Vioxx Whistleblowers

Vioxx/David Graham

On November 18, 2004, Dr. David Graham, a 20-year veteran Food and Drug Administration (FDA) scientist, rocked the pharmaceutical industry with Senate testimony that shook six multinational corporations, drew vital public attention to the secret life inside the FDA, and stopped the sales of a deadly, but hugely popular, arthritis medication. His testimony exposed tragic public health consequences stemming from a legalized conflict of interest: the FDA is one of the few government agencies whose funding depends largely on the success of products of the industry it regulates. Due to Graham's appearance, the deadly market for pain relievers will never be the same.

Background

Graham's association with GAP began earlier in 2004, following the FDA's criminal investigation of scientists working within the Office of Drug Safety (ODS). The inquiry sought to discover who leaked the truth about Paxil, an antidepressant set for approval for use by teenagers, despite epidemiological studies that it had sparked a rise of teenage suicides in Britain. The FDA banned a key scientist, Dr. Andy Mosholder, from attending a public Advisory Committee meeting to make final recommendations. Later, the agency told him that his attendance was permissible under the condition that he only answer questions from an approved script.

This attempt to suppress information was thwarted when the research was anonymously disclosed to the San Francisco Chronicle. Under intense public scrutiny, the FDA declined approval for unrestricted use of Paxil, and many lives may have been saved. But ODS Chief Dr. Paul Seligman continued the investigation to determine the person responsible for leaking the report.

Frightened by threats of incarceration, Graham sought help from GAP officials after being referred by congressional staff and members of the media. GAP Legal Director Tom Devine warned FDA investigators, outlining how they were incurring personal liability by violating laws such as the Whistleblower Protection Act and Anti-gag Statute, resulting in a swift halt of the investigation.

Vioxx

Graham contacted GAP later on, when the same FDA managers made attempts to suppress his study of Merck Corporation's immensely popular arthritis drug Vioxx. Carefully proceeding at a public conference, he was able to present preliminary eye-

popping results of an initial study detailing the correlation between heart attacks and usage of the pill. The conference sent shock waves through the industry. Graham's supervisors privately criticized him for trying to hurt Merck on the basis of "junk science" and "scientific rumor." Senate Finance Committee Chair Charles Grassley (R-Iowa) intervened to ensure the research was not suppressed, and scheduled the November 18 hearing.

In the weeks before the hearing, FDA officials repeatedly charged that Graham's study should not be publicly aired due to possible scientific misconduct – industry jargon for fraud. FDA supervisors contacted medical journals that obtained the study's results, urging that the research not be published. Supervisors then warned Graham that he could be disciplined for releasing it under his own name, prompting him to ask the journals to delay publication. Supervisors characterized Graham as a dangerous demagogue and bully who had to be stopped. Then-Acting FDA Commissioner Lester Crawford personally offered Graham a new position that did not allow for research opportunities.

Graham's testimony at the hearing became front-page news after he identified the FDA's handling of Vioxx as the worst public health disaster in its history, resulting in a probable 30,000-55,000 deaths of Americans alone. No official could credibly challenge his Vioxx findings, and he identified five other suspect drugs: Accutane, Bextra, Crestor, Meridia, and Serevent. Click here to read Graham's testimony.

In a preemptive move, the Merck Corporation withdrew Vioxx in the days prior to the hearing, unable to discredit research by Graham and colleagues that the expensive painkiller had caused 88,000 to 139,000 heart attacks – 30-40% of which were fatal – over the previous five years.

Aftermath

A week after the hearing, sympathetic insider colleagues and press contacts warned Graham that the FDA was finalizing plans to exile him from drug safety work within days. Sen. Grassley and the media rallied to his defense, and the FDA retreated. Commissioner Crawford issued a memo to all staff that they no longer need prior approval to communicate with Congress. Graham's supervisors later approved publication of the study.

Unfortunately, the FDA's actions were only a temporary reprieve. Two months later, in January 2005, the FDA's Advisory Committee was scheduled to meet in a policy showdown on Cox-2 drugs, a new type of pain reliever. FDA supervisors again told Graham that he could not present results from a new study detailing the drugs' effects. After Grassley intervened again, Crawford overruled FDA officials, agreeing it would

be illegal to suppress his views. Although dominated by hand-picked industry and agency scientists, the Committee placed unprecedented safety restrictions on all Cox-2 pain relievers, finding that the drugs were dangerous. Treating Vioxx like cigarettes, it banned product advertisements and required large warning labels.

David Graham still works for the FDA as a safety officer – continuing to monitor potentially unsafe drugs on behalf of the public. In the years since his Vioxx study disclosure, he has been recognized as one of the most important and influential whistleblowers of the past decade. His work alone saved thousands of lives.