

*Editorials***FINANCIAL ASSOCIATIONS
OF AUTHORS**

INFORMATION published in medical journals helps shape diagnostic and therapeutic decisions. For a journal to be of value, it must publish authoritative, up-to-date information that is free of commercial influence. For nearly two decades, the editors of the *New England Journal of Medicine*, along with the editors of other journals, have set policies to ensure that the financial associations of authors are disclosed and that published articles are not influenced by those financial associations.¹⁻⁹ These important editorial policies have raised awareness about conflict of interest in medical research and have helped prevent bias — and the appearance of bias — stemming from authors' financial interests. Because relationships between authors and biomedical companies are growing, it is important to reemphasize the principles that underlie the *Journal's* policies on financial associations. In this editorial we reiterate those principles and introduce revisions to our policies that are intended to enhance the depth and breadth of the *Journal's* content while ensuring that the articles we publish are not influenced by financial interests.

The *Journal's* policies were last revised in 1996.⁶ With regard to Original Articles and Special Articles, we will continue to follow the policy that was restated at that time. In such articles, we disclose the sponsorship of the studies and relevant financial information about the authors. During the editorial process, we ask authors for details of their financial relationships with biomedical companies, such as consulting fees, service on advisory boards, ownership of equity (or options thereon), patent royalties, honorariums for lectures, fees for expert testimony, and research grants. In a statement in such articles, we report all relevant financial relationships; if an author has reported no relevant financial relationships, there is no statement. We apply the same policy to Sounding Board articles, Case Records, and Perspectives. Our purpose in publishing financial-disclosure statements is to inform readers of the existence of financial relationships that, in our judgment, are pertinent to the article, and to affirm that we had access to this information during our deliberations.

Review articles and editorials, which summarize published articles and synthesize conclusions but do not present new data, have fallen under a different policy. More than a decade ago, the editors became concerned about the possible influence of commercial associations on viewpoints and opinions expressed in

the *Journal*.^{4,10,11} The policy is laid out in Information for Authors:

Because the essence of reviews and editorials is selection and interpretation of the literature, the *Journal* expects that authors of such articles will not have any financial interest in a company (or its competitor) that makes a product discussed in the article.

Over the past two years we have carefully assessed the pros and cons of this policy. We have evaluated its effect on the recruitment of authors and on the range and diversity of our editorials and review articles, and we have discussed the issue in depth with the *Journal's* editorial board. We have concluded that our ability to provide comprehensive, up-to-date information, especially on recent advances in therapeutics, has been constrained. For example, in the past two years we have been able to solicit and publish only one Drug Therapy article on a novel form of treatment. Certainly, if we publish nothing on a given subject we run no risk of promulgating a biased opinion, but our silence does not serve our readers. Without authoritative review articles written for scholarly journals by the best possible authors, physicians may find that pharmaceutical companies become their chief source of information about new therapies. This situation is not in the best interest of either physicians or patients.

Therefore, beginning with this issue of the *Journal*, we have modified the statement in Information for Authors to read as follows:

Because the essence of reviews and editorials is selection and interpretation of the literature, the *Journal* expects that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article.

The addition of the word “significant” acknowledges that not all financial associations are the same. Some, such as the receipt of honorariums for occasional educational lectures sponsored by biomedical companies, may be appropriately viewed as minor and unlikely to influence an author's judgment. Others, such as ownership of substantial equity in a company, are of greater concern. It is our intent to focus on the financial relationships that, in our judgment, could produce bias, or the perception of bias, in an article. Our definition of a significant financial interest accords with that of the National Institutes of Health (NIH)¹² and the Association of American Medical Colleges (AAMC).^{13,14} The key provision of the definition sets an upper limit on the annual sum that a person may receive before a relationship is automatically considered significant (the limit, currently \$10,000, is referred to as the *de minimis* level). We also regard as a significant interest any holding in which the potential for profits is not limited, such as

stock, stock options, and patent positions. Our policy includes both publicly and privately traded companies, making our definition stricter than that of the NIH and the AAMC. We do not consider ownership of publicly traded mutual funds to represent a significant financial interest. With respect to research grants, our policy will continue to require that authors of review articles and editorials, through their institutions, not have major research support or a major proportion of their funding from relevant companies. We consider interactions that occur within two years before the publication date of an article to be pertinent. Information about financial relationships below the de minimis level but relevant to the article will be disclosed in the *Journal*.

We regard these revisions as guidelines, not rigid rules. In the end, we as editors are responsible for weighing the available facts about each prospective author and for making the decisions we believe will bring the best scientific and medical information to the *Journal*. No *Journal* editor who makes these decisions has any financial relationship with any biomedical company. With these modifications in policy, we can prevent financial interests from infringing on the editorial content of the *Journal*, while at the same time acknowledging that some level of interaction between academia and industry may facilitate the dissemination of scientific knowledge and its application to patient care.

It is essential that our editorial policies allow the *Journal* to fulfill its mission to publish current, authoritative, and unbiased information about advances in medical research. We believe that the modification of our policy on the financial associations of authors of review articles and editorials will allow us to fulfill this mission more successfully. Patients, whose physicians are guided by the information in the *Journal*, will be the ultimate beneficiaries.

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REFERENCES

1. Relman AS. Dealing with conflicts of interest. *N Engl J Med* 1984;310:1182-3.
2. Rennie D, Flanagan A, Glass RM. Conflicts of interest in the publication of science. *JAMA* 1991;266:266-7.
3. Koshland DE Jr. Conflict of interest policy. *Science* 1992;257:595.
4. Kassirer JP, Angell M. Financial conflicts of interest in biomedical research. *N Engl J Med* 1993;329:570-1.
5. Smith R. Conflict of interest and the BMJ. *BMJ* 1994;308:4-5.
6. Angell M, Kassirer JP. Editorials and conflicts of interest. *N Engl J Med* 1996;335:1055-6.
7. The politics of disclosure. *Lancet* 1996;348:627.
8. Campbell P. Declaration of financial interests. *Nature* 2001;412:751.
9. Davidoff E, DeAngelis CD, Drazen JM, et al. Sponsorship, authorship, and accountability. *N Engl J Med* 2001;345:825-6.
10. Relman AS. New "Information for Authors" — and readers. *N Engl J Med* 1991;323:56.
11. Angell M, Wood AJJ. Authors' conflicts of interest: a disclosure and editors' reply. *N Engl J Med* 1999;341:1618-9.
12. Public Health, 42 C.F.R. ch. 1, § 50, subpart F (2000). (Accessed

May 21, 2002, at http://grants2.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm.)

13. Task Force on Financial Conflicts of Interest in Clinical Research. Protecting subjects, preserving trust, promoting progress — policy and guidelines for the oversight of individual financial interests in human subjects research. Washington, D.C.: American Association of Medical Colleges, December 2001. (Accessed May 21, 2002, at <http://www.aamc.org/members/coitf/firstreport.pdf>.)

14. Kelch RP. Maintaining the public trust in clinical research. *N Engl J Med* 2002;346:285-7.

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CARDIAC-RESYNCHRONIZATION THERAPY FOR HEART FAILURE

THE syndrome of congestive heart failure is responsible for substantial morbidity and mortality.¹ Patients with heart failure have shortness of breath and a limited capacity for exercise, have high rates of hospitalization and rehospitalization, and die prematurely. The primary mode of therapy for this syndrome is based on antagonism of neurohormonal pathways (notably, the sympathetic nervous system² and the renin-angiotensin-aldosterone axis^{3,4}) activated in the failing cardiovascular system. Drugs that antagonize these pathways decrease mortality and morbidity²⁻⁴ and in some cases improve the underlying structural abnormalities of the heart, a process termed "reverse remodeling."⁵ On the basis of a large number of clinical trials, a regimen comprising up to six classes of drugs (neurohormonal antagonists, diuretics, and digoxin) has become the cornerstone of therapy for heart failure.¹ Mechanical support with left ventricular assist devices and heart transplantation are reserved for the minority of patients who have severely decompensated heart failure.⁶ Despite these therapeutic advances, it is generally accepted that current therapies do not adequately address the clinical need of patients with heart failure, and additional strategies are being developed.

Approximately 30 percent of patients with cardiomyopathy have intraventricular conduction delay such as left or right bundle-branch block, leading to loss of coordination of ventricular contraction.⁷ This dyssynchronous pattern of ventricular contraction is believed to contribute to the pathophysiology of heart failure, reducing the already diminished contractile reserve of the heart.⁸ Specifically, dyssynchronous contraction exacerbates inefficient use of energy by the heart (a process termed mechanoenergetic uncoupling⁹), and patients with conduction-system delays, indicated by a widened QRS interval on the surface electrocardiogram, have worse clinical outcomes than those with normal QRS intervals.⁷ Accordingly, the idea that cardiac-pacing technology might be used to restore the synchrony of ventricular contraction has been of theoretical interest for over a decade.