

Special section

Winners of the Geoff Hall Scholarship essay competition

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The Geoff Hall Scholarships (GHSs) are given in honour of a former President of EMWA. Geoff was a very special person, an extremely valued member of EMWA, and a very good friend to many EMWA members. He firmly believed that the future of EMWA lies in our new and potential members, and so it's a very fitting legacy that we have the Scholarship Awards in his memory.

The Scholarships are awarded annually on the basis of an essay competition, and the title of this year's essay was 'Are medical writers ghostwriters?'. There was a record number of entries, and although it sounds like a cliché, it's genuinely true that the essays caused a lot of debate and discussion among the GHS committee and it was not an easy task to choose just two winning entries. However, two were eventually chosen, and the very worthy winners were Andreas Sakka and Nicholas Churton.

Andreas Sakka has worked as a professional medical writer at Caudex Medical since June 2014. After graduating from Imperial College London

with a BSc in Biochemistry, Andreas moved into industry. He has worked for a number of companies, including Smiths Detection and GE Healthcare, primarily developing *in vitro* and *in vivo* diagnostic technologies for various diseases. Following redundancy, Andreas decided to leave the lab to join the world of medical communications.

Nicholas Churton works as a medical writer at ICON Plc involved in medical writing projects concerning clinical study reports, patient narratives, safety documentation such as developmental safety update reports, editorial reviews and book reviews. Before this, Nicholas was a student at the University of Bath, UK, where he studied for a MSc in Biology. After this he moved to the University of Southampton, UK, to study for a PhD in microbiology. He is currently awaiting examination.

Andreas' and Nicholas' winning essays are presented below, and we wish them the very best at the start of their very promising medical writing careers.

Are medical writers ghost writers?

By Andreas Sakka

Are medical writers ghostwriters? Yes.

At least they may appear to be to the layperson. Ostensibly, medical writers and ghostwriters are professional writers, providing a service to paying clients, creating literature that is published under somebody else's name. This much is true and, with such a concise and unambiguous description, one may think that there is little to dispute regarding the difference between the two. However, a deeper look at the subject reveals a crucial difference that clearly separates medical writers and ghostwriters.

The fundamental distinction between medical writers and ghostwriters is that of visibility. Ghostwriters are typically paid to create literature, in whole or in part, on behalf of an author but their own identity and contribution is never

revealed. Without insider knowledge, it would be impossible to recognise that an author did not create a piece of work on their own or what level of assistance was given. The ghosts are invisible, and the invisible cannot be held to account.

Ghostwriting -along with the associated practices of ghost authorship and non-declaration of funding sources or conflicts of interest- has, in the past, contributed to incomplete and misleading publications of scientific data pertaining to various therapies. Ultimately, this caused harm to patients prescribed inappropriate drugs. Two of several such scandals involved Merck's drug Vioxx and Wyeth's hormone therapy drugs. Between these two cases, ghostwritten articles were used to mitigate apparent risks, failed to report adverse events (including

patient deaths) and promoted unsupported benefits and off-label uses of the drugs.¹⁻³ Merck and Wyeth used ghostwriters as part of a campaign to produce literature beneficial to their companies, with leading academics listed as authors to provide 'a veneer of independence and credibility'.⁴ Without transparency in authorship and funding, readers could not have realised the conflicts of interest within these publications and therefore a balanced judgement on their integrity and validity was impossible. These scandals led to Senator Charles Grassley investigating ghostwriting practices in medical literature where he expressed his concerns for the 'lack of transparency that exists in medical ghostwriting'.⁵

Pharma companies must balance an inescapable and inherent conflict of interest: they develop medicines used for the public good but are required to generate revenue and profit for shareholders. To make money, pharma must sell drugs. To sell drugs, they must raise awareness of them and convince clinicians to choose their medicine over that of their competitors. This creates a commercially driven pressure to optimise the way in which a drug is perceived; a pressure that may encourage unethical behaviours such as the poor publication practices described above. In his criticism of Merck over the Vioxx scandal, Dr Eric Topol wrote 'sadly, it is clear to me that Merck's commercial interest in rofecoxib [Vioxx] sales exceeded its concern about the drug's potential cardiovascular toxicity'.⁶

Contrary to the secrecy of ghostwriting, medical writers are clearly identifiable in the material they produce. For example, it is typical for medical writing assistance to be detailed in the acknowledgment section of a journal article. Transparency, and its implication of accountability and openness to judgement, encourages ethical behaviour by making unethical behaviour difficult to hide. In this way, information on new medicines is disseminated to the medical community and public for the benefit of all.

There are a number of industry-developed publication guidelines in which medical writers are trained and adhere to in their work. These guidelines shape the way in which medical writers produce literature and interact with other members of the medical and pharmaceutical industries to ensure that information is communicated ethically. Examples of recommendations within the good publication practice (GPP2) guidelines include: granting authors full access to study data and allowing them the freedom to make public or publish the study results; disclosing potential conflicts of interest and identifying funding sources;

following established reporting standards such as CONSORT, PRISMA, MOOSE, etc.⁷ GPP2 continues to develop in order to maintain and improve the highest standards of publication practice. GPP2, used alongside authorship guidelines such as those of the International Committee of Medical Journal Editors,⁸ help to ensure clear, accurate, complete and unbiased reporting of scientific data, regardless of whether outcomes are positive or negative, and appropriate authorship with authors who are publicly accountable for the published work.

Furthermore, both the American Medical Writers Association and European Medical Writers Association have published position statements on ghostwriting.^{9,10} Examples of statements made within the EMWA position statement include 'involving the named author(s) early in the publication process', 'refusing requests to develop publications without sufficient involvement of the named author(s)', and 'refusing requests to develop publications in an unethical or irresponsible manner.'

Ghostwriters do not need to hold themselves to the high standards set out by a Medical Writers Association or GPP2 guidelines; they can simply write what they are told to by their paymasters, regardless of concerns over ethics, accountability or the potentially disastrous public health impacts of misrepresented science. In this regard they are the polar opposite of the professional medical writer, who must strive to ensure the integrity and transparency of reported science by adhering to internationally recognised and accepted guidelines. Through ethical publication practices, the medical writer can help prevent harms to patients such as those that ghostwriting contributed to in the Merck and Wyeth scandals.

In summary, medical writers provide an important resource to aid academics, investigators and pharmaceuticals companies to publish data ethically with completeness, transparency and integrity. This is achieved by adhering to various publication, authorship and reporting guidelines and provides a critical 'check and balance' to pharma companies who are driven by the conflicted requirements of doing public good while making private gain. In so doing, the medical writer can help promote the benefits of publicising the latest science, build trust and credibility in the pharmaceutical and medical industries and avoid the medical failures that unethical publication practices and ghostwriting have contributed to in the past.

Are medical writers ghostwriters? Absolutely not.

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Are medical writers ghost writers?

By Nicholas Churton

Are medical writers ghostwriters? I feel a chill go down my spine when I hear those words. Perhaps that is because I dislike that statement or perhaps it is just the ghost in me trying to escape. I once spent ten minutes talking to my father-in-law about what I did for a living as a medical writer since leaving the realms of academia. After ruling-out administrator, typist and office assistant, the word ghostwriter begrudgingly slipped out of my mouth, and I was greeted with a response of 'Ah ... now I understand.' I smiled but felt somewhat misunderstood.

The term ghostwriter applies to the situation where the true author of a piece of work is not directly credited and as such it is often associated with suspicion and distrust.¹ However, conventional ghostwriting can be considered an elegant art and is seen in categories such as autobiographies, fictional and non-fictional stories, magazine articles as well as academic literature. The topic of ghostwriting in the academic field has been hotly debated in recent years, attracting the attention of professional medical writers in both Europe and America.^{2,3} The controversy of academic ghostwriting stems from the fact that the author paid to write the publication did not take part in the design or execution of the work they are writing and as such there is a risk that the study will be misrepresented. In a recent article in the *British Medical Journal*,⁴ Dr. Richard Smith and Dr. Peter Gøtzsche discussed with deputy editor Trish Groves the ethical implications of industry-driven publications and the use of

ghostwriters. Although well-argued, the article generated extensive response, including an eloquent response from members of the Global Alliance of Publication Professionals stressing the importance to exercise caution when distinguishing between ghostwriters and professional medical writers.

In essence, a professional medical writer is not a ghostwriter. A medical writer can be defined as a specialist writer who generates scientific documents in a clear and effective way whilst ensuring compliance with all necessary regulatory guidelines. The key word in that description is specialist. To generate complex medical documents such as clinical study reports, safety reports or patient narratives, the medical writer must simultaneously comprehend the roles of the clinicians, statisticians, publishers, auditors and, most importantly, the client. But to someone who is not immersed in the world of clinical research, the role of a medical writer is sometimes hard to explain. In many respects, the term ghostwriter is not that far-off; we do not devise the studies we write, we are not always credited, and we are paid according to the complexity of the document. The fundamental difference between a medical writer and a conventional ghostwriter is that we are governed by guidelines and policies laid out by The International Conference on Harmonisation (ICH)⁵ and those of the European Medical Writers Association,⁶ the American Medical Writers Association,⁷ and the International Society for Medical Publication Professionals,⁸ which ensures writers adhere to ethical practices

and thus prevent the publishing of misconstrued and fraudulent information.

Furthermore, the argument that medical writing services are detrimental to research needs rethinking.^{1,9} Medical writers provide a professional, high-quality and cost-effective way of communicating scientific information. The partnership between a medical writer and the client they write for is founded on shared professional standards which can result in a positive and long-lasting relationship. Ultimately, it is the responsibility of the medical writer to represent a given product in a fair and ethical way based on the data available and in accordance with the ICH guidelines⁵ and medical writing policies,^{6–8} but responsibility also lies with the client to ensure that the final document accurately depicts the true nature of the product or study. Consequently, recent debate over ghostwriters in academia^{1,2} should not result in writers themselves becoming the scapegoats.

A personal and frank account of a medical writer, and self-proclaimed ghostwriter, can be seen in an article by Linda Logdberg.¹⁰ In this article, Logdberg describes her disillusion with a career in academia and the initial appeal medical writing had; namely, the knowledge that her work was helping the sick, whilst enjoying the flexible hours and good pay. A thought shared by many! At first her career was enjoyable, working directly with the physicians responsible for the work and relishing the role she played. But as her career progressed the initial charm of the work disappeared and as she started working for larger companies the gap between the writer and the researchers grew and the ethical burden of what she was writing became more apparent. In her own words, she ‘... was unwilling to turn this ugly duckling ... into a marketable swan’. I am sure that this experience has been shared by many medical writers at least once in their career and highlights some of the issues medical writers encounter, but I do not believe, and I hope, that this is not the norm. My experience of medical writing, limited as it is, has been extremely positive. The members of the team I work with are highly-skilled, ethical writers, many of whom have been published academics. Each writer takes pride in their work and, although they may not be credited, there is a strong sense

that the work generated is their work and that only work of an exceptional quality should be delivered to the client.

The outsourcing of services such as medical writing is an increasing phenomenon in the medical and pharmaceutical industries and the perception of a medical writer as a ghostwriter is likely to continue for some time. However, what perceptions do we encounter if we extend that concept to all services provided by a global clinical research organisation? Do we consider the clinical trials Ghosttrials? Do we consider the clinicians Ghostclinicians? No we do not, and nor should we consider medical writers as ghostwriters. Professional medical writers should be considered as highly-skilled, ethical individuals with a strong medical and scientific background who facilitate the ever-increasing need for effective scientific communication.

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