# Attribution, advocacy, disposable authors, corporate ghosts and cultural assimilation: new themes in the ethical critique of commercial medical literature

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### **Abstract**

To clarify the ethical difficulties surrounding authorship in industry-financed medical journal articles, one must consider their overall attribution rather than authorship alone. Correctly understood, attribution involves not only authorship but everything an article communicates to readers about its stakeholders, origins, and development. Proper attribution requires that the most important aspects of the origins and development of an article are brought most prominently to the attention of readers, rather than disclosed in inconspicuous small print. An important ethical problem arises when, for marketing reasons, attribution including authorship is spun to exaggerate the role of academic recruits and downplay that of the companies themselves. This practice is unethical but consistent with medicine's current editorial recommendations. Here, I introduce new themes and concepts in the ethical analysis of commercial practices, and propose changes to editorial guidelines to ensure that companies, not their contingent academic recruits, are assigned the dominant authorial role in industry-financed journal literature.

To understand the ethical challenges surrounding authorship in industry-financed medical journal articles, one must look beyond authorship alone and examine their attribution considered as a whole. I argue in this essay that the attribution of industry literature including authorship is routinely spun for marketing purposes to exaggerate the role of academics and downplay that of companies. Furthermore, I argue that this practice is not merely misleading but part of a pernicious cultural transformation of science and medicine that should be resisted by everyone concerned for scientific integrity.

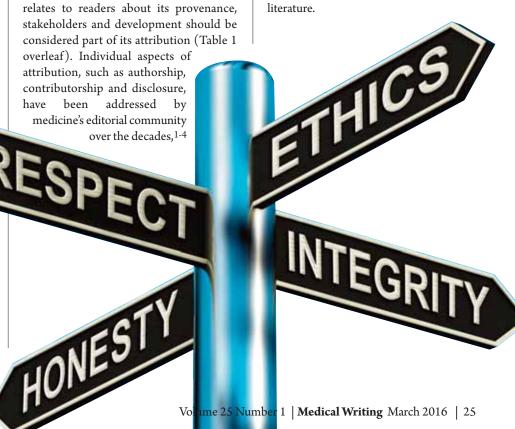
## Attribution

The attribution of journal articles is sometimes thought to be synonymous with authorship, but in fact, everything an article relates to readers about its provenance, considered part of its attribution (Table 1

and balance of all the information communicated about the article, has received scant attention. The current International Committee of Medical Journal Editors (ICMJE) Recommendations exceed 13,000 words,4 but the term "attribution" appears not once. Proper attribution requires clear comm-

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unication with the reader. It is determined not merely by what is documented but also by what is brought to readers' attention. Proper attribution requires key information to be related fully, in clear language and for the most salient information to be made prominent at the head of articles, not buried in small print (Table 1). Articles failing to do this may be misattributed if they give a misleading overall impression of the article's development. In my experience, this is an enduring problem in pharma's journal



#### **Definition**

· The sum and balance of everything an article or presentation communicates to its audience about its stakeholders and contributors, their roles and their interests.

#### Components

- Authorship including number of authors and corporate authorship
- Author sequence
- Contributor listings
- · Acknowledgements and footnotes
- Labeling and advisory statements
- Textual descriptions of stakeholder roles
- Disclosures, including interest disclosures
- Title (if group, company etc. identified in Title)

### Role of perception

- Attribution depends on what the reader notices, not merely what is disclosed.
- · An article with comprehensive "transparent" disclosures, but which places key facts about its provenance and development in the small print while letting secondary details capture reader attention, is poorly attributed.

#### **Testing attribution**

- Does the attribution of an article actively bring to the reader's attention the truth about its provenance and development?
- Salience are the most important facts isolated and presented to the reader?
- Conspicuity Are the most important features brought prominently to the reader's attention at the outset of articles?
- Clarity are facts presented to readers in clear, unambiguous, non-euphemistic language?
- Inclusiveness are any key facts omitted?

Table 1. Understanding attribution

# Advocacy marketing, content steerage, and attributional spin

Advocacy marketing (Table 2) is in my opinion the single greatest ethical problem in contemporary industry publications. Advocacy marketing occurs in numerous retail sectors, when products are promoted by members of the public or respected personas rather than by salespeople. This encourages consumers both to trust and to respect product messages - two key marketing objectives. In pharmaceutical marketing, advocacy occurs when commercial data and argument are presented to customers - chiefly, practicing clinicians by respected academics rather than by the company itself. Many academic "advocates" are recruited by pharma for their status as "key opinion leaders" also known as "KOLs".5-8 Others are "rising stars", with whom companies cultivate longstanding relationships beneficial to the company and academic alike.8

In publications, advocacy involves two steps. Firstly, companies shape the content of literature to deliver the company's intended messages. Secondly, this literature's attribution is assigned primarily to academic recruits.9 In rare cases, content is simply written by a company, then "authored" without modification by a KOL. More generally, in my experience however, when marketing influences scholarly literature, content is developed with academic

participation but subtly steered by the company to incorporate commercial perspectives, after which its attribution is subtly spun to exaggerate its academic credentials, while the company that is the true master is credited with mere "support" "sponsorship".

With respect to article content, the GPP3 guidelines illustrate many points at which it can be commercially guided. These include publication planning, which may propose themes, provisional titles, authors, journals and messages;5,10-12 author selection, either directly by companies or indirectly by committees initiated by companies; inclusion of company co-authors on most industry trials;13 company analysis of data; the use of editorial teams and writers; and company review. Collectively, these devices provide extensive opportunities for content steerage. Of note, GPP3 requires that authors "control" manuscript development and make "final" decisions, but the wording is subtle: GPP3 does not require that authors should have sole control or make all

> decisions. 12 Authors do not: and in any case, most are the company's trusted academic recruits or its employees.

Attribution of industry literature commonly emphasises academic leadership. It is common practice to place academics and their instit-

utions conspicuously at the head of author bylines, whereas industry employees are generally placed inconspicuously in the middle or towards the rear of bylines, and are often fewer in number than academic recruits.<sup>9,14</sup> There is rarely any prominent identification of the company, for instance in the title of the article or as a corporate coauthor. Where it is identified - for instance at the foot of abstracts - it is misleadingly

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Term	Definition
Advocacy marketing	Presentation of marketing-related data or argument to potential customers through their peers and opinion
	leaders, not company representatives.
Corporate authorship	When a company considered as an entity plays an authorial role.
Corporate ghost authorship	When corporate authorship is not given an appropriately frank and prominent attribution.
Disposable author	Academic author recruited into a commercial project who could readily be exchanged for another without
	significant impact on the project or publication.
Content spin	Subtle steerage of content through planning, message formulation, research design, results analysis, author
	selection, manuscript development or review.
Attribution spin	Subtle spinning of attribution through authorship, author sequence, vague language, euphemism, omission,
	poor labeling and small print.
Cultural corruption	State in which the norms of conduct and ethics within culturally linked institutions and discourses are
	distorted by cultural change – typically involving money or power.
Commercial-academic	Blending and merger between commerce and academia, such that the distinction between what is
assimilation	commercial and what is academic becomes progressively less apparent and less important.

Table 2. Terminology used in this analysis

credited with mere "funding" or "support." Contributor listings generally do not distinguish company from academic coauthors and are presented in small print. Interest disclosures typically bury academic relationships with the company amid a mass of small print disclosures. Writers are usually denied co-authorship and acknowledged only in small print. Textual descriptions of the company's role generally omit key facts, such as company instigation or private data ownership, and indeed GPP3's recommendations for disclosure omit these facts. The collective effect of these practices is to position senior academic authors as leaders of publications planned, financed and drafted substantially by companies who analyse and secretly own the data. Such attributional practices provide academic endorsement, and as Hirsch has noted, may increase the likelihood of publication in prestigious journals, whose editors and readers may prefer to see academics at the head of bylines.14

# Disposable authors and corporate ghosts

This picture of content steerage and attributional spin leads to further new concepts in commercial publication ethics. Firstly, ghostwriting remains controversial in industry publications, but in my opinion, the greater ethical problem is *corporate ghost authorship* (Table 2). This occurs when a corporate entity plays an authorial role but is not assigned a commensurate attribution in the published article. Secondly, the chief

ethical problem for academic recruits is, in my opinion, not that they are "guest authors" – most are not – but rather that they are positioned as leaders when their involvement is a contingent detail. If they or their institutions had been unavailable, or if the company's choice had been different, alternative institutions and academic authors could and would have been selected. The *actual* academic who is recruited is not decisively important. What is vital – as much to marketing as science – is that academics *per se* are recruited. The individual academics who happen to sign on are

therefore what may be termed disposable authors. (Table 2) Regardless of the scale of their contribution, they are conditions of possibility for a company project that would proceed regardless of their particular involvement. It is therefore unethical for such participants to head the attribution of this literature.

# Editorial guidelines support advocacy

Medical journal editors have taken many valuable steps to

uphold scientific and ethical standards in journal literature. These include improved documentation of individual contributions, through contributor listings and acknowledgements; enforcement of author accountability; securing author access to company data; promoting compliance with research guidelines; enforcing trial registration; and improving interest disclosures. 1-4,15,16 Yet none of these measures challenges the exaggeration of academic roles and understatement of commercial ones upon which advocacy marketing depends. Rather, the ICMJE Recommendations assist these practices – they exclude writers from byline authorship of research articles; set no requirements for corporate authorship; permit omission and euphemism in descriptions of industry's role, for instance in recommending terms

such as "funding", "support" and "sponsor"; and provide no advice on what information should be brought more actively to readers' attention. 4 Consequently, articles planned, financed, and drafted by companies and reporting their secretly held data continue routinely to be published under supposed academic leadership.

# Cultural corruption and commercial assimilation

All the practices I have described – advocacy marketing, misattribution of commercial literature, corporate ghost authorship and disposable authorship – require the participation of drug companies, marketing companies, publishers, journals and



recruited academic authors. These stakeholders all benefit according to their interests - indeed, the culture of contemporary industry publications could not endure were not the interests of all stakeholders met. Thus, academics gain prominent authorial credit, and their careers benefit from the research and publishing opportunities they find in industry partnership. Drug companies obtain publications and endorsements to promote their products. Marketers secure lucrative publications contracts with the corporations; journals receive copy for their pages; and publishers receive substantial reprint revenues. All of them benefit - and yet are able to claim that their conduct is fully ICMJE-compliant, meticulously transparent and ethical.

Lessig has defined "institutional corruption" as a state in which "there is a systemic and strategic influence which is legal ... that undermines the institution's effectiveness by diverting it from its purpose or weakening its ability to achieve its purpose."17 Insofar as medical research and publishing can be considered as "institutions", then they are vulnerable to institutional corruption as Lessig has defined it, due to the systematic and strategic influence of pharmaceutical marketing.

I want here, however, to place the notion of "institutional corruption" within a more generalised framing. The drug industry, biomedical science, medicine, marketing and the publishing industry – Foucauldians would refer to the interconnected whole as a "dispositif" 5,18 - is composed of a mesh of institutions, practices, discourses, traditions and cultures that are in a process of continual interaction and evolution. What Lessig would term "institutional corruption" occurs when commercial drives within this setting deflect the scientific, clinical and publishing domains from their traditional goals. Because commercial forces reach across many institutions and discourses, the term "cultural corruption" is to be preferred to "institutional corruption", although the latter term remains valid within individual institutions and discourses. Yet the term "corruption" does not capture the full range and subtlety of change wrought within science and medicine, and editorial opinions differ over whether industry's presence is harmful or beneficial. 19,20 Perhaps the most troubling trend is best characterised not so much as a deflection, deception or corruption of traditional academic discourse but rather a gradual merger between the domains of commerce and medical science, generating a hybrid research culture in which the distinction between what is scientific and what is commercial is by slow decrements becoming less apparent and less important. Such

commercial-academic assimilation occurring on many levels: institutions and the geographical organisation of research; universities, research groups, research personnel and academic appointments; clinical research; and publications, whose webs of small print disclosure function more to integrate than differentiate the contributions of commerce and academia. The practices described in this essay are pernicious not only in respect of advocacy marketing but also because they too subvert the boundary between what is commercial and what is not. Once commerce becomes so blended into academia that its presence becomes a mere detail, routine in nature and

giving little pause for thought, then marketing's campaign for access into the soul of medicine is won.

# Policy proposals

In this essay I have argued that attribution is a poorly developed concept in medical editorial thought; that the attribution of industry literature frequently

exaggerates its academic and downplays its commercial credentials, in the service of advocacy marketing; that companies are frequently corporate authors, such that corporate ghost authorship is an important problem; and that academics who make honest contributions are nonetheless contingent, "disposable authors" who

### Recommendations

For any article financed by a company and reporting on its product, in which the company, its employees or hirelings have participated at any stage, the first author should be the company itself. Alternatively, the company should be named at the beginning or end of the title.

For all articles financed by industry, the Abstract and Introduction should state the article's commercial provenance and marketing functions.

Research articles should include a dedicated "Commercial Considerations" section in the Methodology, explaining the commercial rationale and how this influenced the study design.

There should be joint measures by journals, societies, and academic institutions to ban physician advocacy from medicine.

> should not front this literature. I have argued that the ICMJE Recommendations facilitate these practices, and that biomedical science is threatened not merely by commercial corruption, but by creeping merger between the worlds of science and commerce.

> To address these issues, the medical editorial community must develop a more sophisticated conceptualisation of attribution. Editors must understand that while transparency, disclosure and documentation are vital, they do not equate with good attribution if readers are not actively presented with the most salient facts about the material they are reading. Academic lead authorship should never be allowed to

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The problems of misattribution in commercial literature could be solved by taking corporate authorship seriously. For any article financed by a

company and reporting on its product, and in which the company has participated in research or manuscript development, I recommend that the first author should be the company itself - for example, Merck, Inc. Other authors could remain unchanged, although in my opinion writers should be co-authors. An alternative would be to begin

or end the *title* of the article with "A Merck, Inc. Trial". In addition, for all articles financed by industry, including review articles and consensus statements, the abstract and the introduction should state: "This article has been planned and financed by Company X with assistance from YZ Medical Communications, in connection with the marketing of Drug D, a Company X product." There should also be a dedicated "Commercial Considerations" section within the Methodology section, explaining the commercial rationale and how this influenced the review themes or study design. For instance:

"The study proprietors, XY Pharma, chose to measure 24-hour blood pressure control rather than absolute blood pressure reduction in this study in part because the investigational product they manufacture, votasartan, has a long elimination half-life, and is therefore likely to perform favorably according to 24-hour assessment. The proprietors chose the comparator drug, plodipine, in part because votasartan is competing for its market share, and in part because while plodipine yields greater absolute blood pressure reductions votasartan, it has a shorter elimination half-life, offering potential advantages for votasartan with respect to the selected assessment criteria. The proprietors conducted the study at 35 centres rather than a small number of centres, because while statistically less robust, this enabled them to familiarise more physicians with the use of votasartan, which may lead to higher sales."

These or similar measures should have been enforced by journals decades ago, but that would have been incommodious to advocacy marketing, to academic authors, to the vanities and anxieties of professional medical culture, and to publishers eager to fill journals with literature and coffers with reprint sales. The only beneficiaries of truthful attribution and a true description of commercial considerations would be scientific integrity, the scientific record, journal readers, and their patients, whose

bodies are the ultimate target of the marketing enterprise. Measures such as these would not only prevent misattribution and reduce advocacy but would bolster the distinction between commercial and noncommercial science and combat cultural blending. To support this goal and assist research on industry practices, the US National Library of Medicine should introduce an obligatory new publication category, "Commercial", for all industry-financed literature.

### Conclusion

I end with an appeal to my friends in the pharmaceutical and publications trades. There is much to celebrate in mercantile science, as pharma's own traditions of scientific research and discovery demonstrate. Likewise, collaboration between commerce and science can be beneficial, and whether welcome or not, increasing commercial-academic interaction is the reality we must live with. The challenge then is to maintain scientific rigor, frankness, freedom from bias, and intellectual independence in a world of growing commercial partnership. Much of today's commercially financed medical publications culture is an exemplar for how not to achieve this: its output is vulnerable to bias in framing and content, may incorporate subtle commercial positioning into scientific text, and may report or discuss research that is designed to sell rather than discover; whose patient-level data are secret; and their attribution is commonly spun the better to impress readers. Many trade writers are former scientists, who understand the importance of absolute truthfulness and frankness in the way science is done, and who, I believe, know that whatever the ICMJE might allow, the published output of the pharmaceutical, marketing and publications trade too often falls short of the standards science should attain. Not only do science, medicine and patients deserve better, but the trade deserves better - to have the frankness to call itself a trade, to be open with readers about the commercial objectives of publications, to abhor euphemism, omission, understatement,

vagaries and small print in reporting industry roles, and to respect and vigorously defend the distinction between commercial and noncommercial science. In my opinion the publications trade needs new guidelines, a new trade association, and new leadership to realise these goals.

# Conflicts of Interest and Disclaimers

Between 1994 and 2012 the majority of my income came from consultancy and writing services provided to pharmaceutical corporations, either directly or via marketing agencies. In 2015 I acted as a paid expert witness on behalf of the plaintiffs in a US federal legal action against a pharmaceutical corporation.

I received no support, remuneration or benefits of any kind for researching and writing this article.

I consider myself a supporter of bona fide scientific research including for-profit industry research but an opponent of marketing practices in the setting of scientific research and publication.

### References

- 1. Huth EJ, Case K. The URM: twenty-five years old. Science Editor 2004; 27: 17-21
- Rennie D, Yank V, Emanuel L. When authorship fails. A proposal to make contributors accountable. JAMA 1997; 278: 579-585.
- 3. Rennie D. Integrity in scientific publishing. Health Serv Res 2010; 45: 885-896.
- 4. International Committee of Medical Journal Editors (ICMJE)
  Recommendations for the Conduct,
  Reporting, Editing, and Publication of
  Scholarly Work in Medical Journals
  (ICMJE Recommendations). Available:
  http://www.icmje.org/
  recommendations/. Accessed
  November 30, 2015.



- 5. Matheson A. Corporate science and the husbandry of scientific and medical knowledge by the pharmaceutical industry. BioSocieties 2008; 3: 355-
- 6. Sismondo S. Key opinion leaders and the corruption of medical knowledge: what the Sunshine Act will and won't cast light on. J Law Med Ethics. 2013;41:635-43.
- 7. Moynihan R. Key opinion leaders: independent experts or drug representatives in disguise? BMJ. 2008;336:1402-3.
- 8. White Paper: Key Opinion Leader Identification and Selection. A Pharma Matters Report. Thomson Reuters, January 2009. Available: http://www.slideshare.net/driceman/ kol-management?related=1 Accessed November 10 2015.
- 9. Matheson A. The disposable author: how pharmaceutical marketing is embraced within medicine's scholarly literature. Hastings Center Report 2016; 10.1002/hast.576.
- 10. Wittek MR, Williams MJ, Carlson AM. Evidence development and publication planning: strategic process. Curr Med Res Opin. 2009;25:2723-7.
- 11. Sismondo S. Ghost management: how much of the medical literature is shaped behind the scenes by the pharmaceutical industry? PLoS Medicine 2007; 4: e286.
- 12. Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. Ann Intern Med. 2015;163:461-4.
- 13. Hoekman J, Frenken K, de Zeeuw D, Heerspink HL. The geographical distribution of leadership in globalized clinical trials. PLoS One 2012; 7: e45984.
- 14. Hirsch LJ. Conflicts of interest, authorship, and disclosures in industryrelated scientific publications: the tort bar and editorial oversight of medical journals. Mayo Clin Proc. 2009;84: 811-21.

- 15. Davidoff, F, C.D. DeAngelis, J.M. Drazen, M.G. Nicholls, J. Hoey et al. 2001. Sponsorship, authorship, and accountability. New England Journal of Medicine. 345:825-826.
- 16. DeAngelis CD, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. JAMA. 2004 Sep 15;292(11):1363-4
- 17. Lessig L. "Institutional corruption" defined. J Law Med Ethics 2013; 41:
- 18. Foucault, M. (1980). The confession of the flesh. In M. Foucault (C. Gordon, Ed.), Power/knowledge: Selected interviews and other writings, 194-228. Brighton: Harvester Press.P 195.
- 19. Horton R. The Dawn of McScience. New York Review of Books. March 11
- 20. Drazen JM. Revisiting the commercialacademic interface. N Engl J Med 2014;372;19:1853-4.



Alastair Matheson, PhD, worked as an independent consultant and writer specialising in product analysis, publications planning, and manuscript development in the pharmaceutical, marketing, and publications industries from 1994-2012. He has worked with over 20 medical communications agencies and most of the major pharmaceutical corporations. He retains friendships and contacts in these trade sectors.



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### Abstract

This interview provides solutions to some of the common pitfalls that face medical writers when working with large teams. Practical tips are provided on key topics including manuscript planning, agreeing on key messages and the use of figures, tables and other contents, deciding on the criteria for authorship, and dealing with contributors who fall short of their commitments.

Professor Ruth Roberts is founder and director of ApconiX, a pre-clinical consultancy and ion-channel expertise company based in the UK. In the last 20 years, she has published over 130 peer-reviewed research articles and reviews as well as numerous scientific posters, several book chapters and two books. In addition, she has been chief editor for several authoritative text books.