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Side Effects | Are Doctors' Loyalties Divided?

Drug firms' cash skews doctor classes

Company-funded UW courses often favor medicine, leave out side effects

By Susanne Rust and [John Fauber](#) of the Journal Sentinel

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Do your legs feel tingly? Do you suffer from mood swings before your period? Would you take a mind-altering drug to quit smoking?

If so, the pharmaceutical industry and the University of Wisconsin-Madison want to teach your doctor a lesson.

Drug companies have largely taken over the field of doctor education, in part by bankrolling physician education courses at medical schools.

Critics say the practice increases medical costs by encouraging doctors to write prescriptions for expensive brand-name drugs and by exaggerating the frequency and prevalence of rare conditions. It also promotes the use of drugs not approved for the ailments.

A Journal Sentinel investigation found that industry-funded doctor education courses offered at UW often present a slanted view by favoring prescription medications over non-drug therapies and by failing to mention important side effects.

Among the findings:

- Pharmaceutical giant Pfizer is spending \$12.3 million on an online UW course for doctors to tell them how to get their patients to quit smoking. A top priority is prescribing Pfizer's drug, Chantix, which has been linked to serious side effects, including a rash of suicides. But mention of the side effects can't be found in course materials.

- The German company Boehringer Ingelheim Pharmaceuticals paid more than \$320,000 to fund a UW

course on a condition known as restless legs syndrome. The course said 10% of adults have the disorder, when other research suggests the actual figure is much lower.

•&enspTwo companies, Pfizer and Bayer, have spent more than \$340,000 to fund a UW continuing education course for doctors that touts their drugs, among others, to treat an extreme form of PMS. Doctors taking the course online aren't told that some of these drugs may not work much better than a placebo.

Four of the nine UW doctor education courses offered online are funded by industry. Those courses are free, while the university-funded courses require doctors to pay a fee. UW officials defend the relationship with drug makers.

"All CME (Continuing Medical Education) courses at UW are evidence-based, free of commercial bias, and are designed to help physicians provide optimal, state-of-the-art care of patients," said George Mejicano, director of UW's Office of Continuing Professional Development.

It's in the financial interest of both academia and industry to join forces to teach doctors: Universities receive large sums of money from drug makers, while the companies get a stamp of legitimacy from the academic center. But critics see ethical problems with the relationship.

"What you are seeing in Wisconsin is just another example of what is going on all over the country," said Arnold Relman, professor emeritus at Harvard Medical School and a former editor of the *New England Journal of Medicine*. "It's unethical, and it is not in the public interest because it is going to bias doctors to use certain drugs."

Drug companies spend about \$13 million a year to fund UW medical education courses, and the university receives about 27%, or nearly \$3 million of that money, according to records. The rest is going to private firms that put together the course materials.

And because doctors are required to earn continuing medical education credit, the drug companies have a captive audience, said Daniel Carlat, an associate clinical professor of psychiatry at Tufts University Medical School.

In Wisconsin, doctors must take 30 credits every two years. The UW's online courses run up to 2 credits per course.

"Drug companies have found this to be a highly effective way to attract the attention of physicians," Carlat said.

Mejicano countered that the courses "are not educational venues for pharmaceutical companies, but in fact are developed with the aim of improving the health of the public."

Jack Cox, a Pfizer spokesman, said continuing medical education helps improve understanding of disease, expands evidence-based treatment and contributes to patient safety. He said all grants made by Pfizer are unrestricted. "We don't shape the curriculum."

In January, the *Journal Sentinel* reported that a \$12 million grant from Wyeth Pharmaceuticals was used to fund a UW course on hormone therapy that promoted its benefits and downplayed its risks.

The course ran for several years despite strong evidence that such drugs can cause breast cancer, heart disease, stroke and blood clots. Wyeth makes two of the most popular hormone therapy drugs. Course materials were taken off the Web site only after reporters began asking questions.

Panel appointed

The drug industry has increased spending on doctor education from \$302 million in 1998 to \$1.2 billion in 2006, according to the Journal of the American Medical Association. It now pays for more than half of all such courses.

"Drug companies have essentially hijacked the highest level of medical education we have in this country," said Carlat, who also publishes a monthly continuing medical education psychiatry report that does not accept drug company funding.

UW officials in January appointed a panel to investigate the university's doctor education office. The action was taken after the Journal Sentinel exposed conflicts of interest and raised other questions about the university course on hormone therapy. The probe is part of a wide-ranging plan under consideration at UW to change the way its doctors interact with drug companies.

The UW continuing education courses offered at no cost to enrolling doctors all claim that drugs are the first line of treatment for the various diseases they discuss.

The five non-industry courses cost \$20 a person and stress nutrition and quality of life issues for patients.

The Wisconsin Medical Society and Stanford University are among those that have called for severe restrictions on industry money.

How courses initiated

A quick look at several drug company Web sites provides information about how these continuing medical education courses are initiated.

Drug makers solicit proposals from universities and private firms to create course materials for specific disorders.

For instance, Wyeth is currently asking for [proposals for ailments such as "menopausal health,"](#) AstraZeneca is looking for someone to [create courses on migraines and generalized anxiety disorder,](#) and Boehringer Ingelheim is [soliciting a course on a condition called female hypoactive sexual desire disorder.](#)

Drug makers are eager to fund such courses because it allows them to get favorable treatment for their newer and more expensive brand-name drugs, according to records and several observers interviewed by the Journal Sentinel.

Indeed, it would cost \$1,200 a year for Mirapex, Boehringer Ingelheim's restless legs syndrome drug touted in the UW course. Or, in the case of Pfizer's anti-smoking drug Chantix, \$1,760 would buy an annual supply.

Observers and critics of the practice say drug companies solicit proposals soon after they have received FDA approval to market a brand-name medication.

Eager to promote their drug to doctors, the drug company typically will work with a private medical education company. The medical education company is paid a large fee to put together course materials about the disease.

While there may not be a written agreement, it is expected that the course materials produced by the medical education company will favorably mention the drug.

In the UW's restless legs syndrome course, Boehringer Ingelheim's drug, Mirapex, is described as one of two "first-choice" therapies.

In the case of the smoking-cessation course, Pfizer's drug Chantix, is described as the "first-line" therapy.

The companies also may hand-pick doctors who have financial ties to companies to serve as course faculty.

This pattern was seen in all of the UW courses reviewed by the Journal Sentinel. Each course relied on faculty with ties to the funder.

Once the medical education company is granted a drug company contract, it typically approaches a medical school such as UW to run the course. The medical school is paid a fee that can range from tens of thousands of dollars to several million dollars.

The arrangement works out well for most everyone involved: Doctors get their education subsidized by drug companies. Drug companies sell more of their products. Universities and medical education companies get a steady stream of big money.

But beyond the inherent conflict posed by drug companies paying for courses that disseminate information about their products, the funding raises a larger question: Why shouldn't doctors pay for their own education?

"American doctors are the best paid doctors in the world," said Carl Elliott, a professor of bioethics at the University of Minnesota Medical School. "To hear them plead poverty and say they can't pay for their own education is the height of hypocrisy."

Smoking cessation course

Some of the biggest money paid to UW has been for its smoking cessation course, part of a national campaign funded by Pfizer.

Of the \$12.3 million paid by the drug company to fund the course, \$3.5 million is going to UW.

The course materials heavily promote Pfizer's drug, Chantix, considered to be the most effective drug on the market. But the drug is under investigation by the FDA, and in its relatively short history on the market, it has been linked to serious side effects, none of which is mentioned in the course.

Side effects include depression, agitation, suicidal behavior and blackouts. For two consecutive quarters, Chantix was connected with more serious injuries than any other prescription drug, according to an October report by the Institute for Safe Medication Practices. Since its approval in 2006, the drug has been linked to 3,325 serious injuries and 112 deaths in the U.S.

Last May, the FAA ordered pilots and air traffic controllers to immediately stop taking the drug because of safety concerns.

Course materials also fail to mention that large numbers of people were excluded from the clinical trials that led to the drug's approval, raising questions about its real world effectiveness.

For instance, a 2006 study headed by UW researcher Douglas Jorenby and funded by Pfizer found that 23% of Chantix users had abstained from smoking for one year, compared with 15% who got the drug bupropion and 10% who got a placebo.

But the study excluded a wide-range of subjects, including people with heart disease, mental illness, allergies and other conditions.

UW's Mejicano said he did not think the side effects or the people excluded from the clinical trials should have been included in the course. He said such courses are rarely comprehensive and are designed to meet

selected learning objectives.

No strings, firms say

Drug companies argue that funding for doctor education courses comes with no strings attached.

But when the content of such courses is put under a microscope, questionable practices are common.

Consider UW's restless legs syndrome course, which Boehringer Ingelheim paid nearly \$321,000 to fund, including \$17,000 to UW. Boehringer Ingelheim's Mirapex is used to treat the condition, which is marked by an irresistible urge to move limbs, along with a tingling sensation. The condition reduces the quality of life.

The course says about 10% of adults have the disorder.

But a 2005 study in the Archives of Internal Medicine found that moderate to severe restless legs syndrome, the kind that might be treated by a doctor, existed in only 2.7% of adults. And even that figure probably is too high, according to a 2006 article in the journal PLoS Medicine. The article noted that the survey used to do the 2005 study was done in a way that likely exaggerated the number of people who have the condition.

UW's Mejicano said it is common to have different prevalence rates for disorders. He said the course author and reviewer were comfortable with the 10% figure.

The percentage is important because critics say the more common doctors believe a condition is, the more likely it is they will diagnose it in a patient and prescribe medication.

Boehringer Ingelheim also paid speaker's fees and provided research funding for two non-UW doctors who served as faculty for the course.

Although the course can still be accessed online, as of August 2008 it was no longer available for credit.

Boehringer Ingelheim spokeswoman Lara Crissey said the company has no control over course content.

In October, the FDA issued a warning to the German drug company, demanding that it stop misleading consumers about the effectiveness of Mirapex.

Among other things, the FDA cited pharmacy handouts for consumers that suggested the drug could be used to treat up to 10% of the adult population when, in fact, it is approved to treat only a much smaller percentage of people with moderate to severe forms of the disorder.

The other drug mentioned in the course as a first choice therapy is Requip, made by GlaxoSmithKline. The company also provided funding to two outside faculty members for the course.

Financial ties

For more than six years, the drug makers have relied on UW to promote its drugs to treat an extreme form of PMS.

Of the \$340,000 Pfizer and Bayer spent to fund the course on premenstrual dysphoric disorder, UW received about \$24,000.

The course was designed by the nonprofit Madison Institute of Medicine. The institute's three founders, all psychiatrists affiliated with the medical school, have financial ties to nearly two dozen drug companies, including Pfizer.

Several of the drugs promoted in the course are not approved by the FDA to treat the condition and have serious side effects not mentioned on the course Web site, including depression, stroke and blood clots.

Consider Pfizer's anti-anxiety drug Xanax.

The course cites a small study of Xanax, but fails to point out that only 37% of women who took it had significant improvement, compared with 30% who got a placebo. The course also does not mention Xanax's side effects, including the potential of dependency.

An internal UW review last June said the course could be viewed as "significantly commercially biased" in favor of treating the disorder with drugs. Little was done to address that concern in the final version.

Bayer spokeswoman Rose Talarico said company policy prohibits grants that are conditioned on prescribing, purchasing or reimbursement of any Bayer product.

In an interview, James Jefferson, the course's author and co-founder of the Madison Institute of Medicine, said the course material is unbiased and supported by scientific evidence.

"I don't believe in hyping products that haven't established themselves with good literature as being useful," he said.

Jefferson said the course materials make it clear which drugs are approved by the FDA.

UW's Mejicano said the course is in full compliance with national standards for disclosing potential conflicts of interest.

Drug approval

Premenstrual dysphoric disorder, or PMDD, affects less than 8% of menstruating women. The condition can be diagnosed when at least five of 11 symptoms are found, including debilitating anxiety, depression, irritability and moodiness.

Pfizer stopped funding the class in 2006. The course started up again in 2008 with funding from Bayer, which got approval in 2006 for its heavily advertised drug Yaz to treat the condition.

In a review published in the Cochrane Collaboration earlier this year, the authors wrote that a "placebo would be less expensive for treating PMS and has fewer side effects than the active pill," meaning Yaz and similar drugs.

And while the course cited the review, it did not mention the conclusion.

Jefferson said it's up to doctors to warn their patients about potential side effects.



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