

PRODUCTS LIABILITY¹--PRESCRIPTION DRUGS--SELLER'S AND
MANUFACTURER'S DEFENSE OF DELIVERY OF ADEQUATE WARNING OR
INSTRUCTION TO PRESCRIBERS OR DISPENSERS. N.C.G.S. § 99B-5(c).

NOTE WELL: Use this instruction only with causes of
action arising on or after January 1, 1996.

ALSO NOTE WELL: The availability of this defense to a
manufacturer or a seller of prescription drugs is predicated
on two circumstances, both of which must be determined as
matters of law: first, that the drug in question is a
prescription drug;² second, that the United States Food and
Drug Administration does not require direct consumer
warnings or instructions to accompany the prescription
drug.³

The (state number) issue reads:

"Did the defendant provide an adequate warning or
instruction for the (name prescription drug) to the [physician]
[name other legally authorized prescriber or dispenser] who
[prescribed] [dispensed] it for the plaintiff?"

¹"Products liability action" includes any action "brought for or on
account of personal injury, death or property damage caused by or resulting
from the manufacture, construction, design, formulation, development of
standards, preparation, processing, assembly, testing, listing, certifying,
warning, instruction, marketing, selling, advertising, packaging or labeling
of any product." N.C.G.S. § 99B-1(3)(1994). Thus, this defense applies to
all product liability actions, whether they sound in contract or in tort.

²A "prescription drug" is a drug that can be bought only when prescribed
by a person authorized by law.

³Labeling, 21 C.F.R. § 201.100-201.161 (1995).

PRODUCTS LIABILITY--PRESCRIPTION DRUGS--SELLER'S AND
MANUFACTURER'S DEFENSE OF DELIVERY OF ADEQUATE WARNING OR
INSTRUCTION TO PRESCRIBERS OR DISPENSERS. N.C.G.S. § 99B-5(c).
(Continued.)

You will answer this issue only if you have answered the
(*state number*) issue "Yes" in favor of the plaintiff.

On this issue the burden of proof is on the defendant. This means that the defendant must prove, by the greater weight of the evidence, that the defendant provided an adequate warning or instruction for the (*name prescription drug*) to the [physician] [*name other legally authorized prescriber or dispenser*] who [prescribed] [dispensed] it for the plaintiff. (Instructions or warnings are "adequate" if they are sufficient in content to inform foreseeable [prescribers] [dispensers] how to [prescribe] [dispense] the (*name prescription drug*) safely, and if they are communicated so that they are reasonably likely to reach such [prescribers] [dispensers] and be understood by them.)

Finally, as to this issue on which the defendant has the burden of proof, if you find by the greater weight of the evidence that the defendant provided an adequate warning or instruction for the (*name prescription drug*) to the [physician] [*name other legally authorized prescriber or dispenser*] who [prescribed] [dispensed] it for the plaintiff, then it would be your duty to answer this issue "Yes" in favor of the defendant.

If, on the other hand, you fail to so find, then it would be your duty to answer this issue "No" in favor of the plaintiff.