

LAW & MEDICINE

Learned-Intermediary Doctrine

Question: A patient develops life-threatening angioedema after taking an angiotensin receptor blocker (ARB) prescribed by her doctor for diabetic nephropathy. The Physicians' Desk Reference (PDR) mentions this side effect, but the doctor did not warn the patient because it's uncommon. When promoting the drug, pharmaceutical sales representatives have regularly emphasized its benefits but not the risks. Which of the following is true in a malpractice action?

A. A good defense is to emphasize that the benefits of an ARB in diabetic nephropathy greatly outweigh any potential side effects.

B. The prescribing physician is justified in not informing the patient about the risk of angioedema, in accordance with the customary practice of doctors not to disclose this rare adverse effect.

C. The pharmaceutical manufacturer shares malpractice liability because its drug is "defective."

D. The pharmaceutical manufacturer is liable because its sales reps are supposed to consistently emphasize this serious risk.

E. The learned-intermediary doctrine shields the pharmaceutical manufacturer, placing full liability instead on the prescribing doctor.

Answer: E. Choices A and B are incorrect. Benefits outweighing risks may indeed form the basis for Food and Drug Administration approval of a drug, but this does not constitute a defense against a malpractice lawsuit. And in cases alleging lack of informed consent, the

"professional" standard (what physicians would ordinarily disclose) is no longer the law in some jurisdictions, being replaced by the more onerous "reasonable person" standard (what a reasonable person in the patient's position would want to know, even if it's a rare risk).



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Choices C and D are also incorrect. Drug or device manufacturers can be sued for a "defective" product, a legal term of art used in products liability litigation, but not in malpractice lawsuits. And although pharmaceutical sales representatives have a responsibility to inform doctors of both benefits and risks, a process termed "fair balance," they frequently defer to the drug's package insert, as featured in the PDR, to completely discharge this duty.

Generally speaking, if a doctor fails to warn the patient of a medication risk, and injury results, the patient may have a claim against the doctor but not against the drug manufacturer. This is termed the "learned-intermediary" doctrine, and it is also applicable to medical devices such as dialysis equipment, breast implants, blood products, penile prostheses, and even contact lenses, although the situation is less clear where an optometrist does the prescribing (Products Liability 63A Am. Jur.2d Products Liability §1214, updated Sept. 2008). The justification is that manufacturers can reasonably rely on the treating doctor to warn of adverse effects, which are disclosed to the profession through its sales reps, in the drug's package insert, and in the PDR. The treating doctor, in turn, is expected to use his or her professional judgment to adequately warn the pa-

tient. It is simply not feasible for the manufacturer to directly warn every patient without usurping the doctor-patient relationship.

In a litigated case where a woman developed a hypertensive crisis after being prescribed Deconamine, a sympathomimetic decongestant, the pharmaceutical company successfully relied on the learned-intermediary doctrine for its defense. The plaintiff happened to be taking Nardil, an MAO inhibitor antidepressant, which is a contraindication to the concurrent use of a sympathomimetic agent. She contended that drug manufacturers should directly provide a wallet-sized informational card to all patients taking an MAO inhibitor since the simultaneous consumption of various foods, beverages, and interacting drugs can raise the blood pressure to dangerous levels. The court, however, sided with the defense's position that its legal duty was to inform only the physician and not the patient (*Ferrara v. Berlex Laboratories Inc.*, 732 F. Supp. 552 [E.D. Pa. 1990]).

Occasionally, a court sidesteps the doctrine. When a manufacturer knows that the drug will reach the consumer without the intervention of a physician (e.g., over-the-counter preparations), it must take reasonable action to directly warn the consumer. Another situation is where there has been extensive advertising of a drug to the public. For example, the manufacturer of the oral contraceptive Norplant was successfully sued because the Supreme Court of New Jersey ruled that the company's nationwide direct-to-consumer advertising created a duty to directly warn all patients using its drug (*Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 [N.J. 1999]). Manufacturers may also be liable if they have not dis-

closed all known risks, as alleged in the recent litigation surrounding rofecoxib (Vioxx) and rosiglitazone (Avandia).

The latest development in drug products liability law comes from the landmark case *Wyeth v. Levine* (555 U.S. 2 [2009]), in which a plaintiff lost her arm after the drug Phenergan, given by intravenous push, extravasated into the surrounding tissues and entered an artery, resulting in gangrene. This serious drug risk was known to the company and to the FDA, which had approved a warning statement contained in the drug's package insert, but the lawsuit asserted that the warning was inadequate and should have been modified. A Vermont jury had earlier awarded damages of \$6.7 million. On appeal, the defendant pharmaceutical company maintained that its warning was appropriate because it had been approved by the federal government through the FDA. It further argued that the drug's package insert could not be unilaterally altered or modified without running afoul of federal regulations. However, in a 6-3 decision, the U.S. Supreme Court held that the company was at liberty to issue a more rigorous warning, that FDA approval does not bar lawsuits, and that federal law was not pre-emptive of state law claims involving drug injuries. ■

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Release of Medicare Claims Data Faces Legal Showdown

BY BRUCE JANCIN

SAN FRANCISCO — You won't believe who's seeking access to your Medicare claims data—and what they want to do with it.

A little-known consumer group aiming to force the Health and Human Services department to provide Medicare billing data with physician identifiers recently was rebuffed by a narrow margin in federal appeals court. Meanwhile, another federal court has ruled in favor of a similar Freedom of Information Act request by another organization, setting the stage for a likely legal showdown with major implications for physicians.

"We might actually see this going to the Supreme Court," Dr. Jack S. Resneck Jr. said at the

annual meeting of the American Academy of Dermatology.

A bit of background: Consumers' Checkbook, a small nonprofit group, sued the HHS seeking data on Medicare payments to physicians for the express purpose of reporting on the volume and appropriateness of procedures individual physicians were performing as a guide to quality of care.

In 2007, the group prevailed in U.S. District Court. The American Medical Association then joined the HHS in appealing the verdict, with the American Academy of Dermatology and other medical organizations filing friend-of-the-court briefs on their behalf. AARP was among the groups that did the same for Consumers' Checkbook.

In late January, the U.S. Court

of Appeals for the District of Columbia reversed the lower court decision on a 2-1 vote, awarding victory to the HHS and the AMA.

"This was a big surprise, actually, because arguing for physician privacy interests was seen as a pretty big uphill battle," noted Dr. Resneck, a dermatologist at the University of California, San Francisco, and chair of the AAD Council on Government Affairs, Health Policy and Practice.

Consumers' Checkbook is expected to ask for reconsideration of the decision by the full appeals court.

Meanwhile, a similar Freedom of Information Act-based lawsuit filed by Jennifer Alley, owner of a small company called Real Time Medical Data, had a

very different outcome. A U.S. District Court in Alabama ruled in her favor and ordered the HHS to provide Medicare claims data with physician identifiers for five southern states so Real Time Medical Data could sell it to hospitals, insurance companies, and pharmaceutical companies. The HHS and AMA have appealed. Ms. Alley has asked the 11th U.S. Circuit Court of Appeals in Atlanta to hold the HHS in contempt for not releasing the data.

Legal scholars have framed the core issue in these cases as a conflict between the public's right to know how federal tax dollars are spent as expressed in the Freedom of Information Act vs. physicians' right to privacy, including details of their income and the nature of their medical practices. But using Medicare

billing data to characterize quality of care is likely to create a misleading picture, Dr. Resneck said.

"Volume is just one tiny piece of measuring physician quality. This is a little scary. These folks [at Consumers' Checkbook] have no experience with evidence-based quality measures, no experience with risk adjustment, and have no access through these claims data to outcome measures," he said.

"Medicare is a big payer, but it's just one payer. So if you're going to put out how many knee surgeries someone is doing or how many Mohs surgeries someone is doing and you're just basing it on one payer, depending on somebody's patient mix you could miss the vast majority of what they're doing," Dr. Resneck noted. ■