UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-12257-PBS
THIS DOCUMENT RELATES TO: UNITED STATES ex rel. LINNETTE SUN and GREG HAMILTON, RELATORS v. BAXTER HEALTHCARE CORPORATION	SUBCATEGORY NO. 08-11200-PBS
THIS DOCUMENT RELATES TO: UNITED STATES ex rel. VEN-A-CARE of the FLORIDA KEYS, INC. v. BAXTER HEALTHCARE CORPORATION	SUBCATEGORY NO. 10-11186-PBS

MEMORANDUM AND ORDER

May 31, 2013

Saris, C.J.

I. INTRODUCTION

This litigation involves two actions by different relators under the federal False Claims Act, 31 U.S.C. § 3730, alleging that Baxter Healthcare Corporation ("Baxter") fraudulently inflated the prices of its anti-hemophilic drugs and caused overpayments by Medicaid and Medicare. They are now involved in a tangled dispute over who was the first to file. On September

7, 2012, Relators Linette Sun and Greg Hamilton filed a motion pursuant to Fed. R. Civ. P. 60(b)(6) to reopen a similar lawsuit against Baxter filed by Relator Ven-A-Care of the Florida Keys ("Ven-A-Care"). Ven-A-Care had settled its claims with Baxter for $25 million in 2011; the settlement contained a release which effectively barred Sun and Hamilton's litigation. In an earlier hotly disputed ruling, this Court ruled Sun and Hamilton were entitled to obtain a hearing regarding the fairness of the settlement and to seek a share of the proceeds of the settlement with respect to any viable claims barred by the settlement. See United States ex rel. Sun v. Baxter Healthcare Corp., 892 F. Supp. 2d 341, 344-46 (D. Mass. 2012)(discussing 31 U.S.C. § 3730(c)(5)). Baxter and Ven-A-Care oppose the motion, arguing, *inter alia*, that this Court lacks jurisdiction because the first-to-file rule bars Sun and Hamilton claims. See 31 U.S.C. § 3730(b)(5). After hearing and review of the record, the Court **DENIES** Sun and Hamilton's motion.

II. PROCEDURAL HISTORY

This twelve-year-old, nationwide multi-district litigation involves the pricing of pharmaceutical drugs reimbursed by Medicare, Medicaid, private insurers, and patients making coinsurance payments based on average wholesale price ("AWP")

between 1991 and 2005. The Court assumes familiarity with AWP drug pricing discussed in the related multi-district litigation.[1]

In 1995, Ven-A-Care filed under seal its complaint alleging various drug companies, including Baxter, inflated the prices of many drugs, to cause overpayments by Medicaid and Medicare. Ven-A-Care expressly listed Recombinate in the complaint, but does not mention Advate, which was not sold until 2003. In 2005, Sun and Hamilton filed their complaint, which alleged that Baxter inflated drug prices of both Advate and Recombinate to cause overpayments by Medicaid and Medicare.[2] The Ven-A-Care complaint was unsealed in 2010.

On October 5, 2011, Ven-A-Care agreed to settle its claims with Baxter for $25 million. The government, which had not intervened, consented pursuant to 31 U.S.C. § 3730(b)(1). On January 26, 2012, this Court allowed Baxter's motion for partial[3]

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[1] See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., No. 01-12257-PBS, 2010 WL 1375298 (D. Mass. Mar. 25, 2010); In re Pharm. Indus. Average Wholesale Price Litig., 491 F.Supp. 2d 20 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009).

[2] The Court previously denied Sun and Hamilton's claims as to Recombinate, because that drug was explicitly mentioned in the Ven-A-Care complaint. See Doc. 205 at 5, 1:08-cv-11200-PBS.

[3] The other counts related to relator Linnette Sun's retaliation and employment discrimination claims were not challenged.

summary judgment against Sun and Hamilton based upon the broad release in Ven-A-Care's settlement agreement with Baxter. See In re Pharm. Indus. Average Wholesale Price Litig., No. 01-12257-PBS, 2012 WL 366599 (D. Mass. Jan. 26, 2012). In exchange for the payment of $25 million, the release "'fully and finally releases, acquits, and forever discharges' Baxter from any 'claim, action, suit, demand, right, cause of action, liability, judgment, damage, or proceeding . . . which has been asserted, could have been asserted, or could be asserted in the future . . . for or arising from any of the Covered Conduct.'" Id. at *1. "Covered Conduct" includes the reporting of false prices for "any and all drugs manufactured, marketed and/or sold by or on behalf of any Baxter Party . . . .'" Id. The Court held that this broad release language extinguished Sun and Hamilton's claims regarding Recombinate and Advate. Id. at *3-5.

On August 7, 2012, the Court denied without prejudice Sun and Hamilton's motion to reconsider its earlier decision and permitted the relators to file a motion to reopen the Ven-A-Care lawsuit to obtain a hearing required by the False Claims Act with respect to the fairness of the settlement. See Sun, 892 F. Supp. 2d at 346. Although Sun and Hamilton received actual notice of the settlement because it was docketed on the multi-district litigation docket, they were never notified that the settlement

effectively extinguished their claims. Id. at 343 & n.2. Moreover, while the government consented to the settlement, it added "that it did not understand or intend that the broad release language cover drugs not asserted in the Ven-A-Care complaint." Id. at 343. The Court concluded that "the government's consent to the dismissal of Ven-A-Care's claims against Baxter pursuant to the broad Settlement Agreement and Release . . . constitutes an 'alternate remedy'" for Sun and Hamilton's claims, and the relators are entitled "to obtain a fairness hearing with respect to the Ven-A-Care settlement." Id. at 344, 346.

III. FACTUAL BACKGROUND

The following facts are relevant to the first-to-file issue.

A. Development of Recombinate

Hemophilia A is a congenital bleeding disorder characterized by bleeding episodes that vary in severity and frequency. The disease is caused by insufficient coagulation levels of Factor VIII, the most common blood factor missing in hemophiliacs. Because the disease was historically treated with blood transfusions and human plasma replacement therapies, hemophilia patients were uniquely at risk for the transmission of blood-borne illnesses, including HIV/AIDS. By the mid-1980s, almost

half of all hemophilia patients in the United States were infected with HIV/AIDS.

In response to the HIV/AIDS epidemic, Baxter released the anti-hemophilic drug Recombinate in 1992. Almost all human plasma or animal protein was removed from materials used in the production of Recombinate except for the culture medium, where human- or animal-derived proteins were required to stabilize the formulation. As a result, the drug was believed to be 99.9 percent safe from the risk of viral transmissions. Since Recombinate has been on the market, no cases of disease transmission have been reported.

B. Ven-A-Care's lawsuit

Baxter marketed its drugs, including Recombinate, to Ven-A-Care, a specialty infusion/homecare pharmacy. Ven-A-Care found out that actual market prices of certain Baxter drugs, which were not available to the public, were dramatically lower than the published prices of the same drugs in compendia such as First DataBank ("FDB"). Many drug companies, including Baxter, would report these inflated prices as Wholesale Acquisition Costs ("WAC"). Government insurance companies believed the WAC was the average price paid by a wholesaler to a manufacturer for a given product and based reimbursement on the prices reported in the

compendia. The compendia would take the falsely reported WACs, add a percentage to them to determine the Average Wholesale Price ("AWP"), and report overstated AWPs. This fraudulent reporting caused government insurance companies and others to overpay for the drug reimbursements. With this information, in 1995, Ven-A-Care began suing drug companies under the False Claims Act for defrauding Medicare and Medicaid by inflating AWPs. Through its qui tam lawsuits, Ven-A-Care has reportedly recovered for the United States and state Medicaid programs more than $3 billion.

Ven-A-Care's suit against Baxter was originally filed under seal on June 23, 1995. Ven-A-Care amended its complaint in 1997, 1999, and most recently on December 22, 2002. The complaint alleges that Baxter and other drug companies created large spreads between their market prices for drugs and published prices by falsely reporting the costs and price information to compendia such as FDB. See Ven-A-Care 4th Amend. Compl. ¶¶ 14, 161. The complaint states that Baxter would report false prices to the compendia as WACs, "list prices," or other similar terms, which Baxter knew would be used to determine AWPs after FDB added its mark-up percentage to the WACs. Id. ¶ 161. The complaint adds that Medicare's reimbursement was calculated with reference to a given drug's AWP. Id. ¶ 11. Therefore, the complaint

alleges that Baxter's fraudulent marketing scheme caused Medicare to overpay for its reimbursements. The complaint lists many Baxter drugs and their alleged false spreads between the market price and published price. Recombinate is specifically mentioned in the complaint, and its spread is listed at 41 percent. Id. Ex. 2 at 6.

C. The Advent of Advate

In August 2003, months after Ven-A-Care filed its most recent complaint, Baxter released another anti-hemophilic drug Advate. Advate was created in response to a request from the Medical and Scientific Advisory Council of the National Hemophilia Foundation to develop an anti-hemophilic drug devoid of any human- or animal-derived proteins to ensure that patients are 100% safe from the risk of viral transmissions. Advate and Recombinate are identical in almost every way except that Advate is stabilized in a culture medium devoid of human- or animal-derived proteins. Both drugs are based on the same Factor VIII protein, they are processed using the same purification methods, they are used by the same patient population, in the same manner (intravenous infusion), suffering from the same disease, hemophilia A. Furthermore, Recombinate and Advate are reimbursed by Medicare under the same HCPCS Code, J7192, and are marketed,

developed, priced, and distributed the same way by the same Baxter division, Baxter BioScience. At the time Advate was launched, Baxter had hoped to convert patients from Recombinate to Advate, and to charge a premium over Recombinate between 5 and 25 percent. Despite this initial hope, over time the price difference between the two drugs declined, and Baxter set both market pricing and published pricing for Advate within 5 to 7 percent of Recombinate's price.

D. Sun and Hamilton's lawsuit

On April 22, 2005, Sun and Hamilton filed their own qui tam action under seal against Baxter. Sun was Baxter's Director of Medical Outcomes Research and Economics from 2002 to 2003, and was responsible for pricing Advate. Hamilton worked for Express Scripts, a pharmacy benefit manager and customer of both Baxter and FDB. Both Sun and Hamilton had specific knowledge of Baxter's fraudulent scheme. See United State ex rel. Linnette Sun v. Baxter Hemoglobin Therapeutics, 2010 U.S. Dist. LEXIS 30218, *10 (D. Mass. Mar. 25, 2010).

Generally speaking, Sun and Hamilton's complaint is similar to Ven-A-Care's. The complaint alleges that Baxter defrauded Medicaid, Medicare, and other programs that reimburse for drugs on the basis of false AWPs published in various compendia,

including FDB. However, Sun and Hamilton's complaint also describes in detail how Baxter's fraudulent scheme worked after 2000, when federal and state governments became aware that drug manufacturers were reporting false AWPs and WACs. The complaint states that "in May 2000, FDB entered into an agreement with the Department of Justice and various states to stop reporting AWPs published by the manufacturers and to instead report them on the basis of market prices." Sun and Hamilton 2d Amend. Compl. ¶ 25. In an attempt to do so, FDB compiled the WACs reported by the manufacturers and multiplied the reported WACs by 1.25, as the mark-up applied by wholesalers. Id. ¶41. Knowing how FDB now calculated AWP, Baxter reported only what it called a "list sales price" to FDB and not a WAC. Id. ¶ 39. FDB responded by asking Baxter to report a WAC and not a "list sales price," and warning that if it continued to refuse to provide a WAC, FDB would use Baxter's "list sales price" as its WAC and proceed to calculate Baxter's AWP on the basis of that figure. Id. ¶ 40. Baxter falsely inflated the "list sales price" of its drugs to increase the spread between its actual market price and the published price. For example, the complaint alleges that Baxter reported a "list sales price" of $1.30 for Recombinate, which FDB used to calculate an AWP of $1.625. In fact, Recombinate was sold to

providers for $0.89. Id. ¶ 37. Similarly, the AWP for Advate was $1.60, but it was sold to providers for $0.99. Id. ¶ 44.

IV. DISCUSSION

A. Standard of Review

Baxter and Ven-A-Care contend that the Court must deny Sun and Hamilton's Rule 60(b)(6) motion to reopen the Ven-A-Care lawsuit because the Court lacks subject matter jurisdiction over Sun and Hamilton's Advate claim under the first-to-file bar. See Fed. R. Civ. P. 12(h)(3) ("If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action."); Arbaugh v. Y & H Corp., 546 U.S. 500, 506 (2006) ("The objection that a federal court lacks subject-matter jurisdiction may be raised by a party, or by a court on its own initiative, at any stage in the litigation, even after trial and the entry of judgment.")(internal citation omitted); see also Ahmed v. Rosenblatt, 118 F.3d 886, 891 (1st Cir. 1997)("[A] 60(b)(6) movant must make a suitable showing that the movant has a meritorious claim.").

The False Claims Act provides, "When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). Courts

have interpreted § 3730(b)(5) to bar a later allegation if it states all the "essential facts" of a previously-filed claim or the "same elements of a fraud described in an earlier suit." United States ex. rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 32 (1st Cir. 2009)(internal quotations omitted). This is a jurisdictional rule that is "exception-free." Id. at 33.

The first-to-file rule is intended to "provide incentives to relators to promptly alert the government to the essential facts of a fraudulent scheme." Id. at 32 (internal quotations omitted). "Under this 'essential facts' standard, § 3730(b)(5) can still bar a later claim 'even if that claim incorporates somewhat different details.'" Id. (quoting United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232-33 (3d Cir. 1998)).

B. Essential Facts

Sun and Hamilton contend that Ven-A-Care's earlier complaint does not bar their Advate claim because it does not state all of the essential facts of Baxter's AWP fraudulent scheme as to Advate. First, they argue that Ven-A-Care's complaint failed to mention Advate, a drug that was introduced by Baxter months after Ven-A-Care's most recent complaint was filed. In United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott

Laboratories, Inc., 2008 WL 2778808 (D. Mass. July 15, 2008), this Court held that in some circumstances the first-to-file rule does not bar a subsequent complaint that lists a different drug sold by the same manufacturer. Id. at *3. The Court stated:

> The [first complaint] did not provide the government with notice of the essential fact that the alleged fraudulent scheme involved Erythromycin. The complaint . . . involved different drugs marketed by a different division of Abbott. Significantly, Erythromycin is primarily a self-administered drug and the other drugs are generally administered by physicians. Notice of fraud in one drug's pricing is not notice of fraud in another drug's pricing . . . This is because drugs are often marketed, reimbursed, sold, and priced in different ways.

Id. However, in this case, Advate, which came onto the market after Ven-A-Care's last complaint was filed, is administered, marketed, reimbursed, sold, and priced in almost the exact same way as Recombinate, which is listed in Ven-A-Care's complaint. Because Baxter's fraudulent scheme did not differ in any material way between Recombinate and Advate, the listing of Advate in Sun and Hamilton's complaint is not an essential fact missing from Ven-A-Care's complaint. See LaCorte, 149 F.3d at 237 (holding that "the original complaints' failure specifically to mention [a new] blood test[] for which [the defendant] fraudulently billed the government is of no significance" because the original relator alleged the same essential facts and the second relator

did not describe a separate fraudulent scheme as to the new blood test).

Next, Sun and Hamilton argue that the Ven-A-Care complaint only alleges a general fraudulent scheme, and Duxbury requires an original relator to allege specific details about the scheme to gain first-to-file status over a subsequent relator. In Duxbury, the First Circuit held that the first-to-file rule did not bar a subsequent relator where the original relator's complaint "fail[ed] to allege the 'essential facts' of the 'off-label' [drug] *promotion scheme* contained in the [subsequent] Complaint." 579 F.3d at 33 (emphasis in original). The subsequent complaint "contained a number of allegations that discuss, in significant detail, [the defendant's] promotion of the 'off-label' use . . ."[4] Id. The original complaint, on the other hand, "only allege one method by which [the defendant] promoted the 'off-label' use of [the drug], the use of 'clinical trials' . . ." Id. The court concluded that "this allegation fails to encompass the

[4] The alleged new promotion efforts included: "(1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in the form of 'educational grants' and 'clerkships;' (4) payments to medical professionals for giving presentations on increased dosage of [the drug]; or (5) attending consulting conferences sponsored by [the defendant] which pushed increased dosage of [the drug]; and (6) rebate programs offered to induce increased prescriptions of [the drug]." Duxbury, 579 F.3d at 33.

other allegations contained in the [subsequent] Complaint concerning [the defendant's] 'off-label' *promotion*." Id. (emphasis in original).

In this case, Sun and Hamilton contend that the Ven-A-Care complaint fails to provide important details about Baxter's fraudulent scheme, specifically after 2000, when the government became aware that drug manufacturers were reporting false AWPs and WACs. It is true that Sun and Hamilton's complaint provides more detail about the fraud and describes specific Baxter meetings about the pricing and marketing of Advate. However, unlike the original relator in Duxbury, Ven-A-Care provides enough detail "to promptly alert the government to the essential facts of [the AWP] fraudulent scheme" as it relates to both Recombinate and Advate. Id. at 32. The Ven-A-Care complaint alleges that Baxter violated the False Claims Act by knowingly submitting inflated pricing information, including WACs and "list prices" to compendia, including FDB, causing government insurers to pay falsely inflated reimbursement amounts. The complaint also lists Recombinate and its alleged spread percentage. The fraudulent scheme in Sun and Hamilton's complaint alleges the same essential facts. Therefore, the first-to-file rule bars Sun and Hamilton's Recombinate and Advate claims.

C. Postscript

This tangled, costly procedural dispute could largely have been avoided if Ven-A-Care and Baxter had plainly alerted the Sun and Hamilton relators, the government, and the Court in the initial motion to approve the settlement that the settlement release would/could extinguish Sun and Hamilton's claims. This is a massive multi-district litigation, involving multiple drugs, companies, and actions. Simply electronically filing a broad, complex release in these circumstances is not always sufficient to give fair notice to all parties, particularly when the government is a non-intervening party. In joint motions to approve settlements, counsel have a duty under Fed. R. Civ. P. 11 to disclose that a settlement may require a fairness hearing under the False Claims Act.

V. ORDER

Sun and Hamilton's Rule 60(b)(6) motion to reopen (Doc. No. 29, 1:10-cv-11186) is **DENIED**.

/s/ PATTI B. SARIS
PATTI B. SARIS
CHIEF UNITED STATES DISTRICT JUDGE