

What Is a Pharmacist's Liability When Selecting Generic Drugs?

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Question:

What are the liability risks for pharmacists when switching brand-name drugs to generics?



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Pharmacists face clinical, economic, and legal challenges in managing medication therapy for patients. One such type of legal challenge arises from drug product selection decisions. Each time a drug product is selected for a patient, legal claims may arise from the laws of negligence, express or implied warranties, and strict product liability.^[1]

We might predict that drug products used to treat epilepsy require particular care in their selection. The literature on use and selection of generic products provides a mixed review, with some studies showing changing blood levels when using a generic product^[2] and others being less clear.^[3] Pharmacists might reasonably wonder about their degree of liability when selecting a particular drug product for a particular patient.

A pharmacist commits negligence in drug product selection when he or she has a duty to select a suitable product, fails to do so, and the patient suffers harm as a result. For medications used to treat seizure disorders, this type of claim could be hard to prove. Even if a patient had a seizure after a particular medication was given, the seizure and the pharmacist's drug product selection may not be related. In other words, it could be a coincidence that the 2 events happened at about the same time; the events are not necessarily causally related.

Warranties arise out of transactions involving the sale of goods and may vary from state to state. Pharmaceuticals are goods. One example of an implied warranty is "fitness for particular purpose": "Where the seller ... has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is ... an implied warranty that the goods shall be fit for such purpose."^[4] In other words, when a pharmacist knows a drug product is being used for a particular purpose, and the patient/buyer is relying on the pharmacist's skill or judgment to select that drug product, the law will impose a warranty that the drug product selected by the pharmacist will be "fit" for that purpose. This does not mean that the pharmacist legally guarantees that the drug will be effective or produce no side effects.

Another implied warranty is "merchantability."^[5] This assures buyers that goods are fit for the ordinary purposes for which such goods are used and that the goods "pass without objection in the trade." In the context of a drug product selection, a product would probably pass merchantability if it contained the amount of active ingredient that it claimed to contain (eg, carbamazepine 100 mg per tablet) and had not been adulterated in some way.

In most instances where the pharmacist is alleged to have done something that harmed a patient, implied warranty claims are probably not of primary importance. This is because the pharmacist is usually accused of making a much more obvious mistake. Most civil lawsuits will allege that the pharmacist dispensed the wrong drug, labeled a container with the wrong directions, dispensed the wrong drug strength, or failed to counsel or warn. These types of mistakes are probably easier to prove, and are more compelling, than whether the tablets of carbamazepine contained 97 mg instead of the 100 mg as claimed on the packaging.

Product liability law is another potential source of protection for patients. However, states offer significant limitations when applying product liability law to drug products. For example, in Ohio, a prescription drug (or device) is not defective in design or formulation because some aspect of it is unavoidably unsafe, provided that the manufacturer of the prescription drug provides "adequate warning and instruction."^[6] Thus, the legal issue is often what constitutes "adequate warning and instruction" for a particular drug product. This can come down to what the manufacturer knew or, in the exercise of reasonable care, should have known about a risk associated with the product.^[7]

Also, product liability law usually does not require warnings against open and obvious dangers, such as "this knife is sharp."^[7] Product liability law applied to prescription drug products usually only requires the manufacturer to disclose "adequate warning and instruction" to the prescriber (physician, practitioner) or dispenser (pharmacist). In other words, there may be no duty for the drug product manufacturer to warn the patient.^[7] By contrast, the pharmacist may have a duty to counsel the patient when a particular generic product is selected.

Consider these practical suggestions for product selection:

- 1. Avoid products with reported manufacturing problems.**

The patient and prescriber often do not know which production lots are being dispensed and which manufacturers may have a history of problems. Most labeling laws require disclosure of the manufacturer of the product dispensed. When a recall is issued, lot numbers of suspected batches are often provided. Pharmacists will have the best access to this information and can lead the way in providing consistency in the medication being supplied.

- 2. Keep the prescriber and patient in the decision-making process.**

In rare situations, such as drug shortages, the patient may face the prospect of receiving less-than-ideal drug product selection choices. When such situations arise, consider informing the patient and prescriber of any known risks and anything likely to arise.

- 3. Try to stick with as few manufacturers as possible.**

Fewer changes in manufacturers would seem to provide fewer variations in the drug product produced. With reductions in reimbursement, it may be tempting to simply always pick the cheapest product, no matter what. Keep in mind that logistical challenges can arise, such as

updating National Drug Code (NDC) numbers in the appropriate databases, and small amounts of intermanufacturer variation may accumulate and affect patient care.

In conclusion, implied warranty claims may arise in instances of drug product selection, though these are rarely thoroughly litigated. Negligence and product liability law may provide consumer protection and require the pharmacist to be diligent in selecting a product and counseling the patient. Such duties and claims may vary from state to state. A few common-sense principles can assist in selecting appropriate drug products.

References

1. Christensen TP, Kirking DM, Ascione FJ, Welage LS, Gaither CA. Drug product selection: legal issues. *J Am Pharm Assoc (Wash)*. 2001;41:868-874. [Abstract](#)
2. Burkhardt RT, Leppik IE, Blesi K, Scott S, Gapany SR, Cloyd JC. Lower phenytoin serum levels in persons switched from brand to generic phenytoin. *Neurology*. 2004;63:1494-1496. [Abstract](#)
3. Talati R, Scholle JM, Phung OP, et al. Efficacy and safety of innovator versus generic drugs in patients with epilepsy: a systematic review. *Pharmacotherapy*. 2012;32:314-322. [Abstract](#)
4. Lawriter. Ohio Revised Code. 1302.28 Implied warranty -- fitness for particular purpose -- UCC 2-315. <http://codes.ohio.gov/orc/1302.28> Accessed April 16, 2012.
5. Lawriter. Ohio Revised Code. 1302.27 Implied warranty -- merchantability -- usage of trade -- UCC 2-314. <http://codes.ohio.gov/orc/1302.27> Accessed April 16, 2012.
6. Lawriter. Ohio Revised Code. 2307.75 Product defective in design or formulation. <http://codes.ohio.gov/orc/2307.75> Accessed April 16, 2012.
7. Lawriter. Ohio Revised Code. 2307.76 Product defective due to inadequate warning or instruction. <http://codes.ohio.gov/orc/2307.76> Accessed April 16, 2012.

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