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NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FIVE

JAMES HORTON, SR., et al., Plaintiffs and Appellants, v. ENDOCARE, INC., et al., Defendants and Respondents.	B265724 (Los Angeles County Super. Ct. No. SC116569)

APPEAL from a judgment of the Superior Court of Los Angeles County, Craig D. Karlan, Judge. Affirmed.

Law Office of Martin Stanley and Martin Louis Stanley for Plaintiffs and Appellants.

Reed Smith, Stephen J. McConnell, Zareh A. Jaltorossian and Natasha Sung, for Defendants and Respondents.

Beatrice Horton (Horton) died several weeks after undergoing a "cryoablation" procedure to treat recurring lung cancer. Her husband, son, and estate (plaintiffs) sued Endocare, Inc. and HealthTronics, Inc. (defendants), the manufacturer of the cryoablation device used during the procedure. Plaintiffs alleged multiple causes of action, including strict products liability, negligence, breach of warranty, and fraud. The trial court granted summary judgment for defendants on all of plaintiffs' claims, and we now consider whether there are any issues of material fact requiring trial such that the grant of summary judgment must be reversed.

I. BACKGROUND

A. Facts Concerning Horton's Treatment

Horton was diagnosed with stage IIIA lung cancer in 2002 and entered remission after being treated with chemotherapy and radiation. In 2007 and 2009, she developed additional malignancies, which physicians surgically removed. Then, in 2010, doctors found two new growths in Horton's lungs, one of which appeared to be a recurrence of her 2002 cancer. According to her doctors, the mass was difficult to biopsy and treat because of its proximity to blood vessels and because of previous radiation therapy Horton had undergone.

After doctors determined Horton's new tumor could not be treated with surgery or radiation, she agreed to undergo cryoablation, a procedure we will describe in greater detail momentarily. Interventional radiologists Dr. Robert Suh (Suh) and Stephen Pan performed the cryoablation using two Perc-24 cryoablation probes manufactured by defendants. Suh described Horton's case as "very challenging" because the tumor was close

to her esophagus and trachea, risking injury to those structures though the ablation procedure. Horton's referring physician told Suh radiation was not an option and Horton "underst[ood] the limitations."

Defendants' Perc-24 CryoProbe is a single-use device designed to cause cell death through freezing. After being connected to defendants' "cryosurgical system" (essentially, a generator), the probe is positioned by the treating physician with the guidance of imaging tools. The physician then uses the probe to deliver "ice balls" to the targeted cells. The Food and Drug Administration (FDA) authorized defendants to market their cryoablation probe for use in pulmonary surgery in 2002. Defendants sell the probe only to hospitals and physicians, not to the general public.

The directions for use prepared for each Perc-24 CryoProbe identified the following "WARNINGS" among others: "The cryosurgical system produces extreme cold which results in a necrotic effect on tissue. The effects of cryosurgery on tissues of various types must be well understood. . . . [¶] Tissue perforation can occur if the CryoProbe™ is applied for excessive periods of time. [¶] Position the CryoProbe™ tip only in tissue intended for treatment. [¶] Screen tissues that are in close proximity to known arteries or veins to precisely locate these circulatory structures." The directions also advised of the following possible "COMPLICATIONS": "As with all surgical procedures, the possibility of adverse reactions such as pain, fever, chills, sepsis, edema, perforation, ulceration and hemorrhage may occur." The directions warranted that "reasonable care ha[d] been used in the design and manufacture

of th[e] instrument" but otherwise disclaimed all other warranties not expressly provided for in the directions.

Defendants' Vice-President of Manufacturing Operations and Quality, Scott Eden (Eden), who had been with the company since 2010, was not aware if defendants had tested the Perc-24 probe on animal or human tissue, if tests had been performed to measure the nature and extent to which the probe caused inflammation outside the targeted freeze area, or if tests had been done to determine at what temperatures and after what duration of time use of the probe could cause tissue perforation. To his knowledge, there had been just one death associated with the Perc-24 probe prior to Horton's, and it involved prostate surgery.

Eden was aware the FDA sent a "warning letter" to defendants in May 2010 (before Horton's cryoablation) notifying them a review of defendants' complaint files revealed "unintended frosting of these devices [Perc-24 probes] during patient treatment"; such occurrences were "examples of events that reasonably suggest [the device] may have caused or contributed to a serious injury, or have malfunctioned"; and the probe "would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." The agency directed defendants to correct the problem. Defendants thereafter commenced a remediation program of some sort. In November 2011, the FDA sent another letter to defendants acknowledging they had adequately addressed the issue. The Perc-24 directions for use did not include a warning regarding any risk of unintended frosting. Defendants did not inform doctors, including Suh, a warning letter had been issued because, according to Eden, doing so "[wasn't] standard procedure in the

medical device industry . . . ." Nor did defendants inform Suh that any complaints of injuries had been submitted to the FDA.[1]

Suh had performed "several hundred" cryoablation procedures prior to Horton's procedure in April 2011. UCLA Medical Center, where he practiced, was one of the most experienced facilities in the country in treating the lung with ablation, and the volume of procedures performed at the facility was close to the highest, if not the highest, in the country. According to Suh, "ablation in general is much more inherently safe and less invasive than surgery [because physicians performing ablation] can offer local control or tumor eradication at sites much more safely than a surgeon could." Since 2005 or 2006, Suh had exclusively used defendants' probe to perform cryoablation, and it was the only device available at UCLA for the type of procedure performed on Horton.

Among the general risks associated with pulmonary cryoablation of which Suh was aware were the possibility of "freezing tissue that's either vital or not in the tissue that you want to damage," including areas affecting "certain vital structures" such as "the esophagus, the trachea, the heart, the pericardium that covers the heart, [and] the larger pulmonary vessels both in the lung and at the root of the lung," as well as post-procedure complications including infection, fever, and inflammation that could affect tissues beyond the treated area. Suh was also aware cryoablation could perforate or damage

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[1] When plaintiffs' counsel asked Suh at deposition if he would have liked to have known about such complaints, he responded, "It would have been useful, depending on what—the nature and scope of injury." Counsel did not inquire further.

structures surrounding the targeted area, though he believed such complications rarely occurred.

Prior to Horton's procedure, Suh had never had a patient experience a tracheal or esophageal perforation from cryoablation. Nor, to his knowledge, had any of his patients died or suffered from serious injuries caused by cryoablation. Based on a 2005 or 2006 study he read, Suh was aware cryoablation had infrequently resulted in death, but he could not recall what cryoablation method or methods had been used in those circumstances or how the patients had died. Suh had reviewed the Perc-24 directions for use at some point prior to Horton's procedure and the warnings and complications set forth in the directions were consistent with his knowledge. But Suh did not recall ever seeing any advertisements or promotional literature for the Perc-24 probe, and he never relied on any representatives of defendants to instruct him on how to perform a procedure or use their device. Suh and his colleagues performed their own tests to determine the best methods for treating patients with cryoablation.

The day before Horton's procedure, Suh discussed with her the risks of injury to her trachea and esophagus because of their proximity to her tumor. Suh told Horton he would place her under general anesthesia in order to monitor and protect those areas during treatment. Suh also tested both the probes and the generator prior to the procedure to ensure they were functioning correctly, which he determined they were.

During the procedure, Suh treated Horton by positioning the probes "to achieve adequate coverage of the ablation zone to encompass the entire targeted mass" and applying alternating freeze and thaw cycles to the targeted area. Suh had seen the

cryoablation devices malfunction in the past, but he noticed no indications the devices performed improperly during Horton's treatment. He saw no frosting of the probe "beyond what would be normally expected." He deemed the procedure "[t]echnically successful," reporting that "[p]ost-treatment CT images confirm[ed] adequate coverage of the freeze zone to encompass the entire targeted lesion." Images showed no contact had been made with Horton's trachea during the procedure.

Horton died approximately one month after the cryoablation procedure. She was 66 years old. According to plaintiffs, the Perc-24 perforated Horton's trachea, or caused it to become perforated, which resulted in tracheal necrosis (cell death) and a fistula (an abnormal passage from an organ or body part), along with complications including pneumonia, respiratory failure, and septic shock.[2] Suh opined that the tracheal perforation did not occur until weeks after the procedure because images showed no contact was made with the trachea during the procedure and "if [the medical staff] caused a tracheal perforation or significant tracheal injury or even a minor tracheal injury, we would have seen those signs and symptoms much earlier." Suh was uncertain how Horton's trachea was perforated but theorized her tumor may have been "buttress[ing] the tracheal wall or . . . close enough to it" such that eradicating the tumor affected the integrity of the trachea itself. Alternatively, he postulated an inflammatory response to the procedure may have damaged the trachea.

Defendants maintained they had never received a complaint associating the Perc-24 probe with a possible tracheal

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[2] The record does not contain Horton's autopsy report, which might shed further light on the cause of death.

perforation prior to Horton's death. Eden reviewed all identifiable lots of the Perc-24 probes sold to UCLA that might have been used during Horton's procedure and none deviated from defendants' manufacturing specifications. Defendants asked UCLA for the actual probes used during Horton's procedure but were informed the probes were unavailable. Plaintiffs acknowledged neither they nor Horton had ever seen any documentation or advertisements regarding the Perc-24 probe.

B. Procedural History

Plaintiffs sued defendants in 2012 for (1) strict products liability based on theories of design defect, manufacturing defect, and failure to warn; (2) negligence; (3) breach of implied and express warranties; (4) deceit/fraudulent concealment; (5) negligent misrepresentation; (6) loss of consortium; (7) wrongful death; and (8) survival.[3] Plaintiffs alleged Horton died after defendants' cryoablation probe caused a perforation of her trachea and asserted defendants were liable because they did not adequately test the probe, did not safely design or engineer it, and concealed and misrepresented its risks, rendering the device unsafe even when it was used as intended. Based on allegations defendants' conduct was willful, plaintiffs sought punitive damages.

Defendants successfully demurred to plaintiffs' breach of implied warranty cause of action, and subsequently moved for

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[3] Plaintiffs asserted their causes of action for negligence, wrongful death, loss of consortium, and survival against various physicians and medical facilities involved in Horton's surgery and care, in addition to defendants Endocare and HealthTronics. Those claims are not at issue in this appeal.

summary judgment or, in the alternative, summary adjudication, as to plaintiffs' remaining claims. Defendants supported their summary judgment/adjudication motion with portions of Suh's deposition testimony, portions of the deposition testimony given by Horton's husband and son, Horton's medical records, defendants' product literature for the Perc-24 probe, a declaration by Eden, and responses by plaintiffs to defendants' interrogatories. Defendants contended there was no evidence of any manufacturing defects in the Perc-24 probes used during Horton's procedure and plaintiffs thus could not establish a cause of action under strict liability or negligence on the basis of such a defect. Defendants additionally contended they were immune from strict products liability on a design defect theory, analogizing to cases holding manufacturers of prescription drugs and certain medical devices immune from such liability.[4] Defendants also argued the record showed no triable issues regarding plaintiffs' causes of action for strict liability and negligence based on a failure to warn theory. They asserted they had provided warnings about the risks of the Perc-24 probe that were adequate as a matter of law, and that, in any event, plaintiffs could not establish any failure to warn caused Horton's death because Suh was independently aware of the pertinent

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[4] Defendants believed a design defect theory of products liability was no longer viable because defendants had demurred to plaintiffs' strict liability cause of action and the trial court had described plaintiffs' strict liability claim as "improper manufacture of the device or the failure to warn of its known or knowable dangers" when overruling defendants' demurrer. Defendants interpreted the court's statement as sustaining their demurrer insofar as it challenged plaintiffs' design defect theory of strict liability.

risks, regardless of defendants' disclosures. Nor was there evidence Suh would have treated Horton differently had he received a different warning.

As to the breach of express warranty claim, defendants contended plaintiff could not prevail because there was no evidence Suh or Horton had relied upon any literature, advertisements, or other statements of defendants about the product, and because plaintiffs had not identified any express warranty or a breach thereof. They argued plaintiffs' claims for deceit and negligent misrepresentation were subject to summary judgment or summary adjudication for similar reasons, i.e., there was no evidence defendants made any misstatements or omissions upon which Suh or Horton relied. (Without evidence in support of a fraud cause of action, defendants argued plaintiffs' punitive damages claim also failed.) Finally, defendants asserted plaintiffs' causes of action for loss of consortium, wrongful death, and survival were derivative of plaintiffs' other causes of action and were consequently without merit.

Plaintiffs countered that defendants failed to carry their burden to prove by undisputed evidence the Perc-24 probes used in Horton's procedure were properly manufactured or designed such that summary judgment for strict liability or negligence was warranted. Plaintiffs asserted defendants were not immune from strict liability on a design defect theory because the case authority cited by defendants in support of immunity applied only to prescription drugs and implantable medical devices (and the Perc-24 probe was neither). Plaintiffs also contended the evidence showed defendants' warnings were inadequate because critical information had been withheld from Suh, namely, defendants had never tested the probe on human or animal

tissue, no scientifically established proof showed cryoablation to be effective in treating the lung, the probe was subject to unintended frosting, the probe could cause inflammation, and defendants were aware of a death associated with use of the probe. Plaintiffs additionally maintained defendants' alleged withholding of information concerning the risks of cryoablation, the lack of testing, and the FDA warning letter was intentional and sufficient to support liability for fraud and punitive damages.

In support of their opposition to summary judgment, plaintiffs submitted an expert witness declaration from Dr. Carl Boylen (Boylen), a physician and professor of pulmonary medicine. He opined cryoablation of the lung was an experimental procedure without any scientifically proven efficacy. He further opined the procedure should not have been offered to Horton because the risks of the procedure were substantial (given the fragility of lung tissue, the tumor's placement near her trachea and esophagus, and the lack of proven results from cryoablation) and there was no potential benefit. The trial court sustained objections to portions of Boylen's declaration opining on the cause of Horton's death, namely, that it was in his view attributable to inflammation caused by the cryoablation, defectiveness of the Perc-24 probe, and defendants' failure to provide adequate warnings.

The trial court held a hearing on defendant's summary judgment/adjudication motion but the record on appeal contains no reporter's transcript or settled statement of the proceeding. The court, however, issued a written ruling that describes some of what transpired. The ruling states, for example, that during oral argument plaintiffs "conceded no evidence supports a claim for manufacturing defect." The court's ruling also states that

"[d]uring oral argument, [plaintiffs] clarified their design defect claim is based on [defendants'] failure to test the Perc-24 CryoProbe on human or animal tissue" and that the lack of such testing also formed one of the bases of their failure to warn claim.

Apparently owing to plaintiffs' "clarification" of their theories, the court continued the summary judgment hearing and asked the parties to address in supplemental submissions whether or not the Perc-24 probe was tested on human tissue, whether Suh would have acted differently had he been warned the device was not tested on human tissue, and whether the device failed to perform as designed because it was not tested on human tissue. In their supplemental filing, defendants argued there was no evidence defendants had *not* tested the Perc-24 on human tissue, only that Eden was unaware of any such testing. Defendants also argued there was no evidence Suh would have treated Horton differently had he known there was no such testing, nor evidence the device malfunctioned because of the absence of such testing. Defendants pointed in particular to Suh's testimony that the probes did not malfunction during Horton's procedure and testing his own team had done using the probes—albeit not on humans, because doing so would risk harming the subjects. Plaintiffs' supplemental submission cited portions of Eden's declaration in which he acknowledged he had not seen documentation stating defendants tested the probes on human tissue, portions of Suh's deposition in which he described what testing materials of defendants he reviewed, and portions of Boylen's declaration that were later excluded, in relevant part, by the trial court.

The trial court granted summary judgment for defendants in full. As to plaintiffs' strict liability cause of action, the court

stated plaintiffs had conceded no evidence supported their manufacturing defect theory. Plaintiffs' design defect theory fared no better in the court's view because defendants had made a prima facie showing there was no evidence of a defect. The court explained plaintiffs had presented no admissible evidence the Perc-24 performed less safely than expected by "an ordinary consumer—in this case a surgeon," and there was no evidence that any failure by defendants to test the device on human or animal tissue made it defective. Regarding plaintiffs' failure to warn theory on the products liability claim, the court found it failed for lack of any evidence of causation: Suh was independently aware of the risks associated with the Perc-24 and there was no evidence he would have treated Horton differently had he received additional warnings from defendants. The court concluded plaintiffs' negligence cause of action failed on the same bases as their strict liability cause of action. As to plaintiffs' express warranty, deceit, and negligent misrepresentation claims, the court ruled plaintiffs had not put forward evidence that would permit a trier of fact to conclude defendants made any warranties, fraudulent statements, or misrepresentations, which also meant plaintiffs by definition could not show reliance on any such statements. The court also ruled in favor of defendants on plaintiffs' loss of consortium, wrongful death, and survival causes of action because these claims were derivative of plaintiffs' claims for strict liability and negligence.

In rendering its ruling, the trial court overruled plaintiffs' evidentiary objections to Eden's declaration but said the "objected to matters had no bearing on the Court's ruling" because it had granted summary judgment for defendants on plaintiffs' manufacturing and design defect theories for "reasons

independent from Mr. Eden's testimony." Significantly, however, the court did sustain defendants' evidentiary objections to substantial portions of plaintiff expert witness Boylen's declaration, as well as to a declaration offered by Horton's husband.

II. DISCUSSION

At its core, plaintiffs' case is predicated on the claim that the Perc-24 probes were defectively designed because they could suffer from "unintended frosting" and that the probes were accompanied by inadequate warnings of this potential for unintended frosting and inadequate warnings the probe might cause inflammation. Plaintiffs attributed the alleged defective design largely if not entirely to defendants' undisclosed failure to test the probe on human or animal tissue. On appeal, plaintiffs continue to assert defendants could be found liable at trial under multiple tort theories, but our independent review of the record convinces us otherwise. There are no triable issues as to strict products liability, negligence, or the other causes of action because defendants have shown plaintiffs cannot establish a defect in the probes used in Horton's procedure caused her harm or that Horton relied on defendants' representations or nondisclosure to her detriment.

A. Adequacy of the Record

Initially, we address whether plaintiffs' failure to provide a reporter's transcript or suitable substitute of the summary judgment hearings in the trial court requires us to affirm because the record is inadequate to warrant reversal. (*Osgood v. Landon* (2005) 127 Cal.App.4th 425, 435 [trial court decision presumed

correct and appellant has affirmative duty to show error by a adequate record].) Plaintiffs argue the appendix they submitted includes documents sufficient to support their contentions on appeal and that the trial court's written ruling on summary judgment adequately conveys the arguments made by the parties for which no transcript or settled statement is provided. Defendants contend the record is insufficient because significant events occurred at oral argument, including plaintiffs' abandonment of their manufacturing defect claim and "clarif[ying]" their theories of design defect and failure to warn. Because the limited record does not fully reflect how those claims were addressed at oral argument, defendants argue, it is unclear what claims plaintiffs have forfeited.

We find the record adequate to decide the parties' contentions on some issues. But where plaintiffs have failed to provide a sufficient record on particular points relevant to our disposition of the appeal, we necessarily resolve those points in defendants' favor. (*Maria P. v. Riles* (1987) 43 Cal.3d 1281, 1295-1296.)

B. Standard of Review

A party is entitled to summary judgment where "all the papers submitted show that there is no triable issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." (Code Civ. Proc., § 437c, subd. (c).) We review a grant of summary judgment de novo, "considering all the evidence set forth in the moving and opposition papers except that to which objections have been made and sustained.

[Citation.]"[5] (*Guz v. Bechtel Nat., Inc.* (2000) 24 Cal.4th 317, 334; *Coral Const. Inc. v. City and County of San Francisco* (2010) 50 Cal.4th 315, 336 ["'[I]t is axiomatic that we review the trial court's ruling[ ] and not its reasoning'"].) We evaluate the evidence and all reasonable inferences therefrom "in the light most favorable to the opposing party." (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 843 (*Aguilar*).) A moving

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[5] Our Supreme Court has not yet decided whether a trial court's evidentiary rulings are subject to review de novo or for abuse of discretion. (*Reid v. Google, Inc.* (2010) 50 Cal.4th 512, 535.) This lingering uncertainty does not impact our resolution of this appeal because plaintiffs have not adequately challenged, and have therefore forfeited, any objections to the correctness of the trial court's evidentiary rulings. (*Wall Street Network, Ltd. v. New York Times Co.* (2008) 164 Cal.App.4th 1171, 1181 [plaintiff forfeits appellate review of unchallenged evidentiary rulings made by trial court in summary judgment proceedings]; *Roe v. McDonald's Corporation* (2005) 129 Cal.App.4th 1107, 1114 (*Roe*).) Specifically, plaintiffs rely heavily on portions of the declaration of their expert witness, Boylen, that the trial court excluded. Plaintiffs, however, do not "identify the court's evidentiary ruling as a distinct assignment of error" (*Roe*, *supra*, 129 Cal.App.4th at p. 1114) or provide any analysis of why the court's ruling was improper other than to state, in a single sentence in their opening brief: "The Superior Court erred in failing to properly consider and find triable issues of material fact in the declaration of . . . Boylen." That statement is insufficient to place in issue the correctness of the trial court's evidentiary ruling. (*Badie v. Bank of America* (1998) 67 Cal.App.4th 779, 784-785.) Consequently, we deem those portions of Boylen's declaration excluded by the trial court to have been properly disregarded and we do not consider them in our independent review. (See, e.g., *Lopez v. Baca* (2002) 98 Cal.App.4th 1008, 1014-1015.)

defendant succeeds by demonstrating the plaintiff cannot establish one or more elements of the ' plaintiff's cause of action (Code Civ. Proc., § 437c, subd. (p)(2); *Aguilar,* 25 Cal.4th at p. 853), either by showing "the plaintiff 'has not established, and cannot reasonably expect to establish, a prima facie case . . . .' [citation]" (*Miller v. Dept. of Corrections* (2005) 36 Cal.4th 446, 460) or by conclusively negating an essential element of the plaintiff's claim (*Aguilar*, *supra*, 25 Cal.4th at p. 853). If the defendant relies on the first alternative, the defendant must show "the plaintiff does not possess, and cannot reasonably obtain, needed evidence . . . ." (*Id*. at p. 854.) The defendant may establish an absence of evidence by pointing to "factually devoid discovery responses . . . ." (*Collin v. Calportland Co.* (2014) 228 Cal.App.4th 582, 587.)

C. Strict Liability

"'The elements of a strict products liability cause of action are a defect in the manufacture or design of the product or a failure to warn, causation, and injury.' [Citations.] Plaintiff must ordinarily show: '" (1) the product is placed on the market; (2) there is knowledge that it will be used without inspection for defect; (3) the product proves to be defective; and (4) the defect causes injury . . . ."' [Citation.]" (*Nelson v. Superior Court* (2006) 144 Cal.App.4th 689, 695, italics omitted.) Here, plaintiffs' strict liability cause of action was premised upon all three possible theories: manufacturing defect, design defect, and failure to provide adequate warning.

1. Manufacturing defect

Manufacturing defects may be found where the product failed to conform to its intended design or performed differently from other units of the same product line—for instance, because of a flaw in the manufacturing process. (*Webb v. Special Electric Co.* (2016) 63 Cal.4th 167, 180 (*Webb*); *Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 429 (*Barker*).) Although the trial court granted summary adjudication for defendants on the ground plaintiffs "conceded no evidence supports a claim for manufacturing defect," plaintiffs contend the theory remains viable because defendants failed to meet their initial burden under the summary judgment standard. The argument is meritless. Defendants' burden was to show plaintiffs "do[ ] not possess, and cannot reasonably obtain, needed evidence" to establish a prima facie case. (*Aguilar*, *supra*, 25 Cal.4th at p. 854.) Defendants did just that by highlighting the absence of facts in plaintiffs' responses to their special interrogatories on the issue of manufacturing defect, as well as Suh's deposition and post-operative report. Plaintiffs then cemented the point by conceding they lacked evidence to support their manufacturing defect claim.

2. Design defect

A product is defectively designed if it "'failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner' (consumer expectations test)"or "'the risk of danger inherent in the product's design outweighs the design's benefits (risk-benefit test). . . .'" (*Webb*, *supra*, 63 Cal.4th at p. 180 [citing *Barker*, *supra*, 20 Cal.3d at p. 432].) Under the risk-benefit test, "once

the plaintiff makes a prima facie showing that the injury was proximately caused by the product's design, the burden should appropriately shift to the defendant to prove, in light of the relevant factors, that the product is not defective." (*Barker*, *supra*, 20 Cal.3d at p. 431.) Such factors include "the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design." (*Ibid.*)

Plaintiffs do not rely on a consumer expectations theory to argue the trial court incorrectly granted summary judgment on their design defect theory of strict liability. Rather, they only assert the trial court erred because defendants did not produce evidence to defeat a design defect claim under the risk-benefit test, i.e., that the benefits of the Perc-24 probe outweighed its risks.

Plaintiffs are correct to observe defendants' motion for summary judgment did not engage in an analysis of the risks and benefits of their cryoablation probe. Instead, defendants presented two arguments that would have the effect of demonstrating plaintiffs could not prevail on a risk-benefit design defect theory: (1) they were immune from strict liability on a design defect theory pursuant to *Brown v. Superior Court* (1988) 44 Cal.3d 1049 (*Brown*), and (2) there was no evidence by which plaintiffs could make the requisite prima facie showing that the harm to Horton was proximately caused by the Perc-24 probe's design.

As we have noted, there is no reporter's transcript or settled statement of the summary judgment hearings in the

record. We do have, however, the trial court's statement that "[d]uring oral argument, [plaintiffs] clarified their design defect claim is based on [defendants'] failure to test the Perc-24 Cryoprobe on human or animal tissue" and the court's finding that defendants "made a prima facie showing there is no evidence of design defect." We also know the court relied on Suh's testimony that the probe performed as expected during Horton's procedure. Considering that testimony and other evidence, the court concluded: "Plaintiffs have failed to present any admissible evidence that the device failed to perform as safely as an ordinary consumer—in this case a surgeon—would expect. Nor have Plaintiffs presented any evidence of a defect in the design of the product. Rather, Plaintiffs' design defect theory is duplicative of their failure to warn theory in that both Plaintiffs' design defect and failure to warn theories are premised on the lack of human or animal tissue testing. There is no admissible evidence before the court, though, that the device is defective due to Defendants' failure to test it on human or animal tissue. As such, Plaintiffs' design defect theory fails."

Particularly in light of the references in the trial court's ruling to clarifications that plaintiffs apparently made during the summary judgment hearing concerning this specific issue, we conclude the absence of a transcript or settled statement of the proceedings—which would precisely detail the clarifications and concessions made—precludes reversal of the trial court's resolution of the strict liability design defect claim. (*Randall v. Mousseau* (2016) 2 Cal.App.5th 929, 935; *Henderson Brothers Stores, Inc. v. Smiley* (1981) 120 Cal.App.3d 903, 920, fn. 10.)

Even on the inadequate record that is before us, we would hold summary resolution of the claim was proper because there is

no admitted evidence that would support a prima facie case of proximate causation, i.e., that defendants' cryoablation probe caused Horton's injuries and death via unintended frosting. Suh testified the probes were functioning properly both before and during the procedure, no abnormal frosting was evident, and images showed the probe did not freeze more tissue than intended. Suh also averred he did not typically rely on testing done by device manufacturers because while, "as an investigator of some type in a kind of academic environment, you want companies to do certain protocols and so forth . . . that might not be in their best interest . . . ." Suh further indicated he and his colleagues relied on their own experiments, which they *had* conducted on animals. (They did not use human subjects because they "couldn't sacrifice the humans that we [performed tests] on.") We see no admitted evidence in the record that establishes a material dispute of fact on any of these points. Accordingly, there was no evidence that would establish, prima facie, a causative link between Horton's injuries and a defect in the Perc-24 probe design.[6]

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[6] Suh's statement that he would have found it "useful" to have information about patients' complaints about the Perc-24 to the FDA "depending on . . . the nature and scope of injury" does not establish a triable issue. Suh stated that UCLA used only defendants' device for the type of cryoablation procedure performed on Horton and that, given the nature and extent of her condition, cryoablation was the only viable treatment option for her.

3. Failure to warn

Failing to provide an adequate warning about a product's inherent danger may render the product defective. (*Anderson v. Owens-Corning Fiberglas Corporation* (1991) 53 Cal.3d 987, 995-996 (*Anderson*).) Thus, manufacturers can be held strictly liable for not warning consumers about known or knowable hazards in their products. (*Webb*, *supra*, 63 Cal.4th at p. 181; *Anderson*, *supra*, at p. 1000.) While the manufacturer's duty runs "to all entities in a product's supply chain" (*Webb*, *supra*, at p. 185), the manufacturer of a prescription drug or medical device discharges its duty to warn the ultimate user of its product, that is, the patient, where it provides adequate information to the patient's treating physician. (*Id.* at p. 187, fn. 10; *Brown*, *supra*, 44 Cal.3d at p. 1062, fn. 9.)

The record reveals no triable issues of material fact on plaintiffs' strict liability failure to warn claim because defendants have shown plaintiffs cannot establish a prima facie case of a warning defect, particularly with respect to the element of causation. The Perc-24 probe was accompanied by numerous warnings of potential risks and complications including tissue necrosis, perforation, the importance of proper probe placement relative to critical structures, and sepsis. Suh testified to his independent knowledge of these explicitly stated risks as well as to other risks defendants did not identify, including inflammation,[7] infection, and death. Although Suh agreed that

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[7] Plaintiffs asked Suh at his deposition whether defendants had warned him of the potential for inflammation from the use of Perc-24 probes prior to Horton's cryoablation. Suh replied, "Well, not warned by the company, but we have—again, that's

defendants had not advised him "about this unintended frosting issue," Suh also testified that he had sometimes seen frost on the handle of the device and that malfunction of a cryoablation device was "a known [inherent] risk with doing cryo" because gases would be pushed through the probes and "could escape in the patient" if the probe were defective. Of course, Suh also testified without contradiction that there was no unintended frosting of the devices during Horton's procedure and he would not have treated Horton differently had he known defendants did not test their cryoablation probes on humans or animals. There is no contrary admitted evidence that would permit us to conclude plaintiffs can establish, as they must to survive summary judgment, defendants' failure to warn caused Horton's injury and death. (*Ramos v. Brenntag Specialties, Inc.* (2016) 63 Cal.4th 500, 509 [to prevail on strict products liability claim for failure to warn, plaintiffs must show defendants breached a duty to provide adequate warnings and that such failure to warn caused injury]; CACI No. 1222 [element of proof on a failure to warn strict liability claim is that the failure to warn was a substantial factor in causing the plaintiff harm]; see also *Webb*, *supra*, 63 Cal.4th at p. 182 [sophisticated product users need not be warned about dangers of which they are already aware or should be aware].)

D. Negligence

Liability for negligence requires a plaintiff to establish the defendant breached a legal duty to the plaintiff to use due care and that the breach was the proximate or legal cause of the plaintiff's injury. (*Beacon Residential Community Assn. v.*

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something that we are well accustomed to, having ablated numbers of patients."

Skidmore, Owings & Merrill LLP (2014) 59 Cal.4th 568, 573; see also CACI Nos. 1220, 1222.) Plaintiffs alleged defendants breached duties to use reasonable care when designing, testing,[8] and manufacturing the Perc-24 probe, and when warning of its inherent dangers. Plaintiffs assert these breaches of duty foreseeably resulted in Horton's death.

A product may be negligently designed if the gravity of reasonably foreseeable harm from its design outweighs the product's utility or, put another way, the burden on the manufacturer to design the product differently in order to avoid the harm. (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479.) Thus, proving a negligent design cause of action is similar to proving strict liability for design defect under the risk-benefit test. (*Id*. at p. 480.)

In their motion for summary judgment, defendants contended plaintiffs could not establish liability for negligent design because they could not establish any design defect or show defendants breached a duty of care. In their opposition to defendants' motion, plaintiffs responded by heavily relying on portions of Boylen's declaration that the trial court later excluded. On appeal, plaintiffs continue to rely on the excluded portions of Boylen's declaration and, for reasons we have already

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[8] Plaintiffs' contention that defendants were negligent in their testing of the Perc-24 probe is not a freestanding basis for liability. (See *Valentine v. Baxter Healthcare Corporation* (1999) 68 Cal.App.4th 1467, 1486 [because inadequate testing will not cause injury unless it causes the manufacturer to create a defective design, manufacture, or warning, there can be no independent claim for negligent testing].)

noted, we reject their arguments that are premised on such reliance.

Plaintiffs also offer an additional argument they did not raise below, namely, that defendants breached a duty to recall and correct or otherwise retrofit the design of the Perc-24 probe after being warned by the FDA of its potential for unintended frosting. We decline to entertain this belatedly raised argument. (*City of Scotts Valley v. County of Santa Cruz* (2011) 201 Cal.App.4th 1, 28-29.) Moreover, even if the argument were properly before us, there was no evidence before the court at summary judgment indicating the probes used during Horton's procedure experienced any unintended frosting. Consequently, plaintiffs' argument would fail because there is no evidence the breach of any assumed obligation to recall the Perc-24 probes caused Horton's injury.[9]

As to plaintiffs' theory of negligence predicated on defendants' failure to warn of a product's inherent danger, plaintiffs would have to be able to show at trial that the decision not to warn "fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." (*Anderson*, *supra*, 53 Cal.3d at p. 1002.) Because the bar for proving a failure to warn claim in negligence is higher than in the strict liability context (see *Webb*, *supra*, 63 Cal.4th at

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[9] While we do not address whether defendants' receipt of the FDA warning letter imposed upon them any particular duties toward Suh or Horton, we note that such letters are not conclusive evidence the recipient has violated an FDA regulation or is otherwise guilty of the conduct described in the letter. (See *Holistic Candlers and Consumers Assn. v. Food & Drug Admin.* (D.C. Cir. 2012) 664 F.3d 940, 944.)

p. 181; *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1112-1113; *Anderson*, *supra*, at pp. 1002-1003), our resolution of the warning defect strict liability cause of action in favor of defendants dictates we reach the same outcome for plaintiffs' negligence claim based on the same theory.

We likewise conclude plaintiffs cannot prevail on their claim for negligent manufacturing. Plaintiffs admitted there was no evidence of any manufacturing defect in the Perc-24 probe and they have not pointed to any evidence suggesting defendants failed to exercise due care in manufacturing the device, regardless of any defect.

E. Fraudulent Concealment and Negligent Misrepresentation

Fraud or deceit is a cause of action requiring a "'"(a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or 'scienter'); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage.'" [Citation.]" (*Small v. Fritz Companies, Inc.* (2003) 30 Cal.4th 167, 173 (*Small*); see also Civ. Code §§ 1709 [establishing liability for "[o]ne who willfully deceives another with intent to induce him to alter his position to his injury or risk"], 1710, subd. 3 [defining deceit as "[t]he suppression of a fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact"].) Negligent misrepresentation is a species of fraud that does not require an intent to defraud or actual knowledge the misrepresentation is false; it does require, however, that the defendant induce the plaintiff to rely on the misrepresented fact and that the defendant have no reasonable

basis for believing the truth of the fact. (*Small*, *supra*, 30 Cal.4th at pp. 173-174; *Daniels v. Select Portfolio Servicing, Inc.* (2016) 246 Cal.App.4th 1150, 1166.)

In opposing summary adjudication of their deceit and negligent misrepresentation causes of action, plaintiffs again relied on their failure to warn theory, arguing defendants never disclosed (1) they did not test the Perc-24 probe on human or animal tissue, (2) the device was potentially subject to unintended frosting, and (3) the probe's use could cause inflammation. But summary judgment was proper on the record before us because plaintiffs cannot establish they justifiably relied on any deceptive statements or omissions by defendants, or that such reliance resulted in Horton's death. Defendants' duty to warn ran to Horton's treating physicians, and we have concluded plaintiffs cannot establish a triable issue regarding defendants' failure to warn Suh of the facts on which plaintiffs' deceit and misrepresentation claims depend. Moreover, Horton's husband and son (i.e., the plaintiffs other than Horton's estate) admitted neither they nor Horton saw any literature or advertisements regarding the Perc-24 probe prior to Horton's death, nor did they have any contact with defendants' representatives.

F. Breach of Express Warranty

A defendant may be liable for breaching an express warranty where the defendant breaches an "'affirmation of fact or promise'" it made to a purchaser plaintiff that formed "'part of the basis of the bargain'" between them. (*Weinstat v. Dentsply Internat., Inc.* (2010) 180 Cal.App.4th 1213, 1227 [quoting Cal. U. Com. Code, § 2313, subd. (1)(a)].) A patient may sue a medical

device manufacturer for breach of an express warranty if the patient is treated with the device by a physician to whom the warranty was made (see *Evraets v. Intermedics Intraocular, Inc.* (1994) 29 Cal.App.4th 779, 789, fn. 4) or if the patient personally saw the warranty, such as through labels or advertising (*Burr v. Sherwin Williams Co.* (1954) 42 Cal.2d 682, 696).

Here, defendants' directions for use of the Perc-24 probe expressly warranted "that reasonable care has been used in the design and manufacture of this instrument." Plaintiffs contend defendants breached that warranty by failing to test the device on human or animal tissue. There is, however, no material dispute of fact requiring trial because defendants were properly entitled to summary judgment on the negligence and strict liability causes of action based on a failure to warn, and the summary resolution of those claims establishes defendants could not have breached any promise to use "reasonable care."

G. Loss of Consortium, Wrongful Death, and Survival

Plaintiffs' loss of consortium, wrongful death, and survival causes of action depend on the viability of their other tort claims. (*LeFiell Manufacturing Co. v. Superior Court* (2012) 55 Cal.4th 275, 284-285 [loss of consortium predicated on tort to spouse]; Code Civ. Proc., §§ 377.34 [damages recoverable in survival action limited to those "the decedent would have been entitled to recover had the decedent lived"], 377.60 [wrongful death action predicated on another's "wrongful act or neglect"].) Because we have concluded the trial court correctly granted judgment for defendants on those tort claims, defendants were likewise entitled to summary resolution of the loss of consortium, wrongful death, and survival causes of action.

H. Asserted Procedural Errors

Plaintiffs also urge us to reverse the grant of summary judgment on procedural grounds. They emphasize defendants supplemented their summary judgment motion with a supplemental declaration of Eden and a new separate statement of undisputed material facts without leave of court, and just 22 days before the scheduled hearing. Plaintiffs claim these filings deprived them of adequate time to respond and violated Code of Civil Procedure section 437c, subdivision (a)(2), which requires the party moving for summary judgment to provide notice and its supporting papers at least 75 days before the time appointed for the hearing.

Plaintiffs' argument is meritless. The sole purpose of Eden's supplemental declaration was to substitute corrected exhibits—the relevant directions for use of the Perc-24 probe—in place of erroneous versions that defendants provided when first filing their motion for summary judgment or summary adjudication. The replacement exhibits were identical to the versions they replaced in all material respects; that is, the language regarding the warranty, warnings, and complications associated with the Perc-24 were the same in all documents except for an added warning concerning hepatic surgery that is immaterial on the facts of this case. Defendants revised their separate statement of undisputed material facts merely to amend the references to the substituted exhibits. There is no indication plaintiffs challenged defendants' supplemental filing in the trial court, nor have they shown how they could have been prejudiced by the replacement documents. Reversal is therefore unwarranted. (See *Professional Engineers in California Government v. Brown* (2014) 229 Cal.App.4th 861, 875 [trial court

properly considered supplemental declaration where it "raised no new theories or arguments" and opponents did not establish prejudice].)

Plaintiffs also argue the trial court should not have considered various of defendants' exhibits because they were not properly authenticated. Plaintiffs did not object to those exhibits in the trial court and have consequently forfeited any challenge on appeal. (*Reid v. Google, Inc., supra,* 50 Cal.4th at p. 525 [party must object to specific evidence in writing or at summary judgment hearing to preserve evidentiary issues on appeal]; see also Cal. Rules of Court, rule 3.1352.)

DISPOSITION

The judgment is affirmed. Defendants are to recover their costs on appeal.

NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

BAKER, J.

We concur:

KRIEGLER, Acting P.J.

KUMAR, J.*

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* Judge of the Los Angeles Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.