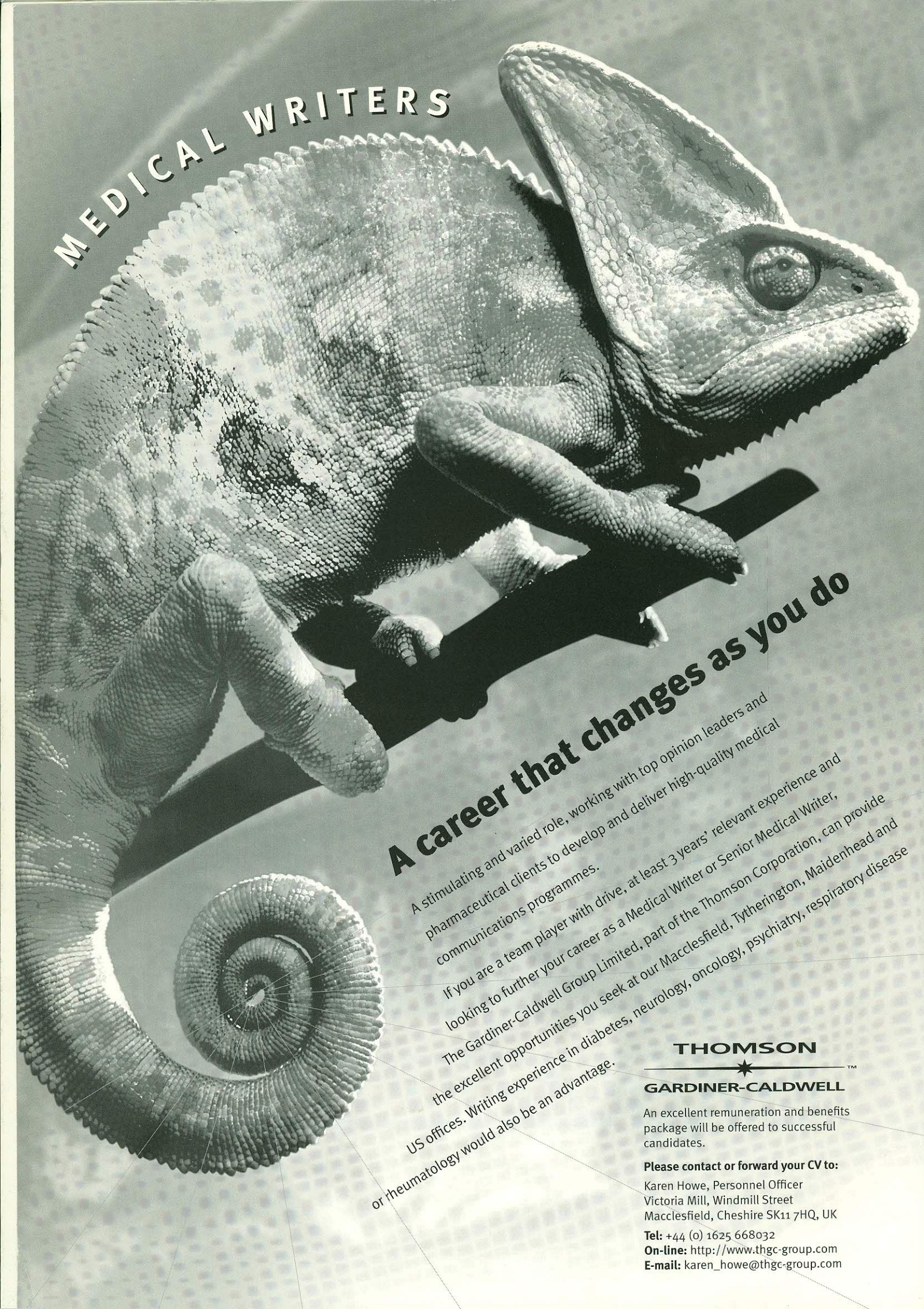
The Write Stuff

The Journal of the European Medical Writers Association

New Horizons

EMWA
European
Medical Writers
Association

Vol. 11, No.2, 2002



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New Horizons Vol. 11, No. 2, 2002

The 11th Annual EMWA Meeting:

Yippee! Dumplings Again *33*

Geoff Hall

Find out what you missed – particularly from a culinary point of view, and make your resolutions, bug your boss, mark your calendar, save your pennies, whatever it takes, but plan to be there at the next EMWA annual conference. [INT]

New Horizons in Medical Writing:

A Brief Overview of the Pharmaceutical Industry in Singapore *35*

Jing Ping Yeo

As part of our attempt to peek back at articles, people and issues we've addressed before, we return to our EMWA outpost in the Far East and ever-popular Jing Ping Yeo for a 2-part series on how things are going on the farthest outpost of EMWA.

Go for the Authorities – a Bio-psychological Point of View *38*

Sylvia Hering

OK, so you've got a big submission for the authorities for a biotech product, what to do? Well, enough of that cowering before the authorities, it is time to take up the challenge and tell them what they need to know.

Why Not? *41*

Patricia Bünz

Despite the fact that approximately one-third of EMWA members are non-native English speakers (not to mention the new Vice-President!), one still hears the question "Can non-native English speakers be medical writers?". I think the title of this article by our new Linguistic Diversity Editor says it all. [INT]

News from the EMWA Professional Development Committee *43*

Wendy Kingdom

All the latest from the EPDP, including the new "double" workshops shortened "mini" workshops.

Shake that Sokaled Thing *45*

Karen Shashok

In a previous issue of TWS (Win 2000, Vol 9, No.1) Karen reviewed a book discussing probably the biggest controversy of the last 50 years in the life sciences, the David Baltimore/Imanishi Kari data falsification scandal. Now she reviews a book discussing an equivalent occurrence in sociology, the now infamous trashing of post-modern sociological academic writing by the physicist Alan Sokal. For anyone interested in academic or intellectual integrity – a must read. [INT]

Regular Columns

From the Editor's Desk *28*

Message from the President [INT] *30*

Hey, it's Only My Opinion *48*

Meetings of Interest *50*

[INT] - this symbol indicates that the article also has been or will be published at the EMWA internet site: http://www.emwa.org

Journal Insights

The Write Stuff is the official publication of the European Medical Writers Association. It is issued quarterly and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims.

Articles or ideas should be submitted to the Editor-in-Chief (see back cover) or another member of the Editorial Board.

Subscriptions

Subscriptions are included in EMWA membership fees. Non-members can subscribe at an annual rate of:

- 35 within Europe
- 50 outside Europe

Instructions for Contributors

- **The Write Stuff** typically publishes articles of 500 - 1500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted electronically on computer diskette or by email as an MS Word file using Arial font (or equivalent), 11 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style).

Back Issues

Subject to availability, previous issues of **The Write Stuff** can be obtained for the cost of mailing by contacting the EMWA Head Office (see back cover for address).

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From the Editor's Desk: Transparency by Process

by Barry Drees

An important part of any leadership role, whether the group of people is a business, family, or professional association, is to search out the opinions of the other members on how things are being run. This serves two important purposes: it gives crucial feedback to help the leaders assess the job they are doing but it also helps show the members that their opinions matter and that they truly have a say in how things are run. One hears a lot of talk these days about how to generate organisational commitment and loyalty, but I think that an important first step is to involve the members. Of course, getting opinions won't do any good if they appear to vanish into a black hole and nothing is ever heard of them again. People need to see how their opinions are considered and the reasons for the resulting action or inaction.

One hears a lot of talk these days about how to generate organisational commitment and loyalty, but I think that an important first step is to involve the members.

One way that this can be accomplished is by instituting what is called transparency (even if it is an appallingly overused corporate and political buzzword). Transparency, in this case, refers to being open about the leadership decisions and the how and the why they are being made. With small groups (family, for example) transparency is mostly a matter of communication. Certainly communication is also very important in larger organisations, and this is the main reason why, as president back in 1997, I initiated the *Message from the President* on the EMWA website (the EMWA newsletter was a much more humble affair in those days). This gave the president the chance to explain to the members what the executive committee of their organisation was doing and why.

Of course, the real difficulty with larger groups like a business or an association such as EMWA, is trying to communicate with large numbers of people. I believe that a critical part of maintaining transparency in such cases is having clearly defined processes, so that the how for many decisions is clearly defined for all to see. The importance of having such "rules" which everyone must follow was brought home to me recently by something I saw on television. Europe at the time, like much of the rest of the world except the USA, was immersed in World Cup football mania, and consequently one saw and heard a lot about what the sport means to various countries. One programme I was watching was interviewing a Brazilian sports journalist who said that the appeal of football to everyone in Brazil is that unlike politics or just about anything else in that country, football has clearly defined rules that everyone, rich or poor, important or downtrodden, understand and have to follow. Any game is, by its nature, subject to chance and the quirks of fate, but since everyone knows the rules, it is much easier to accept decisions you don't like – and this applies just as well to any group activity.

From the Editor's Desk

Of course, the negative side to this is that it restricts the freedom of the management or leadership, but I really believe that it is a price well worth paying. Just as a democratic form of government means that you have to get public support for programs before initiating them, so once you have defined processes and rules, you have to follow them. In the case of EMWA, it may seem overly bureaucratic to have rules and regulations covering many of the Executive Committee's (EC) decisions, but it does make clear the process by which such decisions are taken and thus greatly increases the acceptance of such decisions.

I think that it is very easy to underestimate the value transparency has for many members. I recall in the early days of EMWA, when things were much less organised than today, the most common criticism of EMWA and the EC was that there were no elections for the committee officers. Of course, we were hesitant in those days to let out the unfortunate truth that, in fact, there was very little interest in what was then a rather thankless job. We had a very hard time getting people to agree to do it, let alone resorting to elections. Those days, thankfully, are gone, but it is even more important as EMWA has grown and developed real financial resources, that the process for the election of EC officers, for example, is now a transparent one and not suggestive of the back-room politics so typical of many organisations and companies.

So that's what they are doing at the bar during the EMWA conferences with a drink in hand talking to the other members and apparently having a great time – important work for the EC

The other aspect to all this that is frequently overlooked, is that communication is a two-way street. We can write articles and put processes in place, but the members have to read them and then, even more importantly, give us their opinions. I and the other EC members certainly always try to get as much feedback from the members as possible at the EMWA meetings (so that's what they are doing at the bar during the EMWA conferences with a drink in hand talking to the other members and apparently having a great time - important work for the EC), but you should all make an effort to let the EC know what you think of what they're doing as well as what you think they should be doing.

Finally, on a personal note, I'd like to express my appreciation to previous winners of the Nick Thompson Honorary Membership Award, the other members of the EC, and all EMWA members who nominated me and congratulated me or wished me well after I received the award in Prague. I think that one of the greatest things that one can accomplish in life is to be acknowledged by one's peers for having done a good job for work that was a labour of love. My deepest and most sincere thanks to all of you.

Barry Drees
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Message from the President

Julia Cooper

It was great to meet many of you at EMWA's annual spring conference in Prague. The conference marked the end of my year as Vice-President, during which my main responsibility was to organise the Prague meeting, with the help of EMWA Head Office and the Education Officer. In previous years, the Vice-President has also been assisted by an EMWA member living in, or close to, the conference venue, who has "willingly volunteered" (read: had arm twisted after a few drinks in the bar at last year's conference) to act as conference manager. This year, although the EC was very keen to hold a conference in Prague, we did not have any members based in that area. Instead, we were fortunate to have the combined talents of Kathy Thomas-Urban and American Express Travel Services at our disposal. Kathy is a Czech-born EMWA member and her language skills and knowledge of the local business culture were indispensable, particularly during inspection visits on EMWA's behalf in June 2001 and March 2002.

There were many memorable aspects of the conference. In particular, the Don Giovanni Welcome Buffet will not be forgotten in a hurry by those EC members who dressed up in period costume for all or part of the evening. I was laced into a costume so tightly that I could hardly eat! In response to requests from the membership, this year's conference was scheduled from Tuesday evening to Saturday lunchtime, and many delegates took advantage of the opportunity to spend the weekend in Prague. Thanks are due to Phillipa Clow and her team (Laura, Nicky and Sandra) who worked tirelessly to ensure that everything ran smoothly throughout all stages of the conference. Thanks also to Stephen de Looze and the EPDP committee for organising the largest EMWA workshop programme yet, encompassing a varied range of topics that offered something for everyone.

The AGM marked the end of Julia Forjanic Klapproth's term as President. Fortunately for EMWA, the organisation will continue to benefit from her dedication and enthusiasm. In her new role as Immediate Past President, Julia will chair the Long Term Planning Committee. EMWA has undergone considerable growth in recent years – we are now an organisation of over 500 members – thus it is vital that we start to take a long-term look at our development and future plans. The EC has therefore decided to set up the Long Term Planning Committee, comprising the five previous EMWA Presidents, to develop a 5-year plan for EMWA's growth. One of the first topics to be considered is the strategy for selection of conference venues. The increased scale of the spring conference, from around 50 participants five or six years ago, to around 150 at this year's conference, means that EMWA needs to book conference locations much further in advance to secure venues that meet our size and workshop room requirements. Thus, one of the Long Term Planning Committee's initial tasks will be to recommend locations of future conferences of strategic benefit to

Message from the President

EMWA. Together with the EC, EMWA Head Office will then book venues accordingly. The chosen venues and dates will be publicised as bookings are made.

Julia was very successful in raising sponsorship for the Prague conference, and she will be continuing this sponsorship drive, both for future conferences and also for more general sponsorship of EMWA. Isabelle Thirolle, who served as Public Relations Officer from 2000 to 2002, will continue to help Julia in this effort, and I encourage you to contact Julia or Isabelle if you know of potential sponsorship leads. Isabelle is now our Vice-President, and in her new role, she will organise the 2003 spring conference, which the EC has agreed will take place in Lisbon. Other changes on the EC include Michelle Derbyshire as our new Public Relations Officer, and the departure of one of our Membership Officers, Adam Jacobs. Thanks are due to Adam for all his hard work over the past two years. Since the function of Membership Officer can now be performed by a single person, our second Membership Officer, Judi Proctor, will be carrying on the good work alone. Sadly, Mike Matthews has resigned from his post of Executive Secretary and I will be taking on his role until the elections at the next AGM. We are grateful to Mike for initiating a review of EMWA's business processes, which need to be fine-tuned as the organisation grows.

In the forthcoming year, EC activities will include efforts to raise the profile of the profession in Europe. Our University Liaison Officer, Teresa Roberts, has just finalised a leaflet that explains all about medical writing as a career and gives examples of the variety of opportunities in our profession. It also provides tips and information for anyone considering embarking on a medical writing career. The leaflet will be translated into a range of languages and will be distributed widely to university careers services, as well as being available to download from the EMWA website. In addition, Teresa and other EC members will pilot an EMWA presence at careers fairs, to spread the word about this fascinating profession.

Other EC plans include fostering a closer relationship with professional organisations that share mutual interests with EMWA. One such organisation is the European Association of Science Editors (EASE). EASE's activities and conferences will be of interest to those EMWA members involved in editing as well as writing. One of the plenary speakers at the Prague meeting, Dr Hervé Maisonneuve, is an ex-President of EASE and the current editor of European Science Editing (the journal of EASE). Hervé has helped EMWA to negotiate an agreement that EMWA members may attend EASE conferences at the same rate as EASE members. Look out for EASE news and conference information in future editions of TWS.

Throughout the year, I will update you on the EC's activities via this column. I also hope to meet as many of you as possible at the autumn conference in Amsterdam. In response to requests from members, this will be scheduled over a Friday and Saturday, on 8th and 9th November 2002. See you there!

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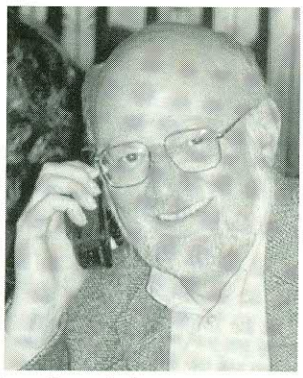

The 11th Annual EMWA Meeting: Yippee! Dumplings Again

by Geoff Hall

The Czech immigration authorities must use a different guidebook from me. Mine (new) clearly states that UK, US and Canadian passport holders need no visa when visiting the Czech Republic. Unfortunately, the sudden need for visas for Canadians and some others meant that the 11th annual conference of EMWA in Prague was missing a few important participants, and so it was an extra special pleasure to see so many new EMWA members.

An innovation at this year's conference was a special welcome reception for first-timers and a dot on the badge so that they could be made to feel among friends. I hope you will agree that warmth of welcome has never been a problem at EMWA meetings and it was a delight for us old hands to watch as new friendships were forged over lunch or a drink at the bar. The general welcome reception saw various Executive Committee (EC) members in traditional dress. Julia Cooper as conference chair made a welcoming speech as everyone tucked into a superb buffet. An introduction to Czech food, but no indication of the dumplings that were to follow. A great start to the conference and a pleasure to just watch as the realisation dawns on keen intelligent minds that they are discovering something that is going to be a special part of their professional lives for years to come.

The conference, as ever, was a frantic affair mixing education (30 workshops) and superb social events. I could have happily taken part in everything, but when the tour of Prague Castle, a river cruise and a visit to the U Fleků brewery clashed on Wednesday night, I had to choose. U Fleků beer is one of the wonders of the world, it is served unpasteurised, unfiltered and without the addition of extraneous gas. The food at U Fleků was interesting, if highly dumpling-orientated.

Significant firsts included a workshop on presentation skills by Mel Churcher and Chris Roose. Mel's is a talent much in demand in film and theatre, and reports indicated that this was a great success. There have been attempts in the past to present an introduction to health economics as a workshop. Not easy. Yet from what I hear, Andrea Spannheimer made this potentially dry topic fascinating. It was good to see other new workshop leaders, and a glance at the assessment forms indicates that the standard of teaching remains as high as ever. Thanks to everyone.

Among the established teachers were American visitors Tom Lang, Art Gertel and Ann Hudson Jones. Ann's workshop on Kafka's *The Metamorphosis* was a brilliant idea, and, I hear, an intellectual and cultural treat for those who took part. Ann also joined in another innovation, a Friday evening forum on ethics. Although the attendance was fairly small (fatigue was winning by then), most that attended thought that this is something we should repeat. Future topics, please.

Another regular American visitor to EMWA made her debut as a conference speaker. Suzann Johnson, who as Art Gertel's wife has been at most EMWA conferences over recent years, finally earned her participant's badge as she shared with us her thoughts on the health benefits of tea. Thanks for the "cup that cheers but does not inebriate" slide, Suzann! Keynote speaker at the same AGM plenary session was Dr Martin Boyer, a well-regarded ethicist, leading neurologist and a former Czech health minister. He gave us a fascinating insight into the changes in health service provision since the collapse of communism. Neither "The state knows best" nor "The market will fix everything if left alone" philosophies have served the country well on their own. Nevertheless, standards of health care are already on a par with some EU countries, so they must be doing something right.

The business part of the AGM was, well business-like. The president's and treasurer's reports were adopted in near-record time and a number of improvements to the constitution were voted into force. Julia Cooper, our new president, conducted elections for two posts on the executive committee. Michelle Derbyshire became the new Public Relations Officer and Isabelle Thirolle took on the difficult task of Vice-President and conference organiser. Isabelle already has a good grounding in conference organisation for EMWA. She was behind the very successful one-day conference in Lille 18 months ago. Next year's conference in Lisbon is in good hands. Thanks are due to retiring EC members for their important contributions over the past few years: Keith Veitch as Immediate Past President and Adam Jacobs as Membership Officer. No doubt, both will be contributing more to EMWA in the future.

One of the best things about an EMWA conference is having a conversation without wasting the first 10 minutes explaining what you do for a living

Back to food. The conference banquet was held in the magnificent setting of the Troja Palace. Traditional Czech food of the highest standards (several sorts of dumpling included) and attentive wine waiters made for a memorable evening. And a chance to keep fit. For those who couldn't be bothered to count, there were 66 steps required for every call of nature. The banquet was a special event for me personally as Art Gertel and I conferred the Nick Thompson Honorary Membership on Barry Drees.

So another conference is past. One of the best things about an EMWA conference is being able to have a conversation without wasting the first 10 minutes explaining what you do for a living. In Prague, we've all had great conversation, learned new things and made new friends. And thanks to the beer and dumplings put on a lot of weight. Here's to the salt cod in Lisbon.

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A Brief Overview of the Pharmaceutical Industry in Singapore

by Jing Ping Yeo

The pharmaceutical industry in Singapore is a rapidly growing industry with a considerable amount of government support. It is the strongest component of the biomedical sciences sector in this country, the others being the medical device, and biotechnology industries and the healthcare services. These four industries are clustered together as they have synergies and address common issues of human healthcare. With the rapid establishment of new discoveries and robust growth, the biomedical sciences sector is targeted to be the fourth pillar of manufacturing in Singapore. The nation aims to develop the biomedical sciences to achieve the same level of success as for the other three industry pillars - electronics, chemicals and engineering. Furthermore, it is hoped that, by 2010, Singapore will host 15 world-class biomedical science companies and become the region's hub (including drug discovery and development, clinical research, and health care delivery). The companies present so far include Glaxo SmithKline, Merck & Company, Schering-Plough, Aventis, Genset, Oculex, Baxter and Becton Dickinson. This is in line with Singapore's aim to be a knowledge-based economy that places a premium on technology, innovation, capabilities and talent.

The importance of pharmaceuticals in Singapore is reflected in the growth of the industry. It has been a driving force behind the boom in life sciences since 1997 and is expected to continue to do well, despite the economic downturn in the region. According to the Singapore Economic Development Board (EDB) Report, in the year 2001, the pharmaceutical industry's output of $5 billion accounted for 76% of total biomedical sciences manufacturing output, and the industry enjoyed a growth in employment of 7.6%. The governmental agencies such as the EDB Biomedical Sciences Group and Biomedical Research Council (BMRC)/A*STAR are working in close partnership with other agencies to adopt an integrated approach with synergistic initiatives in R&D, education and industry development.

A myriad of laws govern pharmaceuticals activities in Singapore. The Medicines Act and the Medicines Regulations promulgated therein provide the control of all aspects of dealings in medicinal and related products, as well as Chinese proprietary medicines. This legislation provides for the licensing of all medicinal products to be sold, manufacturers, wholesalers and importers, as well as dealing with issues relating to advertisements. All these are to ensure the safety, efficacy and quality of medicinal products. Besides the Medicines Act, other regulations such as the Misuse of Drugs Regulations, the Sale of Drugs Act, the Poisons Act and the Poisons Rules are also in place to regulate the industry.

Licensing, import and wholesaling of pharmaceutical products are governed by the Medicines Act. There are four types of licence: product, import, wholesale dealer's, and manufacturer's licences. Apart from these licences, the Drug Administration Department also issues a Certificate for Importers of Medicinal Products. This is required as Singapore, like many importing countries, requires proof of registration of medicinal products in the country of origin before sales are permitted.

For the conduct of clinical trials, a Clinical Trial Certificate (CTC) is required from the National Pharmaceutical Administration (NPA). The Medical Clinical Research Committee (MCRC) was set up to advise on the licensing of clinical drug trials: it deliberates upon and reviews new applications for CTCs, amendments to clinical trial protocols and informed consent documents, serious adverse event reports and requests for CTC extension. Not long ago, the Medicines (Clinical Trials) Regulations were revised and the Singapore Guideline for Good Clinical Practice (SGGCP) was implemented. The SGGCP, which was adapted from the International Conference on Harmonisation (ICH) Guideline for GCP, sets ethical and scientific standards for the conduct of clinical trials. It also serves as an assurance that results obtained from clinical trials are credible. In addition, an ethical code of practice was drawn up to guide doctors and drug companies on how they should deal with each other.

Like many other Asian countries, there is an increasing interest in involvement in clinical trials. This is primarily because of (i) the ease of access to treatment-naive patients; (ii) the ability to generate Asian data to address ethnic diversity; (iii) early exposure of key Asian opinion leaders to new therapies; (iv) the potential for shortening the investigational drug development time; and (iv) the capacity to reduce research costs in Asia (due to the lower cost of medical care in Asia).

Singapore is an attractive site for clinical trials due to its excellent infrastructure. This includes the establishment of the SGGCP, training activities, new clinical research organisations and site monitoring organisations in hospitals and institutions, as well as changes in regulatory guidelines (so that the time required for application and approval of CTCs has been reduced from 3-6 months to about 2 months). Hence, it is not surprising that a number of clinical trials have been performed here.

In conclusion, Singapore is making great strides towards becoming a leading regional hub for biomedical sciences. The pharmaceutical industry is clearly one that is granted tremendous governmental support and numerous incentives have been provided to encourage the multinational companies. Although the approaches taken have been fairly successful, the industry is still young and more needs to be done.

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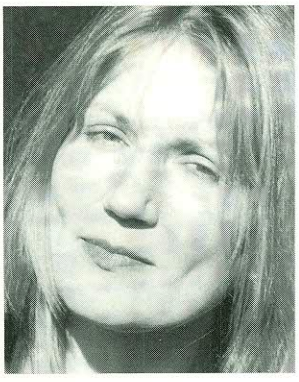

Go for the Authorities: A Bio-psychological Point of View

by Silvia Hering

A former biotechnologist, who left the bench about ten years ago for the regulatory and writing business, when asked whether the move was good or bad, replied, "I have yet to decide, but writing in this new biotechnological atmosphere is really challenging". Here, I'd like to suggest a more aggressive interaction between biotech start-up (and generic) companies and the CPMP. As evident from guidelines recently released by the CPMP, the current position towards regulatory requirements for new biotech products is a defensive, not a truly "regulatory" one. Perhaps we can see this position as a challenge, an invitation to the manufacturers to enter the dialogue.

The appeals of biotechnology have brought a fresh wind to the pharmaceutical scenery. However, there is a sizable gap between the innovative concepts of (smaller) biotech companies and their willingness to deal with regulatory aspects on the one side, and the (un)preparedness of the CPMP/Biotech Working Party (BWP) for decision-making on quality, safety and efficacy requirements for biotechnological medicinal products on the other side.

The defensive position of the CPMP/BWP becomes evident, for example, with respect to the so-called generic biotech products, and can be extended to nature-identical molecules. Are the usual concessions made for generics to copy conventional pharmaceuticals also applicable to biotech drugs? Would a limited pre-clinical and clinical development program be accepted? It has been said that decisions on the comparability between original and "generic" biologicals will be made on a "case by case" basis, which of course leaves a lot of room for interpretation.

What does the "comparability exercise" mean?

- The identity of the two molecules (within the limits of a described microheterogeneity) has to be shown by a battery of biological, molecular-genetic, and biophysical methods, as described, for example, by the European Pharmacopoeia.

- Specified limits for impurities (e.g. due to foreign protein) should not exceed the limits set for the original product, or, if those are not known, the variation deduced from different batches of the original by direct comparison or from published data (i.e., various batches of a product – manufactured in a validated production cycle – vary to a certain degree with respect to foreign protein impurities, proportion of isomeric forms, and glycosylation variants in the final product. The range of variations is controllable and, sometimes, has been published).

The knowledge of variations in the original product can be related to the clinical safety of the product. For example, it is known that commercial erythropoietin exhibits

differences in the ratio of glycosylation to sialisation forms, and this is within the limits of "microheterogenity" known from natural forms of this substance. The current information on treatment failures due to anti-EPO-antibody formation could be related, hypothetically, to this microheterogeneity. This knowledge can provide a basis for a definition of microheterogeneity acceptable for the generic product.

Writing in this new biotechnological atmosphere is really challenging.

However, similar comparisons may be not sufficient to evaluate the quality, safety and efficacy for a biotech protein. As stated in the CPMP guidelines, "pre-clinical and/or clinical bridging studies required to show comparability will depend on the nature of the drug substance and formulation". This wording is very defensive. How convincing is a comparability programme conducted by the manufacturer of the comparator product? Current experience suggests a clear need for clinical safety studies, while new toxicological and other preclinical data may be omitted (or, at least reduced to a minimum), if the basic requirements concerning molecular identity and purity are fulfilled.

What do the terms "similarity" and "comparability" mean?

The definitions of terms like "similarity" and "comparability" provide a convention of various subjective views, because these terms are not precise. The CPMP/BWP is under multiple legal pressures preventing the formulation of more precise guidelines on comparability. As various influences, scientific, legal, commercial, and political, are in conflict, the descriptions are tending to become less precise and it is not clear, whether a more specific view will eventually result. In order to find agreement, the CPMP is seeking input from scientific institutions like the "National Institute of Biological Standards & Control" in London. Thanks to highly developed methodical standards, it appears easier to define a minimum package for quality requirements than for clinical safety requirements. Applicants are therefore encouraged to put their maximum effort into the clinical safety documentation.

There is considerable concern about immunotoxic safety risks. There have been rumours that long-term safety studies in patients would be required to estimate the immunogenic potential of a "new" biotech drug. The recognised uncertainty opens up possibilities for argumentation as stated above (to follow the history of the safety of the original drug and to relate it to its microheterogeneity). It can be hoped, however, that more clarity in the quality and preclinical comparability definitions will help to reduce the necessary clinical safety effort.

What is required to demonstrate comparability to the original?

Both for generic biotech products and for nature-identical molecules, "proof of concept" is determined by the "original" product. Demonstration of molecular identity and purity would allow use of the published literature concerning pharmacodynamics, pharmacokinetics in animals, toxicology in animals, etc., as usually done for the original for an abridged application. If published studies in, for example, animal toxicology are lacking, it may be pertinent to discuss whether there is really a need for the whole spectrum of animal toxicology. As biologicals are more variations of human

molecules, studies with similar molecules in animals might cause more toxic or unexplainable effects not to be expected in humans. Therefore, the preclinical overview might consist of a discussion of why particular studies can be omitted (or would be superfluous, unethical, or ineffective because of interspecies toxicity, etc.).

An "extended" bioequivalence study (i.e. using a surrogate parameter for drug-effect in addition to plasma concentration or other pharmacokinetic parameters) is necessary but probably not sufficient. A large, treatment-oriented safety study would probably be unavoidable to make an estimation of the frequency of expected (like antibody formation) and unexpected, unwanted effects compared to those published for the original product. If the known incidence of side effects for the original is very small, the study size to show comparable safety characteristics for the biogeneric drug with acceptable power might be impractically large, and in this case the applicant could provide a benefit-to-risk assessment.

Why are people more afraid of biotech drugs?

Although a fear of biotech drugs may appear irrational, i.e. not based on the actual chemical structure of the product but rather on the way it is produced, such fears appear to be quite common and widespread. However, it should be remembered that the tradition for identifying safety risks in chemically defined drugs is long and highly developed. Society has a feeling for the risks associated with these kinds of drugs. In contrast, no such feeling exists for biotech drugs. The performance of any new biotech drug is therefore observed much more suspiciously. The "evil" (and the "good") which is expected from biotech drugs does not lie as much in impurities or degradation, but, paradoxically, in the degree of similarity with the original substance. This similarity is the mystery of biotech drugs, and makes it more difficult to design a valid safety programme since it is not clear what kind of risks to prepare for.

As for the risks of terrorism, safety thinking needs to be flexible and open-minded. A preventative strategy is, however, often dictated by fear, and therefore tends to be narrow-minded. If biotech manufacturers, with the help of regulatory people and writers, introduce their product more openly and less defensively to the authorities (for they know their product best), this might be a timely approach versus the wait-and-see policy of the CPMP. To move beyond the current climate of suspicion and mistrust, a more aggressive presentation of the scientific arguments supporting biotech drugs could be the answer.

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Why Not?

by Patricia Bünz
Linguistic Diversity Editor

After spending several years as a biologist at the University of Hamburg, the Swiss Federal Institute of Technology (ETH) in Zurich and Yale University in New Haven, I decided to forget my academic career and joined Kendle International Inc. in 1999. However, I did not totally give up my former research interests. I also work for Bayer AG and BASF AG as a freelancer on their scientific journal "VtB Verfahrenstechnische Berichte", where I am responsible for publications in the fields of microbiology, biochemistry and molecular biology.

Living as a north German in south Germany has definitely made me aware of the cultural and linguistic differences of the country (getting blank faces by saying "Grüß Gott" visiting Hamburg and even more blank faces by saying "Moin, moin" back in Munich). However, when I attended my first EMWA meeting in Brighton, I could not possibly have known that I would soon be engaged in the international aspects of this subject. In Brighton, Barry Drees convinced me that being the Linguistic Diversity Editor for TWS would be the greatest fun on earth. The fun started some months later when Barry asked me to write an article for TWS to introduce myself.

I have frequently been asked during my time as medical writer how, I, as a non-native speaker, could possibly work as a medical writer.

The medical writing group at Kendle consists of eleven great people and the head of the group, Beate Wieseler, seems to be a big fan of Barry's much praised diversity. She employs native as well as non-native English speakers, lots of south Germans and one single north German as medical writers in her group at Kendle. However, the diversity does not extend to the sex of the writers because we are all women. Here, a touch more diversity would be welcome.

I have frequently been asked during my time as medical writer how, I, as a non-native speaker, could possibly work as a medical writer. My first reaction to the question of native vs. non-native English speakers is the same as to another frequently asked question, "why I, as a fishhead (south German slang for a north German) prefer to live in Bavaria". My reply to both questions is usually a "why not?".

Sure, I will never be able to manage all the nuances of the English language as well as a native speaker. For example, speaking of diabolic blood pressure instead of diastolic blood pressure or talking of disodors instead of disorders were slips of the native tongue of one of my humorous colleagues from Great Britain which may have

never occurred to me. However, thinking of patents instead of patients seems to be a mix-up associated with my former life as a researcher.

Nevertheless, in my opinion, the most important requirements for being a good medical writer are enthusiasm for writing in general, the ability to interpret and present data in a clear, accurate and concise way, the ability to be a good team player and work to timelines, excellent writing, planning and verbal skills, and an understanding of the drug development process. These requirements apply regardless of whether one has a native or non-native English-speaking background.

I know that the question "to be or not to be a native English speaker" is a well and frequently discussed subject in EMWA and this article is not intended to change other people's minds. However, the percentage of non-native speakers in EMWA is increasing and already one third of the members are non-native English speakers (The Changing Face of EMWA, TWS 2001; 10, 95-96). I think this is a clear indication that non-native speakers are becoming more and more accepted as medical writers in Europe and that they are doing a great job even with a non-native English-speaking background.

I know that the question "to be or not to be a native English speaker" is a well and frequently discussed subject at EMWA, and this article is not intended to change other people's minds.

I am used to working in an international atmosphere and therefore enjoy working together with all of my colleagues, native and non-native English-speaking alike. As Barry pointed out (From the Editor's Desk: Diversity makes for good teamwork, TWS 2002; 11 (1), 3-4), different backgrounds enables us to look at a problem from another perspective. A fact which could be very helpful in the life of every medical writer.

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FOOD FOR THOUGHT

"He that will write well in any tongue, must follow this counsel of Aristotle, to speak as the common people do, to think as wise men do; and so should every man understand him, and the judgement of wise men allow him."

Roger Ascham (1515-1568)
JAMA 2001; 285: 1266

News From The EMWA Professional Development Committee

by Wendy Kingdom

At the end of this year's conference, when everyone had gone home, or had rushed out to do some last minute sight-seeing in Prague, the EPDC met to review the conference workshops and to plan for the future.

There were seven new workshops under assessment in Prague. Each workshop was attended by two observers nominated by the EPDC (one observer in each case from the EPDC itself). All of the workshop evaluation forms were entered into a database and summarised. Many thanks to Phillipa, Sandra and Laura for compiling and calculating all of the information in time for the EPDC meeting.

We discussed each workshop, reviewed the evaluation forms and made suggestions for feedback to the workshop leaders. We also looked at the evaluations for the credit workshops and were delighted (and relieved) to see that all of the workshops received positive feedback. The overall assessment scores were also up on previous years, which suggests that we are on the right track with the new format and quality assurance measures that the EPDC has introduced into the programme.

We think that "less is more" in terms of professional development and training

There were a total of 30 workshops at this year's conference, an all-time record. Until now, there has not been a restriction on the number of credit workshops that may be attended at one meeting. Thanks to the expanded programme, the Prague meeting allowed, for the first time, the possibility for participants to attend up to six credit workshops. Initially we thought that people would limit themselves on the number of credit workshops that they applied for because of the time needed to complete the pre- and post-workshop assignments. However, we now know that some people did indeed take six credit workshops at the meeting. We think that "less is more" in terms of professional development and training, since participants can study for the workshops and complete the homework more thoroughly if they are not overloaded with topics. We also think that the EPDP should accompany work-related experience, and that the value of the certificate is greater if it is not possible to complete it in less than two years. Furthermore, unlimited booking of credit workshops meant that they were quickly booked out, and so all except the earliest applicants had difficulties in finding a place on the credit workshop of their choice. We have therefore decided to set a limit of four on the number of credit workshops that can be attended at a single conference.

Next on the agenda was a review of proposals for new workshops. We currently have three proposals: "Clinical Study Design", "Medical Writing Between Dossier Submission and Drug Approval", and "Writing Plain English". We plan to assess these new workshops during the November meeting in Amsterdam.

There is a constant need for new workshops. Some of the current workshop leaders are not always available to attend the conference, whilst other workshops have a low demand and do not need to be run every year. We are also interested in exploring new workshop areas (options) in the EPDP. At the moment, there are only two credit workshops in the Public Relations and Marketing section, and none in other areas of potential interest such as broadcasting or the media. Although this situation probably reflects the current professional environment of the EMWA membership, variety in the range of workshops available is good for the conference and good for personal development. If you have an area of expertise and you would like to give a workshop, please submit a proposal to the Education Officer, Stephen de Looze. Full details of what is involved in being a workshop leader are provided in the Workshop Leaders Handbook, which is available on the EMWA website.

Also on the agenda for the EPDC meeting was a discussion of EPDP policy issues. We have decided to try out two new types of workshop. At the May 2003 meeting in Lisbon, there will be at least one "double" workshop. This is to account for the fact that some subjects are too big to accommodate into a 3- or 3½-hour slot but cannot easily be divided into separate workshops (e.g. basic and advanced). The double workshop will incur twice the fee but will provide two credits. If there is interest from the membership and workshop leaders in the double workshop concept, we will continue to provide more opportunities in the future.

Variety in the range of workshops available is good for the conference and good for personal development

The second new format that we will be trying in Lisbon is a 1½-hour slot for non-credit workshops at a reduced fee. These will be less formal workshops, and will include topics that are either not suitable for the credit programme or may be developed as credit workshops later on. Some of the topics offered during the networking lunch may fit better into this format. The shorter workshop slots will also enable participants to plan some free time during the conference, useful for meeting colleagues, catching up with one's e-mail or just having a break. Following on from the 1½-hour workshop theme, the rooms that become vacant when the short workshops have finished will be available for those who would like the opportunity to do their post-workshop assignments in groups. If you would like to give a short workshop, particularly if you have an area of expertise but haven't the time to commit to a 3-hour credit workshop, please submit a proposal to Stephen as soon as possible. We have to start planning the Lisbon meeting in the summer and the brochures must be ready for printing in early December!

The EPDC is currently reviewing the workshop materials for the new credit workshops and planning our next steps. If you have any comments on the EPDP or if you would like to propose a new workshop, please let us know.

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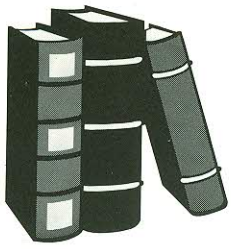

In the Bookstores... Shake that Sokaled Thing

by Karen Shashok

Editors of Lingua Franca, editors. The Sokal Hoax. Lincoln, Nebraska (USA): University of Nebraska Press, 2000. ISBN 0 8032 7995 7

The Spring-Summer 1996 issue of the journal *Social Text* was special for several reasons. It was a two-part issue devoted to the "science wars", a topic close to the hearts of the postmodern sociologists and experts in cultural studies who make up most of the journal's editors, authors and readers. It contained articles from the foremost minds in the discipline. And, as an extra treat for the most radical of the "pomos", there was an intriguing, if often turgid and jargon-laden article by a "real" scientist, physicist Alan Sokal. The editorial board accepted his offering—titled "Transgressing the Boundaries: Toward a Transformative Hermeneutics of Quantum Gravity"—only after some hesitation. The author was not known in pomo circles, and was from a different discipline; was he really the editors' peer? He seemed a bit too determined that the article be published with its 55 footnotes and 295 references intact (Seventy-five source notes were eventually moved from the reference list to the body of the text at the editors' insistence.). Was he really an expert in the type of sociological and cultural analysis *Social Text* was well known for?

Ah, if only the editorial board had thought to send his manuscript for outside peer review before they accepted it. But the journal's policy was to forgo such distasteful "disciplinary policing" and rely instead on the judgement of its editorial board members, several of whom were cited favourably in the article. And the reference list was filled to the brim with names like Lacan, Haraway, Deleuze, Irigaray, and many other of the field's most revered heroes.

Besides, Sokal talked the talk like the very best of them. Prose such as that excerpted below, although it contained terms that were unfamiliar to the journal's editorial board members, used complex grammatical structures and semantic devices that are commonplace in postmodern writing:

> In mathematical terms, Derrida's observation relates to the invariance of the Einstein field equation $G\mu\upsilon = 8\pi GT\mu\upsilon$ under nonlinear space-time diffeomorphisms (self-mappings of the space-time manifold that are infinitely differentiable but not necessarily analytic). The key point is that this invariance group "acts transitively": this means that any space-time point, if it exists at all, can be transformed into any other. In this way the infinite-dimensional invariance group erodes the distinction between observer and observed; the π of Euclid or the G of Newton, formerly thought to be constant and universal, are now perceived in their ineluctable historicity; and the putative observer becomes fatally de-centered, disconnected from any epistemic link to a space-time point that can no longer be defined by geometry alone (p. 16).

Heavy stuff—wouldn't it make great material for an EMWA workshop editing exercise? Aren't you sick to death of editing ponderous nonsense like this into something that will not maul the readers' neurons?

As some of you may know, any serious attempt to edit this sample into something comprehensible is doomed to failure. In an article that appeared in the May-June 1996 issue of *Lingua Franca* (which came out the very next day after the special issue of *Social Text* was published), the author admitted that his article was a hoax meant to wake the intellectual left up to its failure to value substance over (vacuous) style:

> So, to test the prevailing intellectual standards, I decided to try a modest (although admittedly uncontrolled) experiment: Would a leading North American journal of cultural studies—whose editorial collective includes such luminaries as Fredric Jameson and Andrew Ross—publish an article liberally salted with nonsense if (a) it sounded good and (b) it flattered the editors' ideological preconceptions?
>
> The answer, unfortunately, is yes (p. 49).

His confession triggered a furious controversy that involved (among others) experts in cultural studies, sociologists, philosophers, feminists, ethicists, editors and editorialists.

Published in 2000, "The Sokal Hoax" is a compilation of newspaper articles, op-ed pieces, letters to the editor and email exchanges about the case. The now-famous "Transgressing..." article from *Social Text* and its exegesis "Revelation: A Physicist Experiments with Cultural Studies" from *Lingua Franca* are of course included. (Surprisingly few specialists in communication studies or linguistics are represented in this book; perhaps their contributions to the debate are to be found elsewhere.)

Aren't you sick to death of editing ponderous nonsense like this into something that will not maul the readers' neurons?

The case is analysed from many angles by experts from different disciplines: sides are taken, reasons (and some poor excuses) given, and conclusions drawn. The major issue is whether or not the discipline, at least as practised in the USA, will be able to change its ways after the exposé. Also discussed is whether submitting a bogus manuscript to a serious journal is "fair play", (The answer seems obvious to me, given Sokal's honourable intentions, but some authorities—especially those on the journal's editorial board who utterly failed to realise that the text was a hoax—found his tactic deeply unethical.). Most authors are from the USA; there are also articles originally published in major English, Brazilian, Italian and French newspapers. Articles published in Portuguese, Italian or French have apparently been translated into English; unfortunately the translators are not credited.

The variety in length, style and viewpoint makes tackling this compendium of texts easier than it may seem. Most of the writing is, thankfully, *not* typical pomo fare! In

fact, for those EMWA members who were educated in the USA but have since emigrated, there are several very well done essays that show there's hope yet for academic standards in the USA. A couple of the articles do a good job of summarising and explaining (from a mainly leftist viewpoint) the political and cultural changes the country has undergone since the 1960s and 70s.

Even if essays on cultural studies are not high up on your list of must-reads, this book about one person's successful attempt to prick US postmodernists' hot air balloon will impress you in many places, and provide a welcome workout for some parts of your brain that you thought had taken premature retirement. In some other places it will exasperate you with shoddy reasoning, but cultural studies certainly don't have the monopoly on that particular sin!

Note: Zillions of places on the web contain information on the "Sokal hoax" or the "Sokal affair". One of the funniest sites is Monash University's "The Postmodern Generator" (www.elsewhere.org/cgi-bin/postmodern; visited 9 July 2002), which, at the time of writing, had generated 550,403 nonsensical (but grammatically and syntactically impeccable) pomo assays, complete with references. Sample quote from one, titled "Prepatriarchal discourse and cultural socialism": "In the works of Madonna, a predominant concept is the concept of posttextual reality. In a sense, in *Sex*, Madonna deconstructs cultural socialism; in *Material Girl*, however, she reiterates semiotic construction".

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The Last Word

"As an adolescent I aspired to lasting fame, I craved factual certainty, and I thirsted for a meaningful vision of human life - so I became a scientist. This is like becoming an archbishop so you can meet girls."

Matt Cartmill,
Anthropology professor and author (1943 -)

Hey, it's Only My Opinion: Authorship

by Diana Epstein

The subject of authorship seems to be a problem for medical writers. Many writers seem to believe that their name should appear on the title page of papers submitted for peer review. Is this a correct assumption?

The names which appear on the title page are usually those of the individuals who contributed to the study and helped in collecting the data. Those who assisted with laboratory work, technical assistance, obtaining information or proof reading should not appear. This is not due to their work being insignificant, this is just the mentality and the way that high-impact, peer reviewed journals work. Some journals allow the names of technical support individuals and laboratory workers to appear in the acknowledgement section at the end of the paper. Also allowed to appear there are the names of those who advised the authors, not forgetting the medical writer. Ouch! That hurt, the medical writer appearing just in the acknowledgements section. Hmm, lets see, are there any ways around this? After all, as the saying goes where there's a will, there's a way! Currently in many journals if the paper involves a lot of statistics and the statistician is also the medical writer then, BINGO, the name can appear on the title page. Apart from that, not much chance.

Many writers seem to believe that their name should appear on the title page on papers submitted for peer-review. Is this a correct assumption?

Those of us who are regular visitors to EMWA's web page (www.emwa.org) will have read in the "Members" section about the current situation regarding the submission of papers from pharmaceutical companies and the fact that journals like, *The Lancet* now refuse to publish papers submitted from these companies. (Medical journals rebelling against drug companies!) But is this really such a bad thing? Well, that depends on who you are and what you want For the pharmaceutical companies it is bad news. After all, when a company is able to advertise that their drug was published in a high-ranking journal like *The Lancet*, it does have a big impact and makes a good impression. But is this bad news for the medical writer? I think it is a blessing in disguise. Taking into account that we are lucky if our names appear at all and then perhaps only in the acknowledgements section, it is great news! In fact it couldn't be better. How is that, you might ask? Well the fact of the matter is that there are many other journals out there with a lower impact factor, which means less bureaucracy in getting published. Such journals do not have so many strict rules and regulations regarding the number of authors appearing on the title page and do not require justification of each and every author's contribution to the paper. In the long-term this could work to the medical writers advantage regarding authorship.

Only My Opinion: Authorship

Of course, our job as medical writers will now be to "sweet-talk" our bosses or clients into why a particular lower-impact journal would be advantageous to the firm (assuming one has a client or boss who listens to the medical writer, as it should be). After all, we ought to know our profession. We might then be able to maintain our position and even get our names on the title page. The problem of authorship, for medical writers at least, will belong to the past.

So, fellow medical writers, opposing the view taken on the web page, I believe that in the long run, journals like *The Lancet* have done not only us, the medical writers, a big favour but have also helped the lower-impact factor journals. Maybe in the not too distant future, due to the internet, they will end up begging pharmaceutical companies to submit manuscripts to their journals. Who is thinking about that? After all, their loss is our gain

But hey, it's only my opinion!

And, while we're on this subject . . .

Meetings of Interest

The following list is presented as a service to EMWA members and is not meant to be complete. EMWA does not endorse these meetings in any way. Those having the **[EMWA]** symbol include presentations from EMWA members. All meetings are conducted in the English language unless otherwise indicated. If you would like to have something listed here to share with other members, please contact Barry Drees (details on back cover).

Date	Meeting/Sponsor	Location
Sep 12-13	**Developing Training Skills in the Pharma. Industry** Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	London, UK
Sep 19	**Planning Successful Meetings** Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879; Fax: (+44) 1189 335 436 Internet: www.rostrumtraining.co.uk	London, UK
Oct 1 **[EMWA]**	**Effective Writing** Tim Albert Training Paper Mews Court, Dorking, Surrey, RH4 9AU, UK Tel: (+44) 1306 877993; Internet: www.timalbert.co.uk	London, UK
Oct 7 **[EMWA]**	**Writing a Scientific Paper** Tim Albert Training Paper Mews Court, Dorking, Surrey, RH4 9AU, UK Tel: (+44) 1306 877993; Internet: www.timalbert.co.uk	London, UK
Oct 9-11 **[EMWA]**	**Successful Medical Writing (Intensive Course)** Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	Brussels, Belgium
Oct 10-11	**Medical Writing** International Pharmaceutical Training (IPT) Customer Service Manager, IIR Ltd., 29 Bressenden Place, London SW1E 5DR, UK Tel: (+44) 20 7915 5055; Fax: (+44) 20 7915 5056 Internet: www.ipt-courses.com; e-Mail: registration@iir-conferences.com	Basel, Switzerland
Oct 17-18	**Medical Writing (German language)** IIR Deutschland GmbH Otto-Volger-Straße 17 D-65843 Sulzbach/Ts. Tel: (+49) 6196 585 460; Fax: (+49) 6196 585 485 Internet: www.iir-pharma.de; e-Mail: anmeldung@iir.de	Frankfurt, Germany

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