Recognizing Pharmaceutical Industry Conflicts of Interest

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To receive 1.5 AMA PRA Category 1 Credits™ you must review this section and answer 8 CME questions at the end.

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Office for Oregon Health Policy & Research

OSU Oregon State University College of Pharmacy

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Target Audience: This educational activity is intended for health care professionals who are involved with medication prescribing .

Educational Objectives: Upon completion of this activity, the participants should be able to: 1. Recognize the psychological basis of conflicts of interest; 2. Recognize the extent and perception of financial conflicts of interest among clinicians; 3. Describe some documented shortcomings of industry sponsored research; 4. Recognize and be aware of pharmaceutical industry influence on journal publications, non-profit organizations, and professional organizations; 5. Identify the potential conflicts of interest occurring between the pharmaceutical industry and the FDA

Accreditation: This activity has been planned and implemented in accordance with the Essential Areas & Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The University of Texas Southwestern Medical Center and the Federation of State Medical Boards Research and Education Foundation. The University of Texas Southwestern Medical Center is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation: The University of Texas Southwestern Medical Center designates this educational activity for a maximum of 1.5 *AMA PRA Category 1 Credits™.* Physicians should only claim credit commensurate with the extent of their participation in the activity.

Conflict of Interest: It is the policy of UT Southwestern Medical Center that participants in CME activities should be made aware of any affiliation or financial interest that may affect the author's presentation. Each author has completed and signed a conflict of interest statement. The faculty members' relationships will be disclosed in the course material.

Discussion of Off-Label Use: Because this course is meant to educate physicians with what is currently in use and what may be available in the future, "off-label" use may be discussed. Authors have been requested to inform the audience when off-label use is discussed.

DISCLOSURE TO PARTICIPANTS

It is the policy of the CME Office at The University of Texas Southwestern Medical Center to ensure balance, independence, objectivity, and scientific rigor in all directly or jointly sponsored educational activities.

Program directors and authors have completed and signed a conflict of interest statement disclosing a financial or other relationship with a commercial interest related directly or indirectly to the program.

Information and opinion offered by the authors represent their viewpoints. Conclusions drawn by the audience should be derived from careful consideration of all available scientific information. Products may be discussed in treatment outside current approved labeling.

FINANCIAL RELATIONSHIP DISCLOSURE

Faculty	Type of Relationship/Name of Commercial Interest(s)
David Pass, M.D.	None
Dean Haxby, Pharm.D	Employment - CareOregon
Daniel Hartung, Pharm.D., MPH	None
Nancy Lee, PharmD, BCPS	None
Barbara S. Schneidman, MD, MPH	None

UT SOUTHWESTERN MEDICAL CENTER

Learning Objectives

1. Recognize the psychological basis of conflicts of interest
2. Recognize the extent and perception of financial conflicts of interest among clinicians
3. Describe some documented shortcomings of industry sponsored research
4. Recognize and be aware of pharmaceutical industry influence on journal publications, non-profit organizations, and professional organizations
5. Identify the potential conflicts of interest occurring between the pharmaceutical industry and the FDA

Influencing Clinicians

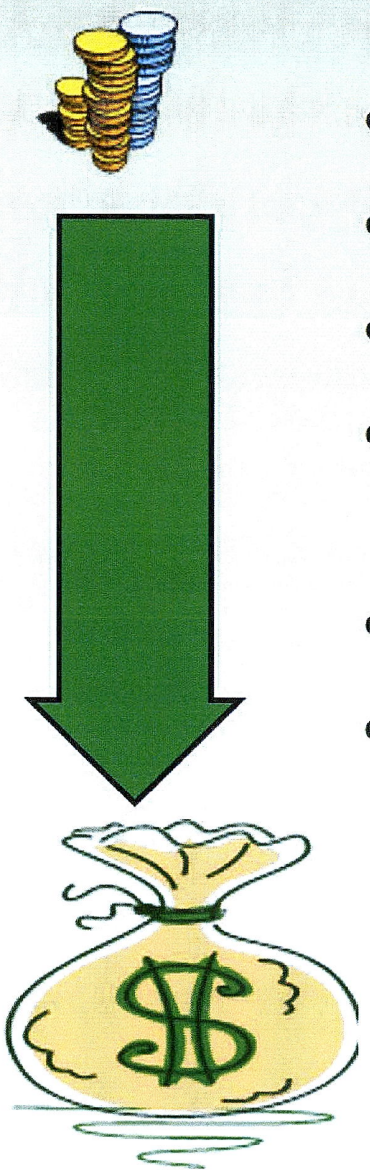
Competing Obligations

- Health Care Professionals
  - To promote the best interests of patients
  - Clinical competence
- Pharmaceutical Industry
  - Increase profitability
- Competing goals may produce conflicts of interest where primary clinical responsibility is eroded

Conflict of Interests (CoI)

- A set of conditions whereby judgment concerning a primary obligation is unduly influenced, consciously or subconsciously, by a secondary interest
- Primary interest
  - Patients, integrity of research, profession
- Secondary interest
  - Financial, career advancement, prestige

Financial Conflicts of Interest



- Pens, pads, food in workplace
- Dinners at restaurants
- CME arrangements
- Conferences (registration, travel, lodging)
- Grants for research
- Payments for Consulting
  - Speaking honoraria
  - Scientific advisory boards

Gifts: Food, Flattery, and Friendship

- Create a relationship
- Create obligation or need to reciprocate
  - Not necessarily related to size of gift
- Create an unconscious and unintentional "self-serving bias"
- Can create and foster sense of entitlement
- Cost money
  - $30 - $50 billion (2005) in promotional costs
  - ~$12,000 per practicing physician

COI and Psychological Rationalization

- Most would deny being influenced by conflicts of interest
  - Protected by professionalism and training as scientists
- Psychology and neuroscience research suggests individuals rationalize their decision making process
  - Social science experiments demonstrate even random suggestion can influence or anchor a response

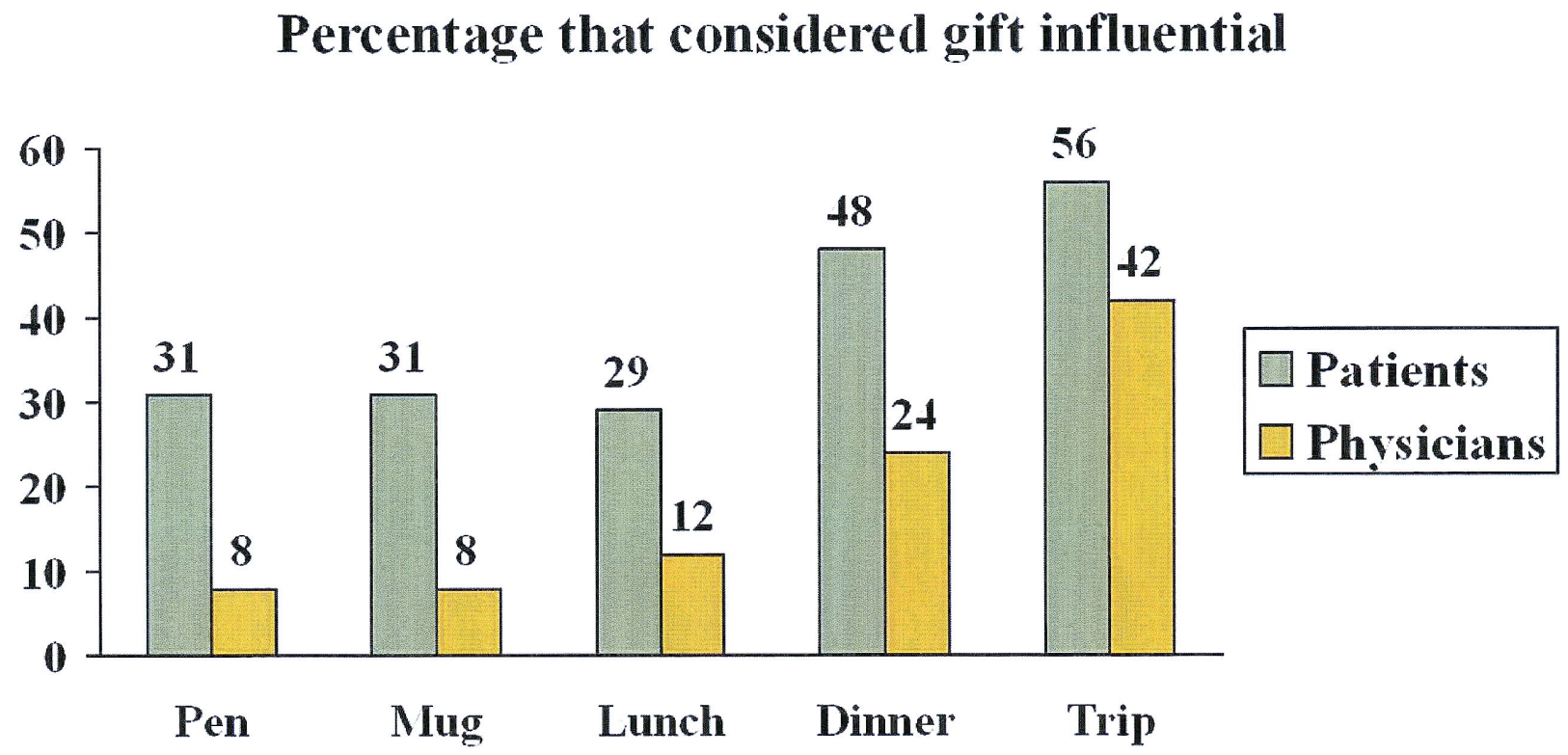
Dana J. JAMA 2003;290:252-55
Cain DM. JAMA 2008;299:2893-95

Perception of Influence

- Most deny gifts influence behavior
- Most equivocal about ethical aspects
  - Related to value
- Favorable attitudes related to amount pharmaceutical industry exposure and amount of gifts received

Perception of Influence

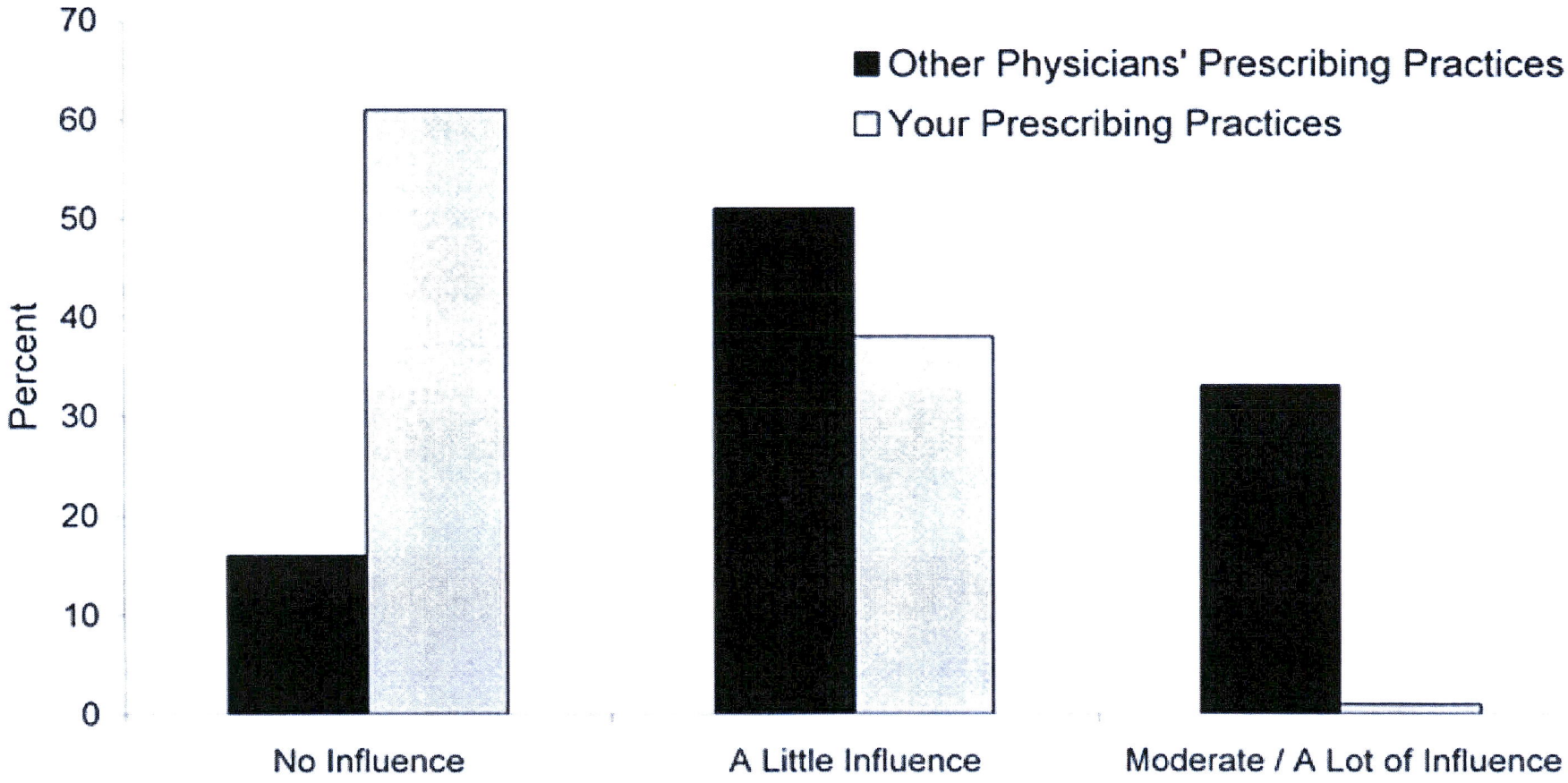
A comparison of physicians' and patients' attitudes toward pharmaceutical industry g



Gibbons RV et al. J Gen Int Med 1998;13:151

Perception of Influence

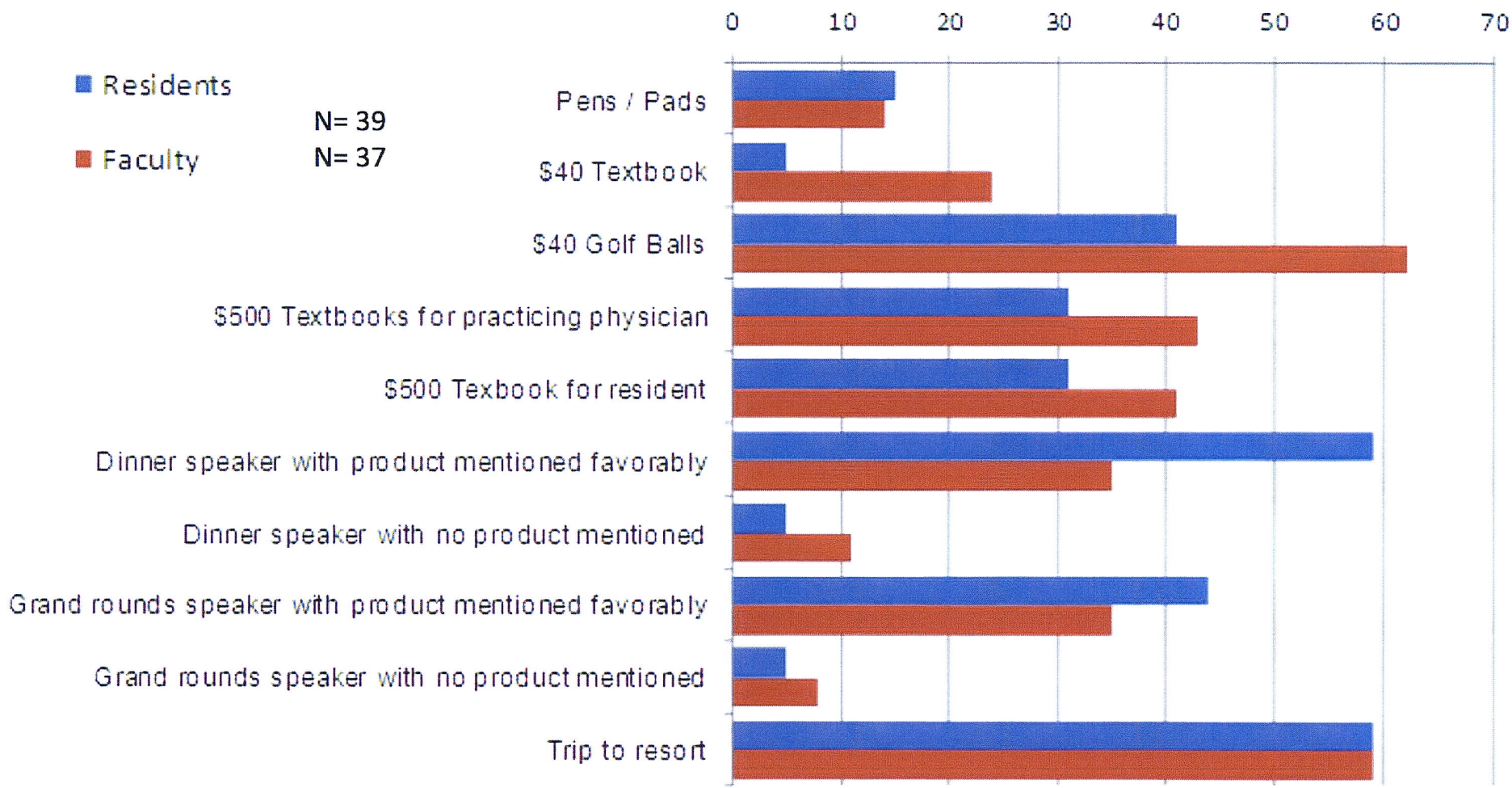
Pharmaceutical Industry Promotions/Steinman et al



Am J Med. 2001;110:551–557

Perception of Influence

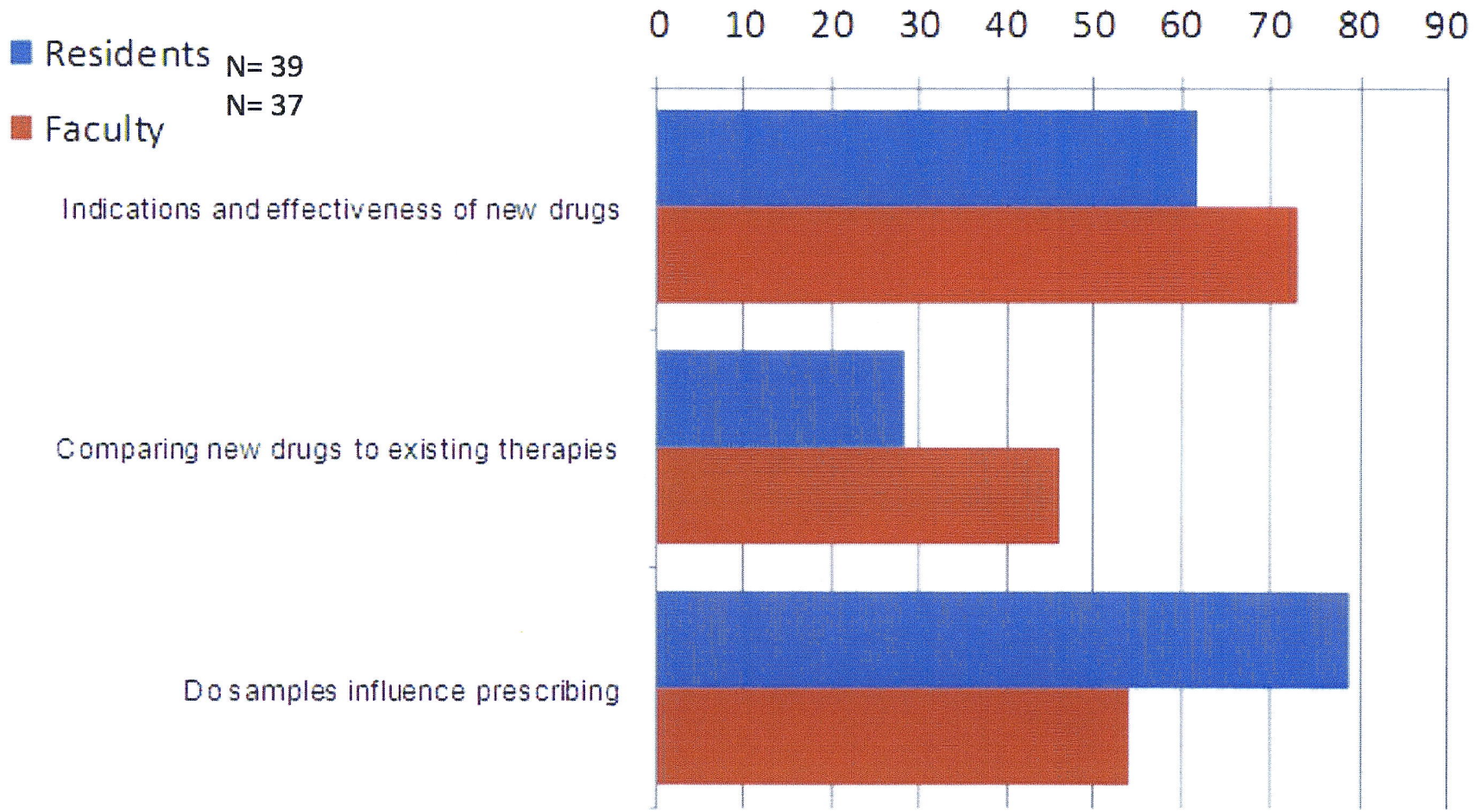
Proportion of MDs responding that activity is moderately or very ethically problematic



Brett AS. Arch Intern Med 2003;163:2213-18

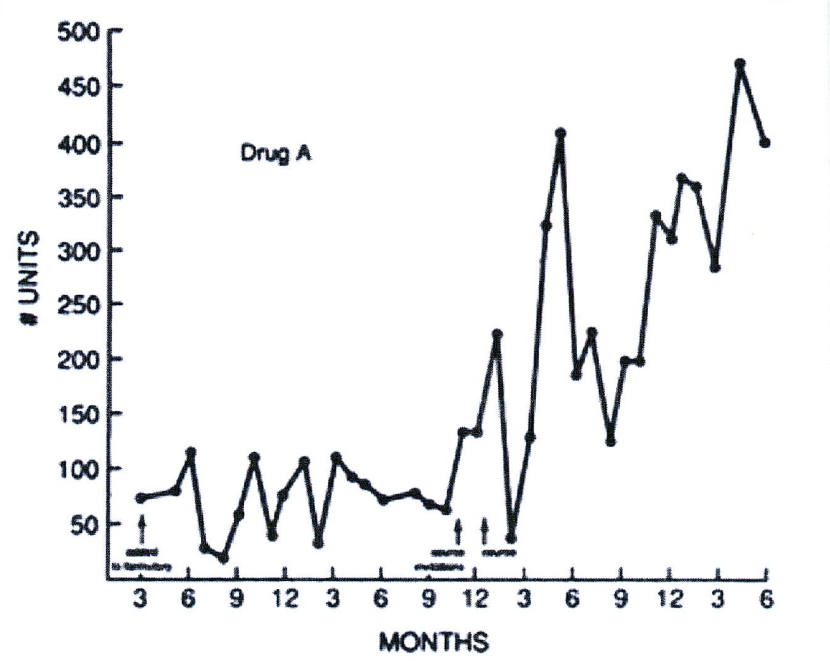
Perception of Influence

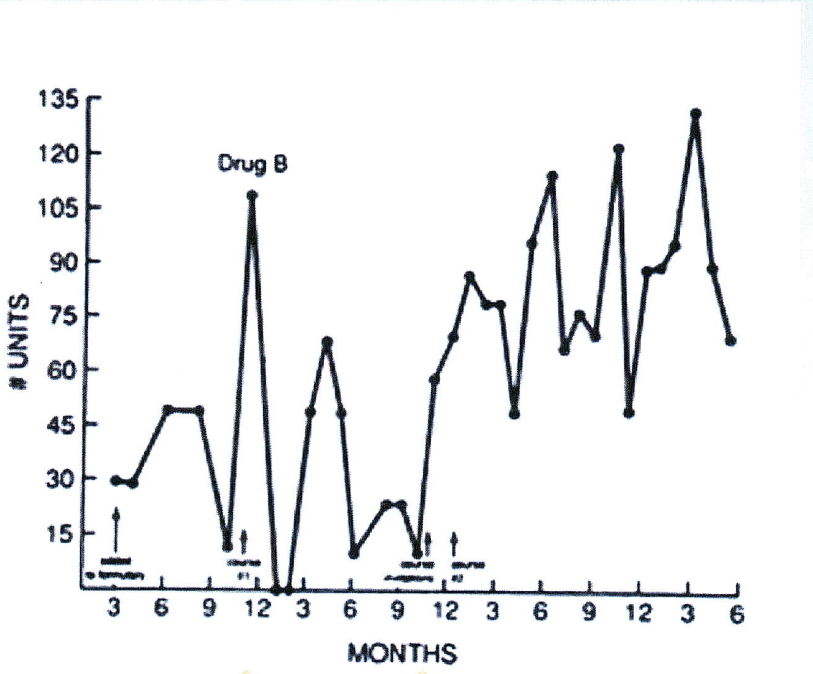
Proportion of MDs responding that drug rep information is moderately to very reliable or influential



Brett AS. Arch Intern Med 2003;163:2213-18

Influence on Physician Behavior





All Expense-paid resort on west coast (drug A) and in Caribbean (drug B) for physicians at Cleveland Clinic Hospital

Orlowski JP, Wateska L. The effects of pharmaceutical firm enticements on physician prescribing patterns. Chest 1992;102:270-73

Influence on Physician Behavior

	Cases N=47	Controls N=82	OR	Adjusted OR
Met with drug reps	24 (51%)	6 (7%)	13.2*	3.4*
Accepted money to:				
Attend symposia	2 (4%)	0 (0%)	9.1	7.9*
Speak at symposia	5 (11%)	0 (0%)	21.4*	3.9*
Conduct research	5 (11%)	1 (1%)	9.6*	9.5*
Any of the above	9 (19%)	1 (1%)	19.2*	5.7*

* $p<0.05$

Chren M, Landefeld CS. Physicians' behavior and their interactions with drug companies: a controlled study of physicians who request additions to a hospital drug formulary. JAMA 1994:271:684-89

Influence on Physician Behavior

- A retrospective cohort study of hospital residents attending a industry sponsored Grand Rounds compared to residents who did not attend
- 3 months after, residents who attended were:
  - More likely to choose the manufacturer's product
  - Less likely to select scientifically preferred antibiotic over sponsored product

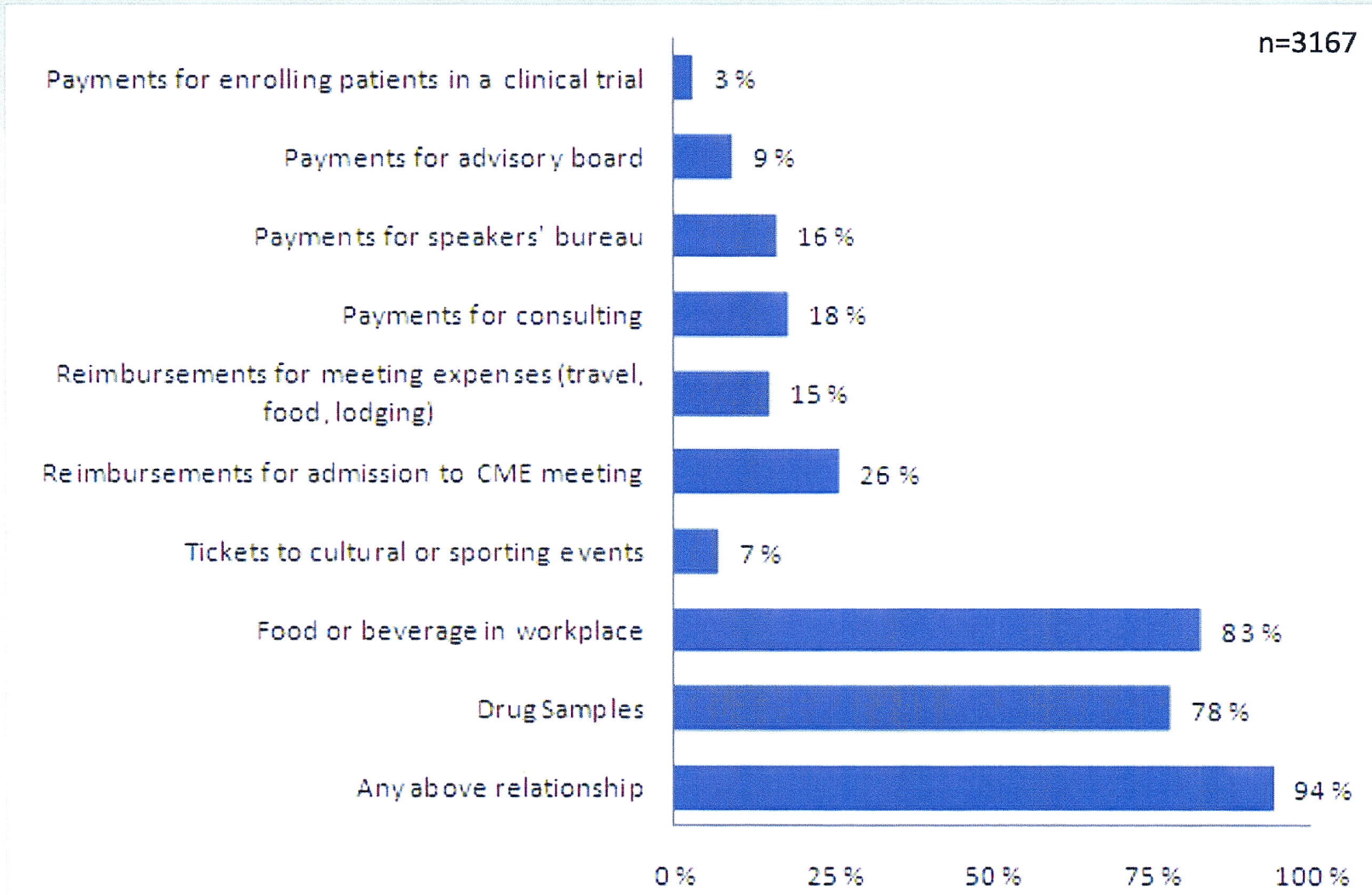
Spingarn RW, Berlin JA, Strom BL. Acad Med. 1996;71:86-88

Influence on Physician Behavior

- ↑ requests for formulary additions
- Rapid prescribing of new drugs
- ↑ Irrational prescribing
- ↑ Costs
- ↓ generic prescribing

Wazana A. JAMA 2000;283:373-80

Prevalence of Physician Industry Interaction



Campbell EG. NEJM. 2007; 356:1742-50

Physician Payments

- 5 States and D.C. mandate disclosure of payments
  - Consulting, advisory board, Detailing, education, marketing, speaker, research (MN only)
- Vermont: July 1,2002 – June 30, 2004
  - 21,409 payments of any value - $4.9 million
  - 5539 (26%) payments exceeded $100
  - ~3000 licensed MDs =~$1600 / MD
- Minnesota: January 1,2002 - December 31, 2004
  - 6946 payments >$100 ($30 million)
  - 14% of licensed physicians received $>100 payment (median payment $1000)
  - >100 people received >$100,000
  - 11 people received >$500,000
  - 250 psychiatrists received $6.7 million

JAMA 2007;297:1216-55
Harris G, Roberts J. NY Times 3/21/07
JAMA 2008; 300: 1998-2000

Physician Payments

The New York Times
nytimes.com

October 4, 2008

Top Psychiatrist Didn't Report Drug Makers' Pay

By GARDINER HARRIS

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.

Position Statements

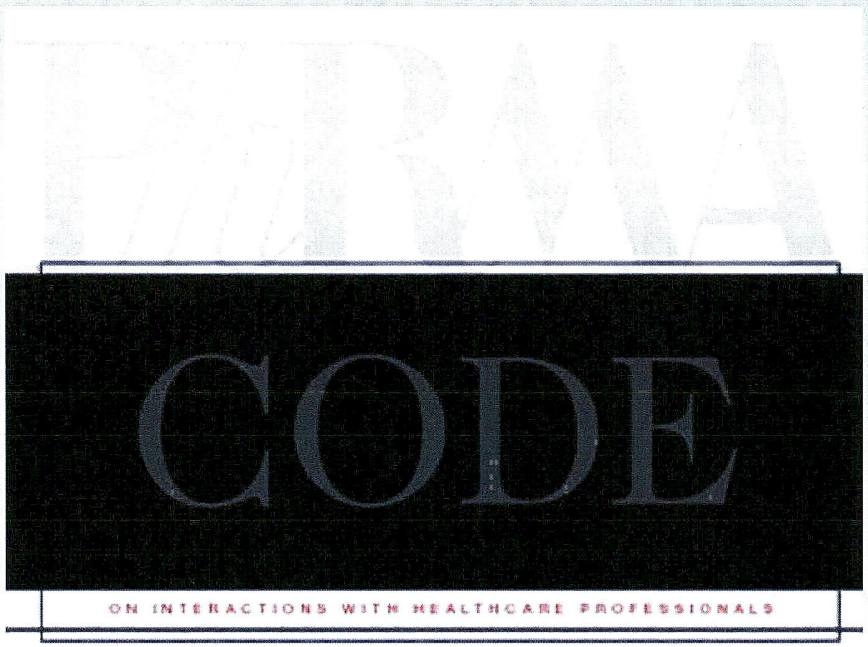
ACP - ASIM (2002)

- Individual gifts, hospitality, trips, subsidies is strongly discouraged
- Financial relationships require disclosure when research is conducted
  - –Grants, consultancies
  - –Speakers
  - –Investors

AMA (2002)

- Gifts should:
  - –Primarily benefit patients
  - –Not be of substantial value (no cash)
- Subsidies for educational meetings are permissible
  - –No subsidies for travel or physician time
  - –Student travel is acceptable

Position Statements

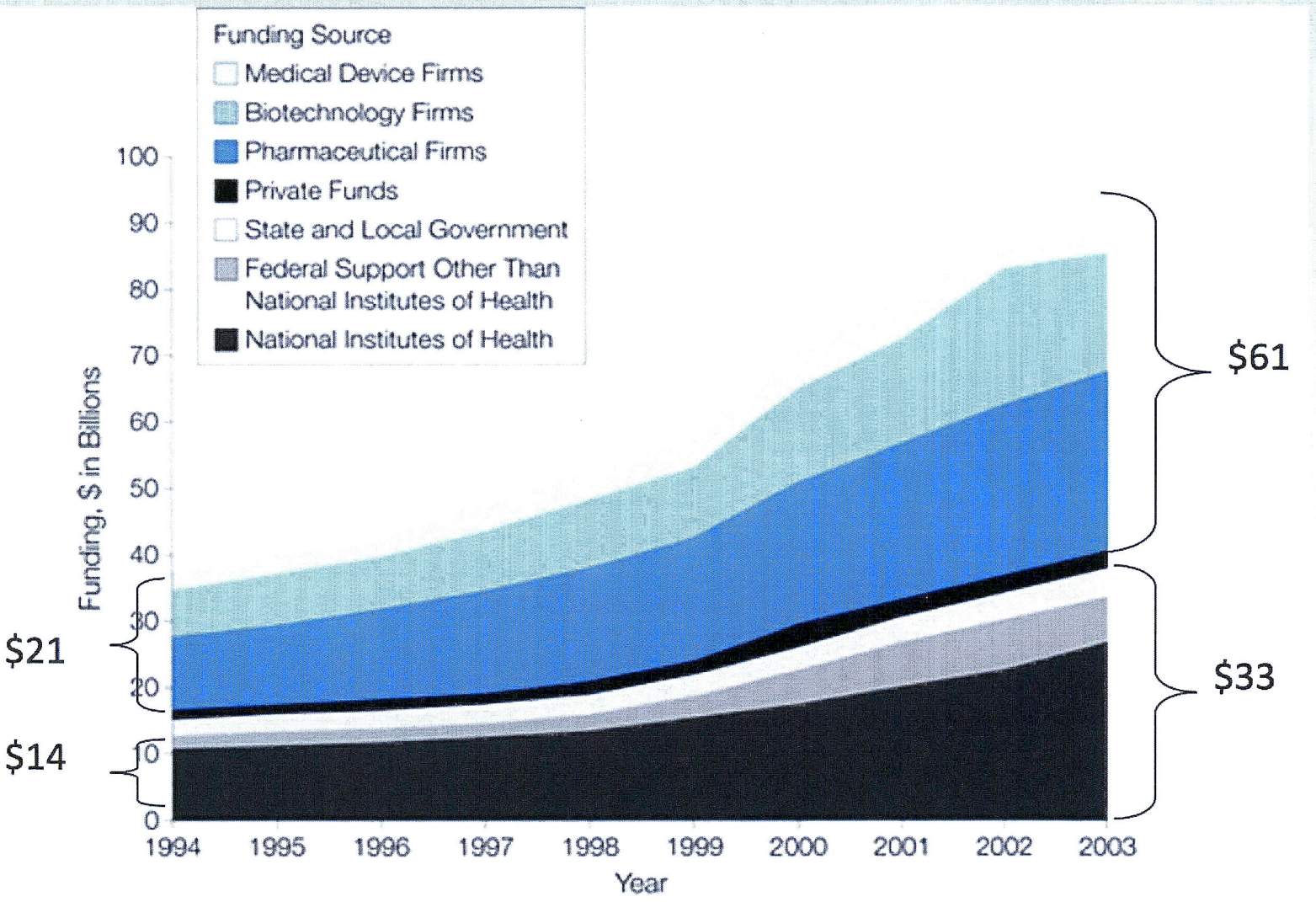


- Released in 2002
  - (revised in 2008)
- Voluntary guidelines to restrict controversial sales practices
- Food
  - Modest
  - In the workplace
- Educational Gifts
  - limit <$100
- Prohibition:
  - Entertainment
  - Non-educational practice-related (pads, mugs, etc)
- No enforcement

http://www.phrma.org/files/PhRMA%20Code.pdf

Influencing the Data

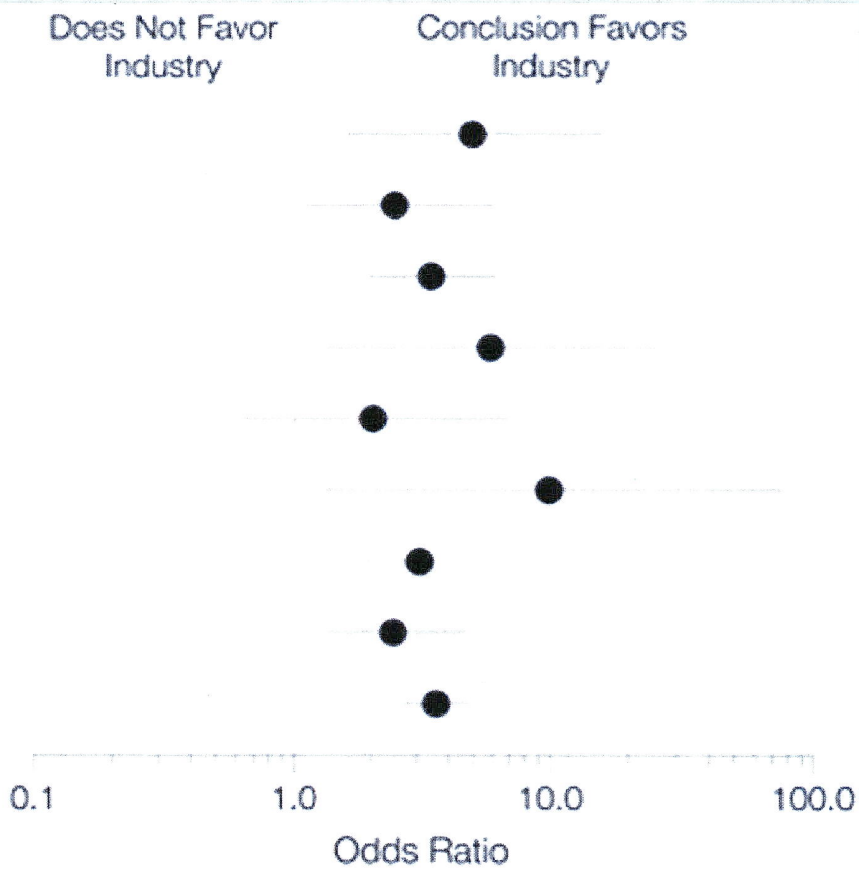
Anatomy of Biomedical Research



Moses H. JAMA 2005;294:1333-42

Association between Industry Funding and Research Outcome

Source	Type of Studies
Davidson,[38] 1986	RCT
Djulbegovic et al,[40] 2000	RCT
Yaphe et al,[39] 2001	RCT
Kjaergard and Als-Nielsen,[48] 2002	RCT
Friedberg et al,[43] 1999	Economic Analyses
Cho and Bero,[41] 1996	Original Research
Turner and Spilich,[42] 1997	Original Research
Swaen and Meijers,[44] 1988	Retrospective Cohort
Overall	

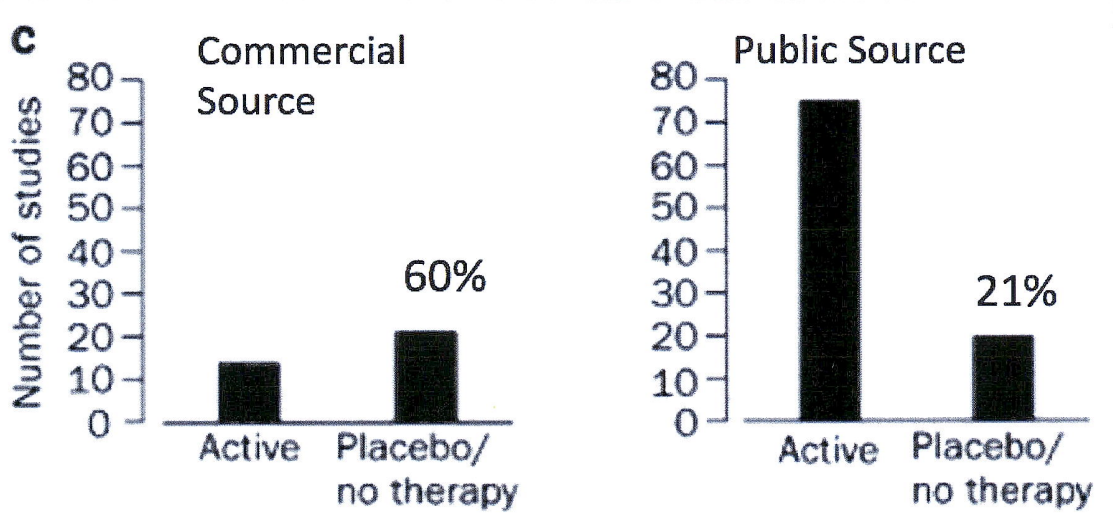


Pooled OR = 3.6 (95% 2.63-4.91)

Bekelman JE. JAMA 2003;289:454-65

Biased Comparisons

- Industry sponsored research more likely to use placebo / no therapy comparison

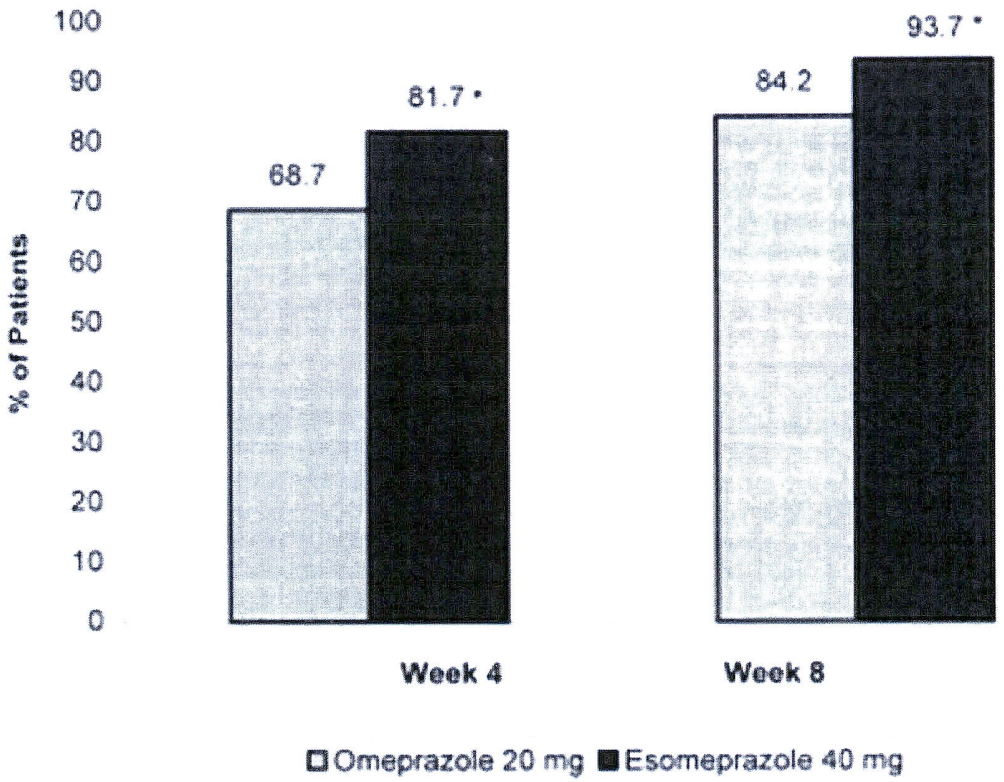


- Placebo controlled studies persist in RCT in hypertension and psychiatry

Djulbegovic B Lancet. 2000;356:635-8
Rothman K. NEJM. 1994;331:394-398

Biased Comparisons

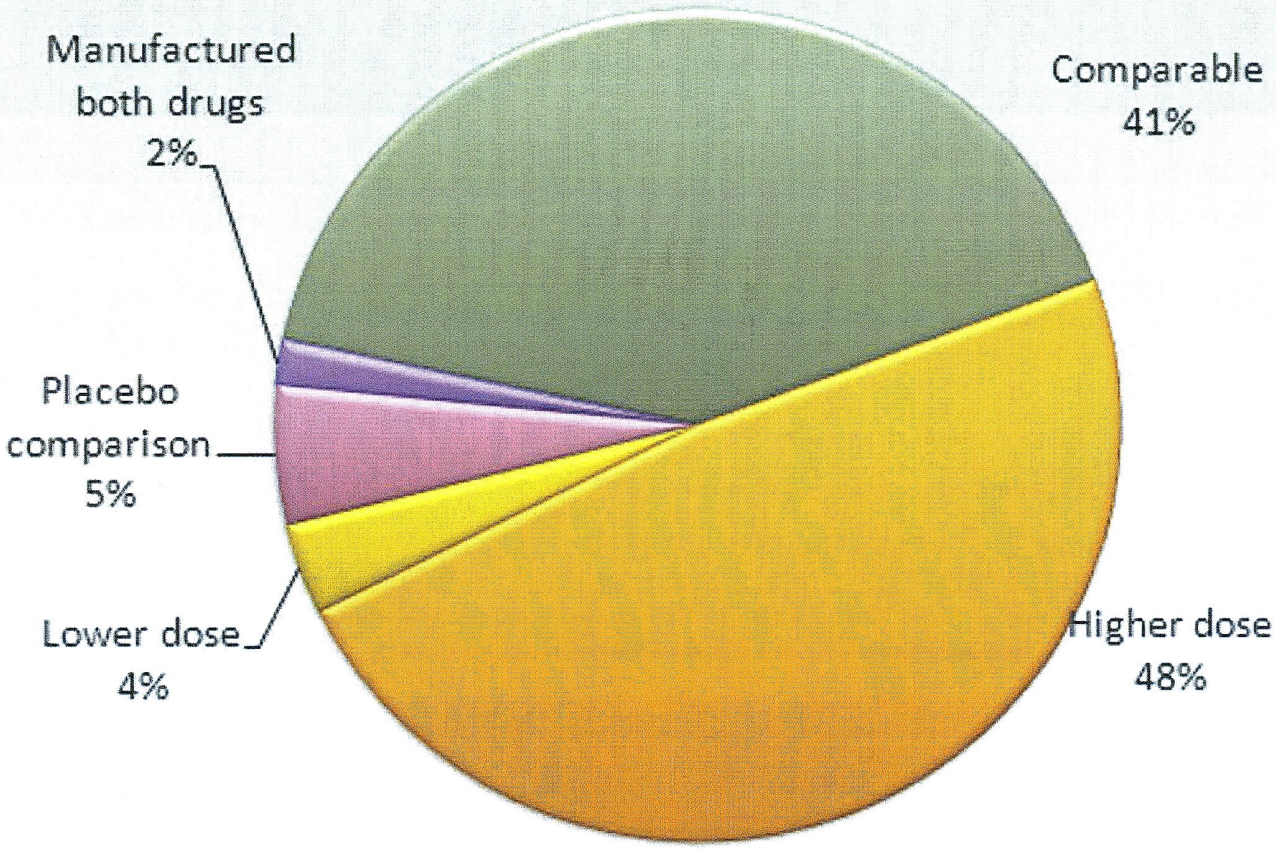
Efficacy and safety of esomeprazole compared with omeprazole in GERD patients with erosive esophagitis: a randomized controlled trial



Richter JE. Am J Gastroenterol 20001;96:656-65

Biased Comparisons

Comparative dosages in pharmaceutical manufacturer-associated drug trials (n=56).



Rochon PA. *Arch Intern Med* 1994;154:157-6.

Biased Design Features

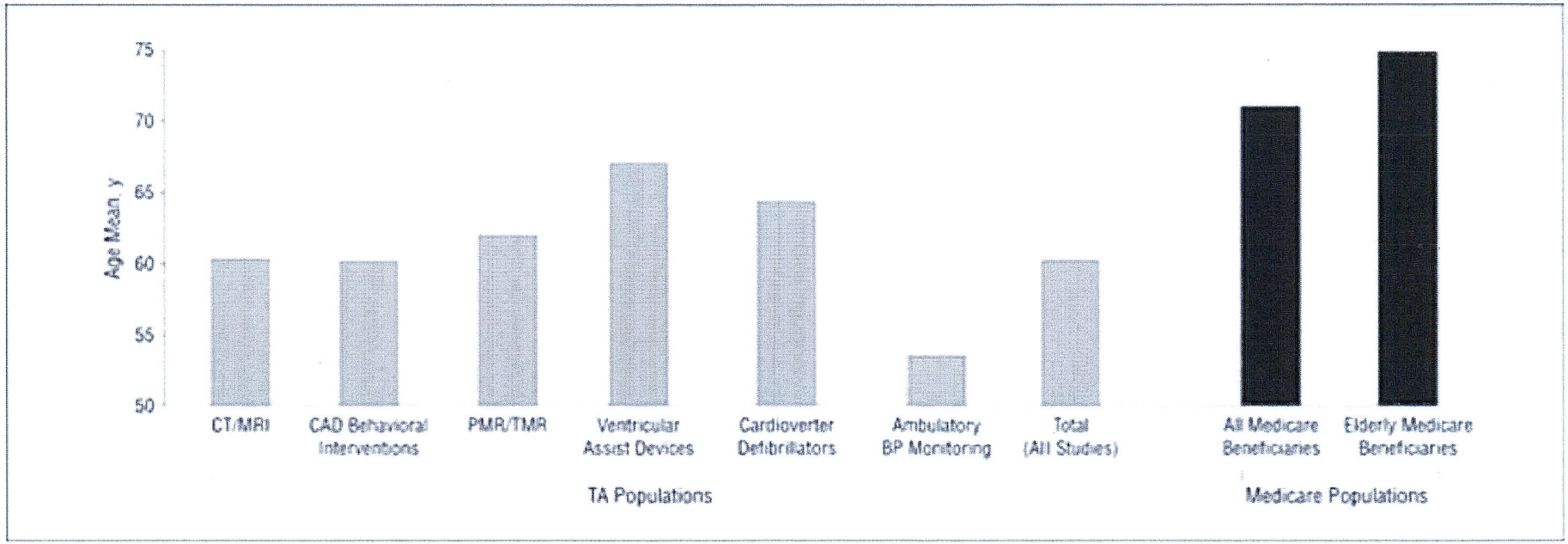
- Employ design features less likely to detect differences in adverse effects
  - 4 times more likely to assess nonspecific or laboratory based adverse effects
  - 40% less likely to use higher or medium doses (inhaled corticosteroids)
  - 69% less likely to state safety as only study aim
- Industry funded trials 4x more likely to conclude drug is safe given statistically significant differences in adverse effects

Nieto A. Arch Intern Med 2007;167:2047-53

Biased Design Features

- Enroll subjects most likely to benefit

Mean age in technology assessment (TA) study populations compared with Medica beneficiary populations



Dhruva, S. S. et al. Arch Intern Med 2008;168:136-140.

Biased Design Features

- Inadequately power studies to produce equivocal results
  - Verapamil vs. atenolol vs. HCTZ (CONVINCE) in hypertension
    - "stopped 2 years early by the sponsor for commercial reasons."
  - Study underpowered to detect differences between groups Salmeterol Multicenter Asthma Research Trial (SMART) stopped early producing inconclusive results

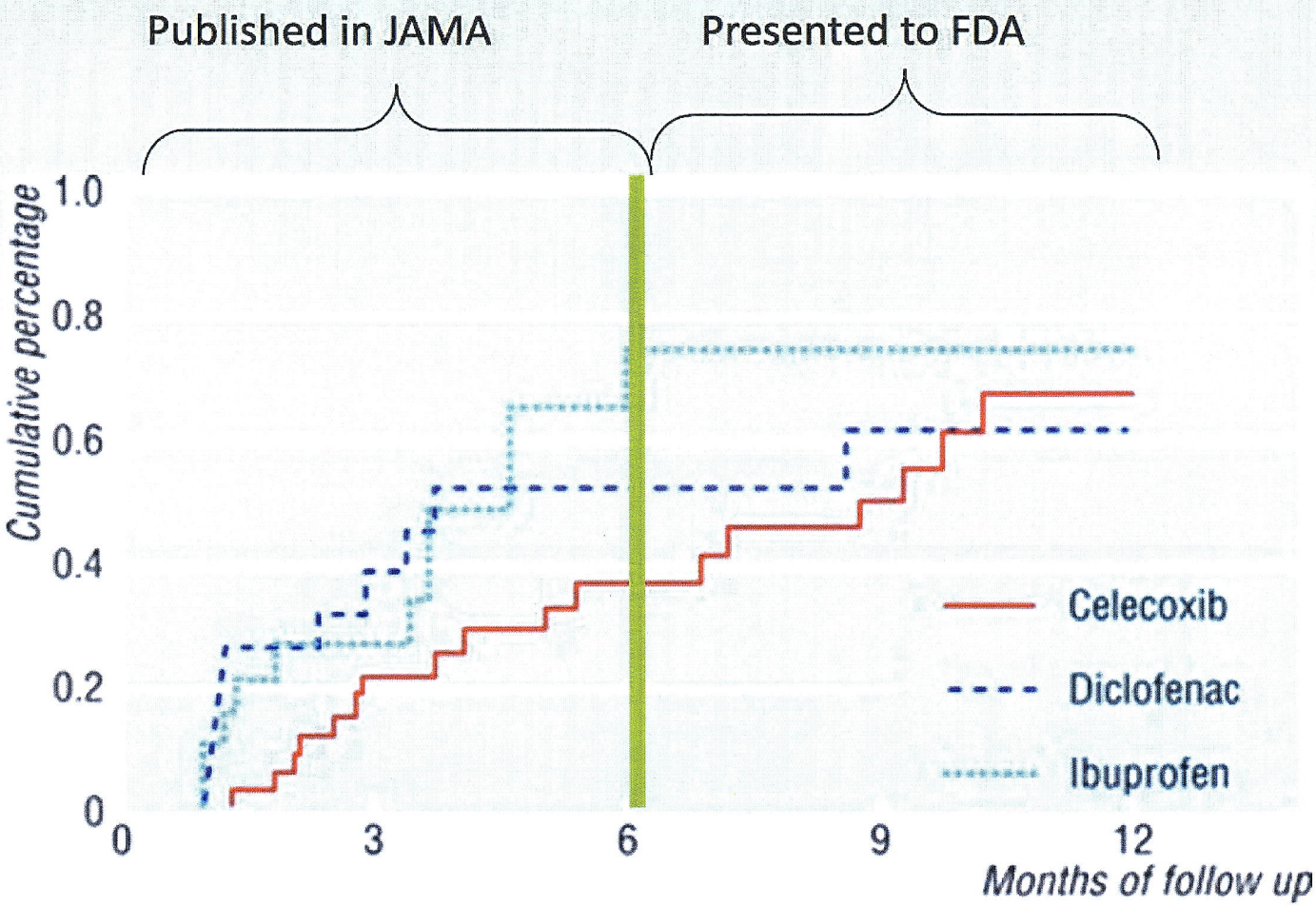
Lurie. Lancet 2005 366:1261-62
Black HR. JAMA 2003;289:2073-2082

Biased Reporting

- Omit specific findings
  - 60-70% of all RCT have unreported outcomes
    - 42% of efficacy outcomes per trial unreported
    - 50% of harm outcomes per trial unreported
  - Related to statistical significance
  - Contributes to biased estimates of benefit and harm
- Delay or omit all findings
  - Publication bias

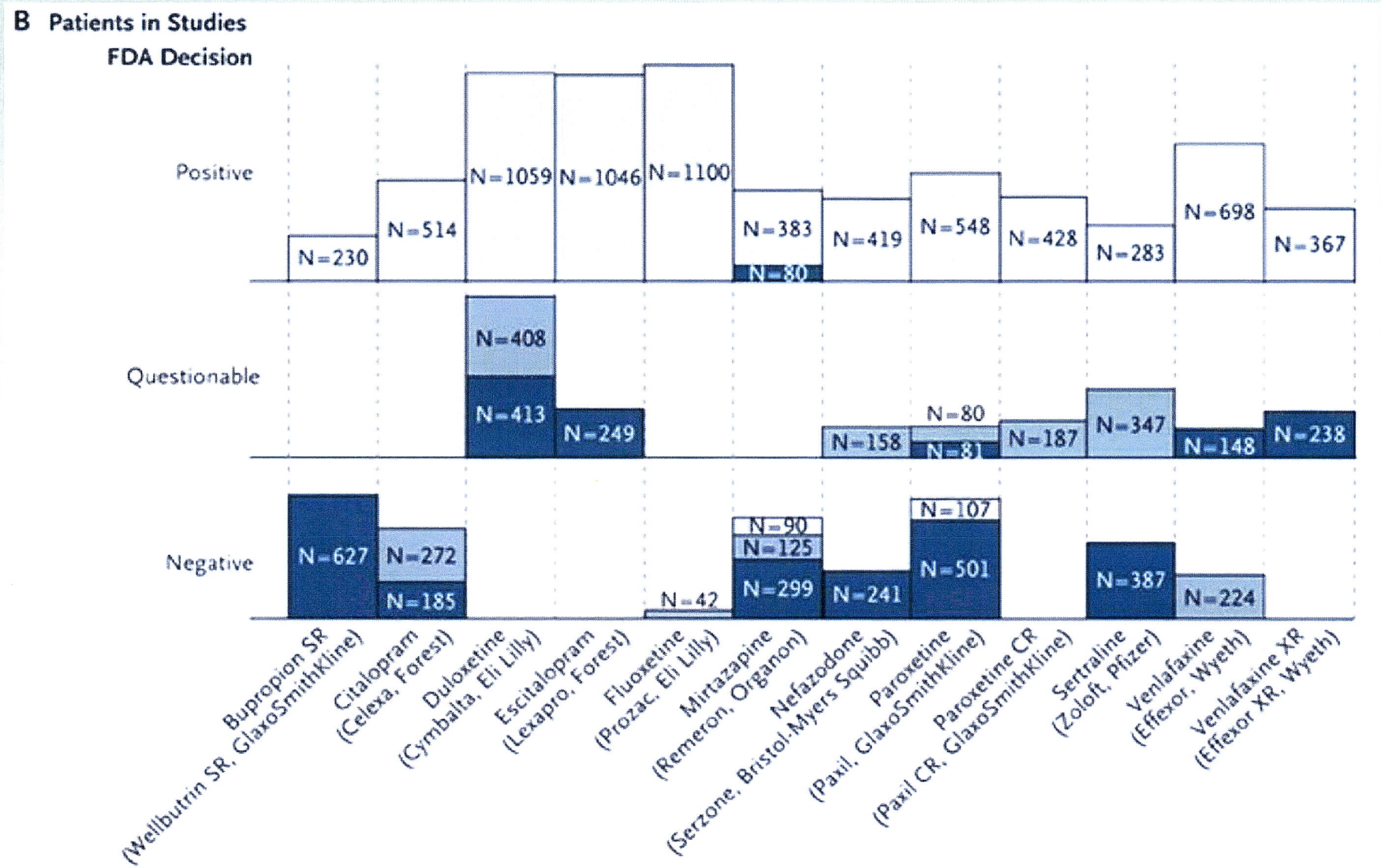
Lexchin J. BMJ 2003;326:1167
Chan A. JAMA 2004;291:2457-65

Biased Reporting



- CLASS trial published in JAMA in 2000 included only 6 months of data
- Many patients followed for 12 months
- 12 month data negated positive findings of published study

BMJ 2002;324:1287-1288



Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy.
NEJM 2008;358:252-60

Honorary and Ghost Authorship

- Honorary author: Naming an author who has not met usual authorship criteria
  - 11-25% of articles
- Ghost author: Failure to name, as an author, an individual who has made substantial contributions to research or writing of article
  - 7%-16% of articles

Flanagin A. JAMA 1998;280:222-24

Draft Version and Final Version of Article Describing the Results of Protocol 078

Rofecoxib does not delay the onset of Alzheimer's disease: results from a randomized, double-blind, placebo-controlled study

External author?, W.H. Visser[1], E. Yuen[2], C. Assaid[1], M.L. Nessly[1], B.A. Norman[1], C.C. Baranak[1], C.R. Lines[1], S.A. Reines[1], G.A. Block[1] on behalf of the Rofecoxib Protocol 078 study group

A Randomized, Double-Blind, Study of Rofecoxib in Patients with Mild Cognitive Impairment

Leon J Thal[1], Steven H Ferris[2], Louis Kirby[3], Gilbert A Block[4], Christopher R Lines*[,4], Eric Yuen[4], Christopher Assaid[4], Michael L Nessly[4], Barbara A Norman[4], Christine C Baranak[4] and Scott A Reines[4], on behalf of the Rofecoxib Protocol 078 study group[5]

[1]University of California, San Diego, CA, USA; [2]New York University School of Medicine, New York, NY, USA; [3]Pivotal Research Centers, Peoria, AZ, USA; [4]Merck Research Laboratories, West Point, PA, USA

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

JAMA

Seeding Trials

- Anti-kickback laws prohibit direct payment for prescribing
- Industry-sponsored clinical trial of little or no scientific purposes
  - Allow payment for patient recruitment
  - Promotes drug-specific preferences in classes with many agents

Andersen M. How conducting a clinical trial affects physicians' guideline adherence and drug preferences. JAMA 2006;21:2759-64

Annals of Internal Medicine | ARTICLE

Gastrointestinal Tolerability and Effectiveness of Rofecoxib versus Naproxen in the Treatment of Osteoarthritis

A Randomized, Controlled Trial

Jeffrey R. Lisse, MD; Monica Perlman, MD, MPH; Gunnar Johansson, MD; James R. Shoemaker, DO; Joy Schechtman, DO; Carol S. Skalky, BA; Mary E. Dixon, BS; Adam B. Polis, MA; Arthur J. Mollen, DO; and Gregory P. Geba, MD, MPH, for the ADVANTAGE Study Group*

Background: Gastrointestinal (GI) toxicity mediated by dual cyclooxygenase (COX)-1 and COX-2 inhibition of nonsteroidal anti-inflammatory drugs (NSAIDs) can cause serious alterations of mucosal integrity or, more commonly, intolerable GI symptoms that may necessitate discontinuation of therapy. Unlike NSAIDs, rofecoxib targets only the COX-2 isoform.

Objective: To assess the tolerability of rofecoxib compared with naproxen for treatment of osteoarthritis.

Design: Randomized, controlled trial.

Setting: 600 office and clinical research sites.

Patients: 5557 patients (mean age, 63 years) with a baseline diagnosis of osteoarthritis of the knee, hip, hand, or spine.

Intervention: Rofecoxib, 25 mg/d, or naproxen, 500 mg twice daily. Use of routine medications, including aspirin, was permitted.

Measurements: Discontinuation due to GI adverse events (primary end point) and use of concomitant medication to treat GI symptoms (secondary end point). Efficacy was determined by patient-reported global assessment of disease status and the Australian/Canadian Osteoarthritis Hand Index, as well as discontinuations due to lack of efficacy. Patients were evaluated at baseline and at weeks 6 and 12.

Results: Rates of cumulative discontinuation due to GI adverse events were statistically significantly lower in the rofecoxib group than in the naproxen group (5.9% vs. 8.1%; relative risk, 0.74 [95% CI, 0.60 to 0.92]; $P = 0.005$), as were rates of cumulative use of medication to treat GI symptoms (9.1% vs. 11.2%; relative risk, 0.79 [CI, 0.66 to 0.96]; $P = 0.014$]). Subgroup analysis of patients who used low-dose aspirin (13%) and those who previously discontinued using arthritis medication because of GI symptoms (15%) demonstrated a relative risk similar to the overall sample for discontinuation due to GI adverse events (relative risk, 0.56 [CI, 0.31 to 1.01] and 0.53 [CI, 0.34 to 0.84], respectively). No statistically significant difference was observed between treatments for efficacy in treating osteoarthritis or for occurrence of other adverse events.

Conclusions: In patients with osteoarthritis treated for 12 weeks, rofecoxib, 25 mg/d, was as effective as naproxen, 500 mg twice daily, but had statistically significantly superior GI tolerability and led to less use of concomitant GI medications. Benefits of rofecoxib in subgroup analyses were consistent with findings in the overall sample.

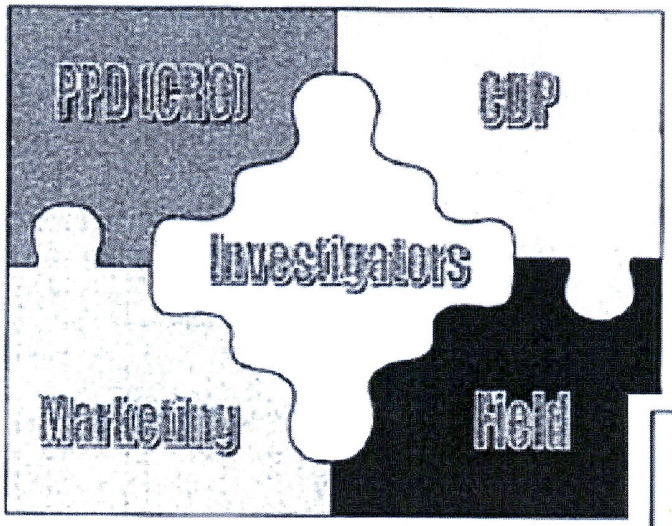
Ann Intern Med. 2003;139:539-546. www.annals.org

For author affiliations, see end of text.

* For members of the ADVANTAGE (Assessment of Differences between Vioxx and Naproxen To Ascertain Gastrointestinal Tolerat... Group, see the Appendix, available at www.annals...

Hill KP. Ann Intern Med 2008;149:251-258

ADVANTAGE
aluable Players



http://dida.library.ucsf.edu/tid/vio28x10

Investigators

- Gain experience with VIOXX® prior to and during critical launch phase
- Exposure to data at investigators' meetings
- Involvement of primary care in a predominantly rheumatology-driven clinical trial process
- Status as investigators allows exchange of scientific information with Merck not available to general prescribing audience

Seeding Trials

To: Brandon Smith, VIOXX Specialist
From: James Webb, Sr. Professional Representative
Re: Vioxx Seeding Study Selection

Brandon, these are the physicians that we, Cluster 0707, would like for you to consider for the seeding studies with Vioxx. The physicians will e listed in order of importance and the reason for selection given following the name. The physicians are as follows:

1. Timothy Overlock MD
2700 Richmond Rd.
Texarkana, Texas 75503
Phone
MedEd 3050191015
DEA BO4984919

Dr. Overlock was selected because he is the Chief Clinician at one of the Senior Health Clinics in Texarkana. His patient practice would afford him the opportunity to place patients in the trial quickly. Merck friendly customer.

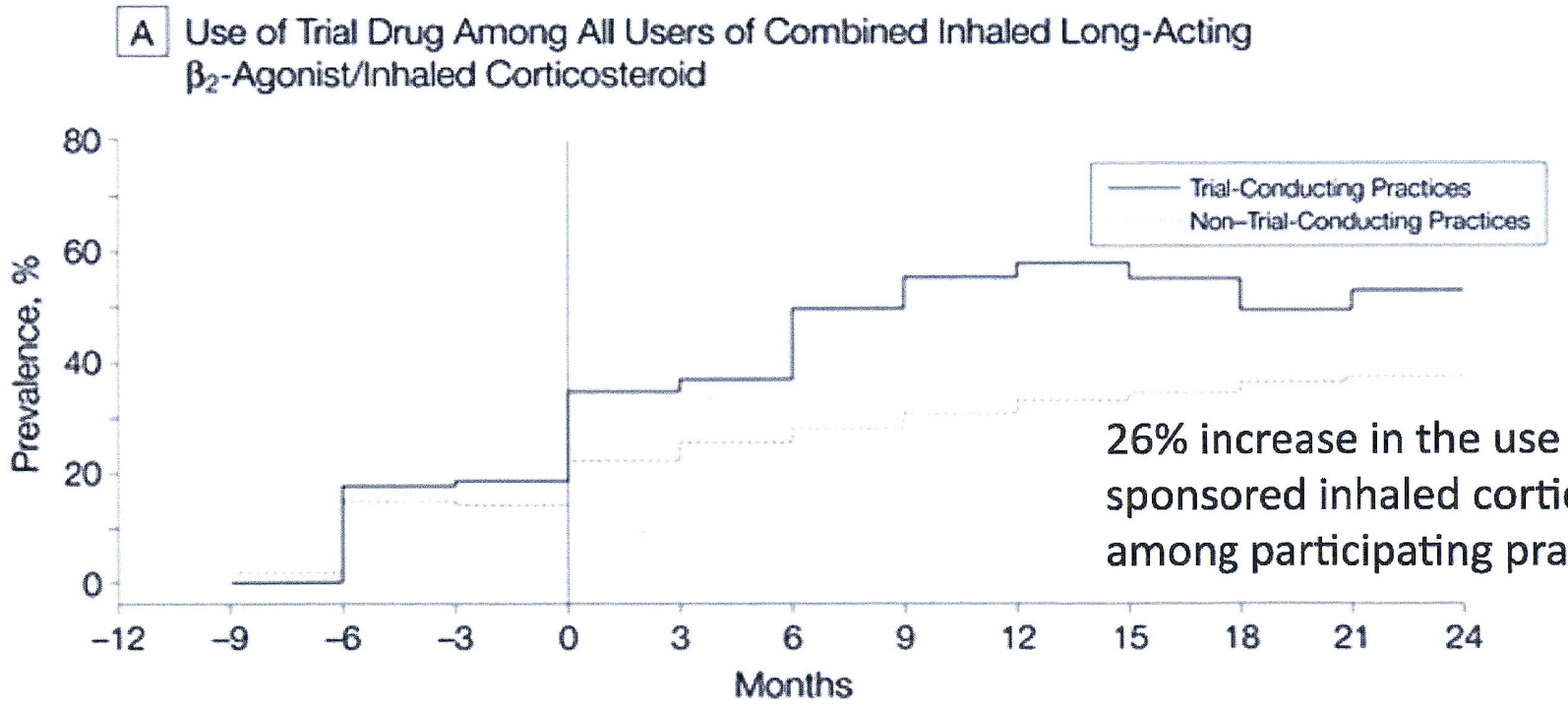
3. O.M. Reichert DO
Rt. 8 Box 1646 Hwy 1402
Mount Pleasant, Texas 75455
Phone
MedEd 0487880068
DEA AR9528172

Dr. Reichert is and Early Adopter and is extremely influential in new product releases. He also is an A+ Portfolio rating.

http://dida.library.ucsf.edu/tid/vio27x10

Seeding Trials

- Dose optimization study of fixed combination inhaled corticosteroid/long-acting b agonist
- GP paid 5000 DKK ($800) for each enrolled subject



26% increase in the use of sponsored inhaled corticosteroid among participating practices

Andersen M JAMA 2006;295:2759-2764

Influencing the Influential

Medical Nonprofit Organizations

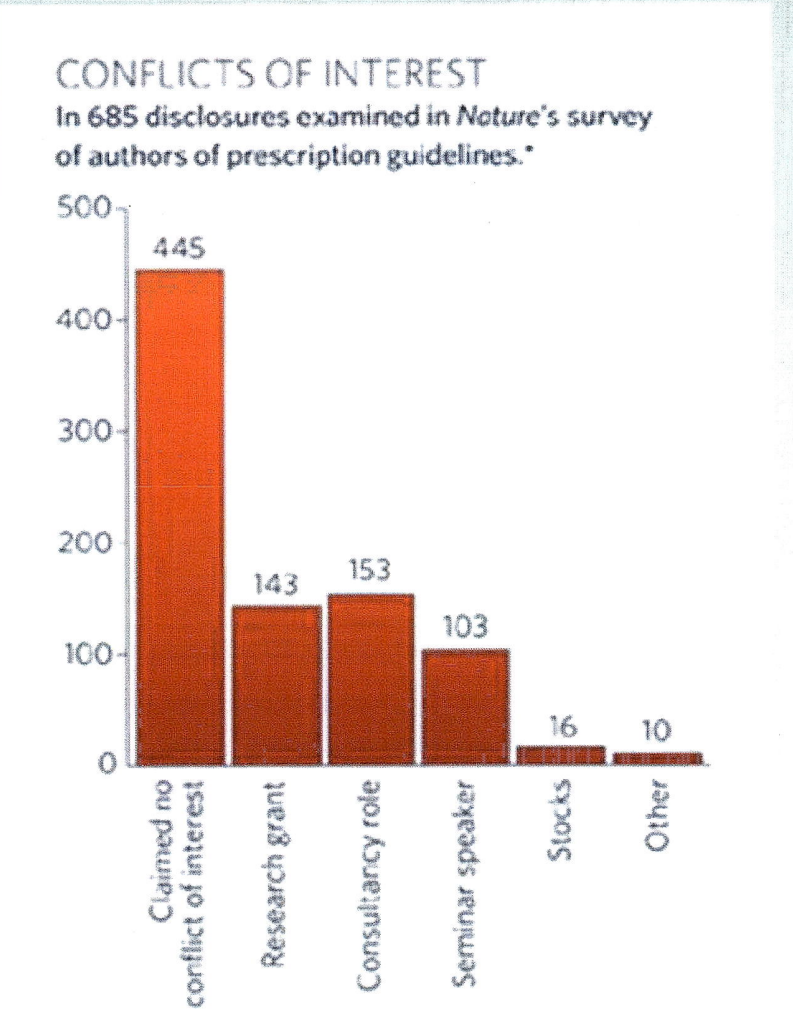
- Professional organizations, health advocacy groups, academic centers
  - Organize clinicians, fund research, produce guidelines
- Often a major portion of revenue comes from industry
- Financial relationships may create potential conflicts of interest related to practice guidelines that are developed by these organizations

Medical Nonprofit Organizations

- Health Advocacy Organizations
  - National Kidney Foundation
    - $19.7 (60%) of $32.7 million in revenue from corporate sponsor (http://www.kidney.org/about/pdf/annual_report06.pdf)
- Academic Centers
  - Tufts Center for the Study of Drug Development
    - Produces industry friendly figures supporting drug production costs ($802 million to develop 1 drug)
    - >55% of total revenue from corporate sponsors (http://csdd.tufts.edu/About/FinancialDisclosure.asp)
- Professional Organizations / Medical Societies
  - American Society of Hypertension
    - $1.5 (34%) of $4.4 million revenue from corporate sponsors (Roland C. Doctors fight over drug firm influence. www.bostonglobe.com; 16 June 2005)

Practice Guidelines

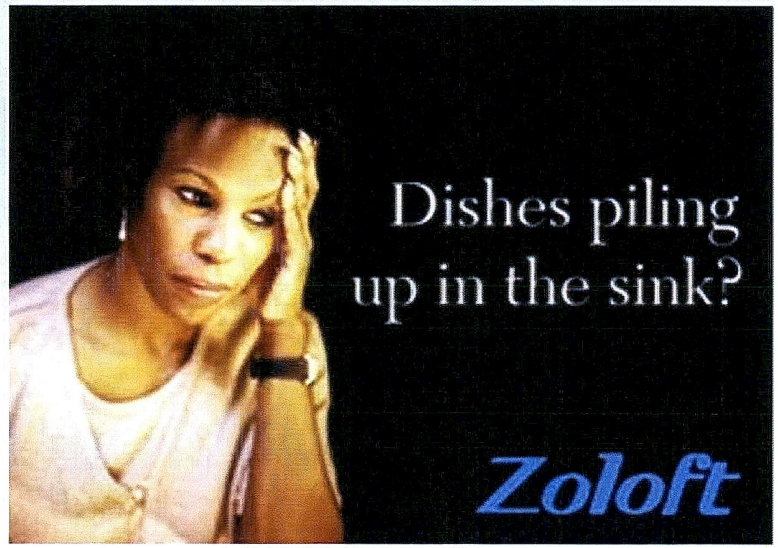
- Present synthesis of evidence by clinical experts
- Affect large numbers of practitioners
- Survey of 200 guidelines published on guideline.gov found
  - 35% of authors involved with industry
  - 50% of guidelines have author with financial conflict of interest



Nature 2005:437;1070-71

Practice Guidelines

- Diagnostic and Statistical Manual (American Psychiatric Association) - DSM
  - Develops diagnostic criteria for psychiatric diseases
  - Used by payers and agencies for funding decisions
- 95 (56%) of 170 panel members have associations with industry
  - Mood disorders (100%)
  - Schizophrenia and other psychotic disorders (100%)
  - Anxiety disorders (81%)



Cosgrove L. Psychother Psychosom. 2006;75:154-60

Medical Journals

- ~$450 million spent on medical journal advertising (2003)
  - Reprints from a high profile can bring in $1 million in journal revenue
- Total US promotional budget = $30-$50 billion
- Represents a significant portion of journal revenue stream
  - NEJM -21%
  - JAMA (AMA) -10%
  - Clinical Infectious Disease (IDSA) – 31%

Smith R. BMJ;2003:1202-5.
Glassman PA. WJM;1999:234-38.

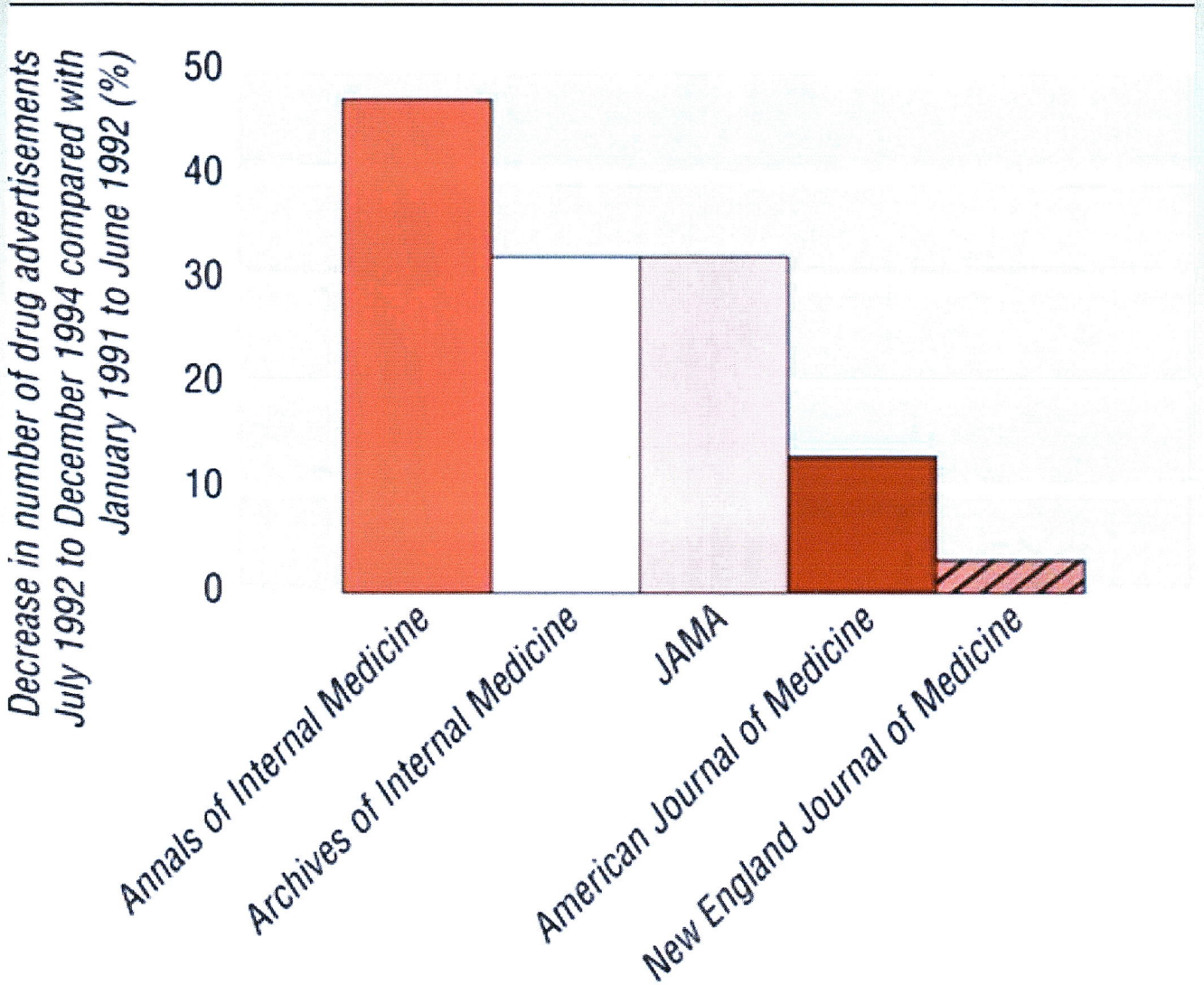
Pharmaceutical Advertisements in Leading Medical Journals: Experts' Assessments

Michael S. Wilkes, MD, MPH; Bruce H. Doblin, MD, MPH; and Martin F. Shapiro, MD, PhD

Annals of Intemal Medicine. 1992;116:912-919.

- Advertisements appearing in 10 medical journals sent to peer-reviewers for assessment with standardized survey
- 30% disagreed with claims for "drug of choice"
- 39% disagreed with claim that drug was more effective than another
- 40% thought ad presented unfavorable balance between efficacy and side effects
- Only 4% of ads deemed fully compliant with FDA standards and publishable as is

Medical Journals



Annals of Internal Medicine Lost $1-$1.5 million dollars in revenue subsequent to publication of Wilkes et. al. paper

BMJ 2006:332:1444-7

Journal Supplements

- Heavily financed by industry
- Little peer-review
- Listed in same databases as parent journal papers (e.g. Medline)
- Research published in supplements on average of poorer methodologic quality
  - Incomplete information on endpoints
  - Quality/completeness of statistical analysis
  - Violations of intent to treat
  - Misleading titles
  - More likely to use brand names

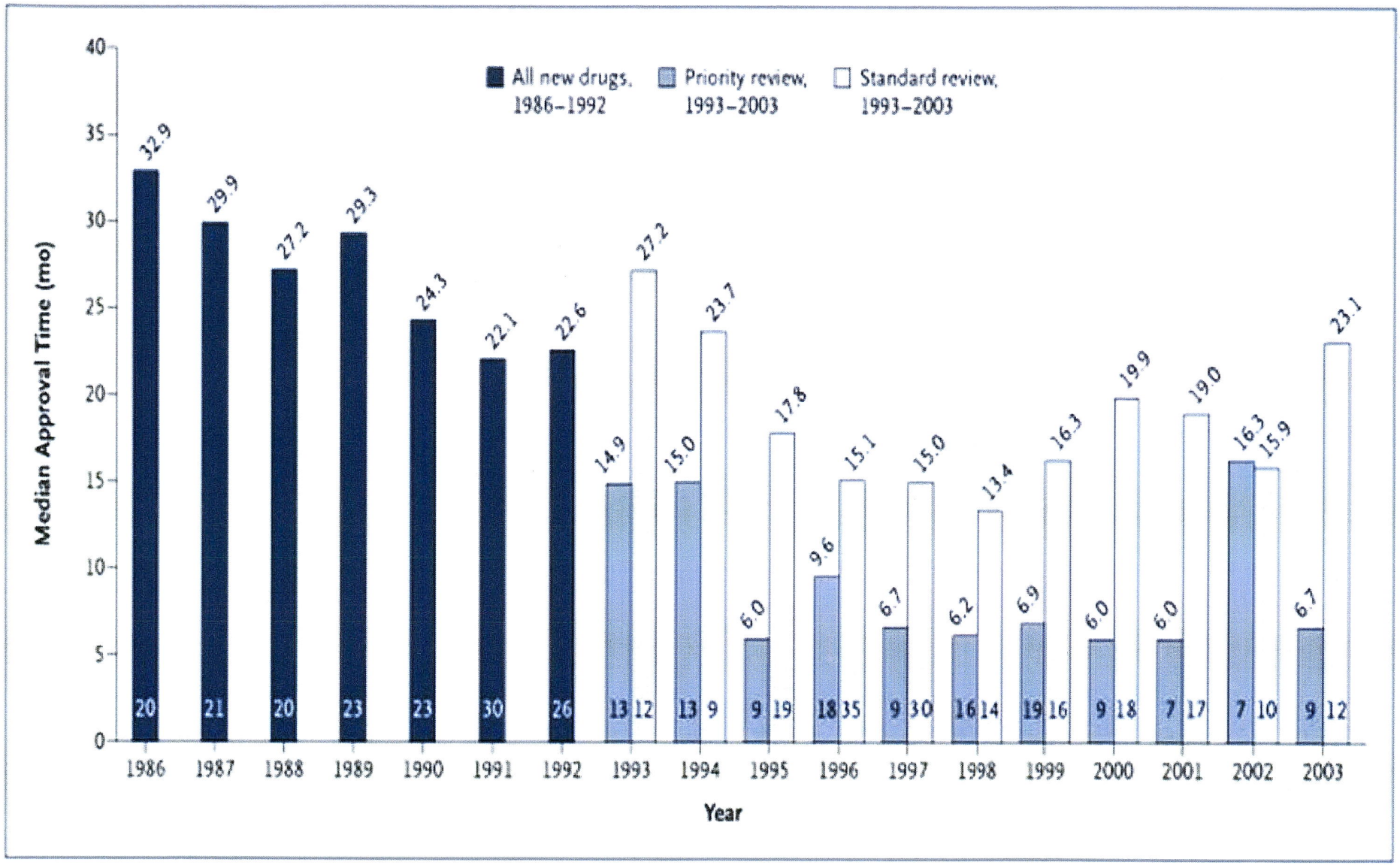
NEJM. 1992;327:1135-40.

JAMA 1994;272:108-113

Influencing the Regulators

FDA User Fees

- Prescription Drug User Fee Act (PDUFA) 1992
  - Allows industry to pay FDA in order to receive expedited NDA review
  - Specific timelines (PDUFA clocks) for reviews
- FY2005 $269 million in user fees collected
  - 56% of total budget for reviewing NDA
- Until reauthorization in 2002 (PDUFA III) all revenue mandated for reviewing new drugs
- Prohibited from post approval monitoring
    - PDUFA III applies 5% to post approval

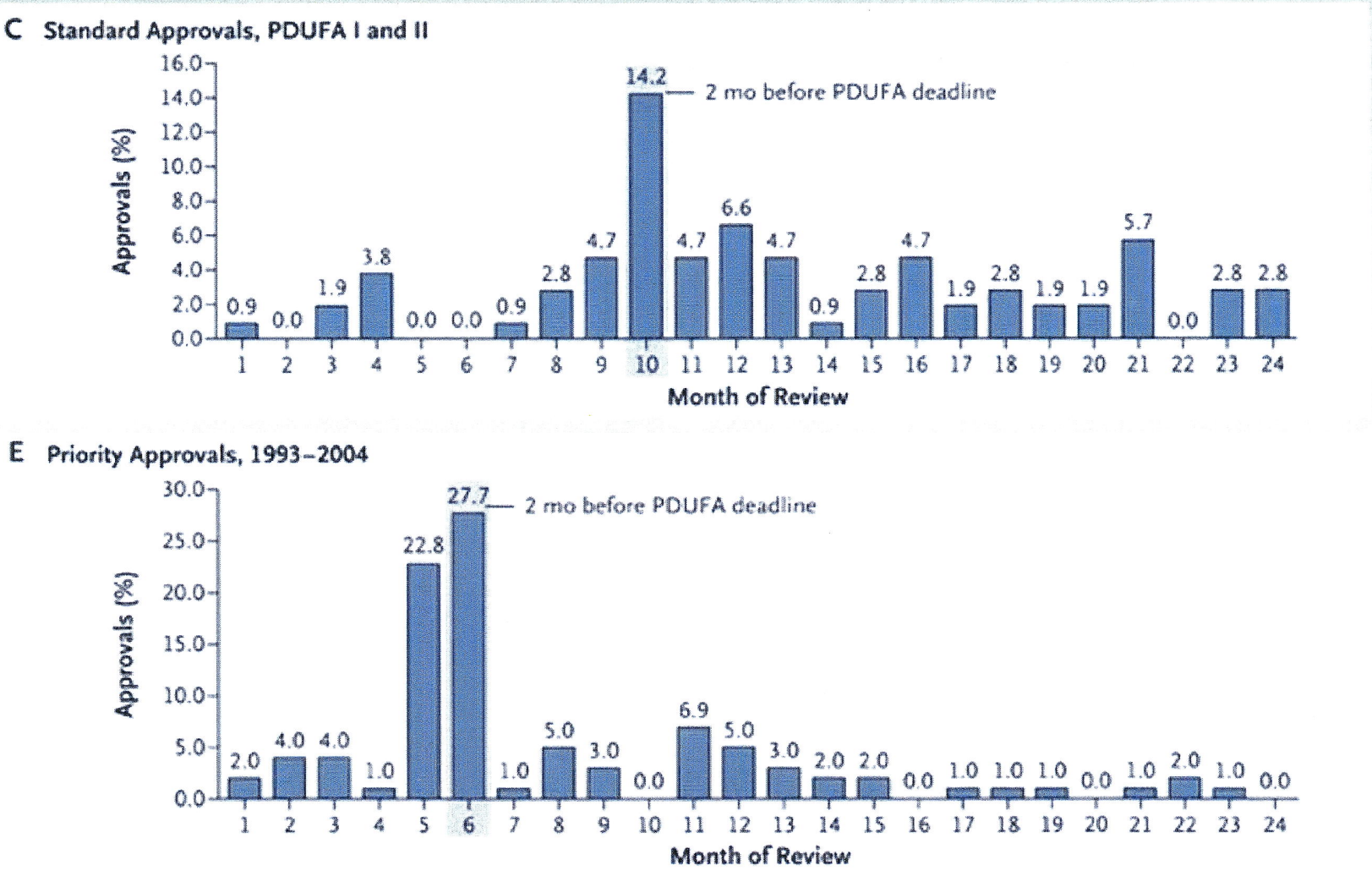


NEJM 2005 35 2:11:1063-6

http://www.oig.hhs.gov/oei/reports/oei-01-01-00590.pdf

FDA User Fees

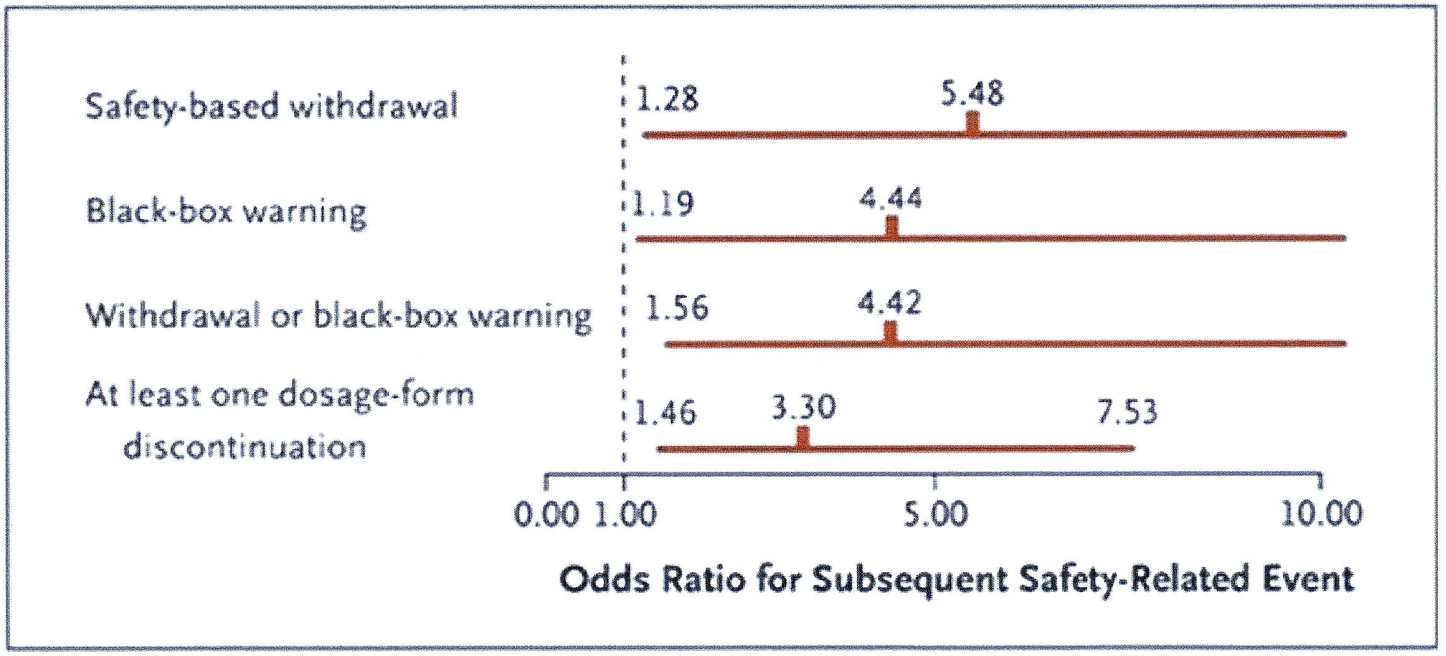
FDA approvals according to month of review cycle



Carpenter D, Zucker EJ, Avorn. Drug-review deadlines and safety problems. NEJM 2008;358:1354-61

FDA User Fees

PDUFA Deadlines and Post Approval Safety Problems



Carpenter D, Zucker EJ, Avorn. Drug-review deadlines and safety problems. NEJM 2008;358:1354-61

FDA Advisory Committees

- FDA Advisory Committees
  - Comprised outside experts
  - Make nonbinding approval recommendations
  - 30 committees (85 meetings/year)
- Conflict of interest policy
  - Voting members must submit detailed CoI
  - FDA may grant waivers when individual's service outweighs potential for CoI
  - 2003-2004 12% of all committee members were granted waivers
  - 73% of meetings between 2001-2004 had one member with a CoI

Steinbrook. NEJM;2005;353:116-18
JAMA 2006;295:1921-1928

FDA Advisory Committees

- February 2005 joint meeting of arthritis and drug safety and risk management advisory committee

> Because general topics impact so many entities, it is not practical to recite all potential conflicts of interest as they apply to each member, consultant and guest speaker. FDA acknowledges that there may be potential conflicts of interest but, because of the general nature of the discussions before the committee, these potential conflicts are mitigated.

- Voted 13 to 17 in favor to remove valdecoxib from market
- Voted 17 to 15 in favor of return of rofecoxib

Source: http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4090T1.pdf

FDA Advisory Committees

- Later revealed 10 of 32 voting members had financial CoI with industry
- If excluded from vote:
  - Valdecoxib – 12 to 8 in favor of withdrawal
  - Rofecoxib – 8 to 14 in favor of return
- FDA dissented
  - Valdecoxib to be removed
  - Rofecoxib remains off market

NEJM 2005;353:116-8
Harris G. NYTIMES. 2/5/2005

FDA Advisory Committees

- April 2008 CoI policy revisions
- If CoI >$50,000
  - Cannot participate
- If CoI is >$0 and <=$50,000
  - Can be granted waiver if individual's services outweigh potential CoI
  - Non-voting member
- Cap on number of waivers granted

Source: http://www.fda.gov/oc/advisory/newacguidance0808.html

CME instructions

- Answer 8 evaluation questions
- Complete survey questions
- Click the finish button and fill out form and send (email/fax/mail) in to address supplied to receive CME

Question 1 of 14

Research suggests that clinicians feel others are more influenced by the pharmaceutical industry than themselves

- ○ True
- ○ False

PROPERTIES

On passing, 'Finish' button:	Goes to URL
On failing, 'Finish' button:	Goes to Next Slide
Allow user to leave quiz:	After user has completed quiz
User may view slides after quiz:	At any time
User may attempt quiz:	Unlimited times

Properties...

Edit in Quizmaker