

The New Corporate Ethos: Why Orthopedic Device Manufacturers Turn “State’s Witness” Against Physicians

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Five major manufacturers of orthopedic devices and their executives recently evaded criminal prosecution for health care fraud and abuse charges by biting the skilled hands of the surgeons that use their products. Federal prosecutors have long contended that the payment of money by medical device manufacturers to hip and knee surgeons that use their devices, were nothing more than illegal “kickbacks.” They contend that such payments are punishable as criminal offenses under the “Anti-Kickback” statute, a federal law that prohibits both the: (a) “solicitation or receipt” and (b) “offering or payment of remuneration” in return for referring a patient for goods or services paid for by Medicaid or Medicare. While many believed that the kickback investigation effectively ended with the payment of \$310 million in fines by Biomet, DePuy, Smith & Nephew and Zimmer, nothing could be further from the truth.

To the contrary, in order to avoid prosecution, the manufacturers entered into what is known as “Deferred Prosecution Agreements” (DPA’s). In order to receive this benefit, the manufacturers, amongst other things, became “informants” and provided to the government lists of physicians to whom they made cash payments, provided plane tickets, lodging, food or other gifts and other evidence to support kickback cases against the doctors. Thus, while the physicians remain at risk of prosecution, the manufacturers have been promised that criminal charges will be dropped if they “name names” and begin to behave like good corporate citizens.

As required by the DPA’s, lists of physicians that received payments last year (and the amounts they received) are now posted to each corporation’s website. The lists may be found at <http://www.nytimes.com/2008/03/22/business/22device.html?ref=business>. According to other recently published reports, some physicians have already received subpoenas from the United States Attorney for the District of New Jersey.

In addition to criminal liability under federal law, the receipt of payments (or other benefits) from device manufacturers or pharmaceutical companies may expose a physician to other criminal, civil and administrative penalties. Such payments may be deemed criminal violations of

various states’ own version of the anti-kickback statute and may also constitute physician misconduct. Any of these sanctions could have far reaching effects, including exclusion from Medicaid, Medicare, managed care programs, loss of hospital privileges and even loss of licensure. Adding insult to injury, the acceptance of such remuneration may expose a physician to monetary penalties under both the federal and recently enacted state false claims statutes.

It was recently reported that pharmaceutical companies and medical device manufacturers spend \$13 billion per year on direct-to-physician promotion. In response, through their by-laws, several major university hospitals enacted policies aimed at limiting their corporate reach. In California, Kaiser Permanente strictly limits its physicians’ relationships with drug and medical device companies. The New York State Assembly passed a bill that would require drug makers to report the conferral of any benefit upon a physician that is valued at over \$75. However, the bill was never signed into law and it did not address payments or gifts made by device manufacturers. In the final analysis, the circumstances under which such “payments” are permissible remains unclear; physicians remain at risk and investigations persist.

Relationships with pharmaceutical or medical device companies are fraught with danger. Corporations and those that run them will do whatever is necessary to avoid prosecution. In a document referred to as the “McNulty Memo,” the U.S. Justice Department issued guidelines to its prosecutors concerning how to determine whether a corporation should be allowed to avoid prosecution. The McNulty Memo is required reading for all counsel to device and pharmaceutical manufacturers for it is nothing less than a primer on how to avoid corporate prosecution. First and foremost, it encourages the corporations to become government informants. They are required to: (a) surrender all incriminating evidence and (b) turn in anyone who may have participated in activity that is even arguably criminal – even when they have done so at the request or command of corporate management. This, of course, includes their low level sales staff and, yes, their physician-customers. Finally, the corporations may even be required to waive the attorney-client privilege and provide to the government evidence or information that would otherwise be constitutionally shielded from disclosure.

Unfortunately, there is no analogue to the McNulty Memo for individuals – it only applies to corporations.

Accordingly, the prudent physician that accepts Medicaid or Medicare has to protect himself or herself and we offer the following to physicians as the next best thing to a McNulty antidote.

1. Reassess relationships with your vendors. Remember that they are in the business of making money and may say whatever is necessary to make a sale. If they offer remuneration, ask them: (a) if they have been provided with written assurance from their corporate counsel that the arrangement does not offend federal or state law and (b) to provide you with a copy of that opinion. Chances are no such document exists and we suggest that you simply decline remuneration of any sort.
2. Determine if the by-laws of your hospital or your group prohibit accepting gifts or other forms of remuneration from vendors. Violating such policies could result in adverse action and a report to the National Practitioner Databank that may have far reaching effects upon your practice.
3. Implement, through counsel, formal written policies that delineate exactly how to respond to inquiries from law enforcement, other governmental agencies or insurance investigators. Such policies take control of the flow of information away from your employees and put it squarely in the hands of counsel.
4. Implement a corporate "document retention plan" that calls for the systematic elimination of certain types of documents at set intervals.

If your relationships with vendors place you in jeopardy:

1. Do not destroy documents or other potential forms of evidence, even if you have a document retention plans already in place. Copies inevitably exist in one format or another and you may expose yourself to prosecution by simply destroying potential evidence.

2. Stop communicating with other potential targets -- physicians and sales reps alike. You do not know who is already cooperating with the government (or who may do so in the future).
3. Do not speak to government investigators. Despite any inclination you may have to prove you have nothing to hide, call your attorney. You should politely ask them to leave and pursue the matter with your attorney at a later time.
4. Do not speak with your partners, staff, colleagues or vendors about the matter. Remember today's friend may very well be tomorrow's enemy and your words and actions may come back to haunt you.
5. Neither you nor your staff has any obligation to speak with government investigators, provide them with information or with documents on the spot, even if presented with a subpoena.
6. Do not be thrown off guard by the government's tactics. Government investigators may find you when and where you least expect them. They may show up at your home or office very early in the morning or late at night. They are even permitted to engage in certain types of deception in order to secure your cooperation.
7. Consult with appropriately experienced counsel immediately so that he or she will become the only conduit through which information may flow.
8. Allow counsel to conduct his or her own investigation of the matter. This will permit them to assess: (a) the extent of your exposure to civil, criminal or administrative penalties and (b) whether your interests conflict with those of others in your office and (c) whether a proactive approach to the investigation warranted, whether you should or must provide information or whether you should simply "lie low."

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