

# Dr. Lester Sandman

## ABOUT GENERICS

From the Desk of Lester M. Sandman M.D.  
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Your decision to choose between a generic and a brand drug will depend on several factors. The main two considerations are cost & quality.

### COST:

The difference between the full retail price of generic vs. a brand drug can easily run several hundred dollars a month. The actual cost difference to you may be the difference between co-pays or co-insurances which varies a great deal from plan to plan. To be accurate about your out of pocket costs you may need to investigate either directly with your third party payor or through your pharmacy. Don't forget many insurance companies add a cost through denying coverage without "prior authorization", which may require considerable effort by our office & could result in some charges to you.

The retail or wholesale price of a brand drug under patent will generally be set to whatever "the market will bear". When a patent expires, one additional company will make the drug which will drive the price down a little. After six months any company can make the drug and competition will bring the price down further. Drug stores will charge you a price for a generic & will obtain their supply usually from the cheapest wholesale price they can find. (The difference is their profit.) It pays to shop around as generic prices can vary dramatically from pharmacy to pharmacy.

### QUALITY

When a company makes a new branded drug it does studies with its new chemical compound using certain binders and inert substances. These findings are presented to the FDA which then authorizes the company to market the drug for a certain indication, within a certain dose range, and with certain side effects and risks.

(Note that FDA guidelines are a restriction on what a company can advertise, not on what a physician can prescribe. Physicians prescribe drugs "off label" all the time when an available drug is subsequently found to be effective for another condition or found to be useful at doses other than in the studies presented to the FDA)

Brand drugs are manufactured with a name to protect, so there is a high incentive to keep rigorous quality controls in place and plenty of profit to support those controls. A generic manufacturer usually does not have the same incentives as they are trying to sell at a discount with thin margins.

A generic drug must have the same active ingredient as the brand drug. The amount of active ingredient in the generic drug must be within 7% above or below the stated amount. But a generic does not have to use the same binders & inactive ingredients as the brand drug. Inactive ingredients can alter the amount of medication absorbed by the body or the speed of absorption. The FDA requires that there is reasonable certainty (90% "confidence interval") that these "bioavailability factors" are similar to the brand drug. But they allow peak absorption (Cmax) & total absorption (AUC) to vary between 80% & 125% of the brand drug.

Note that these FDA controls allow the possibility that when switching from one generic to another generic (labeled as the same drug with the same strength) the actual absorbed amount could change from 80% to 125%- which is a change of 56%. \* And after the FDA's initial approval of a generic, a company may further change the inactive ingredients without approval.

## BALANCING COST & QUALITY

When a drug is used at a dosage that is far below possible side effects & for a condition that is not very serious, then a generic will be low risk. Even if the bioavailability increases by 50%, the dose is still far away from side effects. And if the dose should drop by 50% & the condition is activated; since it's not a serious condition, it's not a major concern.

However with a severe or life threatening condition, the risk of failing to control the condition (as a result of a generic change with lower bioavailability) may be a substantial risk. It may in that case warrant paying the higher cost of a brand drug.

Likewise when there is a narrow range between the effective dose and a dose that produces side effects, especially if side effects are serious, paying the higher cost of a brand drug again may be warranted.

Ultimately, your decision to choose a brand or generic drug will depend on your individual values & circumstances.

\* Countries with stricter standards than the U.S. includes Australia, Canada, European Union, Japan, & South Africa according to R. L. Horne M.D. (presented at the Las Vegas Psychiatric Society 40th Anniversary Psychopharmacology Conference 2/16/12)