



From the editor's desk:

Perspectives

by *Elise Langdon-Neuner*

'Perspective' is an enormous word. Perspectives stretch back as far as we can see, allow us to view a thing in one of many possible ways and give us an understanding of how important one thing is in relation to others. Sometimes there would seem to be only one perspective—the one that is most familiar to us, and which corresponds to our own opinion—but there are always more viewpoints if we look at things 'in perspective'.

An extreme example of this is provided by the drug thalidomide, which caused the tragedy that more than anything else was responsible for the escalation of regulatory writing, the career mainstay of the majority of medical writers. This year marks the 50th anniversary of the grant of a licence to sell the drug in the UK. In 1961, three years after its introduction, William McBride, an Australian doctor, wrote a letter to *The Lancet* reporting a link between babies born with deformities in his hospital and mothers who had taken thalidomide during their pregnancy to cure morning sickness. Thalidomide was withdrawn from the market later that year. An estimated 10,000 babies worldwide were born with deformities caused by thalidomide. It was abundantly clear that, to avoid future catastrophes of the same kind, tighter controls would be needed before a drug could be released onto the market. Legislation that was under consideration by the US Congress at the time gained urgency, and what came to be known as the Kefauver-Harris Drug Amendments Act was passed unanimously in 1962. This act considerably tightened provisions relating to marketing drugs and testing them in clinical trials, and it increased the amount of documentation that needed to be written and submitted to the FDA.

However, there is another side to thalidomide. There are reports that it is an effective treatment for various disorders, including leprosy, multiple myeloma, HIV/AIDS and ulcers. The manufacturers have provided the medication free for such conditions, but even so the World Health Organization advises that it should not be used because the risks are too high. Despite attempts to impose strict precautions against the use of the drug by pregnant women and to persuade men to use condoms because thalidomide is present in semen, three children are known to have been born with thalidomide-related deformities in Brazil over the last three years and apparently there have been other such cases in Mexico, India and Africa. On the other hand, people have died because they have not been able to obtain the drug [1].

This is paralleled by the more recent cases of the analgesics Vioxx and Co Proxamol, which in post-marketing research

had been shown to entail a small but detectable risk of heart failure and death. Many chronic pain patients were distressed about the withdrawal of these drugs from the market, and the view was often heard that the risk was acceptable against the alternative of perpetual, severe pain.

Another perspective when considering drug development is to contrast our concerns about drugs today with the situation in England before drugs were developed. Take the time of Shakespeare's birth in 1564, for example. The population was diminishing dramatically; it had fallen by 6% in the previous decade. This was the result of numerous premature deaths, of which the plague was only one cause among many, which included tuberculosis, leprosy, measles, rickets, scurvy, smallpox, cholera, dysentery and a mass of fevers that have now slipped from our vocabulary, such as the 'English sweat', which could hit people in the morning and kill them by the evening of the same day. Today, immunity has been developed to many of these diseases. Effective treatments have been evolved using drugs to replace such mediaeval practices as bleeding with leeches. Today we face the problem of an ageing population and a diminishing workforce—at least these are the concerns in Western society because we tend to forget that there are still places in the world where people continue to battle with mediaeval diseases. Meanwhile pharmaceutical companies are seeking to develop treatments for a new generation of Western disorders such as Alzheimer's disease. And developing cures, once seen as a humanitarian enterprise, is now controlled by commercial whims.

Time, place and circumstances change perspectives. A number of articles in this issue show how current changes are altering the perspectives of regulatory writers. Art Gertel and Nancy J Stark trace the late increase in the regulation of devices. In the process, more work has been created for regulatory writers, perhaps adding to the headaches that Linda Donnini describes in her article on adverse events—but tips are also given for curing the headaches. The obligation for the pharmaceutical industry to provide 'adverse reaction' reports was, in fact, brought in with the 1962 amendments mentioned above. Then there are the new provisions for registration of clinical trial results enacted by the Food and Drug Administration Amendments Act 2007, which will come into force in September this year. Kathy Thomas and Claudia Tesch give a detailed account in their article of what this will mean for regulatory writers. Examples of how things can be seen from different sides are to be found in Adam

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Jacobs' article in *Journal Watch* in which he outlines the extremely polarised views held by opponents and proponents of ghost-writing. The subject has come to the fore again with the publication of a study by Ross et al., which is the centre point of Adam's article. I also had the opportunity to see a different side to decision-making in manuscript publication, that of the editors at the *bmj*, and have reported my experiences.

But this issue of *TWS* does not only take a perspective on continuing developments in regulatory writing and different viewpoints relating to these developments; it also features two articles that show how views about the most widely used language of science—English—can change depending on your background and location. Joy Burrough describes how her attitude towards English changed when, after spending many years as an author's editor in Holland, she returned to the UK, her native English-speaking country. Kathy Nelson describes a similar experience, but in her case the return migration was from Austria to the USA.

Finally, an article by Richard Clark looks at PowerPoint, often seen as the equivalent of a wonder drug in communication. Could there be another view—that it in fact hinders communication?

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Reference:

1. Murphy C. Thalidomide: a curse or blessing? BBC News. Available at: <http://news.bbc.co.uk/2/hi/health/7326588.stm>

Perils of the slash

Study objective: To show superiority in terms of overall survival time in subjects receiving chemotherapy A/chemotherapy B plus MabX compared with subjects receiving chemotherapy A/chemotherapy B alone in the first-line treatment of Stage IIIb NSCLC.

It would have been so easy for the author here to have written:

To show superiority in subjects receiving MabX combined with chemotherapy A and chemotherapy B compared with subjects receiving chemotherapy A and chemotherapy B alone in ...

It would then have been clear that subjects were to receive EITHER MabX plus chemotherapy A AND B OR chemotherapy A AND B and not MabX plus chemotherapy A OR B OR chemotherapy A OR B.

See how complicated the slash can make things?

Alistair Reeves

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Call for Applicants for EMWA Professional Development Committee

A vacancy has arise on the EMWA Professional Development Committee (EPDC). I would like to invite applications from EMWA members for this position.

As an EPDC member, you will be involved in all aspects of developing and maintaining the EMWA Professional Development Programme (EPDP), ensuring quality of the workshops in the programme and supporting the development of new workshops through mentoring of new workshop leaders. By serving on the EPDC you can help shape the future of this vital programme at the heart of EMWA's activities. Furthermore, as in the past, future candidates for the post of EMWA Education Officer will be drawn from the EPDC members.

If you would like to apply for this position, or would like to know more about it, please contact me at stephen.delooze@accovion.com, or any EPDC member (details on the EMWA website) who will be happy to provide further details.

Stephen de Looze

Education Officer

Call for articles for the September issue of TWS Guest editor: Alistair Reeves

The Sword of Damocles in the shape of time with a very sharp point hangs close to the head of every writer, editor and manager in our business—whether freelance or employed. The theme of the September 2008 issue of *TWS* is 'Who manages your time?' The focus will be on time management of medical writing from the point of view of writers and managers.

This is a perennial discussion point at conferences ('How many days do you allot for a clinical study report?' or 'Whatever I do, I always seem to end up working at the weekend'), so I expect that many of you have something to say on this topic. Any contribution relevant to time management—however small or large—will be welcome, and should reach me by 4 August 2008.

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