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## Drugs and Devices

### Senate Aging Panel Hears Support For Physician Payment Disclosure Proposal

Proposed legislation that would require medical device and drug manufacturers to disclose information about payments to doctors (S. 2029) is important and necessary, senators from both parties and device industry representatives generally agreed at a Feb. 27 hearing.

"Apparently we all see a path towards effecting some considerable improvement, something that doesn't occur at every hearing," Senate Special Committee on Aging Chairman Herb Kohl (D-Wis.) said as the hearing drew to a close.

Generally, stakeholders said the threat of malpractice litigation, government enforcement actions (including a 2007 settlement concerning orthopedic manufacturers' consulting agreements with physicians), and industry codes of ethics are not sufficient to ensure ethically sound relationships between industry and physicians.

However, a device industry group suggested changes to the legislation, such as bringing smaller companies into its reach.

### Proposed Bill Assessed

The hearing, *Surgeons for Sale? Conflicts and Consultant Payments in the Medical Device Industry*, assessed the proposed Physician Payments Sunshine Act (S. 2029) in the context of the medical device industry. The bill was introduced by Kohl and Sen. Chuck Grassley (R-Iowa) in September 2007 after the committee examined the relationship between the pharmaceutical industry and physicians in a June 2007 hearing.

S. 2029 would require industry to report the value of any physician payments, the name of the physician, the date of the gift, its purpose, and what, if anything, was received in exchange. The new requirements would apply to manufacturers with \$100 million or more in annual gross revenues. Penalties for not reporting payment would range from \$10,000 to \$100,000 per violation. The bill also would require the Health and Human Services secretary to create a Web site and post payment information in a clear and understandable manner.

The bill was referred to the Senate Finance Committee last year.

At its Feb. 27 hearing, the Aging Committee examined the financial interactions between medical device companies and surgeons, which often involve substantial payments in the form of consultant fees, educational grants, royalties, funding for clinical trials, travel, and gifts, according to a Feb. 27 release from Kohl. These relationships can create conflicts of interest and violate anti-kickback and self-referral statutes, according to the release.

### **'Pervasive' Problem**

Charles Rosen, clinical professor at the University of California, Irvine, and president of the Association for Ethics in Spine Surgery, testified that conflicts of interest embedded in the relationship between medical device manufacturers and a small group of well-paid spine surgeons is "ingrained."

These select physicians are those who write trend-setting medical journal articles, he explained. "I believe that getting enormous sums of money from a company about whose product [you are] writing--money that might go away if you write a negative paper--makes the research neither objective nor independent," he said.

It is important that other physicians are aware of the journal article authors' financial interests, he said, because it would change how the majority of physicians view those articles. "That would be the most valuable [outcome]," he said.

His association's purpose, according to its Web site, is to "promote patient care and evidence-based medicine and to provide increased public awareness of the detrimental and pervasive financial influence of industry on many health care providers and patients."


His testimony and others' prompted Committee Ranking Member Gordon H. Smith (R-Ore.) to say that what he is hearing is that the problem has "become so pervasive as to become alarming."

Still, Smith suggested that the threat of malpractice suits--which would hypothetically arise if physicians were implanting lower quality devices in patients because they were receiving kickbacks from manufacturers--might be a deterrent to this behavior.

Rosen demurred, saying the nature of the problem is not about choosing an inferior device over a superior one, since most devices are comparable, but is about a more subtle type of conflict of interest. He said the threat of malpractice suits does not serve as an adequate deterrent to creating these cozy doctor-company relationships.

He added that voluntary guidelines promulgated by industry groups are not capable of bringing about change, and that outside action is required.

### **Recent Settlements**

The two device companies that testified before the committee voiced support for the bill. Both companies, Stryker and Zimmer, made available on their Web sites in 2007 information about their payments to physician consultants, in compliance with a recent enforcement action affecting several orthopedic device makers (No. 212 HCDR 11/2/07 ).

Both Edward Lipes, executive vice president of Stryker Corp., and Chad Phipps, senior vice president and general counsel for Zimmer Holdings Inc., said the proposed legislation, when combined with recommendations from an industry lobbying group, could bring about changes in what they admitted had been questionable practices.

The companies were accused of using consulting agreements with doctors as inducements for surgeons to use a particular company's product. The Department of Justice has said some doctors did little or no work for the compensation they received as consultants, but agreed to use a company's products exclusively.

As announced in September 2007, four companies--Biomet Orthopedics Inc., DePuy Orthopaedics, Zimmer, and Smith & Nephew--are the subject of deferred prosecution agreements, which require the companies take certain steps to avoid prosecution for violating Medicare anti-kickback law provisions. These four companies also will pay a total of \$311 million to settle civil claims. Stryker is the subject of a nonprosecution agreement to implement the same reforms as the other four companies, but did not enter into a civil settlement.

### **HHS OIG Views**

This action, however, was not sufficient to change business as usual, according to testimony from Greg Demske, assistant inspector for legal affairs in the Health and Human Services Office of the Inspector General.

"[It is] impractical and inappropriate to rely solely on government enforcement actions to address this issue," he said, emphasizing the "significant risk that such payments will improperly influence medical decision making."

Similarly, Kohl's questioning of industry representatives indicated voluntary ethics codes promoted by industry groups are not sufficient to ensure change.

Addressing Christopher White, the executive vice president and general counsel for the Advanced Medical Technology Association (AdvaMed), Kohl asked why a government intervention was required in order to compel companies to follow the code.

White explained that, while the code does have meaning in the industry, it is voluntary, and, as a trade association, AdvaMed does not have the resources to enforce it.

## Industry's Four Recommendations

Industry voiced support for the proposed legislation, but sought a few modifications. AdvaMed recommended four central changes to the proposed legislation in its testimony:

- state laws requiring disclosure of relationships with physicians should be expressly preempted, creating one comprehensive federal standard for disclosure;
- companies with annual revenue over \$250,000, as opposed to the higher proposed threshold of \$100 million, should be required to disclose their financial arrangements with physicians;
- companies in which physicians have an equity ownership interest and generate a significant amount of the company's revenue through ordering devices sold or manufactured by the company should not be exempt from disclosure; and
- legislation should provide companies the opportunity to put physician payments in context.

Incorporating these four points into the proposed legislation garnered Republican support.

"It appears to me that you [Sen. Kohl] have created a piece of legislation that is addressing a need; it appears to me that people on both sides ... agree generally with it; it appears to me that Mr. White's four points addressed things we might want to look at to make legislation even better," Sen. Bob Corker (R-Tenn.) said.

Sen. Norm Coleman (R-Minn.) said he believes in a "public-private partnership," and "welcomes the collaboration" of AdvaMed and industry to ensure the bill is executed properly.

Medtronic Inc., a device manufacturer from Coleman's home state, applauded the bill in a Feb. 26 release. Echoing AdvaMed's contention that company size should play a smaller role in determining disclosure requirements, Medtronic said it "believes a level playing field for all companies is appropriate and that these entities should operate under the same disclosure requirements, recognizing that transparency can help alleviate any real or perceived conflicts of interest." Medtronic did not testify at the hearing.

Grassley applauded industry in a Feb. 27 statement. "These device makers deserve a lot of credit for getting ahead on this important issue and endorsing the objectives of our legislation. It's good to see corporate support for bringing transparency to practices in the pharmaceutical drug, device and biotechnology industry," he said.

More information about the hearing, including lawmakers' statements and witness' testimony, is available via the Senate Aging Committee's Web site at <http://aging.senate.gov/hearings.cfm>. 