

ANALYSIS



Ghostwriting: the importance of definition and its place in contemporary drug marketing

Alastair Matheson describes how the pharmaceutical publications industry seeks to legitimise ghostwriting by changing its definition while deflecting attention from wider marketing practices in academic publishing

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During the past decade, the pharmaceutical publications trade has campaigned to persuade medicine, journals, ethicists, and the media that it is opposed to ghostwriting. Yet industry practices have changed little, and commercial drafting of clinical trial reports, consensus statements, and reviews that are authored by recruited academics remains routine. Here, I show that industry's opposition is based on a redefinition of the term ghostwriting that obscures the continued, widespread use of the practice as originally defined in medical journal literature. I also argue that the ghostwriting debate has deflected attention from the broader set of strategies through which marketing influences medical publications. The use of writers, regardless of whether they are called ghosts, is just one of several options for building commercial perspectives into academic literature, then spinning their attribution to strengthen credibility.

Rebranding of ghostwriting

Outside medicine, a ghostwriter is "a person whose job it is to write material for someone else who is the named author."¹ Drug companies and their agencies use writers to develop articles for academic authors, and in the 1990s and early 2000s this was commonly understood as ghostwriting, both by journal editors and the pharmaceutical publications trade.²⁻⁵ But today, the trade promotes an alternative definition, whereby writers are not classified as ghosts if they are named in a footnote.

The International Society for Medical Publication Professionals, a trade association, states: "Ghostwriters are individuals who contribute substantially to a medical publication but do not appear on the byline and are not acknowledged for their contribution."⁶ The Global Alliance of Publication Professionals, a trade advocacy unit, states: "A ghostwriter is someone who writes a paper, but whose name does not appear on the paper."⁷ Simply by acknowledging writers for editorial or writing "assistance"—a practice always widespread—commercially written literature is by these definitions freed from the egregious ghostwriting label. Consider, for instance, two commercially drafted studies of paroxetine, both criticised for using

ghostwriting to produce allegedly biased content.⁸⁻¹² One, study 352, mentions no writer but the other, the notorious study 329, discloses at the end of a tract of small print that "Editorial assistance was provided by Sally K Laden, MS." By the traditional definition, both articles are ghostwritten, but according to the trade definitions quoted above, Study 329 is not, even though the medical writer's credit is inconspicuous.

As figure 1 shows, this attempt to redefine ghostwriting is based on two arguments.¹³⁻¹⁶ Firstly, it is claimed that a critical characteristic of ghostwriting is secrecy, and if industry writers are disclosed it should not be considered ghostwriting. The second argument is that the appropriate level of credit is what matters in medical journal articles, and because writers merit only a footnote rather than authorship, they should not be called ghosts when they receive one. In support of this contention, it is argued that composition is technical, not intellectual; that writers are not experts in the subject matter; and, by industry, that academic authors "direct" content and have the final say over the manuscripts that medical writers compose. Furthermore, the International Committee of Medical Journal Editors (ICMJE) recommendations bar writers from coauthorship unless they make substantial contributions to the conception or design of the work or to the acquisition, analysis, or interpretation of data, whereas contributors to these tasks are not required to take part in drafting to qualify as authors.¹⁷

These arguments do not withstand scrutiny. The "problem" with ghostwriting is not secrecy but inadequate communication to readers about how the text was developed. This problem is sustained, not solved, when the writer is named in an inconspicuous footnote. Even if a footnote were considered more appropriate than byline authorship, as the ICMJE mandates, it does not follow that a writer so credited should no longer be described as a ghost. Ghostwriters in popular fiction or journalism are often credited in footnotes, yet it remains unquestionably ghostwriting. What matters in diagnosing ghostwriting is who is attributed as the author and who wrote the text.

Furthermore, writing manuscripts should be considered an intellectual task. The role of trade medical writers and the editorial teams of which they are a part is often more than mere “assistance.” Many writers have PhDs—they are also in my experience honest and professional—and they require high scientific literacy and expert ability to align scientific and commercial perspectives. Commercial writing companies do not provide a service to authors but are contracted for profit to pharmaceutical companies to plan and develop articles. They are answerable to their paymasters, who review and contribute to their outlines and manuscripts.¹⁸⁻²² The academic authors who provide “direction” or “final” say are often selected in advance, and while their contributions are honest and substantial, this has little effect on the output anticipated by planners.

Roots of rebranding

The arguments for rebranding ghostwriting have a nuanced history, originating in the writings of journal editors and their dialogue with industry over some 10 years. With the benefit of hindsight, editorial comment on these matters shows three key limitations: underestimation of the intellectual importance of composition; lack of knowledge of industry practices; and an approach to attribution and disclosure that did not give sufficient consideration to the perceptions of the reader (table 1⇓). In 1994-95, *JAMA* editors Rennie and Flanagan argued that writer “assistance” did not deserve coauthorship but called for writers to be credited in the acknowledgments.²⁴⁻²⁶ They recommended disclosure as a remedy for the involvement of writers but did not consider its conspicuity. Rennie and Flanagan still referred to writers who had been acknowledged as “ghosts,” but in subsequent commentaries by other editors, published during a period of dialogue with industry, the idea that disclosure would be sufficient to remove the “ghost” label from a writer strengthened.²⁷⁻²⁸ Finally, in October 2005, Laine and Mulrow, deputy editors of *Annals of Internal Medicine*, explicitly stated that “in ghostwriting, individuals who wrote the paper are not acknowledged.”²⁹

Structured dialogue between senior editors and industry had begun in 1998, at the instigation of industry executives who sought greater mutual understanding with editors, improved transparency for commercial writing practices, and had suggested “discarding the term ghostwriter.”³⁰ The dialogue led to increasing familiarity between editors and industry, collaborations, guidelines for the writing trade, and in due course, greater industry representation within editorial societies considering these matters.¹⁵⁻³⁴

The pharmaceutical publications industry began serious efforts to improve transparency in 2004-5, in response to mounting public concern about trade practices. The European Medical Writers Association introduced guidelines distancing itself from the term ghostwriting, two publications trade associations were formed, and contemporaneously with the developments in editorial thought described above, the trade began to promote a distinction between “professional medical writers,” who were disclosed, and “ghostwriters,” who were not.³²⁻³⁷ Since 2005, the trade has increasingly campaigned on ghostwriting and related ethical issues through academic publications, letters to journals, press statements, research, alliances, lobbying, citation of prestigious authorities, meetings, and guidelines, in a commercial consensus building process exhibiting similarities to drug marketing.⁶⁻⁴³

Content steering: the marketing “tool kit”

The ghostwriting debate has had the further adverse consequence of blunting understanding of the broader operations of marketing within scholarly media, including journal literature, educational materials, and electronic media. The construction of scholarly content can be considered systematically on the basis of four functional domains—namely, stakeholders, research and planning, content determination, and attribution. A key strategy for marketing is “opinion leader advocacy,” in which content is first subtly configured to serve commercial purposes and then attribution is spun to highlight readers’ respected academic peers. In ghostwriting, content is drafted by writers then attributed to academics, but this is merely one option within a “tool kit” of potential interventions for spinning content and attribution. The options for influencing content include:

Planning—Before authors are recruited, the company may broadly anticipate the content or plan it in detail. Product positioning messages may also be preplanned for insertion into manuscripts.¹⁸⁻²²

Author selection—Cultivation of relationships with academics is central to marketing. Drug companies court, groom, and monitor academic recruits, subdividing them into established opinion leaders and “rising stars.”¹⁸⁻⁴⁵ Relationships may include paid consultancy; participation in clinical trials or consensus groups; presenting and lecturing, media work, and article authorship. Reliable partnerships help companies develop content with confidence and enable authors to be selected at the planning stage.²⁰⁻²² Most academic authors are not “guests” as typically defined, since they contribute substantively. Nonetheless, as preplanning and preselection of author and research institution all indicate,¹⁸⁻²² a hallmark of commercial literature is that similar articles could have been produced using alternative academics. The companies, their trials, publications, and marketed products are the fixed points; individual academics are contingent and replaceable. Only their functions—to provide expertise and credibility, and serve as “advocates”⁴⁵ for the drug among fellow clinicians—are essential.

Discussion, project briefings, and manuscript review take place between drug companies, publications and “medical communications” agencies, and academic authors. For instance, marketing and pharmaceutical trade association guidelines reserve companies the right to review all publications arising from their trials, and to “debate” with academic authors who dispute their interpretation.⁴⁶⁻⁴⁷ These interactions do not give companies a veto but afford potential leverage over content.

Documentary guidance developed by companies and provided to authors or writers may also steer content. It may include article outlines, results summaries, and clinical study reports. For instance, the Pharmaceutical Research and Manufacturers of America states that “all authors will be given the relevant statistical tables, figures, and reports needed to support the planned publication.”⁴⁶ Documentary guidance steers manuscripts towards company framings and interpretations, while coopted academics receive primary credit for the publication.

Hands-on involvement—Companies often have substantial input into framing questions, study design, statistics, interpretation, and follow-up analyses.⁴⁸⁻⁵¹ Corporate employees participate as manuscript coauthors on most clinical trials.⁵²

Commercial writers and editorial teams may perform tasks such as creating outlines or adding detail to manuscripts, collating or editing text, or full drafting. Regardless of whether these activities are designated as ghostwriting, they all permit leverage over content.

Medicine's culture of misattribution

Properly understood, attribution involves not merely authorship but everything an article communicates about its stakeholders, planning, and development. What readers notice is crucial, and articles should be considered misattributed if key facts are communicated ambiguously or in small print. The attribution of commercial literature uses these subtleties to aggrandise the role of academics and downplay that of companies through the following subtle, cumulative steps.

Author selection is important for academic credibility. Both the identity of authors and their numbers are important, and industry coauthors may be limited to reduce commercial impressions.⁵³ Writers are routinely omitted.

Author order is critical. Academics and their institutions are commonly assigned lead byline locations and industry coauthors minor ones, creating an impression of academic leadership.²² An effect similar to ghostwriting may be achieved without writers if content is heavily steered by industry coauthors but lead authorship assigned to academics.

Disclosures and labelling generally portray companies in a "supportive" role. Most disclosures are in small print, and drug companies are routinely described as "sponsors," implying they merely meet the costs of research when in fact they plan and own it. Even prestigious trial publications with expert academic collaboration rarely state clearly that they are planned and instigated, and their data owned, by corporations. Acknowledgments often credit only individual writers rather than commercial teams and use stock vagaries such as "writing assistance" to describe their role.

These methods allow commercially planned content to be routinely presented as an academic or academic led enterprise. But importantly, they are facilitated by medical culture as much as marketing. Academic authors readily accept the laurels of principal credit. The ICMJE recommendations bar writers from authorship,^{54 55} require neither data ownership nor company interests to be disclosed, and give no advice on author order or prominent labelling.¹⁷ The roots of misattribution lie not in commercial calculation alone but the customs, standards, and self interest of medicine and its publishing practices. Ghostwriting is merely one part of an entrenched culture of misattribution that serves the interests of commercial and academic stakeholders alike.

Communicating with readers

Ghostwriting by the standard definition remains widespread in industry financed medical journal literature, for reasons that have not changed—it delivers articles to order and on schedule, and ensures they are commercially useful, professionally finished, and, most importantly, attributed to academics. The difficulty with medical ghostwriting is not confined, as the publications trade claims, to wholly secret production of texts for sign-off by academics but is also evident in the extensive role of commercial teams in planning and crafting this literature being recognised only in a footnote. Industry's disavowal of ghostwriting turns on a redefinition, whereby notorious articles such as Study 329 do not count as ghostwritten. By promoting this redefinition, the trade has sought to exculpate its practices

from the ghostwriting label. Ethicists perplexed about how academic reasoning is so readily steered by marketing to drive sales of pharmaceutical drugs should study how medicine's understanding of ghostwriting is being influenced by the marketers. But they should bear in mind too that the reasoning on which rebranding is based originated in the writings of journal editors as well as industry executives.

Changes to editorial policy could solve these problems. Firstly, ICMJE authorship criteria should be changed, such that writers contributing to manuscript composition or revising the manuscript for intellectual content are required to be coauthors—an approach taken by *Neurology*.⁵⁶ This would be ethically and intellectually appropriate, raise the standing of medical literature within academia, and allow unambiguous reinstatement of the standard definition of ghostwriting as writing by someone who is not listed as an author. Regardless of ICMJE policy, this definition should be used in medicine.

To address the broader problem of attributional spin, ICMJE should develop guidance on author order, corporate coauthorship, and, most importantly, clear commercial labelling. Editors should understand that the injudicious use of small print, euphemism, and vagary plays into the hands of marketing and should develop a richer articulation of the concepts of attribution, disclosure, and transparency, in which communication with the reader is given greater priority (table 2⇓). Innovative industry science should be celebrated, and writing companies potentially have a role, but whenever industry instigates and finances research and owns the data, publications must be presented to readers as industry projects with academic contributions, not spun as academic led ventures.

Finally, the pharmaceutical publication trade's inroads into publication ethics should themselves be subjected to ethical study. Medical publishing is currently in transition from print to electronic media, and this may offer new ways to deal with authorship, contributorship, attribution, transparency, and labelling. The ghostwriting debacle is a tale of conceptual error, commercial calculation, and cultural debasement, which continues to compromise medicine's learned literature, and should now be critically reassessed.

Contributors and sources: The author worked from 1994 to 2012 as an independent consultant in the pharmaceutical, marketing and medical communications sectors, with extensive experience of market analysis, strategic communications planning, publications planning and medical writing. He has also studied the interface between academia and commerce from the standpoints of anthropology and publications policy.

Competing interests: I have read and understood BMJ policy on declaration of interests and declare the following interests: Between 1994 and 2012 most 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 drug company. I have valued friendships and acquaintances in the corporate pharmaceutical and marketing sectors. I consider myself to be a supporter of innovative pharmaceutical research, but a critic of some forms of marketing. I was solely responsible for all aspects of conception, design, and writing of this article and am the guarantor.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Key points

Ghostwriting remains widespread in industry financed medical journal literature, although redefinition means it is not always labelled as such

The drug industry's use of medical writers is only one of various means through which scholarly literature may be influenced for marketing purposes

ICMJE rules should be modified to ensure that industry medical writers are credited with coauthorship and to ensure that industry instigated literature is better attributed and labelled

The standard definition of ghostwriting should be reasserted within medicine, and industry's promotional activities within publication ethics subjected to ethical study

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Tables

Table 1 | Common misconceptions about ghostwriting and related practices

| Misconception | Reality |
|--|---|
| Ghostwriting occurs when a manuscript's writer and funding source are not disclosed in the small print | This is a recent redefinition successfully promoted by the pharmaceutical marketing industry. In everyday usage, ghostwriting is when a manuscript is written by a non-author |
| Professional medical writers are not ghostwriters | "Professional medical writer" is a trade term for trade writers, who often are ghostwriters as traditionally defined |
| Ghostwriting is the main way marketing shapes academic content | Steering of content involves many subtle mechanisms. Writers are just one means of steering content, and many commercial manuscripts do not use writers. |
| Ghostwriting and ghost authorship are equivalent terms | Ghost authorship generally refers to all contributions which merit byline authorship but do not receive it. ²³ Not all ghost authors are writers—eg, statisticians may be ghost authors. And not all ghostwriters are ghost authors—eg, ghostwriters composing minor parts of a text may not deserve authorship |
| Ghostwriting is always accompanied by guest authorship | Trade writers and academic recruits often both make substantial contributions, but only the academic is retained as an author |
| Ghostwriters merely carry out academic authors' instructions and are not qualified to defend the articles they draft | Most industry writers are embedded in editorial teams who also instruct them and may review and develop their work according to commercial objectives. Many industry writers have science PhDs, can skilfully draft text which is both scientific and commercial, and are better qualified than academics to account for the commercial nuances of articles |
| Academics are paid to accept authorship of industry manuscripts | Direct honorariums for authorship are rare in peer review literature. However, academic authors may receive fees for other tasks such as trial participation, consultancy, or speaking |
| ICMJE's recommendations protect medical literature against ghostwriting | The recommendations facilitate and arguably mandate ghostwriting by excluding writers from authorship. They merely require ghosts to be mentioned in the small print |
| Transparent disclosure is the cure for ghostwriting | Transparency is of limited value if it does not bring key facts to readers' perception. Small print undermines "transparent" disclosure |

Table 2| Attribution, transparency, and disclosure: communicating with readers about industry projects

| Requirement | What to consider | Suggested measures |
|---------------|--|--|
| Inclusiveness | Are all principal facts required for readers to understand the origination of the article reported? | Company's commercial interest (eg, the drug) should be highlighted Company instigation should be disclosed (<i>The BMJ</i> requires this) Company database ownership should be highlighted (currently rarely done) |
| Clarity | Are the disclosures stated in clear and unambiguous language? Are they free from text giving countervailing impressions? | Company should not be described as a "sponsor" when it is a data proprietor or participates in the research Avoid vague language (company was "involved in" activities; writing "assistance") |
| Salience | Are the most pertinent disclosures singled out? | In author interest declarations, payments from the funding company should be separated from relations with other companies and proactively drawn to readers' attention |
| Conspicuity | Are the most salient disclosures conspicuous to the reader? | Identify company in the title (eg, "A Merck study") or require a company employee to be first author Paragraph in abstract—eg, "This study was financed and planned by GlaxoSmithKline in connection with the clinical evaluation and marketing of its product, paroxetine. GSK designed the study, analysed and owns the data, and financed and took part in drafting this manuscript." Include writers who draft articles as coauthors |

Figure

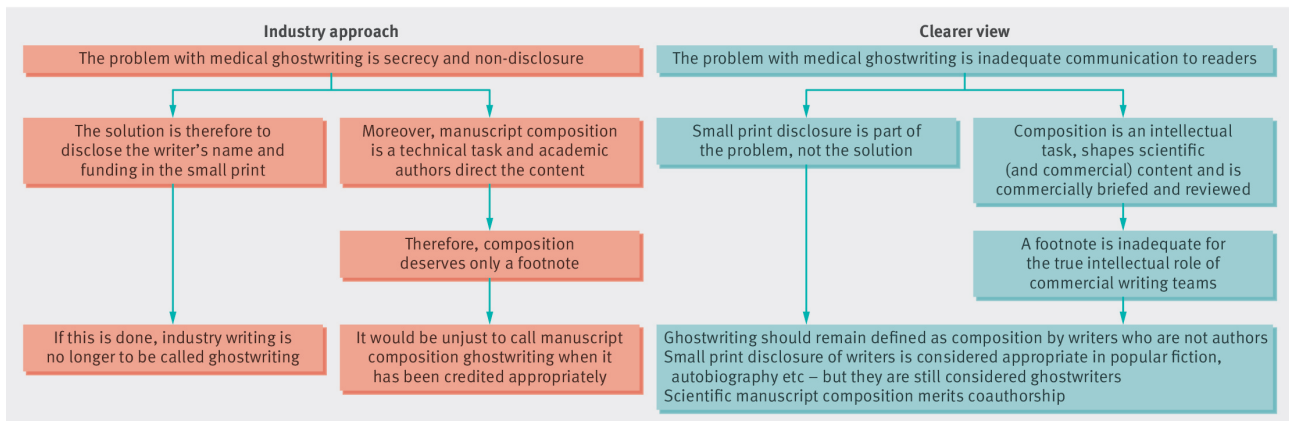


Fig 1 Reasoning pathways for rebranded and traditional non-commercial conceptions of ghostwriting