Use As Directed_1999.pdf

LEGAL CONSIDERATIONS

'Use As Directed'

Although a potent lotion was labeled to be used as directed, neither the physician nor pharmacist instructed the patient how to use it.

Should pharmacists be liable when they fail to warn patients about risks that are well known to be associated with the improper use of the drug when the physician prescribes the drug to be used "as directed"? Is the answer any different when the manufacturer includes specific patient inserts with the product that are intended to be distributed with the drug at the time it is dispensed? These questions were recently addressed by the Oregon Court of Appeals in Griffith v Blatt, Slip Op. No. CA-A93458 (February 3, 1999), 1999 Ore. App. Lexis 160.

Facts

On February 26, 1993, the patient went to her physician seeking treatment for a dermatologic problem. The doctor prescribed two ounces of lindane 1% lotion with instructions to use the product "as directed." She took the prescription to a pharmacist who dispensed and labeled the lotion exactly as prescribed. In addition to the normal pharmacy label, the pharmacist also affixed supplemental labels indicating "shake well" and "for external use only." No other instructions or warnings were provided. The patient applied the lotion over her entire body once a day after her daily shower. This went on for 5 or 6 days until the entire bottle had been used. She did not rinse off the lotion for 24 hours until she took a shower when she reapplied it. Properly used, this drug should be applied no more than twice and washed off within 12 hours after each application. In other words, the patient was exposed to an extreme overdose of the drug.

Within two weeks after first applying the lotion, the patient began to suffer severe medical problems including convulsions, dizziness, weight loss, hair loss, sleep disturbance and cognitive dysfunction. On June 3, 1993, while watching a morning television news show, she saw a story about a child who experienced convulsions after using lindane lotion. She located her empty prescription bottle and realized that she had been using the same medication that she had just seen on the news program. In August 1993, she consulted a different physician, who diagnosed her symptoms to be the result of central nervous system toxicity due to overexposure of the drug.

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Lawsuit

On February 23, 1995, almost two years after the drug was first prescribed, the patient filed a complaint against the prescribing physician and the pharmacist who dispensed the drug. She also named a drug manufacturer as a defendant. It was discovered later that the wrong manufacturer had been named and an amended complaint was filed in July 1995 identifying the correct manufacturer. Her original theory of liability against the pharmacist was negligent failure to warn the patient of how to use the drug correctly and warn her on the risks of overuse. In the amended complaint, she also alleged that the pharmacist should be held strictly liable for distributing a product that is unreasonably dangerous because it was not accompanied with adequate directions to prevent the risks and dangers suffered by the patient. On the motion of the pharmacist, both claims were dismissed. The trial court judge ruled that the strict liability claim was barred under the state's two-year statute of limitations. The negligence claim was dismissed under the notion that as a "learned intermediary" the pharmacist could not be held liable for failing to warn of risks known to the manufacturer.

Appeal

The dismissal of charges against the pharmacist was upheld on appeal, but for somewhat different reasons. It is the difference in reasoning between the two courts that makes this case interesting and instructive. The upper court assumed, for purposes of argument, that the two-year statute of limitations did not apply to bar the strict liability claim. Instead, the judges on this panel reasoned that this claim was properly dismissed because the learned intermediary doctrine prevents product liability claims against healthcare professionals when the manufacturer has provided adequate warning to the professionals. Under this doctrine, the practitioner, after learning about the manufacturer's warnings, makes a determination about which risks and warnings are passed on to the patient.

Put another way, the manufacturer must pass any known risks on to the practitioner. Because this doctrine applies to prescription drugs only available from a physician and pharmacy, the physician and pharmacist act as learned intermediaries between the manufacturer and the patient. Practitioners make independent judgments based on knowledge of the patient and the prescribed drugs as to just how much and what kind of information about known risks should be given to the patient. While the doctrine was originally created to protect physicians from strict liability claims, it has been extended to pharmacists by nearly all courts that have considered the issue. If pharmacists were not afforded this protection, they would, in effect, be held to a higher standard of care than would the prescribing physician. Accordingly, it was proper to dismiss the strict liability count against the pharmacist.

The claim for negligent failure to warn was dismissed on appeal for a different reason, however. The trial court had ruled in the pharmacist's favor by extending the learned intermediary doctrine to cover negligence as well as strict liability allegations. The appeals court noted this erroneous interpretation and held that allegations of negligence should be determined based on whether the defendant violated the applicable standard of care. Using earlier caselaw from that state, this court stated that a pharmacist could certainly be held liable for failing to warn. To be successful on a claim of this type, a plaintiff would have to submit evidence that the standard of care applicable to pharmacists requires warnings to patients about known hazards associated with a particular drug.

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Such evidence would normally be produced in the form of testimony from experts who are familiar with pharmacy practice standards.

In this case, the pharmacist submitted an affidavit indicating that he is familiar with prevailing standards of practice and that all of his actions in dispensing the medication to the patient were reasonable under the circumstances. Unfortunately for the patient, no countervailing expert testimony was offered. Under this condition and absent evidence in support of the patient's claim, the Court of Appeals held that it was proper to dismiss the negligence claim against the pharmacist.

Analysis

The patient lost this case based on what appears to be as much poor legal representation as bad facts or law. The negligence case was dismissed for lack of evidence. The strict liability case was lost because it was not filed timely and, even if it had been, could not overcome the barrier of the learned intermediary doctrine.

The heart of this case is dependent on whether the pharmacist acted reasonably in dispensing lindane lotion with only a "use as directed" label and no additional accompanying directions or warnings against overuse of the product. That question should have been decided in light of the fact that this product is well known to cause toxic reactions when overused. The manufacturer's labeling contains explicit warnings against using the product more than twice in a row and directs that the medication be rinsed off after 12 hours. When the product is distributed to pharmacists, it is accompanied with patient-oriented information that should be given out when the drug is dispensed. None of these facts, however, are even mentioned in the Court of Appeals Opinion. It seems that the patient and her attorney chose not to present this evidence or the testimony of a pharmacist that could have provided the courts with an accurate picture of what would be reasonable advice to a patient purchasing this medication. This is somewhat amazing in light of the Court of Appeals' willingness to hold a pharmacist liable for failure to warn if only the threshold evidence of a breach of a standard of care were to have been presented. It would have been fairly easy to convince the trial court judge, and likely, the jury, that pharmacists do act negligently when they type "as directed" on a label and then do not bother making sure that the patient does know what the directions are. Telling the patient to use the drug "as directed" without directions leaves the patient directionless.

No doubt, the pharmacy defenders would argue that the pharmacist should be able to rely on the prescriber to give the directions needed or desired to the patient. That reliance is, of course, well founded and reasonable. But it should only create a presumption in the minds of pharmacists. The accuracy of the presumption should be verified by making sure that the patient does, indeed, understand how to use the product—as directed. A simple question, "Do you understand how to use this medication?" followed by careful listening to the patient's explanation for accuracy will avoid great potential harm. In this case, the patient's erroneous understanding of how the product should have been used could have easily been corrected and the harm that she suffered could have been avoided.

The lesson of this case is not that a court held in favor of the pharmacist and against the patient. Instead, it should be that pharmacists can and will be held liable for failing to warn when proper evidence is presented. The plaintiff's lawyers are paying attention and will not, in the future, likely make procedural mistakes like the one that occurred here. Pharmacists should pay attention as well to make sure patients have all the necessary and appropriate information to safely optimize the use of their medications. ∎