

Scientist, drug firm in court

Spanish lawsuit over a report in a newsletter raises concerns about freedom of scientific debate | [By Xavier Bosch](#)

Questions of scientific freedom of expression have been raised in Spain this month at the beginning of a court case brought by drug firm [Merck Sharp and Dohme](#) (MSD) against Juan Ramón Laporte, a renowned Spanish pharmacologist at the [Autonomous University of Barcelona](#).

The case, which began on January 16 in Madrid, relates to an article in which the scientist commented on irregularities surrounding clinical trials of COX-2 inhibitors.

COX-2 inhibitors are antiinflammatory agents potentially devoid of the upper gastrointestinal effects of standard drugs. The article in question was published in the July–September 2002 issue of *Yellow Bulletin*, an independent pharmacovigilance newsletter addressed to Spanish and Latin American physicians and pharmacists.

Laporte is the editor-in-chief of this publication, of which some 35,000 copies in Catalan and Spanish are distributed 5 times a year. In his article, Laporte—who chaired the World Health Organization Expert Committee on Essential Medicines in 2002 and 2003—criticized a pivotal study of the COX-2 inhibitor rofecoxib for allegedly minimizing cardiovascular side effects.

The VIGOR clinical trial, published in the [New England Journal of Medicine](#), compared the upper gastrointestinal toxicity of rofecoxib and the classic nonsteroidal antiinflammatory agent naproxen in patients

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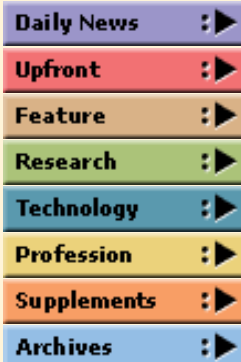
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with rheumatoid arthritis.

Although the study found an apparently unexpected higher incidence of myocardial infarction among rofecoxib-treated patients than among those treated with naproxen, in his *Yellow Bulletin* article, Laporte cited previously published reports to suggest that the company was already aware of this side effect and that it might have introduced a selection bias in the trial, leading to an underestimation of rofecoxib cardiovascular toxicity.

In fact, editorials from a Spanish version of the [Lancet](#) and the [British Medical Journal](#) were delivered to the judge by Laporte's defense as evidence.

In his article, the pharmacologist recalled that the US Food and Drug Administration (FDA) had warned the owner of rofecoxib against promotional activities in which the cardiovascular adverse events were minimized. He also wrote that “the evaluation and financing of [rofecoxib] were based on false information released to the European Medicines Evaluation Agency, contrary to the [information] available to the FDA.”

According to documents presented to the court, MSD decided to sue him and the [Catalan Institute of Pharmacology](#)—the publisher of the bulletin—last October, because Laporte's opinions allegedly damaged the company's name. However, Laporte never mentioned the name of the company in his paper, and this was the main argument used by his lawyer at the trial.

The document makes it clear the company was upset by Laporte's statements, such as “manipulation of scientific results to the detriment patients' health” “serious ethical transgressions in the design, analysis and publication of the results,” and “scientific fraud.”

MSD denies that it delivered any information to the European Medicines Evaluation Agency and says that rofecoxib was in fact assessed by the various European national drug agencies.

According to the MSD documents, the company wants a rectification to be published both in the *Yellow Bulletin* and the Catalan Institute's Web

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site stating, among other things, that “the protocol of the VIGOR multicenter trial was approved by international ethics committees” and that “the information delivered to the various drug evaluation agencies was rigorously true, methodologically impeccable and in no case does it contradict the information released to the FDA.”

Laporte told *The Scientist* he has received hundreds of support letters. A statement by MNG Dukes, a pharmacologist at the Unit for Drug Policy Studies at the University of Oslo, who is the editor of both *The International Journal of Risk and Safety in Medicine* and the popular book *Meyler's Side Effects of Drugs*, reads “[my] conclusion is that your publication was entirely accurate and that there is no reason to withdraw or replace it.”

Joe Collier, president of the [International Society of Drug Bulletins](#)—to which the *Yellow Bulletin* belongs—says in an E-mail sent to Laporte that “following the revelation of these irregularities, on July 2002, MSD was asked by the European Medicines Evaluation Agency (EMA), as well as by other regulatory bodies, to resubmit the complete results of the clinical trials and other studies on rofecoxib for reassessment.”

In another statement backing Laporte, Miquel Bruguera, president of the Official Medical College of Barcelona, says “Discrepancies between drug companies and clinicians must be debated in scientific forums such as medical publications, but not in courts.”

Irene Andrés, director of the MSD legal advice office, told *The Scientist*: “We believe in freedom of expression, and the only thing we ask is the right to rectification, which is a constitutional right.”

She also says that the lawsuit comes after several attempts to reach an agreement without need to go to courts, but that Laporte has never wanted to make a rectification himself.

During the trial, MSD lawyer Francisco Javier Carrión argued, “The most grave affront that a serious and rigorous pharmaceutical company can receive is to say that it neglects the health of patients.”

Laporte told the judge, “We were aware that these were very serious facts. The toxicity studies carried out by the [company] needed an

independent evaluation. We have scientifically confirmed the risk. Moreover, we didn't mention the [generic] name of the drug or the name of its manufacturer.”

Laporte told *The Scientist* that he felt a lawsuit brought by a giant like MSD against a small independent publication like the *Yellow Bulletin* raises serious concerns.

“Scientists have the right to publish and express what they think about studies,” he said, adding that “this is the key point—at stake is the possibility of criticizing a company, however big it is.”

The verdict of the trial will be known by the end of this month.

Links for this article

Merck Sharp and Dohme

<http://www.msd-nrc.co.uk/>

Autonomous University of Barcelona

<http://www.uab.es/english/default.htm>

C. Bombardier et al., “Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. VIGOR Study Group,” *New England Journal of Medicine*, 343: 1520-1528, November 23, 2000.

[\[PubMed Abstract\]](#)

M. Boers, “Seminal pharmaceutical trials: maintaining masking in analysis,” *Lancet*, 360: 100-101, July 13, 2002.

[\[PubMed Abstract\]](#)

P. Juni et al, “Are selective COX 2 inhibitors superior to traditional non steroidal anti-inflammatory drugs?” *British Medical Journal*, 324: 1287-1288, June 1, 2002. Erratum in: *British Medical Journal*, 324: 1538, June 29, 2002.

[\[PubMed Abstract\]](#)

Catalan Institute of Pharmacology

<http://www.icf.uab.es/>

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