Withdrawal of article by the FDA after objection from Medtronic

The Journal of Vascular Surgery is the principal vehicle for disseminating scientific information about new devices for endovascular aneurysm repair. In April 2003, the Journal set the precedent of cooperating with the Food and Drug Administration (FDA) and manufacturers to ensure timely publication of new data related to device trials simultaneous with the initial public release of data by the FDA. At that time, a peer-reviewed article concerning the Phase II Medtronic AneuRx study was published, with accompanying comments by a representative of the FDA and the Editors to explain this new initiative. It is therefore with dismay that the Editors must now report the recent withdrawal of an accepted article concerning the AneuRx device by authors from the FDA after strong objections were made by Medtronic, Inc.

On December 17, 2003, the FDA posted on its Web site a Public Health Notification entitled “Updated data on mortality associated with Medtronic AVE AneuRx stent graft system.” On December 24, a scientific manuscript based on these data was submitted to the Journal by 4 authors from the FDA. This manuscript, entitled “Aneurysm-related mortality rates in the US AneuRx clinical trial,” underwent peer review and was accepted after revision on March 18, 2004. After copyediting and author approval, it was posted in the pre-publication area of the Journal Web site as an Article in Press on May 7.

On May 20, 2004, the authors contacted the Journal to request that this accepted article be removed from the Journal Web site so that changes could be made prior to print publication. They related that Medtronic Inc had raised major concerns about the content of the article, which had prompted a re-review of this submission by the FDA Center for Devices and Radiologic Health (CDRH), from which the article originated. Subsequently, on May 21, the Journal was contacted by an attorney at Medtronic Inc, who alleged that the authors had used confidential and proprietary data to write the article without the permission of Medtronic Inc. On the basis of this allegation, the authors and an attorney for the FDA requested time to review the entire matter and reiterated their request to remove the article from the pre-publication area of the Journal Web site.

On May 25, the Editors and Publisher received a “request to cease and desist unauthorized publication of Medtronic, Inc’s Confidential Data,” from the law firm King & Spaulding, LLP, representing Medtronic, Inc. This letter indicated that Medtronic, Inc strongly objected to the publication of analyses of post-market approval study data, which had been submitted to the FDA by Medtronic under the confidentiality provisions of the Federal Food, Drug, & Cosmetic Act and the Freedom of Information Act. The letter also alleged that public release of such information would constitute both criminal and civil violations under these acts, and indicated that if the Journal chose to ignore this request, Medtronic would pursue all available legal remedies against the Journal and protect its interests in court if necessary. The letter requested the immediate removal of the article from the Journal Web site and assurances against future publication. On the basis of the seriousness of the allegations of inappropriate publication of confidential information, and following receipt of a request by the authors to remove the article, the Editors and Publisher temporarily removed the article from the pre-publication area of the Journal Web site on June 8, 2004, pending review by the authors and the FDA of the accusation made by Medtronic, Inc.

On June 25, 2004, Dr Daniel Schultz, Acting Director of the CDRH, informed the Journal that the FDA wished to withdraw the accepted article because the conclusions drawn in the article went beyond the information provided in the Public Health Notification and, therefore, did not reflect the FDA’s current position regarding AneuRx-related mortality. The allegations by Medtronic concerning inappropriate publication of confidential information were not addressed. Dr Schultz stated that the FDA was acting on behalf of the authors who developed the article within the scope of their employment at the FDA. By this action the FDA prevented our publication of this article.

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The Editors have carefully reviewed the data contained in this article and compared them with data from the FDA Public Health Notification of December 17, 2003, as well as an abstract publicly presented by the authors at the 2004 FDA Science Forum. It is our conclusion that the data submitted to the Journal, and alleged to be confidential by Medtronic, Inc, are identical to the data in these other public documents. In these documents, the FDA analyzed aneurysm-related deaths in 942 patients from the Phase II trial who received the flexible AneuRx graft currently mar-

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They reported a 1-month post-implant death rate of 1.5% and thereafter an annualized aneurysm-related mortality rate of 0.4% per year. They estimated the cumulative aneurysm-related mortality to be 2.7% at 3 years after implant. Furthermore, the FDA concluded that the risk of late aneurysm-related mortality associated with the AneuRx stent-graft system may exceed that associated with open surgery in some institutions, and that the overall aneurysm-associated mortality from the AneuRx stent graft is likely to cross over and exceed the aneurysm-associated mortality from open surgery at some point in time. They encouraged surgeons to carefully consider patient risk factors, including the risk of subsequent events, when recommending open versus endovascular repair.

On the basis of this analysis, the objection to publication of these data in the Journal by Medtronic Inc can hardly be attributed to confidentiality concerns. The data have been publicly available since December, although few vascular surgeons may have seen them. We can only speculate about the motivation for Medtronic’s actions. The results do not appear inferior to other published reports concerning aneurysm-related mortality following endovascular repair, but perhaps they were interpreted that way. In addition, the explanation by the FDA that the conclusions in the article go beyond the Public Health Notification cannot apply to the data, which were identical, but rather must apply to interpretations and discussion by the authors, which we regard as appropriate scientific discourse. This action taken in response to objections by a manufacturer of a device regulated and approved by the FDA is very disturbing.

The Editors are extremely disappointed by the actions of the FDA and Medtronic Inc, which have prevented the publication of an article containing data that we believe are important to readers of the Journal. We encourage readers to make themselves aware of the data concerning aneurysm-related mortality concerning the AneuRx stent graft that are available on the FDA Web site.

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REFERENCES