2007 DRUG AND DEVICE FRAUD ISSUES
PROSECUTING DRUG AND DEVICE VIOLATIONS-FDA REGULATORY SYMPOSIUM

James G. Sheehan
JGS05@OMIG.state.ny.us
518 473-3782
DISCLAIMER

- My opinions, not State of New York or US 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

- NOT JUST CRIMINAL- CIVIL AND ADMINISTRATIVE EXPOSURE-AND EXCLUSION RISK
- NOT JUST FDA REFERRALS-MOST DOJ PHARMACEUTICAL CASES DO NOT ORIGINATE WITH FDA
- NOT JUST FEDERAL-JOINT TEAMS WITH STATE ATTORNEYS GENERAL, MEDICAID FRAUD CONTROL UNITS, AND MEDICAID INSPECTORS GENERAL
- NOT JUST GOVERNMENT-PRIVATE FEE COUNSEL FOR GOVERNMENT AGENCIES
THE OLD FASHIONED FDA CASE-MISBRANDING

- Cannot sell product in interstate commerce which is not approved by the FDA
- Allegation: botox product labelled “for research purposes only; not for human use” sold as alternative to more expensive approved Botox
- Allegation: Intent of labelling to “avoid FDA detection and regulation.”
- Allegation: defendants held workshops where they promoted drug for use in human beings, “potentially dangerous” instructions
THE OLDER FDA CASE

- Dr. Ivy Wells Indictment-CR05-185-S-EJL (D. Idaho 2005)
- Allegation: ran “Perfect Skin Laser Center,” ordered unapproved Botox labelled “for research purposes only” and used it on humans
- “Delivery or proffered delivery for pay or otherwise” 21 U.S.C. 331
- Defendant pleaded guilty to mail fraud counts and misbranding, adulteration counts. Sentence-6 months-began sentence January 2007-$40,000 fine, $87,777 restitution
THE NEWER FDA CASE-MISBRANDING

- USA v. Ross Caputo-2006 WL 2946191 ND Ill. 10/16/2006)-ten year sentence in misbranding case
- FDA approval obtained for sterilizer for flat stainless steel instruments without tubes or hinges; marketed to hospitals for sterilizing endoscopes and other devices
- “Too often, as in this case, corporate officials . . . answer . . lack of criminal intent in the face of repeated and unheeded red flags.”
- Six year sentence for compliance officer-”Riley’s actions as AbTox’s Chief Compliance Officer were woefully and criminally inadequate.”
THE NEWER FDA CASE-MISBRANDING

- Dr. Peter Gleason-CR-1:06-cr-00229(EDNY)
- Xyrem (controlled substance) approved only for patients with both narcolepsy and certain other related conditions
- Psychiatrist alleged to promote Xyrem through lectures for off-label indications, including Parkinson’s and bipolar disorder
- Lectures promoting drug for off-label use was part of misbranding conspiracy
WHAT DO WE KNOW ABOUT EACH OF THESE MISBRANDING CASES?

- Each misbranding indictment also contained a mail fraud or health fraud allegation
- Why?
THE EXPANSION OF EXPOSURE-CRIMINAL, CIVIL, ADMINISTRATIVE

- Parke-Davis (Warner-Lambert/Pfizer) neurontin-2004
  - $240 million criminal fine
  - $83.6 million-federal civil false claims settlement “fraudulent drug promotion and marketing misconduct”
  - $68.4 million -50 states and DC
THE EXPANSION OF EXPOSURE-CRIMINAL, CIVIL, ADMINISTRATIVE

  - Prosecution and $567 million settlement
  - Off-label market and misbranding serostim

- Intermune settlement-2006-ND Cal.
  - Deferred prosecution;$36.9 million settlement for off-label marketing
  - Schering settlement-2006-settlement included off-label marketing
NOT ALL DECISIONS FOR GOVERNMENT

Off-label qui tam dismissed with prejudice:
CRIMINAL, CIVIL EXPOSURE

- FRAUD ON THE FDA – CLINICAL TRIALS AND REPORTS–HOW DID THE PRODUCT GET APPROVED?
- FRAUD ON THE FDA AND PAYORS–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
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 followup=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 labelling, and you do not disclose to FDA, product is misbranded
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 labelling and FDA approval as basis for payment.
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
- RANGE OF PARTICIPANTS, SOME WITH ONLY RICO AS THEIR CASE THEORY—See, e.g., Lilly litigation in Brooklyn
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
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
- Use of product in unapproved settings
- Misleading quality and outcomes data
- 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 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)
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-labelling/branding implications
- Growth in federal and state qui tams, RICO actions- focused on marketing and payments to physicians
- Increasing emphasis on Medicaid investigations and prosecutions
- Industry codes and standards
  - Excellent effort by reputable