

# Delawriter

Spring 2009

The Quarterly Newsletter of the American Medical Writers Association–Delaware Valley Chapter (AMWA-DVC)

## AMWA-DVC Nominations for 2009–2010

The American Medical Writers Association–Delaware Valley Chapter (AMWA-DVC) Nominations Committee (Lisa Breck; John Smith, BS, PhD; Lori De Milto, MJ; Brian Bass) is pleased to announce the following nominations for the 2009-2010 calendar year: Jennifer Maybin, MA, ELS, for President-Elect, and Alan Struthers, PhD, for Treasurer. Both have made significant contributions of time, energy, and effort to our chapter. We are happy to formally recognize them and are pleased to have them participate in even greater roles in the coming year. Their biographies follow.

The committee would also like to take this opportunity to thank Eileen Girten, MS, who has agreed to take over as editor of the *Delawriter* if Alan is elected to the treasurer role.

### Jennifer Maybin, MA, ELS

Jennifer Maybin, MA, ELS, has been a medical writer and editor for more than 20 years. She worked as an editor, conference director, and continuing education manager for Lippincott, Williams & Wilkins, and as a senior medical writer for several medical education companies before starting a freelance writing and editing business, Maybin Healthcare Communications, in 2004.

Jennifer currently provides writing and editing services for medical education companies and publishers and is the editorial director for two geriatric care journals, *Medicare Patient Management* and *Assisted Living Consult*.

Jennifer earned her BA in English from Pennsylvania State University

and an MA in English from Arcadia University in Glenside, Pennsylvania. She recently completed the core certificate in editing and writing from AMWA and earned certification as an editor in the life sciences from the Board of Editors in the Life Sciences.

Currently AMWA-DVC's volunteer coordinator, Jennifer also co-chairs the Freelance Workshop and is the production editor of AMWA-DVC's *Delawriter*.

### Alan Struthers, PhD

Alan Struthers, PhD, is a contract and freelance medical writer with varied experience creating medical education materials, research documents, and journal articles. He has been a professional writer for most of his career, and his work has been published in the *Wall Street Journal*, the *New York Times*, *Business Week*, and the *Chicken Soup for the Soul* series, as well as in medical journals.

Before becoming a medical writer, he worked as a corporate communications director for two Fortune 500 companies, Travelers Corp and Overseas Shipholding Group, where he wrote corporate annual reports, press releases, and speeches for the top officers. Earlier, he served as a speechwriter in Washington, DC, on the staff of the US Senate Committee on the Budget and, before that, as an editor and writer in the research department of the Federal Reserve Bank of Minneapolis. In addition, he has worked as a licensed investment advisor and financial planner.

Currently, Alan chairs the Newsletter Committee of AMWA-DVC and is co-editor of the *Delawriter*. He has served as a member and president of his church council and as a member and president of the Visiting Homemakers Home Health Aide Service of Bergen County, New Jersey.

Alan earned his BA from Northwestern University in Evanston, Illinois, majoring in pre-med and English. He received an MA in English and a PhD in American Studies from the University of Minnesota in Minneapolis. While pursuing his graduate studies, he taught composition classes and a course in American Studies.

*See Nominations on 2*

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## The Evolution of Clinical Trial Registries and Results Databases

By Mary Howe

At the AMWA-DVC NJ Spring meeting held March 18, 2009, in Princeton, New Jersey, Aaron Bernstein, PhD, Director of Global Regulatory Planning at Hoffmann-La Roche, presented an overview of the evolution of clinical trial registries and results databases entitled “What Medical Writers Need to Know About Clinical Trial Reporting.”

Clinical trial registries and results databases have emerged in response to awareness of bias in the publication of data from clinical trials. A 1986 study indicated that pooled analyses of cancer therapies in journal publications showed more positive results than those that were registered with an international cancer registry.<sup>1</sup> In the 1990s, reports in journals such as *JAMA* and *The Lancet* confirmed the existence of publication bias, in which journals preferred to print positive rather than inconclusive or negative results.

The response to concerns over publication bias came from trade organizations in the pharmaceutical industry, the International Committee of Medical Journal Editors (ICMJE), and regulatory agencies. A coalition of trade organizations called for the disclosure of clinical trial information in two types of repositories—clinical trial registries for information on new or ongoing trials and results databases for summary results from completed trials. The ICMJE required registration in a suitable clinical trial registry prior to patient enrollment as a condition for publication in all member journals. The US Food and Drug Administration (FDA), the European Medicines Agency

1. Simes RJ. Publication bias: the case for an international registry of clinical trials. *J Clin Oncol*. 1986;4(10):1529-1541.

(EMA), SwissMedic, and other governmental authorities enacted regulations on clinical trial reporting. While these regulations vary among agencies, they include requirements that protocols must be submitted to a registry or health authority, results must be posted in a results database registry, and databases must be public. Failure to comply results in penalties.

The US-based Clinical Trial Database and the European Union Drug Regulating Authorities Clinical Trials (EudraCT) are public, government-sponsored databases. The National Institutes of Health maintains the Clinical Trial Database that includes the Clinical Trial Registry and the Basic Clinical Trial Results Databank. Both the registry and the results are Web-based, searchable, free databanks that are available to the public at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). FDA regulations require that the registry provides information on new and ongoing clinical trials (excluding Phase I trials) of drugs and devices pre- and post-approval. The required information includes study descriptions, summaries of protocol designs, key dates, eligibility requirements, and contact information. Information must be submitted and posted within 2 months of initial patient enrollment for new clinical trials. Results of previous clinical trials (excluding Phase I trials) must be submitted within 60 days of the approval of a new drug or device; results from new trials of previously approved drugs must be submitted within 12 months of the last patient visit.

Although the EMA requirements are similar to the FDA requirements, there are notable

differences. Currently, there is no government-sponsored clinical trial registry in Europe; instead, detailed protocols must be submitted to all participating health authorities. EMA requires that all trials, including Phase I, be reported to health authorities and in EudraCT.

Dr Bernstein also discussed public clinical trial Web sites sponsored by nongovernmental organizations within the pharmaceutical industry. The Pharmaceutical Research and Manufacturers of America administers the Web site [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org), in which individuals can search for detailed clinical trial information. Many companies, including Hoffmann-La Roche, provide clinical trial Web sites with registries and results databases for company-sponsored trials. The International Federation of Pharmaceutical Manufacturers and Associations sponsors <http://clinicaltrials.ifpma.org>, a portal to many databases, including Clinical Trial Database, EudraCT, [www.ClinicalStudyResults.org](http://www.ClinicalStudyResults.org), and company-sponsored databases.

*Mary Howe, PhD, is a freelance medical writer specializing in pharmaceutical research and development.*

### Nominations . . . from 1

Alan's main outside interest is playing southern Appalachian-style banjo. He has appeared on the *Prairie Home Companion Show* and currently performs in a duo with his daughter.

The election will take place at the next chapter meeting, scheduled for June 30 at the Park Ridge Hotel in King of Prussia, Pennsylvania.

## Highlights from the Spring AMWA Board of Directors Meeting

By Barbara Rinehart and Lisa Breck

The spring AMWA Board meeting and chapter delegates' session was held on April 3-4, 2009, in Gaithersburg, Maryland. As always, members from other chapters were very impressed with the vitality and programs of the Delaware Valley Chapter. We were asked for advice on everything from programs to membership. All appreciated our Web site.

### Leaders and Membership

The national office now has 9 full-time staff in new headquarters. Watch for new marketing activities and Web changes. Membership hovers around 5,600 with a 73% renewal rate. The top primary job functions are writing/editing (2,362), pharmaceutical (1,222), and freelance (922). Our new national officers are Melanie Ross, president-elect; Mary Royer, secretary; and Judi Pepin, treasurer.

### Activities

- Several pertinent articles from the AMWA archives will be republished or brought to members' attention, eg, "The Unemployment Syndrome: Working Your Way Through Joblessness" by Elayne Clift, March 1988:3(1).
- The endowment fund has approximately \$7,000. If you have

an idea that is sustainable and benefits all members, send it to Lili Fox Velez, administrator for Special Projects, at [rhetrx@verizon.net](mailto:rhetrx@verizon.net).

- AMWA has an exclusive LinkedIn group of more than 450 members and is growing. Donna Miceli is the moderator.
- Three new AMWA fellows were approved; one is a member of AMWA-DVC.
- Nonprint media are being considered as an inclusion for the Eric Martin Awards.

### Education and Conferences

- A new venture—Pocket Trainings—or short "how to" mini tutorials are being solicited for Web posting (eg, How to Edit a PDF). For more information, contact Scott Thompson at [scott.thompson@medtronic.com](mailto:scott.thompson@medtronic.com).
- Read the monthly e-Update for 2009 Annual conference news. Registration opens July 20, 2009. Don't forget that conference coaches are available. Credit workshops require homework. Get it done early!
- Workshop leaders are needed for the Science Fundamentals program. Contact Susan Aiello at [susan@words-world.net](mailto:susan@words-world.net).

- The Education Committee is considering a reorganization of the current "tracks" and the possible addition of a Regulatory and Research track.

- Webinars have been suspended until they can support themselves economically.

In addition, the issue of ghost writing was discussed, including endorsement of the checklist from the "What Should Be Done to Tackle Ghostwriting in the Medical Literature" article written by several AMWA members and nonmembers ([www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000023](http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000023)). Ongoing e-discussions will ensue prior to a vote.

MD Consult, a collection of full-text journals and other medical resources is a member benefit available from the home page of AMWA's Web site ([www.amwa.org](http://www.amwa.org)).

*Barbara Rinehart, MS, the current president of AMWA-DVC, is a freelance medical writer. Lisa Breck is president-elect for the 2008-2009 fiscal year and is president of Breck & Company, Inc, a medical marketing and communications company based in St. Davids, PA. Both are AMWA chapter delegates.*

## AMWA Journal Receives Bronze Award

The *AMWA Journal* has received the Bronze Award in the EXCEL Awards competition hosted by the Society of National Association Publications.

There were over 1200 entries this year, and the judging considered

the quality of the writing, content, graphic design, and overall packaging.

Kudos to Lori Alexander, the editor, and all the contributors and volunteers who made this possible!

### Not Getting Our E-mails?

**Add these e-mail addresses to your e-mail safe list:**

**[amwa-dvc-members@dudley.casano.com](mailto:amwa-dvc-members@dudley.casano.com)**

**[amwa-dvc-announce@dudley.casano.com](mailto:amwa-dvc-announce@dudley.casano.com)**

## Bingo! A Winning Strategy for Networking

By Lori De Milto

**D**o you know an AMWA member who has traveled to more than three continents? Or someone who knows what SEO means?

On February 25 at AMWA-DVC's Networking Get-Together, hosted by ReSearch Pharmaceutical Services, Inc (RPS), attendees used those questions and others like them to get to know each other better and to win great prizes. As part of the bingo game, attendees tried to find someone who fit the question posed and have that person sign their bingo card. If the players reached bingo, they qualified to win tickets for the prize drawing. Each attendee could get up to 12 bingos on each of two cards, which contained 25 squares.

In their quest to find people who had given a workshop at the AMWA national meeting, completed a Sunday *New York Times* crossword puzzle, etc, attendees had the chance to make dozens of contacts and collect many business cards. For each bingo, they earned a chance to win one of two artisan chocolate gift baskets by Donna and Company in Cranford, New Jersey.

About 80 people attended the lively networking event, held at RPS headquarters in Fort Washington, Pennsylvania. RPS provided a festive reception area, decorated with balloons and purple tablecloth-topped tables, as well as hot hors d'oeuvres, gourmet sandwiches, and more.

Congratulations to the winners of the gift baskets, Nellie Forwood and Hemang Barbhैया.

AMWA-DVC warmly thanks the RPS staff members and AMWA-DVC volunteers who made the event a success. Those from RPS included Joe Arcangelo, Monica Hawkins, Chris Rogers, Jennie Van Sant, and the team of RPS staff who helped throughout the evening.

Those from AMWA-DVC included Janet Manfre, chair of the Pennsylvania Program Committee and inventor of the concept for the AMWA-DVC networking bingo game, Eileen Girten, who coordinated registration, Mary Howe and Alisa Mayor, who manned the registration desk, and Julie Munden, who developed the bingo cards.

### About RPS

RPS is a contract research organization that provides Phase 1 through Phase IV clinical development solutions to the pharmaceutical, biotechnology, and medical device industries. The company's Web site is [www.rpsweb.com](http://www.rpsweb.com).

*Lori De Milto, MJ, is a marketing medical writer in Sicklerville, NJ.*

## The New World of CME in Pennsylvania

By Don Harting

**S**tringent new national policies aimed at preventing commercial bias in educational activities certified for continuing medical education (CME) credit are affecting how CME coordinators are doing their jobs at local hospitals. From December 2008 to January 2009, I conducted a series of interviews with CME coordinators and committee chairs at several small hospitals in Pennsylvania and found that, in their opinions, CME is very different now than in the recent past.

Educational grants are harder to get funded. Grant requests are more time-consuming to write because more preparation is required at the front end and more follow-up is required at the back end. Despite the additional work, fewer awards are being made. One hospital has given up on writing grants altogether. The sole exception appears to be oncology, in which educational grant funding remains viable.

The bar has been set higher in terms of activities that qualify for American Medical Association Physician's Recognition Award (PRA) Category 1™ credit. More outcomes data are also required, forcing CME providers to collect much more information after an

activity takes place than in previous years. Activity providers find the new requirements burdensome.

Hospital CME coordinators, many of whom wear multiple hats, suddenly find this part of their job much more time-consuming. Discouraged by additional work at a time when additional personnel simply aren't available, at least two small Pennsylvania hospitals are discussing letting their state accreditations expire at the end of the current approval period.

Lack of funding for technology puts distance learning for smaller hospitals out of reach. In rural areas, where the closest accredited CME provider may be an hour's drive away, this could dramatically increase the time doctors must take away from patient care to attend live educational events.

Further change in Pennsylvania CME appears likely in response to initiatives at the national level. The Josiah Macy Jr Foundation, a New York charity devoted to advancing the education and training of health professionals, summoned leading educators from the nation's top medical schools, specialty societies,

*See CME on 6*

## DVC Volunteer Corner

By Jennifer Maybin

This month's DVC Volunteer Corner is dedicated to the many volunteers who help make AMWA-DVC the most active chapter within the national organization. Here's what a few of our chapter's volunteers say about their experiences.

As a recent member of AMWA-DVC, I wanted to get involved and experienced a welcoming group who were immediately responsive to my offer to help. Being a newbie, I come with a "learning" attitude with a nonscience background but solid SEO and marketing skills. Imagine my surprise being asked to write two articles for an upcoming issue of *Delawriter* at the Blue Bell Conference. I am grateful for the trust shown to me, and I look forward to contributing now and in the future. I can't wait to meet DVC members.

—Rebecca Jacoby

Tom Lang gave me great advice—join AMWA and get involved. Volunteering for AMWA-DVC has been rewarding and fun. While learning new things about the medical writing field and networking have positively impacted my life, the greatest reward has been building relationships with the membership. People are so quick to help one another and share resources, which makes the DVC outstanding. Who would not want to get involved? Many of the volunteering opportunities require so little of one's time and, yet, can make a difference in the chapter. Volunteer! Make new friends, learn something new, and have fun in the process.

—Eileen Girten, MS

Over the past 5 years, I have volunteered my time and talents within the AMWA-DVC group by helping plan programs for upcoming chapter meetings, helping register attendees at chapter meetings, and

writing articles on events for the *Delawriter*. This volunteer experience has provided me with the opportunity to have a say in which programs are planned, network with other medical writers (very important because I work entirely remotely from my home), showcase chapter events such as courses and meeting programs, and hone my writing skills on topics of personal interest. Although I have devoted only a limited amount of time to volunteering, what time I have given has been fruitful in the professional and personal benefits I have received.

—Pat Bartling, MLS, MS

I have been happily sharing my time, energy, and skills for the 2009 AMWA-DVC Freelance Workshop. Volunteering has been an energizing experience.

—Ana Maria Rodriguez-Rojas, MS

Volunteering for AMWA-DVC has no downside; it provides networking, learning, and writing opportunities, often all in one shot. As a volunteer, you work with people who are uniformly helpful,

informative, and appreciative; it is a win-win option.

—Mary Howe, PhD

As chair of the Membership Committee, I welcome new members to AMWA-DVC. I also help members further (or start) their careers in medical communication—whether it's discussing the benefits of AMWA membership, reviewing a resume, explaining the types of medical writing opportunities, or offering suggestions on job searches, it is a great feeling to be able to help those who are new to the field, just as I once was.

—Elizabeth A. Manning, PhD

AMWA-DVC thanks all of our volunteers who give their time, talents, and energy to make our chapter such a dynamic group. We encourage all newcomers and seasoned AMWA-DVC members to become more involved in our chapter and its activities.

*Jennifer Maybin, MA, ELS, is AMWA-DVC's Volunteer Chair.*

### Delawriter

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## News and notes from the American Medical Writers Association— Delaware Valley Chapter ([www.amwa-dvc.org](http://www.amwa-dvc.org))

### 6 CME . . . from 4

and government agencies to a high-level conference in Bermuda in late 2007. In a consensus report released afterward, conferees called for sweeping changes in how CME is funded and delivered nationwide.

Macy conferees are calling for fewer lectures, new metrics to assess outcomes, a greater emphasis on educating teams rather than individuals, and a greater emphasis on point-of-care learning. The Macy report also recommends formation of a new Continuing Education Institute at the national level, and a 5-year phase-out of all commercial support for accredited CME from pharmaceutical or medical device companies.

*Don Harting, MA, ELS, specializes in writing educational grant proposals and is based in Chester Springs, PA.*

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