

## 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 19<sup>th</sup> Century and Early 20<sup>th</sup> 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
- C. The New Law and Its Provisions

### 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