

# AMWA POSITION STATEMENT ON THE CONTRIBUTIONS OF MEDICAL WRITERS TO SCIENTIFIC PUBLICATIONS

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The unacknowledged contributions of professional medical writers (i.e., ghostwriting) to the preparation of manuscripts for publication continue to be controversial, particularly when funded by the pharmaceutical industry.<sup>1-6</sup> Critics charge that the use of professional biomedical communicators<sup>7-10</sup> encourages commercial bias in publications, whereas proponents hold that these biomedical communicators provide a valuable service that improves the quality and timeliness of publication.<sup>11-14</sup> The controversy became of critical interest to AMWA members in the early 1990s when the U.S. Food and Drug Administration (FDA) proposed severe restrictions on industry-sponsored biomedical communicators in their draft guidelines “Regulation of Drug-Company–Sponsored Activities in Scientific or Educational Contexts.”<sup>10,12,15</sup> In response, AMWA formed the Advisory Task Force on Medical Writing (hereafter, the 1991 task force) to educate the FDA about the role of biomedical communicators in the writing process and to address the FDA’s concerns about that involvement.<sup>16</sup>

AMWA, founded in 1940, has recognized the contributions of biomedical communicators for decades. Evidence of AMWA’s commitment to biomedical communicators can be found in the Code of Ethics (Table 1), written in 1973, and in the 1991 task force’s response to the guidelines proposed by the FDA in the early 1990s.<sup>16,17</sup> As a result of the continuing controversy, AMWA formed a new task force in 2001 to develop a statement regarding AMWA’s position on the contributions of biomedical communicators to scientific publications (hereafter, the 2002 task force).

The purpose of this paper is to explain the process the 2002 task force used to prepare, adopt, and present the position statement. In addition, plans for 2003 will be described briefly.

## Process

The members of the 2002 task force, listed previously,<sup>18</sup> represented a wide range of interests, including pharmaceutical companies, medical communication companies, clinical research organizations, educational

and health care institutions, and journals. The 2002 task force also included freelance writers and editors, as well as a member of the 1991 task force. Two subcommittees of the task force were formed, one to draft the position statement and one to present the statement to the AMWA membership at the 2002 Annual Conference in San Diego.

The 2002 task force first established the following objectives: (1) to research the ghostwriting controversy; (2) to define AMWA’s position on ghostwriting; (3) to prepare a position statement and reiterate AMWA’s ethics statement on biomedical communications; (4) to write and publish document(s) on ghostwriting, including AMWA’s new position statement; and (5) to educate people about the role of the biomedical communicator. To address the first objective, the 2002 task force reviewed papers identified by a literature search, articles from members’ personal libraries, and related correspondence between AMWA and the FDA. On the basis of this review, the 2002 task force compiled a history of the 1991 task force and its interaction with the FDA.<sup>19</sup> In addition, the 2002 task force reviewed other relevant statements, such as the Uniform Requirements for Manuscripts Submitted to Biomedical Journals,<sup>20</sup> the draft Good Publication Practice (GPP): Guidelines for Pharmaceutical Companies, the Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results by the Pharmaceutical Research and Manufacturers of America (PhRMA),<sup>21</sup> and the AMWA Code of Ethics.

The writing subcommittee collaborated to achieve consensus on a draft position statement and then presented it to the 2002 task force as a whole. After further discussion and refinement, the revised draft statement was presented to the AMWA Board of Directors, which comprises the Executive Committee and at least one voting delegate from each of the 19 AMWA chapters. The position statement was adopted unanimously by the AMWA Board of Directors on October 30, 2002.

## Position Statement and Discussion

The literature review led to the conclusion that much of the controversy about the role of biomedical communicators arises from (1) a general lack of understanding in

**Table 1. AMWA Code of Ethics**

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**Preamble**

The American Medical Writers Association (AMWA) is an educational organization that promotes advances and challenges in biomedical communications by recommending principles of conduct for its members. These principles take into account the important role of biomedical communicators in writing, editing, and developing materials in various media and the potential of the products of their efforts to inform, educate, and influence audiences. To uphold the dignity and honor of their profession and of AMWA, biomedical communicators should accept the ethical principles and engage only in activities that bring credit to their profession, to AMWA, and to themselves.

**Principle 1**

Biomedical communicators should recognize and observe statutes and regulations pertaining to the materials they write, edit, or otherwise develop.

**Principle 2**

Biomedical communicators should apply objectivity, scientific accuracy and rigor, and fair balance while conveying pertinent information in all media.

**Principle 3**

Biomedical communicators should write, edit, or participate in the development of information that meets the highest professional standards, whether or not such materials come under the purview of any regulatory agency. They should attempt to prevent the perpetuation of incorrect information.

Biomedical communicators should accept an assignment only when working in collaboration with a qualified specialist in the area, or when they are adequately prepared to undertake the assignment by training, experience, or ongoing study.

**Principle 4**

Biomedical communicators should work only under conditions or terms that allow proper application of their judgment and skills. They should refuse to participate in assignments that require unethical or questionable practices.

**Principle 5**

Biomedical communicators should expand and perfect their professional knowledge and communications skills.

**Principle 6**

Biomedical communicators should respect the confidential nature of materials provided to them. They should not divulge, without permission, any confidential patent, proprietary, or patient information.

**Principle 7**

Biomedical communicators should expect and accept fair and reasonable remuneration and acknowledgment for their services. They should honor the terms of any contract or agreements into which they enter.

**Principle 8**

Biomedical communicators should consider their membership in AMWA an honor and a trust. They should conduct themselves accordingly in their professional interactions.

Original: Eric W. Martin, PhD 1973

First revision: June 1989

Second revision: April 1994

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**Table 2. AMWA Position Statement on the Contributions of Medical Writers to Scientific Publications**

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The American Medical Writers Association (AMWA) recognizes the valuable contributions of biomedical communicators to the publication team. Biomedical communicators who contribute substantially to the writing or editing of a manuscript should be acknowledged with their permission and with disclosure of any pertinent professional or financial relationships. In all aspects of the publication process, biomedical communicators should adhere to the AMWA Code of Ethics.

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the medical publishing and health care communities about the nature and the value of the contributions of biomedical communicators to manuscript preparation and (2) a perception that these contributions are often not disclosed so readers cannot make informed judgments about the objectivity of medical publications.

The Position Statement on the Contributions of Medical Writers to Scientific Publications (Table 2) addresses both concerns and is consistent with the AMWA Code of Ethics. Formally acknowledging the contributions of biomedical communicators and disclosing pertinent professional or financial relationships should allay concerns that arise when such information is not disclosed. Acknowledging biomedical communicators who contribute substantially to the writing or editing of a manuscript and obtaining their permission before making this acknowledgment is consistent with the GPP and with statements made by AMWA to the FDA in 1992,<sup>16,17</sup> by the International Committee of Medical Journal Editors,<sup>20</sup> and by PhRMA.<sup>21</sup> Disclosing professional or financial relationships is consistent with the Guidelines for Authors in the Uniform Requirements,<sup>20</sup> which have been accepted by more than 500 biomedical journals, and is a new recommendation for biomedical communicators.

### Future Actions

This year, a new task force will publicize the position statement and conduct an educational campaign on the role of biomedical communicators. Target audiences include AMWA members, journal editors, authors, pharmaceutical companies, and medical communication companies.

AMWA members are invited to comment on the position statement and to make suggestions for the publicity and educational campaigns. Comments and suggestions should be posted on the bulletin board of the AMWA Web site at [www.amwa.org](http://www.amwa.org).

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### References

1. DeBakey L, DeBakey S. Ghostwriters: not always what they appear. *JAMA*. 1995;274:870-871.
2. Levy D. Ghostwriters a hidden resource for drug makers. *USA Today*. September 25, 1996:1A, 2A.
3. Peterson M. Whistle-blower says marketers broke the rules to push a drug. *The New York Times*. March 14, 2002.
4. Boseley S. Scandal of scientists who take money for papers ghostwritten by drug companies. *The Guardian*. February 27, 2002.
5. Altman LK. Some authors in medical journals may get paid by 'spin doctors.' *The New York Times*. October 4, 1994:C3.
6. Larkin M. Whose article is it anyway? *Lancet*. 1999;354:136.
7. Bodenheimer T. Uneasy alliance: clinical investigators and the pharmaceutical industry. *N Engl J Med*. 2000;342:1539-1544.
8. Brennan TA. Buying editorials. *N Engl J Med*. 1994;331:673-675; discussion, 676.
9. Coyle SL. Physician-industry relations. Part 1: individual physicians. *Ann Intern Med*. 2002;136:396-402.
10. Food and Drug Administration. Regulation of drug-company-sponsored activities in scientific or educational contexts (draft proposed policy, October 8, 1991). Division of Drug Marketing, Advertising, and Communications (HFD-240), Rockville, Md.
11. Saiers J. The medical writer: a reaction to Bodenheimer's assessment in "uneasy alliance." *AMWA Journal*. 2001;16(1):2.
12. FDA's proposed concept paper. *AMWA Journal*. 1991;6(4):23.
13. Phillips SG, Carey LA, Biedermann G. Attitudes toward writing and writing assistance in peer-reviewed articles. *AMWA Journal*. 2001;16(3):10-16.

14. Royer MG. Preparing manuscripts for publication: a team approach. *Drug Info J.* 1986;20:97-102.
15. Sanchez RJ. FDA considers restrictions on medical writers in pharmaceutical industry. *AMWA Journal.* 1991;6(4):23.
16. AMWA creates Advisory Task Force on medical writing. *AMWA Journal.* 1992;7(3):14.
17. AMWA Task Force meets with the FDA. *AMWA Journal.* 1992;7(3):13.
18. Foote M, Hamilton CW, Royer MG. Contributions of medical writers to scientific publications. *AMWA Journal.* 2002;17(4):48.
19. Royer MG, Hamilton CW. The story behind the AMWA Task Force on the Contributions of Medical Writers to Scientific Publications. *AMWA Journal.* 2002;17(3):5-6.
20. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. 2001. Available at: [www.icmje.org/index.html](http://www.icmje.org/index.html). Accessed October 4, 2002.
21. Pharmaceutical Research and Manufacturers of America. PhRMA Principles on conduct of clinical trials and communication of clinical trial results. 2002. Available at: [www.phrma.org/publications/policy/2002-06-24.430.pdf](http://www.phrma.org/publications/policy/2002-06-24.430.pdf). Accessed November 7, 2002.

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