

**COLE, SCHOTZ, MEISEL,
FORMAN & LEONARD, P.A.**

A Professional Corporation
Court Plaza North
25 Main Street
P. O. Box 800
Hackensack, New Jersey 07602-0800
(201) 489-3000
(201) 489-1536 Facsimile
Attorneys for Plaintiff/Relator Jeffrey D. Feldstein, M.D.

UNITED STATES OF AMERICA, ex rel.	:	UNITED STATES DISTRICT COURT
JEFFREY D. FELDSTEIN, M.D.,	:	FOR THE DISTRICT OF NEW JERSEY
	:	
Plaintiff/Relator,	:	Civil Action No. 07-2690 (DMC)(MF)
	:	
v.	:	
	:	
ORGANON, INC. and SCHERING-	:	
PLOUGH, INC.	:	
	:	
Defendants.	:	

**PLAINTIFF/RELATOR’S MEMORANDUM OF LAW IN OPPOSITION
TO DEFENDANTS’ MOTION TO DISMISS THE
AMENDED COMPLAINT**

Of Counsel and on the Brief:
Steven I. Adler

On the Brief:
Christopher P. Massaro

TABLE OF CONTENTS

	<u>Page</u>
PRELIMINARY STATEMENT	1
STATEMENT OF FACTS	3
LEGAL ARGUMENT	11
I. DEFENDANTS' MOTION TO DISMISS SHOULD BE DENIED BECAUSE THE ALLEGATIONS IN THE AMENDED COMPLAINT ARE NOT SUBJECT TO THE PUBLIC DISCLOSURE BAR CONTAINED IN THE FALSE CLAIMS ACT.....	11
II. RELATOR IS AN ORIGINAL SOURCE OF THE INFORMATION UNDERLYING THE ALLEGATIONS CONTAINED IN THE AMENDED COMPLAINT	18
III. DEFENDANTS' MOTION TO DISMISS PURSUANT TO FED. R. CIV P. 9(B) SHOULD BE DENIED BECAUSE THE AMENDED COMPLAINT PLEADS FRAUD WITH THE REQUISITE SPECIFICITY	20
IV. DEFENDANTS' MOTION TO DISMISS PURSUANT TO RULE 12(B)(6) SHOULD BE DENIED BECAUSE THE AMENDED COMPLAINT ADEQUATELY SETS FORTH A CLAIM	25
V. RELATOR SHOULD BE GIVEN AN OPPORTUNITY TO AMEND THE COMPLAINT IF THE COURT CONCLUDES THAT IT FAILS TO SATISFY THE REQUIREMENTS OF FED. R. CIV. P. 12(B)6 OR (9)(B).....	29
CONCLUSION.....	30

TABLE OF AUTHORITIES

CASES	PAGES
<u>In re Burlington Coat factory Sec. Litig</u> , 114 F.3d 1410 (3d Cir. 1997)	21, 30
<u>Caldwell Trucking PRP Group v. Spaulding Composites Co.</u> , 890 F. Supp. 1247 (D.N.J. 1995)(additional citation omitted)	26
<u>Cestonaro v. United States</u> , 211 F.3d 749 (3d Cir. 2000).....	12
<u>Clausen v. Laboratory Corporation of America, Inc.</u> , 290 F.3d 1301 (11th Cir. 2002)	23, 24
<u>Erickson v. Pardus</u> , 127 S. Ct. 2197, 167 L. Ed. 2d 1081 (2007).....	26
<u>Frederico v. Home Depot</u> , 507 F.3d 188 (3d Cir. 2007).....	20
<u>Grayson v. Mayview State Hosp.</u> , 293 F.3d 103 (3d Cir. 2002)	29
<u>Haskins v. Omega Institute, Inc.</u> , 25 F. Supp. 2d 510 (D.N.J. 1998)	18, 19
<u>Hutchins v. Wilentz, Goldman & Spitzer</u> , 253 F.3d 176 (3d Cir. 2001), <u>cert. denied</u> , 536 U.S. 906 (2002).....	12, 13
<u>Pennsylvania Dep't of Env'tl. Prot. v. Concept Scis., Inc.</u> , 232 F. Supp. 2d 454 (E.D. Pa. 2002)..	29
<u>In re Rockefeller Ctr. Props., Inc. Sec. Litig.</u> , 311 F.3d 198 (3d Cir. 2002).....	21
<u>Landsberg v. Levinson</u> , 2008 WL 2246308 (W.D. Pa.)	24
<u>Scheuer v. Rhodes</u> , 416 U.S. 232 (1974).....	26
<u>Sixth Camden Corp. v. Township of Evesham, Cty. of Burlington</u> , 420 F. Supp. 709 (D.N.J. 1976)	29
<u>Turicentro v. American Airlines, Inc.</u> , 303 F.3d 293 (3d Cir. 2002).....	12
<u>United States ex rel. Atkinson v. Pa. Shipbuilding Co.</u> , 473 F.3d 506 (3d Cir. 2007)	12
<u>United States ex rel. Cantekin v. University of Pittsburgh</u> , 192 F.3d 402 (3d Cir. 1999)	28
<u>United States ex rel. Franklin v. Parke-Davis</u> , 147 F. Supp. 2d 39 (D.Mass.2001)	24, 25, 27, 28

United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 238 F. Supp. 2d 258 (D.D.C. 2002)24

United States ex rel. Quinn v. Omnicare Inc., 382 F.3d 432 (3d Cir. 2004)23

United States ex rel. Siller v. Becton Dickinson, 21 F.3d 1339 (4th Cir. 1994).....14

United States v. Catholic Healthcare West, 445 F.3d 1147 (9th Cir. 2006).....13

United States v. Kensington Hospital, 760 F. Supp. 1120 (E.D. Pa. 1991).....24

United States v. Paranych, 396 F.3d 326 (3d Cir. 2005)14, 18

STATUTES AND RULES

N.J.S.A. 34:19-1.....5

U.S.C. § 3729, et seq......10

31 U.S.C. § 3729.....12

31 U.S.C. 3730(e)(4)(B)18

Fed. R. Civ. P. 9(b)2, 3, 20,
22, 23, 25,
27, 30

Fed. R. Civ. P. 12(b)(6).....2, 11, 12,
26, 29, 30

PRELIMINARY STATEMENT

Plaintiff/Relator Jeffrey D. Feldstein, M.D. (“Dr. Feldstein”), individually and on behalf of the United States of America, commenced this qui tam action under the False Claims Act against Defendants Organon USA, Inc. (“Organon”) and Schering-Plough, Inc. (“Schering”)(collectively, the “Defendants”) to recover all sums that Organon fraudulently caused the United States Government to pay in connection with a dangerous drug known as Raplon, which Organon later unilaterally pulled from the market after numerous deaths. Organon knowingly misrepresented and concealed information from the Food and Drug Administration (“FDA”) in order to gain approval for Raplon. Unaware of Organon’s deception, physicians across the country administered Raplon to countless patients. Many of those patients suffered serious adverse events from the drug and some even died from Raplon. Moreover, Organon’s conduct caused many physicians, hospitals and/or patients to submit claims to Medicare and Medicaid for reimbursement of charges associated with Raplon. Both of those government agencies would have denied reimbursement claims had they known of the circumstances under which Organon obtained “approval” for the drug’s use.

In an effort to avoid having this Court consider Dr. Feldstein’s claims on its merits, and in an attempt to deny access to discovery materials that will likely disclose additional facts demonstrating Organon’s fraudulent conduct with respect to Raplon, Defendants now move to dismiss Dr. Feldstein’s complaint on several grounds, all of which lack merit.

Defendants first claim that the allegations Dr. Feldstein has raised in his Amended Complaint were disclosed in several articles and state court complaints prior to the commencement of this qui tam action. Under the False Claims Act, a relator cannot bring a claim based upon allegations that have already been disclosed to the public. However, even a

cursory review of the complaints and articles submitted by Defendants reveals that they differ substantially from the allegations asserted by Dr. Feldstein. Although the complaints and articles reference bronchospasms, which are non-life threatening adverse events (“AEs”), associated with Raplon and allege that Organon acted negligently, they do not so much as mention the allegations that are at the heart of this litigation. Dr. Feldstein is not asserting that Organon was negligent, or even reckless, in its testing or conduct with respect to Raplon. Dr. Feldstein is asserting that Organon knowingly withheld information from the FDA concerning an unexpected, life-threatening side effect (i.e., a serious adverse event or “SAE”) caused by Raplon to obtain an invalid approval, which ultimately caused Medicare and Medicaid to pay false claims.¹ The material submitted by Defendants are bereft of any such allegations of fraud. See Point I, infra. Furthermore, despite the fact that Dr. Feldstein’s allegations have not been publicly disclosed, he is also an original source as that term is defined in the FCA and, therefore, has the right to proceed on the merits of his claim. See Point II, infra.

Defendants next attack the sufficiency of Dr. Feldstein’s Complaint under Fed. R. Civ. P. 9(b) and Fed. R. Civ. P. 12(b)(6). See Points III and IV, infra. According to Defendants, Dr. Feldstein has failed to plead fraud with sufficient particularity and has failed to adequately state a claim against Organon and Schering. As will be explained below, the Amended Complaint has apprised Defendants of the basis of Dr. Feldstein’s claims in detail and there is absolutely no basis to dismiss the Amended Complaint under Fed. R. Civ. P. 9(6) or 12(b)6. At the very least,

¹ Because this SAE was never disclosed to the FDA and a treatment protocol was never established, physicians were ill prepared to deal with this SAE in the seconds available before a patient succumbed to it. (Dr. Feldstein Cert. ¶ 15). “Dr. Feldstein Cert.” refers to the Certification of Jeffrey D. Feldstein, which has been submitted along with this Memorandum of Law.

should the Court be of the opinion that there is any deficiency, Dr. Feldstein should be granted leave to replead. See Point V, infra.

Defendants' motion is nothing more than a weak attempt to preclude this Court from considering this matter on its merits. Organon's criminal behavior should be exposed to public scrutiny and the United States is entitled to compensation for all sums wrongfully paid by Medicare and Medicaid in connection with Raplon. Accordingly, Dr. Feldstein respectfully requests this Court to deny the Defendants' motion in its entirety.

STATEMENT OF FACTS

Before it was purchased by Schering in 2007, Organon was engaged in creating, manufacturing, distributing and marketing pharmaceuticals throughout the United States and abroad. (Amended Complaint ¶¶ 1, 2). For many years, Organon expended enormous time, money and resources developing a neuromuscular blocking agent known as Raplon. (Amended Complaint ¶ 6). Raplon was designed to paralyze a patient's throat muscles to allow the painless insertion of an endotracheal tube into a patient's trachea. An endotracheal tube establishes an airway to facilitate the administration of oxygen and anesthetic agents to patients during surgical or obstetric procedures. (Amended Complaint ¶ 6).

On August 18, 1999, Raplon received regulatory approval from the FDA. Organon subsequently engaged in extensive efforts to market Raplon to physicians in the United States and abroad. (Amended Complaint ¶ 7). Organon hoped that Raplon would be superior to its competitor drugs because it induced paralysis so rapidly. For example, Raplon would paralyze a patient's throat muscles more quickly than the drug most often used, succinylcholine, an older generic drug that competed with Raplon. (Amended Complaint ¶ 8).

Raplon, however, inexplicably produced an unexpected, serious, and sometimes fatal, side effect which met the definition of a serious adverse event (“SAE”) as set forth in the FDA regulations. (Amended Complaint ¶ 9). Certain individuals would be unable to breath and, at times, would even suffer “chest rigidity” after receiving Raplon, nothing like a brief bronchospasm (an expected, non-life threatening condition that occurs when a patient’s bronchial tubes close and prevent breathing, which is easily reversed.) (Amended Complaint ¶ 9).² SAEs and AEs must both be reported to the FDA.

The cause of the SAEs generated by Raplon were unknown and unique in their severity when compared with similar drugs of its class. (Amended Complaint ¶ 10). The seriousness of these episodes was described as “like having a clamp over the airway” or “the chest felt like concrete”. These SAEs would cause a patient’s entire thoracic region to contract so completely that it became extremely difficult or impossible for physicians to ventilate patients. In certain instances, physicians were unable to reverse the condition before the patient succumbed from a lack of oxygen. (Amended Complaint ¶ 10).

On May 31, 2000, Organon hired Dr. Feldstein to serve as Associate Director of Medical Services for Antithrombotics. (Amended Complaint ¶ 11). During his employment, Dr. Feldstein acquired non-public information concerning the clinical problems associated with Raplon. This included evidence that Organon had knowingly concealed information and made misrepresentations to the FDA during and after the regulatory approval process concerning SAEs caused by Raplon. (Amended Complaint ¶ 11).

² Bronchospasm was an expected AE for Raplon, just as it is for Raplon’s generic competitor drug, succinylcholine. (See Dr. Feldstein Cert. ¶ 15).

Dr. Feldstein is a licensed physician with over 34 years experience. (Dr. Feldstein Cert. ¶ 2). Prior to joining Organon, he oversaw the operations of a large Health Maintenance Organization in Chicago, Illinois, and participated in numerous clinical trials concerning drugs that were being evaluated for the global marketplace. (Dr. Feldstein Cert. ¶ 2). His duties at Organon included assisting with the launch of a new drug, Arixtra, and developing post-marketing trials and research grants for that drug. (Dr. Feldstein Cert. ¶ 3). Arixtra is a drug that is used after knee replacement, hip replacement, or hip fracture surgeries to help prevent blood clotting. (Dr. Feldstein Cert. ¶ 3). During his tenure at Organon, Dr. Feldstein discovered that Organon personnel were concealing instances of bleeding associated with Arixtra from the FDA and medical community. In fact, Dr. Feldstein's supervisor, Dr. Jonathan Deutsch ("Deutsch"), who was Organon's Director of Hospital Products, attempted to coerce Dr. Feldstein into disseminating information that would conceal the bleeding associated with Arixtra. (Dr. Feldstein Cert. ¶ 4). Dr. Feldstein refused to comply with Deutsch's demands, which ultimately led to his wrongful termination. (Dr. Feldstein Cert. ¶ 5).³

Prior to his termination, Dr. Feldstein voiced his concerns about Arixtra to one of his colleagues, Dr. Daniel Sack, who served as Organon's Associate Director of Anesthesiology. Dr. Feldstein and Dr. Sack worked together in Organon's Department of Medical Affairs for approximately one year. During that time, they collaborated on various matters, including the Arixtra project. (Dr. Feldstein Cert. ¶ 6). Dr. Feldstein approached Dr. Sack to inquire further

³ Dr. Feldstein commenced an action against Organon in the Superior Court of New Jersey for violating the Conscientious Employee Protection Act, N.J.S.A. 34:19-1 to -8, which is currently being held in abeyance pending the resolution of this litigation. (Dr. Feldstein Cert. ¶ 5).

about Deutsch. In response to his inquiry, Dr. Sack informed Dr. Feldstein that Raplon had caused numerous SAEs and multiple deaths since its approval. Moreover, Dr. Sack told Dr. Feldstein that he was in possession of a private e-mail from Deutsch indicating that personnel at Organon knew prior to Raplon's approval by the FDA that Raplon caused SAEs. (Amended Complaint ¶ 12; Dr. Feldstein Cert. ¶¶ 6-7).

The e-mail had been prepared by Deutsch, Organon's Director of Hospital Products, and sent to Organon's Vice President of Medical Services, Dr. Deborah Shapse, prior to the FDA's approval of Raplon. Dr. Sack discovered the e-mail on Dr. Shapse's laptop computer after Organon had reassigned the laptop to Dr. Sack for his use. (Amended Complaint ¶ 13). The e-mail references an earlier "bronchospasm" e-mail (quote from original) and further states as follows:

at the Dallas meeting [bronchospasm] was heatedly discussed by the investigators as a potential problem that needed to be addressed prior to [Raplon's] launch.

(Amended Complaint ¶ 14).⁴

The e-mail further notes, in pertinent part, as follows:

My understanding is that Cari is concerned, hence her inclusion in the PIP of a mention that Medical Services needs to have a treatment protocol in place for bronchospasm prior to launch.

(Amended Complaint ¶ 15).

Finally, the e-mail indicates that "Michael may be correct in not wanting to draw attention to bronchospasm." (emphasis added). Plaintiff believes that the Michael referenced in

⁴ Plaintiff attached a copy of this e-mail to the Amended Complaint. For the Court's convenience, another copy of the e-mail is attached as Exhibit B to the Dr. Feldstein Cert.

the e-mail is Michael Novinsky, Organon's Vice President of Marketing. (Amended Complaint ¶ 16).⁵

Upon reviewing the e-mail and other internal, non-public documents and Organon's various submissions to the FDA, Dr. Feldstein was further convinced that Organon had failed to disclose to the FDA as part of its NDA instances and the severity of the SAE associated with Raplon both before and after obtaining FDA approval. (Amended Complaint ¶ 19). Upon information and belief, Organon's submissions to the FDA contained numerous quantitative and qualitative misrepresentations concerning Raplon's propensity to cause SAEs, which were purposely labeled only as expected and non-life threatening adverse events, such as coughing or wheezing, bronchospasm and other airway symptoms, contrary to the FDA and CFR definitions. (Amended Complaint ¶ 19). Moreover, after receiving FDA approval, Organon never advised the doctors who administered Raplon to patients of the potential for SAEs in any labeling or package insert and never had a treatment protocol in place prior to or even after launch. (Amended Complaint ¶ 20).

Immediately upon reviewing the e-mail at issue in this litigation, it was clear to Dr. Feldstein that Organon had taken steps to conceal material information from the medical community and the FDA, just as it did with Arixtra. As a result, in March or April of 2001, Dr. Feldstein contacted the FDA and informed it that he possessed evidence that Organon had suppressed information during Arixtra and Raplon's approval processes. The FDA later

⁵ The other individuals identified in the e-mail are believed to be an Organon marketing employee (Cari Overman) and two of Raplon's physician-investigators. (See Dr. Feldstein Cert. ¶ 7).

provided Dr. Feldstein with a confidential identification number to protect his identity and indicated that an investigator would contact him in the near future. (Dr. Feldstein Cert. ¶ 8).

In or about late May 2001, Dr. Feldstein drove from Livingston, New Jersey to the United States Attorney's Office in Boston, Massachusetts, to discuss the matter with Government representatives. (Dr. Feldstein Cert. ¶ 9). When he arrived in Boston, he spoke with two Assistant United States Attorneys, Nancy Rue ("AUSA Rue") and Roberta Brown. He provided AUSA Rue with a copy of the "smoking gun" e-mail and other information he possessed concerning Raplon. He informed the Government that it was his opinion Organon had intentionally concealed information regarding Raplon from the FDA based not only on the e-mail, but also his understanding of Organon's conduct concerning Arixtra. Furthermore, as an experienced physician and researcher, Dr. Feldstein knew that Raplon would have been administered to patients by physicians who, along with hospitals, would have then submitted claims for reimbursement to Medicare and Medicaid. He indicated to AUSA Rue that if Organon had obtained an invalid approval for Raplon, then all of the claims that Medicare and Medicaid paid in connection with the drug would have been made under false pretenses. AUSA Rue indicated that the United States Attorney's Office was interested in the matter, but would not act until after Dr. Feldstein commenced a suit under the False Claims Act. Dr. Feldstein made sure to provide the e-mail and the information he possessed in relation to this qui tam action to the Government before commencing this action. Moreover, he never saw any of the complaints or articles attached to Defendants' motion to dismiss before they were filed with this Court. (Dr. Feldstein Cert ¶¶ 9-11). Accordingly, this qui tam action is not derived from any publicly available information.

Subsequently, Dr. Feldstein continued his investigation. He remained in contact with Dr. Sack and asked him for any additional information he might have concerning Raplon. Dr. Feldstein had learned that the reference in the e-mail to the Dallas meeting was related to a meeting of the physician-investigators involved in Raplon's US Phase III Pivotal trial at which Organon disbursed topline data only. During that meeting various investigators expressed serious concerns about Raplon's propensity to cause SAEs in certain patients. The investigators understood that these SAEs were caused by Raplon, even though they had used a double-blinded trial, because the investigators never experienced this SAE during the many years they had worked with the comparator drug succinylcholine.⁶ (Amended Complaint ¶ 17; Dr. Feldstein Cert ¶ 12). Dr. Feldstein also discovered that, as a result of the investigators' meeting, in early 1998 a representative from Organon's Clinical Development Department, Organon Technika, contacted Dr. Carol Hirshman, a Professor of Anesthesiology at Columbia University, and asked her if she could perform a mechanism of action study to determine the cause of the SAEs associated with Raplon. (Amended Complaint ¶ 18; Dr. Feldstein Cert ¶ 13). In other words, Organon knew, well before the FDA approved Raplon, that this drug caused SAEs. Dr. Hirshman, an expert in these types of studies, indicated that she could and would be able to perform the study, but Organon failed to authorize the study and never discussed the matter with her again. (Amended Complaint ¶ 18; Dr. Feldstein Cert ¶ 14). This only reinforced Dr.

⁶ A double-blinded study is one in which the sponsor (*i.e.*, Organon), physicians and patients do not know which of two or more drugs the patients are receiving. Here, succinylcholine was the other drug used for the Raplon clinical trials. Although the trial was double-blinded, it was clear to the physicians that Raplon was causing these SAEs because the other drug used in the study, succinylcholine, had been in use for forty years and never produced the SAEs associated with Raplon. (Dr. Feldstein Cert. ¶ 12).

Feldstein's conviction that Organon had intentionally withheld information concerning Raplon's propensity to cause SAEs in the NDA submitted to the FDA. (Dr. Feldstein Cert ¶ 14). It is critical to note that Dr. Feldstein immediately recognized that fraud had occurred upon reviewing the e-mail and NDA because nothing in the NDA referenced the findings of the physician-investigators in connection with the double-blinded study.

The extent of the unexpected danger posed by Raplon came to light following its approval by the FDA. In or about August 1999, physicians began reporting instances of SAEs related to Raplon to Organon's safety department. Organon disingenuously suggested that the cause of these SAEs might have been related to the incorrect insertion of endotracheal tubes by physicians when it knew that Raplon was the true cause. (Amended Complaint ¶ 21). Many individuals died from Raplon. Additionally, physicians indicated that Raplon also caused a significant number of non-fatal cases of SAEs in patients which, in turn, led to innumerable surgical delays, cancellations and/or other unnecessary medical expenses associated with treating same. (Amended Complaint ¶ 22).

Organon's actions have caused false claims to be submitted to and paid by Medicare and Medicaid in violation of 31. U.S.C. § 3729, et seq. (Amended Complaint ¶¶ 4, 23, 26-30). 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. (Amended Complaint ¶¶ 23, 26-30). Organon, therefore, caused many hospitals, physicians and/or patients to submit false reimbursement claims to Medicare and Medicaid associated with Raplon they otherwise would not have been able to submit. (Amended Complaint ¶¶ 23, 26-30). Moreover, Medicare and Medicaid would not have reimbursed hospitals, physicians and/or patients for the use of Raplon had those agencies known that the FDA approved Raplon without

knowing the potential for SAEs. (Amended Complaint ¶¶ 23, 26-30). Organon's actions also have caused Medicare and Medicaid to pay for medical costs associated with treating SAEs that never would have been incurred had adequate disclosures been made. (Amended Complaint ¶¶ 23, 26-30). Furthermore, Organon never informed the FDA, hospitals, physicians or patients that Raplon posed a serious threat to public health and safety before it unilaterally decided to pull the drug from the market on or about March 27, 2001. (Amended Complaint ¶ 24). It is believed that Organon removed Raplon from the market to avoid intervention and scrutiny by the FDA. (Amended Complaint ¶ 24).

In 2007, Schering acquired Organon and succeeded to its rights and liabilities. (Amended Complaint ¶ 25). Accordingly, Schering and Organon are jointly and severally liable for compensating the United States for the damages caused by Organon's actions and/or inactions. (Amended Complaint ¶ 25).

LEGAL ARGUMENT

I. DEFENDANTS' MOTION TO DISMISS SHOULD BE DENIED BECAUSE THE ALLEGATIONS IN THE AMENDED COMPLAINT ARE NOT SUBJECT TO THE PUBLIC DISCLOSURE BAR CONTAINED IN THE FALSE CLAIMS ACT

Organon and Schering moved to dismiss this case pursuant to Fed R. Civ. P. 12(b)(1) on the ground that the allegations underlying the Amended Complaint were disclosed to the public before Plaintiff commenced this action and, therefore, this Court lacks jurisdiction under the FCA to consider Plaintiffs' claim on its merits. Defendants are simply incorrect.

As a threshold matter, the Defendants have asserted a factual challenge to the jurisdiction of this Court. See Fed. R. Civ. P. 12(b)(1). "Challenges to subject matter jurisdiction under Rule 12(b)(1) may be 'facial' or 'factual.'" See Turicentro v. American Airlines, Inc., 303 F.3d 293,

308 n.4 (3d Cir. 2002); Cestonaro v. United States, 211 F.3d 749 (3d Cir. 2000). A “facial” challenge is brought when a defendant contends that a plaintiff has failed to properly allege jurisdictional facts in the complaint. Turicentro, 303 F.3d 293, 300 n.4 (3d Cir. 2004). In contrast, a defendant bringing a motion to dismiss based on a “factual” challenge is attacking more than just the face of the complaint. Id. Instead, such a challenge is brought when it is alleged that the facts underlying the complaint do not establish that a court has subject matter jurisdiction over the claims raised. Id. When a “factual” attack is asserted, the court is “not confined to the allegations in the complaint . . . and can look beyond the pleadings to decide factual matters relating to jurisdiction.” Cestonaro, 211 F.3d 749, 752 (3d Cir. 2000). Thus, unlike a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), this Court should not simply make a determination as to whether subject matter jurisdiction exists based on the allegations contained in the Amended Complaint alone. Moreover, “[w]here jurisdictional and substantive facts are intertwined, [courts] demand less by way of jurisdictional proof for a plaintiff to survive a Rule 12(b)(1) challenge.” United States ex rel. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 515 (3d Cir. 2007).

“The False Claims Act seeks to redress fraudulent activity which attempts to or actually causes economic loss to the United States government.” Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 184 (3d Cir. 2001), cert. denied, 536 U.S. 906 (2002); 31 U.S.C. § 3729. “It encourages the uncovering of such fraud by permitting private persons to bring qui tam actions on behalf of the government.” See United States v. Catholic Healthcare West, 445 F.3d 1147, 1151 (9th Cir. 2006)(citing 31 U.S.C. § 3730(b)). The False Claims Act (“FCA”) provides, in pertinent part, as follows:

(a) Liability for certain acts — Any person who —

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false claim or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

[Wilentz, 253 F.3d at 182 (citing 31 U.S.C. § 3729)].

Under Section (a)(1), “[t]o establish a prima facie case under the False Claims Act a plaintiff must prove: (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.” Wilentz, 253 F.3d at 182. It is also a violation of the FCA to knowingly make a false statement to the government in an effort to obtain payment under Section (a)(2), or to engage in a conspiracy to cause the government to pay a false claim under Section (a)(3). Id. at 181.⁷

The FCA includes a provision to prevent suits “based on information that would have been equally available to strangers to the fraud transaction had they chosen to look for it as the relator.” See United States v. Paranych, 396 F.3d 326, 332 (3d Cir. 2005). The text of that provision reads as follows:

⁷ Defendants’ suggestion that the Amended Complaint has failed to allege a claim under section (a)(2) of the FCA is without merit. (See Defendants’ Brief, p. 28 n.9). The Amended Complaint indicates that Organon personnel willfully submitted false documentation to the FDA as part of their NDA. (See, e.g., Amended Complaint ¶ 19). It is impossible to believe that Organon’s personnel did not realize and intend that Medicare and Medicaid would eventually pay for Raplon once it was placed in the marketplace. The allegations in the Amended Complaint also indicate that Organon personnel conspired to misrepresent information to the FDA, which would constitute a violation of Section (a)(3) of the FCA.

(A) 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 [General] 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.

[Id. at 332 (citing 31 U.S.C. 3730(e)(4)].

It is only allegations that have been published in one of the limited class of sources identified in this provision that can constitute a public disclosure within the meaning of the FCA. Paranich, 396 F.3d 326, 332. Furthermore, the complaint filed by the relator under the FCA must be “based upon” the allegations or transactions contained in the public disclosure before the jurisdictional bar will apply. In this Circuit, the term “based upon” has been interpreted to mean “supported by” or “substantially similar to” for the purpose of determining the viability of a claim brought pursuant to the False Claims Act. Id. at 334.⁸ Thus, the public disclosure bar cannot apply in this matter unless the allegations contained in Dr. Feldstein’s Amended Complaint are supported by or are substantially similar to the allegations in the alleged public disclosures. Moreover, an action under the FCA is only “‘based upon’ a qualifying disclosure if the disclosure sets out either the allegations advanced in the qui tam action or all of the essential

⁸ The propriety of the Third Circuit’s prior interpretation of the term “based upon” is very much in doubt. Other circuits have interpreted “based upon” to mean that the allegations in the relator’s complaint must be actually “derived from” the allegations in the alleged public disclosure. See, e.g., United States ex rel. Siller v. Becton Dickinson, 21 F.3d 1339 (4th Cir. 1994). Legislation is currently pending in Congress to amend the FCA, and the bill proposed in the United States House of Representatives confirms that “based upon” means actually “derived from” under the FCA. (See the Certification of Christopher P. Massaro, Esq., Exhibit A, p.6, which has been submitted along with this Memorandum of Law). Using that standard, it is patently clear that Dr. Feldstein’s allegations were not actually derived from any of the public disclosures cited by the Defendants considering that he has certified he had not seen and was unaware of them before this lawsuit was filed. (See Dr. Feldstein Cert. ¶ 11).

elements of the qui tam action's claims." Id. at 335 (citing United States ex rel. Mistick PBT v. Housing Auth. of Pittsburgh, 186 F.3d 376, 388 (3d Cir. 1999)(emphasis added).

Here, the allegations contained in Dr. Feldstein's Amended Complaint and those contained in the complaints and articles submitted by defendants are not "substantially" similar. In fact, they are not similar at all. Moreover, the information contained in these alleged public disclosures do not set forth all of the essential elements of Dr. Feldstein's qui tam claim. The essence of Dr. Feldstein's claim is found in Paragraph 23 of the Amended Complaint:

Organon's actions have caused false claims to be submitted to and paid by Medicare and Medicaid, which are agencies of the United States government. 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. Organon, therefore, caused many hospitals, physicians and/or patients to submit false reimbursement claims to Medicare and Medicaid associated with Raplon they otherwise would not have been able to submit. Moreover, Medicare and Medicaid would not have reimbursed hospitals, physicians and/or patients for the use of Raplon had those agencies known that the FDA approved Raplon without the benefit of adequate disclosures regarding the potential for SAEs. Organon's actions also have caused Medicare and Medicaid to pay for medical costs associated with treating SAEs that never would have been incurred had adequate disclosures been made.

[Amended Complaint ¶ 23].

These allegations stand in stark contrast to the allegations contained in the complaints cited by Defendants. It is readily apparent that those actions concerned garden-variety negligence and strict liability claims arising from personal injuries that were allegedly caused by Raplon. Nothing in those complaints even suggests that Organon orchestrated a conspiracy to knowingly conceal SAEs from the FDA in order to gain approval of Raplon, which then led to the submission of false Medicare and Medicaid claims.

In Rogers, et al. v. Organon, Inc., et al., the plaintiffs alleged that Organon negligently failed to conduct studies concerning Raplon and acted inappropriately in marketing the drug. (See Defendants' Exhibit 4). The complaint is devoid of any allegation, like here, that Organon knowingly concealed and misrepresented any information from the FDA during the approval process. Furthermore, neither Medicare nor Medicaid are even referenced in the Rogers' Complaint. Similarly, in Payne v. Organon, Inc., and Spencer v. Organon, et al., the essential allegations were that Organon negligently failed to conduct adequate studies to learn of the dangers posed by Raplon or provide adequate warnings. Again, these complaints do not assert that Organon knew of and intentionally failed to disclose or misrepresented information or SAEs to the FDA, which thereafter led to the submission of false claims to the United States Government. (See Defendants' Exhibits 5 and 6).

The articles cited by Defendants stand on the same footing. None of them identify the allegations of fraud cited by Dr. Feldstein in the Amended Complaint. All of the newspaper articles discuss the withdrawal of Raplon from the marketplace after the NDA was approved and individuals began suffering bronchospasms to an unexpected degree. None of these articles address any allegation of pre-approval fraud on Organon's part and one even specifically states that the adverse reaction of bronchospasm (which is the extraordinary SAE referenced in the Amended Complaint) "did not show up in the [clinical] trials." (Defendants' Exhibits 7, 10-13). The medical literature simply indicates that bronchospasms associated with Raplon after it was approved and on the market occurred with greater frequency than in the pre-market clinical

studies.⁹ Nothing in that literature references fraud. The best indication that the FDA and the public remained unaware of any fraudulent conduct committed by Organon after Raplon was withdrawn from the market is contained in the Wall Street Journal article attached as Defendants' Exhibit 10, in which an FDA official stated as follows:

Dr. Jenkins of the FDA said that during Raplon's approval process, the bronchospasm issue "did not appear to be a severe problem." There was no internal dissent on whether to approve the drug[.]

[Defendants' Exhibit 10].

It is thus clear from the public disclosures that no one alleged that Organon was aware of Raplon's propensity to cause the SAE referenced in the Amended Complaint prior to its approval, and that Organon failed to report this life-threatening SAE to the FDA in order to gain approval of its NDA. In contrast, the e-mail attached to the Amended Complaint indicates just that fact. (See Amended Complaint ¶¶ 12-16).

Dr. Feldstein's allegations were not actually derived from the public disclosures referenced by Defendants. The allegations also are not substantially similar to the allegations and information referenced by Defendants. Moreover, taken as whole, none of these alleged public disclosures contain all of the essential elements of Dr. Feldstein's qui tam claim. Accordingly, Dr. Feldstein's qui tam action is not precluded by the public disclosure bar found in the FCA.

⁹ This occurrence is not uncommon since the statistics post-approval are based upon a much larger universe of individuals than that comprising the participants in the pre-market clinical studies. (Dr. Feldstein Cert. ¶ 15).

II. RELATOR IS AN ORIGINAL SOURCE OF THE INFORMATION UNDERLYING THE ALLEGATIONS CONTAINED IN THE AMENDED COMPLAINT

Defendants next contend that Dr. Feldstein is not entitled to maintain this action as an original source under 31 U.S.C. 3730(e)(4)(B). As will be explained, even if the public disclosure bar would otherwise apply in this case, although it clearly does not, see Point I, supra, Dr. Feldstein is an original source of the allegations contained in the Amended Complaint. Therefore, Dr. Feldstein is permitted to prosecute this action. The term “original source” is defined in 31 U.S.C. § 3730(e)(4):

(B) For purposes of this paragraph, "original source" means 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)].

An individual possesses “direct” knowledge when he or she has obtained first-hand knowledge through his or her own efforts and not the efforts of an intermediary. See, e.g., Paranych, 396 F.3d at 335-336. “[T]he paradigmatic ‘original source’ is a whistleblowing insider[.]” See Haskins v. Omega Institute, Inc., 25 F. Supp.2d 510, 514 (D.N.J. 1998). Dr. Feldstein easily fits that description. “Indeed there is no requirement that Plaintiffs be physically present during the alleged acts (as plaintiff can amass evidence through an independent investigation[.]” Id. at 514. An individual has obtained “independent” knowledge when “knowledge of the fraud [is not] dependent upon a public disclosure[.]” See Paranych, 396 F.3d at 336. In other words, the relator must have acquired the information from some source other than the public disclosure. Id. at 337.

Here, it is readily apparent that Dr. Feldstein qualifies as an original source of the information that is the focal point of this lawsuit. He discovered the information through direct and independent means, and voluntarily provided that information to the government prior to filing this lawsuit. As explained in detail earlier, Dr. Feldstein was a “whistleblowing insider,” who acquired the e-mail through his own efforts during the course of his employment with Organon and provided it to the United States Government of his own volition. His conclusion that this e-mail is evidence of fraud was informed by his personal knowledge concerning Organon’s unlawful conduct with Arixtra. Moreover, his knowledge as a physician and extensive education, training and first-hand experience at Organon and elsewhere in the pharmaceutical industry allowed him to quickly conclude that Raplon’s approval by the FDA was unlawful because Organon had withheld key information about the drug. Thus, Organon’s conduct allowed physicians to administer a drug (without knowing of its potential to cause SAEs and without a treatment protocol at the ready) that had not obtained a valid approval for use by the public. Based on his experience, Dr. Feldstein also knew that physicians (along with hospitals and patients) would have administered Raplon to members of the general population, a large number of whom would have received medical benefits through Medicare and Medicaid.

Dr. Feldstein voluntarily provided all of his information to the government before he commenced this lawsuit. This information was obtained as a direct result of his employment with Organon and the information was not derived from any of the public disclosures cited by defendants. Even Defendants concede that Dr. Feldstein was a corporate insider, and applicable case law establishes that such an insider is the paradigmatic example of an original source. (Defendants’ Brief, p. 24).

For these reasons, Dr. Feldstein is an original source with respect to the critical allegations underlying the Amended Complaint and the Court should, therefore, deny Defendants' motion to dismiss.

III. DEFENDANTS' MOTION TO DISMISS PURSUANT TO FED. R. CIV P. 9(b) SHOULD BE DENIED BECAUSE THE AMENDED COMPLAINT PLEADS FRAUD WITH THE REQUISITE SPECIFICITY

Defendants next claim that Dr. Feldstein's Amended Complaint must be dismissed with prejudice because the Amended Complaint fails to satisfy the pleading requirements of Fed. R. Civ. P. 9(b). (See Defendants' Brief, p. 19). Federal Rule of Civil procedure 9(b) provides as follows:

(b) Fraud or Mistake; Conditions of Mind. In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.

[Fed. R. Civ. P. 9(b)].

Under Rule 9(b), a plaintiff alleging fraud merely needs to state the circumstances of the alleged fraud "with sufficient particularity to place the defendant on notice of the 'precise misconduct with which [it is] charged.'" See Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007)(citing Lum v. Bank of America, 361 F.3d 217, 223-224 (3d Cir. 2004)). Contrary to Defendants' assertions, however, Rule 9(b) does not require Dr. Feldstein to set forth every detail of the alleged fraud in his complaint:

[R]ule 9(b) falls short of requiring every material detail of the fraud such as date, location, and time, [but] plaintiffs must use 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'"

[In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 216 (3d Cir. 2002)(quoting In re Nice Systems, Ltd. Sec. Litig., 135 F. Supp.2d 551, 577 (D.N.J. 2001))].

Moreover, “in applying Rule 9(b), courts should be ‘sensitive’ to situations in which ‘sophisticated defrauders’ may ‘successfully conceal the details of their fraud.’” Id. at 216. (quoting In re Burlington Coat factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997)). As in this case, “[w]here it can be shown that the requisite factual information is peculiarly within the defendant’s knowledge or control, the rigid requirements of Rule 9(b) may be relaxed.” Id. Under these circumstances, plaintiffs simply must “accompany their legal theory with factual allegations that make their theoretically viable claim plausible.” In re Burlington Coat Factory Sec. Litig., 114 F.3d at 1418.

Here, Dr. Feldstein has done much more than state conclusory allegations of fraud in his amended complaint. The allegations have apprised Defendants of the precise misconduct with which they are charged. Defendants even demonstrate their clear understanding of the allegations by summarizing Dr. Feldstein’s claim in the very brief they have submitted in support of their motion to dismiss:

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.

[Defendant’s Brief, p. 3].

Although Defendants go on to challenge the sufficiency of those allegations, it simply cannot be said that Dr. Feldstein has not provided them with adequate notice of the claim. In any event, the Amended Complaint provides sufficient detail to withstand scrutiny under Fed. R. Civ.

P. 9(b). Dr. Feldstein alleges that he obtained an e-mail during his employment that led him to believe Organon hid information from the FDA regarding Raplon before the drug was approved. The e-mail contains statements from which an inference easily can be drawn that Organon fraudulently concealed information from the FDA before the drug's approval regarding the side effects of Raplon. He has identified the individuals at Organon who sent, received and were referenced the e-mail, and who participated in the plan and conspired to withhold information from the FDA. Dr. Feldstein has explained that after reviewing the e-mail he subsequently learned that the investigators who participated in the US Phase III Pivotal trial for Raplon had serious concerns about Raplon's propensity to cause serious adverse events in some patients.

To the extent that Defendants complain that Dr. Feldstein has not supplied further details concerning the alleged fraud in his Amended Complaint, that information is peculiarly within the Defendants' control. Any additional evidence of fraudulent conduct would be contained in e-mails, correspondence and other documents maintained by Defendants. The suggestion that Dr. Feldstein would have access to each and every document relating to Raplon is simply absurd. Dr. Feldstein was one employee in an international pharmaceutical company. He could not possibly have access to all of the relevant documents maintained by Organon.

Finally, Defendants suggest that Dr. Feldstein has failed to adequately meet the pleading requirements of Rule 9(b) because he failed to identify specific instances where Medicare and Medicaid actually paid false claims. Defendants cite to United States ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 439-40 (3d Cir. 2004) for the proposition that "failure to present evidence of the actual submission of a single false claim to Medicaid is fatal to [the] qui tam action"(Defendants' Brief, pp. 20-22). In Quinn, however, the Third Circuit Court of Appeals affirmed the trial court's decision granting summary judgment in a qui tam action brought under

the FCA. It was not an appeal from a motion to dismiss. In Quinn, the summary judgment motion had been granted because the relator had failed to demonstrate a genuine issue of material fact that any false claims had been submitted to Medicaid. However, the Court expressly noted that the district court had concluded that the relator's complaint satisfied the pleading requirements of Rule 9(b):

Quinn asserts that the District Court erred by relying on [Clausen v. Laboratory Corporation of America, Inc., 290 F.3d 1301 (11th Cir. 2002)]. Whereas the dismissal in Clausen was pursuant to Federal Rule of Civil Procedure 9(b) for failure to plead fraud with particularity, Quinn points out that the District Court held that his complaint satisfied Rule 9(b)'s requirements. The present case differs from Clausen, however, because Clausen was dismissed on the pleadings for failure to satisfy the pleading requirements of Fed. R. Civ. P. Rule 9(b). While Quinn survived this first step, he then succumbed at the summary judgment stage for failure to establish a necessary element of FCA liability.

[Id. at 439 n. 10].

The Quinn Court did not criticize the district court's decision to deny the defendant's motion to dismiss pursuant to Rule 9(b) even though the relator apparently did not identify any specific instances where claims were paid by Medicaid.

Moreover, in Landsberg v. Levinson, 2008 WL 2246308 (W.D. Pa.) the Court specifically rejected a defendant's claim that a qui tam action failed to satisfy the requirements of Rule 9(b) because the "[r]elators had not identified a single false claim, the date of any such claim or the contents of such claim nor had they identified a single instance when Dr. Levinson or any LEWC practitioner performed a medically unnecessary test or billed the United States for any unnecessary or unperformed procedure." Id. at *1. The Court noted as follows:

[T]he Third Circuit Court of Appeals has rejected a strict application of Rule 9(b), requiring only that plaintiffs plead with particularity the "circumstances" of the alleged fraud in order to place the defendants on notice of the precise misconduct with

which they are charged, and [the] Relators [have] sufficiently identified the scheme of fraudulent behavior in which the defendants allegedly engaged[.]

[Id. at *1].

The Court specifically rejected Clausen v. Laboratory Corporation of America, Inc., 290 F.3d 1301 (11th Cir. 2002), as “contrary to the Third Circuit’s approach to Rule 9(b).” Id. at *3 n. 16; see also United States v. Kensington Hospital, 760 F. Supp. 1120, 1128-1126 (E.D. Pa. 1991)(noting that the standard for satisfying Fed. R. Civ. P. 9(b) is a generous one in this Circuit); United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 238 F. Supp. 2d 258, 268-269 (rejecting Clausen’s overly stringent view of the application of Rule 9(b). Moreover, in United States ex rel. Franklin v. Parke-Davis, 147 F.Supp.2d 39, 46 (D.Mass.2001), the relator alleged that a defendant pharmaceutical company engaged in a scheme to convince physicians to improperly bill the government for prescription drugs. The defendant claimed that the relator did not satisfy Rule 9(b) because he did not reference the specific claims submitted to the government, but the court rejected that argument:

Defendant contends that the pleading of the basic scheme of fraud or the identification of certain instances of fraudulent conduct does not satisfy Rule 9(b). Indeed, Defendant goes so far as to argue that Rule 9(b) requires no less than the identification of every ineligible prescription submitted to the government for payment. This view of Relator's pleading obligation may fit a scenario where the alleged fraud is confined to a small number of transactions about which Relator had knowledge. However, where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the FCA have not placed the bar so high as to require pleading with total insight.

[Id. at 49].¹⁰

It is simply inconceivable that the defendant pharmaceutical companies are even suggesting that the sale of Raplon, which was approved by the FDA and disseminated for widespread use by physicians and hospitals both nationally and internationally, did not result in claims for reimbursement being submitted to Medicare and Medicaid in connection with its use.¹¹ Put simply, Dr. Feldstein has described Organon's scheme to obtain the FDA approval and defraud Medicare/Medicaid with more than sufficient detail to satisfy Fed. R. Civ. P. 9(b).

IV. DEFENDANTS' MOTION TO DISMISS PURSUANT TO RULE 12(B)(6) SHOULD BE DENIED BECAUSE THE AMENDED COMPLAINT ADEQUATELY SETS FORTH A CLAIM

Defendants next contend that this Court should dismiss Dr. Feldstein's Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim.

Motions to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) are generally disfavored because of the "long-established federal policy of civil litigation is to decide cases on the proofs." Caldwell Trucking PRP Group v. Spaulding Composites Co., 890 F. Supp. 1247, 1252 (D.N.J.1995) (citing Melo-Sonics Corp. v. Cropp, 342 F.2d 856 (3d Cir. 1965))(additional citation omitted). The United States Supreme Court has recently held that a complaint will

¹⁰ A district court in Massachusetts later criticized the Franklin case because it believed that the United States Court of Appeals for the First Circuit was hostile to a "complexity" exception to Fed. R. Civ. P. 9(b) even though it admitted that the First Circuit never "specifically reject[ed] the application of a complexity exception to Fed. R. Civ. P. 9(b)." United States ex rel. Rost v. Pfizer, Inc., 446 F. Supp.2d 6, 27 (D. Mass 2006). In any event, such an interpretation is inconsistent with the Third Circuit's more liberal view of Fed. R. Civ. P. 9(b).

¹¹ This is particularly true when one considers that over 1 million doses of Raplon were apparently prepared by Organon. (Feldstein Cert. ¶ 15).

survive a 12(b)(6) motion so long as it contains allegations sufficient to show that a plaintiff is entitled to relief:

Federal Rule of Civil Procedure 8(a)(2) requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief.’ Specific facts are not necessary; the statement need only ‘give the defendant fair notice of what . . . the claim is and the grounds upon which it rests.’

[Erickson v. Pardus, 127 S. Ct. 2197, 2200, 167 L. Ed. 2d 1081 (2007)(citing Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)(slip op., at 7-8)].

Furthermore, when deciding a 12(b)(6) motion, the court must accept all of the allegations in the complaint as true and must give the plaintiff “the benefit of every favorable inference that can be drawn from those allegations.” Caldwell Trucking, 890 F. Supp. at 1252; see also Erickson, 127 S.Ct. 2197 at 2200. Rule 12(b)(6) does not permit a court to dismiss a complaint simply because it doubts the accuracy or validity of the factual allegations. Caldwell Trucking, 890 F. Supp. at 1252. “The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” Scheuer v. Rhodes, 416 U.S. 232, 236 (1974).

As explained earlier, the allegations in the Amended Complaint satisfy the heightened pleading requirements contained in Fed. R. Civ. P. 9(b). It thus appears self-evident that those allegations would satisfy the less rigorous requirements of Rule 12(b)(6). The Amended Complaint provides a detailed account of the facts and legal theory upon which the claim against Defendants are based. Defendants do not challenge the validity of the legal theory generally, but instead assert that Dr. Feldstein has failed to adequately plead specific aspects of the claim:

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[.]

[Defendant's Brief, p. 28].

With respect to the first claimed deficiency, if Rule 9(b) does not require Dr. Feldstein to identify specific instances of false claims submitted to Medicare and Medicaid at this juncture, then Dr. Feldstein cannot possibly be required to do so under the more relaxed standards of Rule 12(b)(6). Defendants also challenge the sufficiency of Dr. Feldstein's allegation that Organon's conduct caused the submission of false claims to the United States Government. Dr. Feldstein has specifically alleged that Organon obtained an invalid approval for Raplon by misrepresenting or concealing information about Raplon from the FDA. This, in turn, caused physicians to administer Raplon to patients and to submit (along with patients and hospitals) reimbursement claims to Medicare and Medicaid for a drug that should have never been approved. The allegations adequately plead the causation element; Dr. Feldstein need not actually prove that element at this stage of the litigation. In fact, United States ex rel. Franklin v. Parke-Davis, 147 F.Supp.2d 39, 46 (D.Mass.2001), rejected the same "lack of causation" argument in a similar context. In Franklin, the relator alleged that a pharmaceutical company caused doctors to prescribe medication for unapproved uses and then submitted false claims for payment to Medicaid. The defendant pharmaceutical company claimed that the Relator had failed to adequately plead that its actions caused the physicians to submit false claims. The Court addressed that argument as follows:

Defendant argues that Relator has not stated a claim because he has not accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions. In other words, Defendant argues that — as a matter of law — Relator's allegations cannot establish the causation requirement of the FCA because the actions of these professionals were an intervening force that breaks

the chain of legal causation. See [United States ex rel. Cantekin v. University of Pittsburgh], 192 F.3d 402, 416 (3d Cir. 1999)] (applying intervening cause analysis to claim under the FCA). Under black letter law, however, such an intervening force only breaks the causal connection when it is unforeseeable. See *id.* Accord D. Dobbs, et al., *Prosser and Keeton on Torts* § 44, at 303-04 (5th ed. 1984) ("The courts are quite generally agreed that [foreseeable intervening forces] will not supersede the defendant's responsibility."); *Restatement (Second) of Torts* § 443 (1965) ("The intervention of a force which is a normal consequence of a situation created by the actor's . . . conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about."). In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.

[Franklin, 147 F.Supp.2d 39, 46 (D.Mass.2001)].

Notably, Franklin relied upon a Third Circuit decision. Finally, Defendants assert that Dr. Feldstein has not adequately plead that Schering is liable as Organon's successor-in-interest. Dr. Feldstein has alleged that "Schering acquired Organon and succeeded to its rights and liabilities." (Amended Complaint ¶ 25). Schering does not deny that it acquired Organon and has even identified Organon in its Rule 7.1 Disclosure Statement as "an indirect wholly-owned subsidiary of Schering-Plough Corporation, a publicly held corporation established under the laws of the State of New Jersey." The Amended Complaint alleges that Schering acquired Organon and that fact appears undisputed. The acquisition of one company by another is the key predicate for a determination of successor liability and that has been established here. See, e.g., Pennsylvania Dep't of Env'tl. Prot. v. Concept Scis., Inc., 232 F. Supp. 2d 454, 461 (E.D. Pa. 2002)(interpreting Pennsylvania law and finding that "alleging that a defendant is a corporate successor is sufficient to survive a motion to dismiss."). Defendants cannot seriously assert that the statement does not provide them with adequate notice of the successor liability claim and the

ground upon which it is based. The facts that will ultimately determine the validity of that claim are within Schering's possession.

For these reasons, this Court should deny Defendants' motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6).

V. PLAINTIFF/RELATOR SHOULD BE GIVEN AN OPPORTUNITY TO AMEND THE COMPLAINT IF THE COURT CONCLUDES THAT IT FAILS TO SATISFY THE REQUIREMENTS OF FED. R. CIV. P. 12(b)6 OR (9)(b)

Even if a court determines that a complaint fails to state a claim, the appropriate remedy is to provide the plaintiff/relator with an opportunity to amend the complaint rather than to simply dismiss the action. See Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002) ("When a plaintiff does not seek leave to amend a deficient complaint after a defendant moves to dismiss it, the Court must inform the plaintiff that he has leave to amend within a set period of time, unless amendment would be inequitable or futile.")(emphasis in original); see also Sixth Camden Corp. v. Township of Evesham, Cty. of Burlington, 420 F. Supp. 709, 720 (D.N.J. 1976). The same holds true for a determination that a complaint fails to satisfy the pleading standards embodied in Fed. R. Civ. P. 9(b). See In re Burlington Coat factory Sec. Litigation, 114 F.3d at 1435 ("Ordinarily where a complaint is dismissed on Rule 9(b) 'failure to plead with particularity' grounds alone, leave to amend is granted"). Accordingly, if this Court determines that the Amended Complaint fails to satisfy the requirements of Fed. R. Civ. P. 9(b) or Fed. R. Civ. P. 12(b)(6), Dr. Feldstein respectfully requests this Court to grant leave to file an amended pleading.

CONCLUSION

For the foregoing reasons, Dr. Feldstein respectfully requests this Court to deny Defendants' motion to dismiss the amended complaint in its entirety.

COLE, SCHOTZ, MEISEL,
FORMAN & LEONARD, P.A.
Attorneys for Plaintiff/Relator, Jeffrey D.
Feldstein

By: s/ Steven I. Adler

Steven I. Adler

DATED: August 4, 2008