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A newsletter on the current legal issues facing today's health care industry

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Federal Drug and Device Enforcement Efforts Spread to Physicians

By William H. Maruca



"Don't look back: Something may be gaining on you." — Satchel Paige

Those footsteps you hear behind you may be federal investigators, and hot on their heels, state lawmakers and regulators. They are targeting questionable relationships among drug and device makers and the physicians who order their products. And this time, physicians may get swept up along with the traditional larger targets.

Signaling a new initiative to seek civil and criminal sanctions against physicians who receive kickbacks from drug and device companies, OIG chief counsel Lewis Morris told the *New York Times*:

"What we need to do is make examples of a couple of doctors so that their colleagues see that this isn't worth it. We want to send the message to the physician community — particularly surgeons — that you can't do this."

The OIG is zeroing in on surgeons who they believe demanded payments disguised as consulting or travel agreements from device makers in exchange for using their products. Several high-profile government settlements with drug and device makers have required the companies to publicly disclose the names of physicians who received consulting fees and other remuneration. In particular, orthopedic surgeons who received payments from implant makers Biomet, DePuy, Smith & Nephew, Stryker and Zimmer found their names reported in their hometown newspapers and on the companies' web sites. These disclosures were a condition of the feds' combined \$311 million settlement with the manufacturers,

and were mandated regardless of whether the payments represented valid consulting fees, patent royalties or more aggressive and risky transactions. Other companies disclosing their physician payments include Eli Lilly, Pfizer, Merck, Cephalon, GlaxoSmithKline and Medtronic. Opponents of mandatory disclosure believe that guilt-by-association may be inferred by readers when they see physicians' names on these lists.

These developments should not surprise anyone who has followed the government's evolving efforts to crack down on cozy deals between drug/device companies and physicians over the past few years. Lupron maker TAP Pharmaceutical paid a record \$875 million in 2001 to settle claims of misconduct including kickbacks to physicians.

The Pharmaceutical Research and Manufacturers of America (PhRMA), a prominent industry trade association, adopted a strict code of conduct partially in response to the TAP case, and the OIG raised the ante by prescribing compliance with the voluntary PhRMA code as the baseline under its 2003 Compliance Program Guidance for Pharmaceutical Manufacturers. PhRMA beefed up its code of conduct effective January 2009. Common practices such as distribution of non-educational logo items (pens, mugs and other "reminder" objects) are prohibited under the new code because such items, even though of minimal value, "may foster misperceptions that company interactions with health care professionals are not based on informing them about medical and scientific issues." The revised code also prohibits company sales representatives from providing restaurant meals to health care professionals but allows them to provide occasional meals in health care

professionals' offices in conjunction with informational presentations. The changes reaffirm and strengthen PhRMA's existing ban on entertainment or recreational benefits to health care professionals.

Following suit, on Dec. 18, 2008, the Advanced Medical Technology Association (AdvaMed) approved a major update of its Code of Ethics on Interactions with Health Care Professionals, effective July 1, 2009, which further clarifies and distinguishes between appropriate and inappropriate activity between health care professionals and representatives of AdvaMed member companies.

Meanwhile, state and federal regulators are ramping up their efforts to curb improper dealings between manufacturers and doctors. The Massachusetts Department of Public Health has adopted a Marketing Code of Conduct for pharmaceutical and medical device manufacturers and requires the disclosure of certain payments made to health care practitioners. The Massachusetts Code draws on the PhRMA code and the AdvaMed code and implements additional restrictions required by state law. For instance, gifts of entertainment or recreation and meals in conjunction with entertainment or recreation and complimentary items such as pens, mugs, calendars, etc. are prohibited. Meals are restricted and in some instances prohibited. Generally, meals provided to health care providers must be modest and occasional in nature and cannot occur outside of a practitioner's office or hospital setting. So, pizza for the office staff is OK, a "dine and dash" dinner at an upscale restaurant for the physicians is not.

Vermont and Minnesota have passed legislation requiring public disclosure of industry payments to physicians, and

California, Maine, West Virginia and the District of Columbia require similar disclosures to be made to state agencies.

Not to be left behind, in January, U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) reintroduced a bill titled "The Physician Payment Sunshine Act" that would require manufacturers and group purchasing organizations to report all physician payments over a cumulative value of \$100. If passed, the first report would be due by March 31, 2011, and made available to the public by September 30, 2011. A similar bill fizzled in 2007.

Some health systems and other providers are jumping on the bandwagon and voluntarily adopting strict conflict-of-interest policies, many of which exceed government requirements and industry guidelines:

- The Association of American Medical Colleges recommends that its members limit drug and device representative access without appointments and ban gifts and other freebies.
- The University of Pittsburgh Medical Center's 2007 comprehensive Industry Relations Policy addresses gifts, meals, drug/device samples, site access, continuing education support, sponsorship of meetings, speaker fees and ghostwriting arrangements and other industry support for research.

- In May 2009, Stanford University Medical Center revised its 2006 policy, banned on-campus meals and sales rep gifts of any size to physicians and practitioners. The policy also restricts reps' access to patient care areas and medical school facilities except for in-service training on devices and equipment and by appointment only.
- Henry Ford Health System has forbidden gifts and vendor drop-ins and requires reps to pay a \$100 certification fee to Henry Ford before being allowed to schedule sales appointments.
- Yale and the University of Pennsylvania are also among the teaching hospitals that have limited drug/device representative interactions with physicians.
- The *AMA News* reports that one in four physicians works in a practice that refuses to see drug reps. Of doctors who do see reps, about 40 percent will meet with detailers only with scheduled appointments.

An increasing number of doctors have chosen individually to take the high road, going as far as exchanging drug-logo giveaway pens for pens bearing the NoFreeLunch.org logo under its "amnesty" program. NoFreeLunch.org was formed by New York internist Bob Goodman, M.D. and

is supported by practitioners who believe that pharmaceutical promotion should not guide clinical practice. The organization's stated mission is to encourage health care providers to practice medicine solely on the basis of scientific evidence, and they discourage the acceptance of all gifts from industry by health care providers, trainees and students.

As relationships between physicians and industry become more transparent, physicians should expect that their arrangements may come under scrutiny and should exercise an abundance of caution when considering entering into these relationships. Experienced health care counsel can help you evaluate these arrangements before they result in public embarrassment, or worse, litigation, fines and sanctions.

For more information about this topic, contact William H. Maruca at 412.394.5575 or wmaruca@foxrothschild.com.

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