A mother purchased over-the-counter pain medication for her daughter, who suffered from headaches. The packaging indicated that the pills were "coated" but did not list the ingredients in the coating. A few days after she bought the medication, because the daughter was in extreme pain, the mother gave the daughter three times the recommended dose of the medication. Thirty minutes later, because the daughter had a very rare allergy to an ingredient in the coating, she had a severe allergic reaction, for which she was hospitalized. The mother was aware of the daughter's allergy, but she did not know that the medication contained the ingredient to which the daughter was allergic.

In a failure-to-warn action brought against the manufacturer of the medication, which of the arguments below would be the LEAST promising as a defense?

A. The daughter's allergy to the ingredient in the coating was very rare.
B. The manufacturer's duty was to warn learned intermediaries, not consumers of the medication.
C. The mother should not have given her daughter a triple dose of the medication.
D. The mother, knowing of her daughter's very rare allergy, should not have purchased the medication without knowing what ingredients were in the coating.

Incorrect

Correct answer B

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Explanation:

Under products liability law, a **commercial supplier** (eg, drug manufacturer) generally is **strictly liable** for harm caused by its **defective product**. A product is defective due to inadequate warnings or instructions or the **manufacturer's failure to warn** when:

the product poses a **foreseeable risk of harm** that is not obvious to an ordinary user *and* **reasonable instructions or warnings** by the manufacturer could have **reduced that risk**.

Under the **learned-intermediary rule**, a ***prescription* drug** or medical device is **not defective** due to inadequate warnings or instructions or the manufacturer's failure to warn the product's user when its **manufacturer warned the prescribing physician** about the risk of harm associated with that product.* When this occurs, the manufacturer will not be held strictly liable because the physician is expected to convey the manufacturer's warning to the user.

Here, the daughter suffered a severe allergic reaction from the pain medication because she had a very rare allergy to an ingredient in the medication's coating. The mother did not know that the medication contained this ingredient because the manufacturer failed to list the ingredients. But the manufacturer cannot argue that its duty was to warn learned intermediaries (not consumers) since the medication was purchased *over-the-counter*—not prescribed by a physician. Therefore, this is the manufacturer's least promising defense in a failure-to-warn action.

*The learned-intermediary rule does not apply (1) when the manufacturer is aware that the drug or device will be dispensed or administered without the personal intervention or evaluation of a healthcare provider (eg, mass vaccine inoculation) or (2) to birth control pills, due to a federal statute.

(Choice A) The fact that the daughter's allergy to the ingredient in the coating was very rare would help the manufacturer show that the medication was not defective because it did not pose a foreseeable risk of harm.

(Choices C & D) The manufacturer can plausibly argue that the mother should not have given her daughter a triple dose of the medication or purchased the medication without knowing its ingredients. Both arguments would help show that the mother's actions were superseding causes that negate the manufacturer's liability.

Educational objective:

The learned-intermediary rule provides a defense in strict products liability actions under a failure-to-warn theory involving *prescription* drugs or medical devices—not *over-the-counter* drugs—if the manufacturer warned the prescribing physician about the risk of harm associated with that product.

References

Restatement (Third) of Torts: Products Liability § 6 (Am. Law Inst. 1998) (explaining strict products liability for commercial sellers of defective prescription drugs or medical devices).