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Merck Says It Regrets Strong-Arming Italian Researcher

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[Merck \(/companies/merck/\)](/companies/merck/) says that it “regrets” using legal threats to push a leading Italian researcher to muffle his public critiques of one of the company’s cholesterol drugs.

Merck spokesman Steve Cragle writes:

“ Merck is committed to the open and transparent exchange of scientific information. We believe this exchange should take place in medical meetings and peer-reviewed scientific publications. We believe this to be an isolated incident in Italy and regret how it was handled by our company. Merck has not taken any legal action in connection with this situation.

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In a phone conversation, Cragle confirmed that the physician could post his arguments about the drug, ezetimibe, on his web site again without fear of legal reprisal coming from Merck. “We wouldn’t take any action against him,” Cragle said. Would the company take any internal action to keep this situation from repeating itself? “We’re certainly reviewing the situation,” Cragle said.

As first reported by the [British Medical Journal](http://www.bmj.com/content/349/bmj.g4441) (<http://www.bmj.com/content/349/bmj.g4441>), Alberto Donzelli, the director of education, appropriateness, and evidence-based medicine at the public health authority of Milan, had posted an analysis of ezetimibe’s effectiveness on the web that said that the drug should only rarely be used. He’d also been telling other doctors that he didn’t think they should prescribe the drug.

Ezetimibe, sold in the U.S. as Zetia and as Vytorin, which combines it with another cholesterol-lowering drug, is sold under the names Ezetrol and Inegy in much of the world. In both forms, the drug generated \$5.6 billion in sales for Merck globally last year.

Executives at Merck, [Sharp \(/companies/sharp/\)](/companies/sharp/), and Dohme in Italy sent two cease-and-desist letters to Donzelli’s superiors, who initially supported him. [According to the BMJ \(http://www.bmj.com/content/349/bmj.g4441\)](http://www.bmj.com/content/349/bmj.g4441):

“ A letter telling Donzelli to “cease and desist” was sent in February by MSD’s medical director, Patrizia Nardini, and was cosigned by the company’s director of legal affairs. They accused Donzelli of serious misconduct and a breach of medical ethics and threatened to sue him and Milan Healthcare for as much as €1.3m (£1m; \$1.78m). The letter was addressed to Donzelli, with a copy sent to Milan Healthcare’s director general and to the president of the Order of Physicians of Milan (the doctors’ regulatory body), Roberto Carlo Rossi.

Rossi replied in April, declaring that the medical commission had analysed and discussed the issue in depth and concluding that there was no reason to object on ethical grounds to Donzelli’s behaviour. Donzelli also replied to each point raised in the letter. “I exercised my right to tell the general practitioners what emerged from our in-depth analyses of the published literature, on a peer to peer basis,” he told *The BMJ*.

Nevertheless, in late May the company sent a second “cease and desist” letter to Donzelli, listing several decisions by international and Italian regulatory authorities and international guidelines that favoured ezetimibe. The letter also lamented the impossibility of establishing “a fruitful scientific dialogue” with Donzelli.



Merck then reiterated that it intended to take legal action, and Donzelli removed his ezetimibe analysis from his website. Patrizia Nardini, the medical affairs director of the Italian unit, defended this move to the *BMJ*. “We are in favor of balanced information, and we decided to write those letters because we didn’t see a willingness to evaluate all the information in a balanced way.” she told the journal. (<http://www.bmj.com/content/349/bmj.g4441>)

Ezetimibe has been a controversial drug since 2007, when it was revealed (<http://www.forbes.com/forbes/2008/0211/088.html>) that Merck and then-partner Schering-Plough, with whom Merck would later merge, had been avoiding analyzing the data of a study testing the medicine’s ability to keep arteries from thickening. That study showed no benefit for the drug, and led some doctors to publicly question whether ezetimibe was useful for preventing heart attacks and strokes when used on top of well-proven statin medicines like Crestor, Lipitor, and Merck’s own Zocor. Results of a large study intended to measure Vytorin’s heart-attack-preventing-potency are expected late this year.

Donzelli did not respond to a request for comment.

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