The Disposable Author:

How Pharmaceutical Marketing Is Embraced within Medicine's Scholarly Literature

by ALASTAIR MATHESON

The creatures outside looked from pig to man, and from man to pig, and from pig to man again; but already it was impossible to say which was which.

-George Orwell, Animal Farm, 1945

s medicine the manipulated victim of the pharmaceutical corporations, or their colleague in Lorruption? The answer, of course, is both. Sometimes medicine is pharma's unwitting dupe, sometimes its eager bedfellow. The best studies have recognized the ambiguous nature of the relationship.1 Yet most scholarship has pursued a simpler, more saleable narrative in which pharma is a scheming villain and medicine its maidenly victim. This framing is exemplified in titles such as The Truth about the Drug Companies: How They Deceive Us and Bad Pharma: How Drug Companies Mislead Doctors.² Much of this scholarship, not least, in these two works, is excellent, but I argue that such crude moral framing blunts understanding of the murky realities of medicine's relationship with pharma and, in consequence, holds back reform. My goal in this article is to put matters right in respect to one

critical area of scholarly interest, the medical journal publication.

Pharma relies on peer advocacy to sell its wares to prescribing doctors. This is an arrangement in which clinicians' qualified colleagues, including "key opinion leaders," are recruited by pharmaceutical corporations and marketing agencies to deliver commercially expedient content to their professional fellows. A more technical definition of peer advocacy is provided at the end of this essay, but precisely how this practice works in the setting of publications is not well understood because ethicists studying the problem have made too much of the narrative of corporate villainy and medical victimhood. Accordingly, criticism of industry publications has been preoccupied with the crudely dishonest practices of ghostwriting, ghost authorship, and "ghost management," vices condemned as "dirty little secrets" perpetrated from "behind the scenes" with the connivance of academic "shills" or "guest authors," in contempt of standards set by the International Committee of Medical Journal Editors (ICMJE).3 This account is appealing, and yet it is wrong or, at the very least, seriously incomplete, with only limited relevance to the actualities of contemporary industry practices. In truth, many commercial publications are not developed in secret but fashioned within a culture of open collaboration, where academic authors make substantial, indepen-

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dent contributions; pharmaceutical companies are showcased rather than hidden; and medicine's editorial standards assist rather than impede the workings of commerce. Ghostly practices are real and important, but publications-based marketing works with a broader canvas, involving a culture of influence and accommodation that naturalizes the presence of commerce within medicine and normalizes the vice of peer endorsement. For want of a rubric, I refer to this here as "mainstream marketing."

Bad Pharma, Good Pharma: My Experience

any scholars have looked at these cultural dimensions of industry's relations with medicine, and Arnold Relman, Richard Horton, Richard Smith, Trudo Lemmens, David Healy, and Carl Elliott have all influenced the ideas I discuss here.4 My own professional experiences have been equally important, though. Following a brief career as a biologist, I worked in pharmaceutical marketing between 1994 and 2010, first in a "medical communications" company and then as a freelance consultant working directly or indirectly for most of the major pharmaceutical corporations and over thirty marketing agencies in North America and Europe. I worked on over one hundred drugs, most of which were, in my estimation, mediocre products that could be better pitched if a more persuasive scientific angle could be found for them. I visited corporate headquarters and congresses; analyzed markets, products, and competitors; groomed key opinion leaders; ghostwrote manuscripts; developed publications plans; and devised marketing strategies.

This experience has afforded me detailed inside understanding of how industry and medicine work together on clinical research and publications. It has also left me with a bivalent attitude toward industry. On the one hand, it remains my belief that pharmaceutical research and development efforts are capable of great good. I think highly of the work on molecular medicines in virology and oncology, for example. Many clinical trials are interesting and informative, and numerous negative trial results representing commercial failures are published every month.5 Critics should be prepared to acknowledge the good, if only to better understand the bad; and indeed, every last "pharmascold" will swallow, inject, or infuse pharma's wares at some point in his or her life.

On the other hand, pharmaceutical marketing is anathema to science, corrupting to medicine, wasteful to economies, and harmful to patients, and I must acknowledge the moral difficulty that for many years I sold my intellect in its service. Pharma itself, of course, has never truly acknowledged its underbelly of secrets, half-truths, corruption, power, and death, and it flaunts the language of ethics like a silk cummerbund over a paunch. If it is a lie to dissemble, distort, or omit, then pharma must be considered a liar whose subtle falsehoods stock the annals of medicine. It is to these annals—the peer-reviewed journals of the academic medical profession—that I now turn.

Advocacy Marketing and the Committed, Disposable Academic

In order to clarify how advocacy-■based marketing works within mainstream medical literature, the first step is to adopt a systematic rather than metaphorical approach and to ask with each article,

- · Who are the stakeholders, and what are their stakes?
- How was this article financed, planned, and placed?
- How was the content determined?
- How is it attributed?

The lead stakeholders are of course pharma companies, but academic authors and institutions have agendas, too, as do journals and publishers.

Industry articles emerge from a process of negotiation that must gratify all parties. I return to this theme below. As for finance and planning, industry often plays a secret and indeed ghostly role in determining the themes, top-line content, authorship, and placement of articles, without the articles' academic authors, let alone readers, knowing about it.6 Overall, however, the balance between secret planning and public negotiation varies. In large clinical trials, for instance, academic institutions are frequently contracted to help organize the research, and doctors and senior academics often head the study and publications committees, helping plan and place articles in this capac-

It is when we come to the third question, concerning content, that the significance of multiple stakeholders becomes critical. Throughout my experience of commercial publications planning, crude ghostwriting was extremely rare. Many industry articles do not rely on ghostwriters, and when they do, one or more academic authors generally amend the text produced by the writing team. The notion that academics are passive "guests" or "shills" is a misunderstanding of their function: their contributions should be both substantive and independent, stamping publications with intellectual distinctiveness and credibility. The art of publications development lies not in coating commercial content with an academic veneer, but in meshing commercial positioning and academic expertise as deeply as possible, creating content that is scientifically compelling but instilled with subtle commercial valence. Nonetheless, a diagnostic feature of this literature is that academic recruits and their institutions are readily replaceable by others without any decisive impact on the published product. Alternative academics and institutions might add varying intellectual content to the work, but its commercial functions will be served just as well. The leading problem with the use of academic authors in today's industry publications is not passivity but *disposability*. Only the corporate project itself is fundamental, and particular academic contributions are exchangeable details.

How, then, are the commercial dimensions of industry literature delivered? They are not prefabricated, as "ghost" metaphors suggest, but woven into text using a variety of interventions. These include in-house planning, as related above; selection of reliable authors and institutions whose contributions can be broadly anticipated; well-documented techniques for manipulating the design and analysis of clinical trials;8 commercial ownership and analysis of data; documentary guidance for manuscript development in the form of article outlines, clinical study reports, or results summaries; review and discussion of emerging content; and the use of company employees as coauthors on most clinical trials.9 On some articles trade writers are used as well. Sometimes these commercial writers draft text, but in other cases they develop outlines, compile bibliographies, add details such as tables, or collate or amend text. Not all such contributions qualify as "ghostwriting," but all of them influence content. These numerous options for subtle steerage and framing are alloyed with the bona fide contributions of academic recruits to yield a product that works commercially but enables academics to feel a sense of intellectual ownership. Some key opinion leaders knowingly accommodate commercial positioning, but most do not feel especially compromised. They stand foursquare behind their work, and the companies smile.

Collective Misattribution

It is with the final question—concerning the attribution of industry-financed literature—that the language of "ghosting" is most misleading. To appreciate why, one must first keep in mind that, correctly understood, attribution involves more than mere authorship. Every feature

of an article that communicates information to readers about its stakeholders, planning, and development should be considered part of its attribution. Furthermore, readers' perceptions are crucial, and articles in which important disclosures are made but the disclosures are in vague language, endnotes, or small print should be considered poorly attributed.

The attribution of commercial journal articles is nuanced. Marketing based on peer advocacy demands that academics are portrayed as the masters; but far from hiding companies, mercantile literature also uses corporate display so that the article promotes not only the drug but also the company—as academic medicine's trustworthy partner. As with content development, these attributional goals are achieved through a bricolage of subtle interventions. Academics are commonly placed at the front of bylines, company employees in the middle, and commercial writers in the small print. An effect functionally analogous to ghostwriting can be achieved when content is heavily influenced by industry coauthors while the conspicuous lead authorship position is assigned to an academic. Content control and academic endorsement can thereby be delivered without any recourse to ghostwriting or guest authorship.

Beyond the author byline, the spin continues. Frequently, readers are simply not told what drug is being promoted, whether the work was instigated by the "sponsor," and whether the data are the company's private property. The company is regularly described as a provider of "support" or "funding," and when accounts of its role are given, these are often sketchy or in small print, while commercial writers are credited with "assistance," leaving their precise contribution obscure. "Contributor" listings, which describe in small print what tasks were carried out by whom, help record accountability,10 but considered as a means of attribution, these lists merely enable the academic-dominated author byline to command readers' attention. Through a patchwork of diminutions, aggrandizements, omissions, euphemisms, fudges, and misnomers, academics are positioned as masters, and proprietors as their worthy aides. The company is placed in the shop window—but nobody is told it owns the shop.

Such devices are widespread in medicine's peer-reviewed journal literature.11 But who is behind them, and whose interests are served? Here we come to the crux. Everyone is behind them, and each party benefits in its own way. Companies get the elixir of endorsement on which advocacy marketing depends; academics reap the rewards of authorial status and generally feel that they deserve top billing; journals sell reprints; and culturally, I believe, academic medicine and its journals crave the sense that the research scene remains in their hands. It is customary for academic "investigators" to be placed at the front of the byline, and indeed, it is understandable that readers who will prescribe the drug want to read the opinions of qualified peers who have used it in their patients. But when the project is not in truth an academic one but wholly or partly commercial, these sentiments open the door to advocacy marketing. The language of corporate "sponsorship" and academic "investigators" and superficial arrangements of trial committees suggest that companies merely provide finance and that independent academic institutions are in true command, while the actual role of commerce in instigation, analysis, framing, writing, and data ownership is politely shepherded into the margins by diverse attributional tricks-and that is how medicine likes it. A former head of publications at Merck has noted that industry articles may be more likely to secure publication in prestigious journals if their authorship is led by academic authors, whereas articles fronted by industry authors have been scorned by readers, who expect academic-led fare.12 Advocacy-based marketing is a disgrace to medicine and its journals, but it has, to use an Orwellian phrase, long been "too normal to be noticed"13—perhaps above all for the simple reason that doctors like to feel in charge.

Finally, although it is beyond the scope of this essay to consider the matter in detail, medicine's editorial guidelines lend support to this culture of misattribution. In previous work I and others showed how the ICMJE authorship formula supports commercial byline avoidance.14 All the forms of spin I have discussed in this section are overlooked, tolerated, or mandated by ICMJE requirements. By complying with ICMJE diktats, industry literature may lay claim to the highest ethical standards. Far from a dirty little secret, drug marketing is ostentatiously robed in the standards of medicine itself.

The VIGOR Study: Still a **Paradigm for Mainstream** Marketing

These practices are illustrated ■ by the publication in the *New* England Journal of Medicine of the Vioxx Gastrointestinal Outcomes Research study (VIGOR), which compared the analgesic rofecoxib (Vioxx) with an older generic drug, naproxen, in patients with rheumatoid arthritis.15 VIGOR was organized and financed and its data owned and analyzed by Merck. In a major clinical and commercial setback, the trial detected an excess of cardiovascular events in the Vioxx group. The company's response was to pursue the hypothesis that the difference between the treatment groups was not caused by a harmful effect of Vioxx but, rather, a hypothetical "protective" effect of naproxen.16 When VIGOR was published, this interpretation was central to the manuscript, which reported that the incidence of cardiovascular events was "lower in the naproxen group," rather than higher with Vioxx, and explicable as a cardioprotective effect. Yet the manuscript was not ghostwritten: the academics contributed

substantively alongside industry colleagues and forthrightly defended the publication when criticized.¹⁷ There is no reason to doubt their sincerity—but the article delivered just the interpretation the company wanted.

How, then, was VIGOR attributed? Notwithstanding the role of the company in financing and organizing the trial, influencing the themes of the paper, owning and analyzing the data, and developing the manuscript, only two of the fourteen authors were company employees, the lead and corresponding author were academic, and the journal declared that the report came "from" a list of institutions, the first and most visible being academic. A footnote stated, "Supported by a grant from Merck." It is not known whether the impression of academic leadership persuaded any readers who might otherwise have thought twice to trust the "cardioprotective" interpretation. What is known is that Merck ordered a vast number of reprints—allegedly over 900,000—the journal's publisher profited handsomely, the reprints were used to market Vioxx to prescribing doctors, and many thousands of patients were killed before Vioxx was withdrawn from sale.¹⁸

VIGOR was published sixteen years ago, but pharmaceutical marketing is still based on this form of subtle peer advocacy, in which commercially functional content is presented under the leadership of honest academics. The ICMJE has introduced piecemeal reforms over the years, several of which have been beneficial, but the basic calculus of advocacy has remained intact. Companies still instigate the work, own the data, provide low-profile coauthors and editorial teams, and obtain the framing they want. Academics still dominate author bylines and front the research. Journals still state frequently that articles come "from" academic institutions and omit to tell readers who instigated the work, who owns the data, and what is being marketed. There is little to stop a publication like VIGOR from happening again.

"Ghost" Metaphors

host" metaphors have shamed Isome egregious marketing practices and been the basis of some important scholarship.¹⁹ Unfortunately, the critical weakness of the word "ghost" is that it steers attention to industry's role, and industry secrecy, and away from the multistakeholder responsibilities for mercantile literature and its misattribution. Ghostly practices are merely part of the overall activities and continuous with the subtler and less secretive ones I have described. By focusing on them, publication ethics has missed the bigger picture. Worse still, it has become bogged down in problems of definition and, in consequence, has been outflanked by commerce. For example, the standard definition of "ghostwriting" is manuscript composition by a writer who is not a named author.20 By this definition, ghostwriting is widespread in industry publications, but marketers and journal editors have successfully promulgated an alternative in which articles are not considered ghostwritten if the writer's name and funding is mentioned—some would say buried—in the small print.²¹ On this basis, industry may claim ghostwriting is not part of its modus operandi, and it is unfortunate that even some ethicists have been drawn into using this loaded formula.22

How, then, should these metaphors be used? In my view, the everyday definition of ghostwriting should be strictly adhered to and the industry-friendly rebranding firmly rejected. As for the term "ghost authorship," the standard meaning -namely, any contribution deserving author status that is not credited on the byline—remains valid, but the question of which contributions deserve authorship is difficult. The ICMJE authorship criteria are flawed, and studies of ghost authorship predicated upon them are correspondingly limited.²³ Future empirical studies should use a range of distinct metrics, and published literature should

always discuss the problems of definition. Similar considerations apply to guest authorship-although, as I have discussed, this is not the chief problem surrounding the role of academics in commercial literature. Most academics probably deserve to be authors, and bylines are manipulated by excluding others who should be coauthors, such as commercial writers, or by massaging author order. The greater problems with pharma's academic authors are that they are replaceable and recruited for their names' sales value. Alternative terms such as "advocate," "selling," or, as I have used here, "disposable" author would better articulate these issues.

Finally, "ghost management" is a useful metaphor for criticizing the secretive aspects of commercial planning and development.24 The value of "ghost management" is polemical, not analytical, and as such, it might be useful beyond publication ethics. One might suggest, for instance, that the United States Grand Jury system is "ghost managed" by prosecutors. But "ghost management" does not provide a conceptual basis for understanding all publications-based marketing. It is preferable to describe industry literature as "commercially managed publications" or simply "commercial publications." These terms apply to all industry output rather than a secretive subset, cannot be negated by disclosure, expose the mercantile function of academic authors, and correctly imply that the fundamental issue with commercial publications is, quite simply, commerce—irrespective of the degree of secrecy involved.

Integration, Not Subterfuge, as the Danger

The overenthusiastic promotion of ghost metaphors serves the popular narrative in which the primary threat posed by pharma to medicine is one of deception and external manipulation. This threat is indeed important, but it is not the foremost danger. The greatest

threat is blending and assimilation, such that the distinction between the commercial and academic is by slow gradations ceasing to be apparent or even important within medical culture. This transformation in the quality of medical science and discourse is not being driven by deception or trickery so much as cultural and institutional proximity of commerce and academia, involving philanthropy, patronage, and most importantly, the increasingly routine nature of industry-academic research partnership. The medical journal article should be a point of resistance and distinction between commerce and academia, but it operates instead as one of merger and ratification, its meticulous guidelines working not to differentiate but to bring the worlds of medicine and commerce more minutely together. As the distinction between the commercial and academic diminishes, marketing has progressively less need for ghostly subterfuge in communicating its propositions; the commercial-academic landscape is continuous. Contemporary industry literature positions academics, corporations, journals, and readers side by side in the pursuit of truth: public, civilized, rational, and humane, it leads today's assimilated medicine naturally to the point of sale.

Let me then define contemporary advocacy-based marketing punctiliously, as a practice in which content with potential commercial or promotional utility is planned, convened, funded, influenced or owned by a company, but communicated by, or disproportionately attributed to, the peers or opinion leaders of the intended customers. Advocacy marketing thus defined is routine in medicine and its scholarly literature, and the chief policy conclusion of this essay is that it should be banned outright. This is a matter for academic medical institutions and societies as well as journals, and the first step to achieving it is to understand the nature of attribution. This concept has never been adequately understood by medicine's editors and is not even discussed in the ICMJE guidelines. Medicine's construction of authorship has long envisaged a "two-sided coin" of credit and responsibility,25 and in thus focusing on the author has not adequately addressed the needs of the reader; but in any case, as I have shown here, attribution runs far wider than authorship and turns on what readers perceive as much as what is disclosed. If a project is instigated and funded by a company and its data are privately owned, then it is a commercial project, and by means both of authorship and other attributive devices, it should be presented clearly to readers as commercial, not the ambiguous, supposedly academic-led fare that is a staple of medicine's intellectual diet.

To ensure that readers perceive mercantile content for what it is, it would ideally be published separately from noncommercial research. Publishers could, for instance, restrict industry-funded content to new publications such as a "JAMA Commercial Medicine" or quarantine it in clearly labeled "Commercial Pages" within existing journals. Failing this, there should at least be conspicuous commercial attribution. Mercantile science should be welcomed with scholarly courtesy and respected on its merits but presented as commercial from the outset. Companies could, for instance, be identified in the titles of articles they finance ("A Pfizer Trial," for example) or listed as corporate coauthors. Abstracts should clearly state commercial finance, instigation, planning and data ownership, and identify the product the article promotes. Ideally, such measures would be introduced in a cross-media standard.26 If every commercial article, web page, and lecture was introduced to its audience with stark labeling, this would encourage readers to think twice, expose the advocacy function of the academic authors, limit the unmarked seepage of marketing into medicine, and counter the creeping cultural merger of science and commerce. Differentiation can reverse integration.

In an ethics framed by the narrative of medicine's victimhood and the allure of ghostly explanations, medicine's journals have escaped adequate scrutiny, and the advocacy-based marketing they host has been insulated from reform. It is for journals to put these matters right and for ethicists to encourage them in the task. It is time to think more about the everyday mainstream of commercial publications, and less about ghosts. In words I came upon years ago, in my biologist's past, "as the road to hell is paved with good intentions, so the road to confusion is paved with good metaphors."27

Notes

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- 9. J. Hoekman et al., "The Geographical Distribution of Leadership in Globalized Clinical Trials," *PLoS One* 7 (2012): e45984.
- 10. D. Rennie, "Integrity in Scientific Publishing," Health Services Research 45 (2010): 885-96.
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