IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BARBARA MACK, as ADMINISTRATRIX of the ESTATE of WILLIAM A. MACK, JR., deceased,	)	Civil Action No. 10-cv-02142
Plaintiff	)	
v.	)	
VENTRACOR, LTD., trading and doing business in the United States as Ventracor, Inc., also known as Ventracor; ROHINTON J. MORRIS, M.D.; MICHAEL A. ACKER, M.D.; MARIELL L. JESSUP. M.D.; THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA trading and doing business as University of Pennsylvania also trading and doing business as The Hospital of the University of Pennsylvania also trading and doing business as University of Pennsylvania Health System; and VENTRACOR, INC.,	)	
Defendants	)	

* * *

APPEARANCES:

SHANIN SPECTER, ESQUIRE
MARK A. HOFFMAN, ESQUIRE
CHARLES L. BECKER, ESQUIRE
On behalf of Plaintiff

TERRY M. HENRY, ESQUIRE
LAUREN A. TULLI, ESQUIRE
On behalf of Defendants, VENTRACOR, LTD. and VENTRACOR, INC.

JAMES A. YOUNG, ESQUIRE
RICHARD S. MARGULIES, ESQUIRE
On behalf of Defendants ROHINTON J. MORRIS, M.D., MICHAEL A. ACKER, M.D., MARIELL L. JESSUP. M.D., and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

* * *

O P I N I O N

JAMES KNOLL GARDNER,
United States District Judge

This matter is before the court on the Motion to Remand and for Costs, Expenses, and Attorneys' Fees filed together with a memorandum of law[1] on behalf of plaintiff Barbara Mack, as Administratrix of the Estate of William A. Mack, Jr., deceased, on June 9, 2010. Defendants responded on July 7 and 9, 2010.[2]

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[1] Plaintiff's memorandum was titled Memorandum of Law in Support of Plaintiff's Motion to Remand and for Costs, Expenses and Attorneys' Fees.

[2] Defendant Ventracor, Inc.'s Memorandum of Law in Opposition to Plaintiff's Motion to Remand and for Costs, Expenses and Fees was filed July 9, 2010. All of the other defendants filed a joint response on July 7, 2010 and a joint memorandum of law on July 9, 2010. Their memorandum was titled Certain Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Remand and for Costs, Expenses and Attorneys' Fees.

The complete title of the other defendants' response was Certain Defendants' Response in Opposition to Plaintiff's Motion to Remand and for Costs, Expenses and Attorneys' Fees, filed on behalf of defendants Rohinton J. Morris, M.D., Michael A. Acker, M.D., Mariell L. Jessup, M.D. and the Trustees of the University of Pennsylvania, trading and doing business as University of Pennsylvania, also trading and doing business as The Hospital of the University of Pennsylvania, also trading and doing business as University of Pennsylvania Health System.

Plaintiff's reply was filed with permission on September 15, 2010.[3]

Oral argument on plaintiff's motion was held before me on January 13, 2011.

For the reasons articulated in this Opinion, I grant in part and deny in part plaintiff's Motion to Remand and for Costs, Expenses and Attorneys' Fees.

Specifically, because I find that there is no federal question presented in this case, I grant plaintiff's motion to remand and remand this matter back to the Court of Common Pleas of Philadelphia County, Pennsylvania, for further proceedings. I also deny that portion of plaintiff's motion seeking costs, expenses, and attorneys' fees arising from an allegedly improper removal under 28 U.S.C. § 1447(c).

JURISDICTION

Defendants allege jurisdiction in this case based upon federal question jurisdiction pursuant to 28 U.S.C. § 1331.

VENUE

Venue is proper pursuant to 28 U.S.C. § 1391(b) because the events giving rise to plaintiff's claims allegedly occurred in Philadelphia County, Pennsylvania, which is located within this judicial district.

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[3] Plaintiff's reply was titled Plaintiff's Reply Memorandum in Support of Motion to Remand and for Costs, Expenses and Attorney's Fees.

PROCEDURAL HISTORY

On February 4, 2009 plaintiff filed her initial complaint as a wrongful death and survival action in the Court of Common Pleas of Philadelphia County, Pennsylvania. The initial complaint did not contain a battery claim.

After numerous amendments, on February 19, 2010 plaintiff filed her Eighth Amended Civil Action Complaint in the Court of Common Pleas of Philadelphia County. The Eighth Amended Civil Action Complaint included a cause of action sounding in battery based upon a lack of informed consent because defendants allegedly violated multiple federal regulations.

On March 16, 2010, alleging federal question jurisdiction, defendants removed the case to this court, the United States District Court for the Eastern District of Pennsylvania. On March 26, 2010, plaintiff filed with this court a Notice of Voluntary Dismissal Pursuant to F.R.C.P. 41(a)(1)(A)(i), thereby dismissing her Eighth Amended Civil Action Complaint.

Plaintiff filed her current complaint, entitled Civil Action Complaint ("Complaint"), in the Court of Common Pleas of Philadelphia County, Pennsylvania on March 31, 2010. Plaintiff's Complaint includes a cause of action sounding in battery based upon a lack of informed consent pursuant to state statutory and common law. On May 10, 2010, defendants again removed this case

by filing a Notice of Removal on the basis of plaintiff's battery claim, Count VIII of the state Complaint.

As noted above, on June 9, 2010, plaintiff moved to remand this action to the Court of Common Pleas of Philadelphia County, Pennsylvania, and defendants filed responses in opposition on July 7, 2010 and July 9, 2010. On July 7, 2010 plaintiff filed in the Court of Common Pleas of Philadelphia County a Praecipe to Reinstate her March 31, 2010 Civil Action Complaint.

PLAINTIFF'S COMPLAINT

According to plaintiff's current Complaint, the parties, claims and other allegations pertinent to plaintiff's motion to remand are as follows.

Parties

Plaintiff Barbara Mack is the Administratrix of the Estate of William A. Mack, Jr., deceased ("decedent"). Plaintiff is the widow of the decedent. Mr. Mack suffered from end-stage cardiac disease and was a participant in a human research study entitled Evaluation of the VentrAssist™ Left Ventricular Assist Device for Treatment of Advanced Heart Failure-Destination Therapy ("VentraAssist Study").

Defendant Ventracor, Inc., a global medical device company, sponsored the VentraAssist Study. It designed and

manufactured the device ultimately implanted into Mr. Mack.[4] The Trustees of the University of Pennsylvania facilitated the study by entering into an Institutional Clinical Trial Agreement with Ventracor, Inc.[5] The surgical implantation of the device occurred at the Hospital of the University of Pennsylvania. Defendant doctors Rohinton J. Morris, M.D., Michael A. Acker, M.D., and Mariell L. Jessup, M.D. were the primary investigators conducting the VentraAssist Study.

Claims

The ten-count Complaint filed on March 31, 2010 in the Court of Common Pleas of Philadelphia County by plaintiff Barbara Mack, as Administratrix of the Estate of William A. Mack, Jr., deceased, alleges products liability and medical malpractice claims brought against defendants under the Pennsylvania Wrongful Death Act[6] and the Pennsylvania Survival Act.[7]

Specifically, Count I of plaintiff's Complaint is brought pursuant to the Restatement (Second) of Torts, § 402A as adopted in Pennsylvania state common law.[8] It alleges against defendant Ventracor, Inc. a cause of action for strict liability

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4 Complaint, paragraph 6.

5 Complaint, paragraph 9.

6 42 Pa.C.S.A. § 8301.

7 42 Pa.C.S.A. § 8302.

8 Webb v. Zern, 220 A.2d 853, 854 (Pa. 1966).

for the injuries and death suffered by plaintiff's decedent. Plaintiff alleges that Ventracor, Inc. is the manufacturer of a ventricular heart assist device implanted into the decedent.

Count II of the Complaint is a negligence claim under state common law. It is brought against defendant University of Pennsylvania and the defendant doctors who were involved in the clinical research study in connection with their supervision, use, and inspection of the device implanted in the decedent.

Count III is a strict liability cause of action pursuant to Section 402A of the Restatement (Second) of Torts as adopted in Pennsylvania state common law. Count III seeks damages for injuries to, and the death of, plaintiff's decedent. The claim is against the University of Pennsylvania, which allegedly distributed, marketed, sold, and implanted the device.

Count IV alleges negligence pursuant to state common law. Count IV is brought against defendant Ventracor, Inc. for the design, manufacture, and failure to warn of the risks, of the device implanted into the decedent.

Count V asserts causes of action against Ventracor, Inc. for breach of express warranty pursuant to 13 Pa.C.S.A. § 2313. It is based upon Ventracor's written materials, representations, and statements regarding the ventricular heart assist device.

Count VI alleges a cause of action against Ventracor, Inc. for breach of the implied warranty of fitness for a particular purpose pursuant to 12 Pa.C.S.A. § 2315. Count VI specifically alleges breach of an implied warranty that the device was suitable for implantation and use to support the decedent's circulation.

Count VII is a cause of action against Ventracor, Inc. for breach of the implied warranty of merchantability pursuant to 13 Pa.C.S.A. § 2314. Plaintiff bases Count VII upon Ventracor's alleged distribution of the device implanted into the decedent.

Count VIII is brought pursuant to state common law and the Medical Care Availability and Reduction of Error Act ("MCARE Act").[9] It asserts a battery claim, under the Survival Act, against defendant doctors and the University of Pennsylvania for their failure to obtain the decedent's informed consent.

Count IX is a claim under the Survival Act for fraudulent misrepresentation against defendant doctors, the University of Pennsylvania, and Ventracor, Inc. In Count IX, plaintiff alleges that defendants fraudulently misrepresented to plaintiff's decedent that he retained legal rights in connection with his participation in the clinical research study.

Count X asserts a claim under the Survival Act against defendant doctors, the University of Pennsylvania and The

[9] Act of March 20, 2002, P.L. 154, No. 13, § 504, as amended, 40 P.S. § 1303.504.

Hospital of the University of Pennsylvania. In Count X, plaintiff alleges breach of a fiduciary duty owed the patient arising from the physician-patient and hospital-patient relationships, and which requires the physician and hospital to act in the best interests of their patient.

VentraAssist Study

The VentrAssist Study evaluated the safety and efficacy of the VentrAssist LVA4, an implantable cardiac assist device designed and manufactured by Ventracor, Inc.[10] The device was in the earliest stages of approval by the United States Food and Drug Administration ("FDA"), and the study was performed pursuant to an FDA conditional Investigational Device Exemption ("IDE") under 21 C.F.R. § 812.[11]

An IDE exempts a device on a conditional basis from the more rigorous requirements of premarket approval in order to foster research into useful devices intended for human use. 21 C.F.R. § 812.1. The device had not received premarket approval under 21 C.F.R. § 814.[12] Premarket approval occurs after the device has generated enough data on its safety and effectiveness during the IDE phase for the FDA to evaluate it and

[10] Complaint, paragraph 6.

[11] Complaint, paragraph 53.

[12] Complaint, paragraphs 43, 53 and 63.

allow it to be sold and marketed on a routine basis.[13] See 21 C.F.R. §§ 814.1 to 814.126.

On April 27, 2008, Mr. Mack was admitted to the Hospital of the University of Pennsylvania because of his end-stage cardiac disease.[14] After determining that Mr. Mack was not a candidate for other routine therapies, he was recruited by the doctors at the Hospital of the University of Pennsylvania to participate in the VentraAssist Study on April 25, 2008.[15] Mr. Mack agreed to the procedure and signed the University of Pennsylvania Research Subject Informed Consent Form ("Consent Form") that day.[16]

On April 29, 2008, Mr. Mack underwent surgical implantation of the VentrAssist model LVA4, along with the replacement of one of his heart valves, at the Hospital of the University of Pennsylvania.[17] The hospital discharged Mr. Mack on May 30, 2008.[18]

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[13] Complaint, paragraph 43.

[14] Complaint, paragraph 58.

[15] Complaint, paragraphs 59-62.

[16] Complaint, paragraph 66.

[17] Complaint, paragraphs 71 and 72.

[18] Complaint, paragraph 74.

On June 7, 2008 Mr. Mack collapsed in his home and was pronounced dead the next day.[19] An autopsy performed on Mr. Mack confirmed that the external power pack of the VentrAssist LVA4 was not connected to the external device leads, thereby disconnecting the pump from the power supply.[20]

STANDARD OF REVIEW

Any civil action brought in state court may be removed to the federal district court embracing the place where the action is pending, if the district court would have had original jurisdiction. 28 U.S.C. § 1441(a). One possible basis for original jurisdiction is federal question jurisdiction. 28 U.S.C. § 1331.

However, if at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case must be remanded. 28 U.S.C. § 1447(c). When considering a motion for remand, a district court "must focus on the plaintiff's complaint at the time the petition for removal was filed...[and] must assume as true all factual allegations of the complaint." Guckin v. Nagle, 259 F.Supp.2d 406, 409 (E.D.Pa. 2003) (quoting Steel Valley Authority v. Union Switch & Signal Division, 809 F.2d 1006, 1010 (3d Cir. 1987)).

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[19] Complaint, paragraphs 77-79.

[20] Complaint, paragraphs 80 and 81.

CONTENTIONS OF THE PARTIES

Plaintiff's Contentions

In her motion to remand, plaintiff contends that this case should be remanded to the Court of Common Pleas for Philadelphia County, Pennsylvania, because this court does not have subject matter jurisdiction to hear it. Specifically, plaintiff avers that she properly initiated this action in Philadelphia County on March 31, 2010 by filing a Complaint, which asserts, among other things, a claim sounding in battery pursuant to section 1303.504 of Pennsylvania's MCARE Act,[21] and corresponding state law claims for fraudulent misrepresentation and breach of fiduciary duty.

More specifically, plaintiff contends that because defendants base their grounds for removal on plaintiff's battery claim, or Count VIII of the Complaint, the case should be remanded because this claim solely involves state statutory law and state common law. Plaintiff further contends that her battery claim does not "arise under" federal law, as required by 28 U.S.C. § 1331 for federal question, subject matter jurisdiction.

Additionally, plaintiff alleges her fraudulent misrepresentation (Count IX) and breach of fiduciary duty (Count X) claims revolve around the same issues as the battery

[21] Act of March 20, 2002, P.L. 154, No. 13, § 504, as amended, 40 P.S. § 1303.504.

claim in Count VIII, and are also brought solely pursuant to state law. Plaintiff asserts that it is well established that plaintiff is the "master of the claim", and that a case is removable only if it presents a federal question on the face of plaintiff's well-pleaded complaint.

Plaintiff argues that her Complaint does not make reference to, or rely on, federal law. Instead, the Complaint simply asserts a claim for battery based on the lack of informed consent provided by defendants to the patient, which plaintiff contends is solely governed by the MCARE Act.

Plaintiff asserts that the MCARE Act specifically addresses informed consent in the context of using an experimental device, requiring the physician to disclose the risks and alternatives to the procedure. Plaintiff alleges that part of the "risks" which are required to be discussed with a patient under Pennsylvania law include a discussion of the patient's legal rights, particularly an explanation of state law claims that may be preempted by federal law.[22]

Plaintiff contends that defendants did not obtain informed consent from Mr. Mack because the Consent Form he signed indicated that he was not waiving any legal rights by participating in the investigational study. However, plaintiff

[22] Notes of Testimony of the oral argument held January 13, 2011 in Allentown, Pennsylvania, styled "Oral Argument before the Honorable James Knoll Gardner[,] United States District Court Judge" ("N.T."), page 14.

avers that in other motions filed in state court on previous versions of the Complaint and in motions to dismiss this Complaint, defendants have subsequently argued that Mr. Mack had in fact waived legal rights because of federal preemption of many state law claims.

Plaintiff alleges that in the informed consent presented to Mr. Mack, defendants misrepresented the rights the patient retained because defendants believed Mr. Mack was in fact waiving legal rights, although the informed consent stated that he was not. Furthermore, plaintiff contends that defendants assert that their compliance with federal regulations regarding informed consent denies the patient any further legal rights.

Therefore, plaintiff argues that the Consent Form provided defective informed consent under the MCARE Act because the patient was not properly apprised of the "risks" of the procedure. These allegations form the basis of plaintiff's claim for battery, as well as plaintiff's claims for fraudulent misrepresentation and breach of fiduciary duty.

At oral argument, plaintiff's counsel Charles L. Becker, Esquire, made clear that defendants' conformity with federal regulations was not at issue.[23] In fact, Attorney Becker agreed that defendants were in compliance with the federal regulations governing informed consent for human research

[23] N.T., page 7.

subjects.[24] Instead, plaintiff asserts that the sole issue is whether defendants complied with the additional informed consent requirements imposed by state law through the MCARE Act.

Plaintiff further argues that defendants' federal defense does not grant federal jurisdiction. Instead, plaintiff asserts that the relevant inquiry is whether Congress intended the federal regulations, 21 C.F.R. § 50.1 through 21 C.F.R. § 50.27 and 45 C.F.R. § 46.101 through 45 C.F.R. § 46.124, to confer federal question jurisdiction.

Plaintiff argues that these regulations do not create a private right of action because they are not phrased in terms of the persons benefitted, and so Congress did not create a federal right of action. Gonzaga University v. Doe, 536 U.S. 273, 283-284, 122 S.Ct. 2268, 2275-2276, 153 L.Ed.2d 309, 321-322 (2002); Wright v. Fred Hutchinson Cancer Research Center, 269 F.Supp.2d 1286, 1289 (W.D.Wash. 2002).

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[24] Attorney Becker stated in pertinent part:

> And I would note that with regard to Defendants' argument that the complaint necessarily brings into question a construction of the common - the so-called common rule, which is reflected in a variety of Federal regulations, that the premise of this complaint, the premise of this battery claim and fraudulent misrepresentation claim is that the common rule was complied with. We would have no quarrel with the common rule as far as the informed-consent form is concerned. This is, pure and simple, a state law claim which is specifically and carefully pled under Pennsylvania decisional law and Pennsylvania statutory law.

N.T, page 7.

As additional evidence of the intent of Congress, plaintiff asserts that the federal regulations vest the states with enforcement power over the regulations by stating: "This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects." 45 C.F.R. § 46.101(f). Plaintiff contends that even if these federal regulations were relevant to the disposition of her state law claims, this would not give rise to a federal question in the absence of Congressional intent to the contrary.

Finally, plaintiff seeks an award of her costs, expenses, and attorneys' fees pursuant to 28 U.S.C. § 1447(c) because she contends that defendants lacked an objectively reasonable basis for removal. In support of this part of her motion, plaintiff argues that the battery, fraudulent misrepresentation, and breach of fiduciary duty claims plainly arise under state statutory and common law.

Therefore, plaintiff argues that defendants ignored the tenets of removal, the plain language of the agency regulations, and the legislative and agency intent regarding these regulations. Thus, plaintiff concludes that an award of costs, expenses, and attorneys' fees for having to file a motion to remand are appropriate.

Defendants' Contentions

Defendants oppose plaintiff's motion for remand because they assert that the battery claim arising from the alleged lack of informed consent raises a federal question under 28 U.S.C. § 1331. In their Notice of Removal, defendants rely solely upon plaintiff's battery cause of action as the basis of federal question jurisdiction. However, in their responses and at oral argument, defendants argued that plaintiff's causes of action for fraudulent misrepresentation and breach of fiduciary duty in Counts IX and X also require interpretation of the same federal regulations on informed consent, and therefore all three of plaintiff's claims give rise to federal question jurisdiction.

Defendants assert that while plaintiff is the master of the claim, the "artful pleading doctrine" allows federal courts to exercise jurisdiction despite the absence of a federal question on the face of the claim if: (1) federal law has completely preempted the relevant state law; or (2) a federal question is intrinsic and central to plaintiff's cause of action. Guckin, 259 F.Supp.2d at 410 (citation omitted). Defendants argue that plaintiff's complaint falls into the second category.

Contrary to plaintiff's assertions, defendants argue that a federal private right of action is not a prerequisite to exercising federal question jurisdiction according to the United States Supreme Court decision in Grable & Sons Metal Products,

Inc. v. Darue Engineering & Manufacturing, 545 U.S. 308, 318, 125 S.Ct. 2363, 2370, 162 L.Ed.2d 257, 267 (2005). Instead, defendants contend that federal courts have jurisdiction over claims recognized under state law which "turn on substantial questions of federal law." 545 U.S. at 312, 125 S.Ct. at 2367, 162 L.Ed.2d at 263. Defendants argue that this court must interpret and apply federal regulations in order to determine the scope of the legal duty of informed consent, and therefore the state law battery, fraudulent misrepresentation and breach of fiduciary duty claims turn on these determinations of federal law.

Defendants assert that the FDA and the United States Department of Health and Human Services have issued a scheme of regulations regarding human research subjects in accordance with the Common Rule, which refers to the effort of federal agencies to promulgate consistent regulations for human research subjects across government. See 45 C.F.R. § 46. Defendants claim this evidences congressional intent for uniform requirements in human research studies, which often span across multiple states.

Particularly, defendants contend that Congress intended to avoid the creation of fifty different standards for informed consent.[25] Defendants argue that the definition of informed

[25] At oral argument, Terry M. Henry, Esquire, counsel for defendants Ventracor LTD. and Ventracor Inc., stated:

(Footnote 25 continued):

consent for human research subjects, the elements of informed consent, and the need for a written consent form appear in FDA regulations. See 21 C.F.R. §§ 50.20, 50.25, and 50.27.

Defendants also contend that plaintiff's actual claim involves the question of whether defendants violated the patient's right to informed consent under these federal regulations. Furthermore, defendants argue that only the federal regulations address waiver of the patient's legal rights, whereas the state law statute upon which plaintiff relies does not.

Defendants assert that in determining whether defendants gave inadequate informed consent, fraudulently misrepresented the patient's legal rights, or breached their fiduciary duty to honestly disclose Mr. Mack's legal rights, the court must interpret federal regulations on informed consent.

(Continuation of Footnote 25):

> [T]his case clearly illustrates that here it is appropriate for the uniform application of Federal law, because not only is the Federal Government involved in reviewing and approving that informed-consent form, but it would be near impossible and at least impractical to run multi-center, multi-state clinical trials if every state can enforce its own regulations and rules as to what goes in that informed-consent form, resulting in incredible costs that would make multi-center clinical trials impractical and in fact may result in inconsistent data, making the clinical trials themselves useless. So it's important when thinking about these clinical trials, the one in particular in this case as well as clinical trials, you know, involving any medical device, that there is a uniform application of Federal regulations.

N.T., pages 23-24.

Defendants argue that the MCARE Act does not require or address the discussion of plaintiff's legal rights as necessary to informed consent, and it also does not define the elements of informed consent. Instead, defendants assert that the MCARE Act couches informed consent in terms of giving the patient a description of the procedure and of its risks and alternatives, but it fails to address the waiver of legal rights.

Finally, defendants oppose plaintiff's motion for an award of attorneys' fees, costs and expenses based on improper removal under 28 U.S.C. § 1447(c). Defendants assert that they clearly have not raised frivolous or insubstantial reasons for removal. Thus, defendants argue that attorneys' fees, costs and expenses are not warranted in this case.

DISCUSSION

Any discussion of plaintiff's claims in this case must begin with an analysis of the jurisprudence regarding federal question jurisdiction. Pursuant to Section 1331 of Title 28 of the United States Code, a district court has original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." A civil action filed in a state court may be removed to a federal court if the claim arises under federal law. 28 U.S.C. § 1441(b).

The well-pleaded complaint rule sets out the primary means of determining federal question jurisdiction. Dukes v.

U.S. Healthcare, 57 F.3d 350, 353 (3d Cir. 1995). Plaintiff is the "master of the complaint." Caterpillar Inc. v. Williams, 482 U.S. 386, 398-399, 107 S.Ct. 2425, 2433, 96 L.Ed.2d 318, 331 (1987). As such, the court has "arising under" jurisdiction when plaintiff pleads a federal cause of action on the face of the properly pleaded complaint. Dukes, 57 F.3d at 353 (citing Franchise Tax Board v. Construction Laborers Vacation Trust, 463 U.S. 1, 9-12, 103 S.Ct. 2841, 2846-2848, 77 L.Ed.2d 420, 430-432 (1983)).

Ordinarily, plaintiff may avoid federal jurisdiction through "exclusive reliance on state law" in the complaint. Caterpillar Inc., 482 U.S. at 392, 107 S.Ct. at 2429, 96 L.Ed.2d at 327.

While the well-pleaded complaint rule provides the main method of establishing federal question jurisdiction, the artful pleading doctrine captures additional cases that also create "arising under" jurisdiction. Kline v. Security Guards, Inc., 386 F.3d 246, 252 (3d Cir. 2004) (citations omitted). Under this more amorphous doctrine, although plaintiff does not raise a federal question on the face of the complaint, "arising under" jurisdiction still exists where either: (1) a substantial federal question remains embedded in the state law claim; or (2) the state law claim is essentially a federal claim because it is

completely preempted by federal law. Guckin, 259 F.Supp.2d at 410.

The artful pleading doctrine is a narrow exception to the well-pleaded complaint rule, and has been applied primarily in those cases involving complete preemption of the state law claim raised by plaintiff. See Caterpillar, Inc., 482 U.S. at 393, 107 S.Ct. at 2430, 96 L.Ed.2d at 327-328; Metropolitan Life Insurance Co. v. Taylor, 481 U.S. 58, 65, 107 S.Ct. 1542, 1547, 95 L.Ed.2d 55, 64 (1987); Franchise Tax Board, 463 U.S. 1, 24, 103 S.Ct. 2841, 2854, 77 L.Ed.2d 420, 440. See also Conway v. Peco Energy Co., 1997 U.S.Dist. LEXIS 747, at *12 (E.D.Pa. Jan. 28, 1997)(Yohn, J.).

In Conway, my colleague, then United States District Judge, now Senior District Judge William H. Yohn, Jr., noted the emphasis courts have placed on the complete preemption doctrine. He explained that:

> the test for a "substantial question"...appears to involve the same factors our court of appeals has instructed me to consider when determining whether a state cause of action has been "completely preempted" by federal law.... It seems quite probable, therefore, that the complete preemption doctrine swallows any remnant of the "substantial question of federal law."

1997 U.S.Dist. LEXIS 747, at *12.

In Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing, 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005), the United States Supreme Court expanded

on what constitutes a substantial question of federal law. An action creates "arising under" federal jurisdiction where: (1) plaintiffs plead a cause of action created by federal law on the face of the complaint; or (2) a state law cause of action implicates significant federal issues. 545 U.S. at 312, 125 S.Ct. at 2366-2367, 162 L.Ed.2d at 263.

In Grable & Sons Metal Products, Inc. ("Grable"), the Supreme Court clarified this second ground for "arising under" jurisdiction by providing the relevant inquiry: "does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities[?]" 545 U.S. at 314, 125 S.Ct. at 2368, 162 L.Ed.2d at 265.

The Supreme Court also noted that the absence of a federal private right of action is not dispositive in determining Congressional intent under this second ground. 545 U.S. at 318, 125 S.Ct. at 2370, 162 L.Ed.2d at 267. While it is one relevant factor in determining congressional intent, a state law cause of action will still give rise to federal question jurisdiction where a state law claim "turn[s] on substantial questions of federal law," thereby justifying "resort to the experience, solicitude, and hope of uniformity that a federal forum offers on

federal issues." 545 U.S. at 312, 125 S.Ct. at 2367, 162 L.Ed.2d at 263.

The Supreme Court likewise acknowledged that although it offered additional guidance on what types of state law claims fit into this second category, no bright line rule exists because courts must consider on a case-by-case basis whether they are disrupting the balance between state and federal courts intended by Congress. 545 U.S. at 313-314, 125 S.Ct. at 2367-2368, 162 L.Ed.2d at 264-265.

Grable did not arise in the context of preemption, and so the intersection remains unclear between the two categories of "arising under" jurisdiction identified by the Supreme Court and the artful pleading doctrine, particularly concerning the category of preemption. Two questions remain unanswered after Grable: (1) whether the complete preemption doctrine is a separate test for "arising under" jurisdiction; and (2) whether claims for ordinary preemption can rise to the level of significant federal issues.[26]

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[26] The Supreme Court identified the basis for the distinction between "complete preemption" and the defense of preemption, or "ordinary preemption," as an 1887 Congressional amendment to the removal statute, which before this amendment allowed a federal defense such as preemption to provide a basis for removal. Caterpillar Inc., 482 U.S. at 392-393, 107 S.Ct. at 2430, 96 L.Ed.2d at 327.

The Supreme Court interpreted this amendment to mean ordinary preemption was no longer a basis for removal. Id. Unlike ordinary preemption, the Supreme Court considered complete preemption to be a proxy for original federal jurisdiction, which

(Footnote 26 continued):

The complete preemption doctrine has been recognized as an exception to the well-pleaded complaint rule because the state cause of action, in effect, is a federal cause of action from its inception. Caterpillar, Inc., 482 U.S. at 393, 107 S.Ct. at 2430, 96 L.Ed.2d at 327-328 (quoting Taylor, 481 U.S. at 65, 107 S.Ct. at 1547, 95 L.Ed.2d at 64 (1987); Franchise Tax Board, 463 U.S. at 24, 103 S.Ct. at 2854, 77 L.Ed.2d at 440).

In Railway Labor Executives Association v. Pittsburgh & Lake Erie Railroad Co., 858 F.2d 936, 942 (3d Cir. 1988) (citations omitted), the United States Court of Appeals for the Third Circuit identified a two-part test for complete preemption: (1) "whether the statute relied upon by the defendant as preemptive contains civil enforcement provisions within the scope of which plaintiff's state claim falls"; and (2) "whether there is a clear indication of a Congressional intention to permit removal despite the plaintiff's exclusive reliance on state law."

However, in Schaefer-Condulmari v. US Airways Group, Inc., 2009 U.S.Dist. LEXIS 114723, at *19 (E.D.Pa. Dec. 8, 2009)

(Continuation of Footnote 26):

essentially converts a state law cause of action into a federal law cause of action. Id. For a fuller discussion on the distinction between complete preemption and ordinary preemption, see Salsgiver Communications Inc. v. Consolidated Communications Holdings Inc., 2008 U.S.Dist. LEXIS 50320, at *14-23 (W.D.Pa. Jun. 30, 2008) (Schwab, J.). The Supreme Court in Grable did not discuss the two types of preemption.

(McLaughlin, J.), my colleague United States District Judge Mary A. McLaughlin opined that the second part of the Railway Labor test has been modified by the United States Supreme Court decision in Beneficial National Bank v. Anderson, 539 U.S. 1, 123 S.Ct. 2058, 156 L.Ed.2d 1 (2003). Although the first prong remains the same, the modified test requires that Congress must have intended to provide an exclusive remedy in the federal statute, instead of examining congressional intent to permit removal. Schaefer-Condulmari, at *21-22.

In the absence of congressional intent to provide an exclusive federal remedy, it is well established that merely asserting the federal defense of preemption does not give rise to federal question jurisdiction. Beneficial National Bank ("Beneficial"), 539 U.S. at 6, 123 S.Ct. at 2062, 156 L.Ed.2d at 7; Caterpillar, Inc., 482 U.S. at 393, 107 S.Ct. at 2430, 96 L.Ed.2d at 327. For example, in Beneficial, the Supreme Court noted that if Congress had not intended the federal cause of action for usury to be exclusive, then even defendant's compliance with federal usury laws which preempt state usury laws would only provide a defense and would not create grounds for removal. 539 U.S. at 9, 123 S.Ct. at 2063-2064, 156 L.Ed.2d at 9. In Grable, the Supreme Court did not address the status of this jurisprudence, particularly the issue of

whether ordinary preemption could ever present a significant federal issue conferring "arising under" jurisdiction.

Here, plaintiff alleges that she is bringing Count VIII of her Complaint solely pursuant to state law. The Complaint makes no reference to federal law, and instead asserts a cause of action for battery based upon a lack of informed consent under the Pennsylvania MCARE Act. Plaintiff alleges that the Consent Form signed by her decedent did not provide adequate informed consent under the MCARE Act because the patient was not fully apprised of the risks, namely, the preemption of state law claims that would act to limit his legal rights.

The relevant portion of the Consent Form states:

> Nothing in this informed consent shall act to waive any of your legal rights or to release the University of Pennsylvania Health System and school of medicine, the study sponsor, Ventracor, Inc., or any of their agents from liability for negligence.[27]

Plaintiff argues that her decedent should have been told about the "legal rights" to which he would not be entitled because of federal preemption. She claims that this violates the informed consent requirements of the MCARE Act. Specifically, the MCARE Act requires a doctor to inform a patient of the "risks" in using an experimental device:

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[27] See Complaint, Exhibit B, page 11.

> (a) DUTY OF PHYSICIANS.-- Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
>
> . . .
>
> (5) Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner
>
> (b) DESCRIPTION OF PROCEDURE.-- Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide....

40 P.S. § 1303.504.

Plaintiff contends that because defendant did not advise her decedent that one of the alleged "risks" was the loss of certain state law causes of action, the consent obtained by defendants was deficient under the MCARE Act. It is defendants' alleged failure to inform Mr. Mack of his limited legal rights which plaintiff cites as giving rise to her state law claims for battery, and the same alleged failure to provide information

forms the basis for plaintiff's state law claims for fraudulent misrepresentation and breach of fiduciary duty.[28]

Accordingly, plaintiff asserts that all three of these causes of action rise or fall completely on the interpretation of state law, and require neither the interpretation nor the application of federal laws or regulations. For the following reasons, I agree with plaintiff in part, and with defendants in part, and conclude that remand of this action back to state court is appropriate.

Applying the Grable analysis, neither party asserts that a federal cause of action exists on the face of plaintiff's complaint (the first category articulated in Grable). However, plaintiff cannot rest on the well-pleaded complaint doctrine because of the second category laid out in Grable (that is, an action creates "arising under" federal jurisdiction where a state law cause of action implicates significant federal issues). Furthermore, contrary to plaintiff's contention, I conclude that Grable makes clear that the lack of a federal cause of action

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[28] One could logically conclude that the "risks" which the physician is required to describe to the patient to obtain the informed consent of the patient before using an experimental device pursuant to sections 1303.504(a)(5) and (b) of the MCARE Act are the medical risks of using the medical device, not the legal risks of losing certain rights if one signs an informed consent document. However, because I have remanded this matter back to the Philadelphia Court of Common Pleas, interpretation of Pennsylvania's MCARE Act is more appropriately determined by the Pennsylvania Courts.

does not preclude the existence of a significant federal issue raising federal question jurisdiction.

Defendants argue that a significant federal issue exists. Defendants assert that plaintiff's battery, fraudulent misrepresentation, and breach of fiduciary duty claims actually rely on an interpretation of federal regulations governing informed consent. Specifically, defendants reason that an FDA regulation governing informed consent on human subjects expressly states that informed consent cannot require a patient to waive his legal rights:

> No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases the investigator, the sponsor, the institution, or its agents from liability for negligence.

21 C.F.R. § 50.20.

Additionally, defendants argue that FDA regulations provide the definition and elements of informed consent for human research subjects, as well as the requirement for a written consent form. 21 C.F.R. §§ 50.20, 50.25, and 50.27. The patient's Consent Form was drafted pursuant to these regulations, and defendants argue that its content also needs to be evaluated pursuant to these regulations.

Defendants assert that the MCARE Act is inapplicable to whether the patient was adequately advised regarding the waiver

of his "legal rights," and that plaintiff's true cause of action requires interpretation and application of these federal regulations. Additionally, defendants claim that the concern with congressional intent raised in Grable has been satisfied here because Congress could not have contemplated fifty different standards for informed consent in large multi-state human research trials.

I conclude that defendants have misapplied the standard articulated in Grable because the merits of plaintiff's causes of action are not a part of the relevant inquiry. Instead, I must examine the plaintiff's causes of action as they are pled and determine whether they raise significant federal issues.

The proper inquiry is whether the state law claim "necessarily raise[s] a stated federal issue, actually disputed and substantial." Grable, 545 U.S. at 314, 125 S.Ct. at 2368, 162 L.Ed.2d at 265. Defendants' compliance with federal laws and regulations is not at issue, and no dispute even exists because plaintiff agrees that defendants followed the federal requirements governing informed consent. See Footnote 24, supra.

Beginning with plaintiff's state law claim under the MCARE Act, a court can interpret and apply this law to plaintiff's stated claims for battery, fraudulent misrepresentation, and breach of fiduciary duty. In applying the MCARE Act, the only potential significant federal issue raised is

whether the topic of informed consent for human research subjects has been preempted by federal law. If Congress intended to preempt this area of the law, then it would be impermissible for the MCARE Act to impose additional or different informed consent requirements for human research subjects.

In examining whether the potential preemption of the MCARE Act raises a significant federal issue, the Supreme Court's emphasis on congressional intent in Grable is instructive. There, the Supreme Court found federal question jurisdiction over a state law action to quiet title.

Although no federal cause of action existed, the essential issue in Grable was whether the Internal Revenue Service had given adequate notice to plaintiff of its seizure of plaintiff's property pursuant to a tax sale conducted under federal law. The meaning of notice in the federal statute was actually in dispute, and the Supreme Court determined that Congress wanted federal courts to decide this meaning because of the importance of uniformity in federal tax law. Grable, 545 U.S. at 314, 125 S.Ct. at 2368, 162 L.Ed.2d at 265.

In assessing congressional intent to preempt the area of informed consent for human research subjects, strong evidence exists that the MCARE Act has not been preempted. The federal statute pursuant to which the regulations governing informed consent were promulgated does not shed much light on the intent

of Congress regarding preemption. 21 U.S.C. § 360j(g)(3)(D). However, the FDA regulations make explicit that they do not preempt state law requirements and, in fact, contemplate state and local authorities imposing additional informed consent requirements.

The FDA regulation governing the elements of informed consent provides: "The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective." 21 C.F.R. § 50.25(d). See also 45 C.F.R. § 46.116(e). Defendants fail to address the meaning of this provision in their policy arguments for uniformity in human research subjects' informed consent requirements.

It is true, as defendants argue, that the FDA monitors compliance with the informed consent regulations of clinical investigators who have been granted an Investigational Device Exemption. 21 C.F.R. § 812.119. However, section 50.25(d) suggests that it is possible for clinical investigators to follow the federal regulations while still being in violation of additional state and local requirements. In determining the balance Congress intended between state and federal courts, I conclude that this regulation suggests Congress did not envision federal courts determining all issues of informed consent.

Even assuming the complete preemption doctrine survives Grable as a separate analysis, it is difficult to argue that the MCARE Act is completely preempted by federal regulations. The test laid out in Schaefer-Condulmari requires that the federal statute at issue contain civil enforcement provisions which encompass plaintiff's claims and requires that Congress intended to provide an exclusive remedy in the federal statute.

The Supreme Court found complete preemption of state usury laws governing national banks where the federal usury statute provided a federal remedy for the plaintiff. Beneficial National Bank v. Anderson, 539 U.S. 1, 123 S.Ct. 2058, 156 L.Ed.2d 1. The Supreme Court also determined that Congress intended that to be the sole remedy for usury involving national banks. Id.

Here, applying the test for complete preemption, the federal statute on informed consent does not provide civil enforcement provisions. Additionally, the FDA regulations make clear that state and local authorities have retained the power to create civil enforcement provisions. Therefore, the federal regulations for informed consent are not exclusive.

The Supreme Court in Grable seems to conduct the preemption analysis under the rubric of congressional intent by focusing on whether the federal issue raised by defendants is significant enough to warrant review in federal courts. In

assessing an earlier Supreme Court case discussing both "arising under" jurisdiction and preemption, the Court in Grable found it an "important clue" that Congress did not confer federal question jurisdiction where "the combination of no federal cause of action and no preemption of state remedies" existed. 545 U.S. at 318, 125 S.Ct. at 2370, 162 L.Ed.2d at 267 (discussing Merrell Dow Pharmaceuticals, Inc., v. Thompson, 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986) and asserting its consistency with the rule announced).

Using the language in Grable, I conclude that it is an "important clue" that no federal cause of action is present and the FDA regulations make clear that state remedies for lack of informed consent have not been preempted. These factors suggest that Congress did not intend that informed consent for human research subjects be considered a significant federal issue to be resolved by federal courts.

Furthermore, it is difficult to imagine that even defendants' ordinary preemption claims in this case would give rise to federal question jurisdiction. Prior to Grable, courts had established that a federal defense of preemption does not confer federal question jurisdiction. Beneficial National Bank, supra. Instead of being a jurisdictional doctrine, ordinary preemption merely raises questions of choice of law. Guckin, 259 F.Supp.2d at 414.

The Supreme Court in Grable has given no indication that a defense of preemption can raise a significant federal issue. Instead, the Supreme Court focused on congressional intent and sought to avoid an "enormous shift of traditionally state cases into federal courts." 545 U.S. at 319, 125 S.Ct. at 2371, 162 L.Ed.2d at 268. Allowing the federal defense of preemption to be considered a significant federal issue would likely result in such an enormous shift which the Supreme Court explicitly wanted to prevent.

Because defendants cannot establish federal question jurisdiction under either of the categories laid out in Grable, this court lacks subject matter jurisdiction. Accordingly, in the absence of original jurisdiction, this action was improperly removed and must be remanded. 28 U.S.C. § 1447(c).

Costs, Expenses, and Attorneys' Fees

Defendants have no basis for removing to federal court plaintiff's battery claim, or the corresponding claims for fraudulent misrepresentation and breach of fiduciary duty, because the claims arise solely under state law and raise no other significant federal issues. Nevertheless, plaintiff is not entitled to reimbursement of her costs, expenses, and attorneys' fees pursuant to 28 U.S.C. § 1447(c).

Plaintiff may recover expenses arising from improper removal of a claim to federal court where the removing party

lacked an objectively reasonable basis for removal. Martin v. Franklin Capital Corporation, 546 U.S. 132, 141, 126 S.Ct. 704, 711, 163 L.Ed.2d 547, 555 (2005). Defendants argue that they have not raised frivolous or insubstantial reasons for removal, and so fees are not warranted in this case. See Mints v. Educational Testing Service, 99 F.3d 1253, 1261 (3d Cir. 1996). I agree.

In light of the federal regulations on informed consent for human research subjects, and the recent Supreme Court decision in Grable expanding on "arising under" jurisdiction, I conclude that defendants, although unsuccessful, did not lack an objectively reasonable basis for removal. Accordingly, I deny plaintiff's motion for costs, expenses, and attorneys' fees related to the motion to remand.

CONCLUSION

For all the foregoing reasons, I grant in part and deny in part plaintiff's Motion to Remand and for Costs, Expenses, and Attorneys' Fees. Specifically, I conclude that Counts VIII through X of plaintiff's Civil Action Complaint raise battery, fraudulent misrepresentation, and breach of fiduciary duty claims pursuant to state law alone and do not confer federal question jurisdiction. Therefore, I grant the motion to remand the matter to the Court of Common Pleas of Philadelphia County, Pennsylvania.

However, I further conclude that defendants established an objectively reasonable basis for removal, although not a legally successful one, and, therefore, I deny plaintiff's motion for costs, expenses, and attorneys' fees.