Conflict of Interests in Health Care

Frank Chessa, Ph.D.
Director, Clinical Ethics, Maine Medical Center
Assistant Professor, Tufts University School of Medicine

September 21, 2012

Disclosure

- I am employed by Maine Medical Center.
- I have no commercial interest in any medical device, medication or clinical service outside of my responsibilities at Maine Medical Center.

The doctor is made to feel he needs more "education" because of the prolific outpouring of strange brands but not really new drugs, produced for profit rather than to fill an essential purpose; and then the promoter offers to rescue him from confusion by a corresponding brand of education.

The physician expects himself to make up his own mind on the basis of objective evidence. And yet he finds himself confronted, like a housewife in a supermarket aisle, with a misery of choice which he tends generally to resolve by irrational and emotional factors.

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Charles May, Editor *Pediatrics*, 1961

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Ernst Dichter, Advertising Professional, 1955

Senate Hearings on Pharma Marketing and Medical Education

- Senator Kefauver (D, Tenn), 1959
- Senator Nelson (D. Wisc), 1976
- Senator Kennedy (D, Mass), 1992
- Senator Grassely (R, Iowa), 2009

Podolsky, Historical Perspective on Pharmaceutical Promotion and Physician Education, *JAMA*, 2008

Conflict of Interest Definition

A Conflict of Interest is "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."

Primary Interests
- Welfare of patients
- Integrity of research
- Quality of medical education

Secondary Interests
- Financial gain
- Professional advancement
- Recognition of achievement
- Favors for friends/family/students/colleagues

Lo, Bernard and Marilyn J. Field, Editors; Committee on COI in Medical Research, Education and Practice; IOM. *Conflict of Interest in Medical Research, Education, and Practice.* (2009)

What are the secondary interests that have the potential to influence you or your co-workers in your work setting?

Discuss with your neighbor.
Write down at least two.

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There will be financial winners and losers with every change in the pattern of providing health care.

Quick Example

Palliative Care

N ENGL J MED 363;8 NEJM.ORG AUGUST 19, 2010

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer

Jennifer S. Temel, M.D., Joseph A. Greer, Ph.D., Alona Muzikansky, M.A., Emily R. Gallagher, R.N., Sonal Admane, M.B., B.S., M.P.H., Vicki A. Jackson, M.D., M.P.H., Constance M. Dahlin, A.P.N., Craig D. Blinderman, M.D., Juliet Jacobsen, M.D., William F. Pirl, M.D., M.P.H., J. Andrew Billings, M.D., and Thomas J. Lynch, M.D.

CONCLUSIONS

Among patients with metastatic non–small-cell lung cancer, early palliative care led to significant improvements in both quality of life and mood. As compared with patients receiving standard care, patients receiving early palliative care had less aggressive care at the end of life but longer survival. (Funded by an American Society of Clinical Oncology Career Development Award and philanthropic gifts; ClinicalTrials.gov number, NCT01038271.)

Palliative Care Improves Outcomes For Patients and Families

Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer Temel et al. NEJM 2010

- N= 151 advanced lung cancer patients randomized to usual care or usual care + palliative care consultation
- Compared to usual care patients, palliative care patients were observed to have:
  - Improved quality of life (p=.03)
  - Fewer depressive symptoms (p=.02)
  - Fewer burdensome treatments (p=.05)
  - Improved survival: 11.6 months versus 8.9 months for usual care group (P=.02)

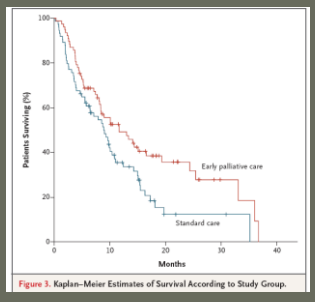
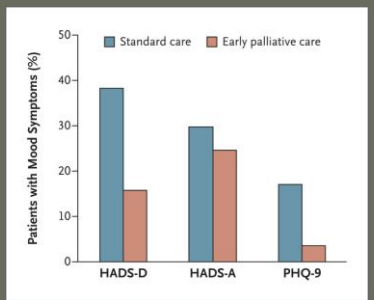


Figure 3. Kaplan–Meier Estimates of Survival According to Study Group.

Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer

Jennifer S. Temel, M.D., Joseph A. Greer, Ph.D., Alona Muzikansky, M.A.

Twelve-Week Outcomes of Assessments of Mood



Temel JS et al. *N Engl J Med.* 2010;363:733-742.

The NEW ENGLAND JOURNAL of MEDICINE

Palliative Care Reduces Hospital Costs

ORIGINAL INVESTIGATION

Cost Savings Associated With US Hospital Palliative Care Consultation Programs

R. Sean Morrison, MD; Joan D. Penrod, PhD; J. Brian Cassel, PhD; Melissa Caust-Ellenbogen, MS; Ann Lithe, MFA; Lynn Spragens, MBA; Diane E. Meier, MD; for the Palliative Care Leadership Centers' Outcomes Group

Background: Hospital palliative care consultation teams have been shown to improve care for adults with serious illness. This study examined the effect of palliative care teams on hospital costs.

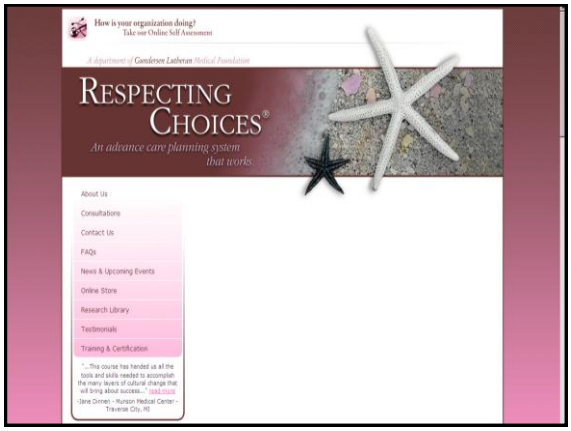
Methods: We analyzed administrative data from 8 hospitals with established palliative care programs for the years 2002 through 2004. Patients receiving palliative care were matched by propensity score to patients receiving usual care. Generalized linear models were estimated for costs per admission and per hospital day.

Results: Of the 2966 palliative care patients who were discharged alive, 2630 palliative care patients (89%) were matched to 18 427 usual care patients, and of the 2388 palliative care patients who died, 2278 (95%) were matched to 2124 usual care patients. The palliative care patients who were discharged alive had an adjusted net savings of $1696 in direct costs per admission (P=.004) and $279 in direct costs per day (P<.001) including significant reductions in laboratory and intensive care unit costs compared with usual care patients. The palliative care patients who died had an adjusted net savings of $4908 in direct costs per admission (P=.003) and $374 in direct costs per day (P<.001) including significant reductions in pharmacy, laboratory, and intensive care unit costs compared with usual care patients. Two confirmatory analyses were performed. Including mean costs per day before palliative care and before a comparable reference day for usual care patients in the propensity score models resulted in similar results. Estimating costs for palliative care patients assuming that they did not receive palliative care resulted in projected costs that were not significantly different from usual care costs.

Conclusion: Hospital palliative care consultation teams are associated with significant hospital cost savings.

Arch Intern Med. 2008;168(16):1783-1790

(REPRINTED) ARCH INTERN MED/ VOL 168 (NO. 16), SEP. 8, 2008 WWW.ARCHINTERNMED.COM



A Comparative, Retrospective, Observational Study of the Prevalence, Availability, and Specificity of Advance Care Plans in a County that Implemented an Advance Care Planning Microsystem

Bernard J. Hammes, PhD, Brenda L. Rooney, PhD, MPH,† and Jacob D. Gundrum, MS**

CONCLUSION: A system for ACP can be managed in a geographic region so that, at the time of death, almost all adults have an advance care plan that is specific and available and treatment is consistent with their plan. J Am Geriatr Soc 58:1249–1255, 2010.

- **All adults have a plan**
- **It is specific**
- **It is available at the point of care**
- **It is followed**

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Table 2. Prevalence, Availability, and Creation Date of Advance Directives (ADs), La Crosse Advance Directive Study (LADS) I (N = 540) Versus LADS II (N = 400)

Advance Directive Status	LADS I	LADS II	*P*-Value
Decedents with ADs, n (%)	459 (85.0)	360 (90.0)	.02
Of these, ADs in medical record, n (%)	437 (95.2)	358 (99.4)	<.001
Type of AD, n (%)			
Power of attorney for health care	353 (77)	324 (90.0)	<.001
Living will	46 (10)	30 (8.0)	.41
Dictated note	60 (13)	120 (33.0)	<.001
POLST, n (%)	NA	268 (67.0)	NA
Of these, POLSTs in medical record, n (%)	NA	264 (98.5)	NA
Years from AD creation to death, oldest date used, median (range)	1.3 (0–13.6)*	3.8 (0–21)*	<.001
Months from POLST creation to death, median (range)	NA	4.3 (0–114)	NA

JAGS 58:1249–1255, 2010

Comparative Cost of Care: Last 2 Years of Life

Hospital	Reimbursement per deceased pt (2-yr total)	Reimbursement per day	Hospital days per deceased pt
Gundersen	$18,359	$1,355	13.5
Marshfield/St. Joseph's	$23,249	$1,126	20.6
US Nat'l Average	$25,860	$1,096	23.6
University of WI	$28,827	$1,462	19.7
Cleveland Clinic	$31,252	$1,307	23.9
Mayo Clinic	$31,816	$1,497	21.3
UCLA	$58,557	$1,871	31.3

Dartmouth Institute

- A significant portion of health care spending is driven by the desire to fill empty hospital beds (and empty operating rooms, and gaps in doctor's schedules).
- For care at the End of Life, if we listened to what patients actually wanted, we'd provide palliative care rather than intensive care, and we would be spending less money.

Patients may refuse without penalty, but many will bow to white-coated authority. Once they're in the meeting, the bill does permit "formulation" of a plug-pulling order right then and there. So when Rep. Earl Blumenauer (D-Ore.) denies that Section 1233 would "place senior citizens in situations where they feel pressured to sign end-of-life directives that they would not otherwise sign," I don't think he's being realistic.

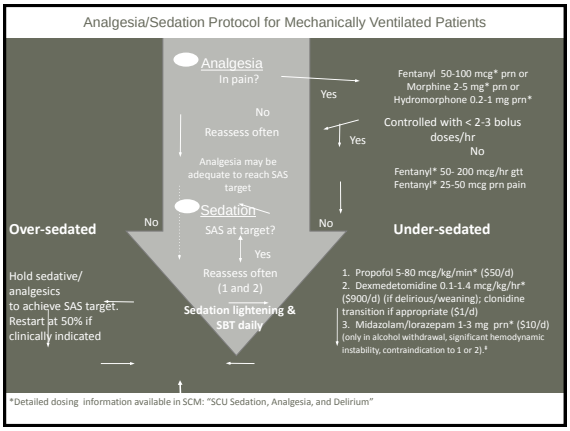
Sarah Palin, Concerning the "Death Panels"
Facebook, August 13, 2009

- Recognizing that there will be financial winners and losers with any change…
- How do we make sure that changes in treatment patterns are made to serve the best interest of the patients?
  - Rather than merely save the government money
  - Rather than direct profits to particular companies
  - Rather than to benefit a class of professionals

What are the drivers of change in treatment patterns?

- Medical Research
- Expert opinion
- Quality (and other) regulations
- Reimbursement rates
- Provider decisions
- Patient choice

An even quicker example



Pharmaceutical and Medical Device Industry

Drug Makers Pay for Lunch as They Pitch

Phil Marino for The New York Times

A lunch order arrives at North Shore Diabetes in New Hyde Park, N.Y. A pharmaceutical company paid for the food.

By STEPHANIE SAUL
Published: July 28, 2006

Anyone who thinks there is no such thing as a free lunch has never visited 3003 New Hyde Park Road, a four-story medical building on Long Island, where they are delivered

Narcotic Maker Guilty of Deceit Over Marketing

From left, Howard R. Udell, the top lawyer for Purdue Pharma; Dr. Paul D. Goldenheim, the company's former medical director, and Michael Friedman, Purdue's president.

By BARRY MEIER
Published: May 11, 2007

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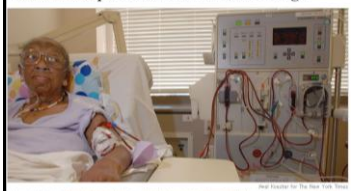
ABINGDON, Va., May 10 – The company that makes the painkiller OxyContin and three of its current and former executives pleaded guilty Thursday in federal court here to criminal charges that it had misled doctors and patients when it claimed the drug was less likely to be abused than traditional narcotics.

The company, Purdue Pharma, agreed to pay $600 million in fines and other payments to resolve the criminal

Information on

Doctors Reap Millions for Anemia Drugs



Bernice Wilson, 80, receiving dialysis treatment at Crescent Heights Dialysis Center, operated in Los Angeles by DaVita, a large dialysis chain. Her treatment includes a dose of Epogen, a drug used to treat anemia.

By ALEX BERENSON and ANDREW POLLACK
Published: May 9, 2007

E-MAIL

Two of the world's largest drug companies are paying hundreds of millions of dollars to doctors every year in return for giving their patients anemia medicines, which regulators now say may be unsafe at commonly used doses.

THE WALL STREET JOURNAL. ONLINE

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PAGE ONE

Delicate Operation

How a Famed Hospital Invests In Device It Uses and Promotes

Cleveland Clinic Set Up Fund That Has Stock in Maker Of Heart-Surgery System

Dr. Cosgrove's Multiple Roles

By DAVID ARMSTRONG
Staff Reporter of THE WALL STREET JOURNAL
December 12, 2005; Page A1

CLEVELAND -- Since 2001, more than 1,200 patients at the prestigious Cleveland Clinic have had an operation aimed at correcting atrial fibrillation, a form of heart fluttering.

Doctors commonly call it the "AtriCure procedure," after the maker of the equipment used in the surgery, a company called AtriCure Inc. In medical journals and at conferences, the Cleveland Clinic and its doctors have been leading advocates of the AtriCure procedure.

The Clinic's relationship with AtriCure, however, goes deeper. A venture-capital partnership that the Clinic helped found and invested in owns about 4.1% of AtriCure's stock, valued at about $7 million. The Clinic's chief executive, heart surgeon Delos "Toby" Cosgrove, sat on AtriCure's board of directors until March. He also invested personally in the fund and was one of the general partners managing it until, according to a Clinic spokeswoman, he cut his ties to the fund at the end of October.

Top Psychiatrist Didn't Report Drug Makers' Pay

By GARDINER HARRIS
Published: October 3, 2008

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One of the nation's most influential psychiatrists earned more than $2.8 million in consulting arrangements with drug makers from 2000 to 2007, failed to report at least $1.2 million of that income to his university and violated federal research rules, according to documents provided to Congressional investigators.

Related
Select Documents

June 2004

A report from Emory's conflict of interest committee in June 2004, which detailed multiple "serious" and "significant" violations of university procedures intended to protect patients.

Download PDF of the Report

The psychiatrist, Dr. Charles B. Nemeroff of Emory University, is the most prominent figure to date in a series of disclosures that is shaking the world of academic medicine and seems likely to force broad changes in the relationships between doctors and drug makers.

In one telling example, Dr. Nemeroff signed a letter dated July 15, 2004, promising Emory administrators that he would earn less than $10,000 a year from GlaxoSmithKline to comply with federal rules. But on that day, he was at the Four Seasons Resort in Jackson Hole, Wyo., earning $3,000 of what would become $170,000 in income that year from that company – 17

Doctors' groups welcome medical company dollars

By Charles Ornstein and Tracy Weber, ProPublica

SAN FRANCISCO — From the time they arrived to the moment they laid their heads on hotel pillows, the thousands of cardiologists attending this week's Heart Rhythm Society conference have been bombarded with pitches for drugs and medical devices.

St. Jude Medical adorns every hotel key card. Medtronic ads are splashed on buses, banners and the stairs underfoot. Logos splay across shuttle bus headrests, carpets and cellphone-charging stations.

And at night, a drug firm gets the last word. A promo for the heart drug Multaq stood on each doctor's nightstand Wednesday.

Who arranged this commercial barrage? The society itself, which sold access to its members and their purchasing power.

INTERACTIVE: How the Heart Rhythm society sells access
STORY: Heart Society's Tip sheets fail to mention risks
STORY: Medical groups shy on detailing industry financial support

Last year's four-day event brought in more than $5 million, including money for exhibit booths the size of mansions and company-sponsored events. This year, there are even more "promotional opportunities," as the society describes them.

Ads by Google
Angie's List Doctors
Defibrillators On Sale
Medical Device Database

USA Today
May 6, 2011

Heart Rhythm Society, 2011
San Francisco
$5 million from promotional opportunities

Hotel Keys
Night Stand Tent
Shuttle Buses
Carpets
GPS Name Tags

Heart Rhythm Society Revenue
2006; Total $12 million, 37.5 from corporations
2010: Total $16 million. 49.4 from corporations

SPECIAL COMMUNICATION

Guest Authorship and Ghostwriting in Publications Related to Rofecoxib

A Case Study of Industry Documents From Rofecoxib Litigation

Joseph S. Ross, MD, MHS
Kevin P. Hill, MD, MHS
David S. Egilman, MD, MPH
Harlan M. Krumholz, MD, SM

Context Authorship in biomedical publication provides recognition and establishes accountability and responsibility. Recent litigation related to rofecoxib provided a unique opportunity to examine guest authorship and ghostwriting, practices that have been suspected in biomedical publication but for which there is little documentation.

Objective To characterize different types and the extent of guest authorship and ghostwriting in 1 case study.

Data Sources Court documents originally obtained during litigation related to rofecoxib against Merck & Co Inc. Documents were created predominantly between 1996 and 2004. In addition, publicly available articles related to rofecoxib identified via MEDLINE.

Data Extraction All documents were reviewed by one author, with selected review by coauthors, using an iterative process of review, discussion, and rereview of documents to identify information related to guest authorship or ghostwriting.

Data Synthesis Approximately 250 documents were relevant to our review. For the publication of clinical trials, documents were found describing Merck employees working either independently or in collaboration with medical publishing companies to prepare manuscripts and subsequently recruiting external, academically affiliated investigators to be authors. Recruited authors were frequently placed in the first and second positions of the authorship list. For the publication of scientific review papers, documents were found describing Merck marketing employees developing plans for manuscripts, contracting with medical publishing companies to ghostwrite manuscripts, and recruiting external, academically affiliated investigators to be authors. Recruited authors were commonly the sole author on the manuscript and offered honoraria for their participation. Among 96 relevant published articles, we found that 92% (22 of 24) of clinical trial articles published a disclosure of Merck's financial support, but only 50% (36 of 72) of review articles published either a disclosure of Merck sponsorship or a disclosure of whether the author had received any financial compensation from the company.

Conclusions This case-study review of industry documents demonstrates that clinical trial manuscripts related to rofecoxib were authored by sponsor employees but often attributed first authorship to academically affiliated investigators who did not always disclose industry financial support. Review manuscripts were often prepared by unacknowledged authors and subsequently attributed authorship to academically affiliated investigators who often did not disclose industry financial support.

AUTHORSHIP IN BIOMEDICAL publication provides recognition while establishing accountability and responsibility. Guest authorship has been defined as the designation of an individual who does not meet authorship criteria as an author.[1,2] It was identified in 16% of research articles, 26% of review articles, and 21% of editorials in a survey of 6 peer-reviewed medical journals,[3] in addition to 41% of Cochrane reviews.[4] Ghostwriting has been defined as the failure to designate an individual (as an author) who has made a substantial contribution to the research or writing of a manuscript.[1] Ghostwriting was demonstrated in 13% of research articles, 10% of review articles, 6% of editorials, and 11% of Cochrane reviews[3,4]; other research has found similar rates.[5]

Two studies have characterized the practices of guest authorship and ghostwriting using industry documents, one examining practices related to gabapentin by Pfizer Inc and Parke-Davis, Division of Warner-Lambert Com-

JAMA Ross, J. S. et al. JAMA 2008;299:1800-1812.

Letter from STI to Merck 1st draft of Rofecoxib Manuscript

FILE COPY

October 9, 2000

Deborah Matzura-Wolfe
Medical Program Coordinator
Clinical Development
Merck US Human Health
PO Box 4, HM-202
West Point, PA 19486

RE: VIOXX C-1 MANUSCRIPT (PROTOCOL 116)

Dear Deborah:

We are pleased to enclose Draft I of the "A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study to Evaluate the Safety and Efficacy of Rofecoxib 25 mg and Celecoxib 200 mg in Patients with Osteoarthritis of the Knee or Hip" manuscript to be submitted to *JAMA Express*.

Please feel free to mark your revisions directly on the hard copy provided.

We look forward to receiving your comments by **October 23, 2000**. If you have any questions during your review, do not hesitate to contact me at (970) 204-4446.

Sincerely,

Grace E. Johnson, PharmD
Senior Editor

encl

cc: J Romankiewicz, U Kistner, G Geba (MER), .1617

JAMA Ross, J. S. et al. JAMA 2008;299:1800-1812.

E-mail between STI and Merck discussing Rofecoxib publications

Dear Susan,

At the request of John Romankiewicz, I am providing you with an update on development and estimated delivery dates for various publications related to VIOXX that STI is working on.

1) Rofecoxib for the Treatment of Pain: Role of COX-2 Inhibitors for the Treatment of Nonmalignant Pain
- intended author: [redacted]
- intended journal: Analgesia
- estimated delivery of Draft 2 to Merck: 10/22

2) Clinical Implications of Drug Interactions with COX-2 Inhibitors
- intended author: [redacted]
- intended journal: Pharmacotherapy
- estimated delivery of Draft 2 to Merck: 10/22 (John Romankiewicz recently e-mailed you Draft 1 of this manuscript)

3) Overview of Clinical Pharmacology and Clinical Experience with Rofecoxib
- intended author: [redacted]
- intended journal: American Journal of Medicine or Archives of Internal Medicine
- estimated delivery of Draft 1 to Merck: 11/5

4) Review of Pharmacology and Clinical Experience with Rofecoxib for Osteoarthritis
- intended author: [redacted]
- intended journal: Journal of Rheumatology
- estimated delivery of Draft 1 to Merck: 10/29

5) Osteoarthritis in the Elderly: The Role of COX-2-Specific Inhibitors
- intended author: [redacted]
- intended journal: Geriatrics
- Draft 1 provided to Merck (C. Yarbrough) 9/27 - await comments; this manuscript cannot be sent via E-mail at this time as it is being actively edited based on additional internal comments; please call if you would like a copy FAXed to you

6) Changing Paradigm for Management of Osteoarthritis
- intended author: [redacted]
- intended journal: Journal of Osteopathic Medicine or Journal of Family Practice
- estimated delivery of Draft 1 to Merck: 11/12

7) Pharmacoeconomic Considerations in Treating Osteoarthritis: COX-2-Specific Inhibitors Versus NSAIDs
- author (confirmed): [redacted]
- intended journal: Journal of Managed Care
- extended outline provided to Merck (C. Yarbrough) and author 9/27 - copy attached for your reference. Outline approved by author; no comments received from Merck to date
- estimated delivery of Draft 1 of manuscript to Merck: 11/5

8) Managed Care Perspective on the COX-2 Inhibitors
- intended author: [redacted]
- intended journal: Managed Care
- estimated delivery of Draft 1 to Merck: 11/19

If you have any questions or require additional information at this time, please do not hesitate to contact me.

JAMA Ross, J. S. et al. JAMA 2008;299:1800-1812.

Ross's Conclusions

- Industry staff frequently ghost wrote articles on clinical trial results
- "Guest" authors with academic affiliations frequently signed on after the fact
- Recruited authors were paid honoraria, but played little or no role in the actual research or writing
- Industry support of research not always acknowledged
  - review articles acknowledged support only 50% of the time
  - clinical trial authors acknowledged industry support 92% of the time

Ross et al. *JAMA.* 2008;299:1800-1812.

Minnesota Limit on Gifts to Doctors May Catch On

By GARDINER HARRIS
Published: October 12, 2007

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There are bagels and fruit in the morning, sandwiches at lunch, fresh cookies in the afternoon and an occasional restaurant dinner, but many of the doctors who routinely accept these goodies from pharmaceutical sales representatives say they see sales people for the educational messages they bring, not the food.

Maybe doctors in Minnesota are different.

Two years after Minnesota officials forbade drug makers to give doctors more than $50 worth of food or other gifts per year, drug company sales representatives there are having a far harder time marketing to doctors. The rule change was small and almost accidental — a state official decided to interpret a 1993 law differently from his predecessor. But the effect on drug makers has been profound.

The year after the change, the number of visits that Minnesota primary care doctors accepted from drug sales representatives decreased at about twice the rate of the decline reported by primary care doctors nationwide, according to a survey by ImpactRx, a New Jersey firm that tracks pharmaceutical marketing. A growing number of Minnesota hospitals and clinics have banned routine visits from them.

Vermont Statute

Effective July 2009

AS PASSED BY HOUSE AND SENATE
2009

S.48
Page 1

S.48

An act relating to the marketing of prescribed products

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. § 4631(b) is amended to read:

(b) As used in this section:

* * *

(3) "Health care professional" shall have the same meaning as health care provider in section 9402 of this title.

* * *

Sec. 2. LEGISLATIVE FINDINGS; INTENT

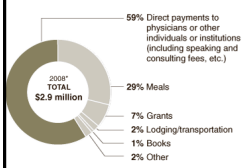
(a) The general assembly finds that the legislative findings in Sec. 1 of No. 80 of the Acts of 2007 provide a sound basis for instituting a ban of certain gifts to prescribers and disclosure of marketing activities as provided for in this act. Findings (1) through (8), (13), (15), (17), (19), and (21) shall be incorporated into this act by reference.

Vermont 2007-2008 Data

Marketing to Doctors

Under a new Vermont law, drug and device manufacturers will have to disclose the payments they make to health care providers. The law will require specific disclosure of doctors' names, dollar amounts and the medical products to which the spending is pegged. The state's previous law required only general information. The law will also ban free meals for doctors.

Payments by medical product companies to doctors in Vermont



Fiscal year, from July 1, 2007 to June 30, 2008.

Drugs for which the most marketing dollars were spent on doctors

RANK		MANUFACTURER	INDICATIONS
1	**Strattera**	Eli Lilly	Attention deficit disorder
2	**Cymbalta**	Eli Lilly	Depression, anxiety disorder
3	**Exelon**	Novartis Pharmaceuticals	Alzheimer's, Parkinson's
4	**Januvia**	Merck	Diabetes
5	**Lexapro**	Forest Pharmaceuticals	Depression, anxiety disorder
6	**Lantus**	Sanofi Aventis	Diabetes
7	**Levemir**	Novo Nordisk	Diabetes
8	**Namenda**	Forest Pharmaceuticals	Alzheimer's
9	**Lipitor**	Pfizer	Cholesterol
10	**Lyrica**	Pfizer	Pain

Source: Vermont Attorney General's Office

111TH CONGRESS
1ST SESSION

S. 301

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

IN THE SENATE OF THE UNITED STATES

JANUARY 22, 2009

Mr. GRASSLEY (for himself, Mr. KOHL, and Mr. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

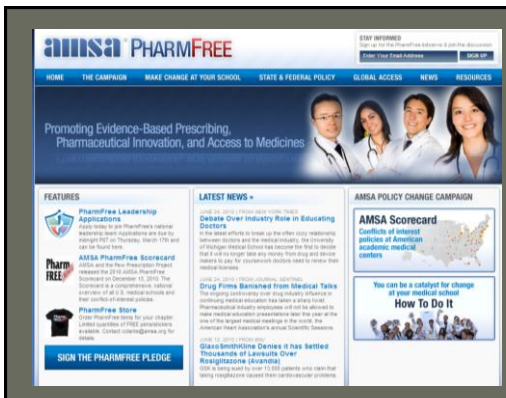
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Physician Payments Sunshine Act of 2009".

Senator Charles Grassley
Republican, Iowa

ProPublica – Dollars for Docs



An Act To Restrict Gifts to Health Care Practitioners from Pharmaceutical and Medical Device Manufacturers

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §2697, sub-§1, as enacted by PL 1999, c. 786, Pt. A, §3, is amended to read:

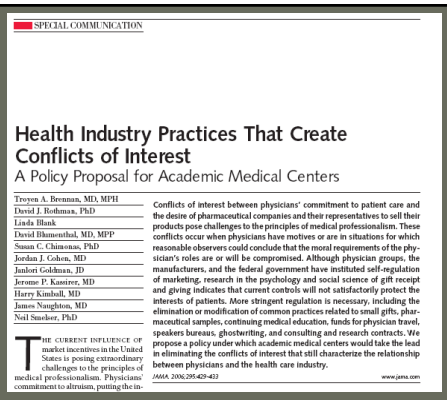
1. **Definitions.** As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

A-1. "Health care practitioner" means a person who is licensed in the State to provide health care and prescribe prescription drugs, including an organization consisting of persons licensed in the State to provide health care and prescribe prescription drugs and an employee, agent or contractor of a person licensed to provide health care in the State and to prescribe prescription drugs.

B. "Manufacturer" means a ~~manufacturer of~~ person who manufactures, prepares, propagates, compounds, processes, packages, repackages, distributes or labels prescription drugs and includes a subsidiary or affiliate of a manufacturer.

C. "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory that



SPECIAL COMMUNICATION

Health Industry Practices That Create Conflicts of Interest

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

Conflicts of interest between physicians' commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products pose challenges to the principles of medical professionalism. These conflicts occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised. Although physician groups, the manufacturers, and the federal government have instituted self-regulation of marketing, research in the psychology and social science of gift receipt and giving indicates that current controls will not satisfactorily protect the interests of patients. More stringent regulation is necessary, including the elimination or modification of common practices related to small gifts, pharmaceutical samples, continuing medical education, funds for physician travel, speakers bureaus, ghostwriting, and consulting and research contracts. We propose a policy under which academic medical centers would take the lead in eliminating the conflicts of interest that still characterize the relationship between physicians and the health care industry.

JAMA. 2006;295:429-433 www.jama.com

THE CURRENT INFLUENCE OF market incentives in the United States is posing extraordinary challenges to the principles of medical professionalism. Physicians' commitment to altruism, putting the in-

Recommendations for Academic Medical Centers

Brennan, et. al. *JAMA* 295(4), 2006: 429-433

- Myth: Small gifts don't matter
- Myth: Disclosure is adequate protection of patients' interests

- Recommendations

1. ***Gifting***: $0.00 limit on gifts.
2. ***Samples***: No samples given directly to physicians.
3. ***Formularies***: Formulary committees exclude anyone who receives payments, gifts or inducements from industry.
4. ***Education***: Contributions to central office. Public acknowledgment.
5. ***Travel***: Funds given to central office, which disburses.
6. ***Speaker's Bureaus/Ghost Writing***: No membership on industry speaker's bureaus. No ghostwritten publications.
7. ***Consulting/Research Contracts***: Only contracts with specific deliverables.

IOM Definition

A Conflict of Interest is "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."

Primary Interests
- Welfare of patients
- Integrity of research
- Quality of medical education

Secondary Interests
- Financial gain
- Professional advancement
- Recognition of achievement
- Favors for friends/family/students/colleagues

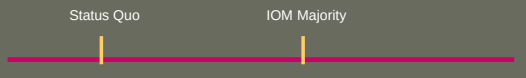
Lo, Bernard and Marilyn J. Field, Editors; Committee on COI in Medical Research, Education and Practice; IOM. *Conflict of Interest in Medical Research, Education, and Practice*. (2009)

IOM on Medical Education

- CME "has become far too reliant on industry funding."
- Industry funding "tends to promote a narrow focus on products," and not "a broader education on alternative strategies for managing health conditions … such as communication and prevention."
- "[T]he current system of funding is unacceptable and should not continue."

Lo, Bernard and Marilyn J. Field, Editors; Committee on COI in Medical Research, Education and Practice; IOM. *Conflict of Interest in Medical Research, Education, and Practice*. (2009)

Industry Sponsorship of CME



Current regulation adequate

Need stronger protections

Industry Sponsorship of CME

Current regulation adequate

Need stronger protections

No protections sufficient; Eliminate all funding.

Table 7: Income and Expense by Organization Type - 2007

Organization Type	Count	Total Income	Total Commercial Support	Advertising and Exhibits Income	Other Income*	Total Expense
Government or Military	15	$ 69,452,247	$ 254,626	$ 376,278	$ 68,821,343	$ 69,222,034
Hospital / Health Care Delivery System	93	$ 105,013,564	$ 47,496,388	$ 7,496,533	$ 50,108,644	$ 100,320,041
Insurance Company / Managed Care Company	14	$ 3,488,670	$ 318,068	$ 35,250	$ 3,135,352	$ 6,723,031
Non-profit (Other)	38	$ 160,396,623	$ 78,412,499	$ 11,852,102	$ 70,132,022	$ 126,509,771
Non-profit (Physician Membership Organization)	270	$ 887,180,992	$ 215,388,224	$ 217,906,617	$ 453,886,151	$ 625,307,686
Not Classified	33	$ 55,187,810	$ 29,263,130	$ 2,422,895	$ 23,501,785	$ 43,716,292
Publishing / Education Company	150	$ 830,811,192	$ 594,419,878	$ 10,831,027	$ 225,560,282	$ 615,705,205
School of Medicine	123	$ 427,667,558	$ 245,790,391	$ 23,202,854	$ 158,674,315	$ 375,781,679
Grand Total 2007	**736**	**$ 2,539,198,656**	**$ 1,211,345,204**	**$ 274,033,556**	**$ 1,053,819,894**	**$ 1,943,285,741**
Grand Total 2006	**729**	**$ 2,384,581,430**	**$ 1,199,405,519**	**$ 244,913,684**	**$ 940,262,229**	**$ 1,820,708,534**
Grand Total 2005	**716**	**$ 2,250,468,669**	**$ 1,115,597,071**	**$ 235,721,224**	**$ 899,150,373**	**$ 1,717,466,541**
Grand Total 2004	**716**	**$ 2,052,577,784**	**$ 1,071,064,979**	**$ 197,032,732**	**$ 784,480,073**	**$ 1,612,476,355**
Grand Total 2003	**697**	**$ 1,774,516,395**	**$ 971,100,098**	**$ 183,293,597**	**$ 620,122,700**	**$ 1,539,686,438**
Grand Total 2002	**686**	**$ 1,596,198,865**	**$ 746,015,426**	**$ 187,327,756**	**$ 662,855,683**	**$ 1,327,042,030**
Grand Total 2001	**674**	**$ 1,393,926,271**	**$ 568,767,299**	**$ 159,956,455**	**$ 665,203,517**	**$ 1,179,631,684**
Grand Total 2000	**680**	**$ 1,271,189,580**	**$ 466,971,749**	**$ 168,864,400**	**$ 635,353,431**	**$ 1,053,684,130**
Grand Total 1999	**655**	**$ 1,110,482,468**	**$ 387,619,740**	**$ 148,241,160**	**$ 574,621,568**	**$ 920,897,968**
Grand Total 1998	**632**	**$ 888,544,752**	**$ 301,948,112**	**$ 125,901,179**	**$ 457,694,461**	**$ 842,061,037**

* Other income represents income other than commercial support and advertising and exhibit income, for instance, participant registration fees, and allocations from a provider's parent organization or other internal departments.

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* Other income represents income other than commercial support and advertising and exhibit income, for instance, participant registration fees, and allocations from a provider's parent organization or other internal departments.

REGARDING THE INDEPENDENCE OF ACCREDITED CONTINUING MEDICAL EDUCATION

The ACCME has considered the feedback to its Summer 2008 Calls-for-Comment. **The ACCME will not be taking any action to end the commercial support of accredited continuing medical education.** Of course, the ACCME reserves the right to re-evaluate this position from time to time – but at this point no action will be taken. "**CME as a Bridge to Quality**™" and its impact on patient care is mission critical to ACCME, right now. Of secondary importance – but important none-the-less – is the independence of CME from the influence of commercial interests. While putting new resources into the management of issues to ensure the independence of CME from commercial influence, the ACCME is steadfast in ensuring its delivery of a valid accreditation system based upon the 2006 ACCME Accreditation Criteria and the ACCME Standards for Commercial Support℠.

Industry Sponsorship of CME

Current regulation adequate

Need stronger protections

No protections sufficient; Eliminate all funding.

SPECIAL COMMUNICATION

Professional Medical Associations and Their Relationships With Industry

A Proposal for Controlling Conflict of Interest

David J. Rothman, PhD
Walter J. McDonald, MD
Carol D. Berkowitz, MD
Susan C. Chimonas, PhD
Catherine D. DeAngelis, MD, MPH
Ralph W. Hale, MD
Steven E. Nissen, MD
June E. Osborn, MD
James H. Scully Jr, MD
Gerald E. Thomson, MD
David Wofsy, MD

Professional medical associations (PMAs) play an essential role in defining and advancing health care standards. Their conferences, continuing medical education courses, practice guidelines, definitions of ethical norms, and public advocacy positions carry great weight with physicians and the public. Because many PMAs receive extensive funding from pharmaceutical and device companies, it is crucial that their guidelines manage both real and perceived conflict of interests. Any threat to the integrity of PMAs must be thoroughly and effectively resolved. Current PMA policies, however, are not uniform and often lack stringency. To address this situation, the authors first identified and analyzed conflicts of interest that may affect the activities, leadership, and members of PMAs. The authors then went on to formulate guidelines, both short-term and long-term, to prevent the appearance or reality of undue industry influence. The recommendations are rigorous and would require many PMAs to transform their mode of operation and perhaps, to forgo valuable activities. To maintain integrity, sacrifice may be required. Nevertheless, these changes are in the best interest of the PMAs, the profession, their members, and the larger society.

JAMA. 2009;301(13):1367-1372 www.jama.com

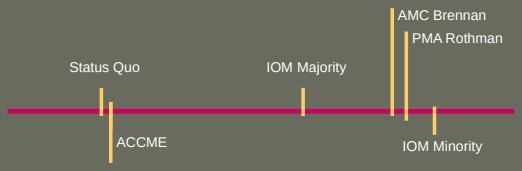
Industry Sponsorship of CME

Current regulation adequate

Need stronger protections

No protections sufficient; Eliminate all funding.

Industry Sponsorship of CME



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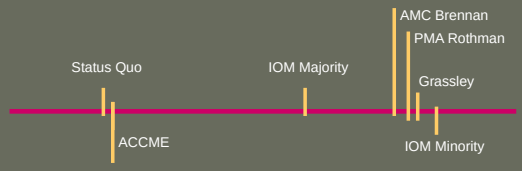
Industry Sponsorship of CME



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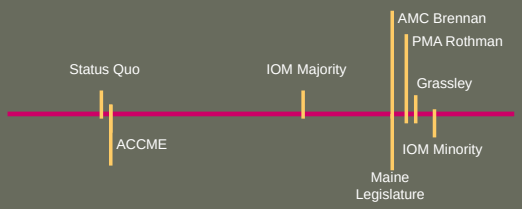

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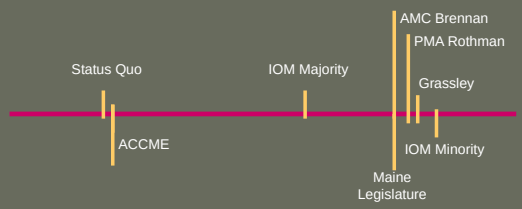

Current regulation adequate

Need stronger protections

No protections sufficient; Eliminate all funding.

MMC Policy Summary

It is the policy of Maine Medical Center to protect the integrity of clinical decisions, healthcare education, research activities and the purchasing or prescribing of medical devices and pharmaceuticals from real or perceived conflicts of interest created by gifts, payments, or other remuneration from those who sell health care goods and services.

Main Provisions

- Disclosure
- Gifts
- Education
- Samples
- Authorship
- Speakers Bureaus
- Consulting
- Purchasing

Disclosure

- COI form revised and on-line
- More individuals must complete
  - MMC employees managers and above;
  - Physicians employed by MMC or MMP;
  - Other practitioners with prescribing rights (e.g., NP, PA);
  - Pharmacists;
  - Faculty in MMC educational programs (Not occasional presenters);
  - Members of MMC committees which make purchasing decisions.

Gifts

- MMC employees, faculty, and learners may not accept gifts or hospitality from representatives of the health care vendors regardless of the value of the gift.
  - Health care vendors may not support business meetings, retreats, social gatherings
  - Donations may be accepted by employees on behalf of charitable organizations
  - The Development Office may accept gifts and bequests

MMC Educational Events

- Health care vendor support or sponsorship for MMC educational conferences is prohibited
  - May not receive educational grants from HCV
  - May not receive fees for displays outside conferences
  - Must report all outside support
- May accept educational support from non-health care vendors, not for profit organizations, educational institutions, professional organizations and direct care providers in Maine.

Non-MMC Educational Events

- Payment for attendance is prohibited
- Funding of travel, lodging, meals and entertainment for oneself or one's spouse is prohibited
- Must be open to all (not select invitees)
- Financial ties of planners and presenters fully disclosed
- Content determined by presenter and not produced by company

Authorship and Speakers Bureaus

- Authorship on publications to be guided by the standards of the International Committee of Medical Journal Editors
- Participation in speakers bureaus is prohibited (except in narrow conditions with prior approval).
  - Speakers bureau defined as mentioning a company's products in a presentation while being paid by the company for the presentation.
- MMC employees may accept reasonable compensation and travel support for academic or scholarly presentations

Consulting for Health Care Vendors

- Consulting relationships must be approved by supervisor
- Consulting must occur under a contract that specifies deliverables and compensation

Purchasing Decisions

- All new drugs, biologicals and products must be approved prior to use
- Committee members must disclose potential COI and recuse themselves
- Trialing a product must be coordinated with the Purchasing Department
- Off-site evaluation of products must be coordinated by the Purchasing Department

Pharmaceutical Samples

Drug samples may not be accepted by MMC employees, faculty or learners or in any MMC or MMP clinical settings.

Conflict of Interest Advisory Committee

- Help staff determine if an activity is in compliance with the policy and suggest ways to modify activities to bring into compliance
- Cannot grant exemptions to policy; Advise on future revisions of the policy
- Membership: Neurosurgeon, Cardiologist, Cardiac Surgeon, Hospitalist, Radiology Director, Ethicist, Pharmacy, Nursing, Compliance.
- Meets monthly, lots of inquiries

What do you think?

Will this solve the problem?

Samples Replacement Program

Struggles with Samples

- Stakeholder groups (e.g., Chiefs) accepted the “no samples” policy contingent on finding an alternative
- Numerous clinicians vocal about the importance of samples
- Many passionate inquiries to COI advisory committee
- Outpatient clinic (partnering with pharmacy) had organized, thoughtful approach to dispersing samples.
- Diabetes and Endocrinology Center last stop (before ED) for insulin samples.
- Cardiology: Plavix post drug eluting stents

Critical Need Medication Assistance Program

- Purposes:
  - Create a bridge for patients in financial need from the time there is a recognized need for a critical medication to the time when the patient can access a stable source of the medication.
  - Integrate and standardize the process by which MMC patients receive medication assistance
- Partnership
  - MMC Out-patient clinics
  - Pharmacy
  - MaineHealth MedAccess
  - MMP practices
- Funded by Special Purpose Fund ($70,000); budget based on pharmacy estimate on prior use of samples

What is a critical need medication?

- A medication required soon to prevent an adverse health event or ED visit.
- A medication which is not immediately available from a low or no cost sources (e.g, $4 prescription program)

Other Requirements:

- Patient demonstrate financial need
- Patients initiate PAP application with MedAccess
- Medications provided only as a bridge to PAP

Ongoing Rough Spots

- Continued funding for samples replacement
- When are consulting contracts really “marketing.”
- Philanthropic gifts vs. prohibited gifts/educational support
- External partners who receive grants from industry
- Evolving “opportunities” offered by industry

Thank you

chessf@mmc.org