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# Commonwealth of Kentucky

# Court of Appeals

NO. 2018-CA-1762-MR

KARIN J. STIENS — APPELLANT

v.

APPEAL FROM FAYETTE CIRCUIT COURT
HONORABLE PAMELA R. GOODWINE, JUDGE
ACTION NO. 14-CI-02829

BAUSCH & LOMB INCORPORATED — APPELLEE

OPINION
AFFIRMING

** ** ** ** **

BEFORE: DIXON, JONES, AND MAZE, JUDGES.

JONES, JUDGE: Appellant, Karin Stiens ("Stiens"), initiated the underlying action in Fayette Circuit Court against Bausch & Lomb Incorporated ("B & L"), Insite Vision, Inc., and Commonwealth Eye Surgery on a variety of products liability claims. After extensive motion practice and a multitude of discovery issues, on July 30, 2018, the Fayette Circuit Court entered an order granting

summary judgment to B & L on Stiens's last remaining claim, which was based in negligence.

On appeal, Stiens argues the circuit court erroneously concluded that she could not present *prima facie* evidence of foreseeability. According to Stiens, B & L should have foreseen that an injury could result from the "off-label" and untested use of a pharmaceutical product, and so B & L should have warned of unknown risks and tested the product for its marketed purpose. B & L counters that it had no duty to prevent unforeseen risks caused by its product under negligence law and that Stiens failed to present evidence suggesting that B & L knew or should have known there were risks associated with that particular use of its product. Following review of the record and applicable law, we AFFIRM the Fayette Circuit Court's order in favor of B & L for reasons more fully explained below.

## I. FACTUAL AND PROCEDURAL BACKGROUND

In 2011, B & L began marketing a new drug, Besivance, for ophthalmological use. Besivance is a topical antibiotic comprised of besifloxacin, a fluoroquinolone antibiotic, and DuraSite, a viscous adhesive compound designed to increase the effectiveness of the antibacterial properties by prolonging eye surface contact. Besivance is proven to prevent a wide range of bacterial infections of the eye, including methicillin-resistant Staphylococcus aureus

("MRSA"). Besivance was approved to treat bacterial conjunctivitis ("pink eye") and has not been approved for surgical purposes.

On January 19, 2012, Dr. Lance S. Ferguson of Commonwealth Eye Surgery in Lexington, Kentucky, used Besivance as Stiens's prophylactic and post-operative antibiotic following her photorefractive keratectomy procedure ("PRK") for nearsightedness. Following her surgery, Stiens suffered irreparable damage to her left eye, impairing her vision.

PRK is a type of refractive eye surgery performed to permanently improve eyesight without the use of glasses or contact lenses. An alternative to the more common LASIK surgery, PRK is available for patients with thinner corneas than is safe for LASIK surgery. The procedure requires an ophthalmologist to remove the outer layer of the cornea and reshape the stroma layer of the cornea beneath with a laser. In a successful PRK, the subsequent epithelial regeneration results in permanent correction of the patient's vision. Ophthalmologists often use a bandage contact lens to protect the eye during the healing process.

Ophthalmologists like Dr. Ferguson use various antibiotics as post-procedural prophylactics to prevent ensuing infections following PRK and other refractive surgeries. However, no fluoroquinolone, including Besivance, is approved for use as a prophylactic by the Federal Food, Drug, and Cosmetic Act ("FDCA"). Food and Drug Administration ("FDA") approval is use specific, and

the labeling that accompanies the product must accurately reflect its approved use. Use for any purpose other than what is approved by the FDCA is "off-label." Under the FDCA, drug manufacturers are only permitted to market their products for on-label usage. It is unlawful for a manufacturer to introduce a drug into interstate commerce with the intent that it be used for an off-label purpose. 21 United States Code ("U.S.C.") § 331(a) & § 352.

While federal regulations bar drug manufacturers from marketing their products for off-label uses, the off-label use of a drug is not similarly restricted. In fact, doctors are permitted and even encouraged to use medications off-label in patient care. The evidence is in agreement that in refractive eye surgeries, off-label use of antibiotics for infection prevention is the standard of care.

The FDA approved Besivance for use in pink eye prevention in 2009. However, it was not until the summer of 2011 that B & L, through its representative Julie Lawrence ("Lawrence"), began calling on ophthalmologists throughout Kentucky and the greater Cincinnati area to promote Besivance, targeting those ophthalmological practices reported to use fluoroquinolones regularly. Commonwealth Eye Surgery was one such practice. Lawrence first contacted the practice in July of 2011. While Commonwealth Eye Surgery used fluoroquinolones, its practice was limited to surgeries. It did not provide routine

eye care, such as the treatment of pink eye, to its patients, a fact that was made known to Lawrence through her discussions with the practice. In short, Lawrence knew or should have known that any need Commonwealth Eye Surgery would have for Besivance would be in using it off-label for infection prevention following surgery. At the time Lawrence first sought out Commonwealth Eye Surgery, its physicians were fairly satisfied with their current fluoroquinolone; they were not actively investigating any potential new drugs.

On July 20, 2011, Lawrence met with two of Commonwealth's surgeons, Dr. R. Marty Smith and Dr. Howell M. Findley, regarding Besivance. She provided them with information about Besivance and its benefits, including its superior coverage for patients and its higher rates of infection prevention. Lawrence noted that Besivance had better coverage against MRSA than any other fluoroquinolone. During this meeting, Drs. Smith and Findley informed Lawrence that they were considering using Besivance in their surgical practice and discussed with her whether it could be used in LASIK, PRK, and cataract surgery. Lawrence also gave the doctors samples of Besivance and coupons for patients' use. At this time, there were no published clinical trials or articles regarding the use of Besivance in any kind of refractive surgery.[1]

[1] In 2010, Dr. Nick Mamalis, Stiens's expert witness, published a study concerning the toxicity of Besivance in the eye, which referenced a prior Canadian study concluding that topical ointment applied after cataract surgery could enter the anterior chamber of the eye and cause

According to office staff, the entire practice switched from using another fluoroquinolone to Besivance that fall. Dr. Ferguson testified he, Dr. Smith, and Dr. Findley jointly decided to use Besivance. The decision was motivated by the increased coverage against MRSA and the decreased cost to patients. Even without discounts or coupons, Besivance would cost 25% less than any other fluoroquinolone. On September 26, 2011, a Commonwealth office manager emailed Lawrence to inform her that they had decided to prescribe Besivance for LASIK surgeries and requested information regarding dosages. By that time, the office had already begun using Besivance for cataract surgeries. Patient records show that the practice prescribed Besivance in connection with PRK surgeries as early as October 13, 2011.

Dr. Findley encouraged his partner, Dr. Ferguson, who specializes in cataract and refractive eye surgeries, including PRK, to consider using Besivance as he believed it to be the "latest, greatest" drug on the market. Dr. Ferguson interacted with Lawrence on his own on two separate occasions. The first was a brief greeting while Lawrence was dropping off coupons for patient use. The second was an extended visit. Dr. Ferguson and B & L dispute who approached

toxic anterior segment syndrome. Another 2009 article quoted Dr. Randall Olson, Dr. Mamalis's mentor, who warned against the potential toxicity of Besivance in clear corneal surgery if allowed to leak into the anterior chamber of the eye. Dr. Mamalis later testified that his articles were "not germane" to PRK. The circuit court ruled these articles inadmissible.

whom about arranging the second visit. At one point in his testimony, Dr. Ferguson stated that Lawrence first approached him in the fall of 2011 about using Besivance in his surgeries. However, in an earlier deposition,[2] Dr. Ferguson testified that Commonwealth's office manager reached out to Lawrence about Besivance. In any event, it was eventually agreed that Lawrence would meet with Dr. Ferguson, and as part of the meeting would observe one of Dr. Ferguson's surgeries.

On November 1, 2011, Lawrence watched Dr. Ferguson perform both cataract and PRK surgeries. During the PRK surgery, Dr. Ferguson used Besivance. The two then had lunch together during which time they discussed Ferguson using Besivance in refractive surgeries, although they dispute who initiated this particular part of the conversation. When asked by Dr. Ferguson about the efficacy of Besivance in refractive surgeries, Lawrence told him that Besivance could be used in an equivalent fashion as other antibiotics in refractive surgeries, including PRK. Lawrence compared Besivance to other fluoroquinolones, saying that it was more resistant against MRSA and that it was used by other practitioners in the area. Lawrence additionally talked about the

[2] Dr. Ferguson gave an earlier deposition in a different case regarding the same subject matter, which he has adopted for the present case.

benefits of using Besivance in PRK surgeries with Dr. Ferguson, promoting it as a cheaper and safer antibiotic than the other antibiotics ophthalmologists used.

Dr. Ferguson also asked whether other practitioners used Besivance in refractive surgeries, and Lawrence responded, "They say yes." Dr. Ferguson testified that Lawrence added that not only do other doctors use it, but that B & L had a paper coming out on Besivance demonstrating its safety and efficacy in refractive surgery. Lawrence denies making any statement about an upcoming study.

Under B & L company policy as well as the FDCA, Lawrence was permitted only to promote Besivance for its on-label purpose and truthfully answer questions regarding off-label use. Lawrence testified that she did not directly promote Besivance for use in eye surgery, although she was aware when she promoted the drug that it would likely be used by the surgeons at Commonwealth Eye Surgery for off-label uses. Dr. Ferguson was also aware that Besivance was only approved for use in treating pink eye and that his use would be off-label. In earlier testimony, Dr. Ferguson admits to asking Lawrence about Besivance as a prophylactic in refractive surgeries, although his later testimony was that Lawrence initiated this particular portion of their conversation about Besivance.

Ultimately, Dr. Ferguson decided to begin using Besivance in all his refractive surgeries. He testified that in making this decision, he relied upon his

training, education, and experience as an ophthalmologist as well as Lawrence's assurances about the safety and efficacy of Besivance in refractive surgeries. Dr. Ferguson formed his decision upon the literature and informational pamphlets provided by B & L, coverage comparisons with other fluoroquinolones, and discussions with his practice associates. He also reached out to other ophthalmologists in the surrounding area about their experience using Besivance in their own practices. Dr. Ferguson then conducted his own research on Besivance and read "extensively," reviewing the available medical literature.

Regarding Lawrence's role in his decision, Dr. Ferguson testified that her assurances about Besivance's safety and efficacy were a factor in his decision and that he relied upon them "very much." However, Dr. Ferguson additionally stated that no pharmaceutical representative, no matter how knowledgeable, could persuade him to use a drug against his better judgment.

Neither Lawrence nor the available medical literature warned that Besivance had not been tested for use in refractive surgeries or suggested that there may be risks associated with such use. During his research, Dr. Ferguson failed to find the article to which Lawrence referred on her November 1, 2011 visit.[3] In

[3] Discovery did not conclusively establish which paper Lawrence referenced in her conversation with Dr. Ferguson. B & L did publish an animal study in April of 2012 regarding the safety and efficacy of Besivance in refractive surgeries such as LASIK and PRK, although the drug was not applied directly to the stroma bed or covered with a bandage contact lens. At one point, Stiens contended that Lawrence actually referred to a paper published in 2010 concerning the toxicity

fact, Dr. Ferguson found no medical literature that either supported or warned against his intended use for Besivance.

On January 19, 2012, Dr. Ferguson used Besivance in a PRK on Stiens's left eye. Following her January PRK surgery, Stiens experienced delayed healing. Stiens's vision never improved and, in fact, greatly declined. She eventually underwent a subsequent corneal transplant in December of 2014. The second surgery was also unsuccessful, leaving Stiens with extremely blurred vision in her left eye.

Dr. Ferguson was the first medical professional to openly express any concerns about the negative effects of Besivance if used for infection control post-surgery. After a number of his PRK patients experienced delayed healing, including Stiens, Dr. Ferguson deduced that Besivance was the cause of the delay and Stiens's damaged vision. Dr. Ferguson then discussed his suspicions with colleagues at a medical conference. He later wrote a letter expressing his concerns to several ophthalmology journals, which was ultimately published in *Review of Ophthalmology*.

B & L ophthalmologists responded to the letter with surprise, stating that "no cases of delayed re-epithelialization after PRK have been reported to the

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of Besivance during cataract surgery. Regardless, neither party was able to demonstrate to which paper, if either, Lawrence allegedly referred.

company" even though Besivance had been applied to "thousands of eyes with large epithelial defects and bandage contact lenses." They suggested that there was a "yet unidentified cause" for the healing delays but admitted that Dr. Ferguson's report required further investigation. However, Dr. Ferguson and Stiens's expert witness have since testified that the DuraSite component of Besivance was the most likely cause of Stiens's delayed healing and injury. For the purposes of summary judgment, B & L has not contested that Besivance caused Stiens's eye injury.

It was not until February 2013 that the American Society of Cataract and Refractive Surgery issued an alert jointly with a peer-reviewed study that certain topical medications, Besivance in particular, should not be used intraoperatively during LASIK and PRK due to the adverse effects of its adhesive component.

On July 24, 2014, Stiens filed her complaint against B & L, Insite Vision, the manufacturer of DuraSite, and Commonwealth Eye Surgery in Fayette Circuit Court. She asserted claims of negligent testing, marketing, and distribution, strict liability, and express and implied warranty claims against B & L. Insite and B & L filed a joint motion for summary judgment on April 2, 2018. Stiens opposed the motion. The circuit court granted the motion for Insite on the grounds of personal jurisdiction. On May 7, 2018, the circuit court also dismissed

Stiens's claims of strict liability and breach of warranty but denied summary judgment for B & L on the negligence claim.

The circuit court denied summary judgment on the negligence claim based on two factual disputes regarding the issue of foreseeability. First, the circuit court stated that several scientific articles published in 2010 warning against the injection of Besivance into the eye during refractive surgery could suggest that B & L knew or should have known of the risks associated with using Besivance in PRK at the time of Stiens's surgery. Second, the court held that Lawrence's November 1st statements could be seen by a jury to be a substantial factor in Dr. Ferguson's decision to use Besivance in Stiens's PRK.

On May 31, 2018, B & L moved *in limine* to exclude evidence concerning any alleged "off-label promotion" under the FDCA. The circuit court found that because Stiens chose to forego pursuing a claim under the FDCA, she could not be permitted to allege that B & L engaged in off-label promotion in violation of the FDCA. Therefore, all testimony regarding off-label promotion was excluded.[4]

B & L also moved to exclude three articles about the use of Besivance in PRK and related testimony. The circuit court excluded the articles and all

[4] While the FDCA prohibits off-label promotion and imposes fines and civil liability for doing so, there is no corresponding state-law prohibition against off-label marketing.

related testimony as irrelevant and unduly prejudicial. Stiens's expert witness and co-author of two of the articles admitted in deposition that his research on the use of Besivance injected into the anterior of the eye and his subsequent warnings of toxicity were "not germane" to the use of Besivance as a topical antibiotic in PRK. The third article concerned the same use of Besivance.

Following these evidentiary rulings, B & L moved to renew its motion for summary judgment. The circuit court granted the motion in a July 30, 2018 order, holding that Stiens lacked the evidence to support a *prima facie* negligence claim. The court held that even in the light most favorable to Stiens, she had failed to present sufficient evidence of foreseeability and causation.

Stiens filed a Motion to Vacate and Reconsider Summary Judgment under Kentucky Rules of Civil Procedure ("CR") 59.05, arguing that foreseeability was an issue for the jury. The circuit court denied the motion as improper under CR 59 for failure to present new evidence or arguments. A motion that "[does] nothing more than reassert the same arguments . . . made in challenging [the] motion for summary judgment" is properly denied under CR 59.05. *Rogers v. Integrity Healthcare Servs., Inc.*, 358 S.W.3d 507, 513 (Ky. App. 2012).

The circuit court further stated that summary judgment was proper because Stiens failed to assert *prima facie* evidence of her negligence claim that "the defendant owed a duty to the plaintiff, breached that duty, and consequent

injury followed." *Shelton v. Ky. Easter Seals Soc'y, Inc.*, 413 S.W.3d 901, 906 (Ky. 2013) (footnote omitted). In a products liability context, a consequent injury is defined by whether a defendant's conduct was a "substantial factor" in bringing about the injury. *CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 77 (Ky. 2010). The circuit court concluded that Stiens could not present any evidence of foreseeability beyond sheer speculation, stating, "Stiens has not identified any specific identifiable injury causally connected to Besivance® that [B & L] knew was possible or should have known was possible."[5]

The circuit court also rejected Stiens's repeated assertion that B & L is "presumed to know the quality and characteristics of its product when it markets/sells it" as a presumption only applicable in strict liability, not negligence. (Citing *Isaacs v. Smith*, 5 S.W.3d 500, 502 (Ky. 1999).) Finally, the circuit court again denied Stiens's contention that B & L violated a duty to refrain from off-label promotion. Stiens brought state claims, and Kentucky law does not provide for a state law claim for off-label promotion. The circuit court explained that because Stiens had chosen to exclusively pursue state law claims, she could not rely upon any federal law prohibiting certain kinds of off-label promotion to establish B & L's duty of care.

This appeal followed.

[5] This conclusion of law is incorrect for reasons to be discussed.

## II. STANDARD OF REVIEW

"[S]ummary judgment is to be cautiously applied and should not be used as a substitute for trial." *Steelvest, Inc. v. Scansteel Serv. Ctr., Inc*., 807 S.W.2d 476, 483 (Ky. 1991). A motion for summary judgment should only be granted "when it appears impossible for the nonmoving party to produce evidence at trial warranting a judgment in his favor" even when the evidence is viewed in the light most favorable to him. *Id.* at 482; *Shelton*, 413 S.W.3d at 905. To survive a properly supported summary judgment motion, the opposing party must present at least some affirmative evidence showing that there is a genuine issue of material fact for trial. *Steelvest*, 807 S.W.2d at 482.

The standard of review on appeal from summary judgment is "whether the trial court correctly found that there were no genuine issues as to any material fact and that the moving party was entitled to judgment as a matter of law." *Scifres v. Kraft*, 916 S.W.2d 779, 781 (Ky. App. 1996) (citing CR 56.03). "A trial court's decision to grant summary judgment for insufficient evidence is to be reviewed *de novo* on appeal." *Ashland Hosp. Corp. v. Lewis*, 581 S.W.3d 572, 577 (Ky. 2019). On appeal, the record must be viewed in a light most favorable to the party who opposed the motion for summary judgment, and all doubts are to be resolved in his favor. *Malone v. Kentucky Farm Bureau Mut. Ins. Co.*, 287 S.W.3d 656, 658 (Ky. 2009).

## III. ANALYSIS

Stiens raises numerous assignments of error as part of this appeal. The primary issue put forth by Stiens, and the one we conclude is ultimately dispositive, is whether the circuit court erred as a matter of law when it granted summary judgment to B & L on Stiens's negligence claim.[6] Stiens argues that the circuit court erred in concluding that she could not present *prima facie* evidence of foreseeability. Because we find the issue of foreseeability to be determinative in affirming the circuit court's decision, Stiens's other issues raised on appeal are moot and will not be addressed.

To recover under a claim of negligence, a plaintiff must present evidence that "(1) the defendant owed a duty of care to the plaintiff, (2) the defendant breached its duty, and (3) the breach proximately caused the plaintiff's damages." *Lee v. Farmer's Rural Elec. Co-op. Corp.*, 245 S.W.3d 209, 211-12 (Ky. App. 2007) (citation omitted). "The absence of any one of the three elements is fatal to the claim." *M & T Chems., Inc. v. Westrick*, 525 S.W.2d 740, 741 (Ky. 1974) (quoting *Illinois Cent. R.R. v. Vincent*, 412 S.W.2d 874 (Ky. 1967)).

The court's "first inquiry must always involve the legal question of the existence of a duty." *Pearson v. Pearson*, 552 S.W.3d 511, 514 (Ky. App.

[6] At different points in this litigation, Stiens has styled her claim as negligent marketing, failure to warn, and failure to test. For the purposes of this Opinion, we will predominantly address her claim under the broad category of negligence.

2018). Kentucky law imposes the "universal duty" of care. Under the universal duty, "[e]very person owes a duty to every other person to exercise ordinary care in his activities to prevent foreseeable injury." *Isaacs*, 5 S.W.3d at 502 (quoting *Grayson Fraternal Order of Eagles, Aerie No. 3738, Inc. v. Claywell*, 736 S.W.2d 328, 332 (Ky. 1987)). Therefore, it is clear that B & L has a duty to every person, including Stiens, to prevent *foreseeable* injury.

The Kentucky Supreme Court has held "that so far as foreseeability enters into the question of liability for negligence, it is not required that the particular, precise form of injury be foreseeable—it is sufficient if the probability of injury of some kind to persons within the natural range of effect of the alleged negligent act could be foreseen." *Id.* (quoting *Miller v. Mills*, 257 S.W.2d 520, 522 (Ky. 1953)). Such risk must be foreseeable based on what the tortfeasor knew or should have known at the time of the accident rather than what might be deemed foreseeable in hindsight. *Bruck v. Thompson*, 131 S.W.3d 764, 767 (Ky. App. 2004). This is in contrast with the circuit court's mistaken emphasis on the importance of identifying a specific, identifiable injury that can be causally connected to B & L's alleged breach of duty. Record ("R.") at 1045. To demonstrate foreseeability, a plaintiff must only demonstrate the probability of some *general* risk of injury resulting from the defendant's negligent act – not that of the exact injury actually manifested.

Each of Stiens's claims under the Kentucky Product Liability Act ("KPLA") – negligent marketing, failure to warn, and failure to test – is founded in negligence and requires evidence of foreseeability. *CertainTeed*, 330 S.W.3d at 79 (explaining that under the failure to warn theory, liability for a manufacturer follows only if injury was foreseeable based on the inherent dangerousness of the product and the manufacturer still failed to provide warning); *Vanden Bosch v. Bayer Healthcare Pharm., Inc.*, 13 F. Supp. 3d 730, 747 (W.D. Ky. 2014) (explaining that testing can be relevant to the duty of care, which is premised on preventing foreseeable injury). "There is no language in the [KPLA] which suggests that products liability actions mean only those actions based on strict liability in tort . . . ." *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997). If a claim is brought against a manufacturer "of a product which is alleged to have caused injury, then the [KPLA] applies . . . ." *Id.* This is true regardless of whether a claim is founded in strict liability, negligence, or breach of warranty, even though "each of these theories of recovery in products liability cases requires proof of different elements and has different implications . . . ." *Id.* All of this goes to say that the classification of an action as a products liability claim does not change its essential elements from what they would be under common law.

Despite this well-settled law, Stiens repeatedly attempts to shoehorn her failure to warn/failure to test/negligent marketing claim into a claim imposing

the presumption of knowledge standard. This is incorrect. Kentucky follows the Restatement (Second) of Torts, which imposes the strict liability presumption *only* when a product manufacturer or seller "sells any product in a defective condition unreasonably dangerous to the user." *Dealers Transp. Co. v. Battery Distrib. Co.*, 402 S.W.2d 441, 446 (Ky. 1965) (quoting RESTATEMENT (SECOND) OF TORTS 402A(1)). Stiens has admitted that B & L did not sell Besivance in a defective condition, preventing her from maintaining a viable strict liability claim against B & L. Without a strict liability claim, Stiens cannot rely upon any presumption that B & L knew that off-label use of Besivance could cause injury.

Our Supreme Court has previously provided clarification as to the difference between negligence and strict liability under the KPLA.

> [N]egligence depends on what a prudent manufacturer . . . by the exercise of ordinary care actually should have discovered and foreseen, whereas strict liability depends on what he would have anticipated had he been (but regardless of whether he actually was or should have been) aware of the condition of and potentialities inhering in the product when he put it on the market. Where the one is actual, the other is postulated.

*Ulrich v. Kasco Abrasives Co.*, 532 S.W.2d 197, 200 (Ky. 1976); *see also Worldwide Equip., Inc. v. Mullins*, 11 S.W.3d 50, 55 (Ky. App. 1999). Even under Kentucky products liability law, the elements of negligence remain the same, including foreseeability.

The KPLA imposes upon manufacturers a duty to test their products for risks that they or the medical community "had a reasonable basis to suspect" might exist. *Prather v. Abbott Labs.*, 960 F. Supp. 2d 700, 713 (W.D. Ky. 2013) (citation omitted) (applying Kentucky law). Kentucky courts do not require manufacturers to lead scientific research into the forays of cutting-edge medical advances. "The law does not require a company to test for hidden risks that neither it nor the medical community had a reasonable basis to suspect." *Id*. (citation omitted). Manufacturers "d[o] not have an obligation to spearhead medical research by testing for every conceivable risk[] posed by use of" their products. *Id*. at 714. Conversely, it follows that manufacturers like B & L do have an obligation to test and warn regarding products *known or suspected* to be dangerous.

A manufacturer may similarly be held liable under a failure to warn claim. *CertainTeed*, 330 S.W.3d at 79. A manufacturer's liability for failure to warn follows only if it knew or should have known of the inherent dangerousness of the product and failed to accompany it with the quantum of warning adequate to guard against the inherent danger. *Id.*; *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 109-10 (Ky. 2008), *as modified on reh'g* (Nov. 26, 2008). In *Proctor v. Davis*, the Appellate Court of Illinois held that a pharmaceutical company defendant has a duty to warn when there is "unequal knowledge and the defendant, possessed of such knowledge, knows or should know that harm might

occur if no warning is given." 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997) (quoting *Kokoyachuk v. Aeroquip Corp.*, 526 N.E.2d 607 (Ill. App. Ct. 1988)). In that case, Upjohn, the drug manufacturer, failed to warn of risks associated with off-label periocular injection of Depo-Medrol, a corticosteroid, and in fact published research validating the safety and efficacy of the drug application in question to increase sales. *Id.* at 1212. At the time of the plaintiff's disastrous injection procedure, Upjohn had two decades' worth of knowledge of the drug's dangerous propensities when injected intraocularly. *Id.* at 1213.

Further, a manufacturer's calculated marketing tactics may undermine warnings given if marketing was pervasive enough to essentially "undo" the warnings of known danger. *Id.* at 1214-15. In *Hyman & Armstrong, P.S.C. v. Gunderson*, a new mother was found dead following a seizure after taking Parlodel to prevent lactation. 279 S.W.3d at 99. Her estate successfully brought a products liability claim against Sandoz Pharmaceutical Corporation after evidence demonstrated that Sandoz "repeatedly attempted to *downplay or conceal* the risks of Parlodel and intentionally undermined any existing warnings." *Id.* at 112 (emphasis added). Despite knowledge of at least ninety-eight reported cases of hypertension, eighty-six cases of seizure, and thirty-three cases of stroke, Sandoz had been instructing its sales representatives not to mention any risks unless directly asked. *Id.* at 111-12. The Court stated that any warnings contained in the

product packaging were rendered inadequate due to Sandoz's "efforts to minimize or conceal" the associated risks of the drug. *Id.* at 112. Again, actual knowledge of risk was requisite to this theory of the duty to warn.

Stiens claims that these cases demonstrate that B & L had a duty to warn of potential risks that could arise when using Besivance. However, this argument is not supported by any of the cases Stiens cites, which are readily distinguishable from the present set of facts. Each case Stiens cites turns on the presence of evidence that the drug manufacturers had actual knowledge of reported risks or dangers associated with the use of their pharmaceutical products. *See*, *e.g.*, *Hyman*, 279 S.W.3d 93; *Proctor*, 682 N.E.2d 1203; *Smith v. Pfizer Inc.*, 714 F. Supp. 2d 845 (M.D. Tenn. 2010) (holding that the drug manufacturer promoted its product, Neurontin, for use as a pain reliever without adequate warnings of its known side effects of depression and suicidal ideation). Additionally, more recent case law reaffirms that warnings must be given for off-label use only where there is empirical evidence of harm that is known by the manufacturer. *See T.M. v. Janssen Pharms. Inc.*, 214 A.3d 709, 728 (Pa. Super. Ct. 2019).

Unlike those decisions, there is simply no evidence suggesting that B & L knew or should have known that the use of Besivance in PRK was associated with any adverse effects. Following the circuit court's evidentiary holdings, Stiens was left with no evidence suggesting that B & L knew or should have known that

there could be risks associated with Besivance use at all. In fact, Dr. Ferguson testified that his use of Besivance in PRK was on the "bleeding edge," meaning that he was one of the first ophthalmologists to do so. Like B & L, he also expressed surprise when he realized that Besivance was the culprit behind Stiens's injury. Stiens states that B & L had a duty to notify physicians of any additional side effects discovered from its use; while this is an accurate statement of law, there had not yet been evidence to suggest that using Besivance in PRK could be dangerous. Without even a scintilla of evidence to support this element of Stiens's claim, we cannot hold that summary judgment was improvidently granted.[7] While Stiens's injury is undoubtably lamentable, we cannot hold that B & L had a duty to warn of or test for risks without any reason to suspect that there may be risks associated with this particular use of Besivance.

Given the lack of specific evidence that B & L had prior knowledge that its product posed a risk to patients when used for infection control following surgery, Stiens makes the argument that we should infer that B & L's promotion of its product for an off-label use without prior testing is a sufficient basis upon which

[7] Stiens did not raise any evidentiary issues on appeal despite referencing evidence the circuit court clearly excluded. Following the exclusion of Dr. Mamalis's research and article, the circuit court stated, "Same with respect to . . . *Last Generation* article." Video Record ("V.R.") 6/15/18 at 10:47 a.m. Although Stiens contends that the circuit court did not exclude the article quoting Dr. Olson, the video record makes clear otherwise. Regardless, this article does not address the use of Besivance as a topical medication in any kind of refractive surgery but rather as an injection during clear corneal surgery.

to predicate foreseeability of harm. Given that Kentucky does not prohibit the off-label promotion and marketing of drugs, we do not believe that it is appropriate to extend the law of negligence in this regard. This is an issue for the General Assembly to take up, not the courts.

Off-label use is not unlawful under state or federal law. *United States v. Caronia*, 703 F.3d 149, 166-67 (2d Cir. 2012). Doctors are permitted and even encouraged to prescribe drugs for both FDCA-approved and -unapproved uses for the benefit of their patients. *Id.* at 153. Courts have repeatedly noted that off-label promotion is not a private right of action that exists under state law.[8] *See Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1010-11 (S.D. Ohio 2016) (citation omitted) ("Off-label promotion" is "not a part of [state] law."); *Thorn v. Medtronic Sofamor Danek, USA, Inc.*, 81 F. Supp. 3d 619, 628 (W.D. Mich. 2015) ("[T]here is no state law duty to abstain from off-label promotion."); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219-20 (W.D. Okla. 2013) ("'[O]ff-label use' . . . is not a part of [state] substantive law."). Stiens has not established an industry or company standard for off-label promotion outside of the FDCA against which B & L's promotion of Besivance could be weighed. If Stiens wanted to rely upon FDCA

[8] The FDCA preempts private actions for "off-label" marketing, as such claims would "not exist in the absence of the FDCA[.]" *McDaniel v. Upsher-Smith Pharm., Inc.*, 229 F. Supp. 3d 707, 713 (W.D. Tenn. 2017); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353, 121 S. Ct. 1012, 1020, 148 L. Ed. 2d 854 (2001). Under *Buckman*, such claims are "impliedly preempted." *McDaniel*, 229 F. Supp. 3d at 710 (citation omitted).

regulation of off-label promotions, Stiens should have brought a claim under the FDCA.

While we agree with Stiens that the issue of foreseeability is a question for the jury, Stiens failed to provide any affirmative evidence on that issue in favor of her case. "The question whether the appellees will be able to present proof of circumstances sufficient to infer that the defendant knew, or should have known, of the likely results of his conduct, or whether the results were beyond the foreseeable risk" is an issue for the jury after the presentation of the evidence. *Grayson*, 736 S.W.2d at 334 (citation omitted) ("Except in such cases where reasonable minds could not differ, where the court would conclude as a matter of law that it was clearly unreasonable to foresee the potential harm from the misconduct involved, the question of foreseeable risk is covered by the usual instruction relating to proximate cause, which is an issue framed for the jury in terms of whether the misconduct was a 'substantial factor.'").

After the circuit court excluded much of Dr. Mamalis's testimony and publications, Stiens was unable to identify *any* admissible evidence tending to show that B & L knew or should have known that Dr. Ferguson's decision to use Besivance in PRK might lead to medical complications. Therefore, we hold that

Stiens failed to meet her *prima facie* burden of proof, making summary judgment the appropriate result.[9]

## IV. CONCLUSION

In light of the foregoing, we affirm the judgment of the Fayette Circuit Court.

ALL CONCUR.

| BRIEFS AND ORAL ARGUMENT FOR APPELLANT: | BRIEF AND ORAL ARGUMENT FOR APPELLEE: |
|---|---|
| Thomas K. Herren<br>Lexington, Kentucky | John L. Tate<br>Louisville, Kentucky |
| | Robin E. McGuffin<br>Lexington, Kentucky |

[9] Stiens also contests the circuit court's holding that B & L's alleged breach of duty was a "substantial factor" in causing Stiens's injury. R. at 1043. The substantial factor test is a factual inquiry applied to the event which causes the injury rather than the injury itself. *Deutsch v. Shein*, 597 S.W.2d 141, 145 (Ky. 1980), *abrogated on other grounds by Osborne v. Keeney*, 399 S.W.3d 1 (Ky. 2012). Thus, under this test, a jury would be asked to determine whether B & L's marketing of Besivance was a substantial factor that led to Dr. Ferguson's use of Besivance, the event that caused Stiens's injury. We disagree with the circuit court's ruling that no jury could reasonably have found that B & L's promotion of Besivance and assurances of its safety and efficacy were a substantial factor in Dr. Ferguson's decision to use Besivance. The circuit court went so far as to call this connection "sheer speculation." R. at 1043. We believe that this is too strong of a description and that a reasonable jury could possibly have found for Stiens based upon the facts. However, because the outcome of this appeal has already been determined by the issue of foreseeability, the issue of causation is not dispositive and is ultimately moot.