[Cite as *Kennedy v. Merck & Co., Inc.*, 2003-Ohio-3774.]

IN THE COURT OF APPEALS FOR MONTGOMERY COUNTY, OHIO

JON KENNEDY	:	
Plaintiff-Appellant	:	C.A. CASE NO. 19591
v.	:	T.C. CASE NO. 01-4649
MERCK & CO., INC.	:	(Civil Appeal from Common Pleas Court)
Defendant-Appellee	:	
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O P I N I O N

Rendered on the 3rd day of July, 2003.

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FREDERICK N. YOUNG, J.

{¶1} Plaintiff-Appellant Jon Kennedy is appealing a decision from the Montgomery County Court of Common Pleas granting summary judgment to Defendant-Appellee Merck & Co., Inc., ("Merck") and granting Merck's motion to strike the affidavit

of Plaintiff's expert, Albert J. Patterson, Pharm.D.

{¶2} The facts of this case are not in dispute. This case arises as a result of the September 7, 2000 death of Jon Kennedy's wife, Glynda Kennedy.[1]

{¶3} On August 11, 2000, Glynda's personal physician, Dr. Striebel, diagnosed her with hip arthritis and prescribed VIOXX®, a nonsteroidal anti-inflammatory drug ("NSAID"). NSAIDs relieve pain through inhibition of the synthesis of prostaglandin, which is responsible for the sensation of pain, and by reducing inflammation, swelling, and irritation all of which worsen pain. VIOXX was designed to reduce the gastrointestinal side effects commonly associated with other NSAIDs.

{¶4} At the time that Dr. Striebel prescribed VIOXX, Glynda chose not to have the prescription filled because the cost was not covered by her health insurance. During a follow-up visit on August 28, 2000, Dr. Striebel supplied Glynda with free samples of VIOXX. The samples, which were originally packaged in a larger container, were packaged in blister packs with foil backings. At the time the samples were given to Glynda, Dr. Striebel did not verbally inform her of the possible adverse reactions, nor did he provide her with Merck's product circular that described and warned of the possible adverse reactions. Dr. Striebel instructed Glynda to take two twenty-five milligram tablets of VIOXX per day for the first two days, then one tablet per day thereafter.

{¶5} On September 6, 2000, Jon arrived home from work to find Glynda lying ill on the couch. She declined Jon's invitation to attend mid-week church services. After

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[1] For clarity, we will refer to Jon Kennedy and Glynda Kennedy as "Jon" and "Glynda."

returning home from church, Jon joined Glynda in bed at approximately eleven o'clock. Jon was awakened by an indescribable noise at approximately 12:30 a.m. He could not detect the source of the noise, so again he attempted to sleep. Soon thereafter Jon heard a bang; he ran to the bathroom to discover Glynda lying unconscious on the floor. He immediately called 911. Paramedics arrived and rushed Glynda to Good Samaritan, but they were unable to resuscitate her.

{¶6} After Glynda's death, Jon discovered the unused samples of VIOXX and turned the samples over to the Montgomery County Coroner's Office. Based upon the presence of VIOXX in Glynda's bloodstream, as well as an elevated level of tryptase, the coroner ruled that Glynda's death was caused by an adverse anaphylactoid reaction to VIOXX.

{¶7} Jon, individually and as the administrator of Glynda's estate, filed a complaint against Dr. Striebel and Merck on August 24, 2001, alleging wrongful death, malpractice, and product liability. Jon filed a motion for summary judgment to which Merck filed a cross-motion for summary judgment. The trial court overruled Jon's motion but granted Merck's motion on August 19, 2002. Jon now appeals, asserting two assignments of error.

{¶8} Jon's first assignment of error:

{¶9} "The Trial Court Erred In Granting Summary Judgment Dismissing Mr. Kennedy's Claims Against Merck."

{¶10} Preliminarily, we note that when reviewing a trial court's grant of summary judgment, an appellate court conducts a de novo review. *Grafton v. Ohio Edison Co.*, 77 Ohio St.3d 102, 105, 671 N.E.2d 241, 1996-Ohio-336. "De novo review means that this

court uses the same standard that the trial court should have used, and we examine the evidence to determine whether as a matter of law no genuine issues exist for trial." *Brewer v. Cleveland City Schools Bd. of Edn.* (1997), 122 Ohio App.3d 378, 383, 701 N.E.2d 1023, citing *Dupler v. Mansfield Journal Co.* (1980), 64 Ohio St.2d 116, 119-120, 413 N.E.2d 1187, 18 O.O.3d 354. Thus, the trial court's decision is not granted any deference by the reviewing appellate court. *Brown v. Scioto Cty. Bd. of Commrs.* (1993), 87 Ohio App.3d 704, 711, 622 N.E.2d 1153.

{¶11} Summary judgment can be appropriately granted where (1) "there is no genuine issue as to any material fact; (2) *** the moving party is entitled to judgment as a matter of law; and (3) *** reasonable minds can come to but one conclusion, and that conclusion is adverse to the party against whom the motion for summary judgment is made, who is entitled to have the evidence construed most strongly in his favor." *Harless v. Willis Day Warehousing Co., Inc.* (1978), 54 Ohio St.2d 64, 66, 375 N.E.2d 46, 8 O.O.3d 73; see, also, Civ.R. 56(C). The movant has the burden to prove that no genuine issues of material fact exist by specifically pointing to evidence in the pleadings, depositions, answers to interrogatories, written admissions, affidavits, etc., which show that the non-movant has no evidence to support its claims. *Harless*, supra; *Dresher v. Burt* (1996), 75 Ohio St.3d 280, 293, 622 N.E.2d 264; Civ.R. 56(C).

{¶12} Within this assignment of error, Jon argues that the trial court erred in granting Merck's motion for summary judgment on his failure to warn claim and on his design defect claim. He asserts that both are questions of fact for the jury to determine.

A. Failure to warn claims.

{¶13} Jon claims that material factual questions exist regarding whether the

warnings provided by Merck about VIOXX were inadequate, making the drug defective. Jon asserts that Merck failed to adequately warn Glynda that (a) VIOXX can cause deadly anaphylactoid reactions in some patients, and (b) patients must seek immediate medical attention when they believe such a reaction is occurring. We note that at no time does Jon assert that the warnings provided to Dr. Striebel by Merck were inadequate. Instead, he contends that Merck's warnings were inadequate in their manner and in the way they were conveyed to Glynda.

{¶14} The VIOXX warnings at issue in the circular state, in pertinent part:

{¶15} "As with NSAID's in general, anaphylactoid reactions have occurred in patients without prior exposure to VIOXX. In post-marketing experience, rare cases of anaphylactoid reactions and angiodema have been reported in patients receiving VIOXX. VIOXX should not be given to patients with aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially bronchospasm after taking aspirin or other NSAIDs (see CONTRAINDICATIONS and PRECAUTIONS, Preexisting Asthma). Emergency help should be sought in cases where an anaphylactoid reaction occurs."

{¶16} In *Temple v. Wean United, Inc.* (1977), 50 Ohio St.2d 317, 322, 4 O.O.3d 466, 364 N.E.2d 267, the Ohio Supreme Court adopted the Restatement of the Law 2d, Torts (1965), Section 402A, comment k, regarding strict product liability for "unavoidably dangerous" products, such as prescription drugs. Comment k provides an exception to the strict liability of manufacturers for injuries caused by certain products which are currently "incapable of being made safe for their intended and ordinary use" but nonetheless provide a societal benefit to justify their production and marketing.

{¶17} Although many prescription drugs such as VIOXX are incapable of being made completely safe for their intended use, these drugs are not considered defective or unreasonably dangerous as a matter of law so long as their manufacturer provides proper warnings and instructions to the prescribing physician. See R.C. 2307.75(D) and 2307.76(C); *Seley v. G.D. Searle & Co.* (1981), 67 Ohio St.2d 192, 21 O.O.3d 121, 423 N.E.2d 831, paragraph one of the syllabus. However, a manufacturer may be held strictly liable in tort for injuries caused by a drug where the manufacturer has failed to provide an adequate warning and where it is proven "(1) that the lack of adequate warnings was a proximate cause of the plaintiff's ingestion of the drug, and (2) that ingestion of the drug was a proximate cause of the plaintiff's injury." Id. at paragraph three of the syllabus. Furthermore, to aid a plaintiff in satisfying the first branch of the proximate cause requirement, there exists a rebuttable presumption that the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug. Id. at paragraph four of the syllabus.

{¶18} The Ohio Supreme Court has adopted the learned intermediary doctrine and applied it in product liability actions involving prescription drugs. Id.; *Tracy v. Merrell Dow Pharmaceuticals, Inc.* (1991), 58 Ohio St.3d 147, 569 N.E.2d 875. The doctrine serves as an exception to a manufacturer's duty to warn the ultimate consumer and protects manufacturers from liability where the warning to the prescribing physician is adequate. "The rationale behind these holdings is that the physician stands between the manufacturer and the patient as a learned intermediary. The physician has the duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use." *Tracy*, supra, at 878.

{¶19} However, under R.C. 2307.76(C), a manufacturer is precluded from using the learned intermediary doctrine as a defense if the manufacturer does not comply with FDA regulations requiring a manufacturer to supply warnings directly to the consumer. One such regulation is 21 U.S.C. §352(n), which states:

{¶20} A drug or device shall be deemed to be misbranded "[i]n the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of *** such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary[.]"

{¶21} Another regulation, 21 C.F.R. §202.1(e)(1) states:

{¶22} "True statement of information in brief summary relating to side effects, contraindications, and effectiveness: (1) When required. All advertisements for any prescription drug *** shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section 'side effects, contraindications' include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness."

{¶23} In this instance, Jon contends that the learned intermediary doctrine does not apply, because printed on the backside of the VIOXX sample blister pack provided to Glynda by Dr. Striebel, there is a reference to the circular stating "See accompanying circular," thus Merck intended that the consumer receive the warnings directly. Jon

claims that VIOXX was "misbranded" to consumers in its advertisement on the back of the blister pack under 21 U.S.C. §352(n) and 21 C.F.R. §202.1(e)(1). According to Jon, the FDA requires that complimentary drug sample programs contain such warnings in any written materials given to consumers. Furthermore, because it is the consumer, not the physician, who removes the pill from the back of the blister pack, the wording "See accompanying circular" indicates that it is the consumer who should be given the circular and read the warnings within it.

{¶24} The trial court found that under the regulations, Merck had no requirement of ensuring that the advertisements or printed materials reached consumers, and thus the learned intermediary doctrine would be a valid defense in this instance. The trial court stated,

{¶25} "Construing these facts and R.C. 2307.76(C) in a light most favorable to Mr. Kennedy, reasonable minds could only conclude that Merck discharged its duty to warn Mrs. Kennedy of the possibility of adverse reactions to VIOXX® by warning Dr. Striebel of the risks. As a result, Mr. Kennedy failed to create a genuine issue of material fact that Merck failed to adequately warn Mrs. Kennedy." (Doc. No. 95, p.6.)

{¶26} We disagree with Jon's claim that 21 U.S.C. §352(n) and 21 C.F.R. §202.1(e)(1) were violated in this instance, as they provide regulations for advertisements of prescription drugs. Advertisements subject to Section 352(n) include "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast though media such as radio, television, and telephone communication systems." 21 C.F.R. §202.1(l)(1). In those instances, there is no physician to serve as the "intermediary" for the manufacturer. To the contrary, Merck

provided samples to Dr. Striebel, who provided the samples to Glynda.

{¶27} Moreover, there are only two current recognized exceptions to the learned intermediary doctrine. The first is for mass immunization programs, where vaccines such as polio are administered and where a physician has little or no contact with the patient being immunized. See *Pumphrey v. C.R. Beyond a reasonable doubt, Inc.*, 906 F.Supp. 334 (N.D.W.Va.,1995); *Plummer v. Lederle Laboratories*, 819 F.2d 349 (2d Cir.1987), cert. denied, 484 U.S. 898, 108 S.Ct. 232, 98 L.Ed.2d 191 (1987); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir.1968). The second exception involves contraceptive medications and devices "where the patient is actively involved in the decision and the products are used for extended periods of time without medical assessment." *Pumphrey*, supra, at 337-38, citing *Hill v. Searle Labs*, 884 F.2d 1064 (8th Cir.1989); and *Odgers v. Ortho Pharmaceutical Corp.*, 609 F.Supp. 867 (E.D.Mich.1985).

{¶28} We do not find that either of these narrow exceptions apply here. Absent a recognized exception, we find that Ohio's learned intermediary doctrine controls this case and agree that Merck discharged its responsibility by providing adequate warnings to Dr. Striebel of the possible risks of VIOXX.

{¶29} Jon also claims that it is a question of fact whether Merck's warnings for Glynda were inadequate. Jon points out that during discovery, Merck produced circulars that were designed for health care professionals and circulars that were designed for patients. Because Merck's expert only discussed the circulars designed for health care professionals, and these were the circulars provided to Dr. Striebel with the samples of VIOXX, the manner conveying this warning was "too sophisticated" for

Glynda, and thus inadequate.

{¶30} We disagree. Under the learned intermediary doctrine, there exists no requirement that Merck give any warnings for VIOXX to the consumer if the warnings provided to the physician are adequate.

{¶31} Jon also asserts that the "manner" in which the warning was conveyed was inadequate. Jon contends that a question of fact still exists whether the Merck representative, who had provided Dr. Striebel with samples, violated the standard of reasonable care and was aware of Dr. Striebel's practice of not keeping the VIOXX packaging intact and thus not providing the warning circulars to his patients.

{¶32} Again, we find that the learned intermediary doctrine is an exception to a manufacturer's duty to warn the ultimate consumer, and it protects manufacturers from liability where the warning to the prescribing physician is adequate. See *Tracy*, 58 Ohio St.3d, at 878. Based upon our previous discussion, we find that the learned intermediary doctrine applies in this instance, and thus Merck had no additional duty to ensure that the treating physician, Dr. Striebel, provided the warning to Glynda.

B. Design defect claims.

{¶33} In the last portion of this assignment of error, Jon contends that whether VIOXX is defectively designed is a question of fact for the jury, and thus summary judgment was not appropriate. Specifically, Jon asserts that prescription drugs are not unavoidably unsafe per se, but need to be evaluated on a case-by-case basis. Jon claims that evidence of a design defect in this instance is the Montgomery County Coroner's report indicating that VIOXX, despite prescribed and used for its intended use to treat osteoarthritis, failed to perform in a safe and expected manner.

{¶34} It has been stated that "where a product is deemed unavoidably unsafe, a plaintiff is deprived of the advantage of a strict liability cause of action, but may proceed under a negligence cause of action[.]" *White v. Wyeth Laboratories, Inc.* (1987), Cuyahoga App. Nos. 52108, 52564. However, under R.C. 2307.75 (D), "[a]n ethical drug *** is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug *** provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect."

{¶35} Furthermore, "a product is unavoidably unsafe if, at the time of its distribution, there existed no alternative design which would have as effectively accomplished the same purpose or result with less risk." *White v. Wyeth Laboratories, Inc.* (1988), 40 Ohio St.3d 390, 395.

{¶36} It is undisputed that Merck did provide adequate warning to Dr. Striebel. Thus, under R.C. 2307.75(D), VIOXX cannot be found to be defectively designed. Additionally, as the trial court correctly noted, Jon conceded in his reply to Merck's cross-motion for summary judgment that other NSAIDs pose risks of anaphylactoid reactions. Unfortunately VIOXX posed a greater risk than other NSAIDs to Glynda, but there is no evidence that VIOXX poses any greater risk to the ordinary consumer than other NSAIDs. Based upon these reasons, we find no error in the trial court's granting of summary judgment on this issue.

{¶37} Jon's first assignment of error is overruled.

{¶38} Jon's second assignment of error:

{¶39} "The Trial Court Erred By Striking The Affidavit Of Mr. Kennedy's Expert."

{¶40} Jon asserts that the expert affidavit of Dr. Patterson should be admitted in full to contradict Merck's expert opinion that VIOXX was unavoidably unsafe, and thus overcome the standard for summary judgment. Jon concedes that Dr. Patterson was not on his expert disclosure list, however he relies on Ohio law that does not require rebuttal witnesses to be disclosed. *Phung v. Waste Management, Inc.* (1994), 71 Ohio St.3d 408, 410-411, 644 N.E.2d 286.

{¶41} The trial court acknowledged Jon's interpretation of Ohio law, however struck paragraphs one through thirteen of Dr. Patterson's affidavit because they are matters that should be brought in Jon's case-in-chief. Additionally, the fourteenth paragraph, which would be appropriate for rebuttal, states a "legal conclusion," and not an expert pharmacological conclusion, thus it sustained Merck's motion to strike.

{¶42} A trial court's decision to grant or overrule a motion to strike is within its sound discretion and will not be overturned on appeal absent a showing of abuse of discretion. *Riley v. Langer* (1994), 95 Ohio App.3d 151, 157. An abuse of discretion amounts to more than a mere error in judgment but connotes that the trial court demonstrated an unreasonable, arbitrary, or unconscionable attitude. *Blakemore v. Blakemore* (1983), 5 Ohio St.3d 217, 219, 450 N.E.2d 1140.

{¶43} In this instance, Jon asserted a design defect claim against Merck. Merck had filed a motion for summary judgment on Jon's design defect claim, contending that VIOXX is "unavoidably unsafe" in its design, but no design defect existed because adequate warnings had been made to the prescribing physician. Paragraphs one through thirteen of Dr. Patterson's affidavit describe his affiliation and familiarity with NSAIDs, and briefly explain how NSAIDs work. They state the purpose of VIOXX, how

it works, and the possible reactions from it and other NSAIDs. Paragraph fourteen states Dr. Patterson's opinion that VIOXX is not an "unavoidably unsafe drug," and that it is "no more effective in treating pain, including osteoarthritis pain, than other NSAIDs and pain medications. A patient who has extensively used other NSAIDs and pain relievers without suffering an anaphylactoid reaction is at a lower risk for such an adverse reaction by remaining on these medications than by switching to Vioxx." (Doc. No. 72, p.2.)

{¶44} We find no abuse of discretion in the trial court's decision to strike Dr. Patterson's affidavit. Jon wished to present Dr. Patterson's affidavit to rebut Merck's defense that VIOXX is "unavoidably unsafe," however we agree with the trial court that the evidence contained in paragraphs one through thirteen is evidence that should have been presented through Jon's case-in-chief. They support his theory that there is a design defect, and would have to be presented in his case-in-chief to avoid a directed verdict. Additionally, paragraph fourteen is an unsupported conclusion that VIOXX is not unavoidably safe. With no underlying facts on which to base the opinion that VIOXX is not "unavoidably unsafe," the statement is inadmissible under Evid.R. 705.

{¶45} Accordingly, we overrule Jon's second assignment of error.

{¶46} The judgment of the trial court is affirmed.

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BROGAN, J. and WOLFF, J., concur.

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