

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

KD, a minor, by his parent and natural guardian, Kenneth Dieffenbach, and KENNETH DIEFFENBACH, in his own right	:	
	:	
	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civ. No. 07-515-GMS-MPT
	:	
UNITED STATES OF AMERICA,	:	
	:	
Defendant.	:	

REPORT AND RECOMMENDATION

Procedural Background

This matter arises out of a complaint brought by plaintiff, KD, a minor, by his parent and natural guardian, Kenneth Dieffenbach, for the personal injuries and losses sustained by the minor plaintiff as a result of the medical malpractice and failure to warn by an agent of the National Institute of Health (“NIH”). Kenneth Dieffenbach (“Dieffenbach”), in his own right, also brings suit for medical expenses paid on behalf of his son, loss of earnings, and future medical expenses. KD underwent multiple follow-up surgeries relating to a pacemaker that was surgically implanted on December 13, 1995 under the care and supervision of Dr. Lameh Fananapazir, an employee of the NIH. KD’s most recent heart surgery in connection with the alleged fraud, failure to warn, and malpractice of the NIH occurred on May 9, 2004. On March 24, 2006, an administrative claim for relief and damages was filed with the NIH by Dieffenbach as

legal representative on behalf of KD.

Plaintiffs filed suit in the United States District Court for the District of Delaware on August 23, 2007 under the Federal Tort Claims Act (“FTCA”). On December 5, 2007, defendant filed a motion to dismiss for failure to state a claim or in the alternative, for summary judgment. Subsequently, plaintiffs filed their answer in opposition to the motion. On January 30, 2008, defendant filed its reply brief in support of its motion.

Factual Background¹

KD was admitted to the NIH on December 9, 1995 for evaluation of a heart condition, obstructive hypertrophic cardiomyopathy (“OHC”). Dr. Lameh Fananapazir, who was employed by the NIH, and therefore the United States, advised KD’s father, Dieffenbach, that KD would require a pacemaker implantation operation in order to sustain his life. At that time, KD was completely asymptomatic. Dr. Fananapazir did not instruct KD and his father that the procedure was part of an experiment at the NIH and that there were safer alternatives available. KD remained under the care of the NIH for the following three years and became increasingly symptomatic. Dr. Fananapazir informed Dieffenbach that there was nothing else that the NIH could do for KD and that a heart transplant was required.

In October 1998, KD was taken off the medications previously prescribed by Dr. Fananapazir and KD exhibited dramatic symptomatic improvements. On May 29, 2002, a physician at the Children’s Hospital in Boston, Massachusetts determined that the pacemaker’s battery had reached the end of its useful life and placed the device in

¹The facts are taken from plaintiffs’ complaint, and brief, and Dieffenbach’s affidavit.

stand-by mode. At that time, the pacemaker was not removed because this would have required additional surgery that was not deemed necessary.

On September 8, 2003, KD suffered cardiac arrest and underwent surgery to have the pacemaker removed and an implantable cardioverter defibrillator (“ICD”) implanted. On arrival to the hospital, KD had no significant arrhythmias, but he did experience pacer spikes from the pacemaker. At that time, plaintiffs were informed that the pacemaker was a “rogue pacemaker” and that it needed to be removed. On May 10, 2004, a few months after his initial cardiac arrest, KD underwent cardiopulmonary bypass and cardiac surgery due to the exacerbation of his underlying valve disease, OHC. Following the procedure, the surgeon informed Dieffenbach that the pacemaker should never have been implanted by the NIH. Dieffenbach was also advised that had the pacemaker not been implanted, no cardiac arrest would have occurred and no ICD implantation would have been required. At that time, Dieffenbach also discovered that the NIH had failed to warn him about the full risks involved with the treatment of KD’s valve condition with the implantation of a pacemaker.

On March 24, 2006, Dieffenbach filed a claim with the NIH as the legal representative and parent of KD, the claimant. The claim was denied by the NIH and Dieffenbach filed the instant action on behalf of KD and in his own name under the FTCA.

Legal Standards

Motion to Dismiss Rule 12(b)(6)

Rule 12(b)(6) permits a party to move to dismiss a complaint for failure to state a

claim upon which relief can be granted.² The purpose of a Rule 12(b)(6) motion to dismiss is to test the sufficiency of a complaint, not to resolve disputed facts or decide the merits of the case.³ Evaluating a motion to dismiss under Rule 12(b)(6) requires the court to accept as true all material allegations of the complaint.⁴ “The issue is not whether a plaintiff will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims.”⁵ A motion to dismiss may be granted only if, after, “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to the plaintiff, plaintiff is not entitled to relief.”⁶

To survive a motion to dismiss under Rule 12(b)(6), however, the factual allegations must be sufficient to “raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).”⁷ A plaintiff is obliged “to provide the ‘grounds’ of his ‘entitle[ment] to relief’ beyond labels and conclusions.”⁸ Although heightened fact pleading is not required, “enough facts to state a claim to relief that is plausible on its face” must be alleged.⁹ While the court assumes that all factual allegations in the complaint are true and draws all reasonable factual inferences in the light most favorable to the plaintiff, it rejects

² Fed. R. Civ. P. 12(b)(6).

³ *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993).

⁴ *Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004).

⁵ *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks and citation omitted).

⁶ *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks and citations omitted).

⁷ *Bell Atlantic Corporation v. Twombly*, 127 S. Ct. 1955, 1965 (2007); see also *Victaulic Co v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007).

⁸ *Twombly*, 127 S. Ct. at 1965.

⁹ *Id.* at 1974.

unsupported allegations, “bald assertions,” or “legal conclusions.”¹⁰ “When a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint.”¹¹

“Courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record” when reviewing a motion to dismiss.¹² Rule 12(d) addresses the use of materials which are outside the pleadings in motions to dismiss under Rule 12(b)(6). When such materials are presented, the motion is treated as one for summary judgment. However, certain additional materials may be considered without converting the motion to dismiss into a motion for summary judgment. Moreover, a court is not limited to the four corners of the complaint and may consider “matters incorporated by reference integral to the claim, items subject to judicial notice, matters of public record, orders [and] items appearing in the record of the case.”¹³ A plaintiff is entitled to notice and a fair opportunity to respond to any evidence the court might consider in its review of a motion to dismiss. Where a plaintiff had such notice, however, it is proper for the court

¹⁰ *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citations omitted); see also *Schuylkill Energy Res., Inc v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (“unsupported conclusions and unwarranted inferences” are insufficient); *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996) (allegations that are “self-evidently false” are not accepted).

¹¹ *Twombly*, 127 S. Ct. at 1969.

¹² *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 988 F.2d 1192, 1196 (3d Cir. 1993).

¹³ *Buck v. Hampton Tp. School Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (citing 5B Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1357 (2004)). Further, “exhibits attached to the complaint whose authenticity is unquestioned” may also be considered. 5B Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (2007).

to consider that evidence.¹⁴

Summary Judgment

Summary judgment is appropriate if the “pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.”¹⁵ Once there has been adequate time for discovery, Rule 56(c) mandates judgment against the party who “fails to make a sufficient showing to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.”¹⁶ When a party fails to make such a showing, “there can be no ‘genuine issue as to any material fact’ since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.”¹⁷ The moving party is therefore entitled to judgment as a matter of law because “the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.”¹⁸ A dispute of material fact exists where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.”¹⁹

The moving party bears the initial burden of identifying portions of the record

¹⁴ *Pension Benefit*, 998 F.2d at 1196-97 (“When a complaint relies on a document, however, the plaintiff obviously is on notice of the contents of the document, and the need for a chance to refute evidence is greatly diminished.”) (internal citations omitted).

¹⁵ Fed. R. Civ. P. 56(c).

¹⁶ *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

¹⁷ *Id.* at 323.

¹⁸ *Id.*

¹⁹ *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

which demonstrate the absence of a genuine issue of material fact.²⁰ However, a party may move for summary judgment with or without supporting affidavits.²¹ Therefore, “the burden on the moving party may be discharged by ‘showing’ – that is, pointing out to the district court – that there is an absence of evidence supporting the nonmoving party’s case.”²²

If the moving party has demonstrated an absence of material fact, the nonmoving party must then “come forward with specific facts showing that there is a genuine issue for trial.”²³ If the nonmoving party bears the burden of proof at trial, he “must go beyond the pleadings in order to survive a motion for summary judgment.”²⁴ That party “may not rest upon the mere allegations or denials of his pleadings, but must set forth specific facts showing that there is a genuine issue for trial.”²⁵ At the summary judgment stage, the court is not to “weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial.”²⁶ Further, “there is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party.”²⁷ The threshold inquiry therefore is “determining whether there is a need for trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may

²⁰ *Celotex*, 477 U.S. at 323.

²¹ *Id.*

²² *Id.* at 325.

²³ Fed. R. Civ. P. 56(c).

²⁴ *Yeager’s Fuel v. Pennsylvania Power & Light Co.*, 22 F.3d 1260, 1273 (3d Cir. 1994).

²⁵ *Anderson*, 477 U.S. at 248.

²⁶ *Id.* at 249.

²⁷ *Id.*

reasonably be resolved in favor of either party.”²⁸

Parties’ Positions

Defendant maintains that a motion to dismiss or, in the alternative, summary judgment is warranted because KD’s administrative claim does not satisfy the two-year statute of limitations requirement of the FTCA. Defendant points out that any tort claim filed against the United States under the FTCA must be forever barred unless it is first presented to the appropriate federal agency within two years of the claim’s accrual. Defendant asserts that the claim accrued no later than September 15, 2003 when the pacemaker was surgically removed and possibly as early as 1998 when the plaintiff was first treated for complications arising from care at the NIH by the Children’s Hospital of Boston. Defendant contends, therefore, that the administrative claim filed by Dieffenbach on behalf of KD on March 24, 2006 was more than two years after the accrual of the claim and thus, untimely.

In addition, defendant insists that Dieffenbach never filed an administrative claim with the NIH, but rather, filed only as legal representative on behalf of his son and is barred from bringing suit in his own name under the FTCA. Defendant points out that Dieffenbach only signed the administrative claim as a legal representative and not as a claimant. Defendant states that the claim on behalf of Dieffenbach in his own name must be dismissed because he failed to file a timely administrative claim with the appropriate federal agency before filing suit in federal court.

Plaintiffs contend that the accrual date should be May 9, 2004 and not

²⁸ *Id.* at 250.

September 13, 2003 as defendant proposes. They argue that it was not until May 9, 2004 that they knew or could have known the cause of KD's injuries because of fraud and a failure to warn by the NIH. It was at this time that plaintiffs were informed of the harmful nature of the original implantation and that KD's injuries were caused by the NIH's medical malpractice. Plaintiffs defend their position that it was not until this date that they were made aware of the injury and had knowledge of what caused the injury.

With regards to Dieffenbach's failure to file a timely administrative claim separate from KD's claim, plaintiffs argue that the purpose of the administrative claim requirement is not to erect a barrier of technical requirements to defeat legitimate claims, but rather, to provide notice to the relevant federal agency of the claim. Plaintiffs insist that the agency was put on notice because Dieffenbach's name was on the administrative claim and he was listed as the parent of the minor claimant. Plaintiffs cite *Munger v. United States* for the proposition that every requirement of the FTCA need not be applied because the purpose of the filing is to give notice.²⁹ Ultimately, plaintiffs urge that Dieffenbach satisfied the requirements to file a claim under the FTCA and was not required to file a separate claim with the NIH because the agency was put on notice by KD's claim.

Analysis

Accrual of a Tort Claim

28 U.S.C. § 2671 is a limited waiver of sovereign immunity and must be strictly

²⁹ 116 F. Supp. 2d 672, 676 (D. Md. 2000) (holding that FTCA claims could be maintained when there is more than one claimant and they did not file separate claims: however, the claims must be for the same amount and must rely on the same set of facts).

construed.³⁰ Before filing a claim pursuant to the FTCA in district court, a plaintiff must first file an administrative claim with the appropriate agency.³¹ 28 U.S.C. § 2401(b) provides that “a tort claim against the United States shall be forever barred unless it is presented in writing to the appropriate Federal agency within two years after such claim accrues”³² Defendant argues that plaintiffs did not meet this requirement and, therefore, all claims should be dismissed.

Federal law determines the time when a claim accrues for purposes of the FTCA’s statute of limitations.³³ In *United States v. Kubrick*, plaintiff, Kubrick, had an infected leg which was treated with the drug, neomycin, at the Veterans Administration hospital in 1968.³⁴ A few weeks after its administration, Kubrick suffered hearing loss.³⁵ In 1969, Kubrick was informed by a private physician that the hearing loss was likely caused by the administration of neomycin.³⁶ Two years later in 1971, Kubrick was informed that the drug did cause his hearing loss. Subsequently in 1972, he filed a claim under the FTCA.³⁷

The Court, held that Kubrick’s claim accrued when he learned that his deafness probably resulted from the administration of neomycin and not when he learned that the

³⁰ *United States v. Kubrick*, 444 U.S. 111, 119 (1979).

³¹ 28 U.S.C. § 2401(b).

³² *Id.*

³³ See *Ciccarone v. United States*, 486 F.2d 253, 256 (3d Cir. 1973) (stating “that principles of federal law govern the statute of limitations provision of the Federal Tort Claims Act”).

³⁴ *Kubrick*, 444 U.S. at 113.

³⁵ *Id.*

³⁶ *Id.* at 114.

³⁷ *Id.* at 115.

treatment constituted malpractice.³⁸ The Court determined that “accrual” of a claim under the FTCA occurs when “the crucial facts that he has been hurt and who has inflicted the injury” are known to the plaintiff.³⁹

In addition, *Kubrick* places an affirmative requirement on a plaintiff who is armed with the knowledge of and the identity of who inflicted the injury to inquire as to whether substandard care was given.⁴⁰ *Kubrick* held that a claim accrues “within the meaning of the Act when the plaintiff knows both the existence and the cause of his injury” and does not require that “he also know that the acts inflicting the injury may constitute medical malpractice.”⁴¹ Once a plaintiff is armed with the facts regarding the existence and cause of the injury, he is obliged to inquire whether improper care occurred.

However, there are distinctions between injuries caused by affirmative treatment, like in *Kubrick*, and injuries which result from a failure to diagnose, treat, or warn.⁴² In *Augustine v. United States*, the court stated that the *Kubrick* holding “cannot be applied mechanically to cases involving the failure to diagnose, treat, or warn.”⁴³ In *Augustine*, an Air Force dentist failed to diagnose a lump on the palate of the plaintiff as possibly cancerous.⁴⁴ In determining when the plaintiff’s action accrued, the court noted that the failure to diagnose resulted in the progression of the cancer itself.⁴⁵

The injury is the development of the problem into a more serious condition

³⁸ *Id.*

³⁹ *Id.* at 122.

⁴⁰ *Id.* at 123.

⁴¹ *Id.* at 122.

⁴² See *Green v. United States*, 180 Fed. Appx. 310, 314 (3d Cir. 2006).

⁴³ *Augustine v. United States*, 704 F.2d 1074, 1078 (9th Cir. 1983).

⁴⁴ *Id.* at 1076.

⁴⁵ *Id.* at 1078

which poses greater danger to the patient or which requires more extensive treatment. In this type of case, it is only when the patient becomes aware or through the exercise of reasonable diligence should have become aware of the development of a pre-existing problem into a more serious condition that his cause of action can said to have accrued for purposes of 2401(b).⁴⁶

In addition, the court held that a cause of action would not accrue until a reasonable person would have “discovered that the failure of his doctors to diagnose, treat, or warn him led to his deteriorating physical condition.”⁴⁷

In *Hughes v. United States*, which involved the failure to diagnose, warn or treat, the Third Circuit applied the reasoning of *Augustine* to a medical tort claim under the FTCA.⁴⁸ In 1997, Hughes was administered heparin, a blood thinner, in preparation for coronary bypass and cardiac catheterization surgeries.⁴⁹ Due to the side effects of the heparin, Hughes developed gangrene which led to quadruple amputations.⁵⁰ Hughes was informed after his amputations that a bad reaction to the heparin had caused the gangrene which lead to the amputations. He was not informed that if the physicians had timely diagnosed and properly treated the complication, then his amputations would have been avoided.⁵¹ In *Hughes*, the court concluded that the injuries were not caused by the heparin, but rather, the failure to monitor and treat the reaction to the heparin.⁵²

The court determined that Hughes’ claim did not accrue until he was informed that the failure to treat and diagnose caused his injuries.⁵³ When Hughes was

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Hughes v. United States*, 263 F.3d 272, 276 (3d Cir. 2001).

⁴⁹ *Id.* at 272.

⁵⁰ *Id.* at 274.

⁵¹ *Id.*

⁵² *Id.* at 275.

⁵³ *Id.* at 266-7.

discharged from the hospital, he was only informed that he had an allergic reaction to heparin which caused the amputations, and therefore, his claim did not accrue.⁵⁴ For accrual to operate, Hughes had to know or reasonably should have known that the cause of his injuries was the failure to treat and diagnose by his doctors.⁵⁵ Under *Hughes*, when a failure to diagnose, treat, or warn results in an injury, the statute of limitations is tolled until the plaintiff learns that the failure to properly treat, diagnose, or warn played a role in that injury.⁵⁶

KD's situation is more synonymous to *Hughes* and *Augustine* than to *Kubrick*. In *Kubrick*, the plaintiff alleged that the administration of a particular drug was negligent and such conduct caused his injuries.⁵⁷ In *Hughes*, the plaintiff suffered further physical injuries resulting from the failure to treat a preexisting condition and not directly from the negligent treatment. Like the injury in *Hughes*, KD's injuries occurred because Dr. Fananapazir and the NIH failed to warn and inform of the potential risks, and alternate treatments, and failed to treat KD's condition correctly and timely. The failure to warn that the pacemaker implantation surgery was experimental allegedly caused a worsening of KD's condition.

The analysis from *Hughes* and *Augustine* applies since KD's injuries did not occur solely because of a defective pacemaker, but allegedly resulted from the failure to warn about the risks involved. KD first underwent surgery on December 13, 1995 to have the pacemaker implanted. At that time, plaintiffs assert that they had no knowledge of the

⁵⁴ *Id.* at 277.

⁵⁵ *Id.* at 278.

⁵⁶ *Id.* at 277.

⁵⁷ *Kubrick*, 444 U.S. at 114.

risks involved with the experimental procedure or that there were other options available. On September 8, 2003, KD suffered cardiac arrest. As a result, plaintiffs knew or reasonably should have known about the existence of KD's injury. The cause of the injury, however, was not known because, at the time of the cardiac arrest, plaintiffs were advised that the pacemaker was a "rogue" device, which required removal.

Finally, after KD underwent open heart surgery on May 9, 2004, his father was allegedly informed for the first time about the NIH's failure to advise of the experimental nature of the pacemaker implantation procedure, the risks associated with that procedure, and other possible available medical options. Plaintiffs maintain that the failure to advise and warn resulted in the continued deterioration of KD's health. Since plaintiffs were not aware that the medical problems KD experienced were allegedly related to the failure to advise or warn as noted herein, the tort claim did not accrue until after the May 9, 2004 procedure. The instant FTCA action was filed on behalf of KD on March 24, 2006, within the two year limitations period under 28 U.S.C. § 2401(b).

Dieffenbach's Claims Pursuant to FTCA

In addition to bringing suit on behalf of his minor child, Dieffenbach filed a claim under the FTCA in his own name. Defendant reiterates that a claim must be filed with the appropriate administrative agency before the two year statute of limitations expires. By enacting the FTCA, Congress waived the immunity of the United States of America for a certain tort claims.⁵⁸ As a condition to the waiver of immunity, Congress also enacted 28 U.S.C. § 2401(b).⁵⁹ 28 U.S.C. § 2401(b) requires that tort claims be brought

⁵⁸ *Id.* at 117.

⁵⁹ *Id.*

against the government within two years of the accrual of the claim.⁶⁰

Dieffenbach never filed a separate claim to the NIH seeking damages.

Dieffenbach was only listed as a “Legal Representative” on his son’s claim, and was not included as a claimant. As the defense points out, the claim for damages only refers to KD. The administrative claim does not seek any separate damages for Dieffenbach.

Plaintiffs argue that even though Dieffenbach did not file a separate administrative claim, he should be allowed to continue with his current action. Congress enacted the two requirements in the FTCA and each must be satisfied in order to proceed against the government. A plaintiff must file a complaint with the appropriate agency within two years of the accrual of the tort claim. Dieffenbach does not satisfy those two requirements.

It is not sufficient that Dieffenbach is merely mentioned in the administrative complaint as the legal representative or as the parent of the complainant. “If multiple claimants exist, each claimant must individually satisfy the jurisdictional prerequisite of filing a proper claim.”⁶¹ Further *Kubrick*, recognized that the court “should not take it upon [itself] to extend the waiver beyond that which the Congress intended.”⁶² Since, Dieffenbach failed to satisfy the requirements of 28 U.S.C. § 2401(b), judgment in favor of the defendant on his claim is appropriate.

ORDER AND RECOMMENDED DISPOSITION

For the reasons contained herein, I recommend that:

⁶⁰ See 28 U.S.C. § 2401(b).

⁶¹ *Frantz v. United States*, 791 F. Supp. 445, 447 (D. Del. 1992).

⁶² *Kubrick*, 444 U.S. at 117.

(1) Defendant's motion to dismiss, or in the alternative, for summary judgment [D.I. 6] be GRANTED as to the claims filed by Kenneth Dieffenbach in his own name.

(2) Defendant's motion to dismiss, or in the alternative, for summary judgment [D.I. 6] be DENIED as to the claim filed on behalf of K.D. by his guardian.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D.Del.LR 72.1. The parties may serve and file specific written objections within ten (10) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b).

The parties are directed to the Court's standing Order in Non-Pro Se matters for Objections Filed under Fed. R. Civ. P. 72, dated April 7, 2008, a copy of which is available on the Court's website, www.ded.uscourts.gov.

May 26, 2009

/s/ Mary Pat Thyng
UNITED STATES MAGISTRATE JUDGE