

# THE STORY BEHIND THE AMWA TASK FORCE ON THE CONTRIBUTION OF MEDICAL WRITERS TO SCIENTIFIC PUBLICATIONS

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Member<sup>1</sup> and Chair<sup>2</sup> of the AMWA Task Force on the Contribution of Medical Writers to Scientific Publications

**I**N response to the continuing controversy surrounding the issue of ghostwriting and at the request of AMWA President Helen Hodgson, the AMWA Task Force on the Contribution of Medical Writers to Scientific Publications was formed in December 2001. The mandate of the task force is to develop a position statement for AMWA on publications and medical writing.

The use of professional medical writers in the preparation of scientific publications has been a subject of considerable debate for the last decade. The issue became critical for AMWA members in the early 1990s when the FDA drafted guidelines titled "Regulation of Drug-Company-Sponsored Activities in Scientific or Educational Contexts," which proposed severe restrictions on industry-sponsored medical writers.<sup>1-3</sup> An early draft of these proposed guidelines stated:

Independent scientific and educational articles about a company's drug or directly competing drugs should not be written by medical writers employed by the firm, including freelance writers hired by the firm for specific projects. In addition, medical writers employed by the firm should not ghostwrite, edit or otherwise influence the

content of articles, purporting to be independent, on the company's drugs or directly competing products written by others.

Elizabeth Smith, then president of AMWA, responded to the FDA in a written statement in which she described the importance of the professional writer in the publication team.<sup>3</sup> She concluded that adoption of the proposed guidelines could severely and unnecessarily restrict the timely dissemination of scientific information and threaten the livelihood of a significant number of AMWA members. In late January 1992, AMWA received an unsigned form letter from the FDA acknowledging its receipt of AMWA's response to the guidelines.<sup>4</sup> In February 1992, the FDA decided to include the prohibition against medical writers in its second draft of the proposed guidelines.

In March 1992, the AMWA Board of Directors met with the FDA regarding the proposed guidelines. The representatives of the FDA at this meeting indicated that the agency needed more information about the activities of industry-sponsored medical writers, especially their role in preparing documents for physicians.<sup>5</sup> According to the *AMWA Journal*, "The Agency's concern was that medical writers

who are employed by or whose fees are paid for by industry have the potential to be biased toward the company's products and views and may use their writing to unduly influence physicians by distorting data."<sup>5</sup> Clearly, AMWA needed to take action.

After the March meeting with the FDA, AMWA formed the Advisory Task Force on Medical Writing to educate the FDA about the role of the medical writer in the writing process and to address the agency's concerns about that involvement.<sup>6</sup> This task force met with the FDA in September 1992.<sup>5</sup> At the meeting, the task force presented an overview of AMWA, including descriptions of its membership and educational programs, and a summary of the kinds of projects that include medical writers and their involvement in those projects. As a result of the recommendations made by this first task force, AMWA's Code of Ethics was refined to include specific standards to ensure balance, scientific rigor, and objectivity in the writing of all scientific materials. In addition, workshops, plenary sessions, and roundtable discussions on the ethics of authorship and editorship were added to the AMWA annual conferences.

In 1997, the FDA issued the "Guidance for Industry: Industry-Supported Scientific and

Educational Activities.<sup>77</sup> Medical writers are not mentioned in the final guidance.

Even though the final FDA guidance does not mention the use of professional medical writers, their role in the preparation of scientific papers continues to be very controversial. In the last decade, many articles about ghostwriting have been published in the medical literature<sup>8-14</sup> and lay press.<sup>15-17</sup> The volume and content of these articles suggest that ghostwriting continues to be perceived as both newsworthy and problematic. Through the creation of the new task force in 2001, AMWA will develop a position statement on this issue and initiate a program of publications and presentations to educate the medical community about the contribution of medical writers to scientific communication. The position statement will be presented to the membership and voted on by the Board of Directors during the annual conference this fall. After the position statement is finalized and accepted, it will be published in the *AMWA Journal*.

The AMWA Task Force on the Contribution of Medical Writers to Scientific Publications consists of the following members: Cindy W. Hamilton, PharmD (chair); Brian Bass; Sherri Bowen, MA, EL5; MaryAnn Foote, PhD; Marianne Mallia; Devora Mitrany, EL5; Mary G. Royer, MS, EL5; Jane Saiers, PhD; Barbara Schwedel, MS, EL5; Gayle N. Scott, PharmD; and Robin Weaver.

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