

Sciensationalism

To the Editor:

Ohman et al.'s¹ commentary in the June 2010 issue of the *Journal* addressed several issues regarding clinical trials, and their solutions relied on the accountability of investigators, institutional review boards (IRBs), and data safety monitoring boards—but these added little to the challenge.

In their first paragraph, Ohman et al. cited, as the “key issue,” “the requirement that patients are not randomized to a clearly inferior treatment” (Helsinki declaration, point 32)—but they failed to discuss the fact that breaches still occur.

Since 1998, the American Society of Gastroenterology has stated that “corticosteroids should be used in patients with severe alcoholic hepatitis in whom the diagnosis is certain.” Five patients need to be treated with corticosteroids to prevent 1 death.² This has not precluded several phase III multicenter trials from using placebo as a comparator. The most recent trial tested etanercept.³

I was unsuccessful in publishing a letter to the editor raising the point 32 issue and in obtaining the information form from both the investigator and his IRB. I contacted the National Institute of Health (the funding body), the Office of Extramural Research, the Office of Research Integrity, and the Department of Health and Human Services. The response, if one, was “we lack the jurisdiction to deal with matters of this sort.”

This study raised other basic concerns, including an effect size of 35%, based on hope, and a dosage chosen in reference to rheumatoid arthritis that seems to neglect the fact that patients with alcoholic hepatitis are more prone to

infection. This bypasses the drug development process (pre-clinical, phases I and II) as in another study with a tumor necrosis factor- α -neutralizing agent at a dose 3 times higher than usual!⁴ Warnings were useless. Coincidentally, I was fired by the sponsor on the year of the recruitment. The trial was stopped prematurely (36 inclusions/140 planned) because the mortality rate in the infliximab group was twice as high as the mortality rate in the control group.

To avoid sciensationalism (sensationalism in science), three things must happen: a) editors must keep room for correspondence to promote controversies; b) the whistleblower must be protected; and c) research must not be exempted from accreditation programs as those for care. From all points of view, clinical research and care must be integrated. The end of the Human Research partnership between the Joint Commission and the National Committee for Quality Assurance in 2006 was a major setback. Accreditation programs that protect participants in clinical trials in public and private hospitals are needed. Lastly, we must acknowledge that IRBs, as hospital-based committees, generate too many conflicts of interest.

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Authorship: The author takes responsibility for the contents of this letter.