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## **AMA recommends that DHHS establish a registry for all U.S. Clinical Trials**

**For immediate release  
June 15, 2004**

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CHICAGO — In response to concerns about the impact of pharmaceutical industry sponsorship on research outcome, quality and publication bias, the American Medical Association House of Delegates called for the Department of Health and Human Services to establish a comprehensive registry for all clinical trials conducted in the United States.

The new registry would ensure that trials with negative as well as positive results are publicly available, by providing every clinical trial with a unique identification and ensuring publication or placement on an electronic database of all results from registered trials.

The new policy, approved at the AMA's annual meeting, also calls for the AMA to urge institutional review boards (at hospitals, universities and medical centers) that must approve any research involving human subjects to consider registration of clinical trials as a condition for approval.

"Studies with positive findings are more likely to be published than studies with negative or null results," said AMA Trustee [Joseph M. Heyman, MD](#). "We are concerned that this pattern of publication distorts the medical literature, affecting the validity and findings of systematic reviews, the decisions of funding agencies and, ultimately, the best practice of medicine."

The AMA cited growing concern about the influence commercial support of drug trials may have on this publication bias. There are potential problems arising from clinical trial agreements that may delay publication or delete information from publications. There may be outcome bias resulting from the use of unreliable methods and inadequate sample size or comparison groups. Industry-funded studies may be more likely to use placebos or inactive controls, increasing the likelihood of achieving positive study results.

In studying this issue, the AMA also found direct sources of publication bias. Investigators and authors are reluctant to submit studies unless the results are positive or significant, believing that journals will not publish them. Journals are more interested in publishing studies that are likely to affect clinical practice. As a result, confirmatory trials, trials with negative results, and trials that show no significant result are less likely to be published.

The new policies were based on recommendations put forth in a report from the AMA's Council on Scientific Affairs (CSA). Authors of the study reviewed the available scientific literature on the relationship between pharmaceutical sponsorship and research outcome, quality or publication bias, including 12 systematic reviews of thousands of original studies.

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Last updated: Jan 03, 2006  
Content provided by: Media Relations

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