Pharmaceutical Law

Module 5

Pharmaceutical Law

- In this Module we are going to look at:

- The presents principles and practices of the Federal Food, Drug and Cosmetic Act governing the research and development of pharmaceuticals and biologics for both humans and animals including an analysis of legal and social constructs affecting industry and

- The academic and clinical investigator with emphasis on FDA enforcement actions
- The FDA Enforcement well explained in FDA Regulations Relating to GCP and Clinical trials : https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials#FDARegulations
- Of course, in the previous modules we'd discussed some parts of 21 CFRs

- https://uscode.house.gov/browse/prelim@title21&edition=prelim

Pharmaceutical Laws

Pharmaceutical regulations, Pharmaceutical Legislations, or medicines regulations, have been defined as the combination of legal, administrative, and technical measures that governments take to ensure the safety, efficacy, and quality of medicines, as well as the relevance and accuracy of product information

[“***Legislation***” refers specifically to the creation of laws that are usually written in fairly general terms to meet present and possible future needs. They have language that enables the government to issue regulations based on the law. Passing new laws requires a lengthy process and involves a country’s legislative body. While

“***Regulations***” are the rules established by an agency that interprets the laws to facilitate their practical implementation. They can be passed more quickly and simply than laws. For example, the United States Food and Drug Administration (US FDA) has the rule-making responsibility for the “Food, Drug, and Cosmetic Act” of 1938 in the United States (US). Regulations have a way of expanding far beyond the size of the enabling law. For example, the “Food, Drug, and Cosmetic Act” consisted of a mere 19 pages.

Today, Code of Federal Regulations Title 21, which enforces the law, requires nine volumes containing over 4,000 pages.] - **Pierre-Louis Lezotre MS, PhD**

Pharmaceutical law

Pharmaceutical law is the set of regulations and policies embedded in the Federal Food, Drug , and Cosmetic Acts which is the basic food and drug law of the USA.

The Congress maintains the United States Codes which are in the custody of the Law Revision Counsel

The laws are intended to assure the consumers that:

- foods are pure and wholesome, safe to eat, and produced under sanitary conditions;
- drugs and devices are safe and effective for their intended uses;
- cosmetics are safe and made from appropriate ingredients; and that
- all labeling and packaging is truthful, informative, and not deceptive.

Pharmaceutical Laws

- Pharmaceutical Laws need to be put in place due to:
  - The role of pharmaceuticals has become more prominent on international platforms as health indicators have been increasingly linked with a country's development,
  - Also the legal and economic issues that surround pharmaceuticals have become more complicated and politicized due to increase in global trade.

Pharmaceutical Laws

Why Pharmaceutical laws and regulations are important?

1. The use of ineffective , poor –quality or harmful medicines can result in therapeutic failure, exacerbation of disease, resistance to medicines, congenital deformities (Thalidomide's – limbless babies) and sometimes death

2. Important in undermining confidence in health systems, health professionals, pharmaceutical manufacturers and distributors

3. To protect public health, governments need to approved comprehensive laws and regulations and to establish effective national regulatory authorities to ensure that the manufacture , trade and use of medicines are regulated appropriately and that the public has access to accurate information on medicines

Pharmaceutical Laws

What is Pharmaceutical Law:

- These laws include:
  - 1. Intellectual property rights to protect drug manufacturers' research, [**Intellectual Property]**

    e.g. a new guidance was released by FDA on conduct of CTs of medical products during this COVID-19 Pandemic
  - 2. safety standards to protect the public from harmful side effects and restrictions on marketing drugs to the public, [**Safety and Marketing]** and

    The Safety of the public is paramount to the office of Human Research protections in compliance to the laws, rolled out guidance on safety of human in this covid-19 per 45 CFR part 46
  - 3. rules regarding how drugs may be prescribed and distributed. [**Distribution].** For instance, the FDA rolled out a Guidance on Manufacturing, Supply chain and drug and biological product inspections during the covid-19

    All these regulatory guidance are to protect the lives of human subjects

Pharmaceutical Laws

- Pharmaceutical Law Articles;
  - All Health care and Social law articles
  - FDA regulations Relating to Good Clinical Practice and Clinical Trials
  - Food and Drug Law Institute https://www.fdli.org/2020/08/a-practical-guide-to-fdas-food-and-drug-law-and-regulation-seventh-edition/
  - Pharmacist Code of Ethics and Oath
  - Prescription Drug User Fee Act
  - The Office of Prescription Drug Promotion

Pharmaceutical Laws

The Pharmaceutical laws are regarded in the usa as Federal Food, Drug and Cosmetic Act (sections 321 to 399i):

https://uscode.house.gov/browse/prelim@title21/chapter9/subchapter1&edition=prelim

The United States Code is a consolidation and codification by subject matter of the **general** and **permanent** laws of the United States. https://uscode.house.gov/browse.xhtml

It is prepared by the Office of the Law Revision Counsel of the United States House of Representatives.

- The Title 21/ Chapter 9 subchapter V- Drugs and Devices: https://uscode.house.gov/browse/prelim@title21&edition=prelim

- The USA code for Food and Drugs = TITLE 21 that includes all the regulations that guide drugs and Food productions: https://uscode.house.gov/browse/prelim@title21/chapter9&edition=prelim

1. Part A - Drugs And Devices (351 – 360n-1)
2. Part B – Drugs for Rare diseases or conditions (360aa -360ff-1)
3. Part H-Pharmaceutical Distribution Supply Chain (360eee -360eee-4)

Pharmaceutical Laws

- **Food, Drug, and Cosmetic Act (FDCA)**
- Also known as the FFDCA and FD&C Act. The federal statute giving the **Food and Drug Administration** (FDA) the authority to monitor and regulate the safety of food, drugs, and cosmetics.
- The FDCA authorizes the FDA to, among other things:
  - Inspect products already on the market.
  - Regulate companies' manufacturing practices.
  - Evaluate new drugs, medical devices, and food additives for safety and effectiveness before companies can market them to the public.
  - Recall or seize, or both, products it determines are unsafe or not FDCA-compliant.
  - Issue standards for product labeling and other marketing communications, such as:
  - the nutritional information found on food packaging; and
  - the side effects and drug interactions listed on pharmaceutical labels.
- (21 U.S.C. §§ 341 to 350f, 351 to 360ccc-2, 371 to 379dd-2.)

Pharmaceutical Laws

- Important sites:
- On policy, legislation and Regulations https://msh.org/our-work/health-systems/pharmaceutical-management/policy-legislation-and-regulation
- https://clinregs.niaid.nih.gov/country/united-states#_top The aggregate clinical research regulations around the globe put together by National institute of Allergy and infectious diseases. **Anthony Fauci's**
- https://www.fda.gov/about-fda/virtual-exhibits-fda-history/80-years-federal-food-drug-and-cosmetic-act
- The History of the Federal Regulation: https://www.fdareview.org/issues/history-of-federal-regulation-1902-present/