

More on legal remedies for ghostwriting

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In an Essay that expands on a previous proposal to use the courts to prosecute those involved in ghostwriting on the basis of it being legal fraud, Xavier Bosch from the University of Barcelona, Spain and colleagues lay out three outline specific areas of legal liability in this week's *PLoS Medicine*.

First, when an injured patient's physician directly or indirectly relies upon a journal article containing false or manipulated safety and efficacy data, the authors (including "guest" authors), can be held legally liable for patient injuries, says the article. Second, guest authors of ghost-written articles published by Medicare- and Medicaid-recognized peer-reviewed [medical journals](#) used as [clinical evidence](#) for indications for off-label drugs articles may be liable under the federal False Claims Act for inducing the [United States government](#) to reimburse [prescriptions](#) under false pretenses. Finally, the authors argue, paying guest authors of ghostwritten papers—which may influence clinical judgment, increase product sales and government health care costs, and put patients at risk by misrepresenting risk-benefit— can mean that both physicians and sponsor companies may be liable under the federal Anti-Kickback Statute.

Although guest authors and pharmaceutical defendants may argue a First Amendment right to participate in ghostwriting, the authors say, the US Supreme Court has firmly held that the First Amendment does not shield fraud.

In the previous proposal, published in [PLoS Medicine](#) in August 2011,

Simon Stern and Trudo Lemmens from the Faculties of Law and Medicine at the University of Toronto, Canada argued that it is irrelevant whether publications with academic guest authors are factually accurate. Rather, ghostwriting of medical journal articles raises serious ethical and legal concerns, bearing on the integrity of medical research and scientific evidence used in legal disputes. Furthermore, the false respectability afforded to claims of safety and effectiveness through the use of academic investigators risks undermining the integrity of biomedical research and patient care—an integrity that also underpins the use of scientific evidence in the courtroom.

According to these authors, medical journals, academic institutions, and professional disciplinary bodies have failed to enforce effective sanctions. Some journals, such as PLoS Medicine, have called for bans on future submissions by authors who act as guests, formal retraction if unacknowledged ghostwriting is discovered after publication, and reporting of authors' misconduct to institutions. Although the authors agree that such actions may have an impact on academics concerned about their status and future publication options, they say that it is unclear whether journals can adequately monitor the practice.

They made the case for more effectively deterring the practice of ghostwriting through the imposition of [legal liability](#) on the "guest authors" who lend their names to ghostwritten articles. The authors say: "We argue that a guest author's claim for credit of an article written by someone else constitutes legal fraud, and may give rise to claims that could be pursued in a class action based on the Racketeer Influenced and Corrupt Organizations Act [RICO]."

The authors said: "The same fraud could support claims of "fraud on the court" against a pharmaceutical company that has used ghostwritten articles in litigation. This claim also appropriately reflects the negative impact of [ghostwriting](#) on the legal system."

More information: Bosch X, Esfandiari B, McHenry L (2012) Challenging Medical Ghostwriting in the US Courts. PLoS Med 9(1): e1001163. [doi:10.1371/journal.pmed.1001163](https://doi.org/10.1371/journal.pmed.1001163)

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