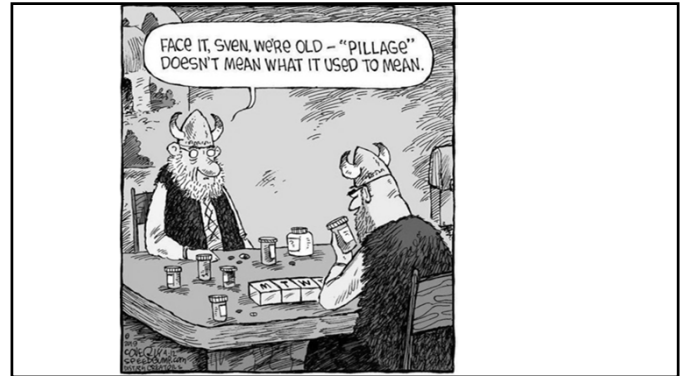


Do You Have Access to High Quality Generic Drugs?

PART II

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SUMMARY of Part I – A Balanced View

- Benefit of well-made generic drugs indisputable.
 - Essential to our health care system, & quality is critical to us all.
 - Save \$millions in expenditures compared to brand-name drugs.
 - Most seem to be well-made.
- Yet their quality is not guaranteed. Things can go wrong. We must **take care** with generics

Taking Care With Generic Drugs

- Takes effort on the part of the patient or caregiver
- Increases the importance of the pharmacist

Practical strategies for using generic drugs safely and effectively

1. Be Vigilant
 - Appearance
 - Response
2. Consult Pharmacist
Consult prescriber before stopping any prescribed medication
3. Avoid switching manufacturer for certain medications and delivery systems (Inhalers)
4. Learn the generic name of your medicines
5. Be aware – use – the “Orange Book”
6. Evaluate the manufacturer

Practical Advice (1)

Be vigilant, skeptical, and proactive . . .

- a. regarding the appearance, odor, etc of generics
- b. regarding your responses if you have changed the source (manufacturer), especially if you can monitor drug effects (BP, blood sugar)

Practical Advice (2)

If you have concerns about a drug product --

- A. Speak to your pharmacist. Pharmacist is obliged to evaluate bioequivalence
- B. Do not discontinue a prescription medicine until you have consulted the prescriber.

Practical Advice (3)

Avoid switching generic manufacturer if you take a NTI drug or one known to have bioequivalence issues (3-letter designations in Orange Book)

Narrow therapeutic index (NTI) Drugs

NTI drugs are drugs where small differences in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions.

- Serious events are those which are persistent, irreversible, disabling, or life-threatening, (L.X. Yu, FDA, 2010)

NTI Drugs(2)

NTI drugs generally have the following characteristics:

- Steep drug dose-response relationship within the usual dose range or
- Narrow span between effective drug concentrations and concentrations associated with serious toxicity

Examples of NTI Drugs

warfarin	digoxin
levothyroxine	lithium carbonate
carbamazepine	phenytoin
theophylline	

NTI Drugs (3)

Patients taking NTI drugs should receive regular therapeutic drug monitoring based on . . .

- clinical response (e.g., blood sugar, blood pressure), and/or
- pharmacokinetic or pharmacodynamic measures to ensure safe and effective use of the drug,

Variable Drug Absorption

- digoxin (Lanoxin), propranolol (Inderal), procainamide (Pronestyl)
- phenytoin (Dilantin)
- Lithium
- amitriptyline, nortriptyline (Aventyl), desipramine (Norpramin), trimipramine (Surmontil)

Variable Drug Absorption (2)

- Diltiazem, (Cardizem)
- Nifedipine (Procardia)
- Theophylline
- Sustained release dosage forms

Practical Advice (3)

Avoid switching manufacturer if you take a drug known to have bioequivalence issues (3-letter designations in Orange Book) or variable drug absorption

Orange Book
https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

Orange Book Bioequivalence AA Codes

AA designates products in conventional dosage forms not presenting bioequivalence problems

- Multisource drug products coded as AA contain active ingredients and are in dosage forms that are not regarded as presenting either actual or potential bioequivalence problems or drug quality or standards issues.

Orange Book Bioequivalence AB Codes

AB designates multisource drug products with identical active ingredient(s), dosage form, route(s) of administration and strength that meet necessary bioequivalence requirements

AB1, AB2, AB3... Three-character codes are assigned when *more than one reference drug* of the same strength has been designated. If a study demonstrates bioequivalence to a reference drug product, the generic product will be given the same three-character code as the reference drug it was compared to.

Orange Book Bioequivalence Codes (2)

"B" CODES Drug products that FDA . . . considers not to be therapeutically equivalent to other pharmaceutical products. These often have a problem with specific dosage forms rather than with the active ingredients.

Practical Advice (4)

To avoid unintentional duplication

- Carry a list of your medications including OTC's
- Learn the generic name of your medications
- Know ingredients of OTC's

Practical Advice (5)

Ask about the Orange Book

If you receive a drug from a new manufacturer, ask your pharmacist/PBM about the Orange Book rating especially if it is NTI or variably absorbed.

Orange Book
https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

Practical Advice (6)

If you have real doubts, evaluate the manufacturer – your pharmacy should be able to help you identify who made the finished product.

Evaluate the Manufacturer

- It can be very hard to track where your drugs come from. Sometimes drugs are repackaged and rebranded along the way. The package need include only one of packager or manufacturer or distributor.
- If contacted, some manufacturers will disclose what country the medication came from and some will not.

Find Manufacturer
 I got lucky with my generic lansoprazole because the capsules were imprinted

**Practical Advice (6) Use the internet to research your generic manufacturers**

My search for NATCO product recall yielded a story about adverse action by FDA against a NATCO plant.

“Natco Pharma . . . [has] received an adverse observation report, known as Form 483, after inspections conducted . . . earlier this year by the US Food and Drug Administration. The letter was issued after the regulatory body found deviations from the standard quality control practices.”

FURTHER
COMMENTS/QUESTIONS?