IN THE COURT OF APPEALS FOR MONTGOMERY COUNTY, OHIO

JON W. KENNEDY, Individually and as Administrator of the Estate of Glynda Kennedy	:	
Plaintiff-Appellant	:	C.A. Case No. 19777
vs.	:	T.C. Case No. 01-4649
MARK H. STREIBEL, D.O., et al.	:	(Civil Appeal from Common Pleas Court)
Defendants-Appellees	:	

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O P I N I O N

Rendered on the 31st day of December, 2003.

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BROGAN, J.

{¶1} This appeal arises from claims for damages brought against Dr. Mark Striebel and Merck & Co., Inc. (Merck), for the death of Glynda Kennedy (Glynda). At the time of her death, Glynda was the wife of Appellant, Jon Kennedy (Jon). Glynda died in the early morning hours of September 7, 2000, and the coroner attributed her death to an adverse reaction to VIOXX®. VIOXX® is the trade name

for rofecoxib, a nonsteriodal anti-inflammatory drug manufactured by Merck.

{¶2} The complaint alleged that Dr. Striebel had committed medical malpractice by failing to warn Glynda of risks associated with VIOXX®. Subsequently, Jon filed an amended complaint, adding Merck as a defendant, and making product liability claims against Merck, including claims for a manufacturing defect, a design defect, and failure to warn.

{¶3} Prior to trial, Jon filed a motion for summary judgment, asking the court to find that he had established a breach of duty as to Dr. Striebel, and proximate cause as to both Dr. Striebel and Marck. The breach of duty claim was based on the undisputed fact that Dr. Striebel gave Glynda free samples of VIOXX®, but did not give her a Merck product circular that contained various warnings about the drug. After considering the facts and law, the trial court concluded that Dr. Striebel had breached a duty of care to Glynda, and was negligent *per se*.

{¶4} However, the court denied the proximate cause portion of the summary judgment motion, due to the presence of genuine issues of fact. In particular, the court relied on an affidavit from Merck's expert, who stated that there was insufficient evidence to conclude that Glynda's death was due to an adverse reaction to VIOXX®.

{¶5} Subsequently, the court granted Merck's cross-motion for summary judgment. The court first found that Merck had satisfied its duty to warn Glynda of adverse drug reactions by informing Dr. Striebel of risks associated with the drug. The court also found no issues of fact concerning a design defect. Finally, the court

noted that Jon had elected not to pursue the manufacturing defect claim. Following a Civ. R. 54(B) certification, we affirmed the summary judgment in Merck's favor. See *Kennedy v. Merck & Co., Inc*., Montgomery App. No. 19591, 2003-Ohio-3774.

{¶6} In the meantime, the remaining claims were tried to a jury, which unanimously found that Dr. Striebel's failure to provide the manufacturer's information sheets with the VIOXX® samples was not a proximate cause of Glynda's death. As a result, judgment was granted in Dr. Striebel's favor. Jon now appeals, raising as a single assignment of error, that "[t]he trial court erred in denying summary judgment in Jon Kennedy's favor establishing that the heeding presumption applied to his claim as a matter of law."

{¶7} After considering the record and applicable law, we find the assignment of error without merit. Accordingly, the trial court judgment will be affirmed.

I

{¶8} Before addressing the assignment of error, we will briefly outline the background facts of this case. At the time of her death, Glynda Kennedy was 52 years old and had been married to Jon for more than twenty years. Glynda worked at RTA as a bus driver for most of her married life, and suffered from back pain when she drove the buses. During the 1980's, Glynda used over-the-counter medication. She first saw Dr. Striebel in 1991, for complaints of back pain. Multiple approaches were used to treat the pain, including medication, chiropractic treatment, physical therapy, and a TENS unit. However, nothing worked. A specialist thought Glynda had fibromyalgia, which is a condition involving achiness

in the joints. There is no cure for fibromyalgia, but medicines like Elavil are used to help with sleep patterns. If sleep patterns are better, a patient's pain threshold improves. Nonsteriodal anti-inflammatory drugs (NSAIDs) are designed to help with pain and inflammation, and various NSAIDs were also prescribed over the years.

{¶9} Around 1991, RTA transferred Glynda to Project Mobility, which used smaller buses, and allowed Glynda to get on and off the bus, to help clients. This helped her back. In 1998, she returned to Dr. Striebel with complaints of back pain, and he referred her to Dr. Wolfe, a rheumatologist. At that time, Glynda told Dr. Wolfe that her sister had given her Lodine, an anti-inflammatory, which helped. As a result, Dr. Wolfe prescribed Lodine. He also recommended Tylenol PM at night for Glynda's sleep problems. Another anti-inflammatory, Duract, was also used, along with Axid, which helped control the stomach acid that anti-inflammatory drugs can cause.

{¶10} In August, 2000, Glynda was being transferred from Project Mobility back to the larger buses. As a result, she returned again to Dr. Striebel for completion of Family Medical Leave Act (FMLA) papers. The purpose of the FMLA papers was to let Glynda miss work for back problems without being suspended. Glynda also wanted medicine to help with her pain. This time, Dr. Striebel prescribed VIOXX®, because it had less gastrointestinal side effects and would eliminate the need to prescribe a second drug for stomach problems. Although Glynda had been on a number of anti-inflammatory medicines by that time, she had never reported any allergic reactions.

{¶11} During a return visit, Dr. Striebel gave Glenda samples of VIOXX®

because she could not obtain it from her pharmacy, and had to send away for it. Dr. Striebel had received these samples in bulk from Merck, and had separated them into a special bin. Merck also enclosed a circular with the samples, similar to what was contained in the Physician's Desk Reference (PDR). However, Dr. Striebel did not give either Glynda or other patients the circular. At the time, he was unaware that he was required to do so.

{¶12} Although both sides submitted circulars at trial, the actual circular that accompanied the samples was not identified. Jon submitted a circular that was neither identified nor discussed by any witness. However, the defense did not object. This circular (which we referred to in our prior opinion), stated that:

{¶13} "As with NSAIDs in general, anaphylactoid reactions have occurred in patients without known prior exposure to VIOXX. In post-marketing experience, rare cases of anaphylactoid reactions and angioedema have been reported in patients receiving VIOXX. VIOXX should not be given to patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal 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." Plaintiff's Ex. C, p. 2. See, also, *Kennedy*, 2003-Ohio-3774, at ¶15.

{¶14} The circular does not define anaphylactoid reaction. It does discuss various side effects under a section called "Information for Patients." The first paragraph of this section mentions gastrointestinal bleeding, and then says in the

next paragraph that "[p]atients should promptly report signs or symptoms of gastrointestinal ulceration or bleeding, skin rash, unexplained weight gain, or edema to their physicians." After a paragraph on warning signs and symptoms of hepatotoxicity (which is not relevant to this case), the circular states that "[p]atients should be instructed to seek immediate emergency help in the case of an anaphylactoid reaction (see WARNINGS)."

{¶15} At trial, Dr. Striebel submitted an extract from the 2000 PDR, which he identified as being similar to the circular that came with the samples. This extract was also admitted without objection. The information in the extract differed from Jon's submission, by stating that "[a]naphylactoid reactions were not reported in patients receiving VIOXX in clinical trials." According to Dr. Striebel, VIOXX® was a relatively new drug, and no actual cases of anaphylactic reactions had been reported in clinical trials. The 2000 PDR extract went on to say that "[h]owever, as with NSAIDs in general, anaphylactoid reactions may occur in patients without known prior exposure to VIOXX." In all other pertinent respects, the 2000 PDR extract contained the same information as the circular Jon submitted, including the warning to seek emergency help in case of an anaphylactoid reaction. Both circulars were given to the jury.

{¶16} Dr. Striebel gave Glynda the VIOXX® samples during an office visit on August 28, 2000, and did not see her again before her death, which occurred about 10 days later. The record does not reveal exactly when Glynda began taking VIOXX®, nor does it indicate how much of the drug she took before her death. Jon was either out of town or working long hours the five or six days before Glynda's

death; as a result, he did not see her much.

{¶17} Glynda died in the early morning hours of September 7, 2000. On September 6, Jon called Glynda from work and they made plans to attend church together that evening. Apparently, nothing was said during the telephone call about her health. Jon arrived home at around 6:00 or 6:30 p.m., and was running late. When he arrived, Glynda was on the couch, covered up. She said she didn't feel well, and Jon did not ask her what was wrong. At that point in their relationship, if she said she did not feel well, Jon interpreted it to mean that her back hurt. Since Jon was in a hurry, he changed his clothes and left for church.

{¶18} When Jon arrived home that evening, around 9:30 or 10:00 p.m., Glynda was already in bed. He watched television until 11:00 p.m., and went to bed. When he got in bed, Glynda said, "Good night, I love you." Jon did not talk to Glynda further, because he did not want to wake her up.

{¶19} Sometime after midnight, Jon was awakened by a loud or strange noise. He did not hear anything further, and laid back down. He then heard a banging sound and realized Glynda was not in bed. Jon then found Glynda in the bathroom, unconscious. He believed she was dead when he found her. Jon called for emergency help, and Glynda was taken to the hospital, where she was pronounced dead.

{¶20} The coroner did not immediately establish a cause of death, and a deputy came to search the house for anything that could have caused Glynda's death. At that point, Jon found the VIOXX® in a drawer in the kitchen. A few days later, the coroner declared that her death was due to an adverse reaction to

VIOXX®.

{¶21} Jon testified that he did not notice anything out of the ordinary in Glynda before her death. He did not notice any swelling, itching, rash, runny nose, or anything like that. When he saw her on the couch before he left for church, she looked normal. She made no complaint to him about anything odd going on with her physically.

{¶22} The autopsy report showed the presence of some medications, including the compounds in Tylenol PM (diphenhydramine and acetaminophen), digoxin (used for congestive heart failure), and VIOXX®. The report also showed a very high level of tryptase, at 5900 nanograms per milliliter. Tryptase is a marker used to determine the presence of anaphylaxis or anaphylactoid shock.

{¶23} Anaphylactoid reactions typically occur on the first exposure to a substance, while anaphylaxis involves prior sensitization, which produces antibodies. Because the autopsy showed a normal antibody level, the death was not consistent with anaphylaxis. It was more consistent with an anaphylactoid reaction, which involves a high tryptase level and a normal antibody level. In both anaphylaxis and anaphylactoid reactions, a foreign substance stimulates parts of the body called mast cells, and causes the cells to degranulate. Degranulation then releases substances into the blood, including tryptase and histamine. This occurs during what is called the "first-phase" response.

{¶24} If degranulation occurs over a long period of time, it causes "late-phase" responses like swelling of the face, hives on the skin, mucus secretion, recruitment of cells called eosinophils, and swelling of the airway and larynx. These

responses would show up on autopsy as foam in the front of the mouth and nostrils, swelling of other involved tissue, swelling of the upper airway, swelling in the trachea and brochi, pulmonary distention or collapse, pulmonary edema, and accumulation of eosinophils in the lungs and spleen. These findings were not present at autopsy. In particular, eosinophils were absent from the lungs and spleen, where they should have been found.

{¶25} Anaphylactic death can occur from a late-phase response, which causes the airway to swell and choke the individual. It can also occur in the first-phase, with a very massive, sudden release of tryptase, and with direct effects on the heart, such that the heart just stops beating. Because the level of tryptase was very high and there were no "late-phase" responses, the defense pathologist concluded that the death was a very sudden event, without warning symptoms. Another defense expert, a family physician, also concluded that Glynda died from a sudden event that occurred very shortly, or within minutes of death. He also found that there were no clinical signs or symptoms of any serious medical condition that occurred before death. Jon did not submit expert testimony. Instead, he relied on cross-examination of the defense doctors.

{¶26} As we mentioned, histamines are released when the mast cells degranulate, and cause the symptoms, like swelling, hives, etc., of an allergic reaction. Antihistamines work to counter the histamines. An antihistamine (the diphenhydramine or Benadryl contained in the Tylenol PM) was found in Glynda's system after death. However, there was no testimony indicating that Glynda took Tylenol PM because she had allergic reactions – or that allergic reactions occurred

that she would have been aware of before death. To the contrary, Glynda had taken Tylenol PM for a number of years, to help with her sleep.

{¶27} Glynda also received epinephrine from the emergency squad. Epinephrine is a drug that is given to counteract anaphylactic shock. However, there was no indication that it was administered for this purpose. Instead, epinephrine is part of the standard protocol for treating patients who have pulseless electrical activity, i.e., it is used to try to start the heart in emergency medical situations. The emergency squad report indicated that Glynda had pulseless electrical activity.

{¶28} According to the medical experts, if the antihistamine had resolved the symptoms of an allergic reaction, anaphylactic shock would not have occurred. In addition, the epinephrine would not have reversed the massive amount of swelling that is seen with anaphylactic shock. More important, neither medication would have removed the eosinophils from the lungs and spleen. The fact that eosinophil recruitment was not found on microscopic examination indicated that there were no manifestations of the allergic reaction to be seen before death.

{¶29} As we mentioned, Jon moved for summary judgment on the issues of Dr. Striebel's negligence and on the issue of proximate cause. The trial court concluded that Dr. Striebel was negligent *per se* because he had removed the warning circulars from the blister packs of VIOXX®. However, the court denied summary judgment on the proximate cause issue.

{¶30} Concerning proximate cause, Jon argued on summary judgment that he had established the elements of proximate cause against Dr. Striebel and one

prong of proximate cause against Merck (which was also included in the summary judgment motion). Based on *Seley v. G.D. Searle & Co.* (1981), 67 Ohio St.2d 192, Jon contended: (1) that Glynda would not have ingested VIOXX® if Dr. Striebel had given her warnings about the risk of adverse reactions; and (2) that the Montgomery County Coroner's report established a rebuttable presumption that an adverse reaction to VIOXX® caused Glynda's death.

{¶31} Notably, the claim advanced on summary judgment is different from what was presented at trial. Specifically, Jon stipulated at trial that Glynda would have taken the drug even if she had received the warnings about its risks. His argument instead was that Glynda would have called for emergency assistance if she had received the warning circular.

{¶32} *Seley* involved product liability claims against a manufacturer who allegedly failed to warn of risks associated with taking an oral contraceptive, and medical negligence claims against the prescribing doctor. 67 Ohio St.2d at 193-94. When the Ohio Supreme Court considered the products liability claim, it adopted a two-prong approach for analyzing proximate cause. The court noted that causation in failure to warn cases would be divided into these sub-issues:

{¶33} "(1) whether lack of adequate warnings contributed to the plaintiff's ingestion of the drug; and (2) whether ingestion of the drug constitutes a proximate cause of the plaintiff's injury." 67 Ohio St.2d at 200.

{¶34} The court went on to adopt what has been called a "heeding presumption." In this regard, the court noted that:

{¶35} "Comment j to Section 402 A (2 Restatement of Torts 2d 353)

establishes a presumption that an adequate warning, if given, will be read and heeded. In such a situation, the presumption established works to the benefit of the manufacturer. However, where no warning is given, or where an inadequate warning is given, a rebuttable presumption arises, beneficial to the plaintiff, that the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug. This presumption, absent the production of rebutting evidence by the defendant, is sufficient to satisfy the first branch of the plaintiff's proximate cause burden." Id. at 200 (citations omitted).

{¶36} If the presumption were applied on summary judgment to Dr. Striebel, as Jon requested, it would have established the first branch of proximate cause, i.e., it would have established that lack of adequate warnings caused Glynda to ingest VIOXX®. However, the trial court found *Seley* inapplicable because Jon did not allege a claim for product liability against Dr. Striebel.

{¶37} The second branch of proximate cause that the trial court discussed on summary judgment was the connection between VIOXX® and Glynda's death, i.e., whether an adverse reaction to VIOXX® caused her death. The trial court found issues of fact as to both Dr. Striebel and Merck, because Merck's expert indicated, within a reasonable degree of medical certainty, that there was insufficient evidence to conclude that an adverse reaction to VIOXX® caused Glynda's death.

{¶38} As we mentioned, Jon's sole assignment of error is that the trial court erred in denying summary judgment. According to Jon, *Seley's* "heeding presumption" applies in failure to warn cases, even if they are based on negligence,

rather than products liability. Alternatively, Jon contends that the complaint did state all the essential elements of supplier liability under Ohio's products liability act, even if it did not make a specific products liability claim against Dr. Striebel. Without reaching the merits of these issues, we reject the assignment of error.

{¶39} First, and most important, the Ohio Supreme Court has indicated that " 'if a motion for summary judgment is improperly denied the error is not reversible for the result becomes merged in the subsequent trial.' " *Continental Ins. Co. v. Whittington*, 71 Ohio St.3d 150, 157, 1994-Ohio-362 (citation omitted). We have followed this principle. See *Forsyth v. Forsyth* (June 14, 1996), Montgomery App. No. 15487, 1996 WL 325507, *4, and *Natl. City Bank v. Rhoades*, 150 Ohio App.3d 75, 2002-Ohio-6083, at ¶31.

{¶40} In *Whittington,* the Ohio Supreme Court agreed with the following analysis, which assumes (1) that the movant's summary judgment motion was improperly denied; and (2) that the jury verdict in favor of the non-movant is not against the manifest weight of the evidence. Specifically, the court stated that:

{¶41} " 'under these assumptions the evidence must have differed at the time of the motions and at the time of the trial. Obviously, a greater quantity or a better quality of evidence was produced by * * * [the prevailing party] at the trial than on the motions.

{¶42} "An incorrect ruling * * * deprived the moving party of a judgment it should have had. It could not immediately appeal from the orders denying its motions because the orders were not final and appealable. * * * If it cannot appeal after judgment, * * * what remedy does it have? To deny a review seems to be

unjust. But to grant it would necessarily result, under our first assumption, in the finding that the judgment entered upon the verdict should be set aside and that judgment should be awarded upon one of the motions. This would be unjust to the party that was victorious at the trial, which won judgment after the evidence was more completely presented, where cross-examination played its part and where witnesses were seen and appraised.

{¶43} "The greater injustice would be to the party which would be deprived of the jury verdict. Otherwise, a decision based on less evidence would prevail over a verdict reached on more evidence and judgment would be taken away from the victor and given to the loser despite the victor having the greater weight of evidence. This would defeat the fundamental purpose of judicial inquiry.' " 71 Ohio St.3d at 157, quoting from *Home Indemn. Co. v. Reynolds & Co.* (1962), 38 Ill. App.2d 358, 187 N.E.2d 274.

{¶44} The concerns the Ohio Supreme Court expressed are exemplified by the circumstances of the present case. For example, Jon contends that the jury did not need to decide whether Glynda died from an adverse reaction to VIOXX® because the coroner's report and a defense expert both indicated that this was the case. Jon argues, therefore, that the "heeding presumption" sought on summary judgment was critical because the only proximate cause issue before the jury was whether Dr. Striebel's failure to provide the product warning was a proximate cause of Glynda's death. However, we disagree.

{¶45} In the first place, the issues at trial were different from those considered on summary judgment. In addition, the jury verdict was based on far

more detailed testimony.

{¶46} The issue raised on summary judgment was whether Glynda would have taken VIOXX® if she had been warned of risks associated with the drug, such as anaphylaxis or anaphylactoid reaction. Whether the death was due to an adverse reaction to VIOXX® was pertinent to this inquiry, and was the proximate cause issue considered at that time. As we noted, the trial court found genuine issues of fact on that point, due to the testimony of Merck's expert.

{¶47} In contrast, the issue at trial was whether Glynda would have sought emergency help if she had been given a product circular. The defense position, expressed through the testimony of all the medical experts, was that Glynda did not have an opportunity to seek emergency help, due to the lack of warning signs and the sudden nature of her death. From this standpoint, what caused the reaction was not completely irrelevant. However, the critical proximate cause issues were whether Glynda had the symptoms of an allergic reaction, and if so, whether she would have had an opportunity to seek medical assistance.

{¶48} Furthermore, there were, in fact, factual issues at trial concerning whether the death was caused by an adverse reaction to VIOXX®. For example, Dr. Striebel testified that he did not believe Glynda's death was caused by an adverse reaction to VIOXX®. Likewise, Dr. Sickles, a family physician, testified that the cause of death was an issue of some debate. Dr. Sickles agreed that there was evidence of some sort of allergic reaction, but he did not connect the reaction to VIOXX®. Indeed, the experts indicated that anaphylactic reactions can be caused by many substances, including food, insect stings, and medications.

{¶49} Dr. Balko, a pathologist, testified that the cause of death was not really determinable. Dr. Balko did say that "a lot of smoke" existed for evidence of an anaphylactoid reaction, because of the high tryptase level and low antibody levels. However, the gross anatomic correlates were missing. Dr. Balko indicated that while these omissions did not rule out an anaphylactoid reaction, they did mean that the reaction was very acute. On cross-examination, Dr. Balko agreed that Glynda died of an adverse reaction to VIOXX®. However, he also said that even if the cause of death was an anaphylactoid reaction, it occurred suddenly. According to Dr. Balko, Glynda's death was sudden, unexpected, and without warning symptoms.

{¶50} Again, these were not issues addressed in the motion for summary judgment, and a summary judgment in favor of Jon would have been based on less evidence than was given to the jury. Accordingly, the denial of summary judgment was merged in the subsequent jury verdict in favor of Dr. Striebel, and Jon may not base error on the trial court's failure to grant summary judgment.

{¶51} In arguing that we may review denial of summary judgment following an adverse jury verdict, Jon relies on *Balson v. Dodd* (1980), 62 Ohio St.2d 287.

{¶52} In *Whittington*, the Ohio Supreme Court recognized that its decision might impact *Balson*, which had allowed review of a denial of summary judgment in a subsequent appeal. See *Whittington*, 71 Ohio St.3d at 158. However, the court distinguished *Balson* because it failed to address whether the harmless error doctrine applies to decisions denying summary judgment motions. Id. The court also remarked that the denial of summary judgment in *Balson* could not have been

harmless, because it was predicated on a pure question of law. Id.

{¶53} After *Whittington*, some courts have applied the "pure question of law" distinction as a rationale for considering error based on denial of summary judgment. See, *e.g.*, *First Capital Corp. v. G & J Industries, Inc.* (1999), 131 Ohio App.3d 106, 111 (holding that *Whittington* was inapplicable because issues involving a contract raised "pure questions of law").

{¶54} On appeal, Jon does not specifically claim that the question of the "heeding presumption" is one of pure law. However, even if we assume that the issue is purely legal, and that error occurred, there is no relevant connection between the error and the verdict. As we noted, the summary judgment motion was based on Dr. Striebel's failure to warn Glynda of risks associated with taking VIOXX®. Because Jon elected not to pursue that theory at trial, there is no basis, other than speculation, for concluding that the jury verdict was impacted by the denial of summary judgment.

{¶55} Furthermore, even if this problem could be overcome, Jon waived any error because he failed to amend the complaint to raise claims of supplier liability. Jon also failed to raise the issue of a "heeding presumption" at trial, and did not request any jury instructions on supplier liability or the heeding presumption. Failure to object at trial waives all but plain error, which is used only in " 'exceptional circumstances where error, to which no objection was made at the trial court, seriously affects the basic fairness, integrity, or public reputation of the judicial process, thereby challenging the legitimacy of the underlying judicial process itself.' "(citation omitted). See, *e.g.*, *Weiner v. Kwait,* Montgomery App. No. 19289, 2003-

Ohio-3409, at ¶96.

{¶56} Having reviewed the trial transcript in its entirety, we find no such evidence of error affecting the fairness or integrity of the judicial process. To the contrary, there appears to be overwhelming evidence that even if Glynda had received warnings to seek emergency help, her death was not proximately caused by the lack of warnings. Instead, her death was proximately caused by a sudden event that occurred unexpectedly, without warning symptoms. Accordingly, the single assignment of error is overruled, and the judgment of the trial court is affirmed.

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FAIN, P.J., and WOLFF, J., concur.

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