In the
United States Court of Appeals
For the Seventh Circuit

No. 02-3446

KATHLEEN ZILIAK,

Plaintiff-Appellant,

v.

ASTRAZENECA LP and ASTRAZENECA AB,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Indiana, Evansville Division.
No. 00 C 249—**Richard L. Young**, *Judge.*

ARGUED FEBRUARY 28, 2003—DECIDED MARCH 31, 2003

Before POSNER, MANION, and ROVNER, *Circuit Judges*.

ROVNER, *Circuit Judge*. Kathleen Ziliak suffers from bronchial asthma. To treat her disease, her physician, Dr. Frank Amodio, prescribed Pulmicort Turbuhaler ("Pulmicort"), an inhaled corticosteroid manufactured by AstraZeneca LP.[1] Following clinical studies conducted in 1996 and 1997, AstraZeneca determined that on rare occasions Pulmicort users developed glaucoma, cataracts, and increased intraocular pressure. As a result,

[1] The other appellee, AstraZeneca AB, distributes Pulmicort in the United States; we will refer to the two appellees simply as "AstraZeneca."

AstraZeneca issued package inserts warning that "rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported following the inhaled administration of corticosteriods." Although he was aware of AstraZeneca's warnings and of the risks of using Pulmicort to treat asthma, Dr. Amodio decided to prescribe Pulmicort to Ziliak because, in his view, the benefits of using the drug outweighed the risks. Ziliak began using Pulmicort in January 1998. The following month, she informed to Dr. Amodio that she was "doing great" and had stopped coughing as a result of her asthma. In July, Ziliak saw Dr. Amodio again and reported that she had run out of Pulmicort and that she had started wheezing and having difficulty breathing again. Dr. Amodio decided that Ziliak should continue taking Pulmicort, and gave her a refill for her inhaler. Ziliak did not see Dr. Amodio again.

In November 1998, after a routine eye exam, Ziliak received the unfortunate news that she had developed severe glaucoma, cataracts, and high intraocular pressure. Following this diagnosis, Ziliak brought this products liability action against AstraZeneca in state court, alleging that AstraZeneca had failed to adequately warn of the risks of developing glaucoma, cataracts, and high intraocular pressure after using Pulmicort, and that the lack of adequate warnings rendered Pulmicort a defective or unreasonably dangerous product. Because the parties are diverse (Ziliak is a citizen of Indiana; AstraZeneca AB is incorporated and has its principal place of business in Sweden; AstraZeneca LP is a limited partnership with citizenship in Sweden, Delaware, and New York) and the amount in controversy exceeds $75,000, AstraZeneca removed the action to federal court. It then moved for summary judgment, arguing, among other things, that the firm could not be held liable for Ziliak's injuries under Indiana's "learned intermediary doctrine," and that the warning accompanying Pulmicort was adequate as a matter of law.

After receiving several extensions of time to respond to AstraZeneca's motion for summary judgment, Ziliak filed a response in which she argued that genuine issues of material fact existed concerning whether the warnings were adequate. In support, she tendered an affidavit from her medical expert witness, Dr. Donald Marks. Dr. Marks asserted that he was "aware of case reports and also two small studies of the incidence of glaucoma and cataracts with inhaled steroids, indicating a small, but not what I would try to minimize and dismiss as a rare risk," but opined that the studies were neither adequate in size nor in design to reasonably estimate the risk of developing the adverse side effects. These observations led him to conclude that "the information made available [to a prescribing physician] about the side effects of glaucoma and cataracts related to the use of inhaled corticosteroids was insufficient to warn him adequately of the risk of those side effects." He further concluded that "the information provided to the prescribing physician needs to state that there is a causal relationship between the use of Pulmicort and development of cataracts and glaucoma, that monitoring is necessary for development of these problems, and that cessation of inhaled steroid use needs to be considered, as part of any changing therapeutic regimen."

The district court found that Dr. Marks' testimony was inadequate because he had not sufficiently established his expertise. The court noted that in discussing the "case reports" and "two small studies," Dr. Marks had failed to mention when the reports and studies were made or published, and that he had failed to mention the results of the studies. But instead of rejecting Dr. Marks' testimony outright, the district court gave Ziliak 30 days to submit additional affidavits establishing his qualifications. The order was dated June 5, 2002. Ziliak tendered the supplemental affidavit on July 9. AstraZeneca then objected to Ziliak's submission on timeliness grounds and asked the

district court to rule on its summary judgment motion. The district court rejected Dr. Marks' supplemental affidavit as "clearly late." The court then entered summary judgment in favor of AstraZeneca, concluding that the firm was shielded by Indiana's learned intermediary doctrine, that without Dr. Marks' testimony Ziliak had identified no evidence suggesting that AstraZeneca's warnings were inadequate, and that even if Dr. Marks' testimony was considered, the warning accompanying Pulmicort was consistent with his opinion of what the warning should have said.

Ziliak appeals, contending that the district court abused its discretion in rejecting her evidentiary submission as untimely, that genuine issues of material fact exist concerning whether the warnings accompanying Pulmicort were inadequate, and that the district court misapplied the law. We review *de novo* the district court's order granting summary judgment, viewing the facts and making all reasonable inferences that flow from them in the light most favorable to the non-moving parties. *Nelson v. Sandoz Pharm. Corp.*, 288 F.3d 954, 962 (7th Cir. 2002). Summary judgment is appropriate where the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits, show that there is no genuine issue of material fact for trial and that the moving parties are entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). We review the district court's decision to disregard an affidavit submitted in support of summary judgment for abuse of discretion. *Abioye v. Sundstrand Corp.*, 164 F.3d 364, 368 (7th Cir. 1998).

At the outset, we think it worth noting that a party's failure to comply with summary judgment evidentiary requirements is traditionally remedied not by dismissing the case, but by excluding the non-conforming submission and deeming the opposing party's proposed findings of fact admitted and then determining whether those facts entitle the moving party to judgment as a matter of law. *E.g.*,

Salvadori v. Franklin Sch. Dist., 293 F.3d 989, 992 (7th Cir. 2002); *Hedrich v. Bd. of Regents of Univ. of Wis. Sys.*, 274 F.3d 1174, 1178 (7th Cir. 2001); *Waldridge v. American Hoechst Corp.*, 24 F.3d 918, 922 (7th Cir. 1994). That said, even if we ignore the untimeliness of Ziliak's submission and consider Dr. Marks' testimony, we can discern no genuine issue of material fact for trial.

Under Indiana law, manufacturers are strictly liable to consumers for injuries caused by defective or unreasonably dangerous products placed in the stream of commerce. Ind. Code § 34-20-2-1; *Moss v. Crossman Corp.*, 136 F.3d 1169, 1171 (7th Cir. 1998). Indiana recognizes, however, that some products such as pharmaceuticals are "unavoidably unsafe" in that they are incapable of being made completely safe for their intended or ordinary use. "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 545-46 (Ind. Ct. App. 1979) (quoting Restatement (Second) of Torts § 402A cmt. K (1965)). The duty to provide adequate warnings arises only when the manufacturer knows or should know of a risk posed by the product, and, in cases involving drugs available only by prescription, extends only to the medical profession, not the consumer. *See id.* at 548. Accordingly, AstraZeneca is absolved of strict liability so long as it has imparted adequate warnings to treating physicians. *See Phelps v. Sherwood Medical Indus.*, 836 F.2d 296, 299 (7th Cir. 1987). A warning is adequate if it is reasonable under the circumstances. *Ortho*, 388 N.E.2d at 549.

The warning accompanying Pulmicort stated that "rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported following the inhaled administration of corticosteriods." Dr. Marks opined that, at a minimum, AstraZeneca should have warned that there exists a "causal relationship between use of Pulmicort and

development of cataracts and glaucoma, that monitoring is necessary for development of these problems, and that cessation of inhaled steroid use needs to be considered, as part of any changing therapeutic regimen." We fail to see any inconsistency between what Dr. Marks believes that AstraZeneca should have said and what AstraZeneca actually said. If a pharmaceutical manufacturer warns doctors that specific adverse side effects are associated with the use of a drug, then a causal relationship between use of the drug and development of potential side effects is implicit in the warning, as is the doctor's need to monitor the patient and to consider alternative therapies. Here Ziliak does not dispute that Dr. Amodio was aware of AstraZeneca's warnings, and that he took the risks that Ziliak would develop adverse side effects into account when prescribing Pulmicort. Ziliak therefore has not identified any evidence demonstrating the existence of a triable question of fact whether the warnings accompanying Pulmicort were inadequate.

The judgment of the district court is AFFIRMED.

A true Copy:

Teste:

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Clerk of the United States Court of Appeals for the Seventh Circuit