

2006  
NATIONAL DEVICE  
AUDIOCONFERENCE  
ADVANCED CODE AND  
COMPLIANCE ISSUES

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- 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

# ROLE OF ADVAMED AND OTHER VOLUNTARY INDUSTRY CODES OF ETHICS IN INVESTIGATION AND ENFORCEMENT DECISIONS

- Advamed Code-September 3, 2003
- New FAQs-April 15, 2005
- Advamed Code of Ethics Logo-6/19/06
- Request for Guidance on Physician Investments-September 6, 2006

# ISSUES VOLUNTARY CODES ARE TO ADDRESS

- Guidance for members and employees
- Guidance for industry partners and customers
- Level playing field-working with inventors, opinion leaders
- Preventing illegal conduct
- Demonstrating senior management, board commitment to compliance program
- Shortening investigations
- Evidence of effective compliance program

# THE ADVANCED LOGO ISSUES

- IF YOU SHOW IT, YOU ARE REPRESENTING AN ORGANIZATIONAL COMMITMENT TO COMPLIANCE TO PARTNERS AND US.
- GOOD IF YOU ARE COMMITTED, BAD IF YOU ARE NOT.

# THE ADVANCED CODE OF ETHICS ISSUES

- SPONSORED PRODUCT TRAINING AND EVALUATION
- SUPPORTING THIRD PARTY CONFERENCES
- SALES AND PROMOTIONAL MEETINGS
- ARRANGEMENTS WITH CONSULTANTS
- GIFTS AND GRANTS
- REIMBURSEMENT AND OTHER ECONOMIC INFORMATION

# CODE OF ETHICS ISSUES

- Not a guarantee-intentional and wrongful conduct caught on tape or in documents can still result in investigation and prosecution.
- In good faith-technique for demonstrating the character of organization, commitment to compliance, unusual event
- Failure to accept/endorse code-Why?

# FEDERAL INVESTIGATION AND ENFORCEMENT-ISSUES FOR DEVICE COMPANIES

- CRIMINAL, CIVIL AND ADMINISTRATIVE EXPOSURE-AND EXCLUSION RISK
- CONDUCT BASIS OF INVESTIGATION
- FEDERAL GOALS
  - Preventing, addressing patient harm
  - Assuring integrity of medical care and providers
  - Assuring accuracy of provided information to physicians, patients, and federal agencies
  - Protecting fiscal integrity of federal health programs

# CRIMINAL, CIVIL EXPOSURE

- FRAUD ON THE FDA-HOW DID THE PRODUCT GET APPROVED? (ROLE OF CONSULTANTS AND INVESTIGATORS)
- FRAUD ON THE FDA-HOW DID THE COMPANY RETAIN APPROVAL? (MANDATORY REPORTING COMPLIANCE)

# CRIMINAL, CIVIL EXPOSURE

- FRAUD ON PAYOR PROGRAMS-BUT FOR (FALSE OR MISLEADING) PROMOTION OR ENDORSEMENTS, PHYSICIANS WOULD NOT HAVE USED THIS PRODUCT WITH OUR PATIENTS
- FRAUD ON PAYOR PROGRAMS-FALSE OR MISLEADING INFORMATION TO PUBLISHED JOURNALS, PHYSICIANS, PATIENTS (GHOST WRITERS, FAILURES TO DISCLOSE FINANCIAL RELATIONSHIPS)

# CRIMINAL, CIVIL EXPOSURE

- KICKBACKS TO PHYSICIANS OR OTHER REFERRAL SOURCES FOR MEDICARE, MEDICAID, OTHER GOVERNMENT PROGRAM PATIENTS
- KICKBACKS IN CONNECTION WITH HEALTH PLANS WITH A FEDERAL CONTRACT
- UNREPORTED HOSPITAL REBATES (OIG WORK PLAN 2007)

# FRAUD ON THE FDA-HOW DID THE PRODUCT GET APPROVED?

- FALSE STATEMENTS ABOUT CLINICAL TRIALS
  - Results (efficacy, adverse events)
  - Compliance with protocol (patient selection, end points)
  - Participant protections

# FRAUD ON THE FDA-HOW DID THE PRODUCT RETAIN APPROVAL?

- Endovascular Technologies-failure to report serious adverse events
- In Re Grand Jury Subpoena 220 F.R.D. 130(D. Mass. 2004) –if you knew the product was likely to fail more frequently than disclosed in your labeling, and you do not disclose to FDA, product is misbranded
- United States v. Caputo 374 F. Supp. 2d 632(N.D. Ill. 2005)-evidence allowed that “defendant intentionally avoided information about potential safety hazards.”

# FRAUD ON PAYOR PROGRAMS

- But for fraud on the FDA, our patients would not be using or paying for this product (SERONO)
- Information communicated which is inconsistent with the scientific evidence is “false or misleading” and evidence of misbranding (SERONO)
- Knowing false statement about drug efficacy (Dr. Peter Gleason indictment)
- Payor relied on labeling and FDA approval as basis for payment

# FRAUD ON PAYOR PROGRAMS

- Payments to physicians, health plans, advisory panels, consultants to advocate for, promote, or write for given product ( Poteet complaint, Gleason indictment)
- Steven Fiorello-chief pharmacist, Pa. Department of Public Welfare fined \$27,000 in 2005 for accepting money from Pfizer while serving on a state committee selecting drugs

# FRAUD ON PAYOR PROGRAMS

- But for misleading information to physicians, we would not have claims for this product.
- But for misleading off-label promotion of this product, we would not have claims. *United States ex rel. Franklin v. Parke-Davis* 147 F. Supp. 2d 39(D. Mass. 2001) See generally Glaxo SmithKline settlement with New York.
- But for misleading information to journals or compendia, we would not have paid these claims because they were not for a medically accepted indication.

# WHY THE FOCUS ON PROGRAM FRAUD?

- FRAUD STATUTES BASED ON CONCEPT OF ECONOMIC HARM
- QUI TAM WHISTLEBLOWER PROVISIONS OF FALSE CLAIMS ACT
- EXTENSIVE CASE LAW ON FRAUD AND FALSE CLAIMS, MUCH LESS ON FDA VIOLATIONS
- ARGUMENTS ABOUT INADMISSABILITY OF HARM EVIDENCE IN REGULATORY CASE

# RECENT EXAMPLE: SERONO

- October 2005-government settles whistleblower allegations for \$704 million:
- Serono was giving physicians non-FDA approved computer software “device” calculating body mass; device was set to falsely diagnose AIDS wasting
- Serono engaged in off-label marketing of Serostim for AIDS wasting, including misleading information
- Serono paid kickbacks to physicians to advocate for Serostim

# 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
- User physician and 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

# TRAINING ISSUES-THE CAROTID STENT-FDA

- Significant advance in treatment of carotid stenosis with related stroke risk
- FDA approval of Guidant CAS system CAS system and embolic protection devices-
- FDA-requires specific training of physicians, delivery only to trained persons

# THE CAROTID STENT-CMS

- DECISION MEMO FOR CAROTID ARTERY STENTING (CAG-00085R)
  - [www.cms.hhs.gov/mcd/viewdecisionmemo.asp](http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp)

# THE POTEET QUI TAM

- Brought by Ms. Poteet, senior manager of travel services at Sofamor Danek
- Allegation: company gave spine surgeons “excessive remuneration, unlawful perquisites, and bribes in other forms” for purchasing devices
- Allegation: \$400,000 to Wisconsin physician for 8 days work
- Internal company documents filed as part of suit-”at least \$50 million to doctors over some four years.” (New York Times 1/24/06)

# THE ZIMMER 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)

# 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.

# ACCREDITING COUNCIL FOR CONTINUING MEDICAL EDUCATION AND CODE

- 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](http://www.accme.org)
- Match with Section III of Advamed Code

# 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)

# CONCLUSION

- New involvement of manufacturers in safety and outcomes
- Growth in qui tams focused on marketing and payments to physicians
- Advanced Code and standards
  - Excellent effort by reputable manufacturers to address a complex issue
  - Failure to follow places companies and their companies at risk