



American College of Cardiology

Position Statement

Therapeutic Substitution

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The evaluation of the health needs of a patient involves integration of full knowledge of the individual patient's medical history, physical status and the disease process, and is the province and the responsibility of the physician who has been trained to collect and integrate such data. It follows, therefore, that the choice of specific drug therapy and the necessary evaluation of a patient's response to that treatment must also be the province and the responsibility of the physician. Therefore, the American College of Cardiology and the American Heart Association express vigorous opposition to efforts to permit pharmacists to dispense prescription drugs to patients without the specific prescription of a physician.

Furthermore, recent actions to permit so-called "therapeutic substitution" by pharmacists (i.e., the practice of dispensing an alternate chemical entity from the same therapeutic class for the drug product prescribed by a physician, e.g., procainamide for quinidine) represent a real and present danger to individual patients. For each patient, a specific drug or combination of drugs has been or should be prescribed for a specific problem by the patient's physician. Since the pharmacist does not have available complete clinical information for specific patients and does not possess the medical training on which to base a therapeutic decision, "therapeutic substitution" may result in the patient receiving a drug agent that may lack efficacy, that produces life-threatening toxicity or that interacts adversely with other drugs the patient is receiving. Each of these possibilities is an unacceptable consequence and should not be permitted.

Therefore, the American College of Cardiology and the American Heart Association strongly oppose legislation that would permit prescription "therapeutic substitution" by pharmacists as an action that is not consistent with quality of patient care and may pose an unnecessary risk to the patient's well-being. This statement should not be construed to represent opposition to generic substitution, the act of dispensing a different brand or an unbranded drug product that is the same chemical entity and bioequivalent to the drug product prescribed.

