2005 FRAUD ISSUES IN MEDICAL DEVICES

James G. Sheehan
Associate U.S. Attorney
215-861-8301
Jim.Sheehan@usdoj.gov

DISCLAIMER

- My opinions, not Department of Justice policy
- In cases where there has not been a trial or guilty plea, Government has duty to present evidence and carries burden of proof at trial, if defendants elect a trial
- Allegations of indictment or complaint are not evidence

CONSULTANT ISSUES

- Special role in device industry
  - Designer
  - Customer
  - Advisor to buyer
  - Beta tester
  - improvements

CONSULTANT ISSUES

- Reasonable services
- Reasonable payments
- Motive
- Demand or Request
- Competitive Response

GPO LEGAL ISSUES

- ANTITRUST ISSUES-COLLUSION AMONG BUYERS
- MEDICARE/MEDICAID ANTIKICKBACK ACT
- Mail fraud/ kickbacks(breach of duty of honest services)

NEW ATTENTION TO GPOs PAST FIVE YEARS

- ANTITRUST
- ANTIKICKBACK
- NEW YORK TIMES
- ACADEMIC SCRUTINY
- CONGRESSIONAL SCRUTINY
- DEVICE INDUSTRY COMPLAINTS

GPO ENFORCEMENT ISSUES

- Inflation of costs to cover % commission, fees, stock
- Barrier to access for new vendors, better products
- Kickback opportunities for executives
- Limited clinician role in buying decision

ACCREDITING COUNCIL FOR CONTINUING MEDICAL EDUCATION

- 2004 UPDATED ACCME STANDARDS FOR COMMERCIAL SUPPORT-model for interaction
- ADOPTED 9/28/04
- EFFECTIVE FOR NEW CME ACTIVITIES AFTER MAY 2005
- EFFECTIVE FOR ALL CME ACTIVITIES AFTER NOVEMBER 2006
- www.accme.org

FOCUS OF ACCME GUIDELINES

- DISTINGUISH INDEPENDENT CONTINUING MEDICAL EDUCATION FROM SPONSORED PRODUCT PROMOTION
- ASSURE PRESENTATIONS GIVE A BALANCED VIEW OF THERAPEUTIC OPTIONS, REPRESENTING THE PRESENTERS' PROFESSIONAL OPINIONS AND WORK
- ASSURE SOURCE OF FUNDING FOR PROGRAM AND PRESENTATIONS ARE DISCLOSED

UNDERSTANDING INVESTIGATIONS: the case of Endovascular Technologies

- Guidant's problem-3% of employees,2% of sales, acquired in 1997
- One major product, significant failure to report malfunctions
- Sales force knowledge of malfunctions, participation in the fix

Endovascular Technologies Timeline

- 1997-Guidant acquisition of Endovascular
- 1998-FDA approval-Ancure Endograft system
- 1998-2001 Bad stuff (non-reporting of adverse events)
- August, 2000-FDA inspection-documents withheld

Endovascular Technologies Timeline

- August 2000-call to FDA from whistleblower
- October 2000-seven employees complain to compliance officer and FDA
- October 2000-company retains auditors
- December, 2000-auditors find Endovascular "significantly out of compliance" with FDA reporting requirements

Endovascular Technologies Timeline

- March 2001-company notifies FDA of "preliminary audit" showing problems, pulls device from market
- March-June 2001-company files 2628 additional reports of device malfunction out of 7632 units sold
- June 2003 guilty plea

Endovascular Technologies Timeline

- 2003-
  - Guilty plea to 10 felonies
  - $92.4 million payment
  - September unsealing of qui tam
  - Ongoing securities litigation

GUIDANT- NEW YORK TIMES

- As reported by New York Times 6/2/05
  - Implantable heart defibrillator-Ventak Prizm
  - 26 failures because of short circuit problems
  - product enhanced in 2002 to address short circuit issues
  - Pre-enhanced product sold out of inventory after April 2002 enhancement
  - Two suits filed 6/1 in Indianapolis

The Zimmer/Premier case

- USA ex rel. Schmidt v. Zimmer 386 F. 2d 235(3d Cir. 2004)
  - "Conversion incentive" to Premier participants including price reduction, plus 2% bonus on implant purchases if market share and volume purchase
  - Payments to physicians and orthopedic departments from Premier payments if they helped meet goals
  - HCFA 2552 certification by hospital were false-
    - Did not disclose Zimmer/Premier rewards
    - Certified compliance with all laws(includes Stark and AKA)

Zimmer/Premier

- Premier had clause in contract requiring that "members disclose" discounts or reductions on cost reports-"It thus appears that Zimmer was at least aware of the possibility that Mercy might file a false claim for more than it paid Zimmer. . ."
- Schmidt alleges that "false certifications of compliance were necessary consequences of Zimmer's marketing scheme."(at 245)

Safe Medical Device Act Reporting Requirements for Facilities

- 21 U.S.C. 360i(b)(1)(a)
- "Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable, but not later than 10 working days after becoming aware of the information, report the information to the secretary and . . . to the manufacturer."

SAFE DEVICE REGULATIONS

- 21 C.F.R. Section 803.10(a)(1) (individual adverse events)
- 21 C.F.R. 803.10(a)(2) (annual reports)
- "Device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment or diagnostic facility that is not a physicians office.

SAFE DEVICE ISSUES

- Relationship to payments to physicians and facilities
- Sale of medical devices to surgeons for resale to hospitals
- How do you find out about adverse events MEDWATCH@LIST.NIH.GOV

PARALLELS TO DRUG PROSECUTIONS

- US ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass 2001)
  - Settlement announced June, 2004
- Off label marketing, false information about uses, side-effects

PHARMA CODE AND INSPECTOR GENERAL'S COMPLIANCE GUIDANCE FOR PHARMACEUTICALS

- Pharma Code 4/28/03, 68 FR 23731 http://oig.hhs.gov/fraud/docs/compliance
- OIG Guidance www.OIG.HHS.GOV

Advamed Code - effective January 2004

- Member sponsored product training and education
- Supporting third party educational conferences
- Sales and promotional meetings
- Arrangements with consultants
- Gifts

Advamed Code (continued)

- Provisions of Reimbursement and other economic information
- Grants and other charitable donations

Quality of Care/Medical Errors

- WHO IS RESPONSIBLE FOR PHYSICIANS WHO ARE NOT CAPABLE OF USING PRODUCTS SAFELY?
- IS A WEEKEND OF TRAINING ENOUGH?
- WHAT IS THAT REP DOING IN THE OR?
- PATIENT DISCLOSURE/CONSENT
- NHC
- Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001)

QUI TAM ENFORCEMENT

- Next frontier after pharmaceutical cases
- Whistleblowers
- Whistleblower attorneys

CRIME-FRAUD ISSUE IN MEDICAL DEVICE ENFORCEMENT

- "TO THE EXTENT THAT xyz, ATTORNEY, AND Firm argue that they were shipping a product that was failing at a rate higher than label specifications suggest, and that they knew field failures were likely to occur at such a rate, the crime fraud exception makes any claim to work product immunity (fail) . . . In Re: Grand Jury Subpoena, 3/16/04 D. Mass., 2004 WL 515651

FIRST AMENDMENT

- United States v. Caputo 2003 WL 22431547(N.D. Ill. 10/21/03)
- "This Court believes that permitting defendants to engage in all forms of truthful, non-misleading promotion of off-label uses would severely frustrate the FDA's ability to evaluate" off-label uses.
- Conspiracy count to introduce "misbranded" device into commerce through use of off-label information upheld

3) Caputo – Good Faith Defenses

- The Defendants cannot argue that they did not need to file a pre-market notification because they believed in good faith that the modified sterilizer was as safe and effective as the FDA cleared sterilizer.
- Defendants subjective belief that subsection 807.81(a)(3) permitted them to market the modified sterilizer . . . Does not constitute a valid good faith defense. 2004 WL 524684

CONCLUSION

- Advamed Code
  - Excellent effort by reputable manufacturers to address a complex issue
  - Failure to follow places companies and their companies at risk