Drug company secretly briefed medical societies on HRT

Ray Moynihan *Washington, DC*

Pharmaceutical giant Wyeth has admitted that it secretly briefed a number of medical societies about the results of a study into hormone replacement therapy (HRT) and dementia before they were published this week.

On Wednesday *JAMA* published the study, funded by Wyeth, which shows that the company's combined oestrogen and progestogen pill doubled the risk of dementia among elderly women from about 1% to 2% over five years. The latest data on dementia come after findings last year which showed that long term use of the drug slightly increases the risks of breast cancer, heart attacks, and strokes in healthy women aged over 50 years (*JAMA* 2002;288:321-33).

The company's briefings of outside bodies has caused grave concern in the research community, including among the researchers who conducted the study, although Wyeth is standing by its actions.

"Under a written confidentiality agreement Wyeth medical personnel shared a limited and balanced summary report of the data with a senior medical expert at certain critical medical societies," said Dr Victoria Kusiak, the company's North American medical director. "These discussions were meant to allow those individuals to respond knowledgeably to their constituents, at the time the [study] data became public."

Normally, strictly embargoed copies of peer reviewed journal articles are distributed to news organisations several days before publication to help in the preparation of stories. However, Wyeth's briefings to medical societies happened long before embargoed copies of the article were distributed.

With top quality randomised controlled trials showing that its HRT causes harm, Wyeth has been forced to concede that its product increases the long term

risks of blood clots, strokes, heart attacks, and breast cancer, while fighting hard to maintain mass markets for short term relief of symptoms.

This week the company's

public relations strategy has been to play down the significance of the findings on dementia for younger users, stressing that women in the latest study were over 65 years old. □

Schering uses German medical association to promote HRT

Klaus Koch *Brühl, Germany*

Several thousand German gynaecologists have been the target of a campaign promoting postmenopausal hormone replacement therapy (HRT) which claimed that the negative findings of a major US study were of "highly limited relevance" to the German population. The message was, in part, disguised as the official statements of a large professional organisation for gynaecologists, the Berufsverband der Frauenärzte.

The campaign came after the sudden ending of part of the Women's Health Initiative's

study into HRT in the United States in July 2002 (*BMJ* 2002;325:61). The study, involving 16 600 women, showed a small increased risk of breast cancer, cardiovascular disease, blood clots, and stroke among women taking a combined form of postmenopausal HRT.

Just three days after the news concerning the US study most German gynaecologists received a fax from Professor Alexander Teichmann, from a clinic in Aschaffenburg, southern Germany, and head of the Berufsverband's hormone commission. He wrote that "the presented data are

of highly limited relevance for German circumstances."

Doctors became suspicious when they realised that the statement had been sent out from fax servers of two German companies that sell hormone treatments, Schering Germany and Jenapharm, a subsidiary of Schering AG in Berlin.

The fax also included an "information sheet" that doctors could copy and hand out to their patients. This sheet was, it said, authored by Professor Teichmann and members of the Berufsverband. However, after being criticised in the *Deutsches Ärzteblatt*, the official journal of the German Medical Association, for his apparent involvement in the leaflet, Professor Teichmann declined to take responsibility for it. "I had never seen the information for patients before it was sent

out," he said. Schering then admitted that the text had been written by the company without the involvement of Professor Teichmann or the Berufsverband. The company "regretted the misunderstanding."

The information sheet provoked criticism in the journal because it did not mention that part of the US trial had been stopped early for safety reasons. However, according to a company spokesperson, Schering provided only logistical help and did not influence the wording of the paper.

● Since at least April 2001 Jenapharm has been registered as the owner of the commission's internet domain name. After a press inquiry about the domain last November the company removed the web page in a matter of hours. □