Department of Justice Imposes More Than $110 Million in Fines on Medical Device Makers

April 3, 2015

Introduction

On March 19, 2015, the U.S. Department of Justice and the U.S. Department of Health and Human Services issued their joint annual report on health care fraud and abuse control. The annual report states that during fiscal year 2014, the federal government won or negotiated approximately $3.3 billion in judgments and settlements, and attained additional administrative impositions in health care fraud cases and proceedings.

The annual report details high-profile actions taken against pharmaceutical companies, physicians, pharmacies, hospitals, medical clinics, dental clinics, entities engaged in prescription drug fraud, and medical device companies. This WSGR Alert highlights the high-profile government actions against medical device manufacturers.

Federal Government Actions Against Medical Device Companies

1) Boston Scientific and its Guidant subsidiaries agreed to pay $30 million to settle civil False Claims Act (FCA) allegations that over a period of three years, Guidant knowingly sold defective defibrillators to health care facilities, which in turn implanted the devices into Medicare patients. The settlement resolved allegations that two lines of Guidant’s implantable defibrillators contained an “arcing” defect that caused the defibrillators to short circuit. The government alleged that although Guidant fixed the defect, the company continued to sell its remaining stock of the old, defective versions of the devices and took steps to hide the problem from patients, doctors, and the U.S. Food and Drug Administration (FDA). In February 2010, Guidant pleaded guilty to criminal charges of misleading the FDA and failing to submit a labeling change to the FDA relating to the defective devices.

2) Abbott Laboratories, Inc., agreed to pay $5.5 million to resolve civil FCA allegations regarding false claims submitted to Medicare for surgical procedures involving carotid and peripheral vascular and biliary stents. The government alleged that Abbott knowingly paid prominent physicians unlawful kickbacks with the expectation that these physicians would arrange for the hospitals with which they were affiliated to purchase Abbott’s vascular products for use in treating Medicare beneficiaries.

3) Genzyme Corp. agreed to pay $22.3 million to resolve civil FCA allegations relating to its marketing of an unapproved version of Seprafilm. The settlement resolves allegations that Genzyme sales representatives taught doctors and other staff to dissolve Seprafilm sheets in saline to create a “slurry” for use in laparoscopic surgeries by inserting a catheter filled with the mixture into the body and squirting it into the abdominal cavity. Seprafilm is FDA-approved for use in open abdominal surgery, but not for minimally invasive surgeries, such as laparoscopic surgery. As a result of this conduct, Genzyme allegedly caused hospitals and other purchasers of Seprafilm to submit false and fraudulent claims to federal health care programs for uses of Seprafilm that were not reimbursable.

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4) CareFusion Corp. agreed to pay $40.1 million to settle civil FCA allegations that it paid kickbacks and promoted its products for uses that the FDA had not approved. The settlement resolves allegations that CareFusion: (1) paid kickbacks to the physician co-chair of the Safe Practices Committee at the National Quality Forum, a nonprofit organization that reviews, endorses, and recommends standardized health care performance measures and practices; and (2) knowingly promoted the sale of Chloraprep for uses that the FDA had not approved, some of which were not medically accepted indications, and made unsubstantiated representations about the appropriate uses of Chloraprep.8

5) Medtronic, Inc. agreed to pay $9.98 million to resolve civil FCA allegations that the company paid kickbacks to induce physicians to use certain of the company’s cardiac rhythm management devices, including pacemakers and defibrillators. The government alleged that Medtronic: (1) paid implanting physicians to speak at events intended to increase the flow of referral business; (2) gave physicians tickets to sporting events; and (3) developed marketing/business development plans for physicians at no cost.9

6) Smith & Nephew agreed to pay $8.3 million to settle civil FCA allegations that the company violated the Trade Agreements Act by selling medical devices to the government that had been manufactured in Malaysia, when they were required to be manufactured in the United States.10

7) Omni Surgical L.P. (also known as Spine 360) and an Indiana spinal surgeon agreed to pay a combined $2.6 million to settle civil FCA allegations that Spine 360 paid illegal kickbacks to the physician to induce him to use the company’s products. The government alleged that payments made by Spine 360 to an entity controlled by the physician pursuant to a series of intellectual property agreements were actually shams, and that the payments were intended to compensate the physician for using Spine 360 products in his surgeries.11

Conclusion

Being the target of government actions consumes time and resources. In addition, statutory and regulatory violations can result in injunctions, seizures, significant fines, criminal penalties, consumer and shareholder lawsuits, unwanted publicity, and the fraying of key government agency-company relationships. Medical device companies can minimize these unwanted events through a variety of actions, including regularly consulting legal counsel. For questions regarding government action against medical device companies or any related matter, please contact David Hoffmeister or another member of Wilson Sonsini Goodrich & Rosati’s FDA or life sciences practices.

Charles Andres contributed to the preparation of this alert.

8 Id. at pages 22-23.
9 Id. at page 23.
10 Id.
11 Id.