The Write Stuff

The Journal of the European Medical Writers Association

Medical Writers Strike Back

EMWA European Medical Writers Association

Winter 2001

Vol. 10, No. 1

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Medical Writers Strike Back
(Winter 2001) Vol. 10, No. 1

Regular Columns

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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 for address) or another member of the Editorial Board.

Subscriptions:

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

- £20 within Europe
- £30 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 discussd with the author before publication.
- Submissions should include the full address of the author, including the telephone/fax numbers and e-mail 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 disc or by e-mail as an MS Word file using Arial font (or equivalent), 11-point, 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 secretariat.

Advertising Rates:

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• Full page	£200
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Private

Freelance members only

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Behind the Press, The Editorial Board:

From the (Deputy) Editor's Desk:

by Judi Proctor

I think that I am going to have to stop going to EMWA conferences. At the first conference I attended, in Copenhagen, I found myself volunteering to be a copy-editor for Barry – as a single parent with a full-time job – I had time for this!?! But I coped and even enjoyed it. I then went to Dublin and found myself in a whiskey distillery volunteering to be the Deputy Editor for The Write Stuff (do you think there might be some sort of connection?), with absolutely no idea what would be involved. Who knows what I might agree to if I go to the next conference!

Anyway, when I got home, I thought that it would be a good idea to ask Barry what I had let myself in for, and I was a little . . . well, nervous to discover that I was going to have to put a whole issue together! At the time, I was in the middle of planning my wedding, so Barry relented a little and said he could wait and I could do the winter issue. I thought that perhaps, if I kept my head down and stayed quiet, Barry would forget about me . . . but if you read "From the Editor's Desk" in the last two TWS issues, you will know that I was deluding myself! With it written in black and white, there was no escape!

Medical writers are often treated as "poor second cousins" by the likes of regulatory affairs people, statisticians and programmers as they often feel that "anyone can write a protocol/report/manuscript etc." but no one but a regulatory officer/statistician/ programmer/QA officer etc. can do what they do!! Of course, having seen some of the documents produced, it is all too clear that not everyone can produce a document that is well written, easy to read and to the point. The article from Nick Thompson on the care and feeding of Regulatory Affairs illustrates this, while Linda Mizen's broad "care and feeding of your client" article shows that medical writing isn't all fighting uphill. Nick has worked in the pharmaceutical industry for 11 years, six years as a freelancer and until recently was a senior medical writer with Scotia Pharmaceuticals. Linda spent 35 years in R&D at SmithKline Beecham and now pursues an independent role as a consultant and freelance medical writer specialising in anti-infectives. Both Linda and Nick are first-time contributors for The Write Stuff. I hope that they will find time to write more articles in the future.

It is all too clear that not everyone can produce a document that is well written, easy to read and to the point.

I was hoping to bring you an article from a "guest writer", a statistician who sees things from the other side of the fence. Sadly, due to work pressures, he has been unable to contribute this time, but I hope that we will be able to succeed with this plan some time in the future!

From the (Deputy) Editor's Desk

As you can see below, we'd like to congratulate seven of our members who are the first members to have qualified for the EPDP certification. Since the split with AMWA, I think that many of us were a little worried that any credits already earned could have been "lost". So congratulations to you all, and for those of you still working towards accreditation, good luck!

I had no idea how hard producing this issue would be, but I have really enjoyed the challenge. It is fun to be able to nag and not be shouted at (teenage daughter!). Since beginning work on this issue, I find myself in awe of Barry, not only does he produce The Write Stuff in his spare time, as well as having a full time job and a family, but he does it four times a year! I think that most of us have always taken that for granted so I would like to take this opportunity to thank Barry for all his hard work – both in the past and for the future.

I would also like to remind you that everyone who contributes to The Write Stuff, not just writing articles, but preparing adverts, copy-editing *et cetera*, does so in their own time for no money. If you feel that you can do better . . . well, the more contributions we get to The Write Stuff the more diverse and interesting the issues can be! Don't sit at home or work complaining – join in and help to move The Write Stuff on to even bigger and better things. Anyway, the following is my offering. I hope that you enjoy it.

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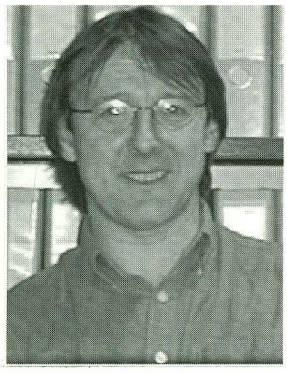
CONGRATULATIONS!

EMWA congratulates the first members to qualify for EPDP certification:

Chris Priestley - Editing/writing

Nancy Howat - Pharmaceutical
Hilde Joosen – Pharmaceutical

Paul Gisby – Multidisciplinary
Marian Hodges – Multidisciplinary
Debbie Jordan – Multidisciplinary
Nick Thompson - Multidisciplinary



Message from the President . . .

by Keith Veitch

So, I can finally wish you all not only a happy and prosperous New Year but also a happy New Millennium. It may be the scientist in me, or perhaps I am just pedantic, but I fell into the camp that held that the third millennium only started on January 1st, 2001. The change from 1999 to 2000 may have seemed to be the turning point, but those of us in the know, perhaps of a less "romantic" nature, held that there was still one year to go and that the celebrations last year should only have been a rehearsal. But it did not seem that many others shared my opinion. Fortunately I did not have to write about it last year, as I suspect I would have spent the first six months arguing the point.

That brings me to the theme of this issue, which is once again the essential role that team-work plays in our daily professional lives. The writers may have his or her own opinions, but ultimately the ones written down are those of the team. There may be agreement by the time they are written, but it is fairly certain there would not have been at the beginning. Our role as writers is to assimilate all the various differences into a final agreed product. An outsider may think that, being scientific writers, we are simply reporting facts, but - as we all know - there are ways of reporting and ways of reporting...

I have frequently been involved in discussions on job titles when the job description is the same. I am officially a Scientific Writer, but doing the same job in another company I could be a Medical Writer, Clinical Writer or even Clinical Scientist. My personal favourite is Medical Communicator, which I feel best describes what we do. Not only because we as a profession communicate the data from our clients to the outside world, but we also facilitate the communication within the team responsible for the information. Working in the Project Team, the MASCOT* is the pivot around which the Project Managers, Medical Directors, Study Managers, Statisticians and Data Managers turn (although the pivot seems to do the moving!). That is why a neglected, but vital aspect of our job is the communication with co-workers and clients, and one that we once again explore in this issue.

Finally, in previous issues one of my main themes has to been to encourage members to do what they can for EMWA. This issue shows how successful that can be, as it is the result of one member, Judi Proctor, helping out our editor, Barry Drees, by standing in for an issue. I am not in any position to say whether she has done a better job than Barry, but I can attest that she is as good at nagging for an article as he is!

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** Medical And Scientific Communication Technician. If you have any more pertinent acronyms please let me know!!!*

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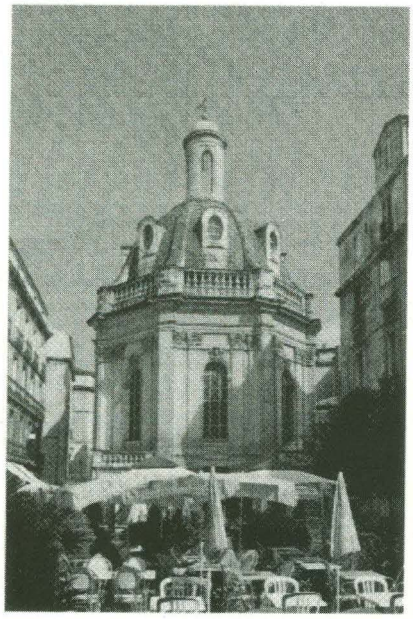

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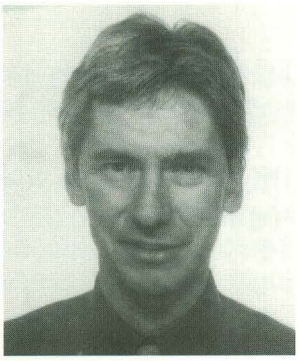

How to Live with Your Regulatory Affairs Department

by Nick Thompson

When I landed my first job in the pharmaceutical industry, in 1990, I'd never heard of regulatory affairs before (or, rather, Regulatory Affairs – it considers itself far too important for mere lower case). It sounded rather fun until I discovered that it had nothing to do with lunchtime assignations with lawyers and everything to do with 21 CFR, Notices of Claimed Investigational Exemption for a New Drug and the ABPI Code of Practice. I went off it rapidly.

The high priesthood

As I became more familiar with the workings of the pharmaceutical industry, I began to realise just how rule-driven its culture is. In some ways, it's less like a science-based industry and more like a rather intolerant religious sect. There is only one path to redemption: that of Good Clinical Practice, and heretics are cast wailing into the darkness. And if it's a religion, then the high priests are up the corridor in Regulatory Affairs. They're the people who know how to read the entrails. Moreover, they are the only ones who can intercede with the unseen gods (FDA and CPMP) when miserable sinners such as we have gone astray. It is not for the uninitiated to question their methods, since we have not passed the hidden door of enlightenment.

Some might question whether it's Regulatory Affairs who are the priesthood. Surely that is the role of the biometricians? I would disagree. The position of a statistician in our religious hierarchy is more that of an early Christian hermit seeking enlightenment through mortification of the flesh.

If it's a religion, then the high priests are up the corridor in Regulatory Affairs.

The heretics

Where do medical writers fit within this rather narrow church? Most of the time I'm afraid we are supplicants seeking guidance, or even penitents seeking forgiveness. Either way we are suspected of heterodoxy, if not outright heresy. The problem is that we're an odd bunch. There are medical writers whose original qualifications were in just about every scientific or literate academic discipline. Besides the obvious professions – medicine, nursing, pharmacology and the like – I know of medical writers who began their careers in journalism, teaching, law, sports medicine and every branch of science[1]. I like to think that this is what makes us such fascinating company[2].

Unfortunately, the interdisciplinary, slightly "arty" professional outlook of medical writing (yes, even regulatory writing) sits rather uneasily with the keepers of the flame. In the words of Dilbert's pointy-haired boss: "This cuts across departmental boundaries. I

[1] Since you ask, I was (mostly) a marine biologist. Go on, ask me how sea urchins mate, although I should warn you that – like Regulatory Affairs – it's not nearly as interesting as it sounds.
[2] To other medical writers, at any rate.

fear it." Chief amongst those who like to have everyone clearly labelled and tied-up with string tend to be Reg Affairs officers. I'm not suggesting, when I say this, that Regulatory Affairs people are any more likely than anyone else to be compartmentalised by nature. Many are wonderful human beings who are kind to children and animals, and have no difficulty whatever in forming warm, loving personal relationships based on mutual respect and understanding. If you ever meet one, let me know.

Slightly less flippantly, how do pharmaceutical companies deal with us (ahem) rugged individualists? I'm probably in as good a position to judge as most people, having had dealings with around 25 different companies during my career. I'm afraid though, that I have to report that every single one had a different model of the medical writing function and of where it fitted in with the rest of the company.

Broadly, there are two principal schools of thought, though with a multitude of variations within each:

1. Report writing is part of the process of scientific enquiry and therefore belongs within the medical or scientific function.
2. Report writing is part of the regulatory process and therefore belongs within the regulatory function.

I honestly don't know which model is better. I have worked in companies in which I was part of the medical department, and others where I was in Regulatory Affairs, and I can only say that either approach can be successful—or a disaster.

What can go wrong

I was only half joking when I described Regulatory Affairs as high priests. Knowledge is, as they say, power. If you control the flow of information within a structure, you control that structure. You are what is called a *gatekeeper*. Because of their quasi-legal position within the company, Reg Affairs officers can – if so inclined – act as gatekeepers. After all, as a medical writer your work is always reviewed by Regulatory Affairs, but do you ever review theirs? I doubt it. There is hence an inevitable tendency for them to think they know their job better than you do, and to presume a position of authority over you.

There are some people in all walks of life who get their kicks out of this sort of thing, and some Reg Affairs officers are no different. You'll know if you've come across the sort of person I've described because they will control the supply of information that comes to you. You can expect to be fed information – whether it's comments on a draft report or feedback from a regulatory body – on a strictly need-to-know basis, sometimes justified on the grounds of "commercial confidentiality" or some such nonsense. You will *not* be told, up front and in full, just what it is you need to do to get your document to conform to regulatory requirements. On the contrary: they like to spring surprises. You may think your draft report is pretty much finalised, until the Reg Affairs person suddenly demands that a section be completely rewritten for reasons too obvious to require explanation (by them).

Those of you lucky enough never to have dealt with the kind of Reg Affairs person I'm describing may find this hard to believe. All I can say is that I have seen all the things I've mentioned. In badly run companies, the relationship between the writing and

regulatory functions can be catastrophically bad – to the point of near-fisticuffs (but I'm not saying which company that was).

How to make it right

What I've described is essentially a turf war. This is a Bad Thing, and in order to have a happy and constructive relationship with your Regulatory Affairs Department, it's essential to avoid engaging in one – but without an unconditional surrender.

It's essential to define – beforehand, as part of your job or project specification – just where the boundary lies between the responsibilities of the medical writer and those of the Reg Affairs officer. The exact position will, of course, vary from company to company and will also depend on whether the medical writing function is part of Reg Affairs or of the clinical or scientific function. In a small business, it can be a difficult line to draw because people have to wear so many different hats: in addition to the in-house medical writer, a variety of other people such as Reg Affairs officers, medics and CRAs (not to mention freelance medical writers) may all contribute to a report. I would suggest that – regardless of who actually puts fingers to keyboard – the medical writing function should have ultimate responsibility for what is written. The Regulatory Affairs function is there to ensure that your document, and the package as a whole, conforms to regulatory requirements. That does *not* make them your bosses.

Your Regulatory Affairs Department can make two other invaluable contributions to the finished report, in addition to its strictly regulatory function:

1. Firstly, at the stage of planning the report, Reg Affairs are the people (together with your statistician) who can tell you whether the report will actually be capable of supporting your submission. Writers new to the business may find this incredible, but a significant minority of clinical trial reports cannot support the company's main efficacy or safety claim, *even if the results are as hoped*, either because of poor study design or sampling technique, or because the report simply doesn't address the key issue.

2. Secondly, Regulatory Affairs are generally the first people – outside the medical writing function and the study clinician – to see the draft report. They are therefore in a position to act as "second author". Because they are familiar with the study they may pick up issues regarding scientific aspects of the study that a QA person (for instance) may not.

Too often, medical writers see Regulatory Affairs as a dead hand. Regulatory Affairs, in turn, may regard medical writers as ill-disciplined and sloppy. We have to remind ourselves that we're in the same team, with the same objective: putting together a package that is capable of convincing the regulatory authorities that our new drug is effective and safe. Talk to your priest.

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Freelance Medical Writing; The Complexities of Client/Freelance Interactions

by Linda Mizen

Well, having agreed to give it a go, i.e. contribute "something" that would be suitable for the theme of this issue of The Write Stuff, I panicked, phoned up Judi, gave up trying to get out of it and decided I had better look willing, so here goes:

Scientific medical writing started to be taken seriously as a career within the pharmaceutical industry over 20 years ago when requirements for the reporting of data to regulatory bodies became considerably more complex. At that time, most of us "at the bench" considered this intrusion to be a "pain in the proverbial", after all, "who were these medical writers, what on earth would they know about OUR research?" was one comment. "Did they really need to be so pedantic?" was another. Well, it was a long time ago!! I soon realised how important it was to have a system to follow and to have well constructed, easy-to-read documentation. I was only too glad to use the services of medical writers.

But what of the other side? – Following are a few of my observations on being a freelance medical writer.

- You are suddenly alone. When working for a company, there's cover for illness, cover if a job doesn't materialise and of course, a regular income.
- Soon after I started, I encountered problems of 1) getting myself known (because of confidentiality agreements, it is virtually impossible for freelancers associated with R&D to advertise their wares), and of 2) branching out into other areas of writing (there are no in-house training schemes which will lead to at least some chance to try out your new skills). Why should clients take you on trust? Time is money. One needs a lifeline here - perhaps "phone a friend"?

"Who were these medical writers, what on earth would they know about OUR research" . . . "Did they really need to be so pedantic?"

- A new client – great! Often a brief communication for reassurance that you and the client are speaking the same language is important – but it doesn't always work out like that even though it may have been agreed during the negotiations. Ever had a client that receives your quick preliminary draft (almost an outline but with an explanatory email) halfway though the time allotted and sits on it? There is that nagging feeling that they are never going to get back to you in time. If only they were just down the corridor, you think. It is at times like these that you almost regret being freelance. Of course they could be out of the country, on holiday or ill or dead or they could have deleted all their emails or they might be too busy editing your brief draft under the misconception that that was it. Shudder!!

Client/Freelance Interactions

- One of the hassles of being a freelancer (which is often not appreciated by "clients") is finding the best way to access published data, reference books and pharmacopoeias without spending a small fortune. It is possible to obtain general information by surfing the net, and by using Medline abstracts, but obtaining in-depth data always requires some financial outlay – ever enquired how much it is to access SCRIP?

- Deadlines – tell me about them!! I'll always regard them as the major complication of being a freelance writer. I can never seem to win. Do the following examples sound familiar? (no they were not members of EMWA)

  - "Our deadline is - - - - - " – "fine by me" says I, as I sign the agreement and plan my workload accordingly. I even refused another job to avoid a clash and a month of seven day weeks of 18 hour days. So what happened? It went very very quiet. The job did come in eventually, but I could have done the original job and I had yet another clash with a later deadline!!! Did I moan, did I create merry he--? No of course not. I said nothing. I nurtured the client, completed the job, resigned myself to the loss of income and vowed never again to refuse anything.

  - "Our clients have no idea of how to approach it - we'll leave it up to your judgement." Flattery gets people everywhere. I made a judgement, agreed a deadline with my client, signed up and, following a comprehensive literature search, I sent the list of required papers off (as requested). Oh dear!! Three months after they were due, all the references eventually arrived and, of course, deadlines had come and gone and were clashing all over the place.

One of the hassles of being a freelancer is finding the best way to access published data, reference/text books and pharmacopoeias without spending a small fortune."

So there we are, I am almost at the end of my allotted space. The title was "the complexities of client/freelance interactions". On either side of the fence, these interactions are complicated if there is lack of communication and no give and take. If in doubt, ask. The speed and convenience of e-mail helps to avoid many communication problems and I have found it is often far better to communicate by email than to use the telephone – voice mail – ugh!! Negotiating skills are important – how far can the writer push the client to wait and how far can the client push the writer to finish early? Not easy - unforeseen circumstances always seem to take over. However, give and take did help me in my deadline predicaments and I was compensated – stressed, but compensated!!!

I have been lucky overall and interactions with clients are mostly synergistic – information is adequate and they are helpful. Problems come and go, well they did before, and deadlines will always be a problem. On the other hand, I would rather have the clashes than no deadlines at all!!

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The Lighter Side . . . Pharmaceutical Definitions

Thanks to e-mail circulation for these!

Head of Drug Development - A temporary Pope; one who is infallible for two years and leaves by the means by which his arrival was announced: a cloud of white smoke.

Global Company - Implementing the American system around the world.

Clinical Trial - An experiment which any fool can design and frequently does.

Sequential Analysis - A means of stopping a trial before it becomes useful.

Marketing Forecast - Twice what you dare not even hope the product might earn, multiplied by three.

US Marketing Forecast - Twice the above.

Marketing Graph - A pictorial representation which uses three dimensions, four colors and five cartoons to show one fact which probably isn't true.

Statistics - A subject which most statisticians find difficult but in which nearly all physicians are experts.

Team Alignment - A process whereby sharks teach gulls to behave like lemmings.

Medical Statistician - One who won't accept that Columbus discovered America because he said he was looking for India in the trial plan.

Equivalence Trials - Proving that apples are pears by comparing their weight.

Regulatory Affairs - The Eskimos of drug development; they have 180 ways of saying "perhaps".

Clinically Relevant Difference - That which will produce 80% power given the supposed standard deviation and the number of patients the medical advisor is prepared to recruit.

Trend towards Significance - An ever present help in times of trouble.

Matrix Management – Two-dimensional confusion.

Patient Listings - So called because they take an age to produce.

Open Study - A means of using prejudice and regression to prove effectiveness.

Quality of Life - A means, it is hoped, of rescuing boring drugs from the rubbish dump of history.

Standard Operating Procedure - A vitally important document whose rate of obsolescence exceeds its rate of implementation.

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The Publication Game: Life is Easy

by Norbert de Clercq

Imagine you are a publication writer or you co-ordinate the writing of publications in a large company which runs studies all over the world. Although the writing as such may not be very different from writing up your own research, there are just a few more things that may need your attention before the fruits of your work finally appear in print or, as is nowadays more and more the case, flashes around the globe in cyberspace. The next tale guides you through some of the potential pitfalls.

Life is easy, ground level: You go home after a long stressful day in the office and on your way home you decide to buy a lottery ticket, why not. The next Saturday you hit the jackpot big time. You take early retirement, buy some land in Tuscany, watch your olives ripen in the summer sun whilst sipping some local Chianti Classico, and cook wild boar in your own olive oil during winter. Life could not be easier.

You take early retirement, buy some land in Tuscany, watch your olives ripen in the summer sun whilst sipping some local Chianti Classico. . .

Life is easy, level 1: Saturday arrives, all you win is 1 euro so you stay on as publication writer. The company does a clinical study with a licensed product but for a new indication. This is a single-centre study and the investigator has already done numerous trials for the company and you have a good working relationship with her. The subsequent publication is straightforward with only a few people as authors. The marketing manager is happy because there will be a publication he can use with minimal implications for his budget. The patent people have no issues. Life is easy.

Life is easy, level 2: An annual event is a particular European conference for which you often have to submit numerous abstracts. The deadline is known to all players, yet for one important study the results are still being analysed. All you can do is wait, negotiate shorter review times with those who have to approve the abstract prior to submission. A week before the deadline, the results come in and in the end all goes well, everybody is happy and, as a bonus, the abstract gets accepted as an oral communication. Life continues to be easy.

Life is easy, level 3: The company is developing a new product for which they have an agreement with another company and the large feasibility study is run together with a third partner who has a well established network in the country the trial is run in. About 15 scientists and clinicians work on this project, as well as the 10 people within the company who are directly involved in the trial. The results are very interesting but somewhat controversial. Pressure from the investigators is mounting to publish but not all players are convinced. This sparks off an intense debate. Marketing finds it too

early to publish. The patent department makes it extremely difficult to write up the exact methodology and requires you to wait three more months.

You start to think about who are the players to field (the authors) and their batting order. In despair, you look for the United Nations phone number to ask advice on how to handle this potential diplomatic incident. But slowly the manuscript evolves into a something everybody accepts, although maybe some not wholeheartedly. After months of reviews and waiting for patent clearance, you can change the file name from

DraftManuscriptVersion17_I_hope_its_final_but_fear_it_is_not.doc

into FinalManuscript.doc. The day comes when you finally get to write that letter "Dear Sir, We would like to submit...". Life is less easy.

Life is easy, doomsday level: The results of a clinical trial are better than expected and turn out to be late breaking material for a conference for which the deadline is next Friday. Quickly, an abstract is drafted, management clears release of the material, patent department has no issues. All seems to be going well. Submission day is looming but the investigator has not got back to you with the final approval. Tension is rising but a nice email can work wonders. At 6 p.m. on submission day (a Friday of course), you finally get the go-ahead. You log on to the internet site to submit the abstract and start filling in the bits and pieces, paste in the text in the appropriate box (after typing numerous HTML codes for italics, Greek symbols, bolds) and hit the submit button two hours before the web submission site closes. Pfffew. But, something in the back of your mind tells you to go check on the web site if everything has gone through. To your horror you discover that under the correct title there is the text of a completely different drug from the competition. In panic you phone the administrator on the other side of the world who tells you to mail him the correct text. You log into your e-mail and suddenly three words blink at you from a blue screen: GENERAL SYSTEM FAILURE. When you hear the answering machine from the hotline you give up. On your way home you decide to buy a lottery ticket...

Submission day is looming but the investigator has not got back to you with the final approval.

Do you recognise some of these situations? They are based on true experiences (except unfortunately the winning lottery ticket) and illustrate many of the challenges a "corporate publications manager" has to deal with. In retrospect, the writing bit of it can be the most relaxing part. There is a lot of diplomacy and negotiating skill required. This can give you, however difficult it is sometimes, a lot of fulfilment and adds a lot of flavour to the job. These aspects of the writer's job, whether he or she is in a corporate or CRO position or is a freelancer is probably often unrecognised but are equally important. Remember Barry's plea for diplomat status for medical writers (TWS, 1999 Vol. 8, No. 4)? If you have similar experiences (or you want to write on this issue from a different position, e.g. the freelancer or CRO or the editor of a journal) and you do want to start a debate, the Editor's address is on the back cover.

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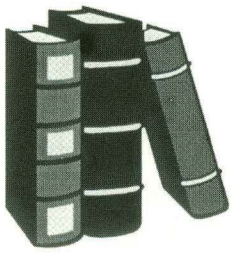

In the Bookstores . . . Publication Ethics in the Spotlight...authors in the hot seat

by Karen Shashok

Anne Hudson Jones and Faith McLellan, eds. Ethical Issues in Biomedical Publication. Baltimore: Johns Hopkins University Press, 2000. ISBN 0 8018 6315 5

This book is for anyone who is concerned about the changing (many would say declining) ethical standards in biomedical publication. It identifies several of the most worrisome issues, analyses them in depth in the light of current views from recognised experts and available research, and offers suggestions on how to deal with the problems.

The depth of detail and balance between opposing views are maintained across chapters with no significant overlap or repetition

The editors deserve the highest praise for assembling a very large amount of information from 14 different experts into a well-organised work that stands as an excellent example of how a multi-authored book should be edited. The depth of detail and balance between opposing views are maintained across chapters with no significant overlap or repetition, and each chapter is well referenced and up to date. Judicious line editing is in evidence on every page of the text, and as a result readability remains consistently high across chapters. The use of the name-date system for the reference call-outs in the text (rather than consecutive numbering) is an apt choice, as it facilitates the reader's task of building associations between ideas and names.

The contents are divided into three main parts. Part One specifies "The Major Ethical Issues" that the book examines (authorship, ethics of peer review, repetitive publication, conflict of interest, and ethics in electronic publishing). In Part Two, "Responses and Remedies: Law, Policy, Education", solutions to the problems are suggested. Part Three, "Commentaries and Epilogue", contains essays that offer personal views from an expert in academic research integrity, a researcher, and a journal editor. The front matter (Foreword, Preface, Acknowledgments and List of Contributors) and back matter (Selected Key Resources—itself divided into 14 sections covering as many topics—and Index) are perfect complements to the main content, and each element adds information that helps the reader get the most out of this lengthy (374-page) tome. No part of the book is gratuitous, and nothing is out of place. Hudson Jones and McLellan definitely get my vote for Editors of the Year.

The use of the name-date system for the reference call-outs in the text is an apt choice, as it facilitates the reader's task of building associations between ideas and names.

It is likely that the book will be most useful to journal editors, policy makers, and researchers investigating current ethical problems in biomedical information transfer. Administrators with responsibilities for developing and implementing policies for ethical publication practices, as well as educators responsible for training in ethical conduct, will find this book indispensable. Scientists, students and legal advisors may not have the time to read and digest the whole book, or may lack the background knowledge needed to critically assess the discussions. However, each of these latter groups will find at least one or two chapters relevant to their daily efforts to become better professionals.

In their Preface, the editors are honest about the scope and coverage of the book, and point out some inevitable limitations, one of which is the predominance of views from the USA. There is very little mention of the problems identified or the solutions attempted in other countries, although the editors' hope is that "The information we provide here will lead to further international discussions and creative solutions to these cross-disciplinary, transnational problems". For members of EMWA who work mainly with authors whose first language is not English, Susan Eastwood's chapter, "Ethical Scientific Reporting and Publication: Training the Trainees", offers intriguing material. Her "curriculum for postdoctoral trainees who want to publish in English-language journals" provides a useful starting point for efforts to develop courses on good publication practice. Moreover, Eastwood is the only contributor to explicitly acknowledge the potential role in writing and publication of "academic editors who teach in one-to-one consultation with physicians and scientists" and "teachers of English as a second language who have specialized in English for scientific or medical purposes".

The voice of the scientific authors themselves, the producers and ultimate consumers of biomedical knowledge, is barely heard.

But there is a perplexing omission from the debate. The voice of the scientific authors themselves, the producers and ultimate consumers of biomedical knowledge, is barely heard. Despite the well-reasoned explanations for why authors appear to be "cheating" more often now than they did before, the overall tone of the book with regard to the infractors tends toward the paternalistic. This is a reflection of the seemingly inevitable "us versus them" mentality and power imbalance that characterise relations between editors and administrators on one hand and authors on the other. The predominant view seems to be that well-intentioned researchers are "forced" by circumstances beyond their control (diminishing sources of funding, increasingly vicious competition, fuzzy professional standards and absence of effective punitive measures) to resort to unethical practices to remain competitive, or simply to survive professionally. An author who makes the effort to read the book as a self-help aid might be forgiven for feeling disenfranchised!

I therefore applaud the editors' goal, as stated in the Preface, to "encourage more members of the research community to become knowledgeable about current standards and to participate in debates about changing them". But if journal editors, academic officials and government policy makers sincerely wish to involve authors in the debate—and perhaps even in decision-making about ethical standards—they will need to make greater efforts to reach out to them.

In the Bookstores

Several contributors observe frankly that there are now serious ethical problems with biomedical publication, and that hard work is needed to keep the problems from spreading. Most of the solutions that this book proposes to forestall further declines in ethical standards revolve around formal institutional guidelines, education in ethics as early as possible in the future biomedical researcher's training, and oversight procedures. But will education and training alone—without back-up from procedures to punish violators—suffice to change researchers' attitudes toward practices that, although considered unethical, nonetheless help them lengthen their list of publications and obtain financial support? And what can be done about misdeeds committed by peer reviewers and editors—the "gatekeepers" of new knowledge? Perhaps some answers to these questions will be offered at the Fourth International Congress on Peer Review in Biomedical Publication, to be held in Barcelona in September 2001.

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The EMWA One-day Conference – A Fledgling's Eye View

Lille, France - 3 November 2000

by Samantha Hurley

This was my first EMWA meeting as a fledgling medical writer, having defected from the world of data management, just three weeks ago. I arrived in Lille late on Thursday afternoon with some of my fellow medical writers from Parexel. This was in good time to attend the early registration get-together in the Café Leffé, right in the heart of Lille. At this thriving café we had the opportunity to chat to other early birds and to sample the local Blonde beer which Lille, with its Belgian influence, is famed for. The one-day conference was held in the Novotel in the city centre and the Novotel bar provided a final venue for nightcaps for the more hardy amongst us!

The conference was well attended. The 66 medical writers present were a good mix of writers from CROs, the pharmaceutical industry and freelance writers. The conference offered a choice of six half-day workshops. Most of the workshops offered the opportunity to gain credit for the EMWA Professional Development Programme (EPDP), which was introduced earlier in the year at the Ninth Annual Meeting in Dublin.

I attended the presentation from Stephen de Looze on "Writing Clinical Study Reports using ICH E3". This course gave a very concise review of what a clinical study report (CSR) is, why it is needed and how to prepare one. Stephen was open to questions throughout the presentation and answered them clearly, as he had an excellent understanding of the subject area. He clarified that the ICH guideline is clearly a guideline, not a template; if it is necessary to add or omit information then this is perfectly acceptable, as long as you can justify why you have done this. Whilst the presentation was based around the ICH E3 guideline, tips were offered from personal experience, which was interesting and will prove helpful in preparing CSRs. The workshop was certainly useful to me as a new medical writer and should provide a helpful reference when I prepare CSRs for clients.

My only problem now is that I will probably be too critical of my own writing style!

The other workshop I attended was "Syntax, Meaning and Word Order" presented by Alistair Reeves. The course objective was to motivate writers to look more critically at their writing, in order to help improve readability and comprehension. The pre-course material provided essential background reading for the workshop.

The course reinforced the grammatical rules and concepts introduced in the pre-course material. The concepts were expressed using specific examples, from medical and pharmaceutical writing. It was well presented and enjoyable. Alistair also pointed out that some grammar is a matter of personal preference, and the author should not be afraid to use these preferences. The workshop was helpful and I picked

up some useful tips. My only problem now is that I will probably be too critical of my own writing style!

Other courses on offer were "Writing Global Clinical Submission Dossiers" presented by Stephen de Looze, "Data Presentation I: Tables & Graphs" and "The Investigator Brochure" presented by Barry Drees and "Medical Writing and Drug Safety" by Mike Matthews. After chatting to colleagues during the excellent 3-course lunch, I was given the impression that these courses were also extremely interesting and well presented.

All the people I spoke with, both delegates and presenters, were extremely friendly.

As a newcomer to EMWA and medical writing, I was made to feel extremely welcome both at the pre-meeting drinks the evening before and at the conference workshops. All the people I spoke with, both delegates and presenters, were extremely friendly. One question I was commonly asked was how I could have worked as a data manager for two and a half years; my answer to this is that I did actually enjoy it! The second question was why medical writing? To answer this question, I was keen to see what actually happened to the data after data management had finished with it and gain a bigger overall picture of the clinical trial process.

The Novotel in Lille offered an excellent venue for a one-day conference. Lille itself is a beautiful City, with many imposing buildings and plenty to offer for a weekend's stay, which is exactly what I decided to do!

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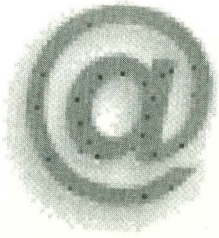
FOOD FOR THOUGHT

"A study of I.B.M. workers found that letters that were handwritten or typed were modified, on average, eight times. Letters produced on a word processor were modified, on average, forty-one times, but with no discernible difference in quality."

THE NEW YORKER, November 27, 2000, page 116.



Networking: the Webscout

by Amanda Bennett

Effective communication is an important aspect of good science; scientists depend on written scientific communications whether they be clinical reports, presentations, brochures, manuscripts, or web pages to keep abreast of their fields and to inform others of their contributions. It doesn't matter how pleased a writer might be to have converted all the right information and data into sentences and paragraphs. What is important is that the reading audience accurately understands what the author had in mind. The sites listed below might provide you with a few ideas on improving your journal writing style.

http://www.oup-usa.org/sc/0841234620/0841234620_1.html

A chapter from the American Chemical Society (ACS) style guide with tips on writing a scientific paper. There are guidelines for text length, preparation of figures and tables, and instructions on how to submit your paper.

http://webster.commnet.edu/apa/apa_index.htm

A guide (presented in a question-and-answer format) for writing research papers based on styles recommended by the American Psychological Association.

http://www.mco.edu/lib/instr/libinsta.html

A site from the Raymon H. Mulford Library which contains an alphabetical list of links to websites that provide instructions to authors for over 3,000 journals in the health and life sciences. All links are to "primary sources", that is to publishers or organisations with editorial responsibilities for the titles.

http://www.freemedicaljournals.com

Definitely check out this site - a relatively new feature that is dedicated to the promotion of free access to medical journals over the Net. Journals that offer free full-text articles are linked; those that only offer abstracts to non-subscribers are not. The resource is impeccably maintained with an intuitive interface and international flavour. Extras such as "Impact Factor" (how many times a journal reference is downloaded) highlight the most popular free online journals.

http://www.hon.ch/HONselect

HONselect is Health On The Net (HON)'s new medical and health browser/search engine. Using Medical Subject Headings (MeSH) hierarchy, HONselect includes four types of information content: web sites (using HON's MedHunt); scientific articles (using PubMed; with or without clinical search filters); healthcare news (using NewsPage), and HON's Media Gallery for medical images (such as it is). HONselect not only integrates the user's search for Internet information types and databases, it also offers a selection of resources available in each database. It is a new concept which gives users the possibility of learning more about a given condition or disease in a scientifically structured fashion.

Networking: the Webscout

It won't take long exploring the Web before you'll get the itch to have a go yourself and create your own Web page. For the novice there are a multitude of sites recommending how to get started. The World Wide Web Consortium (http://www.w3.org/) is the gospel on correct deportment in cyberspace; but this is just plain scary. The following site puts a more human face on the rituals of creating your own home page:

http://www.devry-phx.edu/webresrc/webmstry/mastery.htm

Planning to write your very first web page, need help on appropriate design, or need an HTML editor to help you with your web page programming, then this site has something to offer you.

The appeal of online books is that they are free and convenient as a reference source. The following online statistics texts are excellent; browse or search all of them to find the information you need.

A New View of Statistics (http://www.sportssci.org/resource/stats/index.html). This is an impressive work that clearly explains many statistical concepts, basic and advanced. It explains things for biologists, with almost no maths. Although the examples are from sports physiology, the clear illustrated explanations should be of help to us all.

HyperStat online (http://davidmlane.com/hyperstat) is a concise statistics textbook. Each chapter also contains extensive links to other resources.

StatSoft's Electronic Statistics Textbook (http://www.statsoft.com/textbook/stathome.html). Statistics is presented as a bunch of nuggets. This makes the book impossible to read as a text, but quite useful as a reference.

Although English may seem to hold sway as the international business language it would be wrong to assume that other languages are not fighting for a presence on the Web. These links show that the Internet may turn out to be a lifeline for the preservation of a multilingual society:

http://www.independent.co.uk/news/Digital/Update/2000-10/web011000.shtml

http://www.nua.ie/nkb/index.cgi?f=VA&art_type=NKN&art_id=513

If you should come across an interesting or useful website that you think fellow writers would enjoy, please send the URL of the site to Bennetta@iconuk.com. Also, let me know if there is a particular area or topic that you would like to see included.

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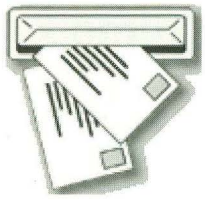

Vital Signs:
Correspondence from our readers

Dear TWS,
In a recent TWS issue (Article descriptions, Vol. 9, No. 3, page 25), there was a mention of questioning evolution in Kansas. What exactly were you referring to?

Ah, a sorry story indeed, but perhaps one with a bit of a happy end.
Many EMWA members may be unaware that in a large part of the central part of the USA, fundamentalist Christians who are opposed to the evolutionary explanation of human origins for religious reasons (known as creationists for the explanation they prefer) have long battled to ban the teaching of evolution in science classes. Last year, the Kansas Board of Education decided to remove knowledge of evolution from the school standards of the state of Kansas. This reflects similar attempts in other states such as New Mexico, Nebraska, and Alabama to permit the teaching of evolution in science classes only if it is taught alongside the "scientific theory" of creationism. This so-called scientific theory, to those who haven't experienced it yet, includes the usual biblical "earth created in seven days" stuff together with some more recent additions like dinosaurs on Noah's ark, Neanderthals hunting Brontosaurids, etc. Apparently, the Board, which is elected by popular vote, managed to end up with a majority of creationists, and thereafter voted to remove evolution. The storm of controversy this move generated and the ensuing bad publicity about the educational system in Kansas, however, resulted in the electoral loss of several of the creationists from the school board this year and their replacement with educators supporting the teaching of evolution. One can only hope that sanity will therefore be restored to America's Midwest.

Barry Drees

NEWS FROM OZ:
AuMWA inaugurates APDP

Imitation is surely the sincerest form of flattery and particularly when one's own way is chosen from among other choices available.

The Australian Medical Writers Association recently launched their Australasian Professional Development Program with 2 workshops at their annual conference: *Evaluating Clinical Journal Articles*. We have been told that they were at least in part inspired by EMWA's EPDP (note the similarity in names). Here's sending our best wishes and hope for continued success to our colleagues in Oz.

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
Mar 27-28	**Communication Skills for Pharma Professionals** Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879	London, UK
Apr 24-25 **[EMWA]**	**Successful Medical Writing** FORUM Institut für Management GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500 500; Fax: (+49) 6221 500 505	Dusseldorf, Germany
May 1-2	**Presentation Skills for Pharmaceutical Professionals** Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879	London, UK
May 2-3 **[EMWA]**	**Effective Medical Writing** Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879	London, UK
May 8-9	**Effective Writing for Biomedical Professionals** University of Oxford Dept. for Continuing Education CPD Centre, Suite 1 Littlegate House, 16/17 St. Ebbes Street, Oxford, OX1 1PT, UK Tel: (+44) 1865 286946; Fax (+44) 1865 286934 Chris.bamford@conted.ox.ac.uk	Oxford, UK
May 10-11	**Presenting in Biomedicine, Science and Technology** University of Oxford Dept. for Continuing Education CPD Centre, Suite 1 Littlegate House, 16/17 St. Ebbes Street, Oxford, OX1 1PT, UK Tel: (+44) 1865 286946; Fax (+44) 1865 286934 Chris.bamford@conted.ox.ac.uk	Oxford, UK
May 29	**Projektmanagement klinischer Prüfung (German)** Kendle Munich Postfach 81 04 09 D-81904 Munich, Germany Tel: (+49) 8999 3913 160; e-Mail: info.muc@kendle.com	Munich, Germany
Jun 25	**Integrierte Studienberichte nach ICH (German)** Kendle Munich Postfach 81 04 09 D-81904 Munich, Germany Tel: (+49) 8999 3913 160; e-Mail: info.muc@kendle.com	Munich, Germany

Coming Next Issue . . . (Spring 2001)

The Common Technical Document

Stephen de Looze

Is it a bird? Is it a plane? No, it isn't even Superman. Here it comes, the object of more speculation than the last version of Windows or the Millennium Dome – the dreaded CTD or Common Technical Document. Billed as the future of international submissions, the idea is to stop having to submit completely different dossiers in the European Union, the US, and Japan. Find out all about it here.

What the Regulatory Authorities Want to See

Eva Pike

Here is a unique opportunity to find out from the source. EMWA member Eva Pike has worked for the Norweigen Medicinal Control Authority and regales us with tales from dossiers she's seen. Now we can find out from a writer what the reviewer really likes to see and, even more important, what they hate to see. This is a must-read for all of us who write Clinical Expert Reports and prepare European submission dossiers. Besides commenting on the Clinical Expert Report, she will comment on documentation submitted for evaluation of clinical trials, including the Investigator Brochure, as well as the SmPC and PIL.

Questions and Answers: Size Matters

Chris Priestley

A frequently asked question is how to handle the often huge computer files that result from writing Clinical Study Reports, Investigator Brochures, and other documents of modern pharmaceutical industry writing. Here we'll explore some of the theory and practice of how an experienced medical writer deals with these behemoths and that, as the advertising campaign for the movie Godzilla stated, "Size Matters".

The Best and the Worst of EMWA

Barry Drees

Here it is – warts and all. The first results from the EMWA Questionnaire 2000, where members said what they liked most and least about EMWA as an organisation. We, the editorial board of TWS, promise to hold nothing back!

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