

Ghosts, Guests and other Distortions of Authorship

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Funded by Office of Research Integrity,
the Flight Attendants' Medical Research
Institute (FAMRI). No personal financial
ties.

A ghost author is.....

- MECC offered substantial assistance in the development of manuscripts, reporting in a status report that "at [the author's] request, we did an extensive literature search and submitted selected articles to him for reference.... We have offered him help in identifying and collecting his appropriate cases, analyzing data, writing a manuscript, or whatever he needs."

Creating a study....

- Tobacco industry created a study – with ghost and guest authors – to refute an influential study about secondhand smoke
- Hirayama study (1981) showing association of secondhand smoke and lung cancer
 - Most frequently cited study in regulatory hearings on indoor air regulation
 - Misclassification: 1 of 9 most frequently used arguments to refute Hirayama (and other studies)

“A Japanese study” ... or not?

“Also, I am of the opinion that Dr. Chris Proctor might **supervise this work** but his presence should be low key and **not appear in any of the publications**, particularly since this is a Japanese study”

[2023544449: April 16, 1991 from T.S. Osdene, R&D at PM to Steve Parrish, Senior VP at PM]

“Proctor (and his fee) may be necessary to help get this done... but **this should be a Japanese study: Proctor should not be a coauthor on any publication** that comes out of it”

[2023544456: April 15, 1991 from Bob Pages, R&D team at PM reporting to Steve Parrish, Senior VP, PM]

Who should design and conduct it?

- Project management would be undertaken by **Covington and Burling**. The project managers would remain **remote from any scientific publications**. **Two Japanese scientists will be the principal investigators** [...will serve as principal authors of the resulting scientific reports]. **Mr. Peter Lee** also will be asked to **assist in reviewing the study design** and in **interpreting the data**. It is **not anticipated**, however, that **Mr. Lee will serve as a co-author** of any of the publications...” [2023544523: Aug.12,1991 from Covington and Burling Attorney Work Product re: proposal to study ETS exposure in non-smoking Japanese women]

Who should publish? Who is accountable?

- Draft 1: Yano and Kagawa (guests)
- Draft 2: Yano, Kagawa and Lee (guest + ghost)
- Draft 3 – 7: Lee
- Christopher Proctor (ghost)

Lee, PN. "Marriage to a smoker" may not be a valid marker of exposure in studies relating environmental tobacco smoke to risk of lung cancer in Japanese non-smoking women.

International Archives of Occupational and Environmental Health
1995, 67(5):287-94.

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I am extremely grateful to Dr. Eiji Yano of Teikyo University for assistance provided in Japan, and to Emu Efu Co. Ltd. for help in sample collection and analysis. I also thank Dr. John Fry for assistance in statistical analysis, Dr. Francis Roe for numerous helpful comments, and Mrs. Pauline Wassell and Mrs. Diane Morris for typing the various drafts.

RESEARCH PAPER

Japanese spousal smoking study revisited: how a tobacco industry funded paper reached erroneous conclusions

E Yano

.....
Tobacco Control 2005;14:227-233. doi: 10.1136/tc.2003.007377

Are journal policies sufficient?

Objective: Examine the publication success of targeted ghost written articles by variation in policies regarding ghostwriting.

Reviewed Drug Industry Document Archives, identified 2 proposals

June 18, 1997

Nancy Kohler
Parke-Davis
201 Tabor Road
Morris Plains, NJ 07950

<http://dida.library.ucsf.edu/pdf/xf00a10>

Dear Nancy,

Dear Nancy,

Medical Education Systems, Inc. is requesting an educational grant to publish a series of scientific articles in peer reviewed journals surrounding antiepileptic drug use in epilepsy.

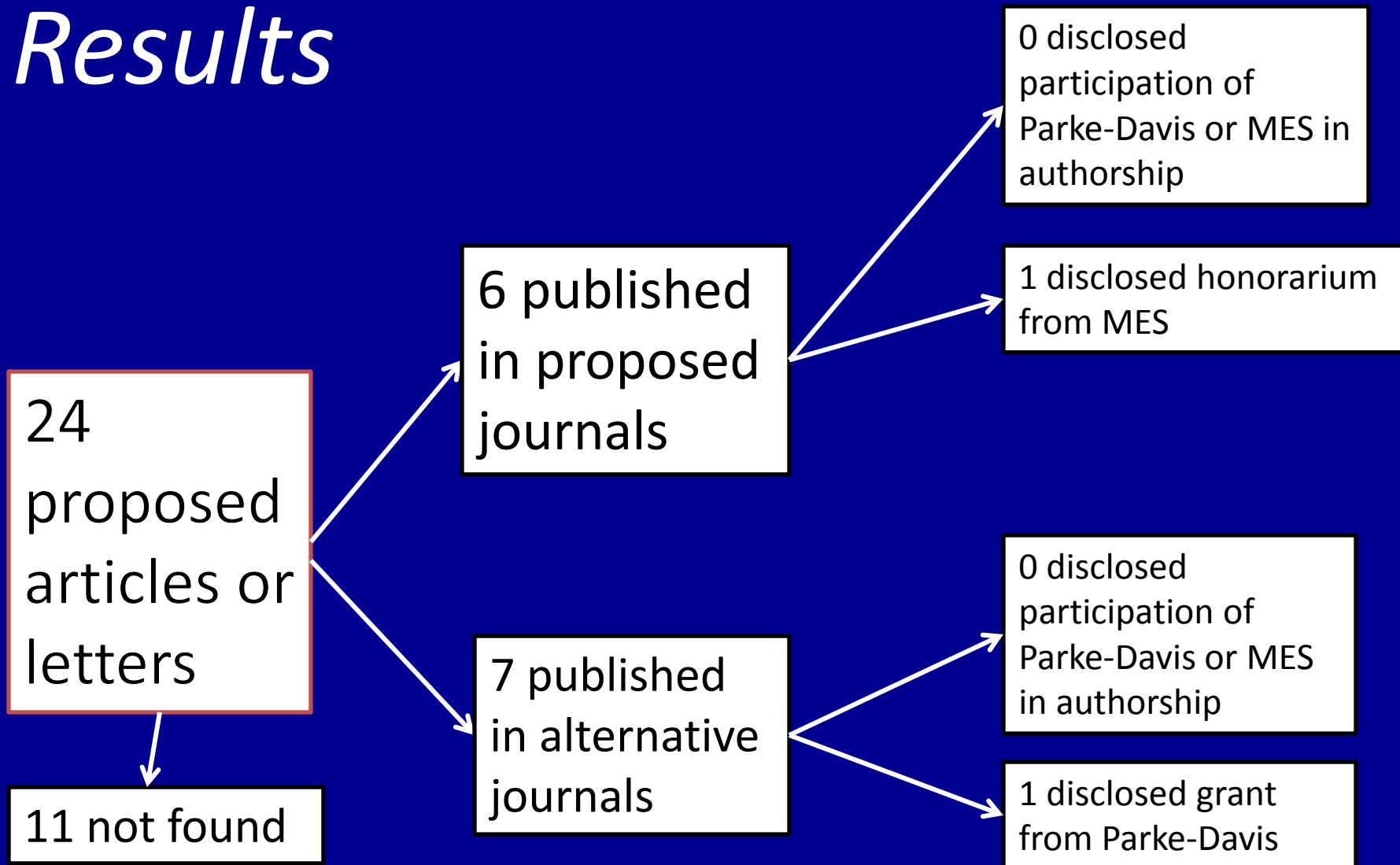
The proposed articles, authors, and journals are listed below:

| Author/Working Title | Target Journal(s) |
|---|-------------------------------------|
| Michael Merren, MD <i>Gabapentin for Treatment of Pain and Tremor: An Open-Label Study</i> | <i>Journal of Southern Medicine</i> |
| John Pellock, MD <i>Exact Title TBD</i> | <i>Epilepsia</i> |
| <i>Antiepileptic Drug Use in the Elderly</i> | |

MES is requesting a grant in the amount of \$160,500 for the editorial development, honoraria, and miscellaneous fees (mailing, permissions, etc.) of these articles.

The Cost to Treat Seizure Patients in a Managed Care in a Organization

Results



Journal Policies by Publication Status 1997-2000

| | Journals where proposed articles WERE published (n = 10) | Journals where proposed articles were NOT published (n = 16) |
|--|---|---|
| Criteria for authorship | 40% (n=4) | 50% (n=8) |
| Explicit disclosure of funding for ghostwriting | 0% (n=0) | 0% (n=0) |
| General COI/ Disclosure policy | 60% (n=6) | 88% (n=14) |

MES proposal to Parke-Davis, June 18, 1997:

| Author/Working Title | Target Journal(s) |
|---|-------------------------------------|
| Michael Merren, MD <i>Gabapentin for Treatment of Pain and Tremor: An Open-Label Study</i> | <i>Journal of Southern Medicine</i> |

MES status update, July 18, 1997:

| | | | | | |
|-----------------------|--------------|---|---|-----------------------------|----------------|
| Pain Short article | 1 6/30/97 | Michael Merren, MD Gabapentin for Treatment of Pain and Tremor: An Open- Label Study | <i>Journal of Southern Medicine</i> | Final draft sent to P-D 7/1 | <u>Rewrite</u> |
|-----------------------|--------------|---|---|-----------------------------|----------------|

Gabapentin for Treatment of Pain and Tremor: A Large Case Series

August 1998 • SOUTHERN MEDICAL JOURNAL • Vol. 91, No. 8

MICHAEL D. MERREN, MD, San Antonio, Tex

Conclusions. Gabapentin offers an effective, safe alternative therapy or co-therapy for the listed painful conditions and tremor; it does not affect the metabolism of other medications and is well tolerated.

PHARMACOTHERAPY

___ The corresponding author (and co-authors) must respond to the following Conflict of Interest questions online.

Do you have a potential conflict of interest? ___ Yes ___ No

If yes, please check all that apply and provide details below:

___ Member of company advisory board

___ Member of company speakers bureau

___ Ownership or Employment by pharmaceutical, biotechnology, for-profit pharmacy service or medical company

___ Paper has been ghost written by an individual sponsored by a pharmaceutical, biotechnology or medical company or other entity (see Authorship & Ghost Writing policy on the Article Submission and Review page of www.pharmacotherapy.org).

___ Paper has been ghost written by an individual sponsored by a pharmaceutical, biotechnology or medical company or other entity (see Authorship & Ghost Writing policy on the Article Submission and Review page of www.pharmacotherapy.org).

___ Received funding to prepare this paper (e.g., honorarium or writing fee).

Strong Ghost Authorship Policies

“Professional writers employed by pharmaceutical companies or other academic, governmental or commercial entities who have drafted or revised the intellectual content of the paper **must** be included as authors.”

Moderate Ghost Authorship Policies

“To manage potential bias, authors and reviewers...are required to make certain attestations and disclosures...Describe the role of sponsors in study design, data acquisition, interpretation of data, writing and revising the manuscript, and in the decision to approve the manuscript for publication”

Weak Ghost Authorship Policies

Authorship statement:

____I have **participated sufficiently** in the conception, design, data analysis (where applicable), and writing of this manuscript to take public responsibility for the content.
(2000)

Weak Ghost Authorship Policies

- Published policy about authorship?
“Not really, we took people at their word” (1996-2000)
- Any procedures to verify the truthfulness and completeness of authorship?
“No, we rely on the integrity of the authors” (2009)

- Rather than obstructing industry, the current International Committee of Medical Journal Editors (ICMJE) authorship guidelines provide a ready tool for misattributing authorship. Industry also relies on selective interpretations of key authorship concepts.

The “Triple Lock” formula

ICMJE Requirements

1. Conception & design
or acquisition of data
or analysis and
interpretation



2. Drafting *or* revising



3. Final approval

Disclosures

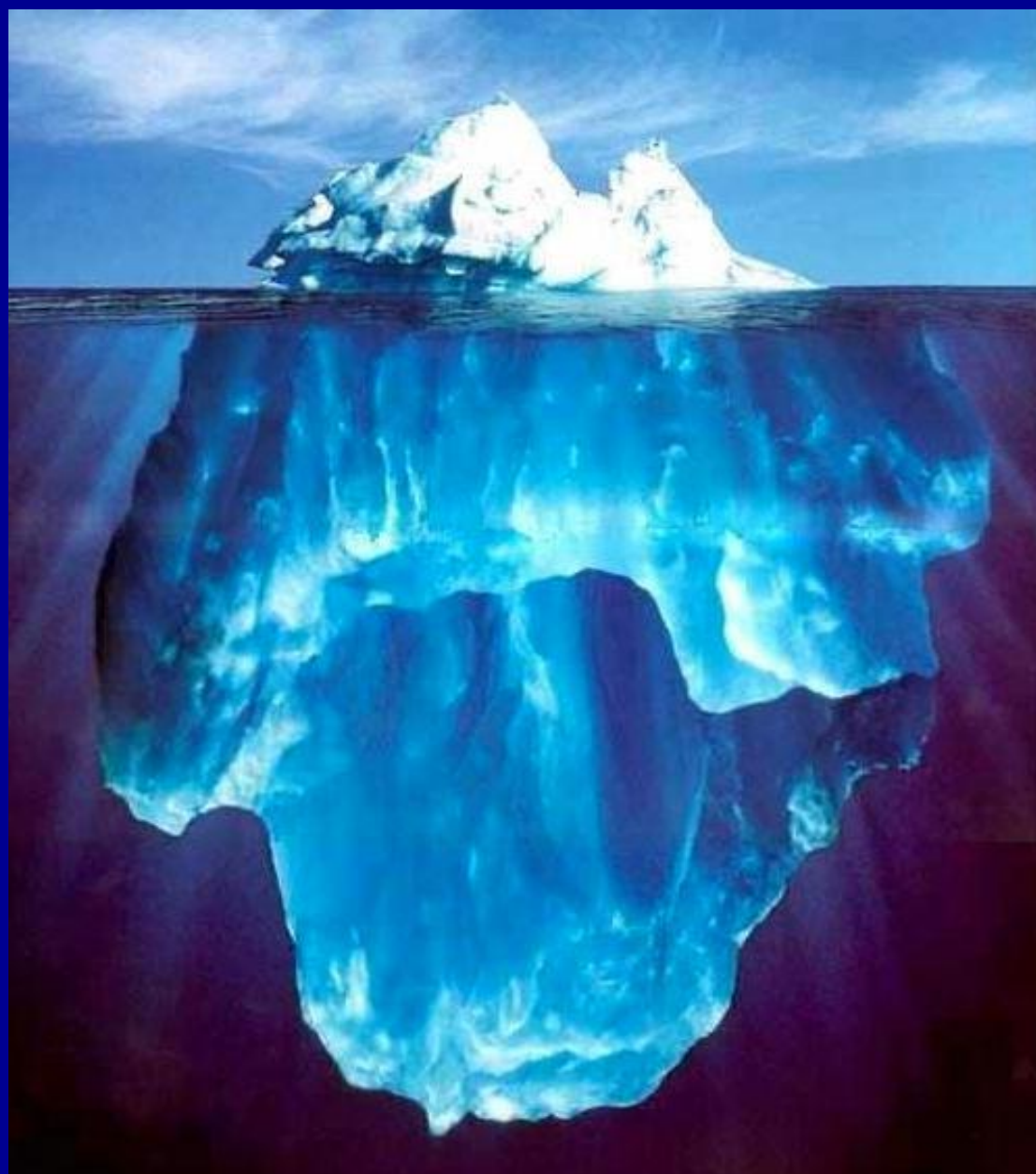
- Most commonly used “management strategy”
- Do they protect against bias?
- Can you trust them?

“Best disclosure ever....”

“The authors are interested in encouraging tobacco harm reduction..... In addition to this actual substantial interest, the authors also have what some mistakenly consider to be the only real conflict of interest, funding from the private sector: Dr. Phillips and his research group are partially supported by an unrestricted (completely hands-off) grant to the University of Alberta from U.S. Smokeless Tobacco Company. The grantor is unaware of this study, and thus had no scientific input or other influence on it.“...Dr. Phillips has consulted for U.S. Smokeless Tobacco Company in the context of product liability litigation and subsequent to the completion of this paper became a member of British American Tobacco's External Scientific Panel advising on issues of tobacco harm reduction. Though these do and might (respectively) represent interests, and credibly influence what research we consider important, our interest in accurately assessing the barriers to harm reduction means it is not clear to us how these interests might be seen as justifying the knee-jerk accusation of bias -- that we somehow altered the presentation of these results based on nonscientific interests -- that we often face from the political activists who work to influence the science in this area.”

Verifying disclosures:

- Check the Drug Industry Document Archives (<http://dida.library.ucsf.edu/>)
- Use your peer reviewers
 - Acknowledgements and Disclosure statements
 - Drugs favorably mentioned
 - Be aware of any potential biases or conflicts
- Use an experienced editor who is able to assess writing style (inconsistencies etc.)
- Authors sometimes inadvertently disclose conflicts of interest



- Long term projects, updates of systematic reviews
- Author order
- Restrictions on publication / author delays
- Author number
- Disciplinary differences

1. Rennie D, Yank V, Emanuel L. When authorship fails. A proposal to make contributors accountable. *JAMA*. 1997;278:579-85.

American Journal of Pharmaceutical Education 2005; 69 (4) Article 61.

SPECIAL ARTICLES

Equity, Accountability, Transparency: Implementation of the Contributorship Concept in a Multi-site Study

Emily Beth Devine, PharmD, MBA,^{a,b} Johnny Beney, PhD,^{b,c,d} and Lisa A. Bero, PhD^{b,d}

Table 1. Contributorship Worksheet

| Contributorship Item for Byline = Authorship (in order of occurrence) | Level of Importance 3=high 2=moderate 1=low | Participation Some=1 None=0 | Level of Participation High=2 Low =1 | Score |
|--|---|-----------------------------------|---|------------|
| (1) Conceiving the idea for the project* | 1 | x | x | = |
| (2) Conducting literature searches | 2 | x | x | = |
| (3) Participating in study design (attending meetings) | 1 | x | x | = |
| (4) Developing & refining study design | 3 | x | x | = |
| (5) Designing the database | 3 | x | x | = |
| (6) Collecting data & providing Call-Back | 3 | x | x | = |
| (7) Developing analyses plans | 3 | x | x | = |
| (8) Writing first draft† | 3 | x | x | = |
| (9) Reviewing & commenting on first draft* | 1 | x | x | = |
| (10) Revising first draft & finalizing publication | 3 | x | x | = |
| (11) Coordinating & managing project operations & progress | 3 | x | x | x |
| (12) Responding to peer reviewer comments | 2 | x | x | = |
| (13) Answering letters to the editor | 2 | x | x | = |
| Acknowledged (not scored) | 0 | x | x | = |
| (14) Obtaining funding | | | | Not scored |
| (15) Collecting data to determine inclusion in/exclusion from the study | | | | Not scored |
| (16) Providing telephone reminders | | | | Not scored |
| (17) Entering data into database | | | | Not scored |
| (18) Analyzing data | | | | Not scored |
| | Total | = | | |

*Does not qualify for authorship if only contribution

†This is a "..."

Table 2. Contributorship Worksheet Scores

| Investigator/Participant | Intended Contributor Recognition | Score |
|---------------------------------|---|--------------|
| JB | First in byline | 39 |
| EBD | Second in byline | 24 |
| LAB | Third in byline | 20 |
| VC | Fourth in byline | 13 |
| RJI | Fifth in byline | 12 |
| LM | Sixth in byline | 10 |
| MS | Seventh in byline | 10 |
| AM | Eighth in byline | 6 |
| Nine others | Acknowledged | Not scored |

gators. Although we requested publication of the Contributorship Statement by the journal to which we submitted our manuscript, ultimately only our Acknowledgment Statement was published.¹³ Even so,

