# 2007 PHARMACEUTICAL REGULATORY COMPLIANCE CONGRESS-ROLE OF THE STATES IN REGULATING PHARMACEUTICAL ENTERPRISE

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# DISCLAIMER

- My opinions, not State of New York policy
- I cannot give legal advice, since I am not yet a New York lawyer
- No peeking at name badges during question time

# KEY TRENDS IN STATE REGULATION AND ENFORCEMENT

- Growth in Medicaid-$330 billion and counting-and Medicaid oversight
- Improvements in data reporting, data aggregation and data mining
- Capture of quality improvement-mandatory reporting information
- State investigation and enforcement of FDA and pharma relationship issues

# Medicaid growth and oversight

- Default national health care-12%+of population, $330 billion this year  and growing
- CMS-Incentives to states-$1.5 billion for health modernization-but you better collect it all back through fraud and abuse recoveries (NY)
- 2 CMS oversight to 100 CMS oversight staff in two years
- PERM(payment error rate measurement)-first results for first 13 states  on eligibility errors and provider payment errors out in next two weeks
- Medicaid enforcement growth in next five years looks like Medicare over part 10 years-migration of experience, expertise, contractors

# Medicaid Growth and Oversight

- "Unique opportunity to identify, recover, and prevent inappropriate Medicaid payments"(CMS Medicaid Integrity Plan statement)
- How many auditors in the Medicaid area?
  - State program integrity audits
  - State controller, MFCU audits
  - CMS Medicaid Integrity Contractors (MICs)
  - CMS Medicaid Integrity Program (MIP) audits-rolled out by Summer 2008
  - State qui tams False Claims Acts(37 states)
  - County audits in New York
  - CMS PERM auditors

# Data Reporting, Data Aggregation, Data mining

- More than 20 firms have competing analytics systems to dice and slice health data (not just claims) for improper payments
- Teradata platforms to aggregate claims data across programs, across states, across state-federal lines
- Fraud identification moving away from law enforcement/investigative agencies toward program agencies and analytics contractors-credit card model
- Speed of data analysis has increased exponentially
- Major concern-integration of human intuition, confidence

# Data Reporting, Aggregation

- A coming attraction-but coming soon
  - Part D data not yet reconciled
  - Part D data not yet integrated w/Medicaid data
  - Medicaid data not integrated between states
  - Medicaid claims include inconsistent codes for same products
  - DUR and override data needs integration with claims data
  - BUT ALL THESE THINGS WILL BE HAPPENING BEGINNING NEXT YEAR

# Issues for Pharma in Data Aggregation, Data Mining

- Longitudinal patient care and outcome data
- Pharmacy single biggest area of claims, most reliable coding, largest players-perfect demo area for data mining products-and cases
- Example: New York suit against Merck for cardiovascular patients on Vioxx

# Opportunities for Pharma in Medicaid data mining by states

- Drugs don’t work if you don’t take them
- Demonstration of outcomes improvement in Medicaid population with specified interventions
- Partnership opportunities with fraud data miners for audit, compliance purposes
- Use of state databases? (privacy concerns, free or pay)

# Quality Improvement-Mandatory Reporting information

- Pennsylvania statutory model-independent patient safety authority
- New York model-IPRO reviewed of Medicaid case sample to identified unreported reportable events
- 30 states-some mandatory reporting
- Institute for Health Care Improvement -100,000 lives campaign
- CMS-no payment for mistakes

# Compliance Risks for PHARMA in mandatory reporting

- Greatly enhanced reporting and analysis of drug mishaps in acute inpatient care, improving reporting in long-term care
- More effective longitudinal studies of patient progress, adverse events, similar to Bennett studies of EPO
- Early identification, motivated analysis of adverse event patterns
- Does your company know what others are discovering from the data? Are marketing and medical avoiding finding out?
- Real world information-not just controlled trials

# STATE INVESTIGATION AND ENFORCEMENT-FDA ISSUES

- NOT JUST CRIMINAL- CIVIL AND ADMINISTRATIVE EXPOSURE-AND EXCLUSION RISK
- NO AUTOMATIC DEFERENCE TO FDA ON LAW OR POLICY
- -JOINT TEAMS WITH STATE ATTORNEYS GENERAL, MEDICAID FRAUD CONTROL UNITS, AND MEDICAID INSPECTORS GENERAL
- NOT JUST GOVERNMENT-PRIVATE FEE COUNSEL FOR GOVERNMENT AGENCIES, QUI TAM COUNSEL

# NOT JUST CRIMINAL . . .

- CIVIL RISK-NEW YORK AG SUIT VS. Merck on VIOXX-failure to disclose and false statements about cardiovascular risk to prescribing physicians
- ADMINISTRATIVE RISK-state penalty provisions for “improper practices”-censure, penalties-issue preclusion

# NOT JUST CRIMINAL . . .

- ADMINISTRATIVE RISK-
  - Exclusion risk for enterprise low because of need for sole source drugs, but . . .
  - Potential exclusion of executives, consultants, medical directors, customers
  - Collateral effects of individual exclusions
    - One program = all programs
    - Can't employ
    - Affiliated persons exclusions

# NO AUTOMATIC DEFERENCE TO FDA ON LAW OR POLICY

- Federal position-how can we take a position not supported by the federal agency charged with oversight of the subject (which is also a client)
- State position-what science or policy supports the position FDA has taken? What evidence did FDA consider (or ignore) in the positions it took? Does it gather any evidence?

# Pharma State Litigation

- Problem-federal process has been extremely slow, focussed primarily on settlement
  - Greater federal resources meant federal lead
  - Resource balance now shifting to states
  - First state that successfully goes it alone may shift balance
  - Should big states go it alone? (better, more comprehensive data, higher reimbursement, more control over case, large groups other than Medicaid, litigation in state forum)
  - Do states have better statutes? Consumer protection vs. fraud, different damages calculations, parens patriae standing

# Pharma State Litigation

- Fed lead-but will everyone follow
- Individual State Lead
- NAAG (National Association of Attorneys General ) or multistate project
- Private contingent fee counsel-single or multiple states (e.g., Lilly Zyprexa litigation)
  - Often, counsel who have separate class actions
- Qui tam counsel (37 states)
- County counsel

# 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 FEDERAL 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

- Serono settlement-2005-DMass.
  - -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

# 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

# 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 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

# 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

# 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 systemand embolic protection devices-
- FDA-requires specific training of physicians, delivery only to trained persons

# 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

# CONCLUSION

- MEDICAID-NOT JUST PROSECUTION
- PROGRAM INTEGRITY-Build controls on front end
- But-many entities in this space
- Not all are as reasonable as the New York Office of Medicaid Inspector General