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This slide presentation was compiled and produced by Robert McCarthy, Ph.D., Professor and Dean *Emeritus* at the University of Connecticut School of Pharmacy for his class "The History of American Pharmacy." Prof. McCarthy created this version of the slide talk for his class in the Spring of 2016.

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Regulating Pharmacy Practice

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The History of American Pharmacy

Spring 2016

Federal Laws

- 1848: Drug Importation Act: First federal drug legislation—aimed at preventing the importation of adulterated drugs; required examination of imported drugs at the port of entry; law proved to be ineffective due to lack of standards to be used by the examiners, as well as unqualified examiners
- 1851: New York College of Pharmacy was appointed to investigate the issue of drug standards; this committee recommended a convention of delegates from other schools of pharmacy; the convention recommended standards for several drugs.

Federal Laws

- The APhA annual meetings in the late 19th century urged federal legislation to deal with the problem of patent medicine quackery.
- 1902: At APhA's urging, the US Department of Agriculture established a laboratory to study the composition and adulteration of drugs; nevertheless, Congressional opposition to a comprehensive drug law remained until several journalists published a series of exposes of the patent medicine industry; "The Great American Fraud" series published in *Colliers* was most notable (as was Upton Sinclair's *The Jungle* on the meat packing industry).

Federal Laws

- By 1895, about half of the states had passed laws regarding food and drug safety, but they were inconsistent and manufacturers could circumvent the law by selling a drug/food product in another state.
- 1906: The Pure Food and Drug Act
  - Outlawed interstate commerce in adulterated or misbranded food and drugs
  - Mandated labeling the quantities of 11 drugs (including heroin, morphine, cocaine, and alcohol)
  - Established the *U.S. Pharmacopeia* and *National Formulary* as official compendia of drug standards

Dr. Harvey Washington Wiley, an analytical chemist and physician was a key advocate for food and drug safety.

Federal Laws

- 1911: US Supreme Court held that the Food and Drugs Act did not prohibit false health claims, only false statement about the ingredients on the label.
- 1912: Congress passed the Sherley Amendment, which prohibited false claims about the therapeutic effects of drugs, although this law was tough to enforce since it required demonstration that the manufacturer's intent was fraudulent.

Federal Laws

- 1914: Harrison Narcotics Act
  - Regulated the distribution of narcotics within the United States; the regulations were delayed and did not go into effect until 1920
  - Despite the Harrison Act, there remained concern by pharmacists that federal and state laws allowed for unregulated distribution of exempt narcotics.
  - In order to dispense narcotics, pharmacists had to register with the IRS and could only do so with a written prescription from a physician or dentist.

Federal Laws

- 1917: Trading with the Enemy Act
  - Rescinded drug patents held by German pharmaceutical companies and allowed the FTC to issue licenses to American companies to produce these drugs
- 1922: 18th Amendment to the US Constitution--The National Prohibition (Volstead) Act
  - Made alcohol a prescription drug; required the use of special prescription order forms for medicinal liquors; made pharmacies with soda fountains a busy gathering place; created a new demand for patent medicines with alcohol; one patent medicine, containing triorthocresyl phosphate (found in lacquers), led to the paralysis/death of 35-50K

Federal Laws

- 1938: Food, Drug, and Cosmetic (FD&C) Act
  - Required drugs to be safe prior to marketing; enactment of this legislation was spurred by the death of over 100 individuals from a toxic solvent used in sulfanilamide elixir
- FD&C Amendments:
  - 1941—requiring safety and efficacy of insulin
  - 1945--requiring safety and efficacy of penicillin (and later all antibiotics)
  - 1946—Miller Amendment—safeguarded goods in interstate commerce

Federal Laws

- 1948: US Supreme Court decision that a pharmacist violated Federal law by selling a restricted drug without a physician's prescription.
- 1951: Durham-Humphrey Amendment: established two classes of drugs, prescription (legend) and non-prescription (non-legend or OTC drugs); gave legitimacy to telephone prescription orders and refill orders; transformed pharmacists from drug therapists to drug dispensers (era of count, lick, stick, and pour).
- 1954: Congress passed legislation allowing pharmacists to receive telephone prescriptions for certain codeine-containing drugs.

Congressman Carl Durham (NC) was a pharmacist (legislation co-sponsor Minnesota Senator Hubert Humphrey was also a pharmacist).

Anti-Substitution Laws

- Late 1960s: Top 20 brand name pharmaceutical companies supplied medications for about 75% of all new prescriptions; states had anti-substitution laws that prohibited substituting one drug product for another without authorization from the prescriber
- By the early 1970s, APhA took a position that urged repeal of state ant-substitution laws.

Federal Laws

- 1962: Kefauver-Harris Amendments (passed as a result of the thalidomide disaster):
  - Required proof of drug effectiveness
  - Extended drug clearance provision
  - Enhanced factory inspection authority
  - Increased control over clinical research
  - Use of non-proprietary drug names
  - More vigorous GMP
  - FDA oversight of prescription drug advertising

Thalidomide Disaster

- Originally marketed as a non-barbiturate sedative
- In the early 1960s, since it was thought to be safe in pregnancy, it was used to treat morning sickness (off-label use); the drug was not approved by the FDA for use in the U.S., though it was used in U.S. clinical trials (not controlled by FDA at the time).
- Its use led to severe birth defects (phocomelia--shortened, absent, or flipper-like limbs).
- By March 1962, the drug was removed from the market in countries where it had been approved.
- Today, thalidomide is FDA-approved for two uses: the treatment of inflammation associated with Hansen's disease (leprosy) and as a chemotherapeutic agent for patients with multiple myeloma.

Photo by Leonard McCombe//Time Life Pictures/Getty Images)

In 1962, Dr. Frances O. Kelsey (FDA) received the President's Distinguished Service Award from President Kennedy for her refusal to allow thalidomide to enter the US market.

Federal Laws

- Kefauver-Harris Amendments required all drugs on the market introduced to the market between 1938 and 1962 to be evaluated; National Academy of Sciences and National Research Council established panels of experts to evaluate these drugs; more than 7000 drugs were removed from the market; 1500 changed their labels (a similar review of OTC drugs began in 1972).

Federal Laws

- 1963: APhA recommended the establishment of "pharmacists only" medicines, a third class of drugs.
- Title XVIII Social Security Act of 1965 (Medicare Parts A & B) and Title XIX Social Security Act of 1965 (Medicaid)
  - 2003: Medicare Prescription Drug Plan (Part D)
  - 2003 (although managed care option goes back to the 1970s) Medicare Advantage Plan (Part C): managed care plan (e.g., HMO or PPO) that offers Medicare prescription drug coverage

Federal Laws

- 1970: Poison Prevention Packaging Act
  - Legislation was to help address accidental medication overdose in children
  - Required child-resistant packaging for certain over-the-counter medications and prescription drugs
- 1990: Omnibus Reconciliation Act (OBRA '90)
  - Mandated drug-utilization review (DUR) for all Medicaid patients
  - Required pharmacists to offer counsel patients about their medications
  - Although OBRA only applied to Medicaid patients, nearly all states mandated its use for all patients

Federal Laws

- 1991: FDA announced it would take action against community pharmacies that manufactured large amounts of commercially-available drugs; the Joint Commission of Pharmacy Practitioners worked with FDA to ensure the continuation of drug compounding, pursuant to a prescription for an individual patient.
- 2003: Medicare Prescription Drug Improvement and Modernization Act
  - Medicare Part D
  - Medication Therapy Management (MTM) for seniors

Massachusetts Pharmacy Compounding Tragedy

- October 2012, outbreak of fungal meningitis traced to the new England Compounding Center in Massachusetts
- Methylprednisolone for epidural injection
- Products were distributed to 75 medical facilities in 23 states
- 48 deaths, hundreds treated for persistent fungal infections
- Raised issue again of manufacturing vs. compounding

State Laws

- 1868 (published 1869): APhA General Secretary John Maisch drafted the first model state pharmacy law, which proposed the creation of a state "pharmaceutical board" and created the term "registered pharmacist." It was sent to all US governors and many states adopted the model law (Rhode Island being the first in 1870). At the time, only Georgia had a statewide pharmacy law, but in 1868, only 5 individuals were formally licensed.
- By 1878, 8 states had adopted pharmacy laws; 21 additional states/territories in the 1880s; 12 additional states in the 1890s.

State Laws

- 1887: The APhA Section on Pharmaceutical Legislation was created, whose goal was to be a national organization that would bring together state boards of pharmacy and ensure uniformity of licensure examinations so that pharmacists licensed in one state would be recognized by all states.
- 1890: The Association of Boards of Pharmacy and Secretaries of State Associations was formed by 16 boards of pharmacy.
- 1891: A new model pharmacy law was adopted by the APhA Section on Legislation and Education; it was hoped that all state boards of pharmacy would adopt the revised model law to facilitate reciprocation of pharmacist licenses among states.

National Association of Boards of Pharmacy

- 1904: The National Association of Boards of Pharmacy was established at the APhA Annual Meeting.
- "The National Association of Boards of Pharmacy (NABP) is the impartial professional organization that supports the state boards of pharmacy in protecting public health. NABP aims to ensure the public's health and safety through its pharmacist license transfer and pharmacist competence assessment programs, as well as through its VIPPS, Vet-VIPPS, VAWD, and DMEPOS accreditation programs." (NABP website, 2015)

National Association of Boards of Pharmacy

- The North American Pharmacist Licensure Examination (NAPLEX)—assesses a candidate's minimum competency to enter the practice of pharmacy (originally called the National Association of Boards of Pharmacy Licensure Examination [NABPLEX]); used by all U.S. Boards of Pharmacy
- Multistate Pharmacy Jurisprudence Examination (MPJE)—contains both federal and state-specific laws to assess a candidate's knowledge of pharmacy law.