

# Conflicts Over Conflicts of Interest

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CONFLICTS OF INTEREST HAVE TAKEN AN INCREASINGLY prominent role in politics, business, and medicine. High-profile examples of undisclosed or incompletely reported financial conflicts of interest have been well publicized. There have been recent investigations by academic centers and lawmakers into unreported conflicts of interest by physicians<sup>1,2</sup> and recommendations for more transparent reporting of potential conflicts of interest by faculty and researchers.<sup>3,4</sup>

Despite this increased attention, episodes of unreported financial conflicts of interest continue to occur. Recently, allegations of unreported financial conflicts of interest by an author of an article in *JAMA*, circumstances and events related to the investigation of those allegations, and sensationalized media accounts<sup>5</sup> regarding communications surrounding reporting of those undisclosed conflicts have generated an inordinate amount of misrepresentation, misunderstanding, and concern.

In the May 28, 2008, issue of *JAMA*, Robert Robinson, MD, and colleagues published a randomized trial evaluating use of escitalopram and problem-solving therapy for prevention of poststroke depression.<sup>6</sup> The study was sponsored solely by the National Institute of Mental Health and had no reported industry involvement. Three of the authors of the study—Robinson, Ricardo Jorge, MD, and Steven Small, PhD, MD—reported financial disclosures indicating relationships with pharmaceutical companies. In the October 15, 2008, issue, 4 letters to the editor about the article were published, including a letter from Jeffrey Lacasse, PhD, and Jonathan Leo, PhD, along with a reply from Robinson et al.<sup>7</sup>

On October 16, 2008, *JAMA* received an e-mail message from Leo inquiring, “Does being on a speakers’ bureau for a pharmaceutical company constitute a conflict of interest that should be declared?” We responded indicating that such conflicts should be declared. Leo then indicated he had evidence that Robinson had not reported in his article that he had served on the speakers’ bureau for pharmaceutical companies; Leo also had copied this e-mail reply he sent to *JAMA* to a reporter at the *New York Times*. On October 29, 2008, we responded to

Leo that we would take the necessary steps to investigate this allegation and would correct the record as appropriate based on that investigation. We also asked why he felt compelled to notify the media about these allegations before they were investigated. On October 30, 2008, Leo replied, “The reason I wrote to the press is that I am hoping someone writes about this issue.”

*JAMA* editors take issues of undisclosed conflicts of interest very seriously and investigate such allegations rigorously. In investigating this allegation, we followed our standard policies and procedures, which involve conducting our own independent investigation and contacting the authors whose disclosures are challenged. We require the authors to verify or refute the allegations and to provide a detailed explanation to support their position. In addition, we also ask all other authors listed on the article to verify that their published disclosure information was complete and accurate. Once the investigation is complete, we publish a letter in *JAMA* that reflects the results of the investigation, including the authors’ explanation for why the conflicts were not initially reported as well as an apology from the authors, along with a formal correction, and thereby correct the record and the medical literature. We have never hesitated to do this and have published several such letters<sup>8-10</sup> following these same procedures.

However, these investigations require due diligence to ensure that the allegations are evaluated fairly and the record is corrected as necessary. This approach is important to ensure that no one’s reputation is unfairly damaged due to inaccurate charges and at the same time to make certain that all relevant disclosures—including those that might not have been included in the original allegation—have been identified and addressed. Moreover, because of the sensitive nature of these investigations, we have conducted them confidentially and ordinarily have not revealed the identity of the individual bringing the allegations to the person being accused of failing to report conflicts of interest. In this case, Robinson was unaware that Leo had made the accusations about unreported conflicts. Moreover, the results of the investigation ordinarily are not revealed to any third parties until the letter of explanation and the formal correction are published.

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Clearly, with this level of diligence, these investigations into undisclosed conflicts of interest are time-intensive and require careful attention. Following this investigation, the letter of explanation from Robinson was received and finalized on January 31, 2009, accepted for publication on February 5, 2009, and along with an accompanying formal correction, was scheduled for publication in the next available print issue of *JAMA*: March 11, 2009.<sup>11</sup> The investigation also revealed additional relevant disclosures by Robinson and a coauthor, none of which had been identified by Leo. There were no other reasons for the time that had elapsed since *JAMA* was notified about the possible undisclosed conflicts of interest allegations until publication of the letter and correction. Speculation that these delays were intended to enable the manufacturer of escitalopram to purchase reprints<sup>5</sup> are unfounded; the *JAMA* editors would never condone nor engage in this type of action. In fact, according to the reprints sales staff, to date, there have been no reprint orders filled and none will be forthcoming for the article by Robinson et al.<sup>6</sup>

On March 5, 2009 (6 days before the publication date of Robinson's letter and the accompanying detailed correction in *JAMA*<sup>11</sup>), we were notified by Leo about his posting that day on the *BMJ* Web site<sup>12</sup> discussing the study by Robinson et al, including the allegation about Robinson's unreported conflicts of interest. Leo sent the following e-mail message to us: "You asked in your previous email why I contacted the press. At the time, I was highly skeptical that *JAMA* would set the record straight on this matter. It has been almost five months since this matter was brought to your attention and *JAMA* has done nothing to correct the record. It seems that my initial skepticism was well founded."

While the confidential investigation of unreported conflicts of interest is under way, we consider involvement of third parties—such as Leo had done by his posting on the *BMJ* site and by contacting the media—to be a serious ethical breach of confidentiality that not only potentially damages our ability to complete a fair and thorough investigation (of the specific issue that Leo had brought to our attention), but also potentially damages *JAMA*'s reputation by the insinuation that we would fail to do so. A telephone conversation intended to inform Leo that his actions were inappropriate transformed into an argumentative discussion, as Leo continued to refuse to acknowledge any problems with his actions, even after he was informed that the investigation was completed and was advised to read the upcoming March 11 issue of *JAMA* (where the letter of explanation and apology from Robinson and the formal correction were in press).<sup>11</sup> Leo also was informed that, if his actions represented his apparent lack of confidence in and regard for *JAMA*, he certainly should not plan to submit future manuscripts or letters for publication.

Although we appreciated Leo alerting us to the potential omission of some financial disclosure information by Rob-

inson, we maintain that his actions were inappropriate in contacting the media and by his posting on the *BMJ* Web site prior to publication of the correction and letter of apology from Robinson. However, since Leo apparently did not appreciate the serious implications of his actions, despite our attempts to explain, we felt an obligation to notify the dean of his institution about our concerns of how Leo's actions were potentially damaging to *JAMA*'s reputation. We sought the dean's assistance in resolving this issue involving a member of the faculty of his institution, to assure there would be no need to publicly identify that faculty member. No dean wants his or her institution implicated in a publication reflecting improper behavior by a faculty member. We fully expected a professional and appropriate response and assistance with resolution, as has occurred when we have notified other deans about related issues in the past, such as in other cases involving undisclosed financial conflicts of interest<sup>13</sup> and cases of duplicate publication.

Our tone in these interactions was strong and emphatic, reflecting just how seriously we take the responsibility to ensure a fair process of investigation and above all, to protect the integrity of science and the reputation of *JAMA*. We regret if anyone involved in these communications interpreted our intentions in any other way.

It is unfortunate that the details surrounding this investigation into these undisclosed conflicts of interest and inaccurate excerpts from these private conversations have now become public and have been misrepresented by the media and widely misinterpreted. One of us (C.D.) was erroneously reported to have referred to Leo as "a nothing and a nobody."<sup>5</sup> As a faculty member (assistant dean of students) of a school preparing physicians who will care for patients, Leo certainly is "somebody doing something" very important. To characterize Leo any other way would be erroneous and disrespectful, and this was never done by the editor in chief of *JAMA*.

In addition, we were dismayed that *BMJ* would post the article by Leo with the allegations against Robinson and the negative insinuations about *JAMA*, without at least contacting *JAMA* to verify the veracity of the report. In fact, the published letter from Robinson and the accompanying correction<sup>11</sup> were more comprehensive than the allegation in Leo's *BMJ* posting,<sup>12</sup> supporting the value and effectiveness of our thorough and deliberate process for investigating these issues.

As a result of these recent events we are making the following modifications to our already rigorous approach for investigations into allegations of unreported potential conflicts of interest. *JAMA* will require that the individual bringing the allegations provide a written detailed explanation of the unreported conflicts of interest and provide documentation to support the allegation. The person bringing the allegation will be specifically informed that he/she should not reveal this information to third parties

or the media while the investigation is under way, will be informed about progress of the investigation, upon request, as appropriate, and will be notified when the investigation is completed. In addition, once the investigation into unreported conflicts of interest is completed and the letter of explanation and the correction are finalized, those documents will be immediately posted online and linked from the article, and then subsequently published in the print journal.

The duty to disclose and report potential conflicts of interest hinges on trust and patience, and a common bond among authors, editors, and readers recognizing that reporting the best available biomedical science matters most. Pressures to publish rapidly, reports in the news media, and comments on blogs and advocacy sites cannot overwhelm the process of thorough and fair investigation when reputations are at stake. A rush to judgment may spark heat and controversy, but rarely sheds light or advances medical discourse.

*JAMA* has been a leader in developing and enforcing policies on conflicts of interest.<sup>14-16</sup> We have dedicated our professional efforts to doing all we can to ensure that articles published in *JAMA* meet the highest scientific and ethical standards, and will continue to put forth the strenuous and emphatic efforts necessary to do so.

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## REFERENCES

1. Harris G. Top psychiatrist didn't report drug makers' pay. *New York Times*. October 3, 2008.
2. Giles J. Exposing the links between doctors and big pharma. *New Scientist*. February 2009.
3. AAMC. Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research. [https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd\\_id=220&prv\\_id=268&pdf\\_id=107](https://services.aamc.org/Publications/showfile.cfm?file=version107.pdf&prd_id=220&prv_id=268&pdf_id=107). February 2008. Accessed March 20, 2009.
4. Steinbrook R. On-line disclosure of physician-industry relationships. *N Engl J Med*. 2009;360(4):325-327.
5. Armstrong D. *JAMA* editor calls critic a "nobody and a nothing." *Wall Street Journal Health Blog*. March 13, 2009.
6. Robinson RG, Jorge RE, Moser DJ, et al. Escitalopram and problem-solving therapy for prevention of poststroke depression: a randomized controlled trial. *JAMA*. 2008;299(20):2391-2400.
7. Escitalopram, problem-solving therapy, and poststroke depression [letters]. *JAMA*. 2008;300(15):1757-1759.
8. Ridker PM. Incomplete financial disclosure for study of funding and outcomes in major cardiovascular trials. *JAMA*. 2006;295(23):2725-2726.
9. Natanson C. Incomplete financial disclosure in a study of cell-free hemoglobin-based blood substitutes and risks of myocardial infarction and death. *JAMA*. 2008;300(11):1300.
10. Yao GL, Albertson P, Shih W, Yao SL. Failure to report financial disclosure information. *JAMA*. 2009;301(1):35-36.
11. Robinson RG, Arndt S. Incomplete financial disclosure in a study of escitalopram and problem-solving therapy for prevention of poststroke depression. *JAMA*. 2009;301(10):1023-1024.
12. Leo J, Lacasse J. Clinical trials of therapy versus medication: even in a tie, medication wins. *BMJ Rapid responses*. March 5, 2009.
13. DeAngelis CD. The influence of money on medical science. *JAMA*. 2006;296(8):996-998.
14. Flanagan A, Fontanarosa PB, DeAngelis CD. Update on *JAMA*'s conflict of interest policy. *JAMA*. 2006;296(2):220-221.
15. Fontanarosa PB, Flanagan A, DeAngelis CD. Reporting conflicts of interest, financial aspects of research, and role of sponsors in funded studies. *JAMA*. 2005;294(1):110-111.
16. DeAngelis CD, Fontanarosa PB. Impugning the integrity of medical science: the adverse effects of industry influence. *JAMA*. 2008;299(15):1833-1835.