

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CAROL LUCARELLI, Special
Administratrix, et al.,

Case No 2:08-cv-0049

Plaintiffs

Judge James L. Graham
Magistrate Judge Mark R. Abel

v.

DVA RENAL HEALTHCARE, INC., et al.,

Defendants.

OPINION AND ORDER

This matter is before the court on defendant DVA Renal Healthcare Inc.'s (DVA) motion to dismiss plaintiffs' second amended complaint, for a more definite statement, and to strike certain allegations therein. Plaintiffs are Carol Lucarelli, Special Administratrix of the Estate of Frances Flowers, deceased ("deceased"), and surviving heirs Jerry Flowers, Jr., Amanda Flowers, Shane Flowers, and Wayne Flowers (collectively, plaintiffs). Also pending is defendant's motion for leave to file *instanter* a response to Plaintiffs' motion for leave to supplement plaintiffs' opposition to defendant's second amended complaint. The court grants the motion for leave to file *instanter* and has considered the materials provided by defendant in its response.

I. FACTUAL BACKGROUND

DVA¹ is in the business of owning and operating kidney hemodialysis centers and, through its employees, is responsible for maintaining, developing, sustaining, disinfecting, sterilizing, testing, inspecting, examining, investigating and researching its equipment, tools and facilities. The deceased received hemodialysis treatments in Columbus, Ohio at a treatment facility operated by DVA and died on July 19, 2005, allegedly as a result of the treatment she received at the facility.

Plaintiffs allege that in 2000, when Gambro Healthcare owned DVA, it undertook research concerning “injurious and deadly problems with the hemodialysis provided by subsidiaries such as Defendant DVA.” (Complaint at ¶11). Plaintiffs assert that the research involved inquiry into biofilm-associated mycobacteria and other biological contaminants which acted as agents for infections in patients such as the deceased. According to plaintiffs, after the research was concluded, Gambro and DVA were aware of contamination problems in the facility used by the deceased, but disregarded this information which led to the deceased being exposed to deadly levels of biofilm-associated organisms and contaminants. According to plaintiffs, Ms. Flower’s death was the proximate result of DVA’s negligence in “disregarding research undertaken in approximately 2000 that disclosed biofilm levels at Defendant DVA could quickly and inexpensively be monitored, such that hemodialysis received by Plaintiffs’ decedent would not have high levels of biological contaminants.” (Complaint at ¶ 17a).

In addition, plaintiffs assert that the defendant negligently allowed product water used to

¹ DVA is a wholly-owned subsidiary of DaVita, Inc. Prior to DaVita’s purchase of DVA in 2005, both companies were owned by Gambro Healthcare. Plaintiffs allege that Gambro Healthcare had control over facility management, personnel, research and treatment.

exceed the total viable microbial count of the AAMI (Association for Advancement of Medical Instrumentation) guidelines, and knew that the AAMI standards were being comprised by the formation of biofilm-information in the hemodialysis system. Plaintiffs also assert that the DVA failed to exercise reasonable care in ensuring that the equipment used did not pose a significantly increased risk of injury or death to the decedent, and failed to exercise quality control over the hemodialysis treatment even though it knew, or should of known, that the current hemodialysis treatment system posed a serious risk of bodily injury to patients. Plaintiffs also make claims for *res ipsa loquitur* and for punitive damages as a result of reckless, malicious, or wanton misconduct.

On July 23, 2008, this court denied the defendant's first motion to dismiss and ordered plaintiffs to file an amended complaint. Plaintiffs amended complaint was filed on August 11, 2008. The defendant's instant motion was filed on August 28, 2008.

In its motion, DVA asks this court to dismiss the plaintiffs complaint for failure to state a claim because: 1) defendants owe no duty to plaintiffs to conduct or monitor scientific research, and 2) Ohio does not recognize claims for "corporate negligence." Defendant further asks that the plaintiffs be required to provide an affidavit of merit in support of their claim for medical malpractice claim. Finally, defendant asks that certain allegations in the complaint be struck as insufficient, immaterial, impertinent and/or scandalous. For the reasons set forth below, DVA's motion is DENIED.

II. LEGAL STANDARD

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court must construe the complaint in the light most favorable to the plaintiff and

accept all well-pleaded material allegations in the complaint as true. Erickson v. Pardus, 550 U.S. ___, 127 S.Ct. 2197, 2200 (2007) (citing Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)); Sensations, Inc. v. City of Grand Rapids, 526 F.3d 291, 295 (6th Cir. 2008). A motion to dismiss under Rule 12(b)(6) will be granted only if the complaint is without merit due to an absence of law to support a claim of the type made or of facts sufficient to make a valid claim, or where the face of the complaint reveals that there is an insurmountable bar to relief. Rauch v. Day & Night Mfg. Corp., 576 F.2d 697 (6th Cir. 1978). Under Rule 8(a), “[s]pecific facts are not necessary; the statement need only ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” Erickson, 127 S.Ct. at 2200 (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). Because a motion under Rule 12(b)(6) is directed solely at the complaint itself, the court must focus on whether the claimant is entitled to offer evidence to support the claims, rather than whether the plaintiff will ultimately prevail. Scheuer, 416 U.S. at 236; Bell Atlantic Corp. v. Twombly, 550 U.S. ___, 127 S.Ct. 1955, 1965 (2007) (Rule 8 “does not impose a probability requirement at the pleading stage”).

Despite this liberal pleading standard, a court is “not bound to accept as true a legal conclusion couched as a factual allegation.” Papasan v. Allain, 478 U.S. 265, 286 (1986); see also Morgan v. Church’s Fried Chicken, 829 F.2d 10, 12 (6th Cir. 1987) (“[W]e need not accept as true legal conclusions or unwarranted factual inferences.”). Though the complaint need not contain detailed factual allegations, the factual allegations must be enough to raise the claimed right to relief above the speculative level and to create a reasonable expectation that discovery will reveal evidence to support the claim. Bell Atlantic, 127 S.Ct. at 1964-65; Associated Gen. Contractors of Cal., Inc. v. Carpenters, 459 U.S. 519, 526 (1983). The plaintiff must provide the

grounds of his entitlement to relief “rather than a blanket assertion of entitlement to relief.” Bell Atlantic, 127 S.Ct. at 1965 n.3. Labels, conclusions, and formulaic recitations of the elements of a cause of action “will not do.” Id. at 1965. “Accordingly, a complaint ‘must contain either direct or inferential allegations respecting all the material elements to sustain a recovery under some viable legal theory.’” Ferron v. Zoomego, Inc., No. 07-4007, 2008 WL 1988587, at *2 (6th Cir. May 7, 2008) (quoting Lewis v. ACB Business Serv., Inc., 135 F.3d 389, 406 (6th Cir. 1998)).

III. ANALYSIS

This matter is before the Court on the basis of diversity jurisdiction. See, 28 U.S.C. § 1332. Federal courts sitting in diversity must apply the choice-of-law rules of the forum state. Muncie Power Prods. v. United Techs. Auto., Inc., 328 F.3d 870, 873 (6th Cir. 2003). This court has already concluded that Ohio has the more significant relationship to the action and therefore will apply Ohio law. See, Opinion and Order dated July 23, 2008 (doc. 23).

A. Whether Plaintiffs have failed to state a claim upon which relief can be granted.

1. Medical Malpractice

In its motion to dismiss, defendant asserts that the plaintiffs’ second amended complaint fails to properly plead and support a claim for medical malpractice because plaintiffs did not attach an affidavit of merit pursuant to Ohio R. Civ. P. 10(D)(2). This section provides that a complaint that contains a “medical claim” shall include an “affidavit of merit relative to each defendant named in the complaint for whom expert testimony is necessary to establish liability.” Ohio Rev. Code §2305.113 (E)(3) defines “medical claim” as:

(3) "Medical claim" means any claim that is asserted in any civil action against a physician, podiatrist, hospital, home, or residential facility, against any employee or agent of a physician, podiatrist, hospital, home, or residential facility, or against a licensed practical nurse, registered nurse, advanced practice nurse, physical therapist, physician assistant, emergency medical technician-basic, emergency medical technician-intermediate, or emergency medical technician-paramedic, and that arises out of the medical diagnosis, care, or treatment of any person. "Medical claim" includes the following:

(a) Derivative claims for relief that arise from the medical diagnosis, care, or treatment of a person;

(b) Claims that arise out of the medical diagnosis, care, or treatment of any person and to which either of the following applies:

(I) The claim results from acts or omissions in providing medical care.

(ii) The claim results from the hiring, training, supervision, retention, or termination of caregivers providing medical diagnosis, care, or treatment.

© Claims that arise out of the medical diagnosis, care, or treatment of any person and that are brought under section 3721.17 of the Revised Code.

The statute defines a "medical claim" as one that is asserted against a "physician, podiatrist, hospital, home, or residential facility. . . or against a licensed practical nurse, registered nurse, advanced practice nurse, physical therapist, physician assistant, emergency medical technician-basic, emergency medical technician-intermediate, or emergency medical technician-paramedic." Ohio Rev. Code §2305.113(E)(3). Nothing in the plaintiffs' complaint indicates that defendant DVA qualifies as any of these types of individuals or businesses.

Moreover, although plaintiffs' claim arguably arises from the medical care or treatment of a person, it does not arise from either "acts or omissions in providing medical care" or from "the hiring, training, supervision, retention, or termination of caregivers providing medical diagnosis, care, or treatment." Ohio Rev. Code §2305.113(E)(3)(b)(i)(ii). Rather, plaintiffs' claims arise from acts or omissions in the maintenance of equipment used at defendant's clinic, and the

alleged actionable conduct does not fall under the confines of “medical claim.” *See e.g., Lucarelli v. Renal Treatment Centers-Illinois, Inc.*, No. 4:08CV00099 ERW, 2008 U.S. Dist. LEXIS 72553 (E.D. Mo. Sept. 24, 2008) (finding that the plaintiff’s claim regarding the condition of equipment used within a medical facility to be different from a claim involving the actual provision of medical services); *Lucarelli v. DVA Renal Healthcare, Inc.*, No. 08-2067, 2008 U.S. Dist. LEXIS 67211 (W.D. Tenn. Mar. 17, 2008) (finding that claims for failing to address known problems with hemodialysis equipment was not a claim for medical malpractice, but rather, one for general negligence).

Nothing in the plaintiffs’ complaint indicates that they are making a claim for medical malpractice. Indeed, the plaintiffs’ insist that they are not making such a claim. Thus, defendant’s motion to dismiss on this ground, and its request for a more definite statement, are both denied.

2. Negligence

In its Opinion and Order dated July 23, 2008, this court found that the plaintiffs had sufficiently stated a claim for negligence against DVA. Nonetheless, DVA now argues that plaintiffs have failed to state a claim for failure to engage in scientific research, corporate negligence², and negligent undertaking. The allegations in plaintiffs’ complaint state a claim for

² In its motion, defendant states that Ohio courts “have not recognized a cause of action for corporate negligence.” (Def Motion at p. 6). The broad assertion made by the Defendant is wrong and misrepresents the state of the law in Ohio. *See, Yancey v. Woodson*, C. A. No. L-88-231, 1989 Ohio App. LEXIS 4689 (Ohio Ct. App. Dec 15, 1989) (“the simple fact is that this court [Ohio Court of Appeals, Sixth District] has recognized the existence of such a claim” [for corporate negligence]). Counsel for defendant is cautioned to be more careful in its advocacy.

The defendant is correct only in that Ohio does not recognize “corporate negligence” as a form of imposing strict liability on a hospital for the negligence or malpractice of its employees or physicians. *See, Albain v. Flower Hospital*, 50 Ohio St. 3d 251 (Ohio 1990). The reasoning of *Albain* is inapplicable to the instant case. Here, the plaintiffs are not attempting to hold

negligence and merely uses these other claims as alternative means of establishing a duty on the part of the defendant. *See e.g., Lucarelli v. DVA Renal HealthCare, Inc., Report and Recommendation*, Case No. 08-0406 (W.D. La. Dec. 23, 2008) (claims for corporate negligence and negligent undertaking are merely alternative means to establish that DVA owed a duty to plaintiff). To maintain a cause of action for negligence, plaintiff must show: (1) that plaintiff was owed a duty of care; (2) a breach of that duty; and (3) proximate causation between the breach of duty and the death. *Bennison v. Stillpass Transit Co.*, 5 Ohio St. 2d 122, 214 N.E. 2d 213 (Ohio 1966).

The first issue, therefore, is whether the plaintiff has sufficiently alleged facts that give rise to a duty on the part of defendant DVA. Defendant suggests that the second amended complaint does not establish that it owed a duty to plaintiffs. The court disagrees with defendant. First, as a hemodialysis center, DVA owed certain duties of care towards its clients. Ohio Admin. Code 3701-83-23.1 sets forth service standards that a dialysis center shall employ, including developing and following “protocols for the prevention of disease transmission” (Ohio Admin. Code 3701-83-23.1(A)(2)), and developing and following “procedures for the provision of water in compliance with association for advancement of medical instrumentation (AAMI) standards, including criteria for the biological and chemical composition of the water” (Ohio Admin. Code 3701-83-23.1(A)(5)). In addition, a dialysis center must work to prevent and control infections (Ohio Admin. Code 3701-83-23.4(A)), must analyze and treat water supplies

defendant strictly liable for the negligent actions of a physician or employee. Rather, the plaintiffs are alleging that the defendant had an independent duty of exercising reasonable care towards its clients, and that the defendant breached that duty. This is a claim for general negligence against defendant DVA.

(Ohio Admin. Code 3701-83-23.1((C)(1)) and, upon notice of infection associated with the dialysis service, take remedial action (Ohio Admin. Code 3701-83-23.1 (E)). In addition to the specific duties imposed upon a dialysis center in Ohio, a business such as DVA owes a general duty to exercise reasonable care for the safety of its invitees. Johnson v. Metrohealth Med. Ctr., No. 87976, 2007 Ohio 392 (Ohio Ct. App. Feb. 1, 2007) (hospital owes a duty of ordinary care in maintaining the premises in a reasonably safe condition so that its customers are not unnecessarily and unreasonably exposed to danger).

Plaintiffs have also alleged facts giving rise to an additional duty on the part of defendant DVA. Specifically, that defendant owed a duty to exercise reasonable care once it voluntarily chose to test its own equipment for safety. See Neal v. Bergland, 646 F.2d 1178, 1181-82 (6th Cir. 1981) (it is well established that “one who undertakes to act, even though gratuitously, is required to act carefully and with the exercise of due care and will be liable for injuries proximately caused by failure to use such care”). Although the defendant attempts to frame the issue as one of whether it had a duty to conduct research³, what plaintiffs allege is that once the defendant voluntarily chose to conduct research into the safety of its hemodialysis equipment it had a duty to use reasonable care in responding to the findings of that research. Specifically,

³ The two Pennsylvania cases cited by defendant in support of its position, Karibjanian v. Thomas Jefferson Univ. Hosp., 717 F. Supp. 1081 (E.D. Pa. 1989) and Cafazzo v. Central Medical Health Servs., 430 Pa. Super. 480 (Pa. 1993) are unpersuasive. In Karibjanian, the plaintiff’s complaint alleged negligence for “failing to undertake or support research to find a remedy or palliative procedure for the conditions, symptoms or untoward effects caused by Thorotrast [a substance injected into decedent during a diagnostic medical procedure].” Id at 1083. Plaintiff’s complaint does not allege that the defendant failed to undertake research. In Cafazzo, the plaintiffs essentially sought to hold the hospital liable under a products liability theory and the court declined to allow a strict liability claim, based on a defective product, to proceed against the defendant hospital. Plaintiffs’ complaint does not allege a products liability or strict liability claim.

plaintiffs assert that defendant had a duty to follow its own ongoing research and to institute remedies once exposure to high levels of contaminants was found in its hemodialysis system. Plaintiffs have alleged sufficient facts to establish that the defendant owed the decedent a duty of care.

Moreover, plaintiffs allege facts sufficient to establish, for purposes of a motion to dismiss, that the defendant breached its duty of care to decedent. Plaintiffs' amended complaint alleges that the defendant chose to conduct scientific research to address levels of biological contaminants in water and systems used to provide hemodialysis treatment. Plaintiffs further allege that the research conducted showed biofilm-associated problems at a facility utilized by the deceased, but that defendant chose to disregard its research and any potential remedies for the problems discovered. The second amended complaint sufficiently alleges a claim for failing to exercise reasonable care in remedying known or suspected hazards with its equipment, once defendant voluntarily chose to study whether the equipment was in fact, safe.⁴ These alleged

⁴ This is not the same thing as a claim for negligent undertaking. Negligent undertaking claims stem from § 324A of the Restatement (Second) of Torts which provides, in pertinent part:

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to [perform] his undertaking, if

- (a) his failure to exercise reasonable care increases the risk of such harm, or
- (b) he has undertaken to perform a duty owed by the other to the third person, or
- (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

An example of a negligent undertaking claim would be where A employs B to inspect its telephone poles, B negligently inspects the poles, and because of the pole's defective condition, traveler C is injured. B is now liable to C. See § 324A of the Restatement (Second) of Torts, Comment C(2). The plaintiffs are not making a claim as a third party who was injured by the negligent acts of someone other than DVA, with whom decedent had a relationship and was owed an independent duty. Defendants argument that plaintiff is attempting to state a claim for

facts also suggest a breach of the defendant's duty as set forth in the regulations governing dialysis centers in Ohio. See Ohio Admin. Code 3701-83-23.1 through 3701-83-23.4; See Zimmerman v. St. Peter's Catholic Church, 87 Ohio App. 3d 752, 754-755 (Ohio Ct. App. 1993) (evidence of a violation of an administrative regulation is admissible as evidence regarding the issue of the want of ordinary care).

Finally, Plaintiffs assert that as a proximate result of defendant's breach of its duty, the decedent "developed inflammatory responses from exposure to increased bacterial contaminants of Defendant DVA's hemodialysis treatment." (Complaint ¶ 18). As a result of this exposure and inflammatory response, she suffered from aggravations or exacerbations of her medical condition and died on July 19, 2005. On the face of the complaint, therefore, plaintiffs have properly and sufficiently made a claim for negligence. Defendant's motion to dismiss is denied.

B. Motion to Strike

Defendant also moves this court to strike paragraphs 9 and 11 from the second amended complaint pursuant to Fed. R. Civ. P. 12(f). Defendant seeks to have the following paragraphs struck as "redundant, immaterial, impertinent, or scandalous matter":

9. In 2001, Gambro Healthcare became the focus of a federal healthcare fraud investigation resulting in a 2004 settlement requiring payment of more than \$350,000,000 in criminal fines and civil penalties, and the sale of various aspects of Gambro Healthcare's operations.
10. In 2005, DaVita, Inc., purchased Gambro's Healthcare's operations, subsidiaries and facilities, to include Defendant, DVA. DaVita, Inc., through approximately 200 subsidiaries, operates over 1300 outpatient facilities, and hemodialysis treatment in over 800 hospitals, in 42 states and the District of Columbia. DaVita, Inc. Maintains the same direct control over its subsidiaries, such as Defendant DVA, as exercised by Gambro Healthcare.

negligent undertaking is therefore unpersuasive.

11. Contemporaneous with the national healthcare fraud and investigation, Gambro Healthcare, in approximately 2000, commenced research concerning injurious and deadly problems with the hemodialysis provided by subsidiaries such as Defendant DVA.

Defendant asserts that these allegations are irrelevant to the decedent's injuries and are only included to prejudice the Defendant.

Fed. R. Civ. P. 12(f) authorizes a court to strike from a pleading any "redundant, immaterial, impertinent, or scandalous matter." However, "strike orders have long been recognized as a relatively 'drastic' remedy 'to be resorted to only where required for the purposes of justice.'" Mapp v. Board of Ed. Of the City of Chattanooga, Tenn., 319 F.2d 571, 576 (6th Cir. 1963) (internal citations omitted); see also, U.S. Diamond & Gold d/b/a Stafford's Jewelers, et al. v. Julius Klein Diamonds LLC, 2007 U.S. Dist. LEXIS 23076 (S.D. Ohio March 29, 2007) (motions to strike "should be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties"). Matters should not be struck from a pleading "unless it is clear that it can have no possible bearing upon the subject matter of the litigation." Battle v. National City Bank, 364 F. Supp. 416, 419 (N.D. Ohio 1973).

The plaintiffs assert that the allegations in the complaint are matters of public record and are relevant to the breach of duty alleged in the instant case. At this point in the proceedings, the court cannot be certain whether or not the allegations are relevant to the claims made by the plaintiffs and therefore cannot consider the allegations in paragraphs 9-11 as so scandalous, redundant, impertinent or immaterial as to require that they be struck from the complaint. Moreover, as the information contained in paragraphs 9-11 is already a matter of public record, maintaining the information in the complaint does not unduly prejudice defendant. The motion to strike is therefore denied.

IV. CONCLUSION

For the foregoing reasons, DVA's Motion to Dismiss (doc. 25) is DENIED.

IT IS SO ORDERED.

S/ James L. Graham
James L. Graham
UNITED STATES DISTRICT JUDGE

Dated: February 2, 2009