

Physician Payments Sunshine Act would call for full disclosure

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Sen. Grassley

Physicians and the medical industry have long had intertwining paths. Physicians serve as consultants to drug and device companies or work with manufacturers to develop an idea for a new instrument. Companies might pay physicians to conduct research or to present lectures at medical conferences.

Both physicians and industry would say they pursue these relationships to help patients. Although that sounds altruistic, drug and device manufacturers also have another audience to please: their shareholders, who hope that their investment in these physicians will boost sales.

Now these relationships are starting to attract the attention of legislators, other physicians, and the public as questions are raised about how much influence drug and device companies have on physicians who accept gifts or financial compensation.

A new bill introduced Sept. 6 by Sen. Charles Grassley (R-IA) aims to shed unprecedented light on those relationships by requiring drug and medical device manufacturers with revenues greater than \$100 million to declare publicly the amount of money they pay physicians. According to the bill, called the Physician Payments Sunshine Act, the U.S. Secretary for Health and Human Services would create a Web site in which companies would be required to disclose payments, gifts, honoraria, and travel, along with the name of each physician, the value of each payment or gift, its purpose, and what, if anything, was given in exchange.



Dr. Hoskins

"Companies wouldn't be paying this money unless it had a direct effect on the prescriptions doctors write and the medical devices they use," Sen. Grassley said on the Senate floor as he introduced the bill.



Dr. Lichter

Sen. Grassley's efforts coincide with a House of Representatives bill, introduced in August by Rep. Maurice Hinchey (D-NY), in which he proposes that all conflicts of interest should be eliminated from the FDA's advisory panels.

Meanwhile, the American Academy of Ophthalmology (AAO) is considering a tougher stance on disclosure of financial interest. H. Dunbar Hoskins Jr., MD, the association's executive vice president, said members are reviewing a policy that requires AAO peer-review committees to "manage" the conflict of interest rather than simply disclose it. One speaker with financial ties to a

company might be paired with another speaker from another company for a balanced presentation, he said.

"I have been to meetings where it's been clear where industry was in charge of the meeting," Dr. Hoskins said. "You didn't know what to think of it."

Full disclosure

Sen. Grassley said he was driven to pursue this kind of public disclosure after learning that a child psychiatrist had been paid more than \$100,000 in 2003 as a drug consultant. Her studies of that company's pediatric antipsychotic medicine led to widespread use of the drug, he said in a speech on the Senate floor.



Dr. Parke



Dr. Lindstrom

That led him to discover that some states —Minnesota, Vermont, Maine, and West Virginia—already require some form of public disclosure of the amounts physicians receive from industry. Not all are easily accessed, though, he said.

His bill already has the support of several key senators, including Sens. Clair McCaskill (D-MO), Amy Klobuchar (D-MN), Ted Kennedy (D-MA), Herb Kohl (D-WI), and Chuck Schumer (D-NY).

"This bill will shine a much-needed ray of sunlight on a situation that contributes to the exorbitant cost of health care," Sen. Schumer said in a news release. "Patients have the right to know if drug and device makers are attempting to influence physician prescribing decisions with gifts, consultations, and travel."

According to Sen. Kohl, a study published earlier this year in the *New England Journal of Medicine* reported that 94% of physicians have received food and beverages, medication samples, or other gifts and payments from drug companies (Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, and Blumenthal D. A national survey of physician-industry relationships. *N Engl J Med.* 2007;356:1742-1750).

Meanwhile, the pharmaceutical industry is one of the most profitable industries in the world, returning more than 15% on investments, he said on the Senate floor. Sen. Kohl said it has been estimated that the drug industry spends \$19 billion annually on marketing to physicians in the form of gifts, lunches, drug samples, and sponsorship of education programs.

"Companies certainly have the right to spend as much as they choose to promote their products," he said. "But as the largest payer of prescription drug costs, the federal government has an obligation to examine and take action when companies unfairly or illegally attempt to manipulate the market."

Divisive subject

The subject has led to a great deal of debate among ophthalmologists, who often fall squarely into two camps: those who see value in industry relationships, and those who eschew them completely, said Dr. Hoskins.

Paul R. Lichter, MD, called industry-funded medical conferences "a well-executed marketing ploy." He pointed out that the money for these conferences and other physician collaborations comes from industry's marketing departments.

"Industry wants its own representatives to attend these meetings so they have access and influence over attendees. They want to hear what's said and feed off of that," said Dr. Lichter, the F. Bruce Fralick Professor of Ophthalmology; chairman, Department of Ophthalmology and Visual Sciences; and director, Kellogg Eye Center, University of Michigan. "There's probably very little room for industry to be involved in continuing medical education."

At the University of Michigan, he said, his ophthalmology department has never taken any money from industry to run departmental programs, a position he thinks is very uncommon in ophthalmology and other medical fields. His department has declined industry-sponsored lunches for residents, for example.

"It's a valuable thing for industry, but we've never taken that in our department," Dr. Lichter said. "Our faculty is very much opposed to these kinds of relationships with industry."

Dr. Lichter said he has refused to participate in certain continuing education programs when he learned he would be paid by industry. He believes it is appropriate for industry to provide grants for programs that are operated independently, however.

"Industry has every right and reason to want to be able to talk to knowledgeable physicians about their products, about whether a particular drug might be of use, or whether a copycat drug that's been successful in one area would be successful in another area," he said. "They would pay these people as bona fide consultants, not for going to a chicken-dinner meeting where the consultant speaks with other physicians."

Early in his career, David W. Parke II, MD, accepted payment as an industry consultant. That was before he was "sensitized" to the controversial nature of that relationship.

Dr. Parke, the Edward Gaylord Professor and chairman, Department of Ophthalmology, University of Oklahoma College of Medicine, Oklahoma City, called financial compensation by industry "one of the most significant issues" of the moment and predicted that physician acceptance of industry gifts would be very different in 5 years.

"The key issue here is, the patients and the public must have trust in their physicians and must have trust that the care they are receiving is free of any taint of bias, regardless of how unintentional it is," he said.

"As a physician, I feel very comfortable that the vast majority of my colleagues would never intentionally make a patient-care decision on the basis of corporate bias," Dr. Parke added. "And yet, study after study [has] revealed the pervasive nature" of industry gifts.

Even if physicians think they can remain objective while accepting industry compensation, they really cannot, Dr. Lichter agreed.

"If industry can make us feel it's done to educate our colleagues in an 'up and up' way, the better it is for industry," he said. "But, in fact, industry is doing this to increase its bottom line."

Not that it's wrong for drug and device manufacturers to seek out the most efficient ways to generate a return for their investors, Dr. Parke said.

"However, what we have to do is to separate and carefully scrutinize the difference between being an end-user of those products and having a more substantive relationship that, regardless of reality, may be perceived as inappropriate," he said.

Not everyone agrees, though, that such compensation is improper. For more than 30 years, Richard L. Lindstrom, MD, has accepted payment from industry as a consultant, teacher, and product developer—and he said that role has made him a motivated, educated ophthalmologist. He is aware of the latest product developments and trials, and he remains on the cutting edge of new ideas, ready to discuss them with fellow physicians and patients alike.

"If you want to utilize a new instrument or a new surgical procedure, who best to learn from than the person who has been involved in its development for 10 or 20 years?" Dr. Lindstrom asked. "It makes no sense to me to take the pioneering inventors off the podium, because they are the ones who have suffered with this technology and can tell the next generation of surgeons all the things they did that didn't work, and the things that do work."

In fact, he said, his patients often admire his work for advancing the science as well as

practicing it. He said he always shares his background with them so they are aware of his potential bias.

Dr. Lindstrom acknowledged he is paid as a consultant in a number of areas: by Bausch & Lomb for his expertise in cataract surgery, by Advanced Medical Optics Inc. for work in refractive surgery, by Alcon Inc. for pharmaceutical issues, and by several smaller device manufacturers. He also serves on the boards of several companies.

Sometimes, he recuses himself from voting on a particular issue because of his financial involvement with another company—something he sees as no big deal. After all, judges often recuse themselves from court cases in which they may have a conflict, he noted.

Where it gets awkward, he said, is if a continuing medical education instructor who is a paid consultant tries to compare or contrast the benefits of one device or drug with another. In that case, he said, it would be appropriate to balance that viewpoint with another one.

"It would be a terrible thing to make it illegal for ophthalmologists to consult with industry," Dr. Lindstrom said. "That would basically bring all future product development to a screeching halt. We want to have innovative ophthalmologists come up with new ideas and be motivated to bring those ideas to market and put them to work for the benefit of our patients."

In an age when medical costs to practices are so high, even altruistic physicians are looking for additional ways to earn money. Dr. Lindstrom said he believes physicians who have a good idea for a new surgical instrument or pharmaceutical should be compensated for their efforts. And companies need physicians to inform them that they should tweak a device or try a different pharmaceutical approach, he said.

"It isn't realistic to expect that one can bring new products to the marketplace without the involvement of some bright, talented ophthalmologists in the process," Dr. Lindstrom said. "If we want new products in the marketplace, many of them will be the ideas of ophthalmologists who may have the idea and have a patent on it, and they should be compensated for their ingenuity and not just donate it to society."

The middle ground

The discussion surrounding the ethics of accepting financial compensation from industry might get dicey for some, but John W. Simon, MD, said he sees middle ground. The chairman of Albany Medical College's ophthalmology department said the issue can be solved by requiring full disclosure—and let the audience decide.

He can see why physicians working with—and for—industry might be best-suited for some educational presentations. Yet, he understands the apprehensions some [people] have about these links, despite the presenter's best intentions to be objective. Full, honest disclosure of those relationships puts the onus on the listener.

"If your audience, whether it's your patient or a group you're speaking to, knows you've been paid for some function having to do with what you're talking about, [it] can judge," Dr. Simon said. "You might say you can be totally objective. Let them know so they can judge whether you can."

That's a policy Dr. Lindstrom can live with, even though he's not sure where lines get crossed with personal privacy issues. He doesn't care—he said he'd pass around his audited tax returns for the past 5 years if that would stop the questioning. Besides, when it comes down to it, most physicians who have mutual funds will own stock in an ophthalmology company or have some other bias, he said.

"I've always been an advocate of disclosure," Dr. Lindstrom said.

AAO's Dr. Hoskins predicted that the issue will not soon go away without some kind of action. What's most important, in his mind, isn't whether physicians should believe colleagues are objective when making presentations, but whether the public believes physicians are

trustworthy, with the patients' best interests coming first. As members of the AAO debate the subject, he said he wants the patients' ability to trust their physicians to remain foremost.

"My own personal belief, if you will, is it's absolutely essential that the academy continues to be the credible source of information for which it is regarded today," Dr. Hoskins said. "Whatever is necessary to maintain the credibility of the material people hear at the meetings, the academy will have to undertake."

That means a policy change could be looming, if only to satisfy a cynical public.

"The public perception is so critical to physicians' acceptance," he said. "That trust that exists between physician and patient —if that's destroyed, the profession is not in good shape."