UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLORADO

Civil Action No. 13-cv-00573-RBJ
(*Consolidated with* 13-cv-00574-RBJ-KMT, 12-cv-00576-RBJ-KMT, 13-cv-00579-RBJ-KMT, 13-cv-00892-RBJ-KMT and 13-cv-00893-RBJ-KMT)

DONALD THORNTON, individually, and as Personal Representative of the ESTATE OF JEAN THORNTON, and on behalf of all others similarly situated,

Plaintiffs,

v.

DAVITA HEALTHCARE PARTNERS, INC.,

Defendant.

MOTION TO DISMISS PURSUANT TO RULE 12(b)(6)

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Pursuant to Fed. R. Civ. P. 12(b)(6), Defendant DaVita Healthcare Partners, Inc. ("DaVita") moves to dismiss the First-Amended Master Consolidated Complaint ("MCC") of Plaintiffs Suzette Allen, Tony Armstrong, Gaile Goosby, Sharon Harris, Helen McAdams, Armando Moreno, Doris Morris, Melvin Nunes, Emanuel and Louse Minta, Jose and Candida Perez, Donald Thornton, and Donald Young brought in their individual capacities and on behalf of others similarly situated.

INTRODUCTION

Despite three attempts to plead viable claims, Plaintiffs still fail to articulate any sustainable basis for liability against DaVita. Plaintiffs allege that they or their family members sustained injury as a result of receiving prescribed hemodialysis treatment that used GranuFlo and/or NaturaLyte prescription products manufactured, researched, distributed, and sold by Fresenius Medical Care ("Fresenius"). (MCC ¶¶ 4, 7, 23-34, 58.)[1] And Plaintiffs again contend that Fresenius hid and misled from all non-Fresenius physicians and clinics that GranuFlo contained an ingredient that may increase the risk of cardiac arrest in certain dialysis patients. (*Id.* ¶¶ 7, 53-56, 65-67.) But rather than sue Fresenius in this case,[2] Plaintiffs continue to bring this lawsuit against DaVita claiming that twelve clinics in ten different states[3] allegedly administered GranuFlo to Plaintiffs while providing their patients with medical dialysis services.

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[1] Plaintiffs use the terms "GranuFlo and/or NaturaLyte" to refer to Fresenius's products. DaVita will refer to the products by the term "GranuFlo" unless quoting from the MCC.

[2] Plaintiffs' Counsel is well aware of Fresenius's responsibility for the manufacture of the GranuFlo product—the MCC is rife with references to Fresenius's acts and omissions, and Plaintiffs' Counsel previously filed at least four separate complaints against Fresenius in the District of Massachusetts. *See, e.g.*, *Alford v. Fresenius USA, Inc.*, No. 13-cv-10060-JLT, Dkt. 1 (D. Mass. Jan. 10, 2013). *See* Declaration of James E. Tyrrell, Jr., dated August 7, 2013 ("Tyrrell Decl."), Exhibit A (*Alford* complaint).

[3] Hereinafter, in accordance with the allegations in the MCC, DaVita will refer to these facilities collectively as "DaVita clinics." Each of the DaVita clinics is a separate entity. For

In this latest effort to hold DaVita liable, Plaintiffs simply repeat—with minor variation—the same flawed claims and allegations contained in their prior complaints. They still attempt to re-cast their potential medical malpractice claims as actions that instead sound in fraud, contract, and strict product liability. But, as before, this re-casting of medical malpractice claims is futile as liability cannot be imposed upon medical service providers under such theories. Medical service providers—such as dialysis clinics—provide treatment and care. They do not manufacture, sell, or otherwise place products into the stream of commerce and thus, cannot be liable under those laws governing alleged defects in "products." Plaintiffs' causes of action for strict liability, failure to warn, and breach of warranties therefore should be dismissed.

Plaintiffs' negligence, wrongful death, and loss of consortium claims likewise fail because DaVita has no duty to re-warn patients of a prescribed treatment's risks after the physicians have already used their own expertise and intimate knowledge of their patients in issuing individualized prescriptions. This latest complaint remains bereft of any allegation establishing that DaVita had a duty to warn of the alleged general risks of GranuFlo or that Plaintiffs would have altered their conduct in reliance on such information had it been provided. Moreover, several Plaintiffs fail even to bring timely negligence, wrongful death, or loss of consortium claims, waiting as long as five years to sue even though they allege that the unusual nature and severity of their injuries was apparent during or shortly after their dialysis treatment.

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instance, DaVita Vacaville Dialysis Center in Vacaville, California—where Plaintiff Nunes alleges his wife received dialysis treatment—is licensed as "Renal Treatment Centers – California, Inc." (MCC ¶ 31.) For purposes of the instant Fed R. Civ. P. 12(b)(6) motion only, DaVita has assumed all of the MCC's allegations as true, including Plaintiffs' claims that DaVita is a "provider of kidney dialysis services for patients." (*Id.* ¶ 35.) DaVita reserves any and all defenses available to it including but not limited to the lack of any ultimate liability and/or preemption.

Plaintiffs' cause of action for fraudulent concealment also continues to lack the requisite specificity under Fed. R. Civ. P. 9(b). This is unsurprising given the internally contradictory facts pleaded regarding Fresenius. Plaintiffs speculatively allege DaVita did not disclose facts regarding GranuFlo but do not provide the substance of the time, place, and identity of those at DaVita who learned about GranuFlo's allegedly dangerous properties nor do Plaintiffs offer any facts whatsoever to substantiate that DaVita allegedly concealed this information. And the facts that Plaintiffs do allege belie their contention that DaVita knew or could have known this information at the time of the alleged injuries. Plaintiffs continue to assert that it was Fresenius, the manufacturer, that concealed information about GranuFlo from all non-Fresenius physicians and clinics (including DaVita). As a result, the facts that Plaintiffs plead actually contradict and ultimately preclude their claims that DaVita concealed information.

Finally, Plaintiffs cannot maintain a cause of action under the Colorado Consumer Protection Action ("CCPA"). Insofar as Plaintiffs seek damages on behalf of a class, the CCPA expressly excludes monetary damages as a remedy. In addition, Plaintiffs' CCPA claims involving an alleged failure to warn must be dismissed because DaVita had no duty to warn patients of the potential effects of a prescription drug. And to the extent Plaintiffs aver that DaVita violated the CCPA by misrepresenting the safety of GranuFlo, those claims fail because Plaintiffs did not allege that they relied on specific affirmations by DaVita in selecting dialysis treatment. For the foregoing reasons, DaVita respectfully urges that the Court dismiss Plaintiffs' MCC in its entirety pursuant to Fed. R. Civ. P. 12(b)(6).

FACTUAL BACKGROUND

Fresenius's GranuFlo Product. Fresenius manufactures GranuFlo, a product used in the hemodialysis process. (MCC ¶ 7.) Hemodialysis is used to treat patients who suffer from ESRD—the stage of advanced kidney impairment that requires continued dialysis treatments or a

kidney transplant to sustain life—at least three times per week for the rest of their lives. (*Id.* ¶¶ 37, 39.) GranuFlo is a component of dialysate, a formulation administered to patients during dialysis to maintain a proper balance of acid and base in the blood. (*Id.* ¶¶ 43-44.) Plaintiffs aver that Fresenius manufactures GranuFlo in powder form which DaVita then allegedly mixes with purified water before administration to patients. (*Id.* ¶¶ 7, 13, 45.) All dialysates—which are only available by prescription—are solutions containing both bicarbonates and acid. (*Id.* ¶¶ 16, 43, 56.) As Plaintiffs allege, prescribing physicians must "carefully balance[]" the levels of bicarbonates and acid "because both low pH levels ('acidosis') and high pH levels ('alkalosis') are extremely dangerous"—and may lead to cardiac arrest. (*Id.* ¶ 44.)

The MCC contends that Fresenius's GranuFlo product "makes patients several times more susceptible to cardiac arrest" because it contains sodium diacetate. (*Id.* ¶ 42.) Sodium diacetate may "produce[] higher levels of bicarbonate in the body." (*Id.* ¶ 46.) Higher levels of bicarbonate in the body purportedly can lead to alkalosis, and consequently, cardiac arrest. (*Id.* ¶ 48.) Plaintiffs assert that this allegedly dangerous property of GranuFlo was "unnoticed" by some prescribing physicians, who remained in the dark because Fresenius failed to share relevant product information with DaVita and others. (*Id.* ¶¶ 7, 53-56, 65-67.) Plaintiffs further allege that if Fresenius had decided to "share this information with the thousands of non-Fresenius physicians and clinics that were using the GranuFlo product," physicians "could have altered their prescription practices." (*Id.* ¶¶ 12, 89.) On March 29, 2012, the FDA issued a "recall" of GranuFlo that permitted it to remain on the market, but noted that Fresenius was to issue a memorandum to "non-Fresenius clinics and physicians" describing the internal information about GranuFlo that Fresenius had concealed. (*Id.* ¶¶ 58-59, 68.)

Plaintiffs' Claims. Plaintiffs allege that DaVita is liable for injuries suffered by patients arising from administration of Fresenius's GranuFlo product during dialysis treatment at DaVita clinics. (*Id.* ¶¶ 16, 23-34.) Plaintiffs aver that, at varying times over a four-and-a-half-year span, they (or their family members) received dialysis treatment in DaVita clinics in their respective states of residence.[4] (*Id.* ¶¶ 23-34.) According to the MCC, personnel at the DaVita clinics in Arizona, Arkansas, California, Florida, Georgia, Michigan, Minnesota, North Carolina, Pennsylvania, and Wisconsin administered GranuFlo to these patients. (*Id.*) Separate personal physicians in each of those states prescribed the GranuFlo used during the alleged treatments based on each patient's unique medical condition. (*Id.* ¶¶ 14, 56.) Plaintiffs claim that—at differing times, ranging from the time of treatment to the following day—they or their family members experienced injuries leading to hospitalization and even, on five occasions, death. (*Id.* ¶¶ 23-34.) Plaintiffs attribute these injuries to Fresenius's "defective NaturaLyte and/or GranuFlo products" which were allegedly administered in DaVita's clinics. (*Id.* ¶¶ 7, 23-34.)

Plaintiffs do not claim that the "machines used to control the dialysis process" were defective or malfunctioned in any way. (*Cf. id.* ¶ 47.) Plaintiffs also do not claim that the dialysis treatment provided deviated in any way from their prescriptions or that the alleged

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[4] Plaintiffs Harris, Allen, and Minta claim that their alleged injuries were sustained more than three years ago: on July 1, 2008; December 26, 2008; and November 11, 2009, respectively. (MCC ¶¶ 23, 26, 28.). The conduct alleged by other Plaintiffs occurred between 2010 and 2011: Perez on August 12, 2010; Goosby on November 17, 2010; Young on July 18, 2011; Armstrong on August 15, 2011; Moreno on September 8, 2011; and Thornton on November 3, 2011. (*Id.* ¶¶ 24, 25, 29, 32, 33, 34.) Plaintiffs Morris, McAdams, and Nunes aver that they suffered their respective injuries on April 17, 2012, November 20, 2012, and December 26, 2012—after the FDA issued a recall of GranuFlo and NaturaLyte and, for the latter two, after the New York Times published its "exposé" about Fresenius. (*Id.* ¶¶ 27, 30, 31, 65, 68.) Although the MCC states that Plaintiff Nunes's wife suffered injury and died on December 26, 2012, Ms. Nunes's death certificate, which is properly subject to judicial notice, establishes that Ms. Nunes actually died one year earlier, on December 27, 2011. *See* Tyrrell Decl., Exhibit B; *G-I Holdings, Inc. v. Baron & Budd*, No. 01 Civ. 0216, 2003 WL 193502, at *8 (S.D.N.Y. Jan. 29, 2003).

water/GranuFlo mixture altered the product from its original design or was otherwise administered improperly. Plaintiffs instead claim that "GranuFlo products were supplied, sold and administered at DaVita clinics" and that "DaVita either knew—and failed to take remedial action—or should have known of the dangerous propensities of the GranuFlo product." (*Id.* ¶ 20; *see also id*. ¶ 35 (describing DaVita as a "provider of kidney dialysis services for patients").)

LEGAL STANDARD

Dismissal of a complaint is proper under Fed. R. Civ. P. 12(b)(6) if the complaint fails to state a claim on its face, either because it lacks a cognizable legal theory or sufficient facts to support a cognizable legal claim. *Rosenfield v. HSBC Bank, USA*, 681 F.3d 1172, 1178 (10th Cir. 2012). A plaintiff has an obligation "to provide the grounds of his entitle[ment] to relief [that] requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (alteration in original). Where a plaintiff does not, the Court may dismiss the compliant. *Id.*

ARGUMENT

I. The Laws of Plaintiffs' Respective States of Residence Govern this Action.

To determine the law that applies in a diversity action, the Court should follow the choice of law rules of the forum state—here, Colorado. *Berry & Murphy, P.C. v. Carolina Cas. Ins. Co.*, 586 F.3d 803, 808 (10th Cir. 2009). Colorado follows the Restatement (Second) of Conflict of Laws, which provides that the substantive law of the state with "the most significant relationship" to the parties and the occurrence governs. *Boone v. MVM, Inc.*, 572 F.3d 809, 811-12 (10th Cir. 2009). "When . . . the case involves claims of personal injury, the location of the injury presumptively provides the controlling law unless some other state has a more significant relationship." *Elvig v. Nintendo of Am., Inc.*, 696 F. Supp. 2d 1207, 1210 (D. Colo. 2010). Here, under Colorado choice of law rules, the laws of Plaintiffs' respective states of residence apply

because they were the states where the alleged injuries occurred, where the parties' alleged relationship is centered, and where Plaintiffs are domiciled. (MCC ¶¶ 23-34.) That DaVita's current principal place of business is Colorado does not overcome the presumption favoring application of the aforementioned states' laws.[5]

II. Plaintiffs' Strict Liability Claims are not Cognizable under Applicable Law.

Despite this third chance to plead viable strict liability claims, Plaintiffs' claims are still barred as a matter of law. Although Plaintiffs allege three different types of defects that can give rise to strict liability (manufacturing and design defect theories contained in Count Six (*see id.* ¶¶ 125-36) and a warning defect (*i.e.*, a failure to warn) in Count One), none are sustainable here.

A. Strict Liability Does not Apply to Medical Service Providers

Strict liability claims are not recognized as against a medical services or healthcare provider in any of the relevant jurisdictions. *See e.g., Kohl v. American Home Prods.*, 78 F. Supp. 2d 885, 895-96 (W.D. Ark. 1999); *Hoff v. Zimmer, Inc.*, 746 F. Supp. 872, 876 (W.D. Wis. 1990); *Doe v. Travenol Labs., Inc.*, 698 F. Supp. 780, 782 (D. Minn. 1988) (citing *Balkowitsch v. Minneapolis War Mem'l Blood Bank, Inc.*, 132 N.W.2d 805, 810 (Minn. 1965)); *Strong v. Merck & Co. Inc.*, No. CV 2005-053195, 2009 WL 7233281, at *4 (Ariz. Super. Nov. 8, 2009); *San*

[5] DaVita recognizes the economy in this Court's consolidation of Plaintiffs' twelve individual complaints for pre-trial purposes. (Dkt. 14.) However, because these matters are more dissimilar than alike—vis-à-vis the applicable laws as well as factually—DaVita respectfully submits that consolidation of these medical malpractice actions (fashioned as products liability cases) beyond the pre-trial stage of litigation is inappropriate. *See Garcia v. Hotel Powers, Inc.*, No. 11-cv-02239, 2011 U.S. Dist. LEXIS 125841, at *4 (D. Colo. Oct. 28, 2011). According to the MCC, each patient had a unique medical condition, was prescribed a separate dialysis prescription, received dialysis treatment at different clinics, and allegedly suffered varying complications at differing time periods. (MCC ¶¶ 23-34); *Leeds v. Matrixx Initiatives, Inc.*, No. 2:10cv199, 2012 U.S. Dist. LEXIS 47279, at *5 (D. Utah Apr. 2, 2012). These factual differences outweigh any similarities and will present different issues at trial concerning causation, damages, and ultimate liability. For these reasons, a single consolidated trial of these cases would not be appropriate.

Diego Hosp. Ass'n v. Superior Court, 35 Cal Rptr. 2d 489, 491 (Cal. Ct. App. 1994); *Porter v. Rosenberg*, 650 So. 2d 79, 81-83 (Fla. Dist. Ct. App. 1995); *Ayyash v. Henry Ford Health Sys.*, 533 N.W.2d 353, 355-56 (Mich. Ct. App. 1995); *Cafazzo v. Central Med. Health Servs., Inc.*, 668 A.2d 521, 524-26 (Pa. 1995).[6] The rationale for this rule is that medical service providers offer treatment, not the sale of products. *See Strong*, 2009 WL 7233281, at *4; *Hector v. Cedars-Sinai Med. Ctr.*, 225 Cal Rptr. 595, 599-600 (Cal. Ct. App. 1986). The "distinction [between a sale of services and a sale of products] is made clearer" by courts holding that strict liability may still apply "where what has been provided is not medical service or products connected with diagnosis and treatment, but rather materials related to mechanical or administrative functions," such as hospital gowns prone to catching fire or defective items sold in a medical service provider's gift shop. *Cafazzo*, 668 A.2d at 525 (citing cases). Thus, even where allegedly defective products are used during treatment, the medical service provider cannot be liable under strict liability. *Podrat v. Codman-Shurtleff, Inc.*, 558 A.2d 895, 897-98 (Pa. Super Ct. 1989). In determining whether a transaction is the sale of a product or a service, "courts have recognized that the essence of the transaction between the retail seller and the consumer relates to the article sold." *Pierson v. Sharp Mem'l Hosp., Inc*., 264 Cal. Rptr. 673, 675 (Cal. Ct. App. 1989) (internal quotation marks omitted); *Ayyash*, 533 N.W.2d at 355.

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[6] In Georgia, "strict liability applies only to those actively involved in the design, specifications, or formulation of a defective final product or of a defective component part which failed during use of a product and caused injury." *In re Stand 'n Seal, Prods. Liab. Litig*, MDL No. 1804, 2009 U.S. Dist. LEXIS 89987, at *8-9 (J.P.M.L. Sept. 28, 2009). One who "sells and distributes; installs; prepares; blends; packages; labels; markets; or assembles pursuant to a manufacturer's plan, intention, design, specifications, or formulation" is not considered a manufacturer and cannot be held liable under a strict liability theory. *Id.* at *8 (quoting Ga. Code Ann. § 51-1-11.1(a) (2013)). Since Plaintiffs do not allege that DaVita was involved in the design process—but only that it mixed the GranuFlo powder with purified water (MCC ¶ 7) as required by the manufacturer Fresenius—a strict design defect claim cannot be maintained.

Here, the MCC specifically avers that GranuFlo is "administered in [DaVita's] clinics" (*id.* ¶ 3) in order "to maintain the balance of acid and base in the blood." (*Id.* ¶ 43.)[7] This treatment usually is "performed at a freestanding outpatient dialysis center, at a hospital-based outpatient center, or at the patient's home." (*Id.* ¶ 39.) As such, Plaintiffs' occasional, conclusory references in the MCC to DaVita as a seller or supplier cannot overcome their specific allegations that DaVita administers dialysis services. (*Compare id.* ¶ 16 *with* ¶¶ 3, 23-35.) DaVita does not "sell" or "supply" GranuFlo. Instead, GranuFlo is only administered in connection with prescribed dialysis services. Indeed, there is no allegation in the MCC that Plaintiffs purchased GranuFlo directly from DaVita. Plaintiffs' allegations that DaVita "sold" GranuFlo directly to these patients in the course of administering dialysis treatments is merely an attempt, based on rhetoric and not facts, to circumvent the black letter law barring Plaintiffs' purported strict liability claims against DaVita. (*See id.* ¶¶ 1, 2, 3, 16, 23-34.) Plaintiffs' causes of action for strict liability—Counts One and Six—should be dismissed.

B. DaVita Cannot be Strictly Liable for a Medical Device's Design Defect

Even if DaVita "sold" GranuFlo to Plaintiffs—which it did not—Plaintiffs' strict liability claim premised on a design defect should also be dismissed under the laws of the relevant jurisdictions. California, Pennsylvania, Arizona, Georgia, and Michigan have each adopted the exception to comment k of § 402A of the Restatement (Second) of Torts which requires the dismissal of design defect claims arising from "unavoidably unsafe" products such as

[7] Dialysis treatment clinics are "health care providers." For instance, California's medical malpractice statute defines the term "health care provider" to include "any clinic, health dispensary, or health facility" licensed under the Health and Safety Code of California. Cal. Civ. Proc. Code § 340.5(1); *see* Tyrrell Decl., Exhibit C. As it is a matter of public record, the Court may take judicial notice of the relevant licenses of the clinics here without converting the instant motion to one for summary judgment. *Tal v. Hogan*, 453 F.3d 1244, 1264 n.24 (10th Cir. 2006).

prescription medical products. *See Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978); *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988); *Nichols v. McNeilab, Inc*., 850 F. Supp. 562, 570 (E.D. Mich. 1993); *Hahn v. Richter*, 673 A.2d 888, 889-91 (Pa. 1996); *cf. Walker v. Merck & Co*., 648 F. Supp. 931, 933 (M.D. Ga. 1986).[8] For this reason, where prescription drugs or devices are involved, design defect claims are not cognizable. *See Gaston*, 588 P.2d at 340; *Brown*, 751 P.2d at 477; *Hahn*, 673 A.2d at 889-91.[9] California has taken a categorical approach that all prescription medical drugs and devices are, by definition, inherently "unavoidably unsafe." *See Brown*, 751 P.2d at 477. The Pennsylvania Supreme Court has gone one step further and announced that where prescription medical devices or drugs are involved "negligence is the ***only*** recognized basis of liability" and ***all*** other causes of action rooted in such a design defect theory must be dismissed. *Hahn*, 673 A.2d at 891 (emphasis added); *Kee v. Zimmer, Inc*., 871 F. Supp. 2d 405, 409 (E.D. Pa. 2012); *Kline v. Pfizer, Inc*., No. 08-3238, 2008 WL 4787577, at *2-4 (E.D. Pa. Oct. 31, 2008). Arizona courts apply the comment k exception on a case-by-case basis but generally limit design defect claims related to prescription products

[8] Under North Carolina law, a health care provider may not be held strictly liable, even under the "chain of distribution" theory of liability. *Batiste v. Am. Home Prods. Corp*., 231 S.E.2d 269, 272-73 (N.C. Ct. App. 1977). Indeed, "North Carolina does not recognize strict liability in product liability cases." *Stoddard v. Wyeth, Inc*., 630 F. Supp. 2d 631, 632 (E.D.N.C. 2009). Therefore, even if DaVita "sold" a product, there can be no strict liability under North Carolina law, and Plaintiff Allen's claims premised on product liability must be dismissed.

[9] Wisconsin courts have determined to reject comment k. *See Collins v. Eli Lilly & Co.*, 342 N.W.2d 37, 52 (Wis. 1984). Wisconsin, however, enacted Wis. Stat. § 895.047(2)(a), which provides that a non-manufacturer that purportedly sold a product cannot be liable for a claim of strict liability "unless the manufacturer would be liable" and "[t]he claimant proves by a preponderance of the evidence that the seller or distributor has contractually assumed one of the manufacturer's duties to manufacture, design, or provide warnings or instructions with respect to the product." Thus, even assuming that DaVita could be construed as a "seller" of GranuFlo, the MCC does not allege that DaVita "contractually assumed" any of Fresenius's duties. Plaintiffs' strict liability claims must therefore be dismissed under Wisconsin law as well.

to the limited circumstance where no doctor would prescribe the allegedly defective device to ***any*** class of patients.[10] *Harrison v. Howmedica Osteonics Corp.*, No. 06-0745, 2008 WL 906585, at *21 (D. Ariz. Mar. 31, 2008). The MCC is devoid of any such allegation. Similarly, Arkansas courts apply comment k as an affirmative defense to defeat design defect claims where there is "no feasible alternative design which accomplishes the product's purpose at lesser risk." *West v. Searle & Co.*, 806 S.W.2d 608, 612-13 (Ark. 1991).[11] In the MCC, Plaintiffs do not allege that a safer alternative exists. Thus, under the applicable law, Plaintiffs' design defect claim must be dismissed.

C. Plaintiffs' Purported Manufacturing Defect Strict Liability Claims Also Fail

DaVita cannot be liable for an alleged manufacturing defect because it did not manufacture GranuFlo. Although the MCC strives to minimize Fresenius's role, the MCC nonetheless acknowledges that Fresenius designed, manufactured, and supplied GranuFlo. *See* MCC ¶ 7 (admitting that "Fresenius manufactures the GranuFlo and NaturaLyte products"); *id.* ¶

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[10] Like their counterparts in Arizona, Colorado courts apply comment k on a case-by-case basis to determine whether a particular prescription medical product is "unavoidably unsafe." *See Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 415 (Colo. 1986), *overruled on other grounds*, *Armentrout v. FMC Corp.*, 842 P.2d 175, 183 (1992). For the exception to apply, "[t]he product's utility must greatly outweigh the risk created by its use; the risk must be a known one; the product's benefits must not be achievable in another manner' and the risk must be unavoidable under the present state of knowledge." *Id.* Under Colorado law, evidence of these issues may be submitted to a jury. *See Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290, 1308 (D. Colo. 1984). This conflict in law—amongst others not highlighted herein in the interest of judicial economy—requires application of the laws of the Plaintiffs' home states. *Iskowitz v. Cessna Aircraft Co.*, No. 07-cv-00968, 2010 U.S. Dist. LEXIS 88791, at *6 (D. Colo. Aug. 5, 2010).

[11] Minnesota law dictates that a "passive" seller—as the MCC characterizes DaVita—"should not be saddled with the costs of defending a product it did not design." *Kolberg-Pioneer, Inc. v. Belgrade Steel Tank Co.*, 823 N.W.2d 669, 675 (Minn. Ct. App. 2012). Indeed, where a seller "did not participate in the design of the [product], the only defects for which [the seller] may be potentially liable are manufacturing flaw and failure to warn." *Leedahl v. Rayco Mfg.*, No. 06-310, 2006 U.S. Dist. LEXIS 98157, at *6 (D. Minn. May 15, 2006).

35 ("DaVita[] . . . is a leading provider of kidney dialysis services for patients suffering from chronic kidney failure or ESRD."). Thus, Plaintiffs' manufacturing defect claim is not cognizable because it concedes that Fresenius (not DaVita) manufactured GranuFlo.

The MCC's opportunistic use of the term "manufacture" when describing the preparation of dialysate for administration cannot transform DaVita into a manufacturer. (*See, e.g.*, MCC ¶ 13 ("DaVita had control over the process of manufacturing and selling the end product – a liquid acid concentrate – to Plaintiffs . . . .").) The process of manufacturing and distribution ends with the entity that sells the purportedly defective product or drug to the medical services provider. *Silverhart v. Mount Zion Hosp.*, 98 Cal. Rptr.187, 190 (Cal. Ct. App. 1971). Where (a) "the drug was available only to a limited segment of the public who could present a medical doctor's prescription," (b) "the prescription was filled precisely in accordance with its directions," (c) "there was no adulteration," and (d) "both the patient-purchaser and the retail druggist relied upon the doctor's prescription," "[t]he concept of strict liability without fault should not be applied." *McLeod v. W. S. Merrell Co.*, 174 So. 2d 736, 738-39 (Fla. 1965). Instead, the duty imposed on an entity that provides medical products pursuant to a prescription is simply that: "(1) [it] will compound the drug prescribed; (2) [it] has used due and proper care in filling the prescription (failure of which might also give rise to an action in negligence); (3) the proper methods were used in the compounding process; [and] (4) the drug has not been infected with some adulterating foreign substance." *Id.* (citing *Gottsdanker v. Cutter Laboratories*, 6 Cal. Rptr. 320 (Cal. Ct. App. 1960)).

Plaintiffs do not (and cannot) allege that DaVita altered the product in any way not intended by GranuFlo's manufacturer, Fresenius, or that DaVita created the allegedly defective properties in GranuFlo itself. As the MCC alleges: "GranuFlo is a newer product composed of a

dry acid powder which replaces the traditional liquid concentration. . . . GranuFlo, unlike liquid acid concentrates, uses sodium diacetate, the powder form of acetic acid. That power ***must be mixed with purified water to create a liquid solution*** before it can be . . . used in the dialysis process." (MCC ¶ 45 (emphasis added).) The MCC thus alleges that DaVita's clinics mix the product in accordance with its specifications and then use it while providing hemodialysis services. (*Id.* ¶¶ 13, 45, 62.) And the MCC is bereft of any allegation that DaVita altered or "assembled" the product in any way. Plaintiffs' manufacturing defect claim therefore does not allege that DaVita manufactured the product nor does it identify a flaw in DaVita's purported manufacturing process. *See Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1168-69 (Cal. 1984). For these reasons, Count Six must be dismissed.

III. Plaintiffs' Breach of Warranty Claims are not Sustainable as a Matter of Law

A. Service Providers Cannot Be Liable for Breach of Implied Warranty

The laws of the relevant states also reject Plaintiffs' claims for breach of implied warranties arising from a defendant's provision of services. *Whitehurst v. Am. Nat'l Red Cross*, 402 P.2d 584, 586 (Ariz. Ct. App. 1965); *Graham Contr. Co. v. Earl*, 208 S.W.3d 106, 111 (Ark. 2005); *Hector*, 225 Cal. Rptr. at 602 & n.3; *Jackson v. L.A.W. Contracting Corp.*, 481 So. 2d 1290, 1292 (Fl. Dist. Ct. App. 1986); *McCombs v. S. Reg'l Med. Ctr., Inc.*, 504 S.E.2d 747, 749 (Ga. Ct. App. 1998); *Leith v. Henry Ford Hosp.*, No. 211008, 2000 Mich. App. LEXIS 2121, at *13-15 (Mich. Ct. App. May 16, 2000); *Balkowitsch*, 132 N.W.2d at 809-11; *Preston v. Thompson*, 280 S.E.2d 780, 784 (N.C. Ct. App. 1981); *Micro-Managers, Inc. v. Gregory*, 434 N.W.2d 97, 102 (Wis. Ct. App. 1988). It is axiomatic that any breach of implied warranty claim requires at least two elements: a "sale" involving "goods." *Blennis v. Hewlett-Packard Co.*, No. 07-00333, 2008 U.S. Dist. LEXIS 106464, at *7-10 (N.D. Cal. Mar. 25, 2008); *Preston*, 280 S.E.2d at 784; *Borden, Inc. v. Advent Ink Co.*, 701 A.2d 255, 258 (Pa. Super. Ct. 1997). Thus,

where a provision of services is alleged, a breach of implied warranty claim is not cognizable. *Philipp v. U.S. Air., Inc.*, No. 92 Civil 3072, 1993 WL 742805, at *5 (Pa. Comm. Pl. Feb. 23, 1993) (dismissing breach of implied warranty claims because "[s]upplying the [allegedly defective medical device] was only a secondary adjunct to [defendant's] primary function of providing professional medical services"). This is so even where the services involve an allegedly defective product. *Marshfield Clinic v. Munkholm*, No. 92-2078, 1993 WL 184585, at *1 (Wis. Ct. App. June 3, 1993).

While the MCC repeatedly alleges that DaVita "sold" GranuFlo to Plaintiffs or their family members (*see e.g.*, MCC ¶¶ 1, 2, 3, 16, 23-34), taken as a whole, the facts alleged and relevant legal principles do not support the version of events that Plaintiffs have concocted. Throughout the MCC (as well as in Plaintiffs' prior complaints), Plaintiffs allege that DaVita administered medical services in the form of dialysis treatment to its patients. (*See e.g.*, Dkt. 1, ¶¶ 18-20; MCC ¶¶ 35-36.) The latest conclusory labels used by Plaintiffs—that DaVita now "sold" GranuFlo, rather than administered it through dialysis services—belie Plaintiffs' previous representations, as well as common sense. *See Grimes v. Fremont Gen. Corp.*, No. 08-CV-1024, 2013 U.S. Dist. LEXIS 40748, at *4 n.1 (S.D.N.Y. Mar. 22, 2013) (considering prior complaint's allegations that the amended complaint "neither expressly state[d] nor denie[d]" because "Plaintiffs may not directly contradict their previous allegations . . . for strategic benefit").

Plaintiffs' self-serving framework fails on the law as well: "In the context of prescription medical devices and pharmaceuticals, the transaction is between the manufacturer and the physician, not the patient." *Adams v. I-Flow Corp.*, No. CV09-09550, 2010 U.S. Dist. LEXIS 33066, at *11 (C.D. Cal. Mar. 30, 2010). In those situations, a patient lacks privity to assert a breach of implied warranty claim where, as here, he relied only on his "physicians' skill and

judgment in selecting and prescribing" the allegedly defective product. *Id.*; *Crayton v. Rochester Med. Corp.*, No. 1:07-CV-1318, 2011 U.S. Dist. LEXIS 11112, at *50 (E.D. Cal. Feb. 4, 2011) (finding no privity where defendant "did not sell the product directly to Plaintiff," medical personal chose the product, and plaintiff "relied on the advice of his doctors"). Instead, "[i]f the activity of [the defendant] . . . [can] be viewed as the rendering of professional services, then no matter how the basis of liability is described it amounts to no more than a claim of negligence in failing to perform these services with due care." *Micro-Managers*, 434 N.W.2d at 102. Thus, Plaintiffs' breach of implied warranty claim—Count two—should be dismissed.

B. Plaintiffs' Breach of Express Warranty Claims Also Fail

In addition to failing because service providers cannot be liable for breach of warranty claims as described above, Plaintiffs' express warranty claim fails for several other reasons. To state a breach of express warranty claim, Plaintiffs must identify a particular "affirmation of fact or promise" that would give rise to a reasonable inference that, as Plaintiffs allege, DaVita "expressly warranted" that its purported products "were safe and fit for use in dialysis treatment." *See Maneely v. Gen. Motors Corp.*, 108 F.3d 1176, 1181 (9th Cir. 1997); *Montgomery v. Kraft Foods Global, Inc.*, No. 1:12-CV-00149, 2012 U.S. Dist. LEXIS 173035, at *36 (W.D. Mich. Dec. 6, 2012); *Windsor Craft Sales, LLC v. VICEM Yat Sanayi ve Ticaret AS*, No. 10-297, 2012 U.S. Dist. LEXIS 25212, at *13-14 (D. Minn. Feb. 28, 2012); *Mills v. Bristol Myers Squibb*, No. 11-00968, 2011 WL 4708850, at *4 (D. Ariz. Oct. 7, 2011); *Am. Coach Lines of Orlando, Inc. v. N.A. Bus Indus., Inc.*, No. 6:09-cv-1000, 2011 U.S. Dist. LEXIS 14417, at *46-48 (M.D. Fl. Feb. 14, 2011); 13 Pa. Cons. Stat. § 2313(a); (MCC ¶ 101.). Plaintiffs have not done so. The MCC contains no detailed factual information of any kind regarding what specific alleged warranty Plaintiffs or their family members viewed, the time or place they viewed it, or how they relied on the purported warranty. *See Gross v. Stryker Corp.*

858 F. Supp. 2d 466, 501-02 (W.D. Pa. 2012); *Garcia v. M-F Arhletic Co., Inc.*, No. 11-24330, 2012 WL 531008, at *3 (E.D. Cal. Feb. 17, 2012); *Goodson v. Boston Sci. Corp.*, No. 1:11-CV-3023, 2011 U.S. Dist. LEXIS 149193, at *12-13 (N.D. Ga. Dec. 29, 2011); *Brooks v. Remington Arms Co.*, No. 1:09-cv-01054, 2010 U.S Dist. LEXIS 143398, at *14 (W.D. Ark. Oct. 27, 2010). In fact, Plaintiffs do not allege a single fact supporting the notion that DaVita ever made any specific representations about—or even mentioned—Fresenius's GranuFlo product in the course of providing dialysis treatment. And should Plaintiffs contend that statements from DaVita's website identify some type of purported warranty, such generalized statements or opinion information is non-actionable. *See Pulvers v. Kaiser Found. Health Plan, Inc.*, 160 Cal. Rptr. 392, 393 (Cal. Ct. App. 1979). Without alleging a specific affirmation of fact or reliance thereon, Plaintiffs' claim for breach of express warranty fails under the applicable laws.[12] *Singh v. Hestad*, 809 N.W.2d 901, 901 (Wis. Ct. App. 2012) (rejecting express warranty claim where plaintiff failed to show reliance on warranty); *Murphy v. Nat'l Iron & Metal Co.*, 227 P.2d 219,

[12] Plaintiffs' express warranty claim likewise fails because it does not plead the *prima facie* element of notice. Under Arkansas, California, Florida, North Carolina, and Pennsylvania warranty law, a buyer must "within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." 13 Pa. Cons. Stat. § 2607(c)(1) (2012). Plaintiff must "plead, at a minimum, . . . that [he] provided reasonable notification . . . to state a viable claim for recovery . . . or be barred from any remedy." *Am. Fed'n of State Cnty. & Mun. Emps. ("AFSCME") v. Ortho–McNeil–Janssen Pharm., Inc.*, No. 08-cv-5904, 2010 WL 891150, at *7 (E.D. Pa. Mar. 11, 2010); *see also Jovine v. Abbott Labs., Inc.*, 795 F. Supp. 2d 1331, 1339-40 (S.D. Fl. 2011); *Butcher v. DaimlerChrysler Co.*, No. 1:08CV207, 2008 U.S. Dist. LEXIS 57679, at *10 (M.D.N.C. July 29, 2008); *Williams v. Mozark Fire Extinguisher Co.*, 888 S.W.2d 303, 305-06 (Ark. 1994). Constructive notice of a breach is not sufficient, as the plaintiff is required to actually "notify" the seller of the breach of warranty. *See Vanalt Elec. Constr. Inc. v. Selco Mfg. Corp*., 233 F. App'x 105, 108-11 (3d Cir. 2007). Here, Plaintiffs failed to plead any semblance of "notice" given to DaVita and thus they do not "state a viable claim for recovery." *AFSCME*, 2010 WL 891150, at *7. Absent such necessary facts, Count Three must be dismissed on this ground as well. *Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, at *4 (W.D. Pa. Nov. 10, 2011).

221 (Ariz. 1951). Plaintiffs' Count Three thus violates *Iqbal*'s requirement that legal conclusions be supported by factual allegations and should be dismissed.[13]

IV. Plaintiffs' Negligence, Wrongful Death, and Loss of Consortium Claims Fail

A. Plaintiffs' Allegations Do Not Establish a Breach of a Recognized Duty under Any of the Relevant States' Laws

Plaintiffs have not and cannot state a claim that DaVita breached a duty of care under the facts alleged. Although the MCC contains allegations based on an alleged duty to warn by DaVita's officers and directors, Plaintiffs principally allege that DaVita "knew, or was negligent in not knowing, that its patients' pre-dialysis serum bicarbonate levels were gradually increasing and that patients were at an increased risk of cardiac arrest as a result." (MCC ¶ 16.) With prescription products, the duty to warn runs from manufacturer to physician, and then from the physician to the patient. *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 404 (Cal. Ct. App. 1971). Nevertheless, Plaintiffs argue that DaVita (a medical services provider who was not acting as the individual Plaintiff's respective physicians) somehow has a legal duty to warn in this context—but that is not the law. Plaintiffs seek to impose a duty on DaVita that would run contrary to the principles of the learned intermediary doctrine, which is followed by each relevant state, except

[13] The breach of warranty claims brought by Plaintiffs Allen and Harris should also be dismissed as untimely. In North Carolina, the three-year statute of limitations for breach of warranty claims begins to run "on the date of the breach." *Kaleel Builders, Inc. v. Ashby*, 587 S.E.2d 470, 477 (N.C. Ct. App. 2003); *see* N.C. Gen. Stat. § 1-52(1) (2013). Since Plaintiff Allen alleges that DaVita breached its supposed warranties to her mother when she received dialysis treatment on December 26, 2008, (MCC ¶ 23), and the MCC was not filed until July 8, 2013—more than four years later—her breach of warranty claims are time barred. The same is true for Plaintiff Harris, who also filed her breach of warranty claims on July 8th—over five years after her alleged breach occurred on July 1, 2008, (MCC ¶ 26). *See Alongi v. Bombardier Recreational Prods., Inc.*, No. 12-13374, 2013 U.S. Dist. LEXIS 26486, at *22-25 (E.D. Mich. Feb. 27, 2013) (applying four-year statute of limitations to claim for breach of express warranty and noting that statute begins to run when plaintiff knew or should have known of alleged breach); *Allstate Ins. Co. v. Icon Health & Fitness, Inc.* 361 F. Supp. 2d 673, 677 (E.D. Mich. 2005) (noting that claim for breach of implied warranty is governed by "a three-year statute of limitations," and "the period starts to run at the time of the discovery of the breach of warranty or at the time the breach should have been discovered").

Wisconsin. *Id.*; *Brown v. Roche Labs., Inc.*, No. 1:06-cv-3074, 2013 U.S. Dist. LEXIS 79250, at *20-22 (N.D. Ga. June 6, 2013); *Bruzer v. Danek Med., Inc.*, No. 3-95-971, 1999 U.S. Dist. LEXIS 4483, at *20-24 (D. Minn. Mar. 8, 1999); *Renwick v. Wyeth-Ayerst Lab. Co.*, No. 94-CV-75276, 1997 U.S. Dist. LEXIS 18405, at *25-27 (E.D. Mich. Sept. 30, 1997); *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 536 (E.D.N.C. 1987); *Dyer v. Best Pharmacal*, 577 P.2d 1084, 1088 (Ariz. Ct. App. 1978); *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 378 S.W.3d 109, 120-21 (Ark. 2011); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *Simon v. Wyeth Pharms., Inc.*, 989 A.2d 356, 368 (Pa. Super. Ct. 2009).

DaVita's role is the administration of dialysis treatment pursuant to physician prescriptions, and there is no allegation that DaVita interfered with those prescriptions or in any patient's relationship with his/her personal physician. (MCC ¶¶ 2, 3, 18, 23-34.) Such administrating entities have no duty to warn lest they improperly insert themselves in the physician-patient relationship and undermine the advice and care of a patient's chosen physician. *Murphy v. E. R. Squibb & Sons, Inc.*, 710 P.2d 247, 257 (Cal. 1985); *Wong v. Merck & Co.*, No. 08-409628, 2009 WL 7145956, at *3 (Cal. Super. Ct. Apr. 30, 2009). And under Wisconsin law, Plaintiff Thornton's failure to warn negligence claim fares no better because Plaintiff has not alleged facts establishing DaVita's duty to warn or how, if he was adequately warned, the injured party would have acted differently. *See Lemmermann v. Blue Cross Blue Shield of Wis.*, 713 F. Supp. 2d 791, 813 (E.D. Wis. 2010). The MCC contains no facts on what would have occurred differently had Plaintiff Thornton or any other Plaintiff received a warning from DaVita about the alleged dangers of GranuFlo after their doctors had issued their prescriptions. *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004) ("Absent proof that a more complete or explicit warning would have prevented Kurer's use of Loestrin, she cannot establish

that [defendant's] alleged failure to warn was the proximate cause of her injuries."). Nor does the MCC allege that DaVita had any ability to alter Plaintiffs' physician-issued prescriptions.

Therefore, any result here other than a dismissal would impose a greater duty on DaVita than would be imposed on a manufacturer. *Cf. Carmichael*, 95 Cal. Rptr. at 404; *see also Wong*, 2009 WL 7145956, at *1 (sustaining demurrer where dispensary of prescription drugs manufactured by third party owed no duty to warn purchaser even though it was alleged to have "superior knowledge" of risks); *accord Dyer*, 577 P.2d at 1088; *Makripodis v. Merrell Dow Pharms., Inc.*, 523 A.2d 374, 378-79 (Pa. Super. Ct. 1987). This Court cannot—and should not—impose a duty to warn on DaVita under these facts. *Moore v. Regents of Univ. of California*, 271 Cal. Rptr. 146, 155 (Cal. 1990) (instructing courts applying California law to be reluctant to impose new tort duties when to do so would involve complex policy decisions more appropriately the subject of legislative resolution); Ariz. Rev. Stat. § 12-563.

This is particularly true in the case of Plaintiffs McAdams and Morris, whose alleged injuries occurred after they, their family members, or their physicians were put on notice about the potential risks associated with Fresenius's GranuFlo product. Indeed, there is no duty to warn of defective products where users independently knew or should have known of the potential defects. *See Rush v. Wyeth*, 514 F.3d 825, 830 (8th Cir. 2008); *Balder v. Haley*, 399 N.W.2d 77, 81-82 (Minn. 1987). This is so because without a causal connection between the alleged failure to warn and the purported injury, courts have determined, "as matter of public policy, . . . there is no duty, and consequently no liability." *Balder*, 399 N.W.2d at 81 (citation omitted). According to the MCC, physicians, and therefore their patients, were sufficiently notified as to the possible risks associated with GranuFlo when the FDA issued a recall of the product and Fresenius disseminated a memorandum to "non-Fresenius clinics and physicians"

describing those risks on March 29, 2012. (MCC ¶¶ 58-59, 68-69.) Weeks later, on April 17, 2012, Plaintiff Morris allegedly received dialysis treatment at a DaVita clinic, which she now claims caused her injuries. (*Id.* ¶ 30.) Plaintiff McAdams's mother allegedly received her treatment even later, on November 20, 2012—more than five months after the New York Times published an article about Fresenius and its failure to notify its customers about GranuFlo's "potentially lethal risk." (*Id.* ¶¶ 27, 65.) These facts, as alleged in the MCC, establish that Plaintiffs McAdams and Morris knew or should have known of the potential risks related to GranuFlo prior to receiving treatment, and that DaVita therefore had no duty to warn those Plaintiffs as to the same. Plaintiffs' negligence, wrongful death, and loss of consortium claims in Counts Five, Seven, and Eight should be dismissed.

B. Three Plaintiffs' Claims are Barred by the California Statute of Limitations

California law provides: "[I]n an action for injury or death against a health care provider based upon such person's alleged professional negligence, the time for the commencement of action shall be three years after the date of injury or one year after the plaintiff discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first." Cal. Civ. Proc. Code § 340.5 (2013). Professional negligence "means a negligent act or omission to act by a health care provider in the rendering of professional services, which act or omission is the proximate cause of a personal injury or wrongful death, provided that such services are within the scope of services for which the provider is licensed." *Id.* at § 340.5(2).

According to the MCC, Plaintiff Nunes's wife and Plaintiffs Armstrong and Goosby allegedly began experiencing symptoms after receiving dialysis treatment at a DaVita clinic. (MCC ¶¶ 24-25, 31.) As alleged, these injuries were "not the result of a renal failure . . . , but rather [were] brought on by the defective NaturaLyte and/or GranuFlo products." (*Id.*) Plaintiff Nunes and his wife, as well as Plaintiffs Armstrong and Goosby, thus suspected, or should have

suspected, the possibility that they were wronged at that time. Even assuming *arguendo* that they did not know the responsible party's identity or that a legal cause of action had accrued, the statute of limitations still began running the day each Plaintiff allegedly suffered a heart attack. *Knowles v. Superior Court*, 13 Cal. Rptr. 3d 700, 703 (Cal. Ct. App. 2004) (holding that "mere suspicion of negligence suffices to trigger" the one-year limitations period in action against medical services provider, and the plaintiff "need not know of the actual negligent cause of the injury" or death). Plaintiff Armstrong allegedly suffered injury on August 15, 2011. Plaintiff Goosby allegedly suffered injury on November 17, 2010. Ms. Nunes died on December 27, 2011. Yet, Plaintiff Nunes did not file until March 6, 2013 and Plaintiffs Armstrong and Goosby did not file until April 5, 2013. Thus, Plaintiffs Nunes's, Goosby's, and Armstrong's claims are barred by the one-year statute of limitations and must be dismissed.

C. Plaintiff Allen's Claims are Barred by the Statute of Limitations

North Carolina law provides for a three-year statute of limitations for personal injury actions based on purported medical malpractice. *See Williams v. Haigwood*, No. 08-CT-3138, 2012 U.S. Dist. LEXIS 139235, at *14 (E.D.N.C. Sept. 27, 2012). The statute accrues once the bodily harm to the claimant becomes apparent or ought reasonably to have become apparent, whichever comes first. N.C. Gen. Stat. § 1-52(16) (2013); *In re Zypreza Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 269-70 (S.D.N.Y. 2007).

As alleged in the MCC, Plaintiff Allen's mother "[w]hile undergoing her dialysis treatment [on December 26, 2008], [] suddenly became unresponsive and lost consciousness," and eventually passed away due to that treatment on January 3, 2009. (MCC ¶ 23.) Plaintiff Allen alleges these injuries were "not the result of a renal failure . . . , but rather [were] brought on by the defective NaturaLyte and/or GranuFlo products." (*Id.*) Based on Plaintiff Allen's allegations, she was aware of her mother's injury as early as December 26, 2008 and no later

than January 3, 2009. (*Id.*) Because Plaintiff Allen did not file suit until July 8, 2013, her claims are barred by the three-year statute of limitations and must be dismissed.[14]

D. Plaintiff Harris's Claims are Barred by the Statute of Limitations

Under Michigan law, "[t]he statute of limitations for medical malpractice . . . is two years from the date of accrual. A medical malpractice claim 'accrues at the time of the act or omission that is the basis for the claim of medical malpractice, regardless of the time the plaintiff discovers or otherwise has knowledge of the claim.'" *Taunt v. Oakwood United Hosps.*, No. 07-12710, 2008 U.S. Dist. LEXIS 36000, at *12 (E.D. Mich. May 2, 2008) (citations omitted); *see* Mich. Comp. Laws Serv. § 600.5805(6) (2013); Mich. Comp. Laws Serv. § 600.5838a(1) (2013). Medical malpractice claims are those against "licensed health facilities and agencies," including "clinical laborator[ies]." *Kuznar v. Raksha Corp.*, 750 N.W.2d 121, 126 (Mich. 2008).

Plaintiff Harris claims that her husband suffered a heart attack and died as a direct result of dialysis treatment received at a DaVita clinic "[o]n or about July 1, 2008." (MCC ¶ 26.) Accordingly, Michigan's two-year statute of limitations accrued on that date—the date of injury. Since Harris filed her complaint on July 8, 2013—more than five years after accrual—her medical malpractice claims must be dismissed as untimely.[15]

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[14] Even if Plaintiff Allen's negligence, wrongful death, and loss of consortium claims are not construed to involve acts of medical malpractice, the claims still must be dismissed because they were brought well after the three-year statute of limitations governing personal injury and the two-year statute of limitations governing death "caused by the wrongful act, neglect, or fault of another" under North Carolina law. *See* N.C. Gen. Stat. § 1-52(16); N.C. Gen Stat § 1-53(4).

[15] And even if Plaintiff Harris's allegations against DaVita do not constitute "medical malpractice" claims, they are also still untimely pursuant to Michigan law, which imposes a three-year statute of limitations on all personal injury and products liability claims. *See* Mich. Comp. Laws Serv. § 600.5805(10). Those claims, like those for medical malpractice, "accrue[] . . . at the time the wrong upon which the claim[s] [are] based was done regardless of the time when damage results." *Donawa v. Discount Tire Co.*, No. 1:11-cv-1361, 2012 U.S. Dist. LEXIS 10744, at *2-3 (W.D. Mich. Jan. 30, 2012) (internal quotation marks omitted); *see* Mich. Comp. Laws Serv. § 600.5805(13). Since her husband received dialysis treatment—the alleged

E. Plaintiff Minta's Claims are Barred by the Statute of Limitations

In Georgia, "an action for medical malpractice shall be brought within two years after the date on which an injury or death arising from a negligent or wrongful act or omission occurred." Ga. Code Ann. § 9-3-71(a) (2013). "Thus, the statute of limitation commences to run when the plaintiff knows of the injury or reasonably should have been aware of such injuries from his symptoms." *Miller v. Kitchens*, 553 S.E.2d 300, 303 (Ga. Ct. App. 2001). Georgia defines an "action for medical malpractice" as "any claim for damages resulting from the death of or injury to any person arising out of . . . [c]are or service rendered by any public or private hospital, . . . clinic, . . . [or] facility." Ga. Code Ann. § 9-3-70 (2013).

Here, Plaintiffs Emanuel and Louis Minta allege that Mr. Minta "began experiencing a number of painful, frightening and extreme symptoms associated with a stroke" only "one hour after completing" dialysis treatment at a DaVita clinic "[o]n or about November 11, 2009." (MCC ¶ 28.) Despite having been aware of Mr. Minta's injuries, these Plaintiffs failed to file suit against DaVita until July 8, 2013, more than one year after the two-year statute of limitations expired. Their medical malpractice claims are therefore time barred and must be dismissed.[16]

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wrong—more than five years before Harris filed suit, her personal injury and products liability claims are time barred. Her wrongful death cause of action is likewise untimely. *Fournier v. Mercy Cmty. Health Care Sys.*, 657 N.W.2d 550, 553 (Mich. Ct. App. 2002).

[16] Even if Mr. and Mrs. Minta's allegations are not considered "medical malpractice" claims, they too are nonetheless untimely. Personal injury actions in Georgia must be brought within two years after "a plaintiff discovers, or with reasonable diligence should have discovered, both the injury and the cause thereof." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1379 (M.D. Ga. 2010) (internal quotation marks and citation omitted). Given Plaintiffs' averments that Mr. Minta's injuries were evident only one hour after receiving dialysis treatment and that they believed those injuries were "brought on by the defective NaturaLyte and/or GrauFlo (MCC ¶ 28), the two-year statute of limitations began to run on November 11, 2009 and expired approximately twenty months before this lawsuit was filed. Thus, the Minta Plaintiffs' personal injury claims should be dismissed as time barred.

F. Plaintiff Perez's Claims are Barred by the Statute of Limitations

Florida law provides a two-year limitation period for medical malpractice actions. *Rosario v. Blakely*, No. 10-cv-353, 2013 U.S. Dist. LEXIS 1008, at *29 (M.D. Fla. Jan. 3, 2013) (citing Fla. Stat. Ann. § 95.11(4)(b)). "[T]he statute of limitations begins to run in a medical malpractice action either when the plaintiff has notice of the negligent act giving rise to the cause of action or when the plaintiff has notice of the physical injury which is the consequence of the negligent act." *Gonzalez v. Tracy*, 994 So. 2d 402, 405 n.3 (Fla. Dist. Ct. App. 2008).

Plaintiff Perez alleges that, "[s]hortly after completing his typical four hour dialysis treatment [on or about August 12, 2010], [he] began experiencing a number of painful, frightening and extreme symptoms associated with a stroke, beginning with a severe and debilitating headache." According to the MCC, he identified those symptoms "not [as] the result of a renal failure . . . , but rather [as] brought on by the defective NaturaLyte and/or GranuFlo products." Plaintiff Perez thus had notice of physical injury on or about August 12, 2010. Because Plaintiff did not file his Complaint until July 8, 2013, claims arising from allegations of negligence are barred by the two-year statute of limitations and must be dismissed.[17]

G. Plaintiffs Moreno and Young Failed to Comply with Statutory Requirements

Plaintiffs Moreno's and Young's negligence claims are governed, respectively, by Arizona's Medical Malpractice Act ("MMA"), Arizona Revised Statutes §§ 12–561 through 12–594, and, its "companion statutes," §§ 12–2603 and 12–2604, and by Pennsylvania Rule of Civil Procedure 1042.3. *See Mann v. United States*, No. CV-11-8018, 2012 WL 273690, at *8 (D.

[17] Plaintiff Perez's claims would still be barred even if construed solely as a claim based on wrongful death. "In Florida, a cause of action for wrongful death accrues on the date of death and has a two-year statute of limitations period." *Fulton Cnty. Adm'r v. Sullivan*, 753 So. 2d 549, 552 (Fla. 1999); *see also* Fla. Stat. Ann. § 95.11(4)(d) (2013). Because Plaintiff Perez waited nearly three years to bring suit against DaVita, his claims are barred by the statute of limitations and must be dismissed.

Ariz. Jan. 31, 2012). Because Plaintiffs Moreno and Young failed to comply with these statutes—even after being alerted to these requirements in DaVita's previous motions to dismiss—the Court must dismiss Plaintiffs Moreno's and Young's negligence claims.

Under Arizona law, § 12-2603(A) mandates that a plaintiff bringing claims under the MMA for injury or death against a licensed health care provider based upon such provider's alleged negligence, misconduct, errors or omissions "shall certify in a written statement that it filed and served with the claim . . . whether or not expert opinion testimony is necessary to prove the health care professional's standard of care or liability for the claim." *See also* Ariz. Rev. Stat. § 12–561(2) (2013). Licensed dialysis treatment clinics qualify as "licensed health care provider[s]" under Arizona law. The Arizona legislature imposed this threshold requirement on plaintiffs bringing claims under the MMA to "certify [whether or not this testimony is necessary] in a written statement that is filed and served with the claim," § 12-2603(A), as part of its efforts "to curb a perceived increase in malpractice suits [and] to curtail the filing of frivolous lawsuits against health care professionals." *Moreland v. Barrette*, No. 05-480, 2006 WL 3147651, at *3 (D. Ariz. Oct. 31, 2006) (internal quotation marks omitted). Plaintiff Moreno has not complied with this statutory prerequisite to suit.[18] While a claimant may file a certificate with his complaint that no affidavit is necessary, *see* Ariz. Rev. Stat. § 12–2603(A) (2013), Plaintiff Moreno here has neither filed an expert affidavit nor a certificate—despite being on notice of his obligation to do so since DaVita filed its first motion to dismiss months ago. The MCC is therefore deficient under § 12–2603(A).

[18] Arizona federal courts have uniformly imposed this substantive requirement on plaintiffs proceeding in diversity. *Amor v. Arizona*, No. CV-06-499, 2010 WL 960379, at *9 (D. Ariz. Mar. 15, 2010).

Similarly, Plaintiff Young is in violation of Pennsylvania's rules governing claims against medical service providers. Penn. R. Civ. P. 1042.3(a) (2013) provides that, "[i]n any action based upon an allegation that a licensed professional deviated from an acceptable professional standard," Plaintiff Young was to have filed a certificate of merit by May 6, 2013 (within 60 days of the filing of the initial Complaint on March 6, 2013) to maintain his negligence claim based on Pennsylvania law. *See Velazquez v. UPMC Bedford Mem'l Hosp.*, 328 F. Supp. 2d 549, 556-57 (W.D. Pa. 2004). Plaintiff Young has failed to meet this threshold requirement of substantive law, and his claims governed by Pennsylvania law should thus be dismissed. *Iwanejko v. Cohen & Grigsby, P.C.*, No. 2:03-CV-1855, 2005 WL 3234327, at *3-4 (W.D. Pa. Nov. 30, 2005).[19]

V. Plaintiffs' Fraudulent Concealment Claims Are Not Cognizable

As a matter of federal procedure, the Tenth Circuit requires plaintiffs raising fraudulent concealment claims to comply with Fed. R. Civ. P. 9(b). For a cognizable claim, this heightened pleading standard mandates that a plaintiff must set forth "particular details regarding time, place, method [and] content of the alleged fraudulent concealment." *P.R. v. Zavaras*, 49 F. App'x 836, 840 (10th Cir. 2002). Plaintiffs fail to specify how DaVita concealed facts regarding the safety and efficacy of GranuFlo with an intent to mislead. Indeed, Plaintiffs repeatedly allege a contradictory factual scenario—namely, that Fresenius concealed all purportedly relevant information, even from DaVita. (MCC ¶¶ 7, 53-56, 65-67.)

[19] Several Plaintiffs also fail to comply with the relevant affidavit of merit statute for their respective claims. *See, e.g.*, Fla. Stat. § 766.104 (2013); Mich. Comp. Laws Serv. § 600.2912d (2013). This failure is particularly problematic because individuals suffering from ERSD often have several other serious medical conditions, elevating the importance of an affidavit from a medical expert commenting on the purported basis and cause of their alleged injuries.

The allegation that Fresenius decided to hide, mislead, and obscure information about the patient safety hazard associated with the use of GranuFlo and NaturaLyte products in order to maintain market share (MCC ¶ 7, 53-5, 65-67) contradicts and precludes Plaintiffs' cursory, conclusory, and factually unsupported contention that DaVita concealed—or even possessed—the same information. *See In re PPA*, No. MDL 1407, 2002 WL 34418423, at *3 (J.P.M.L. Nov. 27, 2002) (rejecting misrepresentation claim because allegations that manufacturer defendants concealed material facts directly undermines the idea that non-manufacturer defendant had knowledge or reason to know of alleged defects). The allegations of Fresenius's concealment of the purported risks of GranuFlo disprove any notion that DaVita had knowledge of any concealed information. As such, the MCC's detailed recitation of Fresenius's alleged fraudulent concealment highlights that Plaintiffs fail to allege *any* facts supporting an inference that DaVita had knowledge of these purportedly material facts—a required *prima facie* element of a fraudulent concealment claim. *In re Toyota Motor Corp.*, 785 F. Supp. 2d 883, 924 (C.D. Cal. 2011) (recognizing that plaintiffs must "allege specific facts regarding each [defendant's] knowledge of, and concealment of, purported defects"); *Gilmore v. DJO*, 663 F. Supp. 2d 856, 859 (D. Ariz. 2009); *FDIC v. Deloitte & Touche*, 834 F. Supp. 1129, 1151 (E.D. Ark. 1992).

Moreover, even if the MCC had adequately alleged such knowledge, under state law, there needs to be a factual basis to claim that DaVita did anything more than merely know and not disclose such knowledge. *See Herron v. Best Buy Co. Inc*., ___ F. Supp. 2d ___, 2013 WL 595474, at *11 (E.D. Cal. Feb. 14, 2013) (mere nondisclosure does not constitute active concealment because specific "affirmative acts on the part of the [D]efendants in hiding, concealing or covering up the matters complained of" are required); *U.S. Trouser, S.A. de C.V. v. Int'l Legwear Grp., Inc.*, No. 1:11-cv-00244, 2012 U.S. Dist. LEXIS 177456, at *29 (W.D.N.C.

Dec. 14, 2012); *Saginaw Hous. Comm'n v. Bannum, Inc.*, No. 08-12148, 2012 U.S. Dist. LEXIS 13320, at *38 (E.D. Mich. Feb. 3, 2012); *Sec. Life of Denver Ins. Co. v. Shah*, No. CV411-008, 2012 U.S. Dist. LEXIS 133417, at *9 (D. Ga. Sept. 18, 2012); *Cannon Techs., Inc. v. Sensus Metering Sys., Inc.*, 734 F. Supp. 2d 753, 769 (D. Minn. 2010). That also is absent here. Plaintiffs' only active concealment allegation is the unsupported assertion that DaVita "deceived Plaintiffs and others . . . by concealing from them the true and material facts concerning NaturaLyte and GranuFlo." (MCC ¶¶ 109, 141.) Such threadbare allegations are insufficient, and Plaintiffs' fraudulent concealment claim in Count Four should be dismissed. *Herron*, 2013 WL 595474, at *11; *see Gerawan Farming, Inc. v. Rehrig Pac. Co.*, No. 1:11-cv-01273, 2012 WL 691758, at *9 (E.D. Cal. Mar. 2, 2012).[20]

VI. Plaintiffs' Claims Under the Colorado Consumer Protection Act Lack Merit

Plaintiffs' claims under the CCPA, Colo. Rev. Stat. §§ 6-1-101 *et seq.*, also fail on several grounds. To the extent Plaintiffs seek economic relief, their CCPA claims should be dismissed. The portion of the CCPA that covers available monetary remedies expressly excludes "class action[s]." Colo. Rev. Stat. § 6-1-113(2). Consequently, "monetary relief is not available to a class under the CCPA," and plaintiffs proceeding on a class-action theory may only pursue "other types of relief, such as declaratory or injunctive relief." *Martinez v. Nash Finch Co.*, No. 11-cv-02092, 2013 U.S. Dist. LEXIS 45576, at *12-13 (D. Colo. Mar. 29, 2013). The MCC requests monetary damages. (MCC ¶¶ 140-48.) Thus, insofar as Plaintiffs are pursuing class-action damages under the CCPA, their claims should be dismissed as statutorily barred.

[20] Plaintiffs not only fail to allege facts supporting a fraudulent concealment claim, they do not allege how they relied on the purportedly concealed information—a critical element of the claim under Wisconsin and Arizona law. *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 54 (Wis. 1984) ("Even assuming that the defendants made misrepresentations concerning DES, since there was no reliance on those misrepresentations, there can be no recovery under this cause of action."); *Hearn v. R.J. Reynolds Tobacco Co.*, 279 F. Supp. 2d 1096, 1114 (D. Ariz. 2003). Without an allegation of reliance, Count Four of the MCC should be dismissed for this additional reason.

Plaintiffs' CCPA claims based on an alleged failure to warn should also be dismissed. (*See* MCC ¶¶ 144-47.) Such claims cannot be maintained "absent a duty to disclose" on the part of the defendant. *Francis v. Mead Johnson & Co.*, No. 1:10-cv-00701, 2010 U.S. Dist. LEXIS 137630, at *16 (D. Colo. Dec. 17, 2010). As with other states described above, Colorado recognizes the learned intermediary doctrine, whereby "[i]t is the responsibility of the physician as the learned intermediary to assess the risks and benefits of a particular course [of] treatment." *Caveny v. Ciba-Geigy Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992). Indeed, under Colorado law, "where prescription drugs are concerned, the manufacturer has a duty . . . to advise the prescribing physician," and it is left to the physician to provide sufficient warnings to the patient. *O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281-82 (Colo. App. 2010), *cert. denied*, No. 10SC456, 2010 Colo. LEXIS 917 (Colo. Mar. 18, 2010). Since DaVita was neither the prescribing physician nor a manufacturer of GranuFlo, it had no duty to warn Plaintiffs. The CCPA claims based on an alleged failure to warn therefore must be dismissed.

Plaintiffs' averments that DaVita violated the CCPA by allegedly providing misleading statements about the safety of its dialysis treatments are likewise unsustainable. (*See* MCC ¶¶ 143.) Misrepresentation claims under the CCPA must be dismissed where a plaintiff fails to allege that he actually relied upon the purported misrepresentations of the defendant. *See Pauley v. Bank One Colo. Corp.*, 205 B.R. 272, 276 (Bankr. D. Colo. 1997); *Martinez v. Lewis*, 942 P.2d 1219, 1226 (Colo. App. 1996). Although Plaintiffs assert that DaVita's "statements that its products were the 'safest choice' and offered 'superior clinical outcomes'" were "misleading" (MCC ¶ 143), the MCC is devoid of any specific allegations that Plaintiffs actually relied on these comments when deciding to undergo dialysis treatment. *See HealthONE of Denver, Inc. v. UnitedHealth Grp. Inc.*, 805 F. Supp. 2d 1115, 1121 (D. Colo. 2011) (recognizing that the

heightened pleading standards of Rule 9(b) apply to claims under the CCPA). This is consistent with the common-sense view that a patient receiving dialysis treatment relies on his doctor's diagnosis and orders, and not on representations made by the clinic administering the treatment. For these several reasons, Plaintiffs' CCPA in Count Nine should be dismissed.

CONCLUSION

For the foregoing reasons, Plaintiffs' MCC should therefore be dismissed with prejudice.

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Dated: August 7, 2013

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 7th day of August, 2013, a copy of the above **MOTION TO DISMISS PURSUANT TO RULE 12(b)(6)** was filed electronically with the Clerk of the Court, using CM/ECF system, which sent notification of such filing to:

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