

## Senators Express Disappointment Over CMS Response on Sunshine Act

Written by Grassley Press

Thursday, 03 November 2011 15:15

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WASHINGTON -- On Oct. 3, Sens. Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.) wrote to the administrator of the Centers for Medicare and Medicaid Services (CMS), seeking an explanation for the agency's missed deadline for drafting the implementing details of the Physician Payment Sunshine Act (Sunshine Act), a new law requiring public disclosure of the financial relationships between physicians and the pharmaceutical, medical device and biologics industries. The administrator [responded](#). The senators made the following comments on the response.

Sen. Grassley comment: "The administrator's response doesn't tell us anything new. There's no explanation for the delay and no indication of when to expect completion. It's an inadequate response any way you look at it. Meanwhile, the U.S. government just settled with a medical device maker for \$2.4 million over allegations of kickbacks to doctors to use the company's products. The payments to doctors are the kind that might be prevented through disclosure as soon as the Sunshine Act is in place. The longer we wait, the more taxpayers miss out on the benefits. I'll continue to press for answers from CMS."

Sen. Kohl comment: "Given how straightforward and detailed the Sunshine Act provisions were, it's troubling that the response to our letter would come a month late without any indication on progress, a timeline or what caused the delay. With medical device and pharmaceutical companies facing the January 1, 2012 deadline to begin collecting information about all payments to physicians, the lack of guidance leaves a great deal of uncertainty and I'm sure that's why many of the affected companies have joined us in calling for swift implementation."

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Here's an article describing the settlement referred to in Sen. Grassley's comment.

### Fraud and Abuse

#### California Medical Device Maker to Pay \$2.4 Million to Settle Kickback Charges

By Tom Gilroy

LOS ANGELES—A San Jose, Calif., maker of devices to treat spinal fractures has agreed to pay the United States \$2.4 million to settle Department of Justice allegations that the company paid kickbacks to induce physicians to use its products, DOJ said in an Oct. 26 announcement (United States ex rel. Eberhard v. DFine Inc., W.D. Tenn., No. 10-CV-2474, settlement announced 10/26/11).

The settlement, which came as a result of a qui tam whistleblower lawsuit brought under the False Claims Act, resolves the government's contention that DFine Inc. used customer surveys, known as User Preference Evaluations (UPEs), to pay participating doctors illegal kickbacks to induce them to use DFine's vertebral augmentation devices.

“Although DFine ostensibly collected product information from participating physicians, each UPE survey required use of a new DFine device in a patient, the majority of which were Medicare beneficiaries,” DOJ noted.

#### \$500 Payment to Fill Out Survey

In each case, DFine paid the physicians \$500 per patient to participate in the survey, DOJ added. The government also alleged that DFine provided improper remuneration in the form of travel expenses, lavish dinners, entertainment, and promotional speaker fees to doctors located in Chicago and Little Rock, Ark. DFine also solicited doctors to convert their business from a competitor's product and/or persuaded the physicians to continue to use DFine products, DOJ alleged. DOJ charged that DFine's alleged conduct violated the anti-kickback statute, which prohibits offering or paying remuneration to induce referrals or services covered by Medicare, Medicaid, or other federally funded programs. The lawsuit was filed in U.S. District Court for the Western District of Tennessee. The investigation of the case was handled by the DOJ's Civil Division, the U.S. Attorney's Office for the Western District of Tennessee, and the Office of Inspector General at the U.S. Department of Health and Human Services.

#### Company Admits No Wrongdoing

In a statement, DFine said it fully cooperated with the investigation and “continues to deny all

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of DOJ's unproven allegations. "The terms of the agreement specifically state that DFINE and its employees admit no wrongdoing, liability or illegal activity," the statement said. "The decision to settle prior to completing the full investigation was a very difficult one, but one we felt was best for the company based upon the significant disruption and associated costs to continue the investigation, as well as the uncertainty regarding its duration." According to the settlement, the company was represented by Leo Cunningham and Lee-Anne V. Mulholland of Wilson Sonsini Goodrich & Rosati. The settlement is at <http://op.bna.com/hl.nsf/r?Open=bbrk-8n3rv2>