MEDICAL DEVICE ISSUES IN HEALTH CARE FRAUD CASES

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Common Types of Cases

- Marketing Unapproved Devices
- Marketing Misbranded Devices
- Kickbacks
- Upcoding
- Failure To Report Adverse Events

Old Wine in New Bottles

- 1993 HIMA adopted a Code of Ethics
- 2004 ADvaMed (HIMA successor) adopts a Code of Ethics.
- Panel discussion of compliance programs and how to cope with the criminal process should internal process fail.

What I said in 1994

- Good science and sound management with the incentives of the Sentencing Guidelines can benefit firms subject to the Food, Drug, and Cosmetic Act.
- Lawyer joke---how many lawyers does it take to screw in a light bulb?
- I hope you make money by making the public healthier.
- Organizational Sentencing Guideline defines a minimally acceptable compliance program

Common Statutes

- Federal Food, Drug, and Cosmetic Act (FDCA)
  - Misdemeanor
  - Felony
- Mail and Wire Fraud
- Health Care Fraud
- Kickback Statutes

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- The **Office of Consumer Litigation** (OCL), a section in the Civil Division of the Department of Justice (DOJ), enforces through criminal prosecutions and civil litigation a number of Federal statutes that protect public health and safety and defend consumers from unfair practices.
- Views expressed are my own and not necessarily those of the Department of Justice.
- OCL monograph is at

http://www.usdoj.gov/civil/ocl/monograph/index.htm

How Are Medical Devices Sold and Distributed in America?

- Manufacturers
- Wholesalers
- Hospitals
- DME Suppliers
- Medical Practitioners

Device Violations

- Section 301 of the FDCA, 21 U.S.C. 331, lists 26 prohibited acts, most notably:
- Adulteration or misbranding of a device.
- Adulteration occurs if it has not been prepared, packaged, or held in conformance with good manufacturing practices.
- It is a class III device and is in interstate commerce without an approved Premarket Application.
- "The submission of any report that is required by this Act that is false or misleading in any material respect." 21 U.S.C. 331(q)

Individual Liability

- Civil Monetary Penalty
- Personal involvement in prohibited activity is not necessary for liability. United States v. Dotterweich, 320 U.S. 277 (1943)
- 21 U.S.C. 333(a)(2)
- Committed with intent to defraud or mislead or defendant was previously convicted for a violation of the statute.

Misbranding

- The product is not what the label says it is
- 21 U.S.C. 352 – misbranded device definitions
- Misbranding pursuant to 21 U.S.C. 352 (false or misleading labeling)
  - labeling is a term of art defined as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”

Adulteration

- Purity/manufacturing of device has been compromised
- 21 U.S.C. 351 – adulterated device definitions

Substitution of materials and alteration of design affecting safety

- Lab testing is critical

Certification Requirements

- 510(k) Truthful and accurate statement
- 18 U.S.C. 1001
- 510(k) reprocessing validation
- 510(k) Class III certification “I certify that I am aware of the types of problems...”
- 510(k) Declaration of conformity to design controls
- All certifications must be signed and dated by a “responsible individual.”

Sentencing Issues

- Regulatory Offenses - 2N2.1
- **U.S. v. Ballistrea,** 101 F.3d 827 (2nd Cir.1996)
- Fraud Offenses – 2B1.1
- Product Tampering – 2N1.1
- Upward Departures
  - Physical Injury – 5K2.2
  - Extreme Psychological Injury – 5K2.3
    United States v. Courtney, 362 F.3d 497 (8th Cir. 2004)
  - Public Welfare – 5K2.14

Civil Issues

- Injunctive Relief 21 U.S.C. 332
- United States v. Abbott Laboratories
- Compliance with FDA's Quality System Regulation ("QSR") in the production of a number of diagnostic test kits and similar biologic products.
- Company made total payments to the government of almost $350 million.

Disgorgement

- Disgorgement-- United States v. Universal Management, 999 F. Supp. 974 (N.D. Ohio 1997), aff'd, 191 F.3d 750 (6th Cir. 1999)
- Schering disgorged $500,000,000 for failure to manufacture its drug products in compliance with CGMP

Where to Get More Information

- FDA Website
  http://www.fda.gov/cdrh/devadvice/

CMS Website
http://www.cms.hhs.gov/suppliers/dmepos/

- United States Attorney's Manual Website
  http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title4/8mciv.htm

Reducing Your Compliance Risks

- In 2004 ADvaMed adopted a Code of Ethics on Interactions with Health Care Professionals
- Build awareness about the Code and its meaning within your company
  - Review/revise company policies & communication tools to align with the Code
  - Demonstrate CEO/management support of the Code
  - Communicate through multiple means (voicemail, posters, websites, reminder cards)
- Train on how your company will apply the Code
  - Training for employees -all relevant levels & functions

Old Virtues in New Clothes

- Guiding principles of the Code:
  - AdvaMed Members encourage ethical business practices and responsible industry conduct
  - AdvaMed Members shall not use unlawful inducement to sell, lease, etc. their products.

The Alternative: Operation Headwaters

- Prosecutions of a number of small durable medical equipment ('DME") suppliers for Medicare fraud during 1996-98.
- DME manufacturers were claimed to be responsible for the fraudulent practices
- FBI, with assistance from HHS-OIG began a Group One undercover operation in the SD-IL

Operation Headwaters

- “Undercover" for almost two years with health care companies pitching deals to the business and extending it credit
- Explored the real source of DME fraud, at its “headwaters,” rather than just prosecuting the “downstream” DME suppliers and nursing homes that directly sought reimbursement from Medicare.

Operation Headwaters

- Claims for goods or services ultimately used by Medicare beneficiaries were not true and accurate
- Paperwork claiming medical device is being rented when it is given away for free
- Market the medical device not as what's best for the patient, but because a big "bonus" will be paid in exchange for a long term contract

U.S. v. CG Nutritionals

- US Attorney in Southern District of Illinois charged CG Nutritionals with violating 18 U.S.C. 1518(a)
- Plea agreement provides: fine of $200,000,000 and restitution of $200,000,000
- Corporate Integrity Agreement

US v. Endovascular Technologies

- US Attorney and OCL charge EVT with 10 felony counts of FDCA, nine misbranded device and one count of false statements
- Plea agreement provides: $32,500,000 in criminal fines
- $10,900,000 forfeitures
- $49,000,000 in civil remedies under the false claims act

Failure To Submit Adverse Reports

- EVT failed to submit 2,628 Medical Device Reports
- Procedures in which conversions of abdominal aortic aneurysms became necessary
- Medicare patients
- Misdirecting FDA investigators during the inspection

US v. Lifescan

- US Attorney and OCL charge Lifescan, Inc. with misdemeanor violations of the FDCA
- Blood glucose monitors give erroneous results
- Plea agreement $29,400,000 criminal fine
- $30,600,000 civil remedies and restitution

HHS IG Says Medical Devices Will Be A Focus

- US Department of Health and Human Services plans to accelerate its investigations of alleged fraud and abuse by medical device companies.
- Cases against "other device makers are going to be coming into the pipeline."
- Boston Globe, May, 19, 2004

What Do You Tell US?

- Associate Attorney General Robert McCallum emphasized that the DOJ fully encourages and endorses the efforts of industry to promote compliance programs and self-governance, notably in the health care industry, as law enforcement efforts have been stepped up in that area.

What Do You Tell US?

- McCallum stated that compliance programs must
  1) Be effective
  2) Have high-level executive support
  3) Address the root causes of fraud
  4) Provide adequate mechanisms to prevent and detect them before they result in harm to the procurement or health care systems

  This should include a means by which industry can disclose wrongdoing that it does detect to the government

Principles of Federal Prosecution

- The principles do recognize that the existence of an adequate and effective compliance program may be one of several relevant factors in determining whether to charge a corporation. What does this mean? What is an adequate and effective program?
- Sentencing Guidelines
- DOJ Corporate Policy

Conclusion

- We want you to be successful--make money and follow the law. Before the events overtake you, work with the agencies that have the responsibility to enforce the law.

We want you to