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No. 11-4005

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Nov 29, 2012
DEBORAH S. HUNT, Clerk

SANDY SYKES, Individually,

Plaintiff – Appellant,

and

SANDY SYKES, Administrator of the Estate of David John Muir on behalf of David John Muir; MARGARET MUIR; ROBERT MUIR; ERIC MUIR; PAUL A. MUIR; KATHERINE MUIR,

Plaintiffs,

v.

UNITED STATES OF AMERICA; VETERANS ADMINISTRATION; UNIVERSITY OF CINCINNATI MEDICAL CENTER, nka University Hospital; ROCHE MOLECULAR SYSTEMS, INC.; CENTOCOR ORTHO BIOTECH PRODUCTS, L.P., nka Janssen Products, L.P.; MERCK, SHARP & DOHME CORPORATION, fka SCHERING CORPORATION; ROCHE PHARMACEUTICALS, aka Hoffman-La Roche Inc.; AMGEN MANUFACTURING LIMITED; DEPARTMENT OF VETERANS AFFAIRS; MERCK & COMPANY, INC., fka SCHERING-PLOUGH CORPORATION; PFIZER, INC.; GLAXOSMITHKLINE LLC,

Defendants – Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO

OPINION

Before: CLAY and STRANCH, Circuit Judges, and BELL, District Judge.[*]

JANE B. STRANCH, Circuit Judge. Sandy Sykes, appearing *pro se*, appeals the district court's dismissal of all claims filed against the United States, the Department of Veterans Affairs, the University of Cincinnati Medical Center, six individuals, and eight pharmaceutical manufacturers under various statutes and theories, including the Federal Tort Claims Act, 28 U.S.C. §§ 2671–2680; 42 U.S.C. §§ 1983 & 1985; *Bivens v. Six Unknown Agents of the Fed. Bureau of Narcotics*, 403 U.S. 388 (1971); the Freedom of Information Act, 5 U.S.C. § 552; the Declaration of Helsinki; and Ohio state law. The claims relate to injuries allegedly sustained by Sykes's brother, David J. Muir, during his participation in clinical drug trials between May 2000 and his death on February 6, 2004. For the reasons stated below, we **AFFIRM** the district court's judgment dismissing the claims under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

I. STANDARD OF REVIEW

We review *de novo* an order dismissing claims for lack of subject matter jurisdiction under Rule 12(b)(1) and for failure to state a claim under Rule 12(b)(6). *McCormick v. Miami Univ.*, 693 F.3d 654, 658 (6th Cir. 2012). In a facial challenge to jurisdiction under Rule 12(b)(1), we construe the allegations of the complaint as true. *Id.* In a factual challenge to jurisdiction, we may weigh evidence to decide whether the factual predicates exist to support subject matter jurisdiction. *Id.*

To survive a motion to dismiss under Rule 12(b)(6) for failure to state a claim, the complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief" in order to provide fair notice to the defendant of what the claim is and the grounds upon which it

[*]The Honorable Robert Holmes Bell, United States District Judge for the Western District of Michigan, sitting by designation.

rests. Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint "must contain more than conclusions and an unsubstantiated recitation of the necessary elements of a claim." *McCormick*, 693 F.3d at 658. We assume the factual allegations of the complaint are true and we decide whether the complaint states a plausible claim for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

When ruling on a motion to dismiss under Rule 12(b)(6), the court may consider public records and exhibits attached to the complaint without converting the motion to one for summary judgment under Federal Rule of Civil Procedure 56. *Amini v. Oberlin Coll.*, 259 F.3d 493, 502 (6th Cir. 2001). The court may also consider documents attached to a motion to dismiss if they are referred to in the complaint and are central to the plaintiff's claim. *Id.*; *Weiner v. Klais & Co.*, 108 F.3d 86, 89 (6th Cir. 1997).

II. FACTUAL ALLEGATIONS OF THE AMENDED COMPLAINT

The plaintiffs below included Sandy Sykes individually and as administrator of the estate of David J. Muir, Katherine Muir, Margaret Muir, Robert Muir, Eric Muir, and Paul Muir. Represented by counsel, the plaintiffs initially filed suit on October 4, 2010.

According to the amended complaint filed on December 29, 2010, plaintiffs' relative, David J. Muir, died on February 6, 2004. An autopsy revealed the cause of natural death was peritonitis due to a perforated sigmoid colon and peritoneal adhesions. The autopsy confirmed that Muir suffered from hepatitis C and cirrhosis of the liver.

Before 2000, Muir was severely injured in a house fire. He suffered third-degree burns over sixty-five percent of his body, which required skin grafts, amputation of one hand and amputation of the fingers on the other hand. Because of these injuries, Muir took methadone for continuous

pain. He also suffered from severe depression and had attempted suicide. Between 2000 and his death in February 2004, Muir received medical treatment at the Cincinnati Veterans Administration Medical Center and its affiliated locations (VA), and at the University of Cincinnati Medical Center and its affiliated locations (UCMC).

The plaintiffs alleged that, between May 2000 and February 6, 2004, Muir was enrolled in human research studies or clinical drug trials at the VA and UCMC for the treatment of hepatitis C in veterans, and was enrolled to participate in the studies even though he did not qualify due to his pre-existing physical and mental conditions. The plaintiffs further alleged that the studies were administered or supervised by Charles L. Mendenhall, M.D., the study doctor; Gary Roselle, M.D., Medical Director of the VA; and Judith M. Harrer, BS Pharm., Ph.D., the investigational drug pharmacist for the Cincinnati VA Medication Development Research Unit. Although plaintiffs also named as defendants Jeffrey Goldsmith, M.D., Robert Weesner, M.D., and Joseph Morelli, M.D., the amended complaint lacked specific factual allegations concerning these physicians. The plaintiffs alleged that all of the individuals acted within the scope of their employment.

The complaint further alleged that, as a participant in the studies, Muir was subjected to the use of certain medical testing devices and was prescribed certain pharmaceuticals and pharmaceutical test kits contrary to the standards or dosages approved by the U.S. Food and Drug Administration for these products. It alleged that the manufacturers of the pharmaceuticals and devices sponsored the studies and allowed their products to be used for purposes outside FDA-approved indications, and Muir was not advised by the VA, UCMC, or the drug manufacturers about any adverse warnings applicable to the pharmaceuticals that were administered to him. Muir signed at least two consent forms agreeing to participate in studies, but the plaintiffs asserted that the forms

were defective in that they did not disclose alternative and safer courses of treatment, did not include proper witness signatures, and did not include adequate descriptions of the compensation or treatment that the VA would provide Muir for any injury he sustained as a result of the studies.

According to the plaintiffs, Muir ingested orally or was injected with approximately ten drugs over a four-year period, including Epogen, Neuprogen, Procrit, Peginterferon, Pegasys, Copegus, Bupriopion, Intron A, Rebetol, Rebetron Combination Therapy, and Gabapentin. Muir suffered adverse reactions to one or more of these pharmaceuticals, which the plaintiffs alleged ultimately led to his death. After Muir died, the plaintiffs repeatedly requested complete copies of Muir's medical records from the VA, UCMC, the U.S. Department of Veterans Affairs, and the University of Cincinnati Institutional Review Board, but the plaintiffs claimed that their requests were denied.

III. PROCEDURAL HISTORY AND STATUS OF APPEAL

The amended complaint alleged eleven counts: (1) failure to obtain proper and informed consent; (2) medical negligence; (3) negligent diagnosis/failure to diagnose; (4) medical malpractice and wrongful death; (5) negligent supervision; (6) violations of the Freedom of Information Act; (7) equitable estoppel; (8) violation of 42 U.S.C. §§ 1983 and the Eighth and Fourteenth Amendments; (9) conspiracy under 42 U.S.C. § 1985; (10) violation of the Declaration of Helsinki, and (11) negligence. The plaintiffs alleged the first nine counts against the VA, UCMC, and the individual defendants. They also alleged the first and ninth counts against the pharmaceutical defendants, Roche Molecular Systems, Inc.; Centocor Ortho Biotech Products, L.P., nka Janssen Products, L.P.; Merck, Sharp & Dohme Corporation fka Schering Corporation; Roche Pharmaceuticals, aka Hoffman-La Roche Inc.; Amgen Manufacturing Limited; Merck & Company, Inc., fka Schering-Plough Corporation; Pfizer, Inc.; and GlaxoSmithKline LLC. The eleventh count

was asserted only against the pharmaceutical defendants. Alleging that all of the defendants were jointly and severally liable, the plaintiffs sought $5 million in compensatory and punitive damages.

The United States Attorney for the Southern District of Ohio certified under 28 U.S.C. § 2679 and 28 C.F.R. § 15.3 that all six individual defendants were employees of the United States Department of Veterans Affairs and that they acted within the scope of their federal employment at the time of the incidents alleged in the amended complaint. Based on these certifications, the individual defendants asked the district court to substitute the United States as a party and dismiss them from the suit. All of the defendants moved to dismiss the amended complaint. The plaintiffs moved for leave to file a second amended complaint.

At the conclusion of briefing on the motions, the magistrate judge issued a comprehensive Report and Recommendation (R & R). The magistrate judge recommended that the district court substitute the United States as the sole federal defendant and dismiss the individual defendants, dismiss all counts of the amended complaint against all defendants, and deny as futile the plaintiffs' motion to file a second amended complaint. Counsel for the plaintiffs then withdrew from further representation.

Sandy Sykes *pro se* filed lengthy objections, with attached exhibits, to the R & R, and responses to the objections were filed. After conducting *de novo* review, the district court adopted the R & R, substituted the United States as the sole federal defendant, dismissed the individual defendants, granted the motions to dismiss, and denied the plaintiffs' motion for leave to file a second amended complaint. Judgment was entered the same day.

Sandy Sykes *pro se* filed a timely notice of appeal from the final judgment. Although the notice of appeal purported to effectuate an appeal on behalf of all plaintiffs, including the estate of

David J. Muir, only Sandy Sykes signed the notice of appeal. Title 28 U.S.C. § 1654 provides that "[i]n all courts of the United States the parties may plead and conduct their own cases personally or by counsel," but the statute does not allow a plaintiff to appear *pro se* where the interests of others are at issue. *Shepherd v. Wellman*, 313 F.3d 963, 970 (6th Cir. 2002). In addition, the administrator of an estate may not litigate claims on behalf of the estate *pro se* if the estate has beneficiaries other than the *pro se* litigant, as is the case here. *See id.* The same rule applies under Ohio state law because allowing a *pro se* litigant to represent others would constitute the unauthorized practice of law. *See Williams v. Griffith*, No. 09AP-28, 2009 WL 2469523, at *4 (Ohio Ct. App. Aug. 13, 2009). Therefore, the only appellant before us is Sandy Sykes in her individual capacity.

In addition to the voluminous record below, we have reviewed Sykes's *pro se* filings on appeal, including her initial appellate brief filed on September 21, 2011, her Amended Appeal filed on October 24, 2011, and her Amended Appeal filed on December 5, 2011. We have considered the nine briefs filed by Appellees, as well as Sykes's two reply briefs. We have also considered Sykes's Motion To Supplement Record On Appeal, filed December 16, 2011. We deny the motion to add additional exhibits to the record because our review is confined to the allegations of the amended complaint and the documents referenced in it.

IV. ANALYSIS

We are sympathetic to the tragic circumstances endured by David Muir, and we recognize the sincerity and passion with which members of his family have pursued this litigation. Having carefully reviewed the record before us, however, we conclude that Sykes cannot prevail on any of the claims included in the amended complaint.

A. Federal tort claims

The Federal Tort Claims Act ("FTCA"), as amended by the Federal Employees Liability Reform and Tort Compensation Act of 1988 ("the Westfall Act"), 28 U.S.C. §§ 1346(b), 2671–2680, provides that a suit against the United States shall be the exclusive remedy for persons who wish to bring claims for damages resulting from negligent acts of federal employees committed within the scope of their employment. *See Dolan v. United States*, 514 F.3d 587, 593 (6th Cir. 2008). Where the Attorney General, through his designee, the United States Attorney, 28 C.F.R. § 15.3, certifies that a defendant federal "employee was acting within the scope of his office or employment at the time of the incident out of which the claim arose," 28 U.S.C. § 2679(d)(1), it is appropriate for the court to substitute the United States as the sole defendant, and thereafter, the court must assess the plaintiff's claims under the FTCA. *Dolan*, 514 F.3d at 593. The district court followed the proper procedures when it substituted the United States as the sole federal defendant and dismissed the individual defendants from the suit.

The district court ruled that, for purposes of the FTCA, any tort claims accrued at the latest on the date of David Muir's death on February 6, 2004. A tort claim against the United States is barred unless it is presented in writing to the appropriate federal agency within two years after the claim accrues. 28 U.S.C. § 2401(b). Sykes filed an administrative claim (Standard Form 95 or SF 95) with the VA dated December 23, 2005, alleging that Dr. Charles Mendenhall engaged in deceit and coercion to enroll Muir in VA drug trials without his informed consent, which eventually led to Muir's wrongful death. Sykes amended the SF 95 on May 4, 2006, to add the claim that the VA failed to safeguard Muir's rights and welfare. The VA denied the amended SF 95 by letter dated February 5, 2008. Sykes requested reconsideration, which the VA denied by letter dated

December 11, 2008. The denial letter informed Sykes that she had six months from the date of the letter to file suit in federal court. *Id.*; 28 U.S.C. § 2401(b). Thus, Sykes was required to file suit no later than June 11, 2009, but the original complaint was not filed until October 4, 2010, sixteen months after the deadline. Although Sykes filed six additional SF 95s with the VA expanding upon her various claims, none of them were filed within two years after Muir's death. Therefore, we agree with the district court that the tort claims asserted in the amended complaint were time-barred due to the two-year and the six-month filing limitations of the FTCA. *See Ellison v. United States*, 531 F.3d 359, 361–62 (6th Cir. 2008).

On appeal, Sykes argues that the SF 95 she filed with the VA dated February 19, 2010, was not a duplicate SF 95 as alleged by the United States. She also contends that the objections and exhibits she filed below in response to the R & R provided evidence that the VA failed to investigate any of the SF 95s she submitted, requiring her to engage in a six-year investigation to uncover the fraudulent scheme to enroll Muir in biomedical research without his knowledge and consent. These arguments, even if accepted as true, cannot change the fact that Sykes submitted the February 19, 2010 SF 95 to the VA more than six years after Muir's death, well after the two-year period for filing administrative claims had expired. *See id.* All of the SF 95s that Sykes filed on or after March 25, 2008, are time-barred. *See id.*

Sykes contends that the district court erred in determining that the doctrine of equitable tolling does not apply to the administrative tort claims she filed. While we acknowledge the debate in the federal courts concerning whether the FTCA time limitations are jurisdictional and therefore not amenable to equitable tolling after *John R. Sand & Gravel Co. v. United States*, 552 U.S. 130 (2008), we need not resolve that question to decide this case. Even assuming equitable tolling

applies, Sykes has not shown her entitlement to equitable tolling. She argues on appeal that, despite all due diligence, she was "unable to obtain complete and unredacted copies of David J. Muir's Scientific Research Records to ascertain who sponsored the Human Experiments he was enrolled into beginning on May 15, 2000, two months after becoming a [VA] patient." This assertion is not sufficient to establish entitlement to equitable tolling because Sykes has not attempted to satisfy at least four of the five factors relevant to the equitable tolling analysis: "(1) lack of actual notice of the filing requirement; (2) lack of constructive knowledge of the filing requirement; (3) diligence in pursuing one's rights; (4) absence of prejudice to the defendant; and (5) a plaintiff's reasonableness in remaining ignorant of the notice requirement." *Glarner v. United States Dep't of Veterans Admin.*, 30 F.3d 697, 702 (6th Cir. 1994). Because Sykes had either actual or constructive knowledge of the filing requirements, and because she has not explained why the alleged lack of medical records prevented her compliance with the FTCA's deadlines, the district court did not err in refusing to apply equitable tolling to excuse the late filing of SF 95s with the VA and the late filing of the original complaint.

The tort claims Sykes asserted against the United States are barred by the time limitations within the FTCA and Sykes has not shown entitlement to equitable tolling. Therefore, the district court properly dismissed those claims.

B. Civil rights claims

1. Federal defendants

To the extent Sykes asserted constitutional claims for damages against the United States and the individual federal defendants in their official capacities, her claims fail as a matter of law. The assertion of constitutional claims against the individual federal defendants as agents of the United

States is, in effect, a suit against the United States. *Blakely v. United States*, 276 F.3d 853, 870 (6th Cir. 2002). The United States has not waived its sovereign immunity in suits for money damages because of alleged constitutional violations. *See id.*; *Davis v. U.S. Dep't of Justice*, 204 F.3d 723, 726 (7th Cir. 2000).

In addition, the amended complaint did not state that the individual defendants were sued in their individual capacities as federal government agents, but even if they were, the plaintiffs failed to allege any viable claims against them under *Bivens v. Six Unknown Agents of the Fed. Bureau of Narcotics*, 403 U.S. 388 (1971). A *Bivens* action is governed by the same personal injury statute of limitations that applies to a § 1983 action. *McSurely v. Hutchison*, 823 F.2d 1002, 1005 (6th Cir. 1987). In Ohio cases, the two-year statute of limitations found in Ohio Rev. Code. § 2305.10 governs. *Browning v. Pendleton*, 869 F.2d 989, 990 (6th Cir. 1989) (en banc). Because suit was brought more than two years after any claims against the individual defendants could have accrued, the *Bivens* claims are time-barred.

2. State defendants

All civil rights claims brought under 42 U.S.C. §§ 1983 and 1985 against the University of Cincinnati Medical Center are barred by Eleventh Amendment immunity. We have previously held that the University of Cincinnati is an arm of the State of Ohio that is immune from suit in federal court. *Johnson v. Univ. of Cincinnati*, 215 F.3d 561, 571 (6th Cir. 2000). Furthermore, "[t]he university's hospital is an agent of the university that is entitled to its immunity from suit in federal court." *Thomson v. Harmony*, 65 F.3d 1314, 1319 (6th Cir. 1995). Therefore, the district court lacked jurisdiction over these claims. To the extent the amended complaint included civil rights claims against the individual defendants in their individual capacities as UCMC employees under

§ 1983 or § 1985, those claims are barred by the Ohio two-year statute of limitations applicable to personal injury actions. *See Browning,* 869 F.2d at 990.

C. Remaining claims

Sykes contends on appeal that the district court erred in determining that the Institutional Review Board was responsible for protecting the rights and welfare of clinical trial participants. Sykes contends, to the contrary, that the study sponsor is responsible for protecting those rights, citing 21 C.F.R. Parts 50 & 812. She asserts that she has been unable to determine who served as sponsor of the clinical trials in which Muir participated because the defendants failed to provide unredacted copies of Muir's medical records that would have disclosed such information.

We resolved a similar argument in *Abney v. Amgen, Inc.*, 443 F.3d 540 (6th Cir. 2006), where we held that "under the FDA's regulatory scheme it is not the pharmaceutical companies that are charged with ensuring trial participants' well being. Rather, it is the Institutional Review Board that is meant to 'protect the rights and welfare' of trial participants during a clinical trial." *Id.* at 551. The district court followed *Abney* and in addition held that any claims against the pharmaceutical defendants would be barred by the statutes of limitations. Ohio Rev. Code §§ 2305.10(A), 2125.02(D). Sykes has not offered a sufficient reason why we should overturn these holdings, nor did she include in her appellate filings any developed arguments concerning any other claims against the pharmaceutical and medical device defendants. Issues mentioned in a perfunctory manner, without any effort to develop them on appeal, are deemed waived. *See McPherson v. Kelsey*, 125 F.3d 989, 995–96 (6th Cir. 1997).

We have carefully reviewed the district court's resolution of Sykes's other claims and find no error. The plaintiffs failed to state a claim under the Freedom of Information Act (FOIA),

5 U.S.C. § 552, because they did not allege that they made a proper FOIA request, that the records requested fall within FOIA, and that they exhausted administrative remedies prior to filing suit in federal court. *See Davis v. City of Dearborn*, No. 2:09-cv-14892, 2010 WL 3476242, *6 (E.D. Mich. Sept. 2, 2010). Specifically, the plaintiffs did not allege that they complied with 38 C.F.R. §§ 1.550–1.562, the FOIA procedures followed by the Department of Veterans' Affairs. Moreover, FOIA does not apply to state entities like UCMC. *See Grand Cent. P'ship, Inc. v. Cuomo*, 166 F.3d 473, 484 (2d Cir. 1999).

Finally, Sykes has not cited any cases to establish that there is a private cause of action under the Declaration of Helsinki. Courts have uniformly held that no private right of action exists under the Declaration of Helsinki. *See e.g.*, *Ammend v. BioPort, Inc.*, 322 F. Supp. 2d 848, 872–73 (W.D. Mich. 2004) (and cases cited therein). Rather, the Code of Federal Regulations governs the conduct of human research in the United States. *See id.*

V. CONCLUSION

The district court properly dismissed the amended complaint under Rules 12(b)(1) and 12(b)(6). We further agree with the district court that permitting the plaintiffs to file a second amended complaint would have been futile for all of the reasons stated in the district court's opinion. Accordingly, we affirm the judgment of the district court.