Pharmaceutical Regulatory and Compliance Congress

Regulator Roundtable

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Quality Of Care Issues

- Courts recognizing FCA as cause of action for poor quality care
- Prosecutors are finding ways to address gaps in law:
  - Kickbacks
  - False Statements
  - Failure to report events to FDA

It's about Medical judgment and patient choice

PBMs and Quality of Care

Incentives for Drug Switching

- Manufacturer Pricing to PBM
- PBM Formulary Services
- Preferred Formularies
- HMO Formulary
- Who is making the decision: Calls to Physicians
  Calls to Pharmacists

Prescription Cancellation

Prescription Decisions in Best interest of patients

Institutional Quality of Care

Nursing Homes and Hospitals affected by nursing shortage;

Hospitals and medical errors:

Medication administration

Infection control

Chemical restraints

Medically unnecessary services

Kensington Hospital: Unlicensed physicians, Kickbacks for staff privileges and for lab and cardiac services– lack of medical necessity

Tenet in Redding CA:Unnecessary Cardiac Procedures - $54 million: August 03

Q of C in Clinical Research Protocols

- Phase II Trials for FDA Approval
  - Patient Informed Consent
  - Kickbacks for participation
  - Trials run by MARKETING Dept., Not Medical Liaison Dept of Manufacturer
- Failure to Report Adverse Events in Trials

Q of C in Medical Devices

USA v. Guidant: Failed to report Malfuinction of ancure device for abdominal aortic aneurisms. 12 Deaths.

$92.4 criminal and civil penalties – June 03

USA v. Dentsply: Failure to report adverse events in dental cement $800,000 – March 03

Drug Manufacturing and Compounding

Manufacturer

1. Adverse Event Reports and
2. Polymorphism in drug substances Reports of Variant Forms in Mfg process

Storage

Delivery

Pharmacist Compounding : Courtney pharmacist who diluted chemotherapy drugs

No adverse Event Reporting

FDA 2002 Guidance on Compounding

Thojpson v. Western States Medical Center struck down Compounding section of FDAMA of 97

State/ Federal Inspections