SENATE BILL NO. 521

INTRODUCED BY J. ESP

A BILL FOR AN ACT ENTITLED: "AN ACT PROHIBITING THE SUBSTITUTION OF ANTIEPILEPSY DRUGS WITHOUT PHYSICIAN AND PATIENT CONSENT; ~~AND~~ AMENDING SECTIONS 37-7-502 AND 37-7-505, MCA; AND PROVIDING AN EFFECTIVE DATE."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 37-7-502, MCA, is amended to read:

"37-7-502. Definitions. As used in this part, the following definitions apply:

(1) "Antiepileptic drug" means any drug prescribed to treat epilepsy or to treat or prevent seizures.

~~(1)~~(2) "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

~~(2)~~(3) "Bioequivalent" means a chemical equivalent which, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

~~(3)~~(4) "Brand name" means the proprietary or the registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.

~~(4)~~(5) "Chemical equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendium standards.

~~(5)~~(6) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

~~(6)~~(7) "Generic name" means the chemical or established name of a drug product or drug ingredient published in the latest edition of an official compendium recognized by the board.

~~(7)~~(8) "Person" has the same meaning as provided in 37-7-101.

~~(8)~~(9) "Prescriber" means a medical practitioner, as defined in 37-2-101, licensed under the professional laws of the state to administer and prescribe medicine and drugs.

~~(9)~~(10) "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of an official compendium recognized by the board.

~~(10)~~(11) "Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.

~~(11)~~(12) "Therapeutically equivalent" means those chemical equivalents which, when administered in the same dosage regimen, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease and/or toxicity."

Section 2. Section 37-7-505, MCA, is amended to read:

"37-7-505. Product selection permitted -- ~~limitation~~ limitations. (1) Except as limited by ~~subsection~~ ~~(2)~~ subsections (2) and (3) and unless instructed otherwise by the purchaser, the pharmacist who receives a prescription for a specific drug product by brand or proprietary name may select a less expensive drug product with the same generic name, strength, quantity, dose, and dosage form as the prescribed drug that is, in the pharmacist's professional opinion, therapeutically equivalent, bioequivalent, and bioavailable.

(2) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product is medically necessary for that particular patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the brand-name drug product prescribed is medically necessary.

(3) A pharmacist may not, without prior notification and the ~~signed~~ informed consent of both the prescribing physician and the patient or the patient's parent, legal guardian, or spouse, substitute for an antiepileptic drug or formulation of an antiepileptic drug:

(a) a generic version for the prescribed brand;

(b) a brand version for the prescribed generic version;

(c) a generic version by one manufacturer for a generic version by a different manufacturer;

(d) a different formulation of the prescribed antiepileptic drug; or

(e) a different antiepileptic therapeutic drug product for the antiepileptic drug product originally prescribed."

NEW SECTION. **SECTION 3. EFFECTIVE DATE.** [THIS ACT] IS EFFECTIVE JULY 1, 2007.

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