SECOND REGULAR SESSION

HOUSE BILL NO. 1524

99TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE NEELY.

4103H.01I D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To amend chapter 338, RSMo, by adding thereto one new section relating to pharmaceutical manufacturers.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 338, RSMo, is amended by adding thereto one new section, to be known as section 338.800, to read as follows:

338.800. 1. As used in this section, the following terms shall mean:

(1) "Biological product", the same meaning described in 42 U.S.C. Section 262;

(2) "Misbranding", the same meaning described in 21 U.S.C. Section 352;

(3) "Off-label use", the use of a Food and Drug Administration (FDA)-approved drug, biological product, or device in a manner other than the use approved by the FDA;

(4) "Truthful promotion", the sharing of information that is not misleading, not contrary to fact, and consistent with generally accepted scientific principles between pharmaceutical manufacturers and licensed health care professionals who can prescribe medication within the provider's scope of practice.

2. Notwithstanding any provision of law to the contrary, a pharmaceutical manufacturer or its representative may engage in the truthful promotion of an off-label use of a drug, biological product, or device.

3. No health care insurer, third-party payor, or other health plan sponsor shall be required to provide coverage for the cost of any off-label use of a drug, biological product, or device as a treatment.

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

4. No official, employee, or agent of this state shall prohibit or prosecute a pharmaceutical manufacturer or its representative for engaging in the truthful promotion of an off-label use of a drug, biological product, or device.

5. No state agency shall revoke, fail to renew, or take any other action against the license of a pharmaceutical manufacturer or its representative, a health care facility, or a physician solely for engaging in the truthful promotion of an off-label use of a drug, biological product, or device.

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