



Over-The-Counter Drugs

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What are OTC drugs?

- OTC are medicines that can be bought without a prescription from the doctor.

100,000 OTC drug products
marketed

800 significant active
ingredients

80 therapeutic categories



- Most OTC agents are no more than “me too” products.
 - drug that is structurally very similar to already known drugs, with only minor differences.
 - less risky to develop.
 - approved 'automatically'
 - create competition and drive prices down.
 - 75 % of all new drugs in the market.



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- According to *Consumer Healthcare Products Association* (CHPA)
 - 73% Americans would rather treat themselves at home than to see a doctor.
- Americans buy more than 5 billion OTC drug products each year – 60% of drugs used.

Advantages of OTC Drugs

- benefits outweigh risks
- low misuse & abuse potential
- consumers are able to
 - ❖ Self diagnose
 - ❖ Self treat
 - ❖ Self manage
- adequately labeled
- health practitioners are not needed.



Disadvantages of OTC Drugs

- Reduced opportunities to receive counseling about possible lifestyle therapies (e.g. exercise & diet),
- Poorer compliance,
- Misdiagnosis, patients won't benefit from the drug but will be exposed to its risks,
- More difficult to study a drug's effects.

The Label

- According to the law, OTC drug labeling must include “all of the information that an ordinary consumer needs for safe and effective use.”

- **Active ingredient**
- **Uses "indications"**
- **Warnings**
- **Directions**
- **Other information**
- **Inactive ingredients**
- **Questions or Comments**

Drug Facts

Active ingredient (in each tablet)

Chlorpheniramine maleate 2 mg

Purpose

Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

■ You may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over

take 2 tablets every 4 to 6 hours;
not more than 12 tablets in 24 hours

children 6 years to under 12 years

take 1 tablet every 4 to 6 hours;
not more than 6 tablets in 24 hours

children under 6 years

ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

The Label (Cont.)



- The OTC drugs
 - labeling is regulated by FDA
 - advertising by Federal Trade Commission (FTC).
- But
- Prescription drugs advertising is strictly regulated only by FDA.

OTC drug regulation



- May 1972, before & after.
- Ingredients fell into three categories.

- ❖ Category I: GRASE
- ❖ Category II: not GRASE
- ❖ Category III: cannot determine if safe and effective

OTC drug regulation

(Cont.)

OTC drug monographs "recipe book"

- "recipe book"
- ingredients, doses, formulations, labeling, and testing
- continually updated.

New Drug Application (NDA) process

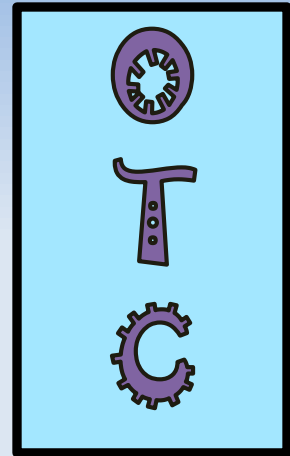
- new ingredients
- Rx-OTC switch

OTC regulation in UK



- Medication will fall into one of three categories:
 - 1) Prescription Only Medication (POM)
 - 2) Pharmacy Only Medication (P), "behind-the-counter".
 - 3) General Sales List(GSL).

Rx-to-OTC Switch

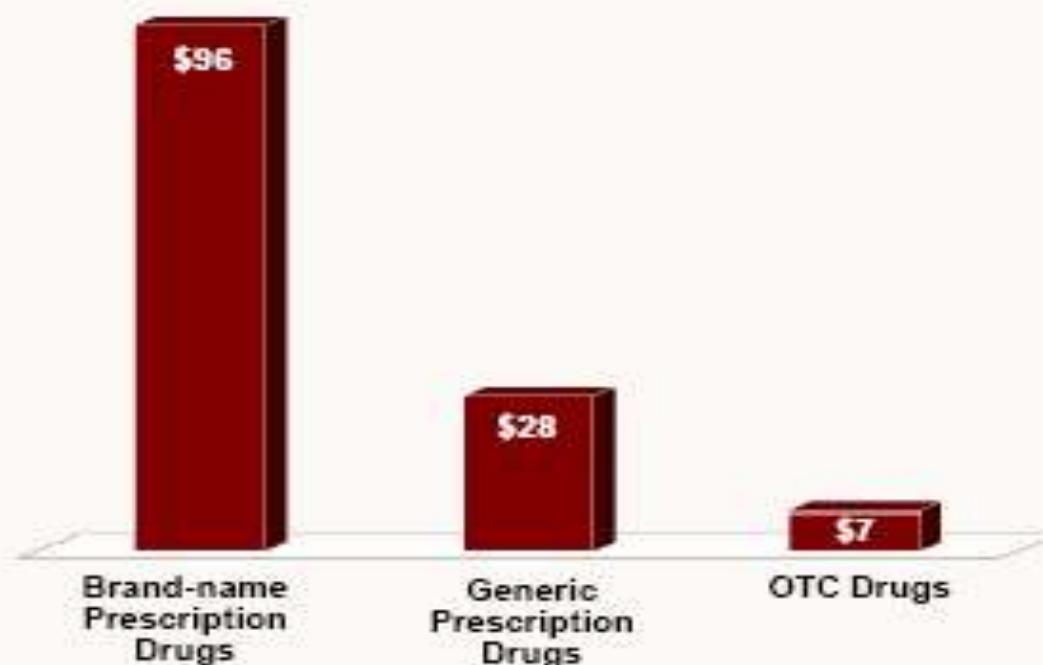


- Over 700 Rx switched to OTC only 30 years ago.

Rx-to-OTC Switch (Cont.)

- The reasons for a drug to become an OTC:
 - 1) Overall risk & potential abuse or dependency.
 - 2) Availability for a larger population early in a disease.
 - E.g. Hyperacidity & ulceration.
 - 3) The company's way of extending the life of their drug
 - By creating reduced strength & reduced price product.
 - 4) Rx drug cost has increase by 15% per year
 - Financial relief.

FIGURE 1
Average Price of Drugs



Source: Prices for prescription drugs are from the National Association of Chain Drug Stores. Average price for OTC drug purchase is estimated at \$7 to \$10 by Timothy R. Covington, Samford University; see Susan L. Comer, "The Generic Solution," *Today's Health*, Fall 2004.

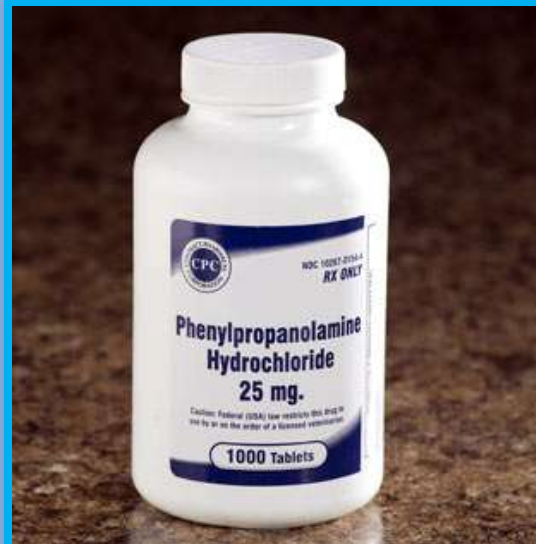
Recall "Tylenol"



- In 2008 McNeil company received complaints of
 - an "unusual moldy musty" odor.
 - nausea, stomach pain, vomiting and diarrhea.
 - "2,4,6-tribromoanisole (TBA)," store packaging materials.
- The FDA has issued a warning letter to McNeil.
- In Jan. 2010 → recall took place.

Recall (Cont.)

- Another example is phenylpropanolamine (PPA)
 - used in some cold and cough remedies.
 - ingredients caused serious allergic reactions.
 - concern regarding strokes in young women.





RECALL

OTCs & Pregnancy



- Data are lacking.
- Some are known to cause birth defects.
- Estimated 50% of products taken during pregnancy are OTC medications.
- According to the *New England Journal of Medicine*, 10-45 % of pregnant women in 1st trimester, unaware of their condition, use aspirin.

Pregnancy (Cont.)

- Aspirin & salicylate drugs should only be used under doctor's supervision, especially during last trimester.
- Acetylsalicylate, may
 - prolong pregnancy
 - cause excessive bleeding before & after delivery.
- **READ THE LABEL.**



OTCs & Driving

- First generation Antihistamines.
- Decongestants- speed up the CNS.
- Night-time cold and flu medications.
- **READ THE LABEL**



Examples of OTC drug Categories

Antacids and Acid Reducers

Antiemetic Medicines

Antidiarrheals

Antihistamines

Cough Medicine

Decongestants

Herbal Products and Supplements

Laxatives

Pain Killers

Vitamins

Laxatives



- Many products relieve constipation,
 - bulk-forming laxatives, lubricants, stool softeners, saline laxatives, stimulant laxatives and combination medicines.
- Constipation usually goes away on its own or if you make changes in diet and other habits
 - e.g.. enough fiber, drinking enough fluids and getting enough exercise.

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Pain Killers


- Two main types
 - acetaminophen “paracetamol”
 - NSAIDs include the following:
 - Aspirin
 - Ibuprofen
- If an OTC medicine doesn't help you may have a more serious problem or need a prescription medicine.





Fruit Fruit Fruit Vitamins!!!

Weight loss OTC drugs

- FDA recently banned 111 ingredients in OTC weight control products  ineffective.
 - E.g. alcohol, ascorbic acid (vitamin C), caffeine, several forms of sugar, phenacetin (a pain reliever), sodium, and yeast.
- In February 7, 2007- (FDA) approved orlistat capsules as an OTC.

Weight loss OTC drugs (Cont.)

- Orlistat was approved in 1999 as a prescription drug for obesity
 - remains a Rx drug at a higher dose.
- OTC orlistat under the name “Alli” became available in drugstores June 15, 2007.

Weight loss OTC drugs (Cont.)

- Alli is indicated for
 - adults ages 18 years & older
 - along with a reduced-calorie, low-fat diet
 - & exercise program.
- Alli is an OTC lower dose version of prescription “Xenical”.





**Your Choice
Your Life!!**

OTC Drugs References



- **Orange Book:** The list of Approved Drug Products with Therapeutic Equivalence Evaluations.
 - Supposed to use in pharmacy all the time in the US.
- **BNF:**
 - Prescription only Medication. PoM
 - Controlled Drug. CD
 - Preparations not available for NHS prescription. NHS

Misuse & Abuse of OTC drugs

- *Pharming* “getting high”.
- Common misconception: OTC drugs are harmless.
- By definition:
 - OTC drugs can be used safely and effectively *by reading and following the directions on the label.*



Misuse & Abuse (Cont.)

- The labeling is written in easily understood language “of low comprehension”
- Recent surveys have reported that
 - Consumers do not read OTC labels,
 - If they do read them, they do not follow the directions on the labels.
 - In one survey, it has been found that only 16% reported reading the entire product label.



Misuse & Abuse (Cont.)

- Abuse is most common in adolescents aged 12-17 years.
- Readily available, no suspicion.
- Alcohol Vs. OTCs
- Adolescents are 18 times more likely to die from an OTC overdose than from an illicit drug overdose
 - Recent data suggests that MDMA (Ecstasy) abuse has decreased over the past two years. Yet OTC abuse is increasing.

Misuse & Abuse (Cont.)

- Since reporting of this type of abuse is not mandatory, the true incidence of OTC abuse is unknown.
- The FDA has responded by trying to create OTC labels that are easier to read and understand.
 - However, there are no warnings against intentional overuse of the drug to get high.



Facts & Numbers

- 36 million Americans use OTC pain drugs daily.
- In 2006, 3.1 million persons aged 12 to 25 had ever used an OTC cough and cold medication to get high, and nearly 1 million had done so in the past year.
- 30,000 people in the UK are addicted to OTC drugs.
- Only 39% of OTC drugs are now purchased in a pharmacy.
 - drug stores, supermarkets, gas stations, airports, vending machines, and mass merchandisers.

OTC drugs Abused

DXM

- Antitussives (especially dextromethorphan):
- DXM is found in more than 140 OTC cough and cold medications in the US .
 - Internet sites explain how to extract DXM !!!
- When taken at very high doses, it acts as a dissociative anesthetic, similar to PCP(angel dust)
 - DXM users consume more than 100 mg per dose.
 - Tolerance develops; so long-term DXM users may need more than 1000 mg per dose to create the psychoactive effect.

DXM

- Adverse effects of DXM in large doses:
 - Decreased thermal regulation
 - Dry mouth and body fluid losses
 - Blurred vision, hallucinations & delusions
 - Irregular heartbeat, high BP, numbness of fingers or toes, flushing, headache
 - Loss of consciousness
 - Death (rarely)



DXM

- The treatment for dextromethorphan overdose is **naloxone**.....

Abuse

CNS Stimulants

- Stimulants are found in
 - nasal decongestants, bronchodilators, appetite suppressants, energy pills, and sports supplements.
- Examples: ephedrine, pseudoephedrine, and caffeine



Abuse Ephedrine

- Ephedrine can be converted to methamphetamine chemically
 - Formulas are readily available on the Internet!!!
- In many states, it is illegal to sell single-entity products containing ephedrine.
- In toxic doses ephedrine causes
 - palpitations that sometimes progress to chest pain,
 - submyocardial infarction & arrhythmia,
 - Paranoia & seizures.



- *Pseudoephedrine:*

- The main nasal decongestant oral cough and cold products today.
- Abused by sport players.

- *Other abused OTC drugs:*

- *Antidiarrheals (loperamide)*
- *Antihistamines*
- *Caffeine*



Role of the clinician

Help the patient select a safe & effective product.

Limit the cost of drugs they prescribe.

Review all medications taken by the patient.

Educate patients, community, friends, & family about OTC medication .

Encourage people to seek guidance from their physician or pharmacist.

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*Thank
You!*

Esther