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

UNITED STATES OF AMERICA, ex rel. STEPHEN A. KRAHLING and JOAN A. WLOCHOWSKI,	:	CIVIL ACTION NO. 10-CV-4374
Plaintiffs,	:	
v.	:	
MERCK & CO.,	:	
Defendant.	:	

UNITED STATES' STATEMENT OF INTEREST
ADDRESSING MERCK'S MOTION TO DISMISS

The United States submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to an argument made by Merck in its Motion to Dismiss the Relators' Amended Complaint. The United States remains a real party in interest in this suit under the False Claims Act, 31 U.S.C. §§ 3729-3733, with a strong interest in the outcome, even though it has not intervened in the case. *United States ex rel. Mergent Serv. v. Flaherty*, 540 F.3d 89, 93 (2d Cir. 2008). The False Claims Act is the primary statute on which the Federal Government relies to combat fraud against the public fisc and to recover taxpayer dollars lost to fraud or false claims. The Government therefore has a keen interest in the development of the law in this area and in the correct application of that law in this and similar cases.[1]

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[1] The Government's decision not to intervene should not be interpreted as a comment on the merits of plaintiff's claims. *See United States ex rel. Spay v. CVS Caremark Corp.*, No. 09-4672, 2012 WL 6645537, at *14 n.3 (E.D. Pa. Dec. 20, 2012); *accord, e.g.*, *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) ("We do not assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrong doing insufficient or the *qui tam* relator's allegations for fraud

This Statement of Interest addresses Merck's argument that the Relators' Amended Complaint must be dismissed because "suits by private citizens – as distinguished from the [G]overnment – may not be premised either on a manufacturer's fraud on the FDA or on a contention that a manufacturer has violated an FDA regulation." (Mem. Supp. Mot. Dismiss at 16.) If the Court dismisses any of the Relators' claims on other grounds, the Court need not consider the legal issues discussed herein. The United States requests, however, that dismissal, if granted on any basis, be without prejudice to the United States. *See United States ex rel. Williams v. Bell Helicopter Textron, Inc.*, 417 F.3d 450, 455-56 (5th Cir. 2005).[2]

BACKGROUND

In their Amended Complaint, the Relators allege that: (1) Merck misrepresented, in its mumps vaccine label and elsewhere, that its mumps vaccine is more effective than Merck knows it to be; and (2) Merck has knowingly failed to disclose the vaccine's diminished efficacy to both the Food and Drug Administration ("FDA"), the agency responsible for overseeing the licensing, approval, labeling, manufacturing and distribution of vaccines, and to the Centers for Disease Control and Prevention ("CDC"), the agency responsible for the Government's purchases of vaccines and for educating the public on the safety and efficacy of vaccines. (Am. Compl. at ¶¶ 1-4, 102.)

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to be without merit. In any given case, the government may have a host of reasons for not pursuing a claim."); *United States ex rel. Chandler v. Cook County, Ill.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002) ("There is no reason to presume that a decision by the Justice Department not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney.").

[2] Merck also does not seek dismissal with prejudice to the United States. (Mem. Supp. Mot. Dismiss at 17 n.10.)

The Relators further allege that Merck owed duties not only to provide the FDA and the CDC with accurate information regarding the efficacy of Merck's mumps vaccine but also to comply with the Food, Drug, and Cosmetic Act and FDA regulations that require Merck to ensure that its mumps vaccine label is not false or misleading. (*Id.* at ¶¶ 107, 112-114, 117.) According to Relators, had Merck reported, in its mumps vaccine label and elsewhere, information that Merck knew concerning the diminished efficacy of its mumps vaccine, such information would have affected, or had the potential to affect, the Government's decisions relating to the purchase of the vaccine. (*Id.* at ¶¶ 4, 145.) On this basis, the Relators claim that Merck has violated the False Claims Act and is liable to the Government for the money that the Government has spent on Merck's mumps vaccine. (*Id.* at ¶¶ 7, 149.)

On April 27, 2012, the United States declined to intervene in the Relators' case. Thereafter, the Relators proceeded with the action. Merck moves to dismiss the action because, according to Merck, "suits by private citizens – as distinguished from the [G]overnment – may not be premised either on a manufacturer's fraud on the FDA or on a contention that a manufacturer has violated an FDA regulation." (Mem. Supp. Mot. Dismiss at 16.) As discussed below, this argument should be rejected because the False Claims Act expressly authorizes private citizens to bring suits on behalf of the Government, and carving out an exception for suits arising from allegations of fraud on the FDA or conduct in violation of FDA regulations is not supported by the statutory text or case law and is inconsistent with the purposes of the False Claims Act.

DISCUSSION

I. Private Citizens May Litigate False Claims Act Suits Such As This.

The whistleblower, or *qui tam*, provisions of the False Claims Act allow private citizens, known as relators, to bring suits on behalf of the Federal Government to enforce the statute. More specifically, the statute provides that a person may bring an action "for the person and for the United States Government" in the name of the United States. 31 U.S.C. § 3730(b)(1). The statute further provides that the United States may intervene and assume the primary responsibility for litigating the action, or the United States may decline to intervene, in which case the relator "shall have the right to conduct the action." 31 U.S.C. § 3730(b)(4). In this case in which the United States declined to intervene, the Relators are litigating the action as contemplated and expressly authorized by the statute.

These Relators, in seeking to recover fraudulently obtained taxpayer dollars, "stand[] in the [G]overnment's shoes." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 (11th Cir. 2006). Even in cases in which the United States declines to intervene, at least seventy percent of the recovery in a False Claims Act suit brought by a relator is returned to the Government. Of the $4.9 billion in fiscal year 2012 recoveries under the False Claims Act, a record $3.3 billion was recovered in suits initiated by relators. Press Release, U.S. Department of Justice, *Justice Department Recovers Nearly $5 Billion in False Claims Act Cases in Fiscal Year 2012* (Dec. 4, 2012) (available at http://www.justice.gov/opa/pr/ 2012/December/12-ag-1439.html).

Congress intended to encourage private citizens to bring suits under the *qui tam* provisions of the False Claims Act because fraud against the Government is usually very difficult to detect without the cooperation of insiders, and the Government's fraud enforcement efforts

can be bolstered by the assistance of insiders and their attorneys in litigating these cases. *See* S. Rep. No. 99-345 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5269, 5273, 5288-89. For a variety of reasons, including limited resources and confidence in a relator's attorney, the Government may exercise its statutory discretion to decline to intervene in, and to allow a relator to litigate, a False Claims Act suit brought on the Government's behalf. Moreover, even if the Government initially declines to intervene in a relator's suit, the Government maintains a degree of control over the litigation and is allowed to intervene later by showing good cause. 31 U.S.C. § 3730(c)(3).

The text of the False Claims Act does not make the viability of a suit by a private citizen dependent on which federal agency was allegedly defrauded, or which federal law affecting the Government's payment of the defendant's claims was allegedly violated. All that is required is an allegation that the defendant's conduct caused false claims to knowingly be submitted. Holding that only the Government, and not a relator, can litigate a False Claims Act suit arising from allegations of fraud on the FDA or conduct in violation of FDA regulations would be inconsistent with the purposes of the False Claims Act. Such an interpretation would discourage insiders from bringing *qui tam* suits exposing fraud against the FDA, and it would require the Government to bear the burden of litigating all False Claims Act suits of this type.

II. Case Law Does Not Support Barring Relators From Litigating Claims Based on Fraud on the FDA or Violation of FDA Regulations.

Because the False Claims Act's text does not bar a relator from litigating a False Claims Act suit alleging that a defendant defrauded the FDA or violated FDA regulations affecting payment of the claims, it is no surprise that Merck cites to no decisions holding that only the Government, and not a relator, can litigate this type of False Claims Act suit. Indeed, the Government is aware of no such holding in a False Claims Act case.

Though Merck relies on *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011) (discussed at pages 26-28 of Merck's Memorandum in Support of its Motion to Dismiss ("Merck's Memorandum")), the Third Circuit in *Wilkins* did not address fraud on the FDA or violation of FDA regulations, nor did it delineate types of false claims that must be prosecuted by the Government as opposed to a relator. In fact, Merck ignores that the *Wilkins* court's holding supports the position that a defendant's failure to comply with FDA regulations, where compliance is a condition of Government payment, renders the defendant's claims false, regardless of whether the case is prosecuted by the Government or a relator. 659 F.3d at 305-06 (holding that a "plaintiff" may bring a False Claims Act suit under the theory of implied false certification liability, which "attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment").

Nor can Merck find support in *United States ex rel. Provuncher v. Angioscore, Inc.*, No. 09-12176-RGS, 2012 WL 3144885 (D. Mass. Aug. 3, 2012) (discussed at page 23 of Merck's Memorandum). The *Provuncher* court did not dismiss the relator on the ground that he was precluded altogether from pursuing a False Claims Act suit involving a violation of FDA regulations. To the contrary, the court held that the relator had failed to sufficiently allege that the medical device at issue was "defective." 2012 WL 3144885 at *1-2.

Also inapposite is *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (discussed at pages 20-23 of Merck's Memorandum). In *Buckman*, the Court did not address the False Claims Act. Rather, it analyzed whether state law fraud-on-the FDA claims were preempted by the federal Food, Drug and Cosmetic Act. Unlike a suit by an individual under state law to recover damages for injuries the individual sustained as a result of alleged fraud

against the FDA, a suit by a relator under the federal False Claims Act seeks to recover damages on behalf of the Federal Government. The United States is a real party in interest in such proceedings and thus there is no risk of a state law conflicting with a federal enforcement regime.

Nor was the False Claims Act addressed in *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) (discussed at pages 24-26 of Merck's Memorandum). In *Sandoz*, the Third Circuit analyzed whether the district court abused its discretion in denying Sandoz's motion for preliminary injunction of its competitor's alleged violation of the Lanham Act. Unlike the Lanham Act, which "is primarily intended to protect commercial interests," 902 F.2d at 230, the False Claims Act is intended to protect the public interest in preventing losses of taxpayer dollars due to fraud against the Federal Government. Also, unlike a Lanham Act case, in which the plaintiff "does not act as a vicarious avenger of the public's right to be protected against false advertising," *id.*, the False Claims Act is specifically designed to allow a relator to stand in the Federal Government's shoes to recover losses that the Government sustained as a result of fraud against the Government. Moreover, unlike in *Sandoz*, in which the plaintiff sought to substitute its judgment for that of the agency's, in this False Claims Act case, to prevail the relators must establish that the alleged conduct had a natural tendency to influence or was capable of influencing the CDC's decision to purchase Merck's mumps vaccine.

The fact that a False Claims Act case may involve omissions to regulatory agencies, discretion in agency action, or violations of regulations does not preclude the action from proceeding. *See United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist.*, 688 F.3d 410, 415 (8th Cir. 2012) (observing that cases including *Wilkins* do not hold that a complex regime of

regulatory sanctions precludes suit under the False Claims Act). In fact, these questions routinely are at the heart of False Claims Act litigation. For example, it is well-established that a defendant's violation of agency regulations may render false a defendant's claims for money from the Government. *See* S. Rep. 99-345 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (a false claim "may take many forms," including "a claim for goods or services not provided, or provided in violation of contract terms, specification, *statute, or regulation*" (emphasis added)). Moreover, judicial interpretation of agency regulations is proper in a False Claims Act case even if the agency has not conclusively determined that the defendant's conduct violated its regulations. *See United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999) (the reasonableness of defendant's interpretation of "unquestionably technical and complex" regulations may be relevant to whether the defendant "knowingly" submitted a false claim, but the meaning of the regulations is "ultimately the subject of judicial interpretation," and it is defendant's compliance with those regulations, as interpreted by the court, that determines whether the defendant's conduct resulted in the submission of a "false claim" under the False Claims Act).

Furthermore, courts have allowed relators to litigate False Claims Act suits based on a defendant's alleged failure to disclose information to a federal agency that, if disclosed, would have affected the Government's decision to pay money to the defendant. *See, e.g., United States ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 79-80 (2d Cir. 2012) (liability based on false statements or omissions to National Institutes of Health). Courts also have permitted False Claims Act suits by relators to proceed on the theory that claims for payment for drugs or medical devices were false because the claims were for uses of the drugs or devices that the FDA had not approved. *See, e.g., United States ex rel. Bui v. Vascular Solutions, Inc.*, No. 1:10-cv-

00883 (W.D. Tex. Mar. 7, 2013) (Exhibit A) (Government stated claim for violation of the False Claims Act based on defendant's alleged promotion of device for use not approved by the FDA); *United States ex rel. Colquitt v. Abbott Labs.*, No. 3:06-cv-1769-M, 2012 WL 1081453, at *31 (N.D. Tex. Mar. 30, 2012) (relator stated claim for violation of the False Claims Act based on defendant's alleged promotion of devices for uses not approved by the FDA).

There is nothing unique about a case involving false statements to the FDA that would warrant creating a special rule precluding such suits from going forward. To the contrary, allowing relators to prosecute such False Claims Act suits (as long as sufficiently pleaded) serves the primary purposes of the *qui tam* provisions.

CONCLUSION

For the reasons stated above, the United States opposes Merck's argument that False Claims Act suits by relators cannot be premised on a manufacturer's fraud on the FDA or violation of FDA regulations.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that today, May 20, 2013, I served, by email and ECF, a copy of the foregoing *United States' Statement of Interest Addressing Merck's Motion to Dismiss* on the following counsel:

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