

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2025

H.B. 75  
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HOUSE PRINCIPAL CLERK

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HOUSE BILL DRH30038-NM-21

Short Title: Pharmaceutical Full Disclosure Act. (Public)

Sponsors: Representative Warren.

Referred to:

1 A BILL TO BE ENTITLED  
2 AN ACT TO REQUIRE ADVERTISEMENTS FOR PRESCRIPTION DRUGS TO MORE  
3 CLEARLY DISCLOSE RISKS.

4 The General Assembly of North Carolina enacts:

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

7 "**§ 106-138.1. Unfair or deceptive trade practices.**

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

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

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

13 (3) For any side effect that must be included in an advertisement for a prescription  
14 drug or biological product under section 352(n) or 353(c) of Title 21 of the  
15 United States Code, or any federal regulation or rule issued pursuant to Title  
16 21 of the United States Code, the regulated advertisement shall include at least  
17 the following details of any clinical trial which evidenced the side effect that  
18 is required to be listed:

19 a. The length of the trial.

20 b. The number of participants in the trial.

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

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

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

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

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



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

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

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

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