An Introduction to the History of Federal Pharmaceutical Regulation

I. Early Federal Laws Covering Medicines
   A. Vaccine Act of 1813
   B. 1848 Drug Importation Act

II. The Drug Marketplace of the Late 19th Century and Early 20th Century Legislation
   A. The Patent Medicine Menace: Advertising and Labeling and Therapeutics Gone Awry
   B. Microbiology and the Rise of Biological Therapy
   C. Diphtheria Disaster and the 1902 Biologics Control Act
   D. The Prescient, Voluntary Regulatory System Under the American Medical Association

III. The Long Search for Domestic Control of Drugs
   A. Muckrakers and their Influence
   B. Harvey Wiley and the 1906 Food and Drugs Act
   C. Applying the New Law, and Impact of Dr. Johnson’s Cancer Cure
   D. Chamber of Horrors

IV. The Food, Drug, and Cosmetic Act of 1938
   A. Election of Franklin Roosevelt and Introduction of Bills in Congress
   B. Elixir Sulfanilamide Disaster

V. Drug Regulation in the Immediate Aftermath of the Law
   A. Creating the Federal Prescription Drug Legend for Non-Narcotics
   B. New Drug Applications Swarm the FDA
   C. Enforcement and Illegal Sales of Amphetamines and Barbiturates

VI. Drug Regulation Revisited
   A. Kefauver Hearings Into Drug Pricing (and Advertising and Efficacy)
   B. Thalidomide, Frances Kelsey, and Global Therapeutic Disaster
   C. Redefining Drug Regulation Under the 1962 Drug Amendments
   D. DESI and Attending to Past Oversights

VII. Subsequent Milestones in Drug (and Non-Drug) Regulation
   A. Patient Package Inserts in the Late 1960s and Early 1970s
B. The Orphan Drug Act of 1983
C. Drug Price Competition and Patent Term Restoration Act
D. User Fees and a New Way to Subsidize Drug Regulation
E. Dietary Supplement Health and Education Act of 1994
F. FDA and Tobacco