

Financial transparency skin-deep at medical journals



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By [Frederik Joelving](#)

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(Reuters Health) - When scientists concluded in a report from November that they had found a potential anti-aging skin treatment, readers had good reason to think they could trust the claim.

After all, the findings appeared in the prestigious British Journal of Dermatology (bit.ly/j8M8Ng), and the authors said they had no financial interests in the product, a hormone called DHEA.

Yet Reuters Health has learned that the senior researcher, Dr. Fernand Labrie, holds patents for DHEA and owns companies dedicated to marketing it for certain medical problems.

His lack of disclosure, a routine requirement at medical journals, points to a bigger problem in the field: Nobody is making sure that authors declare their conflicts of interest.

That has a very real potential to influence public health and corporate bottom lines, experts say, because researchers with industry ties are more likely to promote drugs and downplay side effects.

When scientists from the tobacco industry reviewed the effects of secondhand smoking, for instance, more than 90 percent of them found no evidence of harm. Yet only 13 percent of the reviewers without industry ties came to that conclusion, according to a 1998 report in the Journal of the American Medical Association (bit.ly/mKlyrc).

"At its worst, it can allow patients to have unrealistic hopes about a treatment for their conditions," Dr. Virginia Barbour, chief editor of the journal PLoS Medicine, told Reuters Health. "And it can distort the prescribing practice of physicians."

In a review of 50 reports from the British Journal of Dermatology, a top-tier skin research journal, Reuters Health has found that authors often don't disclose even the most glaring conflicts of interest. And editors are reluctant to do anything about it -- in fact, they don't even agree on when a conflict of interest exists.

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What's more, many journal publishers derive a substantial part of their revenue from drug ads and reprint requests from pharmaceutical companies, and there are examples of editors who moonlight as paid consultants for the industry.

"Editors probably need to be more vigilant than they are at the moment," said Barbour, whose journal doesn't run drug ads. "And I think that editors also need to be very aware that they themselves can be part of the competing interests."

TRANSPARENCY CLOAKS CONFUSION

The disclosure policy of the British Journal of Dermatology (BJD) is deceptively simple.

According to an e-mail from its editor Dr. Tanya Bleiker, "Authors are responsible for disclosing all financial and personal relationships between themselves and others that might be perceived by others as biasing their work."

That includes signing a statement that relevant patent rights, stock ownership, consultancy fees and employers have all been declared -- even if the employer was also listed at the beginning of the manuscript. That statement will show up in the report.

Yet of the 50 most recent BJD reports from scientists at L'Oreal, Shiseido, Novartis and similar companies, 13 declared no conflict of interest.

And that's not counting one study that promoted a L'Oreal-Nestle product on shaky grounds without disclosing that most of the authors were employed by the manufacturer or had been paid by it. The BJD only corrected the problem (reut.rs/eTnMOq) after a Reuters Health story (reut.rs/ujOYb) pointed it out in July.

Asked how more than a fourth of the 50 studies could end up in print without financial disclosure, BJD publisher spokeswoman Nina Goad said: "We have looked at all the papers listed and can see no significant conflicts of interest."

But experts who spoke with Reuters Health -- including other journal editors, ethicists and doctors -- said there is little doubt industry scientists have a financial stake in their publications.

"If it's an article written by people who work for the company, the company has almost certainly invested money in that research," said Josephine Johnston, a bioethicist at the Hastings Center in Garrison, New York.

"That's a massive conflict of interest."

Internal sales documents made available by Pfizer during a lawsuit over its antidepressant Zoloft, and later quoted in an article by University of Minnesota bioethicists, speak to her point.

According to those documents, the "purpose of data is to support, directly or indirectly, the marketing of our products."

Given that backdrop, many experts now say a conflict of interest exists whenever readers might reasonably wonder if a scientist's judgment is biased.

The British Association of Dermatologists, which publishes BJD, apparently disagrees. When pressed on the issue, spokeswoman Goad declined to spell out how it determines when there is a conflict of interest.

Instead, she referred Reuters Health to the Committee on Publication Ethics, which advises the association on ethical matters. But Elizabeth Wager, who chairs the committee, told Reuters Health that industry scientists clearly have financial interests in their findings.

HIDDEN CONFLICTS COMMON

Those interests aren't always obvious, as in the case of patents or dual employment.

"That's a much more troubling conflict of interest, because it's sort of hidden," said the Hastings Center's Johnston. "The research that is ostensibly independent is really not."

In his BJD report on the potential anti-aging treatment, Labrie only listed one affiliation: Laval University in Quebec, Canada.

But when Reuters Health contacted him, he acknowledged that he owns the company that funded the research, EndoRecherche, and holds patents for DHEA, including one for anti-aging skin treatment.

EndoCeutics, a daughter company of EndoRecherche, is currently involved in late-stage development and marketing of DHEA for female sexual problems.

According to a 2010 press release, the company has signed a contract with pharmaceutical giant Bayer, which may net EndoCeutics up to \$330 million (CAD) in addition to royalties from sales.

Of three recent DHEA skin studies published by Labrie and his colleagues, none mentions this relationship.

Labrie told Reuters Health he had not been involved in the decision to leave out his conflicts of interest.

"I have tons of publications, and when there is a conflict of interest I indicate it and I have zero problem with it," he said. "The one that is the first author has got the responsibility."

He explained that he is no longer developing DHEA for anti-aging treatment and that he believes his other investments in the hormone are irrelevant.

Labrie is only one of many scientists who fail to point out financial relationships that could bias their reports, hints work by David Rothman, who runs a think tank at Columbia University in New York.

In a study from January (bit.ly/bdgzOw), Rothman's team went through 95 journal articles published in 2008 by orthopedic surgeons who'd been paid at least \$1 million by medical device makers over the previous year.

Fewer than half of the articles acknowledged those relationships.

THE FLIP SIDE OF ANTI-AGING

The DHEA article, co-written with L'Oreal researchers who like Labrie declared they had no conflict of interest, concludes that the "data suggest the possibility that topical DHEA could be used as an efficient and physiological anti-aging skin agent."

But the findings only looked at skin changes at a microscopic level, and whatever visible effects the hormone might have -- and potential side effects with long-term use -- are uncertain.

In fact, one dermatologist who reviewed the study for Reuters Health said it shows DHEA also boosts skin molecules that may slow wound healing.

"I would ask if giving DHEA actually has a pro-aging effect and not an anti-aging effect," said Dr. Christos C. Zouboulis of Dessau Medical Center in [Germany](#).

Although that point seems absolutely critical, Labrie and colleagues did not discuss it, said Zouboulis, adding that he has collaborated with Labrie and thinks highly of him as a scientist.

DHEA creams claiming to slow skin aging, diminish wrinkles and regenerate cells are already available, and several marketers refer to what "many scientists" believe, or what "research" or "clinical studies" have shown.

Dr. Jean Calleja-Agius of the University of Malta, who has studied skin aging, agreed that using the phrase anti-aging was "a little bit too bold."

"My concern is that cosmetics companies, whoever is promoting a product, might use it," Calleja-Agius said.

WHEN SCIENCE AND MONEY CLASH

Pick up any women's magazine, and ads for "anti-aging" products crowd the pages. That's no accident: According to one estimate from 2008, the global market for cosmetic and medical products designed to stave off skin decay is worth \$15 billion.

"Skin care as an overall category was roughly stagnant in 2009, but the anti-aging products saved it from plummeting," said Timothy Dowd, an analyst with Packaged Facts. "They are certainly driving the market."

While experts contacted by Reuters Health say that none of the anti-aging creams available to consumers has been proven to work better than a simple moisturizer, some products still run well over a hundred dollars.

One way to justify those exorbitant price tags is to tout "clinically proven" effects in consumer ads - even when the science is shaky.

Just a few months ago, for instance, the Swedish Market Court found that L'Oreal had made unsubstantiated claims of dramatic wrinkle reduction in women using Vichy and Lancome products.

"If they want to use these claims, they have to prove them," Gabriella Fenger-Krog, who prepared the case for the Swedish Consumer Ombudsman, told Reuters Health.

"When it's a scientific argument as in this case, it's an increased burden of proof, because consumers get affected more by scientific arguments in ads."

L'Oreal was told by the court to pay a fine of roughly 1 million Swedish kronor (SEK, about \$160,000).

In Labrie's case, no one is arguing that he failed to mention the potentially pro-aging effects of DHEA because he has money riding on the hormone.

Yet it's been found again and again that financial conflicts tend to sway anything from basic lab science to drug trials to literature reviews, so seeing a conflict between cautious science on one hand and company bottom lines on the other doesn't seem far-fetched.

"None of us is bias-free," said Columbia's Rothman. "But in the world of financial bias, we are anxious and worried about the influence by pharmaceutical and device companies."

PASSING THE BUCK

Journal editors and independent experts who vet studies submitted to those journals serve as a filter between the wider community and researchers.

But exactly how they should handle conflicts of interest is still a matter of debate.

"Our job is absolutely to take a very unbiased look at what is submitted to us, and ensure that when it is actually published by us, it accurately reflects what the scientific evidence shows," said PLoS Medicine's Barbour. "It's very important to make sure that people don't slip something in that appears to go beyond the data. It's very common."

Although studies funded by for-profit companies are often quite solid, she added, letting reviewers know about financial conflicts is critical.

"It alerts them to the fact that they just may want to be very sure that when they read the paper, they look for any evidence of bias, they look to see if the design of the paper is appropriate," Barbour explained.

Several medical device companies and drugmakers have already made physician payments publicly available. By 2013, according to the Patient Protection and Affordable Care Act from last year, all such manufacturers must report payments of more than \$10, and this information will be freely available online.

Despite this, most editors say it's not their job to make sure authors reveal financial conflicts, and

there are no repercussions for those who don't.

"We do rely on honesty, and if (conflicts of interest) are not included it is the authors not the journal who are ultimately culpable," Nina Goad of the British Association of Dermatologists told Reuters Health by e-mail. "It is not the role of the BJD to police undisclosed potential conflicts of interest."

Other editors echoed her sentiment.

"It comes down to trusting authors, that they are revealing, and sometimes they don't," said Dr. Margaret Winker, who spoke as the past president of the World Association of Medical Editors, but is also the deputy editor and online editor of the Journal of the American Medical Association.

"I think it is impossible to police," she added.

Rothman said he doesn't know of any journals that enforce their disclosure policies, although he believes it's their responsibility to do so.

"The journals do ask for disclosure, but they trust the authors completely. The question is, why trust if you can verify?" he added. "It's time all these groups -- journals editors, chairmen, deans, continuing medical education leaders, the FDA and NIH -- start to verify even in a spot way."

(Additional reporting by Zach Gottlieb)

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Ocala123456789 wrote:

this how free markets handle healthcare... i am loving it... conflict is good...

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Fescu wrote:

indeed, Ocala, what does capitalism have to do with morally acceptable provision of health and promotion of good/correct treatments? nothing.

on the other hand, to take the anti-aging treatment example, why are people so vain as to buy anti-aging treatments?

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