Ethics Theme Issue

Articles and Information Throughout the Issue on Ethics in Medical Communication

Physician Payment Sunshine Act: Potential Implications for Medical Publication Professionals

2011 Swanberg Address—AMWA and Medical Communication: The Good, the Bad, and the Ugly
The AMWA Journal expresses the interests, concerns, and expertise of members. Its purpose is to inspire, motivate, inform, and educate them. The Journal furthers dialog among all members and communicates the purposes, goals, advantages, and benefits of the American Medical Writers Association (AMWA) as a professional organization. Specifically, it functions to

- Publish articles on issues, practices, research theories, solutions to problems, ethics, and opportunities related to effective medical communication
- Enhance theoretical knowledge as well as applied skills of medical communicators in the health sciences, government, and industry
- Address the membership’s professional development needs by publishing the research results of educators and trainers of communications skills and by disseminating information about relevant technologies and their applications
- Inform members of important medical topics, ethical issues, emerging professional trends, and career opportunities
- Report news about AMWA activities and the professional accomplishments of its departments, sections, chapters, and members

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• 2011 CONFERENCE COVERAGE:
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Cover conference photo © PhotobyJamie.com
I am proud of how far the Journal has come since I took the helm in 2003, and I would like to highlight a few accomplishments. First, manuscript submissions have increased substantially, with 21 manuscripts submitted last year. Admittedly, 21 can be seen as a small number, but it represents a threefold increase in submissions since 2003, and I’m hopeful this trend will continue. One of the greatest increases has been in the number of original research reports: 10 were submitted between 2008 and 2011, compared with one submitted between 2003 and 2007. Again, I hope this trend continues, as original research is essential in further validating our profession.

To supplement the number of manuscript submissions, I have created Journal sections to enhance readers’ knowledge and skills in focused areas. These new sections have been designed to respond to readers’ needs, as documented in AMWA member surveys. With the addition of CME Rising (which debuted in December 2011), the Journal now includes sections that address the needs of the greatest factions within our membership: regulatory writing (Regulatory Insights), freelancing (Freelance Forum), and continuing medical education. Sections also speak to broader subjects, such as career growth, body systems and disease, media reviews, and coverage of our annual conference. New sections help members stay abreast of emerging technology, first bringing you the Social Media section and now, beginning with this issue, Tech Talk (see page 34).

With the addition of these sections and increased submissions, the Journal grew in pages, reaching 60 pages for several issues. Budget constraints have forced us to limit print pages to 48, but we now offer online exclusives as a way to bring you the same amount of pages. Online exclusives have an added “green” benefit and also allow for better integration of the print and online versions of the Journal. As well, we are using a variety of media to bring Journal content to you. First was the Journal Blog (http://amwajournal.blogspot.com), designed to highlight current and past content as well as generate discussion among members. One post last fall—on the topic of certification of medical writers—drew more than 800 page hits, about four times the number of hits for any other Journal Blog post. And the social networking sites where the Journal Blog is promoted were ablaze with discussion of the topic among members and nonmembers alike. Such discussion can only better inform AMWA decision-making. Now with this issue, we venture into new territory with our first podcast. I hope you will take a few minutes to listen to this podcast, which features an interview with Liz Wager, the Chair of the Committee on Publication Ethics (COPE). This interview is also the first in a new recurring Journal feature: Expert Q&A, a series of interviews to provide you with expert, timely commentary on important issues.

Wager’s interview is but one component in this issue’s overall theme of ethics, a topic that is of great importance to our members, our organization, and our profession. Authorship and acknowledgment of medical writers are seen as the greatest ethical issues in our profession, but they are not the sole issues. Ethics permeates every medical communication setting, and I hope the following pages help you better understand the breadth of ethical issues medical communicators face.

Of course, the enhancements to the Journal have been made possible by the dedication of the growing number of AMWA members who volunteer for the Journal. When I came onboard, the volunteer staff included a handful of manuscript editors and peer reviewers and two proofreaders. Now serving the Journal are 20 peer reviewers/manuscript editors, eight proofreaders, 14 regular contributors (nine of whom make up our expert Freelance Forum panel), and 12 section editors. In addition to this burgeoning volunteer staff, the Journal now has an Editorial Board, a body fully committed to providing oversight to the Journal. The nine members of the Board bring a variety of expertise to the table and will help ensure that we develop and adhere to policies guaranteeing high standards and that we continue to develop content to meet the needs of our diverse membership.

Since becoming editor of the Journal in 2003, I have chosen to focus my time on creating a Journal that is of value to the everyday professional lives of medical communicators rather than to provide commentary with an editorial in each issue. Over nearly 10 years, my editorials have taken up just five pages. Why then am I writing an editorial now? As many of you already know, this year will be my last as editor. Ending my term as AMWA Journal editor is a bittersweet decision. I am passionate about the Journal, and it has been an honor and a privilege to lead colleagues in producing the highest quality Journal possible. But 10 years seems like enough time for any editor to be at the helm of any journal. It is time for a new person to make his or her mark with our flagship publication. Still, leaving this post will not be easy. For almost 10 years, the Journal has been my lifeblood—my professional heart and soul. For my last year, I plan to reflect on my tenure as editor with an editorial in each issue, wearing that heart on my sleeve.
THE RIGHT WAY TO AVOID DOING WRONG: A MULTISTEP MODEL FOR MAKING ETHICAL DECISIONS

By Cindy W. Hamilton, PharmD, ELS
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ABSTRACT
Medical communicators encounter a wide variety of ethical situations. To facilitate ethical decision-making, AMWA workshop leaders developed a five-step process known as the RIGHT model. The first step is to recognize the ethical situation, clearly and succinctly define it, and identify all stakeholders. The second step is to investigate the facts and assumptions, especially relevant statutes, regulations, and guidelines including the AMWA Code of Ethics, and to identify conflicts of interest. The third step is to gauge the situation and decide by making a list of all possible courses of action and then choosing the action(s) that maximizes benefit and minimizes cost and risk for the majority of stakeholders. The fourth step is to handle the situation and implement the decision. The fifth step is to tailor the decision by evaluating it for lessons learned and revising it as needed. This article includes a case report to demonstrate the practical application of each step in the RIGHT model.

INTRODUCTION
Medical communicators encounter a wide variety of ethical situations. These situations are continuously evolving because of the dynamic nature of medical communication, including changes in subject material, services, media, and work settings. Ethical situations can involve science or medicine, research or clinical practice, and other subject areas; they can involve writing, editing, and developing materials in various media; and they can involve work in pharmaceutical companies, medical communication companies, health care facilities, independent freelance businesses, and other settings.

To help medical communicators make ethical decisions, leaders of AMWA ethics workshops developed a multistep model (Figure 1). Our goal was to develop a model that would be simple, memorable, and relevant to all medical communicators. We researched other models and ultimately chose five steps. Peggy Boe cleverly chose the mnemonic “RIGHT” for the model.

To demonstrate how to use the model, let’s consider a case report and questions for each step. You may not identify with the specific details in the case, but you can probably remember an occasion when ethical behavior did not result in the desired outcome. To maximize the benefit of this article, plan to do more than simply read it. Imagine that you are in an ethics workshop with other AMWA members representing different specialties, work settings, and levels of experience (Figure 2). Simulate that workshop experience by discussing the case report with your colleagues and customizing it for relevancy to your specialty and work setting. Work through each step of the model in your discussion. To further maximize your learning experience, be receptive to new ideas and remember that everyone needs advice and reminders about best practices because of the evolving nature of medical communication. Some ethical situations may be obvious, but how to handle or avoid them may not be.

CASE REPORT
Vera City is an experienced medical writer and long-term AMWA member. She recently began a full-time position with a start-up medical communication company. Her first assignment was to prepare an article about cancer care offered at a large health care facility. The target publication was a local magazine for seniors. The client provided information that included marketing and public relations materials about the facility’s novel design, technologies offered, and model of care. Collectively, these features made the facility seem extraordinary and implied better outcomes for its patients than for those at other facilities.

Vera was concerned about some of the claims regarding these new tech-
Figure 2. Ethics workshops for the AMWA certificate program. AMWA expanded the program in 2010 and began to require successful completion of an ethics workshop as one of the eight workshops needed to earn the Essential Skills certificate and each of the four specialty track certificates.4 Advanced certificates, planned for the future, are not shown. The initials after the certificate name are the abbreviation for that certificate. *Also available as a self-study workshop.

ologies and approaches. In her initial research effort, she found several solid sources indicating that these claims were not substantiated. As she dug deeper, she discovered that the outcomes touted in her client’s materials were not any more favorable than those at other facilities.

Vera tried to present these findings first to her supervisor at the medical communication company and subsequently to her contact at the health care facility, but was ignored on both attempts. Though uncomfortable with the situation, Vera soldiered on and wrote an article that she hoped reflected the facts in a tone that would be acceptable to the client. Her supervisor, however, rewrote the article to satisfy the marketing team at the health care facility.

Vera remained at the medical communication company and moved on to other projects, but she continued to ponder her experience. Every time she drove by the health care facility, she imagined sick, but hopeful, patients and feared that they might have made treatment decisions on the basis of misleading marketing material. Patients without cancer could be affected if they generalize from the article, especially if they subsequently learned that the article was misleading. In that case, patients could be affected if they question the benefit of noncancer treatments offered by the health care facility or, worse, if they question the benefit of any type of medical treatment. In addition, many reputations may be damaged, including those of the medical communication company and health care facility. Employees of both organizations may be damaged, even if they were not directly involved in the article or the delivery of cancer care.

Why is the decision important to Vera? The case report suggests that she wants to learn from her experience because she wonders whether she should have done anything differently. She wonders whether she should take future action.

Step 2: Investigate the Facts and Assumptions
What are the facts and assumptions? To answer this question, Vera should reflect on a series of related questions. Has she distinguished facts from opinions, desires, and other “wishes”? What assumptions have been made? How certain is she that the article is misleading? Is it possible that her research was incomplete or otherwise flawed?

What is Vera’s intention in making this decision? Is she motivated to do what is best for herself, her medical communication company, her profession, local patients with cancer, society as a whole, or a combination of stakeholders? Or does she have an entirely different intention?

Does Vera have any conflicts of interest? Most medical communica-
tors are familiar with financial conflict of interest that must be disclosed by authors, but Vera should consider the many different types of conflict that are relevant to her situation. Does she have a personal conflict of interest because of her experience with cancer chemotherapy that led to irreversible toxicity, or because of a medication error at the health care facility that led to the death of a family member? Does she have a romantic conflict because of a current or past relationship with an employee at the medical communication company or the health care facility? Does she have religious, cultural, ethnic, political, loyalty, or any other types of conflict of interest?

What are the relevant facts available to Vera, including statutes, regulations, and/or guidelines? What guidance is available from AMWA? Are any of the principles in the AMWA Code of Ethics relevant to the case report (see box)? The Preamble provides the foundation for ethical behavior and notes “the important role of medical 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.” The first, second, and third principles are directly relevant to the case (see box). For example, the third principle states, “Medical 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. Medical communicators should accept assignments only when working in collaboration with a qualified specialist in the area, or when they are adequately prepared to undertake the assignments by training, experience, or ongoing study.

How can Vera find out if there is any relevant information that is unknown? What additional guidance is available from professional industry guidelines, peers, colleagues, and/or ethicists? Does the health care facility have guidelines about marketing materials or an ethics hotline? Does the health care facility belong to an organization that has guidelines about marketing materials? Can fellow AMWA members offer advice?

AMWA CODE OF ETHICS

PREAMBLE
The American Medical Writers Association (AMWA) is an educational organization that promotes excellence in medical communication and recommends principles of conduct for its members. These principles take into account the important role of medical 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, medical communicators should accept these ethical principles and engage only in activities that bring credit to their profession, to AMWA, and to themselves.

PRINCIPLE 1. Medical communicators should recognize and observe statutes and regulations pertaining to the materials they write, edit, or otherwise develop.

PRINCIPLE 2. Medical communicators should apply objectivity, scientific accuracy and rigor, and fair balance while conveying pertinent information in all media.

PRINCIPLE 3. Medical 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. Medical communicators should accept assignments only when working in collaboration with a qualified specialist in the area, or when they are adequately prepared to undertake the assignments by training, experience, or ongoing study.

PRINCIPLE 4. Medical 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. Medical communicators should expand and perfect their professional knowledge and communications skills.

PRINCIPLE 6. Medical communicators should respect the confidential nature of materials provided to them. They should not divulge, without permission, any patent, proprietary, patient, or otherwise confidential information.

PRINCIPLE 7. Medical 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. Medical 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
Third revision: June 2008
http://www.amwa.org/default.asp?id=114
Vera should ask herself, “Why is the situation occurring?” Has the start-up medical communication company not yet had the opportunity to develop standard operating procedures for reviewing deliverables? Is the health care facility unaware of its own marketing guidelines?

**Step 3: Gauge the Situation and Decide**

To gauge the situation and make an ethical decision, Vera should consider exactly what must be decided. Many of her questions have focused on what she might have done differently. Although considering alternatives to past actions has educational value, focusing on future actions may be more productive.

What are all of the possible courses of action? Vera should make a long list. She should avoid the temptation to make judgments about different actions during this initial phase of step 3. Most lists begin with “doing nothing,” which may seem counterintuitive; however, doing nothing is almost always a possible action. How can Vera manage the risk to herself and others? Should she perform additional research to confirm her assumption that the article is misleading? Should she document her efforts to express her concerns and save her version of the article? Should she offer to help the medical communication company develop a standard operating procedure that includes a review process? Should she offer to help the health care facility develop a policy for preparing marketing materials? Should she seek advice from colleagues to identify additional courses of action?

To decide on an action or actions, Vera should consider the likely consequences of each alternative, including the impact on each stakeholder. She should recognize that a single action is rarely ideal for all stakeholders. Therefore, she should attempt to identify the course of action that is best for the majority of stakeholders, which may require multiple actions. In choosing future actions, Vera should consider whether her decision maximizes benefit and minimizes cost and risk. Has she treated others as she would want to be treated? Would she be comfortable if her reasoning and decision were made public?

**Step 4: Handle the Situation and Implement the Decision**

How should Vera handle the situation? When should the decision be implemented and who should act on the decision? In the case report, the situation has already occurred, suggesting that immediate action is probably not required. Instead, progressive corrective actions can probably be implemented gradually over time. Is Vera in the best position to implement the decision? If not, who can—or should—assist in implementing the decision? Should Vera collaborate with her supervisor at the medical communication company, her contact at the health care facility, or another party?

Has Vera communicated the proposed course of action to all of the interested and affected stakeholders? Is she confident that the decision is being implemented in a way that maximizes benefit and minimizes cost to the stakeholders as well as to the situation?

**Step 5: Tailor the Decision (Evaluate and Revise)**

After the decision is implemented, how can it be further tailored? Vera should evaluate her experience. Was the situation handled successfully? How well was the decision implemented? What was the effect of her decision? Should Vera modify her behavior or decision on the basis of the observed effect? What lessons can be learned for future situations?

**CONCLUSION**

To facilitate ethical decision-making, follow the steps in the RIGHT model. First, recognize the ethical situation, clearly and succinctly define it, and identify all stakeholders. Second, investigate the facts and assumptions, especially relevant statutes, regulations, and guidelines, as well as the AMWA Code of Ethics. In addition, identify any and all conflicts of interest, including personal conflicts. Third, gauge the situation and decide. To do this, make a long list of all possible courses of action. Remember that no single action will be ideal for all involved parties. To choose the action that maximizes benefit and minimizes cost and risk for the majority of stakeholders, consider the likely consequences of each action and be prepared for the possibility of multiple actions. Fourth, handle the situation and implement the decision. Fifth, tailor the decision by evaluating it for lessons learned and revising it as needed.

**Acknowledgment**

I thank the following AMWA workshop leaders for contributing to the RIGHT model: Marijke H. Adams, Tami Ball, Peggy Boe, Charmaine Cummings, Andrea Gwosdow, Jill Shuman, and Nancy Taylor. I also thank participants in the AMWA listserves and ethics workshops for their provocative questions, which have provided helpful insight and inspiration. I especially thank the two AMWA members who prefer not to be named for granting permission to use (and combine) their cases. I am forever indebted to Anne Derbes for continuously providing excellent editorial services, for creative input, and for being a model of ethical behavior.

**Author disclosure:** The author notes that she is the author of the self-study module Essential Ethics for Medical Communicators, which is mentioned in Figure 2, and receives royalties.

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**References**

The Physician Payment Sunshine Act (Sunshine Act) was passed in 2010 by the US Congress as part of the Patient Protection and Affordable Care Act (PPACA; known more commonly as the Affordable Care Act) of 2009. The Sunshine Act contains important changes to the law that may affect how medical publication professionals conduct business. The areas that may be affected include the following:

- Relationships with clinical trial investigators and authors
- Scope of information to be tracked, recorded, and managed
- Compliance regulations

The Sunshine Act arose out of activities related to enforcement of the US federal anti-kickback statute involving financial relationships between health care industry (pharmaceutical, biologic, and device) companies and health care providers. Its passage reflects the ever-increasing trend toward requirement of greater transparency in industry-physician interactions. The Sunshine Act is based on the belief that if financial relationships between industry and physicians are made publicly available, not only would this aid government enforcement, but it would also help to curb such activities.

On December 14, 2011, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule interpreting the Sunshine Act. In the proposed regulations, CMS sought to clarify parts of the Sunshine Act that were ambiguous or unclear in the statutory language itself. In addition, CMS provided instructions for companies attempting to comply with the Sunshine Act’s reporting requirements.

The Sunshine Act requires “any applicable manufacturer that provides a payment or other transfer of value to report certain information to the Center for Medicare and Medicaid Services (CMS), part of the US Department of Health and Human Services (DHHS), regarding those payments and other transfers of value.”

With the initial report to be filed by March 31, 2013, the initial collection period for the reporting is expected to begin sometime in 2012, with the exact date for initiation of data collection dependent on when the final regulations are issued. The information is expected to be made publicly available starting September 30, 2013.

**WHAT IS THE PHYSICIAN PAYMENT SUNSHINE ACT?**

As noted, the Sunshine Act is a section within the PPACA that requires reporting of all financial transactions and transfers of value between manufacturers of pharmaceutical/biologic products or medical devices and physicians, hospitals, and covered recipients (Table 1). The Sunshine Act applies to all companies that manufacture products that are reimbursed by the US federal government; however, in considering how and what to report, it may be prudent to track information on products that are not currently reimbursed, as they may become so in the future. This precaution will alleviate the need to reconstruct the past, should the product become eligible for federal reimbursement.

**WHAT ARE THE REPORTING REQUIREMENTS?**

Reporting is required to begin March 31, 2013, for information collected in 2012, and will continue for each full calendar year thereafter. The Sunshine Act requires CMS to establish a Web site to host the aggregated information in a publicly available, electronic, searchable database; the reported data must be clear, understandable, eas-

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**Table 1. Who Is—and Isn’t—Covered Under the Sunshine Act**

<table>
<thead>
<tr>
<th>Applicable manufacturers</th>
<th>Any company “engaged in the production, preparation, propagation, compounding or conversion” of a “drug, device, biological, or medical supply” for which payment is available under Medicare, Medicaid, or a state children’s health insurance program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covered recipients</td>
<td>Physicians and teaching hospitals, except physicians who are employees of the manufacturer Any entity that receives monies from a manufacturer at the request of a covered recipient; eg, grant request to institution or contribution to charity</td>
</tr>
<tr>
<td>Not included</td>
<td>Health care professionals who hold degrees and licenses and provide clinical services other than MDs and DOs, such as PhDs, RNs, LPNs, PAs</td>
</tr>
</tbody>
</table>
ily aggregated, and downloadable. In addition to financial information, the database will also include background on relationship(s) between manufacturers and physicians; information about physicians' ownership interest or investment relationships with the manufacturer, not only for the physician but also for immediate family (eg, spouse, child, sibling); and any enforcement actions that have been taken for noncompliance. The database will be administered by CMS.

Several minimum reporting requirements and exclusions are covered in the Sunshine Act (Table 2). The Proposed Regulations require that manufacturers report the following for each transfer of value:

1. **Covered recipient's name, address, and national provider identifiers**

2. **Amount of payment or transfer of value**

3. **Date of payment**

   For payments made over multiple dates, such as a consulting agreement, manufacturers may report the total payment on the first date or may use separate line items for each payment.

4. **Associated covered drug, device, biologic, or medical supply**

   If the payment is reasonably associated with one drug or device, it must be reported.

5. **Form of payment**

   Manufacturers must select one of the following: Cash/Cash Equivalent, In-Kind Items or Services, Stocks/Stock Options/Ownership/Dividends/ROIs, Other

6. **Nature of payment**

   Manufacturers must select one of the following: Consulting Fees, Compensation for Services other than Consulting, Honoraria, Gift, Entertainment, Food, Travel (including destinations), Education, Research, Charitable Contribution, Royalty or License, Ownership/Investment Interest, Compensation for Faculty or Speaker at Medical Education Event, Grant, Other

 CMS clarified that manufacturers must report a single form of payment and nature of payment for each transfer of value made. For example, if a physician received meals and travel in association with a consulting fee, CMS will require that each segregable payment is reported separately in the appropriate category. The applicable manufacturer would have to report three separate line items: one for consulting fees, one for meals, and one for travel. The amount of the payment would be based on the amount of the consulting fee and the payments for the meals and travel. For these lump-sum payments or other transfers of value, CMS clarified that the applicable manufacturer must break out the disparate aspects of the payment that fall into multiple categories for both form of payment and nature of payment.

The area of most concern for members of the medical publication profession is the lack of definition of “transfer of value” in bullet point 2. Although not specifically listed, fully disclosed medical writing and editorial support provided by an “applicable manufacturer” (eg, pharmaceutical company) to an MD or DO is considered transfer of value. If as expected, an applicable manufacturer pays medical publication professionals acting as its agent to provide support to MDs or DOs, the value of those services is a “transfer of value” to the MD or DO. Accordingly, we anticipate that medical writers and publications and communications companies will need to provide data to their clients for reporting. This will also apply to manufacturers with staff who perform these functions.

As we have experienced with the passage of other acts that affect the medical publication profession,
requirements may be refined or modified as details of the implementation are further delineated.

Failure to comply with the Sunshine Act is not without penalty. Manufacturers who fail to comply will be fined $1,000-$100,000 per missing payment, depending on the circumstances. Fines will be capped at $1,000,000 per company per year.1

**HOW DOES THE SUNSHINE ACT RELATE TO STATE LAWS ON TRANSPARENCY IN INDUSTRY-MEDICAL WRITE RELATIONS?**

Details on individual state laws that mandate disclosure of industry-physician relationships, from disclosing specific information to bans on certain types of activities, are beyond the scope of this article. Of note, however, is that the Sunshine Act preempts state laws only if they are less restrictive than the Sunshine Act; state laws that are more restrictive may still require “applicable manufacturers” to provide additional information not included in the Sunshine Act.

**HOW WILL FAIR MARKET VALUE OF PROFESSIONAL MEDICAL WRITING AND PUBLICATIONS SUPPORT BE DETERMINED?**

The most critical question for all medical publication professionals is how to determine the value of the medical writing support to authors; how do we determine the financial worth of that transfer of value? How do we determine the value to each author on articles with multiple authors, some of whom may be sponsor-authors? As this is charting new territory, there are currently no hard and fast, standardized, financial models available to medical publication professionals.

In attempting to answer these questions, it is important to consider independent objective market data. Some organizations may decide to look to outside valuation consultants for data gathering and/or formal valuation opinion. Professional societies may also provide support. For example, the International Society for Medical Publication Professionals has convened a Sunshine Act Task Force to undertake research and provide guidance to their membership.

Medical writers and medical publication companies should work with their clients to identify needs and develop reporting systems that will capture the data required by manufacturers. Each manufacturer must independently determine fair market value, and the ideal would be to develop a standardized approach for such determination. The bottom line is that medical publication professionals must develop a reasonable way to value the medical writing and publications support provided to physicians that is justifiable and based on objective data.

**Note:** See page 24 for information about the effect of the Sunshine Act on continuing medical education.

**Author disclosure:** The authors note that they have no commercial associations that may pose a conflict of interest in relation to this article.

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**References**

Before I begin, I would like to thank the Swanberg Committee members who saw just cause to present this prestigious award to me. I am humbled and honored. When Sue Hudson called me in April to inform me of the award, I was almost unable to speak. Those who know me know that I am hardly ever at a loss for words. I would also like to thank my AMWA colleagues and clients who have given me so much over the years. A special thank you goes to the Delaware Valley Chapter (DVC), which started me off on this great adventure, especially to Dear Edie who has been a friend and mentor for over 30 years. Finally, I would like to thank my husband and business partner, Richard Bell Smith, who, along with AMWA, taught me everything I have learned about medical communication.

I became a medical writer by marrying into it. My previous career was with airlines and travel agencies. In fact, I met Richard when he bought an airline ticket from me. We began our company in 1979 writing for both medical and nonmedical clients and corporations. At that time, we were located in the Philadelphia suburbs.

I joined AMWA and the DVC in 1980. My first assignment was Chapter Membership Co-chair. I worked my way through the various committees and offices, serving as Chapter President in 1988–1989. We held the first chapter all-day meeting in New Jersey that year. Max Losi, then the national AMWA President, had a regulatory meeting set up with speakers on board to be hosted in Princeton by Ciba, who would cover all expenses. The New York Chapter didn’t want to run the meeting, so he called me. What a gift! It was a sold-out affair, and we made lots of money. When Lillian Sablack, AMWA Executive Director, heard about it, she called and reminded me that since we were a nonprofit arm of AMWA we couldn’t keep it in our treasury. I told her we would spend most of it on the annual conference, to be held that year in Philadelphia. With the approval of our Chapter Board of Directors, Joyce Boyland, who was Chapter Liaison to the Annual Conference, proposed that we offer attendees free Philadelphia soft pretzels in the hospitality room for the entire conference. She also contracted with a Philadelphia Mummers’ Club to play and “strut us” all into the Membership Dinner the first evening. Folks are still talking about them. It was, to the best of my knowledge, the first time a chapter had sponsored an activity at the annual conference.

AMWA NATIONAL SERVICE
I began my service to the national organization as DVC delegate and was later appointed as Audiovisual Section Chair (when we had distinct sections). Richard and I co-wrote and co-presented Scriptwriting for Film and Video, a core course for many years. Over the years, I taught Business Aspects of a Freelance Career, (developed by Past President Cathryn Evans) and an offshoot, Is Freelancing Right for You?, for both many national and regional conferences. During a Houston regional conference, the hotel manager assumed Past President Howard Smith and I were married (two Smiths from Virginia) and tried to room us together. Thus, we refer to each other each time we are together as “Smith-no relation” and others in AMWA have picked it up as well.

I moved up to Section Coordinator, and served as the national AMWA Secretary. I was awarded an AMWA

2011 Swanberg Address

AMWA AND MEDICAL COMMUNICATION:
THE GOOD, THE BAD, AND THE UGLY*

By Elizabeth L. Smith
President and Co-owner, Smith Simon Company, Lyndhurst, VA

*Delivered at the AMWA Annual Conference, Jacksonville, FL, October 21, 2011.
Fellowship in 1988 and elected President in 1991. One of my proudest accomplishments is that four of my new Executive Committee (EC) appointees went on to become AMWA Presidents—Joel Tau, John Ferguson, Art Gertel, and MaryAnn Foote. Throughout the years, I worked with some great folks and together we had great adventures, volunteering for AMWA at the national level. I taught Michelle Vivorito how to make a “snow angel” outside the Arlington Hyatt Hotel during her first-ever snowfall! There we were, lying on the snow-covered grass in front of the hotel dressed in business suits, swinging our arms and legs to become angels, as my entire EC looked on and cheered! Our cab driver admonished us when we stuck out our tongues to taste the snow!


Immediately after my installation as AMWA President in November, 1991 at the annual conference in Toronto (with Prince Charles and the late Princess Di in the hotel), Bob Orsetti, a former AMWA President, said the fateful words that defined my presidency, “We have a problem, Elizabeth.” The US Food and Drug Administration (FDA) had drafted a proposed concept paper that would effectively restrict the role of medical writers in the writing and disseminating of scientific information. I immediately went to Lillian Sablack to say we were going to respond. She said, “We can’t”; I said, “We must and we will.” After several other members and I explained that the livelihood of most of our then members would be impacted negatively if this proposal were to be approved, she agreed. I established the AMWA Task Force on Medical Writing, composed of active members within the pharmaceutical industry: MaryAnn Foote, PhD (Amgen), Harriet Layne, PhD (Lederle), Sandra Purrenhage (Ciba-Geigy), and Bob Orsetti, ex officio member (Ciba-Geigy); in journal publications: Jean Dolan (Excerpta Medica); and within the medical field: the late Jane E. Hodgson, MD, a gynecologist who was renowned for her activities in federal legislation, especially during the Rowe vs Wade deliberations.

In November 1991, we wrote a letter to the FDA urging them to “recognize the professional contributions of medical writers and rescind the proposed prohibitions.” We received a form letter saying, “thank you for your comment”; nothing more. Bob Orsetti was part of an industry task force at the same time and kept us in the loop. Because the FDA was still adamant to advance its proposal, we invited FDA members to participate at the annual conference (FDA) attendees. I showed the most complicated graphic slide from a CME project I could find and fought for the role of medical writers’ involvement in CME by saying, “We cannot go back to the days of a brilliant scientist, researcher, or clinician standing in front of peers rambling on for 20 minutes with an incomprehensible slide on the screen. It is of no benefit to the presenter, the audience or, ultimately, patients.” I received a round of spontaneous applause for that statement and was subsequently invited by Dennis Wentz, MD, then Director of CME at the AMA, to join the Task Force. I eventually served as co-chair of enduring materials deliberations. I served on the Task Force as the AMWA representative until 2001, at which time I felt we

**Any job that can bring frustration, challenge, stimulation, and misery—all at the same time—has to be the best job in the world!**
had accomplished our goals for medical writers. Most important, no formal action on the original concept paper was taken by the FDA. It died a natural death. I fully believe that AMWA’s commitment helped in that decision.

THEN AND NOW
The years between 1992 and 2006 were heady years for medical communication and medical writers and editors. However, recently, the controversies have all come back to haunt us! The ghostwriting issue has resurfaced with a vengeance. The role of professional medical writers and editors is again in question. Other issues impacting our careers are the controversies about industry funding for key opinion leaders, activities at medical meetings, meals and gifts to physicians, pharma representatives’ activities in presenting product information in medical offices and hospitals, and other issues. Firewalls have been established between educational and promotional activities, thereby limiting industry subcontractors and their writers from doing both types of writing.

AMWA is our professional association and needs to continue to speak out for us and to have our support. Past President Cindy Hamilton, along with Mary Royer, took the initiative and several later presidents have been extremely active and vocal in carrying the torch forward. We need to be vigilant professionals in our careers.

A CAREER IN MEDICAL COMMUNICATION
We began our company in 1979 with paper, pens, and a manual and an electric typewriter. Back then, no changes were made to a draft by clients unless it was absolutely necessary, since they knew the entire page would have to be re-keystroked. We bartered with an industrial client for an electronic typewriter which “stored in memory” up to 20 different phrases and released them by the push of a code button! I was writing a six-module sales training program at the time for McNeil Pharmaceuticals. The director of Sales Training said, “Elizabeth, this is great program, except the disease name, ankylosing spondylitis, is misspelled throughout.” Guess what was put in memory. Luckily, I had enough letters in the misspelling to be able to use correction fluid and insert the correct spelling, about 150 times.

We then upgraded to a totally dedicated word processor and a Diablo® printer. The system was noisy, large, and state-of-the-art but very expensive. Ten years later, when we moved our company to rural Virginia, there was no Internet and no e-mail, and one computer was shared between us! Various computers, printers, and software programs later, we are still upgrading.

LESSONS LEARNED
In my 30-plus years as a medical writer I have learned many lessons. Though they mostly apply to freelance writers, others can identify with several issues raised.

Lesson 1: Diversify Your Client Base
Freelance writers need to fully realize that working on six different products and for eight different clients/departments within one pharmaceutical company is NOT a diversified business. Plus, today it would be an Internal Revenue Service (IRS) red flag. We were heavily involved with McNeil Pharmaceuticals in our early years. We worked with six different product managers plus the medical affairs department, international division, medical meetings, corporate communications, public relations, and sales training departments. We even had photo ID badges that enabled us to access all areas of the building except the clinical laboratories. Then the Tylenol® poisonings occurred. Instantly, all budgets for all products across the board were cut dramatically. We scrambled long and hard to replace the lost revenue.

Our solution was to develop a mixed client base among pharmaceutical companies, medical associations, medical publishers, and medical education, advertising, and communication companies.

Lesson 2: Be a Specialist or Generalist?
Each medical writer or editor has several decisions to make that will affect his or her career. Do you want to be a writer or editor, or take on all aspects of the project? We realized after taking on two or three large projects where we hired writers, editors, photographers, typesetters, printers, etc and coordinated and managed all aspects of their activities plus our own, that we preferred to stay doing what we did best; that is, write. The ability to earn more by taking on all aspects of a project is well known, but your own personality and preferences must come first.

Some writers specialize in one disease state while others, like us, work in...
many. We are experienced in all disease states except ophthalmology and that’s only because we haven’t had a client in that area of medicine.

Along the same lines, writers or editors need to decide if they will do only one type of writing (eg, regulatory) or take on several different types of projects (ie, CME, sales training, patient education, journal supplements, medical advisory boards, etc). We do the latter because the mix of project types appeals to our personalities and contributes to our diversified client base.

**Lesson 3: Do the Projects YOU Want to Do**

This is often a hard lesson for newly established freelance medical writers to absorb. Economic necessity can lead you to accept projects you are not entirely happy with. But, once you commit, follow through. As you become established, you should be able to dodge projects that seem to be more trouble than they are worth. Our tag line for 32 years has been “On time, on budget, and most importantly, on target.” Maintaining that motto has, on occasion, required long hours and frustration.

Sometimes, do something for others that you enjoy, regardless of monetary compensation. Larry Liberti, a fellow DVC member, was talking about his young son with Down syndrome and mentioned the fact that, with a very small budget, the parent support group wanted to do two videos to educate children and adults about the disorder. I met with them and together we developed two scripts. Using family photos, photographs from a day care center, and artwork an artist friend developed, we produced two wonderful educational programs. During the AMWA annual conference in Jacksonville, Larry and I spoke about that project completed 25 years ago and how much it meant to the families involved.

The best advice I can give is “follow your gut!” In all you undertake, if it doesn’t feel right, don’t do it.

**Lesson 4: Evaluate Your Business Yearly**

In June 2011, an article on organizing a freelance career was published in the *AMWA Journal*; the article was based on an open session given in Milwaukee in 2010. In both the session and the article, I outlined various strategies to accomplish a yearly evaluation. Questions to ask yourself include “Are you where you want to be money-wise?”, “Do you enjoy your project mix?”, “Are you happy in your professional life?”, “Where do you want to be in 2, 5, or 10 years?”, and “How do you get there?” You alone can answer these questions.

Two other related questions deserve close attention as well. “Do you enjoy your client mix?” Remember the 80/20 Rule: 80% of your projects will come from 20% of your contacts. This will fluctuate over time with some clients replacing others, so stay alert and be in contact with the most likely clients more often. You need to remember that some clients just don’t get it! Which leads to another question to ask: “Do you need to redefine some clients?” As Brian Bass says, “Fire one client a year.” I add, “And, replace him or her with another client whose personality, business practices, project mix, and commitment you respect.”

**AMWA AND YOUR CAREER**

In our experience, more than 80% of our business has come to us through AMWA colleagues. This business is not always received directly but comes from contacts, working relationships, referrals, and the like. For many years, I worked with Past AMWA President Joel Tau at Zeneca Pharmaceuticals, both onsite and offsite. He introduced me to several folks for whom I also did freelance work. In some instances, we collaborated with others. I am still working with two of those folks these many years later. One in particular introduced me to another with whom I have worked for 10 years. She, in turn, had recommended me to several other colleagues—two of whom I have had a steady relationship with for about 6 years. All of these clients I can trace back, like a family genealogy research project, to my business and personal relationship with Joel.

Over the lifetime of a career, many clients will move from one company to another, especially with mergers and acquisitions. Your goal should be to move with them while continuing to work for their replacements.

One way to succeed in your career, freelance or not, is to be active in your local AMWA chapter. Volunteer to serve on committees, run for office, or help with a program.

To get your name out there, write articles for the *AMWA Journal* and participate in the various listserves. Attend every AMWA conference, even if you must save all year to pay for it. Volunteer to do a breakfast roundtable, design and teach a workshop, or serve on an open-session panel. Remember to talk with everyone in classes and in the hospitality room. You never know whom you will meet who can advance your career.

**CLOSING STATEMENTS**

It has been a wonderful ride since 1979 when Richard and I started our company and I began my years as a professional medical writer. It has, indeed, been good, bad and, at times, downright ugly. I wouldn’t change anything that has happened along the way because then I might not be standing here today accepting this wonderful honor. From the bottom of my heart, thank you to everyone who made this ride possible. You know who you are. I love you all. And, I love AMWA.
Discover

GOLDEN OPPORTUNITIES in Sacramento!

By Brian Bass • 2012 Annual Conference Coordinator

EUREKA! There's so much to discover at the AMWA 72nd Annual Conference—about yourself, your career, and the field of medical communications—that come October 4-6, 2012, Sacramento is the place you’ll want to be! As Administrator of the Annual Conference, I am especially excited to report about the enhancements we're making to this year's conference in response to the comments and feedback we've received from so many active and engaged members and past conference attendees.

NEW NETWORKING OPPORTUNITIES

In Sacramento, AMWA will introduce two new networking opportunities for all annual conference attendees. The first is a Networking Luncheon that will be free to all conference registrants on Thursday afternoon, October 4. We envision this to be a great opportunity for people who don’t usually attend luncheon events to mix business with pleasure in an open, but structured, networking environment. We're currently working out the details of how this event will be organized, and we recently put a call out to all members to give us their input by answering the following question: “If you could walk into a room and connect with a group of like-minded people on a particular professional topic, what would it be?” If you haven't already responded to this question, I invite you to send an e-mail right away to becky@amwa.org.

The second new networking opportunity being introduced in Sacramento is a Networking Reception on Thursday evening. This early-evening event, which will also be open to all conference registrants without additional charge, will be held after the close of the day’s workshops and sessions and will end in time for attendees to explore the many excellent restaurants available within walking distance or a short cab ride of the conference center and hotels.

WELCOME BACK THE WORKSHOP LEADERS’ EVENT

For many years, AMWA hosted a special luncheon as a way to thank the many volunteer workshop leaders who give so generously of their time, talent, and expertise to make the annual conference such a valuable educational experience. The luncheon also served as a great opportunity for workshop leaders to network with each other and provide feedback to the Workshop, Education, and Annual Conference committees. This year, we're bringing back the Workshop Leaders’ event as a breakfast, and workshop leaders will receive an invitation to attend the event. If you're interested in becoming a workshop leader, we're working to make the process easier to navigate and you'll hear more about that soon.

FREE LUNCH

We've all heard there's no such thing as a free lunch. Yet, this year in Sacramento, we're giving conference attendees just that! On Saturday, October 6, we're combining the annual Business Meeting, which used to be held on Friday afternoon, with a special kick-off celebration for the 2013 Annual Conference. We would love to see everyone who has registered for the annual conference make this luncheon a part of their conference experience—so come enjoy the camaraderie and great food!

RAISED LIMITS ON CREDIT AND ADVANCED WORKSHOPS

Anyone who has taken a credit or advanced workshop knows the pre-workshop homework can be a rigorous task. For this reason, AMWA has traditionally limited the number of credit workshops someone can take at the annual conference to three, and limited the number of advanced workshops to two. In response to feedback from past conference attendees, starting in Sacramento the number of credit workshops you can take has been increased to four and the number of advanced workshops you can take has been increased to three. This will help those who are enrolled in the certificate program get closer to their certificate goals at a single annual conference.

If you've been to more than one annual conference you know that somehow, as incredible as each conference experience is, the next one is even better. That's because every Administrator of the Annual Conference builds on the knowledge of his or her predecessors and learns from the feedback of conference attendees. As this year's Administrator, I'm excited about the enhancements we're making and the richness this will bring to the annual conference experience. I hope every AMWA member will join us in Sacramento to discover their own EUREKA! moment.
Ethics in Regulatory Writing

By Peggy Boe, RN, a and Barbara Snyder, MA b

 a Medical Writer, Research Pharmaceutical Sciences, Inc. (RPS), Wilmington, NC, and
 b Director, Medical Writing, Warner Chilcott, LLC, Rockaway, NJ

Regulatory writers are often faced with ethical situations, though we may not always recognize them as such. The way we define ethical behavior in general is based on our personal upbringing, religious beliefs, culture, and environment. Ethical behavior in the workplace is further defined by our employers, professional organizations, and in some cases, even the government.

Good Clinical Practice…and Beyond

Regulatory writing supports pharmaceutical research from start to finish, with ethical guidance for clinical (human) research stemming from Good Clinical Practice (GCP) guidelines. 1 Medical writers who plan to write clinical study documents (eg, protocols, informed consents, study reports, and Investigator Brochures) should first be trained in GCPs, which clearly outline patients’ rights and the obligations of investigators and sponsors when conducting research on humans. Violating ethical principles of clinical research is wrong; besides being against the law, such violations can endanger large populations through misrepresentation of the potential risks and benefits of a product.

Some medical writers think that only the individuals actually conducting a clinical study need to have a good understanding of GCPs. Think again. Familiarity with the ethical boundaries of human research is necessary so the medical writer will recognize, for instance, subtle yet problematic phrases in a protocol that could possibly jeopardize subjects and/or render results that are biased, inaccurate, or based on chance alone (unrepeatable). It is the writer’s responsibility to make sure that both expected and prohibited study procedures are adequately defined in the study protocol; just one word can make a difference. Consider, for example, the phrase “chronic use of NSAIDs is prohibited.” A simple undefined word—“chronic”—could lead to spurious data. Ambiguous or missing definitions provide an open invitation to deviate from or violate the protocol. Cases where protocols have been violated intentionally are well documented, 2, 3 and part of our job as regulatory writers is to do our best to close those windows of opportunity with a well-written protocol that leaves very little to chance or interpretation. Writers should also be on the lookout for attempts to add study procedures to a protocol or to add specimen collections that are not warranted by the study objectives, whether intentional or unintentional. Every study method and procedure included should contribute to fulfilling the study objectives. Exploratory tests should have a solid scientific rationale, particularly if they include an invasive procedure or extra specimen collection. Nothing should be done to or taken from a subject without making sure that the subject understands and consents. Bottom line, what the protocol does not say can be as important as what it does say.

After the study is completed and the data are analyzed, medical writers commonly write the clinical study report and may also write submission summaries. By the time the database is locked, writers assume that any problems with the data have been resolved, and writing the report should be fairly straightforward. So what ethical situations could the medical writer possibly encounter at this point? For the answer to that, let’s consider what an expert has to say. Stan Woollen, former Associate Director for Bioresearch Monitoring at FDA’s Office for GCPs and current Senior Compliance Advisor at Stan Woolen and Associates, developed a “Misconduct Scale” to gauge three levels of noncompliance. 4

• Ignorance: Noncompliance based on lack of understanding the regulatory consequences of an action. The act itself is usually intentional, but the noncompliance is unintentional, ie, not usually done to deliberately deceive. A clinical example might include backdating the subject’s signature on a consent form because the subject forgot to date the form originally. 4 Medical writing examples might include failing to identify and correct ambiguous terminology, definitions, or methods, or presenting descriptions of study methods or procedures that are contrary to GCPs.

• Surprising Sloppiness: Noncompliance due to inaction, inattention to detail, inadequate staff, or lack of supervision. The act itself may be intentional or unintentional; the noncompliance is unintentional and usually repeated. A clinical example might include inadvertently failing to obtain informed consent signatures relative to an amendment. 4 Medical writing examples of this might include creating a new protocol from a template without making sure all the text applies to the new study; assuming that the statistician will inform the writer when/if
new tables, listings, or figures are rerun after the originals were delivered for drafting the study report; or accepting content from others without verifying accuracy.

- **Malicious Malfeasance:** Usually noncompliance due to deliberate action to deceive or mislead involves “falsification,” which can include creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred. Falsification of data related to a clinical study can place all subjects in that study at possible safety risk and jeopardize the reliability of submitted and/or published data. Falsification is a serious offense and can lead to criminal prosecution in addition to FDA actions ranging from warning letters to restriction (or disqualification) of an individual or company from participating in the conduct of clinical studies or even permanent debarment. A clinical example might include creating data that were never obtained, or substituting, altering, or omitting actual data. Medical writing examples might include: purposely reporting questionable data in a way that the interpretation is misleadingly positive, making unsubstantiated claims, or purposely avoiding discussion of questionable or negative data altogether.

### Making the RIGHT Decision

AMWA encourages ethical thinking with the AMWA Code of Ethics and the requirement that each specialty certificate includes an ethics workshop. For the Regulatory and Research certificate, AMWA members can choose between two different workshops to fulfill the requirement. Ideally, members will choose to take both (the second as an elective credit), because the two workshops cover different aspects of ethics that are important in the realm of regulatory writing.

Cindy Hamilton’s article in this issue of the AMWA Journal presents the “RIGHT Model,” a tool developed for the ethics workshops that anyone can use to facilitate ethical decision-making (see page 3). There are, of course, several resources readily searchable on the Internet, including books and articles on the subject of ethics. The AMWA ethics workshop leaders particularly like The Elements of Ethics for Professionals, in which the authors present 75 different elements of ethics under 11 categories of behavior: taking the high ground (integrity), doing no harm, according dignity (respect), benefiting others, exercising caution, caring for others, seeking fairness, promoting autonomy, being faithful, delivering your best, and making ethical decisions (sound judgment).

As human beings, we know that no one is perfect, and sometimes we are under pressure to “look the other way” or behave unethically. Subject matter experts working with the writer may encourage the writer to use inflated positive language and avoid any hints of negative results instead of simply reporting the facts. If the writer objects, “encourage-ment” may turn to patronizing finger-pointing or even bullying, leaving the writer with hard choices to make (ignore? report to senior management? resign?). But here, especially, is where the writer needs to stand firm in creating objective, accurate, and complete documents. When that time comes, remind yourself that you are a professional, and do your best to make the right decision.

**Author disclosure:** The authors note that they have no commercial associations that may pose a conflict of interest in relation to this article.

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### References


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**ERRATUM**

In the article “Do Your Nouns Have Anything to Do with Your Verbs?” typographical errors occurred on page 175.

The examples given for causative verbs should be as follows: The emetic caused him to vomit.

The emetic made him vomit.
Dealing with Ethical Situations

Q: When is it time to run away from a client who is not behaving ethically? What do I do when I learn that my client is engaging in unethical practices?

A: The short answer: as soon as you realize your own personal code of ethics is being violated irrevocably. However, in truth these situations are rarely so simple. First, what do we mean by “not behaving ethically”? Is the client hiding data from FDA reports or published articles on clinical studies? Knowingly plagiarizing or using another’s material without permission and/or attribution? Giving a byline to “authors” who had little or nothing to do with planning and creating the manuscript? Hiding financial relationships? Not paying you for your work in a timely manner? Violating confidentiality or noncompete agreements?

Communication is the first step: it is essential to discuss your observations with the client before passing judgment or burning a bridge forever. Be sure you are correct; i.e., that the person is indeed consciously doing something unethical! Possibly he or she is simply unaware. It is part of our role as consultants to point out possible errors and discuss ways to remedy the situation. I have found most often that the person has made this mistake without quite realizing it; once I bring it to his/her attention, she or he will make appropriate changes. If the client refuses to make the change, then you need to decide how to proceed. It is a personal decision. Do you tell the client you do not want to work with the company anymore because of unethical behaviors? Do you report him/her to a higher authority? Do you complete the project but insert clear notes pointing out the problems and leave it to them to do the right thing? Or do you just quietly quit without saying anything (other than you have other pressing commitments, or suddenly have an illness that requires you to take a long leave, etc)?

A: Obviously, this situation is very tricky, and it may be prudent in some cases to consult a lawyer. It is important and helpful to document what you are finding and feeling in a notebook. If there is an opportunity to do so, you could question your client’s practices in a nonthreatening way, and an e-mail note may be a good way to do this, but keep in mind this may eventually be part of a chain of evidence. Do not put anything in an e-mail note that you would not want someone specific or anyone in general to know about and certainly if you do not have real proof of wrongdoing. (I hate to say it, but imagine you may have to testify someday—let that guide whatever you write down in your notebook or in an e-mail note.) It could be hard to walk (or run!) away, depending on your contractual obligations. You will also have to be prepared to forfeit payment if you do walk away. However, it is better to stand on your principles or at least listen to your gut!

Many years ago, I was contracted to write a manuscript on a study that had a very questionable design that I felt should not be ignored in a discussion of the limitations of the study and its conclusions. After several attempts to discuss this in conference calls, I was abruptly removed from the project (which was fine by me!). About 2 years after that, someone associated with that project (who was now at a new company) called me for a new job because she remembered what I did and said and had agreed with me and respected my standing ground!

— Sherri Bowen

A: If a client is behaving unethically, is aware of this, and persists in the unethical behavior, it is time to run away. First, though, you need to tactfully and clearly explain why this behavior is unethical. The client may not know that the behavior is unethical or can be persuaded to stop when presented with the facts. If the client persists in the unethical behavior once you have done this, it is time to run away; that is, fire that client. Continuing to work with an unethical client can only damage your reputation, cause you aggravation, and possibly lead to legal issues. I once had a client who wanted me to include only the benefits you aggravation, and possibly lead to legal issues. I once had a client who wanted me to include only the benefits and leave out the risks of participating in clinical trials in a newsletter for people with cancer. This is clearly unethical. I explained this to the client, who was a physician, and cited the required elements of informed consent described in the Code of Federal Regulations (21 CFR 50.25). The client still insisted on including only the benefits. I documented this conversation. In the article I turned in, I included both the risks and benefits, with a comment about why both were necessary. And then, I fired the client.

If you are legally committed to finishing a job with an unethical client, be sure to put your explanation of the unethical behavior to the client in writing (e.g., in an e-mail note) and document your attempts to resolve the problem in phone calls and e-mail messages. Keep a copy of this documentation. When you have finished the job, run to the land of ethical clients.

— Lori De Milto
A – My short answer: as soon as you realize the unethical actions. However, you must determine if the unethical behavior stems from lack of knowledge of the rules or is something that came down from a higher authority. Years ago, I was working on a pharmacy program with a young, new product manager who had been a highly recognized pharmaceutical representative. Once promoted to corporate headquarters, he was looking to make a name for himself. He wanted to sponsor a multihospital program that only discussed his company’s product and ignored the competition. When I explained “fair balance” to him, he then decided he wanted to use his product’s branded name and refer to the competition only by the drugs’ generic names. After I told him that only generic names for all products were permitted, he told me that the product’s advertising agency representative had suggested the scenarios and he thought they were valid and legal. Needless to say, the advertising agency is no longer in business and he has become a valued client.

In brief, try to determine if the client is truly “in the know” to all the rules and regulations and take the time to educate him or her. If the client persists in an unethical manner, run away as fast as you can. Follow your gut. It is better to lose a project or a client than to compromise your own ethics. If you are not sure of the ethics involved, pose the question to one of us on this panel or go to the AMWA freelance business listserv folks.

— Elizabeth L. Smith

Q – Much of my work has been done for the pharmaceutical industry, and confidentiality does not allow me to use that work as samples. What’s your advice on showing samples?

A – Although I do not write in the regulatory environment, I do write a lot of materials that are confidential, including sales training materials, executive summaries of internal and expert advisors meetings, and other internal documents. It can be a real challenge when I am speaking with a potential new client who wants to see for himself/herself what I have done in one of these areas.

To overcome the problem, I have found it very effective to diffuse the situation by explaining that I am ethically bound to not show confidential information even if it is detrimental to the growth of my business to do so, and that I will respect the potential new client’s confidentiality with equal fervor. Then, and this is the best part, I acknowledge this makes it difficult for the person to assess whether or not to work with me, and I offer the names and telephone numbers of several of my clients who can independently tell the person about their experience with me on these types of projects.

Not only does this give the person I am interviewing with a way to verify my abilities, but it does so with an air of personal recommendation. It also strokes my current clients’ egos by acknowledging how much I think of them, and everyone likes to be on the delivery end of a great recommendation.

— Brian Bass

A – I never show samples. I have a list of my projects (with all protocol titles redacted) that I show to clients, and if they need further proof that I know what I am doing, I give them a list of references they can contact about my job performance. In my experience, people who ask for samples more likely don’t know how to put together such a document and are looking for a way to do it themselves based on your work—they are not looking for proof of your writing abilities!

— Sherri Bowen
Q – *How do I handle assignments for conflicting brands from my clients?*

A – Every so often, I will get a call from a client to work on a project in a therapeutic area in which I am already working for another client. With the amount of competition out there in the pharmaceutical marketplace, it is actually surprising this situation does not arise more often. I have to keep an especially close eye on this because I use a subcontracting business model, so it is not just me working on assignments that could conflict with new work coming in.

Most often, the potential for conflict crops up when a therapeutic area is hot with new drug development and competitors are fighting to be the first to get the word out, communicate their science, and train their sales representatives. When conflict does arise, my only recourse (and the only ethical thing to do) is to turn the conflicting work down. I do not like to turn any work down, but there is really no option here. So I do my best to turn the situation into a marketing opportunity.

I explain to the client with the conflicting project that I (or my team) is already working on a project in the therapeutic area for a competing product, adding that, as they can see, we have current relevant experience should the need arise again. Then I offer to help the client find a suitable alternate writer for the project using my AMWA connections. This way, although I cannot be the solution, I can still be a part of the solution. I make it a point to tell the client how disappointed I am that I cannot help them this time, and stress that when I am working on a project for them, these ethical standards protect them and their clients as well.

Yes, I am pulling a small victory from the jaws of defeat. But it is a victory I am happy to win because it strengthens my reputation and my partnership with my clients.

— **Brian Bass**

Q – *Last month, I wrote sales training materials for a new drug. This month, a different client wants me to write CME materials for the same drug. What do I do?*

A – Switching between promotional and CME writing is a no-no. The Code of Conduct of the National Association of Medical Education Companies (NAMEC) ([www.namec-assn.org/conduct](http://www.namec-assn.org/conduct)) specifically states “Staff and/or freelancers who control content for promotional education should wait an appropriate length of time (eg, a ‘washout’ period of 6 to 12 months) before working on educational content in the same therapeutic area. Accredited providers should verify this ‘washout’ for staff who control content.”

Arguably, this may be an infringement of freelancers’ right to fair trade. But given the potential ethical issues that could arise when a writer switches gears between promotional and CME work in the same therapeutic area, some washout period seems both reasonable and advisable. Note that the wash-out period does not apply to writers moving from CME writing to promotional writing.

I do a lot of CME writing, and I come from a promotional writing background, so I also do a fair amount of branded writing during the course of any given year (including advertising and sales training). I may just be lucky that, to date, I have not encountered a conflict. But if and when I do, just as I do not hesitate to decline work on conflicting brands, I would not hesitate to inform my client that I am, or have recently been involved in promotional work in the same therapeutic area. The washout period stated in the NAMEC Code of Ethics is a range, so I would work with the client to determine what a suitable washout period is, then if this precludes me from working on the CME project, I would respectfully decline, help the client find a suitable alternate writer, and try to use the situation as a marketing opportunity to promote my commitment to high ethical standards.

— **Brian Bass**
Point-Counterpoint: Industry Sponsorship of CME

Introduction to the Debate
By Johanna Lackner Marx, MPH, MSW, CCMEP
President and Founder, InQuill Medical Communications, LLC, Soquel, CA

For more than a decade, professionals in our industry have been engaged in a sea change. Like most profound transformations, ours began with a challenge to the status quo. This challenge not only led to a complete reassessment of how we design, develop, and execute physician education but also required that we reexamine how we fund it.

The relationship between medicine and commercial entities, such as pharmaceutical and device companies, has had a long and renowned history. As early as 1900, the influence of advertising on medical writing was controversial. At that time, P. Maxwell Foshay, MD, wrote:

There being such a multiplicity of journals, few of them could live alone on their subscription receipts, and the pharmaceutical firms are appealed to for advertisements. The greed for advertising patronage leads the editor only too often to prostitute his pen or his pages to the advertiser, so long as he can secure the coveted revenue. So our journals are filled with articles and editorials containing covert advertisements of this and that remedy….¹

Although much has changed in the world of medical writing, over a century later, we are still debating the relative merits of the relationship between commercial support and those who develop and implement the continuing medical education (CME) programs needed by health care practitioners to improve the performance of their craft and maintain their certification and licensure. At the core of the debate are two issues: whether CME that is commercially funded allows for bias of CME content and whether without commercial support the development and availability of CME will be so impeded that the quality and quantity of continuing education available to health care professionals will be diminished and erode our nation’s health care.

These issues have spurred government investigations; voluntary regulatory and guideline changes by government agencies, trade associations, and accrediting bodies; and research into the impact of commercial support on CME and its participants. In keeping with the theme of ethics and medical writing, I am pleased to feature a point-counterpoint by two prominent thought leaders who hold opposing views on the subject of commercial support and CME. In addition, I have included a timeline of major events leading up to the current regulatory environment in the CME industry surrounding the relationship between commercial entities and CME providers (Figure 1).

In Support of Commercial Funding of CME
Thomas Sullivan, a former political consultant, is president and founder of Rockpointe Corporation and its ACCME-accredited subsidiary, Potomac Center for Medical Education. He has parlayed his passion for the political process to inform the medical education community and other stakeholders of emerging trends, threats, and changing practices. Tom serves as editor/author of the Web site Policy and Medicine (www.policymed.com), which is devoted to news and information about political events that affect CME providers and the pharmaceutical and device industries. He is a regular contributor to MedPage Today’s KevinMD (www.kevinmd.com/blog) and is co-founder of the Association of Clinical Researchers and Educators.

Against Commercial Support of CME
Daniel J. Carlat, MD, is Associate Clinical Professor of Psychiatry at Tufts University School of Medicine, and Director of the Pew Prescription Project. He serves as the Chair of the Continuing Medical Education Committee of the Massachusetts Psychiatric Society. Since resigning from drug industry speaker’s bureaus in 2002, he has advocated for phasing out of commercial support for medical education, a topic he blogs about on The Carlat Psychiatry Blog (www.carlatpsychiatry.blogspot.com) and The Carlat CME Blog (www.thecarlatcmeinstitute.com). He publishes two CME newsletters without commercial support: The Carlat Psychiatry Report (www.thecarlatreport.com) and The Carlat Child Psychiatry Report (www.thecarlatchildreport.com).

I firmly believe that as medical writers, we must stay abreast of policy, trends, and opinions of leaders in our field. I recommend the Policy and Medicine Web site and Dr Carlat’s blogs to all medical writers working in the CME industry.

Author disclosure: The author notes that she is a principal in InQuill Medical Communications, LLC, which creates continuing medical education content for a diverse clinical audience.

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Meaningful Health Reform Benefits from Industry Support of Continuing Education
By Thomas Sullivan

The Patient Protection and Affordable Care Act (PPACA), enacted in March 2010, contained an important vision: improve health care quality and efficiency while reducing costs and unnecessary spending. The legislation did not, however, address a critical issue: to achieve the true vision of the PPACA, continuing education (CE) for health professionals must play a vital role in educating clinicians on the new payment options and meeting quality measures outlined in the PPACA.

The Obama Administration and federal health agencies expect that doctors and health professionals will be able to work together across disciplines, use health information technology, update their coding to ICD-10, and “meaningfully use” electronic health records, without offering the kind of high-quality CE necessary to change and improve health professionals’ clinical practices and patient outcomes. But our health care workforce needs additional training and CE to achieve these promising goals. Neither the administration nor the federal health agencies has provided a direct mechanism, let alone funding, to educate health professionals about these expectations, while commercial support of CE funding has declined $297 million (31.4%) since 2007.2

As a result of the lack of government-based focus on CE, coupled with the significant decreases in commercial support, health professionals will face significant challenges accessing the appropriate, high-quality CE necessary to improve the efficiency and cost-effectiveness in our health care system and to implement many of the PPACA programs and initiatives. In fact, a recent survey showed that 52.2% of physician respondents said they have had to spend more time and effort locating appropriate continuing medical education.3

Health professionals will also face challenges accessing appropriate, high-quality CE because the economic climate,
Coupled with decreased commercial support, has affected state-accredited CE providers, universities, and even the federal government. For example, at least one medical school¹ and the Department of Defense² closed their continuing education offices this past year, and the number of CE providers accredited by state medical societies fell by 18.7% to 1,450 between 2003 and 2010.⁴ AMA’s Council on Medical Education noted that, unabated, this trend could “impede the delivery of cost-effective, quality, accessible certified CME” dealing with local health issues.⁶

Curtailing commercial support for CE will only dramatically diminish access to appropriate, high-quality education and negatively affect patient care. In fact, in a recent survey, 25% of physicians reported that the quality of their CE is decreasing.² Such reductions in support are unnecessary and counterproductive, especially considering that studies have shown that commercially supported CE programs have positively affected ICU patients,⁷ as well as patients being treated for chronic obstructive pulmonary disease;⁸ hypertension,⁹ sepsis,¹⁰ and hospital-acquired infections.¹¹

Furthermore, limiting or eliminating commercial funding of CE is not necessary. CE today is vastly different from CE of the past. New standards of commercial support create a principled firewall that prevents undue industry influence. CE providers who accept commercial support are committed to transparency, accountability, and independence in producing CE programs. So, too, are the CME writers they hire to create CME. They strictly adhere to numerous codes and guidances to eliminate any potential bias or conflict of interest, including the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support, Department of Health and Human Services, Office of the Inspector General Guidance, FDA Guidance, and the PhRMA and AdvaMed Code of Conducts. Even more recently, the CME Coalition, an advocacy organization composed of stakeholders in the CME industry, announced a CME Code of Conduct to bring clarity to the rules governing CME.

The combined efforts of these organizations have worked. In fact, studies demonstrate concerns about commercial support of CE are misplaced. In 2010, three large studies, conducted independently at the Cleveland Clinic;¹² Medscape;¹³ and the University of California, San Francisco,¹⁴ were published in peer-reviewed journals; these studies produced substantial data providing evidence of a complete lack of commercial bias in industry-supported CME.

With all the recent changes in health care, and ones coming in the near future, now is not the time to take away resources from the CE system that are necessary to accomplish health care reform. Patients benefit from CE that educates health care providers in practice now. The health problems our country faces today will only continue to grow exponentially with an aging population and a growing epidemic of chronic diseases such as diabetes, obesity, and heart disease. The quality of care provided by the next generation of medical students and our health care system as a whole depends on access to CE that facilitates the continued integration of new advances in medicine and technology into patient care.

It is time to stop focusing on who supports providing CE, because the proper firewalls are in place to ensure quality, integrity, and independence. We must focus on making sure that this country’s health care providers have the highest quality CE, before it is too late.

Author disclosure: The author notes that he has ownership equity in Rockpointe, Inc., a medical education company, and Potomac Center for Medical Education, an accredited CME/CE provider receiving grants for education from public and private entities, including medical products companies.

Commercial Support of CME Biases Medical Education
By Daniel Carlat, MD

In 2010, the pharmaceutical and medical device industries spent an estimated $17 billion on various forms of promotional education, which include detailing, promotional speakers, and promotional mailings.¹⁶ In the same year, industry spent $831 million to support accredited continuing medical education (CME). When it comes to CME, I believe we should all be purists: In the midst of a $17 billion deluge of advertisement/education, patients and doctors deserve a small island of absolutely unbiased medical education. For this reason, the American Medical Association’s (AMA’s) widely accepted PRA Category 1 Credit¹⁶ should be devoid of commercial support.

Accredited CME is subject to the Accreditation Council for Continuing Medical Education’s (ACCME’s) Standards for Commercial Support.¹⁷ If everyone actually followed these standards, which are intended to ensure independence in CME activities, then all CME, industry supported or not, would be unbiased. Standard 5.1 states the crucial criterion for unbiased CME: “The content or format of a CME activity or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.” Unfortunately, these standards are enforced laxly, and extraordinary financial incentives have ensured that that rule-breaking has become the norm rather than the exception.

In my experience, noncompliance with the Standards of Commercial Support is the current daily reality of industry-funded CME. I have had many conversations with medi-
cal writers about their work with companies that specialize in preparing commercially supported CME. I cannot recall a single medical writer who did not perceive pressure to bias the content of his or her work in favor of the sponsor. Sometimes the pressure was blatant, such as in the instance of a medical writer who was given a set of slides developed by the marketing department of the pharmaceutical company supporter and was instructed to create a CME review article giving particular prominence to the sponsor’s drug. In other instances, the pressure was more subtle. Several medical writers told me instances in which they were ostensibly given “free reign” to write about a topic, but they understood that the unspoken expectation was that certain unfavorable studies about the supporter’s product would be either omitted or “explained away.”

None of these medical writers felt good about what they were doing, but they did it for the opportunity to make money doing an activity they loved—writing. This unpleasant ethical two-step is degrading. To the extent that medical writers have allowed themselves to rationalize their way through such assignments, to that same extent the integrity of their profession is diminished.

And the doctors who have participated in preparing biased CME articles, either as guest authors or as legitimate coauthors, equally degrade the trust that we have in the CME process. This is why the AMA recently adopted a set of ethical guidelines\(^\text{18}\) that I believe is reasonable. These guidelines do not absolutely forbid commercial support of CME, but they make it clear that the ideal is for CME not to receive commercial support and not to allow the involvement of faculty who have ongoing financial relationships with companies that make products relevant to the CME topic.

Note that the AMA’s report\(^\text{18}\) comes from its ethics committee, the Council on Ethical and Judicial Affairs, rather than from one of its scientific committees. There are no multisite double-blind trials proving that commercial support of CME adversely affects medicine. There are certain studies showing that physicians—like anybody else—can be influenced by industry salesmanship of various kinds, but to the best of my knowledge, there are no adequately designed studies proving that under current ACCME standards, commercial support is pernicious. But what kind of study could possibly prove such a thing? I can think of no feasible design. And who would possibly fund it?

Commercial support of CME is primarily an issue of ethics and trust, not a scientific one. In that sense, the issue of conflict of interest in relation to commercially supported CME is similar to conflict-of-interest issues in other fields, such as in the following three examples of other professionals vulnerable to corrupting financial incentives:

- Judges are subject to recusal in cases in which they have a financial interest.
- Newspaper reporters cannot be paid by parties that have an interest in the subject of the reporting.
- Baseball umpires (indeed, any national sports referees) cannot accept money from a particular team.

In each of these cases, there are compelling, intuitive ethical issues at play, although I am unaware of scientific studies proving that each policy protects the public welfare.

It is self-evident that we could not trust judges, reporters, or umpires who accepted money from parties standing to benefit from their decisions and other activities. Analogously, it is difficult to fully trust any medical educator who is being paid to educate by a company with a financial stake in the content of the education.

Acknowledgment

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Author disclosure: The author notes that he was formerly president of president of Carlat Publishing LLC, which publishes CME articles for psychiatrists and other mental health professionals. He currently derives no income from subscriptions to CME publications.

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**EFFECT OF SUNSHINE ACT ON CME**

If the Physician Payment Sunshine Act is enacted as written, and indirect payments to physicians become required reportable events, there could be serious unintended consequences for continuing medical education (CME) providers. Two professional organizations are taking steps to illustrate these consequences and suggest modification to the proposed rule.

The Alliance for Continuing Education in the Health Professions (formerly the Alliance for Continuing Medical Education) sent a letter to the Centers for Medicare & Medicaid Services (CMS) in which it offered suggestions for modifying the proposed rule in recognition of the well-defined accreditation system and Standards for Commercial Support already in place for CME providers. You can read the letter on the Alliance’s Web site, at http://ow.ly/92gM0.

In addition, the CME Coalition, a lobbying group established in 2011 to represent the interests of the CME community on Capitol Hill, encouraged the CME community to submit comments on the proposed rule to Health and Human Services and provided model comments on its Web site (www.cmecoalition.org). [The deadline for comments was February 17, 2012]. The CME Coalition also submitted a letter to the editor of The New York Times in a response to an opinion piece regarding the Sunshine Act; you can access the letter on the Coalition Web site. The Web site also includes a slide presentation that offers details on the Sunshine Act and its effect on CME.

**Ethical Principles of Related Professional Associations**

- **Association of Health Care Journalists**
  Statement of Principles
  www.healthjournalism.org/secondarypage-details.php?id=56

- **Council of Science Editors**
  White Paper on Promoting Integrity in Scientific Journal Publications
  www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3358

- **Health & Science Communications Association**
  Code of Ethics
  http://hesca.net/about/code-of-ethics

- **National Association of Science Writers**
  Code of Ethics
  www.nasw.org/nasw-code-ethics

- **Public Relations Society of America**
  Member Code of Ethics
  www.prsa.org/AboutPRSA/Ethics/CodeEnglish

- **Regulatory Affairs Professional Society**
  Code of Ethics for Regulatory Affairs Professionals
  www.raps.org/Portals/0/Documents/Ethics.pdf
Grant proposals are complex documents that can be difficult to write, and two of the most difficult parts are the **Statement of Need(s)** and the concomitant **Goal(s)**. One of the most common reasons a grant proposal is rejected is that the “applicant did not adequately define the need(s) to be addressed by the proposal.” The statement of need(s) must be precise and appropriate for funding to be attained. Many writers experience problems with stating the real need; instead, they describe superficial wants or items related to meeting the need. In contrast, some writers have a good understanding of the real need, but they state the goal of their research or project in terms that are too vague to resonate with a grant-making agency. This article suggests two prewriting exercises to help writers overcome these problems: logical mapping and a six-step method for articulating the goal. Logical mapping can help writers identify real needs and clarify why they should be addressed; mapping can also pinpoint the causes that a solution must address. The six-step method can change vague claims about what a solution-implementation project or research endeavor will accomplish into clear, specific statements of the goal(s). These two exercises are applicable to education and small foundation grants; for more complicated grant proposals, like those to the National Institutes of Health, these exercises are useful but not necessarily sufficient.

It is always important to follow all instructions given in the request for proposals (RFP) and to respond using key words that reflect the values of the funding source. Many proposals with great ideas are rejected because they fail to follow all RFP guidelines. The RFP typically provides explicit instructions about what information is needed in which sections of a proposal; how to format that information; and when, where, and how to submit the proposal. RFPs give detailed requirements for font styles and sizes, document length, due dates, and the types of projects that can be funded for each specific grant. Sloppy formatting or grammar and spelling errors will reflect poorly on the credibility of everyone involved with the project. Furthermore, the “shotgun” method of proposal submission—sending a proposal to several foundations or government agencies—typically “results in high rates of rejection and negative positioning with funding sources.” Sending a proposal in this manner, especially when some of the foundations or government agencies have interests only marginally related to the topic, not only garners rejection of that specific proposal, it also reduces the credibility of the project team members and their organization. Showing that good research has gone into selecting potential funding sources as well as developing the project will enhance credibility and help persuade a reviewer that the applicant’s organization is capable of sound judgment in handling money, activities, and individuals.

**Solving Problem 1: Distinguishing Needs from Wants**

A grant proposal can request funding to conduct research (eg, to test a hypothesis) or to solve a problem (eg, to change treatment protocols or clinical procedures). The major task of writing a grant proposal involves describing a research question that needs to be answered or a problem (such as a high level of sepsis among patients after surgery in a hospital) that needs to be resolved. Too often, grant writers make the mistake of confusing a need with something that will meet a need. This mistake indicates to a funding agency that the project team does not share the agency’s values and ideals. Many RFPs contain a statement of need section, and it is imperative to be specific in showing the difference between what the beneficiaries of the research or project currently have and what they need.

First, you must clearly separate the need from the solution you are proposing to meet the need. Chavkin provides a simple example of this confusion in describing school social workers who “need” a van to transport children to and from afterschool tutoring activities. It is obvious to the school social workers how helpful the van will be. By focusing the proposal on getting a van, however, they are focusing on one part of a solution and not on the needs that the van will meet. The message would be clearer if the social workers explained the learning needs of the students who will be transported in the van and how the van will help improve learning by getting students to tutoring. It is important to stay focused on the problem and not become distracted by one possible solution. A hospital does not “need” a superfast magnetic resonance imaging (MRI) machine; however, the hospital may need a means of providing diagnostic imaging services within a workable time frame to a larger-than-average number of patients in an area where head
and joint injuries are common because of a local tradition of skateboarding. The super-fast MRI is one possible way of meeting the need, but it remains to be proven that it is the best and most cost-effective solution. Perhaps local laws against skateboarding could resolve this problem at a much lower cost.

Most grant-writing experts recommend writing logical, factual descriptions of needs, including a brief review of what relevant experts have said, to verify the existence of these needs and either to document an ongoing history of a problem or to show how a recent change in some circumstance causes the problem. In his step-by-step guide on grant writing, Henson notes, “By simply reviewing the literature and reporting the research conducted by others, grant-proposal writers can build convincing support for their grants.” A viable proposal demonstrates a need for specific knowledge in a discipline or for changes in physical circumstances among a specific population or within a specified physical location. Because the need must not be confused with a solution that might help to meet the need, it is a good practice to brainstorm all aspects of the problem, including causes and effects, in order to ensure that the message is clear to the grant writer before he/she attempts to explain it to proposal reviewers.

A statement of need examines one of the two main aspects of a problem (effects and causes). The seriousness of a problem can be established by looking at its effects. To mentally explore a problem’s effects, begin with a logical map, sometimes called a mind map (Figure 1). Focus on naming all the effects of a problem. Showing the connections between the real problem and its consequences can help to prove that a problem deserves to be solved. If the consequences of doing nothing would involve letting people suffer unnecessarily, then a good case can be made for the need to change the situation.

**Figure 1. Logical mapping exercise to prove the severity of a problem.**

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**Solving Problem 2: Articulating Goals Precisely**

A goal statement in a grant proposal focuses on the second aspect of a problem—its causes. In writing a grant, one must demonstrate that the cause(s) of the problem is understood. The effects are often the perceived problems, but the cause is the underlying problem that produces the effects. To help explore the possible causes of a problem, create a logical map and ask the questions “Why is this happening?” and “What changed to bring about these undesirable effects?” until the ultimate cause is uncovered. A viable solution must target an actual cause of a problem. If one discovers that the problem has multiple causes, one should select the most likely target for an intervention on the basis of what can be feasibly accomplished with limited time and resources. Still, it is a good idea to demonstrate to a funding source that the larger causal chain is understood and that a specific intervention is being advocated because it is the most practical or has the best chance of successfully producing a helpful change in the outcomes. At times, when multiple causes contribute to a problem, it might be feasible to target only one or two of them. Identifying causes of a problem in this way allows one to express a clear and specific goal for producing an identifiable and appropriate change.

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**Figure 2. Logical mapping exercise to determine the real problem and its causes.**

These mapping activities can provide the raw material for the introduction section of a proposal that identifies a real need, explores the issues of who is affected and how severely, establishes when the need began and how long it has been a problem, and persuades readers that a solution is needed. One must first argue for the importance of a problem (based on its effects) so that the readers are convinced that it is truly worth resolving. One can then explain how and why a particular project will solve or mitigate the problem. For research, a proposal writer can first argue for the need for research in an area where knowledge is lacking.
Six Steps to Writing Clear, Specific Goals

1. Identify areas in which results are needed.
2. Specify measurable indicators for these result areas; these indicators should tell how well one is progressing toward the desired results.
3. Determine performance standards to answer the question: How much change of the measurement indicator will signify success (eg, a 5%, 20%, or 100% reduction or increase in the factor being measured)?
4. Specify a timeframe for accomplishing the desired change, then view this as a deadline.
5. Determine the cost range within which the project will operate (the amount of money the project will spend to meet the goal by using the methods described in the rest of the proposal). One can also identify how many beneficiaries will be served for this cost.
6. Articulate a goal statement in the following format: “To action-verb + statement-involving-measurement-indicator by performance-standard by deadline at a cost of no more than cost-range.” Example: To test the hypothesis that radiofrequency thermal coagulation denervation procedures are effective for reducing pain levels experienced by patients with chronic back pain (defined as pain lasting for more than 1 year) by at least 40%, as reported by patients on a 10-point pain scale, with the reduction expected to last at least 6 months, in 50 patients within 1 year, for a cost of $800,000.

Six-Step Method for Articulating Your Goal

The first step in articulating a clear goal is to determine what kind of results are needed in what location or arena. For example, a project may focus on reducing sepsis among surgical patients in a free, inner-city clinic.

The second step is to identify how change will be measured; for example, what test result or clinical outcome determines the extent of the presence of sepsis in the clinic’s surgical patients?

The third step requires estimating how much change will be considered “good enough” to be called a successful outcome. Most clinicians and funding agencies will not consider a 3% reduction of sepsis in surgical patients to be a success worth funding—it might even be seen as a random change. In contrast, a 100% reduction is unrealistic. The key is to determine an amount of change that is reasonably attainable and worth the money and effort. For example, one may compare the sepsis rate at one clinic with the rate at a model clinic and strive to match that standard.

The fourth step is to set a deadline: in what timeframe can the desired change be achieved? Will it take weeks, months, or years?

The fifth step is to determine the costs, and it is important to not inflate or underestimate the costs. Cost is, of course, an issue of great concern to grant-making agencies, and the predicted costs must be reasonable and allow for the change to be made or the hypothesis to be tested. It may also be of value to note exactly how much benefit would be produced for the stated costs so that proposal evaluators can compare the likely return on investment that each competing proposal promises.

The sixth and final step in articulating a clear goal recaps the previous steps in a comprehensive statement of what change will be made (or what knowledge will be gained), according to what measurable criteria for success, by what deadline, and at what cost.

It is possible that you might never write the goal statement obtained from the six steps verbatim in a proposal; however, this statement will be the guiding light for writing a proposal because nearly all of the information that must be included in a proposal is based on this goal statement.

Applying These Techniques to Basic Science Research

Although these techniques for clarifying needs and goals are most relevant to proposals for applied research and program development, they can also be of some use for proposals for basic science research. The main difference between the two types of research is that applied research creates change in physical or social outcomes, whereas basic science changes the body of knowledge available to others who later apply it. Thus, in the case of basic science, the need is for knowledge, the lack of which impedes progress in understanding the causal mechanisms involved in some disease or environmental process. If logical mapping can identify effects but not causes, then basic science research may be needed to explore possible causal connections. In such a case, the need for the research can be explained in terms of what problems arise from the lack of knowledge. In some cases, it may be difficult to describe an expected benefit; it is simply a matter of producing knowledge that will have unforeseen potential applications. For example, the discovery of nuclear fission resulted in the production of atomic weapons as well as nuclear power. If one is writing a proposal for a basic science research grant, one should focus on the generally accepted benefits of expanding human knowledge. The
mapping exercise suggested here may provide limited benefits for proposals related to basic science research with unknown effects and causes, but the six-step method for articulating the goal can still be used to explain how much of what kind of change may be produced in the body of scientific knowledge available for application in the future.

Conclusion
A clear and specific statement of need is a key feature of a good, fundable grant proposal. Logical mapping exercises can identify or clarify real needs as well as causal mechanisms that viable solutions must target. The six-step method described here can enable a grant proposal writer to state the goal(s) of a grant proposal in terms that respond directly to a RFP. These two prewriting exercises can make a grant proposal more appealing to potential funders by giving proposal reviewers exactly what they are seeking. Providing this information in a succinct manner enhances the likelihood of attaining funding for worthwhile projects.

Author disclosure: The author notes that she has no commercial associations that may pose a conflict of interest in relation to this article.

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June 2-5, 2012
Windsor, Ontario, Canada
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Tallinn, Estonia
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October 26-30, 2012
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Freelancing part-time while working in a full-time job is a great way to begin to build a freelance medical writing business. This article describes the experiences of two freelances who built successful businesses by moving from part-time to full-time freelancing.

MARKETING YOURSELF FROM PART-TIME TO FULL-TIME FREELANCING
By Genevieve J. Long, PhD

“How do you get started?” is a common question from would-be freelances. I combined my backgrounds in writing and medicine. While earning my degrees in English and teaching and planning to enter academia, I worked part-time in several health care positions. Then I realized medical communication would allow me to combine my love of writing with the chance to help people in practical ways. I started working at a medical school part-time as a medical communicator and began freelancing during my off hours.

Starting out part-time allowed me to learn about freelance writing and business without the pressure of needing to earn a living. I learned by
• Reading general business books
• Reading about starting a writing business
• Asking all freelance vendors I hired about their businesses
• Accepting projects that helped me build a client base

I could have done all of the above if I had started as a full-time freelance, but starting part-time allowed me to prepare myself for success.

Benefits of Working for a Company While Launching a Business
Working for a health care employer while I started my freelance medical communication career had many benefits. I learned the scope of medical communication and about what clients need. I also had time to choose my freelance emphasis; I started out as a manuscript and grant editor but discovered that I most enjoy writing for patients.

Freelancing part-time provides the flexibility to develop ideas and a client list without the pressure of earning a full-time income. Time to set aside startup funds is another benefit. Some experts recommend having 1 year’s worth of salary, plus money for office furniture, computer equipment, and the monthly expenses of running a business, such as Internet, telephone, and general office supplies. Expenses vary based on many factors, including lifestyle and geographic area, so I recommend doing research to determine your needs.

Is Part-time Freelancing the Right Choice Now?
Part-time freelancing is a great way to try freelancing or to build a business before going full-time. If you have young children or older parents who need your attention, part-time might be best. You don’t have to tell clients you are part-time—only the Internal Revenue Service needs to know how many hours you work.

Differences Between Full-time and Part-time Freelancing
A full-time freelance does everything an employer would do: administration, marketing, operations, and IT. Some books, such as The Wealthy Freelancer and The Four-Hour Work Week, offer tips on delegating activities so you can devote more time to freelancing. A self-employed friend advised me to hire helpers, eg, house cleaners, yard workers, or bookkeepers, if they charge much less than I charge clients. For example, a house cleaner who charges $20 per hour and spends 4 hours cleaning helps you make money if you do more than $80 worth of work in that time. As your business grows, consider hiring subcontractors to help with big writing jobs.

As a full-timer, you will work harder than a part-time freelance and harder than you ever did as an employee. Bottom line: don’t become a full-time freelance writer if you want more free time. Do consider freelancing if you want control over the work you do and the convenience of working at home, with somewhat flexible (though long) work hours.

Before You Market Your Services
You must know two things before you market your freelance services: What do I offer? and Who are my buyers?

Will you do the same work as you did in your corporate job? For example, if you wrote manuscripts and grants, will...
those be among your freelance services? If you have been out of the work force, you might need to ask yourself what you did best and would like to do again.

Consider who needs your services and why. After reading *The New Rules of Marketing & PR* by David Meerman Scott, I wrote detailed profiles of the editors, marketing managers, and others who hired me when I freelanced part-time. Reflecting on their needs helped me hone marketing messages for my full-time business, emphasizing how hiring me would benefit them.

**Switching from Part-time to Full-time**
My part-time freelancing lasted 7 years. I devoted 1 to 3 days to freelance work each week, billing as few as 4 or as many as 15 hours per week and spending any non-billed freelance hours on professional development and marketing. Before I went full-time, I updated my Web site, told clients about my increased availability, and changed my e-mail signature, listing services in areas where I wanted more work. Other suggestions:

- Fine-tune your online portfolio to reflect the types of work you want most.
- Practice telling people what you do in a sentence or two, until it sounds natural.
- Hand out business cards freely.

Several marketing tactics have proved successful for freelances (see list at top right).

Whether you are part-time or full-time, be professional. I recommend the following.

- A professionally designed Web site
- Professionally written marketing copy
- Professionally designed and printed business cards
- Electronic letterhead
- Accounting system
- Time-management software
- Business savings and checking accounts and business credit card

WordPress and other programs make creating a Web site easier than ever, but a professional impression requires some design skill. In addition, time spent designing and building a site could be spent writing or networking. If you lack experience writing Web content, find someone who knows how. Visitors won’t read every word but scan for information about your services, qualifications, and clients. Unless you want to learn about Web sites from the ground up, you might be better off with a marketing writer, Web designer, or both.

I recommend purchasing printed marketing materials from a reputable designer and printer. Homemade business cards don’t look or feel professional. Your card might be the only marketing piece you hand to a contact; it represents the quality of your work, so it’s worth investing in the heavy-weight paper and quality design that are standard for most businesses. The language, colors, and typeface on your cards and other materials should match your Web site.

**Proven Marketing Tactics for Freelances**

- **Web site**: A well-written, professionally designed Web site with writing samples that you update regularly. Some things you can’t show—proprietary information, for example—but you can list client names or journal titles.
- **Business card**: Professionally designed and printed
- **Targeted direct mail**: Develop mailing lists of potential clients and high-quality direct-mail pieces (flyers, postcards, a letter, etc.).
- **LinkedIn**: Write a good profile, build your contacts, and stay in touch with them.
- **Partnering with other freelances**: Freelances often need to refer clients to other freelances for work they do not or cannot do, or when they need help with their projects.
- **For clients**: Holiday gifts—give something neutral, like food—and birthday greetings.

**Market to Current Clients**
It costs less to keep a client than to find a new one, and keeping clients starts with doing great work. Take courses and read literature in the field to improve your work.

Be responsive. The more you value clients, the faster you should call them back. Be collegial; find out something about them, and share something about yourself. Keep it light: you both have Springer spaniels or love shoe shopping. Start slowly, but start building a bond. Business is built on relationships.

When you finish a job and your client is happy, tell her that your business grows by referrals and ask whether she knows two or three people who might use your services. Caveat: ask only if your client is happy with your work.

A note on keeping clients happy: you can be organized, personable, and do terrific work and still occasionally have a client who isn’t thrilled, usually for reasons beyond your control. Don’t take it personally; do your best and move on.

**Finding New Clients**
Focus on the best sources of full-time freelance business, and don’t bother with the worst sources (see below).

**Best and Worst Sources of Full-time Freelance Business**

**Best Sources**

- A former employer (one more reason to start in the corporate world)
- Firms that know the former employer
- Contacts made while working for a former employer
- Clients from part-time freelancing
- The AMWA Freelance Directory and AMWA colleagues
- Referrals (once you are established)

**Worst Sources**

- Local business groups (for example, city business associations)
- Social and personal connections
- Small-business owners, including solo or small-practice physicians
LEARNING HOW TO FREELANCE BEFORE TAKING THE FULL PLUNGE
By Lori De Milto, MJ

I started freelancing part-time while I was doing marketing communications full-time for a business school. My initial goal was to learn about future career opportunities and make some extra money. But as I started freelancing, I found that I really liked it and wanted to do it full-time. At that point, I had 2.5 years before I would be vested in my university’s retirement plan. Because I wouldn’t have a retirement plan once I started a business, I decided to start freelancing full-time the month after I was vested (March 1997).

During those 2.5 years, I marketed my business and took on more freelance work so I would have a steadier income when I finally took the plunge. I developed a business name, tagline, and logo and used them in professional marketing materials (business cards, brochures, envelopes, and direct mail pieces). As a journalism major and a marketing communications writer, I had the expertise to write my own copy. But I hired a professional to design and produce my marketing materials. I also joined AMWA, attended the annual conference, got actively involved with my chapter, and signed up for AMWA’s Freelance Directory.

Investing in a Freelance Business Pays Off
From the start, I treated freelancing as a business. I invested time and money, developing high-quality marketing materials and a direct-mail campaign. I developed my own mailing lists, starting with a search of the AMWA membership directory for companies I might want to work for and contacts in those companies. The Web was in its infancy at the time, so to develop the rest of my mailing list, I went to the library to search directories of hospitals, health care associations, and other health care organizations for other potential clients. All of this took many hours.

In my first year as a full-time freelance, I sent three flyers, each to about 250 people, spending about $10,000. It was worth every penny. Within 1.5 years, I had as much business as I wanted. Some clients contacted me within days of receiving the first flyer. Others hired me after receiving the second or third flyer, and I realized that it was important to continually market my business so that potential clients would remember me when they needed help.

Finding Freelance Opportunities Through AMWA
Getting actively involved with AMWA helped me build my business. Along with using the membership directory in my direct-mail campaign, I found work through the jobs list and the Freelance Directory. As I built my experience and became more involved with AMWA, I began to get referrals for work.

AMWA also helped me learn the business end of freelancing. I talked to freelance colleagues and attended AMWA events geared toward freelancers. I also read a lot of books on running a business, including Secrets of a Freelance Writer, Third Edition: How to Make $100,000 a Year or More and Guerrilla Marketing, 4th edition: Easy and Inexpensive Strategies for Making Big Profits from Your Small Business.

Building the Confidence to Take the Plunge
Freelancing part-time while learning how to market and run a business was a successful strategy for me. By the time I officially launched my business full-time, I had a few steady clients and, thus, some income, a marketing strategy, and the confidence to take the plunge.

Starting a Freelance Business Today: The Importance of the Internet
The Internet has created a very different environment from the one I faced in 1997. When I created my first Web site in 2002, few other writers had one. Today, a good Web site is essential to marketing a freelance business. Clients want to learn about your background and experience and see work samples, often before they even contact you. My first Web site was pretty basic in its design and content. In 2008, I revised my Web site, adding more content and hiring a professional Web designer. Getting the content just right took many hours of research and writing. My new design cost nearly $3,000. Based on positive feedback from clients and colleagues, the time and expense were well worth it.

LinkedIn, a social network for business, is another important marketing tactic for freelances today. I have gotten business through LinkedIn and know other freelances who have also. By building connections with clients and contacts on LinkedIn, you can easily update them on your activities, keep track of them as they move around, and gain access to the people your connections know. LinkedIn has two useful features for freelances:

• “What are you doing?” a Twitter-like feature that keeps your connections thinking about you through periodic network updates LinkedIn sends out. I’ve used this to highlight my interesting projects and other professional activities (eg, moderating a session at the AMWA annual conference).

• Groups, including AMWA, Medical Marketing & Communications Group, and the Freelance Writers Connection, which let you keep in touch with people with similar interests and share your expertise through discussions.

Author disclosure: The authors note that they have no commercial associations that may pose a conflict of interest in relation to this article.

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References
In just 15 years, the Committee on Publication Ethics (COPE) has grown from “a self-help group” for about a dozen journal editors to an international organization of more than 7,000 members that offers seminars at spots around the globe and educational materials in a variety of languages, according to Liz Wager, chairwoman of the COPE Council.

“It started really as a group, a sort of self-help group, for journal editors who were faced by tricky problems, perhaps allegations of misconduct, perhaps, you know, quite serious concerns about a paper, and they really didn't know who to turn to,” Wager says.

The members began meeting to discuss situations that had proved vexing and to offer possible solutions. COPE's Web site (www.publicationethics.org) offers a searchable database of the cases that members have ruminated on through the years. Many of the broad topics are predictable — plagiarism, authorship disputes, informed consent, and conflicts of interest, for example—but the individual (and anonymous) details of the cases help to convey the complexities of translating overarching principles to the day-to-day management of a journal.

What should a journal editor do if an author of a manuscript under review sends a gift?

What actions should an editor take if an author submits patient consent forms signed after an experimental treatment has already been administered?

How should an editor proceed if one author of an article suddenly wants his name removed, apparently because his romantic advances had been spurned by another author?

The database includes summaries of advice offered by other COPE members, and for some, an epilogue that describes how the case ultimately was resolved. Some case discussions also are available as podcasts.

“I find the cases fascinating,” Wager said. “You always think, ‘Surely, there can't be anything new. We've surely heard all the cases before.’ And yet every time you have the cases, there is some interesting twist to it, or something that makes it really difficult to deal with.”

In addition to the case discussions, other resources provided by COPE include guidelines for new editors and flowcharts for handling certain types of ethical quandaries, such as what steps to take if plagiarism or fabrication of data is suspected. Many of the flowcharts have been translated into multiple languages, including Chinese, Arabic, Farsi, Spanish, and Croatian. COPE recently launched Web-based learning modules that are available only to members.

Journal editors and publishers who are COPE members are expected to follow the organization’s codes of conduct. Complaints can be lodged with COPE if there are suspicions of code violations. If the complaint is found to have merit, the COPE Council may recommend a course of action, such as asking the editor to apologize to the complainant, publish a statement from COPE in the editor’s journal, or take steps to improve procedures.

Complaints against members are rare, generally just a few per year, Wager says. COPE is planning to publish a summary of the complaint cases on the organization’s Web site.

Wager, whose 3-year term as COPE chairwoman concludes in the spring of 2012, says it is difficult to measure the direct impact of COPE on publishing ethics, but notes that awareness of its activities is growing, particularly among publishers that pay for journals to be members.

“They see it not just as something nice to have, you know, some sort of little decoration. They actually think that it is really relevant to their work.”

Being Published in the AMWA Journal Gets You Noticed!

Authoring an article in the AMWA Journal has many advantages, and now an additional benefit is an increase in your exposure on social networking sites. Jan Redfern, PhD, whose article “The Risks and Hazards of Interpreting and Reporting Health Study Measures: A Simple, Practical Overview” appeared in the September 2011 issue of the Journal, found a marked increase in LinkedIn hits after publication of the article (Figure 1). Dr Redfern said she listed the article on her LinkedIn page and posted it in several relevant LinkedIn groups. She also sent a PDF of the article to several colleagues in the industry.

“It is difficult to say which of these methods directly led to increased views on my LinkedIn page, but I was delighted with the response,” said Dr Redfern. “Personally, I think writing articles on topics relevant to the industry is an excellent way to get exposure.” Dr Redfern added that another of her articles (“A Prescription for Publication. How to Submit Patient or Physician Attitudinal Survey Data to Medical Journals”), which was published earlier in the year in Quirk’s Market Research Review (March 2011) attracted “nowhere near the response seen with the AMWA Journal article.”

Submit a manuscript to the AMWA Journal and be noticed!

Visit the AMWA Journal section of the AMWA Web site (www.amwa.org) for instructions for contributors.

Gary Schwitzer, a leading authority on health care coverage in the media, publishes HealthNewsReview.org, a Web site designed to show how coverage of health care and reporting on the claims of researchers should be scrutinized. Schwitzer leads a team of experts who grade daily health news reporting by major US newspapers, wire services, and the Web sites of major news outlets. The following are the 10 criteria Schwitzer and his team use in reviewing health news. Read more about these criteria at www.healthnewsreview.org/about-us/review-criteria.

**Review criteria:** Does the story...

1. Adequately discuss the costs of the intervention?
2. Adequately quantify the benefits of the treatment/test/product/procedure?
3. Adequately explain/quantify the harms of the intervention?
4. Seem to grasp the quality of the evidence?
5. Commit “disease-mongering” (exaggeration or overselling of a condition)?
6. Use independent sources and identify conflicts of interest?
7. Compare the new approach with existing alternatives?
8. Establish the availability of the treatment/test/product/procedure?
9. Establish the true novelty of the approach?
10. Appear to rely solely or largely on a news release?

Submit your idea for a Top Ten list to the editor at amwajournal@editorialrx.com.
By Jeanne McAdara-Berkowitz, PhD
Biolexica LLC, Longmont, CO

Technology plays an increasingly important role in the medical writing profession. In this issue of the Journal, we present a new section designed to share information on the tools, software, and applications AMWA members use to enhance their productivity. If you’d like to suggest a topic or contribute to this section, please contact Jeanne McAdara-Berkowitz at jeannejmac@biolexica.com.

“Cloud computing”: the term has become ubiquitous. Whether you’re already a convert or suspect the term is just jargon for “the Internet,” this relatively nascent concept is worth understanding. Medical writers, in particular, may find Cloud services useful for enhancing their productivity and efficiency.

What is the Cloud? It’s like the plumbing behind the walls of the Internet—an amalgamation of the entire networked computing infrastructure that is out there, somewhere, harnessed by Cloud service providers. The Cloud gives tremendous computing capability and storage capacity to anyone—large company, small business, or individual—without huge investments in equipment, personnel, or software licenses. Calling it plumbing belies the Cloud’s power, so as an illustration, consider how the Internet and the Cloud are radically changing the way people listen to music.

Until recently (and this might still be the case for many), a personal music collection consisted of albums, cassettes, and CDs that took up physical space, and had to be physically retrieved and inserted into a player to be enjoyed. With playback software and high-density hard drives, people could transfer music from CDs to their computers and play it from there, but they were still limited to listening on the computer where the music was stored, or on a synchronized portable digital player. So music lovers started uploading music to network servers and accessing it over the Internet. This not only precipitated an enormous debate about intellectual property law, but also spawned the first online music stores that sold licenses to download music over the Internet.

Now, vendors like Amazon, Apple, Pandora, and Spotify allow customers to access music from enormous Cloud libraries. Services are subscription-based or pay-per-use; some give free access to customers who will accept advertising. In most cases, customers don’t have to store the music on any local machine in order to “own” it or listen to it. Instead, it is “streamed” from the Cloud through the playing device to the listener’s ear.

Music is one example, but the Cloud is effecting similar changes in how people store and access files, documents, photos, and even software. For medical writers, some of the chief benefits of Cloud computing are the following.

• Platform/location independence: Use software and access files and information from any computer or gadget, at any time, from any place, using services such as Dropbox, Box.net, FilesAnywhere, or iCloud.
• Software as a service (SaaS): Use software on a subscription basis, through a Web browser, with no installation, licenses, upgrades, or updates, ever. A few examples are: Gmail or Hotmail for e-mail services, WebEx, and GoToMeeting for online presentations, Harvest for tracking billable time, Mendeley for managing references, and Prezi, Google Docs, and Microsoft Office 365 for productivity. (See page 35 for reviews of some of these services.)
• Document sharing and collaboration: Share and work on documents with coworkers using FilesAnywhere, YouSendIt, Google Docs, Dropbox, or Box.net.
• Automated off-site backup: Back up all files to a remote site, without any need for active management, using Carbonite, JungleDisk, Box.net, Dropbox, or iCloud.
• Cheap, virtually unlimited storage: Purchase enough space to store virtually any collection of files or data.

There is no denying that the Internet is not a secure place for confidential data and personal information. AMWA members have expressed special concerns relating to confidential client information and HIPAA regulations. Each potential user of the Cloud must research and understand this, and make the crucial risk-benefit calculation for themselves.

If you use the Cloud, here are some precautions you can take to lessen your risks.

• Do your homework: Research vendors. Review the AMWA listserv archives, search Google, browse support forums, read third-party reviews about how vendors handle privacy, security, and encryption, and consult an IT professional.
• Segregate your data: Use Cloud services for files and work that are not confidential or otherwise sensitive, and reserve confidential information for your local computer or for your company’s virtual private network (VPN).
• Use secure networks and SSL-encrypted sites: Free, public Wi-Fi networks are highly vulnerable to hacks. Encrypt your home Wi-Fi, and if you must use public
networks, look for secure-socket-layer encryption on the Web sites you visit (the URL will include https://).

- **Use strong passwords**: Weak passwords—dictionary words, names of loved ones, passwords derived from biographical information, or single passwords used for multiple sites or purposes—are a major vulnerability. Use unique passwords for each app or Web site you access.

- **Keep your OS and virus protection current**: Always install software upgrades and patches when they are released.

- **Stay vigilant; be skeptical**: View any request for your information as an attempt to steal your password, your identity, and your privacy unless you can confirm it is legitimate.

The issues and examples presented here only scratch the surface of trends in Cloud computing. Readers interested in learning more about Cloud computing are encouraged to seek additional information on its benefits and risks. A great place to start is, well, the Cloud.

### TECH TALK REVIEW

**GoToMeeting (www.gotomeeting.com)**

*Platforms: Mac or PC*

*Cost: Available as 30-day free trial; personal and corporate rates available (A toll-free number involves an additional fee)*

With the advent of electronic media and telecommuting, we often collaborate with team members in other states or countries. For the purpose of discussing complex documents, GoToMeeting by Citrix Online is a top-notch application. This program requires minimal installation on the organizer’s and participants’ computers. Setting up and starting meetings are very intuitive, something I can’t easily say for its closest competitor, WebEx.

GoToMeeting elegantly integrates with Outlook, so when you schedule a meeting, an Outlook appointment automatically pops up, ready for you to fill in the e-mails of the intended participants. This automatic message contains a link participants can click on to join the meeting. They do not have to provide private information or have a GoToMeeting account. The program is available as free iPad, iPhone, and Android applications for participants, but organizers have to start the meeting from a Mac or PC.

— Adi Ferrara, ELS

*Freelance medical writer and editor, Bellevue, WA*

**LibreOffice (www.libreoffice.org)**

*Platforms: Mac, Windows, GNU/Linux*

*Price: Free*

LibreOffice (LO) is an open-source, Microsoft-compatible office suite. The suite includes Writer, which provides word processing; Calc, which competes with Excel in quantitative analysis; Impress, which can be used to create presentations; and Base, LO’s alternative to Microsoft Access. Costly Microsoft Office extensions are standard in LO. Draw composes diagrams. Math edits equations for scientific documents. Writer maintains bibliographies.

When handling nonstandard files, LO saves hours of searching. For example, to edit a PDF, open it up in Draw, revise it line by line, and then export as PDF. Unfortunately, power users relying on Visual Basic (VBA) macros will have compatibility problems. LO provides numerous macro languages, but no VBA translator or interpreter. Proposals for one abound, but none have acquired significant momentum yet.

— Robert Ryley

*LibreOffice Documentation Volunteer, Manchester, NH*

**Mendeley (www.mendeley.com)**

*Platforms: Mac or PC*

*Cost: Free*

Mendeley is an up-and-coming online reference manager and scientific social community. Whether you’re a social media guru, technophobe, or somewhere between, Mendeley has something to offer you. Mendeley is similar to and compatible with EndNote, but may be slightly less robust. Don’t despair, as it is still in beta version.

Mendeley has definite strengths:

- It can be completely mobile but also has a desktop icon.
- It syncs with Endnote.
- You can annotate PDFs and share them.
- You can see what your colleagues are currently reading and build collaborations.
- It inserts and formats citations on many platforms, including text editors, e-mails, and blogs.
- You can explore current trends in research.


— Hilary Graham

*University of Texas MD Anderson Cancer Center, Houston, TX*

**Prezi (http://prezi.com/)**

*Platforms: Mac or PC*

*Cost: Free*

Tired of linear slide presentations? Prezi is a new presentation tool that is based in the Cloud and that is more akin to a scientific poster than a traditional PowerPoint presentation. With Prezi, users put all of their content onto one digital canvas, which is stored online. Users can then move around and zoom in to different areas of that canvas during their presentation. Prezi lets you show relationships among the various elements in a more visual way than can be achieved using a traditional slide set. In essence, Prezi helps you build a “mind map” of your ideas and lead the audience through the various aspects of your project. (Read more about Prezi in the report on the annual conference session “Better Presentation by Design,” an online exclusive in this issue of the AMWA Journal.)

— Hilary Graham

*University of Texas MD Anderson Cancer Center, Houston, TX*
Concerns about privacy issues have kept some professionals from diving into the social media pool. Some of my medical communication colleagues have dipped in their toes only to jump back and reconsider whether the benefits of social media outweigh their anxieties about online privacy. These concerns are justified, particularly in light of reports about hijacked personal identities and stolen financial information, both online and offline.

Online privacy issues are real, but using common sense goes a long way to ensuring peace of mind. Here are some suggestions for how you can control the personal information you share on social media sites.

• Although this may seem basic, **read the privacy policies and practices** for the particular sites on which you plan to network. It’s easy to scroll through the legalese and click the box indicating that you have read and agree with the policy, but it’s your responsibility to actually read and understand each site’s privacy practices. Some sites specifically state they will share certain personal information with third parties; others will not. Your online experience will be more enjoyable and less anxiety-provoking when you understand what is being recorded, how sites use your personal information, and whether or not you can opt out.

• **Manage the privacy settings** of your social networking accounts before you start posting information. Facebook, for example, allows you to create separate lists to organize your personal and professional contacts to control what they can and cannot see.

• **Be mindful of your online presence.** Use good judgment with regard to what you post online and avoid oversharing. Avoid posting photographs and information that could come back to haunt you in the future. Similarly, don’t engage in personal attacks or post information that could be interpreted as demeaning or reflect negatively on you or the organization you represent.

• **Know your audience.** Be aware of who will be reading your posts on Facebook, viewing your tweets, or searching for your profile on LinkedIn. For example, information you post to your public LinkedIn profile is visible to anyone who searches for you, not just individuals who are already in your LinkedIn network. Be cautious of sharing personal tidbits you don’t want your professional contacts to know.

• **Release only information you feel comfortable sharing with the public.** If you don’t want people to know what you look like, then use an image instead of a photograph. Personally, I never post my real birth date, address, or home phone number. Although it would probably be a simple matter for someone to find this actual information, I don’t feel the need to advertise it.

• **Avoid using your primary e-mail or work e-mail address** and establish separate e-mail accounts for online connections. Because some sites actively share your e-mail address with the highest bidders, your inbox could easily overflow with spam. Using an alternate e-mail account is one way to avoid this problem while still enabling recruiters or prospective clients and employers to get in touch with you. Do make sure to check the alternate e-mail account regularly, however.

• **Understand the connections between social media sites.** Many social networking sites allow connections with other Web sites. Facebook, in particular, uses applications that enable you to establish connections with external sites very easily. When you use these applications, however, you must agree to share your personal Facebook information with these external sites.

Once you go online—for banking, shopping, social networking, or any other reason—total anonymity becomes impossible. The bottom line is your level of comfort. If in your opinion the risks of social networking outweigh the benefits, then by all means limit your online experiences until you become more familiar and comfortable with the platform.
Blog Log  By Debra Gordon, MS, Independent Medical Writer, Williamsburg, VA

Ethics on the Blogs

As you can see from the contents of this issue of the AMWA Journal, you won’t get far in our field without a solid ethical core. To that end, check out some of the following blogs that focus on scientific ethics.

Adventures in Ethics and Science: http://scientopia.org/blogs/ethicsandscience/about-2
This site is where Janet D. Stemwedel, PhD, an Associate Professor of Philosophy at San Jose State University, muses “on responsible conduct of scientific research, communication between scientists and nonscientists about the issues that matter to both camps, and teaching science and ethics.” Dr Stemwedel appears well qualified; she teaches the philosophy and ethical conduct of science and has a PhD in physical chemistry.

Blog.bioethics.net
This blog from the editors of the American Journal of Bioethics, features postings from such bioethics heavyweights as Glenn McGee, PhD, David Magnus, PhD, and Paul Root Wolpe, PhD (the Keynote Speaker at the 2011 AMWA Annual Conference), and the journal’s editors, as well as Arthur Caplan, PhD (whom I quoted numerous times in my past life as a newspaper reporter covering medicine), and Ricki Lewis, PhD, who writes and lectures about genetics. Recent topics include a discussion about whether the courts can require a 32-year-old woman with schizophrenia and bipolar disorder to have an abortion or refrain from sex; the use of Justin Bieber to drive organ donation signups in Canada; and the denial of a kidney transplant for a severely disabled 3-year-old.

Research Ethics Blog: Researchethicsblog.com
This blog is written by Nancy Walton, PhD, an Associate Professor of Nursing at Ryerson University in Toronto, Canada, who teaches ethics and chairs the Ryerson University Research Ethics Board. Recent posts include a crackdown on research misconduct in China; the research fraud perpetrated by Netherlands psychologist Diederik Stapel; and the importance of disclosing conflicts of interest when publishing research.

Journal of Medical Ethics Blog: blogs.bmj.com/medical-ethics
This blog, by the editors of the journal of the same name, attempts to provide “our own musings on all things ethical; quick reviews of the most important new books as they appear and some old books before they disappear; reports from interesting and not-so-interesting conferences” and news about the journal. A recent post focused on legislation introduced in the Senate that, I kid you not, prohibits the sale of food “or any other product intended for human consumption which contains aborted human fetuses in the ingredients or which used aborted human fetuses in the research or development of any of the ingredients.” No wonder we can’t get anything done in Congress.

➲ Want to see more?
Visit Masters Degree (www.Mastersdegree.net) and search on “ethics blogs” for a list of “50 Excellent Ethics Blogs Every Science Student Should Read.”
Like a tapestry, each person on AMWA’s LinkedIn discussion thread adds color and depth to the ultimate design. Ethics in medical communication is a consistently hot topic, and one thread in particular showed that our members are willing to speak out about integrity and honesty in our profession.

In “AMWA president helps to clarify medical writing for Medscape,” Kristina Wasson-Blader, PhD, ELS, CMPP, posted a recent article that “inappropriately labeled disclosed medical writing assistance as ghostwriting.” AMWA President Barbara Snyder countered that assumption in a note to the publication, explaining that “proper disclosures were made and the named authors were involved in the manuscript,” and showing that “this was not an instance of ghostwriting and should not be characterized as such.”

Other AMWA members also showed their concern, noting that educating various media sectors is one key to avoiding future misunderstandings. Professor Karen Woolley said, “We have a ‘duty of care’ to our profession to inform journalists who don’t understand the ethical difference between ghostwriters and professional medical writers.” Faith Reidenbach, ELS, CMPP, suggested that “AMWA could do a lot of good by working proactively with the Association of Health Care Journalists, the National Association of Science Writers (most of whose members are journalists), and major news outlets to raise awareness about the legitimate role for medical writers in preparing scientific publications.” Donald Harting, MA, ELS, CCMEP said that as a former journalist, he hesitated to criticize those who may be perceived as over-diligent in the search for unethical behavior. He explained that in the light of corruption and abuse in many areas of society, “The only thing worse than having all these terrible things happen would be to have them happen in secret.”

Even though certain aspects of the profession are controversial, reading the responses to a request for participants to share what they love about being a medical communicator fashioned yet another common thread. The answers reflected a passion for writing, a thirst for new knowledge, delight in the creative process, yearning for interaction with really smart people, and the quest for disseminating research. Kristen Phiel summed it up, “Plus you can hold a tangible product in your hand at the end of the day and say you made a contribution.”

Looking forward to connecting with you on LinkedIn!

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Common Threads Create a Tapestry of Ideas for AMWA’s LinkedIn Group

By Mali R. Schantz-Feld, MA
Freelance Medical Writer, Seminole, FL

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Note from the President

By Barbara Snyder, MA, 2011-2012 AMWA President

I realize that the tradition is for the AMWA President to use this space to talk about the January Executive Committee meeting. For this issue, I’d like to share with you some information and thoughts from a two-day Symposium for Chief Elected and Chief Staff Officers that I attended in November with Doug Haneline (AMWA President-Elect) and Susan Krug (AMWA Executive Director). This symposium was presented by the American Society of Association Executives and, to my knowledge, this is the first time that AMWA has invested in this kind of training and interaction.

The symposium was our opportunity to do three things:
1) Learn from the best practices of our peers in the association industry
2) Have in-depth conversations about AMWA’s current state and plans for the future
3) Develop an understanding of our individual styles
(The elected officers and Executive Director work closely together and we need not only to be aligned on the goals for our particular year but also to understand how to manage our relationship to the best advantage of our members.)

We took full advantage of these two days to learn some things about ourselves and interact with individuals from a widely diverse audience of participants. But mostly we talked about you—our members—about how to match our roles, processes, technology, and capacity so that AMWA is not just a vendor of services and purveyor of information but is a true community of common purpose that provides its members with relevant content.

Because this was a meeting of elected and hired individuals, part of the discussion focused on the difference between oversight (focusing on whether outcomes are being achieved—the role of the Executive Committee) and supervision (how the outcomes are being achieved—the role of the Executive Director). We talked about how to make the most of our respective roles for the benefit of our members.

What Drives Us
AMWA, as an association, and our members, individually and collectively, have benefited significantly from several facts: our educational programs are top-notch, we have an incredibly dedicated volunteer workforce, and health care and communication about health care are booming businesses.

Finances
Of course, we talked about money: how the financing for new programming has to come from either new revenue streams or reallocation of resources, how AMWA has weathered the recession better than some other organizations partly because we’ve understood that this is no time to be cutting member services, how it makes sense to hire consultants for some finite tasks rather than increase the number of permanent employees, and how resource allocation is a big part of financial planning.

I had an “ah-ha” moment when Susan told us that the annual conference is not a big moneymaker for AMWA (especially when you consider the staff time required for the planning and execution). I knew that AMWA has always heavily subsidized the meal events, but had no idea how expensive it really is to put on a program like this, even with our wonderful volunteers. We need to identify new revenue streams and to reallocate resources for the annual conference to continue the quality of the education and networking while attracting more attendees, sponsors, and exhibitors.

Volunteers
AMWA is blessed to have volunteers who freely give of their time and talents. Given the reality that a large segment of our current volunteers consists of baby boomers who may be retiring over the next 10 years or so, we know that our present volunteer workforce is not sustainable. We need to identify more opportunities for more people to contribute and allow folks to do so on a level with which they are comfortable. It’s no longer a matter of fitting members into existing slots, but first asking members what they want to get out of the organization and then figuring out how to provide those opportunities. We know that members who are engaged and involved are likely to maintain their membership because they see the importance of their personal contribution in addition to the value of the organization as a whole. We need to re-engage long-term members and identify best practices to develop upcoming leaders.
Achieving Our Potential

Before we can achieve our potential (both as medical writers and as the organization of AMWA), we have to identify the constraining factors—and our members must be included in that identification process. On an individual member basis, the constraints may be related to a lack of job security (or lack of a job, period), outsourcing, off-shoring, changing expectations (eg, technology or regulations), etc. For AMWA as an organization, two of the major constraints (finances and volunteers) have already been mentioned. We also need to bring our current technology up to industry standards. Some of these things take money; all of them take careful planning and strategic thinking.

Low-hanging Fruit

We can do some things now with little cost:

1) We can ensure that AMWA comes up in Internet searches related to medical writing, medical communication, writing, editing, etc. AMWA is already a trusted source of information among our members. We need to be the first place people go when a need arises, whether it’s an employer looking for a writer, a writer looking for employment, or someone looking for educational resources or information about the profession.

2) Understanding that communication is not just dissemination of information, we can provide opportunities for two-way communication among the members, among chapters, and between the members and AMWA’s leadership. Transparency is key. The Executive Committee (EC) can’t be a black box in which the decisions about AMWA’s governance and direction are made. Committees have to be connected to a larger vision. Current members need to be engaged in shaping our direction, a process that must also address the needs of potential members.

3) The listserves have functioned well as a conduit for issues that require a response, either individually or collectively (eg, the continuing discussion of acknowledgment of medical writers). We can continue to use these as a way to notify leadership that a topic has come up that needs a formal response from AMWA.

After the symposium, my head was swirling with information and a lot of questions to ponder on the drive home:

1) We have about 4,000+ members who don’t come to the annual conference. What do they get from AMWA that keeps them renewing their membership, and how can we better serve their needs?

2) How do we develop and sustain our volunteer pipeline?

3) How do we change our infrastructure to not only encourage growth but to accommodate it? A 10,000-member organization may require a different infrastructure than a 5,000-member one. What do we need to do to be ready for that growth?

4) How do we define “success” for our endeavors—be it our annual conference, our certificate program, our move toward certification, our chapters, or our position within the profession? That is, how can each of these provide the greatest value for our members? For every effort, we must be able to say “yes” to the question, “does this move us closer to where we want to be in terms of member benefits?”

Obviously, I have more questions than answers. But I have no doubt that, together, we can find answers to each and every one. I invite you to join me in this exciting search.

AMWA Members’ Knowledge of AMWA Code of Ethics

The 2010 AMWA Member Needs Assessment included three questions related to the AMWA Code of Ethics (see page 5 for the Code). The following are the questions and responses—along with the number of survey respondents who did not answer the question.

Are you familiar with AMWA’s Code of Ethics?
Yes: 84%
No: 16%
80 (5%) of 1,483 survey respondents did not answer the question

Do you generally follow the principles in the Code?
Yes: 95%
No: 5%
210 (14%) of 1,483 survey respondents did not answer the question

Have you ever advocated the Code or one of its principles?
Yes: 46%
No: 54%
198 (13%) of 1,483 survey respondents did not answer the question
Medical communication—and particularly communication with patients—is such an important part of the practice of medicine that it cannot be repeated or taught often enough. And, unfortunately, it is sparsely taught to embryonic physicians. I report here four actual, real-life situations where a little better medical communication (or more common sense) would have created a good working relationship for physician and patient, and perhaps a better outcome for both.

1. Leonard was visiting a new dermatologist. Noticing that the doctor did not wash his hands before examining him, Leonard asked the doctor if he would do so. The doctor's explosive response, “Get out. I don't want to have you as a patient,” was followed by his formal discharge of Leonard as a patient (even though the doctor had never seen him before or had even examined him at this visit).

Commentary: This almost needs no comment. The physician was totally wrong in not washing his hands between patients; especially as a dermatologist, he had to understand this. If he had washed his hands elsewhere after seeing the previous patient, he could say so and apologize (and learn to wash his hands in front of the patient he is about to examine). If he happened to forget this one time because of office rush, he should have apologized and proceeded to washing. If he did not believe in the need for hand washing (hardly possible in today’s milieu), he should be doing it just for show, to impress his patients.

2. Anita was referred by her physician to a consultant. As her physician-husband started to offer her history, the doctor stopped him, saying to both, with a wave of his hands, “Don't talk to me. Just answer my questions.”

Commentary: The doctor was apparently rushed or was interested only in treating diseases, not patients. Brusque. Hurried. Maybe a good doctor but a poor communicator. Perhaps he never heard (or didn't believe) the famed axiom of Sir William Osler, “Listen, the patient is telling you the diagnosis.” Compare this to another consultant Anita saw the same week. He approached her immediately, eyes focused on her, touched her hand, and asked her, “Why do you think Dr Smith referred you to me?” His approach expressed interest in the patient and he was essentially trying to find out the patient's view of the purpose of the consultation. Good communication—and good medical practice. Osler's succinct advice stresses the great importance (some say the most important aspect) of making a diagnosis.

3. Joy (as reported by the Philadelphia Inquirer) received a telephone call from her surgeon, reporting on a breast biopsy. “You have cancer,” he told her. In shock and trembling, she asked, “What should I do?” The surgeon's reply: “Come into my office on Monday, and we'll discuss your options.” Joy sobbed, “But what will I do until then?” The cold answer was “We can talk about that on Monday. You know you're not my only patient!” (How arrogant!)

Commentary: Cold. Heartless. Should he have said (assuming good intentions on his part), “It can wait until Monday. Everything is not bleak. We have great success with breast cancer treatments, and I have a number of patients who, after treatment, have done well. So just try to relax and I’ll see you Monday, and we can talk fully how to get you better.”? Or was he just immune to a patient's worries and emotional state and didn't give a hoot, as long as what he was doing was scientifically correct?

4. A young internal medicine resident called one of his senior chiefs in great anxiety. “I have a patient who smokes and I've tried everything (and he listed all of them) to get him to stop, with no success.” The older doctor asked, “And what symptoms from the smoking does he have?” Replied the resident, “None.” Instinctively, the senior chief asked, “How old is he?” The unsurprising answer was “94.” The resident was treating a "symptom," not the patient.

Commentary: The resident was taught an important lesson: Never treat someone without considering who the patient is, how old he is, what his lifestyle is. In other words, treat the human being before you, not just the disease or symptom.

Fortunately, doctors like these are in the minority of practitioners. But when such situations do occur, patients often, unfortunately, infer an absence of caring or lack of understanding on the part of the medical profession, not just one renegade member.

As my colleague, the late Morton Terry, DO, founder of the Southeastern College of Osteopathic Medicine, used to say after sitting in on our admissions committee interviews, “I question candidates to see whether they are the kind of physician I would send my mother to.” Amen to that—his comment on their communications skills.

Medical communication is so much an essential part of medical practice and patient care.
Handbook for Mortals: Guidance for People Facing Serious Illness, 2nd ed.
Joanne Lynn, MD; Joan Harrold MD; Janice Lynn Schuster, MFA
New York: Oxford Press, 2011; 274 pp

This popular guide is written for those who wish to approach the final years with greater expectations and awareness and who seek to make the end of life a period for reflection. The lead author, Dr Lynn, was one of the first hospice physicians in the United States and a major contributor to research and policy on end-of-life issues.

A prevailing thesis of the book is that modern technology has changed both the way we live and the way we die; however, most people try to avoid the issues of death and are unprepared to make decisions about death. For example, in our society it is more common to hear words like “is gone,” “was lost,” “passed,” or “expired,” than “died.” The authors address this problem with positive and encouraging statements from different perspectives. The book is intended for people living with serious illness, their relatives, and their friends, providing readers with what they need to know about choices, where to look for help, how the healthcare system operates, and how the entire experience affects the patient, the family, and friends.

How to live with serious illness and death and dying permeates each chapter. Tips on talking with a sick person are featured. For example, instead of saying, “Dad, you’re going to be just fine,” the authors suggest trying this instead: “Dad, are there some things that worry you? It must be hard to come terms with all this.” Also, instead of saying, “Don’t talk like that! You can beat this,” say “We will always be there for you.”

From the onset of the illness to the nitty-gritty of making decisions about final moments, the authors address issues with empathy and compassion. Chapters focus on such topics as talking to your doctor; planning for making choices; dealing with the health care system; taking care of the caregiver; and facing the effect of death on dying persons, their families, and friends. In addition to people who have long illness, chapters also address death of children, sudden death, and enduring loss.

How to communicate and talk about death and dying are mainstays of this book. In society today, people truly avoid talking about living with serious illness and the possibility that death may be near. We often treat people who are dying as if they are a separate world apart, in contrast with those who are living. The authors point out that in reality, they are among the living and want to be with family and friends, pursue hobbies, and keep up with the things that interest them. They posit the idea that one is living with a serious illness and not dying of a disease.

The authors tackle the difficult topic of talking to the doctor in an important chapter. They guide readers to consider questions that are worth asking and suggestions for making the most out of each visit to the doctor. For example, some questions worth asking are the following: What usually happens to people who have this disease? How long do people usually live with this illness? What is the best that I can possibly hope for? What is the worst that I am likely to face? To get the most from the visit, the authors suggest preparing a list of questions and concerns that you want to discuss. The authors include examples of useful and practical conversations with doctors.

A strong feature of the book is the section on resources for end-of-life planning and decision-making, including making advance directives, contacting local agencies on aging, and finding hospice services. Personal anecdotes of how real people have coped help the reader gain perspective and humanize the book. Also, the authors use pertinent passages from literary giants such as Emily Dickinson to illustrate that life has meaning to those who are facing their own mortality.

This book is one that should be in the personal library of all individuals. It is exactly as the title implies—a realistic handbook for mortals, which gives both physical advice and spiritual encouragement.

– Evelyn Kelly, PhD

Evelyn is a freelance writer in Ocala, FL.

The module includes a workbook, CD, and laminated Quick Reference Guide. If you are pursuing an Essential Skills certificate, complete the test sheet in the module and send to AMWA to earn credit. The module is also an excellent enduring resource for people who are not pursuing a certificate or for people who have already participated in the workshop.

Each chapter in the workbook includes a case report about one of the principles in the AMWA Code of Ethics and a series of questions and answers. The cases (most based on real-life situations) have been carefully selected to illustrate the many different types of ethical situations frequently encountered by medical communicators and to demonstrate the practical use of the Code.

Visit the AMWA Web site (www.amwa.org) to purchase the Essential Ethics for Medical Communicators self-study module. Click on Education/Conferences > Self-Study Workshops.

A proliferation of scientific data and advanced medical technologies has heightened the call for professionals who can communicate these concepts—succinctly and articulately. In response, Northeastern University’s College of Professional Services offers the Master of Science in Technical Communication with a concentration in Biomedical Writing.

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Finding Significance in a Career Full of Trials

By Jen LiMarzi

Associate Medical Director, PeerDirect, Winooski, VT

I began college in the mid-1990s majoring in molecular genetics with the intention of becoming a modern female Mendel, albeit with cuter clothes, who would ultimately cure a myriad of diseases and discover an affordable way to clone the family dog. Two years into my pursuits, I found myself turning my plastic organic chemistry models into bracelets and hair accessories more often than complex compounds and molecules. The idea of a life and career filled with scientific benchwork that might never lead to a concrete answer or discovery was something I could no longer fathom.

As you can imagine, the call telling my parents that their future Nobel-prize-winning geneticist daughter was now an English major was a tense one.

“I suppose you could be a medical writer,” my mother reasoned.

I rolled my eyes while on the phone feeling certain that she didn’t comprehend my personal evolution and new goals. I now intended to be a modern Jane Austen, albeit with cuter clothes, who would write the Great American novel and be a pioneer of the writing community.

When I graduated from college, I soon learned that there were very few job postings that came with the title “Aspiring Novelist.” Instead, I went into textbook publishing, where I learned the finer points of photocopying, office politics, putting together a business casual wardrobe, and commuting—given that my meager salary left my childhood bedroom as my only housing option. Hoping that my life and career weren’t over at 23, I sought out the help of a recruiter who afforded me lots of opportunities as well as comic relief during tough times.

It was the late 1990s, and if you were fortunate enough to ride the high of the Internet boom, it’s an experience you will not likely forget, and one that I often wish could be re-created. My new salary meant a move into New York City, and my new work environment introduced me to some of the smartest and most interesting coworkers I’ve ever known. More importantly, my new position allowed me to write. Well, at least a little bit. I worked in the Public Relations department at a time when every day seemed to inspire something press release worthy.

After a few years, the Internet boom began its epic spiral downward. With mergers, takeovers, and layoffs looming, I jumped at an offer to be an account executive at a midtown public relations firm fearing that if I didn’t jump, I might be pushed off the plank. While there, I became an expert press release writer, but our firm soon became hard pressed to find clients. Half the firm was laid off within a year and I spent a summer unemployed and wondering if perhaps I should have taken my organic chemistry models a bit more seriously.

After countless interviews, I finally scored one at a very small ophthalmology magazine that was intrigued by my experience at Medscape. I put on my best interview suit and was about to head downtown to the company’s office located two blocks from the World Trade Center, when my phone rang.

“There seems to be something crazy going on here,” the company’s production manager said. “Perhaps we ought to reschedule for next week?”

My interview was scheduled for September 11, 2001. Despite the tragedy and catastrophe that was downtown Manhattan, 2 weeks later I started as an associate editor at an ophthalmology journal. I was fairly certain that I got the job because I was the only candidate who showed up. As a resilient New Yorker, the challenge of the job quickly shifted from a physical one where I had to wear a dust mask just to make it through the day to a mental one where I had to learn to really write. My boss was an excellent mentor who afforded me lots of opportunities as well as comic relief during tough times.

Unfortunately, the economy again plummeted and with it went the amount of advertising dollars that the magazine was pulling in. Once again laid off, I was now a bit older and wiser and knew that a job hunt would be a challenge. Still clinging to the idea that I was far too creative to be a medical writer, I interviewed at popular magazines, advertising agencies, and any quirky place that would call me back.

One such quirky place was a fairly new medical education company looking for a medical writer. I left the interview confused about what medical education was or what the job would entail. Assuming this confusion shone through on the interview, I was not confident anything would come of it. However, several days later the entire Northeast suffered a massive blackout. When the lights came back on I was notified that the job was mine, though I was again convinced that it was because I was the only candidate who showed up.

For the second time in a row, I had unintentionally become a medical writer. Attempting to get my feet wet in medical education was akin to being baptized by a fire hose. In those early months, I learned about the pharmaceutical regulatory process, annotating, advisory boards, key opin-
ion leaders, and reprint carriers and became more adept at PowerPoint and Internet research than any human really should be. Much like my days at Medscape, my coworkers at my new company were on the ground floor of a burgeoning industry and with that came an energy and strong sense of comradery.

With the growth of medical education came a slew of competitors all chasing after the same piece of the pharmaceutical marketing money pie. Tired of working on tiny projects and fearing that another layoff may be eminent, I returned one of the recruiter calls that had found its way into my voice mail.

My next position was as a senior medical writer at a larger medical education firm with solid clients and out-of-the-box ideas. We created a medical Jeopardy-style program for residents, wrote review articles for physicians, created speaker slide decks for pharmaceutical giants, and had advisory board meetings in every corner of the country and world. Work was intense but highly varied, and I was consistently figuring out how to create something new with every project we proposed and won.

Several years in, now serving as associate scientific director, the pace was burning me out and the diversity of duties had me looking for structure and a little life balance. This is what inspired my last career move and led me to where I am today.

I went into my interview for PeerDirect stating that I wanted to solely be a medical writer, albeit in cuter clothes. Finally confessing that I was a medical writer was, in a sense, similar to an alcoholic admitting their secret at an AA meeting. Everybody apparently knew what I was and needed to be except me. My experiences landed me a job that would both allow me to write and work from home, giving me that work-life balance that I craved.

A week after I started my new job, a steam pipe exploded outside the building where I had last worked. I took this as a sign from the employment gods that I no longer was gaining employment as a result of disasters but should simply be thankful that I had avoided them.

Lately, the medical education, regulatory, and pharmaceutical landscapes are shifting so that medical writers are getting far fewer freedoms in creating interesting and engaging content. More often than not, after completing feats of strength to submit a piece into a client’s complicated review system, we’re simply told to repurpose pieces that are safe and approved, taking language verbatim from something that may make little sense. While I’ll admit that this is discouraging to me in my current role as a medical writer, I know that I and my colleagues have survived worse—layoffs, explosions, implosions, and disasters both physical and perceived.

I have faith that we’ll survive these latest challenges and if you’re still a medical writer when the next incarnation of the industry emerges, it’s likely no accident.

Author contact: JenLiMarzi@gmail.com

The Global Alliance of Publication Professionals (GAPP) has made its debut with the launch of its Web site (www.gappteam.org). The GAPP team is led by Karen Woolley, PhD, CMPP. AMWA’s 2009 Keynote Speaker, and includes three additional AMWA members: Art Gertel; Cindy Hamilton, PharmD, ELS; and Gene Snyder, MBA, as well as Dr Adam Jacobs, a leader in the European Medical Writers Association (EMWA). Each of these GAPP members has demonstrated a strong commitment to ethical publication practices, conducting original research, and providing expert commentary on the ethics and value of medical publication professionals.

GAPP recognizes the difficulty journalists have in gaining timely, international, and credible responses to breaking news stories about medical publication issues, such as ghostwriting. GAPP aims to bridge the gap between journalists and medical publication professionals by helping journalists and their readers understand the difference between ghostwriters and medical publication professionals (eg, professional medical writers, publication planners).

GAPP members look forward to developing respectful relationships with journalists. The public has the right to hear the voice of medical publication professionals and make its own judgments about the ethics and value of these professionals.

“We need to reach out to journalists around the world and provide them with the information they need to prepare well-informed and balanced articles about medical publication professionals. We have been confused with ghostwriters for far too long and, frankly, we have to take some of the blame for that,” says Professor Woolley.

Failure to publish, particularly public-funded research, is unethical, yet according to a recent analysis, less than half of NIH-funded research is published within 30 months.1 “Professional medical writers help busy or inexperienced authors prepare high-quality manuscripts in a timely manner. We help authors meet their ethical and scientific obligations to share results in the peer-reviewed literature,” says Dr Hamilton. Gertel points out another advantage of medical writers: “Evidence indicates manuscripts with medical writing assistance show higher compliance with publication guidelines and are less likely to be retracted for misconduct.”

GAPP is designed to complement, not compete with, AMWA and other professional associations, such as EMWA and the International Society for Medical Publication Professionals (ISMPP). The GAPP Web site offers links to the Web sites, mission statements, and code of ethics for AMWA, EMWA, ISMPP, and other associations “committed to high levels of transparency, integrity, and professionalism.”

For more information, visit the GAPP Web site (www.gappteam.org) or contact GAPP members at contact@gappteam.org.

References
IN MEMORIAM

Milton J. (Red) Schiffrin, PhD
March 23, 1914, to December 2, 2011

No more “Cheers”!

“Cheers” is gone forever, along with Milton J (Red) Schiffrin, PhD, whose use of that greeting accompanied everything he wrote and was his trademark. He passed away peacefully in his sleep. I am heartbroken, as everyone who knew him will be. He was 97.

To gather facts for this obituary, I turned to a Member Profile I had written about Red in 2002 [AMWA J. 2002;17 (3):44]. After re-reading the profile, I could think of no better tribute than to republish (with some minor edits) what I wrote from my heart back then.

Red made many marks—all good ones—in AMWA throughout his many years of activity and service. His genius was intellectual talent, concern for others, and levelheaded, mature judgment.

After 10 years of work in the Metropolitan New York Chapter and at the national level, he became president of AMWA in 1973. Used to solving organizational problems (in a single bound), he never imagined what would face him. Almost immediately, he and the Board of Directors recognized that the company providing AMWA’s secretarial and administrative services was not working out. He and the Board severed relations with the company. There he was, president of an association with no office, no secretarial help, and no administrative assistance for its 400 members.

Red took command. Spending numerous weekends commuting between New York and Washington and working with Bill Nelligan, then AMWA’s Treasurer, he kept the organization intact, hired Lillian Sablack as executive secretary, and found office space. It was like lighting a rocket. Within a year or so, his dedication and diligence started AMWA on the road to where it is now. In 1975, he received the Swanberg Award.

He never stopped working for AMWA. Oh, recently he slowed down a little, befitting his age. But he always made his service, his advice, and his sharp mind available to everyone. He served as a leader without portfolio, a good friend, and, for many, a father figure.

So, who was Red? Trained in physiology and chemistry, he became a Clinical Research Associate at Hoffman-LaRoche, eventually rising to the position of Assistant Vice President. His main duty was getting FDA approval for new drugs, and at one time, he probably knew more than anyone in the country about this complicated process. Along the way, he taught at three medical schools, was a captain in the US Army Air Force, wrote or contributed to several medical textbooks, was inducted into several professional and scientific societies, and contributed more than 40 articles to the scientific literature. (A little known fact is that he started in college as a music major and always retained a deep interest in things musical. But for us, music’s loss was science’s gain.)

Since 1990, when he moved to Seattle, he has continued to serve others as an ombudsman in nursing homes for 7 years and in myriad other activities aiding and serving the elderly.

When I asked him about what he thought was important in his life, almost all his answers referred to helping others in one way or another. He said his philosophy of life could be summed up as follows: “We only go this way once, so be considerate of your fellow struggling creatures.” Finally, and in his own inimitable and self-deprecating style, he wanted to be remembered as “someone who has helped others.”

So Red, who was always concerned about other people, was thrown into a mess on assuming the presidency. He took AMWA by the hand and spoon-fed it. He worked diligently to promote AMWA—worked hand-in-hand with officers and members and often sparked reluctant ones into action. He provided the groundwork for our years of progress and for today’s healthy success. He did it with his competence, his great sense of humor, and, mostly, his unbounded dedication and loyalty.

His legacy: You could easily say that Red was the father—or grandfather—of our modern AMWA.

Red’s other trademark, both in writing and speaking, was “or so it would appear.” It identified him for the 50+ years I knew him. And I can just see Red now, spellbinding the angels and entertaining them with his wit and intelligence and lively talk—or so it would appear.

—Arnold Melnick, DO
1974-1975 AMWA President
Red had the privilege of knowing Red Schiffrin for almost 35 years and working with him in the 1970s and early 1980s on several AMWA committees and projects. In subsequent years, I was fortunate to be among the many friends and colleagues with whom Red remained connected by letter and e-mail.

First and foremost, Red Schiffrin was a “people person.” He always had a smile, ready ear, and advice for fledgling or experienced AMWA members seeking guidance or direction. This characteristic was tested time and again when AMWA rose to national prominence just prior to and during his presidency. Difficult decisions were required as the organization grew its membership and added new member services. Red set the direction for many of these organizational advances, but there was no universal agreement about them. With his smooth and fatherly type style, Red was able to gain consensus and move the organization forward. AMWA was forever in his blood.

As I rose through the ranks within AMWA and was nominated for the presidency, I was not certain that I was up to the task. On many occasions, Red would mentor me, provide sound advice, and help me to acquire the tools needed to lead AMWA. Red took countless other members under his wing, leading to successful careers within AMWA and the profession. Those of us on his holiday mailing list can never forget his yearly message wherein he would relate in most humorous fashion his holiday preparations and activities through the eyes of an inebriated individual. These messages were classic in content and context and were liberally laced with misspellings and totally outlandish concepts. The letters were an awaited annual treasure.

Red showed great compassion and concern for aging and ill AMWA colleagues and reminded many of us of the need to stay in touch with these individuals.

Perhaps above all, Red was a dedicated family man, often sharing family happenings and asking for prayers during the final illness of his beloved wife.

Red Schiffrin will be sorely missed but his legacy will long stand among family and friends, within the ranks of the pharmaceutical industry, and certainly within AMWA.

Rest in peace, my friend.

—Robert Orsetti
1977-1978 AMWA President

Red had many friends in both high and low places, and I am honored to be among them. He was not only a medical writer par excellence but, as a medical company executive as well, he had a profound influence on the entire medical writing profession. As President and then honorary philosopher of AMWA, he was a kindly Dutch Uncle to new members of AMWA.

When I became President, he was a trusted advisor who was always ready with advice and suggestions but never insisted that I accept his solution. He was ready with counsel but always left you to make the decision.

Red was a very funny man. He loved to tell jokes and hear them. Almost every day from Seattle, there in my e-mail box was one or more of Red’s wonderful jokes, of which he had a seemingly innumerable supply.

A chosen few have been called “a man for all seasons.” If anyone belongs in that storied pantheon, it is Red Schiffrin.

—Louis Buttell
1980-1981 AMWA President

Red had been my mentor since the first AMWA meeting I attended; he was behind me all the way and was one of those who nominated me for AMWA President (and convinced me to accept). He was such a kind and thoughtful person; I think everyone who knew him loved him. At 97, I guess he deserved to be able to leave the planet!

—Cathryn Evans
1982-1983 AMWA President

Red Schiffrin and I became near-daily correspondents via e-mail when both of us, as (long) Past-Presidents of AMWA, were invited to write historical segments for the AMWA Journal. We met face-to-face only twice; yet, for all those years until his recent illness, we exchanged jokes, quotes, and comments on the world news, as though we were next-door neighbors. He shared with me the wisdom of his scholarly friends at University House and his dearly loved colleague, Arnold Melnick, as well as cartoons. Maxine was his favorite.

Red always answered my questions; one example is the following: “Phyllis, thank you for your postal mail and your two interesting questions: what did I try and fail, and what did I not try? I tried 2 years at the Eastman School of Music majoring in voice. My father’s illness made me drop out of school, and when I was able to resume education, I majored in chemistry and math because I realized that the best I could do in music would be as a high school teacher. But music remains a most important asset in my life. When I left the Air Force I could have gone to medical school and picked up the MD degree, but surprisingly now, as I look back on it, being a physician, somehow didn’t appeal to me. In addition, I was married and had a son so there was a lot going on in my life.”

And, dear Red, here’s some wisdom you sent: Keep laughing, dear man.

—Phyllis Minick
1994-1995 AMWA President
“Distraction is the only thing that consoles us of our miseries, and yet it is itself the greatest of our miseries.”

– Blaise Pascal, 17th century French philosopher

Driven to Distraction

By Eleanor Vincent

Since I discovered Words with Friends—an online Scrabble game developed by Zynga—my fingers itch when in proximity to my iPhone. My own little digital pet, the phone never leaves my side for a waking minute. I flick the screen to find the friendly icon, a black W on a gold background. When the list of my current games opens, a chime lets me know that one of my nine opponents—ahem “friends”—has made a play. I touch the screen to open the game and disappear down the enticing black hole of faux connection and entertainment afforded by the mini-computer in my hand.

I’ve become the person I used to mock: a digital crackhead. The habit began innocently, as a way to keep in touch with my 31-year-old daughter. Meghan can simultaneously text, Skype, IM, watch TV, post on Facebook, and talk on her cell phone. I’m an antediluvian relic who actually studied typing in high school. I never could do the dance of the thumbs on a standard cell phone.

But when I discovered the built-in keypad on the iPhone, I found that I could text with ease and that my daughter would respond instantaneously. So when Meghan invited me to play Words with Friends, it sounded so... well... friendly that I responded to her invitation by tapping in my first set of letters. Within a few moves I was hooked. That was 6 months ago. Now, as 2012 dawns, I am considering drastic measures.

Writing in the magazine Poets and Writers, Frank Bures confesses his own challenges with “continuous partial attention,” that state where you skim the surface attending to a flood of incoming bits of data unable to form a coherent thought, let alone capture it. Bures finally resorted to purchasing an antidistraction software program that shuts down his Wi-Fi for several hours so that he can concentrate. Other writers work on Internet-disabled computers. Acclaimed essayist and novelist Pico Iyer boasts that he has never used a cell phone, tweeted, or entered Facebook. If that’s what it takes to churn out gorgeous prose, it may be worth it.

In my spare moments, instead of writing, I find that I reach for the phone. I tell myself it’s better than watching TV, it stimulates the few brain cells still functional after a long day at the office, and gosh darn it, it is fun. But when I add up the amount of time I’m investing to manage nine ongoing games—a half hour in the morning, and sometimes more at night—I realize the price is too high. And it isn’t just the time. The obsession with “winning” has become a major distraction, one that keeps me from the kind of rumination that leads to writing, nay, that is absolutely essential to it. My lack of self-control has led me to consider starting a 12-step program for the similarly afflicted. God grant me the serenity to put down this phone and actually write a poem or work on the next chapter of my book. I hold down the off key with a shaking forefinger, and the “slide to power off” message flashes across the screen. In the heart-stopping moment when the screen goes dark, my head clears. I tuck the phone into the inside pocket of my purse. I’ve reclaimed my attention long enough to gaze at the moon hanging like a broken coin outside my window, gold against a black night sky. So much better than anything Zynga could create. Maybe I’ll go write about that.

Eleanor Vincent is the author of the memoir Swimming with Maya: A Mother’s Story (Capital Books, 2004). She lives and writes in Oakland, CA.
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BE YOUR OWN IT DEPARTMENT

Moderator
Faith Reidenbach, ELS, CMPP
Principal, Caley-Reidenbach Consulting LLP, Corvallis, OR

Speaker
Jeanne McAdara-Berkowitz, PhD
Principal, Biolexica, Longmont, CO

By Kelly Schrank

For freelances who want to focus on the core of their business, dealing with the technologies required in a modern medical writing business can seem daunting. Jeanne McAdara-Berkowitz, PhD, was quick to say that if you are not comfortable with many of the information technology (IT) tasks, it is worth your time and energy to pay someone else to do it. She happens to enjoy computers and technology, she said, which was evident in her excitement during discussions. Her knowledge was also adequate to cover for the IT professional who was unable to make it at the last minute.

Dr McAdara-Berkowitz began by discussing computer maintenance tasks that she believes should be done monthly.

• Perform a defrag (puts everything back where it belongs).
• Run the Check Disk (for PC, or Mac equivalent).
• Clear out caches (Web browsers and computer files).
• Reboot every so often.
• Keep equipment clean (specifically, vacuum fans in desktops).
• Keep software up to date (specifically, keep up with patches).
• Run auto updates.
• Keep security software up to date.

She followed with a discussion of disaster recovery, stressing how important it is as professionals to protect the clients’ privacy and their work. She recommended the use of online backup services, so the freelance could “set them and forget them.” Because it is cost-prohibitive to back up everything, she suggests backing up only data, not the operating system or the applications. An external USB hard drive in conjunction with the backup program within the operating system or included with the external hard drive are fine for this purpose. This process will get a backup copy of data quickly, but she cautioned not to use this external hard drive for anything else to limit the chance of corrupting it with other files (photos or personal files).

Dr McAdara-Berkowitz also stressed the importance of keeping the computer’s hardware safe from different types of theft. If a business laptop or phone is lost, GPS-enabled tracking software may be able to help find it. Technology also exists to wipe your iPhone clean if it is stolen, so that names, telephone numbers, and e-mail addresses will not be compromised. She believes all such professional devices should be backed up frequently and password-protected and encrypted with strong passwords. She added that a password needs to include letters and numbers as well as symbols (if possible) and should definitely be “stronger than your dog’s name.” Furthermore, passwords and login names should be different for each account. She acknowledged that it is a challenge to track several passwords and login names, which is why she recommended programs such as Secret Saver and Wallet; these password manager programs store usernames and passwords and securely automatically populates Web forms.

Dr McAdara-Berkowitz switched gears and began a discussion of the Cloud: "the most recent stage in the evolution of data and storage.” She used the following analogy: in the past, we would have photo albums to store all of our photos, but you had to carry the books with you. Now, with digital photography and digital storage, you can store photos on servers, so anyone on the network can access photos from many “form factors” (ie, gadgets like smartphones, tablet computers, and computers). All of these servers decentralized across the country comprise the Cloud.

No discussion of the convenience of the Cloud would be complete without a discussion of its safety. Dr McAdara-Berkowitz knows this is a new frontier for many people, so she recommended that people assess their personal comfort with risk before proceeding. She offered this advice: use reputable vendors, virus/spyware protection, firewall software, and updated operating systems and software.

She discussed some other ways to be secure:

• Be hypervigilant
• Use secure and unique passwords
• Make sure that Web sites are secure (look for https:// instead of just http://)
• Do not transfer information on public networks
• Check the “from” e-mail address of unsolicited e-mails to make sure they are actually from the company they claim to be
She provided some examples of Cloud storage, backup, and sharing options: Dropbox, Carbonite, YouSendIt, and filesanywhere. Dr. McAdara-Berkowitz also likes Evernote, which she described as the “digital equivalent of tearing out articles to read later.” She has some recommendations for task management applications: Remember the Milk is a simple option, Things is a medium-level option, and Daylite is a complicated option for managing your tasks.

Dr. McAdara-Berkowitz ended with a slide that asked “Who’s going to pay for all of these toys?” and discussed two ways to answer this question. A freelance can spend money to make money either by earmarking a percentage of upcoming projects for toys/tools or by considering the money spent as an investment in productivity, the ability to provide great services, and enhancement of the business image.

Kelly Schrank works from her home in Syracuse, NY, as a medical editor for Med Communications.

BECOMING A MEDICAL WRITER: TRAINING AND TRANSITIONING

Moderator and Speaker
Barbara Gastel, MD, MPH
Professor, Texas A&M University, College Station, TX

Speakers
Scott Kober, CCMEP
Director, Content Development, Institute for Continuing Healthcare Education, Philadelphia, PA
Naomi L. Ruff, PhD, ELS
RuffDraft Communications, Duluth, MN

By Jennifer L.W. Fink, RN, BSN

One of the most popular questions at AMWA is, “How did you get into this field?” moderator Barbara Gastel, MD, MPH, told the audience. Because most people come to medical writing via another career, the session included strategies to help attendees transition into medical writing.

Gastel, Scott Kober, CCMEP, and Naomi Ruff, PhD, ELS, discussed three distinct paths to medical writing: from medicine, from science, and from journalism. All agreed that networking and continued education are keys to transitioning to a career in medical communication.

The Myth of the “Perfect Medical Writer”
Kober has a degree in journalism and came to medical writing after 6 years as a sports writer. He encouraged those without a background in science or medicine to reject the idea of the ‘perfect medical writer.’ The ideal candidate listed in many job descriptions simply does not exist, he said, and many companies are willing to consider candidates with less-than-ideal backgrounds.

Journalists bring a variety of skills to medical writing, Kober said, including the ability to work under deadline pressure, familiarity with style guides, and interpersonal skills. He advised journalists interested in medical writing to do the following.

• Master the beat. Hone in on a specific area of expertise and learn everything you can about the technical requirements of your “beat.”
• Communicate with readers. Network—with readers and colleagues—via LinkedIn, Facebook, Twitter, and AMWA listservs and meetings. Set up a professional Web site.
• Reject the pica pole. Unlike journalists, medical writers often do not get a byline. Are you prepared to do 90% of the work for 10% of the credit?

Moving from Bench Science to Medical Writing
Dr. Ruff has a doctorate in neuroscience and moved to medical writing after she realized she had little chance of getting a faculty position. She discussed the transition from bench science to medical writing and offered the following advice to potential medical writers.

• Assess job skills objectively. You probably have more skills than you think. Are you good at organization? Proficient with computer programs, statistics, or graphics? Comfortable with certain scientific or therapeutic areas?
• Add or brush-up on skills as needed. What style and standards are used in a chosen field: AMA, CSE, or AP? Become familiar with the appropriate style guide. Consider taking workshops at AMWA and elsewhere.
• Do the homework. Read relevant books and journals, and talk to others in the field.
• Collect clips and samples. Hold on to your published articles and posters. Consider keeping a few unedited samples around as well; some clients like to see your unpolished prose. If you plan to write for the lay public, volunteer to write for a newsletter or your university’s alumni magazine.
• Carry business cards. Scientists do not often need cards. Medical writers do. You never know when you will meet someone who can connect you to a job.
• Keep up connections with scientists. They can clue you in to important advances and may need to hire a writer or editor.

Passion, Hard Work, and Persistence Pay Off
Dr. Gastel trained as a physician but found that medical writing was a rewarding way to meld her dual interests in
Dr. Gastel also told the audience:
• Do not worry about what you will do forever. Focus on what you want to do next. Each step can be a baby step toward your larger career goals.
• Do not try to become rich. Do good work, and a reasonable income will follow.
• Do not try to become famous. Do good work, and high regard will follow.

Although it can be tough to break into medical writing, all three speakers urged persistence. “There are many ways to get in the door,” Kober said. “You just have to keep kicking.”

Jennifer L.W. Fink is a registered nurse-turned-medical writer. She writes for both consumer and professional audiences.

BETTER PRESENTATION BY DESIGN

Moderator
Karen Blackburn, MS
Medical Writing & Scientific Communications Specialist, i3 Statprobe, Ann Arbor, MI

Speakers
Stephanie Roberson Barnard
Communication Consultant, Business Image Consulting, Wilson, NC
Scott Kober, CCMEP
Director, Content Development, Institute for Continuing Education, Philadelphia, PA

Barbara Kristaponis
Graphic Designer and Medical Grant Writer/Editor, New York, NY

By Carol R. Krcmar, RN, MN

Making Presentations Effective
As a presentation coach, Stephanie Barnard emphasized that the most important thing to remember when planning an oral presentation is the audience. Think about who is listening to your talk and what they want to learn. Barnard’s seven deadly speaker sins include the following.
1. Saying too much
2. Not meeting the needs of the specific audience
3. Not having a clear purpose to your presentation
4. Lacking clear organization of content
5. Speaking with a monotonous voice
6. Reading the talk
7. Using unnecessary or unclear visual aids

Adult learners learn through repetition: repeat the primary message of the talk at least 6 times and use prompts to emphasize the primary point. Barnard suggested using stories to illuminate specific ideas and to connect with the audience. But, she cautioned, be sure to rehearse your stories, especially those with a punch line. She suggested several other ways to improve the delivery of a talk and engage the audience.
• Ask questions.
• Move around, and lean into the audience.
• Use gestures and make eye contact with the audience.
• Use pauses.
• Rehearse the talk, even if you are familiar with the content.

A Primer on Prezi
“Just as I was feeling confident with my PowerPoint skills, along comes a new Cloud-based presentation software called Prezi,” said Scott Kober, who admitted to being artistically challenged. Kober presented a primer on Prezi (www.Prezi.com) as an alternative to PowerPoint.

Prezi was developed by a Hungarian architect as an architectural visualization tool. Using the free Prezi Web-based software, one can create, show, and share prezis (presentations) free online or download finished prezis to present them offline. Numerous users can brainstorm using Prezi online, but not simultaneously. Two Prezi packages allow the user to work offline, but require the purchase of a license. The option of storing data on a personal computer, as opposed to storing data in a Cloud, may be advisable for users concerned about data security.

How does Prezi work? Text, images, videos, and other presentation media are placed on the canvas and can be...
grouped together in frames. Users then designate the relative size and position between all presentation objects and can pan and zoom in and between these objects. For linear presentations, users can construct a prescribed navigation path. Kober suggested that the first-time user of Prezi review "how to" videos on YouTube before putting mouse to canvas. He cautioned that using Prezi is not as easy as depicted in most video clips. In contrast to PowerPoint, it is essential that the user map out the story to be told and the desired flow of the presentation before starting.

Will Prezi be the tool of choice for future slide presentations? Kober is not so sure. It takes time and patience to learn to use Prezi effectively. Using excessive zooming can make an audience dizzy and wise use of layout is advised to avoid excessive visual stimulation. Also, because Prezi uses images to present a thought or idea, few words appear, which might be daunting for some presenters accustomed to using words as prompts for speech content.

**Graphic Design and Semiotics**

Barbara Kristaponis is a woman of many and sundry talents. She is a writer and designer of videos, has experience in grant writing, and has worked as a freelance camerawoman. Her varied background was reflected in her presentation.

What was Kristaponis’ message to would-be presenters? Think outside the box: use novel concepts to make a talk thought-provoking. For example, the triad of thesis, antithesis, synthesis, attributed to German philosopher Georg Hegel, is a useful framework for developing a presentation and is commonly used in political speeches. In this triad, thesis is an intellectual proposition; the antithesis is a negation of the thesis; and the synthesis solves the conflict between the thesis and antithesis by reconciling their common truths, thus forming a new proposition.

As someone familiar with film techniques, Kristaponis strongly suggested incorporating images into oral presentations to help convey the desired message. For example, she discussed using the Russian filmmaker Eisenstein’s film-montage techniques, whereby an image is used to call to mind a desired response from the audience (i.e., showing a sleeping baby to emote calmness and relaxation). Another approach is to use two disparate images, in the same vein as the idea of thesis and antithesis, to evoke a third image in the mind of the audience. The use of visual images can intensify and focus the message of a presentation.

**Scenario 1: The Disappearing Client**

A client is 3 months late on a payment of $5,000. The primary contact has stopped responding to your e-mails and phone calls.

<table>
<thead>
<tr>
<th>What do you do?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Forget the money—it’s</td>
<td>15%</td>
</tr>
<tr>
<td>gone</td>
<td></td>
</tr>
<tr>
<td>Keep on calling</td>
<td>3%</td>
</tr>
<tr>
<td>Reach up the food chain</td>
<td>82%</td>
</tr>
<tr>
<td>Hire a lawyer</td>
<td>0%</td>
</tr>
</tbody>
</table>

A small proportion of the audience felt that, after 3 months, freelances should probably just forget about the money; however, the vast majority felt that it was most productive to reach up the food chain and contact the client’s boss or a different department. Jacobsen noted this strategy usually works, especially since freelances often work with editors who are not in charge of the finances. For bigger projects, pre-agreed payment milestones might

*Carol Krcmar is a freelance writer and editor in Munich, Germany.*
protect a freelance from larger financial losses. No one hired a lawyer in this scenario, as most of the audience felt that hiring a lawyer was an expensive choice and would likely mean the end of the business relationship.

**Scenario 2: In Too Deep**
A new freelance agrees to a project for a repeat client in a therapeutic area that is new to her. The turnaround is very quick. She now realizes that she is in over her head and that she will not be able to produce a good draft in the time allotted.

As a client, Kober would prefer that freelances be honest and straightforward and discuss the situation. The audience agreed. In fact, this situation could be used as an opportunity to build a relationship with a client. If the topic is new to both the client and the freelance, the client is likely to be sympathetic.

**Scenario 3: Lowball Offer**
A freelance with good scientific experience is just beginning to break into the business. A client has offered her a project that will require 100 hours of work for $4,000. She really needs the work, and the client has promised more lucrative work in the future if she proves herself.

The potential benefits and disadvantages of a lowball offer is a common topic on AMWA listserves. Keep in mind that the dangling carrot—future work at a better rate—might not work out, and that saying no for a lower rate might lead to higher offers from the same client at a later date. However, as Kober stressed, the decision must be based on personal circumstances and if a writer is not busy, it may be in her best interest to take the job. The majority of the audience agreed with Jacobsen, who commented that she would continue “negotiating for wiggle room”; for example, trying for a longer deadline that allows time for other projects that may come up, or a smaller deliverable.

**Scenario 4: Timeline? What Is a Timeline?**
The original timeline for a project has been completely blown after the client started the project very late. Now the client is asking for revisions to be turned around quickly, and another project for a different client is starting soon.

Most of the participants thought that the freelance should renegotiate the timeline. However, both Jacobsen and Kober preferred just getting it over with and finishing the job. Jacobsen said she is used to “projects crashing up against each other” and she would not involve her other clients in this botched timeline. From the client’s perspective, it is too late to renegotiate because the project is already running late, said Kober. During a discussion of this scenario, a proportion of the audience was concerned that just finishing the project would reward the client’s bad behavior and one audience member suggested that it would be better to request additional fees.

**Scenario 5: Love vs Money**
A freelance has a romantic weekend planned with her husband. A client offers big bucks to complete a last-minute project by Monday morning. The husband will be very disappointed if the freelance cancels the trip.

The majority felt that it would be best to make your husband a priority. However, Jacobsen confessed that she would not have had the courage to say no until recently. She now believes that sometimes it is important to say no.
to a client. One audience member added that she never brings up her personal activities and situation; instead, she just says she has a prior commitment because clients seem more willing to interrupt a family activity than a work commitment. Kober suggested caution about setting a precedent of cancelling personal commitments for projects, because clients are more likely to approach freelances with rush projects who are known to be willing to cancel plans for work.

Scenario 6: At the 11th Hour
A freelance is given 4 weeks to write a short paper about a client feel that her project is not getting enough time confess to the client in the end, and then she will need to using a tech-savvy relative and searching for the presenta-

3
What do you do?

Enlist your computer-savvy nephew 6%
Search for the slides online 6%
Make up a story for your client 13%
Come clean to the client with the truth 74%

Jacobsen would try all four strategies, starting with using a tech-savvy relative and searching for the presenta-
tion online. It is most likely that the freelance will need to confess to the client in the end, and then she will need to make sure that it is a really good article and is delivered on time. Kober agreed with Jacobsen but added that a writer admitting that she had started so late may make a client feel that her project is not getting enough time and attention.

Scenario 7: Sneaky, Sneaky
A reliable freelance submits a high-quality promotional slide deck to you, the client. He inadvertently includes an e-mail trail that reveals he had farmed out the project to a different freelance.

What do you do?

Don’t worry about it 3%
Give the freelance a call to talk it through 72%
Cross the freelance off your list 0%
Add the new freelance to your list 24%

Most of audience thought that the client should talk it through with the freelance. Kober added that he believes that this is a breach of professionalism to outsource without the client’s knowledge. He does not want to have his projects subcontracted, because he wants to vet the freelances himself.

Providing insight into how freelances cope with challenges, this session proved to be very interactive as audience members contributed stories from their own experiences. Not surprisingly, the audience responses showed that most medical writers have similar strategies for these emergencies; however, the discussion showed that choices are shaped by experience as well as by which side of the paycheck you are on.

Elizabeth Friedenwald is a freelance medical writer with her own company, Communications Nexus, Inc, in Portland, OR.

OUTSOURCING: OPPORTUNITIES AND TRENDS

Moderator
Jeannine Hanson, RN, MS
Global Regulatory Writing Senior Manager, Amgen Inc, Thousand Oaks, CA

Speakers
Alice Curry, PhD
Senior Manager, Medical Writing, Takeda Pharmaceuticals, Deerfield, IL
Mary-Margaret Lannon, MS
Director, Medical & Scientific Publications, Takeda Pharmaceuticals, Deerfield, IL
Christina M. Rogers, PhD
Senior Director, Medical Writing, RPS Inc, Fort Washington, PA
Kathy Spiegel, PhD
President, Spiegel Consulting Inc, Grass Lake, MI

By Pilar Wyman

The pharmaceutical industry has increasingly turned to outsourcing medical writing. In this session, panelists from different perspectives presented the prevalent models for pharmaceutical outsourcing.

First, moderator Jeannine Hanson, RN, MS, explained why there is so much outsourcing these days: There is a huge demand for regulatory writing and for safety documents. Expertise is not always available in-house, with workload fluctuations due to reprioritization of work, acquisitions and partnerships, unplanned events, and personnel issues. Strategic decisions are also a factor, as are desires for continuity of service and work. Hanson cau-
tioned that good vendor relationships are crucial for successful outsourcing.

Christina Rogers, PhD, focused on logistics: writing skills, location, training requirements, and duration or completion of a contract. She shared several scenarios demonstrating different team arrangements. In summary, she recommended needs assessment, planning, and being as flexible and proactive a service provider as possible.

Alice Curry, PhD, discussed regulatory writing. Although increased legislation has resulted in an increased workload, cost containment is still a priority. Dr Curry said that, in her experience, personal recommendations are vital when it comes to hiring subcontractors. She added that even though preferred providers must be worked with sometimes, location can be a factor, and exploratory work is often carried out, referrals and personal contacts are the main drivers in hiring and outsourcing. Fit—between companies and individuals—is what everybody is seeking. Even when the needs are many, hirers prefer working with known providers.

Mary-Margaret Lannon, MS, a former freelance, added, “It is all about transparency.” She suggested identifying personal resources, and stressed the importance of networking. Job boards and online sites such as LinkedIn are being used increasingly, she noted. With regard to agencies versus independent writers, she said “either can work beautifully,” and when it comes to experience requirements, she pointed out, “it depends.”

To get your foot in the door, Lannon recommended networking, continuing professional education and training, and working with medical communication companies. “Educate yourself,” she advised. Build your networks to better ensure that fit—between writers and clients—a step that will result in win-win relationships.

Kathy Spiegel, PhD, gave a current freelance’s perspective and discussed the various contract models currently in use: direct to pharma, through a CRO, and through a third-party vendor. Contracts can be either master service agreements, project-related statements of work, or project-related contracts. In addition, contract payments can be supplied hourly, by project, a combination, or as full-time-equivalent payments. A medical writer can work onsite or offshore, or a combination of the two. Roles and responsibilities can vary and should always be clarified ahead of time, she advised.

“Be honest,” she added. “Build trust,” and “you will get the expertise. It’s difficult to start out as a freelance.” Consider being a Project Manager for yourself, she concluded.

Hanson added, jokingly, “We say we want you to have multiple clients, but we’re lying.”

Pilar Wyman is a freelance medical indexer in Savage, MD.

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**SPACE-BASED RESEARCH AND THE FUTURE OF HUMANS IN SPACE**

**Moderator**

Jim Hudson  
*Medical Writer, Medical Writing Associates, Simi Valley, CA*

**Speakers**

Paul Root Wolpe, PhD  
*Senior Bioethicist, NASA; Emory University Center for Ethics, Atlanta, GA*

Kevin L. Ferguson, MD  
*Director, NASA Medical Support Team; Departments of Emergency Medicine and Anesthesiology, University of Florida, Gainesville, FL*

By Parvathy Hariraran, MS  

**Medical Challenges of Space-Based Research**

Kevin Ferguson, MD, started the session with a discussion of changes in human physiology in space and the training procedures undertaken by astronauts. He began by describing the Challenger disaster, in which most of the emergency air packs of the astronauts were found to have been activated. “… (It was a) valiant but vain attempt to keep the pilot conscious,” he said. Even the Columbia space shuttle disaster was “not salvageable,” he said, emphasizing that NASA should be prepared for similar situations in the future.

Since these disasters, astronauts have been trained for numerous contingencies that simulate different disaster scenarios. Such training involves intensive full-day courses beginning at 6 am, Dr Ferguson said. The medical personnel involved in contingency training include doctors, nurses, and paramedics who are trained in special techniques, such as how to intubate an astronaut wearing a helmet. These personnel are equipped with a complete medical kit containing intravenous fluids, cardiac life support, a locked narcotics box, and a handheld ultrasound machine.

According to Dr Ferguson, the problem in space flight is that people do complex things in severe environments. “Space is probably the most severe environment, and so we need to do things (to simulate similar conditions) in the next best severe environments like microgravity and high pressure. We need to test to see if our devices work in this environment,” he said.

Space flight causes changes in human physiology, and this poses several problems. For example, on earth, the heart pumps blood to the head because of gravity. In space where there is no gravity, an even amount of blood circulates to the head and the feet. The heart recognizes this.
difference and adjusts when an astronaut is in space. But when the astronauts return to earth, they may experience dizziness when standing up. Medications to improve vascular tone are then used, Dr Ferguson said.

Another potential problem for astronauts on space missions is that they lose 1-2% of bone mass per month in space—approximately what most people lose in a year on earth—increasing the risk of fractures and kidney stones. Other medical issues that need to be addressed during long-term space missions include differences in sensorimotor, sleep, and circadian responses; the effects of radiation; the impact on microorganisms; and the psychologic state of the astronauts.

All these issues mean that many decisions must be made. A trip to Mars is long, and water, waste, sweat, and urine need to be recycled during the entire time, Dr Ferguson said. Accordingly, food, water, medications and other supplies must be carefully planned and organized.

**Ethical Perspectives of Space-Based Research**

Dr Wolpe introduced himself with the disclaimer that he was speaking as an academic and not as a representative of NASA. To begin his discussion of ethical perspectives, he noted, "Some questions are unique to longer-term space environment." He added that in space programs, the fundamental ethical concerns are unlike those on earth—they are not related to money or access to basic resources. "So for an ethicist, the questions are pure," he said.

One question in space-based research is how to maintain the confidentiality of the medical status of astronauts. Do the astronauts have a right to the confidentiality of their personal medical information? Dr Wolpe showed an interesting slide listing the limited rights of the astronauts regarding their personal medical records. He then replaced the word "astronauts" with "terminally ill end-stage cancer patients" and asked the audience whether the limited rights were ethical in this case.

Using this demonstration, Dr Wolpe stated that suspending the privacy rights of astronauts, who are healthy volunteers, may not be a good idea. "These are very healthy people before you put them on Mars," he emphasized. However, if astronauts do not share their medical information after participating in billion-dollar research programs, it is a lost opportunity to learn about human physiologic adaptations in space. Hence, this is a complex ethical issue that needs to be sorted out, he said.

Other ethical issues exist in space-based research. Health threats in long-duration space flights include progressive diseases, traumatic injuries, nutritional deficiencies, sleep disturbances, biohazards in spacecraft environment, a psychiatric or cognitive crisis, or failure of life support. Dr Wolpe spoke about many such scenarios. If more than one person gets sick and there is a finite amount of medication, who decides who should get the painkiller? In another situation, if one person becomes sick, another person has to serve as caretaker, but both parties are now left out of the mission.

The most important question, according to Dr Wolpe, is How much risk is enough risk? To make decisions based on these potential risks, he stated that established policies and not ad hoc policies are needed. There should be a consensus regarding ethical principles, not only among astronauts and stakeholders, but also among the families of astronauts, he said.

Sending human beings on long-term space missions requires cooperation and coordination among several people and organizations, Dr Wolpe said. This was why such a mammoth task can only be undertaken by governments and not by private industries, he explained. “Goals should be articulated with a balance between individual health safety and mission safety. Acceptable levels of risk must be determined and not exceeded,” he said. “Before you make decisions, you need to pull up a toolbox of values.”

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**SPEED NETWORKING**

**Moderator**

Faith Reidenbach, ELS, CMPP
Principal, Caley-Reidenbach Consulting LLP, Corvalis, OR

**By Whitney Smalley-Freed, PhD**

Instead of being set up for a lecture, the room for this session was full of two-person tables with white tablecloths and a pink Post-it Note in front of one chair at each table. As we entered the room, we were instructed to sit at one of the tables with someone we did not know. Everyone immediately started talking with their table partners even though the session had not officially started. Faith Reidenbach, ELS, CMPP, gave a few guidelines; those who were sitting in front of the pink note should stay at the table and the others were to move to the closest table to the left. Reidenbach suggested that if we did not know what to talk about, we should start with what we were good at. Reidenbach added, "For example, I am good at hosting parties," and everyone laughed because the session was similar to a party. We were given 7 minutes with each partner before switching to a total of nine partners. Topics of discussion varied from professions and backgrounds to hobbies and hometowns. Most people exchanged business
cards. People from all different professions participated in the event, including writers, editors, and project managers from industry, academia, and freelance businesses, offering a variety of interactions.

Participants had several reasons for attending the session. When asked why he participated in the session, Neil Andrews replied, “to meet people in the medical writing field and to network with them.” Neil was also interested in “talking to any recruiters or others who might know about job opportunities.” Another participant, Parvarthy Hariharan, “thought that a formally organized networking event would make it easier to talk to more people rather than trying to randomly strike up a conversation.”

Participants said they thought they gained something from the session. Jennifer Garcia, DVM, DACVIM, said, “It was a great way to meet a lot of fellow AMWA members in a short amount of time. It was also educational to hear others’ experiences as freelancers.” Dorothy McDuffie noted, “I was able to ask questions about freelancing and get good answers. For example, I asked one person about her Web site, and she gave me the contact information for her Web designer.”

Several suggestions were made for future Speed Networking sessions. Janice Deal said that the session should be scheduled earlier in the conference so that a “relationship could be developed further during the conference,” and Diana Lynnette Fisher said she “would love to see this session continue and expand.” Kristi Boehm suggested that the session could be divided into two groups: “newbies and veterans.” For the first half of the session, she said, newbies would move to veterans’ tables; for the second half, veterans could network with veterans and newbies with newbies. Some attendees suggested offering two sessions in case people could not attend the first one. Participants also suggested that beverages be available at future similar sessions. In general, the first AMWA Speed Networking session was a success, providing participants with plenty of contacts and helpful information.

Whitney Smalley-Freed, principal of Precise Medical Writing, LLC, is a freelance medical writer in Nashville, TN.
The Bioethics Research Library at Georgetown University

When the Bioethics Research Library at Georgetown University began, it contained only a few shelves’ worth of books from the Kennedy Institute of Ethics but today houses more than 300,000 books, journal articles, audiovisuals, and archival materials that cover a diversity of opinions on bioethical issues around the world.

The library’s databases on bioethics literature, organizations, and syllabi are accessible on the Web site and contain many links to full-text materials. Other sources on the site include the digital archives of the Presidential Bioethics Commissions, the Office for Human Research Protections, and the Genetics and Ethics Digital Collections.

The site features two bibliographic databases, ETHXWeb (http://bioethics.georgetown.edu/databases/ethxweb/index.html) and GenETHX (http://bioethics.georgetown.edu/databases/genethx), containing docu-
ments on bioethical issues from around the world. They were developed by the Library and Information Services group of the Kennedy Institute of Ethics, Georgetown University. Unlike PubMed, the databases contain many different publication types, such as book reviews, press releases, unpublished documents, position statements, and news items, as well as bioethics literature from non-medical journals and books. ETHXWeb has 286,000 records in its database; GenETHX is a subset of ETHXWeb and contains 42,000 records. Both databases are updated twice each month.

Make sure you download a copy of Bioethics Searcher’s Guide to Online Information Resources found within the “Publications” tab. There is much more to this Web site which is, without a doubt, a definite “must bookmark.” Log on and find out for yourself.

National Center for Ethics in Health Care
www.ethics.va.gov/index.asp

Founded in 1991, the National Center for Ethics in Health Care (NCEHC) is the primary office of the Veterans Healthcare Administration (VHA) for addressing ethical issues that arise in patient care, health care management, and research. NCEHC provides support on issues in clinical, organizational, and research ethics. Its mission is to clarify and promote ethical health care practices throughout VHA and nationwide.

The NCEHC’s main initiatives resulted in the creation of IntegratedEthics (IE), a program representing a radical departure from traditional approaches to ethics in health care. Conceived in 1999, IE encompasses the full range of health care ethics issues in that it is comprehensive, establishing and integrating a set of clear standards, roles, competencies, methods, and performance metrics. It is a multilevel, multifaceted, organization-wide program supported by a national policy, sophisticated training programs, validated evaluation tools, and a robust electronic data and communications network.

IntegratedEthics is based on principles of continuous quality improvement and strategies for organizational change that have proven effective in other fields. Through its Ethics Consultation function, IE provides much-needed assistance to patients, families, and staff. Through its Preventive Ethics function, IE introduces a novel quality improvement system that empowers staff to take on recurrent ethics problems on a systems level. And IE’s Ethical Leadership function helps leaders create a culture that inspires employees to “do the right thing.”

IE is more than a training program, a quality improvement intervention, or the sum of new policies, standards, tools and structures. As the Web site states, it is a “transformational initiative that redefines ethics as it is both practiced and led in the health care arena.”

Oncology Nursing Society
www.ons.org/Publications/CJON/AuthorInfo/WritingSupp/Ethics

The Oncology Nursing Society Web site has an excellent writing supplement section associated with its Clinical Journal of Oncology Nursing (CJON), which includes a subsection on Ethical Issues in Writing and Publishing written by Cynthia R. King. The section focuses on concerns such as etiquette, fraudulent publication, plagiarism, duplicate publication, authorship, and potential for conflict of interest when writing or editing a manuscript for publication. Also discussed are strategies that can help prevent or detect ethical violations and lend further integrity to the documents you write.

The author stresses the importance of the umbrella term fraudulent publication, giving the definition issued by the Department of Health and Human Services which states

“Misconduct in science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation.”

King goes on to elaborate on each of these concepts, including what they do and do not mean, how to recognize and avoid ethical infractions, and who is responsible for what.

Here is the author’s “Rapid Recap”:

• Author etiquette refers to the courtesies and considerations that an author employs when preparing a manuscript and communicating with an editor.
• Fraudulent publication is a term that includes plagiarism, fabrication, and falsification.
• Plagiarism refers to the theft of intellectual property (eg, stealing someone’s idea for an article) or taking credit for another individual’s work.
• Duplicate publication also is known as redundant publication and involves publishing the same material in the same format in more than one journal, book, or Web site.
• Authorship issues frequently arise when two or more authors are involved in a writing project and can be minimized by clearly delineating authorship roles prior to beginning the project.
• Conflict of interest may arise when personal interests are compromised or have the appearance of compromising an author’s ability to objectively perform duties.
• High standards and ethical integrity must be maintained when writing for publication.