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The Doctor vs. Device Makers

Dr. Charles Rosen is on a mission to end the conflicts of interest between manufacturers and physicians

Rosen has made a habit of hounding the FDA about its policies Thomas Michael Alleman

by Arlene Weintraub May 8, 2008

In February, spine surgeon Dr. Charles D. Rosen stood before the Senate Special Committee on Aging and chastised the medical device industry for its unethical marketing practices. Rosen, a professor of orthopedic surgery at the University of California at Irvine, told legislators that surgeons often receive huge consulting fees from companies in return for using the manufacturers' products or promoting them as participants of medical societies and business ventures. "Patients usually don't know of this conflict, which leads frequently to unnecessary implants and surgery," he told 20 senators.

Rosen, 53, isn't the first to sound such alarms. But his testimony carries unusual weight with lawmakers because of his reputation as a passionate opponent of medical conflicts of interest. In 2006, Rosen founded the Association for Ethics in Spine Surgery to educate patients about how industry-physician ties can influence treatment decisions. About 270 doctors have either joined the

association or applied for membership, which entails vowing not to accept consulting fees, royalties, or other compensation from any company whose products they use. When Rosen isn't teaching residents or operating on patients, he's out proselytizing for a bill called the Physician Payments Sunshine Act of 2008, which would establish a national database listing payments and other gifts companies give to doctors.

In orthopedics, gift-giving is rampant. That was evident last winter, when Zimmer Holdings (ZMH) and four other large device makers agreed, as part of a $311 million settlement with the Justice Dept., to post lists of their paid consultants on their Web sites. Zimmer disclosed that it had handed over $86 million to more than 750 hospitals, doctors, and medical associations in 2007. The DOJ had alleged that some of those payments were not legitimate consulting fees but rather illegal kickbacks—de facto rewards for physicians who used certain products heavily. The companies did not admit wrongdoing, but they agreed to update the lists regularly.

The case, and subsequent outing of thousands of richly paid doctors, sparked a massive rethinking among the five companies about how best to work with physicians. It's not just about hips and knees. On Apr. 18, Warsaw (Ind.)-based Zimmer released a new five-point "compliance model" laying out procedures for engaging surgeons as consultants. Among the no-no's: making gifts to physicians and charitable contributions that could be construed as marketing gestures. The company says the new policies will be applied to all its businesses, including its $197 million-a-year spine unit.

LUCRATIVE ARRANGEMENTS

Rosen dismisses such pledges as "lip service." And he believes they won't stop federal lawmakers or state attorneys from expanding their investigations and possibly pursuing individual doctors who have entered into questionable consulting deals. Spinal devices could be the next big target. Artificial discs and other products used to fix aching backs account for $3.8billion of the $10 billion-a-year orthopedic devices market. And the segment is growing at a 12% annual clip.

Perusing Zimmer's revised policies, Rosen says he saw little that would prevent salespeople from giving physicians kickbacks under the guise of consulting arrangements. "A physician shouldn't be paid a royalty because he redesigned a screw head on a product. He should get a reasonable hourly fee," Rosen contends. Zimmer's policy says the company will "establish new engagement and compensation structures" for physicians, but it doesn't say how, Rosen complains. In an e-mail, a

Zimmer spokesperson says the company is working with an independent consultant "to determine if there are compensation models that would eliminate even the appearance of inappropriate incentives to physician-developers."

Rosen anointed himself an industry watchdog in 2005. It was shortly after Johnson & Johnson (JNJ) subsidiary DePuy Orthopaedics (JNJ) launched an artificial disc called Charité. To decide whether to incorporate the device into his practice, he read up on the clinical trial results. He was surprised to discover that a key study the company used to gain approval from the Food & Drug Administration left out data from 26% of the patients who participated. Furthermore, some authors were paid consultants to DePuy. Rosen complained to the FDA. He even volunteered to serve on future FDA advisory panels as a surgeon who has no financial ties to industry. "They didn't call," says Rosen. A spokesperson for DePuy said in an e-mail that data on the excluded patients were reported to the FDA, and that the company went out of its way to minimize any bias the investigators might have had. Rosen's complaints didn't trigger an investigation. But DuPuy was one of the companies involved in the recent DOJ settlement on hips and knees, and it did vow to make some changes. The company "has continued to refine and enhance our policies and procedures" for working with physicians, the spokesperson writes.

Rosen, meanwhile, continues to hound the FDA when he thinks there are lapses in the orthopedics area. On Apr. 23 he wrote to the agency asking for a list of surgeons who helped draft a new set of rules for approving artificial discs. He wanted to see if the physicians who are influencing the FDA's approval processes are paid by the companies whose products regularly come up for review. An FDA director wrote back saying Rosen would have to file a Freedom of Information request to get the list. He says it's just the latest example of the "transparency problem" in orthopedics.

How to put medical studies under the microscope:
Editors for The Journal of the American Medical Association were stung by the recent revelation that some of the scientists listed as authors of key studies may have done little of the actual research. And some failed to disclose financial support from pharmaceutical companies. The studies concerned Vioxx, the Merck (MRK) arthritis pill that was pulled from the market in 2004 after being linked to heart attacks and strokes. In response, JAMA's editors laid out a manifesto for all journals in its Apr. 16 edition. Among the 11 suggestions: Everyone named as authors of scientific papers should be required to tell the publications exactly how they contributed. And journal editors should seriously consider authors' conflicts of interest when deciding whether to publish a study. Disclosure might not stop unethical behavior, the editors write, but it may give pause "to authors who might reconsider lending their names and reputations to articles in which they did not meet requirements for authorship."

Activism hasn't made Rosen particularly popular, either on campus or in industry. His soft-spoken manner belies a combative intensity and a desire to shine, which may have been honed during the years he spent as a competitive figure skater. Often, he has found himself at

odds with other professors over the appropriate role companies and their physician consultants should play in training other doctors. Dr. Ranjan Gupta, U.C. Irvine's chair of orthopedic surgery, says new rules starting July 1 will restrict companies' activities on campus.

Undeterred by the controversies he has stirred up, Rosen now plans to run an ethics symposium at the university in June. He has already invited 11,000 spine surgeons and other health-care professionals. "Everyone will reveal in detail their industry connections, including the amount they receive, in what form, and what they do [for those companies] in return," says Rosen. The industry will have a chance to participate, he says. At the top of his list of invitees is none other than Zimmer.

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