



# MASSACHUSETTS MEDICAL SOCIETY

*Every physician matters, each patient counts.*

October 1, 2008

Steve Singer, PhD  
Director of Education, Monitoring and Improvement  
Accreditation Council for Continuing Medical Education  
515 North State Street, Suite 1801  
Chicago, IL 60610-4377

Dear Dr. Singer,

Thank you for your letter of September 12, 2008. We are pleased that the MMS was able to clarify that relationships valued below \$10,000 have always been declared in the pages of the *New England Journal of Medicine* (*NEJM*) as financial interests worthy of disclosure.

In your review, you determined that the patent held by Cornell Research Foundation and licensed non-exclusively to General Electric was a relevant financial relationship that needed to be disclosed to our learners when we published the article by Dr. Claudia Henschke and the continuing medical education (CME) examination that accompanied it. We offer this *Notice of Correction Action* to you to provide assurance that these elements of the CME review process have been modified since the late summer of 2006 in such a way as to bring our policies into full compliance with ACCME policies.

When we published Dr. Henschke's article in 2006 it was not routine *NEJM* editorial policy to publish details about pending patents. Since that time our thinking on this issue has evolved in line with material published in our pages and the emerging prevalence of patents as a source of personal and research revenue.<sup>1-3</sup>

As soon as information that clarified Dr. Henschke's relationship to the patent was provided to us, we sought clarification on the issue from the author. The CME examination had been withdrawn more than 2 months before we were aware of the patent-related financial associations as part of our policy not to post out-of-date CME examinations. We also informed our learners about the updated conflict by publishing a correction that updated the disclosure. You indicated in your letter that you find the updated disclosure for the article "Survival of Patients with Stage 1 Lung Cancer Detected on CT Screening" more extensive and adequate.

Before the action from the ACCME we had updated the *NEJM* disclosure forms to reflect our increasing concern about patents and conflicts of interest. The form (Attachment 1) specifically solicits a response from authors to this question: "Do you have patents or royalties, have you served as an expert witness, or do you perform other activities for an entity with a financial interest in this area?" Authors who respond in the affirmative must provide a written description of said relationship, and we now disclose the presence of these patent relationships even if there are not current financial arrangements between the author and any potential licensee. Evidence of our policy disclosing patent-related information can be seen in the appended disclosures that were published with each of the following manuscripts (Attachment 2):

- Maheswaran S, Sequist LV, Nagrath S, et al. Detection of mutations in EGFR in circulating lung-cancer cells. *N Engl J Med*. 2008;359(4):366-77.
- Zheng SL, Sun J, Wiklund F, et al. Cumulative association of five genetic variants with prostate cancer. *N Engl J Med*. 2008;358(9):910-9.

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We continue to increase our vigilance with regard to conflict of interest to ensure that we are fully transparent to our readers and learners. Our editors routinely edit the content of research reports and reviews for balance to ensure that the interpretation matches the data, regardless of the presence of disclosures. If disclosed conflicts and interpretations cannot be resolved, the material is declined for publication. We do not proceed with commentary and review articles if we judge that the author's disclosed affiliations represent a real or apparent conflict that could undermine their impartiality. We will not select material for our CME program until these issues have been resolved. Since the ACCME inquiry, we have further refined our internal CME process for identifying and resolving conflicts of interest. The updated *Journal-based CME Conflict of Interest Policy* (Attachment 3) is currently under review by the MMS Committee on Medical Education.

Furthermore, our editor for CME reviews disclosure statements for the articles chosen for CME. The CME editor now provides an indication in our workflow that the accreditation requirements for learners are met. For web-based readers of the *Journal*, we are in the process of improving the current visibility of our placement of disclosures before the examinations are taken by automating a new graphic that better displays these disclosures. We aim not only to ensure that our editorial requirements are met, but also to meet and exceed the accreditation requirements.

We hope that the corrections we published to the Henschke disclosure, the evidence that we now routinely disclose relevant patents, our introduction of additional safeguards in detecting and displaying disclosures, and our updated *Journal-based CME Conflict of Interest Policy* are sufficient to give you confidence in our process. With these changes we consider that we are fully informing our learners and meeting your expectations for accreditation.

We appreciate your ongoing efforts to ensure learners have the transparency they deserve.

Sincerely,



Corinne Broderick  
Executive Vice President



Caroline B. Carregal  
Director, Continuing Education and Certification



Jeffrey M. Drazen, MD  
Editor-in-Chief, NEJM

#### References

1. Azoulay P, Michigan R, Sampat BN. The Anatomy of Medical School Patenting. *N Engl J Med* 2007;357:2049
2. Murray F. The Stem-Cell Market — Patents and the Pursuit of Scientific Progress. *N Engl J Med* 2007;356:2341
3. Kesselheim AS, Mello MM. Medical-Process Patents — Monopolizing the Delivery of Health Care. *N Engl J Med* 2006;355:2036