



Statement

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Merck Responds to *Journal of the American Medical Association* Articles

WHITEHOUSE STATION, N.J., April 15, 2008 – Merck is committed to high standards of scientific integrity and ethics, and believes that many of the comments in a *Journal of the American Medical Association* (JAMA) news release and in the April 16, 2008 issue of JAMA¹ related to VIOXX are false, misleading or lack context. The articles, based on analyses of documents conducted by consultants hired by trial lawyers as part of their work in the VIOXX product liability litigation, make allegations similar to those previously advanced by these consultants and related attorneys at trial.

Merck is disappointed that we did not have an opportunity to respond to the misleading claims made in these articles prior to their publication. We believe that a full, unbiased evaluation of the Merck papers shows that many of the conclusions put forward by the authors of the JAMA papers are incorrect. Merck remains committed to bringing forward medicines and vaccines that save and improve people's lives, and to continuing to engage in constructive, transparent discussions with the broader scientific and medical community about our innovations.

Important Additional Context About JAMA Articles

One article, "*Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment*," on Merck's study of the use of VIOXX for Alzheimer's disease, and a related editorial, "*Impugning the Integrity of Medical Science*," incorrectly describe Merck's actions related to these studies. As part of its careful analysis of the data, Merck examined the actual causes of death in the Alzheimer's studies and found there was no pattern suggesting any connection to VIOXX. Merck also re-examined the data from other clinical trials to see whether there was any increased risk of death in those studies, and our analysis confirmed that there was not. Merck published the mortality data from the Alzheimer's studies² and provided these data to the FDA.

The statement in the JAMA editorial suggesting that Merck misrepresented mortality data from these studies is wrong; it is the JAMA article that fails to provide appropriate context:

- The JAMA paper does not discuss the specific causes of death in the Alzheimer's trials. However, when Merck received the interim data on deaths from all causes from the Alzheimer's studies in 2001, it provided the data and all subsequent updates to the FDA. Merck carefully analyzed the data and found that there was no pattern suggesting the deaths had any connection to VIOXX; some of the deaths were caused by car accidents, poisonings, infections and other causes that are not related to VIOXX. This information is available online³.
- The JAMA paper does not mention the analyses of the mortality data from Merck's other clinical trials of VIOXX, nor does the paper discuss the finding that there was a statistically significantly lower incidence of deaths on VIOXX than on comparator non-steroidal anti-inflammatory drugs in the Phase IIb/III osteoarthritis trials. This information is available online⁴.
- The JAMA paper does not mention that the FDA, after having reviewed the data from VIGOR (VIOXX Gastrointestinal Outcomes Research) and the Alzheimer's trials, determined that the cardiovascular mortality data (as opposed to mortality from the variety of causes discussed above) for both VIGOR and the Alzheimer's trials were the data that should be included in the Precautions section of the label in April 2002. In December 2003, after conducting a thorough review of the Alzheimer's data, an FDA reviewer concluded no additional regulatory action was warranted.

If JAMA or its reviewers had contacted Merck, they would have learned that all of the data were provided to the FDA for FDA to conduct whichever analyses it considered appropriate. This fact was acknowledged by Mr. Kronmal, one of the authors of this article, who testified as follows during cross-examination when he was a witness paid by one of plaintiffs' trial lawyers:

Q. Merck provided the FDA with all of the data, and accounted for every death in the Alzheimer's studies; true?

A. That's true.

Regarding the second article, "*Guest Authorship and Ghostwriting in Publications Related to Rofecoxib*" Merck believes that scientific discussion and debate can only be achieved when accurate, factual and balanced information is presented. Merck's policies regarding authorship and disclosure were established with this goal in mind. These policies have evolved and become more specific, as have the policies of others in the health care field. In 2003, Merck established a policy for authorship, adopting the criteria of the International Committee of Medical Journal Editors. Merck's guidelines have been available on

www.merck.com since 2004. In 2006, we implemented a policy which requires that, at the start of all Merck's Phase III and IV clinical trials, we convene an advisory group of external scientists who are involved in the conduct, analysis and reporting of our studies.

Merck routinely and repeatedly disclosed its involvement in scientific articles involving VIOXX. These publications reflected the extensive work of Merck scientists, and the input from authors from other institutions. The outside authors in Merck clinical trials were involved in the drafting and review of the papers that bear their name:

- The JAMA paper implies that the authors of the publication of the important, 8,000 patient VIGOR study were less involved than the Merck authors in the drafting of the paper. In fact, the outside authors, who are distinguished research physicians, were highly active in the drafting of the paper.
- In the case of one of the Alzheimer's papers, study 078, the scientists whose names appear in the first, second and third position of the published article were intimately involved in the conduct of the study, having served as a protocol consultant, member of the endpoint adjudication committee or as a study investigator. Financial conflicts of interest were disclosed in the acknowledgement of the published article. The absence of their names on the draft document author list or in the acknowledgment section shown in the article in no way indicates that these scientists were guest authors on this publication.

In order to facilitate the publication of some of the studies cited in the JAMA paper, Merck sometimes worked with outside medical writers who collected relevant data and research and summarized that research in a draft manuscript. We continue to do this, and we have clear policies for ensuring that such professional writers are working under the direction of the named authors. In addition, we have explicit policies about disclosing those who contributed to the writing of a paper, including professional medical writers, as well as for disclosing any financial compensation for this work.

It is important to highlight two facts relevant to an objective review of this JAMA article. First, the extensive list of publications (96) in the JAMA article makes it clear that Merck promptly published data from its clinical trials of VIOXX in the scientific literature, not only for successful studies, but also for those that were "failures," such as the Alzheimer's disease studies discussed in the first JAMA paper. And second, the JAMA article does not identify any inaccuracies in any of the VIOXX papers.

Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause

results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2007, and in its periodic reports on Form 10-Q and current reports on Form 8-K, if any, which the Company incorporates by reference.

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¹ DeAngelis CD; Fontanarosa PB. Editorial: Impugning the integrity of medical science: the adverse effects of industry influence. *JAMA*. 2008;299(15):1833-1835; and Psaty BM; Kronmal RA. Reporting mortality findings in trials of rofecoxib for Alzheimer disease or cognitive impairment: a case study based on documents from rofecoxib litigation. *JAMA*. 2008;299(15):1813-1817; and Ross JS; Hill KP; Egilman DS; Krumholz HM. Guest authorship and ghostwriting in publications related to rofecoxib: a case study of industry documents from rofecoxib litigation. *JAMA*. 2008;299(15):1800-1812.

² Thal LJ, Ferris SH, Korby L; Rofecoxib Protocol 078 Study Group. A randomized double-blind, study of rofecoxib in patients with mild cognitive impairment. *Neuropsychopharmacology*. 2005; 30(6): 1204-1215; and Reines SA, Block GA, Morris JC, et al. Rofecoxib: no effect on Alzheimer's disease in a 1-year, randomized, blinded, controlled study. *Neurology*. 2004; 62(1): 66-71.

³ http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4090B1_11_L-FDA-Tab-G.pdf

⁴ http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4090B1_02_MERCK-Vioxx.pdf