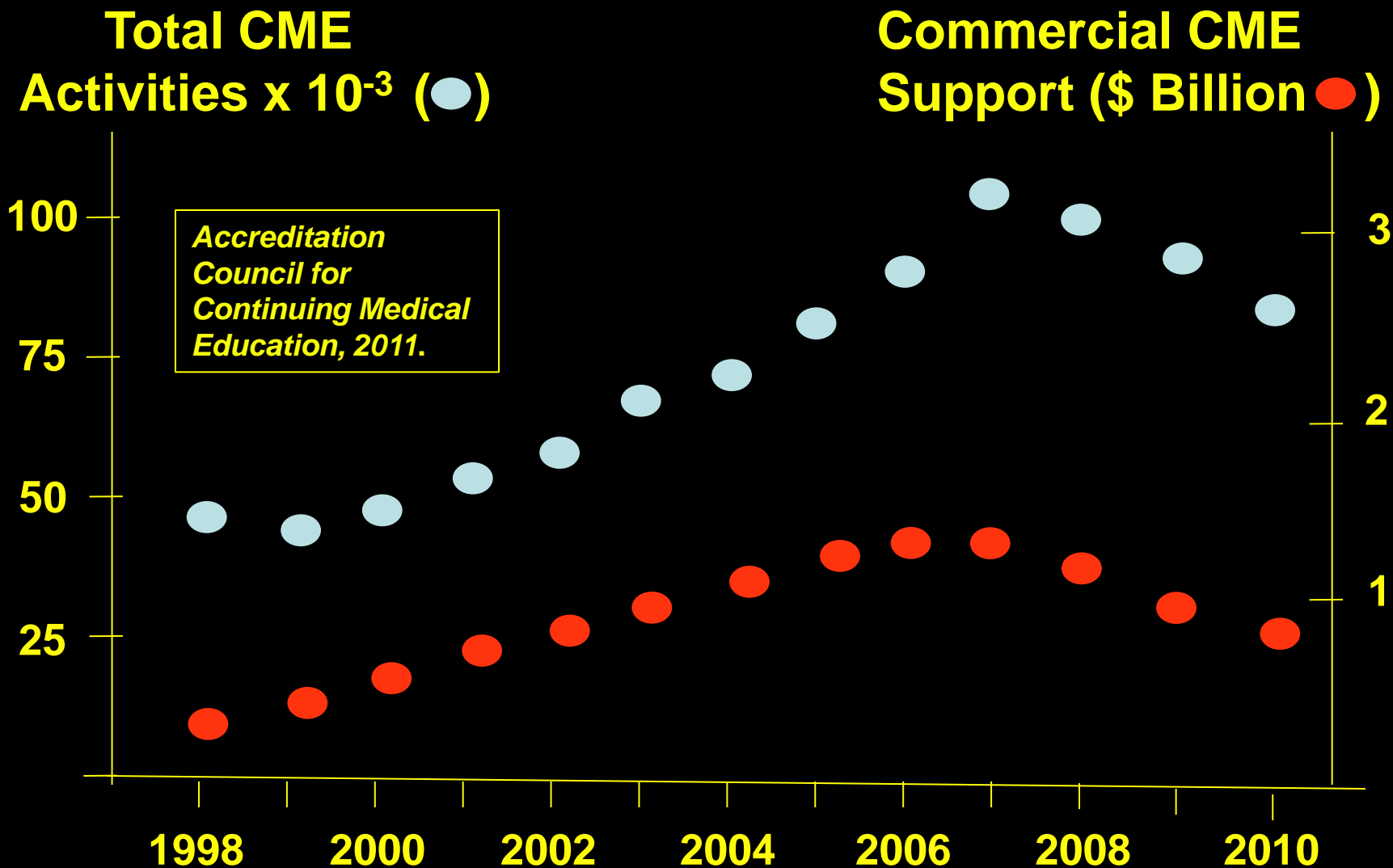
Expensive.

Inaccurate.

Almost Useless.

Abusive.

COST: LESS MEDICAL EDUCATION



\$ BILLION SETTLEMENTS & “CORPORATE INTEGRITY AGREEMENTS” ARE THE MAJOR FACTORS LIMITING COLLABORATION

**PARKE-DAVIS - PFIZER (GABAPENTIN)
DEPUY
SMITH/NEPHEW
STRYKER
MEDTRONIC
JOHNSON & JOHNSON
ORPHAN MEDICAL
WARNER LAMBERT
AMERICAN HOME PRODUCTS (FEN-FEN)
TAP (LUPRON)
CEPHALON (PROVIGIL)
ELI LILLY (ZYPREXIA)
ADVANCED NEUROMODULIN SYSTEMS
CELL THERAPEUTICS
PFIZER (BEXTRA)
ASTRA ZENECA (SEROQUEL)
SERONO (SEROSTIM)**

**ZIMMER
SYNTHES
OTSUKA (ABILIFY)
MERCK (VIOXX)
BOSTON SCIENTIFIC
BIOVAIL
NOVARTIS (TRILEPTAL)
ABTOX
GSK (PAXIL)
ADVANCED BIONICS
PURDUE (OXYCONTIN)
ALLERGAN (BOTOX)
SPECTRANETICS
ATRICURE
FOREST (LEVOTHYROID,
CELEXA, LEXAPRO)
BIOMET**

THE PROSECUTORIAL EXTORTION GAME

(H. Silverglate: *Three Felonies a Day. How the Feds Target the Innocent.* Encounter Books, 2009; Osborn, J: *Yale J Health Policy & Ethics.* 10 : 301, 2010)

**“Conflict of Interest”
Background Music
Witnesses**

**Prosecutors
Threatening
*DEBARMENT***

***Obligatory
Settlements***

Whistleblowers

\$

\$

\$

\$ Billion Fines

***BUT –
INDICTED INDIVIDUALS WHO DEFEND IN COURT WIN!***

WHY THE EMPEROR'S TAILORS ARE PREVAILING

**Failure to pay attention & abdication to
“ethicists,” politicians & policy
entrepreneurs.**

Unaccountable academic leadership.

Industry inattention & appeasement.

CONCLUSIONS

Despite daunting obstacles, industry relationships have delivered huge value.

Evidence that relationships compromise “scientific integrity” is weak or false.

But administrative & legal strangulation is harming innovation & education and bodes ill for better patient care.



ACRE

Association of Clinical
Researchers and Educators

www.acreonline.org

Advocacy for the VALUE of physician-industry collaboration.

Correct misinformation about collaboration.

**cENTER FOR MEDICAL INNOVATION
TRANSLATIONAL MEDICINE UNIT**



Provide information contained in this talk to health care professionals, politicians and the public.

Research to enrich the information base especially regarding consequences of regulation.

Research and education on research commercialization.

STOSSEL “DISCLOSURES”

FINANCIAL

ACTIVE: Velico Medical (Zymequest) (Board of Directors, Scientific Advisory Board; consulting fees, stock options, licensed technology)
Merck (Academic Centers Advisory Board)
BioAegis Therapeutics (Founder, licensed technology)

PAST: Biogen (Scientific Advisory Board, licensed technology)
Dyax (Strategic Advisory Board)
NeoRx (Licensed technology, sponsored research)
Merck (Science Leadership Advisory Board)
Critical Biologics (Founder, director, fees)
Amgen, Bristol Myers-Squibb, Gerson-Lehrman, Roche, Pfizer, Vertex (*Ad hoc* consulting or lectures);
Hundreds of paid meals, pens, sticky notes, meds

CRIMINAL

Jailed for brawling, Mackinac I., Michigan, 1964; escaped

“CONFLICT OF INTEREST:” PAYOFF

“Options for Children in Zambia” (5013c).

Sickle Cell Disease
Center
University Teaching
Hospital, Lusaka





Oregon Bioscience
Association

THANK YOU FOR YOUR ATTENTION!

Enjoy the rest of your meeting.

Tstossel@partners.org