

## President's Message

Nancy R. Katz, PhD



I'm honored to assume the Presidency of the Northern California Chapter of AMWA.

I'm starting my sixteenth year as a medical writer. I held staff positions for 10 years, all in the Bay Area (Covance, Protein Design Labs, and Genentech—I headed up the medical writing groups in the latter two). In 2006, I founded Illyria Consulting Group, Inc., which specializes in documents for eCTD-based submissions.

I am active in the Drug Information Association (DIA) and recently completed a 4-year term as a core committee member of the DIA Medical Writing Special Interest Area Community (SIAC). I also chair the SIAC's E3 task force, an international group of medical writers dedicated to resolving issues related to the International Conference of Harmonization (ICH) guidance, *Structure and Content of Clinical Study Reports*. I have presented on numerous occasions for DIA on issues related to medical writing and have always stressed the importance of the contributions of medical writers. I also mentor writers through AuthorAid, an organization that helps researchers in developing countries publish their work.

I'd like AMWA to be the go-to place for medical writers: whether for getting started or for ongoing professional development. We have events planned for 2011-2012. We invite you to attend all events and to participate in our viable and growing community.

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## AMWA Annual Conference — October 20-22, 2011

### Education

The conference will offer more than 100 educational workshops to help you earn your AMWA certificate or expand your knowledge of the workshop topics, 37 exciting open sessions about timely and relevant issues in the profession, and 77 informative and interesting Breakfast Roundtable discussions.

Remember that all open sessions are included in your registration fee and registrants can attend as many as they want.

### Networking Opportunities

Don't miss the Conference Coach Connection, Connection, Creative Readings, Breakfast With the Exhibitors, the Welcome Reception and President's Reception, Chapter Greet and Go, the Coffee and Dessert Klatches, and AMWA's Jacksonville Tours. They are all great networking opportunities to connect with fellow members and industry peers at the annual conference. And that doesn't even count those unexpected conversations that can change your career or your life!

*I became a member of AMWA when I noticed that the annual conference was being held close to home, in San Francisco. At that time, in the mid-eighties, I was doing more non-medical writing than medical, and I wanted to join a writers' group not made up exclusively of creative writers. What sold me on AMWA was the unexpected: the warm, welcoming interest of the established members, the sincere supportiveness, and the collegiality. The rest, for the sake of brevity, is, as they say, history. AMWA has gotten much, much larger than it was when I first joined it. And perhaps size is reflected in the ambience of the annual conferences. Or perhaps, I've just gotten habituated. Addicting, however, is the intellectual stimulation inherent, and the challenge to learn more and to maintain excellence.*

—Jack Aslanian, MD, ELS

You never know when someone you meet at the annual conference will become your concert buddy, your best friend, or your "in" to your next job!

## Registration

The conference registration brochure is available on the AMWA website. September 14 is the last day to register at the early-bird rate! September 16 is the last day to register for credit workshops and book hotel reservations at the special rate! As you peruse the brochure, keep an eye out for your fellow AMWA NorCal members:

### BREAKFAST ROUNDTABLES

*Getting Your Book Published*, Arushi Sinha

*Cultural and Business Issues When Working with Japanese Authors*, Aya Tokaji

### OPEN SESSIONS

*How to Present Yourself as an Independent/Freelance Professional*, Alisa Bonsignore

### WORKSHOPS

*Introduction to Cancer Pharmacology*, Sunil Patel

*Introduction to Cancer Biology*, Catherine Magill

## Of Interest to Medical Writers

Nancy Katz

**AMWA National Board Meeting, March 2011:** In addition to taking care of business, the Board discussed certification (as opposed to certificates) for medical writers. Right now, many people harbor the illusion that just about anyone can be a medical writer. The rationale for certification is to dispel this notion and establish professional credibility by offering a written exam (analogous to the state bar examinations for lawyers or physicians), preceded by a course of study. Stay tuned.

**DIA Annual Conference in Chicago, 2011:** Two sessions were dedicated to protocol design:

The first was *Protocol Design and Subsequent Amendments: Understanding the Benefits of Well Designed Protocols*. Anne B. Cropp, PharmD, chaired this session, which consisted of presentations by Rachael Zuckerman, MPH, Anna L. Hindle, MSc, and Michelle Marlborough.

Speakers provided data on the underlying causes of protocol amendments, methods of enhancing study design to minimize amendments, and the cost of amendments. An eye-opening revelation was that nearly 40% of amendments occur before the subject receives the first dose of study drug. The take-home message is that amending a protocol is costly and that many amendments can be avoided.

The second was *Designing Robust Protocols*. Jesse A. Berlin, DrSc chaired this session, which consisted of presentations by An-Wen Chan, MD, PhD, FRCPC, Jennifer M. Tetzlaff, MSc, and David Gemzik. Speakers provided academic research into reasons for successes and failures of protocols, a discussion of the Standard Protocol Items for Randomized trials (SPIRIT) initiative, and the Clinical Data Interchange Standards Consortium (CDISC) model. The take-home message of this session is that standard guidance and improved public access are vital to the success of well designed protocols.

**DIA Annual Conference in Chicago, 2011: *The Strategic Impact of Medical Writers on Regulatory Documents and Publications*:** Nancy R. Katz, Ph.D. and David B. Clemow, Ph.D. described the benefits of having a medical writer on board early in the process of creating regulatory documents or peer-reviewed publications. The speakers described the competencies medical writers must have in order their job: knowledge of the regulations; skill in interpreting data and debriefing experts; writing ability, including the construction of a logical argument; ability to repurpose content, and team skills, just to name a few. Speakers relayed stories of document glitches and successes; not surprisingly, the glitches were due to the absence of a medical writer who functioned as an integral part of the team and the successes due to the presence of one.

## Like What You See?

### Don't Like What You See?

The rest of this page is going to be blank. Blank! What would you have liked to have seen fill that space? Medical writing tips and tricks? Advice on how to get that first job? The perils and pitfalls of freelancing? A humorous anecdote about life in the office? This newsletter is for you, and it can even be *by* you! Do you have something to submit or do you know someone who may be able to provide fabulous material to keep this newsletter entertaining and informative? E-mail your new intrepid Newsletter Editor, Sunil Patel, at [pacemaker@amwancal.org](mailto:pacemaker@amwancal.org)! Being featured in the Pacemaker impresses your colleagues, bolsters your credentials, and lowers your cholesterol!\*

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\*This statement has not been evaluated by the FDA. The Pacemaker is not intended to diagnose, treat, cure, or prevent any disease.