



International Society for Pharmacoepidemiology (ISPE) Statement on American Society of Clinical Oncology's New Policy for Relationships with Companies

The American Society of Clinical Oncology (ASCO) and its affiliated journals (Journal of Clinical Oncology (JCO) and Journal of Oncology Management (JOM)) have initiated a new publication policy:

Under the new Policy, ASCO will not accept an abstract or paper describing Company-funded original research if the first, last, or corresponding author has been the Company's employee, investor, or paid speaker during the previous 2 years.ⁱ

This policy also applies to submissions to the ASCO annual scientific meeting and is effective with research initiated after April 2014. It applies to randomized clinical trials and non-interventional (including database) research. The rationale provided by ASCO to support this new policy was: "Experience has further convinced ASCO's volunteer leaders that, for a few specific types of interactions, disclosure and peer review are not adequate to ensure confidence in the objectivity of the work."ⁱ

ISPE has issued statements previously against policies that singled out one type of funding source or author affiliation for enhanced scrutiny of manuscripts by journals. Instead, ISPE called for more transparency in evaluating research irrespective of funding source or author affiliation, consistent with the fundamental intent of peer review. Suggestions for improving transparency included full disclosure of potential conflicts of interest, registration of study protocols, making study protocols and analysis plans available at the time of peer review, and making raw data available for additional analyses should questions arise about the quality of the analysis. Similar measures have been worked out for the European Medicines Agency under what is known as the "ENCePP code of conduct."ⁱⁱ

ISPE urges ASCO's leaders to reconsider its new policy. The policy amounts to a prohibition against authors with certain affiliations taking leading authorship positions creating, in essence, a caste system in authorship. This prohibition applies regardless of the expertise of the author or the quality of the submitted research. ISPE believes this prohibition is unwise for several reasons. First, it restricts the diversity of quality research and expert viewpoints available to journal readers. Second, it threatens to interfere with the assignment of authorship positions consistent with an individual's contributions,

which contradicts widely accepted guidelines for authorshipⁱⁱⁱ and recommended good pharmacoepidemiology practices.^{iv} Third, without evidence, it depends on a conclusion that disclosure of interests and peer review are not adequate to guide the content that is accepted for publication in journals and presentation at ASCO's annual meeting.

ISPE urges ASCO to return to reliance on rigorous peer review for all submissions, not just those involving certain affiliations. Editors and expert reviewers have a range of tools to address any inconsistencies in submitted manuscripts including requesting additional analyses or justification for conclusions or rejection of a submitted paper for methodologic weakness, unconvincing analyses, or overreach in conclusions. From ISPE's standpoint, the key factors in ensuring confidence of readers in the objectivity of the content at the ASCO annual meeting and in JCO and JOM is that rigorous peer review was applied to all submissions, regardless of funding source and author affiliation, and that the Society and its journals were open to contributions from all expert sources.

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.

Endorsed by the ISPE Board of Directors, August 24, 2013

ⁱAmerican Society for Clinical Oncology 2013. American Society of Clinical Oncology Policy for Relationships with Companies: Background and Rationale. J Clin Oncol. Published Ahead of Print on April 22, 2013 as 10.1200/JCO.2013.49.4997

ⁱⁱEuropean Network of Centres for Pharmacoepidemiology and Pharmacovigilance. Code of conduct. (http://www.encepp.eu/code_of_conduct/)

ⁱⁱⁱInternational Committee of Medical Journal Editors; Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship (http://www.icmje.org/ethical_1author.html - last accessed December 13, 2012)

^{iv}Guidelines for Good Pharmacoepidemiologic Practices (GPP). Pharmacoepidemiology and Drug Safety 2008;17:200–208. Also available at (http://www.pharmacoepi.org/resources/guidelines_08027.cfm - last accessed December 13, 2012)