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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Lisa St. Clair and Richard Poulin, individually, and as parents and guardians of H.P., their minor child, Plaintiffs, vs. Nellcor Puritan Bennett LLC, Defendant.	No. CV-10–1275-PHX-LOA **ORDER**

Currently before the Court is the Motion of Defendant Nellcor Puritan Bennett LLC ("Nellcor") for Partial Summary Judgment on Plaintiffs' claims of design defect, informational (warnings) defect, and negligent testing. (Doc. 50) Plaintiffs oppose the motion. (Doc. 55) After considering the briefing and relevant law, the Court finds that a question of fact exists for jury resolution and, therefore, summary judgment is not warranted regarding Plaintiff's design defect claim. The Court will, however, grant Plaintiffs' request and dismiss Plaintiffs' failure to warn/informational defect claim.

I. Factual Background

On August 7, 2009, Plaintiffs Lisa St. Clair and Richard Poulin ("Plaintiffs"), individually and on behalf of their minor child, H.P., filed the instant products liability action in the Superior Court of Arizona, Maricopa County. After several non-diverse parties were dismissed, on June 16, 2010, Nellcor, a corporation located outside the state of Arizona,

removed this action to the District Court of Arizona. (Doc. 1) Plaintiffs allege that their minor daughter, H.P., sustained severe and permanent neurological injuries when treated with an allegedly defective resuscitator bag while a patient at Phoenix Children's Hospital ("PHC").

Plaintiffs' minor daughter, H.P. was born with a complex congenital heart disease. (DSOF ¶ 1[1]) She was born without a pulmonary valve; there was no opening in her heart for blood to move from her right ventricle to her pulmonary artery. (DSOF ¶ 2) H.P. also had a congenital defect known as Double Outlet Right Ventricle, a condition in which the aortic pulmonary artery originates from the right ventricle instead of the left ventricle. (*Id.* at ¶ 3) In November of 2004, H.P. underwent the first stage of an operation known as a Fontan procedure. (DSOF ¶ 4) A Fontan procedure is a palliative procedure that "hooks up all of the venous drainage directly into the pulmonary artery, so that all of [the] blood empties into [the] lungs, goes through [the] lungs, empties into [the] heart and goes out." (*Id.* at ¶ 6; Teaford depo. at 13) On August 22, 2007, H.P. underwent the second stage of the Fontan procedure. (*Id.* at ¶ 7) Following the August 27, 2007 procedure, H.P. had a prolonged post-operative recovery. (*Id.* at ¶ 8) On September 12, 2007, Plaintiff underwent a fenestration procedure in an attempt to improve her cardiac output because she had become very edematous[2] with ascites.[3] In layman's terms, there was fluid in H.P.'s abdomen and she

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[1] Citations to "DSOF ¶" are to Defendant's Statement of Facts in Support of its Motion for Partial Summary Judgment, doc. 51. Citations to "PSOF ¶" are to the Response of Plaintiffs' to the Statement of Facts of Defendant and Plaintiffs' Counter Statement of Facts, doc. 56.

[2] "Edematous" is the adjective for "edema" which is "an abnormal excess accumulation of serous fluid in connective tissue or in a serous cavity—called also *dropsy*." *See*, http://www.merriam-webster.com.

[3] "Ascites" is an "abnormal accumulation of serous fluid in the spaces between tissues and organs in the cavity of the abdomen—called also *hydroperitoneum*." *See*, http://www.merriam-webster.com.

could not be weaned off the ventilator. (*Id*. at ¶ 9) Dr. Teaford's prognosis was that H.P. had "poor cardiac reserve and was clearly struggling." (DSOF ¶ 10)

The next day, September 13, 2007, while H.P. was still recovering from the fenestration procedure, she developed respiratory distress. (PSOF ¶ 54) H.P.'s healthcare providers attempted to assist her, using a Nellcor manual resuscitator bag. (*Id*.) The parties offer differing accounts of precisely when the Nellcor resuscitator bag was used, and what the healthcare professionals observed while that device was being used. Viewed in the light most favorable to non-moving parties, as the Court must, the record contains evidence that the following events occurred on September 13, 2007.

At around 12:20 on September 13, 2007, H.P. was noted to be having some respiratory distress. She was initially attended to by respiratory therapist Isabella Guerena and pediatric intensivist Patricia Teaford, M.D. Ms. Guerena made the following notes regarding the events of that day:

> 12:30 [p.m.], called to patient's room for SATs in the 50s. Patient cyanotic. Extubated by Dr. Teaford after sedation given. Then code called. Compressions started. Difficult intubation tried by Dr. Teaford and Dr. Graham, then intubated by Dr. Tellez with minimal color change in Easy Cap. Visualized ETT through cords by anesthesiologist. Bag changed, then able to vent[ilate]. . . better. Compressions stopped. Heart rate returned.

(Guerena Depo. at 50[4], doc. 59 at 14)

Before extubating H.P., Dr. Teaford unhooked her from the ventilator and put her on the Nellcor manual resuscitator bag at issue. (Doc. 56 at 3; Teaford Depo. at 19) After listening to H.P's chest, Dr. Teaford heard no exchange of air and observed no chest rise. (Teaford Depo. at 19[5]) Dr. Teaford "thought [H.P.'s] tube was either plugged or dislodged."

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[4] Citations to "Guerena Depo." are to the deposition transcript of Isabelle Guerena attached to Defendant's Statement of Facts, doc. 51, Exh. 3, and to Plaintiffs' Exhibits in Support of Response of Plaintiffs to the Motion for Partial Summary Judgment, doc. 59, Exh. 2.

[5] Citations to "Teaford Depo." are to the deposition transcript of Patricia Teaford, M.D., attached to Defendant's Statement of Facts, doc. 51, Exh. 1, and to Plaintiffs' Exhibits

Dr. Teaford extubated[6] H.P., called for a code cart, and prepared the equipment to intubate H.P. (Doc. 56 at 3-4; Teaford Depo. at 19) While Dr. Teaford was preparing to intubate H.P., the respiratory therapist managed H.P.'s airway. (*Id*. at 19) Dr. Teaford then made the first attempt to intubate H.P.; however, when H.P. was "bagged," Dr. Teaford heard no air excursion in H.P.'s chest. (Teaford Depo. at 19, 23-24) Because Dr. Teaford thought she had properly intubated H.P., but heard no air excursion, Dr. Teaford asked Dr. Graham to assume control of H.P.'s airway. (*Id*. at 20, 25-26) H.P. was extubated, and Dr. Graham then re-intubated her. (Teaford Depo. at 21) Once again, no chest rise was noted, and no air excursion was heard. (Graham Depo. at 23-26) Dr. Graham testified that:

> When I intubated H.P., I watched the endotracheal tube go through the vocal cords. So I knew it was in the appropriate position. And yet following that, when we used the Ambu bag, we could not get a chest rise and nothing changed.

(Graham Depo. at 16[7]) Dr. Graham testified that based on "the results once [he] intubated H.P, it . . . became obvious that the Ambu bag was not functioning appropriately." (Graham Depo. at 16, 19) Dr. Graham reiterated that he "knew the tube was where it belonged . . . I began to use the Ambu bag on the endotracheal tube. And there was something, either a feel or a sound, I don't recall correctly which it was, that said something is wrong with this." (Graham Depo. at 19) Dr. Graham asked for another resuscitator bag, removed the ET tube

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in Support of Response of Plaintiffs to the Motion for Partial Summary Judgment, (doc. 59, Exh. 1.

[6] "Extubate" means to remove a tube, especially from the larynx after intubation. "Intubate" is to introduce a tube into a hollow organ (such as the trachea). *See*, http://www.merriam-webster.com.

[7] Citations to "Graham Depo." are to the deposition transcript of Robert Graham, M.D., attached to Plaintiffs' Exhibits in Support of Response of Plaintiffs to the Motion for Partial Summary Judgment, (doc. 59, Exh. 21).

and resumed mask ventilation. (*Id*.) Dr. David Tellez arrived on the scene, reintubated H.P., and "bagged" her. Dr. Tellez "saw there was an air leak. [H]e heard a noise. [He said] this isn't right . . . the bag isn't working right. Hand me – can somebody give me another bag." (Tellez Depo. at 9[8]) When Dr. Tellez used the new bag, H.P. responded with appropriate chest excursion. (Teaford Depo. at 27; Graham Depo. at 20-21; Guerena Depo. at 41) After H.P.'s resuscitation, respiratory therapist Kristi Richardson gave the resuscitator bag used on H.P. to PCH's materials manager, Jason Seckman, who locked the bag in PCH's area called risk management. (Seckman Depo., Exh. 23 at 14-15; doc. 59)

As Nellcor notes, respiratory therapist Guerena gave conflicting accounts of whether she observed chest rise in H.P. (Doc. 56 at 4; Guerena Depo. at 36) She testified that, after Dr. Teaford extubated H.P., while applying mask/bag ventilation to H.P., using the Nellcor resuscitation bag, she observed chest rise in H.P. continuously until she removed the mask from H.P.'s face. (DSOF at ¶ 15; Guerena Depo. at 69) Ms. Guerena also testified that "[d]uring the period of time that [she was] manually ventilating by mask," she did not observe H.P.'s chest rise. (Doc. 56 at 5; Guerena Depo. at 51) She then clarified that "there was no chest rise when we were bagging her." (*Id.*) She testified that, although she did not notice anything unusual about the bag, "the efforts from [her] standpoint to bag the patient prior to the first extubation and intubation attempt by Dr. Teaford," did not take place as she "would typically expect bagging of a patient to occur." (Doc. 56 at 5; Guerena Depo. at 56) Ms. Guerena explained that during that period, H.P.'s chest was not rising. (*Id*.)

H.P. suffered a hypoxic[9] brain injury on September 13, 2007. (PSOF ¶ 50) Plaintiffs argue that H.P. suffered the hypoxic brain injury as a result of the failure of the Nellcor manual resuscitator to function as intended when it was used to provide ventilation to H.P.

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[8] Citations to "Tellez Depo." are to the deposition transcript of David W. Tellez, M.D., attached to Plaintiffs' Exhibits in Support of Response of Plaintiffs to the Motion for Partial Summary Judgment, (doc. 59, Exh. 22).

[9] "Hypoxia" means a deficiency of oxygen. *See*, http://www.merriam-webster.com

during the events of September 13, 2007. (PSOF ¶ 51)

II. Summary Judgment Standard

A motion for summary judgment may be granted only if the evidence, viewed in the light most favorable to the non-moving party, shows "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Jesinger v. Nevada Fed. Credit Union*, 24 F.3d 1127, 1130 (9th Cir. 1994). To defeat the motion, the non-moving party must show that there are genuine factual issues "that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The party opposing summary judgment "may not rest upon the mere allegations or denials of [the party's] pleadings, but . . . must set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e); *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). *Brinson v. Lind Rose Joint Venture*, 53 F.3d 1044, 1049 (9th Cir. 1995). There is no issue for trial unless there is sufficient evidence favoring the non-moving party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted. *Anderson*, 477 U.S. at 249-50. However, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his [or her] favor." *Id*. at 255 (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-59 (1970)). The Court will consider Nellcor's Motion for Partial Summary Judgment in view of the foregoing principles.

III. Arizona Products Liability Law

The Third Amended Complaint alleges counts sounding in negligence and strict liability. A district court applies state law to products liability claims brought in federal court pursuant to diversity jurisdiction. *Adams v. Synthes Spine Co.*, 298 F.3d 1114, 1117 (9th Cir. 2002); *Winters v. Country Home Products, Inc*., 654 F.Supp.2d 1173, 1179 (D.Mont. 2009) ("The task of a federal court in a diversity action is to approximate state law as closely as possible in order to make sure that the vindication of the state right is without discrimination because of the federal forum.") (citation omitted)). "Where the

state's highest court has not decided an issue, the task of the federal courts is to predict how the state high court would resolve it." *Ticknor v. Choice Hotels Int'l, Inc*., 265 F.3d 931, 939 (9th Cir. 2001) (citation and internal quotation marks omitted). "In assessing how a state's highest court would resolve a state law question - absent controlling state authority - federal courts look to existing state law without predicting potential changes in that law." *Id*. (citation omitted).

"Strict products liability does not rest on traditional concepts of fault." *State Farm Ins. Co. v. Premier Manufactured Systems, Inc*., 213 Ariz. 419, 422, 142 P.3d 1232, 1235 (Az.Ct.App. 2006) (citing *Rocky Mountain Fire & Cas. Co. v. Biddulph Oldsmobile*, 131 Ariz. 289, 292, 640 P.2d 851, 854 (Ariz. 1982)). "A strict products liability plaintiff does not have to prove the defendant was negligent." *Id*. (citation omitted) In Arizona, to establish a *prima facie* case of strict products liability, "the burden is upon the plaintiff to show the following: the product is defective and unreasonably dangerous; the defective condition existed at the time it left defendant's control; and the defective condition is the proximate cause of the plaintiff's injuries and property loss." *Dietz v. Waller*, 141 Ariz. 107, 110, 685 P.2d 744, 747 (Ariz. 1984) (quoting *Rocky Mountain Fire*, 131 Ariz. at 292, 640 P.2d at 854) (emphasis and internal quotation marks omitted); *Bonar v. General Motors Corp*., 2009 WL 44872, * 4 (Az.Ct.App. January 8, 2009). Three types of defects can result in an unreasonably dangerous product: (1) manufacturing defects, (2) design defects, and (3) informational defects encompassing instructions and warnings. *Dillon v. Zeneca Corp*., 202 Ariz. 167, 172, 42 P.3d 598, 603 (Az.Ct.App. 2002); *Piper v. Bear Medical Systems, Inc*.,180 Ariz. 170, 173-74, 883 P.2d 407, 410-411 (Az.Ct.App. 1993).

IV. Analysis

A. Design Defect Claim

This case involves an alleged design defect, not a defectively manufactured product where the "manufactured product is . . . flawed as a result of something that went wrong during the manufacturing process." *Gomulka v. Yavapai Mach. & Auto Parts, Inc*., 155 Ariz. 239, 241-42, 745 P.2d 986, 988-89 (Az.Ct.App. 1987).

In its Motion for Partial Summary Judgment, Nellcor argues that Plaintiffs have not presented any competent evidence of a design defect in the Nellcor resuscitation bag. (Doc. 50 at 6) Nellcor's Motion focuses mainly on the deposition testimony of Dr. David Eckman, Plaintiffs' expert. (Doc. 50 at 7-8) Nellcor essentially argues that because Dr. Eckman agreed "that he did not have any criticisms of the design of the Nellcor resuscitation bag," and Plaintiffs have not presented any evidence that the device should have been designed differently, their design defect claim fails. As discussed below, however, Nellcor's overly narrow argument fails to consider Arizona's "myriad standards applied to determine whether a product is defective as a result of its design" described by Arizona courts. *Stilwell v. Smith & Nephew*, 482 F.3d 1187, 1194 (9th Cir. 2007) (citing *e.g.*, *Byrns v. Riddell, Inc*., 113 Ariz. 264, 550 P.2d 1065, 1068 (Ariz. 1976); *Gomulka*, 155 Ariz. 239, 241-42, 745 P.2d 986, 988-89).

There is strict liability on a manufacturer for a design defect if a "product is in a defective condition unreasonably dangerous, . . . and the product fail[s] to perform as safely as an ordinary consumer would expect when used in an intended or reasonable manner (the consumer expectation test)[.]" *Stilwell*, 482 F.3d at 1194 (internal quotation marks and citations omitted). "A defectively designed product is one that is made as the manufacturer intended it to be but that is unreasonably dangerous." *Gomulka*, 155 Ariz. at 242, 745 P.2d at 989. One Arizona test to determine whether a product is defective and unreasonably dangerous is the consumer expectation test. *Dart v. Wiebe Mfg., Inc.*, 147 Ariz. 242, 244-45, 709 P.2d 876, 878-79 (Ariz. 1985). "Under the 'consumer expectation test,' the fact-finder determines whether the product 'failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonable manner.' If so, the product was in a defective condition and unreasonably dangerous." *Golonka v. General Motors Corporation*, 204 Ariz. 575, 581, 65 P.3d 956, 962 (Az.Ct.App. 2003) (citations omitted); *Brethauer v. General Motors Corp*., 221 Ariz. 192, 198, 211 P.3d 1176, 1182 (Az.Ct.App. 2009). The consumer expectation test, however, does not always apply as when "the consumer would not know what to expect, because he would have no

idea how safe the product could be made." *Dart*, 147 Ariz. at 244, 709 P.2d at 878 (citation omitted).

When the consumer expectation test does not apply, Arizona courts can additionally, or alternatively, employ a risk/benefit analysis to determine whether the product's design renders it defective and unreasonably dangerous "despite [the manufacturer's] best efforts to make or design a safe product." *Golonka*, 204 Ariz. at 581, 65 P.3d at 962 (citing *Mather v. Caterpillar Tractor Corp.*, 23 Ariz.App. 409, 411, 533 P.2d 717, 719 (Az.Ct.App. 1975) and *Dart*, 147 Ariz. at 245, 247, 709 P.2d at 879, 881). This test calls for the fact-finder to weigh factors such as these: (1) the product's usefulness and desirability; (2) the availability of safer products to meet the same need; (3) the likelihood and probable seriousness of injury; (4) the obviousness of the danger; (5) common knowledge and normal public expectation of the danger (particularly for established products); (6) the avoidability of injury by care in the use of the product (including the effect of instructions or warnings); and (7) the manufacturer's or seller's ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive. *Dart*, 147 Ariz. at 245-46, 709 P.2d at 879-80 (citation omitted).

Unlike a negligent design case which focuses on whether the defendant's conduct was reasonable in view of a foreseeable risk at the time of design of the product, "[a] strict liability design defect case, where the risk/benefit analysis is appropriate, focuses on the quality of the product." *Golonka*, 204 Ariz. at 582, 65 P.3d at 963. To the extent the risk/benefit analysis involves a consideration of the conduct of the manufacturer or seller, such conduct is weighed as if the risk that the trial has revealed has always been known. *Id.* The fact-finder employs a "'hindsight' test to decide whether it was reasonable for a manufacturer with [knowledge of the product's potentially dangerous consequences, as demonstrated at trial,] to have put the product on the market." *Id.* (citing *Gomulka*, 155 Ariz. at 242, 745 P.2d at 989). "In other words, in strict liability cases, the knowledge of the risk attendant on a product's harmful characteristics is attributed to the manufacturer or seller as a matter of law. In such cases, it is immaterial whether the manufacturer knew

or should have known of the risk accompanying a product's harmful characteristics at the time the product was put on the market." *Gomulka*, 155 Ariz. at 242, 745 P.2d at 989. Based upon the evidence before the Court, it appears that both tests may apply. *See Golonka*, 204 Ariz. at 582, 65 P.3d 956 (giving jury instruction encompassing consumer expectation and risk/benefits test).

Nellcor apparently assumes, without explanation, that only the risk/benefit analysis applies in this case. (Doc. 50 at 7) (citing RAJI (Civil) 4th Product Liability 3, which provides that "[a] product is defective and unreasonably dangerous if the harmful characteristics or consequences of its design outweigh the benefits of its design."). Extrapolating from this Arizona jury instruction relevant to a risk/benefit test, Nellcor argues that "the focus in a design defect claim is the actual design of the product as intended," and Plaintiffs have offered no testimony that the design of the Nellcor resuscitator should have been different or that the design proximately caused H.P.'s injuries. (*Id.*) Nellcor argues that Plaintiffs' medical device expert witness, David Eckman, conceded that he did not have any opinions regarding the design of the Nellcor resuscitation bag. (DSOF ¶ 31, 47) Nellcor relies on Dr. Eckman's following deposition testimony.

> Q: [Y]ou]re not here to say, Well, the duckbill valve should have been made of a different material or the retainer clip should have been different, there should have been a flange that wasn't present, correct?
>
> A: That's correct.

(DSOF ¶ 47) At a later point in his deposition, Dr. Eckman clarified that he was not offering any opinion criticizing the design of the Nellcor resuscitator bag:

> Q: Again, you are focusing on the post-manufacturing post-assembly testing in terms of your criticisms as opposed the to design R&D side?
>
> A: Yes.

(DSOF ¶ 46)

Nellcor's focus on Dr. Eckman's deposition testimony completely ignores the consumer expectation test. "No expert testimony is necessary to establish a design defect under the consumer expectation test because the test 'focuses on the safety expectations

of an ordinary consumer rather than those of an expert.'" *Long v. TRW Vehicle Safety Systems, Inc.*, ___ F.Supp.2d ___, 2011 WL 2457509 (D.Ariz. June 20, 2011) (quoting *Bell v. BMW*, 181 Cal.App. 4th 1108, 1129, 105 Cal.Rptr.3d 485 (2010)); *Martinez v. Terex Corp.*, 241 F.R.D. 631, 641 (D.Ariz. 2007) ("[i]t is apparent that there is no requirement under Arizona law that expert testimony be given in a products liability action.") (citing *Dietz*, 141 Ariz. at 110, 685 P.2d at 747) ("[p]laintiffs . . . must be permitted to rely upon circumstantial evidence alone in strict liability cases . . . .") (citation omitted)). A product's complexity is not controlling. Rather, "[t]he critical question is whether the '*circumstances of the product's failure* permit an inference that the product's design performed below the legitimate, commonly accepted minimum safety assumptions of ordinary consumers.'" *McCabe v. American Honda Motor Co.*, 100 Cal.App.4th 1111, 1122-23, 123 Cal.Rptr.2d 303 (Cal.Ct.App. 2002) (quoting *Soule v. General Motors Corp.*, 8 Cal.4th 548, 568-69, 34 Cal.Rptr.2d 607, 882 P.2d 298 (Cal. 1994)).

Although the Arizona Supreme Court has stated that the consumer expectation test does not resolve "cases in which the consumer would not know what to expect, because he would have no idea how safe the product could be made," *Dart*, 147 Ariz. at 244, 709 P.2d at 878, the consumer in this case - the medical professionals who used the Nellcor resuscitator bag - would have such knowledge. *Adams*, 298 F.3d at 1117 ("Under Washington law, the 'consumer' of a prescription-only medical device such as this is the physician, not the patient in whom it is installed[.]") (citing *Terhune v. A.H. Robins Co.*, 90 Wash.2d 9, 577 P.2d 975, 978 (Wash. 1978) (stating that the relevant "ordinary consumer" under the consumer expectation test is the physician who prescribed the medical device in a product liability involving a spinal plate). In *Brethauer v. General Motors Corporation*, the Arizona Court of Appeals explained that:

> If the consumer expectation test was applicable only when a consumer could form an expectation as to the product's actual design, the test would almost never apply because the average consumer is typically not familiar with any product's intricate design details. On the other hand, consumers do form expectations as to how safely products they purchase will *perform* . . . .

Brethauer, 221 Ariz. at 199, 211 P.3d at 1183 (emphasis in original).

Additionally, in Arizona, the consumer expectation test is not limited to ordinary household products. *Boy v. I.T.T. Grinnell Corp*., 150 Ariz. 526, 724 P.2d 612 (Az.Ct. App. 1986) (permitting finding of defect based on consumer expectation test where the product was a case iron pipe fitting, known as a concentric reducer, used to connect a one inch pipe to a three-quarter inch pipe); *Martinez*, 241 F.R.D. at 642 (finding that both the consumer expectation test and risk/benefit test apply to determine whether a cement mixer was defective). Thus, when certain medical devices are at issue, some courts have recognized that the physician using the device is considered the "ordinary consumer" for purposes of the consumer expectation test. *Adams*, 298 F.3d at 1117. Accordingly, this Court predicts that the Arizona Supreme Court would likely find that as to this medically-related product, the ordinary consumer under the consumer expectation test is the physician who used the Nellcor resuscitator bag.

In this case, there is a dispute regarding whether Dr. Teaford thought something was wrong with the Nellcor bag. Additionally, there is a dispute regarding whether the respiratory therapist observed "chest rise" in H.P. while Dr. Teaford was using the Nellcor bag. Nellcor argues, however, that the testimony of Drs. Graham and Tellez "speaks for itself." (Doc. 69 at 12) Drs. Graham and Tellez both testified that the Nellcor bag did not function as intended. The record contains no evidence that the Nellcor bag was used in manner other than an ordinary and foreseeable manner, and when used in that manner, it failed to function. (PSOF ¶ 59-70, 78-79) To the extent the resuscitator bag did not work, causing the medical professionals to obtain a different bag in order resuscitate H.P., it is for the jury to determine whether the Nellcor resuscitator bag was improperly designed. Even disregarding expert testimony, there is sufficient evidence, when viewed in the light most favorable to Plaintiffs, for the design defect claim to proceed to trial. The circumstances surrounding the incident and witness testimony provide a sufficient basis to create a question of fact that the resuscitator bag was not properly designed.

The Court finds that summary judgment is not warranted regarding Plaintiffs'

design defect claim. This claim is supported by the circumstances surrounding the incident and the witness testimony.

B. Failure to Warn/Informational Defect Claim

Nellcor also moves for summary judgment on Plaintiffs' failure to warn/informational defect claim alleged in the Third Amended Complaint. (Doc. 50 at 8) In their Response, Plaintiffs admit that they "did not plead any claim for misrepresentation, and . . . concede that they are not proceeding under a failure to warn theory." (Doc. 55 at 12) Plaintiffs request that the Court dismiss their failure to warn/informational defect claim. The Court will grant that request and dismiss the failure to warn/informational defect claim.

C. Negligent Testing Claim

Nellcor further argues that Plaintiffs have not properly pled a negligent testing claim, and cannot add such a claim now because the deadline to amend pleadings expired on September 17, 2010. (Doc. 50 at 9, citing Doc. 29 at 4) In response, Plaintiffs argue that the Third Amended Complaint complies with Rule 8(a) by giving Nellcor fair notice that its resuscitator bag failed to deliver oxygen to H.P. during ordinary use, and that "Plaintiffs [are] asserting both strict product liability and negligence claims against Nellcor arising from the design, manufacture, and sale of this defective product."[10] (Doc. 55 at 12) (citing Doc. 32 at ¶¶ 10, 11, 14-16) Plaintiffs contend that Nellcor is recasting the design and manufacturing claims as a "negligent testing claim when testing a product is simply a necessary step in the design and manufacturing process," and, thus, is not a separate claim. (Doc. 55 at 13)[11]

Federal Rule of Civil Procedure 8(a), Fed.R.Civ.P., requires a plaintiff "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell*

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[10] Contrary to Plaintiffs' arguments, the Third Amended Complaint does not allege a negligent design or manufacture claim, only that Nellcor "negligently and/or consciously failed to adequately warn owners, purchasers, and/or users of the potential dangers and problems associated with the use of the Nellcor Resuscitator." (Doc. 32, ¶ 15 at 4)

[11] Because Nellcor only addresses the issue of negligent testing, the Court will not *sua sponte* address other negligence issues not raised in the summary judgment motion.

Atl. Corp. v. Twombly, 550 U.S. 544 (2007). The Supreme Court explained that, under Rule 8(a)(2), "a pleading must contain a 'short and plain statement of the claim showing that the pleader is entitled to relief.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949 (2009) (quoting Fed.R.Civ.P. 8(a)(2)). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id*. Plaintiffs assert that they satisfied the "notice pleading standard and discovery has confirmed both that Nellcor was negligent in its design and manufacture of the resuscitator and was defective and unreasonably dangerous as sold." (Doc. 55 at 13)

The Third Amended Complaint alleges a claim of strict products liability based on a design defect of the resuscitator bag. (Doc. 32, ¶ 14 at 3) Evidence of Nellcor's failure to test the resuscitator bag during the design and manufacturing process is admissible to prove that Nellcor had the ability to eliminate the danger, which is one of the relevant factors to be considered as part of the risk/benefit analysis in a products liability case. *Golonka*, 204 Ariz. at 581, n. 2, 65 P.3d at 962, n. 2 (citing *Dart*, 147 Ariz. at 245-46, 709 P.2d at 879-80).

Additionally, in *Dart*, the Arizona Supreme Court distinguished between the tests for negligent design or manufacture and strict products liability. 147 Ariz. at 246-47, 709 P.2d 880-81. "The true distinction, we believe, between negligent design cases applying the risk/benefit analysis and strict liability cases applying the same word formulation is the time frame in which this determination is made. For a plaintiff to prove negligence he must prove that the designer or manufacturer acted unreasonably at the time of manufacture or design of the product. This test is 'nothing more than the familiar negligence standard.'" *Id*. Thus, while a plaintiff must prove a manufacturer acted unreasonably at the time of design in a suit alleging negligent design or manufacture, in a strict products liability case, "the quality of the product may be measured not only by the information available to the manufacturer at the time of design, but also by the information available to the trier of fact at the time of trial." *Id*. at 247. This "hindsight" test allows the trier of fact to inquire whether "a reasonable manufacturer would continue to market his product

in the same condition as he sold it to the plaintiff with knowledge of the potential dangerous consequences the trial just revealed." *Id*. (citing *Byrns*, 113 Ariz. at 267, 550 P.2d at 1068).

Thus, evidence regarding product testing that was elicited during the depositions is relevant to the design defect claim. Because Plaintiffs do not assert negligent testing as a distinct theory of liability, but rather as a means of proving Plaintiffs' claim of strict products liability based on a design defect, the Court need not consider whether summary judgment is appropriate regarding such a claim.

V. Summary

The Court will grant Plaintiffs' request to voluntarily dismiss their warning/informational defect claim. (Doc. 32, ¶ 15 at 4) Thus, Nellcor's request for summary judgment as to that claim is moot. The Court finds that summary judgment is not warranted regarding Plaintiffs' design defect claim because it is supported by the circumstances surrounding the incident and the witness testimony.

Accordingly,

IT IS ORDERED that, pursuant to Plaintiffs' request, doc. 55 at 12, Plaintiffs' warning/informational defect claim is **DISMISSED** with prejudice.

IT IS FURTHER ORDERED that Defendant's Motion for Partial Summary Judgment, doc. 50, is **DENIED**.

Dated this 7th day of November, 2011.

Lawrence O. Anderson
United States Magistrate Judge