STATE OF MICHIGAN

COURT OF APPEALS

SHELLEY A. BUSH and JOHN BUSH, Plaintiffs-Appellants, v STEVEN E. GOREN and GOREN, GOREN & HARRIS, P.C., Defendants-Appellees.	UNPUBLISHED August 21, 2014 No. 315807 Oakland Circuit Court LC No. 2009-099884-NM

Before: RIORDAN, P.J., and DONOFRIO and BOONSTRA, JJ.

PER CURIAM.

Plaintiffs appeal as of right two orders granting summary disposition in favor of defendants under MCR 2.116(C)(10) in this legal-malpractice action. We affirm.

I. PERTINENT FACTS AND PROCEDURAL HISTORY

This legal malpractice case is before this Court for the second time. The facts that led to plaintiffs' filing suit against defendants were set forth in our previous opinion:

> Plaintiffs assert that they contacted defendant attorney and his firm about a possible medical malpractice claim in 2005 concerning a cardiac surgery that was performed on Shelly Bush on August 24, 2004. According to plaintiffs, the surgery included participation in a research study to evaluate the safety and efficacy of a new, unapproved, vascular closure device that plaintiff maintains was presented to her as a way to shorten the time she would have to remain in the hospital. According to plaintiff, she was not advised by hospital personnel that, under the terms of the study, she was not permitted to participate in it due to the fact that she was a nursing mother. Plaintiff alleges that, as a result of the insertion of the device, she "experienced severe medical complications including a ruptured femoral artery, enormous pain and suffering, lifetime occupational disability, very high medical expenses, mental anguish and emotional distress."
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> According to the complaint, after plaintiff contacted defendants, she provided the information concerning both the surgery and the use of the medical device. A paralegal in defendant's firm sent a letter to plaintiff, which in part confirmed that their conversation was "regarding [Plaintiffs'] potential medical malpractice case

and the possibility of product liability." Plaintiffs subsequently entered into a contingency fee arrangement with defendants. Plaintiffs maintain that the fee agreement referenced both a medical malpractice claim and a possible product liability case.

On June 5, 2006, defendant sent plaintiff a letter explaining that he had had her medical records analyzed by two interventional cardiologists and one vascular surgeon, and that each of the experts "indicated that they cannot support malpractice in their respective specialties." The letter then related defendant's decision not to proceed with plaintiff's case. The letter further provided:

> This is not to say that you do not have a legitimate and proper claim, or that other lawyers would not be interested in taking your case. You have the right to contact another attorney.
>
> Please be advised that you must file a lawsuit before the statute of limitations expires or your claim will be forever barred. Based on the records, **the statute of limitations may expire as early as** August 12, 2006. You should understand that there are certain requirements and deadlines that must be met in order to file a lawsuit. A Notice of Intent to file a claim must be sent by certified mail before the statute expires in order to preserve your legal right to file a lawsuit. Also, appropriate medical experts must submit an Affidavit of Merit stating there was malpractice and the affidavit may require certification. The notarized and certified affidavits must be submitted with the lawsuit.
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> **If you are interested in pursuing this claim, you should not delay in contacting another lawyer.** (Emphasis in original).

In their complaint, plaintiffs maintain that this letter, which appeared to deal only with plaintiffs' medical malpractice claim, indicates that the defendant "apparently either forgot about or quite consciously elected not to pursue these product liability claims on behalf of [plaintiffs]." Plaintiffs also maintained that defendant failed to correctly advise them of the longer three year statute of limitations for the product liability action.

Plaintiffs alleged in the complaint that they then attempted to contact other attorneys but that those attorneys declined to become involved in the case because of the mere two-month time frame remaining in which to proceed with the medical malpractice action. Plaintiff contended that neither she nor her husband knew enough to tell the attorneys they contacted that fourteen months still remained in the statute of limitations for the product liability claim.[2] The complaint specifically alleged that defendants violated their duties to plaintiffs in not advising plaintiffs of the products liability statute of limitations, or possibly not even calculating this statute of limitations, and "abandoning the products liability analysis ... without discussion of that analysis with either of their clients."

> Plaintiffs filed their complaint on April 10, 2009. Defendants did not file an answer, but subsequently filed a motion for summary disposition on June 18, 2009. Defendants sought summary disposition pursuant to MCL 2.116(C)(7), (8) and (10). Defendants alleged that plaintiffs could not maintain the action because defendants' representation of plaintiffs ended more than two years prior to the filing of her complaint, and plaintiffs had pled no facts to support the extension of the limitations period under the discovery rule. Defendants also alleged that plaintiffs' claims were barred under the attorney judgment doctrine, because defendant acted in good faith and in an honest belief that his acts were proper. In support of the motion, defendants attached defendant's affidavit, in which he averred that he was aware of the statute of limitations for the product liability claim, but had decided not to inform plaintiff of "several statutes of limitations," and instead "chose to advise [plaintiff] of only the earliest date that the statute of limitations might expire" because he "thought it critical that [he] explain the importance of the statute of limitations to [plaintiff] and emphasize the need for her to immediately contact an attorney." Defendant stated that he thought plaintiff would advise any attorney that she contacted about the use of the medical device, and that the other attorney would know the statute of limitations for a product liability action. Plaintiffs responded, providing affidavits in support of their contrary positions on both issues.
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> Following a hearing, the trial court granted defendants' motion for summary disposition. It found that plaintiffs were "essentially [seeking] to hold Defendants liable for the new attorneys' inability to recognize the potential and timeliness of the products liability claim on their own [,]"and held that defendant had not breached a duty to plaintiffs. [*Bush v Goren*, unpublished opinion per curiam of the Court of Appeals, issued February 1, 2011 (Docket No. 294779), unpub op at 1-3 (footnotes omitted).]

This Court found that the trial court erred in determining that the "attorney judgment rule" barred plaintiff's claims, stating that

> viewed in the light most favorable to the plaintiffs, the evidence creates a question of fact as to whether defendant acted with professional negligence when he failed to inform them of the statute of limitations for their products liability claim, either because he abandoned the claim entirely or consciously decided not to transmit the information to plaintiffs. [*Id*. at 5.]

Further, with regard to defendants' argument that the statute of limitations for a legal malpractice claim had expired, this Court found, based on the "sparse record" before it, that "defendants have not established at this point that, as a matter of law, plaintiff's actions should have caused them to discover their possible malpractice claim against defendants prior to their meeting with an attorney on October 13, 2008." *Id*. at 6. This Court reversed and remanded for "further proceedings consistent with this opinion." *Id*. at 7.

Following discovery on remand, defendants filed two motions for summary disposition, under MCR 2.116(C)(10), on September 26, 2012. In the first motion, defendants argued that

plaintiffs could not demonstrate that their underlying product-liability claim would have been successful because the learned-intermediary and the sophisticated-user doctrines eliminated any duty the device manufacturer owed to plaintiffs, and because plaintiffs' claim was properly classified as a medical-malpractice case. In the second motion, defendants argued that plaintiffs never had a viable product-liability claim because any such action would have been preempted by federal law, specifically the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 USC 360k. Plaintiffs did not file a response to either motion and did not appear at the date and time set for hearing, and the trial court granted defendants' motions for summary disposition in separate orders.

On November 7, 2012, plaintiffs filed a "Motion for Reconsideration and/or to Reinstate Case," stating that they were not aware of the hearing because defendants did not file separate notices of hearing and placed the notices between their briefs and the accompanying exhibits. Defendants opposed plaintiffs' motion because plaintiffs "timely received Notices of Hearing for the date and time that the Motions were scheduled for hearing" and "reconsideration [was] an inappropriate vehicle upon which to grant the requested relief." The trial court denied plaintiffs' motion for reconsideration in an April 1, 2013 opinion and order, noting that "it was not reasonable for Plaintiffs to simply assume that the [hearing on defendants' motions for summary disposition] would be scheduled by the Court," and "the e-mail notification generated by the Court's e-filing system and sent to both parties explicitly indicates that the filing [of defendants' motions for summary disposition] included not only a summary disposition motion and brief, but also a notice of hearing." This appeal followed.

II. STANDARD OF REVIEW

This Court reviews de novo a trial court's ruling on a motion for summary disposition. *Anzaldua v Neogen Corp*, 292 Mich App 626, 629; 808 NW2d 804 (2011). A motion for summary disposition under MCR 2.116(C)(10) tests the factual sufficiency of the complaint. *Corley v Detroit Bd of Ed*, 470 Mich 274, 278; 681 NW2d 342 (2004). Summary disposition "is proper when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *McCoig Materials, LLC v Galui Const, Inc*, 295 Mich App 684, 693; 818 NW2d 410 (2012). "A genuine issue of material fact exists when the record, giving the benefit of reasonable doubt to the opposing party, leaves open an issue upon which reasonable minds could differ." *Bronson Methodist Hosp v Auto-Owners Ins Co*, 295 Mich App 431, 441; 814 NW2d 670 (2012).

III. GRANT OF SUMMARY DISPOSITION

The elements of a successful claim of legal malpractice are "(1) the existence of an attorney-client relationship; (2) negligence in the legal representation of the plaintiff; (3) that the negligence was the proximate cause of an injury; and (4) the fact and extent of the injury alleged." *Manzo v Petrella*, 261 Mich App 705, 712; 683 NW2d 699 (2004). Although this Court remanded this case based on defendants' failure to establish as a matter of law that they were not negligent and failure to establish that the statute of limitations had expired, the proceedings on remand focused instead on whether a genuine issue of material fact existed as to proximate cause. "In order to establish proximate cause, a plaintiff must show that a defendant's action was a cause in fact of the claimed injury. Hence, a plaintiff must show that but for an

attorney's alleged malpractice, the plaintiff would have been successful in the underlying suit." *Id*. We agree with the trial court that no genuine issue of material fact existed regarding proximate cause, because plaintiffs could not demonstrate that they would have been successful in the underlying suit but for the alleged malpractice.

Plaintiffs first argue that the trial court erred when it granted defendants' motion for summary disposition, under MCR 2.116(C)(10), on the basis that plaintiffs' underlying product-liability claim was preempted by the MDA to the FDCA, 21 USC 360k. We disagree.

The Supremacy Clause of the United States Constitution provides that the federal constitution, laws, and treaties "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." US Const, art VI, cl 2. "Accordingly, it has long been settled that state laws that conflict with federal law are 'without effect.' " *Mut Pharm Co, Inc v Bartlett*, 570 US ___, ___; 133 S Ct 2466, 2473; 186 L Ed 2d 607 (2013), quoting *Maryland v Louisiana*, 451 US 725, 746; 101 S Ct 2114; 68 L Ed 2d 576 (1981). "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v Levine*, 555 US 555, 565; 129 S Ct 1187; 173 L Ed 2d 51 (2009). There is a presumption against preemption, guided by "the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc v Lohr*, 518 US 470, 485; 116 S Ct 2240; 135 L Ed 2d 700 (1996).

Defendants argued below, and the trial court agreed, that plaintiffs' claim of legal malpractice lacked merit because the underlying product-liability claim was preempted by federal law. The MDA include a provision that expressly preempts state law:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. [21 USC 360k(a).]

A state-law claim is, therefore, preempted under 21 USC 360k if (1) a federal requirement exists that is "applicable to the device" in question, (2) a state requirement "with respect to" medical devices exists that is related "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and (3) the state requirement is "different from, or in addition to," federal requirements. *Lohr*, 518 US at 500.

With respect to the first element, plaintiffs argue that their product-liability claim was not preempted because "there are no federal regulations specifically governing vascular closure devices," and the FDA's approval of an investigational device exemption ("IDE") for the vascular-closure device did not constitute a "requirement applicable . . . to the device."

Defendants respond that "the application and approval process under the IDE is a 'device-specific' requirement that has preemptive effect."

Generally, the manufacturer of a medical device intended for human use must obtain premarket approval ("PMA") for the device by providing the FDA with a "reasonable assurance" that the device is both safe and effective. 21 USC 360e(d)(2); *Lohr*, 518 US at 477. The PMA process "is a rigorous one," requiring manufacturers to "submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Lohr*, 518 US at 477. The United States Supreme Court held that the PMA process established "requirement[s] applicable . . . to the device" for the purposes of preemption because "premarket approval is specific to individual devices" and could be granted "only after [the FDA] determines that a device offers a reasonable assurance of safety and effectiveness." *Riegel v Medtronic, Inc*, 552 US 312, 322-323; 128 S Ct 999; 169 L Ed 2d 892 (2008), citing 21 USC 360e(d). Further, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id*. at 323.

The IDE is an exception to the lengthy PMA process that is meant "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose." 21 USC 360j(g)(1). "An approved [IDE] permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device." 21 CFR 812.1(a) (2014). No case law that is binding on this Court has considered the question whether the FDA's decision to grant an IDE establishes a "requirement applicable" to a medical device, as *Riegel* held with respect to the PMA process. However, the United States Courts of Appeals for the Second,[1] Third,[2] Sixth,[3] and Seventh[4] Circuits have held that an IDE establishes device-specific requirements.

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[1] *Becker v Optical Radiation Corp*, 66 F3d 18, 20-21 (CA 2, 1995).

[2] *Gile v Optical Radiation Corp*, 22 F3d 540, 546 (CA 3, 1994) (citing, in the context of the intraocular lens, the "public policy of the discovery and development of new products").

[3] *Martin v Telectronics Pacing Sys, Inc*, 105 F3d 1090, 1098 (CA 6, 1997). In support of this conclusion, *Martin* summarized the federal regulations applicable to investigational devices. See *id.* at 1095-1096, citing 21 CFR 812.20 (application process), 21 CFR 812.25 (investigational plan), 21 CFR 812.27 (report of previous investigations), and 21 CFR 812.30 (FDA action on applications).

[4] *Norgaard v DePuy Orthopaedics, Inc*, 121 F3d 1074, 1075 (CA 7, 1997), citing *Slater v Optical Radiation Corp*, 961 F2d 1330 (CA 7, 1992). The *Norgaard* panel cited *Slater*'s reasoning that the purpose of the investigatory process "is to determine whether the device is suitable for general use, and awards of damages on a defective-design theory to persons who agree to participate in the trials cognizant of the risks would disrupt the progress of medicine,"

We consider the federal case law persuasive. See *Abela v Gen Motors Corp*, 469 Mich 603, 607; 677 NW2d 325 (2004). For example, *Becker*, in which the plaintiff brought state-law claims based in strict liability and negligence after an experimental intraocular lens allegedly caused her a detached retina, held that the plaintiff's state-law claims were preempted by the MDA. *Becker v Optical Radiation Corp*, 66 F3d 18, 21 (CA 2, 1995). The FDA had promulgated regulations that "set forth detailed procedures for determining whether [intraocular lenses] are safe and effective" and that "specifically exempt[ed] experimental [intraocular lenses] from the safety and effectiveness standards usually imposed on medical devices," and the Second Circuit concluded that the plaintiff's "state tort claims would impose requirements on the [intraocular lenses] that are, certainly, additional to those imposed by the MDA scheme." *Id*., citing 21 CFR 813.5 (1996).

While the regulations specific to intraocular lenses at issue in *Becker*, 21 CFR 813.1 *et seq*. (1996), have been repealed, they are sufficiently similar to the regulations that apply to all other experimental medical devices, 21 CFR 812.1 *et seq*. (2014), to warrant the conclusion that the latter regulations also impose federal requirements "applicable to the device," in satisfaction of the first element of the *Lohr* test for preemption under the MDA. 21 USC 360k(1); *Lohr*, 518 US at 500. Each set of regulations exempts devices from the same sections of the FDCA, 21 CFR 812.1(a) (2014); 21 CFR 813.1(b) (1996), sets the procedure for and content of an application for an investigational study, 21 CFR 812.20 (2014); 21 CFR 813.20 (1996), describes the required contents of the investigational plan, 21 CFR 812.25 (2014); 21 CFR 813.25 (1996), requires sponsors to submit a detailed report of previous investigations involving the same device or intraocular lens, 21 CFR 812.27 (2014); 21 CFR 813.27 (1996), places similar responsibilities on investigation sponsors, 21 CFR 812.40-47 (2014); 21 CFR 813.40-50 (1996), and grants an institutional review board the authority to review and monitor investigations, 21 CFR 56.101 *et seq.* (2014); 21 CFR 812.62 (2014); 21 CFR 813.60-66 (1996). The FDA handled applications similarly and reserved similar grounds for disapproving applications, including misstatements or omissions of material fact and undue risk to the subjects of the study. 21 CFR 812.30 (2014); 21 CFR 813.30 (1996).

Each proposed IDE is, therefore, subject to several federal requirements. Plaintiffs' implication that only a regulation specifically pertaining to vascular-closure devices constitutes a federal requirement for the purposes of preemption under 21 USC 360k is unavailing in light of *Riegel*, which held that the PMA process itself established federal requirements despite the nonexistence of regulations specifically pertaining to balloon catheters, the device at issue in that case. *Riegel*, 552 US at 322-323. While the FDA had not established regulations that covered all balloon catheters, the Supreme Court reasoned, it had reviewed the defendant manufacturer's PMA application, specific to the Evergreen Balloon Catheter, for safety and efficacy. *Id.* at 323.

and "[f]ederal law entitles the producers of investigational devices to hold users to their bargains; state tort law cannot undermine contracts protected by federal law." *Id.*

See also *Chambers v Osteonics Corp*, 109 F3d 1243, 1247-1248 (CA 7, 1997) ("[C]laims for strict liability or breach of the implied warranty of merchantability set up a direct collision with federal policy because the FDA has already decided, rightly or wrongly, that a particular device can be sold, subject only to requirements, procedural in character and designed to assure that this experimental distribution was in fact a worthwhile experiment.").

Like PMA applications, IDE applications are focused on safety and efficacy and "specific to individual devices," see 21 USC 360j(g)(2)(A), and plaintiffs do not advance any principled reason for concluding that the latter applications are not device-specific requirements under *Riegel.*

The next question under *Lohr* is whether Michigan's product-liability law imposes a state requirement "with respect to" medical devices that is related "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Lohr*, 518 US at 500. Plaintiffs alleged, relative to the underlying products-liability claim, that the vascular-closure device was contraindicated for nursing mothers and that plaintiff Shelley A. Bush ("Shelley"), should not have been allowed to participate in the research study because she was nursing her five-month-old infant at the time of her surgery. Plaintiffs conclusorily allege that the vascular-closure device "was not appropriate for use on a patient like [Shelley] because she was a lactating mother" and that its sale to her was "unlawful" because it violated "Michigan products liability law," but do not specify any common-law or statutory duty that was breached.

In 1995, the Legislature abolished the common-law duty to warn of dangers involving the use of a product and enacted a series of laws, MCL 600.2945 *et seq.*, with respect to that duty. *Greene v AP Prods, Ltd*, 475 Mich 502, 507-508; 717 NW2d 855 (2006). MCL 600.2948(3) provides:

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a failure to provide adequate warnings or instructions, a manufacturer or seller is not liable unless the plaintiff proves that the manufacturer knew or should have known about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer.

To the extent that this subsection encompasses medical devices,[5] it is a state requirement "with respect to" such devices that is related "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Lohr*, 518 US at 500. Because an FDA-authorized institutional review board approved the IDE application for the vascular-closure device, including the consent form Shelley signed,[6] Michigan's product-liability statutes are state requirements that are "different from, or in addition to," federal requirements. *Lohr*, 518 US at

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[5] " '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." MCL 600.2945(h). " 'Product' includes any and all component parts to a product." MCL 600.2945(g).

[6] The consent form stated that "[w]omen who are . . . nursing a child may not participate in this study" and that one of the risks of the study was tearing or puncture of the artery wall.

The FDA granted the PMA application for the vascular-closure device on December 21, 2005. Shelley's surgery was performed on August 12, 2004, during the study that took place from June 29, 2004 to June 29, 2005.

500. As the Seventh Circuit observed, holding the product-liability defendants liable under Michigan law "could impose liability on [them] for an experimental device that meets all FDA standards and requirements but is still somehow adjudged unreasonably dangerous," contrary to the purposes of preemption and of the closely monitored experiment. *Chambers v Osteonics Corp*, 109 F3d 1243, 1247 (CA 7, 1997).

In summary, *Lohr* held that a state or local requirement is preempted, under 21 USC 360k of the MDA, if (1) a federal requirement exists that is "applicable to the device" in question, (2) a state requirement "with respect to" medical devices exists that is related "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and (3) the state requirement is "different from, or in addition to," federal requirements. *Lohr*, 518 US at 500. As those three elements have been satisfied in this case, plaintiffs' product-liability claim against the individuals and entities that manufactured and sold the vascular-closure device was preempted by the MDA. Accordingly, summary disposition was warranted under MCR 2.116(C)(10). Plaintiffs have failed to establish a genuine of material fact on the question of proximate cause, i.e., that "but for an attorney's alleged malpractice, the plaintiff[s] would have been successful in the underlying suit." *Manzo*, 261 Mich App at 712.

Because we hold that the trial court correctly granted defendant's motion for summary disposition on the grounds that the underlying claim was preempted by federal law, we do not address the trial court's grant of summary disposition on the alternate grounds alleged by defendants, specifically that the learned-intermediary and sophisticated-user doctrines would have caused plaintiffs claim to fail.[7]

Plaintiffs also argue that the trial court's grant of summary disposition, and subsequent denial of their motion for reconsideration,[8] was "too drastic" because plaintiffs were not aware, due to an oversight, that defendants had set a date and time for a hearing on their motions for summary disposition. We disagree. Plaintiffs do not demonstrate any error; rather, their argument oscillates between blaming defendants for the apparent placement of the notices of hearing and citing the interests of justice. For the reasons noted, this is insufficient to demonstrate that summary disposition was improvidently granted. Moreover, plaintiffs have obtained the relief they sought in this section of their brief on appeal, specifically, de novo

[7] We note that, unlike the grant of summary disposition on the grounds of preemption, the trial court did not indicate the basis for its ruling in its order granting defendants' motion for summary disposition based on learned-intermediary and sophisticated-user doctrines; rather, the trial court granted summary disposition "for reasons stated on the record" and noted in its order that "[p]laintiffs failed to appear and no response was filed." The transcript of the motion hearing also reflects no substantive reasoning, but merely further indicates that "We have not had a response, they have not checked in. Motion will be – both motions are granted."

[8] A motion for reconsideration will be granted only if the moving party "demonstrate[s] a palpable error by which the court and the parties have been misled and show that a different disposition of the motion must result from correction of the error." MCR 2.119(F)(3); *In re Estate of Moukalled*, 269 Mich App 708, 714; 714 NW2d 400 (2006).

review of the trial court's grant of summary disposition to defendants. For these reasons also, the trial court did not err in granting summary disposition or in denying plaintiffs' motion for reconsideration.

Affirmed.

/s/ Michael J. Riordan
/s/ Pat M. Donofrio
/s/ Mark T. Boonstra