UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

YOASH GOHIL ON BEHALF OF THE UNITED STATES OF AMERICA, Plaintiff/Relator v. SANOFI-AVENTIS U.S. INC.; AVENTIS, INC., AVENTIS PHARMACEUTICALS, INC., and JOHN DOES #1-50, FICTITIOUS NAMES, Defendants.	CIVIL ACTION NO. 02-2964 (LFS)

ORDER GRANTING PLAINTIFF/RELATOR'S
MOTION TO COMPEL AND FOR APPLICATION OF THE CRIME-FRAUD EXCEPTION

THIS MATTER having been brought before the Court on Plaintiff/Relator Yoash Gohil's Motion to Compel and for Application of the Crime-Fraud Exception, and any response thereto;

IT IS on this _____ day of _____, 2016 **ORDERED** that Plaintiff/Relator Yoash Gohil's Motion is **GRANTED** and Defendant shall produce the following documents to Plaintiff within thirty (30) days of the entry of this **ORDER**:

1. All documents produced by ex-Rhone-Poulenc Rorer ("RPR") employee Elaine Decembrino to Blank Rome LLP in 2007, including any documents which Aventis claims are privileged;

2. All documents relating to communications about Ms. Decembrino between and/or among Aventis/RPR attorneys and management from 1996 to 2004; and

3. All documents relating to any investigations, reviews, and/or inquiries, whether done by counsel or not, of Decembrino's allegations about off-label marketing, the alteration or destruction of records, and/or EM-32 forms from 1996 to 2004.

IT IS FURTHER ORDERED that Plaintiff/Relator shall be permitted to use all of the aforementioned documents in pretrial proceedings, without restriction.

IN THE ALTERNATIVE, IT IS ORDERED that Aventis shall produce to the Court, for *in camera* review and a determination as to whether the crime-fraud exception applies, all of the above documents over which Aventis claims any privilege and that (1) relate to any investigation, inquiry, and/or review made in response to FDA communications and warnings to Aventis/RPR; (2) relate to Aventis/RPR's responses to the FDA communications and warnings; or (3) are among the documents Elaine Decembrino provided to counsel for Plaintiff/Relator.

HONORABLE LAWRENCE F. STENGEL, U.S.D.J.

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UNITED STATES DISTRICT COURT
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PLAINTIFF/RELATOR YOASH GOHIL'S MOTION TO COMPEL AND FOR APPLICATION OF THE CRIME-FRAUD EXCEPTION

Plaintiff/Relator Yoash Gohil ("Gohil"), by and through his undersigned counsel, respectfully moves this Court for an Order compelling Defendant Sanofi-Aventis U.S. Inc. ("Aventis") to produce:

1. All documents produced by ex-Rhone-Poulenc Rorer ("RPR") employee Elaine Decembrino to Blank Rome LLP in 2007, including any documents which Aventis claims are privileged;

2. All documents relating to communications about Ms. Decembrino between and/or among Aventis/RPR attorneys and management between 1996 and 2004; and

3. All documents relating to any investigations, inquiries, and/or reviews about Decembrino's allegations of off-label marketing, the alteration or destruction of records, and/or EM-32 forms between 1996 and 2004.

Gohil also moves for an Order allowing him to use all of the aforementioned documents in pretrial proceedings, without restriction.

In the alternative, Gohil moves for an Order requiring Aventis to produce to the Court, for *in camera* review and a determination as to whether the crime-fraud exception applies, all documents over which Aventis claims privilege and which (1) relate to any investigation, inquiry, and/or review made in response to FDA communications and warnings to Aventis; (2) relate to Aventis's responses to the FDA communications and warnings; or (3) were provided to counsel for Plaintiff/Relator by Elaine Decembrino. Not only are these documents relevant to and admissible in this lawsuit, but any privilege Aventis claims over them has been forfeited by the crime-fraud exception to the attorney-client privilege.

In support of this Motion, Relator relies upon and incorporates the attached Memorandum of Law, Declarations of Nicholas C. Harbist, Esquire and Yoash Gohil, and proposed Order.

Respectfully submitted,

s/ Stephen M. Orlofsky

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF/RELATOR YOASH GOHIL'S MOTION TO COMPEL AND FOR APPLICATION OF THE CRIME-FRAUD EXCEPTION

Aventis's own records reveal that it engaged in an ongoing scheme to fraudulently market Taxotere and other drugs between 1996 and 2004. It actively concealed and covered up this

scheme by making misrepresentations to and concealing material facts from the FDA as well as destroying corporate records. In order to further forestall scrutiny by the FDA, Aventis partially revealed the results of its investigations and reviews in response to FDA warnings, claiming that any transgressions cited by the FDA were mere mistakes, and pledged to fully comply with FDA marketing regulations.

But Elaine Decembrino ("Decembrino"), an ex-RPR employee, turned over 3,000 pages of documents (the "Decembrino Documents") to counsel for Relator, Declaration of Nicholas C. Harbist ("Harbist Dec.") ¶2, which conclusively refute Aventis's[1] claims of mistakes, and show that it engaged in a scheme to fraudulently promote Taxotere and other drugs for unapproved uses as far back as 1996.[2] The Decembrino documents further demonstrate that Aventis instructed various employees to destroy or otherwise alter corporate records evidencing these unlawful acts. Aventis asserts, however, that all but 17 of the Decembrino documents are either privileged or irrelevant and demands their return. Richard L. Scheff Letters, Harbist Dec. Ex. B.

Aventis's position is untenable. First, its instructions to RPR employees to conceal evidence of off-label marketing from the FDA are not privileged. Second, Aventis's instructions

[1] In 1995, Hoechst AG acquired Marion Merrell Dow Inc. and changed its name to Hoechst Marion Roussel, Inc. In 2000, Hoechst Marion Roussel, Inc. changed its name to Aventis Pharmaceuticals Inc. In 2001 Rhone-Poulenc Rorer Inc. ("RPR"), which is now known as Aventis Inc., and Aventis Pharmaceuticals Inc. combined certain parts of their businesses. Answer, D.E. 158 ¶5. Collectively, these entities will be referred to as "Aventis."

[2] Elaine Decembrino, an employee in RPR's marketing department between 1986 and 1997, was a plaintiff in an action against RPR filed in June 1998, in which she and her co-plaintiff alleged that RPR engaged in a scheme to promote Lovenox for off-label uses, they were told by RPR's legal department to destroy or conceal evidence of the company's off-label promotion of Lovenox, Nasacort AQ, ***and Taxotere***, and were harassed by other employees when they protested. *See* Complaint in *Conolly v. Rhone-Poulenc Pharmaceutical, Inc.*, Harbist Dec. Ex. D, ¶¶13-36. They also alleged that RPR used a company called Genecom "as a conduit for illegal payments to speakers whose function was to promote Off-Label use of Lovenox in the medical community." *Id*. ¶17. According to their complaint, almost two thirds of Lovenox sales in 1996 were based on off-label uses and the Lovenox sales goals for that year could not be obtained without promoting the drug for off-label uses. *Id*. ¶20. The company tried to place Ms. Decembrino in a sham position from which she could not observe unlawful promotional activities in an attempt to induce her to maintain silence about the unlawful activities. *Id*. ¶35. Ms. Decembrino began copying certain RPR documents when she suspected that RPR was using her to frustrate discovery in another suit against RPR alleging off-label promotion. *Id*. ¶30; Complaint in *Peller v. Rhone-Poulenc Pharmaceutical, Inc.*, Harbist Dec. Ex. T; *see also* WSJ Article, *id*. Ex. FF (discussing various lawsuits against RPR relating to RPR's off-label promotion and concealment thereof and the FDA's investigation of RPR's off-label promotion).

to destroy evidence of its ongoing fraudulent off-label promotion scheme and repeated misrepresentations to the FDA trigger the crime-fraud exception to the attorney-client privilege. Third, even though many of the Decembrino documents concern drugs other than Taxotere, the documents provide probative evidence under FED. R. EVID. 404(b) of Aventis's common scheme or plan—as well as its corporate intent—to promote numerous prescription drugs for unapproved uses and pay illegal kickbacks to healthcare providers in furtherance of that promotion.

The Decembrino documents and other evidence cited herein conclusively establish that Aventis engaged in ongoing criminal and fraudulent acts that forfeit its right to the protection afforded by the attorney-client privilege. The Court should thus compel Aventis to produce and allow Plaintiff to use in pretrial proceedings without restriction:

1. The Decembrino documents in their entirety, including the documents which Aventis now claims are privileged;

2. Documents relating to communications about Decembrino between and/or among Aventis/RPR attorneys and management between 1996 and 2004; and

3. Documents relating to any investigations, inquiries, and/or reviews about Decembrino's allegations of off-label marketing, the alteration or destruction of records, and/or EM-32 forms between 1996 and 2004.[3]

FACTUAL BACKGROUND

During the time frame in Relator's Third Amended Complaint ("TAC"), Aventis engaged in various ongoing crimes and fraud, including but not limited to: (1) misbranding, pursuant to 21 U.S.C. §352;[4] (2) providing unlawful kickbacks to healthcare providers, pursuant to 42 U.S.C.

[3] Plaintiff/Relator makes this request only with respect to those documents from the relevant time period, *e.g.*, 1996-2004. He does not seek any privileged documents relating to Aventis's defense strategy in this litigation.

[4] While the courts have noted that violations of the FDA misbranding statutes and marketing regulations are not the equivalent of filing a false claim under the FCA, evidence of Aventis's violations of these statutes, as well as its own compliance policies—as explained below—is relevant to its corporate intent and reckless disregard for the truth or falsity of the claims. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) (noting that the FDCA's regulatory regime prohibits manufacturers from directly advertising off-label uses, such as through labeling claims or explicit statements made by sales representatives).

§1320a-7b;[5] (3) knowing and willful falsification and concealment of material facts to the FDA, pursuant to 18 U.S.C. §1001(a);[6] and (4) obstruction of a federal agency proceeding, pursuant to 18 U.S.C. §1505.[7]

A. Aventis Cultivated a Culture of Unlawful Drug Promotion Since 1996

On May 14, 1996, the FDA approved Taxotere for the first time, but only for the second-line treatment of metastatic breast cancer.[8] Only a month later, on June 18, 1996, the FDA chastised RPR for promoting "Taxotere in a manner that [was] in violation of the [FDCA] and applicable regulations." 6/18/96 DDMAC Letter at 1, Harbist Dec. Ex. E.[9] Specifically, the FDA found that RPR made "false and/or misleading" safety and efficacy claims about Taxotere and was "concerned that RPR's promotional materials [made] comparisons that [were] unsupported by substantial clinical evidence, [made] conclusions based upon preliminary data and fail[ed] to adequately provide information relating to risks associated with the use of Taxotere." *Id*. It also found that RPR was unlawfully promoting Taxotere for "head and neck cancer," which was not an approved use at the time, and made efficacy claims about that use that had "not been substantiated by substantial clinical evidence." *Id*. at 3.

This finding by the FDA was not isolated. Between 1996 and 2003, the FDA admonished Aventis and its affiliates no less than 20 times for the unsubstantiated, false, misleading, and/or off-label promotion of numerous prescription drugs. *See*, *e.g.*, 4/8/99 DDMAC Letter, Harbist

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[5] *See* n.38 & 39, *infra*, for an explanation of the Anti-Kickback Statute.

[6] This statute prohibits false statements to and/or concealment of material facts from a federal agency and "is intended to promote the smooth functioning of government agencies and the expeditious processing of the government's business by ensuring that those who deal with the government furnish information on which the government confidently may rely." *U.S. v. Arcadipane*, 41 F.3d 1, 4 (1st Cir. 1994).

[7] *See U.S. v. Laurins*, 857 F.2d 529, 537 (9th Cir. 1988) (concealing documents falls within definition of specific intent required for obstruction of an agency proceeding).

[8] Second-line treatment is that which healthcare providers prescribe when initial, or "first-line" treatment, fails.

[9] The FDA's Division of Drug Marketing, Advertisements and Communications (DDMAC) was the enforcement division of the FDA at this time.

Dec. Ex. F (addressing RPR's "false or misleading" promotion of Lovenox);[10] 6/22/00 DDMAC Letter, Harbist Dec. Ex. G (chastising Sanofi-Synthelabo for the unlawful promotion of Eloxatin as viable treatment for colon cancer when, at the time, Eloxatin was an investigational drug and was not approved for any use); *see also* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm (collecting DDMAC letters to Aventis and its affiliates for unsubstantiated or misleading promotion of Arava, Azmacort, Amaryl, Allegra, Lovenox, Taxotere, Nilandron, Rilutek, Nasacort, Plavix, Eloxatin, and Qvar). But at least with respect to Taxotere, Aventis and RPR never disputed these FDA findings of misleading and off-label promotion. In their responses to the FDA, they at times claimed that its fraudulent promotion was the result of mere mistakes and that corrective action would be taken.

For example, Aventis assured the FDA that its off-label promotion was merely inadvertent because the promotional materials "were intended solely for non U.S.-based physicians" and Aventis had "no intention of promoting [off-label uses] to US physicians." 8/8/01 Aventis Letter, Harbist Dec. Ex. H. Aventis also represented to the FDA that it "committed to promoting Taxotere in accordance with FDA regulations," 7/2/96 RPR Letter, *id*. Ex. L; that it "further states its intent comply with [an FDA warning] by reviewing its procedures for the distribution of promotional materials," 10/23/01 DDMAC Letter, *id*. Ex. K at 1; "the use of [unlawful] sales aid[s] ha[d] been discontinued," 12/30/02 Aventis Letter, *id*. Ex. I at 1; "Aventis Pharmaceuticals commits to ensuring that the appropriate limitations to the product's approved indications will be clearly

[10] In this letter, the FDA made reference to an earlier letter dated January 27, 1999 in which it objected to RPR's promotional claim about Lovenox. RPR agreed to revise this "misleading" claim in its promotional material, but it did not and the DDMAC was "especially concerned about the use of this claim in promotion since RPR was previously informed that this claim would be misleading," yet did nothing to correct it. Harbist Dec. Ex. F.

stated," *id*.; Aventis commits "to ensuring that fair balance, brief summary, or full prescribing information is presented for all Taxotere pieces, *id*. Ex. I at 2; Aventis "will ensure that the approved product indications, including any necessary limitations thereto, are also provided as appropriate on all future Taxotere pieces," *id*.; and that Aventis would take steps "to ensure that there [would] be no similar misunderstandings in the future," 2/6/03 Aventis Letter, *id*. Ex. J. In making these misrepresentations, Aventis and RPR sought to conceal from the FDA their ongoing scheme to fraudulently promote Taxotere and other drugs off-label since 1996. But even as late as November 2003, the DDMAC expressed in a "WARNING LETTER" that it "remain[ed] concerned that Aventis continued to provide false or misleading information about Taxotere to patients…despite the multiple communications between DDMAC and Aventis." 11/12/03 DDMAC Letter, *id*. Ex. S at 4.

[redacted]

C. Aventis Promoted Taxotere Unlawfully Since 1996 and Affirmatively Concealed This Off-Label Promotion From the FDA

1. Fraudulent, Off-Label Promotion of Unapproved Breast Cancer Indications

Despite its 1996 representation to the FDA that it was "committed to promoting Taxotere in accordance with FDA regulations," Harbist Dec. Ex. L, an overwhelming majority of Taxotere sales were for off-label uses. Aventis even paid for third-party services to ensure that healthcare providers were reimbursed for these off-label prescriptions. [redacted]; TAC, D.E. 134 ¶¶174-80. On July 26, 2001, the FDA once again found that Aventis promoted an unapproved use of Taxotere, and this time for the first-line treatment of locally advanced or metastatic breast cancer at the May 2001 ASCO national oncology convention. 7/26/01 DDMAC Letter, Harbist Dec. Ex. M.[11] In its responsive letter dated August 8, 2001, Aventis claimed that its unlawful promotion was inadvertent insofar as the off-label promotional material "was intended solely for dissemination to *non*-US-based physicians" and that the exhibit space "was designed to avoid dissemination of inappropriate materials to US-based physicians by dividing the exhibit space into two clearly marked areas—one for US practitioners and one for practitioners from outside the United States, with a divider in between." 8/8/01 Aventis Letter, *id*. Ex. H. Aventis also vowed to "make every effort to ensure that [the sales] piece [would] not be distributed to US-based physicians." *Id*. Based on Aventis's representations, the FDA considered the matter closed. 10/23/01 DDMAC Letter, *id*. Ex. K.

[11] Taxotere has never been FDA-approved for the first-line treatment of breast cancer. *See* http://www.cancer.gov/about-cancer/treatment/drugs/fda-docetaxel.

[redacted]

[12] *See* http://www.cancer.gov/about-cancer/treatment/drugs/fda-docetaxel. Aventis also enlisted the help of physicians to promote Taxotere for unapproved uses. *See* 3/30/01 Email, Harbist Dec. Ex. CC (praising an oncologist for promoting the use of Taxotere in the adjuvant treatment of breast cancer at a speaking event). In some cases, Aventis simply name-dropped physicians to promote Taxotere for unapproved uses. *See*, *e.g.*, 3/8/02 Voicemail, Gohil Dec. Ex. L ("Certainly we can tell folks that [Dr. F] did himself say that he was using Taxotere in the adjuvant setting…").

[13] Again, neither of these uses were approved or reimbursable. *See* http://www.cancer.gov/about-cancer/treatment/drugs/fda-docetaxel.

[redacted][16]

2. Fraudulent Off-Label Promotion of Unapproved Lung Cancer Indications

[redacted] But only months before, on December 21, 2000, the FDA rejected

[14] As VP of Taxotere sales, Mr. Alles was the second highest ranking official in Aventis's oncology division. All area and regional sales managers—nationally—reported to him and he was responsible for implementing Aventis's marketing strategy. Gohil Dec. ¶5.

[15] ASCO, the American Society of Clinical Oncology, hosts annual conventions and other meetings. *See* http://www.asco.org.

[16] Mr. Alles's actions prove that the unlawful promotion scheme was not isolated in Mr. Baffone's territory. So too does Aventis's evaluation of Tim McCready, a Taxotere sales representative in Northern Virginia. *See* 10/18/00 Report, Harbist Dec. Ex. N ("I agreed to show you how to start the call [to the oncologist] by probing [her] on how she treats her breast cancer patients from the *adjuvant setting* to 2nd line MBC…. I stressed her choice in the *1st line setting* was the right choice…and then asked her to think about making that jump into the *adjuvant setting*") (emphasis added).

Aventis's Supplemental New Drug Application (SNDA) for this indication, concluding that Aventis was unable to "establish the evidence of safety and efficacy of docetaxel [Taxotere] in the setting of first-line treatment of non-small cell lung carcinoma with a high level of confidence." 12/18/02 DDMAC Letter, Harbist Dec. Ex. O at 2. Thus, [redacted], Taxotere was not FDA-approved for the first-line treatment of NSCLC. *Id*. at 1-2.

[redacted]

On December 18, 2002, the FDA sent Aventis another letter, this time admonishing it for promoting Taxotere as first-line treatment of NSCLC at the ASCO national oncology convention

in May 2002. Moreover, even though Taxotere was ultimately approved for the first-line combination treatment of NSCLC in November 2002, after the oncology convention, the FDA also criticized Aventis for promoting Taxotere as first-line *monotherapy* for NSCLC, when it was only approved as first-line therapy of NSCLC *in combination with cisplatin*. 12/18/02 DDMAC Letter, Harbist Dec. Ex. O at 1. In this December 18 letter, the FDA also rebuked Aventis for relying on misleading safety and efficacy information when promoting Taxotere for this unapproved use. *Id*. at 3-4.[17]

Aventis again did not dispute the FDA findings. Instead, it assured the FDA that "effective immediately," it would cease using the offending off-label and misleading sales aids and "any similar materials" and it committed "to ensuring that the appropriate limitations to the product's approved indications [would] be clearly stated." 12/30/02 Aventis Letter, *id*. Ex. I; *see also* 1/17/03 Aventis Letter, *id*. Ex. P; 2/6/03 Aventis Letter, Harbist Dec. Ex. J; 8/1/03 Aventis Letter, Harbist Dec. Ex. Q; 8/21/03 Aventis Letter, *id*. Ex. R (describing the allegedly painstaking process Aventis undertook to destroy and cease publication of all of its offending advertisements). Unsurprisingly, despite the FDA's findings, Aventis did not stop its corporate campaign to promote Taxotere for off-label uses through all available means. *See*, *e.g.* Gohil Dec. ¶¶9-10. On November 12, 2003, the FDA once again found that Aventis disseminated promotional materials that made unsubstantiated and misleading efficacy and safety claims about Taxotere. This time, however, the FDA admonished Aventis for distributing these materials directly to vulnerable consumers, who, unlike physicians, had almost no chance of seeing through Aventis's smoke and mirrors. In this letter, the FDA reminded Aventis that it had already been warned about its

[17] Specifically, the FDA found that "Taxotere as a single agent was not indicated as first-line therapy and certainly was not 'at the center of more strategies every day' as claimed in your sales aid. Therefore, Aventis'[s] false or misleading promotion in the sales aid may compromise patient survival and safety." 12/18/02 DDMAC Letter, Harbist Dec. Ex. O at 2.

unlawful promotional materials in December 2002. 11/12/03 DDMAC Letter, Harbist Dec. Ex. S at 1. It also reminded Aventis about the myriad communications between the FDA and Aventis in 2003 in which Aventis repeatedly assured the FDA that it would discontinue the use of and destroy all misleading sales aids. *Id*. at 3.[18] Finally, the FDA demanded that Aventis cease disseminating the misleading consumer sales ads, some of which went so far as to warn cancer patients that "THE NEXT MOVE MAY BE THE KEY TO SURVIVAL." *Id*. at 4-6.

[redacted]

[redacted]

E. Aventis Instructed Its Employees to Destroy and Alter Documents to Conceal Its Unlawful Promotion

As early as 1996, the year in which the FDA sent its first warning letter to RPR regarding Taxotere, Aventis represented to the FDA that it was "committed to promoting Taxotere in accordance with FDA regulations." 7/2/96 RPR Letter, Harbist Dec. Ex. L at 2; 6/18/96 DDMAC Letter, Harbist Dec. Ex. E. In response to the 1998 Conolly/Decembrino lawsuit, *supra* n.2, it also represented to the public that it was "fully committed to complying with all government regulations" and that "[o]ff-label promotion [was not] permitted." *Id.* Ex. FF at 1.[19] Yet, RPR's documents establish its instructions to its employees to alter numerous records referring or relating

[19] This article explains the various lawsuits RPR faced regarding off-label promotion in the late 1990s and provides an account of RPR's legal department directing RPR employees to destroy evidence of off-label promotion. It also mentions yet another way in which RPR attempted to conceal evidence of wrongdoing, i.e., by wiping incriminating files from employees' laptops. Harbist Dec. Ex. FF at 5.

to the off-label promotion of numerous drugs, including Taxotere.[20]

[redacted]

[20] RPR was on notice of potential liability for off-label promotion as of March 1996, when the first of several former employees sued it for retaliation related to its off-label promotional activities. *See Peller* Complaint, Harbist Dec. Ex. T ¶¶6-9 (alleging off-label promotion of Lovenox). Thus, RPR had a motive to destroy incriminating documents and engage in other cover-up activities almost two decades ago, at the *latest*.

[redacted]

[23] These documents depict the promotion of off-label uses of Lovenox and the promotion of Nasacort AQ, which was not FDA-approved for any use at the time. *See* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/Taxotere and GliUCM362809.pdf. The FDA chastised Aventis at least twice for the unlawful promotion of Lovenox, *see* DDMAC Lovenox Letters, Harbist Dec. Ex. V ("DDMAC is especially concerned about the use of this claim in promotion since RPR was previously informed that this claim would be misleading"), and at least once for the unlawful promotion of Nasacort AQ. *See* 8/18/98 DDMAC Letter, *id*. Ex. W. ***Nasacort*** was an approved drug, albeit one RPR also promoted unlawfully, for which the FDA again rebuked it. *See* DDMAC Nasacort Letters, *id*. Ex. X.

[redacted] *id*. at 1 [redacted]; *id*. at 26 [redacted]

Aventis management also instructed its employees to engage in activities to cover up its unlawful manipulation and marketing of the "spread" of Anzemet,[25] which is alleged as a kickback

[redacted].

[25] "The 'spread' is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer…To the extent that a manufacturer controls the 'spread,' it controls its customer's profit…it is illegal for a manufacturer knowingly to establish or inappropriately

inducement in this lawsuit. D.E. 134 ¶130. [redacted]

The Decembrino documents and other available evidence proves that Aventis engaged in an organized effort to conceal its off-label promotional scheme of numerous drugs from the FDA, including Taxotere. Given the available documents, the amount of employees involved in this concerted effort, and the allegations made in Ms. Decembrino's 1998 complaint, Harbist Dec. Ex. D, the Court can reasonably infer that high-level Aventis employees, including in-house counsel, directed employees to destroy evidence of wrongdoing.

maintain a particular [average wholesale price] if one purpose is to manipulate the 'spread' to induce customers to purchase its product." Office of Inspector General, *Compliance Program Guidance for Pharmaceutical Manufacturers* (2003) at 25-27, *available at* http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf; *see also* McCready Action Plan, Harbist Dec. Ex. Z ("The core message[s] regarding Taxotere therapy that must be conveyed are that Taxotere is safe, that it is effective, and that *its proper use is highly profitable to the oncologist's practice*") (emphasis added).

[26] In September 2007, Aventis paid over $190 million to the federal government and several states to settle allegations of fraudulent pricing and marketing of Anzemet. *See* http://www.justice.gov/archive/opa/pr/2007/September/07_civ_694.html.

F. Aventis Gave Unlawful Kickbacks to Healthcare Providers, Despite Its Own Policies

This is not a case where Aventis merely handed out pens and koozies to doctors. According to Aventis policy, Aventis was required to observe the Anti-Kickback ("AKS") law,[28] which "prohibits offering or paying remuneration *as a reward for*, or *to induce*, the purchase, order, or the recommending or arranging for, the purchase or order of a product that is reimbursed by Medicaid or Medicare."

[28] The Third Circuit has long embraced the theory that AKS violations give rise to FCA liability. *See U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004). This is entirely consistent with "Congress's expressly stated purpose that the FCA should 'reach all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services.'" *U.S. ex rel. Wilkins*, 659 F.3d 295, 306 (3d Cir. 2011) (quoting S.Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274, and citing *U.S. v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)). Kickbacks cause providers to make medical decisions based on "the amount of the kickbacks and rebates offered," not based on the patient's best interests or sound medical judgment. *U.S. v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985) (internal quotations omitted).

[redacted]

[redacted]; *id*. at 25-26 [redacted]; *id*. at 27-28 [redacted]; *id*. at 29-30 [redacted]); *id*. at 31-32 [redacted]).[31]

2. Kickbacks Continued as "Return On Investment" Drove All Aventis Marketing

[redacted]

> [redacted]

[redacted]

[redacted]

[32] The Government suffers a financial loss when it pays kickback-tainted claims – it does not get what it paid for. *Wilkins*, 659 F.3d at 314 ("[t]he government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback").

[33] On one occasion, Tim McCready was told to sign off on a $4,733.69 dinner at the Capital Grille. Shockingly, that bill included three gift certificates—two for $100.00 and one for $50.00—which were to be given to a physician. *See* Capital Grille Receipt, Harbist Dec. Ex. BB; [redacted]

[redacted]

Lavish dinners were just the tip of the iceberg at Aventis. Sales representatives routinely offered healthcare providers tickets to concerts and sporting events and other free entertainment for them and their families, all to influence doctors to prescribe Taxotere. *See*, *e.g.*, McCready Action Plan, Harbist Dec. Ex. Z at 3 ("Since Dr. [C] particularly likes basketball, I propose that Aventis [a]uthorize me to secure four good seats to three games and invite Dr. [C] *and his wife* to a series of games so that we have a personal relationship that might allow him to give me some time to work with him on Taxotere"); [redacted]

[redacted]

[redacted]. Sales representatives routinely arranged for grants to physicians and academic institutions, but always with an eye for *return on investment*, in violation of [redacted] the AKS.[38] [redacted]

[redacted]

[38] Designed to prevent medical professionals from choosing to order or prescribe goods or services based on something other than a patient's best interest, "[t]he statute is aimed at the inducement factor." *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985); *see also U.S. v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29 (1st Cir. 1989) (the "gravamen of Medicare Fraud is inducement"). If any "one purpose" of the remuneration is to induce future referrals, the AKS is violated. *Greber*, 760 F.2d at 69. This is true even when the remuneration has other, legitimate purposes. *Id.* at 72 (the Anti-Kickback Act is violated if one purpose of the payment tendered from hospital to physician is to induce future referrals, even if "the payments were also intended to compensate for professional services"). "Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of *anything of value in any form or manner whatsoever*." Department of Health and Human Services, Office of Inspector General, Rules and Regulations, 42 C.F.R. Part 1001, 56 FR 35952-01 (Jul. 29, 1991) (emphasis added); *see also U.S. ex rel. Fry v. The Health Alliance of Greater Cincinnati*, No. 1:03-cv-00167, 2008 WL 5282139, at *6 (S.D. Ohio Dec. 18, 2008) (remuneration includes "anything of value in any form whatsoever").

[redacted]

[redacted].[39]

LEGAL ARGUMENT

I. AVENTIS CANNOT CLAIM PRIVILEGE AS TO THE DECEMBRINO DOCUMENTS OR RELATED DOCUMENTS

A. Basic Principles of the Attorney-Client Privilege [40]

Third Circuit precedent demands narrow construction of the attorney-client privilege. *See Westinghouse Elec. Corp. v. Republic of the Philippines*, 951 F.2d 1414, 1423 (3d Cir. 1991) ("Because the attorney-client privilege obstructs the truth-finding process, it is construed narrowly."); *In re Grand Jury Investigation*, 599 F.2d 1224, 1235 (3d Cir. 1979) (same). For the privilege to apply, the party asserting the privilege bears the burden to prove: (1) a communication;

[39] While the AKS, for purposes of obtaining a criminal conviction, requires a knowing *and* willful violation, 42 U.S.C. §1320a-7b, "the AKS's scienter requirement, when used as a predicate for an FCA violation, is not a clear-cut issue." *U.S. ex rel. Nehls v. Omnicare, Inc.*, No. 07 C 05777, 2013 WL 3819671, at *10 (N.D. Ill. July 23, 2013). A number of courts have applied the "FCA scienter standard, as opposed to the heightened scienter requirement of 'knowingly and willfully.'" *Id.* (citing *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 167 (D.D.C. 2008); *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, No. 1:01-cv-2184, 2010 WL 1390661, at *10 (M.D. Pa. Mar. 31, 2010) ("[a] violation of the [AKS] under the FCA must have been made knowingly, which can be proven by actual knowledge, deliberate ignorance, or reckless disregard."). Under either standard, Relator has shown more than enough to demonstrate scienter of inducement under the AKS.

[40] FED. R. EVID. 501 governs the attorney-client privilege in federal courts and provides that "[t]he common law—as interpreted by the United States courts in the light of reason and experience—governs a claim of privilege" in a civil case for which state law does not provide the rule of decision. *See also Pearson v. Miller*, 211 F.3d 57, 66 (3d Cir. 2000) ("federal privileges apply to federal law claims"). Thus, as Gohil brings this suit under the federal False Claims Act, federal privilege law applies. *See Davilla v. Patel*, 415 F. Supp. 2d 528, 529 (E.D. Pa. 2005) (holding that federal privilege law applies in FTCA cases); *U.S. ex rel. Stewart v. Louisiana Clinic*, No. 99-1767, 2002 U.S. Dist. LEXIS 24062, at *7 (E.D. La. Dec. 12, 2002) (applying federal privilege law to an action brought under the FCA).

(2) made between privileged persons; (3) in confidence; and (4) for the purpose of obtaining or providing legal assistance for the client. *In re Domestic Drywall Antitrust Litig.*, 2014 U.S. Dist. LEXIS 144263, at *4 (E.D. Pa. Oct. 9, 2014). The privilege "protects only those disclosures necessary to obtain informed legal advice which might not have been made absent the privilege," *id.* (citation and internal quotation marks omitted), and "[t]he privilege applies only to legal advice, and not where the lawyer provides non-legal business advice." *Id.*; *see also Teltron, Inc. v. Alexander*, 132 F.R.D. 394, 396 (E.D. Pa. 1990) (noting that when in-house counsel serves in both a legal and business capacity, statements relating to business advice are not covered by attorney-client privilege).

The attorney-client privilege may be pierced through application of the crime-fraud exception. *In re Grand Jury*, 705 F.3d 133, 151 (3d Cir. 2012). The Third Circuit has construed the crime-fraud exception broadly to apply "to any communications between an attorney and client that are intended to further a continuing or future crime or tort." *U.S. v. Doe*, 429 F.3d 450, 454 (3d Cir. 2005); *see also In re Grand Jury Proceedings*, 604 F.2d 798, 802 (3d Cir. 1979) ("when the lawyer is consulted, not with respect to past wrongdoing but to future illegal activities, the privilege is no longer defensible and the crime-fraud exception comes into play"). The exception applies even where the attorney is the perpetrator of the fraudulent activity. *See In re Impounded Case (Law Firm)*, 879 F.2d 1211, 1213-14 (3d Cir. 1989). In addition, the crime-fraud exception may be applied even where the client did not intend some wrongful action or where the attorney did not know the communications were to further a crime or fraud. *See In re Sealed Case*, 754 F.2d 395, 402 (D.C. Cir. 1985).

B. Decembrino's Allegedly Privileged Documents as Well as Aventis's Internal Communications About Her or Her Allegations Must be Turned Over

The allegedly privileged Decembrino documents are highly relevant and are part of the commission of the criminal and fraudulent conduct against the Government, thereby triggering the crime-fraud exception.[41]

To pierce the privilege, Relator need only make a prima facie showing that: "(1) the client was committing or intending to commit a fraud or crime, and (2) the attorney-client communications were in furtherance of that alleged crime or fraud." *In re Grand Jury*, 705 F.3d at 151. This burden is "not a particularly heavy one" and only requires Relator to show "a reasonable basis to suspect the perpetration of a crime" or fraud based on "adequate evidence." *Id.* at 153. Relator "is not required to introduce evidence sufficient to support a verdict of crime or fraud or even to show that it is more likely than not that the crime or fraud occurred." *Id.* at 153-54; *see also In re Grand Jury Investigation*, 445 F.3d 266, 279 (3d Cir. 2006) ("The government does not have to show that the intended crime or fraud was accomplished, only that the lawyer's advice or other services were misused. Typically that can be shown by evidence of some activity following the improper consultation, on the part of either the client or the lawyer, to advance the intended crime or fraud.").

Thus, Relator only needs to show a reasonable basis to suspect the alleged privileged materials relate to communications in furtherance of contemplated or ongoing criminal or fraudulent activity. *See In re Grand Jury Proceedings (FMC)*, 604 F.2d 798, 802 (3d Cir. 1979); *see also In re Grand Jury*, 705 F.3d at 153 (noting that "reasonable basis" standard is not satisfied through speculation or "show[ing] only a distant likelihood of corruption"). Indeed, numerous

[41] Aventis has claimed privilege over no less than 13 of the documents provided by Ms. Decembrino. *See* Harbist Dec. Ex. B. Aventis also claims privilege as to the second and third categories of documents described in Relator's proposed order.

courts have found the crime-fraud exception particularly applicable where there is evidence of on-going fraud and a scheme to conceal or cover up prior criminal activity. *See In re Grand Jury Proceedings*, 857 F.2d 710, 712 (10th Cir. 1988); *In re Sealed Case*, 754 F.2d at 401-02; *In re John Doe Corp.*, 675 F.2d 482, 491 (2d Cir. 1982); *In re Berkley and Co.*, 629 F.2d 548, 533 (8th Cir. 1980); *see also Specialty Minerals, Inc. v. Pleuss-Stauffer AG*, 2004 U.S. Dist. LEXIS 178, at *26 (S.D.N.Y. Jan. 7, 2004) (applying crime-fraud where party concealed fraudulent activity from Government for purpose of inducing action).; *U.S. v. Mower*, 2004 U.S. Dist. LEXIS 32207, at *10 (D. Utah Oct. 15, 2004) (finding crime-fraud exception applied where communications related to "efforts to conceal ongoing fraud").[42]

Aventis's ongoing off-label marketing through false and misleading information as well as its use of kickbacks is both illegal and fraudulent. Taken together with its repeated cover-up of those crimes by misleading the FDA, the crime-fraud exception is triggered. *See, e.g.*, 42 U.S.C. §1320a-7b (Federal Anti-Kickback Act); 21 C.F.R. 202.1(3)(6)(iv); *see also In re Neurontin Antirust Litig.*, 801 F. Supp. 2d 304, 311 (D.N.J. 2011) (granting *in camera* review for crime-fraud exception for documents that plaintiff contended contained communications "made in furtherance of the scheme to hide illegal off-label promotion"); *Caserta v. Mut. Pharm. Co.*, 1996 U.S. Dist. LEXIS 13581, at *6-7 (E.D. Pa. Sept. 11, 1996) (finding crime-fraud exception may apply where attorney threatened former employee to "remain[] silent about the alleged Food and Drug Act violations"). More importantly, communications relating to the spoliation of evidence do not

[42] This Court also has the option to perform an *in camera* review to determine whether the privilege is forfeited. *U.S. v. Zolin*, 491 U.S. 554 (1989). This requires an even "lesser evidentiary showing" than what is required to ultimately pierce the privilege. *Id.* at 572. An *in camera* review may be obtained through showing an adequate basis "to support a good faith belief by a reasonable person that *in camera review of the materials may reveal* evidence to establish the claim that the crime-fraud exception applies." *Id.* (emphasis added). A reviewing court looks to three factors as a guidepost: (1) the volume of materials to review; (2) the relative importance of the materials to the case; and (3) the likelihood that the documents reviewed, along with other evidence, will establish that the crime-fraud exception applies. *Id*.

benefit from the attorney-client shield because they fundamentally inconsistent with the principles underpinning the privilege. *See Wachtel v. Guardian Life Ins.*, 2007 U.S. Dist. LEXIS 43842, at *7 (D.N.J. June 18, 2007); *Rambus, Inc. v. Infineon Tech. AG*, 220 F.R.D. 264, 283 (E.D. Va. 2004).

Decembrino's documents showing the cover-up beginning in 1996, along with Relator's corroboration of the continuing off-label marketing and kickbacks between 1999 and mid-2002, satisfies the "reasonable basis" standard. So too do the many Decembrino documents that unequivocally show that Aventis launched a campaign to hide any evidence of its off-label promotion and used third parties to launder the off-label marketing funds for various drugs, including Taxotere. The evidence before the Court is far from speculative and not shows not only that Aventis engaged in illegal and fraudulent activity, but it also attempted to affirmatively conceal those activities from the FDA. *See* 7/2/96 RPR Letter, Harbist Dec. Ex. L (RPR was "committed to promoting Taxotere in accordance with FDA regulations"); *see also id*. Ex. FF at 1 ("Off-label promotion isn't permitted. We are fully committed to complying with all government regulations."); 8/8/01 Aventis Letter, *id*. Ex. H (the off-label promotional materials "were intended solely for non U.S.-based physicians"); 10/23/01 DDMAC Letter, *id*. Ex. K, at 1 ("Aventis further states its intent comply with [an FDA warning] by reviewing its procedures for the distribution of promotional materials"); 12/30/02 Aventis Letter, *id*. Ex. I ("the use of [unlawful] sales aid[s] ha[d] been discontinued"); 2/6/03 Aventis Letter, Harbist Dec. Ex. J (Aventis would take steps "to ensure that there [would] be no similar misunderstandings in the future").

Because the ultimate aim of any privilege would be perverted if a client were permitted to abuse that privilege and use it to shield his wrongdoing, the crime-fraud exception to the invocation of both common law privileges was developed. *See In re Grand Jury Proceedings (FMC)*, 604

F.2d 798, 802 (3d Cir. 1979). Aventis's continuing fraudulent off-label promotion and payment of kickbacks on numerous drugs along with its concealment and cover up of these activities by misrepresenting its compliance with the law to the FDA provides the logical link between the alleged privileged communications sought and the ongoing crimes. *See In re Neurontin Antitrust Litigation*, 801 F. Supp. 2d at 310 (citing *Prudential Ins. Co. v. Massaro*, 2000 U.S. Dist. LEXIS 11985, at *27 (D.N.J. Aug. 14, 2000)). So too do the specific communications between the legal department and management that furthered the fraudulent marketing by altering and destroying evidence. Moreover, the multiple misrepresentations to the FDA provide a logical basis to conclude that the privileged communications relating to how to respond to the Decembrino allegations and the FDA were made to further these unlawful acts. Even if the lawyers were unaware that Aventis was planning to misrepresent its compliance with the law to the FDA, the crime-fraud exception applies to these communications because those communications were intended by management to further the continuing cover-up. *See U.S. v. Doe*, 429 F.3d 450, 454 (3d Cir. 2005). In sum, any claims of privilege for the communications made between company counsel and management contemporaneous with the destruction and alteration of documents as well as the lies to the FDA should be exposed.

C. Documents Relating to Aventis's Investigations, Inquiries, and/or Reviews Done in Response to FDA Warnings Are Not Protected Because Aventis Has Waived Any Claim of Privilege and the Court Can Review those Documents *In Camera*

The Court can review Aventis's investigations, inquiries, and reviews in connection with its responses to the FDA to determine if these materials reveal further evidence to establish that the crime-fraud exception applies. *Zolin*, 491 U.S. at 572.[43] In any *in camera* review, the Court

[43] Relator has outstanding discovery requests for Aventis documents relating to communications about the FDA warnings and RPR/Aventis's responses thereto as well as its investigations, inquiries, and/or reviews into the FDA warnings. Aventis has asserted privilege over these documents as well. To the extent that the Court evaluates the

should consider whether Aventis further forfeited any privilege as to all of Aventis's documents and communications relating to its responses to any FDA findings of off-label promotion of Taxotere or other drugs, including but not limited to communications relating to any investigations or reviews undertaken by Aventis.

Aventis has impliedly waived any claim to privilege because it disclosed the results of its internal investigations in its responses to the FDA. Implied waiver applies where there is an abuse of the privilege, such as where there is a manipulation of the truth-seeking process. *See In re Sealed Case*, 676 F.2d 793, 807 (D.C. Cir. 1982). When a party reveals part of a privileged internal investigation report in voluntary disclosure to the government, it "bear[s] the risk that [its] reports will not be accepted as full disclosures…[and] if [it] choose[s] to make a pretense of unconditional disclosure, [it] bear[s] another risk-that [courts] will imply a waiver of privilege with respect to any material necessary for a fair evaluation of [its] disclosures." *Id.* at 823; *see also U.S. v. Jones*, 696 F.2d 1069, 1072 (4th Cir. 1982) ("Any disclosure inconsistent with maintaining the confidential nature of the attorney-client relationship waives the attorney-client privilege. Any voluntary disclosure by the client to a third party waives the privilege not only as to the specific communication disclosed, but often as to all other communications relating to the same subject matter."). Thus, disclosure of "'any significant part' of a communication waives the privilege" and requires the attorney to disclose the details underlying that information." *U.S. v. Cote*, 456 F.2d 142, 145 (8th Cir. 1972); *see also U.S. v. McFadden and Co.*, 1989 U.S. Dist. LEXIS 6154, at *5-6 (W.D. Pa. Jan. 5, 1989) (same).

Aventis made tactical use of its investigations in responding to the FDA to forestall

application of the crime fraud exception to Aventis's claims of privilege, Gohil requests that the Court engage in an *in camera* review of these documents as this decision implicates a more lenient standard of proof than that which applies to the crime-fraud exception. *Haines v. Liggett Group, Inc.*, 975 F.2d 81, 96 (3d Cir. 1992).

regulatory action about its off-label promotion of Taxotere and other drugs. In an effort to remove itself from the FDA's radar, Aventis made numerous misrepresentations to the FDA. In sum, Aventis represented that it was committed to complying with the law in 1996 and provided its innocent mistake explanations for its misconduct in 2001-2002. *See* 7/2/96 RPR Letter, Harbist Dec. Ex. L; 8/8/01 Aventis Letter, *id*. Ex. H; 10/23/01 DDMAC Letter, *id*. Ex. K; 12/30/02 Aventis Letter, *id*. Ex. I. These representations were misleading at best as, behind closed doors, Aventis charged ahead with its fraudulent off-label promotional scheme. The purpose of these representations was, of course, to assure the FDA that Aventis was addressing any issues and taking corrective action to ensure that any mistaken off-label promotion would not recur. Aventis officials explained its conduct in the most favorable light in an effort to curry favor with the regulatory officials responsible for initiating action against Aventis.

When a corporation elects to make a disclosure, "it necessarily decides that the benefits of participation outweigh the benefits of confidentiality for all files necessary to a full evaluation of its disclosure." *In re Sealed Case*, 676 F.2d at 822; *see also In re John Doe Corp.*, 675 F.2d at 489.[44] Thus, fairness and consistency cannot permit Aventis to gain a substantial advantage in this litigation, which is brought on the Government's behalf, by hiding privileged communications relating to these interactions with the FDA, including its investigations and inquiries that formed the basis of its misrepresentations to the FDA. *See In re Martin Marietta Corp.*, 856 F.2d 619, 623 (4th Cir. 1988); *see generally Ziner v. Cedar Crest College*, 2006 U.S. Dist. LEXIS 34858, at *9-10 (E.D. Pa. May 30, 2006) (discussing fairness doctrine). Indeed, Aventis cannot have it both

[44] Selective disclosure for tactical purposes acts as a complete waiver of the privilege since the privilege is intended only as an incidental means of defense, and not as an independent means of attack. "[T]o use it in the latter character is to abandon it in the former." 8 J. Wigmore, Evidence in Trials in Common Law, §2327 at 636, 638. *See In re Grand Jury Proceeding*, 727 F.2d 1352, 1356 (4th Cir. 1984) (loss of the privileges not confined to the particular words addressing a communications content but extends to the entire substance of the communication). Thus, disclosure of "'any significant part' of a communication waives the privilege" and requires the attorney to disclose the details underlying that information. *Cote*, 456 F.2d at 145.

ways. Having revealed the results of its own internal review to the FDA to avoid further scrutiny, Aventis cannot now claim that the facts relating to those representations and investigations are privileged. "The attorney client privilege is not designed for such tactical employment." *Permian Corp. v. U.S.*, 665 F.2d 1214, 1221 (D.C. Cir. 1981).

II. THE NON-TAXOTERE DECEMBRINO DOCUMENTS ARE RELEVANT AND DISCOVERABLE

Apart from its assertion of privilege, Aventis's position that all of Decembrino's documents not pertaining to Taxotere are irrelevant and not discoverable is wrong. *See* 10/8/15 & 9/23/15 Sheff Letters, Harbist Dec. Ex. B. In their 1996 complaint against RPR, Mses. Decembrino and Conolly alleged that RPR's legal department required them to "delete and destroy all of the Marketing Department's incriminating paperwork regarding Off-Label promotion of Nasacort AQ, and to substitute new documentation that would show no evidence of wrongdoing. RPR also required them to become involved in corporate efforts to cover up Off-Label promotion of Lovenox and *Taxotere*." *Id*. Ex. D ¶29 (emphasis added).

Aventis implemented a concerted scheme to conceal evidence of its off-label promotional activities for all of its drugs, including Taxotere. Thus, not only are documents showing this off-label promotion of other drugs relevant and discoverable, they are admissible at trial. The scope of discovery is broad and "goes far beyond that which may be admitted at trial." *Victor v. Lawler*, 2011 U.S. Dist. LEXIS 96114, at *12 (M.D. Pa. Aug. 26, 2011). As long as information is "reasonably calculated to lead to the discovery of admissible evidence" it is discoverable. FED. R. CIV. P. 26(b)(1). It cannot be disputed that the information at issue here is reasonably calculated to lead to admissible evidence. Evidence that Aventis was illegally promoting off-label uses for other drugs could be used to establish Aventis's corporate intent as well as a common scheme or common plan. *See* F.R.E. 404(b); *see also U.S. v. Caldwell*, 760 F.3d 267, 275-76 (3d Cir. 2014);

U.S. v. Thirty Nine Thousand Seven Hundred Eighty Five Dollars ($39,785.00) in U.S. Currency, 828 F. Supp. 2d 740, 743 (E.D. Pa. 2011). It is also plainly relevant to show that the company's upper management had a reckless disregard of the truth or falsity of the claims Aventis made to the FDA. Finally, any evidence of Aventis's spoliation of documents, which is apparent in the Decembrino documents, is admissible. *U.S. v. Krauss*, No. 02-258, 2009 WL 1313296, at *5 (E.D. Pa. May 11, 2009) (quoting *U.S. v. Mendez-Ortiz*, 810 F.2d 76, 79 (6th Cir. 1986)) ("Though not listed in Rule 404(b), spoliation evidence…is admissible to show consciousness of guilt").

Aventis's position that any Decembrino document not related to Taxotere should be returned because Decembrino kept them in violation of her employment agreement is sophistry. *See* 9/23/15 Scheff Letter, Harbist Dec. Ex. B at 1. By the plain terms of Decembrino's employment agreement, she was only obliged to return and maintain the confidentiality of trade secret information. *See* Decembrino Employment Agreement, *id*. Ex. B ¶¶4, 5 & 8. The documents at issue here do not pertain to trade secrets or anything similar, thus they are not subject to the agreement. In any event, even if Ms. Decembrino's documents are subject to the employment agreement, the agreement only prohibits non-disclosure within five years of her termination. *Id*. ¶8. Moreover, Relator is entitled to use them to prosecute this case pursuant to the policy underpinning the False Claims Act. *See*, *e.g.*, *U.S. ex rel. Head v. Kane Co.*, 668 F. Supp. 2d 146, 151-52 (D.D.C. 2009) ("Enforcing a private agreement that requires a qui tam plaintiff to turn over his or her copy of a document, which is likely to be needed as evidence at trial, to the defendant who is under investigation would unduly frustrate the purpose of [the FCA]."); *U.S. ex rel. Grandeau v. Cancer Treatment Ctrs. of Am.*, 350 F. Supp. 2d 765, 773 (N.D. Ill. 2004) (dismissing claim for breach of confidentiality agreement and noting that agreement could not "trump the FCA's strong policy of protecting whistleblowers who report fraud against the government."); *see*

also Vizant Techs., LLC v. Whitchurch, No. 15-431, 2015 WL 1933759, at *14 (E.D. Pa. Apr. 29, 2015) ("When employees or former employees have brought their concerns about unlawful conduct of their employers to the attention of law enforcement, some courts have declined on public policy grounds to enforce contractual confidentiality and non-compete provisions against them").

CONCLUSION

The attorney-client privilege "takes flight if the relation is abused. A client who consults an attorney for advice that will serve him in the commission of a fraud will have no help from the law. He must let the truth be told." *Clark v. United States*, 289 U.S. 1, 15 (1933) (Cardozo, J.). It is time Aventis let the truth be told.

Respectfully submitted,

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Dated: January 7, 2016

CERTIFICATE OF SERVICE

I, STEPHEN M. ORLOFSKY, hereby certify that on January 7, 2016, I served via ECF the foregoing, *redacted*, Plaintiff/Relator's Motion to Compel and for Application of the Crime-Fraud Exception, the accompanying Memorandum of Law, Declarations of Nicholas C. Harbist, Esquire and Yoash Gohil, and the proposed Order upon the following counsel of record:

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