The Changing Landscape of Conflict of Interest Supports Further Study of American Society of Clinical Oncology Authorship Restrictions for Research Studies

As a leading source of cancer information worldwide, the American Society of Clinical Oncology (ASCO) values the trust of its members, the oncology community, and the public. ASCO has long been committed to transparency and independence in financial interactions with health care companies. For nearly two decades, ASCO has had policies in place that require disclosure of financial relationships by authors, presenters, and members volunteers. ASCO uses the information to manage and minimize the potential for bias and maintain the objective voice of its journals, Continuing Medical Education, clinical practice guidelines, and quality improvement programs. The most recent revision to the ASCO conflict of interest (COI) policy was published online in Journal of Clinical Oncology on April 22, 2013, and will be implemented later this year. This updated policy, as explained in an accompanying article on background and rationale, again emphasizes disclosure of interactions with commercial firms. The revised policy names eight types of financial relationships that generally must be disclosed: compensated employment, leadership positions, consulting activities, speaking engagements, expert testimony, ownership interests, research funding (to the individual or institution), and fees for intellectual property interests.

The 2013 policy also imposes specific restrictions on publication and presentation of research in certain ASCO forums. In a substantial change from previous versions of the policy, the new policy applies to all original research, not just clinical trials. In addition, the restrictions imposed by the new policy focus on the role of the authors rather than of the principal investigators (as was the case in the prior policy). Under the new policy, ASCO will not accept an abstract or article 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. These relationships—employment, significant stock ownership, and speakers’ bureaus—are the ones ASCO has found to be the most difficult to address through disclosure and management.

Since its publication, the new COI policy has generally been received well except for the author restrictions. Scientific and medical leaders in both the public and private sector have raised concerns regarding the restriction on company employees being first, last, or corresponding author of a research article or abstract. These colleagues have argued that company scientists, some of whom are ASCO members and who perform important original research, would be automatically barred from submitting such work to an ASCO forum as lead authors. Concerns were expressed that novel clinical, translational and preclinical research performed by highly qualified scientists working for companies would not be presented to an audience of peers who were best equipped to critique, debate, learn and, perhaps most importantly, implement the research for the benefit of patients. It was also asserted that potential conflicts of interest resulting from employment or ownership relationships with commercial research sponsors could instead be highlighted in a transparent fashion and effectively managed through well-established procedures.

In the short time since ASCO developed this new COI policy, the broader landscape of COI disclosure and management has evolved considerably. The introduction of the so-called sunshine provisions of the Affordable Care Act, the decrease in federal funding of biomedical research, and the emergence of new companies focused on genomics and health informatics that have access to unique and sometimes proprietary clinical data sets that are only accessible to company employees for analysis—all contribute to the changes in our environment. The impact of these changes on cancer research and education is not yet fully understood.

ASCO leadership has carefully considered the concerns expressed by the biomedical community regarding the author restrictions in the 2013 COI policy and has decided to suspend enforcement of these restrictions for a period of at least 3 years. Starting this spring, the Society will begin asking whether the first, last, and corresponding authors have employment, significant ownership, or paid speaker relationships with the company that funded their research. However, all abstracts and manuscripts may be submitted and will be evaluated regardless of the author relationships. ASCO will gather data for 2 years regarding the relationships disclosed, the types of research conducted by authors with those relationships and the potential impact of enforcing the restrictions on the presentation of that research to the medical community. In the third year, ASCO will analyze the data and decide on the most appropriate next steps.

All other aspects of the 2013 COI policy will be implemented as planned, beginning in April 2014. At that time, the principal
investigator restrictions from the 2005 policy will be discontinued so ASCO can focus on the role of authors. We will be rolling out new COI disclosure questions and will begin to introduce the option of banking COI disclosures for future ASCO activities.

ASCO’s COI policy reaffirms a commitment to transparency and independence in the development and presentation of scientific and educational content as well as our responsibility to analyze, present, and discuss the most important research results with potential to improve the lives of our patients. ASCO continues to support thorough and accessible disclosure of financial relationships with companies at institutional and individual levels. Our goal is to bring forward important original research that will educate health care providers and benefit cancer patients worldwide. Our responsibility is to be vigilant about the independence of science and professional education. ASCO will conduct further research on the most effective ways to communicate and manage COI information and on the impact of COI policies and encourages others to do so as well.

AUTHOR’S DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST
The author(s) indicated no potential conflicts of interest.

REFERENCES
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