GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1997

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SENATE BILL 945
Commerce Committee Substitute Adopted 4/22/97

Short Title: Prescription Refill Safety Act. (Public)

Sponsors:

Referred to:

April 17, 1997

A BILL TO BE ENTITLED

AN ACT TO REQUIRE THE PRESCRIBER'S AND THE PATIENT'S CONSENT FOR INTERCHANGE OF A LIMITED CLASS OF DRUGS.

The General Assembly of North Carolina enacts:

Section 1. G.S. 90-85.27 reads as rewritten:

"**§ 90-85.27. Definitions.**

As used in G.S. 90-85.28 through G.S. 90-85.31:

(1) 'Equivalent drug product' means a drug product which has the same established name, active ingredient, strength, quantity, and dosage form, and which is therapeutically equivalent to the drug product identified in the prescription;

(2) 'Established name' has the meaning given in section 502(e)(3) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 352(e)(3);

(3) 'Good manufacturing practice' has the meaning given it in Part 211 of Chapter 1 of Title 21 of the Code of Federal Regulations;

(4) 'Manufacturer' means the actual manufacturer of the finished dosage form of the drug;

(4a) 'Narrow therapeutic index drugs' means those pharmaceuticals having a narrowly defined range between risk and benefit. Such drugs have less

than a twofold difference in the minimum toxic concentration and minimum effective concentration in the blood or are those drug product formulations that exhibit limited or erratic absorption, formulation-dependent bioavailability, and wide intrapatient pharmacokinetic variability that requires blood-level monitoring. Drugs identified as having narrow therapeutic indices shall be designated by the North Carolina Secretary of Human Resources upon the advice of the State Health Director, North Carolina Board of Pharmacy, and North Carolina Medical Board, as narrow therapeutic index drugs and shall be subject to the provisions of G.S. 90-85.28(b1). The North Carolina Board of Pharmacy shall submit the list of narrow therapeutic index drugs to the Codifier of Rules, in a timely fashion for publication in January of each year in the North Carolina Register.

(5) 'Prescriber' means anyone authorized to prescribe drugs pursuant to the laws of this State."

Section 2. G.S. 90-85.28 is amended by adding the following new subsection to read:

"(b1) A prescription for a narrow therapeutic index drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product, and the prescriber and the patient give written consent to the dispensing of the other manufacturer's product. For purposes of this subsection, the term 'refilled' shall include a new prescription written at the expiration of a prescription which continues the patient's therapy on a narrow therapeutic index drug."

Section 3. This act becomes effective July 1, 1997.