Drug Safety & Public Health: Legislative Changes to Reform the FDA

- Session Concentrates on Public Law 110-85, signed by the President on September 27, 2007
- The Food and Drug Administration Amendments Act of 2007 or FDAAA

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu

Drug Safety & Public Health: Legislative Changes to Reform the FDA

Presenters:

- **Kathleen Stratton, Ph.D., Institute of Medicine**
- **David Dorsey, Senate Committee on Health, Education, Labor and Pensions (Sen. Kennedy)**
- **Douglas Throckmorton, M.D., Deputy Director FDA, Center for Drug Evaluation & Research**

Moderator:

- **Stan Edlavitch, Ph.D., M.A. UMKC School of Medicine**

Drug Policy and Pharmaceutical Practices Subcommittee. Medical Care Section: Robert Eilers, Stan Edlavitch Co-Chairs

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu

Today's Session Drug Safety - Law Includes Much More

i. **Prescription Drug User Fee Act (PDUFA IV)**
ii. **Medical Device User Fee Act (MDUFA)**
iii. **Pediatric Medical Device Safety and Improvement Act**
iv. **Pediatric Research Equity Act**

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu

Today's Session Drug Safety-Law Includes Much More

V. Best Pharmaceuticals for Children Act of 2007 (BPCA)
VI. Reagan-Udall Foundation and Critical Path Partnerships
VII. Conflicts of Interest
VIII. Clinical Trials
    I. Registry
    II. Results Data Bank

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu

Today's Session Drug Safety-Law Includes Much More

ix. **Post-Market Studies and Clinical Trials; Labeling**

x. **Risk Evaluation and Mitigation Strategies (REMS) (180 days)**

xi. **Direct to Consumer Advertising (DTC)**

xii. **Post-Market Risk Identification and Analysis**

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu

Today's Session Drug Safety-Law Includes Much More

xiii. **Anticounterfieting**

xiv. **Citizens Petitions**

xv. **Antibiotics and Enantiomers**

xvi. **Other Drug Safety Provisions**

- i. **Post-market Drug Safety Information for Patients and Providers**
- ii. **Action Package for Approval**
- iii. **Response to the IOM (1 year)**
- iv. **Database for Authorized Generic Drugs**

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu

Today's Session

- **Help put this important legislation into public health perspective**
- **Historical background**
- **Public health implications of IOM recommendations**
- **Congressional view of legislation**
- **Insight into how FDA sees the legislation being implemented and how it might make a difference**
- **Discussion – panel and audience**

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu

Professor Stan Edlavitch

edlavitchs@umkc.edu

816-235-6617

Copyright 2007, Stanley Edlavitch, edlavitchs@umkc.edu