IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

GERALD MICHAEL RISCOE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 16-2653-CM**
	)	
UNITED STATES OF AMERICA,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM AND ORDER

Pro se plaintiff Gerald Michael Riscoe filed this action pursuant to the Federal Tort Claims Act ("FTCA"), claiming that defendant United States of America/Food and Drug Administration negligently approved a drug—diethylstilbestrol ("DES")—that would cause sexual identity reversal, or what was formerly known as "true hermaphroditism," in offspring. Defendant filed a Motion to Dismiss (Doc. 27), arguing that the court lacks subject matter jurisdiction over plaintiff's claim and, in any event, the claim is barred by the statute of limitations. For the following reasons, the court grants defendant's motion.

I. Standards of Review

A. Rule 12(b)(1)

Dismissal pursuant to Federal Rule of Civil Procedure 12(b)(1) is appropriate when the court lacks subject matter jurisdiction over a claim. Plaintiff claims that subject matter jurisdiction exists and has the burden of establishing it. *Port City Props. v. Union Pac. R.R. Co.*, 518 F.3d 1186, 1189 (10th Cir. 2008). Because federal courts are courts of limited jurisdiction, however, there is a strong presumption against federal jurisdiction. *Sobel v. United States*, 571 F. Supp. 2d 1222, 1226 (D. Kan. 2008).

Motions to dismiss for lack of subject matter jurisdiction generally take one of two forms: (1) a facial attack on the sufficiency of the complaint's jurisdictional allegations; or (2) a challenge to the actual facts upon which subject matter jurisdiction is based. *Holt v. United States*, 46 F.3d 1000, 1002–03 (10th Cir. 1995). Here, defendant has brought a facial challenge, so the court accepts the plaintiff's factual allegations regarding jurisdiction as true. *Id.* at 1002.

B. Rule 12(b)(6)

To the extent this court has subject matter jurisdiction, the court must determine whether plaintiff's action is subject to dismissal because it fails to state a claim upon which relief could be granted. The court grants a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) only when the factual allegations fail to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "All well-pleaded facts, as distinguished from conclusory allegations, must be taken as true." *Swanson v. Bixler*, 750 F.2d 810, 813 (10th Cir. 1984); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009). The court construes any reasonable inferences from these facts in favor of the plaintiff. *Tal v. Hogan*, 453 F.3d 1244, 1252 (10th Cir. 2006).

II. Discussion

Plaintiff's claim in this case is based on the regulatory actions (or failure to act) of the FDA. Specifically, plaintiff claims that the FDA acted negligently in regulatory matters related to DES, a drug that plaintiff's mother took during her pregnancy in 1952 (among other times). Plaintiff claims that the FDA's actions led to extremely negative side effects for both his mother and him. The court will not repeat the details of these side effects here, as they are not central to the court's decision, and plaintiff has expressed a desire to maintain his privacy.

Based on plaintiff's allegations, there are two alternative and independent reasons why this court must dismiss plaintiff's complaint. First: The government is not liable for a regulatory agency's

performance of its regulatory duties under the FTCA. Second: Plaintiff's claim is time-barred, even allowing for some tolling of the statute of limitations.

A. Subject Matter Jurisdiction

Under the FTCA, the United States waives sovereign immunity for injuries caused by the negligence of a federal employee acting in the scope of employment "under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b). An action under the FTCA is the exclusive remedy for a plaintiff claiming personal injuries arising out of the negligent conduct of a federal employee, 28 U.S.C. § 2679(b)(1), and federal courts have exclusive jurisdiction over such actions, 28 U.S.C. § 1346(b)(1). But the plaintiff bears the burden to show that sovereign immunity has been waived. *James v. United States*, 970 F.2d 750, 753 (10th Cir. 1992) (citation omitted).

Plaintiff claims that defendant waived its sovereign immunity because FDA employees negligently performed their regulatory duties when approving DES. A mere violation of a federal regulation, however, is insufficient to state a claim under the FTCA—there must be some other duty under state law. *Klepper v. City of Milford, Kan.*, 825 F.2d 1440, 1448 (10th Cir. 1987) ("[W]here a negligence claim is based on a violation of a federal statute or regulation, no claim will lie under the FTCA in the absence of some other duty under the applicable state law."). This is because the FTCA itself does not create a cause of action; it only waives immunity "under circumstances that would create liability in the same manner and to the same extent as a private individual under like circumstances." *Dorking Genetics v. United States*, 76 F.3d 1261, 1266 (2d Cir. 1996); *United States v. Agronics Inc.*, 164 F.3d 1343, 1345 (10th Cir. 1999) ("It is virtually axiomatic that the FTCA does not apply where the claimed negligence arises out of the failure of the United States to carry out a federal statutory duty in the conduct of its own affairs.").

The court therefore turns to state law to determine whether defendant has waived its sovereign immunity. In looking to state law, the court applies the substantive law of the state of the negligent government act—not the state of the resulting injury. 28 U.S.C. § 1346(b) (requiring courts to apply "law of the place where the [negligent] act or omission occurred"). This requirement also applies to choice-of-law rules. *Richards v. United States*, 369 U.S. 1, 15 (1962). The FDA's headquarters and many of its operational facilities are in Maryland, leading to the reasonable conclusion that the allegedly negligent acts occurred in Maryland.

Maryland applies the law of the place of injury to substantive legal issues. *Lewis v. Waletzky*, 31 A.3d 123, 129 (Md. 2011). According to plaintiff's complaint and attachments, the place of injury in this case was Missouri. Plaintiff claims that his mother used DES while she was pregnant with him in 1952. She lived in Missouri at the time of the pregnancy, and plaintiff was born in Missouri. The court therefore applies Missouri substantive law to determine defendant's liability under the FTCA.

Plaintiff alleges that the FDA was negligent when it failed to follow federal regulations and statutes in approving and labeling new drugs. Specifically, plaintiff alleges that the FDA "decide[d] that it [did] not need to follow a statute of the United States government, the Food Drug and Cosmetic Act of 1938 ["FDCA"] . . . ." (Doc. 1, at 8.) And the FDA failed to "follow the federal statutes in place especially those that were directly written and passed to guide [the FDA], that statute being the above stated [FDCA]," and that "the Commissioner fail[ed] to follow significant portions of [the FDCA]." (*Id.* at 9.) Plaintiff further alleges that the FDA's approval of DES was "in direct opposition to the aforementioned statute [the FDCA]." (*Id.* at 12.)

The critical problem with plaintiff's allegations is they center on violations of federal law—not state law. "The FDA's performance of its duties under federal law is regulatory activity of a type not cognizable under the FTCA." *In re Zyprexa Prod. Liab. Litig.*, No. 04-MDL-1596, 2007 WL

2332544, at *1–2 (E.D.N.Y. Aug. 15, 2007); *see also Coleman v. State Supreme Court*, 697 F. Supp. 2d 493, 512–13 (S.D.N.Y. 2010) ("Because the FDA's actions in regulating pharmaceuticals are not of the type that a private party could undertake, the FTCA does not authorize the claims that Coleman seeks to bring against the FDA."). Plaintiff has not cited—and the court is not aware of—any Missouri state law that would create liability for negligently exercising regulatory authority to approve new drugs. In the absence of a "private analog" under state law creating liability, the United States cannot be liable under the FTCA. The court lacks subject matter jurisdiction over plaintiff's claim.

A. Statute of Limitations

Even if this court had subject matter jurisdiction over plaintiff's claim, he faces another hurdle: plaintiff's injury occurred sixty-five years ago.

The FTCA provides that a tort claim against the United States "shall be forever barred" unless it is presented to the "appropriate Federal agency within two years after such claim accrues" and then brought to federal court "within six months" after the agency acts on the claim. 28 U.S.C. § 2401(b); *United States v. Kwai Fun Wong*, 135 S. Ct. 1625, 1629 (2015).

"The general accrual rule for FTCA claims is the "injury-occurrence rule," where the tort claim accrues on the date of injury." *Bayless v. United States*, 767 F.3d 958, 964 (10th Cir. 2014). The "discovery rule" is an exception and applies to "'protect plaintiffs who are blamelessly unaware of their claim because the injury has not yet manifested itself or because the facts establishing a causal link between the injury and the medical malpractice are in the control of the tortfeasor or otherwise not evident.'" *Id.* (quoting *Diaz v. United States*, 165 F.3d 1337, 1339 (11th Cir. 1999)). In cases applying the discovery rule, the date of accrual is when a reasonably diligent plaintiff knows or should have known of both the existence of and cause of the injury. *Id.*

According to the attachments to plaintiff's complaint, plaintiff sent an email to the Centers for Disease Control in 2000, suggesting that DES could be responsible for gender dysphoria in children whose mothers took DES while pregnant. Plaintiff stated, "My hypothesis is that large doses of DES (diethylstilbestrol) during a woman's pregnancy with her son feminized the brain." (Doc. 1-20.) Based on plaintiff's representations in this email, at the very latest, the statute of limitations expired on plaintiff's claim in 2002. Assuming that plaintiff adequately sought administrative review of his claim, he did so on January 4, 2016—fourteen years after the latest the statute of limitations could have run. The claim is untimely.

B. Claims for Injuries to Others

It is unclear whether plaintiff attempts to bring claims on behalf of others, including his mother, his deceased father, and his stillborn sibling. To the extent that he attempts to do so, plaintiff lacks standing to bring such claims. And as a pro se plaintiff, plaintiff cannot represent his family members. *See* D. Kan. R. 83.5.1(c). Plaintiff's claims on behalf of others are dismissed.

III. Conclusion

While the court sympathizes with plaintiff's situation, there is not a remedy available at this time from the United States or the FDA. This court is without power to exercise jurisdiction over plaintiff's case against the United States. And even if the court could exercise jurisdiction, plaintiff delayed too long in filing his suit. Because plaintiff's complaint and attachments show that he knew of the existence and cause of his injuries much longer than two years before he administratively exhausted his remedies, plaintiff's claim is barred by the statute of limitations.

IT IS THEREFORE ORDERED that defendant's Motion to Dismiss (Doc. 27) is granted.

The case is closed.

Dated this 20th day of April, 2017, at Kansas City, Kansas.

s/ Carlos Murguia
CARLOS MURGUIA
United States District Judge