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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

_____)	
UNITED STATES OF)	
AMERICA, <i>ex rel.</i> JEFFREY D.)	
FELDSTEIN, M.D.,)	
)	Civil Action No. 07-2690 (DMC)(MF)
Plaintiff/Relator,)	
)	
v.)	Motion Return Date: July 21, 2008
)	
ORGANON, INC. and)	
SCHERING-PLOUGH, INC.,)	ORAL ARGUMENT REQUESTED
)	
Defendants.)	
_____)	

MEMORANDUM OF POINTS AND AUTHORITIES

IN SUPPORT OF MOTION TO DISMISS

TABLE OF CONTENTS

	Page
BACKGROUND AND PROCEDURAL HISTORY	4
I. THIS COURT LACKS JURISDICTION OVER THIS ACTION BECAUSE RELATOR’S CLAIM IS BASED UPON ALLEGATIONS THAT WERE PREVIOUSLY DISCLOSED TO THE PUBLIC AND RELATOR IS NOT AN ORIGINAL SOURCE.	6
A. This is a Factual Challenge to Jurisdiction Pursuant To Fed. R. Civ. P. 12(b)(1)	6
B. Relator’s Claim Is Based Upon Allegations In Prior Public Disclosures.	8
C. Relator Is Not An “Original Source” Of The Information At Issue	16
II. THE AMENDED COMPLAINT FAILS TO SATISFY FEDERAL RULE OF CIVIL PROCEDURE 9(b)’S HEIGHTENED PLEADING STANDARD AND MUST THEREFORE BE DISMISSED WITH PREJUDICE.....	19
A. A Violation Of The False Claims Act Must Be Pleaded With Particularity Under Fed. R. Civ. P. 9(b)..	19
B. Plaintiff’s Vague and Unsubstantiated Allegations Do Not Satisfy The Heightened Rule 9(b) Pleading Requirements	22

III.	THE AMENDED COMPLAINT FAILS TO STATE A VIABLE CAUSE OF ACTION UNDER THE FALSE CLAIMS ACT AND SHOULD THEREFORE BE DISMISSED WITH PREJUDICE PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6).....	27
IV.	SCHERING-PLOUGH SHOULD BE DISMISSED FROM THIS FALSE CLAIMS ACT QUI TAM ACTION	30
	CONCLUSION.....	31

TABLE OF AUTHORITIES

	<u>Page</u>
Federal Cases	
<i>Allison Engine Co. v. United States ex rel. Sanders</i> , No. 07-214, 2008 WL 2329722 (U.S. June 9, 2008).....	28
<i>Bell Atl. Corp. v. Twombly</i> , 127 S. Ct. 1955 (2007).....	27, 29, 30
<i>Corsello v. Lincare, Inc.</i> , 428 F.3d 1008 (11th Cir. 2005)	21
<i>Infra-Metals, Co. v. Topper & Griggs Group, Inc.</i> , No. Civ. A. 3:05-559, 2005 WL 3211385 (D. Conn. Nov. 30, 2005).....	31
<i>Morse v. Lower Merion Sch. Dist.</i> , 132 F.3d 902 (3d Cir.1997).....	28
<i>Palladino ex rel. United States v. VNA of S. N.J., Inc.</i> , 68 F. Supp. 2d 455 (D.N.J. 1999).....	20
<i>Pinnacle Choice, Inc. v. Silverstein</i> , No. 07-cv-1379 (DMC), 2007 WL 2212861 (D.N.J. July 31, 2007)	20
<i>In re Rockefeller Ctr. Props. Secs. Litig.</i> , 311 F.3d 198, 217 (3d Cir. 2002)	19, 20
<i>Senn v. Hickey</i> , No. 03-CV-4372 (DMC), 2005 WL 3465657, (D.N.J. Dec. 19, 2005).....	21
<i>United States ex rel. Atkinson v. Pa. Shipbuilding Co.</i> , 255 F. Supp. 2d 351 (E.D. Pa. 2002) <i>aff'd</i> , 473 F.3d 506 (3d Cir. 2007).....	6, 7, 8, 9, 10, 11, 17
<i>United States ex rel. Bartlett v. Tyrone Hosp., Inc.</i> , 234 F.R.D. 113 (W.D. Pa. 2006)	20, 22, 24, 27

United States ex rel. Clausen v. Lab. Corp. of Am., Inc.,
290 F.3d 1301 (11th Cir. 2002) 25, 26, 27, 29

United States ex rel. Dingle v. BioPort Corp.,
270 F. Supp. 2d 968 (W.D. Mich. 2003)9

United States ex rel. Fine v. Sanida Corp.,
70 F.3d 568 (10th Cir. 1995)9

United States ex rel. Fisher v. Network Software Assocs., Inc.,
180 F. Supp. 2d 192 (D.D.C. 2002).....30

United States ex rel. Garst v. Lockheed-Martin Corp.,
328 F.3d 374 (7th Cir. 2003)28

United States ex rel. Karvelas v. Melrose-Wakefield Hosp.,
360 F.3d 220 (1st Cir. 2004).....25

United States ex rel. King v. Alcon Labs., Inc.,
232 F.R.D. 568 (N.D. Tex. 2005)21

United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.,
149 F.3d 227 (3d Cir. 1998).....20

United States ex rel. Mistick PBT v. Hous. Auth. Of City of Pittsburgh,
186 F.3d 376 (3d Cir. 1999).....6, 9, 10, 11

United States ex rel. Paranich v. Sorgnard,
396 F. 3d 326 (3d Cir. 2005).....9, 17

United States ex rel. Quinn v. Omnicare, Inc.,
382 F.3d 432 (3d Cir. 2004).....20, 28

United States ex rel. Schmidt v. Zimmer, Inc.,
386 F.3d 235 (3d Cir. 2004).....20

United States ex rel. Schmidt v. Zimmer, Inc.,
No. Civ. A. 00-1044, 2005 WL 1806502
(E.D. Pa. July 29, 2005)..... 21, 26, 28, 29

United States ex rel. Waris v. Staff Builders, Inc.,
No. CIV. A. 96-1969, 1999 WL 170745 (E.D. Pa. Mar. 4, 1999)25

Weiner v. Quaker Oats Co.,
129 F.3d 310 (3d Cir. 1997).....25

Miscellaneous

31 U.S.C. §§ 3729-334

31 U.S.C. § 3730(b)(4)(B)4

31 U.S.C. § 3730(e)(4)..... 6, 7, 8, 9, 16, 17

Fed. R. Civ. P. 9(b)19

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION

This memorandum of points and authorities is respectfully submitted on behalf of defendants Organon USA Inc. (improperly pleaded as Organon, Inc.) (“Organon”) and Schering-Plough Corporation (improperly pleaded as Schering-

Plough, Inc.) (“Schering-Plough”), in support of their motion to dismiss the Amended Complaint. As discussed more fully herein, the Amended Complaint must be dismissed with prejudice for several reasons.

First, this Court lacks jurisdiction over this action. Where -- as here -- an individual files a *qui tam* action alleging a violation of the False Claims Act, that individual (referred to as a “Relator”) must satisfy the strict jurisdictional requirements of the Act. In particular, the Act explicitly states that no court can claim jurisdiction over any *qui tam* action that is based upon allegations or transactions in prior public disclosures, unless the Relator is an “original source” of the information at issue. In this case, the Relator’s allegations are based upon allegations in prior public disclosures, and he cannot qualify as an original source of the information alleged. In fact, the allegations of which the Relator complains were well-known and amply publicized long before this lawsuit was filed. Accordingly, this action must be dismissed with prejudice for lack of jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1).

Second, the Amended Complaint fails to satisfy the heightened pleading standards of Federal Rule of Civil Procedure 9(b). Because an action alleging a violation of the False Claims Act sounds in fraud, the claim must be pleaded with particularity pursuant to Rule 9(b). The essence of Relator’s Amended Complaint is the allegation that Organon wrongfully acquired the Food and Drug

Administration's ("FDA") approval of a drug called Raplon® by misrepresenting or failing to disclose to the FDA the product's propensity to cause serious injury, and that doctors utilized Raplon® in reliance upon the FDA's approval and/or Organon's failure to disclose Raplon®'s risks. As a result, the Relator alleges, Medicare and Medicaid were presented with claims for the use of Raplon® that were "false" in the sense that the drug should never have been approved by the FDA and, thus, should never have been used by the consuming public. Conspicuously absent from the Relator's Amended Complaint, however, are any specific allegations of Organon's supposed wrongful conduct or the submission of false claims concerning Raplon®; in fact, the Amended Complaint fails to identify even one specific Medicare or Medicaid claim that was filed with respect to the use of Raplon®. These gross pleading deficiencies -- which cannot be cured -- require dismissal with prejudice pursuant to Rule 9(b).

Third, for the same reasons that dismissal with prejudice is warranted pursuant to Rule 9(b), the Amended Complaint must be dismissed with prejudice pursuant to Federal Rule of Civil Procedure 12(b)(6) because it fails to state a claim upon which relief can be granted.

Finally, Schering-Plough must be dismissed from this action because the Amended Complaint fails to allege that it committed any unlawful conduct.

For all these reasons, as discussed more fully herein, Organon and Schering-Plough respectfully request that the Amended Complaint be dismissed with prejudice in its entirety.

BACKGROUND AND PROCEDURAL HISTORY

The allegations comprising this *qui tam* action relate to the FDA's approval of Raplon®, a neuromuscular blocking agent. According to Relator's allegations, Raplon® is "designed to paralyze a patient's throat area to allow the painless insertion of an endotracheal tube into a patient's trachea." Amended Complaint, ¶ 6. The FDA approved Raplon® on August 18, 1999. *Id.*, ¶ 7. Some patients, however, suffered an adverse event called "bronchospasm," or a closing of the bronchial tubes which can interfere with breathing. *Id.*, ¶ 9. Soon after these adverse events began to be reported, Organon voluntarily withdrew Raplon® from distribution on or about March 27, 2001. *Id.*, ¶ 24.

On April 4, 2002, Relator commenced this action, pursuant to the False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), by filing a *qui tam* complaint, against Organon and Akzo Nobel, Organon's then-corporate parent, in the United States District Court for the District of Massachusetts. The complaint was filed under seal. *See* Ex. 1, dkt. entry # 1. In accordance with 31 U.S.C. § 3730(b)(4)(B), the United States was afforded 60 days, or until June 4, 2002, to decide whether to intervene in Relator's action.

Beginning with its first motion filed on May 21, 2002, the Government made 13 separate applications for extensions of time to, ostensibly, investigate the allegations in Relator's Complaint, and decide whether to intervene. *See* Ex. 1, *dkt. entry ## 6, 10, 13, 15, 18, 20, 22, 25, 28, 31, 34, 37, 40.* By its notice, filed on June 13, 2006, the Government ultimately elected not to intervene in the action. *See* Ex. 1, *dkt. entry # 42.*

Upon Relator's unopposed motion, since the case remained under seal, on May 17, 2007, the District of Massachusetts court ordered the case transferred to this Court. On June 8, 2007, the complaint was transferred. [Ex. 2, *dkt entry #1*]. On February 11, 2008, Magistrate Judge Falk ordered the case to be unsealed, and further ordered Relator to serve the complaint upon the defendants. [Ex. 2, *dkt entry #4*].

On April 14, 2008, Relator filed an Amended Complaint and Jury Demand against defendants.¹ [Ex. 2, *dkt. entry #5*]. Counsel for Organon and Schering-Plough were served with the Amended Complaint on April 17, 2008 [Ex. 2, *dkt. entry #6*].

¹ Relator did not name Akzo Nobel as a defendant in the Amended Complaint.

I. THIS COURT LACKS JURISDICTION OVER THIS ACTION BECAUSE RELATOR’S CLAIM IS BASED UPON ALLEGATIONS THAT WERE PREVIOUSLY DISCLOSED TO THE PUBLIC AND RELATOR IS NOT AN ORIGINAL SOURCE.

This action must be dismissed with prejudice pursuant to Federal Rule of Civil Procedure 12(b)(1) because it is barred by 31 U.S.C. § 3730(e)(4)(A) (often referred to as the “public disclosure bar”), which “provides that no court has jurisdiction over a FCA *qui tam* action that is based on certain public disclosures unless the action is brought by an ‘original source.’” *United States ex rel. Mistick PBT v. Hous. Auth. of the City of Pittsburgh*, 186 F.3d 376, 378-9 (3d Cir. 1999) (quoting 31 U.S.C. § 3730(e)(4)(A)). This court lacks jurisdiction over this matter because, as demonstrated below, Relator’s action is based entirely on prior public disclosures and Relator is not an original source of the information at issue.

A. This Is A Factual Challenge To Jurisdiction Pursuant To Fed. R. Civ. P. 12(b)(1).

The standard of review for motions to dismiss under Federal Rule of Civil Procedure 12(b)(1) is well settled and beyond dispute. In considering a motion to dismiss for lack of standing, “the court must first determine whether it is confronted with a facial or factual challenge to its jurisdiction.” *United States ex rel. Atkinson v. Pa Shipbuilding Co.*, 255 F. Supp. 2d 351, 362 (E.D. Pa. 2002), *aff’d*, 473 F.3d 506 (3d Cir. 2007). And where, as here, the jurisdictional challenge concerns a Relator’s failure to comport with the jurisdictional

prerequisites contained in 31 U.S.C. § 3730(e)(4), the challenge is factual.² *Id.* In reviewing a factual challenge to jurisdiction in a Rule 12(b)(1) motion, the court should not confine its evaluation to the four corners of the complaint, nor view the complaint in a light most favorable to the plaintiff by drawing reasonable inferences therefrom - as would be the case with a facial challenge. *Id.* 176 (citing *PBGC v. White*, 998 F.2d 1192, 1196 (3d Cir. 1993)). “Instead, ‘the court may consider and weigh evidence outside the pleadings to determine if it has jurisdiction.’”³ *Id.* (quoting *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000)).

Significantly, once a Rule 12(b)(1) challenge is raised, the burden shifts and the Relator must demonstrate the existence of federal subject matter jurisdiction

² The jurisdictional requirements under 31 U.S.C. §§ 3730(e)(4)(A)-(B) involve assessing whether the allegations and transactions constituting the bases of the claims were publicly disclosed; and, if they were, whether the Relator is an original source. As set forth below, public disclosures did occur and Relator has failed to plead that he is a proper original source under the FCA.

³ “[With a] factual attack . . . the trial court may proceed as it never could under [Fed. R. Civ. P.] 12(b)(6) or Fed. R. Civ. P. 56(b). Because at issue in a factual 12(b)(1) motion is the trial court’s . . . very power to hear the case[,] there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of [this] power. . . . In short, no presumptive truthfulness attaches to plaintiff’s allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. Moreover, the plaintiff will have the burden of proof that jurisdiction does in fact exist.” *Atkinson*, 255 F. Supp. 2d at 363 n.9 (citing *Mortenson v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977)).

over his claims. *See id.* at 363 (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

B. Relator’s Claim Is Based Upon Allegations In Prior Public Disclosures.

Relator has alleged no new information; this action is based entirely upon allegations that were previously made in prior public disclosures -- in particular, in news media reports and civil complaints. Thus, this action falls squarely within the FCA’s public disclosure bar and must be dismissed. 31 U.S.C. § 3730(e)(4)(A).

The Third Circuit has made clear that the public disclosure bar applies where: (1) the information was publicly disclosed via a source listed in § 3730(e)(4)(A); (2) the public disclosure included an “allegation or transaction” within the meaning of the statute; and (3) the relator’s complaint is “based upon” those disclosures. *Atkinson*, 473 F.3d at 519. Each element of the public disclosure bar is satisfied in this case.

First, it is beyond peradventure that allegations in news media reports and filed civil complaints are precisely the kinds of public disclosure covered by the FCA’s public disclosure bar. The statute provides as follows:

No court shall have jurisdiction over an action under this section based upon the *public disclosure of allegations or transactions in a criminal, civil, or administrative hearing*, in a congressional, administrative, or Government Accounting Office report, hearing, audit or investigation, *or from the news media*, unless the action

is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (emphasis added). By its plain terms, the public disclosure bar covers “allegations . . . from the news media.” *Id.* And courts -- including the Third Circuit -- have held that allegations in filed civil complaints constitute “allegations . . . in a . . . civil . . . hearing” within the meaning of the statute. *See, e.g., United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 334 (3d Cir. 2005) (holding that “a complaint in a civil action falls into the context of ‘criminal, civil, or administrative hearings’ and is sufficiently public within the meaning of the Act to constitute a public disclosure”).

Second, as demonstrated below, the allegations of fraud on the part of Organon that were publicly disclosed in the news media reports and civil complaints constitute ‘allegations or transactions’ within the meaning of the FCA’s public disclosure bar. To satisfy this requirement, the public disclosure must either allege the actual fraud, or must allege both the misrepresented state of facts and the true state of facts such that an inference of fraud may be drawn. *Atkinson*, 473 F.3d at 519; *see also Mistick*, 186 F.3d at 385. Public disclosure of the material elements of the fraud will alone bar a *qui tam* action even if the disclosure itself does not allege any wrongdoing. *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 572 (10th Cir. 1995); *see also United States ex rel. Dingle v. BioPort*

Corp., 270 F. Supp. 2d 968, 977 n.1 (W.D. Mich. 2003), *aff'd*, 388 F.3d 209 (6th Cir. 2004).

Third, to be “based upon” the publicly revealed allegations or transactions within the meaning of the FCA, Relator’s allegations “need only be ‘supported by’ or ‘substantially similar to’ the disclosed allegations and transactions.” *Atkinson*, 473 F.3d at 519 (*quoting Mistick*, 186 F.3d at 385-88). Notably, the Third Circuit has expressly held that the phrase “based upon” does not mean “actually derived from,” because such an interpretation would render the original source exception superfluous. *Mistick*, 186 F.3d at 385-88.

A comparison of the allegations in Relator’s Amended Complaint with the allegations in other civil complaints and news media reports -- all of which predate the inception of this suit -- conclusively demonstrates that Relator’s allegations are based upon those public disclosures and, therefore, fall squarely within the FCA’s public disclosure bar. The essence of Relator’s Amended Complaint is the allegation that Organon wrongfully acquired FDA approval of Raplon® by misrepresenting or failing to disclose to the FDA the product’s propensity to cause serious injury, and that doctors utilized Raplon® in reliance upon the FDA’s approval and/or Organon’s failure to disclose Raplon®’s risks. *See* Am. Compl. ¶¶ 23 (“Raplon’s approval by the FDA was invalid because it was obtained by Organon as a result of a willful failure to disclose and/or through the use of

fraudulent and/or deceptive information”); *id.* (“the FDA approved Raplon without the benefit of adequate disclosures regarding the potential for SAEs [serious adverse events]”); *id.* at ¶ 24 (“Organon never informed the FDA, hospitals, physicians or patients that Raplon posed a serious threat to public health and safety”); *id.* at ¶ 30 (“If Organon had not used fraudulent and/or deceptive means to secure regulatory approval for Raplon, the drug would not have been administered to these patients”). As a result of this alleged fraud on the FDA, Relator alleges, the Government (*i.e.*, Medicare and Medicaid) would not have paid claims for the use of Raplon®. *See* Am. Compl. ¶¶ 23, 29, 30.⁴

Prior to the filing of this action on April 4, 2002, however, prior public disclosures revealed the same alleged misrepresentation and the same alleged true state of facts as asserted by Relator. *See Atkinson*, 473 F.3d at 519; *Mistick*, 186 F.3d at 385. To begin with, the allegations related to Raplon®’s adverse events were well-documented and publicized long before Relator filed this action. *See, e.g.*, Raplon® product package insert, dated August 18, 1999 (Ex. 3), at 20 (listing

⁴ The allegation that false claims were submitted to Medicare and Medicaid, which is stated only in general terms and cites no factual particulars whatsoever, is part and parcel of the Amended Complaint’s core charge that defendants concealed safety data and fraudulently obtained FDA approval for Raplon®. This generalized allegation is simply an embellishment of that core charge. Accordingly, as demonstrated herein, the Amended Complaint’s tacked-on general allegation concerning Medicare and Medicaid is also based upon public disclosures and, therefore, subject to the public disclosure bar. Furthermore, as discussed more fully in the following section, the assertion that false claims were made is not alleged with sufficient particularity to survive dismissal.

“Bronchospasm” as one of the “most frequent adverse events” seen with Raplon® in clinical trials); *see also* Exhibits 4-13 (civil complaints and news media reports cited and discussed below).

In addition, well before Relator’s filing, there was public disclosure of substantially similar allegations of fraud and cover-up of adverse event data. For example, the complaint filed in *Rogers v. Organon, Inc.* on February 20, 2002 asserts that Organon “failed to conduct adequate and appropriate studies which would have revealed that Raplon created a high risk of certain personal injuries and/or death and failed to provide any and/or adequate warnings concerning this risk.” *Rogers Compl.* at ¶ 11 (Ex. 4). The *Rogers* Complaint also alleges that Organon “was negligent in the design, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given and sale of Raplon in that, among other things, it . . . (b) Failed to conduct adequate pre-clinical and clinical testing and postmarketing surveillance to determine the safety of the drug Raplon; . . . (f) Recklessly, falsely, and/or deceptively represented or knowingly omitted suppressed or concealed facts of such materiality regarding the safety and efficacy of Raplon® from prescribing physicians and the consuming public, and that had prescribing physicians and the consuming public known of such facts, the drug Raplon would never have been prescribed to plaintiff.”. *Id.* at ¶ 50. Indeed, the Complaint described Organon’s actions as constituting “knowing omissions,

suppression or concealment of material facts, made with the intent that others rely upon such concealment, suppressions or omissions in connection with the marketing of Raplon.” *Id.* at ¶ 53. Moreover, the Rogers Complaint alleged that “Defendant acted unlawfully and negligently, used or employed unconscionable commercial and business practices, engaged in deception, fraud, false pretenses, false promises or misrepresentations, and/or perpetrated the knowing concealment, suppression or omission of material facts with the intent that physicians and consumers including Plaintiffs, rely upon such concealment, suppression or omission, in connection with the sale or advertisement of Raplon.” *Id.* at ¶ 54.

Likewise, the complaint filed in *Spencer v. Organon, Inc.* on October 11, 2001 alleges as follows:

[Organon] knew at all times that the ultimate consumer of this product . . . would receive[] this product without knowledge or inspection of its fitness or safety for its intended use; defendant Organon . . . reported . . . testing results to the FDA . . . [that] were carelessly and negligently formulated and carried out so that they did not represent or reflect the clinical use for which Organon intended to market said product.

Spencer Complaint at p. 5 (March 15, 2002) (Ex. 5).

The complaint filed in *Payne v. Organon, Inc.* on November 28, 2001, is yet another example of a prior public disclosure of Relator’s essential allegation. *See, e.g.,* Payne Compl., Ex. 6, at ¶ 12 (alleging damages as a “result of the fault, strict liability and/or negligence of defendant, Organon, Inc., in the . . . [m]anufacture

and distribution of an unreasonably dangerous drug (Raplon) without adequate and appropriate testing to learn of its unreasonably dangerous side effects”).

Even the more specific assertions underlying the essential basis of Relator’s claim were publicly disclosed in other civil complaints or news media reports prior to the institution of this action. These more specific assertions in Relator’s Amended Complaint, and the prior public disclosures of that information, are set forth in the following chart:

ALLEGATIONS IN THE AMENDED COMPLAINT	PUBLIC DISCLOSURES PRIOR TO INSTITUTION OF THIS ACTION
<p>“Organon knew prior to Raplon’s approval by the FDA that Raplon caused SAEs[,]” most expressly a condition called bronchospasm. Am. Compl. at ¶ 12.</p>	<p>“Defendant Organon knew or should have known that Raplon could cause death . . . as a result of severe bronchospasm.” Rogers complaint, at ¶ 14 (Feb. 20, 2002) (Ex. 4).</p> <p><i>See also</i> Raplon® product package insert, Ex. 3; <u>Dallas Morning News</u> (March 31, 2001) at page 1 (Ex. 7); Public Citizen’s Health Research Group Health Letter (October 2001), at p. 5 (Ex. 8).</p>
<p>Organon did not draw attention to the risk of bronchospasm prior to launch of the drug. <i>Id.</i> at ¶¶ 14-16.</p>	<p>“[Organon] fail[ed] to provide an adequate warning of the dangerous side effects and characteristics of Raplon, and its dangers to users and handlers of the product.” Payne Complaint, at ¶ 12 (Nov. 28, 2001) (Ex. 6).</p> <p><i>See also</i> Rogers Complaint at ¶¶19 and 3 (Feb. 20, 2002) (Ex. 4).</p>

<p>Organon conducted insufficient studies and clinical trials to determine the cause of SAEs associated with Raplon. <i>Id.</i> at ¶ 18.</p>	<p>“Organon failed to conduct adequate and appropriate studies which would have revealed that Raplon created a high risk of certain personal injuries and/or death[.]” Rogers Complaint, at ¶ 11 (Feb. 20, 2002) (Ex. 4).</p> <p><i>See also</i> Payne Complaint, at ¶ 12 (Nov. 28, 2001) (Ex. 6); Spencer Complaint, at page 5 (Oct. 11, 2001 (Ex. 5);</p>
<p>“After receiving FDA approval, Organon never advised doctors or patients of the potential for SAEs in any labeling or packaging insert and never had a treatment protocol in place prior to launch.” <i>Id.</i> at ¶ 20.</p>	<p>“[Organon] fail[ed] to provide an adequate warning of the dangerous side effects and characteristics of Raplon, and its danger to users and to handlers of the product.” Payne Complaint, at ¶ 12 (Nov. 28, 2001) (Ex. 6).</p> <p><i>See also</i> Goudsouzian article, at page 1 (2001) (Ex. 9); Raplon® product package insert (Ex. 3); Rogers Complaint, at ¶ 11 (Feb. 20, 2002) (Ex. 4).</p>
<p>“The extent of danger posed by Raplon came to light following its approval by the FDA.” <i>Id.</i> at ¶ 21.</p>	<p>“The company approached the FDA recently, saying it was concerned about the safety profile that had emerged after the drug was put on the market.” <u>The Wall Street Journal</u> (March 30, 2001) (Ex. 10).</p> <p><i>See also</i> <u>Newark Star Ledger</u>, at page 1 (April 1, 2001) (Ex. 11). <u>The Bergen County Record</u>, at page 1 (March 30, 2001) (Ex. 12); <u>AP Online</u>, at page 1 (April 1, 2001) (Ex. 13).</p>

<p>“Organon never informed the FDA, hospitals, physicians or patients that Raplon posed a serious threat to public health and safety before its unilateral decision to pull the drug from the market on March 27, 2001.” <i>Id.</i> at ¶ 24.</p>	<p>“[Organon] fail[ed] to provide an adequate warning of the dangerous side effects and characteristics of Raplon, and its dangers to users and handlers of the product.”). Payne Complaint, at ¶12 (Nov. 28, 2001) (Ex. 6).</p> <p><i>See also</i> Spencer Complaint at p. 5 (October 11, 2001) (Ex. 5). (“[Organon] knew at all times that the ultimate consumer of this product . . . would receive[] this product without knowledge or inspection of its fitness or safety for its intended use. . . . yet defendant negligently failed to withdraw said product from the market until March 27, 2001.”).</p>
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In light of the foregoing, it is clear that the allegations in Relator’s Amended Complaint are “based upon” the “public disclosure” of “allegations” within the meaning of the FCA’s public disclosure bar. 31 U.S.C. § 3730(e)(4)(A). Thus, no court possesses jurisdiction over this action unless Relator can demonstrate that he is an “original source” of the information at issue. *Id.* For the reasons discussed below, Relator cannot qualify as an original source, and this case must therefore be dismissed with prejudice.

C. Relator Is Not An “Original Source” Of The Information At Issue.

An “original source” within the meaning of the FCA is “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before

filing an action under this section which is based on the information.” 31 U.S.C. § 3730(e)(4)(B). The Third Circuit has explained that to be an original source, a Relator “must have had (1) *direct* and (2) *independent* knowledge of the information on which the allegations are based and (3) have *voluntarily* [provided the] information to the Government before filing the action.” *Paranich*, 396 F.3d at 335 (emphasis in original) (affirming dismissal of *qui tam* FCA complaint under the public disclosure bar because Relator was not an original source). “‘Independent knowledge’ is knowledge that does not depend on public disclosures. ‘Direct knowledge’ is knowledge obtained without any intervening agency, instrumentality or influence: immediate.” *Atkinson*, 473 F.3d at 520 (affirming dismissal of *qui tam* FCA complaint under the public disclosure bar because Relator was not an original source) (internal citations and some quotation marks omitted). If Relator’s pleading fails to satisfy these requirements, the district court must dismiss the action under Rule 12(b)(1) for lack of jurisdiction.

Here, Relator cannot satisfy these statutory requirements for original source status. As an initial matter, Relator has failed to plead that he provided the information to the Government prior to filing this action. 31 U.S.C. § 3730(e)(4)(B); *Paranich*, 396 F.3d at 335.

Furthermore, Relator has failed to plead that he had direct or independent knowledge of the information alleged in his Amended Complaint. First, as

discussed above, the essence of Relator's Amended Complaint is the allegation that Organon wrongfully acquired FDA approval of Raplon® by misrepresenting or failing to disclose to the FDA the product's propensity to cause serious injury, and that doctors utilized Raplon® in reliance upon the FDA's approval and/or Organon's failure to disclose Raplon®'s risks. *See* Am. Compl. ¶ 23. Conspicuously absent from Relator's Amended Complaint, however, is any allegation that Relator had any personal involvement or familiarity with the FDA approval process for Raplon®. Relator's lack of direct or independent knowledge in this regard is underscored by the fact that his Amended Complaint merely alleges “[u]pon information and belief” that “Organon's submissions to the FDA contained numerous quantitative and qualitative misrepresentations concerning Raplon's propensity to cause SAEs” Am. Compl. ¶ 19 (emphasis added). Relator has simply failed to plead the requisite direct and independent knowledge of the information underlying this essential allegation.

Second, the only paragraph in the Amended Complaint to even allege a violation of the FCA is ¶ 23, which alleges that Organon “caused many hospitals, physicians and/or patients to submit false reimbursement claims to Medicare and Medicaid” Relator fails to allege, however, that he had direct and independent knowledge as to any Medicare/Medicaid claims submitted by the “many hospitals, physicians and/or patients.” As a result, because Relator cannot even identify any

entities or individuals by name, nor allege any personal contact with any of them, he is merely speculating that somebody, somewhere, somehow submitted fraudulent claims for reimbursement predicated upon the administration of Raplon®.⁵ Thus, the Amended Complaint falls far short of the statutory requirements for original source status.

For all these reasons, this action must be dismissed with prejudice for lack of jurisdiction pursuant to Rule 12(b)(1) because Relator's action is based upon public disclosures and Relator is not an original source.

II. THE AMENDED COMPLAINT FAILS TO SATISFY FEDERAL RULE OF CIVIL PROCEDURE 9(b)'S HEIGHTENED PLEADING STANDARD AND MUST THEREFORE BE DISMISSED WITH PREJUDICE.

A. A Violation Of The False Claims Act Must Be Pleaded With Particularity Under Fed. R. Civ. P. 9(b).

Pursuant to the Federal Rules of Civil Procedure, “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” Fed. R. Civ. P. 9(b). In other words, “Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of . . . fraud with all of the essential factual background that would accompany the first paragraph of any newspaper story - that is, the ‘who, what, when, where and how’ of the events at

⁵ Furthermore, as discussed more fully in the following section, Relator has failed to identify a single purportedly false claim for Raplon®'s use -- let alone a false claim that was, in fact, paid by Medicare or Medicaid. In short, the entirety of ¶ 23 is speculation, which must foreclose Relator from claiming original source status, and thus fully warrants the Court's dismissal with prejudice of the entire action.

issue.” *In re Rockefeller Ctr. Props. Secs. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citation and internal quotations omitted). As the Third Circuit has recognized, the purpose of this rule is to “provide defendants with notice of the precise misconduct that is alleged and to protect defendants’ reputations by safeguarding them against spurious allegations of immoral and fraudulent behavior.” *See United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 118 (W.D. Pa. 2006) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)).

Notably, a dispositive issue in a FCA action is whether a “false or fraudulent” claim was, in fact, submitted to the government. *See United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 434, 439-40 (3d Cir. 2004) (“failure to present evidence of the actual submission of a single false claim to Medicaid is fatal to [the] qui tam action”). As such, “FCA claims must be pleaded with particularity in accordance with Fed. R. Civ. P. 9(b).” *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 n.9 (3d Cir. 2004). A FCA complaint must therefore “specify[] the time, place, and substance of the defendant’s alleged conduct.” *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998); *see also Pinnacle Choice, Inc. v. Silverstein*, No. 07-cv-1379, 2007 WL 2212861, *2 (D.N.J. July 13, 2007) (“plaintiffs must provide . . . information such as . . . who was responsible for the fraud”); *Palladino ex rel. United States v. VNA of S. N.J., Inc.*, 68 F. Supp. 2d 455,

462 (D.N.J. 1999). And “boilerplate and conclusory allegations will not suffice.” *Senn v. Hickey*, No. 03-cv-4372, 2005 WL 3465657, *4 (D.N.J. Dec. 19, 2005).

The complaint must also “identify with particularity the precise claims submitted to the government that are alleged to be false or fraudulent.” *United States ex rel. Schmidt v. Zimmer, Inc.*, No. 00-1044, 2005 WL 1806502, *2 (E.D. Pa. July 29, 2005). Indeed, a *qui tam* complaint that alleges “simply and without any stated reason” a relator’s belief that claims requesting illegal payment “must have been submitted, were likely submitted or should have been submitted to the Government” does not satisfy Rule 9(b)’s heightened pleading standard. *Schmidt*, 2005 WL 1806502, at *3 (quoting *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)).

A *qui tam* complaint -- such as the one here -- that fails to satisfy Rule 9(b)’s heightened pleading standards for FCA claims must be dismissed. *See, e.g., Schmidt*, 2005 WL 1806502, at *3-4 (FCA complaint dismissed under Rule 9(b) because the plaintiff “failed to identify with particularity a specific false claim”); *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1011 (11th Cir. 2005) (dismissing *qui tam* action with prejudice under Rule 9(b) where “complaint failed to provide any factual support that false claims were actually submitted to the government”); *United States ex rel. King v. Alcon Labs.*, 232 F.R.D. 568 (N.D. Tex. 2005)

(dismissing *qui tam* action with prejudice under Rule 9(b) where relator failed to identify claims or individuals submitting false claims).

B. Plaintiff's Vague and Unsubstantiated Allegations Do Not Satisfy The Heightened Rule 9(b) Pleading Requirements.

Relator's Amended Complaint fails to satisfy Rule 9(b)'s pleading requirements because: (1) the allegations regarding defendant's allegedly wrongful conduct lack specificity, and (2) the Amended Complaint does not identify with particularity even one allegedly false or fraudulent claim for Raplon® that was submitted to the government. Each of these deficiencies warrants dismissal.

First, Relator has failed to plead the "essential factual background" to support his allegation that "Organon knowingly misrepresented and/or concealed relevant information from the FDA in order to obtain, and subsequently retain, regulatory approval for Raplon." Am. Compl. ¶ 27. For example, although Relator alleges that Organon failed to disclose to the FDA the instances and SAEs associated with Raplon®, *id.* at ¶ 19, this allegation fails to provide defendant "with notice of the precise misconduct that is alleged." *Bartlett*, 234 F.R.D. at 118 (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3rd Cir. 1997)). Indeed, Relator does not identify the submissions to the FDA that he is referring to, or the information that was omitted from Organon's submissions to the FDA. As a consequence, defendants are left without a clear or adequate

understanding of the precise misconduct at issue in this case, or the specific information upon which Relator relies to support his allegations.

The only identifiable source of information Relator relies upon is a purported Organon communication that he attaches to his Amended Complaint as Exhibit A. However, this purported email fails to contain any information that would substantiate Relator's allegation that this communication confirms that individuals working at Organon knew that Raplon® caused SAEs prior to FDA approval; it unmistakably lacks the sender's or recipient's email addresses, a subject line, date and time, or any other indication of its origin. *See* Am. Compl. ¶¶ 12-17. Likewise, Relator fails to provide any identifying information concerning the "internal, non-public documents and Organon's various submissions to the FDA" that he vaguely cites to in support of his allegation that Organon failed to disclose pertinent information regarding Raplon® to the FDA. *Id.* at ¶ 19.

Relator also loosely alleges that Organon orchestrated an illicit scheme to conceal clinical information regarding Raplon® from the public. *See* Am. Compl. at ¶¶ 17, 18, 21. These allegations likewise lack the requisite particularized detail to place Organon on notice of the precise misconduct that is alleged. For example, Relator claims that investigators expressed concerns about Raplon®'s side-effects, yet he fails to plead who these investigators are, who they worked for, when their

investigations occurred, what the investigators were specifically tasked to do, or how Relator learned about the alleged investigation. *Id.* at ¶ 17. Nor does Relator provide any details in support of his blanket allegation that Organon acted “disingenuously” regarding Raplon®’s safety because Organon blamed physicians for problems that should have been attributed to Raplon®. *Id.* at ¶ 21. And Relator’s allegations that Organon misrepresented or failed to disclose Raplon®’s side-effects to hospitals, physicians, and patients are insufficient for the same reasons. *See* Am. Compl. ¶¶ 7, 16, 20, 21, 24, 28. In fact, Relator fails to identify a single communication, or a participant in any specific communication, in support of these allegations.

Moreover, Relator asserts that “upon information and belief . . . Organon’s submissions to the FDA contained numerous quantitative and qualitative misrepresentations concerning Raplon’s propensity to cause SAEs.” *Id.* However, pleading “upon information and belief” is not permitted in FCA cases where the relator is a corporate insider, *i.e.*, a relator who worked at the defendant company. *See Bartlett*, 234 F.R.D. at 122. Here, Relator was an Associate Director of Medical Services for Antithrombotics at Organon who claimed to have had access to individuals working with, and documents concerning, Raplon®. *See* Am. Compl. ¶ 11. Thus, Relator, as a corporate insider, cannot shirk his heightened

pleading responsibilities of Rule 9(b) by relying on facts alleged “upon information and belief.”⁶

Second, Relator’s failure to identify any particulars with respect to the allegedly false claims is fatal to his *qui tam* action. Indeed, when stating a claim under the FCA, “details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices” are the types of information that a Relator must plead to state a claim with sufficient particularity. *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004) (emphasis added); *see also Clausen*, 290 F.3d at 1312 (dismissing FCA claim where “[n]o amounts of charges were identified,” “[n]o actual dates were alleged,” “[n]o policies about billing or even second-hand information about billing practices were described,” and “[n]o

⁶ Furthermore, if a plaintiff pleads upon “information and belief,” he must provide information sufficient to particularize his allegations consistent with Rule 9(b). Such “information” would include a statement describing the efforts plaintiff undertook to obtain the relevant information from the defendant, as well as a statement describing the facts that provide a basis for plaintiff’s allegations. *United States ex rel Waris v. Staff Builders, Inc.*, No CIV. A. 96-1969, 1999 WL 179745, at *4 (E.D. Pa. Mar. 4, 1999); *Weiner v. Quaker Oats Co.*, 129 F.3d 310, 319 (3d Cir. 1997). Here, however, Relator has failed to satisfy these requirements.

copy of a single bill or payment was provided.”). Such allegations are unmistakably absent from the Amended Complaint here.

Instead of pleading any particulars regarding the alleged false claims submitted to the government -- which is the “*sine qua non* of a FCA violation,” *Clausen*, 290 F.3d at 1311-- Relator merely asserts in a conclusory manner that “Organon’s actions have caused false claims to be submitted to and paid by Medicare and Medicaid.” Am. Compl. ¶ 23. He does not identify the “hospitals, physicians and/or patients” that have allegedly “submit[ted] false reimbursement claims to Medicare and Medicaid associated with Raplon[.]” *Id.* To be sure, Relator does not even identify any hospitals, physicians, or patients who were recipients of false or misleading information concerning Raplon®, or offer any specific facts to support his contention that Organon “caused” hospitals, physicians, and patients to submit claims to Medicare and Medicaid.⁷ *See id.* at ¶¶ 23, 29, 30.

Nor does Relator identify one false claim that has been submitted -- a pleading deficiency that in and of itself warrants dismissal. *See Schmidt*, 2005 WL 1806502 at *3 (“Because [Relator] has failed to identify with particularity a specific false claim, there is no nexus between the [defendant’s] allegedly

⁷ Relator has failed to plead any detail consistent with Rule 9(b) despite having approximately six years to substantiate his allegations (Relator filed his original complaint on April 4, 2002).

[wrongful conduct] and the FCA,” and therefore, the complaint “does not pass muster under Rule 9(b)”); *Bartlett*, 234 F.R.D. at 122 (“evidence of at least one specific claim submitted by these Defendants through the schemes alleged is required to inject the necessary precision required of a Rule 9(b) pleading in the Third Circuit”). As explained by the Eleventh Circuit in *Clausen*, courts “cannot make assumptions about a FCA defendant’s submission of actual claims to the Government without stripping all meaning from Rule 9(b)’s requirement of specificity or ignoring that the ‘true essence of the fraud’ of a FCA action involves an actual claim for payment and not just a preparatory scheme.” *Id.* at 1312 n.21. In other words, the entire Amended Complaint contravenes the explicit purpose motivating Rule 9(b) -- *i.e.*, that allegations of fraud manifest a reasonable level of particularity and specificity -- and must therefore be dismissed with prejudice.⁸

III. THE AMENDED COMPLAINT FAILS TO STATE A VIABLE CAUSE OF ACTION UNDER THE FALSE CLAIMS ACT AND SHOULD THEREFORE BE DISMISSED WITH PREJUDICE PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6).

For the same reasons set forth in Section III, the Amended Complaint must be dismissed under Rule 12(b) (6) because Relator has failed to plead a viable claim under the FCA.

In deciding a motion to dismiss for failure to state a claim upon which relief can be granted under Rule 12(b)(6), the Court “need not credit a complaint’s ‘bald

⁸ Relator’s failure to satisfy Rule 9(b) only further substantiates his inability to claim original source status, as discussed above.

assertions’ or ‘legal conclusions.’” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation omitted). Indeed, as the Supreme Court recently emphasized, “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007).

In short, Relator has failed to: (1) identify any false claim that was actually submitted to the Government, and (2) allege facts that demonstrate causation, or a link between Organon’s alleged misconduct and those doctors, hospitals and patients who Relator assumes submitted claims for Raplon® to Medicare or Medicaid -- both of which are required under the FCA.⁹ See *Quinn*, 382 F.3d at 438, 440 (plaintiff must prove that “the defendant presented or caused to be presented to an agent of the United States a claim for payment”; in other words, the Relator must arrive to court with a “claim[] in hand.”); *Schmidt*, 2005 WL 1806502, at *2-3 (noting that there must be a causal nexus between the defendant’s alleged wrongful conduct and the submission of a false or fraudulent claim); *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 378 (7th Cir.

⁹ To the extent that the Amended Complaint is predicated upon 31 U.S.C. § 3729(a)(2), as pled it is also inconsistent with the Supreme Court’s recent decision in *Allison Engine Co., Inc. v. United States ex rel. Sanders*, No. 07-214, 2008 WL 2329722 (U.S. June 9, 2008), in that it does not allege any documents were submitted by defendants with the purpose of getting a false or fraudulent claim paid or approved by the Government.

2003) (it is essential to a FCA claim to link specific allegations of deceit to claims for payment).

In particular, Relator's Amended Complaint summarily concludes that Organon "caused many hospitals, physicians and/or patients to submit false reimbursement claims to Medicare and Medicaid associated with Raplon." Am. Compl. ¶ 23. Yet Relator fails to identify a single false claim, or provide any facts supporting his allegation that claims for Raplon® were, in fact, submitted to Medicare or Medicaid -- a deficiency that is fatal to the Amended Complaint. *See Clausen*, 290 F.3d at 1212 n.21 ("[the court] cannot make assumptions about a False Claims Act defendant's submission of actual claims to the Government."). And Relator's conclusory allegation that Organon's conduct "caused" the submission of false claims is likewise inadequate because Relator has failed to plead facts in support of a direct link between defendants' alleged misconduct and the parties who submitted a claim to the government. *See, e.g., Schmidt*, 2005 WL 1806502, at *3 (dismissing FCA claim where Relator failed to link alleged illegal marketing scheme to the submission of false claims by hundreds of unnamed hospitals).

For all of the above reasons, Relator has failed to plead a cognizable claim under the FCA and his *qui tam* action should therefore be dismissed with prejudice now, "at the point of minimum expenditure of time and money by the parties and

the court.” *Twombly*, 127 S. Ct. at 1966 (quoting 5 Wright & Miller § 1216, at 233-234).

IV. SCHERING-PLOUGH SHOULD BE DISMISSED FROM THIS FALSE CLAIMS ACT QUI TAM ACTION

Schering-Plough is not a proper party to this lawsuit because Relator has failed to set forth any allegations that Schering-Plough violated the FCA. In fact, Relator references the company in only three of the thirty-two paragraphs of the Amended Complaint, none of which asserts that Schering-Plough engaged in conduct defrauding the United States Government. *See* Am. Compl. ¶¶ 3, 25, 32. Unable to allege that Schering-Plough violated the FCA, Relator dubiously concludes that Schering-Plough is nonetheless a proper FCA defendant based on the bald assertion that “Schering acquired Organon and succeeded to its rights and liabilities.” *Id.* This statement, by itself, though fails to provide a sufficient basis for retaining Schering-Plough in this case.

In order to establish successor liability, a plaintiff must demonstrate that two conditions are satisfied: (1) that the successor had notice of the claim before the acquisition, and (2) that there is substantial continuity in the operation of the business before and after the sale. *See United States ex rel. Fisher v. Network Software Assocs.*, 180 F. Supp. 2d 192, 195 (D.D.C. 2002). Accordingly, in order to survive a motion to dismiss, a plaintiff’s complaint must contain factual

allegations in support of those two conditions.¹⁰ *Id.* at 196 (allowing successor liability claim to survive motion to dismiss only because plaintiff properly pled allegations in support of both conditions).

Here, Relator once again has failed to set forth any facts supporting his allegation that Schering-Plough has successor liability. *See* Am. Compl. ¶¶ 3, 25, 32. Thus, in the absence of such facts, Relator's claim against Schering-Plough must be dismissed.

Finally, in order for Schering-Plough to be liable as a successor-in-interest to Organon, it must first be established that Organon is liable under the FCA. As discussed in detail above, Relator has failed to state a viable claim against Organon under Rules 12(b)(1) and 12(b)(6). Therefore, Relator's derivative claim against Schering-Plough must also be dismissed.

CONCLUSION

For all of the aforementioned reasons, Defendants Organon and Schering-Plough respectfully request that this Court dismiss, the Amended Complaint in its entirety, and *with prejudice*, pursuant to Rule 12(b)(1) because it is predicated upon public disclosures and Relator has not pled that he is an original source. In the alternative, Defendants respectfully request that the Court dismiss the

¹⁰ It should be noted that at least one district court applied the heightened Rule 9(b) standard to a claim for successor liability where the plaintiff alleges fraud. *See Infra-Metals, Co. v. Topper & Griggs Group, Inc.*, No. Civ. A. 3:05-559, 2005 WL 3211385, *3 n.4 (D. Conn. Nov. 30, 2005).

Amended Complaint *with prejudice* in its entirety because it contravenes Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, and further amendment would be futile. In addition, Defendants respectfully request the Court dismiss Defendant Schering-Plough from this action.

Respectfully submitted,

By: /s/ Alana B. Wexler
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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of June, 2008, I caused a copy of the foregoing Defendant's Motion to Dismiss, Memorandum in Support and Proposed Order to be filed electronically with the Clerk of the Court using the CM/ECF system which will send a notification of such filing to the below-named individuals and I also caused a paper copy of the same Motion, Memorandum and Proposed Order to be mailed, first class mail, postage prepaid to the following:

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