

FCA violations arise from BlueWave's marketing of laboratory tests for two laboratory companies, Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"), between 2010 and 2015. The Government has alleged that Defendants violated the FCA when they engaged in multiple kickback schemes to induce physicians to refer blood samples to HDL and Singulex for large panels of blood tests, many of which were medically unnecessary. For example, the Government alleges that Defendants offered and facilitated the payment of processing and handling ("P&H") fees to physicians to induce referrals in violation of the AKS and FCA.

II. Discussion

As issue are the following to requests for production made by Defendant Mallory to the United States of America:

RFP 26: Produce all documents relied upon or considered by OIG in determining to issue the "Special Fraud Alert: Laboratory Payments to Referring Physicians" Dated June 25, 2014.

RFP 27: Produce all documents, including all emails, correspondence or other communications, exchanged between DOJ and OIG relating to the issuance of the "Special Fraud Alert: Laboratory Payments to Referring Physicians" dated June 25, 2014.

In its previous order, the Court determined that *in camera* review of documents responsive to these two requests was necessary for the following reasons:

HHS's internal communications about the decision to issue the Special Fraud Alert may be relevant to the reasonableness of the Defendants' actions, positions, or interpretations with regard to their determination that the claims at issue were not tainted by an illegal kickback scheme. *See United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 564 (E.D. Va. 2003) ("[B]oth the clarity of the regulation and the reasonableness of a contractor's interpretation are relevant in deciding whether a failure to disclose charging practices is indicative of a reckless disregard of their falsity."); *see also US ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 316 (S.D.N.Y. 2011), *aff'd sub nom. Colucci v. Beth Israel Med. Ctr.*, 531 F. App'x 118 (2d Cir. 2013) ("[W]hether a claimant acted knowingly in submitting a false claim turns on 'the reasonableness of [the

claimant's] interpretation.”) The Court finds that the requested documents may be relevant to defendants’ scienter even if defendants were not aware of the content of the Government’s internal communications. *See SEC v. Kovzan*, No. 11-2017-JWL, 2012 WL 4819011, at *4 (D. Kan. Oct. 10, 2012) (disagreeing with Magistrate’s determination that “scienter relates to what defendant knew or should have known, and that therefore information may be relevant to scienter only if known to the public or to defendant” and allowing discovery of “internal [SEC] documents concerning a final decision as to what guidance, if any, the SEC staff may provide to reporting companies regarding the meaning of the perquisite disclosure regulations and the definition of internal control over financial reporting.”).

Having determined that the Government’s internal deliberations leading up to their decision to issue the Special Fraud Alert may be relevant to Defendant’s scienter, the Court must decide whether Defendants’ interest in discovering the documents outweighs the government’s interest in confidentiality. Courts consider the following factors to determine whether the defendant’s interest in a particular document outweigh[s] the government’s need for confidentiality: (1) the relevance of the document to the litigation; (2) the availability of other evidence; (3) the government’s role in the litigation; (4) the seriousness of the litigation; and (5) the extent to which disclosure would chill future deliberations. *FDIC v. Giancola*, 2015 WL 5559599, *5-6 (N.D. Ill. Sept. 18, 2015) (citations omitted). The Court has no trouble finding that the Government’s role in this litigation is significant and that the litigation is serious. While other evidence is surely available that would shed light on whether Defendants’ interpretation was reasonable, internal government discussions about the need to issue further guidance may contain particularly strong evidence on this point. The Court is also cognizant of the obvious risk that “officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news.” *Dep’t of Interior v. Klamath Water Users Protective Ass’n*, 532 U.S. 1, 8-9 (2001).

(Dkt. No. 494 at 10-12.) The Court has reviewed the documents submitted for in camera review and determined that the overwhelming majority need not be produced because Defendants’ interest in obtaining them is so negligible as to be insufficient to override the Government’s interest in confidentiality. Representative, but not exhaustive, categories of documents include: (1) numerous circulations of drafts of the Special Fraud Alert (“SFA”) with edits and comments that do not contain information that supports Defendants’ arguments with regard to their scienter; (2) agendas and other documents that mention the existence of the SFA but have nothing to

do with its substance or the decision to issue it; and (3) discussions about the logistics of shepherding the SFA through the necessary channels for approval; and (4) duplicates of the first three categories.

The Court finds that Defendants' interest in obtaining the following documents outweighs the Government's need for confidentiality due to the seriousness of this litigation, the Government's role in the litigation, and the potential relevance of these documents to Defendants' argument that they did not have the requisite scienter to be liable for the Government's allegations.¹ For documents responsive to Mallory's RFP Nos. 26 and 27, the Government should produce the following, including entire document families as well as any near-duplicates of the documents described:

From RFP 26 [InCam26-0000001 to InCam26-0001921]

- 0000001: Civil Frauds Report of Investigative Action dated July 18, 2011
- 0000014: Memorandum of Special Fraud Alert dated May 1, 2014
- 0000080: Informational Briefing Notes on Special Fraud alert dated July 11, 2014
- 0000835: Letters from various defendants explaining their understanding of the legality of certain payment practices in response to the Government's position paper.
- 0000905; 0000920: Documents concerning requests from law firms for a special fraud alert about laboratory relationships.

From RFP 27 [InCam27-0000001 to InCam270000984]

- 0000030; 0000080: Internal government communications about the need for a Special Fraud Alert.

¹ The Government has not submitted to the Court that these documents are subject to any other privilege or protection.

- 0000850: White Paper on P&H fees from the Centers for Medicare and Medicaid Services authored by Daniel Duvall

III. Conclusion

The Government is hereby ordered to produce documents to Defendants consistent with this order.

AND IT IS SO ORDERED.



Richard Mark Gergel
United States District Court Judge

August 22, 2017
Charleston, South Carolina