

N.C.P.I.-Civil. 744.13

PRODUCTS LIABILITY - PRESCRIPTION DRUGS-SELLER'S AND
MANUFACTURER'S DEFENSE OF DELIVERY OF ADEQUATE WARNING OR
INSTRUCTION TO PRESCRIBERS OR DISPENSERS.

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N.C. Gen. Stat. § 99B-5(c)

744.13 PRODUCTS LIABILITY¹ - PRESCRIPTION DRUGS - SELLER'S AND
MANUFACTURER'S DEFENSE OF DELIVERY OF ADEQUATE WARNING OR
INSTRUCTION TO PRESCRIBERS OR DISPENSERS.

*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?"

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.

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. Gen. Stat. § 99B-1(3)(1994). Thus, this
defense applies to all product liability actions, whether they sound in contract or in tort.

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

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