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Fracture study in medical journal renews debate over researchers' financial ties

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CHICAGO (AP) – A new study showing that padded hip protectors didn't prevent fractures in the elderly has renewed questions about hidden drug industry ties to medical research.

Three of the authors of the study on bone breaks didn't tell editors of an influential medical journal, which is publishing their research Wednesday, that they had consulted for or received research money from the makers of bone-strengthening drugs. That potential conflict was discovered by The Associated Press.

Editors of the Journal of the American Medical Association – which has tough rules on financial disclosure – had asked the authors about any conflicts and were told there were none. The researchers said later they didn't believe their industry connections were relevant because the study of hip fractures didn't involve bone drugs and didn't recommend them.

The editor of JAMA agrees. Dr. Catherine DeAngelis said that in this case, the drug company connections didn't violate the journal's detailed financial disclosure policy.

DeAngelis said she believes her journal is being unfairly scrutinized by The AP, which found the researchers' ties to drug companies through searches on the Internet and through a consumer database.

"This has nothing to do with drugs," she said. "At what point do you

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say, 'Come on, is this a witch hunt?' "

Undisclosed corporate ties by scientists affect other journals, too. Yet editors of JAMA essentially made the journal a lightning rod for the issue last year when they toughened their financial disclosure for authors and announced the changes in an editorial.

A close reading of JAMA's guidelines suggests the fracture study authors' ties to drug makers are "clearly relevant," said Dr. Michael Callaham, president of the World Association of Medical Editors. "It's a slam dunk," he said.

A consumer advocate with the Center for Science in the Public Interest agrees. Readers could easily interpret the study to say that since hip protectors don't work, "I guess I better take the drugs," even if that's not what the authors intended, said Merrill Goozner. The consumer advocacy group runs a database on scientists' financial ties, an effort to combat corporate influence on science.

In this case, reporting such ties "seems to me to be a no-brainer," Goozner said.

There is strong evidence that studies funded by industry or done by researchers with industry ties are more likely to have results favouring corporate interests.

Disclosing those ties enables readers to better judge a study's credibility. While many journals have added or improved disclosure policies, standards vary widely. There's no consensus on what constitutes relevant financial interests.

The hip protector study "is a nice illustration of how complicated it can be," Callaham said. "It's a huge problem and I think we haven't gotten very far in addressing it."

Callaham said there's a move toward more uniform standards, but with thousands of medical journals worldwide, it's a challenging task.

JAMA announced its tightened disclosure policies in July 2006 after twice in two months, researchers failed to report financial ties to industry.

Days later, The Associated Press discovered another breach in which authors of a JAMA study linking severe migraines with heart attacks in women failed to disclose ties to makers of drugs for migraines or heart-related problems. That led to a published correction and explanation from the authors who didn't think their ties were relevant.

C.K. Gunsalus, special counsel at University of Illinois and an expert on ethics and integrity in research, said failure to disclose often is

an innocent mistake.

"People say, 'I know my heart is pure,'" she said. "You minimize your own conflicts."

Still, the onus to disclose ties is on the researcher, she said, and it would be difficult for journals to crack down by investigating every author who submits a study manuscript.

In the latest case, the new study involved 1,042 nursing home residents who were assigned to wear a cushiony pad on only one hip. Results over several months showed just as many fractures on the padded hip as on the unprotected side.

The hip pad in the study is no longer on the market, but lead author Dr. Douglas Kiel, a Harvard Medical School researcher, said the results probably would be similar for other "energy absorbing" cushion-like pads still being sold.

Previous studies on hip protectors and fractures have produced conflicting results.

A JAMA editorial called the new study's results inconclusive. Hip protectors are designed to be worn on both hips; wearing it on only one side might increase chances of a dangerous fall onto the protected hip, the editorial said.

Kiel said the study was broadened to examine an improved pad and that results are due soon.

He said bone-building drugs could be one of several options to hip protectors for older patients, but that they are not ideal for nursing home residents because they take a year or more to work and these patients often are already taking many other drugs. But he also said the drug company money he and his colleagues have received is not relevant to the current study because it wasn't a comparison of both treatments.

"We have no financial disclosures with hip protectors," Kiel said. "We were asked repeatedly by the editors whether we were following JAMA's full disclosures and we said yes."

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