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A drug company sues an ISDB member bulletin, and loses...

MSD recently sued an independent drug bulletin over an article criticising the clinical evaluation of rofecoxib (Vioxx®). In a resounding victory for independent information sources, the judge ruled against MSD.

In 2002, *Butlletí Groc*, the bulletin of the Catalan Pharmacology Institute—a World Health Organisation (WHO) collaborating centre and member of the International Society of Drug Bulletins (ISDB) (a) — published an article entitled “The so called advantages of celecoxib and rofecoxib: scientific fraud” (1).

The article highlighted methodological flaws in the CLASS and VIGOR trials, the results of which were used to promote these coxibs. In particular, it summarised comments published in the *Lancet* on the VIGOR trial and on the cardiovascular adverse effects of rofecoxib (2). The article raised the possibility that a selection bias had been intentionally introduced in the VIGOR trial, minimising cardiovascular adverse effects. It also mentioned that the US Food and Drug Administration (FDA) had asked Merck Sharp & Dohme (MSD), the company that markets rofecoxib, to modify its promotional material on rofecoxib, which tended to underestimate these cardiovascular risks (1).

Court case. The Spanish arm of MSD was unhappy with the title and contents of this demystifying article, which questioned the position of rofecoxib relative to other nonsteroidal anti-inflammatory drugs and denied the company's scientific credibility. MSD demanded that *Butlletí Groc* retract the article and publish a text prepared by the company. When the editor refused, MSD took *Butlletí Groc* to court. The hearing took place in Madrid, in January 2004.

MSD lost its lawsuit, and chose not to appeal. The com-

pany was also made to pay *Butlletí Groc's* legal fees. The judge rejected MSD's claims and upheld the view that the facts reported in the article were based on articles published in the *British Medical Journal* and the *Lancet* (3).

It is significant that Pfizer, the company that markets celecoxib, another drug criticised in the *Butlletí Groc* article, chose to remain silent (b)(4,5).

International solidarity. More than 700 health professionals in Spain and about 30 other countries signed petitions in support of *Butlletí Groc*. One noteworthy signatory was Michael Rawlins, president of the British National Institute for Clinical Excellence (NICE). The co-ordinator of the WHO action programme on essential drugs, German Velasquez, declared that this attack against the information bulletin of a WHO collaborating centre represented an indirect attack on WHO itself (4).

ISDB member bulletins, including *Prescrire*, also came out in support of their Spanish colleagues (c). The ISDB president and editor-in-chief of *Drugs & Therapeutics Bulletin*, pointed out that this was not the first time a pharmaceutical multinational tried to intimidate an independent publication (6). He also stated that in 2001 the Spanish medicines agency had warned health care professionals about the cardiovascular risks of rofecoxib, and that this information was subsequently added to coxib summaries of product characteristics (SPCs) and to patient information leaflets. And he recalled that the European Medicines

Evaluation Agency had since asked MSD to provide their entire evaluation file on rofecoxib.

Graham Dukes, editor-in-chief of the *International Journal of Risk and Safety in Medicine*, considered that the *Butlletí Groc* article was entirely in keeping with the available data. He also noted that, in terms of efficacy, safety and price, these drugs represent a step in the wrong direction (7).

A distasteful but instructive court case. Drug companies must realise that it is not in their long-term interests to attempt to suppress criticism by taking legal action: sooner or later this conduct, which is unworthy of proper scientific debate, undermines their image.

The international journals that publish clinical trial reports must assume their responsibility. Their credibility depends on the demands they place on authors, and their methodological and editorial rigour, notably with regard to conflicts of interest. And as the share of medical research funded by the private sector increases, these publications must redouble their vigilance.

Once again, this case illustrates the dangers of leaving information on drugs solely in the hands of private companies with obvious vested interests. National and international medicines agencies have a major role to play, as it is they who decide the level of evidence required for marketing authorisation. They must not only be fair, but must also be seen to be fair, by ensuring a maximum of transparency for the public and health care professionals.

The Madrid judgement is a victory for independent information sources, and especially ISDB member publications. Independence is not an end in itself, but rather a necessary condition for identifying true therapeutic advance, unhindered by commercial interests.

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a- The International Society of Drug Bulletins (ISDB) is an international network of more than 80 drug information bulletins independent of the pharmaceutical industry and intended for physicians, pharmacists or patients. La revue *Prescrire* is a founding member of ISDB. For further information see the ISDB website, at <http://www.isdbweb.org>

b- For a brief history of a proven case of manipulation (in the CLASS trial), see: “Celecoxib and the CLASS trial” *Prescrire Int* 2002; 11 (62): 190-191.

c- Another Spanish-language ISDB member bulletin - *Boletín AIS-COIME*, published in Nicaragua - came under the same pressure as *Butlletí Groc* (ref. 8).

Selected references from *Prescrire's* document watch.

- 1- “Las supuestas ventajas de celecoxib y rofecoxib: fraude científico” *Butlletí Groc* 2002; 15 (4): 13-15.
- 2- Boers M “Seminal pharmaceutical trials: maintaining masking in analysis” *Lancet* 2002; 360: 100-101.
- 3- Primera Instancia N.37 Madrid “Sentencia 00009/2004. Procedimiento: Juicio verbal 965/2002 JDO”: 22 January 2004: 3 pages.
- 4- Gibson L “Drug company sues Spanish bulletin over fraud claim” *BMJ* 2004; 328: 188.
- 5- Bosch X “Spanish editor sued over rofecoxib allegations” *Lancet* 2004; 363: 298.
- 6- Collier J “To whom it may concern” Letter to Professor Joan-Ramon Laporte, 3 December 2003: 2 pages.
- 7- Dukes G “Lettre au Pr Joan-Ramon Laporte” 12 January 2004: 1 page.
- 8- Montero J “Lettre au Dr Marchand B, coordinador AIS Nicaragua” Merck Sharp & Dohme, Central America, 10 April 2003.