

## EDITORIALS



## Peer Review in the Balance

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and Jeffrey M. Drazen, M.D.

For many years, the editors of the *Journal* have relied on peer review to ensure the scientific quality of the articles that we publish. Of the thousands of manuscripts submitted to the *Journal* each year, we publish about 1 in 20. To aid us in selecting those manuscripts, we seek advice from thousands of peer reviewers. Confidential peer review is a key component of our manuscript selection process.

We were therefore concerned when in May 2007 lawyers for the pharmaceutical company Pfizer served us with a subpoena demanding that the *Journal* produce peer-review and other editorial documents on all manuscripts concerning Pfizer's cyclooxygenase-2 (COX-2) inhibitors, valdecoxib (Bextra) and celecoxib (Celebrex) — 11 specific articles that we had published and any others that we had rejected for publication. Although Pfizer wanted the peer-review documents, including the critiques prepared by reviewers for the authors, to help defend itself in product-liability litigation, the company was not looking for specific information. Rather, Pfizer's attorneys stated that they wanted the critiques in order to discover "flaws in methodology" in the research that might have been noted by the *Journal's* peer reviewers. Thus, Pfizer was hoping to use the *Journal's* expert reviewers and their critical commentary in an attempt to challenge scientific aspects of the articles, adding what Pfizer's attorneys called the "significant imprimatur" of the *Journal* to their case.

We refused to relinquish any peer-review documents. In January 2008, Pfizer attorneys filed a motion to compel us to produce those documents, including copies of all the manuscripts and the peer reviewers' comments about them. We declined

again. Instead, we filed with the court an Opposition and Motion for Protective Order. We argued that our peer-review documents had been obtained from the reviewers with a promise of confidentiality and should not be subject to subpoena. To provide the requested information would seriously hamper our ability to serve the medical community. The motions from Pfizer and the *Journal* were heard in federal court on March 13, 2008.

Our stand was based on our long-held belief that the peer-review process works best when it is conducted in confidence. When we request advice from peer reviewers, we guarantee confidentiality. The confidential nature of the peer-review process has been underscored in a recent editorial by Kennedy<sup>1</sup> and by the International Committee of Medical Journal Editors (ICMJE). In its Uniform Requirements, the ICMJE states that "Editors must not disclose information about manuscripts (including their receipt, content, status in the reviewing process, criticism by reviewers, or ultimate fate) to anyone other than the authors and reviewers. This includes requests to use the materials for legal proceedings."<sup>2</sup> In fact, in our view, the important elements of any peer reviewer's critique are made part of the article before publication. It is the published work that represents the clearest and most complete statement of the research.

The question of whether a court must enforce a subpoena is governed by the Federal Rules of Civil Procedure, which state that a court must limit discovery if it determines that "the burden or expense of the proposed discovery outweighs its likely benefit." Thus, a balancing test must be applied. In this case, U.S. Magistrate Judge Leo T. Sorokin ruled that the key issue in the balancing

test was the relevance and probative value of the information sought.<sup>3</sup>

The judge decided that while the materials Pfizer sought were relevant, their probative value was limited. As Sorokin concluded, even though the information sought was relevant, “the NEJM’s interest in maintaining the confidentiality of the peer-review process is a very significant one, especially in light of its non-party status, and tips the scales in favor of the NEJM.”

The case could have ended there, but the judge went on to determine that as a matter of public policy editors and peer reviewers are entitled to the same type of confidentiality consideration as academics engaged in prepublication research “to avoid undermining their ability to gather and disseminate information.” The judge concluded that “the batch or wholesale disclosure by the NEJM of the peer reviewer comments communicated to authors will be harmful to the NEJM’s ability to fulfill both its journalistic and scholarly missions.” Sorokin’s ruling states that scholarly journals are entitled to the same protection of editorial confidentiality as journalists. The ruling also makes it clear that disclosure would be harmful not only to the *Journal* but also “to the medical and scientific communities, and to the public interest.”

Magistrate Sorokin’s opinion was announced

soon after a similar federal judicial opinion was rendered in Illinois, where lawyers for Pfizer had served essentially the same subpoena to the *Journal of the American Medical Association*.<sup>4</sup> In that case, the court refused to enforce the subpoena on the basis that the relevant information was in the published articles and that there was a “strong policy behind preserving confidentiality in the peer review process,” the invasion of which would unduly burden and harm the journal.

As we did in this case, we will resist any future attempts to undermine peer review, in the interest of the *Journal* and of those who offer their time and expertise as reviewers. We want to assure our reviewers that we value their comments and will keep them confidential.

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2. ICMJE uniform requirements. Section I.I.E.2. (Accessed April 30, 2008, at <http://www.icmje.org>.)
3. *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. CIV.A. 08-mc-10008-MLW, 2008 WL 859207 (D. Mass. March 31, 2008).
4. *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 08 C 402, 2008 U.S. Dist. LEXIS 21098 (N.D. Ill. March 14, 2008).

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## Does Thrombolytic Therapy Facilitate or Foil Primary PCI?

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Sir Winston Churchill once said, “It’s not enough that we do our best; sometimes we have to do what is required.” Such a sentiment underlies the premise of facilitated percutaneous coronary intervention (PCI), a therapeutic strategy of pharmacologic thrombolysis before mechanical intervention for the treatment of ST-segment elevation myocardial infarction. Despite our best efforts to provide timely primary PCI to improve myocardial salvage, patient-related delays to presentation, the necessity for transfer of the patient to a facility capable of performing PCI, and presentation of the patient to the hospital during off-hours may all conspire to extend the time from the onset of symptoms to PCI.<sup>1</sup> Recognition of these inherent delays led physicians to propose facilitated PCI as a mechanism to establish early reperfusion of the

infarct-related artery when the time to primary PCI for definitive plaque stabilization may be delayed.

In current practice, a door-to-balloon time of 90 minutes or less has been defined as the optimal time from first presentation to treatment in order to attain the lowest in-hospital mortality.<sup>2</sup> This benchmark has proven to be hard to achieve for all patients because only 40% of the population identify a hospital with a primary-PCI program as the closest facility to their home, and only 80% reside within 1 hour of a hospital capable of performing PCI.<sup>3</sup> The appeal of facilitated PCI is, therefore, readily apparent — early pharmacologic reperfusion to limit the duration of total ischemia and offset the deleterious effects of a time delay before PCI can be performed.

Owing to the fact that facilitated PCI combines