

MEDICAL DEVICE DAILY™ PERSPECTIVES

A free weekly perspective on the med-tech industry, from the publishers of Medical Device Daily™



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In This Issue: [Short Takes](#) reports more movement on disclosure brings device kingpin Medtronic into the fold

Protect your med-tech firm with an anti-corruption compliance program

By **ROSS BOOHER** and **TAYLOR PHILLIPS**
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Since Dec. 15, 2008, companies have agreed to pay the U.S. government more than \$1.3 billion to settle charges under the once-little-enforced U.S. Foreign Corrupt Practices Act (FCPA). Also, multiple executives have recently pleaded guilty to FCPA charges and face millions in fines and/or years in prison. Aggressive enforcement is likely to continue. In January, the [Los Angeles Times](#) reported that government officials stated that enforcing the FCPA is one of the highest priorities for the **Department of Justice** (DOJ), second only to combating terrorism. The DOJ's 2008 enforcement action against **AGA Medical** (AGA; Plymouth, Minnesota) provides some useful lessons that can help medical company leaders avoid their own FCPA problems ("[AGA Medical settles charges, agrees to pay DOJ \\$2 million](#)").

The FCPA is a federal law designed to prevent and deter bribery of foreign officials. The anti-bribery provisions of the FCPA prohibit directly or indirectly offering "anything of value" to any "foreign official" for the purpose of influencing the decision of that official to do anything that assists the offerer in the obtaining or retaining of business.

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Businesses should beware that the terms used in the law have been broadly construed and the statute prohibits conduct that may be considered routine by many companies when dealing with private clients. The FCPA also contains accounting and record-keeping provisions that place an affirmative duty on issuers to "make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer."

The healthcare industry has recently received considerable attention from FCPA enforcers from both the SEC and the DOJ. Multiple medical device and pharmaceutical companies have been investigated. In 2008, AGA, which sells medical devices for the treatment of congenital heart defects, settled FCPA charges brought by the DOJ. In court filings, the DOJ alleged that a Chinese distributor working on behalf of AGA made improper payments to patent officials, government hospitals, and physicians in those hospitals.

AGA accepted the facts set forth by the DOJ and acknowledged that the company was responsible for the acts of its officers, employees and agents. AGA agreed to pay a penalty of \$2 million. If the DOJ determines that AGA has breached the terms of the agreement, AGA can be criminally prosecuted for the conduct it has already acknowledged in the agreement as well as any other federal criminal violation of which the DOJ has knowledge.

Lessons learned from AGA

Here are the most important lessons to be learned from AGA's situation:

- **Small companies are also at risk.** Even comparatively small companies with limited operations in a particular country may be prosecuted under the FCPA. According to court filings, AGA sales in China between 1997 and 2005 totaled approximately \$13.5 million.
- **Healthcare companies at risk.** Healthcare companies are at a particularly high risk under the FCPA. Because the DOJ defines "foreign official" broadly, the term can include employees of state-owned entities, including physicians or officials of government-operated hospitals, such as those in the AGA case. Similarly, many healthcare companies need government licenses, permits or patents. Increased contact with foreign officials provides greater opportunity for an FCPA violation to occur.
- **Beware of third-party agents.** Companies can be held liable for the acts of third-party agents, such as the Chinese distributor in the AGA case. Many medical device and pharmaceutical companies employ third-party agents to assist in sales, export or licensing requirements in foreign countries.
- **The dangers of e-mail.** With the click of a button, e-mails can embroil U.S.-based, home office employees in FCPA investigations. In the AGA case, the DOJ relied, in part, on an e-mail sent by a U.S. employee stating: "I understand that the fee you must pay each physician was to be included in your selling price. It should therefore not be an issue."
- **Potential benefits of self-disclosure.** Finally, self-disclosure can mitigate the damage of an FCPA violation. In the AGA case, the government recognized the company's voluntary disclosure after a thorough internal investigation.



Start with an anti-corruption plan

Rest assured there are several things you can and should do to protect your company, your employees and yourself from the high cost of a FCPA problem. The single most important step a med-tech company leader can take to avoid FCPA liability is to establish an effective anti-corruption compliance program.

The first goal of a compliance program is to prevent conduct that could violate the FCPA. Because the FCPA prohibits some conduct which might be considered routine in a private business context (such as meals, travel and entertainment under certain circumstances), a compliance program can significantly reduce exposure by helping to avoid inadvertent criminal violations and by establishing mechanisms to reduce the likelihood of third-party liability.

Second, a compliance program increases a company's ability to detect FCPA problems early and secure the benefits of voluntary disclosure. As in the AGA case, voluntary disclosure, along with a thorough investigation and cooperation with enforcers, may forestall criminal prosecution.

Third, by demonstrating the commitment of the company to preventing violations before they occur, a compliance program can help a company avoid criminal prosecution altogether or can reduce the consequences of a prosecution. Enforcers consistently emphasize that the tone at the top is critical to any effective FCPA compliance effort. Simply having a paper compliance program, such as a section on the FCPA in a company's Code of Conduct, is unlikely to achieve any of these goals.

Whether in medicine or law, prevention and early diagnosis are critical to reducing the risk of a bad outcome. If a company does business internationally, one of the most important steps its leadership can take to help reduce FCPA exposure is to ensure the company maintains a well-designed, active anti-corruption compliance program.

A key question for such leaders is: How would you, your employees and your third-party agents describe your company's current anti-corruption compliance program to an enforcer or your shareholders?

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To learn more about the FCPA, see the audio conference sponsored by *Medical Device Daily* called [Foreign Corrupt Practices Act: The DoJ and SEC](#)

[Are Coming—Are You Ready?](#) A CD of that audio conference is available by [clicking here](#).

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MDD Perspectives **Fun Facts**

Editor's note: In an effort to lighten your day, we now offer a weekly chuckle or two . . .

Grin and bare it

A survey shows that when men are told the doctor is going to do a digital exam to check their prostate, most think he's going to use an advanced med-tech device.

Patient safety version 1.0

Surgeons, when they see an X mark on your leg, say, "OK, so this means working on the other leg . . . or maybe it's this one?"

Short Takes

More movement on disclosure brings device kingpin Medtronic into the fold

By JIM STOMMEN

Medical Device Daily Executive Editor

The ink was barely dry (in a virtual sense) on last week's lead *Medical Device Daily Perspectives* piece by contributing writer Gregory Freeman about disclosure steps being taken in the life sciences sectors when the biggest pure med-tech company announced its intentions to join the party ("[Medtronic latest to disclose its payments to physicians](#)").

[Click here](#) to read the entire story.

Recent News From Medical Device Daily and Related Publications

[510\(k\)—Essentials of Gaining FDA Marketing Clearance](#)

In this 90-minute audio conference scheduled for March 12th and sponsored by *Medical Device Daily*, device submissions expert Karen Bannick will discuss what is expected in 510(k) submissions and how you can effectively respond to the agency's ever increasing demands for more medical and scientific information. [Click here](#) to register or for more information, or call 800-688-2421 or 404-262-5474. **Please mention conference code T09542-7197..**

[Venture capital growing wary of prospects for new devices](#)

WASHINGTON — The jittery financial markets might reasonably be expected to trim the availability of venture capital for medical device start-ups, but a session held by the **Medical Device Manufacturers Association** (MDMA; Washington) last week made clear that venture capitalists (VCs) are more than a little concerned that investment will be profoundly blunted by a convergence of economic and regulatory trends along with recent legislative developments on Capitol Hill, especially patent legislation and comparative effectiveness.

[AdvaMed's agenda for 2009 is long on impending legislation](#)

WASHINGTON — The political climate has shifted dramatically in Washington, so it's no surprise that this year's agenda for the **Advanced Medical Technology Association** (AdvaMed; Washington) is dotted by concerns over a raft of legislation industry sees as potentially harmful.

[Medtronic leads are under fire again as study cites failures](#)

This week of activity for **Medtronic** (Minneapolis) has been the equivalent of taking two steps forward and then one giant step back. On Monday the med-tech powerhouse reported that it would be shelling out \$1.025 billion to snag **CoreValve** (Irvine, California) and **Ventor Technologies** (Netanya, Israel) to expand its cardiovascular business.

[Study boosts emerging combo of digital mammography/CAD](#)

Computer-aided detection (CAD) has been shown to be an aid in detecting breast cancers using analog film technology.



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