

This is the unedited version of a column which appeared in *Australian Doctor* in 2002. The published version may have had minor changes.

### **Media Bites: The inside story on guidelines**

Sleepless nights, strong passions and hot words. These are hardly the sort of images usually associated with clinical practice guidelines, consensus statements and other such drily scientific publications.

Which is a shame. The deliberately bland language and format of many such tomes does no-one any favours, and not just because it makes for dull reading.

It often results in a misleading view of the process involved, and reinforces the myth that science is purely objective and free of human frailties and foibles.

That's why a recent article in *The Medical Journal of Australia* makes fascinating reading. The journal's editor, Martin van der Weyden, believes it is the first time such a publication has reached the medical literature.

The article, "The road to consensus: considerations for the safe use and prescribing of COX-2-specific inhibitors", provides an inside view on the process and deliberations which lead to an accompanying position statement on the drugs.

The group was convened by clinicians on the manufacturers' advisory boards who were concerned the drugs had come to be perceived as "NSAIDs without side effects", and that there was a need for greater caution in their use.

They invited other doctors, health professionals and representatives from Pharmacia/Pfizer and Merck, Sharp & Dohm to join the group. Some people declined as they felt the companies shouldn't have been included.

The account of the subsequent discussions highlights the frictions, biases, and divergent views of those involved.

One of the members, Ric Day, professor of clinical pharmacology at St Vincent's Hospital, reckons he processed at least 1,000 emails during an endless series of drafts and re-drafts of the position statement.

"It was hard yakka, much harder than any of us predicted," he says.

Day, who is also a member of both companies' advisory boards, and is involved with the National Prescribing Service, says he found the process personally confronting at times because it made him consider his biases.

He was an investigator on one of the COX-2 studies. "I feel it's a fantastic study, the data's really good, and the process was great, so I find it a bit challenging when people have all sorts of criticisms of it," he says.

Unusually, the position statement also listed eight of the 31-member group who did not sign off on the document, and their reasons for this.

Rachelle Buchbinder, associate professor in the Department of Epidemiology and Preventive Medicine at Monash University, believed there was insufficient evidence to support the statement on gastrointestinal benefits, but agonised over her decision not to sign off on the document.

"I couldn't sleep," she says.

But even though she disagreed with the document's final wording and believed the companies shouldn't have been involved and that there should have been wider professional representation, she felt the process was worthwhile.

John Edmonds, professor of rheumatology at the University of NSW and chair of the Celecoxib advisory board, says the report usefully highlights that there can be different interpretations of even high quality evidence, as well as different views about how such interpretation should be worded.

"It's much easier to reach consensus if you have a small group of people who think like you do," he says. "I personally think it's very healthy to

show that with these things there is diversity of opinion and diversity of approach. It makes people think.”

Van der Weyden wrote that the report reveals guideline development as a “human affair with all its attendant nuances, complexities and biases”.

“Its central message is that practice guideline development is not a black-and-white affair, and that the time has come for open disclosure of conflicts of interest and the degrees of consensus or dissent,” he said.

“As guidelines have a powerful influence on clinical practice, doctors and patients deserve nothing less than complete openness and transparency.”

You mightn’t agree with how the group went about its work. Perhaps the companies shouldn’t have been involved. Perhaps there should have been fewer advisory board members and more outsiders.

But it’s hard to fault the group on their energy or efforts to provide transparency. They were not paid for all the hard work and hair-pulling that was so evidently involved.

They hope their statement will promote wiser prescribing. Perhaps it will also encourage greater transparency in other such publications. It may even help to make them an interesting read.