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Avoiding Criminal Liability: A Review of Recent Developments In Government Investigations of Medical Device Manufacturers

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Recently, the Department of Justice announced an expansion of the fraud section of the Criminal Division, in part, to bring more health-care-related prosecutions. As a result, the medical device industry, already the focus of criminal and regulatory proceedings and investigations, will come under even more intense scrutiny. This article examines recent medical device legislative trends, recent enforcement actions against medical device manufacturers, including those involving off-label and anti-kickback violations, and recent Food and Drug Administration warning letters that provide guidance on how medical device manufacturers can avoid criminal and regulatory liability.[1]

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Legislative Trends

Pursuant to the Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq., to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., the FDA regulates more than 100,000 different medical devices manufactured by more than 15,000 companies. The FDA may find that a medical device is ''adulterated'' if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation do not conform to the current Good Manufacturing Prac-

[1] FDA medical device enforcement actions and warning letters declined in the 1993-2007 period. *See* testimony of David C. Vladeck before the House Committee on Oversight and Government Reform, May 14, 2008, at 15 n. 21 (''The decline of enforcement activities by the FDA is nothing short of stunning.''); *Justice Department Prepares To Boost Fraud Section,* New York Law Journal (Aug. 11, 2009).

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tice (cGMP) guidelines of the Quality System Regulation in 21 C.F.R. § 820.[2]

The MDA categorizes medical devices in three classes.[3] Class I, which includes devices such as elastic bandages and examination gloves, is subject to the lowest level of oversight: ''general controls,'' such as labeling requirements that are sufficient to reasonably assure their safety and effectiveness. Class II, which includes devices such as powered wheelchairs and surgical drapes, may also be subject to ''special controls,'' such as performance standards and post-market surveillance measures.[4] Class III devices, which include products such as artificial heart valves and other medical devices that are used to support or sustain life or that have substantial importance in preventing impairment of human health, are subject to the most stringent regulatory requirements as general or special controls may be inadequate to reasonably assure safety and effectiveness.

In principle, Class III devices can be marketed only if they successfully pass the FDA's rigorous pre-market approval process.[5] Most medical devices, however, have not had to undergo pre-market approval. Under Sections 360c(f)(1) and 360e(b)(1) of the MDA, devices sold before the MDA's effective date may remain on the market until the FDA promulgates a regulation requiring pre-market approval. And a new device need not undergo pre-market approval if the FDA finds, through the less rigorous FDA 510(k) approval process, that it is ''substantially equivalent'' to another device that is exempt from pre-market approval.[6]

In 2007, Congress held well-publicized hearings about the 510(k) process, after which it enacted the FDA Amendments Act of 2007. The act directed the Government Accountability Office to study and report on the 510(k) process. In January, the GAO issued its report, which found that the FDA had failed to comply with a congressional mandate to implement more stringent procedures for approving Class III devices.[7] According to the GAO, ''when asked for their time frame for doing so, however, the [FDA] officials did not provide one.''[8]

In its 2009 Report, the GAO recommended that the FDA ''expeditiously take steps to issue regulations for each class III device type currently allowed to enter the market through the 510(k) process, including (1) reclassifying each device type into a lower class or requiring it to remain in class III and (2) for those device types remaining in class III, requiring approval for marketing through the PMA process.''[9] The GAO report was unquestionably an embarrassment for the FDA, and it will increase pressure on the agency to more aggressively regulate medical device manufacturers.

[2] Remarks of Rep. Henry Waxman, p. 27, hearing of the Committee on Oversight and Government Reform, House of Representatives, May 14, 2008.

[3] *See generally Riegel v. Medtronic Inc.,* 128 S.Ct. 999, 1003 (2008).

[4] 21 U.S.C. § 360c(a)(1)(B).

[5] *Riegel*, 128 S.Ct. at 1003; *see also* 21 U.S.C. § 360c.

[6] *See Riegel* at 1004.

[7] *FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process,* GAO Report to Congressional Addressees, GAO-09-190, at 7 (January 2009).

[8] *Id.*

[9] *Id.*

Justice Department Criminal Prosecutions

The Justice Department can bring actions against medical device manufacturers under 21 U.S.C. § § 351 and 352 for making adulterated and misbranded devices.[10] In recent years, DOJ has filed numerous proceedings against medical device manufacturers for adulterated and misbranded devices, including actions charging that manufacturers have promoted medical devices for off-label uses.

Some of these actions have resulted in consent decrees, discussed below, in which the manufacturer agrees to implement various remedial measures. Other actions have resulted in substantial civil and/or criminal fines, including:

- $704 million in criminal and civil fines against Serono SA relating to claims concerning off-label use of a bioelectrical impedence analysis device;[11]
- $302 million in criminal and civil fines against Quest Diagnostics and its subsidiary, Nichols Institute Diagnostics, relating to claims based on the misbranding of a device measuring parathyroid hormone levels;[12]
- $92.4 million in criminal and civil fines against EndoVascular Technologies Inc. relating to claims based on on- and off-label uses of a device used to treat aortic aneurysms;[13] and
- a permanent injunction in a civil action against Endotec Inc. for allegedly selling adulterated and misbranded knee and jaw implant devices.[14]

Corporate Integrity Agreements. In addition to fines and injunctions, investigations into adulterated and misbranded devices can lead to government-imposed compliance measures in the form of a corporate integrity agreement. Comprehensive CIAs can last for five years and may require the medical device manufacturer to hire compliance officers, appoint compliance committees, develop written standards and policies, implement employee training programs, obtain an independent review organization, and provide status reports to the Department of Health and Human Services Office of Inspector General.[15]

While FDA warning letters are discussed separately below, the letters reveal one technique used by the FDA to detect off-label use of medical devices. The FDA will check the website of a device manufacturer to ensure that the information on it is consistent with the agency's

[10] Statutes available to the government in other types of prosecutions regarding medical devices include the False Claims Act, 31 U.S.C. § § 3729-33, and the anti-kickback statute, discussed below.

[11] *Serono to Pay $704 Million for the Illegal Marketing of AIDS Drug*, DOJ press release (Oct. 17, 2005), available at http://www.usdoj.gov/opa/pr/2005/October/05_civ_545.html.

[12] *Quest Diagnostics to Pay U.S. $302 Million to Resolve Allegations That a Subsidiary Sold Misbranded Test Kits*, DOJ press release (April 15, 2009), available at http://www.usdoj.gov/opa/pr/2009/April/09-civ-350.html.

[13] *Guidant Corp. Subsidiary Pleads Guilty, Will Pay $92 Million in Medical Device Case,* BNA's Health Care Fraud Report (7 HFRA 483, 6/25/03).

[14] *United States v. Endotec Inc.*, 563 F.3d 1187, 1204 (11th Cir. 2009).

[15] *Corporate Integrity Agreements*, website for the HHS OIG, available at http://oig.hhs.gov/fraud/cias.asp.

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approval of that device.[16] The FDA also will look for devices that are sold without pre-marketing approval. If the website indicates an intended use of the device that was not approved by the FDA, it is considered misbranded under 21 U.S.C. § 352(o) and adulterated under 21 U.S.C. § 351(f)(1)(B).

For example, one manufacturer of a blood pressure monitor claimed on its website that the device could be used as an ''Irregular Heartbeat Detector for better health monitoring.''[17] That indication was not covered by its original 510(k) clearance and was considered a ''major modification'' that would require a new 510(k) submission.[18] Another company sought pre-market approval of a device for reading and storing data such as blood pressure, pulse, and temperature. The company notified the FDA that it wanted to remove all references to ''spirometry and Peak Flow measurements'' because the spirometer used with the device had been discontinued. The FDA cleared the device pursuant to the 510(k) process, but it later issued a warning letter to the manufacturer that its website promoted the device for unapproved uses involving the discontinued spirometer diagnosing asthma ''using a peak flow expiratory flow meter,'' diagnosing chronic obstructive pulmonary disease using a spirometer, and monitoring forced expiratory flow in clinical trials.[19]

The Anti-Kickback Statute. The relationships between medical device manufacturers and physicians require close collaboration. As one federal prosecutor has recently pointed out, device manufacturers rely on physicians to ''develop and test their products and report back on what works and what does not work.''[20] As a result, this prosecutor acknowledged, ''the interactions between device makers and physicians, to a degree, may be more appropriate than those between doctors and drugmakers.'' Accordingly, device manufacturers may be treated differently in charging decisions. At the same time, the close collaboration creates risk both to the physician and the manufacturer.

Under the federal anti-kickback statute, 42 U.S.C. § 1320a-7b, the willful solicitation, receipt, or payment of any remuneration (including any kickback, bribe, or rebate) to influence the referral of any medical service related to a government health care program is a felony. The anti-kickback statute provides penalties of up to five years in prison and a $25,000 fine. Some actions enforcing the anti-kickback statute against medical device manufacturers have resulted in substantial civil and/or criminal fines, including:

- $311 million in civil and criminal fines in 2007 against five manufacturers of hip and knee surgical implants who allegedly entered into consulting deals with orthopedic surgeons as inducements to use the companies' medical devices, with four of the companies entering into deferred prosecution agreements;[21]
- $97.5 million in civil fines against Bayer HealthCare LLC in 2008 for paying diabetic suppliers to convert their patients to Bayer's glucose monitors and testing strips;[22]
- $40 million in civil fines against Medtronic/Sofamor Danek relating to spinal implants;[23]
- $3.7 million in criminal and civil fines against NeuroMetrix in 2009 for making illegal kickback payments to physicians, encouraging them to use the company's *NC-stat* neuropathy diagnostic system;[24] and
- $2.95 million in civil fines against Advanced Neuromodulation Systems Inc. in 2007 for payment of kickbacks to physicians who used the company's spinal cord stimulation devices.[25]

The $40 million Medtronic settlement agreement included a five-year CIA, requiring the company to establish detailed procedures assuring the appropriateness of its arrangements with physicians.[26] Specifically, the CIA required Medtronic to create and maintain an electronic database of all nonsale communications with its customers. This database, as well as the development of corporate compliance policies, employee training initiatives, and annual compliance reports, were subject to internal and external review.[27]

FDA Warning Letters

A medical device manufacturer's failure to comply with cGMP guidelines or reporting requirements can lead to a warning letter from the FDA. As reflected in a

[16] Warning letter from the FDA to David Michaels, managing director of Lexington International LLC (May 22, 2008), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048284.htm.

[17] Warning letter from the FDA to Roman S. Ferber, president of HoMedics Inc. (June 16, 2008), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048238.htm.

[18] *Id.*

[19] Warning letter from the FDA to Sukhwant S. Khanuja, president and chief executive officer of Carematix Inc. (July 3, 2008), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048219.htm.

[20] *Federal Prosecutors Indicate Device Makers Face Different Issues Than Pharma Industry*, BNA's White Collar Crime Report (4 WCR 431, 6/19/09) (the prosecutor's remarks were in an unofficial capacity).

[21] Maureen A. Ruane, Michael T.G. Long, and Syrion A. Jack, *An Ounce of Prevention: Lessons Learned from Recent Enforcement Actions in the Pharmaceutical and Medical Device Industry*, Mealey's Emerging Drugs & Devices, Vol. 14, No. 7 (Apr. 2, 2009). Even in cases where federal payment programs are not at issue, similar state anti-kickback statutes may apply.

[22] *Bayer Healthcare to Pay U.S. $97.5 Million to Settle Allegations of Paying Kickbacks to Diabetic Suppliers*, DOJ press release (Nov. 25, 2008), http://www.usdoj.gov/opa/pr/2008/November/08-civ-1050.html.

[23] *Spinal Implant Vendor Medtronic Settles Lawsuits Over Aggressive Sales, Marketing*, 31–9, Hospital Materials Management, 8, 8(1) (Sept. 1, 2006).

[24] *NeuroMetrix Settles Kickback Charges Related To Device Marketing*, MEDICAL DEVICES TODAY (Feb. 18, 2009), available at http://www.medicaldevicestoday.com/2009/02/neurometrix-settles-kickback-charges-related-to-device-marketing-.html.

[25] *OIG Settles Civil Monetary Penalties Law Case Against Medical Device Manufacturer*, HHS OIG press release (July 2, 2007), available at http://oig.hhs.gov/publications/docs/press/2007/ANS%20Press%20Release.pdf.

[26] Karen A. Gibbs, *Anti-Kickback Enforcement and Legislation Developments: What Drug, Medical Device and Biologics Companies Must Know*, Pharmaceutical Law & Industry, at 1 (March 7, 2008).

[27] *Medtronic to Pay $40 Million to Resolve Allegations of Illegal Payments to Physicians: CIA in Settlement*, BNA's Health Care Fraud Report (10 HFRA 552, 7/19/06); *see also* CIA between Medtronic Spine LLC and HHS OIG, at 1 (May 12, 2008), available at http://oig.hhs.gov/fraud/cia/agreements/kyphon_cia_executed.pdf.

survey of 85 warning letters from April 2008 through June 2009,[28] two cGMP violations were of particular concern to the FDA. The first was a lack of documentation of required procedures and the implementation of those procedures. The second was inadequate investigation and remedial actions regarding product-related complaints.

The penalties for failure to address concerns in a warning letter are potentially severe. The FDA can seek forfeiture of any adulterated medical devices, an injunction, and significant penalties, as well as recover all expenses such as the FDA's costs of its investigation, court costs, fees, and storage fees for any seized devices. The FDA also can require the offending company to post a penal bond. The company can be forced to hire an independent expert to conduct a comprehensive inspection and issue a certification report evaluating numerous issues related to the manufacturer's conduct and thereafter retain an independent auditor to conduct semiannual inspections for the first year, followed by annual inspections for at least the next three years, with the results to be reported to the FDA.

Notably, a failure to comply with a consent decree may subject the company to damages of $15,000 per day, plus an additional $15,000 for each violation up to certain amounts per calendar year. The three maximum yearly amounts in the consent decrees reviewed were $10 million, $15 million, and $35 million. In an extreme case, the FDA may order the company to cease manufacturing and distributing any and all medical devices and to recall products.

Summary of Recent FDA Warning Letters

The following are the most frequently cited cGMP violations in recent FDA warning letters.

The failure to implement and/or maintain an adequate and effective quality control system at all levels of the organization, pursuant to 21 C.F.R. § 820.20(b)(3).

This requirement includes establishing quality control systems as set forth in the written procedures of 21 C.F.R. § 820.20(e) for corrective and preventive actions, design control, complaints, medical device reporting, and acceptance activities. This also includes conducting quality audits to ensure that the quality control system is in compliance with established requirements and assessing the effectiveness of the quality system.[29]

To comply with these requirements, management personnel with executive responsibility should review the suitability, effectiveness, and documentation of the quality control system, at defined intervals and with sufficient frequency, according to established procedures. (Some warning letters suggest that an annual review, or a review every two years, can be sufficient. But the failure to comply with these defined intervals will be cited in a warning letter.)

A related type of quality control cGMP violation is the failure to establish and/or maintain procedures to control the design of the device to ensure that specified design requirements are met, pursuant to 21 C.F.R. § 820.30.

One company was issued a warning letter because its design plan was not approved until nine months after the device was in distribution. Plainly, in that case there was no way to show that the design was developed in accordance with the design control requirements of Section 820.30.

To comply with these requirements, manufacturers should:

- have a procedure for addressing incomplete, ambiguous, or conflicting design input requirements;
- maintain records of approved design changes and verification or validation results of those changes;
- establish, validate, and maintain procedures for acceptance or rejection of finished devices based on written specifications, pursuant to 21 C.F.R. § 820.80(d), and to ensure that finished devices are not released for distribution without documented acceptance; and
- if software is used to determine approval of a device shipment and the software can be overridden by employees, establish procedures for identifying when overriding can be done and require written justification for doing so.

The failure to establish and/or maintain procedures for implementing corrective and preventive action, pursuant to 21 C.F.R. § 820.100, or procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, pursuant to 21 C.F.R. § 820.198.

The warning letters indicate that the FDA takes such violations very seriously because they relate to the manufacturer's diligence in investigating the ''root cause'' of product-related complaints and taking remedial action after being put on notice of a possible product defect.[30] Some of the FDA's complaints in this regard were that investigations and corrective actions were insufficiently documented, that the investigation was inadequate (for example, the manufacturer communicated only with a distributor and not with the complaining party), that the manufacturer considered only the number of complaints and not their seriousness, and that the company did not adequately evaluate the need to take corrective action regarding products that were already distributed, not just correcting the procedures to be used for manufacturing products from then on.[31]

To comply with these requirements, manufacturers should:

- analyze all sources of quality data (e.g., complaints, returned products, service reports, and scrap rate);
- ensure that all complaint files are fully completed and have no missing data so that all complaints are documented. Have all complaint files reviewed by a quality assurance department before they are closed;
- ensure that all corrective activities, such as the actual investigation, analysis of results, and validating changes to the manufacturing process are fully documented;
- contact the complaining party directly to obtain information that may be necessary for a thorough investigation. Make at least a number of attempts to speak to

[28] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm, which contains the warning letters discussed in this article.

[29] 21 C.F.R. § 820.22.

[30] Warning letter from the FDA to Christian Hunt, president of Care Rehab and Orthopaedic Products Inc. (Apr. 22, 2008), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048331.htm.

[31] *See, e.g., id.*

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the party (and doctors, if medical treatment was involved) before a complaint file is closed;

■ if corrective actions are necessary, they should extend to devices that have already been distributed as well as to devices that have yet to be manufactured;

■ ensure that information related to quality problems is disseminated to those directly responsible for assuring the quality of the product or preventing such problems, including suppliers if the problem relates to a component supplied by another company. This can be especially important when the division responsible for reviewing complaints is separate from the manufacturing unit. One warning letter involved a company that received and documented all service complaints, but the device history records were located in the manufacturing entity in China and there was no procedure for a timely exchange of information;[32] and

■ review quality issues and adverse events based on a consistent methodology. One warning letter advised a manufacturer that undefined terms such as ''trending,'' ''statistical methods,'' and ''actionable levels,'' by themselves, are generally too vague for use in analyzing quality problems and adverse events, but they can be used if their definitions are sufficiently sensitive to detect any significant increase in quality problems.[33]

The failure to maintain a device master record (DMR), pursuant to 21 C.F.R. § 820.40 and 21 C.F.R. § 820.181.

To comply with this requirement, manufacturers should maintain device history records (DHR) for each batch, lot, or unit, pursuant to 21 C.F.R. § 820.184, to ensure that each product is manufactured in accordance with specifications set forth in the DMR. Under 21 C.F.R. § 820.180(b), DHRs must be maintained for a period equivalent to the expected life of the device, but in any event not less than two years from the date of release for commercial distribution.

The failure to establish and/or maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements, pursuant to 21 C.F.R. § 820.50, including procedures for acceptance and rejection of incoming products pursuant to 21 C.F.R. § 820.80(b).

These regulations impose an obligation on device manufacturers to exercise quality control over their suppliers.

To comply with these requirements, manufacturers should:

■ have a procedure for receipt and acceptance of raw materials or parts;

■ document all inspections, tests, and other verifications of incoming products;

■ document any labeling changes to the product received;

■ have a procedure that defines the type and extent of control to be exercised over suppliers, including the frequency and type of monitoring to be conducted;

■ have a written agreement with suppliers and contractors that defines their responsibilities, as well as agreements governing quality and ensuring that they will give notice of any changes in the product being supplied, and provide a certificate of conformance; and

■ document evaluations of product suppliers and contract manufacturers.

The failure to establish procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned tasks, pursuant to 21 C.F.R. § 820.56(b).

To comply with this requirement, manufacturers should maintain records documenting that employees have the necessary education, background, training, and experience to ensure that acceptance activities, complaint handling, medical device reporting, labeling, servicing, and repairs are conducted correctly.

The failure to comply with reporting requirements, which can cause a medical device to be misbranded under 21 U.S.C. § 360i.

A manufacturer must submit a medical device report (MDR) within 30 days after becoming aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury, as required by 21 C.F.R. § 803.50(a)(1), or would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 C.F.R. § 803.50(a)(2). Under 21 C.F.R. § 803.50(b)(3), the company must investigate the cause of each event, including treatment and patient outcomes, and document the process used to determine if a device-related death, serious injury, or malfunction is reportable. To comply with these requirements, manufacturers should:

■ document that each complaint received has been reviewed to assess whether an MDR is required;

■ establish a standardized review procedure for determining when an event meets the criteria for reporting; and

■ establish a standardized procedure for evaluating the causal link between the device and the injury—while being sensitive to potential product liability exposure.

Conclusion

As noted at the outset, government regulation and investigation of medical device manufacturers is likely to intensify. Remaining aware of what the government is concentrating upon is essential to avoiding those same pitfalls, as the survey of FDA warning letters quickly reveals. Each manufacturer ought to ensure it is leveraging those lessons in its own practices and compliance efforts.

[32] Warning letter from the FDA to Roman S. Ferber, president of HoMedics Inc. (June 16, 2008), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048238.htm.

[33] Warning letter from the FDA to Mark A. Philip, president of Stryker Biotech (April 25, 2008), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048324.htm.