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PROFESSION

Million-dollar payouts to researchers often go undisclosed in journal articles

When such large amounts are involved, readers deserve to know the details, the authors of a new study argue.

By KEVIN B. O'REILLY, amednews staff. Posted Sept. 27, 2010.

Highly paid consultants for orthopedic device makers disclose their company ties about half the time and rarely share details with readers about their financial relationships, according to a new study calling for more transparency.

Researchers examined payments from five orthopedic device makers to consultants in 2007 and then zeroed in on the 32 researchers, nearly all physicians, who received more than \$1 million each to see whether those relationships were disclosed when they published articles the following year.

When writing directly about the firm's products, authors paid \$1 million or more disclosed their company tie half the time, said the *Archives of Internal Medicine* study, published online Sept. 13. Only one of the 26 orthopedics-related journals studied, *The Journal of Bone and Joint Surgery*, required authors to acknowledge they were paid more than \$10,000.

That needs to change, said study co-author David J. Rothman, PhD, director of the Center on Medicine as a Profession at the Columbia University College of Physicians and Surgeons in New York.

"There is simply no disputing the fact that every reader would want to know that piece of information. We're not in the quibble area," Rothman said. "I'm not saying don't publish these articles. I'm not demonizing the authors. But if I know an author has a million-dollar stake in this area he's writing about, I'll read still more closely."

The information was obtained from payment records made public during government investigations. In total, the five device makers paid \$248 million to consultants in 2007, handing out an average of \$150,000. The *Archives of Internal Medicine* study did not identify individual researchers.

Last November, the influential International Committee of Medical Journal Editors adopted a new, more detailed disclosure form that asks authors submitting for publication to tell about any payment for the research that generated the article as well as other kinds of industry relationships such as consultancies, honoraria and stock options from the last three years. The form does not ask authors to specify the amounts received or whether they exceed a certain payment threshold.

Does disclosure help?

The focus on dollar amounts is a distraction from eliminating conflicts of interest, said Jerome P. Kassirer, MD, professor of medicine at Tufts University School of Medicine in Massachusetts and former editor-in-chief of *The New England Journal of Medicine*. He wrote the 2004 book *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*.

"It's not the lack of disclosure that's the problem -- it's the conflict that's the problem," Dr. Kassirer said. "I'd like to see much more focus on how to deal with the conflicts than how to deal with the lack of disclosure."

32 researchers received more than \$1 million each from orthopedic device makers in 2007.

The American Academy of Orthopaedic Surgeons has a policy calling for "mandatory disclosure of any and all relationships between a study author and an orthopedic device company," said academy First Vice President Daniel J. Berry, MD.

The tie should be disclosed regardless of the size of the payment because "studies have shown that any dollar amount has the potential to create influence, which is why transparency is essential," said Dr. Berry, who chairs the Dept. of Orthopedic Surgery at the Mayo Clinic in Minnesota.

Some physicians were skeptical of the study's conclusions.

"At face value, it's hard to fault 'disclosure,' but the proper question is: What is the disclosure for, and what harm does lack of disclosure cause?" said Thomas P. Stossel, MD, co-founder of the Assn. of Clinical Researchers and Educators, which defends physician-industry relationships. "The prurient interest in the large sums and the pious blathering about the sanctity of the medical literature notwithstanding, there's no evidence for damages. The onus is on Rothman to prove that articles by authors receiving payment are somehow corrupt."

Whether disclosure is helpful to readers, it is likely to grow more common and more detailed, said Susan Chimonas, PhD, who co-wrote the *Archives* study.

Starting Sept. 30, 2013, physicians who receive nearly any kind of payment of \$10 or more from a drugmaker, device maker or other medical industry firm will see the information listed on a publicly searchable website, under a provision of the health system reform law enacted in March.

"For physicians who have financial relationships with companies, I predict major transformations in the way these things are going to be handled. With the new health reform act, there will be sunshine," said Chimonas, an associate research scholar at Columbia's Center on Medicine as a Profession. "If authors are getting payments from companies, they should expect these payments to be fully transparent in the near future."

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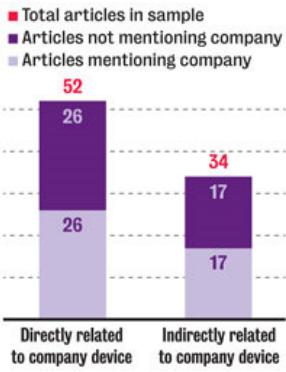
ADDITIONAL INFORMATION:**Spotty disclosure**

Journal authors receiving \$1 million or more as consultants for orthopedic device makers told readers about their company ties only half the time, according to a new study. The study's authors and a panel of medical journal editors are calling for more disclosure of industry ties and compensation.

Source: "From Disclosure to Transparency: The Use of Company Payment Data," Archives of Internal Medicine, published online Sept. 13

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