

Public interest group accuses FDA of trying to discredit whistleblower

New York

Jeanne Lenzer

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A public interest group that aims to protect whistleblowers claimed last week that an attempt had been made by a member of staff at the Food and Drug Administration to discredit Dr David Graham, the FDA executive who testified to the US Senate committee on 18 November.

Dr Graham, associate director in the FDA's Office of Drug Safety, had carried out a study with Kaiser Permanente of northern California that looked at the cardiovascular risks in patients taking rofecoxib (Vioxx). He had submitted the results of the study to the *Lancet*. Dr Graham withdrew the study, however, after getting a warning from his supervisor about publication.

The FDA issued a statement after the Senate hearing last week, claiming that Dr Graham had failed to adhere to agency protocol when he submitted his data to the *Lancet*.

When the *BMJ* inquired about the FDA's statement and the possible publication of the rofecoxib study in the *Lancet*, Dr Graham referred the *BMJ* to his attorney, Tom Devine, for comment.

Mr Devine, legal director of the Government Accountability Project—a public interest group based in Washington, DC, that helps whistleblowers in order to promote governmental and corporate accountability—said Dr Graham, fearing for his job, had sought the group's help in connection with the rofecoxib study about a month ago.

The group's decision on whether to provide legal counsel for Dr Graham was delayed after it received another request for aid from someone claiming to be an anonymous whistleblower at the FDA who was being "bullied" by Dr Graham. The anonymous caller also said that Dr Graham's study could reflect scientific misconduct.

After some investigation the project found out that the "anonymous" charges actually came from FDA management, which, according to Mr Devine, had "full control" over Dr Graham.

"We made demands to call whichever side was bluffing," said Mr Devine. "The FDA flunked every test of credibility, while Dr Graham passed all of them. The FDA was employing a classic law of whistleblower reprisal—the smokescreen syndrome—which shifts the spotlight from the message to the messenger.

"The agency attempted to discredit Dr Graham rather than provide any scientific evidence contradicting his conclusions."

Mr Devine said the FDA's attacks on Dr Graham's credibility were implausible. His scientific findings about the dangers of 12 drugs, including troglitazone (Rezulin), concomitant fenfluramine and phentermine (Phen-fen), and temafloxacin (Omniflox), were upheld when the agency withdrew 10 of the 12 drugs from the market. Many whistleblowers, said Mr Devine, find themselves isolated and shunned at work. It was some measure of the esteem with which Dr Graham is regarded by his colleagues that when he returned to work on Friday after his Senate testimony his colleagues greeted him with applause.

The FDA's statement after the hearing alleging that Dr Graham did not adhere to agency protocol on the Kaiser Permanente study can be found at www.fda.gov/bbs/topics/news/2004/NEW01136.html

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