

Pharmacology

PHARMACODYNAMICS AND KINETICS

PHARMACOLOGY

A. Testing Sequence (FDA)

1. animal testing (LD50)
2. **Phase I** Clinical trials for safety
3. **Phase II** Clinical trials for effectiveness
4. **Phase III** expanded clinical trials (double blind)
5. **Phase IV** - post market surveillance – report problems via web page

II. Legislation

A. **Orphan Drug Act (1983)** – In response to under-treatment of rare diseases, the bill stimulated research of drug therapies for these diseases and added safety research.

B. **Controlled Substances Act (1970)**

1. Added scheduling to controlled substances.

Controlled Substances: Schedule Categories			
SCHEDULE	ABUSE POTENTIAL	MEDICAL USE	DEPENDENCY
C-I	High	None	Severe
C-II	High	Accepted	Severe physical and/or psychologic
C-III	<C-II	Accepted	Moderate/low physical or high psychologic
C-IV	<C-III	Accepted	Limited physical or psychologic
C-V	<C-IV	Accepted	Limited physical or psychologic

2. Nurse who gives controlled substance to someone other than prescribed commits **federal crime**.
3. **Unlabeled uses of drugs** - After the FDA approves a drug for one use, an MD legally may prescribe it for any labeled or unlabeled indication. But the manufacturer cannot advertise it for an unlabeled use. And insurance companies may not pay for prescribed medications indicated for unlabeled uses.

Drugs bought via internet may be bogus

OTC Drugs – A legal loophole allows manufacturers to change the ingredients without changing the name.

Ex: Moxon used to have Al and Mg hydroxides. Now there are many Moxon products, none of which have the original Al and Mg formula.

Risks of OTC drug use:

1. Self-diagnosis (*patients may use the drug to treat an improper self-diagnosis*)
2. Potent drugs
3. Undesirable effects (*Many side effects*)
4. Drug interactions (*Many pts don't report use*)
5. Drug toxicity (*Many pts overuse OTCs*)

OTC safety – There is a low incidence of adverse effects and low potential for harm assuming proper instructions and warnings on label **ASSUMING YOU FOLLOW INSTRUCTIONS** (proper route, dose, administration)!

OTC Effectiveness – Drug, when taken properly, will provide relief of minor sore or illness in a significant portion of the population.

Components of an OTC drug label:

- Active ingredients/amount in each dosage unit
- Purpose
- Uses (indications)
- Specific warnings (when not to use, when to consult with physician or pharmacist, adverse effects, substances or activities to avoid)
- Dosage instructions (when, how, and how often to take)

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