Pressures generated by a constellation of professional, consumer, legislative, and health care provider groups in this era of increasing health care costs have led to enactment of generic substitution laws in 50 states. The general acceptance of this concept, despite conflicting evidence that it has reduced the cost of prescription items to the consumer, has led to the concept of therapeutic substitution. Considerable confusion exists among health care professionals regarding the precise meaning of these concepts.

Generic prescribing is the prescribing of a drug by a physician using the generic name. This leaves the choice of brand to the dispensing pharmacist. Generic substitution is a pharmacist-initiated act by which a different brand or an unbranded drug product is dispensed instead of a drug brand that was prescribed by the physician. This means substituting the same chemical entity in the same dosage form for one marketed by a different company. Therapeutic substitution is a pharmacist-initiated act by which a pharmaceutical or therapeutic alternate for the physician-prescribed drug is dispensed without consulting the physician. This denotes replacement of the prescribed drug with a chemically different drug within the same therapeutic category, eg, hydrochlorothiazide for furosemide; ranitidine for cimetidine; chloramphenicol for erythromycin.

In 1976, the AAP Committee on Drugs published a commentary in Pediatrics (1976;57:275–277) on generic prescribing and concluded that "the lack of data on bioavailability and bioequivalence in children precludes blanket support of generic prescribing for infants and children." The Committee recently reviewed this issue and concluded that the situation has changed little during the past decade. The Committee supports prescribing the least costly drug if therapeutic efficacy and safety are not compromised. This may involve generic prescribing when, based on the physician’s knowledge and experience, the generic choices are considered to be therapeutically equivalent. Because the physician is ultimately responsible for the care of the patient, the choice and/or selection of the drug must be under the physician’s control.

Generic substitution is based on the supposition that therapeutic equivalence, palatability, and equivalent safety/adverse reactions exist among the various brands of a prescribed drug. However, there is little evidence to support the assumption of bioequivalence for most therapeutic agents in infants and children. Therefore, the Committee does not support a blanket recommendation for generic substitution.

The Committee strongly opposes therapeutic substitution. Therapeutic substitution constitutes abrogation by the physician of prescribing prerogatives to the dispensing pharmacist. Therapeutic decisions reached by physicians are based on a complex body of medical information relevant to a specific patient. Therapeutic failure or toxicity may result from substitution of a drug that is chemically different from that prescribed by the physician.

**RECOMMENDATIONS**

1. The Committee on Drugs of the American Academy of Pediatrics supports the concept of prescribing the least costly medication if safety and efficacy are not compromised.
2. Generic prescribing may be appropriate when, in the judgment of the physician, different brands of the same drug will provide equivalent efficacy and safety.
3. The Committee does not support a blanket recommendation for generic substitution.
4. The Committee opposes therapeutic substitution and any legislation that would permit it.

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Generic Prescribing, Generic Substitution, and Therapeutic Substitution

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