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EDITORIALS

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Reporting Financial Conflicts of Interest and Relationships Between Investigators and Research Sponsors

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THE FINANCIAL ASPECTS OF BIOMEDICAL RESEARCH CURRENTLY are under intense examination. Increasing attention and concern have been directed toward the financial ties of individual investigators as well as the complex relationships among researchers, academic medical centers, commercial clinical research entities, and industry.¹⁻⁸ Medical journal editors are responsible for evaluating the scientific validity and credibility of research submitted for possible publication. Editors also have an obligation to present pertinent information related to the financial aspects of the articles they publish so readers can interpret the findings in light of this information. THE JOURNAL has policies governing financial aspects of manuscripts submitted, reviewed, edited, and published.⁹ Herein, we describe a more specific policy for reporting authors' financial conflicts of interest and a new policy for reporting relationships between investigators and research sponsors.

Conflicts of interest are considered to be "ubiquitous and inevitable in academic life, indeed, in all professional life"¹⁰ and may be "as unavoidable in academic science as they are in the rest of life."¹¹ Although many definitions have been put forth,¹² the Association of American Medical Colleges has described conflict of interest in science as "situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research."¹³ Such conflicts may be potential or actual, perceived or real, and harmful or insignificant.¹² Conflicts of interest represent the potential for biased judgment, but are not an indicator of the likelihood or certainty that such judgments or compromises will occur.^{11,14}

Biomedical researchers may experience numerous potential conflicts of interest, including pressures related to academic advancement, enhanced reputation, recognition from peers, increased patient referrals, enhanced competitiveness for grant funding, and media attention.^{10,14,15} These "non-financial" conflicts of interest certainly are strong and influential and may pose a threat to scientific objectivity. How-

ever, financial interests warrant special consideration because in addition to their potential threat to scientific objectivity, they are discretionary, relatively simple to quantify, and usually relatively easy to understand.^{12,14} Moreover, the idea that researchers, and especially physician-researchers, might realize substantial financial gain from conducting research studies involving patients can alarm the public and can threaten the credibility of biomedical research.

Unlike many of the other potential conflicts of interest, financial conflicts of interest usually are not apparent unless they are specifically disclosed.¹⁰ Full disclosure is considered an important method for reporting and managing conflicts of interest and serves to highlight the potential for bias, but cannot and does not eliminate the conflicts.¹¹ On the other hand, failure to prospectively disclose relevant financial interests violates the public's trust, and if such information is revealed subsequently, the credibility of the investigators and of the journal that publishes the work may be seriously damaged.

Since 1985, THE JOURNAL has requested authors to disclose financial interests related to the subject matter of their research¹⁶ and since 1989 has required authors to submit signed financial disclosure statements.¹⁷ In the years that have followed, and because of increased concern about conflicts of interest, we have made our policies for reporting financial interests more stringent and more specific. As outlined in the Instructions for Authors in this issue of THE JOURNAL,¹⁸ authors are required to report detailed information regarding all financial and material support for the research and work, such as grant support, funding sources, and provision of equipment and supplies. Each author also is required to sign and submit the following financial disclosure statement: "I certify that all my affiliations with or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, royalties) with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript are completely disclosed."

Authors are expected to provide detailed information about any relevant financial interests or financial conflicts, particu-

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larly those present at the time the research was conducted and up to the time of publication, as well as other financial interests, such as relevant filed or pending patents, that represent potential future financial gain. Although many universities and other institutions and organizations have established policies and thresholds for reporting financial interests and other conflicts of interests,^{7,19-22} THE JOURNAL requires complete disclosure of all relevant financial relationships and potential financial conflicts of interest, regardless of amount or value. If authors are uncertain about what might constitute a potential financial conflict of interest, they should err on the side of full disclosure and should contact the editorial office if they have questions or concerns. In addition, authors who have no relevant financial interests are now asked to provide a statement of active negative disclosure, indicating that they have no financial interests related to the material in the manuscript.

Individual signed financial disclosure statements from authors are not sent to peer reviewers. However, THE JOURNAL routinely includes in published articles detailed information about the type and nature of authors' financial interests. Decisions about whether financial information provided by authors should be published, and thereby disclosed to readers, are usually straightforward. Although editors are willing to discuss disclosure of specific financial information with authors, our policy is one of complete disclosure of relevant financial interests. Published financial disclosures usually appear on the first page of the article near the author affiliation information or, if necessary for space considerations, may appear in the acknowledgment section of the article, just before information about grant support and other financial or material support.⁹ For articles in which a financial disclosure statement is not included, readers should infer that the authors have reported to the editors that they have no relevant financial interests that require disclosure.

In addition to requiring information on financial interests from authors, THE JOURNAL has, since 1987, routinely requested all peer reviewers who complete a manuscript review to disclose any potential conflicts of interest, financial or otherwise, they may have related to that manuscript.²³ Such information is kept confidential and is not revealed to the authors of the manuscript or to other reviewers. Peer reviewers who believe they have a conflict of interest (financial or otherwise) that prevents them from providing an objective review are instructed to disqualify themselves from reviewing that paper and to return the manuscript without completing a review.⁹

All JAMA editors and editorial board members also are required to sign statements for disclosure of conflicts of interest, including financial interests, and are required to disclose to the Editor (in-Chief) all potential conflicts of interest and relevant financial interests. Editors are expected to disqualify themselves from any involvement (eg, evaluation, review, editorial decision making) about any submission to THE JOURNAL that deals with any matter in which they or a mem-

ber of their immediate family have a direct or competing financial interest. Editors also are strictly prohibited from using any confidential information obtained from their editorial activities with THE JOURNAL to further their own or others' financial interests or for their own professional or personal gain.

Another important and increasingly prevalent aspect of medical research that can lead to conflicts of interest involves the relationships between scientific investigators and industry and the direct involvement of study sponsors in the research. Industry invested approximately \$55 to \$60 billion in research and development in 2000 (compared with \$25 billion in US federal spending on research),¹ and industry also provides an estimated 70% of funding for clinical drug trials in the United States.⁶ Without industry-sponsored research, some important advances and discoveries in medical research might not occur.

However, active involvement in and control of research investigations (such as control of data, performance of statistical analyses, complete authority over manuscript preparation and decisions to submit for publication) by companies whose products are being evaluated and who have a vested financial interest in the study outcome represents a clear conflict of interest. Moreover, this level of involvement and control of the research could be viewed as the sponsor having the potential to influence the study results and might create doubts about the validity of the research. These concerns are not without foundation; previous reports have documented several major problems in some industry-sponsored studies, including issues related to trial design, data availability, and control over publication.^{6,24,25}

Consistent with the approach previously suggested by the International Committee of Medical Journal Editors,²⁶ THE JOURNAL will continue to require that in addition to identifying the source of financial support for the study, the role of the funding organization or sponsor in the design and conduct of the study, in the collection, analyses, and interpretation of the data, and in the preparation, review, approval, or control of the manuscript should be specified.¹⁸ As with other authors of the paper, employees of the research sponsor who are listed as authors on the manuscript should report their specific contributions to the work and to the manuscript.²⁷ Other employees who made contributions to the paper, such as data collection or analysis, or editing or writing assistance, should be listed in the acknowledgment section of the manuscript.¹⁸

For industry-sponsored research studies, an investigator who is not an employee of the sponsoring company, and who ideally is the principal investigator, should provide a statement that he or she "had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analyses."¹⁸ For some studies without industry sponsorship or funding that report original data, especially multicenter investigations, at least one author, such as the principal investigator, will be asked to provide this statement. In addition, we strongly encourage

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that the data analyses for industry-sponsored studies be conducted by an independent entity, such as by biostatisticians at an academic center, rather than only by statisticians employed by the company sponsoring the research.

As another mechanism to help assure complete reporting of study outcomes, the editors may request and review the original study protocol for any research investigation. These approaches should help convince readers about the integrity of the data and analyses presented, and should help eliminate uncertainty that some readers might have because of the sponsor's involvement in the research.

In an ideal world, physicians, patients, and the public would not have to be concerned about conflicts of interest related to medical research or have questions about the role of sponsors in industry-funded research. However, to respond to these current real-world concerns, THE JOURNAL will require clear reporting of authors' financial conflicts of interest and clear description of the involvement of sponsors in medical research. Even though we recognize that these efforts are not fail-safe, we hope that such reporting will help to ensure the integrity of medical science, enable readers to interpret the results of scientific studies appropriately, and maintain public confidence in biomedical research.

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