2006 DRUG AND DEVICE FRAUD ISSUES PROSECUTING DRUG AND DEVICE FRAUDS-FDA REGULATORY SYMPOSIUM AT HARVARD

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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

FEDERAL INVESTIGATION AND ENFORCEMENT- FDA ISSUES

- CRIMINAL, CIVIL AND ADMINISTRATIVE EXPOSURE-AND EXCLUSION RISK
- CONDUCT BASIS OF INVESTIGATION
- WHOSE CONDUCT CAN BE THE BASIS FOR INVESTIGATION
- TIMELINES FOR INVESTIGATIONS AND PROSECUTIONS

CRIMINAL, CIVIL EXPOSURE

- FRAUD ON THE FDA-HOW DID THE PRODUCT GET APPROVED?
- FRAUD ON THE FDA-HOW DID THE COMPANY RETAIN APPROVAL?
- FRAUD ON PAYOR PROGRAMS-BUT FOR FRAUD ON FDA, OUR PATIENTS WOULD NOT BE USING OR PAYING
- FRAUD ON PAYOR PROGRAMS-THIS IS NOT THE BRANDED PRODUCT OR QUALITY WE THOUGHT WE WERE BUYING

CRIMINAL, CIVIL EXPOSURE

- FRAUD ON PAYOR PROGRAMS-BUT FOR(FALSE OR MISLEADING) OFF-LABEL PROMOTION, DOCTORS WOULD NOT HAVE USED THIS PRODUCT WITH OUR PATIENTS
- FRAUD ON PAYOR PROGRAMS-FALSE OR MISLEADING INFORMATION TO COMPENDIA,PBMS,PUBLISHED JOURNALS

CRIMINAL,CIVIL EXPOSURE

- KICKBACKS TO PHYSICIANS OR OTHER REFERRAL SOURCES FOR MEDICARE AND MEDICAID PATIENTS
- KICKBACKS IN CONNECTION WITH PBMS AND HEALTH PLANS WITH A FEDERAL CONTRACT

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
  - Lost to follow up=dead
  - See, AE Shamoo "Adverse Events Reporting-The tip of an Iceberg" 8 Accountability in Research 197-218(2001)

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
- Information communicated which is inconsistent with the scientific evidence is “false or misleading” and evidence of misbranding.
- Payor relied on labeling and FDA approval as basis for payment.

FRAUD ON PAYOR PROGRAMS

- Kickbacks, payments to physicians, health plans, advisory panels, PBMs, pharmacy directors to advocate for, promote, or write for given product
- 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

- This is not the product or quality we thought we were buying. Schering-Plough GMP Consent Decree-$500 million disgorgement of profits-2002

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(42 U.S.C. 1396r-8(k)(3-6)), 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
- 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

HOT ISSUES

- Brave New World of Drug and Device Approvals and Payment-the Carotid Stenting Model
- Future Qui Tams-USA ex rel. Poteet v. Medtronic
- GPOs and Payments through GPOs (USA ex rel. Schmidt v. Zimmer)
- Industry Codes and Consequences

THE CAROTID STENT-FDA

- Significant advance in treatment of carotid stenosis with related stroke risk
- FDA approval of Guidant CAS system/Cordis 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

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/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)

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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

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

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

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)

CRIME-FRAUD ISSUE IN DRUG/ 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

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