History of Pharmacy Law

- Late 1800s-State Regulation
- 1906-Pure Food and Drug Act
- 1938-Food, Drug & Cosmetic Act
- 1951-Durham-Humphrey Amendment
- 1962-Kefauver-Harris Amendment
- 1984-DPCPTRA
- 1990-OBRA 90
- 1997-FDA Modernization Act

The FDCA

Definition of “drug” “article”….
- recognized in official compendium
- intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals
- (other than food) intended to affect the structure or any function of the body of man or other animals
- components of the above.
Dietary Supplements

• “Dietary Supplement” if it contains
  – vitamin
  – mineral
  – herb or botanical
  – amino acid
  – dietary substance

• OK to make structure/function claim re nutrient deficiency disease if there is substantiation statement is truthful and not misleading

FDCA cont

• “new drug” - drug, not GRAS or not GRAE, among scientific experts qualified by scientific training and experience, under conditions prescribed, suggested or recommended in labeling.

New Drug Approval

• Decision within 180 days (Ha Ha)
• If unsafe, ineffective, misbranded, deny….if not, approve
• “Substantial evidence”
  – adequate and well controlled investigations
  – including clinical investigations
  – qualified experts
  – one rct ok, if confirmatory evidence
**Postmarketing Surveillance**

- Phase IV
- Phase V
- Restricted Distribution Programs
  - Accutane
- Drug Labeling Changes
  - Black Box Warning
  - Off-Label Use

**Withdrawal of Approval**

- New evidence of lack of safety
- New and old evidence of lack of efficacy
- Untrue statement of material fact in NDA
- No due process if “imminent hazard”

**The IND Exemption**

- This is not an approval
- Exemption from prohibition against introduction into interstate commerce of unapproved new drug
- Preclinical results supportive
- Plan for use investigations with humans
United States v. Rutherford

• Issue: Whether terminally ill cancer patients may be prescribed laetrile to treat their disease, despite the drug not having been approved by the FDA.

Rutherford: The Facts

• “In 1975, terminally ill cancer patients and their spouses brought this action to enjoin the Government from interfering with the interstate shipment and sale of Laetrile, a drug not approved for distribution under the Act.”

Rutherford: The Issues

• “The Federal Food, Drug and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients.”
• “As this Court has often recognized, the construction of a statute by those charged with its administration is entitled to substantial deference.”
**Rutherford: Reasoning**

- “An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect.”
- “But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible.”

**Rutherford: The Result**

- “to exempt from the Act drugs with no proved effectiveness in the treatment of cancer would lead to needless deaths and suffering among . . . patients characterized as terminal who could actually be helped by legitimate therapy.”
- “Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial interference.”

**Rutherford: Summary**

- The traditional view is that the government exists to protect people from themselves.
- The court is hugely deferential to the FDA, because the agency enforces the FDCA.
- Recent changes have made it easier to access investigational drugs and have sped up approval of innovative new drugs.
Generic Products

- Bioequivalence Standards
  - ANDA relies on NDA
  - Rate and extent of absorption essentially identical
  - Same chemical entity, strength, dosage form
- Orange Book
  - Products given two-letter ratings, first letter counts
  - Two “A” rated products bioequivalent
  - http://www.fda.gov/

Pfizer, Inc. v. Shalala

- Issue: Whether a sustained release dosage form that achieves its purpose in a way that differs from that of the product approved under an NDA can be approved under an ANDA.

Pfizer, Inc.: The Facts

- “Plaintiff Pfizer, Inc. brings this action in hopes that this Court will order the FDA to reject the support of a generic version of a sustained-release nifedipine tablet.”
Pfizer, Inc.: The Issues

• “Pfizer argues that it is not permissible under the FDCA for the FDA to permit two drugs that deliver their active ingredients by different means to be considered the “same” dosage form.”
• “Mylan and Penwest maintain that the products do indeed have the same dosage form because they are both extended release tablets.”

Pfizer, Inc.: Reasoning

• “The FDA’s current and long-standing dosage form classification system appears to be fully in tune with the objectives of the Hatch-Waxman Amendments. If a generic drug manufacturer is able to safely imitate the therapeutic effects of a pioneer drug, whatever release mechanism the manufacturer uses should be irrelevant.”

Pfizer, Inc.: The Result

• “Despite plaintiff’s claims to the contrary, there is nothing in the FDCA to indicate that Congress intended FDA to develop a dosage form classification system based on a drug’s release mechanism.”
**Pfizer, Inc.: Summary**

- FDA standards for bioequivalence are valid only for the same chemical entity, same strength and same dosage form. An Orange Book rating of “A” indicates that two products are rated as bioequivalent.
- Controlled release products need not use the same mechanism.
- Courts usually defer to the FDA.

**Drug Laws in Practice**

- Prescription Exemption
- Therapeutic Interchange
  - P&T Committee
  - Drug Formulary
- Compounding
  - New Drug Issue
  - Adulteration Issue
  - Misbranding Issue