

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

EDMUND EDWARD WARD,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.
)	16-12543-FDS
)	
ERNST J. SCHAEFER, M.D.; ROBERT D.)	
SHAMBUREK, M.D.; and ALAN T.)	
REMALEY, M.D.,)	
)	
Defendants.)	
)	

**MEMORANDUM AND ORDER ON DEFENDANTS
SHAMBUREK AND REMALEY’S MOTION TO
SUBSTITUTE THE UNITED STATES AS DEFENDANT**

SAYLOR, J.

This is a tort and *Bivens* action arising out of the use of a drug in a compassionate-use protocol. Plaintiff Edmund Edward Ward suffers from a rare genetic deficiency that has resulted in, among other things, severe kidney disease. He alleges that he was fraudulently induced to participate in what he contends was a non-therapeutic, experimental drug trial. He alleges that he was led to believe that the drug, ACP-501, would reverse his kidney disease, but that defendants’ true purpose in treating him was to gain data that would be beneficial in selling the company that produced the drug.

Ward has filed suit against two physicians with the National Institutes of Health, Dr. Robert Shamburek and Dr. Alan Remaley, who were involved in the treatment protocol. Shamburek and Remaley have moved to dismiss the claims against them and substitute the United States as defendant pursuant to the Westfall Act, 28 U.S.C. § 2679(d). For the reasons stated below, that motion will be granted in part and denied in part.

I. Background

A. Factual Background

The facts, as alleged in the complaint, are set out fully in the Court’s prior Memorandum and Order on Defendants’ Motions to Dismiss for Failure to State a Claim and for Lack of Personal Jurisdiction. As is relevant here, the facts are as follows.

Edmund Edward Ward was born with an extremely rare genetic deficiency of a bloodstream enzyme, called lecithin-cholesterol acyltransferase (“LCAT”). (Compl. ¶ 9). As a result of his deficiency, referred to as “familial LCAT deficiency” or “FLD,” Ward produces virtually no cholesterol. (*Id.* ¶ 9). He also suffers from other associated health conditions, including kidney disease. (*Id.*). He is in stage 5 kidney failure, and receives dialysis treatment three times a week. (*Id.*).

Defendants Robert Shamburek and Alan Remaley are physicians employed by the United States Department of Health and Human Services, National Institutes of Health (“NIH”), in Bethesda, Maryland. (*Id.* ¶ 4).

The complaint alleges that defendants induced Ward to participate as the only subject in an experimental trial of a drug, ACP-501. (*Id.* ¶¶ 22). According to the complaint, defendants misrepresented to Ward that the drug would reverse his advanced kidney disease, while hiding their true motivations of establishing the drug’s safety and efficacy in increasing the production of high-density lipoprotein cholesterol (“HDL-C”)—the so-called “good cholesterol”—in order to facilitate the sale of the drug to a large pharmaceutical company, from which the defendants allegedly stood to benefit financially. (*Id.* ¶¶ 11, 22, 23, 45-47). The complaint alleges that Ward’s kidney function ultimately deteriorated, and that he withdrew from the trial at the advice of his treating physician. (*Id.* ¶¶ 59, 61).

B. Procedural Background

Ward filed the complaint in this action in July 2016, in Massachusetts state court. The complaint alleges claims for fraud (Count One); lack of informed consent (Count Two); unjust enrichment (Count Three); violations of the Due Process Clause of the United States Constitution, the Massachusetts Declaration of Rights, and the Nuremberg Code (Count Four); violation of the Massachusetts Civil Rights Act (Count Five); and civil conspiracy (Count Six) against all defendants.

On December 16, 2016, defendants Shamburek and Remaley removed the action to this Court pursuant to the Westfall Act, 28 U.S.C. § 2679(d)(2). On February 23, 2017, Shamburek and Remaley moved, again pursuant to the Westfall Act, to substitute the United States as the proper defendant. For the reasons stated below, that motion will be granted in part and denied in part.

II. Legal Standard

The Westfall Act provides that the remedy against the United States under the Federal Tort Claims Act (“FTCA”) “for injury . . . arising or resulting from the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment is exclusive of any other civil action or proceeding for money damages by reason of the same subject matter against the employee whose act or omission gave rise to the claim” 28 U.S.C. § 2679(b)(1). However, that restriction does not apply to claims for violations of the United States Constitution. 28 U.S.C. § 2679(b)(2)(A).

The Act also provides for the removal from state court of actions against employees of the federal government “[u]pon certification by the Attorney General that the defendant 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)(2). Upon removal, “[s]uch action or proceeding shall be deemed to be an action or proceeding brought against the United States under the provisions of this title . . . , and the United States shall be substituted as the party defendant.” *Id.* Certification by the Attorney General alone is “sufficient to substitute the United States as defendant and dismiss the federal employees from the case, [however] the certification is ‘provisional and subject to judicial review.’” *Velez-Diaz v. Vega-Irizarry*, 421 F.3d 71, 75 (1st Cir. 2005) (quoting *Davric Me. Corp. v. United States Postal Serv.*, 238 F.3d 58, 65 (1st Cir. 2001)). The employees may later be re-substituted as the party defendants if the plaintiff is able to establish that the employees acted outside of the scope of their employment. *Id.*

III. Analysis

Defendants Shamburek and Remaley have moved, pursuant to 28 U.S.C. 2679(d), to be dismissed as named defendants in this case and for the United States to be substituted as the party defendant. They have provided a certification from Acting United States Attorney William Weinreb stating that Shamburek and Remaley were “acting within the scope of their employment as employees of the United States at the time of the alleged incident.” (Def. Ex. 1). Under the Act, that certification is sufficient for the United States to be substituted, as least provisionally, as the party defendant in this case. *See Velez-Diaz*, 421 F.3d at 75.

However, plaintiff contends that substitution is inappropriate as the complaint alleges, in addition to a number of state-law claims, that Shamburek and Remaley violated his rights under the Due Process Clause of the Fifth Amendment to the United States Constitution. While plaintiff is correct that the Westfall Act does not apply to claims alleging constitutional violations, *see* 28 U.S.C. § 2679(b)(2)(A), that does not preclude the substitution of the United

States as to the non-constitutional claims. “[T]he fact that this case raises both state law and federal constitutional claims does not render inapplicable the Westfall Act’s requirement for the substitution of the United States for the defendants with respect to the state law claims.” *Velez-Diaz*, 421 F.3d at 76. “Indeed, courts routinely order Westfall Act substitution of the United States as the defendant for state law claims when both state law and federal constitutional damage claims are asserted against federal employees.” *Id.* (citing cases). Accordingly, the United States will be substituted as the party defendant as to the state-law claims, while Shamburek and Remaley will remain party defendants as to the constitutional claim only.

Plaintiff also contends that discovery should be permitted prior to substitution in order to determine whether Shamburek and Remaley were in fact acting within the scope of their employment at the time of the alleged incident. He contends that Shamburek and Remaley have failed to submit sufficient evidence to support that they were acting within the scope of their employment. (Pl. Opp. at 8). However, no such evidence is required in order to warrant substitution. As the First Circuit explained in *Velez-Diaz*, substitution is required under the Act upon certification, “and the defendants may be re-substituted later if the court determines that they were not acting within the scope of their federal employment.” 421 F.3d at 76. Because Shamburek and Remaley have submitted the required certification, substitution is appropriate.

IV. Conclusion

For the foregoing reason, the motion of defendants Robert Shamburek and Alan Remaley to dismiss the claims against them and substitute the United States as defendant is GRANTED in part and DENIED in part, as follows:

1. The motion is granted as to Counts One (fraud), Two (informed consent), Three (unjust enrichment), Five (Massachusetts Civil Rights Act), and Six (conspiracy);

2. The motion is granted as to Count Four to the extent that it alleges claims for violations of state law, and denied to the extent it alleges claims for violations of the United States Constitution.

So Ordered.

Dated: July 10, 2017

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge