



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**



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



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**



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- 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**



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- 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**



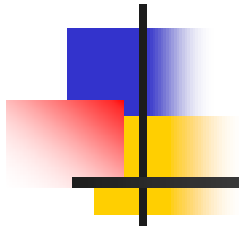
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- xiii. Anticounterfeiting**
- xiv. Citizens Petitions**
- xv. Antibiotics and Enantiomers**
- xvi. Other Drug Safety Provisions**
 - i. Post-market Drug Safety Information for Patients and Providers**
 - ii. Action Package for Approval**
 - iii. Response to the IOM (1 year)**
 - iv. Database for Authorized Generic Drugs**



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**



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