STATE OF MICHIGAN

COURT OF APPEALS

PAMELA L. TREES,

Plaintiff-Appellant,

v

PFIZER, INC., PFIZER INTERNATIONAL, LLC, GREENSTONE LLC f/k/a GREENSTONE LIMITED, and MEIJER INC.,

Defendants-Appellees.

UNPUBLISHED
December 20, 2018

No. 338297
Macomb Circuit Court
LC No. 2015-003623-NP

CAROL BEARUP, BARBARA BEECHAM, SONYA MENCY, VIOLA MOSES, and HEATHER MACKS,

Plaintiffs-Appellants,

v

PFIZER, INC., PFIZER INTERNATIONAL, LLC, GREENSTONE LLC f/k/a GREENSTONE LIMITED, MEIJER, INC., and CVS CAREMARK,

Defendants-Appellants,

and

WAL-MART STORES, INC. d/b/a SAM'S CLUB a/k/a SAM'S EAST, INC., and DOES 1-50,

Defendants.

No. 340191
Wayne Circuit Court
LC No. 15-013604-NP

Before: CAVANAGH, P.J., and SERVITTO and CAMERON, JJ.

PER CURIAM.

In these consolidated product liability cases, plaintiffs appeal as of right trial court orders granting summary disposition in defendants' favor and dismissing their complaints. We affirm.

Plaintiffs, female residents of the state of Michigan, brought these claims against the manufacturer of the drug Lipitor, Pfizer, Inc.[1], and against pharmacies from which they assert they purchased Lipitor.[2] Plaintiffs asserted that they were prescribed Lipitor for lowering their cholesterol and for decreasing their risk of developing cardiovascular disease. They asserted that, as a direct result of taking Lipitor, they suffered physical, economic, and emotional injuries, including being diagnosed with and treated for Type II diabetes. Plaintiffs alleged that Lipitor was unreasonably dangerous and defective in that it caused an increased risk, particularly in women, of developing Type II diabetes, and that defendants knew this. Plaintiffs further alleged the following: the Lipitor label misrepresented the incidences of hyperglycemia in clinical trials; that Pfizer knew that Lipitor could not be demonstrated to benefit women as a means of primary prevention against cardiovascular disease; that the manufacturer of a drug approved by the FDA has a continuing obligation to investigate and report any adverse events associated with the drug, and here, defendants failed to fulfill this duty; that defendants knew, or should have reasonably known, of the hazards and dangerous propensities of Lipitor, and: but for the lack of proper warning by defendants about the risk of developing Type II diabetes from ingesting Lipitor to them or their heath care professional(s), plaintiffs would not have ingested Lipitor. Plaintiffs thus alleged negligence, negligent misrepresentation, negligent design, design defect products liability, failure to warn products liability, breach of express warranty products liability, breach of implied warranties products liability, fraud and misrepresentation, constructive fraud, and unjust enrichment. Plaintiff also alleged that defendants were not entitled to protection under Michigan products liability statutes because Lipitor is a defective product, and that defendants were also estopped from pleading statutes of limitations or repose by virtue of their acts of fraudulent concealment, affirmative misrepresentations and omissions.

The trial courts granted all of defendants motions for summary disposition premised upon MCR 2.116(C)(7) and (8). In docket no. 338297, the trial court found that summary disposition was appropriate in defendants' favor based on immunity granted under MCL 600.2946(5). The court, alternatively, relied on MCL 600.2947, stating that since the Lipitor label was updated in

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[1] Pfizer, Inc, Pfizer International, and Greenstone LLC were all named as defendant manufacturers of Lipitor. These defendants are collectively referred to as "Pfizer" throughout this opinion.

[2] These defendants are Meijer, Inc., from whom plaintiffs Trees and Bearup allegedly purchased Lipitor, and CVS Caremark, from whom plaintiffs Beecham and Moses allegedly purchased Lipitor. These two defendants are jointly referred to as "the pharmacy defendants" in this opinion unless directly referenced by name. Defendant Wal-Mart Stores was voluntarily dismissed in the trial court and is not a party to this appeal.

February of 2012 to include a warning for an increased risk of developing diabetes, users of Lipitor would logically have been aware of the risk of developing Type II diabetes beginning in February of 2012. Regarding defendant Meijer, Inc., the trial court found that plaintiff offered no evidence supporting her claim that "Meijer was involved in promoting Lipitor and disseminating information [regarding] Lipitor" and "provided warning to patients that deviated from FDA approved package inserts." Therefore, the court found that plaintiff had not established a claim against Meijer. In docket no. 340191, the trial court found that all defendants were entitled to immunity under MCL 600.2946(5), and that plaintiffs' claim that immunity did not apply was preempted by federal law.

We review a trial court's summary disposition rulings de novo on appeal. *Al-Shimmari v Detroit Med Ctr*, 477 Mich 280, 287; 731 NW2d 29 (2007). MCR 2.116(C)(7) permits summary disposition where the claim is barred due to immunity granted by law, among other things. In evaluating a claim brought under subrule (C)(7), we accept the allegations of the complaint as true unless contradicted by documentary evidence. *Pusakulich v City of Ironwood*, 247 Mich App 80, 82; 635 NW2d 323 (2001). We must consider any affidavits, depositions, admissions and other documentary evidence submitted by the parties that would be admissible as evidence at trial. *Id*.

This court reviews motions for summary disposition brought under MCR 2.l 16(C)(8) for the legal sufficiency of a claim, deciding the matter on the pleadings alone. *Markis v Grosse Pointe Park*, 180 Mich App 545, 551; 448 NW2d 352 (1989). In making such review, all well-pled facts and reasonable inferences drawn therefrom are taken as true. *Id.* A motion brought under subrule (C)(8) should be granted only when the claim is clearly so unenforceable as a matter of law that no factually development could establish the claim and justify recovery. *Id*. The interpretation and application of a statute are questions of law that we review de novo. *Paige v City of Sterling Hts*, 476 Mich 495, 504; 720 NW2d 219 (2006).

Michigan law provides broad immunity to manufacturers and sellers of products in product liability actions. MCL 600.2946(5) provides:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat 1040, 21 USC 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360,

> 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

MCL 600.2945 defines the relevant terms as follows:

> (h) "Product liability action" means an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product.
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> (i) "Production" means manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling.

Lipitor is undisputedly a "product." And, all of plaintiffs' claims regarding Lipitor are based on its "production" as defined in MCL 600.2945(i). Thus, plaintiffs' claims all sound in product liability. While plaintiffs assert that some of their causes of action fall outside of product liability and title some of their causes of action accordingly, this Court looks beyond mere labels to determine the exact nature of a claim and determines the gravamen of an action by reading the complaint as a whole. *Jahnke v Allen*, 308 Mich App 472, 475; 865 NW2d 49 (2014).

Plaintiffs labeled a cause of action "negligence" yet alleged under that claim that defendants breached their duties to properly test, manufacture, warn, label and sell Lipitor. These allegations all fall within the definition of "production" for purposes of a product liability action. The cause of action labeled "negligent misrepresentation" contains allegations that defendants, through their labeling and distribution of Lipitor, provided false or misleading information to health care professionals and consumers regarding Lipitor. These allegations, too, fall under the umbrella of a product liability action. The same holds true for all of plaintiffs' remaining claims. No matter how they are labeled, all of plaintiffs' allegations concern the "manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling" of Lipitor (MCL 600.2945(i)), and are thus product liability actions. MCL 600.2945(h).

Plaintiffs assert that defendants are nevertheless precluded from asserting immunity to the products liability claims under MCL 600.2946(5) because Pfizer did not comply with the food and drug administration (FDA) approval and the pharmacy defendants did not comply with FDA labeling. We disagree.

While Michigan's product liability immunity act does not define "compliance with FDA approval," as it is stated in MCL 600.2946(5), plaintiffs' claim that Pfizer was not in compliance was squarely addressed in *Marsh v Genentech, Inc*, 693 F3d 546 (CA 6, 2012).[3] In that case, the Michigan plaintiff presented almost identical allegations as the plaintiffs do here with respect to a manufacturer's alleged non-compliance with FDA approval to argue that the manufacturer was not entitled to immunity under MCL 600.2946(5):

> she seems to allege that Genentech failed to comply with the FDA's post-marketing reporting requirements. The complaint alleges that Genentech "intentionally and negligently failed to update statement of contraindications, warnings, precautions, and adverse reactions that Defendant affirmatively knew about" and "intentionally and negligently failed to comply with various but not limited to, 21 CFR 201, 21 CFR 202, 21 CFR 314.80, and 21 CFR 314.81." Marsh contends that these failures constitute non-compliance with the FDA's approval because, as part of its application for approval of Raptiva, Genentech signed FDA Form 356h, which requires the applicant to certify as follows:
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> > "I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindicaitons [sic], warnings, precautions or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by the FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications . . . ." *Id.* at 552.

The *Marsh* Court held that the plaintiff's allegations "do not fit comfortably within the statutory language requiring compliance for immunity to apply. Marsh's complaint alleges that *Genentech* did not comply with the terms of the FDA approval by failing to update its application or submit safety reports, not that 'the drug and its labeling' did not comply." *Id*. at 552. In other words, "the statutory language suggests that immunity requires substantive compliance with FDA approval, but Marsh essentially alleges procedural non-compliance." *Id*.

As in *Marsh*, Plaintiffs here specifically asserted that when Pfizer submitted its application for approval of Lipitor to the FDA, it signed a 356h form certifying that it agreed to update the application with new safety information, to submit safety update reports as provided for by regulation or as requested by the FDA, and to comply with all applicable laws and regulations that apply to approved applications. Plaintiffs alleged that "[a]lthough the application for Lipitor was approved and marketing commenced, Defendants negligently failed to comply with various regulations including, but not limited to, 21CFR § 201, 21 CFR § 202, 21 CFR § 314.80, and 21 CFR § 314.81." Plaintiffs further alleged that "[b]ecause Defendants

[3] "Although case law from the federal circuits and federal district courts is not binding on this Court, it may be considered for its persuasive value." *Johnson v Vanderkooi*, 502 Mich 751, 764; 918 NW2d 785 (2018).

failed to properly monitor the safety of Lipitor as required under 21 CF R § 314.80 and 21 CF R § 314.81, the label for Lipitor was never properly updated as required by 21 CF R § 201.57" and "[c]ompliance with these regulations was a condition precedent of approval of Lipitor. As such, the drug and its labeling were not in compliance with the United States food and drug administration's approval at the time the drug left the control of the Defendants and ultimately administered to the Plaintiffs." As the *Marsh* Court recognized, MCL 600.2946(5) specifically provides that in a product liability action against a manufacturer or seller of a drug, as is the case here, a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if two conditions are met: (1) the drug was approved for safety and efficacy by the FDA and, (2) *the drug and its labeling* were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller (emphasis added).

Plaintiff's assertion that Pfizer was not entitled to immunity because it was not in compliance with the FDA's approval fails for the reasons set forth in *Marsh*. Plaintiffs attempt to distinguish their claims from those in *Marsh* by claiming that their claims set forth substantive rather than procedural non-compliance with FDA approval. Plaintiffs, however, still cite primarily to Pfizer's failure to conduct post-marketing safety surveillance, updating of the label after such post-marketing surveillance, and failure to comply with the 356h form certification, which are exactly the same types of alleged non-compliance addressed by the *Marsh* Court.

Plaintiffs do assert that despite the fact that the FDA requested a label change with respect to Lipitor on August 11, 2011, and Pfizer complied with the request in February 2012, the label still inadequately warned consumers of the serious risk of developing Type II diabetes. This claim, however, still does not present an allegation of lack of FDA approval or non-compliance with the FDA's approval as is required to defeat the application of immunity under MCL 600.2926(5). Our Supreme Court explained that pursuant to this statute:

> unless the fraud exception in subsection a or the bribery exception contained in subsection b applies (plaintiffs make no such claim here), a manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a product liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller. Thus, the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie. [*Taylor v Smithkline Beecham Corp*, 468 Mich 1, 7; 658 NW2d 127 (2003)]

This statute establishes that "a determination of independent significance, here the FDA finding that a drug is safe and effective, will be the measure in Michigan of whether the duty of reasonable care has been met by a drug manufacturer or seller in a tort case." *Id*. at 13. Further, absent a successful claim that immunity does not apply, Michigan plaintiffs are precluded from recovering in failure to warn or inadequate warning cases. *Marsh*, 693 F3d at 554.

Again, plaintiffs have not alleged that the label did not comply with FDA approval. They simply alleged that the label was inadequate. Where the FDA has approved the label and the label is in compliance with that approval — and plaintiffs do not dispute that here — the

manufacturer is entitled to immunity under MCL 600.2946(5). Summary disposition was therefore appropriately granted in favor of Pfizer in both cases under MCR 2.116(C)(7).

With respect to the pharmacy defendants, plaintiffs allege that they were not entitled to statutory immunity because they provided warnings concerning Lipitor that are not the same as the FDA approved warnings. However, plaintiffs made this claim only with respect to defendant Meijer in docket no. 338297. Plaintiffs' allegations against the pharmacy defendants in docket no. 340191 are not separate and distinct from their allegations against Pfizer. Thus, the pharmacy defendants in docket no. 340191 are entitled to statutory immunity and thus summary disposition for the same reason as Pfizer. Moreover, defendant Meijer, in docket no. 338297, is also entitled to summary disposition under the plain language of MCL 600.2946(5).

MCL 600.2946(5) clearly provides that in a product liability action against a seller of a product, which the action against defendant Meijer is, the seller is not liable, if the drug was approved by the FDA and the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the seller. When construing a statute, our primary goal is determine the legislative intent. *Rowland v Washtenaw Co Rd Comm*, 477 Mich 197, 202; 731 NW2d 41 (2007). We begin with the statutory language, and if the statutory language is unambiguous, the words are given their plain meaning and applied as written. *Id*. Subject to two exceptions, MCL 600.2946(5) establishes an *absolute* defense for drug manufacturers and sellers in a product liability action, so long as the drug was approved by the FDA and it and its label complied with the FDA approval. *Taylor, supra* at 6–7.

Plaintiffs do not allege that the pharmacy defendants provided a drug or label for Lipitor that was different from that approved by the FDA. They merely alleged that a *warning* provided by the pharmacy defendants was or may have been different. Plaintiffs concede that Lipitor was approved by the FDA and their argument that Lipitor was not in compliance with the FDA's approval fails, as previously determined by this Court. These are the only two requirements for statutory immunity to apply. A seller is thus entitled to immunity unless one of the two exceptions to immunity specifically stated in the statute has been shown. Plaintiffs have not alleged that either of those two exceptions (fraud upon the FDA or bribery) applies with respect to defendant Meijer. Indeed, they concede that they do not. Because these are the *only* two exceptions to immunity, defendant Meijer is entitled to immunity under MCL 600.2946(5).

Plaintiffs next assert that *Wyeth v Levine*, 555 US 555, 129 SCt 1187, 173 LEd2d 51 (2009) and *Marsh* make clear that their claims are not preempted by federal law and that the trial court in docket no. 340191erred in finding their claims preempted.[4] We need not address federal preemption, however, because all defendants were clearly entitled to immunity under MCL 600.2946(5). To the extent that the trial court relied upon preemption in reaching its decision to grant summary disposition in favor of defendants in docket no. 340191, we find that the trial court reached the right result for the wrong reason. See, e.g., *Gleason v Michigan Dept of*

[4] The trial court in docket no. 338297 found it unnecessary to reach the issue of federal preemption.

Transp, 256 Mich App 1, 3; 662 NW2d 822 (2003) ("A trial court's ruling may be upheld on appeal where the right result issued, albeit for the wrong reason").

Finally, plaintiffs contend that the trial court erred in denying or failing to address their requests to amend their complaints if the trial court found defendants' arguments at summary disposition meritorious. It is clear, however, that plaintiffs' allegations and claims all stem from the alleged failure of defendants to adequately investigate and warn of Lipitor's exposing female patients to an increased risk of acquiring Type II diabetes and their failure to provide a label that adequately warns of the risk. Any claims by plaintiff will therefore fall under the very expansive umbrella of product liability actions, as these are actions "based on a legal equitable theory of liability brought for the . . . injury to a person . . . property caused by . . . the production of a product" (MCL 600.2945(h)) and defendants will thus be entitled to immunity under MCL 600.2946(5) for any claims by plaintiffs. Amendment would thus be futile. See, *Wormsbacher v Seaver Title Co*, 284 Mich App 1, 8–9; 772 NW2d 827 (2009).

Affirmed.

/s/ Mark J. Cavanagh
/s/ Deborah A. Servitto
/s/ Thomas C. Cameron