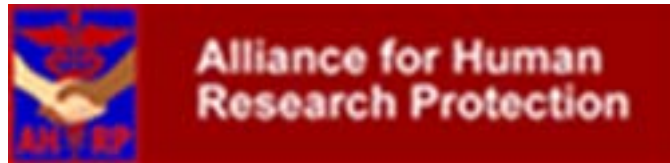


Nonprofit Hits JAMA, Seeks Inquiry_ AHRP Letter of Complaint to AMA



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THE WALL STREET JOURNAL

Nonprofit Hits JAMA, Seeks Inquiry

By David Armstrong

MARCH 26, 2009

A non-profit group that monitors industry links to medical research called for the suspension of the top two editors of the Journal of the American Medical Association, and an investigation into allegations that they threatened a researcher who criticized a study published in the journal.

The Alliance for Human Research Protection, which is often critical of industry-academic ties, made the requests in a letter it sent Wednesday to the AMA and the journal, also known as JAMA.

(This story and related background material will be available on The Wall Street Journal Web site, WSJ.com.)

"We are deeply concerned about the unbecoming and unethical conduct of the editor-in-chief and executive deputy editor of the Journal of the American Medical Association, who were reported to have used unprofessional and intimidating tactics against a conscientious academic," the alliance wrote in a letter requesting the investigation. Many doctors and academics have criticized JAMA's reaction to the academic, Dr. Jonathan Leo, on Internet blogs in recent weeks.

The AMA and JAMA said they were reviewing the letters and declined further comment. Jordan J. Cohen, a professor of medicine at George Washington University, who is chairman of JAMA's oversight committee, hasn't returned telephone and email messages this week.

The controversy stems from a March 5 letter published by the British journal, BMJ, in which Leo criticized how results were reported in a JAMA study last year that looked at the use of the antidepressant Lexapro's use in stroke victims.

Leo also pointed out that JAMA didn't report that the study's author had a financial relationship with Lexapro's maker, Forrest Laboratories Inc.

Leo is a professor of neuro-anatomy at Lincoln Memorial University in Harrogate, Tenn.

Forrest acknowledged that it had paid the author for speeches, but said his research on Lexapro was independent.

The publication of the BMJ letter upset JAMA's editor in chief, Catherine DeAngelis, who acknowledges contacting Leo's dean in an effort to get Leo to retract the letter. Leo says JAMA's executive deputy editor, Dr. Phil Fontanarosa, also called him to request a retraction. Leo has said Fontanarosa told him "You are banned from JAMA for life. You will be sorry. Your school will be sorry. Your students will be sorry." Fontanarosa, through a spokeswoman, has said Leo's version of the conversation is "inaccurate."

JAMA editors have said they were "strong and emphatic" when discussing Leo's letter with him and his dean because of the importance of protecting JAMA's reputation. "We regret if anyone involved in these communications interpreted our intentions in any other way," the editors said in a special editorial published last week.

In an interview with The Wall Street Journal earlier this month, JAMA editor-in-chief Catherine DeAngelis called Leo "a nothing and a nobody."

DeAngelis later said he is "certainly is somebody doing something very important."

In the editorial, DeAngelis and Fontanarosa said Leo was guilty of a "serious breach of confidentiality" by writing about the problems with the JAMA study while it was still investigating the matter. JAMA said that from now on, anyone complaining of an author failing to report a conflict of interest will be told not to disclose an investigation is under way.

That policy has been criticized by other medical journal editors as well as by some physicians and researchers. In her letter, Vera Sharav, the president of the Alliance for Human Research Protection, said journal editors have a responsibility to provide an open forum for scientific debate. "Not only have Drs. Fontanarosa and DeAngelis failed to meet this responsibility, they resorted to threatening retribution against a researcher who detected failures in their editing and gate-keeping processes" Sharav wrote. Her organization has often criticized the efficacy and safety of antidepressants.

JAMA has a unique management structure that was born from another controversy a decade ago when DeAngelis' predecessor was fired by the AMA. George Lunderberg, who had edited the journal for 17 years, was fired in 1999 when he published a study that found most college students didn't consider "oral sex" as "having sex." The article was published during the debate over the impeachment of then-president Clinton.

In wake of that controversy, the AMA ceded direct editorial control of JAMA to its seven-member oversight committee made up of six outsiders and the journal's publisher.

See also, Medical Journal Decries Public Airing of Conflicts, WSJ March 22, 2009:
http://online.wsj.com/article_email/SB123776823117709555-1MyQjAxMDI5MzI3MzcyNjM4Wj.html



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March 25, 2009

Joseph M. Heyman, MD
Chairman, Board of Trustees
Jordan J. Cohen, MD
Chair, *JAMA* Oversight Committee
Nancy H. Nielsen, MD, PhD
President

American Medical Association
515 N. State Street
Chicago, IL 60654

Dear Dr. Cohen, Dr. Heyman, Dr. Nielsen, and members of the Board of Trustees, and members of the Journal Oversight Committee:

The Alliance for Human Research Protection (AHRP) was founded to ensure that clinical research, which relies on the volunteerism of human subjects, should be as safe as possible, in compliance with ethical and scientific standards [1] and be free of conflicts of interest that undermine both the safety of the subjects and the scientific integrity of the research. Our mission includes protecting the independence of conscientious researchers to analyze reported clinical research findings and, when they occur, to point out ethical lapses in research and publication.

We are deeply concerned about the unbecoming and unethical conduct of the Editor-in-chief and Executive Deputy Editor of the Journal of the American Medical Association, who were reported to have used unprofessional and intimidating tactics against a conscientious academic, Dr. Jonathan Leo. Their behavior undermines the integrity of the *JAMA* peer review process, first, by failing to properly vet a manuscript for the accuracy of scientific reporting and for author conflict of interest and bias and, second, by launching an ad hominem attack on the scientist who was attempting to correct the record.

The *JAMA* editors have endangered the public health by failing to correct false information about the comparative benefits and risks of an antidepressant drug. In doing so, the *JAMA* editors have violated Principle #2 of the AMA Code of Ethics, namely:

“A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or

competence, or engaging in fraud or deception, to appropriate entities.” See: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/ama-code-medical-ethics/principles-medical-ethics.shtml>.

Accordingly, the Alliance for Human Research Protection calls for a public apology to Dr. Jonathan Leo by the American Medical Association, the immediate suspension from duty of the two editors involved in this matter, a thorough investigation by the AMA board of directors, and a commitment to reviewing, clarifying and publishing *JAMA*'s editorial policies to protect against future violations of standards for professional conduct.

The essential facts leading to our complaint follow.

The authors of a *JAMA* report (May, 2008) [2] recommended the off-label prophylactic use of the antidepressant, Lexapro (escitalopram) to prevent depression in post-stroke patients. The lead author promoted the expanded use of Lexapro in a flurry of media reports. In a letter to *JAMA* (published Oct, 2008) Dr. Leo, a neuroanatomy professor and assistant dean, and Dr. Jeffrey Lacasse, an assistant professor, raised an important scientific criticism: the authors' failure to compare the two active arms of the study—non-pharmacological, problem-solving psychotherapy to Lexapro. The lead author responded, acknowledging the validity of their assessment, which was that psychotherapy was statistically equivalent to Lexapro.

<http://jama.ama-assn.org/cgi/content/full/300/15/1757>

Separately, Dr. Leo informed *JAMA* editors about the lead author's failure to disclose his financial ties to Forest Labs, the manufacturer of Lexapro. After waiting 5 months for *JAMA* to disclose the author's conflicts of interest to readers, Leo and Lacasse posted a letter in the online *British Medical Journal* in which they reported the conflict of interest and commented on its implications. [3]

http://www.bmj.com/cgi/eletters/338/feb05_1/b463#208503.

In response, the *Wall Street Journal* reported that *JAMA*'s Executive Deputy Editor, Phil Fontanarosa MD, threatened Dr. Leo, and *JAMA* Editor-in-chief, Catherine DeAngelis MD, called the dean of Leo's college demanding a retraction. When interviewed by a *Wall Street Journal* reporter about this dust-up, *JAMA*'s Editor-in-chief called Leo, "a nobody and a nothing." [4] <http://blogs.wsj.com/health/2009/03/13/jama-editor-calls-critic-a-nobody-and-a-nothing/>

Medical journal editors are the gatekeepers of medical science.

Their responsibility is to provide an open forum for scientific debate, and to preserve the scientific integrity of the journal and its content by ensuring against concealed conflicts of interest. Not only have Drs. Fontanarosa and DeAngelis failed to meet this responsibility, they resorted to threatening retribution against a researcher who detected failures in their editing and gatekeeping processes.

This abuse of editorial power is breathtaking. First, the *JAMA* editors have violated the AMA Code of Ethics with respect to Principle #2 (as noted above) as well, Principle # 4:

“A physician shall respect the rights of patients, colleagues, and other health professionals...”

Instead, the *JAMA* editors attacked and attempted to intimidate and punish a responsible researcher who tried to correct the record regarding a misleading *JAMA* report (May 2008) [2] that failed to report that talk therapy proved equally effective to Lexapro.

It appears that the *JAMA* editors were enraged by the fact that their editorial failings were exposed in a reputable medical journal. In the first place, they had missed the sensitive point made by Drs. Leo and Lacasse that the evidence showed the antidepressant Lexapro was no better than talk therapy in preventing post-stroke depression. (Competent peer-review of the report should have brought up this point.) In the second place, it was evident that the *JAMA* editors had to be prodded to reveal conflicts of interest involving the first author of a *JAMA* report—only after Drs. Leo and Lacasse posted a letter on the *BMJ* website, ten months after the original publication of the widely cited *JAMA* report, and five months after Dr. Leo brought the conflict of interest issue to the attention of *JAMA*. http://www.bmj.com/cgi/eletters/338/feb05_1/b463#208503.

Second, the *JAMA* editors have violated several principles of the International Committee of Medical Journal Editors (ICMJE), for example Principle *II.D Conflicts of Interest*:

“Public trust in the peer-review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making.” See: <http://www.icmje.org/>.

The editors’ anger was compounded by their failure to suppress disclosure that *JAMA*’s editorial/peer review process leaves much to be desired. *JAMA* has more than once published promotional—as opposed to scientific—reports by authors with undisclosed financial ties to manufacturers whose products they recommended [5] [6] [7] <http://www.ahrp.org/cms/content/view/544/9/>

Third, the *JAMA* editors have violated several principles of the World Association of Medical Editors (WAME), most notably:

“Journal editors and authors have a responsibility to protect the integrity of the research record from bias related to the funding of research. This is best accomplished by revealing to readers the sponsorship of the research, any roles the sponsor played in the research, the institutional affiliations of the researchers and any relevant financial ties the researchers might have.”

See: <http://www.wame.org/resources/policies>.

The *JAMA* editors’ outrageous unprofessional conduct has ignited quite a firestorm of discontent among physicians:

Questions are also being raised about whether drug advertising influences *JAMA*’s publication of biased reports? Many *JAMA* subscribers identify themselves as one of the “nothings” for whom Dr. DeAngelis has shown contempt. Her arrogance touched off an outpouring of 158 angry responses posted on the *Wall Street Journal* Health blog, the

majority posted by physicians, several respondents indicated they are canceling their *JAMA* subscriptions.

<http://blogs.wsj.com/health/2009/03/13/jama-editor-calls-critic-a-nobody-and-a-nothing/tab/comments>; and <http://blogs.wsj.com/health/2009/03/23/jama-sets-new-policy-in-wake-of-disclosure-flap/tab/comments/>

The Editors' response in a *JAMA* editorial (March 18) adds insult to injury.

In their response, posted online a week after *The Wall Street Journal* reported on their unethical conduct, Drs. DeAngelis and Fontanarosa failed to offer an apology to Dr. Leo or to address their own unconscionable behavior. Instead, they further demonstrated their arrogance by proposing total secrecy during the unspecified time that *JAMA* takes to verify allegations of conflicts of interest—in order to protect the reputation of authors alleged to have undisclosed conflicts of interest. Incredibly, they show a complete lack of regard for their readers and medical colleagues who rely on *JAMA* reviewers and editors to ferret out biased reports before they are published in *JAMA*.

Drs. DeAngelis and Fontanarosa propose “modifications” to the *JAMA* conflicts of interest policy requiring that a person who alleges conflicts of interest about a published *JAMA* author not only provide detailed “explanations” for the allegation, but take an oath of silence until *JAMA* deigns to complete its investigation! The arrogance and imperious tone of *JAMA*'s editors is stunning.

As one of the commentators (#98) on the *WSJ* Health Blog noted: “Since when is writing a thoughtful letter to a medical journal, that raises legitimate and accurate concerns, “inappropriate”? Dr. Leo does not work for *JAMA*. He does not need to abide by the internal “procedures” (which were never communicated to him in any event) forbidding his contacting other journals or the media.”

Clearly, the *JAMA* editors fail to recognize the logical absurdity of claiming the exclusive right to be the sole judge and communicator (in their own time and manner) of errors or omissions in *JAMA*—unless, their objective is to alienate, and therefore lose *JAMA* readership. As a consequence of their “modification”—which amounts to a declaration of unilateral control—conscientious scientists who find scientific errors and / or undisclosed conflicts of interest in *JAMA* reports, will be advised to report them to reputable medical journals such as, the *BMJ* (*British Medical Journal*).

Clearly, the editors show no concern about the adverse impact on patient care resulting from *JAMA* reports that are tainted by undisclosed conflicts of interest. Ten months elapsed between publication of the original paper, and delayed publication of a correction. The intent of the original paper, as demonstrated by the lead author's role in the media flurry that followed it, was to broaden antidepressant prescribing *prophylactically* to stroke patients. [8] The lead author's failure to (a) acknowledge that problem solving therapy was equally efficacious in the prevention of depression in the original paper, and (b) mention his financial conflict of interest, were likely designed to strengthen the paper's promotional impact. Patient care suffers from such maneuvers.

Clearly, the editors show no concern about the reputation of Jonathan Leo. And they still have no idea how far over the line they have gone, and how they have lost all respect

from their readership, including the eroding membership of the American Medical Association. [9] <http://www.highbeam.com/doc/1G1-132978192.html>

The Alliance for Human Research Protection calls for a public apology to Dr. Jonathan Leo by the American Medical Association, the immediate suspension from duty of the two editors involved in this matter, a thorough investigation, and a commitment to reviewing, clarifying and publishing *JAMA's* editorial policies.

Please kindly inform us of your actions with respect to this formal complaint.

Yours truly,



Vera Sharav, President

On behalf of the Board of Directors
Alliance for Human Research Protection

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