Editor's Note: Conflicts of Interest at Medical Journals

Mayo Clinic Proceedings received a large number of letters to the editor and other communications in response to the commentary by Hirsch and the accompanying editorial by Lanier, both addressed bidirectional conflicts of interest (COIs) at medical journals, published in the September 2009 issue of the journal. These communications were evaluated individually and in aggregate by a panel that consisted of both editorial board members and other invited peer reviewers. Submissions were selected for publication on the basis of attributes such as the novelty and clarity of the messages, unique speculative synthesis of information, or introduction of new concepts that the panel thought deserved additional attention. Several of the authors were asked to revise their submissions to improve the quality of the communication and eliminate unnecessary repetition with other submissions. The results of this process, as well as responses from Hirsch and Lanier, are provided herein.

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Conflicts of Interest, Authorship, and Disclosures in Industry-Related Scientific Publications

To the Editor: I applaud *Mayo Clinic Proceedings* for publishing the provocative piece on the oversight of medical journals by Hirsch[1] and the thoughtful accompanying editorial.[2]

The American Association of Clinical Endocrinologists (AACE) recognizes the various "interests" that physicians have. This is reflected in our Position Statement on Physician/Industry Relationships,[3] which states "There is no inherent conflict of interest in the working relationship of physicians with industry and government. Rather, there is a commonality of interest that is healthy, desirable, and beneficial."

Medical journal editors are among those who have "commonality of interest." These interests include the public, the scientific community, the journal's readership, the advertisers, and the organizations they serve. A few notable examples of this commonality of interest are those which Mayo Clinic shares with *Mayo Clinic Proceedings* and the American Medical Association shares with the *Journal of the American Medical Association*.

Historically, and I would argue justifiably so, our editor-colleagues have been entrusted with substantial power to influence the practice of medicine. At the same time, we have expected them to be balanced and transparent. Hirsch points out that this trust may be subject to violation and that such violation may never be entirely preventable despite exhaustive disclosures and onerous restrictions on editors. Indeed, the theory that closely monitoring and regulating physician interaction with industry is the key to ensuring integrity has yet to be supported by balanced scientific evidence. Nonetheless, Hirsch makes a cogent argument that disclosure requirements for journal editors who are entrusted with accepting or rejecting manuscripts or who publish their own manuscripts should be as rigorously scrutinized as those being aggressively promoted for the medical community at large–perhaps no more, but certainly no less.

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2. Lanier WL. Bidirectional conflicts of interest involving industry and medical journals: who will champion integrity [editorial]? *Mayo Clin Proc*. 2009;84(9):771-775.
3. American Association of Clinical Endocrinologists; American College of Endocrinology. AACE and ACE Position Statement on Physician/Industry Relationships. http://www.aace.com/pub/pdf/guidelines/AACEandACEPositionStatementonPhysician.pdf. Accessed December 4, 2009.

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To the Editor: We are responding to the recent article by Hirsch[1] and in particular to his statements regarding *Neurology's* authorship policy.

The ICMJE's (International Committee of Medical Journal Editors) definition of authorship[2] appears in the Instructions for Authors of most journals. Hirsch contends that all authors, as defined by the ICMJE criteria, meet rigorous standards and are intimately familiar with the work. However, those listed in the byline are often "qualified" because they contributed only in 1 or 2 of the listed criteria, whereas others who fulfill none of the criteria are included because they obtained funding or generally supervised the research.

Hirsch misrepresented the importance of the intellectual contribution of first drafts of manuscripts. A common industry practice is to use a professional writer to generate a first draft of a manuscript to facilitate the engagement of a "guest" academic author. Although there may be instances when a first draft by a professional writer is revised beyond recognition by the academic and scientific coauthors, it seems self-evident that a first draft of a manuscript generally serves as the intellectual framework of all subsequent revisions and modifications. We at *Neurology* think that the author of the first draft of a manuscript should be recognized. At *Neurology*, we have created another definition of authorship, one that is just as rigorous but more transparent, so that readers are in a better position to judge the work:

"*Neurology* defines an author as a person who has made a substantive **intellectual contribution** to the submitted manu-

script. A substantive contribution includes **one or more** of the following: design or conceptualization of the study; **OR** analysis or interpretation of the data: **OR** drafting or revising the manuscript for intellectual content. Professional writers employed by pharmaceutical companies or other academic, governmental, or commercial entities who have drafted or revised the intellectual content of the paper **must** be included as authors."[3]

Each person involved in the study, whether funded by industry or not, must disclose his or her contribution in an online form, including anyone who has written the first draft or has responded substantively to reviewers' comments; therefore, we eliminate ghostwriters and guest authors. We opted for transparency based on the assumption that even a major contribution to a study does not necessarily imply that one's knowledge is sufficient to communicate or defend the entire work. Nevertheless, such contributions should be attributed; certainly, many (technicians, graduate students, or writers who have set the tone and direction of the study or of the paper, even though it may be heavily revised subsequently) deserve such recognition with an accurately stated description of the contributions to the paper. Hirsch's desire to cover up the work of professional writers is disingenuous. We at *Neurology* believe that our readers deserve to know who contributed to the intellectual content of studies and the resulting manuscripts.

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Dr Gross receives a stipend as Editor-in-Chief of *Neurology,* and Dr Knopman receives a stipend as Deputy Editor-in-Chief. Ms Baskin is employed by the American Academy of Neurology, publisher of *Neurology.*

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To the Editor: We read with great interest the recent article by Hirsch[1] and the accompanying editorial[2] and appreciate that a venue for rational discourse has been opened. Recently, we have all witnessed increasing scrutiny and regulation of the relationship we, as clinical educators and investigators, have with our partners in industry and the continuing medical education (CME) providers with whom we work. What has been missing from this important dialogue is a concerted response from those who have worked with the pharmaceutical industry and providers of CME to present the opinion that these interactions are in fact of real value. Certain evolving institutional and national trends now in the public domain may seriously curtail the interactions between clinical educators and investigators, industry, and CME providers. This will diminish clinical investigation and education alike, with a consequent negative effect on patient care.[3,4] Indeed, many institutions are considering the adoption of a "zero involvement" policy, which would substantially limit physician involvement in CME activities and new drug development. Although some rare abuses have occurred and we recognize that the risks in this interaction are real, we should nonetheless avoid overzealous, ill-judged, and restrictive regulations that will curtail the current constructive interaction.[3,4] These partnerships have otherwise resulted in unprecedented advances in our field, with a subsequent dramatic improvement in patient outcome,[5-12] and to impede this progress in the treatment of multiple myeloma would be a disservice to our patients and their families.

Accordingly, we as clinical researchers and educators dedicated to the treatment of multiple myeloma assert the following:

1. Synergistic interactions between physicians and the pharmaceutical industry have contributed to the development of safe and effective therapeutics that have improved individual patient outcome and thus have contributed to the greater good of society.

2. The overwhelming majority of interactions between academia and industry have been positive, productive, ethical, mutually respectful, and driven by the shared desire to bring better treatments to patients with multiple myeloma.

3. Conflict of interest concerns in these relationships have been exaggerated and diminish the integrity of physicians and coworkers engaged in clinical research in the public eye.

4. Rather than dwell on perceived worst-case scenarios, we believe that the evidence points to the overwhelmingly positive aspects of clinician-industry interaction and that a "confluence of mutual interest" exists. This congruence has served to advance the field forward faster than could ever be obtained with a "silo" approach to research, which minimizes interaction and stifles progress.

5. We believe that industry-academia interactions, conducting shared research under commonly agreed upon guidelines characterized by full disclosure and clear transparency, are in the best interests of all, and in particular our patients.

6. We believe that enforced disengagement of such partnerships will help no one and hurt many.

7. The support provided by industry for professional meetings and publications designated to promote and foster

research as well as education is a major factor in contributing to the clinical development and subsequent deployment of effective therapies in a timely manner.

8. The support provided by industry to commercial CME providers, with independent review of content for fairness and balance, has resulted in the development and implementation of a variety of educational events directed toward physicians, patients, and allied health care personnel, which has improved their understanding of the disease, the benefits and risks of different treatment strategies, and the existence of additional resources to help in patient care. Through these educational events, the quality of care delivered to patients with myeloma has improved. By accelerating deployment of new therapies, lives have been prolonged and toxicities of treatment decreased.

9. We believe that this learning activity is of high value to the recipients of such education, especially to patients. As such, remuneration to experts of content and presentation for their time (often spent away from family) is reasonable, necessary, and professionally acceptable.

10. Consulting and participation in advisory boards by highly informed specialists with first-hand experience of novel therapeutics, both clinically and preclinically, are important activities of high value to industrial partners during the development of safe and effective new drugs. Optimal sharing of this knowledge occurs with investigators who care for patients and are engaged in clinical research, thus representing a bona fide exchange of information; remuneration for this work is reasonable, necessary, and professionally acceptable.

In aggregate, within the proper boundaries of full disclosure and compensation at fair market value for the effort involved, these interactions should not be limited, but rather encouraged with appropriate guidance and within agreed upon guidelines.

The importance of strengthening these relationships to further improve outcome for our patients with this otherwise incurable hematologic malignancy remains the fundamental principle guiding us. Efforts to decouple these relationships and so weaken the partnership can only be to the detriment of all, in particular our patients.

The Position Statement was authored by the following Myeloma Clinical Researchers and Educators, who fully endorse the statements herein.

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To the Editor: The commentary by Hirsch[1] was enlightening and provided insight into the issues surrounding COIs regarding medical journals. However, the issues he raised simply support the concerns that health information consumers, like me, have with industry-based research being published in peer-reviewed journals. Even 3 years after his employment with Merck, Hirsch still has the need to support his former employer's actions. Such loyalty is to be expected but confirms why industry-based research reports should be held suspect of reporting bias. Savvy health information consumers cannot turn a blind eye to who is sponsoring the research.

Affiliations and funding sources are important to report, and I appreciate that peer-reviewed journals expect such disclosure because these factors do play an important role in how the results and conclusions are weighed in the reader's mind. Why do pharmaceutical companies not produce their own publications to report the research they are performing?

I do not agree with Hirsch's contention that just because an article passed peer review it should be accepted. First, if a student passes an examination and is later found to have cheated, should the student not be punished for cheating? Second, I do not agree that authorship is an art. Those who did the work should be acknowledged as the authors. If a student hands in a paper that was written by someone else, should the student not be punished for cheating?

I doubt that tobacco and chemical companies will ever report that smoking and/or exposure to chemicals causes cancer. Similarly, we cannot expect that pharmaceutical companies will ever publish research showing their products to be ineffective; however, this has not stopped them from publishing research that supports their assertion that their product is no less than or just as effective as their competitor's products.

I understand Hirsch's point that professionals working in industry-based research may be held back in their professional careers, but that is the price one pays for higher salaries vs what academics give up for academic freedom. Of course, the blurring of the distinction among collaborating disciplines due to economic necessities raises issues that need to be resolved when such mixing results in ethical gray areas.

For example, I am concerned that many respected medical experts in their specialty areas who readily accept consulting positions with pharmaceutical companies do not think this would compromise their ability to be impartial in determining the optimal treatment if treatment involves their company's product. Additionally, I am troubled when I hear at medical conferences, even if spoken in jest, that statins should be added to drinking water because that would be easier than trying to convince people to eat healthier.

With the national hypertension and cholesterol guidelines in need of updating, I question whether there will be enough untainted experts to sit on the committees to update these guidelines. Just because the practice of pharmaceutical consulting is pervasive, it does not necessarily indicate that such practices are professionally ethical. I suggest at least a 10-year moratorium for any expert who would sit on these committees and severing all financial ties at least 2 years before volunteering for these committees through 5 years after the guidelines have been implemented.

Finally, many ethically compromising practices, such as guest and ghost authorships, should not be tolerated by the professions that value scientific research for what it should provide toward the advancement of medical knowledge—that the optimal treatment has been discovered through unbiased research.

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*To the Editor***:** In September 2009, *Mayo Clinic Proceedings* published a commentary by Dr Laurence Hirsch[1] that broadly attacked our personal and academic integrity on the false premises that we had not disclosed our COIs and that our research findings were flawed and biased. The criticism was directed at 3 of our published articles[2-4] that described conflicted and unethical collaborations between physicians and industry that distorted clinical research and patient care, particularly acts by physicians and by Merck & Co (Whitehouse Station, NJ) during the development, evaluation, and promotion of rofecoxib (Vioxx). Of these 3 articles, 1 focused

on ghostwriting and guest authorship[4] and was particularly relevant to Hirsch, a former employee at Merck who oversaw medical communications related to Vioxx, including many of the clinical trial articles discussed in our articles.

Although Hirsch repeatedly criticizes our lack of disclosure, it should be noted that he did not disclose the extent of his past role in the publication of Merck-sponsored clinical trials, including those of Vioxx, nor the extent of his current financial relationship with Merck with respect to company stock or options, after many years of employment at the company. To be clear, within the financial disclosure section of our articles, we not only disclosed our role in the litigation at the request of plaintiffs as a potential COI but also reiterated it within the articles' text. No reader of our articles would have been unaware of our relationship to the litigation.

In addition, Hirsch repeatedly denigrates our research contributions. However, he provides no evidence for why he believes our case-study reviews of documents produced as a part of litigation against Merck do not represent research. Reviews of litigation documents have been previously used by other investigators to study issues at the intersection of litigation and health, particularly with tobacco[5,6] and pharmaceutical[7,8] products. Most importantly, Hirsch presents no evidence beyond hearsay to support his assertions or contradict our findings: articles related to Vioxx were ghostwritten and guest authored[4] and a seeding trial was developed by Merck's marketing division to promote prescription of Vioxx.[2]

Finally, among several errors and misstatements, Hirsch declared that one of us (H.M.K.) had received more than $300,000 for work as a consultant at the request of plaintiffs in litigation against Merck & Co related to rofecoxib, suggesting it undermined our research integrity. This amount is inaccurate because it reflects the sum paid to him (H.M.K.) and several research assistants (including J.S.R.), which is clearly stated in Hirsch's source, a rapid response comment by a lawyer who was at that time paid to represent Merck in the Vioxx litigation.[9]

We regret that *Mayo Clinic Proceedings* did not provide us a lengthier opportunity to address the many allegations raised and errors made within Hirsch's extensive commentary and to defend our research and academic integrity, as it was purportedly published in "the spirit of opening the door to a discussion."[10]

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Drs Ross and Krumholz were previously consultants at the request of plaintiffs in litigation against Merck & Co related to rofecoxib in the United States. During the past 5 years, Dr Krumholz has had research contracts with the American College of Cardiology, the Colorado Foundation for Medical Care, and the Centers for Medicare & Medicaid Services. He has previously served on the advisory boards of Alere and Amgen and currently serves on one with UnitedHealthcare, is a scientific advisor for Centegen, has been a subject expert for VHA, has received speakers' compensation from the American College of Cardiology, is an Associate Editor of *Circulation*, and is Editor-in-Chief of *Circulation: Cardiovascular Quality and Outcomes* and *Journal Watch Cardiology* of the Massachusetts Medical Society.

This letter was not directly supported by any external grants or funds nor was it sponsored by plaintiffs' attorneys or in any way related to trial work. Dr Ross is currently supported by the National Institute on Aging (K08AG032886) and the American Federation of Aging Research through the Paul B. Beeson Career Development Award Program. No attorneys or others related to the litigation had any role in the writing, review, or approval of the letter, and the authors were responsible for the decision to submit the letter for publication.

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To the Editor: I congratulate *Mayo Clinic Proceedings* for undertaking an important and necessary effort in publishing the commentary by Hirsch[1] on COIs and the accompanying editorial.[2]

I am a practicing physician involved with clinical research and treatment of AIDs and human immunodeficiency virus disease. In my 24 years of experience, I cannot overstate my gratitude to clinical researchers and the pharmaceutical industries for their accomplishments. As I often reflect, had great opportunity for profit not motivated the owners of these companies, these drugs may never have been developed. Furthermore, had the owners of these companies not paid the researchers adequately, they may not have been able to retain and engage the type of people who have led to these wonderful breakthroughs and advances in drug developments.

Therefore, I have watched with shock the evolving witch hunt against pharmaceutical companies. Just as there are great physicians and poor physicians, good politicians and bad politicians, I am sure there are good drug sales managers

and bad drug sales managers, good drug CEOs and bad drug CEOs.

The tenor of recent guidelines in publications is that pharmaceutical companies are not to be trusted in general. This is not fair. We judge the work of our colleagues on the basis of what they do and what they accomplish, not on the basis of who pays them or how they are paid. I hold the same standards for pharmaceutical companies. Whether I like or dislike Amgen, whether I like or dislike the National Institutes of Health, I judge the work of people from those institutions on the basis of its quality and honesty, not by who writes the paycheck of the investigators. Also, I hold them to the same standards.

It is time for all of us to realize that most of us need to earn a living. Whether we earn our living from the government, from the corporation that runs Harvard University, or from the corporation that runs Johnson & Johnson, we must earn our money, and we want to be paid well. This is not inappropriate; it is appropriate. We should not simply assume that because someone is paid either more or less or by one person or another person, that the quality of his or her work or his or her integrity is either better or worse.

I hope that *Mayo Clinic Proceedings* will help us focus on the quality and innovation of medical research, rather than quibbling about the authors' employers. I pray that the pharmaceutical advances of the past 40 years are a harbinger of future progress, and not the golden age forever gone.

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1. Hirsch LJ. Conflicts of interest, authorship, and disclosures in industry-related scientific publications: the tort bar and editorial oversight in medical journals. *Mayo Clin Proc*. 2009;84(9):811-821.
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In reply: I concur with Dr Garber that there is far more commonality of interest than COI between industry, physicians, and academia and applaud the AACE for taking a clear stand. Although I used the term *conflict* throughout my commentary, I believe the time has come to stop its indiscriminate use. The term *conflict of interest* can prejudice the audience or reader to the material being presented and to the presenter(s), a form of framing bias that leads to presumptions of guilt until proven innocent; the term *competing interests* is much more neutral. Dr Garber's support for balanced and equitable implementation of COI-disclosure policies by journal editors is greatly appreciated.

The editors/staff of *Neurology* (Baskin, Knopman, and Gross) conclude that I wish to "cover up" medical writers' contributions, yet there is no such suggestion in my commentary. I argued that, although some writers might meet authorship criteria (due to meaningful intellectual contributions), others often do less and should simply be acknowledged, case-by-case. The example I gave of a first draft being revised "beyond recognition" may not be common, but there is no "one-size-fits-all" model.[1] To wit, writing the first draft of a manuscript de novo often warrants authorship, but if an investigator interprets study results; chooses data displays, key references, and points of discussion; develops an outline for the paper; and *then* uses the services of a professional writer, the latter essentially acts as a [skilled] facilitator. The investigator makes the "substantive intellectual contribution," and acknowledgment is more appropriate for the writer, in my view. This distinction is frequently not a simple black-and-white decision, as discussed in my commentary. I concur that the contributorship model of attribution may be preferable to current approaches.[2]

I did not state that someone who meets all 3 ICMJE authorship criteria[3] "must" be intimately familiar with the work, able to defend it, etc. However, it stands to reason that someone who meets all 3 of those criteria is more *likely* to be able to "...take responsibility for the conduct of the research,"[4] or to "…defend the entire work" than someone who meets only 1 criterion, as *Neurology* advises. Baskin et al contend that authors today are often named on a byline for doing far less than meeting the 3 ICMJE authorship criteria (for instance, obtaining funding or general research supervision). I could not agree more. I argued that such guest or honorary authorship due to "local academic politics" that is being positioned by critics of industry as acceptable solely because it does not involve the pharmaceutical industry[5] is a kind of double standard. All would benefit if authorship criteria were applied evenly, regardless of a scientist's affiliation. The *Neurology* approach will be more inclusive; the traditional ICMJE standards more restrictive. Whether one approach is "better" than the other remains to be seen.

In their Position Statement for Myeloma Researchers and Educators, Fonseca et al concisely outline the value of industry interactions with physicians, medical associations, and academia, especially for the development of medical interventions, training of health care professionals in optimal use, and industry support of professional meetings and other CME activities. With appropriate disclosures and payments at market value for bona fide services, collaborations with industry by experienced clinicians, educators, and researchers are indeed beneficial and advance the state of health care. Yes, abuses of such interactions have occurred, but they are the exception, and Fonseca et al warn against the potential harms of overzealous forced disengagement of such partnerships.[6] Note that the editor of *JAMA* was a coauthor on the article that advocated such disengagements, which was published in *JAMA*. Readers were asked to simply accept the disclaimer that the editor "…was not involved in the editorial review of or decision to publish the article"[6] and the implication that this prevented any COI for the others at *JAMA* who were involved in those roles.

Jung raises skepticism about various issues related to industry-based research publications in peer-reviewed journals, from the perspective of a health information consumer. How-

ever, I believe she misunderstands and/or misrepresents many aspects of my commentary—it certainly was not a defense of or support for my "former employer's actions." I objected to editors implementing very different degrees of disclosure depending on the apparent "tilt" of an article as generally supportive or critical of industry or of a product, the censoring of work from consideration for publication without review of content, etc.

Jung asks why drug companies do not produce their own publications to report their research. I cannot tell if this is a serious or rhetorical question. Companies cannot publish their research other than in independent, credible scientific journals, or it would be considered product promotion subject to regulation by the Food and Drug Administration.

Jung's comment that drug companies would not "ever" publish research that shows that their products lack efficacy is uninformed. Every week top-tier medical journals publish "negative" industry-supported clinical trials; a few examples of large randomized studies during my tenure at Merck that were not positive for the Merck product are referenced.[7-9] Her concern about medical experts working as consultants to industry is addressed in the Myeloma Position Statement by Fonseca et al. Jung's suggestions for long-term moratoriums, up to 10 years for experts to sit on national guideline advisory committees, are precisely the kind of damaging forced disengagements between industry and physicians, academia and medical associations that Fonseca et al warn against and which are not supported by analyses of several hundred Food and Drug Administration Drug Advisory Committee deliberations.[10]

Regarding statin trials, Jung should know that most of the major statin outcome studies performed since 1994 have been sponsored or supported by industry, and there is no apparent difference in the outcomes of such studies vs the few that were sponsored or funded by government or other agencies.[11,12] I do not argue to "put statins in the drinking water," but patients would fare better if we had more interventions for chronic diseases with the safety, tolerability, and effectiveness profiles of the statins. We should appreciate the enormous amount of high-quality research funded by industry to develop these drugs and demonstrate their value.

Ross and Krumholz question the validity of my commentary on a number of grounds, one of which was my supposed lack of disclosure regarding my work at Merck that was related to clinical trial publications, for Vioxx (rofecoxib) in particular, and about my "current financial relationship with Merck with respect to company stock options…," etc. I spelled these out both in my disclosure statement and early in the body of my article; however, I will add that the Medical Communications Department that I headed did not play a role in 2 major Vioxx publications–the VIGOR trial and the ADVANTAGE trial. Both were written and submitted before the department was formed. I addressed at some length the development of the Vioxx 078 publication in my commentary and rejected the notion by Ross et al[13] that it had been ghostwritten, as did the authors.

Regarding my financial relationship with Merck, I wish I had more to report. Merck stock peaked in the late 2000-January 2001 period and progressively declined during the ensuing years, dropping 35% to 40% immediately when Vioxx was withdrawn. Stock options awarded from 2001 forward, and even those for 2 or 3 years before 2001, quickly went "underwater." When I left Merck in 2006, only my option grants of the last year or 2 had any positive value (a few dollars per share) and had to be exercised within 3 months of leaving the company. I earned approximately $9400 for all options I could exercise when I left Merck. Restricted stock units, a relatively new form of long-term compensation for some employees, had not vested and had zero value. I purchased 400 shares of Merck stock outright at that time, thinking it was probably a good long-term investment. The commentary caused no reaction in financial markets, nor did I expect it to. The implication that I might have been motivated to write my article because of my financial relationship with Merck is baseless.

What I objected to in my commentary regarding disclosures in the 3 articles published by Ross, Krumholz, and Hill et al[13-15] on rofecoxib were statements that are as vague and uninformative as the classic acknowledgment about a medical writer: "We thank Mary Smith for editorial assistance." There is practically universal agreement today that such disclosures are inadequate. In the first of their articles,[14] there is only a statement in the opening paragraph that the authors "…[participated] in litigation at the request of plaintiffs…" and the formal disclosure that "All authors have been consultants at the request of plaintiffs for recent suits against Merck related to rofecoxib." To reiterate my objection, there was no mention of any of the authors being compensated, nor of appearing as expert witnesses in court, etc. The disclosure statements in the 2 other publications mentioned that the authors had been compensated.

I sincerely regret and apologize to Dr Krumholz for misstating his income received for work as a consultant to attorneys such as Mark Lanier in plaintiffs' litigation against Merck. I said it was "more than $300,000" as of January 2007. In fact, the total was "roughly $300,000" for Dr Krumholz and his assistants at that time,[16] and court testimony indicates that about half, or $150,000, was for Dr Krumholz.[17] A very recent article reports that Dr Krumholz personally received "some $200,000" for his work related to rofecoxib litigation.[18] Again, I apologize for misstating Dr Krumholz' income.

Ross and Krumholz contend that because documents obtained in legal discovery proceedings have been used previously for "research" publications, this validates their work on rofecoxib as published. I disagree and objected to the 1-sided nature of *all* such tort-based publications, facilitated by editors of leading journals with clear biases against "industry." I never argued to prevent publication of such work. Instead, I suggested that editors provide some balance in this process by providing a small, finite period for the company or organization accused of misconduct in manuscripts [based on legal discovery] to be able to respond, at the same time, in the same issue. "Research" based on legal discovery proceedings, whether called a *case study* or other euphemistic term, deserves distinctly different handling by editors of medical journals.

Ross and Krumholz complain that they were not provided longer space to address allegations and errors and to defend their research integrity, etc. I understand (and note the irony in this) because it is usually a company that is in that position. I received dozens of e-mails from readers in the United States, United Kingdom, Europe, and Latin America after publication of my commentary and Dr Lanier's editorial. With a single exception, roughly 90% were supportive; the remainder spoke of appreciating a different perspective, including 1 or 2 from journalists. In this regard, I believe my commentary was successful, and I stand by what I wrote.

Laurence J. Hirsch, MD

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In reply: I thank all who contributed to the discussion of bidirectional COIs at medical journals, published in the September 2009 and January and February 2010 issues of *Mayo Clinic Proceedings*. I also express appreciation to the members of the journal's editorial board and the peer reviewers who worked with Dr Hirsch, me, and the authors of letters to critique, select, and offer suggestions to improve the writings eventually published in this journal. I can speak only as a recipient of this process; I am impressed and thankful for the helpful suggestions offered.

The numerous letters, memos, and telephone conversations directed to the journal's staff, editors, and authors on the issue of bidirectional COIs represented one of the greatest responses to journal content in recent memory. Clearly, this topic struck a nerve with many *Proceedings*' readers: typically physicians engaged in the daily care of patients.

The overwhelming majority of communications were supportive of the *Proceedings* addressing the issue of bidirectional COI and of the writings by Hirsch and Lanier that expanded the discussion. Perhaps the most common comment I heard was astonishment that many leading journals, editors, policy makers, and published authors had so exhaustively represented 1 side of journals dealing with the ills introduced by financial COI (particularly those involving drug companies) but had been so remiss in presenting counterarguments or in discussing the larger risk-benefit equation (including a discussion of tort litigation) as it relates to the discovery, invention, and introduction of drugs and medical devices. No correspondent tried to excuse industry-associated misdeeds; he or she simply wanted a broader discussion of the issues.

From the various comments shared with me, I inferred that many of those speaking had firsthand experience with smaller specialty and subspecialty journals, in which editors tend to be more intimately related to those they serve and are chosen for their demonstrated expertise as clinicians, investigators, and providers of CME information. Such editors tend to remain in good standing with their sponsoring organizations and constituents because they are approachable and maintain (through ongoing activities) the clinical, investigational, and educational ideals their constituents admire. In contrast, the largest, most influential medical journals often function as multimillion dollar corporations. Editors may be selected not predominantly on the basis of the credentials aforementioned but instead on other credentials important to the journal, including a history of administrative experience at that journal or similarly complex (typically academic) venues and a presumed ability to advance the many missions inherent to a major journal (including numerous high-visibility presentations such as speaking publicly on issues of national and international medical ethics, health care policy, etc). The journal-as-a-corporation scenario carries with it an increased risk of editors acquiring distance and insulation from the journal's constituency.

Editors' ideas that evolve in isolation can be reinforced by like-minded individuals recruited to be a part of the journal's leadership team. It is not difficult to envision that, in such an environment, journal leaders can easily assume that they have special insights into critical issues and assume a posi-

tion of advocacy for a given position. The rules of deportment that are critical to the integrity of scientific publishing may be seen as less applicable to supporters of a given position than to its critics or vice-versa. Rules of disclosure,[1-5] condemnation of repetitive publication,[6] and other issues may be applied unevenly,[7-9] despite public comments otherwise: ie, "…don't publish papers in more than one place…authors must toil along one publication at a time…."[6] Unfortunately, when making such standards operational, editors sometimes find it easier to talk the talk[1-6] than walk the walk.[7,9] For example, the 5 editorials from the ICMJE on reporting standards, disclosure of COI, and related issues initially published on its Web site[1-5] have now been repeatedly published in multiple indexed medical journals for a total of 60 publications, inflating the PubMed listings of leading ICMJE members by some 55 items (last confirmed, January 8, 2010). The fact that there was repetitive publication and the reputational COI it introduced has not been appropriately disclosed by the authors.

Such capricious application of scientific publishing's rules and traditions will contribute to the long-term deterioration of journals' and editors' credibility and influence, to the benefit of no one.

Mayo Clinic Proceedings has taken another approach, outlined in numerous editorials, commentaries, editor's notes, and other publications,[9-11] that, simply stated, we will treat those with whom the journal's leadership agrees and those with whom we do not agree with equal respect, using the same rules of engagement. We will attempt to avoid a unilateral advocacy position, recognizing that many of the great failings of science in general have resulted from advocacy on the part of "controllers of science." Furthermore, *Mayo Clinic Proceedings* leadership has proclaimed that its work is not complete until the public has had a chance to respond to sentinel publications in the journal.[9-11] This was true for our reports on Gulf War illnesses (August 2000)[12,13] and the response(s) that followed (November 2000),[14,15] physician involvement in capital punishment (September 2007[16-18] and January 2008[19-28]), COI in clinical practice (May and August 2007),[29-31] and the current discussion of bidirectional COI at medical journals. In taking this stance, the journal is critical of publications that, through advocacy, tip the scales in favor of a narrow position and, through executive decisions, tilted peer review, and Draconian restrictions on the collective space allowed dissenting authors to respond, prevent "science" (to use the term loosely) to self-correct its miscalculations, misstatements, and other errors.

This is not to say that any journal's approach to scientific publishing, including that of *Mayo Clinic Proceedings*, is foolproof. Indeed, despite the efforts of the best-intentioned authors and reviewers, mistakes and misstatements are printed. That occurred in Hirsch's commentary: Errors appeared in the reporting of the correct amount of remuneration Drs Egilman and Krumholz had received when contributing to legal actions against Merck and the nature and scope of Dr Egilman's legal activities. The journal became aware of these errors shortly after publication of the September 2009 issue and wanted to publish a correction immediately. However, responsible correction demands that the journal not only know that an error was printed but also have some insights into an appropriate correction. This took additional time. Once the details of the correction were verified, the journal immediately released to its Web site a December 2009 correction, clarification, and apology from Hirsch, and the next printed issue of the journal (January 2010) repeated the correction and apology.[32] Hirsch further addresses this error in the current issue of the *Proceedings*. I join Dr Hirsch in apologizing to the authors for these errors and thank all involved parties for making the errors and corrections public.

All who cherish and benefit from biomedical journals should reaffirm that peer review and the traditions of medical publishing that have evolved over decades and centuries have served us well. Journals function best when they use fair, balanced, and attentive peer review and their messages speak in terms of hypotheses, theories, and probabilities. Shortcuts do not serve us well, particularly when we attempt to jump to some new "truth" based on a portion of the story. Albert Einstein had it correct: "No amount of experimentation can ever prove me right; a single experiment can prove me wrong." Such a realization of the limitations of science, and by extrapolation, scientific publishing, should keep us humble yet diligent to learn more. When we close the door to evidence, debate, and proper decorum, we mock the core of science and set ourselves up for failure.

Credible scientific publication demands adherence to concepts of right and wrong, fairness, and equal applications of core principles to all parties. These are broad brushstroke ideas. Efforts by contemporary journal editors to exhaustively codify author-journal interactions by introducing endless lists of highly specific rules[1-5,33] (eg, that authors disclose their religious and political affiliations[5,34]) in my opinion merely move science and scientific publishing away from its commonsense ideals. Furthermore, these contemporary lists of rules introduce new loopholes that will allow misdirected authors and editors to ignore the spirit of the rules while adhering to the letter of the rules. In such instances, journal reviewers and readers are deceived.

The long-established, sustaining principles of scientific method, peer review, and medical publishing do not need to be abandoned or undergo major revision in the current era. Hopefully, through the examples of contemporary publications in *Mayo Clinic Proceedings*, readers can appreciate how adherence to these traditional rules can be used appropriately for the advancement of knowledge and the benefit of society. The collective exchanges on bidirectional COI at medical journals, and previous exchanges on other sensitive topics, are provided as examples.

William L. Lanier, MD
Editor-in-Chief

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CORRECTION

Incorrect numbers: In the article by O'Leary et al entitled "Hospitalized Patients' Understanding of Their Plan of Care," published in the January 2010 issue of *Mayo Clinic Proceedings* (*Mayo Clin Proc*. 2010;85(1):47-52), some denominators in the Results section of the abstract and text and in Table 2 were incorrect.

The 5th sentence in the Results section of the abstract should read as follows: Specifically, there was no agreement between patients and physicians on planned tests or procedures for the day in 87 (38%) of **231** instances and in 22 (10%) of **231** instances.

In the Results section of the text, right-hand column of page 49 and left-hand column of page 50, in the second paragraph under the heading "Patients' Understanding of Their Plan of Care," the last 2 sentences should read as follows: As indicated in Table 2, there was no agreement between patients and physicians on planned tests or procedures for the day in 87 (38%) of **231** instances and in 22 (10%) of **231** instances, respectively. There was no agreement between patients and their physicians on planned medication changes for the day in 127 (54%) of **233** instances.

The corrected Table 2 is shown here.

TABLE 2. **Agreement Between Patients and Physicians on Aspects of the Plan of Care**

Aspect of care	No. of occurrences/total No. of occurrences (%)[a]		
	No agreement	Partial agreement	Complete agreement
Primary diagnosis	83/230 (36)	43/**230** (19)	104/**230** (45)
Planned tests	87/231 (38)	23/**231** (10)	121/**231** (52)
Planned procedures	22/231 (10)	0/**231** (0)	209/**231** (90)
Medication changes	127/233 (54)	16/**233** (7)	90/**233** (39)
Physician consultations	105/233 (45)	17/**233** (7)	111/**233** (48)
Anticipated length of stay[b]	96/218 (44)	37/218 (17)	85/218 (39)

[a] Sample sizes vary from 218 to 233 because of missing data elements.
[b] Length of stay agreement was rated as follows: none, 1-day difference or longer; partial, 1-day difference; and complete, no difference (exact match).

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