

Dear Parent, Patient, Pharmacist and Insurance Company:

Medical management decisions for my patients are based on many issues and are individually determined based on diagnosis, prognosis, past treatments, medical, family and social histories, examination, patient abilities (ie. ability to swallow pills), patient & parent/guardian preferences, risk-benefit tolerance, pharmacokinetics, pharmacodynamics, risks for side effects (short and long-term), risks of adverse reactions, literature, expert consensus, patient's past experience with treatments, my medical experience and cost issues (which may not be known at time of visit).

Although the FDA considers generic medications "bioequivalent" to brand medications because they share the same active ingredient, efficacy studies for generic medications in patients are not required for FDA approval as are required for brand medications. There are certain clinical situations in which changing from brand to generic medications is not advisable. The risk of seizure recurrence in a seizure-free patient can have serious social, physical and even life-threatening effects. For instance, a seizure-free teen who is legally driving and switched by a pharmacy from a brand AED to a generic AED with a parent's consent but without a detailed discussion by the pharmacy staff regarding risks (as would occur in my office) could result in a serious injurious or even life-ending motor vehicle accident if that patient should have a seizure recurrence while driving.

The decision between brand and generic medications is complex and should be determined in the physician's office, not in the pharmacy or by letter (insurances). After consideration of the many issues listed above, it is the parents'/guardian's and patient's decision to take generic or brand medications.

If the pharmacy staff, pharmacy corporation, insurance company or third-party insurance-pharmacy services' attempts to change a treatment I prescribed based on costs without a detailed discussion of potential risks with patients, then the liability will logically switch from me as physician to one or all of these non-physician parties who would be practicing medicine without a license.

I also will not accept a fax request or telephone call request to change a patient's AED from brand to generic without a written record documenting an appropriate discussion on the risks of such a change.

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