



## INTERNATIONAL SOCIETY for PHARMACOEPIDEMIOLOGY

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# International Society for Pharmacoepidemiology (ISPE) Statement on JAMA Guidelines for Authors

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In 2004, the Journal of the American Medical Association (JAMA) changed its instructions to authors in a manner that reflected a fundamental policy shift. The language appears below:

*"Data Access and Responsibility. For all reports (regardless of funding source) containing original data, at least 1 author (e.g., the principal investigator) who is independent of any commercial funder should indicate that she or he "had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis." For industry-sponsored studies, this statement must be provided by an investigator who is not employed by any commercial funder, and an independent data analysis must be conducted by statisticians at an academic institution with access to the raw data set, rather than only by statisticians employed by the company sponsoring the research. "*

We understand that the intent of JAMA's new policy is to remedy the problems of bias in the presentation and interpretation of results of clinical research. ISPE applauds effective action, which addresses such biases in published research. Bias can arise from many sources in addition to funding source and affiliation, the two characteristics, which the new policy attempts to address

The International Society for Pharmacoepidemiology (ISPE) believes that the new JAMA policy will not meaningfully alter problems of bias in published research. These new instructions create an unfortunate dual standard for submission review based on the funding source of the research (commercial vs. non-commercial). The instructions also imply a hierarchy of research based on affiliation (academic vs. non-academic).

In addition, the recommended remedy, an independent analysis of data, while potentially addressing issues of bias in the analysis, does not address the possibility of bias in the selection, presentation, and interpretation of findings. A more transparent process for evaluating research findings is desirable, and should be applied irrespective of funding source or author affiliation. Suggestions for improving the transparency of the peer review process include making study protocols and analysis plans available at the time of peer review, and making raw data available for additional analysis should questions arise about the quality of the analysis. Such improved transparency should be applied across all submissions, consistent with the fundamental intent of peer review.

In addition, there are concerns among the ISPE members about how the new policy would be implemented. For example, who determines that a statistician is qualified, and what organizations are considered to be academic? Moreover, the statement that "at least 1 author (e.g., the principal investigator) who is independent of any commercial funder"… requires definition of the term "independent". For instance, is an academic PI who receives research grants, honoraria, or consulting fees from that company or a competitor company considered independent? If not, then many active academic clinical researchers would be excluded.

ISPE urges the editors of JAMA to reconsider its new policy. Moreover, ISPE urges editors of JAMA and other biomedical journals to employ processes for review and acceptance of manuscripts that are based on the merits of the research and applied equally and consistently across all submissions.

The International Society for Pharmacoepidemiology is a non-profit international professional membership organization dedicated to promoting the health of the public by advancing the science of pharmacoepidemiology, the discipline that applies epidemiologic approaches to studying the use, effectiveness, value and safety of pharmaceuticals. The Society's more than 1000 members from 40 countries work in academic institutions, the pharmaceutical industry, government agencies, and non-profit and for-profit private organizations. ISPE members are researchers with background and training in epidemiology, biostatistics, medicine, public health, nursing, pharmacology, clinical pharmacology, pharmacy, law, and health economics. It is important to note that the governance of ISPE reflects its membership, with proportionate representation on the Board of Directors from its three primary sectors: government, industry and academia, and with no one sector having a controlling voice or vote. ISPE is firmly committed to providing an unbiased scientific forum to the views of all parties with interests in drug development, drug delivery, drug use, drug costs, and drug effects. This Statement, having been ratified by ISPE's Board of Directors, is based on extensive input from the membership.