Congress probes MD-industry payments

Congress has turned a spotlight on consulting relationships between surgeons and medical device companies. At a hearing Feb 27, the Senate Special Committee on Aging probed what the chairman, Senator Herb Kohl, called the “tangled, murky, and sometimes conflicting financial relationships” between industry and physicians.

Sen Kohl, a Wisconsin Democrat, is cosponsoring the Physician Payment Sunshine Act (S 2029), a bill to create a national database disclosing payments and gifts physicians receive from drug and device companies.

On a related matter, Senator Charles Grassley of Iowa, ranking Republican on the Senate Finance Committee, sent letters of inquiry to Synthes and the Food and Drug Administration (FDA) related to the ProDisc spinal disc.

According to the Feb 28 New York Times, the letters asked about potential financial conflicts of interest of physicians involved in the clinical research leading to the FDA’s approval of ProDisc in 2006.

Meanwhile, 2 academic medical societies called on medical schools and teaching hospitals to put financial conflict-of-interest policies in place within the next 2 years.

Sunshine Act hearing

In his opening statement at the hearing, Sen Kohl noted that physician-industry relationships play an important role in product innovation.

But he said over the last decade “it has become clear” there are often “substantial payments” involved, some of which “have been alleged to be grossly excessive, illegitimate, and not properly documented.”

He said senators are pressing for legislation because they are not convinced voluntary guidelines from industry and physician groups are working.

Some physicians “make it known they will be loyal to the highest bidder,” Sen Kohl said. “If these physicians are essentially putting their medical judgment up for sale, where does the patient’s well-being fit in?”

Sen Kohl referred to a 3-year investigation by the Department of Justice and Health and Human Services Office of Inspector General (OIG). In September 2007, the Justice Department settled with the top 4 orthopedic device makers with 75% of the hip and knee implant market. Though the companies admitted no wrong-doing, they paid the government more than $310 million in settlements and agreed to federal monitoring. They also agreed to post on their websites names of their consultants and payments made.

Kickback settlements

Leading off testimony, Gregory E. Demske of the OIG’s office reported the government’s investigation had found the 4 implant companies had paid physician consultants over $800 million from 2002 through 2004. Sometimes the payments were kickbacks, not related to actual contributions by the physicians, he said.

Demske said payments made to influence a physician to use or recommend a product, rather than serving a legitimate medical purpose, result in higher costs to patients, federal health programs like Medicare, and private insurers.

He described other kickback settlements, including those with Medtronic in 2006 related to spine surgeons; with Advance Neuromodulation Systems in 2007 related to physician payments; and with an individual physician, Patrick Chan, MD, an Arkansas neurologist, who pled guilty in 2008 to soliciting and accepting kickbacks from Blackstone Medical.
Next up was Charles Rosen, MD, a spine surgeon and critic of physician-industry relationships who founded the Association for Ethics in Spine Surgery. To join, surgeons must sign an affidavit that they will not accept any type of compensation from device manufacturers. He says the association has about 250 members.

Dr. Rosen said he became a critic after seeing “dozens of patients” with failed disc replacements with the Charité artificial disc. He testified that he has been attacked by surgeons or others on “industry’s payroll.”

Among his recommendations to the committee are full disclosure of industry compensation by physicians who write research papers and head medical societies, and tighter regulation of funding to individual physicians at universities.

“Money trumps truth and science,” Dr. Rosen said.

Companies testify

Zimmer in its testimony voiced strong support for the Sunshine Act. Zimmer also said it will make broader “fundamental changes” in its compliance program that will include, for example:

- sales and distribution teams and reps having no involvement with physician consultants on their agreements, services, and payments
- ensuring royalties are consistent with fair market value
- for fellowships and education, making donations through independent third parties instead of directly to physicians
- prohibiting all gifts to health care professionals.

In its testimony, Stryker said for years the company has had consulting contracts with a “select group” of orthopedic surgeons to whom it has paid “fair market value” for their services, which include developing new products the company says have advanced patient care. Stryker said the September 2007 settlements with the government will provide a “level playing field” so companies will “play by the same set of rules,” with surgeons being paid fair market value for product development and teaching.

Academic groups call for policies

Meanwhile, a joint report from the American Association of Medical Colleges and the Association of American Universities calls on medical schools and teaching hospitals to implement financial conflict-of-interest policies within the next 2 years.

The report says the policies should cover financial interests of faculty, deans, department chairs, and division chiefs. For more information on the report, go to www.aamc.org.

Access testimony and a webcast of the hearing before the Special Senate Committee on Aging at http://aging.senate.gov/hearings.cfm.

To download the Sunshine Act bill, go to www.thomas.gov. Enter the bill number S 2029 in the search box.