Pharmacy Practice in the United States

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Conflict of Interest

- Nothing to disclose
Presentation Objectives

1. Identify key legislation in the history of pharmacy practice of the United States

2. Understand the beneficial role of pharmacists with other providers on the health care team
History of Pharmacy Law in the United States
Pure Food and Drug Act of 1906

- Prohibited interstate commerce in misbranded and adulterated foods, drinks, and drugs

- Misbrand $\rightarrow$ to brand or label misleadingly or fraudulently

- Adulterated $\rightarrow$ to make impure by adding improper or inferior ingredients
Harrison Narcotics Tax Act of 1914

- Regulated and taxed the production, importation, distribution and use of opiates
- Created to decrease the growing number of opium addictions within the United States
  - Prescribers could not prescribe opiates to an addict as addiction was not considered a disease
Food, Drug, and Cosmetic Act of 1938

• Replaced the Pure Food and Drug Act of 1906 as the previous act did not address safety, false therapeutic claims, and having labels list ingredients, directions for use, and warnings of the product

• In 1937, sulfanilamide elixir made in an untested solvent (diethylene glycol) results in the death of 107 people, many children
  • Forced Congress to take action
Food, Drug, and Cosmetic Act of 1938

- New provisions of this act included:
  - Extending control to cosmetics and therapeutic devices
  - Requiring new drugs to be shown safe before marketing—starting a new system of drug regulation
  - Providing that safe tolerances be set for unavoidable poisonous substances
  - Authorizing standards of identity, quality, and fill-of-container for foods
  - Authorizing factory inspections
Durham-Humphrey Amendment of 1951

- Co-sponsored by former vice president Hubert H. Humphrey, a pharmacist

- Established two types of drugs
  - Rx legend (prescription)
  - OTC (over the counter)

- Required either a written prescription by a physician or an oral prescription by physician immediately reduced to writing

- Authorized refills on prescriptions

- Defined how drug manufacturers can switch their product from Rx to OTC
Durham-Humphrey Amendment of 1951

• Stated at least the following must be included on a prescription label:
  
  • Name and address of the pharmacy
  
  • Serial number of the prescription
  
  • Date of its filling
  
  • Name of the prescriber
  
  • Name of the patient
  
  • Directions for use
  
  • Warning labels
Kefauver-Harris Amendment of 1962

- Developed in 1957, thalidomide was a considered “wonder drug” and was quickly approved throughout most of Europe, Africa, and Canada

- Used for insomnia, coughs, colds, headache, and **morning sickness in pregnant women**

- At the time of drug development most scientists did not believe any drug taken by a pregnant woman could cause harm to fetus

- Dr. Francis Kelsey blocked FDA approval off thalidomide despite political pressures as she believed this medication could affect a developing fetus

- Between 1956 and 1962, it was found that 10,000 children were born with severe malformations because their mothers had taken thalidomide during pregnancy
Kefauver-Harris Amendment of 1962

- Established the steps needed for approving new drugs
  - Initial drug discovery → preclinical (animal) testing → investigational drug application (IND) → Phase 1–3 clinical studies → new drug application (NDA) → FDA reviews → post-marketing (Phase 4) studies

- As a result, the new amendment provided the following requirements when undergoing new drug approval:
  - Drug manufacturers must show effectiveness as well as safety
  - Drug manufacturers must report adverse events to the FDA
  - Drug manufacturers must advertise to physicians both the risks and benefits of drug products
  - Provision of informed consent when conducting clinical studies
  - NDA must be approved before a company could market a new drug
  - Good manufacturing practice guidelines

- FDA was given jurisdiction over prescription drug advertising
Comprehensive Drug Abuse Prevention and Control Act of 1970

• Describes the Controlled Substances Act (CSA)

• Provides classification, acquisition, distribution, registration/verification of prescribers, and appropriate record keeping requirements of controlled substances

• Creation of the Drug Enforcement Administration (DEA) responsible for enforcing the CSA

• Defined controlled substances
Controlled Substances

• Substances with potential of abuse

• Separated into 5 schedules
  • I, II, III, IV, V
  • Schedule I drugs have the highest potential of abuse (e.g., heroin and marijuana)
    • Not available in pharmacies

• Schedule V drugs have the lowest potential of abuse (e.g., Lomotil)
  • In some states may be dispensed by a pharmacist without a prescription if specific requirements are met
Monitoring Programs

- Most states have programs to monitor the sale and distribution of controlled substances
  - e.g., E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program)

- Reported electronically

- To identify potential abuse of controlled substances by patient, pharmacy, or prescriber
Occupational Safety and Health Act of 1970

- Created the Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH)

- Intended to prevent work-related injuries, illnesses, and deaths by issuing and enforcing rules for workplace safety and health

- The following pieces of this act that play a role for pharmacy are:
  - Written hazard communication program
  - Material Safety Data Sheets (MSDS)
  - Air contaminants
  - Flammable and combustible liquids
  - General concerns about hazardous materials
Poison Prevention Packaging Act of 1970

• Before this act poisonings by common household substances, including medications, was considered the leading cause of injury in children under 5 years

• Gave the Consumer Product Safety Commission (CPSC) the authority to require “special packaging” of household products and drugs to protect children
  • Creation of child-resistant packaging
    • On most Rx and OTC medications

• Pharmacists are responsible for ensuring proper packaging before dispensing to patient
Federal Antitampering Act of 1983

- Several poisoning were discovered in Chicago, IL linked to tampered bottles of Tylenol that came from different factories.

- The culprit was believed to have entered various supermarkets and drug stores over a period of weeks, adulterating contents with solid cyanide compound at another location, then replaced the bottles.

- Johnson & Johnson halted Tylenol production and advertising and issued a nationwide recall with over 30 million bottle in circulation.

- Led to reforms in the packaging of OTC substances and the creation of anti-tampering laws.
Orphan Drug Act of 1983

- Provides incentives for manufacturing drugs used to treat rare diseases ("orphan diseases") that affect < 200,000 people in the United States or a prevalence of < 5 per 10,000 in the community
- Tax benefits to companies who produce or research these drugs
- Granting of additional rights above and beyond those granted by the regular patent laws
- Subsidizing and funding clinical research by universities and industry sponsors to develop medical products (including drugs, biological products, devices, and medical foods) for rare diseases
- Creating a government-run company to research and produce drugs
Drug Price Competition and Patent-Term Restoration Act of 1984

• Established the generic drugs
  • Generic drugs save consumers approximately $10 billion per year at retail pharmacies alone

• Marketers of generic drugs can file Abbreviated New Drug Applications (ANDAs) to seek FDA approval
  • Allows 180 day exclusivity

• FDA has established specific statistical standards when considering generic products as equivalent to brand drugs
  • When both rate and extent of absorption are not significantly different when administered in the same dose of the therapeutic ingredient under similar experimental conditions

• Increased the length of time for drug patent to expire from 12 to 17 years (later extended to 20 years by the Uruguay Round Agreements Act of 1994)
Brand and Generic Drugs

• A **brand** name is a trade or propriety name
  • Describes product bearing a trademark
  • E.g., Tylenol

• A **generic** name is a “nonproprietary name”
  • A nonproprietary name is a short name of a chemical, drug, or other substance that is not subject to trademark rights but is the name in general public use for these substances
  • E.g., Acetaminophen

• FDA approves all drugs and recommends that all brand and generic drugs are equivalent
Orange Book

• FDA list of therapeutic equivalents

• Used by pharmacists to check generic equivalence as not all drugs have generic equivalents
Prescription Drug Marketing Act of 1987

• Addressed diversion of large quantities of such drugs into a secondary gray market (free samples and the sale of deeply discounted drugs to health care entities) leading to multi-million dollar drug diversion market through which mislabeled, adulterated, and counterfeit drugs are able to enter the market.

• Prohibited the act or offer of knowingly selling, purchasing, or trading a prescription drug sample
  • This offense is punishable by a fine of up to $250,000 and up to 10 years' imprisonment
  • There is a "finder's fee" of up to $125,000 for individuals who provide information leading to the conviction of a violator

• Prohibited the resale of any prescription drug that was previously purchased by a hospital or other health care entity.
Omnibus Budget Reconciliation Act of 1990

- Requires pharmacists to review Medicaid patients’ entire medication profile before filling prescriptions AND offer counseling

- The following must be screened:
  - Therapeutic duplication
  - Drug–disease contraindications
  - Drug–drug interactions
  - Incorrect drug dosage
  - Incorrect duration of treatment
  - Drug–allergy interactions
  - Clinical abuse/misuse of medication
Omnibus Budget Reconciliation Act of 1990

• Requires pharmacists to make a reasonable effort to obtain, record, and maintain the following information on Medicaid patients:

  • Name, address, and telephone number
  • Age and gender
  • Disease state(s) (if significant)
  • Known allergies and/or drug reactions
  • Comprehensive list of medications and relevant devices
  • Pharmacist's comments about the individual's drug therapy
Dietary Supplement Health and Education Act of 1994

- Defines dietary supplement as a product that is tended to supplement the diet containing one or more of the following:
  - A vitamin
  - A mineral
  - An herb or other botanical (excluding tobacco)
  - An amino acid
  - A dietary substance for use by man to supplement the diet by increasing the total dietary intake
  - A concentrate, metabolite, constituent, extract, or combination

- Also states that the supplement must be
  - Intended for ingestion in pill, capsule, tablet, powder or liquid form
  - Not represented for use as a conventional food or as the sole item of a meal or diet
  - Labeled as a "dietary supplement"
Health Insurance Portability and Accountability Act (HIPAA) of 1996

- Places stringent requirements on pharmacies to adopt policies and procedures relating to the protection of patient protected health information (PHI)
  - Security standards define administrative, physical, and technical safeguards that the pharmacist must consider in order to protect the confidentiality, integrity, and availability of PHI
  - Pharmacies must comply with HIPAA and maintain patient information and financial/administrative transactions in electronic format

- Gives important rights to patients including
  - The right to access their information
  - The right to seek details of the disclosure of information
  - The right to view the pharmacy's policies and procedures regarding confidential information
Medicare Modernization Act of 2003

- Creation of Medicare Part D which provides voluntary prescription drug coverage to patients eligible for Medicare benefits

- Provides some drug coverage for patients with economic hardships or on high-cost medications

- Pharmacists may provide and get reimbursed for medication therapy management (MTM) of the patient’s drug profile
Combat Methamphetamine Epidemic Act of 2005

- Regulates the OTC sales of ephedrine, pseudoephedrine, and phenylpropanolamine products due to illicit manufacturing of methamphetamines or amphetamine
  - A retrievable record of all purchases identifying the name and address of each party to be kept for two years
  - Required verification of proof of identity of all purchasers
  - Required protection/disclosure methods in the collection of personal information
  - Reports to the Attorney General of any suspicious payments or disappearances of the regulated products
  - Non-liquid of regulated product may only be sold in unit dose blister packs
  - Regulated products are to be sold behind the counter to restrict access
  - Daily sales of regulated products not to exceed 3.6 grams
  - A 30-day sales limit not to exceed 9 grams of pseudoephedrine base in regulated products
Patient Protection and Affordable Care Act of 2010

• Reform of private health insurance market

• Provides better coverage for those with pre-existing conditions, improves prescription drug coverage of Medicare patient, and aims to provide coverage for 15% of the United States population that lacks prescription coverage

• Undergone lots of controversy since it requires all citizens to acquire health care insurance or be charged a penalty and all health insurances to provide coverage for items such as birth control
Federal and State Pharmacy Law

• If state law or federal law has stricter requirements, the more strict requirement must be followed

• States require pharmacies and pharmacists to be licensed
  • Some states require pharmacy technicians to be licensed or registered (certified)
  • Laws vary by each state

• State boards of pharmacy regulates pharmacy practice of pharmacies, pharmacists, and pharmacy interns and technicians
  • Licensing, registering, inspection, investigations, disciplinary actions if necessary
Pharmacy Interns and Technicians

• Pharmacy interns and technicians work *under the supervision* of pharmacists
  • Interns participate in direct patient care with close preceptor oversight
  • Technicians are trained to performed data entry, order processing, and tasks that do **not** require professional judgement

• Technicians cannot/Interns can
  • Perform tasks that are limited to pharmacists or interns
  • Use professional judgment
  • Counsel patients on their medications
Pharmacy Licenses

- Retail
- Community
- Hospital
- Institutional
- Long-term care
- Nuclear
- Mail order
- Sterile-compounding
Pharmacists and Other Healthcare Professionals
Interprofessional Team Approach

- Include but is not limited to specialty providers, pharmacists, social workers, physical therapists, hospitalists, nurses, physician assistants, and/or nurse practitioners
- Clinical decision support
- Optimal patient outcomes
Accountable Care Organizations (ACO)

- Groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to Medicare patients

- Goal is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors

- Pharmacists are playing a role in these organizations by providing several beneficial services to both patients and providers and participate in various ACO programs
ACO Programs

• Chronic care management
  • Patients qualify if they have 2 or more chronic diseases
  • Centers for Medicare and Medicaid Services (CMS) require monthly 20 minute non-face to face visits
  • Education on various chronic conditions, i.e., diabetes, hypertension, obesity
  • Strengthens provider/patient relationship

• Transitional care

• Patient-centered care
Benefits of Clinical Pharmacists

• Medication reconciliation
• Transitions of care
• Physician continuing education
• Improvement in patient outcomes
• In-office visits
Benefits of Clinical Pharmacists

- Assist with quality measure benchmark performance/ongoing quality assurance
- Perform annual wellness visits
- Immunizations
- Care for disease-specific “at risk” patients
- Reduce hospitalizations/readmissions
- Financial savings
The Health Care Team

Caregiver

Support System

Patient

Health care provider

Pharmacy
Summary

- Several pieces of legislation has shaped the role of pharmacy practice in the United States throughout the last century

- Pharmacists play a vital role on the health care team and add multiple benefits to assist in the delivery of optimal patient care
Questions?
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