INTRODUCED BY ~~House~~ BILL NO. 225

A BILL FOR AN ACT ENTITLED: "AN ACT DEFINING "DOSAGE FORM" IN THE MONTANA DRUG PRODUCT SELECTION ACT; PROVIDING A POLICY AND PURPOSE STATEMENT; AND AMENDING SECTION 37-7-502, MCA."

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

(3) "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) "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) "Dosage form" means:

(a) the physical form or medium in which a drug product is intended, manufactured, and made available for use, including but not limited to tablets, capsules, oral solutions, aerosols, ointments, injectables, transdermal systems, inhalers, and suppositories; and

(b) the particular form of the drug product that uses a specific technology or mechanism to control, enhance, or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body.

(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 the official United States Pharmacopoeia/National Formulary.

~~(7)~~(8) "Person" means an individual, firm, partnership, association, corporation, or any other entity, whether organized for profit or not.

~~(8)~~(9) "Prescriber" means a practitioner licensed under the professional laws of the state to administer medicine and drugs.

~~(9)~~(10) "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia/National Formulary.

~~(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~~ that, 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~~ or toxicity."

NEW SECTION. **Section 2. Policy and purpose.** (1) The legislature finds that:

(a) with respect to the substitution of prescribed drug products, the safety and welfare of patients necessitate the availability and use only of products that are equivalent in therapeutic effect and toxicity;

(b) drug products are increasingly being developed and prescribed in new and improved forms that employ advanced medical technologies and safeguards to maximize their therapeutic effect and minimize their toxicity; and

(c) products that contain the same active ingredients but that are manufactured in different formulations and that use different technologies may vary in therapeutic effect and toxicity.

(2) It is the policy of the legislature and a principal purpose of this part to ensure that the issues regarding drug performance variability are considered prior to substituting products for patient use.

NEW SECTION. **Section 3. Codification instruction.** [Section 2] is intended to be codified as an integral part of Title 37, chapter 7, part 5, and the provisions of Title 37, chapter 7, part 5, apply to [section 2].

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