2005 FRAUD ISSUES IN GPOs and 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

GROUP PURCHASING ORGANIZATIONS

- "purchasing agent"
- "buying cooperative"
- "hospital alliance" offering variety of services in addition to group purchasing

GPOs

- Business model started as hospital coop in New York in early 1900's
- Over 200 GPOs contract directly with vendors
- Initial Impression: good idea

GPO LEGAL ISSUES

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

GPO LEGAL APPROACHES

- IG URGES GPO PROSECUTIVE EXCEPTION TO M/M ANTIKICKBACK
- DOJ - NO BLANKET EXCEPTIONS
- CONGRESS - exception passed for any amount paid by vendor to person authorized to act as purchasing agent
- Exception requires:
  - Fixed amount or fixed percentage of contract
  - Disclosure of amount received to entity

GPO LEGAL APPROACHES

- IG SAFE HARBOR (BY REGULATION)
  - authorized to act as purchasing agent
  - Written agreement between vendor and purchasing agent that vendor will pay 3% or less
  - If 3% or greater, specific disclosure of amounts to be paid
  - Annual disclosure of fees received from each vendor

GPO LEGAL APPROACHES

- ANTITRUST
- FTC/DOJ GUIDELINES
- STATEMENT No. 7
  - Joint purchasing of 35% of purchases in given geographic market or less are within safe harbor
  - Purchases through GPO must be less than 20% of each member hospital's total revenues

NEW ATTENTION TO GPOs PAST FIVE YEARS

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

GPO ENFORCEMENT ISSUES

- Industry complexity
- It's sort of close to the safe harbors, kind of
- Medicare/Medicaid Anti-Kickback violations are specific intent crimes – "knowing and willful"
- The role of lawyers-marketers, approvers, up-the-chain (usual reviews)
- Who will come forward (cash flows, benefits from manufacturers to GPOs to officers of health care organizations)
- Who is harmed?

GPO ENFORCEMENT ISSUES

- Inflation of costs to cover % commission, fees, stock (Novation-30% of contracts exceed 3%)
- Barrier to access for new vendors, better products
- Kickback opportunities for executives
- Limited clinician role in buying decision

GPO ENFORCEMENT ISSUES

- MONEY WITHOUT VISIBILITY
- UNDISCLOSED DISCRETIONARY DECISIONMAKING
- NO OVERSIGHT
- OFF-LABEL PROMOTION
- FAILURE OF REPORTING OBLIGATIONS

GPO ENFORCEMENT

- Breach of duty of loyal service, fiduciary duty (mail fraud)
- False Claims Act (source of whistleblowers?)
- HHS/OIG administrative penalties for kickbacks
- Violation of Industry Codes - Health Industry Group Purchasing Association (GPOs and vendors)
- ACCME
- Advamed

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
- 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
- September, 2003-qui tam action unsealed
- Securities litigation until eternity

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."

PHARMA CODE AND INSPECTOR GENERAL'S COMPLIANCE GUIDANCE FOR PHARMACEUTICALS-MODELS FOR DEVICE INDUSTRY?

- 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

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

CONCLUSION