UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

SHIRE REGENERATIVE MEDICINE, INC.,

Defendant.
_______________________________________/

CASE NO: 8:11-CV-176-T-30MAP
8:12-CV-575-T-30TBM
8:14-CV-969-T-30TBM
8:14-CV-1055-T-30AAS
8:16-CV-268-T-30TBM
8:16-CV-303-T-30TBM

ORDER

THIS CAUSE comes before the Court upon the following motions:

- Relators Vinca's and Sweeney's Motion to Consolidate Cases (Dkt. 68)
- Relators Vinca's and Sweeney's Motion for Miscellaneous Relief, Specifically to be Deemed First to File as to the Kickback Claim Portion of the United States' Settlement (Dkt. 69)
- Relators Vinca's and Sweeney's Motion to Bar Relator Webb from Receiving any Relator Share of the Shire Settlement Based on the Court's Lack of Jurisdiction (Dkt. 74)
- Relators Vinca's and Sweeney's Motion to Have Relator Webb's "Fraudulently Manipulating Medicare Reimbursement Amount" Claim and Relator Montecalvo's "Inflating Dermagraft's Average Sales Price (ASP)" Claim Valued at $0 of the Shire Settlement Proceeds (Dkt. 75)
- Relators Vinca's and Sweeney's Motion to Limit Relator Monteclavo's Relator Share Award for Non-Kickback and Non-Off Label Promotion Claims to De Minimis Value (Dkt. 76)
- Relators Vinca's and Sweeney's Motion to Limit Relator Petty's Relator Share Award for Non-Kickback and Non-Off Label Promotion Claims to De Minimis Value (Dkt. 77)
- Relators Vinca's and Sweeney's Motion to Have Settlement Proceeds of Off-Label Promotion Claims of Relator Petty, Relator Webb, and Relator Montecalvo Valued at $0 (Dkt. 78)
- Relator Webb's Motion to be Declared the Original Source and the Only Relator Entitled to a Relator's Share of the Kickback and Off Label Marketing Frauds (Dkt. 96)
- Relator Mark Harvey's Motion for Ruling that He Is Entitled to a Relator's Share of the Portion of the Settlement Relating to Payments Made by the U.S. Department of Veterans Affairs (Dkt. 74 filed in 8:16-cv-303).

The Court has reviewed the motions, all of the responses, including the Government's Omnibus Response (Dkt. 114), the record evidence, and all of the respective replies. The Court concludes that the record is now adequately complete to allow the Court to rule on the pending motions and to rule on what portions of the $350 million dollar settlement between the Government and Shire should be attributed to the Relators' claims, which were filed in six separate civil actions. As the Court previously held, and as the Government has also stated, there is no need for an evidentiary hearing to determine the pending issues, which have been fully briefed. Indeed, the filings in this case have been copious, each Relator has had multiple opportunities to advance his position, and any further litigation with respect to these pending issues would cause unnecessarily delay and would further complicate what is already a very complicated proceeding. Notably, the Court's ruling does not determine the exact amount of the Relators' share. The issue of where in the 15-25% range the Relators' share should fall is one that is first subject to negotiation between the Relator and the Government.

To summarize the Court's ruling below, the Court will be allocating the Relators' share of the settlement proceeds consistent with the Government's proposed allocation based on the Court's application of the first-to-file rule. To understand the Court's reasoning, it is important to begin with a summary of the six qui tam actions.

BACKGROUND

I. The Civil Actions

On January 26, 2011, Relators Brian Vinca and Jennifer Sweeney filed the first qui tam complaint under seal (hereinafter referred to as the "*Vinca* Complaint"). The *Vinca* Complaint alleged that Relator Brian Vinca was employed by Shire as a Sales Representative

in the Tampa, Florida region from July 2008, to January 2011, and Relator Jennifer Sweeney worked as a Reimbursement Specialist at Shire beginning in January 2009. The *Vinca* Complaint alleged that Shire caused private physicians to submit false claims to the Medicare program, in violation of the Anti-Kickback Statute, by providing illegal remuneration to physicians to induce them and their staff to purchase and use Dermagraft, an artificial skin tissue product intended to treat diabetic foot ulcers, on Medicare patients. This caused physicians to present unlawful kickback-tainted false claims to Medicare.

On May 13, 2011, Relator Mark Harvey filed the second qui tam complaint under seal (hereinafter referred to as the "*Harvey* Complaint"). Harvey alleged that he was employed by Shire as a Sales Representative, assigned to Shire's VA Division, from November 2008, until late 2009. In that capacity, Harvey traveled across the country to market Dermagraft to VA hospitals and outpatient clinics. Harvey alleged that Shire routinely and systematically violated the False Claims Act ("FCA") by providing remuneration to VA physicians, nurses, and other personnel to induce them to use Dermagraft. Shire trained its Sales Representatives to market its product to VA personnel this way, and provided its Sales Representatives with the necessary resources to shower those personnel with lavish gifts and other remuneration. The *Harvey* Complaint alleged that the VA-specific Sales Representatives operated separate and apart from the salesforce that sold Dermagraft to medical providers outside of the VA system, who may have treated Medicare or Medicaid beneficiaries.

On March 15, 2012, Relator Joseph Medolla filed the third qui tam complaint against Shire under seal (hereinafter referred to as the "*Medolla* Complaint"). Medolla alleged that Shire knowingly violated the FCA by providing kickbacks to physicians, wound care centers,

hospitals, and their staffs, to induce them to purchase Dermagraft for use on Medicare, Medicaid, TRICARE, and the VA patients in the treatment of diabetic foot ulcers, in violation of the Anti-Kickback Statute. The unlawful kickbacks caused physicians to present false claims to Medicare, Medicaid, TRICARE, and the VA.

On November 21, 2012, Relators Daniel Petty, Christopher Bell, Kyle Richardson, and Tara Denney filed the fourth qui tam complaint under seal (hereinafter referred to as the "*Petty* Complaint"). These Relators alleged, in relevant part, FCA violations related to a nationwide scheme of promoting Dermagraft for various off-label uses, which caused physicians, hospitals, and healthcare providers to present false claims. These Relators also alleged violations of the Anti-Kickback Statute and violations related to "improperly billing Government Health Programs for unused units of Dermagraft."

On April 19, 2013, Relator Heather Webb filed the fifth qui tam complaint under seal. Her complaint was amended on May 23, 2013 (hereinafter referred to as the "*Webb* Complaint"). Webb alleged violations of the FCA related to unlawful kickbacks, off-label uses not approved by the FDA, and false reporting of the national average unit sales price of Dermagraft to Medicare, which ultimately caused Medicare to set and pay artificially high reimbursement for Dermagraft claims.

On February 14, 2014, Relator Antonio Montecalvo filed the sixth qui tam complaint under seal (hereinafter referred to as the "*Montecalvo* Complaint"). He alleged violations of the FCA by providing unlawful kickbacks to physicians and other healthcare providers, misleading marketing and selling of Dermagraft for non-approved off-label uses, improper coding claims to Medicare and Medicaid, which resulted in false, inflated claims, and falsely reporting average unit sales prices of Dermagraft.

II. The Government's Settlement of the Six Qui Tam Cases

The Government ultimately settled the six qui tam cases asserted against Shire. The Settlement Agreement identified the following "Covered Conduct:"

> From January 1, 2007 through January 16, 2014, [Shire], marketed and sold Dermagraft® to, among other Government programs: (i) health care providers who used Dermagraft® to treat patients and subsequently made claims for payment for Dermagraft® and related services to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 ("Medicare"); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"), and the TRICARE Program, 10 U.S.C. §§ 1071-1110(b) ("TRICARE"); and (ii) the VA, 38 U.S.C. Chapter 17, pursuant to a Federal Supply Schedule contract. The United States alleges that [Shire], in the course of marketing and selling Dermagraft® during this time period, knowingly submitted or caused to be submitted false or fraudulent claims for Dermagraft® during this time period, knowingly submitted or caused to be submitted false or fraudulent claims for Dermagraft® and related services to Medicare, Medicaid, TRICARE and the VA by: (1) paying or offering to pay kickbacks to induce the purchase, use and/or overutilization of Dermagraft®; (2) marketing Dermagraft® for uses outside the FDA-approved indication (i.e., "off-label" uses); (3) making false statements to inflate the price of Dermagraft®; and (4) causing improper coding, verification, and/or certification of claims for Dermagraft® and related services.

(Dkt. 74-2 at ¶ C.).

The Settlement Agreement listed the six qui tam cases that were filed by the Relators against Shire in paragraph E. *See id.* Under the Settlement Agreement, the Relators agreed to, in relevant part: (1) release Shire and other Released Parties from any and all civil monetary claims the Relators had or may have on behalf of the United States for the Covered Conduct; and (2) sign and file stipulations of dismissal with prejudice as to all claims against the Released Parties.[1] *See* (Dkt. 74-2).

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[1] It is unclear why the Government has not filed the stipulations of dismissal in the six cases. It should proceed to do so.

The Relators also agreed, in relevant part: (1) not to object to the Settlement Agreement and (2) to confirm that the Agreement is fair, adequate, and reasonable under all the circumstances, thereby expressly waiving their right to a hearing on any objection to the Settlement Agreement. *See id.*

III. The Government's May 22, 2017 Letter to Counsel for Relators

On May 22, 2017, the Department of Justice (the "Department") sent a letter to counsel for the Relators in the six qui tam cases that had been settled (hereinafter referred to as the "Letter"). *See* (Dkt. 118-1). Prior to sending the Letter, the Department had invited the Relators to submit their positions on the allocation of the settlement to their claims. The Letter sets forth the Department's views on the main issue pending before the Court: the proper allocation of the Shire settlement among the six cases for purposes of determining the Relators' share under 31 U.S.C. § 3730(d)(1). *See id.*

The Letter states that it was prepared "after full consideration of the factual and legal point and authorities" cited by the Relators in their respective submissions to the Department. *Id.* at 2. The Letter also discusses in detail the Department's "own research and analysis." *Id.* Notably, the Letter contains 10 single-spaced pages of detailed analysis supporting the Department's proposed allocation of the settlement. The proposed allocation is: 55.155% for the *Vinca* Complaint; 40.314% for the *Harvey* Complaint; 3.5299% for the *Medolla* Complaint; 0.4% for the *Petty* Complaint; 0.35% for the *Webb* Complaint; and 0.25% for the *Montecalvo* Complaint. *See id.* at 9-10.

As explained further below, the Letter is highly persuasive to the Court's conclusions contained herein. As such, the Court will cite to the Letter where applicable. Notably, although the Court is not necessarily bound by the Department's findings and conclusions,

the Court gives the Letter substantial deference for numerous reasons. First, deference is appropriate under the principles set forth by the Supreme Court in *United States v. Mead Corp.*, 533 U.S. 218 (2001). Second, as Relator Harvey points out, the Department is the "executive branch agency charged with implementation and enforcement of the False Claims Act, and thus has significant expertise with, and a recurring institutional interest" with respect to the proper application of the FCA. (Dkt. 119). Third, no Relator can dispute that the Government and Shire are the only parties with actual knowledge of the factors that led to the Shire settlement. Fourth and finally, the money at stake here resides in the hands of the Department as a result of the Government's investigation and ultimate settlement of the six qui tam cases.

It is important to note that the Court provided each Relator with an opportunity to respond to the Letter. Not only did each Relator have an opportunity to respond to every motion filed in this case, each Relator was permitted to file a reply to the Government's omnibus brief and, for those Relators who neglected to address the merits of the Letter, the Court *sua sponte* granted them another opportunity to file a substantive reply to the Letter. The Court underscores that it has reviewed approximately fifty filings from the parties in this proceeding. All of the parties have done an exemplary job of advocating their respective positions. The Court is sympathetic to the fact that there is a dearth of case law from the Eleventh Circuit on the salient issues presented here. Indeed, no party has identified even one case from the Eleventh Circuit that is remotely on point to the issues at hand. This is not an oversight on anyone's part. Based on the Court's independent research of the issues, no such opinion exists. In the event that any of the Court's rulings contained herein are appealed, the Court respectfully requests that the Eleventh Circuit address these legal

uncertainties and ambiguities.

The Court now turns to the relevant law, starting first with the issue of consolidation.

DISCUSSION

I. Consolidation of the Six Quit Tam Cases

Relators Vinca and Sweeney filed a motion to consolidate cases (Dkt. 68). The majority of the Relators do not oppose the motion to the extent that it is appropriate to consolidate the cases to determine the pending issues, including the main issue of the appropriate allocation of the settlement to their claims. The Court agrees that consolidation is appropriate for this limited purpose. Accordingly, the motion is granted to this extent. However, consolidation is no longer necessary after the Court issues the instant Order because the remaining issues will be between the Government and the Relators in their respective cases. As such, after entry of this Order, any future filings—other than a filing that would relate to this Order—should be filed in the respective case.

II. The Relevant Provisions of the FCA

The False Claims Act (FCA) imposes liability on any person who "knowingly presents ... a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), "to an officer or employee of the United States," 3729(b)(2)(A)(i). The FCA may be enforced not just through litigation brought by the Government itself, but also through civil qui tam actions that are filed by private parties, called relators, "in the name of the Government." § 3730(b).

In a qui tam suit filed under the FCA, the relator files a complaint under seal and serves the United States with a copy of the complaint and a disclosure of all material evidence. § 3730(b)(2). After reviewing these materials, the United States may "proceed

with the action, in which case the action shall be conducted by the Government," or it may "notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action." § 3730(b)(4). Regardless of the option that the United States selects, it retains the right at any time to dismiss the action entirely, § 3730(c)(2)(A), or to settle the case, § 3730(c)(2)(B).

Claims filed pursuant to the FCA must be pled with particularity under Rule 9(b) of the Federal Rules of Civil Procedure. *See United States ex rel. Clausen v. Laboratory Corp. Of America, Inc.*, 290 F.3d 1301, 1310 (11th Cir. 2002). The Court agrees with the Vinca/Sweeney Relators that a challenge to a qui tam complaint based on a failure to plead the claim with particularity under Rule 9(b) is conducted by a party at the motion to dismiss stage. It follows then that any argument on the part of the other Relators that Vinca/Sweeney are entitled to none of the settlement proceeds because the *Vinca* Complaint was not sufficiently pled with particularity fails.

The Court and the Government conflict on this issue, because, in the Letter, the Government applied a Rule 9(b) analysis to the six complaints. This conflict, however, is of no import because the Court and the Government ultimately arrive at the same outcome by applying a side-by-side comparison of the six complaints under the first-to-file analysis. The Department stated in the Letter that "we take the current position that the complaints in the Civil Actions adequately plead the theories of recovery according to which the United States would allocate the Settlement Proceeds in the Civil Actions." (Dkt. 118-1 at 8). Notably, whether Rule 9(b) should be applied at this stage is yet another issue that has not been addressed by the Eleventh Circuit. Unlike the persuasive authority that exists on this topic, this case is particularly unique because it involves other Relators, i.e., non-parties to

the *Vinca* Complaint, that are asserting the Rule 9(b) challenge. Whether they would even have standing to assert such a challenge is unclear.

As one court aptly noted, "[t]he time for pointing deficiencies under Rule 9(b) has passed" when the Government has settled an FCA case and all that remains is a determination for the relator share. *U.S. ex rel. Rille v. Cisco Sys., Inc.*, No. 4:04CV00988-BRW, 2011 WL 4352309, at *1-2 (E.D. Ark. Sept. 19, 2011), *reversed on other grounds*, 803 F.3d 368 (8th Cir. 2015); *see also U.S. ex rel. Merena v. SmithKline Beecham Corp.*, 52 F. Supp. 2d 420, 436 (E.D. Pa. 1998), *reversed on other grounds*, 205 F.3d 97 (3d Cir. 2000).

In *Roberts v. Accenture, LLP*, 707 F.3d 1011, 1017-18 (8th Cir. 2013), the Eighth Circuit stated:

> We reject the contention that Rule 9(b) plays a part in determining whether a relator is entitled to share in the settlement proceeds resulting from a qui tam action in which the government elects to intervene. Rule 9(b)'s standards are meant to test the sufficiency of a complaint at its outset. If a defendant challenges the sufficiency of a complaint's allegations at the outset of a case, a plaintiff still has the opportunity to cure the deficiency. . . . We find nothing in the FCA's statutory text to support this type of post hoc use of Rule 9(b) to deny a relator the right to a share of the settlement proceeds in an action in which the government intervenes.

This represents the majority view and makes logical sense because it seems counterintuitive to preclude the Vinca/Sweeney Relators from a share of the proceeds when the Government allocated the majority of the settlement, i.e., 55.155% to them. It would also be inequitable to apply a Rule 9(b) pleading standard at the end of a case, when the first-filed relator would no longer have an opportunity to amend his complaint to cure the deficiency.

Having addressed and dismissed any arguments related to Rule 9(b), the Court turns to two FCA restrictions on qui tam suits that are highly relevant here. One, the "first-to-file"

bar, precludes a qui tam suit "based on the facts underlying [a] pending action." § 3730(b)(5).[2] Under this bar, "once one suit has been filed by a relator or by the government, all other suits against the same defendant based on the same kind of conduct would be barred." *Cooper v. Blue Cross and Blue Shield of Fla., Inc.*, 19 F.3d 562, 567 (11th Cir. 1994). The Court agrees with the Department's analysis, as stated in the Letter, that "proper application of the first-to-file rule turns on a clear and readily-applicable standard, involving a straightforward comparison of the earlier- and later-filed complaints." (Dkt. 118-1 at 7) (citing *In re Natural Gas Royalties*, 566 F.3d 956, 964 (10th Cir. 2009) ("The first-to-file bar is designed to be quickly and easily determinable, simply requiring a side-by-side comparison of the complaints.")). The Court also agrees with the Department's point that, when applying this side-by-side approach, it is unnecessary and inappropriate to assess the "largely ephemeral question, in hindsight and with reference to all other sources of government knowledge (including relators' FCA disclosure statements) . . . as to what the government 'would have' discovered 'but for' any given Civil Action complaint." *Id.*[3]

The second applicable restriction, known as the "public disclosure" bar, provides that, at the time the suit was filed "[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions ... unless the action is

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[2] Several circuits have stated or assumed that the first-to-file rule is jurisdictional. See, e.g., *U.S. ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013), aff'd in part, rev'd in part on other grounds sub nom. *Kellogg Brown & Root*, 135 S.Ct. at 1979 (2015); *U.S. ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376-77 (5th Cir. 2009); *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 970 (6th Cir. 2005). The Second Circuit and the D.C. Circuit, however, have reached the opposite conclusion. *See United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 86 (2d Cir. 2017); *U.S. ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 120-21 (D.C. Cir. 2015). The Eleventh Circuit has not addressed this issue to date.

[3] The Letter noted that the Eleventh Circuit has not specifically addressed this issue.

brought by the Attorney General or ... an original source of the information." *State Farm Fire & Cas. Co. v. U.S ex rel. Rigsby*, 137 S. Ct. 436, 440 (2016) (internal quotations and citations omitted); 31 U.S.C. § 3730(e)(4).

Finally, with respect to settlements, the Court agrees with the Eighth Circuit's opinion that:

> § 3730(d)(1) is clear that the relator's share is based only on proceeds of "the claim." The use of the definite article refers back to the claim that is "brought by" the relator in "an action" that he initiates. The next subsection of the statute likewise refers to the relator "settling the claim " that he brought, in a case where the government does not proceed with the action. 31 U.S.C. § 3730(d)(2). The settlement language of § 3730(d)(1) thus does not extend to a different claim that is settled by the government when that claim was not originally "brought by" the relator. The relators' right to recovery is limited to a share of the settlement of the claim that they brought.

Rille v. PricewaterhouseCoopers LLP, 803 F.3d 368, 372 (8th Cir. 2015).

The Court now analyzes the application of the first-to-file bar and the public disclosure bar to the facts of this case.

III. First-To-File Bar

In the Letter, the Department concluded that the *Vinca* Complaint "was the first one adequately to allege that [Shire] knowingly caused kickback-tainted false claims to be made to Medicare." (Dkt. 118-1 at 9). The Letter also noted that, although the lengthy settlement negotiations between the Government and Shire did not explicitly assign values to discrete relator claims or to the Relators' varied theories of recovery, the "evidentiary support and legal basis for the kickback-related damages was the strongest, and *such claims were the predominate driver of the settlement with Shire.*" *Id.* at 8 (emphasis added).

Based on the Court's independent examination of the six complaints, the Court agrees with the Government's conclusion and allocates 55.155 percent of the settlement proceeds

to this theory of recovery. Accordingly, Relators Vinca's and Sweeney's Motion for Miscellaneous Relief, Specifically to be Deemed First to File as to the Kickback Claim Portion of the United States' Settlement (Dkt. 69) is granted to this extent.[4]

Next, the Department turned to the *Harvey* Complaint, which was the second qui tam complaint. The Letter stated: "the Complaint in the *Harvey* Action was the first one adequately to allege that [Shire] knowingly made kickback-tainted false claims and false statement in support of such claims to the VA." The Letter allocated 40.314 percent of the Settlement Proceeds to this theory of recovery. *Id.* at 9. The Court agrees with this conclusion and allocates 40.314 percent of the settlement proceeds to this theory of recovery. Again, applying a side-by-side comparison of the complaints supports the Letter's conclusion given how strong the evidence was with respect to the Anti-Kickback claims. Accordingly, Relator Mark Harvey's Motion for Ruling that He Is Entitled to a Relator's Share of the Portion of the Settlement Relating to Payments Made by the U.S. Department of Veterans Affairs (Dkt. 74 filed in 8:16-cv-303) is granted to this extent.

The Letter then addressed the final kick-back related claims that were alleged by Relator Medolla in the *Medolla* Complaint. Specifically, the Letter stated that the *Medolla* Complaint was "the first one adequately to allege that [Shire] knowingly caused kickback-tainted false claims to be made to the TRICARE and Medicaid programs. We propose to seek authority to allocate $12,196,574.00, or 3.5299 percent, of the Settlement Proceeds to

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[4] Relators Vinca/Sweeney filed a slew of other motions that essentially attacked the other Relators' entitlement to the settlement proceeds for reasons other than the first-to-file bar. (*See* Dkts. 74-78). These motions are now moot. Notably, it is questionable whether Relators Vinca/Sweeney even had standing to attack the other Relators' entitlement to the settlement proceeds *after the Government had settled these claims* other than to request the Court to apply the first-to-file bar.

this theory of recovery as to TRICARE and the federal share of Medicaid." (Dkt. 118-1 at 9). The Court agrees with this allocation because, although the *Vinca* Complaint alleged kickback-tainted false claims as to Medicare and the *Harvey* Complaint alleged kickback-tainted false claims as to the VA, the *Medolla* Complaint was the first complaint to discuss the false claims that were submitted to TRICARE and Medicaid.

Relator Medolla argues that he should receive 33 percent of the settlement proceeds. Essentially, he wants the Court to divide the proceeds in thirds, with each of the first three complaints getting a third and the remaining Relators receiving nothing. Relator Medolla's main point is that he was the first Relator to describe the "nationwide scope" of Shire's scheme. The Court is unpersuaded by this argument. The Government was clearly placed on notice of Shire's scheme through the *Vinca* Complaint and the *Harvey* Complaint regardless of what was technically alleged. A correct application of the first-to-file bar results in Relator Medolla being entitled to a share of the proceeds that relates to the false claims *submitted to TRICARE and Medicaid* because he was the first Relator to allege these FCA violations. The Government has valued this share at 3.5299 percent and the Court accepts that valuation.

The Letter then apportioned one percent of the remaining settlement proceeds to the remaining three complaints, i.e., the *Petty* Complaint, the *Webb* Complaint, and the *Montecalvo* Complaint as follows: .4 percent to Relators Petty, et al. for the off-label false claims to Medicare and Medicaid; .35 percent to Relator Webb for the false price reporting claims to Medicare; and .25 percent to Relator Montecalvo for the upcoded/miscoded false claims to Medicare and Medicaid. The Court also agrees with these allocations.

This remaining one percent relates to non-kickback theories of liability. Certain of the later-filed Relators have argued in their briefs that these non-kickback theories somehow accounted for significant portions of the Shire settlement. The Letter demonstrates that this is not true. The Letter stated that 99 percent of the value of the settlement is attributable to the kickback theory of liability. According to the Department, "the evidentiary support and legal basis for the kickback-related damages was the strongest, and such claims were the predominate driver of the settlement with Shire." (Dkt. 118-1 at 8). The Letter also noted that the Department "did not specifically measure damages to the United States from off-label sales, false price reporting, or improper coding by defendants, largely due to the fact that the kickback-tainted claims were so predominant that they likely consumed many of the claims that might also be implicated by those other theories of liability." *Id.*

IV. Public Disclosure Bar

The Letter discussed the "public disclosure bar" argument asserted by Relator Webb and succinctly dismissed it. The Department noted that, contrary to Webb's position, the allegations or transactions as alleged in the six qui tam complaints were not previously disclosed publicly in a manner that would implicate this bar. *See id.* at 8. The Court agrees. There is simply no support to Webb's argument that the public disclosure bar applies to any of the six complaints. Accordingly, Relator Webb's Motion to be Declared the Original Source and the Only Relator Entitled to a Relator's Share of the Kickback and Off Label Marketing Frauds (Dkt. 96) is denied.

CONCLUSION

The Court has consolidated the six qui tam complaints to resolve the issue of the proper allocation of the Shire settlement among the six cases. The Government settled the

six cases against Shire for $350 million dollars. However, the Settlement Agreement did not allocate how the proceeds were to be divided between the six cases, which must be done prior to determining the Relators' share.

On May 22, 2017, the Department of Justice sent a letter to counsel for the Relators in the six qui tam cases that outlined the Department's views on the issues now before the Court. Although the Court is not bound to follow the Department's proposed allocation, the Court concludes that the proposed allocation is supported under the facts of this case and the applicable law.

For the reasons explained above, the Court allocates the settlement proceeds as follows: 55.155% for the *Vinca* Complaint; 40.314% for the *Harvey* Complaint; 3.5299% for the *Medolla* Complaint; 0.4% for the *Petty* Complaint; 0.35% for the *Webb* Complaint; and 0.25% for the *Montecalvo* Complaint.

Accordingly, it is hereby **ORDERED and ADJUDGED** that:

1. Relators Vinca's and Sweeney's Motion to Consolidate Cases (Dkt. 68) is granted to the extent stated herein.

2. Relators Vinca's and Sweeney's Motion for Miscellaneous Relief, Specifically to be Deemed First to File as to the Kickback Claim Portion of the United States' Settlement (Dkt. 69) is granted in part and denied in part to the extent stated herein.

3. Relators Vinca's and Sweeney's Motion to Bar Relator Webb from Receiving any Relator Share of the Shire Settlement Based on the Court's Lack of Jurisdiction (Dkt. 74), Relators Vinca's and Sweeney's Motion to Have Relator Webb's "Fraudulently Manipulating Medicare Reimbursement

Amount" Claim and Relator Montecalvo's "Inflating Dermagraft's Average Sales Price (ASP)" Claim Valued at $0 of the Shire Settlement Proceeds (Dkt. 75), Relators Vinca's and Sweeney's Motion to Limit Relator Monteclavo's Relator Share Award for Non-Kickback and Non-Off Label Promotion Claims to De Minimis Value (Dkt. 76), Relators Vinca's and Sweeney's Motion to Limit Relator Petty's Relator Share Award for Non-Kickback and Non-Off Label Promotion Claims to De Minimis Value (Dkt. 77), and Relators Vinca's and Sweeney's Motion to Have Settlement Proceeds of Off-Label Promotion Claims of Relator Petty, Relator Webb, and Relator Montecalvo Valued at $0 (Dkt. 78) are denied as moot.

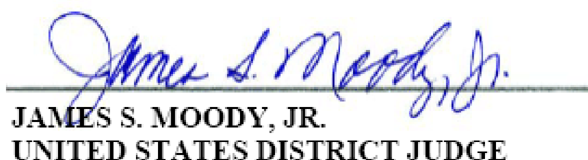
4. Relator Webb's Motion to be Declared the Original Source and the Only Relator Entitled to a Relator's Share of the Kickback and Off Label Marketing Frauds (Dkt. 96) is denied.

5. Relator Mark Harvey's Motion for Ruling that He Is Entitled to a Relator's Share of the Portion of the Settlement Relating to Payments Made by the U.S. Department of Veterans Affairs (Dkt. 74 filed in 8:16-cv-303) is granted to the extent stated herein.

6. As consolidation is no longer necessary, the Relators and the Government shall now proceed to resolve the remaining issue of the exact amount of the Relators' share in each of the six cases. The parties have sixty (60) days from the date of this Order to resolve this issue. If they are unable to reach an agreement, the Relators shall file a motion with the Court in his/her respective case within ninety (90) days of this Order.

7. The Government shall, within fourteen (14) days of this Order, file the notices of dismissal in each case, which should reserve on the issue of a determination of the Relators' share and any other unresolved issues.

DONE and **ORDERED** in Tampa, Florida on November 20, 2017.



JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
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