

MARKETING DRUGS: Debating the Real Cost

Concern about close ties between doctors and pharmaceutical firms are prompting new financial disclosure laws and education efforts.



Academic drug detailer Leigh Bradshaw of Independent Drug Information Service talks with Dr. Ernest Josef at his practice near Enola, Penn., earlier this year about the most appropriate medications for patients.

BY RACHEL BRAND

Like any sales representative, Leigh Bradshaw cold calls her prospect list, befriends office managers and chats up harried physicians.

Unlike her drug industry competitors, she visits doctors simply to educate them.

"My doctors value what I bring," says Bradshaw. "They know I am trying to share information, not manipulate them in any way."

As one of Pennsylvania's 10 academic detailers, the former nurse helps doctors pre-

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scribe the best, most appropriate treatments, including diet and exercise. Her 30-minute sales pitch relies on Harvard University research about drug efficacy, safety and costs.

It's no secret that pharmaceutical companies flood doctors' offices with peppy, well-groomed drug detailers. They're salespeople who arrive bearing bagels, cookies, clocks and calendars. Medical product companies also pay lavish honorariums to physicians who lecture in favor of brand-name drugs, hire doctors as marketing consultants and pay physicians to attach their names to industry-written articles. Although the pharmaceutical

industry does not release figures, published estimates put the cost of physician marketing and distributing free drug samples at about \$25 billion. Of that, an estimated \$7 billion is spent on one-on-one marketing to doctors.

Nobody disputes that innovative biological products and drugs save lives. Pills and injections save money, too, by keeping patients out of the hospital. But a growing number of legislators and patient advocates say cozy doctor-industry ties push up health-care costs and threaten patient safety.

"It's hard to defend it with a straight face," says Senator Mark Montigny of Massachusetts. "How do you defend having a physi-



AP PHOTO/JASON MINICK

\$25 or \$50 a year, and Massachusetts is weighing a complete gift ban. Pennsylvania leads the nation in so-called counter-detailing programs, in which state employees use the drug industry's marketing tactics to promote evidence-based medicine.

Much is at stake. Prescription drugs have been one of the fastest-growing costs in the Medicaid program, climbing each year at double-digit percentages. Total U.S. prescription drug spending has mushroomed fivefold from \$40.3 billion in 1990 to \$200.7 billion in 2005, according to the Kaiser Family Foundation.

Plus, aggressive marketing can promote risky treatments. After the painkilling drug Vioxx was yanked from the market because of its cardiac side-effects, a literature review found the painkiller worked no better than Tylenol.

The pharmaceutical industry and American Medical Association scoff at the idea that a bauble or snack can influence behavior. They maintain laws limiting physician-industry contact are unnecessary since both groups promote ethics guidelines. The AMA permits physicians to accept gifts that cost less than \$100 and help patient care (stethoscopes, not golf bags). Doctors can't get paid to travel to or attend conferences. And both the Office of Inspector General and FDA already regulate pharmaceutical marketing.

"There is no need for the state to get involved in this," says Marjorie Powell, general counsel for the Pharmaceutical Research and Manufacturers Association.

SAFETY CONCERNS

Since 2002, five states and the District of Columbia began forcing drug companies to report how much they pay doctors.

Lawmakers first hoped to uncover drug marketing and advertising costs, according to Maine Representative Sharon Treat, executive director of the National Legislative Association on Prescription Drug Prices.

"In 2002, there was a lot of attention paid to the cost of prescription drugs," says Treat. "The drug companies kept saying, 'The reason our prices are so high is because we spend so much money on research.' The purpose of the laws was to punch holes in that argument."

DO THE LAWS WORK?

Five states and the District of Columbia require drug companies to disclose payments to practitioners. The strictest laws force drug companies to report specific payments to individual physicians for speaking, consulting or conducting research.

In theory, such laws let patients check if their doctor makes more money giving lectures than treating patients. Hospitals can check if employees comply with professional ethics guidelines.

But just how much light do these "sunshine" laws beam on industry practices?

Four years ago, a team headed by Dr. Joseph Ross from the Mount Sinai School of Medicine requested records from Minnesota and Vermont, the two states that make records public. In Minnesota, paper records were stored in a cabinet, were never audited and lacked substantial information. In Vermont, it took a lawsuit by advocacy group Public Citizen before the state released the data. When Vermont's information was finally released, researchers found that more than 60 percent of the money changing hands was shielded from public scrutiny as a "trade secret."

"It was pretty frustrating," Ross says. "We felt like these laws had been passed, and nobody was following them. The data were difficult to get, when you got it there were holes in it, and it was clear there was stuff being claimed as trade secret that wasn't really secret."

Ross' team published its results in the *Journal of the American Medical Association* last year. Minnesota has since put individual records online, and this year has asked drug companies to submit online reports on Excel spreadsheets.

Senator Pete Shumlin, who supported Vermont's disclosure law, would like to revise it.

"The intent was great," Shumlin says. "But as so often happens with legislation that passes, we're doing C-minus work. The pharmaceutical industry has found endless ways to avoid this law, and I'd like to see us close those loopholes."



SENATOR
MARK MONTIGNY
MASSACHUSETTS

can on your payroll ghostwriting articles and then prescribing your product when the doctor-patient relationship is supposed to be sacred?"

LIMITING GIFTS

In response, some states are passing laws that require drug companies to report physician payments. Others limit gifts to



SENATOR
PETE SHUMLIN
VERMONT

INDUSTRY FEARS RULES MAY DERAIL MEDICAL ADVANCES

A young cardiologist had a dream of taking pictures inside blood vessels, with an eye toward making it safer for surgeons to cut plaque from coronary artery walls.

Dr. Paul Yock founded Cardiovascular Imaging Systems, eventually developing a catheter with a miniaturized ultrasound probe attached to the end. Today, his company is part of Boston Scientific, and his invention is used in many common cardiovascular procedures.

Yock's invention—and hundreds like it—would not be possible without close ties between physicians and industry, industry representatives say. Fruitful new product development relies on the unfettered flow of information, patient access, and, yes, money among device companies, physicians and teaching hospitals.

Drug and device companies fear that disclosure laws and gift bans, which make it embarrassing for doctors to accept payments and burdensome for companies to give them, will squelch such innovation. "For us, it is about being able to maintain these relationships, and to be able to do the research we need to do," says Wanda Moebius, vice president of policy communications for AdvaMed, a medical device industry group.

Moebius says a typical medical device is researched and designed in 18 months, hand-in-hand with health-care practitioners.

"There are a lot of improvements that probably wouldn't happen, or would happen much more slowly, without the opportunity to talk to people in the field," says Marjorie Powell, senior assistant general counsel to the Pharmaceutical Research and Manufacturers of America.

Gift bans raise other pragmatic concerns. Device companies typically pay for physicians to travel and learn how to use their equipment. Had Massachusetts' gift ban passed, "all that training would have [had] to be done out of state," says Tom Sommer, president of the Massachusetts Medical Device Industry Council.

Advocates of disclosure laws and gift bans say the crackdowns are directed at marketing relationships, not research partnerships between doctors and industry. But even those laws are unnecessary, says Powell, since the U.S. Food and Drug Administration and the Office of Inspector General already regulate pharmaceutical marketing.

Once the data were available, though, journalists wrote stories about which specialties earned the most money (psychiatrists, it turned out). *The New York Times* documented how increased payments to Minnesota psychiatrists coincided with the growing use in children of atypical anti-psychotics, new and experimental drugs. The newspaper found that doctors who took the most money from drug makers—as underwritten research, consulting fees or honorarium—tended to prescribe the drugs to children the most often.

As a result of such stories, Treat says, the law became a tool to protect citizen safety.

"In Maine, our department of health and human safety wants to be able to look at a

correlation between practices that are unsafe and where the money is going," Treat says.

HARD TO PASS

Disclosure laws have been defeated in many more states than they've been passed. In Washington, a bill died in committee this year that would have required drug makers to report gifts, fees and payments to health-care practitioners.

While Washington Senator Chris Marr has supported preferred drug lists and bulk buying groups, he says the disclosure law seemed more a "poke in the eye" to the drug industry than sound science.

"I didn't feel there was any evidence that

[gifts] influenced whether or not doctors delivered something other than evidence-based care," Marr says. "If you trust someone to adhere to the Hippocratic Oath, you have to trust that they are going to act in the best interest of their patients."

Likewise, the pharmaceutical manufacturers group says payment disclosure is needless. "It doesn't provide any benefit for anybody in the state," says Powell. "It doesn't increase patient access to health care, it doesn't lower health care costs. ... It simply takes away state resources that might be more productively spent in improving or expanding the health-care system."

Cody Wiberg, the executive director of Minnesota's board of pharmacy, supports the state's disclosure law. He believes industry ties do influence doctors' prescribing. But the state has higher priorities than prosecuting companies that fail to report, and Wiberg wonders who uses the information, anyway.

"We've had only a handful of people from the public who want this data," Wiberg says.

In a parallel effort, Minnesota and Vermont limit drug company gifts to health-care practitioners to \$50 and \$25 a year, respectively. New York is considering a \$50 ceiling.

A Massachusetts proposal, part of the state's efforts to contain costs, would have gone even further, banning payments, trinkets, entertainment, meals, travel, honorariums and subscriptions. The legislation would have permitted distribution of drug samples to doctors for their patients' use. Violators could have been fined \$5,000 and would have faced two years imprisonment.

The bill came on the heels of Governor Deval Patrick signing a \$1 billion bill to benefit life science companies. Senator Richard Tisei sees a conflict.

"It's like having a split personality," he says. "On the one hand, we say, 'Please come to Massachusetts, we want your business.' On the other, we're saying, 'You can't trust



REPRESENTATIVE
SHARON TREAT
MAINE



SENATOR
CHRIS MARR
WASHINGTON



SENATOR
RICHARD TISEI
MASSACHUSETTS

anybody in the profession to give anyone a sandwich or a pen.’ ”

The far-reaching law, which was modified in committee to remove the ban, would have stopped medical device manufacturers from paying travel costs when doctors train on their equipment. Device firms feared the end of physician focus groups, from which they better their products.

“We’d lose the opportunity to gain valuable insight into the operations of these devices, and how that operation can be improved,” says Tom Sommer, executive director of the Massachusetts Medical Device Industry Council.

A COUNTER PUNCH

Pennsylvania’s approach mimics practices in many industrialized nations. Instead of banning drug industry marketing, the state sends its sales folks armed with objective information to talk to doctors.

The counter-detailing program is part of a comprehensive effort by Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly, or PACE, program to deliver the best drug treatment to seniors. The \$300 million PACE program—one of the most generous of its kind nationwide—provides comprehensive drug coverage for 380,000 Pennsylvanians, or most of the state’s low-income elderly.

Years ago medical facts came to light: Seniors’ physiology and drug tolerance are different from younger adults. But they were too often getting too much or too little of the wrong medicines.

So the 25-year-old program set up an online, real-time review system. If a pharmacist orders a drug for a PACE client that doesn’t match guidelines, the order is rejected.

“It was all about safety,” says Tom Snedden, PACE director. “It was never done to save any money.”

Physicians complained, saying they’d like to know beforehand why a prescription was rejected. That led to the \$1 million program that summarizes literature reviews of common prescriptions.

“It is an effective supplement,” Snedden concludes. The program has reduced inappropriate drug use enough to justify its \$1 million cost.

Vermont and Mississippi have similar programs, and Maine, New Hampshire and

Vermont will be collaborating on a multi-state effort.

DOCTORS TAKE ACTION

Attention to physician conflicts of interest has brewed for the past 10 years. While lawmakers take action, the medical profession itself is changing. An association of academic medical centers earlier this year urged teaching hospitals to shun gifts and other industry ties. Kaiser Permanente, the influential California-based health system, has banned drug reps for years.

Meanwhile, federal lawmakers have proposed a nationwide counter-detailing program and disclosure law. U.S. Senators Chuck Grassley of Iowa and Herb Kohl of Wisconsin have proposed a disclosure law that would pre-empt state laws, have a higher financial trigger for reporting gifts and a lower penalty for nonreporting. PhRMA and AdvaMed, medical industry trade associations, are both inclined toward supporting the measure.

Lawmakers say they are pressuring the industry to change; the industry says it’s changing on its own.

Regardless, Leigh Bradshaw, the Pennsylvania academic detailer, sees her competition littered about doctors’ offices every day: blue Lunesta clocks and Nasonex tissue boxes. The pharmaceutical industry employs about 100,000 sales representatives, and the most heavily promoted top 15 products account for \$38 billion in sales.

Researchers such as Dr. Joseph Ross, a Mount Sinai School of Medicine professor, says state laws can go only so far.

“What we really need is a sea change in the medical profession wherein physicians need to realize it isn’t OK to get gifts or fill our offices with advertisements for products,” he says. “It demeans patient care.”

Indeed, Bradshaw says some doctors refuse to see her unless she buys lunch for their entire office. So she gets creative, buying Subway sandwiches with her tight budget.

“Whatever,” she says with the laugh of a hardened sales person. “I’m not a very good caterer, I must admit. I’m a better nurse ... [but I’ll do it] if that’s what I have to do to get in the door.”



CHECK OUT an overview of state laws and other issues related to the pharmaceutical industry at www.ncsl.org/magazine.

OREGON’S OBJECTIVE ANALYSIS

Inside an obscure branch of an Oregon university, researchers are busy stripping prescription drugs of their Madison Avenue packaging and celebrity endorsements.

That means systematically reviewing all published literature about every drug within a class, such as every anti-depressant, brand name or generic.

The project’s 15 researchers sift through every study and toss out those that are poorly crafted. This comprehensive analysis allows them to synthesize data and observe trends. It’s work a practicing doctor doesn’t have time to do.

“The drug industry’s usual method of marketing is to present only articles and literature that show their drug favorably,” says Dr. Alison Little, the project’s medical director. “Our method is to look at it all.” Canada and 14 states underwrite this health-technology assessment organization and use its reports, as do state boards of pharmacy and counter-detailing programs.

“If you have good solid research that says, ‘all drugs in a class are pretty much the same,’ ” says Mark Gibson, deputy director of the Center for Evidence-Based Policy, which oversees the project, “you can go to industry and say, ‘it’s time to compete on price.’ ”

Such objective comparative research comes at a time when physicians have become skeptical of academic journals. There is a growing concern that drug companies underwrite much published research, and that those studies are designed for specific marketing purposes. What’s more, negative results don’t get submitted for publication.

The project’s analysis revealed a higher risk of cardiac disease for those who took Vioxx, the now scandalized pain killer. As a result, states that used the Oregon project’s research did not put Vioxx on their preferred drug lists long before the drug’s safety problems became well-known.

“The studies are out there,” Little says. “You have to put them together to see a trend.”

And while the drug industry can comment on drafts of reports, its members cannot contact project researchers directly. Not even for a cup of coffee.