

## Scientific Publications

Twelve years and \$1.3 billion: the typical cost to bring a new drug to market.<sup>1</sup> This staggering sum, according to a representative of Indianapolis-based pharmaceutical company Eli Lilly, could pay for two professional football stadiums, 12.4 million National Football League (NFL) tickets, or 371 Super Bowl Ads. It could buy 11,000 houses in Indianapolis, the host for Super Bowl XLVI, or pay the salaries of 99.53 percent of NFL players.<sup>2</sup> The comparisons are endless, but the point is that new drugs are both expensive and time-consuming to develop.<sup>3</sup>

For Wyeth Pharmaceuticals, 1996 was a big year. Fen-Phen, the company's newly approved diet drug combination, was wildly popular, earning \$305 million in its first year of availability. At that rate, the company would break even in a few short years.<sup>4</sup>

Then the worst happened, at least for the company's bottom line. Half of the drug combo was abruptly pulled from the market in September 1997, and lawsuits began to mount alleging that Fen-Phen was killing people. To make matters worse, there was speculation that the company knew about the drug's risks in advance, but had largely ignored them. Instead, it had launched a publication and education campaign attacking obesity and promoting Fen-Phen as the solution.

In order to manage the extensive campaign, Wyeth hired Excerpta Medica, a medical communications company, to write ten articles for publication in medical journals, all of which were published by media giant and the owner of Excerpta Medica, Reed Elsevier. The articles would minimize the risks of Fen-Phen and emphasize the need to treat obesity, and

would be bylined not by the company's medical writers, but by respected physicians and academic researchers. Wyeth hoped to use academic credibility to persuade patients and physicians that Fen-Phen was the answer to an ever-growing obesity epidemic.

In the end, however, Wyeth's marketing plan backfired and the drug was withdrawn. Over the years, 70,000 lawsuits were filed, costing the company billions of dollars in legal expenses. Despite the financial and reputational costs, Wyeth is still a player in the pharmaceutical industry, as a wholly owned subsidiary of Pfizer.<sup>5</sup> And industry-sponsored ghostwriting is still widely accepted—or at least widely practiced—in the medical and pharmaceutical fields. The practice continues to thrive in spite of near-constant criticism and serious concerns about its ethics.

### MEDICAL GHOSTWRITING: A FEW DEFINITIONS

Before going further, it will be helpful to quickly define some concepts used widely in the literature. In the discussion that follows, we will use the terms “medical ghostwriting” and “scientific ghostwriting” interchangeably, referring primarily to the third-party production of scientific journal articles on behalf of pharmaceutical companies, with respected medical experts typically serving as named authors. An “honorary author,” “guest author,” or “gift author” is the named author of a publication, especially one who is paid for his or her contributions and who in actuality contributed little or nothing to the project. Finally, “medical communications company” and “medical writer” are industry terms that refer to the third-party entities that provide many of the ghostwriting services used by pharmaceutical companies.

With these terms in mind, we might define medical ghostwriting in this way:

Medical ghostwriting is a practice where pharmaceutical or medical device manufacturers hire medical education, marketing or communications firms to draft articles that are presented to prominent physicians and scientists to sign on as authors. Ghostwritten articles also include those drafted by pharmaceutical or device company employees who are not acknowledged in the final publication. The articles may be review articles, editorials or primary research papers. The named authors may not be intimately familiar with the underlying data or relevant research, and their input may be very limited. Authors who make little to no contribution to a publication are also referred to at times as “guest” authors.<sup>6</sup>

With these working definitions in place, we can now proceed to a more nuanced analysis of the pitfalls and advantages inherent in medical ghostwriting as a practice.

### ACADEMIC DISHONESTY, SOUND BUSINESS STRATEGY, OR BOTH?

Is the practice of medical ghostwriting academic fraud, or is it merely an accepted and effective business practice? In the case described above, Wyeth's use of ghostwriters seemed both dishonest and fiscally irresponsible. The company made a poor business decision, and the honorary authors practiced irresponsible scholarship.

But does this question present a false dichotomy and encourage an emotional response? As consumers, we want to believe the medical information we receive is unbiased and accurate. Hearing Wyeth's story, we might assume the company's only intent was to deceive. We might imagine the named authors were lazy or trying to get ahead through fraudulent means. Because of the grave consequences of medical misinformation, we choose to believe the worst simply because it protects us.

To be sure, medical ghostwriting has the potential to result in harm to patients, and scholars credited with the work may obtain unfair advantages over their peers,<sup>7</sup> especially if it is not clear that the authorship is "honorary."<sup>8</sup> Significantly, the practice exists in the dark, in large part due to the euphemistic vocabulary surrounding it.<sup>9</sup> From this perspective, then, scientific ghostwriting meets the same informal definition for academic dishonesty that we developed in the previous chapter. Because establishing credible expertise is the reason for the use of honorary authors for scientific publications, this would suggest that any physician or researcher who is the honorary author of a scientific publication he or she did not write is in jeopardy of committing academic fraud.

This may be an oversimplification nonetheless. In our examples in the previous chapter, the clients initiated the projects and outsourced the work. In the world of medical ghostwriting, however, pharmaceutical companies initiate projects, outsource the work, and select the named authors, often after the fact. In other words, the author's decision to become involved is more passive and is made in a context where the use of ghostwriting is encouraged. This is a significant concept that we will explore in more depth later.

A pharmaceutical company, of course, cannot be party to academic fraud *in the same way* as a member of a university faculty. The organization's role in initiating ghostwritten work is not committed as an act of academic dishonesty, even if it does entail an intent to deceive. It may be considered a violation of honest, straightforward marketing standards, but as we discussed in Chap. 4, there are situations in business where the use of ghostwriting is acceptable and readily acknowledged. Is this the pharmaceutical industry's version of such business practices? This is the second significant issue that we will consider in this chapter.

Let's not decide, then, if ghostwriting is either academic misconduct or sound business strategy until we have explored these critical concepts in more depth, beginning with the question of scientific authorship.

### DEFINING SCIENTIFIC AUTHORSHIP

Think back to the last time you searched for a new physician. You might have asked your friends for recommendations or researched physicians online before making your pick, hoping to find a competent and caring doctor who was up to date in his or her area of practice. You might have used websites that provide consumer ratings and reviews of doctors and medical facilities. In fact, the ranking of physicians is big business, and not just for consumers. Pharmaceutical companies, hospitals, and other firms associated with the medical industry rely on such information,<sup>10</sup> as well as more sophisticated data, to determine which physicians are the best.

A key metric in rankings is the number of publications that any given physician has authored or co-authored.<sup>11</sup> As with other fields, physicians and medical researchers gain prestige through published works demonstrating their expertise and leadership. Thus, physicians who publish extensively may be considered better and more knowledgeable doctors, and more desirable to both patients and corporations.

To test this argument, we examined sample groups of high-achieving doctors within two specialties: oncology and endocrinology. So as not to imply that anyone is involved in scientific misconduct, the origin and makeup of these samples are confidential. Suffice it to say that the samples include top-rated researchers and innovators in their respective fields, and could easily be replicated in any field, and with any group of highly ranked physicians.<sup>12</sup>

In both samples, we examined the level of physician publication between January 2002 and mid-2014, including publications in which one of the physicians was listed as either an author or a co-author. The first sample

group, comprising 10 oncologists, published 973 articles over the roughly 12½-year period—an average of 77.8 per year, or 97.3 per doctor over the period reviewed. This sample exhibited a wide range, with a difference of 201 total articles between the lowest- and highest-performing physicians. Regardless, the least prolific author still published at least one article in most years, while the most prolific published, on average, 17.5 articles each year.<sup>13</sup>

Meanwhile, the sample of endocrinologists included 11 physicians, with a total of 711 publications. It is noteworthy that one physician in this group published nothing over the 12½-year period. Even so, this represents a massive body of work over a relatively short period of time. How are physicians and researchers capable of producing this amount of scholarship? And should this lead us to assume that most—or even all—of these scientific publications are ghostwritten?

The answer lies, in part, in the scientific understanding of the concept of authorship, a concept we touched on earlier. When asked to define authorship, most would likely identify the author as the individual who actually wrote the work in question.<sup>14</sup> In contrast, someone may be named an author of a scientific paper without writing a single word of it. What matters in that case is whether the named author made “a substantial intellectual contribution” to the research project at hand.<sup>15</sup> Thus, academics may collaboratively “author” many more publications than they could individually, even without the services of a third-party ghostwriter.

Using this understanding, a physician or researcher may serve freely as the named author of ghostwritten work, assuming she has no concerns regarding sponsorship, reviews and supports the research, and provides unique insights to the paper before publication. These criteria are critical, yet the honorary, or guest, author is often one with little to no significant involvement in the production or authorship of the publication. By ordinary academic standards, scientific authorship requires meaningful knowledge and involvement, but honorary authorship fails this basic test and may thus be viewed as academic fraud.<sup>16</sup>

Perhaps an even more interesting feature of honorary authorship relates to a perplexing and troubling trend in the literature, namely the convention of distinguishing between ghostwriting and honorary authorship and uncoupling honorary authors almost entirely from the broader practice of ghost authorship.<sup>17</sup> This is perhaps unsurprising, as the phrase connotes nothing dishonorable, and may serve to absolve the named authors from blame. Indeed, the three descriptors we have used—guest, gift, and honorary author—all appear to carry overtly positive connotations.

Before we go further, then, it will be helpful to consider the practice of honorary authorship through the lens of our working definition of ghostwriting, reproduced here with a few minor, italicized changes. In this context, ghostwriting is the writing of material by one person (the writer) *for use by other parties, including an honorary author* who will be credited with its authorship, and where *all* parties agree that the writer's role in producing this material will be invisible to readers or hearers of the words. By this definition, the honorary author is no different than any other named author, making her participation a form of ghostwriting. And in practice, the main difference lies in the fact that the ghost may not be entirely invisible, but will have more of an authorship role than he or she will receive credit for.<sup>18</sup>

In recent years, several surveys have identified large numbers of ghostwritten articles in reputable scientific journals. The distinction between honorary and ghost authorship, though, renders the data nearly meaningless. For instance, in one study of 809 articles, 19 percent were found to have honorary or guest authors, while only 11 percent had ghost authors and 2 percent had both. Similarly, a study of 104 articles found 25 percent with honorary authors and 16 percent involving ghosts.<sup>19</sup> In yet another study, 14.3 percent were found to have honorary authors while only 0.9 percent had ghosts.<sup>20</sup>

But if articles with honorary authors are assumed to be ghostwritten, how can we reconcile these findings? It seems reasonable to say that if 25 percent had honorary authors, then 25 percent listed an author who was credited with the work of someone else. In these studies, however, a ghost is consistently defined as one who “was not listed as an author [but who] made contributions that merited authorship,” or “an unnamed individual [who] participated in writing the article.”<sup>21</sup> Even so, one may argue that even someone who is named as an author or co-author may be thought of as a ghostwriter, if the full extent of his contributions cannot be acknowledged due to the presence of one or more honorary authors.

This results in a substantial amount of at least partially ghostwritten work: for instance, in calendar year 2013, PubMed.gov records 163,730 publications on cancer. Applying the percentages provided earlier, this results in between 1474 and 26,197 publications with ghost authors, and between 23,413 and 40,933 with honorary authors—or according to our definition, up to 40,933 publications with at least the partial involvement of a ghost. Similar calculations reveal that, in 2001, the year before its approval by the Food and Drug Administration (FDA), up to 4415 of

the articles on 2013's top-grossing drug Abilify (a medication to treat schizophrenia) might also have involved a ghostwriter.<sup>22</sup> These are only two examples, but telling ones, and given the potential scope and impact of this practice, it is worth asking whether there should be more transparency about who was actually involved in the creation of these articles, and to what extent.

To provide clarity and, perhaps, move the industry away from such a broad definition of authorship, the International Committee of Medical Journal Editors (ICMJE) has developed a number of helpful, albeit voluntary, guidelines, which require that a named author must engage with all parts of the process, and be responsible for:

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

Drafting the work or revising it critically for important intellectual content; AND

Final approval of the version to be published; AND

Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.<sup>23</sup>

This is only one of many industry statements on authorship, some of which directly forbid ghost authorship (“[The European Medical Writers Association (EMWA)] is an association for professional medical writers, and deplores ghostwriting . . . A medical writer . . . **must** be listed in an acknowledgements section to avoid ghostwriting”<sup>24</sup>), while others dance around the issue (“Biomedical communicators who contribute substantially to the writing or editing of a manuscript **should** be acknowledged with their permission and with disclosure”<sup>25</sup>), emphasis added in both. Any of these statements, especially in partnership with recent government regulations,<sup>26</sup> can be seen as fostering transparency and redefining authorship in medical publications.

This is true only to a point, however, for in practice the use of ghostwriters remains what might best be called an open secret. Phrases like “technical expert” and “author’s editor” are used in lieu of medical writer or ghostwriter.<sup>27</sup> To anyone familiar with the industry, this may be understood. But to someone less in the know, these terms can deceive.

Of course, while patient harm is not the intention of physicians and researchers who participate in this system of ghostwritten publications, assignment of authorship is critical to scientific researchers. And claims of

authorship are “important to disputes and allegations of research misconduct, . . . [access to] [f]unding, . . . [as] evidence of creative contributions that warrant promotion, . . . as a mechanism to attract both new trainees and willing collaborators, . . . [and] in an era of increasing emphasis on commercialization, authorship and credit help to define intellectual property rights.”<sup>28</sup>

Authorship as “evidence of creative contributions that warrant promotion” is perhaps the most critical to an understanding of the practice of ghostwriting, as many academics live by the mantra publish or perish. Junior researchers whose full contributions are minimized to make room for honorary authors may actually benefit from publications where the appearance of collaboration with recognized experts can boost their profile.<sup>29</sup> The factors supporting this system of perverse incentives are numerous, and include both the means by which tenure is assigned and the corporatization of the academy:

[The increase in multi-author publications] is due in part to the modern focus on conducting multidisciplinary research projects . . . the move to an industry-like, team-based approach within an academic research group, and the counting of publications for promotion and tenure review. These changes have led to “deceptive authorship. . . .” The standards for determining legitimate authorship have also been diluted.<sup>30</sup>

Thus, while intent to deceive may not be a motivating factor, it is surely an influence, although perhaps a subtle one. The consequences for some scientists and researchers have included accusations of lending their names to projects without vetting them thoroughly or engaging fully in the work;<sup>31</sup> this is a hazard of the practice.

To be sure, many researchers fully accept the responsibilities of named authorship, and reject opportunities that simply don’t feel right.<sup>32</sup> After all, “[a]uthorship of a scientific paper is a privilege that is all too easily abused. Attempts to solve the problem with general rules encounter insurmountable obstacles, but individual accountability is unavoidable.”<sup>33</sup>

The difference in how one makes this decision may be a matter of professional authenticity. A physician who lends his name to a publication but fails to engage with the project in any meaningful way may be less than authentic as an actor within a profession. But intent is difficult to determine, and academics are far from the only players whose actions and intentions bear on our discussion of scientific ghostwriting.



## BUILDING TRUST AND TRANSPARENCY

As of December 2013, Gallup's ongoing study of honesty and ethics in the professions revealed that 69 percent of the American public rated the ethical standards of medical doctors as high or very high; only 3 percent felt that physicians had low or very low ethical standards. By contrast, just 22 percent had confidence in the honesty of business executives.<sup>34</sup> In a similar study, the Edelman Trust Barometer, 67 percent of respondents said they consider information presented to them by an academic or expert to be very credible, while only 43 percent would place confidence in the same message delivered by a CEO.<sup>35</sup> We might conclude, then, that the public is more likely to blame executives at pharmaceutical companies for critical medical errors than physicians.<sup>36</sup>

This research confirms the obvious: for a health-related enterprise, credibility is of utmost importance. Pharmaceutical companies know this, and see physician support of their products as essential for public acceptance. Thus, ghostwritten, industry-sponsored articles are a strategy to promote the scientific legitimacy of their products and "explain how awesome [insert drug name here] is and why people should buy it."<sup>37</sup>

But as with Wyeth, these strategies can backfire. Other examples include the Parke-Davis anti-seizure drug Neurontin, where ghostwritten articles touted unproven, off-label uses of the drug; Vioxx, where Merck's ghostwritten articles omitted troubling data on related cardiovascular fatalities; Prempro, where Wyeth was accused of using ghostwritten articles to sell hormone replacement therapy to millions who simply didn't need it; and Zolof, where Pfizer's medical communications company downplayed negative side effects in 55 ghostwritten journal articles. The reputation of each of these companies suffered and legal remedies were pursued by plaintiffs.<sup>38</sup>

Yet medical ghostwriting persists as a marketing strategy.<sup>39</sup> It is even considered by some as "the greatest marketing triumph of the pharmaceutical industry."<sup>40</sup> When such messages are backed by sound research, presented accurately, they may be helpful in making prescribers and patients aware of products. Unfortunately, this is not always the case.<sup>41</sup>

The debate over medical ghostwriting is part of a larger debate over the appropriate means of marketing for pharmaceuticals. Other forms of pharmaceutical marketing—such as print and television ads—are widely accepted by patients, even if unpopular among physicians.<sup>42</sup> Ghostwritten, industry-sponsored journal articles, on the other hand, are a source of

much contention, with some professionals arguing that they masquerade as “seemingly respectable academic review articles, original research articles, and even reports of clinical trials.”<sup>43</sup> Others note that competent medical writers, as part of the marketing team, participate in a collaborative system of authorship that offers balance and enhance such articles by providing valuable technical expertise.<sup>44</sup> This is, to an extent, true. Pharmaceutical companies have resources and perspectives that others lack, and medical writers may possess academic and technical qualifications equivalent to those held by physicians and academic researchers.<sup>45</sup> It’s also important to stress that ghostwriting cannot be the scapegoat for all questionable medical writing, as academics, entirely free from the influence of pharmaceutical companies, may at times conduct shoddy research or cause direct harm to patients.

To resolve these conflicting points of view, some advocate the use of paid medical writers, credited with authorship, as an alternative to ghostwriters.<sup>46</sup> This would at least enhance transparency and encourage other named authors to engage more with the process, strengthening collaboration. This may be an idealistic position, though, as incentives abound to maintain the status quo. Medical communications companies profit handsomely from work quietly conducted on behalf of pharmaceutical companies, while academics and researchers profit both from corporate research funding and the prestige of honorary authorship.

While the burden of incentives is shared, it is nonetheless possible that—given our construct of medical writing as marketing—most of the responsibility for the status quo should lie there. Marketing, after all, is built to persuade. Companies rely on the cachet of physician expertise to persuade the public that their drug is the best. An open admission that the experts have little true involvement would be—and indeed, has been, as we saw in our earlier examples—seriously damaging to the bottom line. Pharmaceutical companies necessarily absorb most of this damage, but there are plenty of incentives to go around. This creates a web of relationships criticized—with good reason—for being less than transparent.<sup>47</sup>

To combat these conflicts and promote transparency, an earnest, cross-sector effort is underway. Leading academic institutions<sup>48</sup> and pharmaceutical companies<sup>49</sup> alike have robust conflict of interest guidelines, some specifically addressing the practice of ghostwriting, and government has also begun to play a larger role. Significantly, regulation has been enhanced by the Sunshine Act, a recently enacted provision of the Affordable Care Act (ACA), which is administered by the Centers for Medicare & Medicaid Services (CMS) and primarily serves to curate information on financial

relationships between physicians and the pharmaceutical industry. It does not specifically categorize payments to honorary authors as such, but does capture such transactions in a broader category, “compensation for services other than consulting.”<sup>50</sup>

In addition to the Sunshine Act, Congress has taken significant interest in the practice. Between 2008 and 2010, as a response to earlier Congressional investigations into grant funding for continuing medical education, Iowa Senator Chuck Grassley investigated medical ghostwriting. This investigation culminated in a report that encouraged greater transparency in research conducted under the auspices of the National Institutes of Health (NIH). Much of Grassley’s work was concerned with payments to physicians and researchers by pharmaceutical companies for journal articles (in this sense, a precursor to the Sunshine Act). However, his report—a product of direct research into the practices of pharmaceutical companies, medical communication companies, medical schools, and medical journals—is primarily useful in succinctly summing up the issues that we have discussed to this point:

Despite acknowledgement of medical writers for “editorial assistance,” the role of pharmaceutical companies in medical publication remains veiled or undisclosed, . . . Detection of ghostwriting by medical schools is limited, . . . Strengthening journal authorship policies appears to have limited effect on ghostwriting and disclosure of industry financing of medical articles, . . . National Institutes of Health does not have explicit policies on disclosure of industry financing of ghostwritten articles.<sup>51</sup>

The efforts outlined here may help reduce conflicts of interest, and may clarify the roles of most of the parties involved. As so clearly stated in Senator Grassley’s findings, however, true transparency cannot be legislated, nor can organizational policy completely reveal the intent behind the use of ghostwritten articles as marketing tools. Nonetheless, these efforts are essential as we balance the need for industry–academy collaboration in the development and promotion of new drugs with the vital need for credible and reliable information.

### FRAUD, OR GOOD BUSINESS?

We began this chapter with a twofold question: Is the practice of medical ghostwriting academic fraud, or is it just good business? As we have seen, these are difficult questions to answer. As it is currently conceptualized, the structure of scientific authorship does nothing to discourage

ghostwriting, and may in fact encourage it; thus, to call medical ghostwriting academic fraud would be inaccurate in most cases. Enough has been said on this subject to make it clear that, for this to change, authorship must be redefined.

And while medical ghostwriting is risky for businesses, the benefits are great—perhaps even outweighing the risks. From that standpoint, then, it is good for business. But we also asked whether medical ghostwriting should be a widely accepted business practice, as it is in other industries. It is one thing to employ a ghostwriter on a corporate blog, or social media account, or even as the voice of the CEO, when the topic is the quarterly earnings report or the philanthropic activities of the company. The ramifications are, perhaps, entirely different in the medical enterprise. Medical journal articles are designed to convey highly credible information about vital medications and devices that have life-altering consequences.

Again, a critique of the practice cannot single out any of the parties involved in medical ghostwriting, as the practice could not exist without the engagement of all. And in partnership with academic researchers, physicians, and pharmaceutical companies, medical writers fulfill a critical need. This shared expertise can be used to create much more reliable, accurate, and useful analyses.

Regardless of what any of us may personally feel about the practice of medical ghostwriting, however, it is unlikely to disappear—at least not without a number of truly radical changes, such as the legal and industry modifications discussed throughout this chapter. Whether or not it is an advisable, or safe, business strategy, it is undeniably ingrained very deeply in the habits of both the corporate world and the academy.<sup>52</sup>

## IN BRIEF: APPLYING THE ETHICAL FRAMEWORK

### *Is it ghostwriting?*

At its heart, medical ghostwriting meets our standard definition of the practice, involving the writing of material by one person (the writer) for use by another (the client) who will be credited with its authorship, and where both parties agree that the writer's role will be invisible to readers or hearers of the words. However, as discussed, not all agree that it is necessarily an illicit—or even completely hidden—practice. What is your opinion? Is medical ghostwriting *actually* ghostwriting? Ultimately, is it helpful? Harmful? Or simply context- or practice-dependent?

*Why was a ghostwriter involved? What alternatives were available?*

Some medical ghostwriters are hired to provide technical expertise, and others for their writing skills. Some—specifically, honorary authors—are hired because a company wishes to add prestige to their product. Others are hired to craft a specific marketing message. The alternative to the use of ghosts would be public acknowledgment of all authors and contributors, not necessarily elimination of the practice altogether—but simply an increase in transparency. Complicating this, however, is the fact that some industry partners—and even academics—will simply view medical writers as a part of the public relations team. In this terrain, how can alternatives like greater transparency be enforced? Or is (are) there (a) better alternative(s), similar to practices in other parts of the corporate world?

*Whose interests are at stake in the project?*

The interests at stake in scientific ghostwriting are nearly limitless, given the wide-ranging and nearly incomprehensible impact of medical and scientific research. Obviously, the interests of beneficiaries are paramount and demand transparent and reliable research. However, entities—both education- and research-oriented institutions and for-profit corporations—have a stake in the dissemination of their research through publications, as this allows companies to promote their medical interventions and other products, recouping R&D funds and allowing them to conduct future research. This, of course, drives the use of honorary authors to increase the prestige of publications and products. Who else might have interests at stake? And whose interests are the most important? Why?

Do the benefits of medical ghostwriting or honorary authorship—all in the ultimate interest of the beneficiaries of scientific research—outweigh the risk that entities will, in some cases, commit deliberate fraud? Put another way, how do we balance the legitimate interests of those who practice ghostwriting with good intentions against those with bad?

*What consequences may result from a decision to use a ghostwriter?*

Quite simply, there are three consequences that may result from the use of a medical or scientific ghostwriter: (1) the research product will be strengthened; (2) the research product will remain unchanged; or (3) the integrity of the research project will be compromised. Similarly, the use of an honorary author will either increase the prestige and impact of the research product, or have no positive effect. For each outcome, are the consequences long-term or short-term? On which stakeholder(s) would each outcome have the greatest impact?

*What principles or duties are at stake?*

For academics who engage or participate in medical ghostwriting, the principle of academic integrity remains paramount. For corporations, both the company's bottom line and reputation are at stake, necessitating attention to basic principles of business ethics and social responsibility. Medical professionals are bound to do no harm, and the law provides standards of openness and responsibility that all must adhere to. In short, all participants in the practice of scientific ghostwriting have a duty to perform good work in the interests of their stakeholders. Are any of these principles or duties more compelling than others? Which one(s)? Why or why not?

*How might the ghostwritten work affect the personal authenticity of the client?*

Academic or medical researchers are experts in their field, raising the same concerns about faculty—more broadly—in the previous chapter. Honorary authors are at the most risk of conflating their false identity as prolific author with reality, but all faculty who participate in projects that utilize ghostwriters may find their personal authenticity as scholars and researchers compromised. But what of the corporation as client? Is it capable of having “personal” authenticity? Can that authenticity, or identity, be compromised?

To explore these ethical constructs further, consider the following:

1. The position of first author on a publication is very desirable in the academic community, as it indicates a substantial contribution and is often the only name utilized, especially for publications with more than three authors.<sup>53</sup> Is it right or wrong, then, for a physician or researcher to accept first authorship on a paper without physically writing at least a portion of it? Explain your rationale.
2. Ghostwriting would be unlikely to exist in the scientific community (or for that matter, any area or discipline) without an incentive. It seems that, in this case, physicians and researchers are incentivized to publish extensively in order to build up their reputations and gain the professional and academic support they need. What other incentives do you believe contribute to the use of ghostwriters in scientific publishing?
3. As we discussed, scientific publishing houses have taken significant responsibility for putting a stop to ghostwriting in their journals, but have not been able to (and likely cannot) completely eradicate the practice, due in large part to the compelling incentives discussed

in the previous question. What other individuals (e.g., physicians) or entities (e.g., tenure review boards at research universities) might be able to minimize the practice?

## NOTES

1. Current estimates vary, ranging from \$1.3 to \$5 billion. See (1) Amy O'Connor, "Football—By the Numbers," *LillyPad*, last modified February 3, 2012, <https://lillypad.lilly.com/entry.php?e=1424>. (2) Matthew Herper, "The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change," *Forbes*, last modified August 11, 2013, <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#34471f746bfc>.
2. O'Connor, "Football—By the Numbers."
3. (1) Herper, "The Cost of Creating a New Drug Now \$5 Billion." (2) Roger Collier, "Drug Development Costs Hard to Swallow," *Canadian Medical Association Journal* 180, no. 3 (2009): 279–280. (3) Matthew Herper, "The Truly Staggering Cost of Inventing New Drugs," *Forbes*, last modified February 10, 2012, <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/#7429ed1f4477>.
4. Collier, "Drug Development Costs Hard to Swallow."
5. Company information accessed online at [www.pfizer.com](http://www.pfizer.com).
6. United States Senate Committee on Finance, Minority Staff Report, "Ghostwriting in Medical Literature", last modified June 24, 2010, <http://www.grassley.senate.gov/sites/default/files/about/upload/Senator-Grassley-Report.pdf>.
7. Another lens through which to view this is through the concept of the Matthew Effect. Proposed in the late 1960s by Robert Merton, the theory "consists in the accruing of greater increments of recognition for particular scientific contributions to scientists of considerable repute and the withholding of such recognition from scientists who have not yet made their mark." In the case of scientific ghostwriting, the "particular scientific contributions" may consist solely of the scientist or researcher accepting a position as guest author, but the end result is the same. See Robert K. Merton, "The Matthew Effect in Science," *Science* 159, no. 3810 (1968): 56–63.
8. Leemon McHenry, "Of Sophists and Spin-Doctors: Industry-Sponsored Ghostwriting and the Crisis of Academic Medicine," *Mens Sana Monographs* 8, no. 1 (2010): 129–145.
9. Medical Writer, interview by Azalea M. Hulbert, May 22, 2014.
10. Phil Galewitz, "Hospitals Get into Doctor Rating Business," *Kaiser Health News*, last modified April 17, 2014, <http://khn.org/news/hospitals-get-into-doctor-rating-business/>.

11. “Key Opinion Leader Management: Identify, Profile, Engage and Monitor the Right Set of Influencers for Measurable Business Impact,” *Genpact*, accessed February 13, 2016, <http://beta12.genpact.com/docs/resource-/key-opinion-leader-management.pdf>.
12. Publication histories of the selected samples of physicians were obtained online at PubMed.gov.
13. It’s also important to note that, in this sample, we only examined specialty-specific publications. If a physician specialized in genitourinary cancers, we only examined his contributions in that field. Many of the physicians in this sample, though, also published widely in other areas of special interest or expertise.
14. Definition accessed online at [www.merriam-webster.com](http://www.merriam-webster.com).
15. There are also pertinent culture considerations. For one, scientists do not necessarily enter the academy to write, in contrast to many of their peers in the humanities. Others consider the use of graduate students or junior colleagues as ghosts to be part of academic training, or a token of respect that is given to superiors. In other words, while they may or may not be legitimate, there are nonetheless systemic forces in place that significantly affect practices of scientific authorship. See (1) Moffatt and Elliott, “Ghost Marketing.” (2) Elizabeth Wager, “What Medical Writing Means to Me.” (3) Medical Writer, interview by Azalea M. Hulbert, May 22, 2014. (4) Viroj Wiwanitkit, “Ghostwriting: An Existing Problem.”
16. To better understand this concept, let’s look at it another way. An author should have intellectual ownership of the project and the data; a ghost-writer lacks such intellectual ownership. This distinction, made by a medical writer we interviewed in May 2014, separates named authors who are invested in a project and make significant intellectual contributions from those who are content to rest on reputation and make no such contribution.
17. (1) “Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research: A Joint Journal and Pharmaceutical Industry Perspective,” *Medical Publishing Insights and Practices Initiative*, accessed February 13, 2016, <http://www.mpip-initiative.org/publications/10-recommended-best-practices/end-ghost-writing-and-guest-authorship>. (2) Simon Stern and Trudo Lemmens, “Legal Remedies for Medical Ghostwriting: Imposing Fraud Liability on Guest Authors of Ghostwritten Articles,” *Medical Writing* 22, no 4 (2013): 264–271. (3) “Ghost Writing Persists in Major Medical Journals,” *U.S. News and World Report*, last modified October 26, 2011, <http://health.usnews.com/health-news/managing-your-healthcare/articles/2011/10/26/ghost-writing-persists-in-major-medical-journals>.



18. This would, in particular, be the case in a scientific publication where one researcher wrote the entire paper, giving honorary author status in that sense to the other named authors, while also being given the privilege of authorship. In the situation where a pharmaceutical company or medical communications company wrote the paper, though, the actual writer would truly be invisible.
19. (1) Christine Laine and Cynthia D. Mulrow, “Exorcising Ghosts and Unwelcome Guests,” *Annals of Internal Medicine* 143, no. 8 (2005): 611–612. (2) Annette Flanagan, Lisa A. Carey, Phil B. Fontanarosa, Stephanie G. Phillips, Brian P. Pace, George D. Lundberg, and Drummond Rennie, “Prevalence of Articles with Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals,” *Journal of the American Medical Association* 280, no. 3 (1998): 222–224.
20. Bryan Dotson and Richard L. Slaughter, “Prevalence of Articles with Honorary and Ghost Authors in Three Pharmacy Journals,” *American Journal of Health-System Pharmacy* 68, no. 18 (2011): 1730–1734.
21. Flanagan et al., “Prevalence of Articles with Honorary Authors and Ghost Authors.”
22. (1) “U.S. Pharmaceutical Sales—Q4 2013,” *Drugs.com*, accessed February 13, 2016, <http://www.drugs.com/stats/top100/sales>. (2) Miranda Hitti, “FDA OKs Abilify for Depression,” *WebMD*, last modified November 20, 2007, <http://www.webmd.com/depression/news/20071120/fda-oks-abilify-for-depression>.
23. Encouragingly, many of the top journals are members of the ICMJE, and many more follow the committee’s recommendations. Of those who are members, the list includes top journals like *Annals of Internal Medicine*, *JAMA* (*Journal of the American Medical Association*), *New England Journal of Medicine*, *The Lancet*, and *PLoS Medicine* (*Public Library of Science*). Despite their involvement, however, many of these publications have reported incidences of ghostwriting, in part—presumably—because of the near-impossibility of detecting or tracking ghostwritten work. See ICMJE, “Journals Following the ICMJE Recommendations,” accessed February 11, 2016, <http://www.icmje.org/journals-following-the-icmje-recommendations/>.
24. European Medical Writers Association, “Ghostwriting Positioning Statement,” accessed February 11, 2016, [http://www.emwa.org/EMWA/About\\_Us/Position\\_Statements/Ghostwriting\\_Positioning\\_Statement/EMWA/About\\_Us/Ghostwriting\\_Positioning\\_Statement.aspx?hkey=83fb6c11-f5a8-4e72-ac9d-5da8e7961184](http://www.emwa.org/EMWA/About_Us/Position_Statements/Ghostwriting_Positioning_Statement/EMWA/About_Us/Ghostwriting_Positioning_Statement.aspx?hkey=83fb6c11-f5a8-4e72-ac9d-5da8e7961184).
25. Hamilton and Royer, “AMWA Position Statement on the Contributions of Medical Writers.”
26. We refer in part to the recently enacted Sunshine Act, which we will discuss in more detail later in the chapter.

27. Medical Writer, interview by Azalea M. Hulbert, May 22, 2014.
28. The University of Alaska Fairbanks, "Authorship."
29. Eugene Garfield, "Giving Credit Only Where It Is Due: The Problem of Defining Authorship," *The Scientist* 9, no. 19 (1995): 13.
30. (1) Sean B. Seymore, "How Does My Work Become Our Work? Dilution of Authorship in Scientific Papers, and the Need for the Academy to Obey Copyright Law," *Richmond Journal of Law & Technology* 12, no. 3 (2006): 1–28. See also (2) Dianne M. Bennett and David McD Taylor, "Unethical Practices in Authorship of Scientific Papers," *Emergency Medicine* 15, no. 3 (2003): 263–270.
31. (1) Josh Fischman, "Medical Academics Could Be Legally Liable for Ghostwritten Articles," *The Chronicle of Higher Education*, last modified January 24, 2012, <http://chronicle.com/article/Medical-Academics-Could-Be/130443/>. (2) Anonymous, "Games People Play with Authors' Names," *nature* 387, no. 6636 (1997): 831.
32. Jim Edwards, "AZ Seroquel Trial: Was It 'Ghostwriting' or 'Professional' Writing?" *CBS News*, last modified March 20, 2009, <http://www.cbsnews.com/news/az-seroquel-trial-was-it-ghostwriting-or-professional-writing/>.
33. Anonymous, "Games People Play with Authors' Names."
34. (1) "Honesty/Ethics in Professions," *Gallup*, accessed February 13, 2016, <http://www.gallup.com/poll/1654/honesty-ethics-professions.aspx#1>. (2) J. Duncan Moore, Jr., "U.S. Physician Leaders Suffer Loss of Public Trust," *MedPage Today*, last modified November 4, 2014, <http://www.medpagetoday.com/PublicHealthPolicy/GeneralProfessionalIssues/48402>.
35. "2014 Edelman Trust Barometer," *Edelman*, accessed February 13, 2016, <http://www.edelman.com/insights/intellectual-property/2014-edelman-trust-barometer/>.
36. Similarly, when asked to share their overall view of the pharmaceutical industry, only 35 percent of respondents in a related Gallup poll reported a positive impression; 43 percent had a negative impression. In Edelman's study, on the other hand, 59 percent felt confident that pharmaceutical companies would do the right thing. It is worth noting, though, that the Gallup polls use only a 5-point scale, ranging from very negative to very positive, while the Edelman instrument uses a 9-point scale. It is also interesting to note that, while this reports that a majority of respondents viewed physicians as ethical, another survey found a significantly smaller majority (58 percent) of Americans agreed that physicians were trustworthy ("All things considered, doctors in [America] can be trusted."). Regardless of the precise level of trust, however, the data is clear that physicians are still more trustworthy—in the eyes of the public—than their corporate counterparts. See (1) "Honesty/Ethics in Professions." (2) Moore, "U.S. Physician Leaders Suffer Loss of Public Trust." (3) "2014

- Edelman Trust Barometer.” (4) Jim Norman, “Americans’ Views of Pharmaceutical Industry Take a Tumble,” *Gallup*, last modified September 14, 2015, <http://www.gallup.com/poll/185432/americans-views-pharmaceutical-industry-tumble.aspx>.
37. (1) Michael Brenner, “What Is Marketing?” *Marketing Insider Group*, last modified August 8, 2012, <http://marketinginsidergroup.com/strategy/what-is-marketing/>. This was also addressed in: (2) Medical Writer, interview by Azalea M. Hulbert, May 22, 2014.
  38. (1) McHenry, “Of Sophists and Spin-Doctors.” (2) Adriane J. Fugh-Berman, “The Haunting of Medical Journals: How Ghostwriting Sold ‘HRT,’” *PLoS Medicine* 7, no. 9 (2010): e1000335. (3) Xavier Bosch, Bijan Esfandiari, and Leemon McHenry, “Challenging Medical Ghostwriting in U.S. Courts,” *PLoS Medicine* 9, no. 1 (2012): e1001163.
  39. (1) Moffatt and Elliott, “Ghost Marketing.” (2) The *PLoS Medicine* Editors, “Ghostwriting: The Dirty Little Secret of Medical Publishing That Just Got Bigger,” *PLoS Medicine* 6, no. 9 (2009): 1–2. (3) Jeffrey R. Lacasse and Jonathan Leo, “Ghostwriting at Elite Academic Medical Centers in the United States,” *PLoS Medicine* 7, no. 2 (2010): e1000230. (4) Bosch, Esfandiari, McHenry, “Challenging Medical Ghostwriting.” (5) Carl Elliott and Amy Snow Landa, “Commentary: What’s Wrong with Ghostwriting?” *Bioethics* 24, no. 6 (2010): 284–286.
  40. Jonathan Leo and Jeffrey Lacasse, “Ghostwriting and Academic Medicine,” *The Chronicle of Higher Education*, last modified July 19, 2010, <http://chronicle.com/article/GhostwritingAcademic/123613/>.
  41. As noted earlier, journal articles are not always data-driven, but may appear as review articles, commentaries, presentations, and supplements that are not peer-reviewed and that are, in essence, opinion pieces. See (1) Fugh-Berman, “The Haunting of Medical Journals.” (2) Linda Logdberg, “Being the Ghost in the Machine: A Medical Ghostwriter’s Personal View,” *PLoS Medicine* 8, no. 8 (2011): 1004.
  42. John LaMattina, “Maybe It’s Time for Drug Companies to Drop TV Ads,” *Forbes*, last modified February 15, 2012, <http://www.forbes.com/sites/johnlamattina/2012/02/15/maybe-its-time-for-drug-companies-to-drop-tv-ads/#7ebb073c7e50>.
  43. The *PLoS Medicine* Editors, “Ghostwriting: The Dirty Little Secret.”
  44. (1) Medical Writer, interview by Azalea M. Hulbert, May 22, 2014. (2) Logdberg, “Being the Ghost in the Machine.”
  45. For instance, a 2004 survey reported that 30 percent of medical writer respondents held advanced degrees (e.g., an M.D. or Ph.D.). See Sarah A. Webb, “Working as a Medical Writer,” *Science*, last modified June 22, 2007, <http://www.sciencemag.org/careers/2007/06/working-medical-writer>.
  46. Logdberg, “Being the Ghost in the Machine.”

47. Studies find that a significant percentage of authors report a conflict of interest. As we saw in our discussion of authorship, though, simply reporting an activity does not automatically make it more transparent. See Tobenna D. Anekwe, "Profits and Plagiarism: The Case of Medical Ghostwriting," *Bioethics* 24, no. 6 (2010): 267–272.
48. For example, see "Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry")," *Stanford Medicine*, last modified July 1, 2014, <http://med.stanford.edu/coi/siip/policy.html>.
49. For example, see "The Blue Book," *Pfizer*, accessed February 13, 2016, [http://www.pfizer.com/files/investors/corporate/bluebook\\_english.pdf](http://www.pfizer.com/files/investors/corporate/bluebook_english.pdf).
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51. (1) United States Senate Committee on Finance, "Ghostwriting in Medical Literature." See also (2) Natasha Singer, "Report Urges More Curbs on Medical Ghostwriting," *The New York Times*, last modified June 24, 2010, <http://www.nytimes.com/2010/06/25/health/25ghost.html>. (3) Senator Charles E. Grassley, electronic message to the Honorable Francis S. Collins, Director, National Institutes of Health, June 24, 2010, <http://www.grassley.senate.gov/sites/default/files/about/upload/2010-06-24-Letter-to-NIH.pdf>. (4) Natasha Singer, "Senator Moves to Block Medical Ghostwriting," *The New York Times*, last modified August 18, 2009, <http://www.nytimes.com/2009/08/19/health/research/19ethics.html?pagewanted=all>.
52. Another useful resource for the study of authorship and scientific ghostwriting is by Tim Albert and Elizabeth Wager, "How to Handle Authorship Disputes: A Guide for New Researchers," *The COPE Report 2003*, accessed February 11, 2016, <http://publicationethics.org/files/u2/2003pdf12.pdf>.
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