HEALTH

Lawsuit Says Medtronic Gave Doctors Array of Perks

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A lawsuit brought by a former Medtronic Inc. lawyer alleges the big medical-device maker gave surgeons a variety of incentives to use its products, including regular entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in.

The previously undisclosed allegations involve Medtronic's spinal-devices unit, which has $3 billion in annual revenue. The unit's business relationships with doctors who use its spinal-repair implants are being investigated by Sen. Charles Grassley and have been the focus of lawsuits by other former employees.

Sen. Grassley has been looking into whether inducements for doctors, like those alleged in the lawyer's suit, have led to what surgeons say is widespread off-label use of Medtronic spine products.

The Food and Drug Administration has approved Medtronic's spinal devices to treat certain conditions, and doctors are free to use FDA-approved products as they see fit. But the FDA has warned that surgeons' use of a Medtronic bone graft in ways the agency hasn't approved has led to potentially life-threatening side effects in dozens of patients.

The former Medtronic lawyer's allegations are contained in a 2002 suit filed in U.S. District Court in Memphis against Minneapolis-based Medtronic and 10 doctors. The lawsuit and other filings in the case remain sealed, except for a heavily redacted copy of the complaint, which contains none of the doctors' names nor specifics of the allegations.

Medtronic has refused repeated requests from the Senate Finance Committee's staff for an unredacted version. Sen. Grassley, an Iowa Republican, is the panel's ranking minority member.

Even the identity of the plaintiff has been withheld. But, according to an unredacted copy of the lawsuit reviewed by The Wall Street Journal, she is Ami P. Kelley, a former senior legal counsel for the spine unit.

Medtronic declined to comment on the lawsuit's allegations. It said it has changed many business practices since the suit was filed, and is "committed to reform and transparency in the industry."

Ms. Kelley's lawsuit says kickbacks were "pervasive" and "the culture and way of doing business" at Medtronic. Sales staff, she said, "routinely took physicians" visiting the spine unit's Memphis headquarters to the Platinum Plus strip club, and picked up the tab for the dancers' services during "VIP visits." In 2007, Platinum Plus's owner pleaded guilty to charges related to dancers engaging in acts of prostitution, and the club has closed.

Ms. Kelley's lawsuit sought to recoup damages for the federal government, which prohibits companies from giving doctors inducements to use products covered by Medicare or Medicaid.

Her lawsuit and a separate one that also accused the spine unit of paying illegal kickbacks to doctors were the basis for a $40 million settlement deal between Medtronic and the government in 2006, according to the settlement document.

As part of its deal with the company, the government successfully moved to have the federal court dismiss the two lawsuits. But the other plaintiff, Jacqueline Kay Poteet, who formerly managed travel services for the Medtronic unit, has appealed the dismissal of her suit, arguing the settlement was too small. Under federal law, whistleblowers who recover money for the government can receive a share of that money.

Ms. Poteet's appeal puts the settlement deal at risk. Either Medtronic or the government could pull out of the settlement if the appeals court reverses the dismissal order.

It isn't clear what would happen to the Kelley lawsuit if the settlement agreement were voided. Neither the government, Ms. Kelley's attorneys nor Medtronic would comment on the matter.

Nor is it clear why the lawsuit remains under seal. Typically, such suits are unsealed when the government either declines to get involved in the matter or agrees to a settlement of the case.

Ms. Kelley, who now works at another company, alleges she was dismissed by Medtronic after challenging improper payments. She didn't return phone calls.

The Kelley lawsuit names several top spinal surgeons among the 10 doctor defendants and lists several others as receiving inducements. No finding of wrongdoing has been made against any of the doctors, and Medtronic denies that it engaged in any improper behavior.

The suit says surgeon Jeffrey Wang, now director of the University of California at Los Angeles's Comprehensive Spine Center, "liked to be taken" to Platinum Plus and emailed Medtronic sales official Brad Hancock saying he was "looking forward to going" to the club with him.

A UCLA spokeswoman said Dr. Wang, who isn't named as a defendant in the suit, "denies ever being entertained by Medtronic at the Platinum club" and doesn't recall sending any such email. If he did send it, she said, "it would have been done so in jest."

Attempts to contact Mr. Hancock, who is no longer at Medtronic, were unsuccessful.

Ms. Kelley's suit said Medtronic had consulting agreements with more than 100 surgeons that were "nothing more than a vehicle to pay the surgeons" to use Medtronic devices, instead of rivals' products. She alleged that the company paid patent royalties to doctors who didn't contribute novel ideas to products, created Web sites for them to market their practices, hired business consultants that helped doctors boost profits. She also said Medtronic offered twice-a-year seminars in Orlando and Las Vegas where doctors and hospital administrators received free management advice, and supplied physicians with office staff.

Among the surgeons named in the suit is Hallett Mathews, of Richmond, Va., Ms. Kelley said he was paid $450,000 a year under a consulting agreement. In quarterly reports filed with Medtronic, she said, Dr. Mathews would count his surgeries as time spent doing consulting work for Medtronic. The lawsuit also alleges Medtronic provided Dr. Mathews with a Medtronic credit card.

Last year, Dr. Mathews went to work for Medtronic, where he is vice president of medical and clinical affairs. A spokeswoman for the company said he couldn't comment on the allegations because the suit was sealed.

Medtronic says it overhauled its code of conduct in 2004 to include tougher guidelines on relations with physicians.

Ms. Kelley alleges Medtronic sent physicians on lavish trips under the guise of medical conferences, but where little work was done. Her complaint claims that on a five-day, all-expenses-paid trip to Alaska in 2001, which was billed as a "think tank," doctors were supposed to present case studies. But, according to the complaint, little discussion of the case studies took place. One doctor scheduled to give a talk stood before the group, "said he was sorry, but he had not prepared anything," and "drinking then commenced in place of discussion," Ms. Kelley said in the suit.

Medtronic picked up the cost of fishing guides and clothing for the doctors, the suit said. It said "women were also provided for the doctors," but didn't elaborate.

Maurice Smith, a neurosurgeon at the Semmes-Murphey Neurologic and Spine Institute in Memphis, organized the Alaska trip and joined the other doctors there, according to the lawsuit, which names him as a defendant. Ms. Kelley alleges Dr. Smith had a consulting contract that was prepaid for 10 years. She alleged that Dr. Smith provided few services to the company other than hosting the annual "think tank." He didn't return calls seeking comment.

When Medtronic discovered that neurosurgeon Patrick Johnson was in line for a promotion at a Los Angeles hospital, it arranged a helicopter skiing trip for him, and sent along former spine-unit president Michael DeMane and former regulatory chief Jon Serbousek, the lawsuit said. Dr. Johnson, now director of education at the Cedars-Sinai Institute for Spinal Disorders, wasn't named as a defendant in the suit. He didn't respond to requests for comment. Mr. Serbousek couldn't be reached. Mr. DeMane said, "As far as I know, Medtronic did not pay" for Dr. Johnson's trip.

At a Medtronic-sponsored "discussion group" in New Orleans, according to the complaint, the company paid $20,000 to $25,000 to get a group of doctors on a Mardi Gras parade float and another $15,000 to supply doctors with Mardi Gras beads.

Medtronic said it has changed its policies regarding trips like those described in the lawsuit, no longer conducts medical training in resort locations and has also prohibited the company's payment for the travel and expenses of doctors' spouses or guests.

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