

Generic Drugs:

Myths and Facts



Important Information

- The slides will progress at their own pace.
- Do not attempt to speed up the video.
- The Post Test will only unlock after the entire 17-minute video has been viewed.
- The video can be paused and resumed later.



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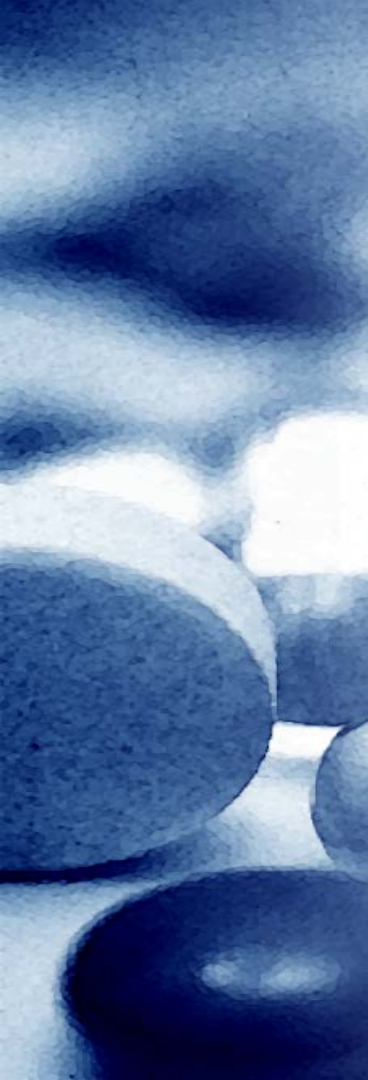
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Program Objectives

This program will show you how generic drugs are developed and approved in the US. After you finish the program, you will be able to:

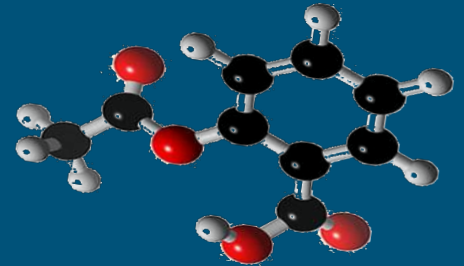
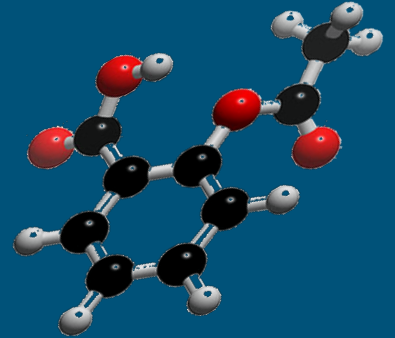
- Describe the standards the FDA uses to approve generic drugs
- Discuss bioequivalence
- List several strategies used by pharmaceutical companies to undermine generic competition
- Identify two advantages of using generic drugs


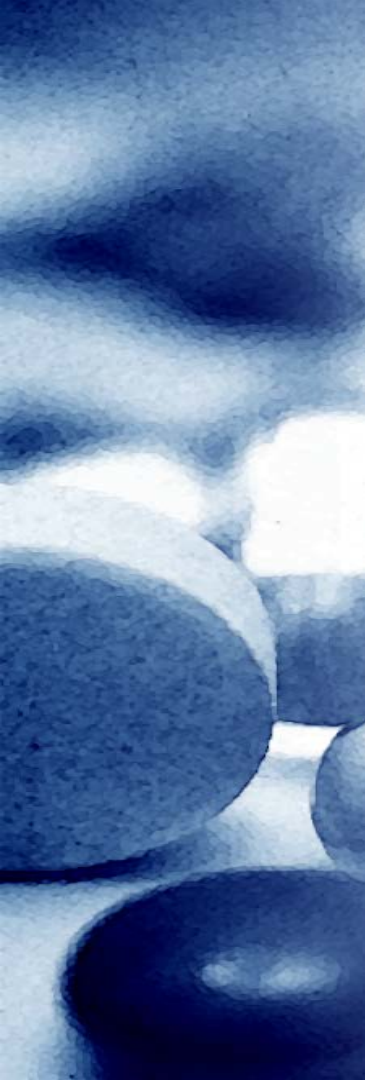


Introduction

A Generic Drug is...

A drug for which the original patent has expired, so the drug can now be produced by manufacturers other than the original patent-holding company.





What's the difference between a generic drug and a generic name?

- Every drug has a generic name.
- Individual drug companies may or may not assign trade names to their versions of the drug, but the generic name remains the same regardless of the manufacturer.
- The drug company that first manufactures a drug usually (but not always) uses a brand name to sell that drug.

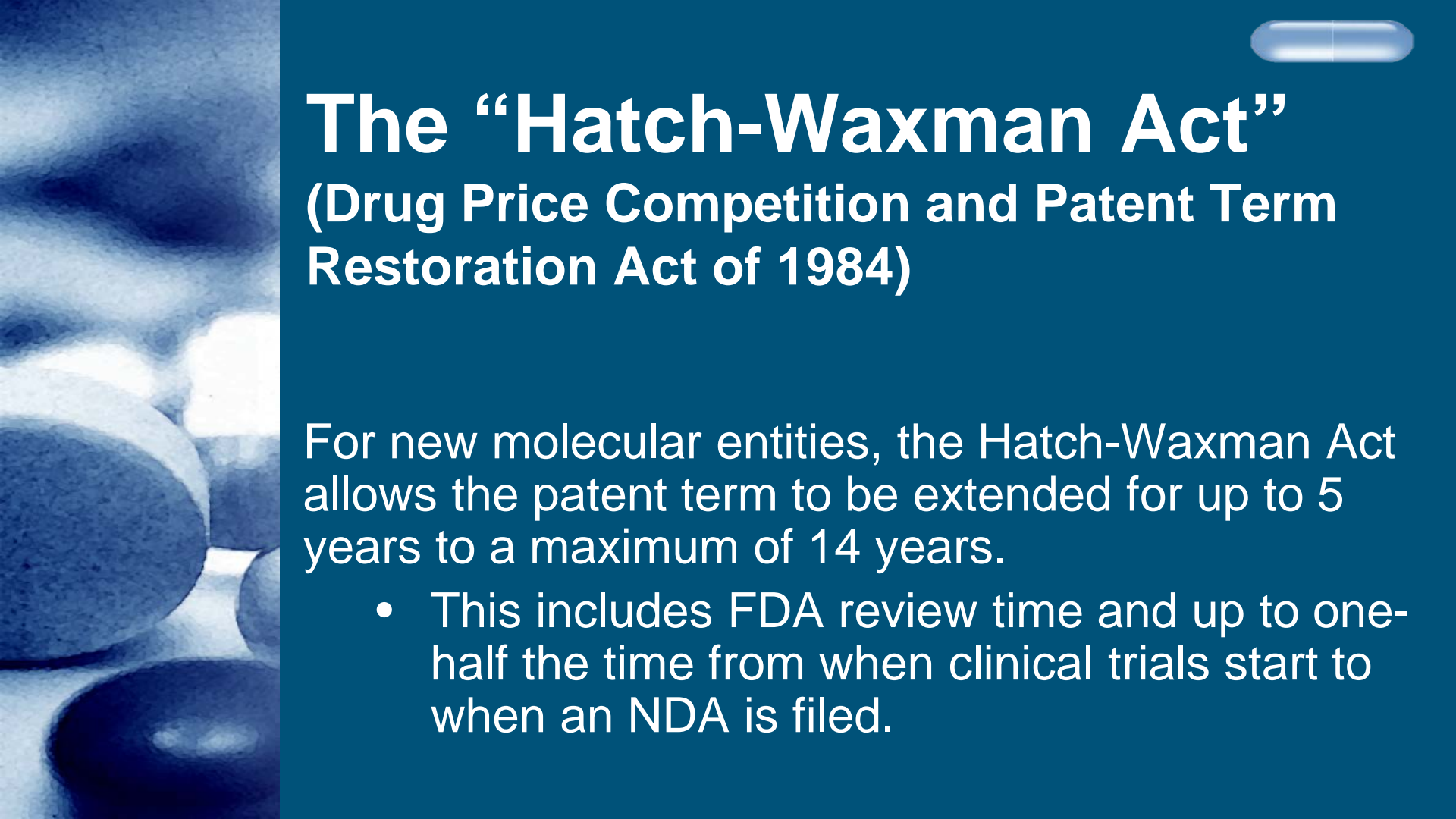
Generic Drug Names

- Since 1961, U.S. generic names have been assigned by the United States Adopted Names (USAN) Council.
- Outside the U.S., many countries use generic names assigned by the World Health Organization's International Non-Proprietary Names (INN) Program.
- For most drugs, the USAN Council and INN Program stems and generic names are the same.



Patent Life of a Drug

- In the U.S., patent life lasts for 20 years from the date the patent application is filed.
- Patent applications are usually made early in drug testing.
- Drug testing and applying for drug approval takes years, so by the time a drug is on the market, it usually has 7-10 years of patent life left.



The “Hatch-Waxman Act”

(Drug Price Competition and Patent Term Restoration Act of 1984)

For new molecular entities, the Hatch-Waxman Act allows the patent term to be extended for up to 5 years to a maximum of 14 years.

- This includes FDA review time and up to one-half the time from when clinical trials start to when an NDA is filed.



Hatch-Waxman Act



- Hatch-Waxman also provides additional periods during which the FDA may not approve a generic application.
- Hatch-Waxman allowed the expansion of the generic drug industry and increased competition in the brand name industry.
- Under Hatch-Waxman, new combinations, new dosage forms, and new uses receive three additional years of exclusivity during which the FDA cannot approve a generic.

Hatch-Waxman Act



- New combinations, new dosage forms and new uses also may be covered by new patents with expiration dates extending well beyond the expiration dates of the original patents.
- When a patent (and additional periods of exclusivity) expire, a drug may be manufactured and sold under its generic name as a generic drug by other companies.



Extending Patent Life



Evergreening: Extending Patent Life

- Pharmaceutical manufacturers may apply for patent extensions for minor changes in method of delivery or type of capsule or tablet.
- Generic drug manufacturers can be blocked from marketing a drug for up to two and one-half years until a patent dispute is settled.

Patent Extension: Reformulations

Delayed-release preparations include:

- Controlled-release (CR)
- Sustained-release (SR)
- Extended-release (XL)
- Long-acting (LA)



New Patents: Minor Changes in Dosing



Yasmin (ethinyl estradiol 30 mcg / drospirenone 3 mg) vs.
Yaz (ethinyl estradiol 20 mcg / drospirenone 3 mg)



AndroGel (testosterone 1%)
vs. *AndroGel* (testosterone 1.62%)



New Patents: Fixed-Dose Combinations

- *Fixed-dose combinations* are two or more drugs in one pill.
- Fixed-dose combinations are eligible for a new patent even if both drugs are available as generic drugs. These drugs
 - Are often more expensive than their components.
 - Provide less flexibility in dosing options.





Fixed-Dose Combinations

Some combination products (for example, some HIV products) enhance compliance. However, in many cases, writing a prescription for the individual drugs preserves dosing flexibility and often saves patients money.



Example: Alendronate


- Fosamax plus D is patent-protected and costs about six times as much as generic alendronate.
- Alendronate and other bisphosphonates must be taken with calcium (all trials tested the combination).
- Calcium supplements are often formulated with vitamin D, but calcium cannot be formulated with bisphosphonates.
- Because patients still need to take additional calcium with Fosamax plus D, the total tablet burden remains the same.



New Patents are Granted for Combinations of Generic Drugs

Can you name the two generically available drugs in the following branded products?

- Advair
- Diclegis
- Symbicort
- Diovan HCT



New Patents are Granted for Combinations of Generic Drugs

Can you name the patented and generic drugs in the following branded products?

- Janumet
- Vytorin
- Benicar HCT



Branded Combinations of Generic Drugs Include:

- Advair (fluticasone/salmeterol)
- Diclegis (doxylamine succinate/pyridoxine hydrochloride)
- Diovan HCT
(valsartan/hydrochlorothiazide)
- Symbicort (budesonide/formoterol)



Combinations of a Branded and Generic Drug Include:

- Janumet (sitagliptin/metformin)
- Vytorin (ezetimibe/simvastatin)
- Benicar HCT (olmesartan medoxomil/hydrochlorothiazide)



New Patents are Granted for Enantiomers

- Many drugs are a racemic mixture, containing equal parts of the left-handed and right-handed enantiomer.
- Receptors may only accept one enantiomer. Effectively one-half of the drug molecules in a racemic drug are active and the other half are inactive.
- Left-handed enantiomers of drugs use the prefix “**es**” or “**levo**”
- Right-handed enantiomers of drugs use the prefix “**ar**” or “**dextro**”



Enantiomers

- Enantiomers are chiral molecules that are *mirror images* of one another
- It has become common practice to introduce a drug as a racemic mixture.
- Then, when the patent is close to expiring, the company releases the active enantiomer as a “new, improved” product.

Ask yourself: Why is the racemic mixture marketed first when it was technically possible to market the active enantiomer initially?



Ask yourself: Can you name a drug released first as a racemic mixture and then as a single isomer?

Nexium (esomeprazole), A Best-Selling Drug, is an Enantiomer



Omeprazole

Esomeprazole

The world's **#1** prescribed proton pump inhibitor¹

PRIOSECC[®]
(**OMEPRAZOLE**)^{30 MG, 20 MG, 7.5 MG TABLETS}

Relief beyond belief[®]

The most frequently reported adverse events with PRIOSECC are headache, diarrhea, and abdominal pain. Symptomatic response to therapy does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with omeprazole.

PRIOSECC is indicated first line for heartburn and other symptoms associated with gastroesophageal reflux disease (GERD).
See brief summary of Prescribing Information for a full list of indications.
© AstraZeneca 2005. All rights reserved.
1. Data on file, AstraZeneca.
2. Data on file, AstraZeneca.
3. Data on file, AstraZeneca.
PRIOSECC is a registered trademark of the AstraZeneca group of companies. 143418 Printed in the U.S.A. 430

SUPERIOR ACID CONTROL
the NEXIUM difference

NEXIUM 40 mg in 24-hour intragastric pH studies^{1,4}
CONTROLS ACID LONGER THAN ANY OTHER BRANDED PPI²

¹In 11 different studies, NEXIUM outperformed other branded PPIs measuring % of time pH<4. Individual studies with varying dosing and comparators, in GERD patients and healthy volunteers.

THE CORRELATION OF pH DATA TO CLINICAL OUTCOME HAS NOT BEEN DIRECTLY ESTABLISHED.

The most frequently reported adverse events with NEXIUM are headache, diarrhea, and abdominal pain. Symptomatic response to therapy does not preclude the presence of gastric malignancy.

As with all PPIs, patients treated concomitantly with warfarin may need to be monitored for increases in INR and prothrombin time.

NEXIUM should be used only for the conditions, dosages, and durations specified in the Prescribing Information. Before prescribing NEXIUM, please see the brief summary of full Prescribing Information on next page. Please visit our Web site at www.Nexium-us.com

Nexium[®]
(esomeprazole magnesium)

JAMA
2005 Jan 19
143(3)

Other Examples Include:

- Escitalopram (Lexapro) is the *S*-enantiomer of citalopram (Celexa).
- Armodafanil (NuVigil) is the *R*-enantiomer of modafanil (ProVigil).
- Adderall is a 3:1 mixture of *d*- and *l*-enantiomers containing a fixed ratio (1:1:1:1) of amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, and dextroamphetamine sulfate.
- Levalbuterol (Xopenex) is the *l*-enantiomer of albuterol (Proventil, Ventolin, etc.)



Are Enantiomers Better?

There is no strong scientific support for the superiority of these isolated enantiomers.

No trials have demonstrated a therapeutic advantage of esomeprazole over omeprazole when used at equivalent therapeutic doses.



Citalopram and Escitalopram

For escitalopram (Lexapro), the *S*-isomer is responsible for almost all serotonin reuptake inhibition. However, there is no compelling evidence to support claims that escitalopram is more effective or has a faster onset of action than citalopram (Celexa), and side effects are similar.



Adderall

- Adderall combines the *d*-isomer dextroamphetamine (Dexedrine) with the *l*-isomer, which is less potent. The half-life of *d*-amphetamine is 10-11 hours, so there is no need for the XR formulation, which delivers half of the dose initially, and the remainder 4 hours post-ingestion. A full day's effectiveness can be ensured by delivering an adequate morning dose of generic dextroamphetamine or Adderall.

Other “Next Generation” Products



Another tactic used when a drug is going off-patent is to release a metabolite or prodrug of the originator drug.

Ask yourself: Can you name a drug that is a metabolite or a prodrug of an originator drug?




Examples of Metabolites

- Desvenlafaxine (Pristiq) and venlafaxine (Effexor)
- Desloratidine (Clarinex) and loratidine (Claritin)
- Acyclovir (Zovirax) and valacyclovir (Valtrex)

An example of a prodrug

- Lisdexamfetamine (Vyvanse)



Are Metabolites and Prodrugs better?

Although there are exceptions, many metabolites, analogs, and prodrugs have no advantage over the originator drug. For example, no studies have compared loratadine (Claritin) with its main metabolite, desloratidine (Clarinex), and there is no evidence that desloratidine is superior.

Lisdexamfetamine



Lisdexamfetamine (Vyvanse), dextroamphetamine linked to a lysine molecule, is almost immediately cleaved to its components upon ingestion. Peak levels of dextroamphetamine may be reached earlier than other formulations, but there is no advantage to this. Earlier peak levels could theoretically increase rates of adverse effects.



New Patents: New Indications

- A new FDA-approved use (“indication”) can extend the patent life of a drug.
- Some drugs are renamed upon approval for a new indication.
- Renaming confuses prescribers into prescribing the brand for which there is no generic equivalent.

New Trademarks: Renamed Drugs



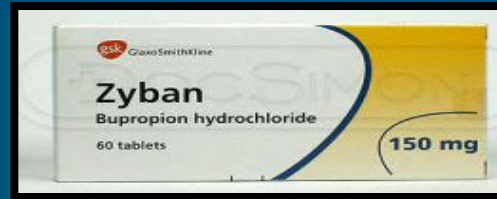
Fluoxetine =



=



Bupropion =



=



Sildenafil =



=



Why you should avoid prescribing renamed drugs

- A renamed drug may be exactly the same medicine, but its name may be trademarked.
- Even if there is a generic available for the **original** drug, in some states a pharmacist cannot substitute a generic medication for the **renamed** drug.
- It is always best to use the generic name of a drug on any prescription - whether branded or generic.



Veterinary Drugs: Reconcile

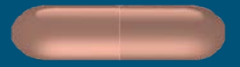
Elanco, Lilly's animal health division, markets Reconcile® (fluoxetine HCl) "for the treatment of canine separation anxiety in conjunction with a behavior modification plan." Reconcile is formulated in 8, 16, 32 and 64 mg chewable tablets.





To Preserve Market Share, Companies May Also:

- Manufacture their own generics
- Refine promotional strategies; foster brand loyalty
- Reformulate off-patent products
- Try to switch a drug from prescription to nonprescription (over-the-counter) status



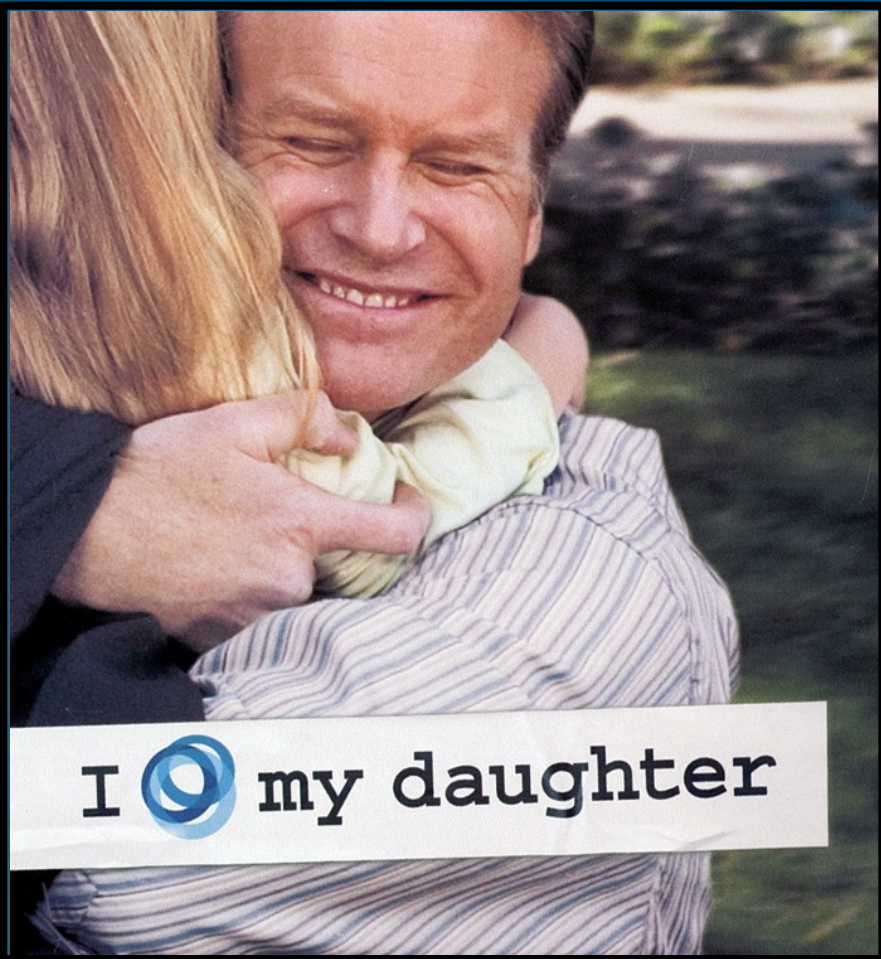
Branded vs. Generic Drugs



Prescribers are Most Familiar with Branded Drugs

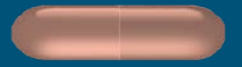
We all think that we are not affected by advertising, but most of us can correctly associate images, logos, and taglines with the products advertised.

Ask yourself: can you identify the drug associated with the following images?



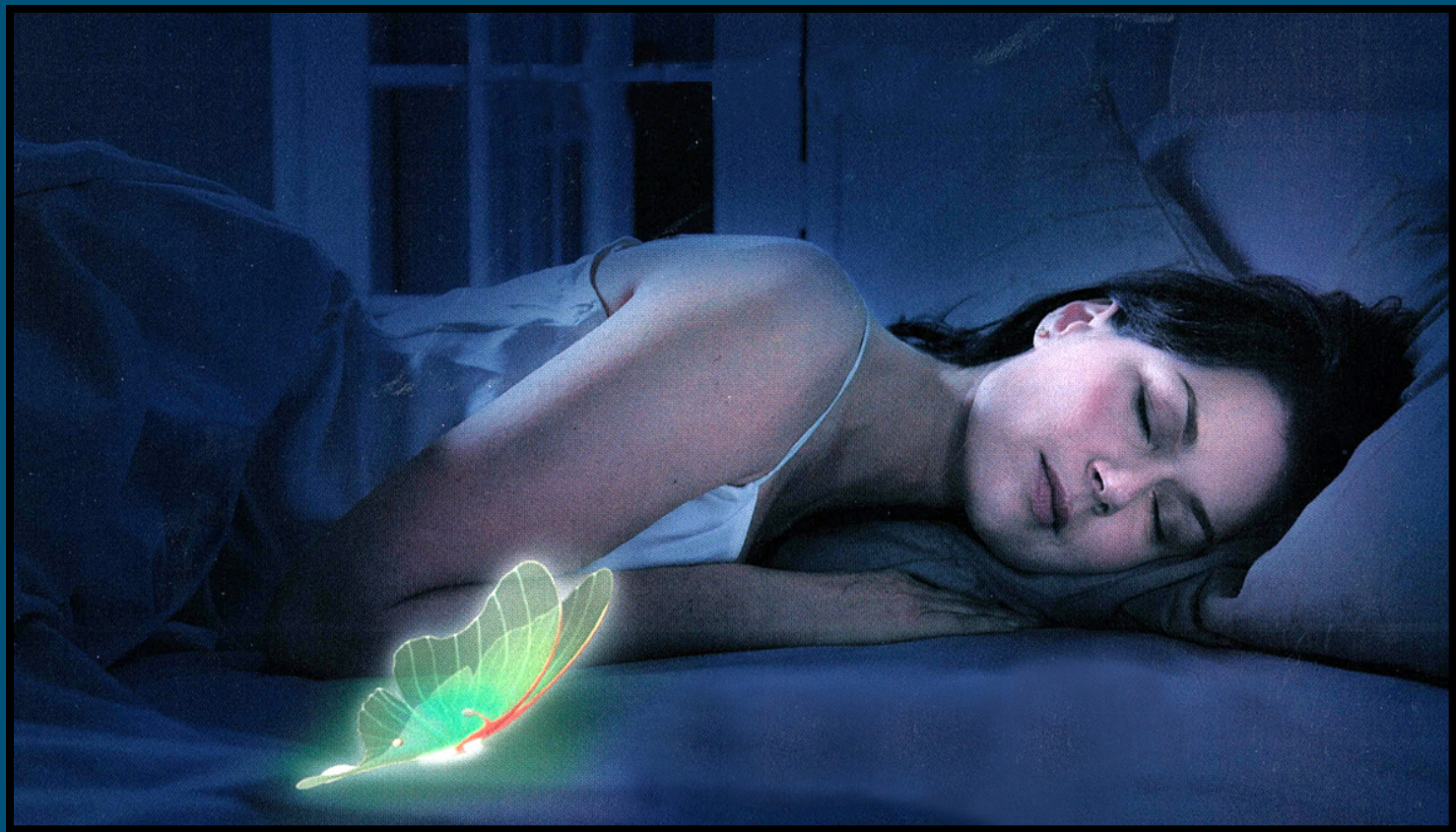
I  my daughter



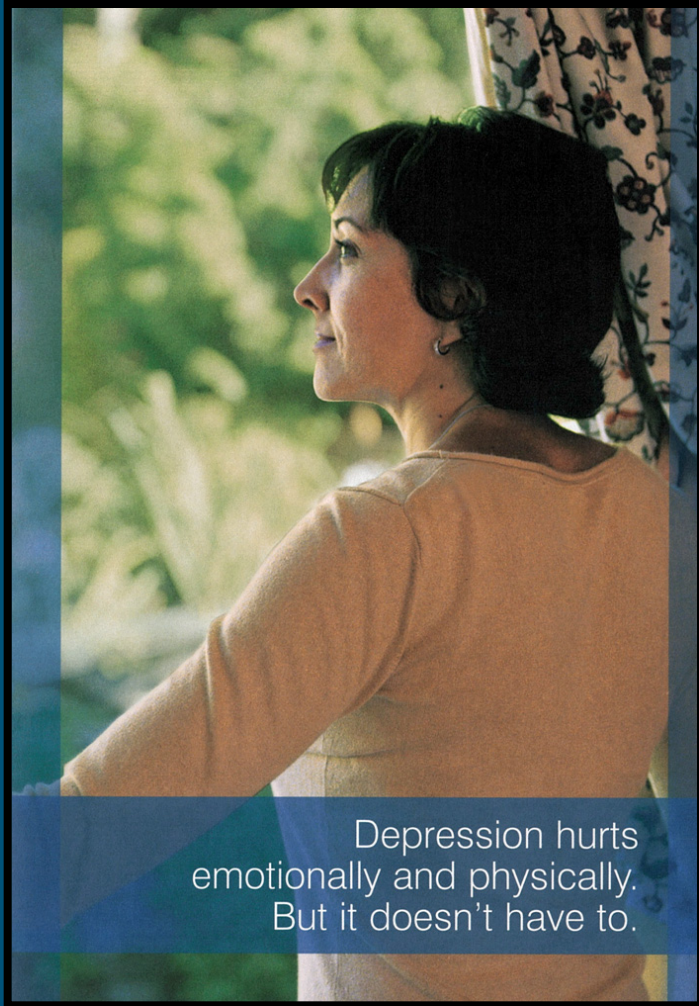
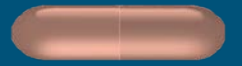




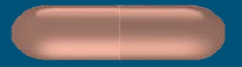
your dreams miss you.



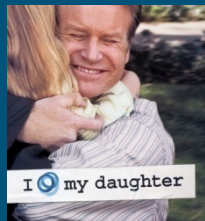




Depression hurts
emotionally and physically.
But it doesn't have to.



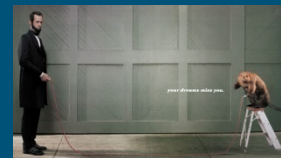
Did you correctly identify more than you thought you would?



Lipitor



Cialis



Rozerem



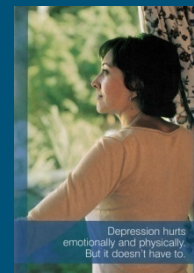
Lunesta



Advair



Nexium



Cymbalta

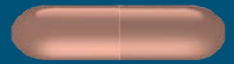


Effective Advertising

The fact that we can name the products means that the ads have served their purpose.

Ads in consumer and medical literature are meant to keep specific drug names uppermost in our minds when we reach for our pens and prescription pads.

Prescribers Are More Familiar With Brand Names Than Generic Names



Ask yourself: What are the generic names of the following drugs?

Lipitor

Nexium

Advair

Plavix

Seroquel

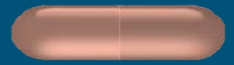
Remicade

Abilify

Sovaldi

Diovan

How many could you identify?



Lipitor	atorvastatin
Nexium	esomeprazole
Advair	fluticasone / salmeterol
Plavix	clopidogrel
Seroquel	quetiapine
Remicade	infliximab
Abilify	aripiprazole
Sovaldi	sofosbuvir
Diovan	valsartan



Consider This:

If you can remember only the brand, not the generic name, of drugs, then you are being affected by promotion. It's not a coincidence that brand names are easier to remember. Much money is spent on creating memorable brand names. Some firms specialize in naming drugs.



Myths and Facts about Generic Drugs



Did you know that...

- Generic drugs are NOT inferior in quality to branded drugs.
- Generic pills do NOT contain less active drug than branded pills.
- Inactive ingredients in generics do NOT affect absorption.
- Patients who are well-controlled on a branded medication CAN be switched to a generic medication.
- Bioequivalence studies in healthy people DO inform us about drug levels in sick people.



NDA and ANDA

- New chemical entities are approved under the **New Drug Application (NDA)** process.
- Generic drugs are approved under the **Abbreviated New Drug Application (ANDA)** process.



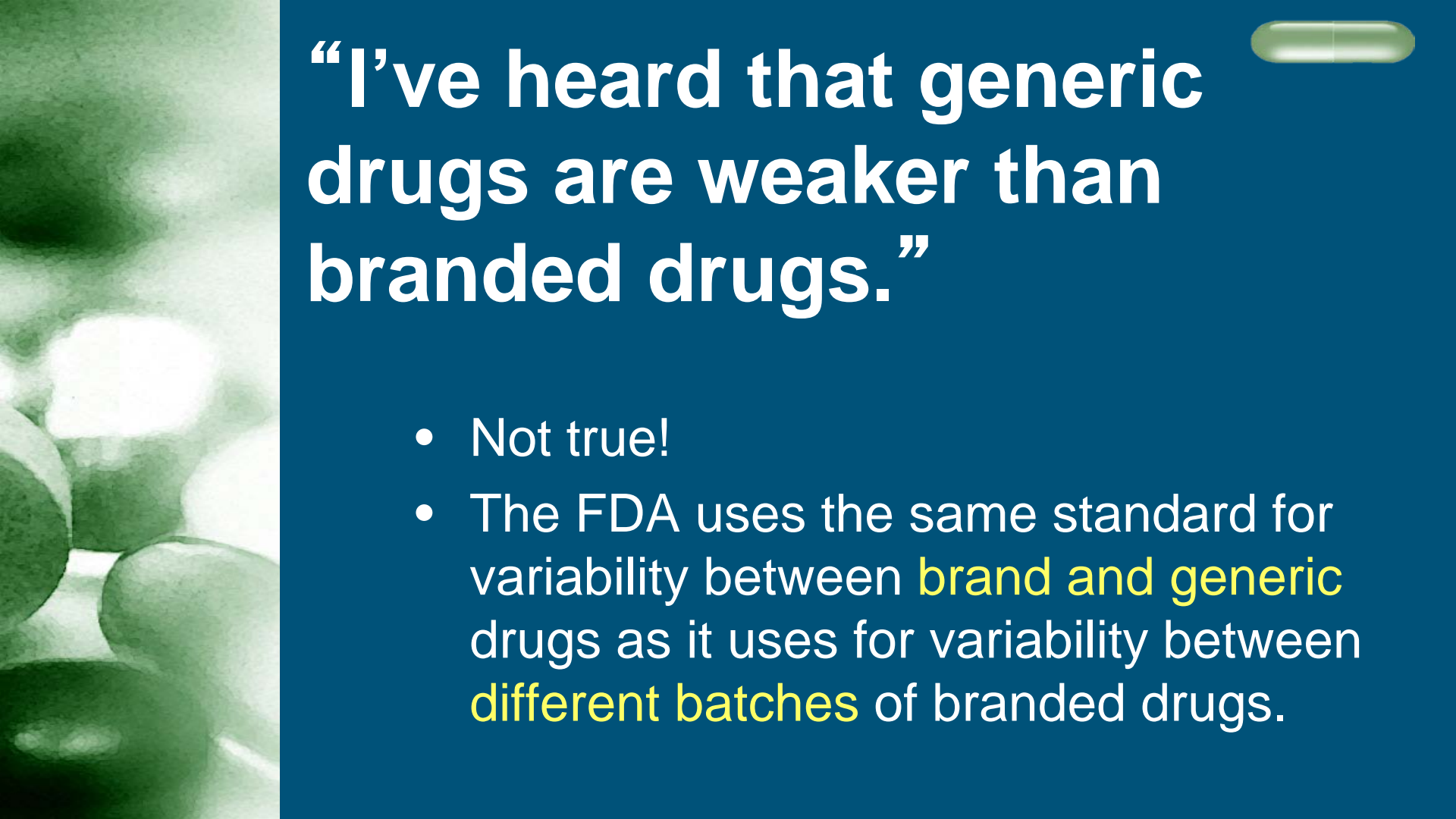
ANDA Review

- Pre-clinical and clinical testing does not have to be repeated for generics
- ANDA reviews include
 - Bioequivalence evaluation
 - Chemistry/microbiologic evaluation
 - Inspection of the manufacturing facility
 - Review of the proposed label



Bioequivalence: Definition

Bioequivalence is: “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” (FDA)



“I’ve heard that generic drugs are weaker than branded drugs.”



- Not true!
- The FDA uses the same standard for variability between **brand and generic** drugs as it uses for variability between **different batches** of branded drugs.



FDA Requirements for Generic Drugs

A generic drug must:

- Contain the same active ingredients as the innovator drug (inactive ingredients may vary)
- Be identical in strength, dosage form, and route of administration
- Have the same use indications
- Be bioequivalent
- Meet the same batch requirements for identity, strength, purity, and quality
- Be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products



“Really? But I’ve heard that generic drugs can contain 20% less active drug than branded drugs.”

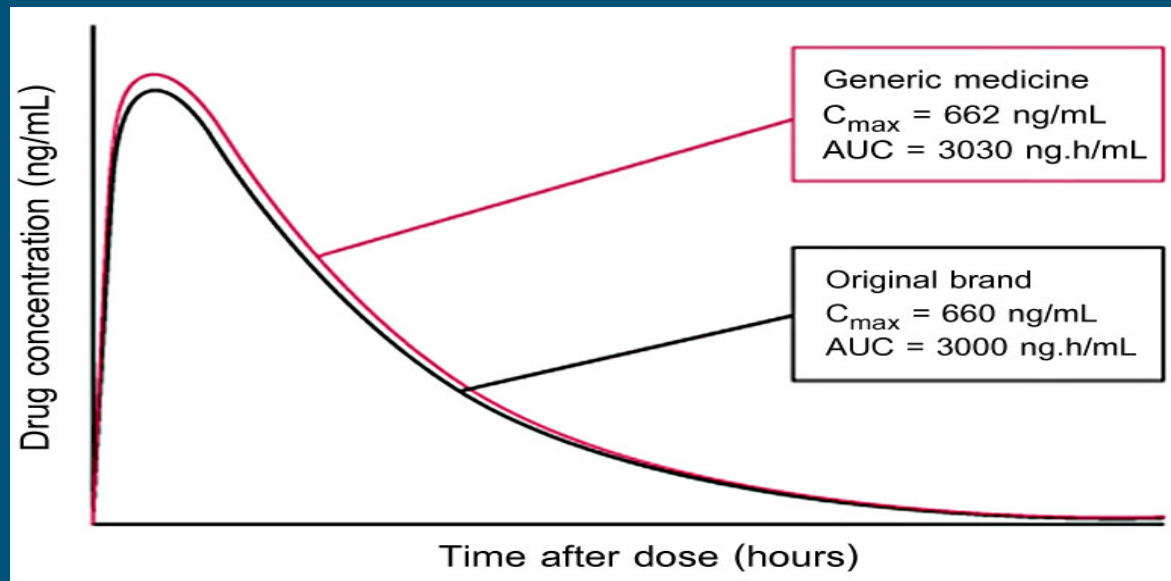
Very misleading! Here are the facts:



Generic Drug Facts:

- In order for the FDA to approve a generic drug, the 90% confidence intervals (CIs) must be between 80%-125% for AUC (area under the time-concentration curve) and C_{max} (peak plasma concentration).
- This does **not** mean that **concentrations** of the reference (branded) and test (generic) drug differ by 20%.
- If drug concentrations differ by about 10%, the CIs will fall outside of range.

Mean Concentration-Time Curves for Single Oral Doses of Two Brands





Bioequivalence Testing: Drug A

- Let's say the AUC for test Drug A, compared to the reference drug, results in the following serum concentrations in six people:*

110%, 120%, 110%, 110%, 90%, 110%

Mean (average) = 110%, 90% CI= 99 -115

- The average is 110%, and there is 90% certainty that the true range lies between 99% and 115%, so this drug **passes** the bioequivalence test.
- The test drug is considered bioequivalent to the reference drug.

*Normally, bioequivalence studies test at least 24 subjects



Bioequivalence Testing: Drug B

- For Drug B, the test/reference AUC in 6 people results in the following concentrations:
110%, 170%, 50%, 130%, 90%, 110%
Mean (average) = 110%, **90% CI** = 75-140
- Although the average concentration of drug (110%) is the same as Drug A, we are 90% certain that the true range lies between 75% and 140%. The confidence intervals are too wide, so the range of possible values is too broad.
- The test drug **fails** to establish bioequivalence with the reference drug.

(Meyer 1998)



Generic Drugs are Equivalent to Branded Drugs

A study that examined 2070 single-dose clinical bioequivalence studies of oral generic medicines approved by the FDA showed that the average difference in absorption into the body between the generic and the originator was 3.5% - comparable to differences between two different batches of the original drug.

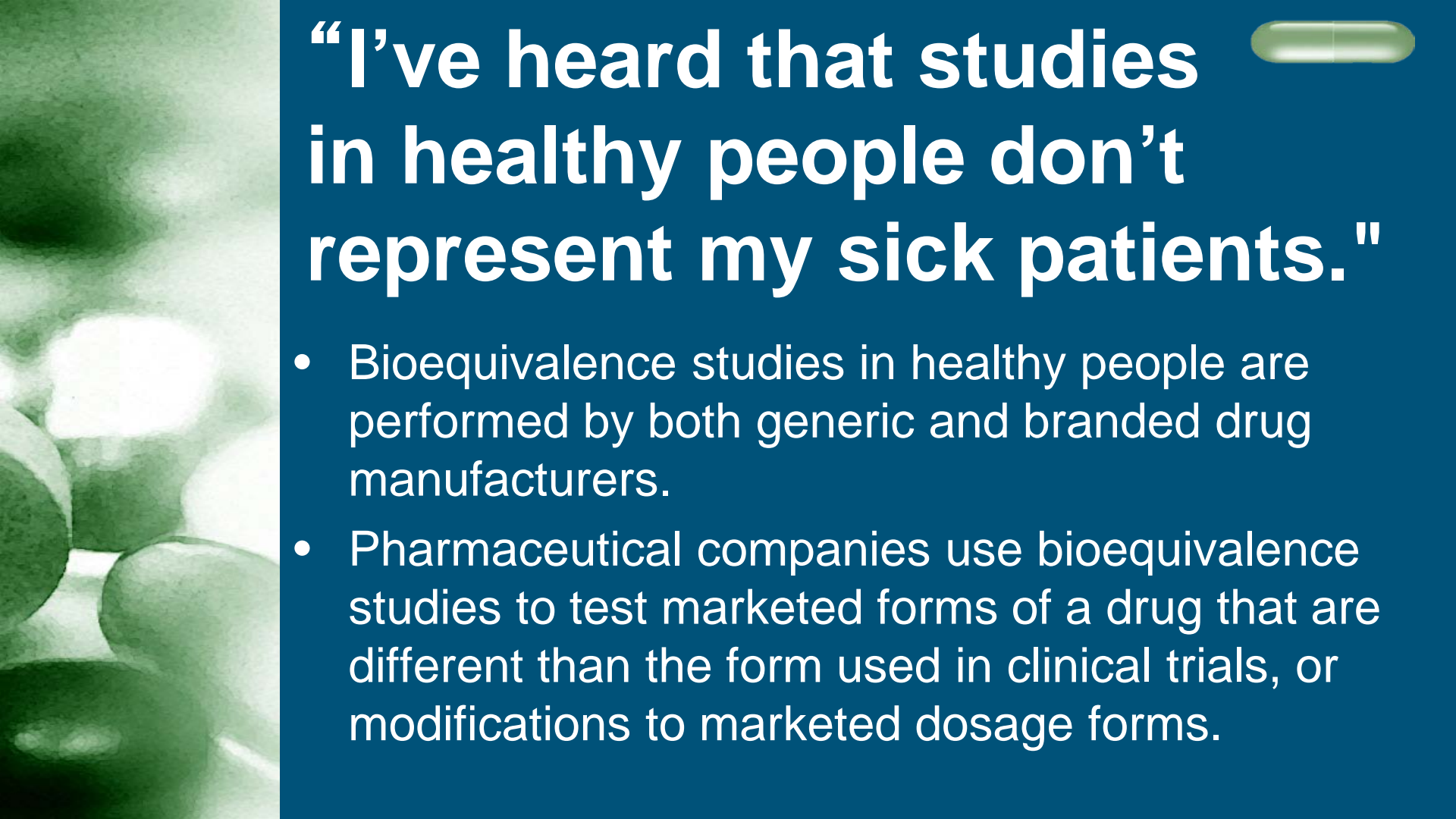
(Davit 2009)

Results of a Systematic Review and Meta-Analysis

Clinical equivalence was noted in

- All 7 RCTs* of β -blockers
 - Ten of 11 RCTs of diuretics
 - Five of 7 RCTs of calcium channel blockers
 - All 3 RCTs of antiplatelet agents
 - Both RCTs of statins
 - One RCT of angiotensin-converting enzyme inhibitors
 - One RCT of α -blockers
- (Kesselheim 2008)

*RCT= Randomized Controlled Trial




“I’ve heard that studies in healthy people don’t represent my sick patients.”

- Bioequivalence studies in healthy people are performed by both generic and branded drug manufacturers.
- Pharmaceutical companies use bioequivalence studies to test marketed forms of a drug that are different than the form used in clinical trials, or modifications to marketed dosage forms.



No evidence to date has shown that two dosage forms that are bioequivalent in normal subjects are not bioequivalent in sick people.



“I’ve heard that inactive ingredients in generics may affect drug levels.”

A generic drug may have different excipients (fillers, binders, coatings, flavoring, coloring) than competing branded (or generic) drugs, but:

- The range of excipients used in pharmaceutical manufacture is small.
- The same excipients are used by many companies.
- A patient may be allergic or intolerant to a specific excipient in a generic – or a branded - drug.



Bioequivalence studies test the final product to be marketed.

If excipients affected drug concentrations, the drug would fail the test for bioequivalence

Narrow Therapeutic Index Drugs



- Narrow therapeutic index drugs are those for which the range between therapeutic and toxic doses is small (i.e. aminoglycosides, digoxin, and phenytoin).
- Critical dose drugs (i.e. warfarin):
 - Require monitoring
 - Have a steep dose-response curve
 - Underdosing or overdosing of critical dose drugs may have serious adverse effects

Narrow Therapeutic Index Drugs



- Narrow therapeutic index drugs must be titrated carefully.
- Different patients may require very different doses (however, the dose required by an individual usually does not vary greatly).



“I’ve heard that generics should be avoided for some drugs”

- Studies show that there is no need to avoid generic substitution in narrow therapeutic index drugs.
- Clinical equivalence was reported in all 5 RCTs (100%) of warfarin.
- Clinical equivalence was reported in one RCT of class 1 antiarrhythmic agents. (Kesselheim 2008)



“I’ve heard that generics should be avoided for antiepileptics.”

A systematic review and meta-analysis of clinical equivalence of anti-seizure drugs found that generic substitution made no difference in seizures.

(Kesselheim 2010)



Drug Problem?

If product failure of any branded or generic drug is suspected, notify the FDA. If possible, include lot number and expiration date, patient drug therapy profile, and the basis for suspecting failure. If possible, keep samples of the drug for testing.

1-800-FDA-1088

<http://www.fda.gov/medwatch>



Advantages of Generic Drugs



Costs of Generic Drugs

- About three-quarters of FDA-approved drugs have generic equivalents.
- Average cost of an Rx for a branded drug \$111.02.
- Average cost of an Rx for a generic drug \$32.23.



Generic Drugs

- Are equivalent to branded drugs
- Are made by reliable manufacturers
 - Brand-name firms manufacture about 50% of generics.
- Save patients money
- Increase adherence
- Are time-tested



Generic Drugs Save Money

- In the U.S., \$250 billion is spent on prescription drugs annually.
- Switching to generics could save 11% in overall drug costs.
- Three-quarters of insured Americans (86% of seniors in Medicare Part D) have tiered pharmacy benefits, so pay more for branded drugs.

(Kohl 2007)



Generic Drugs Improve Adherence

- In a 2005 survey, 25% of insured patients and 51% of uninsured patients said that they or a family member had not filled a prescription, cut pills, or skipped medical treatment because of cost.
Prescription Drug Trends, May 2007 <http://www.kff.org>
- In 3-tiered plans, patients who received generics filled 12.6% more prescriptions in the next year than those who received non-preferred branded drugs.

(Shrank 2006)



The FDA

The FDA's Position



“The American public can be confident that when a generic drug product is approved, it has met the rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency. Through review of data on proposed products, the Office of Generic Drugs assures that generic products will perform the same as their respective brand name reference products.”

Gary J. Buehler
Former Director, FDA Office of Generic Drugs

GDUFA



The Generic Drug User Fee Amendments of 2012 (GDUFA) is a law that requires a fee from drug manufacturers to review applications for generic drugs and inspect facilities.

GDUFA will bring more timeliness to the review of low-cost, high-quality generic drugs and will ensure that foreign and domestic manufacturing facilities are held to a high standard.

PDUFA



Since 1992, prescription drug manufacturers have paid a fee to the FDA as part of the Prescription Drug User Fee Act (PDUFA).

PDUFA has enabled the FDA to expedite its drug approval process for new, branded prescription drugs.

FDA Public Service Ads



You know that question
that goes through your mind
when you take your
generic drug?
Here's the answer.



FDA ensures that your generic drug is safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to rest assured. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

Generic Drugs: Safe. Effective. FDA Approved.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

If you're experiencing anxiety
about taking your
generic drug,
read this ad and repeat as needed.

FDA ensures that your generic drug is safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to rest assured. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

Generic Drugs: Safe. Effective. FDA Approved.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Generic Drugs: Safe. Effective. FDA Approved.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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301-827-1243 or 1-888-INFO-FDA

You know the
questions that go
through your mind
when you take your
**generic
drug?**
Here are the answers.



¿Qué son los
medicamentos
genéricos
y por qué
son importantes
para usted?
Todo lo que
necesita saber
sobre los
medicamentos
genéricos.



What is a generic drug?



When a brand-name drug's patent protection expires, generic versions of the drug can be created and sold. The generic version works like the brand-name drug in dosage, strength, performance and use, and must meet the same quality and safety standards. All generic drugs must be approved by FDA.

How does FDA ensure that my generic drug is as safe and effective as the brand-name drug?

All generic drugs are put through a rigorous, multi-step approval process that includes a review of scientific data on the generic drug's ingredients, performance and effectiveness. FDA also conducts continuous inspections of the manufacturing plant, and monitors drug quality—even after the generic drug has been approved.

If generic drugs and brand-name drugs have the same active ingredients, why do they look different?

The drugs look different because certain inactive ingredients—like colors and flavorings—may be different. These ingredients do not affect the performance of the generic drug in any way, but trademark laws in the U.S. do not allow a generic drug to look exactly like drugs already on the market.

Is my generic drug made by the same company that makes the brand-name drug?

Quite possibly, but not always. Brand-name firms are responsible for manufacturing approximately 50 percent of generic drugs. They frequently make generic versions of their own or other brand-name drugs. There are also other approved companies that produce generic drugs.

Are generic drugs always made in the same kind of facilities as brand-name drugs?

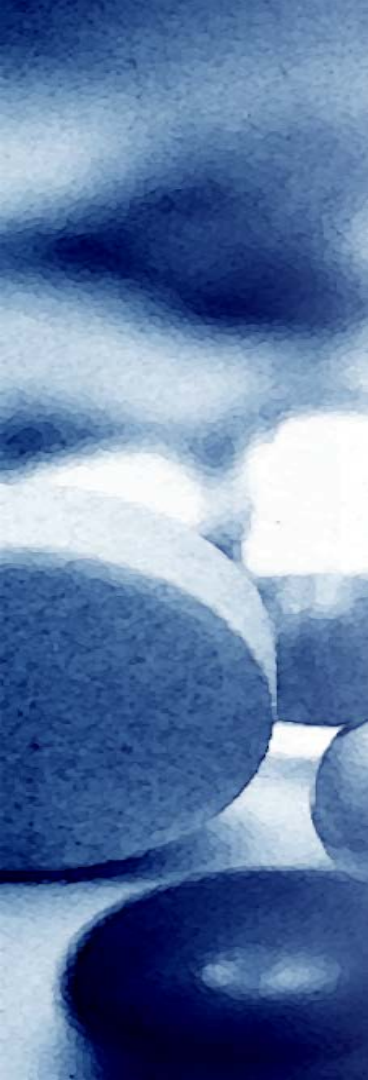
Yes. Both brand-name and generic drug facilities must meet the same standards of good manufacturing practices. FDA will not permit drugs to be made in substandard facilities. FDA conducts about 3,500 inspections a year to ensure standards are met.



FDA makes it tough to become a generic drug in America so you can feel confident about taking your generic drugs. If you still want to learn more, talk with your doctor, pharmacist, medical provider or insurance company. Or call **1-888-INFO-FDA** or visit www.fda.gov/cder today.



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