Conflits d'intérêts et publications

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BICÊTRE

- **Commission d'éthique de la SRLF**:

  Professeur Didier Dreyfuss

- **Groupe de travail**:

  Cédric Daubin, Didier Journois, Guy Le Gall,
  Christian Richard, Marina Thirion

Conflits d'intérêts et publications

- Historique
- Définition
- Nature
- Déclaration
  - Quels intervenants
  - Quelles publications
- Déclaration vs transparence
- Enseignement

Historique

Editorials

Conflicts of Interest and *AJRCCM*

Restating Policy and a New Form to Upload

« Many authors claim that disclosure policies are detrimental to science »

- Rothman KJ: Conflict of interest: the new McCarthyism in science. JAMA 1993;269:2782
- Anonymous. Avoid financial « correctness ». Nature 1997; 385:469

MARTIN J. TOBIN
Editor

Am J Respir Crit Care Med Vol 167. pp 1161–1166, 2003

Historique

- *»C'est le peuple qui possède le vaccin contre la polyomyélite. Il est impossible d'imaginer un brevet pour ce vaccin. Pensez vous qu'on puisse breveter le soleil «*

  Jonas Salk

- **Désintéressé**: qui n'agit pas par intérêt personnel, altruiste et généreux

- **Contraire**: avide, cupide, égoïste, intéressé, sordide

- *« Le bourgeois a la haine du gratuit, du désinteressé »*

  André Gide

Review

Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions

Deborah E. Barnes, MPH; Lisa A. Bero, PhD

JAMA.1998;279:1566-1570

Table 3.—Relationship Between Article Conclusions and Author Affiliations

Article Conclusion	No. (%) of Reviews	
	Tobacco-Affiliated Authors (n = 31)	Non–Tobacco-Affiliated Authors (n = 75)
Passive smoking harmful	2 (6)	65 (87)
Passive smoking not harmful	29 (94)	10 (13)
Significance	$\chi^2_1 = 60.69$; $P<.001$	

Historique

- **Cas du décès de Jesse Gelsinger (1999)**
  - Expérience de transfert de gènes
  - COI de l'université et des chercheurs avec la compagnie

Kaiser J Science 2002; 295:246

Saturday 1 August 1998
BMJ

Beyond conflict of interest

Transparency is the key

Richard Smith ：
»The BMJ policy is disclosure of conflict of interest rather than prohibition »

nature

23 August 2001 Volume 412 Issue no 6849

Declaration of financial interests

Introducing a new policy for authors of research papers in *Nature* and Nature journals.

Historique

« La pureté n'existe pas, pas plus que la perfection. Une vie publique sans « affaires » n'existe pas. Les sociétés totalitaires reposent sur le fantasme d'un contrôle absolu, […]. Il n'est pas question de poursuivre un tel fantasme. Pour autant, il est évident que des progrès doivent être faits. L'élimination des principales sources de conflits d'intérêts est une nécessité «

Martin Hirsch : *Pour en finir avec les conflits d'intérêts (Pluriel, 2011)*

Définition d'un conflit d'intérêt en médecine

- Situation dans la quelle le jugement d'un professionnel à propos de ***l'intérêt premier du patient*** est influencé par un ***intérêt second le plus souvent financier***.

- Il s'agit d'un **constat** et non d'une **conduite**

- L'existence de conflits d'intérêts fait partie de la vie quotidienne

Définition d'un conflit d'intérêt en médecine

- L'existence d'un conflit d'intérêt ne signifie en aucun cas un **manquement aux règles éthiques.**

- C'est une **information** destinée aux lecteurs, à la communauté scientifique et à la société civile, indiquant que les auteurs sont susceptibles de se mettre en situation de manquement.

Définition d'un conflit d'intérêt en médecine

- Différence entre un **conflit d'intérêt** et le **biais** (ou l'impact) qu'il peut potentiellement induire
  - **Validité** des résultats des études publiées, falsification, invention
  - Absence de publication des études **négatives**
  - Impact sur les **patients** se prêtant à la recherche
  - **Ghostwriting** (prête-noms)
- Risque de rupture du **contrat moral et éthique** entre le patient, le médecin et la société civile

British Journal of Anaesthesia **107** (1): 116–117 (2011)
doi:10.1093/bja/aer068

BJA

RETRACTION

Notice of formal retraction of articles by Dr Joachim Boldt

The Editorial Board of the *British Journal of Anaesthesia* has been informed by the Landesärztekammer Rheinland-Pfalz ('LÄK-RLP'), the State Medical Association of Rheinland-Pfalz, Germany that serves as the Institutional Review Board (IRB) for clinical research at Klinikum Ludwigshafen, where Dr Joachim Boldt's recent research was conducted, that they have completed a systematic evaluation of the status of IRB approval for research conducted by Dr Boldt dating back to 1999. They were unable to verify IRB approval for 11 articles published in the *British Journal of Anaesthesia* between 1999 and 2009.

The editors of the *BJA* have therefore, in accordance with the journal's regulations, retracted the following articles authored by Dr Boldt and previously published in the journal.

Mayer J, Boldt J, Beschmann R, Stephan A, Suttner S. Uncalibrated arterial pressure waveform analysis for less-invasive cardiac output determination in obese patients undergoing cardiac surgery. *Br J Anaesth* 2009; **103**: 185–90 (doi: 10.1093/bja/aep133)

Suttner S, Boldt J, Mengistu A, Lang K, Mayer J. Influence of continuous perioperative beta-blockade in combination with phosphodiesterase inhibition on haemodynamics and myocardial ischaemia in high-risk vascular surgery patients. *Br J Anaesth* 2009; **102**: 597–607 (doi: 10.1093/bja/aep062)

Boldt J, Suttner S, Brosch C, Lehmann A, Mengistu A. Influence on coagulation of a potato-derived hydroxethylstarch (HES 130/0.42) and a maize-derived hydroxethylstarch (HES 130/0.4) in patients undergoing cardiac surgery. *Br J Anaesth* 2009; **102**: 191–7 (doi: 10.1093/bja/aen353)

Boldt J, Brosch Ch, Röhm K, Papsdorf M, Mengistu A. Comparison of the effects of gelatin and a modern hydroxyethyl starch solution on renal function and inflammatory response in elderly cardiac surgery patients. *Br J Anaesth* 2008; **100**: 457–64 (doi: 10.1093/bja/aen016)

Mayer J, Boldt J, Schöllhorn T, Röhm KD, Mengistu AM, Suttner S. Semi-invasive monitoring of cardiac output by a new device using arterial pressure waveform analysis: a comparison with intermittent pulmonary artery thermodilution in patients undergoing cardiac surgery. *Br J Anaesth* 2007; **98**: 176–82 (doi: 10.1093/bja/ael341)

Piper SN, Röhm KD, Boldt J, Faust KL, Maleck WH, Kranke P, Suttner SW. Inspired oxygen fraction of 0.8 compared with 0.4 does not further reduce postoperative nausea and vomiting in dolasetron-treated patients undergoing laparoscopic cholecystectomy. *Br J Anaesth* 2006; **97**: 647–53 (doi: 10.1093/bja/ael242)

Boldt J, Haisch G, Suttner S, Kumle B, Schellhaass A. Effects of a new modified, balanced hydroxyethyl starch preparation (Hextend) on measures of coagulation. *Br J Anaesth* 2002; **89**: 722–8 (doi:10.1093/bja/aef242)

Boldt J, Hüttner I, Suttner S, Kumle B, Piper SN, Berchthold G. Changes of haemostasis in patients undergoing major abdominal surgery–is there a difference between elderly and younger patients? *Br J Anaesth* 2001; **87**: 435–40 (doi: 10.1093/bja/87.3.435)

Suttner SW, Piper SN, Lang K, Hüttner I, Kumle B, Boldt J. Cerebral effects and blood sparing efficiency of sodium nitroprusside-induced hypotension alone and in combination with acute normovolaemic haemodilution. *Br J Anaesth* 2001; **87**: 699–705 (doi: 10.1093/bja/87.5.699)

Hüttner I, Boldt J, Haisch G, Suttner S, Kumle B, Schulz H. Influence of different colloids on molecular markers of haemostasis and platelet function in patients undergoing major abdominal surgery. *Br J Anaesth* 2000; **85**: 417–23

Boldt J, Weber A, Mailer K, Papsdorf M, Schuster P. Acute normovolaemic haemodilution *vs* controlled hypotension for reducing the use of allogeneic blood in patients undergoing radical prostatectomy. *Br J Anaesth* 1999; **82**: 170–4

LÄK-RLP was unable to verify IRB approval for 88 articles by Dr Boldt published in 18 different journals, including the *British Journal of Anaesthesia* between 1999 and 2009. A full list of all 88 articles involved is available on our website.

The uncertainty principle and industry-sponsored research

Benjamin Djulbegovic, Mensura Lacevic, Alan Cantor, Karen K Fields, Charles L Bennett, Jared R Adams, Nicole M Kuderer, Gary H Lyman

Source of funding	Favor new therapies	Favor standard therapies	p
Non profit organisations	47%	53%	0.608
Profit organisations	74%	26%	0.004

136 RCT

Lancet 2000; **356:** 635–38

COMPARISON OF UPPER GASTROINTESTINAL TOXICITY OF ROFECOXIB AND NAPROXEN IN PATIENTS WITH RHEUMATOID ARTHRITIS

CLAIRE BOMBARDIER, M.D., LOREN LAINE, M.D., ALISE REICIN, M.D., DEBORAH SHAPIRO, DR.P.H., RUBEN BURGOS-VARGAS, M.D., BARRY DAVIS, M.D., PH.D., RICHARD DAY, M.D., MARCOS BOSI FERRAZ, M.D., PH.D., CHRISTOPHER J. HAWKEY, M.D., MARC C. HOCHBERG, M.D., TORE K. KVIEN, M.D., AND THOMAS J. SCHNITZER, M.D., PH.D., FOR THE VIGOR STUDY GROUP

TABLE 4. INCIDENCE OF GASTROINTESTINAL EVENTS IN THE TREATMENT GROUPS.

TYPE OF EVENT	ROFECOXIB GROUP (N=4047)	NAPROXEN GROUP (N=4029)	ROFECOXIB GROUP (N=4047)	NAPROXEN GROUP (N=4029)	RELATIVE RISK (95% CI)*	P VALUE
	no. with event		rate/100 patient-yr			
Confirmed upper gastrointestinal events	56	121	2.1	4.5	0.5 (0.3–0.6)	<0.001
Complicated confirmed upper gastrointestinal events	16	37	0.6	1.4	0.4 (0.2–0.8)	0.005
Confirmed and unconfirmed upper gastrointestinal events†	58	132	2.2	4.9	0.4 (0.3–0.6)	<0.001
Complicated confirmed and unconfirmed upper gastrointestinal events‡	17	42	0.6	1.6	0.4 (0.2–0.7)	0.002
All episodes of gastrointestinal bleeding	31	82	1.1	3.0	0.4 (0.3–0.6)	<0.001

(N Engl J Med 2000;343:1520-8.)

COMPARISON OF UPPER GASTROINTESTINAL TOXICITY OF ROFECOXIB AND NAPROXEN IN PATIENTS WITH RHEUMATOID ARTHRITIS

CLAIRE BOMBARDIER, M.D., LOREN LAINE, M.D., ALISE REICIN, M.D., DEBORAH SHAPIRO, DR.P.H., RUBEN BURGOS-VARGAS, M.D., BARRY DAVIS, M.D., PH.D., RICHARD DAY, M.D., MARCOS BOSI FERRAZ, M.D., PH.D., CHRISTOPHER J. HAWKEY, M.D., MARC C. HOCHBERG, M.D., TORE K. KVIEN, M.D., AND THOMAS J. SCHNITZER, M.D., PH.D., FOR THE VIGOR STUDY GROUP

Myocardial infarctions were less common in the naproxen group than in the rofecoxib group (0.1 percent vs. 0.4 percent; 95 percent confidence interval for the difference, 0.1 to 0.6 percent; relative risk, 0.2; 95 percent confidence interval, 0.1 to 0.7).

(N Engl J Med 2000;343:1520-8.)

Patients' Views on Financial Conflicts of Interest in Cancer Research Trials

Lindsay A. Hampson, B.A., Manish Agrawal, M.D., Steven Joffe, M.D., M.P.H., Cary P. Gross, M.D., Joel Verter, Ph.D., and Ezekiel J. Emanuel, M.D., Ph.D.

Table 2. Concern about Financial Ties between Researchers or Cancer Centers and Drug Companies.*

Response	Financial Ties of Researcher (N=253)		Financial Ties of Cancer Center (N=253)	
	Start of Interview	End of Interview	Start of Interview	End of Interview
	percent of patients			
Very worried	<1	<1	<1	0
Somewhat worried	6	5	7	6
A little worried	11	17	21	21
Not worried at all	80	77	70	72

N Engl J Med 2006;355:2330-7.

The Impact of Disclosing Financial Ties in Research and Clinical Care

A Systematic Review

Adam Licurse, BA; Emma Barber, BS; Steve Joffe, MD; Cary Gross, MD

Background: Despite increased demand for disclosure of physician and researcher financial ties (FTs) to industry, little is known about patients', research participants', or journal readers' attitudes toward FTs.

Methods: We systematically reviewed original, quantitative studies of patients', research participants', or journal readers' views about FTs to pharmaceutical and medical device companies. The MEDLINE, Scopus, and Web of Knowledge databases were searched for English-language studies containing original, quantitative data on attitudes toward FTs. We screened 6561 citations and retrieved 244 potentially eligible abstracts. Of these, 20 met inclusion criteria.

Results: Eleven studies assessed FTs and perceptions of quality. In clinical care, patients believed FTs decreased the quality and increased the cost of care. In research, FTs affected perceptions of study quality. In 2 studies, readers' perceptions of journal article quality decreased after disclosure of FTs. Eight studies assessed the acceptability of FTs. Patients were more likely to view personal gifts to physicians as unacceptable, compared with professional gifts. In 6 of the 10 studies that assessed the importance of disclosure, most patients and research participants believed FTs should be disclosed; in the other 4, approximately one-quarter believed FTs should be disclosed. Among the 7 studies assessing willingness to participate in research, approximately one-quarter of participants reported less willingness after disclosure of FTs.

Conclusions: Patients believe that FTs influence professional behavior and should be disclosed. Patients, physicians, and research participants believe FTs decrease the quality of research evidence, and, for some, knowledge of FTs would affect willingness to participate in research.

Arch Intern Med. 2010;170(8):675-682

YANKEE DOODLING **Douglas Kamerow**

Who wrote that article?

The latest revelations about ghost authorship of journal articles are truly frightening

> **It is not being overly dramatic to say that public trust in clinical research, in the medical journals that report research, and in medicine in general is at stake**

Guest Authorship and Ghostwriting in Publications Related to Rofecoxib

A Case Study of Industry Documents From Rofecoxib Litigation

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.

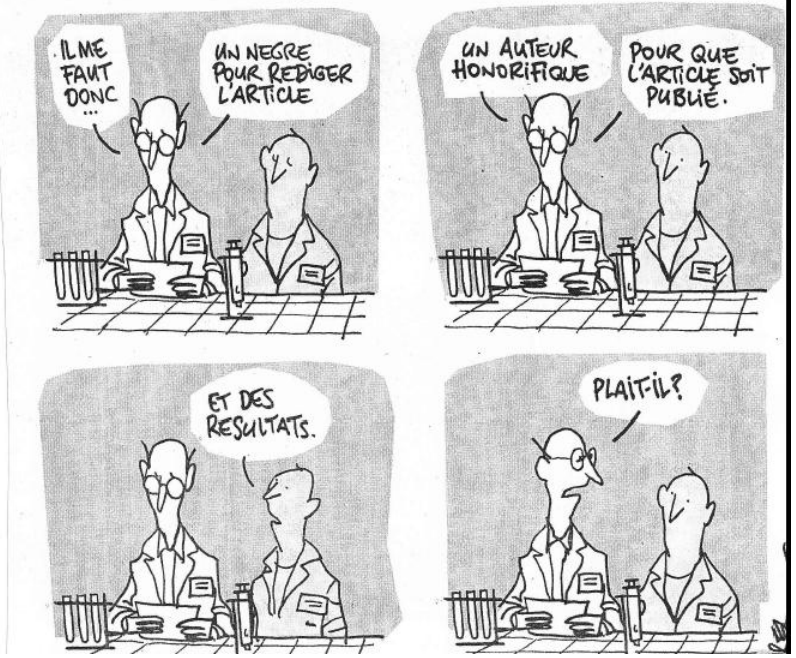
Joseph S. Ross, MD, MHS
Kevin P. Hill, MD, MHS
David S. Egilman, MD, MPH
Harlan M. Krumholz, MD, SM

JAMA. 2008;299(15):1800-1812

La presse médicale gangrenée par les prête-noms

DÉONTOLOGIE

Dans six grandes revues médicales internationales, un article sur cinq n'est pas correctement signé : soit des « fantômes » n'apparaissent pas comme auteurs, soit des « potiches » font office de caution honorifique sans avoir contribué aux recherches



Lacasse and Leo *BMC Research Notes* 2011, **4**:27
http://www.biomedcentral.com/1756-0500/4/27

BMC
Research Notes

SHORT REPORT **Open Access**

Knowledge of ghostwriting and financial conflicts-of-interest reduces the perceived credibility of biomedical research

Jeffrey R Lacasse[1*], Jonathan Leo[2]

OPEN ACCESS Freely available online

PLOS MEDICINE

Policy Forum

Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles

Simon Stern[1]*, **Trudo Lemmens**[2]

1 Faculty of Law, University of Toronto, Toronto, Ontario, Canada, 2 Faculties of Law and Medicine, University of Toronto, Toronto, Ontario, Canada

Summary Points

- Ghostwriting of medical journal articles raises serious ethical and legal concerns, bearing on the integrity of medical research and scientific evidence used in legal disputes.
- Medical journals, academic institutions, and professional disciplinary bodies have thus far failed to enforce effective sanctions.
- The practice of ghostwriting could be deterred more effectively through the imposition of legal liability on the "guest authors" who lend their names to ghostwritten articles.
- We argue that a guest author's claim for credit of an article written by someone else constitutes legal fraud, and may give rise to claims that could be pursued in a class action based on the Racketeer Influenced and Corrupt Organizations Act (RICO).
- The same fraud could support claims of "fraud on the court" against a pharmaceutical company that has used ghostwritten articles in litigation. This claim also appropriately reflects the negative impact of ghostwriting on the legal system.

Nature des conflits d'intérêts

ACADEMIQUES

- Publier les résultats de la recherche dans une revue prestigieuse
- Obtenir une promotion académique
- Faciliter l'obtention d' un financement institutionnel
- Devenir un leader d'opinion reconnu

ETHIQUE INDIVIDUELLE

Nature des conflits d'intérêts

FINANCIERS

- Honoraires de consultant
- Financement de projet
- Rédaction de publications
- Réunions d'enseignement (FMC)
- Royalties
- Brevets
- Stock- options
- Voyages, avantages en nature,etc..

Conflits d'intérêts: Qui est concerné ?

- Auteurs
- Editeurs
- Reviewers
- Jury d'attribution de financement
- IRB, CPP, CE
- Institutions (NIH, AFSSAP)
- hôpitaux, universités, sociétés savantes

Conflits d'intérêts: Qui est concerné ?

- www.iom.edu/conflictofinterest
  - Institute of medicine of the national academies
- www.wame.org/conflict-of-interest
  - world association of medical editor

EDITORIALS

Toward More Uniform Conflict Disclosures — The Updated ICMJE Conflict of Interest Reporting Form

2010;363: 188

EDITORIALS

Uniform Format for Disclosure of Competing Interests in ICMJE Journals

2009;361:1896

Jeffrey M. Drazen, M.D.
Editor-in-Chief, *New England Journal of Medicine*

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in four parts.

1. Identifying information.

Enter your full name. If you are NOT the corresponding author please check the box "no" and a space to enter the name of the corresponding author in the space that appears. Provide the requested manuscript information. Double-check the manuscript number and enter it.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes". Then complete the appropriate boxes to indicate the type of support and whether the payment went to you, or to your institution, or both.

3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence,or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

4. Other relationships.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
2. Surname (Last Name)
3. Effective Date (07-August-2008)

4. Are you the corresponding author? ☐ Yes ☐ No

5. Manuscript Title

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc…)?

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

The Work Under Consideration for Publication

Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant	☐	☐	☐			X
						ADD
2. Consulting fee or honorarium	☐	☐	☐			X
						ADD
3. Support for travel to meetings for the study or other purposes	☐	☐	☐			X
						ADD
4. Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	☐	☐	☐			X
						ADD
5. Payment for writing or reviewing the manuscript	☐	☐	☐			X
						ADD
6. Provision of writing assistance, medicines, equipment, or administrative support	☐	☐	☐			X

ICMJE Form for Disclosure of Potential Conflicts of Interest

The Work Under Consideration for Publication

Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
						ADD
7. Other	☐	☐	☐			×
						ADD

* This means money that your institution received for your efforts on this study.
** Use this section to provide any needed explanation.

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to submission.

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

Relevant financial activities outside the submitted work

Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
1. Board membership	☐	☐	☐			×
						ADD
2. Consultancy	☐	☐	☐			×
						ADD
3. Employment	☐	☐	☐			×
						ADD
4. Expert testimony	☐	☐	☐			×
						ADD
5. Grants/grants pending	☐	☐	☐			×
						ADD
6. Payment for lectures including service on speakers bureaus	☐	☐	☐			×
						ADD
7. Payment for manuscript preparation	☐	☐	☐			×

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Relevant financial activities outside the submitted work

Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
						ADD
8. Patents (planned, pending or issued)	☐	☐	☐			×
						ADD
9. Royalties	☐	☐	☐			×
						ADD
10. Payment for development of educational presentations	☐	☐	☐			×
						ADD
11. Stock/stock options	☐	☐	☐			×
						ADD
12. Travel/accommodations/ meeting expenses unrelated to activities listed**	☐	☐	☐			×
						ADD
13. Other (err on the side of full disclosure)	☐	☐	☐			×
						ADD

* This means money that your institution received for your efforts.
** For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

Section 4. Other relationships

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

☐ No other relationships/conditions/circumstances that present a potential conflict of interest

☐ Yes, the following relationships/conditions/circumstances are present (explain below):

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Hide All Table Rows Checked 'No' SAVE

Evaluation and Feedback

Please visit http://www.icmje.org/cgi-bin/feedback to provide feedback on your experience with completing this form.

B. CONSULTANCY(IES)

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse's, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)

OPEN ACCESS Freely available online

PLoS one

"Members of the Same Club": Challenges and Decisions Faced by US IRBs in Identifying and Managing Conflicts of Interest

Robert Klitzman*

Department of Psychiatry, Columbia University, New York, New York, United States of America

July 2011 e22796

American Thoracic Society Documents

An Official American Thoracic Society Policy Statement: Managing Conflict of Interest in Professional Societies

Holger J. Schünemann[1,2,3], Molly Osborne[4], Joel Moss[5], Constantine Manthous[6], Gregory Wagner[7], Leonard Sicilian[8], Jill Ohar[9], Shane McDermott[10], Lance Lucas[11], and Roman Jaeschke[3], on behalf of the ATS Ethics and Conflict of Interest Committee and the Documents Development and Implementation Committee

TABLE 1. PRINCIPLES FOR THE POLICY

1. Diversity in the ATS membership is valued.
2. All ATS members make unique and valuable contributions to official ATS activities.
3. Influence as a result of COI or even perception of COI can impact the balance of considerations in favor of a particular management option.
4. Although competing interests may cause COI, this depends on the situation rather than the character or actions of individuals.
5. Simple declaration of COI is insufficient.
6. Chairs and organizers of official ATS activities should evaluate the COI disclosures of potential participants and take steps as recommended by the ATS to resolve relevant COIs.
7. Project committee members and/or conference or workshop participants should be apprised of the declared COI of all other participants before deliberations begin
8. COI must be acknowledged in the final document or other product of a project or conference.

Am J Respir Crit Care Med Vol 180. pp 564–580, 2009

Managing Financial Conflict of Interest in Biomedical Research

Sally J. Rockey, PhD
Francis S. Collins, MD, PhD

JAMA, June 16, 2010—Vol 303, No. 23

Afssaps - Tableau de classification des risques de conflits d'intérêts

Abréviation	Champ d'application: entreprise qui fabrique ou commercialise le produit en cours d'évaluation (E), ou entreprise directement concurrente (C)		Risques de conflits d'intérêts élevés	Risques de conflits d'intérêts faibles
IF	**1. INTERETS FINANCIERS DANS UNE ENTREPRISE**	E,C	> 5% du capital ou > 5000 euros	< 5% du capital ou < 5000 euros
	2. ACTIVITES EXERCEES PERSONNELLEMENT			
LD	**2.1. Liens durables ou permanents**			
LD-ODE	2.1.1. Propriétaire, dirigeant, associé, employé, participant d'un organe décisionnel de l'entreprise	E,C	moins de 3 ans	plus de 3 ans moins de 5 ans
LD-AR	2.1.2. Autres activités régulières	E		
IP-EC	**2.2. Interventions ponctuelles: essais cliniques, précliniques et travaux scientifiques**			
EC-INV	2.2.1. Investigateur principal d'une étude monocentrique, investigateur coordonnateur ou expérimentateur principal.	produit E produit C (si moins de 3C)	moins de 5 ans	
EC-CO	2.2. Co-investigateur, expérimentateur non principal, collaborateur à l'étude	produit E		moins de 3 ans
IP-RE	**2.3. Interventions ponctuelles: rapports d'expertise**			
RE-DE	2.3.1. Réalisés en vue de figurer dans un dossier soumis à l'évaluation de l'Afssaps	produit E produit C (si moins de 3 C)	moins de 5 ans	
RE-AUT	2.3.2. Autres rapports d'expertise	produit E	moins de 3 ans (au cas par cas)	
IP-AC	**2.4. Interventions ponctuelles: activités de conseil ponctuel**	produit E	moins de 3 ans (au cas par cas)	
IP-CF	**2.5. Conférences - Invitations**			
CF-INT	2.5.1. Invitations en qualité d'intervenant	produit E produit C (si moins de 3 C)	moins de 3 ans	
		sans relation avec le produit		moins de 3 ans
CF-AUD	2.5.2. Invitations en qualité d'auditeur avec prise en charge des frais	E ou C		moins de 2 ans
IP-AUT	**2.6. Autres**	E ou C	brevet, partie à procédure… (au cas par cas)	
VB	**3. VERSEMENTS SUBSTANTIELS AU BUDGET D'UNE INSTITUTION DONT L'EXPERT EST RESPONSABLE**	E	moins de 2 ans	
PAR	**4. PROCHES PARENTS SALARIES DANS LES ENTREPRISES VISEES CI-DESSUS**	E	lien familial proche avec un responsable ou un employé impliqué dans le produit	lien familial proche avec un employé non impliqué dans le produit
{Autres}	**5. AUTRES**		au cas par cas	

Conflits d'intérêts: Quelles publications ?

- Articles originaux
- Revues de la littérature
- Meta-analyses
- Consensus, conférences d'expert

Requirements and Definitions in Conflict of Interest Policies of Medical Journals

Jared A. Blum, MD
Kalev Freeman, MD, PhD
Richard C. Dart, MD, PhD
Richelle J. Cooper, MD, MSHS

Conclusions In 2008, most medical journals with relatively high impact factors had author COI policies available for public review. Among journals, there was substantial variation in policies for solicitation of author COIs and in definitions of COI.

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Requirements and Definitions in Conflict of Interest Policies of Medical Journals

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Table 3. Prevalence of Journals With COI Disclosure Requirements According to Journal Impact Factor and Whether the Journal Follows ICMJE Guidelines

Comparison Category	No.	Median Impact Factor (Range)	No. (%)		
			Journal Asks for Disclosure of Possible COI	Journal Requires Signed Statement of Disclosure	Journal Defines or Gives COI Examples
Lowest impact factor quartile	64	2.66 (0.87-3.45)	57 (89)	33 (52)	46 (72)
Highest impact factor quartile	64	10.06 (6.85-63.34)	60 (94)	41 (64)	58 (91)
Journals that endorse ICMJE guidelines	69	5.2 (1.52-51.3)	68 (99)	50 (72)	67 (97)
Journals that do not endorse ICMJE guidelines	187	4.75 (0.87-63.34)	158 (84)	88 (47)	130 (70)

Abbreviations: COI, conflict of interest; ICMJE, International Committee of Medical Journal Editors.

Reporting of Conflicts of Interest in Meta-analyses of Trials of Pharmacological Treatments

Michelle Roseman, BA
Katherine Milette, BSc
Lisa A. Bero, PhD
James C. Coyne, PhD
Joel Lexchin, MD
Erick H. Turner, MD
Brett D. Thombs, PhD

Sources de financement: 2/29 méta- analyses
COI des auteurs : 0/509 RCTs

JAMA, March 9, 2011—Vol 305, No. 10

ORIGINAL INVESTIGATION

ONLINE FIRST

From Disclosure to Transparency

The Use of Company Payment Data

Susan Chimonas, PhD; Zachary Frosch, BA; David J. Rothman, PhD

Background: It has become standard practice in medical journals to require authors to disclose their relationships with industry. However, these requirements vary among journals and often lack specificity. As a result, disclosures may not consistently reveal author-industry ties.

Methods: We examined the 2007 physician payment information from 5 orthopedic device companies to evaluate the current journal disclosure system. We compared company payment information for recipients of $1 million or more with disclosures in the recipients' journal articles. Payment data were obtained from Biomet, DePuy, Smith & Nephew, Stryker, and Zimmer. Disclosures were obtained in the acknowledgments section, conflict of interest statements, and financial disclosures of recipients' published articles. We also assessed variations in disclosure by authorship position, payment-article relatedness, and journal disclosure policies.

Results: Of the 41 individuals who received $1 million or more in 2007, 32 had published articles relating to orthopedics between January 1, 2008, and January 15, 2009. Disclosures of company payments varied considerably. Prominent authorship position and article-payment relatedness were associated with greater disclosure, although nondisclosure rates remained high (46% among first-, sole-, and senior-authored articles and 50% among articles directly or indirectly related to payments). The accuracy of disclosures did not vary with the strength of journals' disclosure policies.

Conclusions: Current journal disclosure practices do not yield complete or consistent information regarding authors' industry ties. Medical journals, along with other medical institutions, should consider new strategies to facilitate accurate and complete transparency.

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Table 4. Number of Publications and Disclosure Rates by Authorship Position of the Payment Recipient and by Article-Payment Relatedness

Variable	No. (%)	
	Articles in Sample	Articles in Sample Mentioning Company That Paid Author ≥$1 Million
Authorship rank		
First/sole	25 (26)	15 (60)
Middle	34 (36)	11 (32)
Senior	36 (38)	18 (50)
Article-payment relatedness		
Directly related	52 (55)	26 (50)
Indirectly related	34 (36)	17 (50)
Unrelated	9 (9)	1 (11)
Total	**95** (100)	**44** (46)

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PLoS one

Consistency of Financial Interest Disclosures in the Biomedical Literature: The Case of Coronary Stents

Kevin P. Weinfurt[1,2*], Damon M. Seils[1], Janice P. Tzeng[1¤], Li Lin[1], Kevin A. Schulman[1,3], Robert M. Califf[1,3]

Abstract

Background: Disclosure of authors' financial interests has been proposed as a strategy for protecting the integrity of the biomedical literature. We examined whether authors' financial interests were disclosed consistently in articles on coronary stents published in 2006.

Methodology/Principal Findings: We searched PubMed for English-language articles published in 2006 that provided evidence or guidance regarding the use of coronary artery stents. We recorded article characteristics, including information about authors' financial disclosures. The main outcome measures were the prevalence, nature, and consistency of financial disclosures. There were 746 articles, 2985 authors, and 135 journals in the database. Eighty-three percent of the articles did not contain disclosure statements for any author (including declarations of no interests). Only 6% of authors had an article with a disclosure statement. In comparisons between articles by the same author, the types of disagreement were as follows: no disclosure statements vs declarations of no interests (64%); specific disclosures vs no disclosure statements (34%); and specific disclosures vs declarations of no interests (2%). Among the 75 authors who disclosed at least 1 relationship with an organization, there were 2 cases (3%) in which the organization was disclosed in every article the author wrote.

Conclusions/Significance: In the rare instances when financial interests were disclosed, they were not disclosed consistently, suggesting that there are problems with transparency in an area of the literature that has important implications for patient care. Our findings suggest that the inconsistencies we observed are due to both the policies of journals and the behavior of some authors.

May 2008

Table 1. Articles with disclosure statements for all, some, or no authors.*

Characteristic	Articles (N = 746)			p†
	Disclosure statement for all authors	Disclosure statement for some authors	Disclosure statement for no authors	
Article type				0.05
All	116 (15.5)	10 (1.3)	620 (83.1)	
Research	88 (14.1)	9 (1.4)	526 (84.4)	
Other	28 (22.8)	1 (0.8)	94 (76.4)	
Journal endorsement of ICMJE guidelines				<0.001
No	30 (7.4)	5 (1.2)	371 (91.4)	
Yes	86 (25.3)	5 (1.5)	249 (73.3)	

Special Report

Conflicts of Interest in Research—Towards a Greater Transparency

Jeffrey P Braff, DrPH, CIP

- Simplifier et standardiser les déclarations de Conflits d'Intérêt
- Ne pas focaliser uniquement sur les auteurs
- Impliquer les universités, les sociétés savantes, les institutions hospitalières, le CNOM
- Fichier centralisé *(adaptation française du« physician act sunshine »)*
- Développer la formation et l'enseignement

The Permanente Journal/ Summer 2010/ Volume 14 No. 2

Conflict of Interest Disclosure in Early Education of Medical Students

Kirsten E. Austad, BS

Aaron S. Kesselheim, MD, JD, MPH

JAMA, September 7, 2011—Vol 306, No. 9

French law to make conflict-of-interest disclosure mandatory

In parallel with the restrictions placed on drug advisors, the bill would push for more transparency on the side of industry. Pharmaceutical companies would be forced to publicly declare benefits and incentives that they provide to doctors, students, associations, hospitals, academic societies and trade publications—provisions modeled on the US Sunshine Act. France's health minister, Xavier Bertrand, was quoted on national radio as saying that "everything will need to be declared from the first euro."

Sabine Louët

YANKEE DOODLING **Douglas Kamerow**

NIH updates its conflict of interest guidelines

How much does the public need to know about reports of conflicts?

« Some institutions objected that maintaining a website of all the reported conflicts would have been an expensive undertaking. That seems hard to believe. Websites are not expensive to mount today. »

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Pitfalls in the publication of scientific literature: a road map to manage conflict of interest and other ethical challenges

Clinical article

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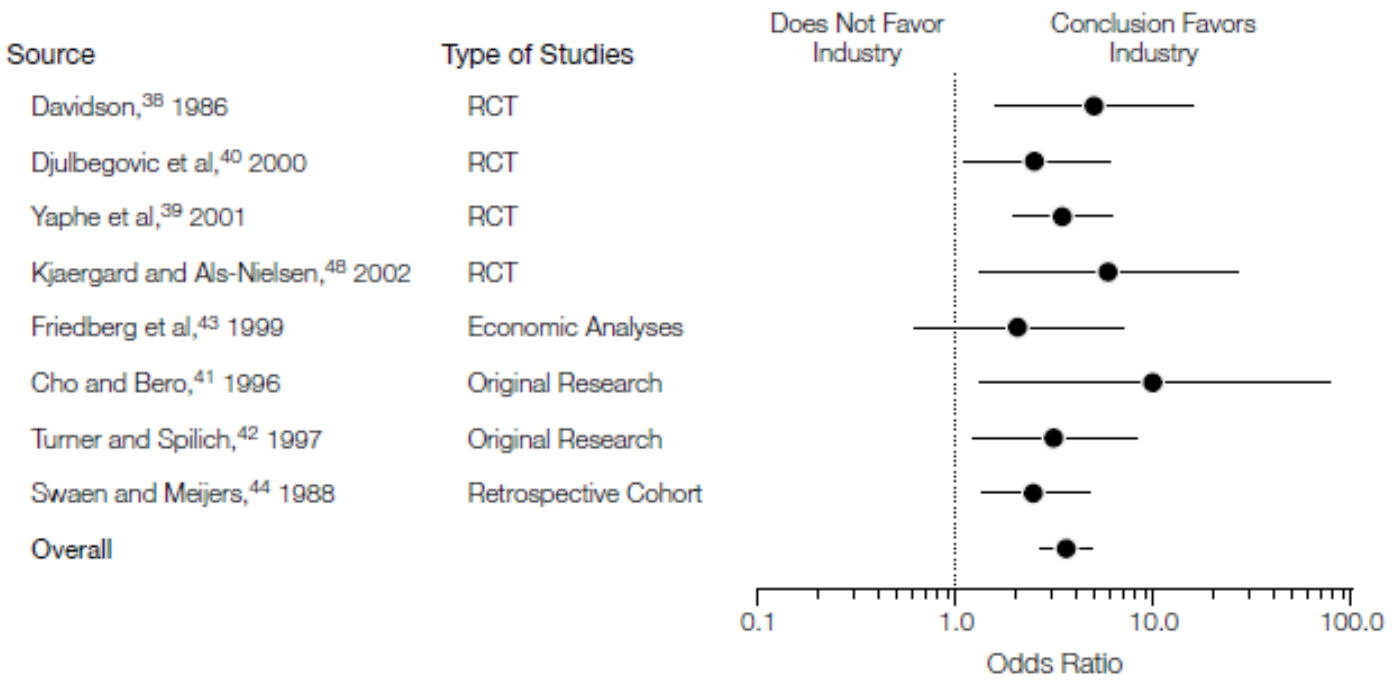
J Neurosurg 114:21–26, 2011

Figure. Relation Between Industry Sponsorship and Study Outcome in Original Research Studies



RCT indicates randomized controlled trial. Error bars indicate 95% confidence intervals.

Clarifying Conflict of Interest

Howard Brody, University of Texas Medical Branch

The American Journal of Bioethics, 11(1): 23–28, 2011

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

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.

JAMA. 2008;299(15):1800-1812

Scope and Impact of Financial Conflicts of Interest in Biomedical Research

A Systematic Review

Justin E. Bekelman, AB
Yan Li, MPhil
Cary P. Gross, MD

Context Despite increasing awareness about the potential impact of financial conflicts of interest on biomedical research, no comprehensive synthesis of the body of evidence relating to financial conflicts of interest has been performed.

Objective To review original, quantitative studies on the extent, impact, and management of financial conflicts of interest in biomedical research.

Data Sources Studies were identified by searching MEDLINE (January 1980-October 2002), the Web of Science citation database, references of articles, letters, commentaries, editorials, and books and by contacting experts.

Study Selection All English-language studies containing original, quantitative data on financial relationships among industry, scientific investigators, and academic institutions were included. A total of 1664 citations were screened, 144 potentially eligible full articles were retrieved, and 37 studies met our inclusion criteria.

Data Extraction One investigator (J.E.B.) extracted data from each of the 37 studies. The main outcomes were the prevalence of specific types of industry relationships, the relation between industry sponsorship and study outcome or investigator behavior, and the process for disclosure, review, and management of financial conflicts of interest.

Data Synthesis Approximately one fourth of investigators have industry affiliations, and roughly two thirds of academic institutions hold equity in start-ups that sponsor research performed at the same institutions. Eight articles, which together evaluated 1140 original studies, assessed the relation between industry sponsorship and outcome in original research. Aggregating the results of these articles showed a statistically significant association between industry sponsorship and pro-industry conclusions (pooled Mantel-Haenszel odds ratio, 3.60; 95% confidence interval, 2.63-4.91). Industry sponsorship was also associated with restrictions on publication and data sharing. The approach to managing financial conflicts varied substantially across academic institutions and peer-reviewed journals.

Conclusions Financial relationships among industry, scientific investigators, and academic institutions are widespread. Conflicts of interest arising from these ties can influence biomedical research in important ways.

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