

CHAPTER 4

Legal, Ethical, and Cultural Considerations

NDEG 26 A – Pharmacology 1
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U.S. Drug Legislation

- 1906: Federal Food and Drug Act
- 1912: Sherley Amendment (to the Federal Food and Drug Act of 1906)
- 1914: Harrison Narcotic Act
- 1938: Federal Food, Drug, and Cosmetic Act (revision of 1906 Act)

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U.S. Drug Legislation (cont'd)

- 1951: Durham-Humphrey Amendment (to the 1938 act)
- 1962: Kefauver-Harris Amendment (to the 1938 act)
- 1970: Controlled Substance Act

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New Drug Development

- Investigational new drug (IND) application
- Informed consent
- Investigational drug studies
- Expedited drug approval

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U.S. FDA Drug Approval Process

- Preclinical investigational drug studies
- Clinical phases of investigational drug studies
 - Phase I
 - Phase II
 - Phase III
 - Phase IV

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Canadian Drug Legislation

- Canadian Food and Drugs Act (1953)
- Canadian Narcotic Control Act (1961)

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Legal and Ethical Principles

- Autonomy
- Beneficence
- Confidentiality
- Justice
- Nonmaleficence
- Veracity

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Ethical Nursing Practice

- American Nurses Association (ANA) Code of Ethics for Nurses
- Canadian Nurses Association Code of Ethics for Registered Nurses

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Cultural Considerations

- Assess the influence of a patient's cultural beliefs, values, and customs
- Drug polymorphism
- Compliance level with therapy
- Environmental considerations
- Genetic factors
- Varying responses to specific agents

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Cultural Assessment

- Health beliefs and practices
- Past uses of medicine
- Folk remedies
- Home remedies
- Use of nonprescription drugs and herbal remedies
- OTC treatments

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Cultural Assessment (cont'd)

- Usual response to treatment
- Responsiveness to medical treatment
- Religious practices and beliefs
- Dietary habits

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