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ADAPT Trial Data

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Dear Dr. Alpert:

We are surprised to see data from the Alzheimer's Disease Anti-inflammatory Prevention Trial (ADAPT) prominently featured in the recent article by Salpeter et al. entitled "Meta-analysis: Cardiovascular events associated with nonsteroidal anti-inflammatory drugs" (2006, 119;552–559). The data did not come from an ADAPT publication or from unpublished data provided by us for the purpose of publication. We therefore are unable to vouch for the accuracy of the ADAPT data as reported in the aforementioned publication since we know neither the source of the data nor the cutoff date for the counts summarized.

The authors state that they "sent 27 correspondences and received eight responses; unpublished information was received for five studies." The implication is that those requests produced data for the five studies listed as "unpublished." In fact, we received an e-mail inquiry from Dr. Salpeter in January 2005, but responded that we could not grant permission to use ADAPT data in a meta-analysis until they had been published. We note the absence of the word "received" with respect to ADAPT data in the comments column of the table listing the studies included. The reference provided for ADAPT (25) is an NIH press release, which does not contain the data published.

The appropriation and publication of our data by Salpeter et al. might well have jeopardized our own efforts at publication (1) if the journal to which we had submitted the data rejected our manuscript because of *The American Journal of Medicine* publication. We also now must give account to our investigators and sponsors because of this publication, and will likely encounter anger and irritation from our study participants and IRBs, to whom we promised advance notice of our results before publication.

We believe that authors of meta-analyses have responsibilities to reveal their sources of unpublished data for readers. We believe further that journals have a responsibility to refuse publication of their meta-analyses involving unpublished data absent written assurance from the authors that the data are being used with consent of the investigators who collected them. Such action by journals would be consistent with journal policies to refuse publication of single study results obtained without proper consent by individuals.

Sincerely,

Officers of ADAPT

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References

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