

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/) MDL NO. 13-02428-DPW
NATURALYTE DIALYSATE)
PRODUCTS LIABILITY LITIGATION)
)
)

This Order Relates To:

JAMES E. COBY IV, individually) CIVIL ACTION NO.
and on behalf of decedent) 14-11965-DPW
BEVERLY D. COBY)
)
Plaintiffs,)
)
v.)
)
FRESENIUS MEDICAL CARE)
HOLDINGS, INC. d/b/a FRESENIUS)
MEDICAL CARE NORTH AMERICA,)
INC., FRESENIUS USA, INC.,)
FRESENIUS USA MANUFACTURING)
INC., FRESENIUS USA MARKETING,)
INC., DIALYSIS CLINIC, INC.,)
USA, INC.,)
)
Defendants.)

MEMORANDUM AND ORDER
January 2, 2015

The plaintiff, James Coby, individually and on behalf of his deceased mother, Beverly Coby ("the decedent"), filed this lawsuit in Missouri state court seeking recovery for injuries sustained by and the wrongful death of the decedent allegedly resulting from the use of NaturaLyte Liquid ("NaturaLyte") or GranuFlo Acid ("GranuFlo") Concentrates during a dialysis treatment she received in October 2010. The named defendants,

collectively "Fresenius," are various corporate entities engaged in the business of manufacturing, labeling, promoting, and distributing NaturaLyte and GranuFlo, as well as the owners and operators of two dialysis centers in Kansas City: Dialysis Clinic, Inc., a Tennessee corporation that owns and operates a free-standing dialysis clinic bearing the same name in Kansas City, and Midwest Division - RMC, LLC ("RMC"), a Delaware foreign limited liability company that owns and operates Research Medical Center in Kansas City. Defendant Dialysis Clinic, Inc., has moved to dismiss the claims against it pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief can be granted, and in the alternative for summary judgment. For the reasons discussed below, I will grant the motion to dismiss on all counts.¹

I. BACKGROUND

A. *Factual Background*

1. Basis for the Multidistrict Litigation Against Fresenius

The underlying negligence claim is part of a multidistrict

¹ Because I grant Defendant Dialysis Clinic's motion to dismiss, I need not consider its alternative request for summary judgment. A motion to dismiss under Rule 12(b)(6) can be treated as one for summary judgment and disposed of as provided in Rule 56 if matters outside the pleadings are presented to and not excluded by the court. Although the defendant has submitted numerous documents and affidavits, I decline to treat this motion as one for summary judgment, given that there are some factual disputes remaining, and given the plaintiff's apparent difficulties in obtaining relevant documents.

litigation proceeding in this District involving product liability actions against Fresenius arising from injuries or deaths allegedly caused by use of GranuFlo and NaturaLyte during hemodialysis. See *In re: Fresenius GranuFlo/NaturaLyte Dialysate Prods. Liability Litig.*, 935 F. Supp. 2d. 1362 (Mem.) (Multidistrict Panel on Litigation Mar. 29, 2013).

Hemodialysis is a form of treatment for patients with late-stage kidney failure that cleanses and removes waste from the blood by drawing blood from the patient, passing it through a dialysis machine that utilizes dialysate solution and then a filtering device that cleanses the blood, and returning the blood to the body. Compl. ¶ 12. In three-stream dialysis machines, dialysate solution is made by mixing water with a bicarbonate (base) concentrate and an acid concentrate. *Id.* ¶ 14. The organic acid used in the acid concentrate may be in the form of acetic acid, citric acid, or sodium diacetate. *Id.* ¶ 15. Sodium diacetate creates a different reaction with bicarbonate when used to form dialysate than when other acids are used. *Id.* ¶¶ 17-18. Bicarbonate acts as a pH buffer in the blood stream to neutralize metabolic acidosis that may be present in hemodialysis patients. *Id.* ¶ 16. Physicians prescribe the amount of bicarbonate, and therefore the composition of the dialysate fluid, to be delivered during

hemodialysis to individual patients. *Id.*; see Fresenius Answer ¶ 16 (Doc. 11).

Fresenius develops, manufactures, markets, and sells dialysis solutions, including GranuFlo and NaturaLyte. See Compl. ¶ 49. GranuFlo is a dry concentrated dialysate marketed and distributed by Fresenius beginning in 2003. *Id.* ¶ 19. It uses acetic acid and sodium acetate to form the final dialysate and metabolizes quickly in the bloodstream. *Id.* ¶ 20. This quick metabolism rate, attributable to the combination of acetic acid and sodium diacetate, results in elevated bicarbonate levels, which may cause metabolic alkalosis. *Id.* ¶¶ 20, 23. Alkalosis is correlated with an increased risk of cardiopulmonary arrest and sudden cardiac death during or after dialysis treatment. *Id.*

Coby, like other plaintiffs in this MDL, asserts that these risks of elevated bicarbonate levels and resulting metabolic alkalosis were known in the medical community as early as 2004, but that Fresenius failed to inform physicians GranuFlo increases the level of bicarbonate in patients and therefore could lead to such risks. *Id.* ¶¶ 21-23. Coby further asserts that Fresenius employees were aware GranuFlo caused unintended elevated bicarbonate levels prior to May 2005 and were aware its dialysis machines required special instructions to reduce the risks of elevated levels from GranuFlo use. *Id.* ¶ 24. However,

Fresenius did not inform the dialysis medical community at large, including other dialysis providers who administered GranuFlo to patients. *Id.* ¶ 24. In 2009 or 2010, Fresenius revised the operator's manual for certain Fresenius-manufactured dialysis machines to instruct users to use half of the acetate value listed on the label for GranuFlo concentrate. *Id.* ¶ 27. Fresenius did not, however, provide notification to all users of GranuFlo that it was necessary to use half of the listed acetate value. *Id.* ¶ 28.

A 2011 study conducted by Fresenius of patients who suffered cardiopulmonary arrest and sudden cardiac death in Fresenius clinics in 2010 revealed that patients with elevated pre-dialysis bicarbonate levels were six to eight times more likely to experience such events than patients with lower bicarbonate levels. *Id.* ¶ 34. Fresenius thereafter instructed its dialysis centers to consider lower bicarbonate prescriptions when using GranuFlo and NaturaLyte in light of these findings. *Id.* ¶ 34-36. It was not until March 2012 that Fresenius informed other dialysis centers using Fresenius products by way of a large-scale notification that certain dangers existed in following label and prescription instructions for GranuFlo, and that users should decrease the amount used to avoid elevated bicarbonate levels and resultant cardiovascular events. *Id.* ¶¶ 38-40.

2. Claims Specific to This Case

Coby contends in his complaint, based on information and belief, that his mother (the decedent) received dialysis treatment using GranuFlo or NaturaLyte during a routine dialysis appointment "at Research Medical Center and . . . Dialysis Clinic, Inc. in October 2010." Compl. ¶ 47. After the decedent returned home, she went into cardiac arrest, was taken to Shawnee Mission Medical Center, and "was eventually pronounced dead on November 1, 2010 from cardiopulmonary arrest." *Id.* In his response to Dialysis Clinic's statement of undisputed facts in support of its alternative summary judgment motion, Coby clarifies this chain of events. He alleges that the decedent received treatment at a Dialysis Clinic location on September 7, 2010, during which she developed chest discomfort and afterwards was taken to the RMC Emergency Department. Doc. 812, Pltf.'s Add'tl Opp, ¶ 6. She was diagnosed with a heart attack and remained hospitalized there for a week. *Id.* ¶¶ 7-8. On September 14, 2010, the decedent received dialysis treatment at RMC, was discharged, and thereafter suffered a cardiac event at home. *Id.* ¶¶ 8-9. She was taken to Shawnee Mission Medical Center, where she died on November 1, 2010. *Id.* ¶ 9.

Coby asserts, like other plaintiffs in this MDL, that GranuFlo and NaturaLyte, and the Fresenius dialysis machines when used with these dialysate solutions, are defective,

unreasonably dangerous products, and that the decedent died as a result of receiving these unreasonably dangerous dialysis chemicals.² Compl. ¶¶ 42, 47. He contends that neither the decedent nor her health care providers were warned that GranuFlo and NaturaLyte are unreasonably dangerous products, or that only half the acetate level of GranuFlo should be used with the Fresenius dialysis machines. *Id.* ¶¶ 43, 47. He alleges that instead of warning of known dangers associated with use of GranuFlo and NaturaLyte consistent with the instructions accompanying these products, Fresenius promoted and marketed GranuFlo and NaturaLyte to the decedent, other consumers, and health care providers as a safe product. *Id.* ¶ 44, 47. In short, he alleges that these products were defective in their design, unreasonably unsafe for their intended purposes, and carried foreseeable risks that exceeded the benefits associated with them. *Id.* ¶¶ 51-52. He contends that the decedent's injuries and death were the direct and proximate result of GranuFlo and NaturaLyte's defective condition and Fresenius' failure to warn of these defects. *Id.* ¶ 53.

² Specifically, Coby asserts that "GranuFlo is defective and unreasonably dangerous for its intended use because it creates an unreasonably dangerous level of bicarbonate in the blood stream during dialysis causing metabolic alkalosis and a corresponding substantial increase in the risk of cardiopulmonary arrest during dialysis treatment." Compl. ¶ 42.

Accordingly, the plaintiff brings claims of strict liability for a defective product (Count I), strict liability for failure to warn (Count II), negligent design/failure to warn (Count III), breach of express warranty (labeled as Count III also but referred to as Count IV here), breach of implied warranty (labeled as Count IV but referred to as Count V here), fraudulent misrepresentation (labeled as Count V but referred to as Count VI here), and violation of the Missouri Merchandising Practices Act (labeled as Count VI but referred to as Count VII here), and for punitive damages (labeled as Count VII but referred to as Count VII here). See Compl. ¶¶ 48-120.

All counts are alleged against all named defendants, including the Fresenius defendants and two dialysis clinics in Kansas City that are owned and operated by entities other than Fresenius: RMC and Dialysis Clinic. RMC has been dismissed from this case by stipulation. In response to the plaintiff's allegation that the decedent's health care providers were not warned that GranuFlo and NaturaLyte were dangerous, Dialysis Clinic "admit[s] that from 2009 through 2010, Fresenius did not notify [it] of the necessity to 'half' Acetate levels when setting the parameters on dialysis machines while using GranuFlo or, to the extent it provided such information, it did not generally disseminate any necessary warnings or instructions nor

identify specific risks associated with GranuFlo." Doc. 20 ¶ 18 (hereinafter "DC Amended Answer").

B. Procedural History

Coby served his petition for damages (referred to herein as both "petition" and "complaint") on the defendants on November 1, 2013, filing the case in the Circuit Court of Jackson County, Missouri at Kansas City. Compl. pg. 1. The case was removed by the defendants to federal court in the Western District of Missouri on April 10, 2014, after which the Fresenius defendants and Dialysis Clinic filed separate answers. Docs. 1, 11, 14. The case was then transferred to this court as part of the ongoing MDL. See *In re: Fresenius Granuflo/Naturalyte Dialysate Prods. Liability Litig.*, 1:13-md-02428-DPW. On May 9, Dialysis Clinic filed an amended answer to the complaint, providing greater specification as to its asserted affirmative defenses. Doc. 20. On June 10, the parties stipulated to the dismissal without prejudice of Defendant RMC. Doc. 32. On October 23, 2014, Dialysis Clinic filed the instant motion to dismiss the plaintiff's petition, or in the alternative for summary judgment. Doc. 33. After the MDL hearing on November 7, 2014, the plaintiff offered to stipulate to dismissal without prejudice of the petition on the basis of Mo. Rev. Stat. § 538.225(6) and opposed Dialysis Clinic's alternative motion for summary judgment. MDL Doc. 812. Dialysis Clinic replied,

pressing dismissal with prejudice and continuing to advocate its alternative motion for summary judgment. Doc. 40. I heard further oral argument on the motion from the parties on December 22, 2014.

II. STANDARD OF REVIEW

Because this case has been transferred here after removal to federal court on the basis of diversity of citizenship, I apply federal procedural law and the substantive law of the forum state, Missouri, by application of its choice-of-law rules. See *In re Propulsid Prods. Liability Litig.*, 280 F.R.D. 133, 140 (E.D. La. 2002) (citing *Klaxon v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941)). To survive a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citation omitted). I "accept as true all well-pleaded facts in the complaint and draw all reasonable inferences in favor of the plaintiff[]." *Gargano v. Liberty Int'l Underwriters, Inc.*, 572 F.3d 45, 48 (1st Cir. 2009). Although I am "generally limited to considering facts and documents that are part of or incorporated into the complaint," *Giragosian v. Ryan*, 547 F.3d 59, 65 (1st Cir. 2008) (citation and internal quotation marks omitted), I may also consider documents to which "a complaint's

factual allegations are expressly linked." *Beddall v. State Street Bank & Trust Co.*, 137 F.3d 12, 17 (1st Cir. 1998). The alleged facts must "nudge the[] claims across the line from conceivable to plausible." *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 569 (2007).

Dismissal for failure to state a claim is appropriate when the pleadings fail to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Berner v. Delahanty*, 129 F.3d 20, 25 (1st Cir. 1997) (quoting *Gooley v. Mobil Oil Corp.*, 851 F.2d 513, 515 (1st Cir. 1988)) (internal quotation marks omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged--but it has not 'show[n] '--'that the pleader is entitled to relief.'" *Maldonado v. Fontanes*, 568 F.3d 263, 269 (1st Cir. 2009) (quoting *Iqbal*, 556 U.S. at 679).

III. DISCUSSION

A. ***Import of Missouri Statutory Protections for Health Care Providers Against Tort Claims***

1. Mo. Rev. Stat. § 538.225 Applies to Dialysis Clinic

Missouri statutory law imposes certain restrictions on tort and products liability claims for damages from personal injury or death against a health care provider. See *Budding v. SSM*

Healthcare Sys., 19 S.W.3d 678, 680 (Mo. 2000) (Holstein, J.).

Specifically, Mo. Rev. Stat. § 538.225(1) provides:

In any action against a health care provider for damages for personal injury or death on account of the rendering of or failure to render health care services, the plaintiff or the plaintiff's attorney shall file an affidavit with the court stating that he or she has obtained the written opinion of a legally qualified health care provider which states that the defendant health care provider failed to use such care as a reasonably prudent and careful health care provider would have under similar circumstances and that such failure to use such reasonable care directly caused or directly contributed to cause the damages claimed in the petition.

The plaintiff does not contest that this statute applies to the instant action against Dialysis Clinic. First, Dialysis Clinic is a health care provider as defined by the statute. See Mo. Rev. Stat. § 538.205(4) ("health care provider" is "any physical, hospital, health maintenance organization, ambulatory surgical center, long-term care facility . . . registered or licensed practical nurse, . . . and any other person or entity that provides health care services under the authority of a license or certificate"). End-stage renal dialysis centers are licensed and regulated by the Missouri Department of Health & Senior Services. According to the plaintiff's petition, Dialysis Clinic operated "a free-standing dialysis clinic" in Kansas City and "sold and transferred dialysis services and treatment, including the use of GranuFlo and NaturaLyte, in its regular course of business." Compl. ¶ 8. *Cf. Smith v. Paslode*

Corp., 7 F.3d 116, 117-118 (8th Cir. 1993) (concluding that Red Cross provides health care services involving "procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for transfusion into the human body," and is health care provider under chapter 538).

Second, Dialysis Clinic allegedly rendered health care services to the decedent, and from this provision of services would have had a provider-patient relationship with the decedent. Compl. ¶ 47. See Mo. Rev. Stat. § 538.025(5) ("health care services" are "any services that a health care provider renders to a patient . . . in the ordinary course of furthering the purposes for which the institution is organized. Professional services shall include, but are not limited to, transfer to a patient of goods or services"). Dialysis is unquestionably "a service which maintains or restores the soundness of the human body or mind, or aids to free the body or mind from disease or ailment," and therefore a health care service under the statute. *Stalcup v. Orthotic & Prosthetic Lab, Inc.*, 989 S.W.2d 654, 660 (Mo. Ct. App. 1999).

Finally, this action arises "on account of the rendering of or failure to render health care services." Mo. Rev. Stat. § 538.225(1). All of the plaintiff's claims arise out of the alleged injuries suffered by the decedent as a result of the dialysis treatment that she allegedly received at Dialysis

Clinic. This treatment was presumably performed "by physicians, nurses, and other health care professionals exercising professional judgment." *Williams v. Am. Nat'l Red Cross*, No. 4:12CV1516JCH, 2012 WL 5471887, at *3 (E.D. Mo. Nov. 9, 2012) (discussing *Smith*, 7 F.3d at 118) (claim arising from drawing of plaintiff's blood by licensed professional nurse is related to health care). Therefore, "the true claim relates only to the provision of health care services." *Devitre v. Orthopedic Center of St. Louis, LLC*, 349 S.W.3d 327, 331-32 (Mo. 2011) (internal quotation marks and citation omitted). Even though some of the claims pertain to the defective nature of the GranuFlo product itself rather than the use and administration of it, "Missouri courts elevate substance over form" in determining the applicability of chapter 538. *Spears ex rel. Clendening v. Freeman Health Sys.*, 403 S.W.3d 616, 618-19 (Mo. Ct. App. 2012) (citations and internal quotation marks omitted); see *Budding*, 19 S.W.3d at 680 ("any action" in § 538.225(1) includes both negligence and products liability actions). Here, the overall petition arises out of personal injuries and death allegedly resulting from the provision of health care services, and therefore § 538.225 applies to this action against Dialysis Clinic.

2. Mo. Rev. Stat. § 538.225 Requires Dismissal of All Claims without Prejudice

Where the statute applies, strict compliance with Mo. Rev. Stat. § 538.225(1) is required. See *Mayes v. St. Luke's Hosp. of Kansas City*, 430 S.W.3d 260, 271-72 (Mo. 2014). Under that provision, a separate affidavit must be filed for each named defendant no later than ninety days after filing the petition for damages, absent an extension of the deadline by the court for good cause. Mo. Rev. Stat. § 538.225(4), (5). The plaintiff filed his petition on November 1, 2013, and the ninety-day period has long passed. The plaintiff concedes that he did not comply with this requirement. Consistent with the statutory directive, I must dismiss the action against Dialysis Clinic without prejudice.³ *Id.* § 538.225(6).

Although the inquiry could end here, I will consider the substance of each of the asserted bases for dismissal as well, particularly where they may merit dismissal of certain counts with prejudice. Dismissal without prejudice is appropriate where the infirmity that prevents the complaint from proceeding is remediable, and it is possible for the plaintiff to re-file

³ Fresenius could, in theory, file a motion to dismiss on this same ground. Such a motion would likely not succeed, however, because Fresenius does not appear to be a health care provider. More importantly, it may not be worthwhile for Fresenius to pursue such a motion, where dismissal for noncompliance is without prejudice, and a properly supported claim could be filed again.

the complaint in a manner that would permit the alleged claims to move forward. *See, e.g., Claudio-de León v. Sistema Universitario Ana G. Méndez*, No. 13-1198, 2014 WL 7269767, at *5 (1st Cir. Dec. 22, 2014) (dismissal without prejudice appropriate where plaintiff failed to comply with forum selection clause governing employment contract, because case could be re-filed in appropriate forum); *City of New Bedford v. Woods Hole*, No. 00-12049, 2003 WL 21282212, at *1 (D. Mass. May 23, 2003) (dismissing complaint without prejudice to avoid “foreclos[ing] later, fully reasoned, resolution of [the] important issues [presented by the case] on their legal merits if they ceased to be moot at some point in the future”).

Complaints meriting dismissal without prejudice include those that fail to comply with some pleading requirement, but that if properly pleaded and filed could present a cognizable claim. Dismissal without prejudice permits re-filing so as not to preclude the pursuit of such potentially meritorious claims. *See Miripuri v. ACT Mfg., Inc.*, 212 F.3d 624, 628 (1st Cir. 2000) (“the phrase ‘without prejudice,’ when attached to a dismissal order . . . signifi[es] that the judgment does not preclude a subsequent lawsuit on the same cause of action either in the rendering court or in some other forum”).

In contrast, dismissal for failure to state a claim upon which relief may be granted under Fed. R. Civ. P. 12(b)(6)

typically is "presumed to be with prejudice," because it serves as "a final decision on the merits." See *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 241 (1st Cir. 2004), abrogated on other grounds by *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40 (1st Cir. 2009); *Acevedo-Villalobos v. Hernandez*, 22 F.3d 384, 388-89 (1st Cir. 1994). Dismissal with prejudice is appropriate where the defect in the claim is irremediable, such as where there is no basis in law for this plaintiff to bring this particular claim against this defendant (even if properly pleaded), or where the statute of limitations clearly precludes the claim, and refiling could do nothing to cure the infirmity. In such instances, preclusion of further litigation of the claim through prejudicial dismissal is the proper and most efficient resolution.

B. *The Import of Budding v. SSM Healthcare System*

As its first basis for dismissal with prejudice, Dialysis Clinic contends that the Missouri Supreme Court decision in *Budding*, 19 S.W.3d 680, precludes Counts I-V of the petition as a matter of law.

1. Strict Liability Claims (Counts I and II)

The Missouri Supreme Court has interpreted chapter 538 to prohibit strict liability claims against health care providers, as defined by the statute. See *Budding*, 19 S.W.3d at 681-82 (determining that "the legislature intended to eliminate

liability of health care providers for strict liability," and stating that "strict liability is not applicable to health care providers); see also *Gaynor v. Washington Univ.*, 261 S.W.3d 650, 653-54 (Mo. Ct. App. 2008) (noting that legislature amended § 538.225 after *Budding* and did not make substantive changes, suggesting that legislature "adopted the judicial construction given" to the section (internal quotation marks and citation omitted)). Accordingly, Counts I and II, the strict liability claims against Dialysis Clinic, must be dismissed with prejudice.

2. Breach of Warranty Claims (Counts IV and V)

Dialysis Clinic contends that the reasoning of *Budding* serves to preclude the plaintiff's breach of warranty claims as well. In reaching its conclusion on strict liability claims, the *Budding* court reasoned that Mo. Rev. Stat. § 538.225 could not be read to require plaintiffs to demonstrate negligence as a condition for proceeding with a claim against a health care provider⁴ for causes of action in which such a deviation from a standard of medical care need not be shown. As a result, the

⁴ The affidavit required by Mo. Rev. Stat. § 538.225(1) must state that the defendant "failed to use such care as a reasonably prudent and careful health care provider would have under similar circumstances and that such failure to use such reasonable care directly caused or directly contributed to cause the damages claimed in the petition."

Budding court reasoned, the legislature must have intended to preclude strict liability claims against such providers.

Dialysis Clinic focuses on this reasoning to suggest that the *Budding* court intended to preclude any claims seeking recovery for personal injury or wrongful death that do not require a showing of deviation from a standard of medical care. Specifically, Dialysis Clinic looks to the language in *Budding* stating that "the general assembly intended that liability of health care providers be rooted in a culpable state of mind that gives rise to traditional tort liability" to contend that claims against health care providers for such damages without such a showing are precluded by the statute. *Budding*, 19 S.W.3d at 681.

Other language in *Budding* noting that § 538.225 applies not only to negligence actions but also to product liability actions provides a further indication that the *Budding* court interpreted chapter 538 as narrowing the universe of personal injury-type claims that could be brought against health care providers. *Id.* at 680; see *J.K.M. v. Dempsey*, 317 S.W.3d 621, 625 (Mo. Ct. App. 2010) (acknowledging that analysis in *Budding* was based in part on understanding that legislature "intended to impose specific limitations on the traditional tort causes of action available against a health care provider," and that statute limited such causes of action by requiring that "cause of action be dependent

upon an affidavit . . . of failure to exercise reasonable care” (quoting *Budding*, 19 S.W.3d at 680)).

The same argument was made in the District Court for the Western District of Missouri nearly ten years ago but was not fully explored, and does not appear to have been revisited since. In *Henry v. Mylan Pharmaceuticals, Inc.*, No. 05-CV-40092-NKL, 2005 WL 2101049, at *4 (W.D. Mo. Aug. 31, 2005), the court observed that the *Budding* court “concluded that it would be absurd to require an affidavit showing a breach of duty when a successful strict liability action requires no breach of duty.” The court in *Henry* was persuaded by the defendant’s argument that “the logic of *Budding* is equally applicable to . . . breach of warranty claims because neither requires a showing that there has been a breach of the standard for care in the profession.” *Id.* However, because the plaintiff represented that he sought recovery of the difference in cost between the generic and branded drug at issue, and specifically did not seek recovery for personal injury or death, the court concluded that the logic of *Budding* was inapplicable, because the claims would not be governed by § 538.225 on the basis of the recovery sought. *Id.* The court noted that if the plaintiff did ultimately pursue warranty damages for personal loss, the issue would need to be “revisited.” *Id.*

Although research indicates that this issue has not been directly revisited by any court yet, there is a suggestion of agreement with this reading in more recent state case law. In *Sides v. St. Anthony's Medical Center*, 258 S.W.3d 811, 820 (Mo. 2008), the Missouri Supreme Court explained that, "[i]n *Budding*, this Court held that even though section 538.225 deals only with the need for affidavits regarding negligence, implicit within it is the requirement that one can submit a claim against a health care provider only on a negligence theory. *Budding* thus found that the strict liability theory asserted by the plaintiff in that case was impermissible under the statute." With this understanding of *Budding*, the *Sides* court rejected the defendant's argument that § 538.225 prohibits the use of a *res ipsa loquitur* theory in a medical malpractice case, just as it prohibits a strict liability theory, because the statute "requires that only a specific negligence theory can be brought against a medical malpractice defendant." *Id.* The court reasoned that although § 538.225 "clearly does require a showing of negligence on the part of each defendant," it does not require a specific showing, and a *res ipsa loquitur* theory requires proof that the harm-causing event is one that does not occur in the absence of negligence. *Id.* at 821-22.⁵

⁵ A month and a half before *Sides* was published, the Missouri Court of Appeals offered an interpretation of *Budding*, stating

Taking the dicta in *Sides* "that one can submit a claim against a health care provider only on a negligence theory," *id.* at 820, as the most accurate reading of § 538.225 available at present, I conclude the breach of warranty claims asserted here cannot survive. Under Missouri products liability law, there are three theories of recovery: breach of warranty, strict liability, and negligence. See *Linegar v. Armour of Am.*, 909 F.2d 1150, 1152-53 (8th Cir. 1990). A reasonable extension of *Budding* - which explicitly ruled out strict liability claims but did not address other theories - and of the discussion of the affidavit requirement in *Sides* is that plaintiffs may not bring breach of warranty product liability claims against health care providers where damages are based on personal loss. See *Henry*, 2005 WL 2101049, at *4. Accordingly, dismissal with prejudice of counts IV and V on the basis of statutory preclusion of these claims by Mo. Rev. Stat. § 538.225 is appropriate.

3. Negligent Design/Failure to Warn (Count III)

Contrary to the suggestion of Dialysis Clinic, it is not so clear that *Budding* and *Sides* intend to extend the limitation of

that "section 538.225.1 did not exempt from its affidavit requirement a medical malpractice case that does not require proof of the standard of care by expert opinion." *Gaynor v. Washington Univ.*, 261 S.W.3d 650, 654 (Mo. Ct. App. 2008). The appeals court concluded that "medical malpractice actions against health care providers in which proof is based on *res ipsa loquitur*" were required to comply with the affidavit requirement - not that they could not be brought at all. *Id.*

§ 538.225 to negligent design/failure to warn claims as well. See *Blevins v. Cushman Motors*, 551 S.W.2d 602, 607 (Mo. 1977) (discussing different theories underlying defective design claims based in negligence and strict liability). Indeed, although departure from a standard of care within the medical profession is not required to establish negligent design, some showing of negligence is clearly required. Cf. *Sides*, 258 S.W.3d at 820 (discussing negligence showing required under *res ipsa loquitur* theory). It is not immediately evident that Dialysis Clinic can be held to some independent duty regarding design or warning apart from a medical standard of care. But these are matters that may not be resolved at this point. For this reason, dismissal with prejudice of Count III is not appropriate.

C. Adequacy of Pleadings

Dialysis Clinic also contends that the plaintiff's petition fails to comply with the pleading requirements of Fed. R. Civ. P. 8(a)(2).⁶

1. Rule 8(a)(2) Pleading Standard

Rule 8(a)(2) requires that a complaint contain "a short and plain statement of the claims showing that the pleader is entitled to relief." The complaint must "give the defendant

⁶ Although Dialysis Clinic cites to Eighth Circuit cases for this argument, I rely on First Circuit precedent in interpreting procedural questions.

fair notice of what the . . . claim is and the grounds upon which it rests.'" *Twombly*, 550 U.S. at 555 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Courts in this circuit (and in the Eighth Circuit) employ a two-pronged approach to considering whether a complaint presents an adequate pleading. See *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 12 (1st Cir. 2011); see also *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009). The first step involves "identifying and disregarding statements in the complaint that merely offer legal conclusions couched as fact." *Ocasio-Hernandez*, 640 F.3d at 12 (alterations, internal quotation marks, and citations omitted). If what remains of factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged, the claim has facial plausibility." *Id.* (internal quotation marks omitted) (citing *Iqbal*, 556 U.S. at 678). Where the Rule 8(a)(2) pleading requirement is satisfied, a Rule 12(b)(6) motion to dismiss is inappropriate, and vice versa. See *id.* at 11-12; see also *Rivera-Almodovar v. Instituto Socioeconomico Comunitario, Inc.*, 806 F. Supp. 2d 503, 506 (D. P.R. 2011) ("The propriety of a dismissal under Rule 12(b)(6) turns on the complaint's compliance with Rule 8(a)(2)").

2. Overall Compliance with Rule 8(a)(2)

Dialysis Clinic correctly observes that the facts attributing legal responsibility to it directly are sparse in

the complaint. Indeed, Dialysis Clinic is mentioned in only two paragraphs of the 120-paragraph complaint: once in ¶ 8, where it is identified as a dialysis center, and once in ¶ 47, where the plaintiff alleges that the decedent received dialysis treatment involving GranuFlo or NaturaLyte in October 2010 at Dialysis Clinic that caused her death. However, factual allegations against one defendant may reasonably be inferred against another in a complaint of this nature. These explicit references to Dialysis Clinic, coupled with the other allegations in the complaint explaining the alleged defects of GranuFlo and NaturaLyte, are sufficient to put Dialysis Clinic on notice that the plaintiff believed that Dialysis Clinic had some involvement in the provision of an unsafe dialysis treatment to the decedent involving GranuFlo or NaturaLyte in or around October 2010. This satisfies the requirement that the complaint "set forth minimal facts as to who did what to whom, when, where and why." See *Rasheed v. D'Antonio*, Civ. No. 10-11253-GAO, 2011 WL 4382517, at * 21 (D. Mass. Sept. 19, 2011) (quoting *Burgess v. Ebay*, 2011 WL 841269, at *2 (D. Mass. Mar. 8, 2011)).

To the extent Dialysis Clinic contends that the petition fails to meet the most basic, threshold pleading standard, that argument is unpersuasive. See *id.* (dismissal for failure to comply with these pleading requirements "is usually reserved for those cases in which the complaint is so confused, ambiguous,

vague, or otherwise unintelligible that its true substance, if any, is well disguised" (citing *Salahuddin v. Cuomo*, 861 F.2d 40, 42 (2d Cir. 1988)). However, to survive a Rule 12(b)(6) motion, the allegations must also state a claim upon which relief may be granted, as a legal matter, and state facts that, if true, would satisfy each material element necessary for the asserted legal theories for relief. Accordingly, I consider each remaining challenged claim in turn.

3. Failure to State a Fraudulent Misrepresentation Claim (Count VI)

Dialysis Clinic asserts that the plaintiff does not set forth with particularity, as required by Fed. R. Civ. P. 9(b), what alleged misrepresentations were made, to whom, and when, to state a claim for fraudulent misrepresentation. Rule 9(b) imposes a heightened pleading standard on claims of fraud or mistake, requiring a party to "state with particularity the circumstances constituting fraud or mistake." To state a claim for fraudulent misrepresentation, a plaintiff must allege: "(1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) the speaker's intent that it should be acted on by the person in the manner reasonably contemplated; (6) the hearer's ignorance of the falsity of the representation; (7) the hearer's reliance on the representation being true; (8) the hearer's

right to rely thereon; and (9) the hearer's consequent and proximately caused injury. . . . A plaintiff's failure to establish any one of the essential elements of fraud is fatal to recovery." *Renaissance Leasing, LLC v. Vermeer Mfg. Co.*, 322 S.W.3d 112, 131-32 (Mo. 2010).

The plaintiff alleges that the "Defendants fraudulently and intentionally misrepresented to Decedent, the FDA, and the general public the safety of GranuFlo and NaturaLyte, and fraudulently and intentionally concealed material facts including adverse information regarding the safety of GranuFlo and NaturaLyte." Compl. ¶ 89. The plaintiff's factual allegations are inadequate to state a claim for fraudulent misrepresentation as to Dialysis Clinic because they do not articulate specific representations that Dialysis Clinic made to the decedent with the intent to incite action by the decedent, nor do they allege that Dialysis Clinic had knowledge of the falsity of any statements made.⁷ See *Renaissance Leasing*, 322 S.W.3d at 131-32. Indeed, the plaintiff has expressly alleged

⁷ Contrary to Dialysis Clinic's characterization, the allegations regarding the plaintiff's fraudulent misrepresentation claim are not "woefully inadequate" as to the defendants overall. The plaintiff provides specific misrepresentations allegedly made by the Fresenius defendants to the decedent, the Food & Drug Administration, and the public. Compl. ¶ 91. Were it not for the lack of a specific connection between Dialysis Clinic and these knowing misrepresentations, the complaint likely could state a claim for relief as fraudulent misrepresentation grounds against Dialysis Clinic. See *id.* ¶¶ 88-100.

otherwise, stating that the decedent's health care providers were not warned that GranuFlo and NaturaLyte were unreasonably dangerous products. Compl. ¶¶ 43, 47; see DC Amended Answer ¶ 18. Although the complaint merits dismissal for failure to state a claim on this count, a claim of fraudulent misrepresentation is not precluded as a matter of law against Dialysis Clinic. Accordingly, because this pleading deficiency could be remedied if the plaintiff can properly marshal factual allegations that would support it, I decline to dismiss this count with prejudice.

4. Failure to State a Claim of Violation of Missouri Merchandising Practices Act (Count VII)

Dialysis Clinic also asserts that the plaintiff fails to state a claim for relief under the Missouri Merchandising Practices Act (MMPA). See Mo. Rev. Stat. § 407.020. The MMPA is intended to "protect[] consumers by expanding the common law definition of fraud." *Conway v. CitiMortgage, Inc.*, 438 S.W.3d 410, 414 (Mo. 2014). "Section 407.020 provides that certain acts 'in connection with the sale or advertisement of any merchandise in trade or commerce' are unlawful." *Huch v. Charter Commc'ns, Inc.*, 290 S.W.3d 721, 724 (Mo. 2009). These acts include "deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact." Mo. Rev. Stat.

§ 407.020.1. "Medical goods and services" are considered "merchandise" for the purpose of this statute. See *Freeman Health Sys. v. Wass*, 124 S.W.3d 504, 507 (Mo. Ct. App. 2004) (citing Mo. Rev. Stat. § 407.010(4)).

The plaintiff alleges that the defendants violated the MMPA by selling GranuFlo and NaturaLyte when they knew or should have known that the products were defective and harmful to consumers in violation of the public policy of Missouri that medical providers give accurate and truthful information to recipients of medical goods and services as to the associated risks and benefits. Compl. ¶¶ 103, 109-113. The plaintiff further alleges the decedent's death and his resulting financial losses are the direct and proximate result of the defendants' concealment or misrepresentation of the risks associated with GranuFlo and NaturaLyte. *Id.* ¶¶ 112-13.

This claim suffers from the same internal contradiction as the fraudulent misrepresentation claim: the plaintiff states that the decedent's health care providers, of which Dialysis Clinic was allegedly one, were not warned that GranuFlo and NaturaLyte were unreasonably dangerous products, and nowhere alleges that Dialysis Clinic should have known that these products were dangerous. Compl. ¶¶ 43, 47; see DC Amended Answer ¶ 18. It therefore cannot be said that the petition plausibly alleges that this defendant knew or should have known

about the risks and therefore engaged in some sort of deception or unfair practice in not communicating this risk to consumers.⁸ As with the claim for fraudulent misrepresentation, however, this is a claim that could in theory survive against a health care provider in this context, if adequately pleaded. I therefore decline to dismiss this count with prejudice.

IV. CONCLUSION

For the reasons set forth more fully above, I GRANT Defendant Dialysis Clinic's motion to dismiss, Dkt. No. 33, dismissing with prejudice as to Dialysis Clinic only, Counts I (strict liability/defective product), II (strict liability/failure to warn), IV (breach of express warranty), and V (breach of implied warranty) of the petition, as I have numbered them here; all remaining counts against Dialysis Clinic are dismissed without prejudice.

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE

⁸ I note that the argument Dialysis Clinic makes regarding the need for a relationship between the alleged unfair practice and the initial sale or advertisement of the merchandise, based on *State ex rel. Koster v. Prof'l Debt Mgmt., LLC*, 351 S.W.3d 668 (Mo. App. Ct. 2011), appears to have been rejected and the Koster decision abrogated by a recent Missouri Supreme Court decision. See *Conway v. CitiMortgage, Inc.*, 438 S.W.3d 410 (Mo. 2014). Because the plaintiff has failed to allege an unfair practice, however, this argument is moot.