GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2025

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HOUSE BILL DRH30038-NM-21

Short Title:	Pharmaceutical Full Disclosure Act.	(Public)
Sponsors:	Representative Warren.	
Referred to:		

A BILL TO BE ENTITLED

AN ACT TO REQUIRE ADVERTISEMENTS FOR PRESCRIPTION DRUGS TO MORE CLEARLY DISCLOSE RISKS.

The General Assembly of North Carolina enacts:

SECTION 1. Article 12 of Chapter 106 of the General Statutes is amended by adding a new section to read:

"**§ 106-138.1. Unfair or deceptive trade practices.**

(a) A manufacturer must include the following in any regulated advertisement:

(1) The date the prescription drug or biological product received approval from the FDA for the advertised use of the drug or product.

(2) The date the prescription drug or biological product was first available for purchase by consumers in the United States.

(3) For any side effect that must be included in an advertisement for a prescription drug or biological product under section 352(n) or 353(c) of Title 21 of the United States Code, or any federal regulation or rule issued pursuant to Title 21 of the United States Code, the regulated advertisement shall include at least the following details of any clinical trial which evidenced the side effect that is required to be listed:

a. The length of the trial.

b. The number of participants in the trial.

c. The frequency of the listed side effect, expressed by the number of participants experiencing the side effect or a percentage of participants experiencing the side effect.

(b) For the purposes of this section, the following definitions apply:

(1) Biological product. – A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) Clinical trial. – A clinical investigation, as defined by the federal Food and Drug Administration (FDA), that involves any trial to test the efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit from the FDA.

(3) Manufacturer. – A manufacturer of prescription drugs or biological products or an affiliate of the manufacturer or a labeler that receives prescription drugs

or biological products from a manufacturer or wholesaler and repackages those drugs or biological products for later retail sale and that has a labeler code from the FDA under 21 Code of Federal Regulations § 207.17.

(4) Prescription drug. – A drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement: "Caution: Federal law prohibits dispensing without a prescription."

(5) Regulated advertisement. – A presentation made to consumers located in North Carolina of a commercial message regarding a prescription drug or biological product by a manufacturer made through any media, including television, radio, internet, and print advertisements."

SECTION 2. This act is effective when it becomes law and applies to advertisements for a prescription drug or biological product published in this State on or after October 1, 2025.