IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. 5:13-CV-649-FL

AMY SPARKS, *individually*, and ROBERT D. SPARKS, *as Personal Representative of the Estate of Jarred B. Sparks*,	)	
Plaintiffs,	)	
v.	)	ORDER (UNDER SEAL)[1]
OXY-HEALTH, LLC and OXY-HEALTH CORPORATION,	)	
Defendants.	)	

This matter is before the court on the motion for summary judgment of defendants Oxy-Health, LLC and Oxy-Health Corporation (collectively "defendant"), made pursuant to Federal Rule of Civil Procedure 56.[2] (DE 39). The issues raised have been briefed fully, and in this posture are ripe for ruling. For the reasons that follow defendant's motion for summary judgment is granted.

[1] The court's analysis relies, in part, on documents filed under seal. Within 14 days, the parties jointly shall return to the court by U.S. Mail, addressed to the case manager, a copy of this order marked to reflect any perceived necessary redactions. Upon the court's inspection and approval, a redacted copy of this sealed order will be made a part of the public record.

[2] The record is not clear as to the exact identity of the defendants. The evidence suggests that Oxy-Health, LLC is the successor in interest to Oxy-Health Corp. For example, Peter Lewis, president of Oxy-Health Corp.'s former business partner Hyperbaric Technologies, Inc., ("HTI"), indicated that Oxy-Health Corp. became Oxy-Health, LLC but could not recall the exact time frame in which that transition occurred. (Lewis Dep., DE 45-6, 23:2–20). The unity of the two business entities is made more apparent upon consideration of the fact that a single individual, Samir Patel, was the corporate designee for both parties at "Oxy-Health's" omnibus Rule 30(b)(6) deposition. Moreover, the California Secretary of State indicates that both businesses are ongoing concerns that share a single address. Given that defendants' address themselves as a single unit, and in light of the fact that plaintiffs do not object to that characterization, the court will refer to both Oxy-Health, Corp. and Oxy-Health, LLC as "defendant."

STATEMENT OF THE CASE

Plaintiff Robert Sparks is the administrator of the Estate of his son, Jarred Sparks. Together with his wife and Jarred's mother, Amy Sparks, plaintiffs filed this product liability action on September 12, 2013. Plaintiffs contend that defendant, the alleged manufacturer of the Vitaeris 320 Hyperbaric Oxygen Therapy Chamber System, ("Chamber" when used in reference to the specific product at issue in this case, otherwise "Vitaeris 320" or "chamber"), negligently designed the Vitaeris 320 and provided insufficient warning about the potential risk of asphyxiation, resulting in Jarred's death. The Estate asserts statutory claims for inadequate design, in violation of N.C. Gen. Stat. § 99B–6; inadequate warning, in violation of N.C. Gen. Stat. § 99B–5; breach of the implied warranty of merchantability, in violation of North Carolina's Uniform Commercial Code (the "UCC"), N.C. Gen. Stat. § 25–2–314; breach of express warranty, in violation of the UCC, N.C. Gen. Stat. § 25–2–313; and violation of the North Carolina Unfair and Deceptive Practices Act ("UDPA"), N.C. Gen. Stat. § 75–1.1, as well as common law claims for negligence and negligent failure to warn. In addition, plaintiff Amy Sparks, suing in her individual capacity, brings a

common law claim for negligent infliction of emotional distress, ("NIED").[3] Plaintiffs seek compensatory and punitive damages, as well as attorney's fees.

After a period of discovery, defendant filed the instant motion for summary judgment on all claims asserted by plaintiffs. Defendant argues the Estate's § 99B–6 defective design claim fails because defendant did not manufacture the Vitaeris 320, did not breach the manufacturer's standard of care, and, in any case, the Estate has not adduced sufficient evidence to survive summary judgment on the issue of proximate cause. Defendant further argues that the Estate's § 99B–5 inadequate warning claim fails because the Chamber's alleged defects were matters of common knowledge requiring no warning, or, in all events, any failure to warn was irrelevant because defendant had no knowledge of the particular asphyxiation hazard and the Estate cannot establish proximate cause. In addition, defendant contends both the Estate's various negligence claims, as

[3] Exposition of two procedural points will facilitate understanding of the posture of this case. First, notwithstanding the language in the complaint, (see Compl., DE 1, at 1), styling this action as a "wrongful death/survival action," the Estate's claims are brought pursuant to the "wrongful death" statute. N.C. Gen. Stat. § 28A–18–2. Survival claims are brought after death for injuries sustained before death and inure to the benefit of the estate. See N.C. Gen. Stat. § 28A–18–1; Bowen v. Constructors Equip Rental Co., 283 N.C. 395, 421 (1973); Alston v. Britthaven, Inc., 177 N.C. App. 330, 339 (2006). By contrast, a wrongful death claim provides relief where a defendant's actions cause injury proximately resulting in the decedent's death, with all recovery inuring to the benefit of decedent's heirs as provided for by North Carolina's Intestate Succession Act. See N.C. Gen. Stat. § 28A–18–2(a); Raferty v. Wm. C. Vick Constr. Co., 291 N.C. 180, 185 (1976). Wrongful death and survival actions are "technically separate, [but] bear an important relationship to one another." Taylor v. Norfolk Southern Ry. Co., __ F. Supp. 3d __, 2015 WL 506852 (M.D.N.C. 2015). Although both may be brought for injuries received by the decedent prior to death, where the only physical injuries complained of are those that actually caused the decedent's death the survival action is moot and only a wrongful death claim may proceed. See Bolick v. Southern Ry. Co., 138 N.C. 370, 50 S.E. 689, 690 (1905); State Auto Ins. Co. v. Blind, 185 N.C. App. 707, 712–13 (2007); cf. Alston, 177 N.C. App. at 338–39 (holding "wrongful death and survivorship claims may be brought as alternative claims for the same negligent acts" and reasoning that the success of the wrongful death action turned on the jury's assessment as to whether the injuries allegedly caused by defendant was the proximate cause of decedent's death).

Second, the post-mortem nature of this action affects plaintiff Amy Sparks's claims. In particular, because this action was brought under the wrongful death statute, plaintiff Amy Sparks cannot be joined in the Estate's various statutory and negligence based actions. "A wrongful death action is a creature of statute and may be brought only as the authorizing statute permits." Burcl v. N.C. Baptist Hospital, 306 N.C. 214, 217 (1982). Under North Carolina's wrongful death statute, N.C. Gen. Stat. § 28A–18–2, "a wrongful death action may be brought only 'by the personal representative or collector of the decedent,'" not by a parent suing in his or her individual capacity. Id.

well as plaintiff Amy Sparks's NIED claim, all are "product liability" claims under§ 99B–1(3), and argues summary judgment also is warranted on each of those claims because plaintiffs cannot establish causation.

With regard to the Estate's UDPA claim, defendant argues that none of the bases asserted by plaintiffs qualify as "unfair or deceptive practices." In addition, defendant contends the Estate has forecast insufficient evidence to show that defendant was the proximate cause of Jarred's death. Finally, in opposition to plaintiffs' punitive damages claim, defendant contends that plaintiffs failed to submit evidence supporting the alleged willful nature of its conduct.[4]

[4] In support of its motion for summary judgment, defendant relies upon: the depositions of Jarred's doctors, Jeff Bradstreet and Jerry Kartzinel, (Bradstreet Dep., DE 45-2; Kartzinel Dep., DE 45-4), along with various medical records including a prescription issued by Kartzinel for decedent's hyperbaric treatment (DE 45-15), a prescription from Bradstreet for the same, (DE 45-21), and a "to whom it may concern" letter, signed by Kartzinel addressing Jarred's disability. (DE 45-19). Defendant further rely on the depositions of Jarred's family, mother Amy Sparks (DE 45-10), father Robert Sparks (DE 45-12), and brother Dylan Sparks (DE 45-11), along with the deposition of plaintiff Amy Sparks's therapist, (Lawyer Dep. DE 45-5), and various of plaintiffs' retained experts (Nancy Grugle Dep., DE 45-3; Ronald Natoli Dep., DE 45-7), as well as the results of an autopsy examination conducted on Jarred dated June 11, 2011. (Autopsy, DE 45-18). Defendant also relies on additional evidence in the form of Janet Presson's deposition. ("Janet Presson Dep.," DE 45-9). Presson owned "A Small Miracle," the company which sold the Sparks family the hyperbaric chamber at issue in this litigation. Defendant relies on Jarred's health profile provided by A Small Miracle. (DE 45-20, 47). With regard to the chamber purchased from A Small Miracle, defendant relies on an "Agreement to Purchase" the chamber as executed between plaintiff Amy Sparks and A Small Miracle, through Presson, ("Agreement to Purchase," DE 45-16), the agreement evidencing A Small Miracle's own purchase of the chamber from a third-party retailer. (Agreement between A Small Miracle and Vita 02, DE 45-17), as well as various photographs of the chamber (DE 45-13; 45-14; Manufacturer Label, 45-32; Concentrator Label, 45-35), and the 2005 Oxy-Health branded operating and reference manual provided to plaintiffs by A Small Miracle. ("Reference Manual," DE 45-22–26). From its own perspective, defendant relies on the declaration of its president, Samir Patel, (Patel Dep., DE 41), which includes an invoice evidencing defendant's sale of the chamber at issue to the third party retailer from whom A Small Miracle purchased the chamber, (Invoice, DE 41-1), as well as defendant's own 30(b)(6) deposition conducted by defendant's corporate designee, Patel, (Oxy-Health Dep., DE 45-7), in addition to a 2002 incident report filed with the Food and Drug Administration ("FDA") addressing an alleged failure of the Vitaeris 320. ("MAUDE Report," DE 45-34). Defendant further relies on a complete list of the design revision history of the Vitaeris 320. (DE 46), as well as a number of documents received from HTI, a third party that, as discussed more fully in the court's analysis, is the manufacturer of the Vitaeris 320. These documents include the deposition of HTI's president, Peter Lewis, ("Lewis Dep.," DE 45-6), the Vitaeris 320's FDA 510(k) market clearance paperwork, ("510(k) Clearance," DE 45-33, 50), and various other documents received from the FDA (DE 45-27; 45-28; 45-31). Finally, defendant relies on a contract and letter between itself and HTI purportedly establishing defendant to be the exclusive distributor of the chamber. ("Distributorship Agreement," DE 45-29 through -30; DE 48; DE 49).

In response plaintiffs attempt to undermine defendant's arguments, as well as raise a number of new theories supporting the Estate's claims previously not developed by the pleadings. In particular, plaintiffs argue defendant is not entitled to summary judgment on the Estate's § 99B–6 claim, as a jury reasonably could conclude from the evidence that defendant was the Chamber's "manufacturer" because defendant either designed or assembled the Vitaeris 320, or was its "apparent manufacturer." In addition, plaintiffs contend they have submitted ample evidence of causation. With respect to the Estate's § 99B–5 failure to warn claim, plaintiffs argue that summary judgment is inappropriate because, even if defendant merely acted as the Vitaeris 320's distributor, defendant failed to warn customer about the known risk of asphyxiation if air stopped flowing into the chamber, and further argue that causation is a disputed question of fact.[5] In opposition to defendant's motion for summary judgment attacking the Estate's UDPA claim, plaintiffs contend that defendant engaged in conduct that amounted to a deceptive "misrepresentation," and that factual questions exist as to the required causative element. Plaintiffs also contend that defendant's motion for summary judgment on their punitive damages claim is unfounded.[6]

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[5] As is explained in more detail herein, although plaintiffs have asserted product liability claims generally alleging a product defect, all the Estate's claims and evidence sound either as inadequate warning or defective design claims under § 99B–5 & –6. In addition, in brief defendant argues that it is entitled to summary judgment on plaintiffs' UCC based claims. Plaintiffs consent to the "dismissal" of their UCC claims. Accordingly, defendant's motion for summary judgment as to these claims is GRANTED.

[6] In opposition to defendant's motion for summary judgment, plaintiffs rely on a number of the same documents relied on by defendant. (Lewis Dep., DE 69-2; Oxy-Health Dep., DE 69-8; Patel Dep., DE 69-12; Janet Presson Dep., DE 69-13; Bradstreet Dep., DE 69-14; Amy Sparks Dep., DE 69-22; Kartzinel Dep., DE 69-23; Dylan Sparks Dep., DE 69-24; Robert Sparks Dep., DE 69-25; Lawyer Dep., 69-27; Natoli Dep., DE 69-31; Grugle Dep., DE 69-37). In addition, plaintiffs rely on an array of other evidence, including HTI's internal memoranda ("Change Notice," DE 69-4, 71; "Bruce Memo," DE 69-5, 72; "Design Input Proposal," DE 69-6, DE 73; "Lewis Memo," DE 69-11, DE 77), emails between HTI and defendant's officers and employees ("Darmofal Email," DE 69-7, 74; "Lewis Email," DE 69-9, 75; "Dolin Email," DE 69-10, DE 76; "Web Site Claim Email," DE 69-18, DE 78), and correspondence between the FDA and either defendant or HTI, ("HTI 2005 FDA Inspection Report," DE 69-3, 70; "2013 FDA Warning Letter to Defendant," DE 69-19; "2001 FDA Letter to HTI," DE 69-20, DE 79). Plaintiffs further rely on Grugle and Natoli's report (DE 69-30), as well as the expert report, declaration, and deposition of Tom Workman. ("Workman Report," DE 69-16; "Workman Decl.," DE 69-17; "Workman Dep.," DE 69-34). In addition, plaintiffs rely on various other depositions and documentary evidence, including the deposition of Jack Presson, co-owner of A Small Miracle and Janet

Defendant replies in-kind to plaintiffs' response without objection to plaintiffs' various new legal theories, thereby constructively amending the complaint.[7] Defendant argues that the "apparent manufacturer" doctrine is inapplicable to the instant matter and further maintains its strenuous objection to the causative element of each of the Estate's substantive product liability and UDPA claims.

STATEMENT OF FACTS

A. Hyperbaric Chambers

"Portable mild hyperbaric chambers" are enclosures that are inflated and allow the occupant to experience higher than normal atmospheric pressure. (Patel Decl. ¶4). The Vitaeris 320 generally, and the Chamber specifically, is a "portable mild hyperbaric chamber," described as a "cylindrical, soft-shelled enclosure that receives continuous fresh air through a valve at one end." (Id. ¶¶4–5). The air is pumped through a hose, secured to the chamber body by a "quick disconnect" valve. (Id. ¶5). The valve itself is manufactured by Colder Products, a non-party, and is a "push button" disconnect, rather than a threaded-style connector. (Id.; see also Natoli Dep. 139:13–15). As fresh air continuously is forced into the chamber through one end, two valves at the opposite end

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Presson's husband, ("Jack Presson Dep.," DE 69-15), a list of autism conferences attended by defendant (DE 69-21); treatment notes from one of Jarred's doctor visits, (DE 69-26); various brochures for the chamber and a competitor chamber, the SOS Hyperlite ("Chamber Brochure," DE 69-29; "SOS Hyperlite Brochure," DE 69-36); the 2002 American Society of Mechanical Engineer's Pressure Vessel for Human Occupancy ("ASME–PVHO") safety standards (DE 69-33); the FDA's product classification for hyperbaric chambers (DE 69-35); a declaration executed by plaintiff Amy Sparks, dated November 26, 2014, (Sparks Decl., DE 69-32); various articles regarding the efficacy of the treatment of autism by hyperbaric oxygen therapy ("IHA, Autism and Its Growing Hyperbaric Movement," DE 69-38; "FDA, Hyperbaric Oxygen Therapy: Don't Be Misled," DE 69-39), as well as the Sheriff's Report detailing the Cumberland County, North Carolina, Sheriff's Department's investigation into Jarred's death (Sheriff's Report, DE 69-28, 81).

[7] Because plaintiffs raised new legal theories unobjected to by defendant in briefing on summary judgment, the court will consider the complaint constructively amended. See United States v. Cochran, 79 F. Supp. 3d 578, 583 (E.D.N.C. 2015) ("[P]arties [may] constructively amend the complaint by, for example, . . . addressing a theory of liability in their summary judgment briefs.") (quoting Interstate Petroleum Corp. v. Morgan, 249 F.3d 215, 227 (4th Cir. 2001)) (internal quotations omitted).

expel carbon dioxide and excess fresh air ("release valves"). (See Patel Decl. ¶5). The Vitaeris 320 also ships with an air compressor to deliver air into the chamber. (See Lewis Memo at 4).

The quick disconnect valve is the only avenue through which fresh air is delivered into the otherwise air-tight enclosure. (See Oxy-Health Dep. 95:18–24, 104:11–105:4). In the event the quick disconnect valve becomes disengaged, or the air compressor supplying air to the occupant malfunctions, the release valves no longer expel excess carbon dioxide. (Id. 105:4–21; see also id. 108:5–10). In the event that occurs, carbon dioxide will build up in the Vitaeris 320 over time, as the occupant respires. (Id. 108:5–21). There is no alarm to alert the occupant to the accumulation of carbon dioxide. (Natoli Dep. 270:13–23).

In 2000, Hyperbaric Technologies, Inc. ("HTI"), the chamber's manufacturer, applied for and received market clearance for the Vitaeris 320 from the Food and Drug Administration ("FDA") through the FDA's § 510(k) clearance procedure.[8] (FDA 510(k) Clearance; Patel Decl. ¶6). The

[8] The Vitaeris 320 is a Class II medical device. Medical devices regulated by the FDA fall into one of three categories or "classes." See Walker v. Medtronic, Inc., 670 F.3d 569, 572 (4th Cir. 2012). A Class I device is one "for which general controls, such as labeling requirements, are sufficient to provide reasonable assurance of their safety and effectiveness." Id. (quoting 21 U.S.C. § 360c(a)(1)(A)(I)) (internal alterations, citations, and quotations omitted). Class II devices include such devices as powered wheelchairs and surgical drapes, and are subject to heightened oversight mechanisms, such as "performance standards" and "postmarket surveillance." Id. (quoting 21 U.S.C. § 360c(a)(1)(B)). Class II devices are "either useful in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health or that present a potential unreasonable risk of illness or injury." Id. (quoting 21 U.S.C. § 360c(a)(1)(C)) (internal alterations, citations and quotations omitted). A Class III device "require[s] the highest level of federal oversight." Id. "Class III devices are those for which the general controls regulating Class I devices and the specific controls that regulate Class II devices are deemed insufficient to ensure safety and effectiveness." Id.

When bringing the chamber to market, HTI sought FDA approval through the FDA's 510(k) clearance process. See 21 C.F.R. §§ 807.87, 807.92, 807.93. (describing the requirements for 510(k) clearance). The Supreme Court has described the 510(k) process as a "limited form of review," Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996), as compared to the more substantial "pre-market approval" ("PMA") process applicable to new devices. See id. at 478–79 ("The § 510(k) process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. . . . The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.") (internal alterations and quotations omitted); Walker, 670 F.3d at 572–73 (describing the PMA process). "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis." Lohr, 518

Vitaeris 320 was cleared only for the treatment of "acute mountain sickness," a relatively rare condition that affects climbers who are exposed to altitudes in excess of 8,000 feet. (Patel Decl. ¶6; Workman Decl. ¶28). However, despite not being "cleared" for the treatment of autism, such use is a recognized "off-label use" in certain medical communities. (Kartzinel Dep. 33:4–34:14). Use of a hyperbaric chamber for the treatment of autism requires a prescription. (See id. 35:2–9).

B. The Sparks Family's Experience with Hyperbaric Oxygen Therapy

Plaintiffs are the mother and father of Jarred Sparks, a 19 year old autistic man who asphyxiated inside a hyperbaric chamber on June 10, 2011. Jarred was diagnosed with autism in 1994. (Amy Sparks Dep. 35:24–25). Sometime prior to November 2005, plaintiff Amy Sparks learned about the purported ability of hyperbaric oxygen therapy ("HBOT") to treat or reduce the symptoms of autism. (Id. 74:18–75:8). Sometime thereafter, in connection with a recommendation from Jarred's treating physician, Jerry Kartzinel, Jarred began HBOT at "Creation's Own," a clinic in Melbourne, Florida. (Amy Sparks Dep. 59:14–25, 69:13–25; Bradstreet Dep. 54:23–24). Jarred's treatments at Creation's Own were intermittent, ideally once every three to four weeks, but realistically once every few months. (Amy Sparks Dep. 77:4–12). During the treatments Jarred first used a Vitaeris 320, but later switched to a "hard sided" chamber. (Id. 126:1–6). Due to the distance between the family's home in North Carolina and the clinic, Jarred also began receiving treatment at A Small Miracle, a clinic in Goldsboro, North Carolina, offering certain services, including HBOT, to children and adults with special needs, owned by Jack and Janet Presson. (See Amy Sparks Dep. 77:14–21, 127:4–22; see also Agreement to Purchase). At A Small Miracle, Jarred was treated using a Vitaeris 320. (See Amy Sparks Dep. 123:16–21). Jarred's treatments at Creation's

U.S. at 478. "[D]evices that enter the market through § 510(k) [are] never . . . formally reviewed . . . for safety or efficacy." Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) (internal quotations omitted).

Own and A Small Miracle overlapped, but Jarred was last treated at Creation's Own on July 1, 2008. (Bradstreet Dep. 69:2–15).

During his treatments at Creation's Own, Jarred rarely was left alone while inside the hyperbaric chamber. Usually, plaintiff Amy Sparks remained in the room, (Amy Sparks Dep. 94:12–16), and a technician employed by Creation's Own frequently was in the room during the course of a 60 minute treatment session. (Id.; Kartzinel Dep. 57:16–58:14). During treatments at Creation's Own two to three technicians were responsible for monitoring five hyperbaric chambers, (Bradstreet Dep. 36:5–16), and were checking on the patients in the chamber at least three times per hour. (See Kartzinel Dep. 74:19–75:12). In addition, during treatments, either Jarred's father, Robert Sparks, or one of his siblings always accompanied him into the chamber. (Amy Sparks Dep. 96:3–13). Similarly, during Jarred's treatments at A Small Miracle, one of the company's employees would "come and go" throughout the duration of the treatment. (Id. 127:4–22).

Beginning in December 2006, for a period of approximately 10 months, the physician-owner of Creation's Own, Jeff Bradstreet, allowed the Sparks family to borrow a Vitaeris 320 for temporary use in their home. (Amy Sparks Dep. 80:8–81:25). Bradstreet shipped the Vitaeris 320 to the Sparkses in North Carolina. (Id.). However, Bradstreet did not include with the shipment any instructions on proper use of the chamber. (Id. 155:4–19). Despite not receiving any instructional material, the chamber was used. (See Robert Sparks Dep. 202:8–203:6).

On February 5, 2011, the Sparks family purchased the Chamber from A Small Miracle. (Agreement to Purchase). The Chamber was the same Vitaeris 320 Jarred had been using during his treatments at A Small Miracle, and had been purchased by A Small Miracle from a third party distributor, that in 2005 had purchased the Chamber from defendant. (Amy Sparks Dep. 123:16–24;

Agreement between A Small Miracle and Vita 02; Patel Decl. ¶15; see also Distributorship Agreement).

Prior to the purchase of the Chamber, the Sparks family had been planning to purchase a hyperbaric chamber for some time. (See Amy Sparks Dep. 137:1–11). In 2009, Amy Sparks attended a "Hope for Autism" conference in Charleston, South Carolina. (Amy Sparks Decl. ¶4). At this conference, she met a representative, employed by defendant, who was touting the efficacy of HBOT, and in particular the efficacy of the Vitaeris 320, in treating the symptoms of autism. (See id. ¶5). The representative distributed an article entitled Autism and Its Growing Hyperbaric Movement, which represented that HBOT had beneficial effects for the autistic brain. (Id. ¶10). This experience affirmed the family's desire, and specifically Amy Sparks's desire, to purchase a hyperbaric chamber for Jarred's use. (Amy Sparks Dep. 307:13–22, 314:14–315:13).

Prior to receiving the Chamber, Amy Sparks reached out to Kartzinel, who wrote Jarred the required prescription. (See Amy Sparks Dep. 137:1–11). On February 5, Jack Presson brought the Chamber to the Sparkses's home and set it up in the upstairs. (Jack Presson Dep. 65:3–67:23; Amy Sparks Dep. 137:25–138:7). Given their experience with the Vitaeris 320 generally, the Pressons provided the Sparkses no training on how to use the Chamber, with the exception of the oxygen concentrator, an after-market component which the Sparkses had never used before. (Jack Presson Dep. 65:3–67:23; Amy Sparks Dep. 137:1–138:7). The oxygen concentrator was an external device that worked as the name implied, by increasing the oxygen concentration in the air inside the Chamber. (See Reference Manual at 36; see also Amy Sparks Dep. 83:7–24). The Pressons delivered with the chamber the Reference Manual, providing instructions on how to use the Chamber properly. (Amy Sparks Dep. 154:2–5). However, no member of the Sparks family ever

read the manual. (See Amy Sparks Dep. 154:2–21; Robert Sparks Dep. 34:4–25; Dylan Sparks Dep. 64:19–65:5).

When using the Chamber, a consistent pattern was followed involving use at night, roughly every other day. (See Robert Sparks Dep. 202:8–23). On evenings when Jarred was to receive HBOT, the family would wait for him to go to bed and after a few hours would wake him up and guide him to the Chamber. (Id. 204:4–205:9). Treatments typically lasted 2–3 hours, but at times lasted up to 6 hours. (Id. 203:10–13, 205:3–6). Usually, the last person in the Sparks family to go to bed would wake Jarred up to get him out of the Chamber. (Id. 205:3–6). The Sparkses never were told to limit the amount of time Jarred spent inside the Chamber explicitly. (Id. 203:20–204:1). Jarred always used the oxygen concentrator, (Amy Sparks Dep. 186:22–24), notwithstanding a label on the chamber body and FDA warning in the Reference Manual to the contrary. (See Concentrator Label; Reference Manual at 36). When the Chamber was in use, the release valves and air compressor could be heard downstairs, despite the Chamber's location upstairs. (Robert Sparks Dep. 217:11–23; Dylan Sparks Dep. 109:8–14).[9]

C. The Incident

Jarred's body was discovered June 10, 2011, at approximately 3:00 a.m.. (Dylan Sparks Dep. 93:2–9). Earlier that evening, at approximately 10:00 p.m., Jarred's brother, Dylan, helped Jarred into the Chamber. (See id. 98:14–24, 104:6–10). Jarred laid in the Chamber and Dylan zipped him in. (Id. 104:6–10). At that time, the air compressor was attached to the Chamber and it was inflating properly. (Id. 104:6–19). After sealing Jarred in the chamber, Dylan turned the

[9] The same pattern was followed in the family's use of the Vitaeris 320 borrowed from Creation's Own. (Robert Sparks Dep. 202:13–23).

lights off, closed the door, and left the room. (Id. 91:22–92:8). Dylan had no trouble closing the door, (id. 112:24–113:2), and went to bed around 11:00 p.m. (Id. 91:22–92:8).

While Dylan was helping Jarred get into the chamber and thereafter, plaintiff Amy Sparks, a teacher, was downstairs filling out report cards for her students. (Amy Sparks Dep. 202:4–18). Robert Sparks was out of town, in Raleigh. (Dylan Sparks Dep. 96:16–25). Sometime after Dylan had gone to bed, plaintiff Amy Sparks fell asleep while working. (Amy Sparks Dep. 202:21–24). When she woke up, plaintiff Amy Sparks, concerned for Jarred, went upstairs to check on him. (Id. 202:24–203:11). She found the Chamber partially deflated despite the fact that the air compressor, which should have been providing fresh air into the chamber, was running. (Id.). At that time, plaintiff Amy Sparks discovered Jarred. (Id.).

Plaintiff Amy Sparks cried for Dylan, waking him up. (Dylan Sparks Dep. 92:9–18). Immediately thereafter, Dylan called 911 to request an ambulance. (Id.). While on the phone, the 911 operator instructed Dylan to pull Jarred's body out of the Chamber and perform CPR. (Id. 92:9–93:1). Dylan stopped performing CPR only when emergency medical assistance arrived a few minutes later. (Id.). Dylan did not notice whether the quick disconnect valve was attached to the Chamber at that time. (See id. 141:7–142:18).

At around 5:30 a.m., officers from the Cumberland County, North Carolina, Sheriff's Department arrived. (See Sheriff's Report). The officers were the first people to point out that the quick disconnect valve had become disengaged from the Chamber. (Dylan Sparks Dep. 141:7–142:18; Amy Sparks Dep. 245:22–246:11). At approximately 8:15 a.m., detectives from the Sheriff's Department asked Dylan to set up the Chamber as he had the night before. (Sheriff's Report at 7). When the Chamber was inflated, the quick disconnect button, the feature that

disengages the quick disconnect valve, was pressed against a book shelf near the head of the Chamber. (Id.). Upon closer inspection, a detective discovered that the book shelf had depressed the button and that the hose would become fully disengaged with only a slight disturbance. (Id.). Specifically, when the detective touched the hose it "fell to the floor and the [C]hamber started deflating." (Id.). Earlier in the evening, other investigators observed that when the hose was disconnected from the Chamber, the hissing noise produced by the hose sounded similar to the hissing noise of the properly functioning chamber, and that the hose being disconnected made the air compressor much louder. (Id. at 3–4). After the investigators left, several of the family's friends removed the Chamber from their home. (Amy Sparks Dep. 245:11–23). Based on the investigators event recreation, the Sparks family believes Jarred shifted while in his sleep, pressing the quick disconnect button against the book shelf and dislodging the quick disconnect valve. (See id. 247:7–15).

D. Defendant's Relationship with HTI

HTI manufactured the Vitaeris 320. (Patel Decl. ¶3). Defendant was the exclusive distributor of certain hyperbaric chambers manufactured by HTI, including the Vitaeris 320, from 1999 until 2009. (See Distributorship Agreement; Patel Decl. ¶¶3, 6). There was no corporate overlap between the companies. (Patel Dep. ¶7).

Defendant, in its capacity as distributor, received certain chamber "bladders," representing the portion of the Vitaeris 320 into which the patient is placed during the course of HBOT, in bulk and repackaged those bladders, along with other components including an air compressor, as a unified product sold as the Vitaeris 320. (See Patel Decl. ¶10). The air compressors shipped by defendant under the Oxy-Health brand were shipped to defendant by Brenner-Fielder, a third party,

at the direction of HTI. (Lewis Dep. 34:17–35:11). During the course of repackaging the bladders, defendant's employees inflated them to ensure that the exterior was clean and wiped them down if necessary. (Patel Dep. 13:15–14:1).

Under the Distributorship Agreement between defendant and HTI, defendant was given certain discretionary authority. Of note, the Distributorship Agreement gave defendant the right to consent to any changes HTI made to the Vitaeris 320. (Distributorship Agreement § 3.3). In addition, in the position of exclusive distributor, defendant relayed to HTI customer complaints and its own suggestions regarding the chamber's design. (See Oxy-Health Dep. 227:21–230:18; Lewis Dep. 55:1–56:24; Change Notice). HTI incorporated into the Vitaeris 320's design certain changes requested or initiated by defendant. (See Oxy-Health Dep. 227:21–230:18; Lewis Dep. 55:1–56:24; Change Notice). Among these changes were the addition of a "Made in the USA" label, (Lewis Dep. 55:19–23), as well as a new hose which would connect the air compressor to the chamber. (Id. 54:3–9; Change Notice).[10] Defendant also made substantial recommendations regarding the content of the Reference Manual, specifically requesting that HTI implement a manual with pictures and detailed explanations as to how the Vitaeris 320 should be operated. (Oxy-Health Dep. 115:11–25).

Despite defendant's limited role in the design and manufacture of the Vitaeris 320, defendant held itself out to be the chamber's manufacturer. (See Reference Manual, passim; Janet Presson Dep. 161:24–162:3; Oxy-Health Dep. 84:11–24). In particular, defendant marketed the Vitaeris 320 to consumers, including the parents of autistic children, as its own product at various trade shows. (Oxy-Health Dep. 25:12–39:24). Further, defendant represented to potential customers in various

[10] Contrary to plaintiffs' assertions, there is no evidence that defendant initiated the changes that incorporated the quick disconnect valve into the Vitaeris 320's design. Rather, defendant only requested a "new hose" be added to the Vitaeris 320. (Lewis Dep. 54:3–6, 58:3–14).

videos and promotional material widely available on the internet that it actively selected the materials incorporated into the Vitaeris 320. (Workman Report at 8). When a consumer purchased the chamber, it was delivered in a box bearing defendant's trade name, "Oxy-Health." (Patel Dep. 24:5–10). In addition, after purchase, defendant represented to consumers that it was the exclusive point of contact for all questions and necessary repairs, including those repairs performed pursuant to defendant's "manufacturer's warranty," (Oxy-Health Dep. 84:11–24), which instructed customers to return the Vitaeris 320 to defendant in the event of a malfunction or defect. (Reference Manual at 35–36).

By 2006, defendant was working hand-in-hand with HTI to develop a new hyperbaric chamber for which the two companies were going to apply for a patent. (See Bruce Memo; Design Input Proposal). Although the specifics are unclear, generally the new product was to incorporate a third zipper into the bladder, an improvement over the Vitaeris 320 which only had two zippers, (See Chamber Brochure); inflatable exterior ribbing; and an improved ability to withstand higher pressures. (See Design Input Proposal). By summer of 2006 the companies were developing a prototype. (See Bruce Memo). In addition, defendant had taken steps independent of HTI to improve upon the air compressors shipped with the Vitaeris 320. Again in 2006, defendant was working closely with Gast, a third party compressor manufacturer, to develop "enclosures" for the pumps shipped with the Vitaeris 320. (Patel Email). However it is unclear whether defendant actually successfully implemented these enclosures into a completed Vitaeris 320, because HTI was responsible for approving the change. (See Oxy-Health Dep. 67:14–24; Lewis Dep. 58:24–60:6, 120:14–17).

COURT'S DISCUSSION

A. Standard of Review

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The party seeking summary judgment bears the initial burden of demonstrating the absence of any genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party has met its burden, the nonmoving party then must affirmatively demonstrate with specific evidence that there exists a genuine issue of material fact requiring trial. Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). Only disputes between the parties over facts that might affect the outcome of the case properly preclude the entry of summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986).

"[A]t the summary judgment stage the [court's] function is not [itself] to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 249. Similarly, "[c]redibility determinations . . . are jury functions, not those of a judge." Id. at 255. In determining whether there is a genuine issue for trial, "evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in [non-movant's] favor." Id.; see United States v. Diebold, Inc., 369 U.S. 654, 655 (1962) ("On summary judgment the inferences to be drawn from the underlying facts contained in [affidavits, attached exhibits, and depositions] must be viewed in the light most favorable to the party opposing the motion.").

Nevertheless, "permissible inferences must still be within the range of reasonable probability, . . . and it is the duty of the court to withdraw the case from the jury when the necessary inference is so tenuous that it rests merely upon speculation and conjecture." Lovelace v. Sherwin-Williams

Co., 681 F.2d 230, 241 (4th Cir. 1982) (quotations omitted). Thus, judgment as a matter of law is warranted where "a reasonable jury could reach only one conclusion based on the evidence," or when "the verdict in favor of the non-moving party would necessarily be based on speculation and conjecture." Myrick v. Prime Ins. Syndicate, Inc., 395 F.3d 485, 489 (4th Cir. 2005). By contrast, when "the evidence as a whole is susceptible of more than one reasonable inference, a jury issue is created," and judgment as a matter of law should be denied. Id. at 489–90.

B. Analysis

1. Defendant as a "Manufacturer" under § 99B–1(2)

Defendant first contends that it is not the Vitaeris 320's "manufacturer," as that term is used in Chapter 99B. Defendant's argument merits separate address, because if defendant is not the Chamber's "manufacturer" that determination reasonably moots the Estate's defective design claim, as well as plaintiffs' negligence and NIED claims. See generally, N.C. Gen. Stat. §§ 99B–1(3) & 99B–6. Plaintiffs advance two divergent theories under which defendant potentially could be considered a "manufacturer." First, plaintiffs suggest that defendant manufactured the "bladder," which includes only the inflatable portion of the Vitaeris 320 into which a patient would be placed during HBOT. Alternatively, plaintiffs contend defendant "manufactured" the Vitaeris 320 as a whole. The court addresses each argument in turn and, as determined below, finds each without merit.

a. Defendant as Manufacturer of the Chamber Bladder

Plaintiffs suggest defendant acted as the "manufacturer" of the bladder in two relevant respects. First, plaintiffs contend defendant "designed" the bladder. In the alternative, plaintiffs contend defendant "assembled" the bladder. See generally, N.C. Gen. Stat. § 99B–1(2) (defining

"manufacturer" as "a person or entity who designs, assembles, fabricates, produces, constructs or otherwise prepares a product or component part of a product"). In support of their argument, plaintiffs point to a contract between defendant and HTI that grants defendant the power to "consent" to any changes HTI proposes in the chamber's "design, materials or color," (see Distributorship Agreement § 3.3), as well as testimony of defendant's president, Samir Patel, wherein he states that defendant "assembled" or "set up" the chamber bladder after receiving it from HTI. In response, defendant argues it did not "design" the bladder, because its limited authority to impact the product's design falls outside the scope of Chapter 99B. In addition, defendant contends it did not "assemble" the bladder, and argues that plaintiffs' assertions to the contrary are based in mischaracterization of Patel's testimony. In support of its position, defendant points to the testimony of Peter Lewis, the president of HTI, and Patel, which provides that defendant only had the right to distribute the chamber, and that HTI actually controlled its design, as well as Patel's testimony addressing defendant's role in "assembling" the product.

Drawing all inferences in plaintiffs' favor, defendant's conduct still falls outside the scope of "design" as that term is used in the statute.[11] The power to accept or reject changes made by a third party, without more, falls short of the degree of autonomy necessary to constitute the ability to "design." The evidence shows that defendant did not have unrestrained power to decide on the bladder's look and function.[12]

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[11] Typically, whether or not a defendant is a "manufacturer" is a question of fact for the jury. See N.C. Pattern Jury Instructions – Civil § 741.71; see also Stark *ex rel.* Jacobsen v. Ford Motor Co., 365 N.C. 468, 478 (2012) ("While the Pattern Jury Instructions are not binding on this Court, they do express the long-standing, published understanding of [Chapter 99B].") (citations omitted). Tellingly, however, that instruction leaves the term "design" undefined. Accordingly, the court concludes that term is susceptible to construction as a matter of law.

[12] The court's understanding of the term "design" is further underscored by definitions gleaned from other sources. For example, Merriam-Webster defines the verb "design" as "to create the plans, drawings, etc., that show how (something) will be made," or alternatively "to create, fashion, execute, or construct according to plan." "Design,"

The statute provides no definition of the word "design" and the court has found no case bearing on its interpretation. "Undefined words are accorded their ordinary meaning, for which [the court] may look to a dictionary." Stark *ex rel.* Jacobsen v. Ford Motor Co., 365 N.C. 468, 476–77 (2012) (defining "party" as used in N.C. Gen. Stat. § 99B–6). As defined by the Oxford English Dictionary, the term "design," means to "[d]ecide upon the look and functioning of [an object]." "Design," Oxford English Dictionary, available at http://www.oxforddictionaries.com/us/definition/american_english/design (last accessed August 18, 2015). In the case at bar, because plaintiffs forecast evidence showing only that defendant had final approval authority over design changes made by HTI, defendant's conduct commonly would not be understood to fall within the definition of "design."

Plaintiffs contend defendant "designed" the bladder because HTI incorporated into the bladder several changes requested by defendant, including a "Made in the USA label" and different variety of hose, which connected the air compressor to the chamber. (See Lewis Dep. 54:3–59:9). The term "design," as it is used in statute, is not so broad as to encompass non-binding recommendations bearing on the physical appearance or functionality of a product. To hold otherwise unnecessarily would expand "manufacturer" liability under Chapter 99B to any customer, where the customer makes a recommendation about the design of a product that eventually is adopted by its manufacturer. Defendant's requests fall short of the autonomy inherent in the "design" of a product. Plaintiffs have submitted no evidence from which the court can infer that HTI was obligated to comply with defendant's requested changes. Rather, the evidence shows that the changes were made in response to customer "feedback" provided by defendant, (id. at 58:24–60:6),

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Merriam-Webster, available at http://www merriam-webster.com/dictionary/design (last accessed August 18, 2015). This confirms that "design" means the ability to create and implement a plan.

but that defendant was "not involved in the design choice of materials, [or the] fabrication processes of the [bladder]." (Id. 120:14–17).

The remaining pieces of evidence upon which plaintiffs rest their "design" theory fare no better. Plaintiffs cite two internal correspondences that suggest defendant and HTI, in 2006, were working together on a prototype chamber, (See Bruce Memo; Design Input Proposal), as well as a 2008 email, wherein an HTI employee requests authority to perform certain repairs on a bladder that had been returned to defendant pursuant to its manufacturer's warranty. (Darmofal Email). The chamber at issue was sent to defendant by a customer to take advantage of defendant's "manufacturer's warranty," and then was sent to HTI for repair. (See Darmofal Email, Invoice, Janet Presson Dep. 161:4–14).

Addressing first the internal correspondences, these documents, viewed in the light most favorable to plaintiffs, do not tend to show that defendant designed the Vitaeris 320. Rather, these documents show only that HTI and defendant were working together on a new hyperbaric chamber that they intended to patent. (See Design Input Proposal; see also Bruce Memo ("Keep in mind that once we submit the patent application in a week or so, we can use the patent pending, but it will have to have the third zipper. Let's start building a lot of 25 now to see if there is any potential problems both here or with Oxy-Health.")). That defendant and HTI were working on a new product is apparent based on the references to a three-zipper design, where the Vitaeris 320 only had two zippers. (See Chamber Brochure). With respect to the Darmofal Email, even though defendant required HTI to obtain its approval to make repairs to products already in the market place, it does not follow that defendant designed the bladder.

In any event, defendant also did not "assemble" the bladder. As before, "assemble" is not defined in the relevant case law or statutes. Thus, the court looks to a dictionary to assist in defining that term. See Jacobsen, 365 N.C. at 476–77. To "assemble" is to "fit together the separate component parts of (a machine or other object)," "Assemble," Oxford English Dictionary, available at http://www.oxforddictionaries.com/definition/english/assemble (last accessed August 18, 2015), or "to fit together parts." "Assemble," Merriam-Webster, available at http://www.merriam-webster.com/dictionary/assemble (last accessed August 18, 2015).

The undisputed facts show that defendant did not "assemble" the bladder within that word's common meaning. Patel testified that defendant's employees "assembled" the bladder only inasmuch as they "[h]ooked up a pump [to the bladder], zip[ped] it up, inflate[d] it, [and inspected it to] see if it's clean." (Patel Dep. 13:20–21, 14:22–24). The extent of any employee's interaction with the bladder involved only "wip[ing] [it] down, if necessary, [and examining the bladder to] see if it's still under pressure." (Id. 13:23–25). Despite plaintiffs' suggestion to the contrary, Patel's non-judicious use of the word "assemble" is insufficient to convert defendant into the bladder's manufacturer in light of the remainder of his testimony bearing on defendant's employees' actual interaction with the bladder. Thus, defendant is not the "manufacturer" of the bladder, and cannot be liable for its design. See N.C. Gen. Stat. §§ 99B–1(2) and 99B–6.

b. Defendant as Manufacturer of the Oxy-Health Vitaeris 320

Notwithstanding the court's holding addressing defendant as the manufacturer of the bladder, plaintiffs also contend defendant "manufactured" the Vitaeris 320, as the product was marketed to consumers, by purchasing the bladder and thereafter assembling or "otherwise preparing" the

chamber by packaging the bladder with an air compressor.[13] In addition, plaintiffs argue defendant "designed" the Vitaeris 320 because it had the power to select the air compressor shipped with the product.

Defendant neither assembled nor otherwise prepared the chamber. "Assembly" connotes at least some amount of fitting products together, not merely packaging them together for sale. See "Assemble," Oxford English Dictionary, supra. Here, defendant only packaged multiple products together into one box. In addition, the phrase "otherwise prepared" is not so broad as to encompass defendant's actions, considered in light of the other words used to define "manufacturer." See N.C. Gen. Stat. § 99B–1(2).

A manufacturer "designs, assembles, fabricates, produces, constructs or otherwise prepares a product." Id. The phrase "otherwise prepares" is an ejusdem generis term, also known as a "catch all." See Meyer v. Walls, 347 N.C. 97, 106 (1997) (holding phrase "all other departments, institutions, and agencies" was an ejusdem generis term where statute listed several specific agencies); State v. Gamble, 56 N.C. App. 55, 57 (1982) (holding phrase "any other structure"

[13] Plaintiffs contend the chamber also was shipped with a mattress. However, plaintiffs cite no evidence to support that contention. (See Lewis Dep. 169:14–17). Because plaintiffs have failed to cite evidence in support of this contention, the court need not consider it further. See Fed. R. Civ. P. 56(c)(3).

In any event, even if plaintiffs had cited admissible evidence tending to show that the Vitaeris 320 was shipped with a mattress, the court does not consider the mattress to be a part of the chamber subject to the instant analysis. In other areas of product liability law, courts have developed tests to determine whether multiple components billed as one "system" actually form one "product" or several "products" for purposes of a product liability action. See, e.g., 2000 Watermark Ass'n, Inc. v. Celotex Corp., 784 F.2d 1183, 1185–86 (4th Cir. 1986); Wilson v. Dryvit Sys., Inc., 206 F. Supp. 2d 749, 753 (E.D.N.C. 2002). These cases generally hold that where a component part of a system is "integral" to the finished product, then it is fairly considered part of the "product" subject to the product liability action. See Wilson, 206 F. Supp. 2d at 753. The court finds these cases instructive, particularly given the consumer protection rationale underlying the rule. See 2000 Watermark, 784 F.2d at 1185–86 (discussing how unnecessary expansion of"manufacturer" liability could lead to increased pricing). The mattresses marketed and sold as part of the chamber are not integral to the system, and should not be considered in the analysis of the "product" at issue. The mattresses are for comfort. As Peter Lewis's deposition makes clear, the chamber is fully operable with only the "bladder" and air compressor. (Lewis Dep. 41:18–43:22).

following a statute defining "building" as "dwelling, dwelling house, uninhabited house, building under construction, building within the curtilage of a dwelling house" to be ejusdem generis term). Under the principle of ejusdem generis, "[w]here words of general enumeration follow those of specific classification, the general words will be interpreted to fall within the same category as those previously designated." Meyer, 347 N.C. at 106.

This principle of statutory construction informs the court's interpretation of the term "manufacturer," particularly the actions that make one a "manufacturer." All of the actions a "manufacturer" might perform connote an active role in either the planning or building of a finished product. See, e.g., "Design," Merriam-Webster, supra; "Assemble," Oxford English Dictionary, supra; "Construct," Oxford English Dictionary, available at www.oxforddictionaries.com/us/definition/american_english/construct ("Build or erect (something, typically a building, road, or machine."); "Produce," Oxford English Dictionary, available at http://www.oxforddictionaries.com/us/definition/american_english/produce ("Make . . . from components or raw material"); id. ("Make (something) using creative or mental skills."); "Fabricate," Oxford English Dictionary, available at http://www.oxforddictionaries.com/us/definition/american_english/fabricate ("Construct . . . (something, especially an industrial product), especially from prepared components."). Here, defendant performed no action that involved the "fitting" of component parts together as one unified product prior to shipment. Rather, the evidence indicates that defendant merely repackaged multiple products into one box. Accordingly, defendant did not "otherwise prepare" the chamber, within the meaning of that phrase, and is not the "manufacturer."

Nevertheless, plaintiffs also suggest defendant "designed" the chamber because defendant was allowed to select the air compressor shipped with the it. However, defendant only

"recommend[ed]" compressors to HTI for inclusion with the Vitaeris 320, (Oxy-Health Dep. 67:21–24), demonstrating that defendant lacked power in the design of the chamber, beyond the mere power of suggestion. Without evidence showing HTI was required to comply with defendant's recommendations, the evidence before the court is insufficient to hold defendant liable as the bladder's "manufacturer."

Plaintiffs make much of an email exchange between Patel and Lewis in which Patel indicated that defendant was working closely with a third corporation, Gast, to develop a certain "enclosures" for compressors shipped with the chamber. (Patel Email). However, these emails do no demonstrate defendant's control over the chamber's design. Rather, the emails only demonstrates that defendant and Gast were collaborating on a design potentially to be implemented in the future, not that a final design actually was implemented. In addition, the record is bereft of evidence to suggest that defendant was involved in the selection of the air compressor actually sold with the chamber. (See Invoice).[14]

2. Defendant as the "Apparent Manufacturer."

Plaintiffs also contend that defendant properly may be considered the "apparent manufacturer" of the chamber, because it provided a "manufacturer's warranty" for the chamber, was the point of contact for all repairs, and actively marketed the chamber, (See Lewis Dep. 26:22–29:6; Distributorship Agreement § 2.1; Janet Presson Dep. 55:1–9, 161:4–164:17; Reference Manual, passim; Oxy-Health Dep. 84:19–24). See Warzynski v. Empire Comfort Systems, Inc., 102

[14] Plaintiffs also suggest defendant is the "manufacturer" because it replaced certain parts on compressors sold into foreign markets. Where the resulting product in that case has a different composition than the product at issue here, despite both chambers being marketed as the Vitaeris 320, the court views them as different products. It does not follow that if defendant is the manufacturer of a Vitaeris 320 as that product is sold into foreign markets defendant also necessarily is the manufacturer of the chamber at issue here.

N.C. App. 222 (1991) (establishing apparent manufacturer doctrine). Defendant disagrees and argues that the apparent manufacturer doctrine applies only in cases where the defendant seller asserts the "sealed container" defense, see generally N.C. Gen. Stat. § 99B–2(a), and in any event, the "apparent manufacturer" doctrine cannot apply here because HTI's name appears on the bladder. (See Manufacturer Label) (depicting a label reading displaying HTI's name on the Chamber). Although this presents a close question, the court agrees with plaintiffs.

In the usual case,

> A retailer who purchases from a reputable manufacturer and sells the product under circumstances where he is a mere conduit of the product is under no affirmative duty to inspect or test for a latent defect, and, therefore, liability cannot be based on a failure to inspect or test in order to discovery such defect and warn against it.

Cockerham v. Ward, 44 N.C. App. 615, 623, disc. rev. denied, 300 N.C. 195 (1980) (internal quotations omitted). However, in a narrow range of cases, North Carolina courts have applied § 400 of the Restatement (Second) of Torts, which imposes liability on the seller of a product as if it were the product's manufacturer, where the seller "puts out [the product] as his own." Restatement (Second) Torts, § 400. See generally, Rulane Gas Co. v. Montgomery Ward & Co., 231 N.C. 270, 275 (1949); Haymore v. Thew Shovel Co., 116 N.C. App. 40, 43–44 (1994); Warzynski, 102 N.C. App. at 225–28. The facts before the court indicate that this may be such a case.

In Warzynski, defendant Empire Comfort Systems, Inc., ("Empire"), distributed a gas heater, manufactured by Safel-Inelsa Orbaiceta, S.A., ("Safel"), a Spanish company. Warzynski, 102 N.C. App. at 224. Empire was Safel's exclusive U.S. distributor and purchased, in connection with Safel, commercial advertising for the heater. Id. Empire serviced the heaters, which came with an "Empire Heating Appliance Limited Warranty." Id. at 228. In addition, the advertising insinuated Empire manufactured the heaters. Id. ("One of Empire's promotional flyers for dealers and

wholesalers called the Empire Corcho 'America's best made and best-selling unvented gas wall furnace.'"). The only indication that Empire was not the heater's manufacturer was a label indicating that the heater was "made in Spain." Id. At summary judgment, Empire asserted a sealed container defense under N.C. Gen. Stat. § 99B–2, arguing that it received the heaters in sealed containers and was nothing more than a "conduit." Id. at 225.

Under these facts, the North Carolina Court of Appeals adopted § 400 of the Restatement and held that the sealed container defense was inapplicable. Id. at 226–28. Quoting from the restatement, the court reasoned "The mere fact that the goods are marked with such additional words as 'made for' the seller, or describe [the seller] as a distributor, particularly in the absence of a clear and distinctive designation of the real manufacturer . . . is not sufficient to make inapplicable the [apparent manufacturer rule]." Id. at 226–27.

The facts of the case at bar nearly are indistinguishable from those of Warzynski. Defendant distributed the Vitaeris 320 in boxes labeled as its own. Inside the box, the chamber was packaged with an "operating and reference" manual that is rife with examples insinuating that defendant was the chamber's manufacturer. In particular, the "Oxy-Health" branded Reference Manual refers to "chambers manufactured after 2002," (Reference Manual at 13–14); discusses the chamber's FDA 510(k) clearance, without ever indicating that defendant was not involved in obtaining that clearance, (id. at 32); and indicates that defendant provides consumers with a "manufacturer's warranty," which requires the product be shipped directly to defendant for service. (Id. at 35). Moreover, defendant made a number of statements in videos provided on its website that may lead reasonable people to believe defendant hand selected the materials from which the chamber was made. (See Workman Report at 8). The evidence suggests that defendant alone manufactured the

chamber. (Agreement § 2.1; Lewis Dep. 26:22–29:6). Based on this evidence, there are genuine issues of material fact about whether defendant was the chamber's "apparent manufacturer."

Defendant contends Warzynski is inapplicable for two reasons. First, defendant highlights a factual distinction, the fact that HTI's name appears on the chamber, whereas in Warzynski, Safel was not named on the heater. Second, defendant argues that, notwithstanding the facts of Warzynski, the "apparent manufacturer" doctrine may apply only when a seller asserts a sealed container defense. The court is not persuaded.

Turning first to defendant's attempt to distinguish Warzynski on its facts, defendant's argument falls short. Defendant contends the Warzynski court attached special significance to the fact that Safel was named nowhere either on the product or in its advertising. Although the court did mention the absence of Safel's name, Warzynski, 102 N.C. App. at 228 ("The decal did not refer to Safel at all."), there is no indication that the presence of Safel's name would have been determinative in the outcome of the case.[15] In addition, the commentary to § 400 counsels against finding the presence of HTI's name determinative of the issue. Comment d provides that there can be no "apparent manufacturer" liability, "where the real manufacturer or packer is clearly and accurately identified on the label . . . and it is also clearly stated that another who is also named has nothing to do with the goods except to distribute or sell them." Restatement, supra § 400 cmt. d; see also Carney v. Sears, Roebuck & Co., 309 F.2d 300, 304 (4th Cir. 1962) (applying "apparent manufacturer" doctrine); Swift & Co v. Blackwell, 84 F.2d 130, 132 (4th Cir. 1936) (holding

[15] The court has found no case supportive of defendant's position. Cf. Kuiper v. Shoei Safety Helmet Corp., 149 N.C. App. 973, 2002 WL 554930, at *3 (2002) ("Plaintiff has not presented any evidence that defendant and the manufacturing company shared the expenses of advertising; that plaintiff serviced repairs for the helmets; that defendant offered its personal warranty for the helmets; that any or all of the advertising materials referenced defendant and not the manufacturer; or that defendant failed to include the manufacturer's information on any of the advertisements.").

defendant could be liable under "apparent manufacturer" doctrine where defendant stated it was the product's "distributor" in "type quite small when compared with the word[s] . . . elsewhere displayed"); Bilenky v. Ryobi Techs., Inc., __ F. Supp. 3d __, 2015 WL 3946612, at *6–8 (E.D. Va. 2015) (relying on Swift in applying "apparent manufacturer" doctrine). Defendant cites no evidence showing that it ever clearly indicated it was nothing more than a distributer or seller.

Defendant's second argument also misses the mark. There is nothing in the case law that indicates the "apparent manufacturer" doctrine only may apply in cases where the statutory sealed container defense is asserted. See generally N.C. Gen. Stat. § 99B–2 (establishing "sealed container" defense). Rather, courts generally apply the "apparent manufacturer" doctrine to impose upon the seller of a chattel vicarious liability commensurate with that which could be imposed on the manufacturer. See, e.g., Swift, 84 F.2d at 132; Kennedy v. Guess, Inc., 806 N.E.2d 776, 785–86 (Ind. 2004) (holding seller held to same standard of care as manufacturer); Stones v. Sears, Roebuck & Co., 251 Neb. 560, 564–65 (1997) (holding purpose of doctrine is to impose liability on "the party whose actions effectively conceal the true manufacturer's identity"); Forry v. Gulf Oil Corp., 428 Pa. 334, 343–44 (1990); Media Prod. Consultants, Inc.v v. Mercedes-Benz of N. Am., Inc., 262 La. 80, 89–90 (1972) ("We hold, therefore, that the liability of MBNA to the American consumer is that of the manufacturer of a defective vehicle."); Burkhardt v. Armour & Co., 115 Conn. 249, 161 A. 385, 391 (1932) (holding one who holds itself out as a manufacturer is estopped from denying its identity as a manufacturer), overrule on other grounds 122 Conn. 80, overruled on other grounds 153 Conn. 356; Martin v. Schoonover, 13 Wash. App. 48, 54 (1975).

In its final effort to distance this case from the apparent manufacturer doctrine, defendant argues that it should not apply here, where the Sparks family purchased the Chamber second hand

and did not actually rely on defendant's advertising or warranty in making the decision to purchase the Chamber. However, defendant's argument must fail. Plaintiffs do not need to show any member of the Sparks family relied on defendant's marketing of the Vitaeris 320 when the family decided to purchase the Chamber. Rather, the appropriate focus of the apparent manufacturer inquiry is the effect of defendant's marketing on the public at large. Hebel v. Sherman Equip., 92 Ill. 2d 368, 374 (1982) ("The primary rationale for imposing liability on the apparent manufacturer of a defective product is that it has induced the purchasing public to believe that it is the actual manufacturer, and to act on this belief - that is, to purchase the product in reliance on the apparent manufacturer's reputation and skill in making it."); see also Carney, 309 F.2d at 304–05; Kennedy, 806 N.E.2d at 784; Dudley Sports Co. v. Schmitt, 151 Ind. App. 217, 225 (1972) ("When a vendor puts his name exclusively on a product, in no way indicating that it is the product of another, the public is induced to believe that the vendor was the manufacturer of the product. . . . When products are held out in this manner, the ultimate purchaser has no available means of ascertaining who is the true manufacturer."). In light of defendant's marketing, as discussed above, a reasonable juror could conclude defendant was the Chamber's apparent manufacturer. Thus, the court now turns to the substance of plaintiffs' claims.

3. Product Liability Claims

North Carolina by statute has adopted a specific structure for product liability actions. See generally N.C. Gen. Stat. ch. 99B. Unfortunately, this statute is not a model of clarity, and many judicial opinions interpreting it have done so piecemeal. As gleaned from the language of the statute, and relevant case law, all claims "brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation,

development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product" properly are termed "product liability actions." See N.C. Gen. Stat. § 99B–1(3). Recovery for a product liability action may be premised either on contract or tort principles. See DeWitt v. Everready Battery Co., 355 N.C. 672, 682 (2002); Tetterton v. Long Mfg. Co., 314 N.C. 44, 50 (1985) ("On the face of this statute, it seems evident that this act . . . was meant and intended to apply to manufacturers and retail sellers alike."); Red Hill Hosiery Mill, Inc. v. MagneTek, Inc., 138 N.C. App. 70, 74–75 (2000).

In the usual case, where a product liability claim sounds in tort, as the parties suggest plaintiffs' claims do here, the plaintiff must prove duty, breach, causation, and damages. Bryant v. Adams, 116 N.C. App. 448, 465 (1994); see also Yates v. Ford Motor Co., No. 5:12-CV-752, 2015 WL 2189774 (E.D.N.C. May 11, 2015); Durkee v. C.H. Robinson Worldwide, Inc., 765 F. Supp. 2d 742, 748 (W.D.N.C. 2011). Those elements are satisfied where the plaintiff demonstrates "(1) the product was defective at the time it left the control of the defendant, (2) the defect was the result of defendant's negligence, and (3) the defect proximately caused plaintiff damage." Red Hill, 138 N.C. App. at 75; see also Farrar & Farrar Farms v. Miller-St. Nazianz, Inc., 477 F. App'x 981, 984 (4th Cir. 2012).

The Estate may prove the first element, product defect, either by direct evidence, such as expert testimony, or by relying on the inference of negligence that arises upon a showing that the product malfunctioned after it was put to its ordinary use. See Bernick v. Jurden, 306 N.C. 435, 450 (1982); City of Thomasville v. Lease-Afex, Inc., 300 N.C. 651, 656 (1980); Red Hill, 138 N.C. App. at 76. However, if the Estate relies on inference to establish product defect, it must present direct evidence that the defect was a result of defendant's negligence. See Red Hill, 138 N.C. App. at 77

n.7; see also McLaurin v. E. Jordan Iron Works, Inc., 666 F. Supp. 2d 590, 600 (E.D.N.C. 2009) (noting that where there is no direct evidence of defect, plaintiff must "come forward with evidence that suggests what a reasonable person would do in similar circumstances"); Carlton v. Goodyear Tire & Rubber Co., 413 F. Supp. 2d 583, 588 (M.D.N.C. 2005) ("[A] plaintiff may not prove negligence by stacking inference upon inference."). Thus, the Estate may not prevail on its claim if that claim solely rests on inferential evidence.

The product liability statute subjects all product liability claims to special statutory defenses. See N.C. Gen. Stat. §§ 99B–2 through –4. In addition, Chapter 99B theoretically imposes upon certain claims heightened proof requirements. See id. §§ 99B–5 & –6. Claims alleging inadequate warning or instruction, N.C. Gen. Stat. § 99B–5, or inadequate design or formulation, id. § 99B–6, require proof of additional statutory elements. See, e.g., Durkee, 765 F. Supp. 2d at 748–49 (noting plaintiff must prove statutory factors in order to establish negligence). These sections, in theory, swallow up a large segment of potential product liability claims. However, they leave unaffected, for example, manufacturing defect claims, see generally, Restatement (Third) of Torts, Products Liability § 2 (defining "manufacturing defect" and contrasting that term with "design defect"), or claims alleging negligent assembly or inspection. See, Crews v. W.A. Brown & Son, Inc., 106 N.C. App. 324, 329–30 (1992) (addressing claims of negligent assembly, installation, and inspection).

Having stated the controlling principles of law, the court now turns its attention to the substance of defendant's motion.

a. § 99B–6: Design Claim

Section 99B–6 provides:

> No manufacturer of a product shall be held liable in any product liability action for the inadequate design or formulation of the product unless the claimant proves that

> at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product, [and] that this conduct was a proximate cause of the harm for which damages are sought.

N.C. Gen. Stat. § 969B–6(a). Further, a claim under § 99B–6 requires a plaintiff prove that "[a]t the time the product left the control of the manufacturer," either "the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product" or "the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design." Id.

To determine whether a manufacturer has breached its duty, the statute supplies a list of relevant considerations including: the scope of the risks associated with the product's design "in light of the intended and reasonably foreseeable uses, modifications, or alterations"; the likely awareness of users of the risks "whether [that awareness is] based on warnings, general knowledge, or otherwise"; design compliance with applicable government standards; extent to which labeling conformed to applicable government or private standards; utility of design; feasability of alternative designs at the time of manufacture; and the nature and magnitude of foreseeable risks. Id. § 99B–6(b).

Plaintiffs contend the Chamber contained two design defects, which form the basis of the Estate's § 99B–6 claim. First, plaintiffs argue that using the "quick disconnect" valve to secure the sole means of delivering oxygen to the chamber was a design defect, because of the ease with which the valve could disconnect. Plaintiffs suggest the quick disconnect valve should have been replaced by a threaded connector. Second, plaintiffs argue that failure to incorporate an oxygen sensor (or

as the alternative side of the coin, a carbon dioxide sensor) with an alarm was a design defect, because patients inside the chamber might not appreciate that oxygen levels were depleting if the quick-disconnect valve became disengaged.

Defendant argues that plaintiffs have failed to forecast any evidence supporting the statutorily enumerated factors contained in § 99B–6(a) or § 99B–6(b) with regard to either alleged design defect, or, in any event, that plaintiffs cannot present evidence to raise proximate cause above the speculative level. In response to defendant's first argument, plaintiffs lay out their evidence on the § 99B–6 factors. In response to defendant's proximate cause argument plaintiffs rely heavily on the testimony of their expert, Ron Natoli, as well as the Cumberland County Sheriff's Department's Report detailing the agency's investigation into Jarred's death. In addition, plaintiffs contend that, even if Natoli's testimony and the Sheriff's Report are insufficient, the inference of negligence is sufficient to preclude summary judgment and carry this case to the jury. The court agrees with defendant. Plaintiffs have failed to adduce sufficient evidence of proximate cause.

Plaintiffs have presented sufficient evidence of the factors set out in § 99B–6(a) & (b). "A showing that a defendant acted unreasonably under section 99B–6(a)(1) requires evidence" in satisfaction of four separate factors. They are as follows:

- that the proposed alternative design or formulation was "a safer, practical, feasible, and otherwise reasonable" design or formulation;
- that the alternative design or formulation "could then have been reasonably adopted";
- that the alternative design or formulation would have prevented or substantially reduced the risk of harm complained of; and
- that the alternative design or formulation would not have substantially impaired the usefulness, practicality, or desirability of the product.

See DeWitt v. Everready Battery Co., 144 N.C. App. 143, 159 (2001) aff'd 355 N.C. 672 (2002); see also N.C. Gen. Stat. § 99B–6. Here, plaintiffs have satisfied these four factors with respect to both the threaded connector and alarming oxygen sensor. To support the feasibility of implementing a threaded disconnect valve and alarming oxygen sensor, plaintiffs rely on a competitor hyperbaric chamber, the SOS Hyperlite, which possessed these features. (See SOS Hyperlite Brochure). Plaintiffs have submitted an expert report indicating that these features would have improved the Chamber's safety. (See Natoli Report at 10–12). In addition, Natoli's report suggests that these features were available in 2005, at the time the Chamber was manufactured. (See id.). Finally, Natoli's report indicates that use of a threaded connector and alarming oxygen sensor could have prevented or reduced the likelihood of Jarred's death without impairing the Chamber's usefulness. (Id.).

In addition, plaintiffs have presented evidence bearing on a number of the factors set out in § 99B–6(b). This list of factors is non-exclusive and "[a] plaintiff is not required to present evidence on all of these factors in order to meet his burden of proving a defective design claim, as some of these factors may not be relevant to a particular plaintiff's claim." DeWitt, 144 N.C. App. at 514–15. In particular, plaintiffs have shown that asphyxiation was a harm associated with the chamber as designed, (Oxy-Health Dep. 105:8–21, 108:5–109:15, 166:10–17);[16] the utility of the chamber would not have been affected by plaintiffs' proposed design changes, (Natoli Report 8–9, 16) ("The benefit[] of using a quick disconnect for the air supply connections on the [chamber] [is] the simplicity of not requiring a special tool and speed of setup."); implementing the proposed design changes would have been feasible at the time the chamber left HTI, (SOS Hyperlite Brochure); the

[16] Although defendant is not the manufacturer, defendant's knowledge of the potential asphyxiation hazard posed by the chamber system is relevant to show the nature of the risk.

changes would have been economically feasible, (id.); and there were few risks associated with adding a threaded connector. (Natoli Dep. 219:24–220:5). This evidence, viewed in the light most favorable to plaintiffs, is sufficient to carry the Estate's burden of showing that the chamber's manufacturer, HTI, acted unreasonably. Thus, defendant may be liable because, when the evidence is viewed in the light most favorable to plaintiffs, defendant was the Chamber's apparent manufacturer.

Next defendant argues the Estate's design defect claim fails because there are too many factors unaccounted for that could have proximately caused Jarred's death, rendering plaintiffs' proof of causation speculative. The court agrees.

Typically, proximate cause is a question of fact. Ross v. Wash. Mut. Bank, 566 F. Supp. 2d 468, 479 (E.D.N.C. 2008), aff'd sub nom, Ross v. F.D.I.C., 625 F.3d 808 (4th Cir. 2010). To survive summary judgment on the issue of proximate cause, a non-movant's evidence must be fact-specific and not merely speculative. Id. Although the issue proximate cause usually should be submitted to the jury, where there are multiple intervening factors and insufficient evidence to raise above speculative the proximate causal element linking defendant's conduct to the alleged harm, the issue properly is decided as a matter of law. See, e.g., Sakaria v. Trans World Airlines, 8 F.3d 164, 172–73 (4th Cir. 1993); RLM Comm'ns, Inc. v. Tuschen, 66 F. Supp. 3d 681, 698 (E.D.N.C. 2014). Stated another way, to survive a motion for summary judgment there must be sufficient evidence to indicate that the product defect was the "probable," rather than merely a possible cause of Jarred's death. Sakaria, 8 F.3d at 172–73; cf. Md. Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 785–86 (4th Cir. 1998) (finding question of fact as to existence of proximate cause where plaintiff had introduced evidence excluding other possible causes).

Plaintiffs cannot demonstrate a causal connection between the alleged product defects and the harm suffered with the requisite degree of probability. Throughout their briefing plaintiffs propound Natoli's theory of causation, that the quick disconnect button came into contact with shelving near the chamber, as the proximate cause of Jarred's death. However, plaintiffs' evidence does nothing more than show that, at best, the quick disconnect button was a but-for cause of Jarred's death, to say nothing of the speculative basis for Natoli's testimony. (See Dylan Sparks Dep. 92:9–93:2; Sheriff's Report at 1, 7) (collectively indicating that the quick disconnect valve was identified as the but-for cause of Jarred's death several hours after his death occurred, and only after the Chamber had been introduced to numerous outside factors).

The issue with plaintiffs' causal theory is that other factors potentially could have prevented Jarred's death. Most notably, operation of the Chamber consistent with the instructions found in the Reference Manual provided by A Small Miracle, as well as operation of the Chamber consistent with the practice which plaintiff Amy Sparks had observed while Jarred was receiving treatment from Creation's Own and A Small Miracle. The Reference Manual specifically refers to an attendant being present at all times during HBOT. (See Reference Manual at 26 ("7th OBSERVE . . . Set a clock or timer for the prescribed treatment period. Reassure the person inside the chamber that the attendant will remain with them during the entire treatment and will be regularly checking on them."); id. at 23 ("We recommend that an attendant be present during the entire time someone is inside the chamber.")).

Moreover, in all previous experiences with HBOT an attendant regularly had checked on Jarred throughout the treatment. (Amy Sparks Dep. 77:4–12, 94:12–16, 96:3–13, 127:4–22; Kartzinel Dep. 57:16–58:14). And when no attendant was present, someone frequently was in either

the room or the chamber with him. (See Amy Sparks Dep. 77:4–12, 94:12–16, 96:3–13, 127:4–22). It is undisputed that on the night of Jarred's death there was no attendant present in the room, nor was any member of the Sparks family intermittently checking on Jarred. Finally, plaintiffs have cited no evidence as to how long Jarred could have survived in the Chamber without an influx of fresh oxygen. Without that evidence plaintiffs cannot be heard to argue that the presence of an attendant would have made no difference.

In addition, there is no evidence to suggest that the same harm would have occurred had either Amy or Dylan Sparks been awake throughout Jarred's treatment. The Sheriff's Report created following Jarred's death shows that, although the whistling noise associated with the Chamber remained constant, the air compressor actually made a much louder sound when the hose became disconnected from the Chamber. (See Sheriff's Report at 3–4). The evidence suggests that the standard noise created the air compressor already was audible throughout the Sparkses's home. Accordingly, it is speculation to assert that either Amy or Dylan Sparks would not have heard and appreciated the new, distinct, and louder noise being produced by the air compressor had they been awake.

Without evidence tending to show that the same result would have occurred even if Jarred's use of the chamber had been supervised consistent with the instructions provided in the Reference Manual and Amy Sparks's experience, the causal connection between the quick disconnect valve, as well as the lack of an oxygen sensor, and the harm suffered by Jarred is too speculative. Without a showing that defendant's conduct was "probably" the legal cause of Jarred's death, the Estate is not entitled to have this claim submitted to the jury.

Nevertheless, plaintiffs submit a number of contrary arguments. The court, however, finds each unpersuasive. Chiefly plaintiffs contend it was "foreseeable" that someone might not read the Reference Manual. The import of plaintiffs' argument is that because it was foreseeable a purchaser might not read the Reference Manual, inclusion of the quick disconnect valve and failure to implement an alarming oxygen monitor proximately caused Jarred's death. "Foreseeability" is an oft-cited aspect of probable cause typically used to limit a defendant's liability to that group of harms that reasonably could have been predicted. See Harison v. Alexander Tank & Equip. Co., 310 N.C. 227, 234 (1984); Hart v. Curry, 238 N.C. 448, 449 (1953) (internal quotations omitted) ("All that the plaintiff is required to prove on the question of foreseeability, in determining proximate cause, is that in the exercise of reasonable care, the defendant might have foreseen that some injury would result from his act or omission, or that consequences of a generally injurious nature might have been expected."). In the instant matter it hardly can be argued that the harm suffered was not foreseeable. However, plaintiffs' argument misses the mark. The Estate also must show that the foreseeable harm suffered was "probably" caused by a product defect, which it cannot do. Without evidence tending to deemphasize the impact the lack of supervision had on the harm Jarred suffered, the court is not persuaded that the requisite causal element is met in this case. See Therm-O-Disc, 137 F.3d at 785–86; cf. Champs Convenience Stores, Inc. v. United Chem. Co., 329 N.C. 446, 450, 456 (1991) (allowing issue of contributory negligence to go to jury where plaintiff was fully informed of proper instructions and acted in accord with those instructions).

Plaintiffs also argue that it was foreseeable that a patient might use the Chamber without an attendant present, based on assertions in defendant's promotional material that users could "self treat." However, plaintiffs cite no evidence that suggests "self treat," as used in defendant's various

advertisements, meant treatment without any attendant present. To the contrary, Lewis testified that self treatment, as used in defendant's promotional materials still means treating with an attendant present. (See Lewis Dep. 196:2–15). In support of their theory that "self treatment" really means "treatment without an attendant" plaintiffs submitted to the court a video found on defendant's website which plaintiffs argue reenforces their definition of "self treatment." It does not. Throughout the video, patients are shown entering the chamber either with another person or with an attendant present in the room; sometimes both.[17] Moreover, plaintiffs cannot create a genuine dispute of fact as to the causative element simply by arguing that it is foreseeable that a patient, in the abstract, might self treat. The undisputed evidence shows that both Amy and Dylan Sparks were present the night of the incident and both could have followed the instructions in the Reference Manual.

In any event, plaintiffs contend that the inference of negligence, commonly called res ispa loquitur, can carry the Estate's § 99B–6 claim to the jury. It cannot. The "doctrine of [r]es ipsa loquitur recognizes that common experience sometimes permits a reasonable inference of negligence from the occurrence [of an injury] itself." Page v. Sloan, 12 N.C. App. 433, 437 (1971). "When a thing which causes injury is shown to be under the exclusive management of the defendant and the accident is one which in the ordinary course of events does not happen if those in control of it use proper care, the accident itself is sufficient to carry the case to the jury on the issue of [the defendant's] negligence." O'Quinn v. Southard, 269 N.C. 385, 390 (1967). Where res ipsa applies, the inference of negligence precludes summary judgment. Page, 12 N.C. App. at 437.

[17] The video was submitted to the court on a disk. The video is available online at http://www.oxyhealth.com/tradition-of-safety.html.

Res ipsa loquitur is inapposite at this stage of the analysis. First, the Estate already has been granted the inference of negligence, which arises upon proof of a product defect by direct evidence. See Bernick,306 N.C. at 450; City of Thomasville, 300 N.C. at 656; Red Hill, 138 N.C. App. at 76. In any event, at heart, any product liability action sounding in negligence requires proof that the product was defective as a result of defendant's negligence, and that the defect itself proximately caused plaintiffs' injury. See Red Hill, 138 N.C. App. at 75. Even inferring HTI's negligence, and imputing such negligence to defendant, "plaintiff must also establish the element of causation by proving by a preponderance of the evidence that it was some aspect of the challenged design that rendered the product's performance less safe than an ordinary consumer would expect, resulting in injury." See Am. L. Prod. Liab. 3d § 30:54; see also 1 Owen & Davis on Prods. Liab. § 2:27 (4th ed. 2014 & Supp. 2015) ("[R]es ipsa served in certain cases as an important mechanism for unburdening plaintiffs from having to establish specifically how a manufacturer or other supplier had been negligent."). Thus, in a product liability action the inference of defendant's negligence, without more, does not carry the plaintiff's claim to the jury. Rather, the plaintiff must demonstrate a causal connection between the product itself and the harm suffered. Here, because plaintiffs cannot show a proximate link between the alleged design defects and the harm suffered, the Estate is not entitled to present this claim to the jury.

In any case, res ipsa only may apply where the thing causing the harm was under defendant's exclusive control. O'Quinn, 269 N.C. at 390. Here, the evidence establishes that the Sparks family purchased the Chamber from A Small Miracle several years after defendant originally sold it to Vita02, who in turn sold it to A Small Miracle. As a result, the Chamber hardly can be considered to have been in defendant's exclusive control.

In summary, defendant's motion is granted as to the Estate's § 99B–6 claim. Plaintiffs have failed to forecast sufficient evidence showing that the alleged design defects were the proximate cause of Jarred's death. There is no evidence that suggests that if Jarred's use of the Chamber had been supervised during HBOT, consistent with plaintiff Amy Sparks's experience and the explicit instructions in the Reference Manual, that the same harm would have resulted. Any argument to the contrary is speculation.

b. § 99B–5: Warning Claim

Section 99B–5 provides that:

> No manufacturer or seller of a product shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant proves that the manufacturer or seller acted unreasonably in failing to provide such warning or instruction, [and] that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought.

N.C. Gen. Stat. § 99B–5(a). In addition, a plaintiff also must prove that at the time the product left the manufacturer or seller, "the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant," or that thereafter the manufacturer or seller "became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances." Id.

Unlike § 99B–6, the statute does not provide factors dictating the applicable standard of care. However, North Carolina courts have formulated two applicable standards of care, depending on whether the defendant properly is characterized as the Chamber's manufacturer or seller. "A

manufacturer . . . [has] the duty to perform reasonable tests and inspections to discover latent hazards." Nicholson v. Am. Safety Util. Corp., 124 N.C. App. 59, 65 (1996), aff'd as modified, 346 N.C. 767 (1997). In addition, "a manufacturer is under an obligation to provide warnings of any danger associated with the product's use [that are] sufficiently intelligible and prominent to reach and protect all those who may reasonably be expected to come into contact with the product." Id. (alterations, internal citations, and quotations omitted). By contrast, a non-manufacturing seller "has the duty to warn of hazards attendant to the assembled and installed product's use but only where the seller has actual or constructive knowledge of a particular threatening characteristic of the product." Crews, 106 N.C. App. at 330. The seller's duty to warn is not triggered unless the seller "has reason to know that the purchaser will not realize the product's menacing propensities for himself." Id. In addition, neither the manufacturer nor seller have the obligation to warn where the risk posed by the product is "open and obvious . . . [or is] a risk that is a matter of common knowledge." N.C. Gen. Stat. § 99B–5(b).

In support of its motion for summary judgment, defendant raises a number of arguments. First, defendant contends that plaintiffs have not submitted any evidence to support the inference that defendant knew or should have known that the quick disconnect valve had a propensity to disconnect inadvertently. In addition, defendant argues that the Chamber's lack of oxygen sensor was obvious, and thus required no warning. In any case, defendant also contends Jarred's death was not caused by a failure to warn. Defendant argues that the Sparks family did not read the Reference Manual, which was provided to them with the Chamber, and in addition flagrantly disregarded the warnings already supplied on the Chamber such that no evidence can support the inference that an additional warning would have prevented the incident.

In response, plaintiffs argue that defendant misstates the nature of the hazard; that the real hazard was asphyxiation. In addition, plaintiffs argue that defendant's assertion as to plaintiffs' failure to follow the instructions already on the chamber is of no moment, because that fact has no bearing on whether Amy or Dylan Sparks would have followed an additional warning addressing the risk of asphyxiation.

At the outset, the court must address the standard of care applicable to defendant under the circumstances. This determination is necessary in a case such as this, where the court already has held that defendant was not the Chamber's manufacturer but may be the Chamber's "apparent manufacturer." After consideration of the record evidence, it is clear that the Estate may proceed against defendant only as the Chamber's "seller or distributor." Because the "apparent manufacturer" theory imposes upon defendant liability commensurate with that which could be imposed on the actual manufacturer, See, e.g., Swift, 84 F.2d at 132; Kennedy, 806 N.E.2d at 785–86; Stones, 251 Neb. at 564–65, to proceed on such theory requires evidence of the actual manufacturer's failure to warn. Here, plaintiffs cite no evidence and advance no argument suggestive of HTI's negligence. Accordingly, the court concludes that the Estate's § 99B–5 claim properly is considered as one against defendant as the Chamber's distributor.

Plaintiffs argue that the primary hazard of which defendant failed to warn is the risk of asphyxiation. As the seller, defendant had a duty to warn only if it had "actual or constructive knowledge" of the particular asphyxiation risk. Crews, 106 N.C. App. at 330. Plaintiffs' evidence shows defendant had actual knowledge that a lack of air in the chamber could lead to death by asphyxiation, and that if the quick disconnect valve disengaged air would stop flowing into the chamber. (Oxy-Health Dep. 166:10–17; see also id. 105:8–21, 108:5–109:15). However, the

particularity requirement demands more specificity when defining the risk necessitating a warning. See, e.g., Mitchell v. City of Warren, __ F.3d __, 2015 WL 4978685, at *2–4 (6th Cir. 2015) (holding knowledge that a taser poses a risk of cardiac arrest generally does demonstrate knowledge that the taser may cause cardiac arrest from ventricular fibrillation)[18]; Taylor v. Am. Chem. Council, 576 F.3d 16, 27–28 (1st Cir. 2009) (holding manufacturer's knowledge that exposure to chemical damages the liver does not prove knowledge that exposure causes cancer); Perlmutter v. U.S. Gypsum Co., 4 F.3d 864, 869–70 (10th Cir. 1993) (holding knowledge that some varieties of asbestos cause lung damage does not prove knowledge that all varieties did); Basko v. Sterling Drug, Inc., 416 F.2d 417, 421 (2d Cir. 1969) (holding manufacturer's knowledge that a drug causes blurred vision does not prove knowledge the drug caused retinal damage). In the case at bar, the real risk of which plaintiffs complain is the risk of asphyxiation posed by the unintentional disconnection of the quick disconnect valve. Although there is evidence that defendant appreciated the risk posed by the quick disconnect valve if it disengaged, (Oxy-Health Dep. 162:4–11), there is no evidence of record to suggest that defendant knew the quick disconnect valve unintentionally would disengage with someone in the chamber, thus leading to asphyxiation.[19] Accordingly, because plaintiffs cannot

[18] Although the Fourth Circuit has addressed similar subject matter, see Fontenot v. Taser Int'l, Inc., 736 F.3d 318 (4th Cir. 2013), the court has not addressed squarely the duty issue raised in Mitchell v. City of Warren, 2015 WL 4978685. In Fontenot the Fourth Circuit reversed the district court's grant of judgment as a matter of law on a § 99B–5 claim alleging failure to warn about the risk of cardiac arrest caused by ventricular fibrillation. The distinction between the two cases is this: in Mitchell there was no admissible evidence regarding the particular risk of cardiac arrest caused by ventricular fibrillation, see 2015 WL 4978685, at *2, 6–8 (2015), while in Fontenot such evidence did exist. See Fontenot, 736 F.3d at 332–33.

[19] There is in the record an incident report filed with the FDA after an incident at a 2002 trade show where a quick disconnect valve was forcibly separated from the hose connecting the valve to the air compressor. (See MAUDE Report). However, for two reasons, that evidence is not entitled to consideration. First, plaintiffs do not cite this evidence in their brief. See generally Fed. R. Civ. P. 56(c)(3). In any event, the MAUDE report indicates that the reporting individual actually did not see the device malfunction, but, rather, assumed that the quick disconnect valve became disconnected from the chamber. However, other evidence indicates that the reporter's assumption was incorrect. (See Patel Decl. ¶13). Specifically, Patel's declaration indicates that the sales representative did not have the valve connected to the chamber, but that the representative was holding the valve in her hand at the time of the incident. (Id.).

establish that defendant owed a duty to warn, defendant's motion must be granted as to the Estate's failure to warn claim.

In any event, the Estate's § 99B–5 claim also must fail because plaintiffs have put forward no evidence showing defendant's failure to warn was the proximate cause of decedent's death. Proximate cause requires something more concrete than mere speculation or conjecture. See Edwards v. ATRO SpA, 891 F. Supp. 1074, 1078 (E.D.N.C.) supplemented, 891 F. Supp. 1085 (E.D.N.C. 1995); see also Stiles v. Chloride, Inc., 668 F. Supp. 505, 507 (W.D.N.C. 1987) aff'd 856 F.2d 187 (4th Cir. 1988) ("[P]laintiff's evidence . . . must exceed mere conjecture") (alterations and internal quotations omitted); cf. Champs, 329 N.C. at 450, 456. Given the Sparks family's collective failure to read the Reference Manual sold with the Chamber, as well as their noncompliance with other warnings on the Chamber, any suggestion that Amy or Dylan Sparks would have acted differently on the night of Jarred's death if supplied with an additional on-chamber warning is inherently speculative.

The evidence shows that neither Robert, Amy, nor Dylan Sparks ever read the instruction manual that came with the Chamber when it was purchased from A Small Miracle, and plaintiffs do not dispute this claim. (See Amy Sparks Dep. 154:2–21; Robert Sparks Dep. 34:4–25; Dylan Sparks Dep. 64:19–65:5). Rather, the Estate's inadequate warning claim rests entirely on a lack of on-chamber warnings. However, the undisputed evidence shows the Sparkses failed to follow a pre-

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The declaration further indicates that the error was caused by a check valve in the hose, which prevented air from freely flowing out of the hose without being engaged with the chamber, not the valve's "quick disconnect" feature. (See id.). As a result of increasing air pressure caused by the running air compressor, the valve disconnected from the hose. (Id.). The evidence suggests that the specific issue with the quick disconnect valve giving rise to the 2002 incident had been remedied by the time the Chamber was sold. (Lewis Dep. 54:6–9, 58:3–14; Change Notice). Because the nature of the defect was different than that alleged by plaintiffs, the 2002 MAUDE Report cannot be relied upon to establish defendant's knowledge of the particular hazard at issue in this case.

existing on-chamber warning. (See Concentrator Label; Amy Sparks Dep. 186:20–187:6) (indicating plaintiffs "always" inflated the chamber with enriched oxygen, despite explicit on-chamber warning). Moreover, there is no evidence to suggest that Amy or Dylan Sparks would have followed any additional on-chamber warning on the night of the Jarred's death. As plaintiffs' expert, Nancy Grugle, testified, there is no way to "guarantee that someone [would] read . . . or comply with [an on product warning]." (Grugle Dep. 144:4–12). Accordingly, because the Sparks family did not read the Reference Manual or follow existing warnings, and because there is no credible evidence to suggest an on-chamber warning would have changed Amy or Dylan Sparks's behavior, plaintiffs cannot establish causation as a matter of law. Defendant's motion is granted as to this claim.

In sum, defendant's motion for summary judgment mounting an attack on the Estate's § 99B–5 claim is granted. Plaintiffs cannot demonstrate defendant's knowledge of the particular risk at issue and thus cannot demonstrate that defendant had a duty to warn about the alleged asphyxiation hazard. Moreover, plaintiffs cannot establish that defendant's failure to warn proximately caused Jarred's death. Of particular importance is the Sparks family's collective failure to read the Reference Manual provided with the Chamber and failure to follow warnings already on the Chamber. These failings, in combination with the deposition testimony of plaintiffs' expert, Grugle, who cannot say with certainty that an additional warning would have been read, demonstrate that this issue is too speculative to present to the jury.

c. Other Negligence Claims

Defendant also suggests it is entitled to summary judgment on plaintiffs' product liability based negligence and NIED claims. Plaintiffs' complaint recites a host of other common-law

negligence claims, including claims alleging negligent manufacture and distribution of the Chamber; negligent failure to provide proper and safe materials for use in the Chamber; and negligent inspection or testing. (Compl., DE 1, ¶66). By operation of statute, these claims also are product liability claims. N.C. Gen. Stat. § 99B–1(3).

With reference to the Estate's negligence claims, to prevail on those claims the Estate must demonstrate 1) a product defect, 2) caused by defendant's negligence, 3) which proximately caused Jarred's death. The Estate may prove the existence of a defect by direct or circumstantial evidence. Where defect is proved directly, the inference of negligence arises. However, if the Estate proves the existence of a defect by circumstantial evidence, it must prove negligence with specific evidence. Carlton, 413 F. Supp. 2d at 588("[A] plaintiff may not prove negligence by stacking inference upon inference."); Red Hill, 138 N.C. App. at 77 n.7.

Plaintiffs' briefing does not address directly any negligence claim outside of the design and warning claims disposed of previously. Plaintiffs have presented no direct evidence regarding any defect falling into one of the broad categories outlined in the complaint. Moreover, plaintiffs have not pointed to specific acts of defendant's negligence. Any proof of a negligence claim thus necessarily would require the stacking of inferences, which is prohibited. Accordingly, defendant's motion is granted as to the Estate's outstanding negligence claims. In any event, for all the reasons discussed above, plaintiffs have failed to demonstrate a causal connection between any product defect and the harm suffered.

Plaintiff Amy Sparks's NIED claim merits separate address. Defendant contends that it is a product liability claim under § 99B–1(3). In response, plaintiffs offer no specific argument, but instead choose to analyze that claim contemporaneously with the Estate's negligence claims.

Regardless, the court deems plaintiff Amy Sparks's NIED claim susceptible to address herein and for the reasons that follow will grant defendant's motion for summary judgment.

It is unclear whether plaintiff Amy Sparks's NIED claim is a product liability claim. Section 99B–1(3) states that all claims brought "for or on account of" personal injury or death qualify as product liability claims. N.C. Gen. Stat. § 99B–1(3). Certainly plaintiff Amy Sparks's NIED claim was not brought "for" death or personal injury as the Estate's negligence claims were. See Lassiter v. Cecil, 145 N.C. App. 679, 682 (2001) (suggesting "emotional distress" represents a different category of harm that "personal injury"). However, the claim likely was brought "on account of" a death caused by a product, as contemplated by § 99B–1(3). The phrase "on account of" has been used in North Carolina case law to mean "because of" or "stemming from." See, e.g., State v. Moore, 366 N.C. 100, 105–06 (2012) (using "on account of" consistent with "stemming from"); Fleming v. Carolina Power & Light Co., 230 N.C. 65, 66 (1949) (using "on account of" synonymous with "because of"). Here, plaintiff Amy Sparks's NIED claim arises because of, or otherwise stems from Jarred's death caused by an allegedly defective product. In particular plaintiff Amy Sparks contends the Chamber's defective design caused Jarred's death, which in turn caused her severe emotional distress. Because plaintiff Amy Sparks's NIED claim was brought "on account of" death caused by a product defect, it is a product liability claim within the scope of N.C. Gen. Stat. § 99B–1(3), and fails for the reasons discussed above.

In any event, even assuming plaintiff Amy Sparks's NIED claim is not a product liability claim, her claim still fails for lack of foreseeability. NIED requires the plaintiff prove: 1) defendant negligently engaged in conduct; 2) it was reasonably foreseeable that the conduct would cause plaintiff severe emotional distress; and 3) the conduct did in fact cause plaintiff to suffer severe

emotional distress. Andersen v. Baccus, 335 N.C. 526, 530 (1994). To determine foreseeability, North Carolina courts do not follow a particular mechanical test, but, rather, apply various factors. See Sorrells v. M.Y.B. Hospitality Ventures, 334 N.C. 669, 672–73 (1993). Among those factors are 1) the plaintiff's proximity to the negligent act causing injury to the other person; 2) the relationship between the plaintiff and the other person; and 3) whether the plaintiff personally observed the negligent acts. Id.

In this case, the possibility that HTI's negligence, as imputed to defendant, would harm plaintiff Amy Sparks was not reasonably foreseeable. Although the existence of a parent-child relationship typically weighs heavy in analyzing an NIED claim, plaintiff Amy Sparks did not personally observe the negligent acts nor did she immediately perceive the harm the alleged negligence had done to Jarred. See Gardner v. Gardner, 334 N.C. 662, 666–67 (1993) (no recovery where mother learned of harm after the fact); cf. Fox–Kirk v. Hannon, 142 N.C. App. 267, 274–75 (2001). Moreover, plaintiff Amy Sparks was not in close proximity to the injury, as that requirement is commonly understood. In Gardner, the court emphasized that the plaintiff was not in close proximity to the negligent act where she was several miles away and was unable to see, hear, or otherwise sense the act causing injury to her child. Gardner, 334 N.C. at 666–67. Here, although plaintiff Amy Sparks was downstairs, she was asleep at the time the harm occurred. Thus, she could not see, hear, or sense the resulting harm and was not within "close proximity" to the harm within the meaning of the rule.

Accordingly, for all the foregoing reasons, defendant's motion for summary judgment is granted as to plaintiffs' various product liability claims. Plaintiffs have failed to establish a proximate causal link between defendant's alleged negligence and the harm suffered. With regard

to plaintiff Amy Sparks's NIED claim, that claim either is a product liability claim under § 99B–1(2), in which case it fails for lack of causation, or fails on its own merits where the harm suffered was not reasonably foreseeable.

4. The Unfair and Deceptive Practices Act

Defendant next moves for summary judgment on the Estate's UDPA claim. Plaintiffs contend defendant violated the UDPA in three ways: 1) representing to plaintiff Amy Sparks that the chamber was FDA approved for the treatment of autism, when it in fact was not; 2) falsely marketing the chamber as being fabricated according to the American Society of Mechanical Engineer's Pressure Vessel for Human Occupancy ("ASME–PVHO") safety standards; and 3) marketing the chamber as safe for in-home use without medical supervision.

a. General Principles

North Carolina General Statute § 75–1.1 provides "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful." N.C. Gen. Stat. § 75–1.1(a). Section 75–16 allows any individual "injured by reason of any act or thing done by any other person, firm or corporation" in violation of the UDPA to bring a civil action. N.C. Gen. Stat. § 75–16. To state a prima facie claim under the UDPA, plaintiffs must successfully show: 1) that defendant committed an unfair or deceptive act or practice, 2) in or affecting commerce, 3) which proximately caused Jarred's injury. See Bumpers v. Cmty. Bank of N. Va., 367 N.C. 81, 88 (2013).

"Occurrence of the alleged conduct, damages, and proximate cause are fact questions for the jury, but whether the conduct was unfair or deceptive is a legal issue for the court." Gilbane Bldg. Co. v. Fed. Reserve Bank, 80 F.3d 895, 902 (4th Cir. 1996). "Unfair or deceptive conduct" fairly

may be categorized into five types: 1) general "unfair" conduct that "offends public policy . . . [or] is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers,"; Walker v. Fleetwood Homes of N.C., Inc., 362 N.C. 63, 72 (2007); see also Gilbane, 80 F.3d at 902; 2) "deceptive" misrepresentations that have the capacity or tendency to deceive the average person, Gilbane, 80 F.3d at 902; Johnson v. Phoenix Mut. Life Ins. Co., 300 N.C. 247, 265 (1980), overruled on other grounds, Myers & Chapman, Inc v. Thomas G. Evans, Inc., 323 N.C. 559 (1988); 3) per se violations of § 75–1.1 established upon proof of a statutory or regulatory violation or the commission of certain torts, see, e.g., Gray v. N.C. Ins. Underwriting Ass'n, 352 N.C. 61, 71 (2000) (statutory violation); E. Roofing & Aluminum Co. v. Brock, 70 N.C. App. 431, 433–35 (1984) (regulatory violation); Bhatti v. Buckland, 328 N.C. 240, 243 (1991) (fraud); 4) a breach of contract accompanied by aggravating circumstances, see, e.g., Broussard v. Mineke Disc Muffler Shops, Inc., 155 F.3d 331, 347 (4th Cir. 1998); and 5) anti-competitive conduct, see, e.g., ITCO Corp. v. Michelin Tire Corp., 722 F.2d 42, 48 (1983); R.J. Reynolds Tobacco Co. v. Philip Morris, Inc., 199 F. Supp. 2d 362, 395–96 (M.D.N.C. 2002). See generally Matthew W. Sawchak & Kip D. Nelson, Defining Unfairness in "Unfair Trade Practices," 90 N.C. L. Rev. 2033, 2042–50 (2012).

b. The Estate's Claim

Each ground advanced by plaintiffs in support of the Estate's claim is based in an alleged misrepresentation of the Vitaeris 320's safety and efficacy. Defendant contends plaintiffs cannot establish proximate cause, as is required for a prima facie showing of proof under the UDPA. The court agrees and for the following reasons grants defendant's motion

When a claim is based in an alleged misrepresentation, plaintiffs cannot show proximate cause without establishing both actual and reasonable reliance. Bumpers, 367 N.C. at 90. To

demonstrate reliance, plaintiffs exclusively cite plaintiff Amy Sparks's declaration, executed on November 11, 2014. (Sparks Decl. at 3). The affidavit details plaintiff Amy Sparks's attendance at a 2009 "Hope for Autism" conference, where she met an Oxy-Health representative who gave her various information concerning the Vitaeris 320, and made certain representations. In particular, that representative told plaintiff that the chamber was "safe for use in the home setting," and that it was "approved by the FDA for the treatment of autism." (Id. ¶¶5–7). The representative also gave plaintiff a brochure which indicated that the chamber was manufactured in accordance with ASME–PVHO safety standards. (Id. ¶11). Plaintiff Amy Sparks's declaration makes clear that she relied on these representations when making the decision to purchase the Chamber from A Small Miracle in 2011. (Id. ¶¶15–17).

Before turning to the substance of defendant's argument, defendant objects to plaintiffs' use of plaintiff Amy Sparks's declaration, contending it is in direct conflict with her prior deposition testimony, and that it must be struck pursuant to the "sham affidavit" rule. The court agrees and sustains defendant's objection.

At summary judgment, if an affidavit is inconsistent with the affiant's prior deposition testimony, the court may disregard the affidavit. *In re* Family Dollar FLSA Litig., 637 F.3d 508, 512–13 (4th Cir. 2011). "A genuine issue of material fact is not created where the only issue of fact is to determine which of the two conflicting versions of the plaintiff's testimony is correct." Barwick v. Celotex Corp., 736 F.2d 946, 960 (4th Cir. 1984); accord Rohrbough v. Wyeth Labs., Inc., 916 F.2d 970, 975 (4th Cir. 1990). This rule applies only where there is a "bona fide inconsistency" between two differing versions of an individual's testimony. Spriggs v. Diamond Auto Glass, 242

F.3d 179, 186 n.7 (4th Cir. 2001). However, where such an inconsistency exists, the proper remedy is to strike the later-given testimony. See Family Dollar, 637 F.3d at 512–13.

Plaintiff Amy Sparks's affidavit will be struck. The affidavit provides a number of cursory statements that generally support the Estate's UDPA claim, specifically that plaintiff Amy Sparks relied on certain misrepresentations at the time she purchased the Chamber in 2011. However, at her February 17, 2014, deposition, plaintiff was asked about the factors affecting her 2011 decision to purchase the Chamber. Plaintiff stated that she relied on her conversations with Janet Presson, the fact Presson was a nurse, and the tangible benefits she saw reflected in her son's improved behavior and health. (Amy Sparks Dep. 314:14–315:13). Defense counsel pointedly asked plaintiff if she relied on anything else. (Id.). She replied "no." (Id.). There is a "bona fide inconsistency" between the two versions of plaintiff's testimony. The affidavit is a sham and accordingly is struck from the record.

Plaintiffs' attempt to qualify this testimony is of no effect. Plaintiffs highlight another portion of Amy Sparks's deposition where defense counsel asked her whether she relied on "the material [she] received from [defendant] those years earlier" at the time she purchased the Chamber. (Amy Sparks Dep. 307:13–22). In response plaintiff said "yes," but went on to say "because of the results that kids had gotten and - - and my doctor even used it." (Id.). The portion of plaintiff Amy Sparks's testimony cited by plaintiffs does not qualify or otherwise frame differently the inconsistency between the challenged portion of her deposition testimony and affidavit. To the contrary, the deposition testimony to which plaintiffs have directed the court indicates only that plaintiff Amy Sparks relied on the materials provided by defendant to the extent they promoted the

results of HBOT. Notably, plaintiffs never argue that defendant's representations as to the effects of HBOT support the Estate's UDPA claim.

Turning next to the merits of the Estate's UDPA claim, defendant's motion must be granted because plaintiffs cannot demonstrate actual reliance and thus have failed to show proximate cause. Actual reliance is an element of proximate causation and requires proof Amy and Robert Sparks "affirmatively incorporated the alleged misrepresentation into [their] decision making process." Bumpers, 367 N.C. at 90. Plaintiff Amy Sparks's deposition testimony indicates that defendant's deceptive misrepresentations were not "affirmatively incorporated" into her decision making process, (Amy Sparks Dep. 314:14–315:13), but, rather, that she relied only on the results she had seen touted in the literature, and Jarred's improved behavior. (Amy Sparks Dep. 307:13–22). There is no evidence as to Robert Sparks. Thus, because plaintiffs have failed to demonstrate the elements of a prima facie claim under the UDPA, defendant's motion for summary judgment is granted on this issue.

5. Punitive Damages

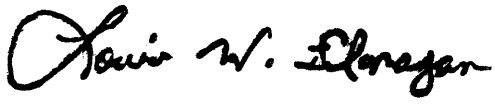
Defendant's motion as to plaintiffs' punitive damages claim is granted. "Punitive damages" is not an independent cause of action. Cloaninger v. McDevitt, 555 F.3d 324, 336 (4th Cir. 2009). Rather, punitive damages only may be awarded where the plaintiff is awarded some compensatory damages. See id. As the court has dismissed all other claims pending in this case, plaintiffs' claim for punitive damages cannot stand.

CONCLUSION

Based on the foregoing discussion, defendant's motion for summary judgment, (DE 39), made pursuant to Federal Rule of Civil Procedure 56, is GRANTED. Given that, all remaining

motions now pending in this case are DENIED as MOOT. (DE 36, 42, 44, 114). The clerk of court is DIRECTED to close this case.

SO ORDERED, this the 15th day of September, 2015.



LOUISE W. FLANAGAN
United States District Judge