

# Ethics of Medical Ghostwriting

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## **ABSTRACT:**

Medical ghostwriting, while in and of itself ethical, is used for unethical purposes. Many ghostwritten articles are used by pharmaceutical companies to present manipulated data in order to increase sales. In response to the rise of ghostwritten articles responses such as stricter laws and publishing regulations are proposed. It is believed that the proposed laws and regulations will return trust to the medical field.

As medical ghostwriting is becoming more widespread and prevalent it has become a topic subject to much discussion. Much of the discussion about medical ghostwriting addresses the ethical implications of the practice. Literature, including books, scientific articles, and newspaper articles, were reviewed alongside several examples of known ghostwritten articles.

The ghostwritten articles covered were the Vioxx VIGOR trial (Bombardier et al., 2000) and the Paroxetine 352 study (Nemeroff et al., 2001). Responses to the two articles were reviewed alongside literature review articles detailing finances, ethical considerations, publishing regulations, and laws pertaining to ghostwriting.

It was determined that while ghostwriting isn't unethical the use of medical ghostwriting is. Pharmaceutical companies use ghostwriting in an unethical manner to manipulate the results of studies and increase profits. This causes a loss of trust in the medical field by allowing harmful drugs to be prescribed and preventing the best possible care from being received by patients. To combat this and help regain the lost trust stricter publishing regulations and laws have been proposed.

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## **1. INTRODUCTION:**

The prevalence of medical ghostwriting is a large issue appearing in biomedical literature. While much has been done to address the issue it still raises many ethical questions. Another problem presented by medical ghost writing is the question of trust in the medical field, especially as there is relatively little regulation of ghostwriting and only loose legal ramifications.

## 2. METHODS:

Literature on the topic of medical ghostwriting was found and reviewed to create a clearer picture of the issue and potential solutions. Several books on the topic were used as well as journal articles found through databases such as PubMed and Google Scholar and articles used as references in previously found works.

### 3. BACKGROUND:

Within the field of technical writing exists a practice called ghostwriting.

Ghostwriting is the act one author of writing a piece which other authors take credit for.

While much of popular ghostwriting is speech writing for politicians or media

personalities, the practice also takes place in scientific journals. The act of ghostwriting,

especially in the sciences, is done to the extent that guides such as *101 Ways to Find Six-*

*Figure Medical or Popular Ghostwriting Jobs & Clients* (Hart, 2006), are widely sold. Other

literature also addresses ghostwriting in terms of ethics (Stichler, 2004) and in law

(Dukes, 2014).

The widespread practice of ghostwriting has even pervaded sensitive genres such as medicine and more specifically pharmaceuticals. Due to the sensitive nature of the

topic there has been much written on medical ghostwriting and the pharmacy industry

itself. This writing comes in many forms such as journal articles, books , and newspaper

articles. Ethicist Carl Elliot's book on the topic, *White Coat Black Hat: Adventures on the*

*Dark Side of Medicine* views the ethics of the pharmaceutical industry from several

standpoints. Elliot looks in depth at pharmaceutical test subjects, drug reps, doctors, and

ghostwriters. In the case of ghostwriting Elliot uses personal interviews and scholarly

articles to delve into the ethics of ghostwriting. While Elliot's position on the topic is left

ambiguous much of the evidence he presents paints a picture of ghostwriting being an

unethical soul sucking profession. This view comes from the personal accounts of both

current and former ghostwriters as well as medical literature.

One of the most prominent examples of medical ghostwriting, and the main article mentioned by Elliot, is the Vioxx VIGOR study released in 2000. Vioxx was a drug marketed by the company Merck in the early 2000's which was pulled from the shelves in 2004 after many negative side effects, such as heart failure, were revealed. The controversy stemmed from the fact that the VIGOR study authored, on paper, by *Bombadier et al.* in 2000 and published in the prestigious *New England Journal of Medicine* (NEJM) was found to be ghostwritten and contained false information. Upon Vioxx's removal from the market it was revealed that the "authors" of the VIGOR study were consultants paid by Merck who were either completely or mostly uninvolved with the study or writing of the article (Krumholz et al., 2007). The omitted and falsified information in the VIGOR study caused a public outcry aimed mostly at the NEJM for not realizing the article was written by Merck itself (Armstrong, 2006).

While Vioxx is a prime example of ghostwriting many others exist. Mixed sciences magazine *The Scientist* published an article overviewing another high profile ghostwriting incident in a 2009 article by Bob Grant (Grant, 2009). The article highlights a situation in which Merck paid scientific publisher Elsevier to publish a special issue containing six fake articles. By themselves the six articles showed no corporate sponsorship and were written to seem like legitimate journal articles. Further research disclosed that Merck both funded and wrote the six articles for the purpose of increasing sales. Another major example of ghostwriting is the Paroxetine 352 bipolar trial (Nemeroff et al., 2001).



Like the Vioxx VIGOR study the Paroxetine 352 trial was an industry sponsored study published in a major medical journal. In 2001 the *American Journal of Psychiatry* published the study which contained no indication of industry sponsorship. In 2012 Amsterdam and McHenry disclosed the ghostwritten nature of the study (Amsterdam, 2012). The Paroxetine 352 study, funded by GlaxoSmithKline, reported positive results when the trials showed that there was no difference between paroxetine and placebos in the treatment of bipolar depression.

While there are a significant number of ghostwritten articles in circulation at present much of the literature on ghostwriting is written in response to ghostwritten articles. The response articles cover material ranging from literature reviews to ethics and legality. Many of the review articles are like the aforementioned Krumholz and Amsterdam articles, but some review the prevalence of ghostwriting as a whole. While considering all publication types a sample of 848 articles were reviewed with nearly 100 showing signs of ghostwriting (Stretton, 2014). Another review study was done focusing on high impact journals published by Elsevier and Wiley-Blackwell. This study consisted of 399 articles from 15 top rated journals and it found that only 10% of the journals had an explicit definition of ghostwriting and less than 6% had detection and response procedures (Bosch, 2013). The article goes on to state that the low scores indicate that either journals don't view ghostwriting as a serious problem or they are influenced by industry payments. A consistent statement from both of the literature review articles is

the need for a clear definition of ghostwriting to be given by publishers as well as explicit ghostwriting response policies.

Much of the remaining ghostwriting literature focuses on the ethics of ghostwriting as well as the ethics of publishing ghostwritten articles. Carl Elliot's book *White Coat Black Hat* devotes a chapter to the ethics of ghostwriting and the ethicists involved in overseeing the journal review boards. Elliot interviews ethicists and does an overview of many of the review boards. Elliot places the review boards into two categories: non-profit and for profit. The non-profit boards are generally more prestigious and harder to get approved by. On the other hand the for profit boards show a correlation between cost, prestige, and approval rate. Many of the review boards are private and don't release the basis of their decisions.

Beyond the ethical review boards many biomedical journals require published work to follow certain guidelines. One of the best known sets of guidelines is the *AMA Manual of Style*, which entering its tenth edition addresses both ethical and legal issues in publishing (Christiansen, 2008). The *AMA Manual of Style* addresses topics such as authorship and disclosure of conflicts of interest. While much of this information is for formatting the journal it is also used to help combat ghostwritten articles.

An article focusing on ethics was written by Almassi in 2014. In the article Almassi argues that ghostwriting, while not outright plagiarism is a type of fraud. This fraud doesn't necessarily come from bad science but instead from a lack of credibility and trust.

With little to no corporate interest disclosure ghostwritten articles erode the trust that is implicitly placed in the healthcare system. The erosion of trust comes from the idea that articles are written as a way to increase corporate profits as opposed to having the health of the people in mind. In addition ghostwriting causes a loss of credibility to both the article and the publishing journal. The loss of credibility for both the article and publishing journal comes from the fact that the medical writer, who is not mentioned in the article, may have had little to no contact with the research team or primary author and just as importantly there is no evidence that proper scientific procedure is followed.

Another article focusing on ghostwriting viewed ethics from the point of view of publishers (Stichler, 2014). Stichler outlines a code of conduct for reporting research in journals as well as the ethics involved in the research and writing. Some of the points which Stichler outlines are a clear dissemination of data throughout the entirety of the published article, transparency of authors and findings, and following the guidelines of the Committee on Publication Ethics, founded in 1997. Stichler also mentions that many professional associations and universities have developed their own code of ethics which become part of published articles.

Many other articles comment on the ethics of ghostwriting from different angles. Aside from standards of professionalism and published articles on the ethics of ghostwriting, the practice has been examined on the basis of financial analysis as well as the scrutiny of the law. While these are important lens through which to evaluate

ghostwriting they are seen to a lesser degree than the ethics of professionalism and publishing and this is in part due to the sensitivity of the topic.

In 2003, Bekelman conducted a study into financial conflicts of interest in biomedical research. The article brings to light the fact that over a twenty year period (1980-2000) industry's share of investment in biomedical research increased by nearly 30%, making industry the largest investor. The problem which arose from this is that many medical journals do not require financial interests to be disclosed within the article. The study explored this fact by analyzing 37 articles for financial conflicts of interest as well as analyzing past studies on financial conflicts of interest. The analysis suggested that about 25% of research studies receive industry funding and nearly 33% of lead authors of research articles have industry ties either from direct payments or through their universities. While the study initially seemed to imply that the industry-sponsored studies showed promising results, further analysis proved that industry-sponsored research articles showed delays in publishing as well as a higher likelihood of reporting altered or misinterpreted data. Out of the 37 articles analyzed, Bekelman found that only eight addressed financial conflicts of interest and that less than half of peer-reviewed journals have financial disclosure policies. Due to the sensitive nature of finances the study suggests that close scrutiny of research articles is advisable as well as reform to disclosure laws and regulations.

In terms of laws ghostwriting falls into a grey zone. While many ethicists view ghostwriting as fraud it is rarely pursued in court to establish legal precedent. Much of

the law enforcement in cases of ghostwriting comes from the settlement of charges levelled against the industry sponsors (Dukes, 2014). One such instance of this was after the Vioxx VIGOR study was shown to be ghostwritten. As part of the settlement, Merck was obliged to have the author of an article be the main contributor instead of a figurehead. While Dukes' book just does an overview of ghostwriting in the law, other literature urges action.

Many ethicists believe that ghostwriting should fall under the federal False Claims Act, which protects against fraud and slander (Bosch, 2012). The reasoning behind this is that ghostwritten articles may contain false or manipulated data which may influence the judgment of doctors and cause patients harm or at least prevent them from receiving the best possible treatment. Bosch's article presents several legal remedies for medical ghostwriting. By claiming that ghostwriting is a form of fraud it will not be protected as free speech as the US Supreme Court has ruled that the First Amendment does not shield fraud. Bosch also argues that ghostwritten articles should be liable under the Anti-Kickback Statute used to protect Medicare and Medicaid against inappropriate use. This would make guest authors and physicians hired to sign off on studies they didn't work on legally liable and subject to up to \$25,000 in fines and five years of imprisonment for harmful unethical articles. Bosch claims that these legal proposals will help to prevent medical ghostwriting as well as help restore credibility to medical journals and professionals.

#### **4. DISCUSSION:**

Ghostwriting is a tool, and like all tools it is only as ethical as its user. In the case of medical ghostwriting it is more unethical than not, unlike political ghostwriting which has become standard practice. Ghostwriting is used by the biomedical industry to manipulate data and increase profits which is decidedly unethical.

The unethical nature of medical ghostwriting comes in part from the fact that ghostwritten articles may not have the public's best interest at heart. For example the 2000 Vioxx Vigor study and the 2001 Paroxetine 352 study were ghostwritten. Both studies posed false claims based on manipulated data to improve the sale of the respective drug. The false information created a situation in which many doctors, who use medical journals to learn about the next big therapeutic advance, inadvertently prescribed a harmful and/or inferior medicine. The fact that falsified information is being fed to the very people we trust to keep us healthy is unnerving and what's worse is that it is for profit. What's more surprising is the relative leniency that the reported 25% of studies (Bekelman, 2003) that are influenced by money from the pharmaceutical companies get in the court of law.

With no laws currently policing medical ghostwriting the pharmaceutical companies are only subject to paying civil reparations claims and other small settlements out of court. In the case of Vioxx, besides paying reparations Merck agreed to have future articles primary authors be the main contributors to research articles (Dukes, 2013), a

small price to pay when you can buy someone's word. To combat the relatively low punishment rate harmful ghostwriting should be considered fraud and subject to the same punishments as someone who tries to abuse programs such as Medicare or an industry making false claims about its product. Of course all this requires that the ghostwritten article gets published in the first place.

To help stem the tide of unethically driven medical ghostwriting, articles must meet a series of requirements set by the prospective journal as well as gain the approval of several institutional review boards. Many journals have a list of standards and practices that an article must meet before being published, such as the AMA manual of style. While these standards are meant to inhibit the inclusion of false information and bad science only in recent years have they begun to look for ghostwriting. To combat ghostwritten articles many journals have started to include standards asking for transparency of authors and conflicts of interest, the problem being that transparency is asked for but not required. The institutional review boards are a system of peer review that an article must go through before being considered for publishing. Like the various journals' standards of practice the review boards are meant to prevent false information and bad science from being published. Each journal requires a set number of approvals from the review boards before an article can be published. While this was set up as a safeguard, ways around it have been found. While many ethics-driven review boards exist, they are vastly outnumbered by for profit review boards. The for profit boards will review an article for a fee and are not legally required to explain their judgement on a particular article. If the

for profit boards were required to explain their reasoning on the approval of an article it would help curb the number of ghostwritten articles being approved purely because of money.

The fact that harmful ghostwritten articles can get published for money instead of merit creates a bad situation in the medical field. If the information given to our doctors can be falsified how can the public be expected to intrinsically place their trust in medicine? Medical ghostwriting has eroded the trust that the public has placed in doctors as well as the trust that many doctors place in medical journals. In the eyes of the public the concept of medical ghostwriting raises the question of whether or not the best possible care is being received because how can one know that their doctor isn't getting paid to prescribe, or not prescribe, a certain drug. As for the professional side doctors are losing trust in medical journals. If the pharmaceutical companies can pay to get an article published or authored by key opinion leaders then how can doctors trust the medical journals? Since medicine is not like politics this erosion of trust is a significant source of damage to the field and measures should be taken to rebuild this trust. Many of the suggestions listed above on laws and regulations would help to return trust to the medical field.

Another erosion of trust comes from the fact that medical ghostwriting is an open secret. That is, the profession knows many people participate in ghostwriting but it is purposefully overlooked as a secret. This open secret becomes visible through an analysis of studies and the responses given to ghostwriting. Various studies show that



ghostwritten articles are still being published despite the fact that journals know them to be ghostwritten. Another way this practice is enabled is through the lack of a centralized standard for publication. If there was a standard which every journal kept requiring transparency in both authorship and discussed financial conflicts of interest, much of the professional distrust in the medical field would be alleviated.

## **5. CONCLUSION:**

The act of ghostwriting is not ethically wrong but how medical ghostwriting is used is. By ghostwriting articles pharmaceutical companies create big scandals, as in the cases of Vioxx and Paroxetine, which stemmed from the want of profits. This profit hungry attitude has eroded public trust in the medical community and brought both physical and financial harm to various individuals.

To prevent ghostwriting from further eroding public trust many ethics committees and review boards have come into being. The for profit nature of many of these institutions show that greater regulations should be placed on medical articles. The publishing companies should require articles to have full disclosure with regards to corporate sponsorship and conflicts of interest. Also publishers should require transparency with authorship. Legally ghostwritten articles found to be showing false or manipulated data which causes harm should be considered fraud. This will make both authors and sponsors legally responsible for their work. Those suggestions should curb the unethical use of medical ghostwriting and work to rebuild any lost trust in the medical field.

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