Conflict of Interest: In the Eye of the Beholder?

Honesty is not to be based on policy.
Policy must be based on it. — John Ruskin

The January 2008 issue of The Oncologist faced the editors with a dilemma. It contained a peer-accepted review article on computed tomography (CT) screening by Drs. Claudia Henschke and David Yankelevitz, an article that strongly supported spiral CT for early detection of lung cancer in high-risk patients [1]. That issue of The Oncologist was already in press and about to be distributed when our attention was drawn to articles in The Cancer Letter [2] and The Wall Street Journal Health Blog [3], in which it was alleged that the authors of our article had significant, previously undisclosed, financial interests in technology related to CT screening. As an immediate response, and until we could secure further facts, the editors took several steps: we withheld the article’s Continuing Medical Education availability, we published a notice on The Oncologist’s web site calling attention to a potential conflict of interest (COI) [4], and we requested clarification and explanation on the part of the authors [5]. On February 7, 2008, we received the response [6], in which Drs. Henschke and Yankelevitz acknowledged their financial interests, which include patents for CT software that facilitates evaluating lung screening films and for a needle used to biopsy lung nodules, respectively. They asserted that, because this technology was never explicitly mentioned in their article, they had no obligation to disclose these interests.

Thus, we are left with the problem of interpreting what actually represents COI. Is it the explicit and direct promotion of one’s own financial interest, or does COI extend to potential personal financial benefit that might derive from a publication at some future date?

The test for COI is relatively simple. In common usage, COI exists, and should be acknowledged by a disclaimer accompanying an article, when there could be a reasonable presumption that an author has a financial interest in the outcome of a study. Most leading medical journals, such as the Journal of the American Medical Association, ask that all “potential” conflicts, including any that “could influence (or bias)” the published work, be disclosed [7]. Thus, their definition extends beyond the specific mention of a product or drug, or device, in which the author has a financial interest, and includes all relevant relationships and potential COIs. The policy of the New England Journal of Medicine states that it expects an author not to have significant financial relationships in a product mentioned in an article, and at the same time calls for disclosure of “relevant financial relationships” if such exist [8]. Admittedly, it is unclear how an author with a significant, relevant financial relationship could author an article under this policy.

The Oncologist’s COI Disclosure Statement [9], which all authors are required to sign, states that authors are to disclose any financial interest that they own in a product, service, technology, or program discussed in the article. It is entirely clear that, if the authors mention by name a product, service, or technology in which they have a financial interest, that interest should be disclosed. Interest in a “program” is less clearly defined, but may include a financial interest in an entity encompassed by the field of study, whether or not that entity is explicitly mentioned in the article.

The authors in this case denied having such a financial COI when they signed this statement, because their patents and technology were not explicitly mentioned in the text. While there is no explicit reference to the software patents or biopsy needles, it is equally clear that the widespread adoption of CT screening as the standard of care for the early detection of lung cancer would increase the commercial value of these patents and products. It seems to us that the readership of a scholarly journal deserves to know when an author could reasonably be expected to derive personal benefit from the results of his/her paper.

Not all journals share our view about the series of lung screening papers written by these authors. While Nature and The Lancet, which also have recently published articles by Henschke and Yankelevitz, have asked
for clarification from the authors, a third publisher, the New England Journal of Medicine, told the editor of The Cancer Letter that they considered the authors’ position and found no specific conflict [2]. Interestingly, Dr. Jerome Kassirer, a former editor of the New England Journal of Medicine, took an opposing view in his recent editorial in the Boston Globe, citing the Henschke and Yankelevitz paper as an example of failed surveillance of COI [10]. Thus, while the definition of COI may seem straightforward, the interpretation of that concept and its application to specific cases appear to vary from journal to journal, and from editor to editor.

There are additional scientific issues raised by the paper in question. The Henschke and Yankelevitz article, which appeared in our January issue, will be followed in an upcoming issue by an article by Dr. James Jett that takes an alternative point of view, in which the author disputes the conclusion that CT screening is of proven benefit. Dr. Peter Bach, a former Deputy Director of the Centers for Medicare and Medicaid Services of the federal government, takes further issue with the Henschke and Yankelevitz article in a forthcoming Letter to the Editor that questions both the facts and interpretation in their paper. Drs. Henschke and Yankelevitz have been invited to respond to Dr. Bach, and, as always, it will be you, our readers, who are now faced with the challenging task of sorting out your own position on CT screening. Your perspective will be informed, we hope, by the transparency of The Oncologist in dealing with controversial and evolving areas of cancer medicine.

Regarding COI, we are interested in your opinion on this important subject. Do you assume full disclosure of all financial interests that constitute a real or potential financial interest, or do you espouse a more limited view of disclosures that encompasses only those technologies, patents, devices, and drugs mentioned explicitly in the text? To facilitate your correspondence and to enable others to read your opinions, we have launched a new communications channel called “e-Letters.” Please follow the simple directions below to access this web-based communications conduit.

Unless your editor changes his mind, we will maintain the broader view and continue to ask our authors to fully disclose all relevant, real and potential COIs.

Bruce A. Chabner, M.D.
Editor-in-Chief

REFERENCES
6 Claudia I. Henschke’s reply to Editor-in-Chief, February 7, 2008.
7 Flanagan A, Fontanarosa PB, DeAngelis CD. Update on JAMA’s conflict of interest policy. JAMA 2006;296:220–221.

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