

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, ex rel.)
VEN-A-CARE OF THE FLORIDA KEYS,)
INC., a Florida corporation, by)
and through its principal officers))
and directors, ZACHARY T. BENTLEY)
and T. MARK JONES,)
)
Plaintiff,)
)
v.) MDL No. 1456
) CIVIL ACTION NO.
) 08-CV-10852-PBS
ACTAVIS MID ATLANTIC LLC, et al.,)
)
Defendants.)

MEMORANDUM AND ORDER

October 2, 2009

Saris, U.S.D.J.

I. INTRODUCTION

Relator Ven-A-Care of the Florida Keys, Inc., ("VAC") brings this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, to recover penalties and damages for allegedly false claims and statements resulting from fraudulent conduct of the Defendant pharmaceutical companies.¹ Relator alleges that

¹ The Defendants are Actavis Mid Atlantic LLC, Alpharma Inc., Alpharma USPD, Inc., f/k/a Barre-National, Inc., Barr Pharmaceuticals, Inc., Barr Laboratories, Inc., Barre Parent Corp., Goldline Laboratories, Inc., Ivax Pharmaceuticals, Inc., Ivax Corporation, Mylan Pharmaceuticals, Inc., Mylan, Inc., f/k/a Mylan Laboratories, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Sandoz, Inc., f/k/a Geneva Pharmaceuticals, Inc., Schein Pharmaceutical Inc., Teva Pharmaceuticals USA, UDL Laboratories, Inc., Watson

Defendants reported inflated pricing information for certain drugs which caused the Medicaid program to make substantial overpayments. Defendants have moved jointly to dismiss VAC's complaint, asserting that VAC cannot satisfy the FCA's public disclosure/original source rule, VAC has failed to state a claim for relief under 31 U.S.C. §§ 3729(a)(1) or (a)(2), VAC has failed to plead its claims with the specificity required by Fed. R. Civ. P. 9(b), and VAC's claims are barred by the FCA's six-year statute of limitations. Three individual motions to dismiss have also been filed by companies claiming that they are merely parent companies and not appropriate defendants.² After briefing and a hearing, Defendants' joint motion [Docket No. 34] is **DENIED** and the individual motions [Docket Nos. 29, 31, 37] are **DENIED**.

II. BACKGROUND

This case comes as part of the massive AWP litigation currently in front of this Court. The Court assumes familiarity with the drug pricing schemes discussed in its previous AWP-related decisions. See In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172 (D. Mass. 2003); In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196 (D.

Pharmaceuticals, Inc., and Zenith Goldline Pharmaceuticals, Inc.

² The individual motions have been filed by (1) Barr Pharmaceuticals, Inc., (2) Ivax Corporation, and (3) AlphaPharma, Inc., AlphaPharma USPD Inc., Barre-National, Inc., and Barre Parent Corporation.

Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 321 F. Supp. 2d 187 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 339 F. Supp. 2d 165 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d 277 (D. Mass. 2006); In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 2007 WL 1051642 (D. Mass. Apr. 2, 2007); In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d 367 (D. Mass. 2008); In re Pharm. Indus. Average Wholesale Price Litig., 252 F.R.D. 83 (D. Mass. 2008); see also Massachusetts v. Mylan Labs., Inc., 357 F. Supp. 2d. 314 (D. Mass. 2005); Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127 (D. Mass. 2008).

The false claims at issue here arise from tens of millions of Medicaid transactions for almost 1400 generic drugs (the "Subject Drugs") manufactured by the Defendants over a period of 16 years, which were offered to VAC at prices substantially below the Average Wholesale Price ("AWP") and Wholesale Acquisition Cost ("WAC") reported by the Defendants.

Under the Medicaid program, the funding process begins forty-five days before the relevant quarter, when each state

submits to the Centers for Medicare and Medicaid Services ("CMS") a projected budget for the quarter. 42 C.F.R. § 430.30(b). As part of the budget, states provide estimates of various types of service costs including drug costs. Regional CMS analysts review the budget and make recommendations as to whether they agree with the state's funding request. Id. § 430.30(d). These recommendations are then reviewed by the central CMS office. Id. § 430.30(d)(1). In determining the appropriate level of funding, CMS "considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant." Id. Adjustments under paragraph (d)(2) entail an examination of expenditures from previous quarters. Id. § 430.30(d)(2).

Once the budget is approved, the state can draw down on a federal letter of credit for the allotted amount as costs are incurred. Id. § 230(d)(3)-(d)(4). The awarded funding amount "authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements." Id. § 230(d)(3). States draw down federal funds as actual reimbursement claims are made by Medicaid providers. Id. § 430.30(d)(3)-(d)(4).

After each quarter, the state submits its actual Medicaid expenditures to CMS as part of a reconciliation process. Id. § 430.30(c). If CMS believes that it has overpaid a state, CMS may adjust future authorizations to offset the overpayment or seek to

recover the amount overpaid. See 42 U.S.C. § 1396b(d) (5) .

III. DISCUSSION

A. The Defendants' Joint Motion

Defendants' joint motion to dismiss stakes out four grounds for dismissal: (1) VAC cannot satisfy the FCA's public disclosure/original source rule; (2) VAC has failed to state a claim for relief under 31 U.S.C. §§ 3729(a) (1) or (a) (2); (3) VAC has failed to plead its claims with the specificity required by Fed. R. Civ. P. 9(b); and (4) VAC's claims are barred by the FCA's six-year statute of limitations.

1. Public Disclosure

Section 3730(e) (4) of the FCA provides:

No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e) (4) (A) . This operates as a jurisdictional bar when (1) there has been a "public disclosure," (2) the relator has "based" its suit on the disclosure, and (3) the relator was not the original source of the information on which its suit is based. See In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d at 375-79.

Defendants argue that reports prepared by the United States

Department of Health & Human Services, Officer of the Inspector General ("OIG") and the United States General Accounting Office ("GAO") constitute public disclosures on which this action is based. Defendants specifically point to an OIG report from August of 1997 entitled "Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products." The report found that pharmacies' actual acquisition costs for generic drugs were, on average, 42.5% less than reported AWP. (Carroll Decl. Ex. 9.)

To support their claim that VAC's case is based upon public disclosures, the Defendants point to a number of similarities between the Complaint and information in the 1997 report and other OIG and HHS reports. Specifically, they note that:

the Complaint alleges, and the 1997 Report states, that drug manufacturers set the AWP reported by drug pricing compendia. The Complaint alleges, and the 1997 Report states, that the AWP provided by drug manufacturers to pricing publications are significantly higher than Medicaid providers' actual acquisition costs. Finally, the Complaint alleges, and the 1997 Report states, that, as a result, Medicaid reimbursement payments for drugs are significantly higher than providers' actual acquisition costs.

(Defs.' Mem. in Supp. of Joint Mot. to Dismiss 15.)

Although the reports do disclose some of the Complaint's essential background information, that manufacturers' reported prices were higher than actual acquisition costs and thus that Medicaid was paying too much in general for drugs, they do not reveal nearly enough information to constitute public disclosures

on which the Complaint is based.

'[I]f X+Y=Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.' Under the framework, X stands for the allegedly false set of facts set forth in the claim at issue, and Y is a proxy for the allegedly true set of facts. Thus 'when X [the false set of facts] and Y [the true set of facts] surface publicly, or when Z is broadcast . . . there is little need for qui tam actions' and the claim will be barred.

In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d at 383 (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654 (D.C. Cir. 1994) (citations omitted)). Here, the "Z," the allegation of fraud, was not "broadcast." The government reports lack any suggestion of fraudulent activity by drug manufacturers or anyone else. The reports merely note an average difference between reported AWP and actual acquisition cost. There is no discussion about the reason for these differences or any suggestion of wrongdoing by anyone. There is certainly no discussion or suggestion that AWPs are being used as part of a scheme to defraud the government, or any indication of how the scheme works - using Medicaid payments grossly inflated by fraud as a promotional tool for drugs.

Further, while the reports may have disclosed the X, the allegedly false set of facts, they fall far short of identifying Y, the actual true set of facts. Most notably, the reports fail to disclose the central issue in this case, that AWP and WAC were

so inflated, they "could hardly even be called true *list* prices," that the "discounts" taken off AWP were frequently larger than the price providers actually paid. Mylan, 608 F. Supp. 2d at 154. At no point do the government reports point to the existence of the mega-spreads at the heart of this case, or to the fact that they were being used as a marketing tool to promote drug sales.

Likewise, neither the Defendants nor the drugs at issue in this case were revealed in the reports. The reports primarily disclosed average price differences, calculated on the basis of information concerning varying numbers of companies and drugs. No particular drugs, NDCs, individual manufacturers, or actual prices were identified. Although these averages certainly hinted at an industry wide-practice, the reports did not disclose that any particular company had engaged in the fraudulent conduct, or that any particular drug's price had been fraudulently inflated, nor can (or could) they support the conclusion that all companies or all drugs had been affected by the scheme.

Defendants argue that even though the reports did not disclose specific drugs or manufacturers, "[i]ndustry wide public disclosures bar *qui tam* actions against any defendant who is directly identifiable from the public disclosures," which includes them. United States ex rel. Gear v. Emergency Med. Assocs. of Ill., Inc., 436 F.3d 726, 729 (7th Cir. 2006). The

law is not necessarily as the Defendants see it. At least the 9th and 11th Circuits have required more targeted disclosure. See Cooper v. Blue Cross and Blue Shield of Fla., Inc., 19 F.3d 562, 566 (11th Cir. 1994) (requiring allegations specific to particular defendants because "[t]o hold otherwise would preclude any *qui tam* suit once widespread - but not universal - fraud in an industry was revealed. The government often knows on a general level that fraud is taking place . . . [b]ut it has difficulty identifying all of the individual actors engaged in the fraudulent activity"); United States ex rel. Found. Aiding the Elderly v. Horizon West Inc., 265 F.3d 1011, 1016 n.5 (9th Cir. 2001) (citing Cooper and noting that "Appellees also point to general allegations of fraud that were directed at the nursing home industry in general. But, as pointed out by Appellants, none of these 'disclosures' related to Horizon West or specifically to any of its facilities. Therefore, they do not trigger the jurisdictional bar.").

Moreover, the cases the Defendants cite as supporting their view specifically cabin an industry-wide disclosure bar to very small industries. See United States ex rel. Fine v. Sandia Corp., 70 F.3d 568, 572 (10th Cir. 1995) (finding industry-wide allegations sufficient because "[w]hen attempting to identify individual actors, little similarity exists between combing through the private insurance industry in search of fraud and

examining the operating procedures of nine, easily identifiable, DOE-controlled, and government-owned laboratories."); In re Natural Gas Royalties Qui Tam Litig., 562 F.3d 1032, 1042 (10th Cir. 2009) (finding industry-wide allegations sufficient because "[a] general allegation of Medicare fraud - or even more a specific allegation of Medicare fraud through the practice of incorrectly informing patients or healthcare providers that claims should be submitted first to Medicare and not the primary insurer - does not help the government know where to focus in an investigation of the countless individual Medicare claims submitted to the government by vast numbers of health care providers and individuals. By contrast, the specific allegation that measurers of natural gas on federal and tribal lands engage in identified techniques to mismeasure gas obtained from federal or tribal properties allows the government to target its investigation toward specific actors and a specific type of fraudulent activity."); United States v. Alcan Elec. & Eng'g, Inc., 197 F.3d 1014, 1019 (9th Cir. 1999) (finding industry-wide disclosures sufficient for a "narrow class of suspected wrongdoers - local electrical contractors who worked on federally funded projects over a 4-year period."); United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 687 (D.C. Cir. 1997) (finding industry-wide disclosures sufficient because "[l]ittle similarity exists between combing through the myriad of transactions performed by the various defense contractors in

search of fraud and finding easily identifiable federal employee organizations that provide vending services on federal property.").

More importantly, even if the Defendants were right about the law, they are wrong about the facts. The Defendants and the drugs at issue are not readily identifiable from the generalized discussions of averages in the reports. Many manufacturers and drugs could be (and likely are) innocent of the conduct alleged here, and unrelated to the averages discussed in the reports. While some of the documents pointed out by the Defendants discuss AWP and WAC in generalized industry-wide terms, none of the reports allege or disclose industry-wide wrongdoing, and the differences between AWP and actual acquisition cost are reported as average figures. Which drugs and which manufacturers caused the averages to be at the levels reported are not disclosed by any of the reports, and the Defendants and the drugs at issue are not readily identifiable from them.

Because VAC's allegations are not based upon a public disclosure, its suit is not barred by 31 U.S.C. § 3730(e)(4), and the Court has jurisdiction.

2. Failure to State a Claim

a. Section 3729(a)(1)

The False Claims Act provides a penalty for any person who presents or causes to be presented a false or fraudulent claim

for payment or approval to the government. 31 U.S.C. § 3729(a)(1). Defendants argue that the claims at issue here were not presented to the federal government, relying heavily on United States ex rel. Totten v. Bombardier Corp., 380 F.3d 488 (D.C. Cir. 2004), where the D.C. Circuit held that defrauding Amtrak, given its block grant funding, could not be the basis for liability under 3729(a)(1). Unfortunately for the Defendants, their argument is off track, as Medicaid is funded very differently.

Virtually every court that has considered the issue after Totten has found that Medicaid fraud claims are actionable under § 3729(a)(1). See, e.g., United States v. Rogan, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006); United States ex rel. Tyson v. Amerigroup Ill., Inc., 2005 WL 2667207 at *2 (N.D. Ill. Oct. 17, 2005); United States ex rel. West v. Ortho-McNeil Pharm., Inc., 2007 WL 2091185, at *2 (N.D. Ill., Jul. 27, 2007); United States ex rel. Nichols v. Omni H.C., Inc., 2008 WL 906425, at *4 (M.D. Ga. Mar. 31, 2008); United States v. Cathedral Rock Corp., 2007 WL 4270784, at *3 (E.D. Mo. Nov. 30, 2007). These courts have found that Medicaid claims are presented to the federal government. Although a single court has agreed with the Defendants' position, United States ex rel. Atkins v. McInteer, 345 F. Supp. 2d 1302 (N.D. Ala. 2004), the same court later rejected its earlier interpretation as too restrictive. United States ex rel. Brunson v. Narrows Health & Wellness, LLC, 469 F.

Supp. 2d 1048, 1053, 1053 n.1 (N.D. Ala. 2006) ("Liability under the False Claim Act may . . . attach if a fraudulent claim is presented to a non-government intermediary, and the intermediary subsequently presents the claim to an officer or employee of the United States government The court recognizes that this might run contrary to what this court said in McInteer.").

The Court finds persuasive the almost unanimous reasoning of these other courts. As the court in Ortho-McNeil stated:

Medicaid providers, such as pharmacies, pay drug manufacturers for prescription drugs and, in turn, submit claims to state Medicaid agencies for reimbursement. 42 U.S.C. § 1396a(a)(23), (a)(32). While claims are submitted to state Medicaid agencies, the federal government reimburses states for a substantial portion of the funds allotted. 42 U.S.C. § 1396. For this reason, claims submitted to state Medicaid agencies are considered claims presented to the federal government and may give rise to liability under the FCA.

Ortho-McNeil, 2007 WL 2091185, at *2. This reasoning is supported by the legislative history indicating Congress' intent for Medicaid fraud to be covered by the FCA. See S. Rep. No. 99-345 (1986), as reprinted in 1986 U.S.C.C.A.N. 5266, 5274.

Medicaid is "based upon a comprehensive funding and reimbursement structure between the state and federal government [that] is different from the federal funding mechanism for Amtrak" considered in Totten. Amerigroup, 2005 WL 2667207, at *2. Medicaid is not funded by a static block grant. Instead, the state seeks federal funding through quarterly requests, draws down from federal letters of credit as providers seek payment for

Medicaid claims, and then submits reconciliations to the federal government which affect future funding. Under this funding scheme, in which false claims lead to direct draw downs from federal letters of credit, a provider who submits a false Medicaid claim to the state presents a false claim for payment or approval to the United States. As the claims at issue here were presented to the federal government, VAC has stated a claim under § 3729(a)(1) of the FCA.

b. Section 3729(a)(2)

The False Claims Act also provides a penalty for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2). In a recent interpretation of this section, the Supreme Court stated that "a plaintiff asserting a § 3729(a)(2) claim must prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." Allison Engine Co. v. United States ex rel. Sanders, 128 S. Ct. 2123, 2130 (2008). Defendants argue that VAC has failed to state a claim under § 3729(a)(2) because it did not plead that Defendants made false statements with the specific intent that the United States rely on the statements to approve their claims. Defendants are attempting to shift Allison Engine into too high a gear; its requirements are not nearly as daunting as the

Defendants make out.

Allison Engine held that:

If a subcontractor or another defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim "by the Government." In such a situation, the direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability.

Id. at 2130. The issue there was thus somewhat similar to the issue in Totten: the FCA does not cover cases where false statements are used to get a piece of a block grant, already approved by the government; that is, the FCA does not cover scenarios where subcontractors defraud contractors, with no indication that the government was meant to pick up the bill.

Allison Engine did not hold that the defendant must have a subjective intent to defraud the government, but only that the defendant must intend to get a false claim paid by the government "and not by another entity." Id. at 2129. Here, the funding structure is critically different from the structure in Allison Engine: each claim submitted to Medicaid leads directly to a federal outlay - there is nothing "attenuated" about it. Id. at 2130. It is well-established that a defendant intends the natural consequences of its actions. See, e.g., Reno v. Bossier Parish Sch. Bd., 520 U.S. 471, 487 (1997) ("people usually intend the natural consequences of their actions"); Personnel Adm'r of Mass. v. Feeney, 442 U.S. 256, 278 (1979) (recognizing "the

presumption, common to the criminal and civil law, that a person intends the natural and foreseeable consequences of his voluntary actions.”). The Court in Allison Engine specifically noted that its reading would “protect the Government from loss due to fraud but also ensures that ‘a defendant is not answerable for anything *beyond* the natural, ordinary, and reasonable consequences of his conduct.’” Allison Engine, 128 S. Ct. at 2130 (quoting Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 470 (2006)) (emphasis added).

Given the structure of the Medicaid system, the natural and foreseeable consequence of submitting a false claim to Medicaid is that the United States will provide funds to pay the false claim. VAC’s complaint sets forth the Medicaid funding structure and alleges that the Defendants knew that their false price representations would result in the government making inflated reimbursements for claims submitted to Medicaid. (Amended Compl. at ¶¶ 29-40, 48.) VAC has thus alleged that the Defendants intentionally made false statements to cause inflated Medicaid reimbursements. That is sufficient to satisfy the requirement in Allison Engine that the false statement be made with the purpose of inducing payment “by the Government.”

VAC’s complaint also satisfies the requirement in Allison Engine that the false “statement be material to the Government’s decision to pay or approve the false claim.” Allison Engine, 128

S. Ct. at 2126. As this Court has discussed at length elsewhere in this MDL, the FCA's materiality requirement is governed by the concept of "natural tendency:" to be material, "the false statement merely need be the type of statement that is 'capable of influencing' the government's decision (that is, the falsehood must be potentially relevant to the decision)." Mylan, 608 F. Supp. 2d at 153. "Reporting false [AWPs] had a natural tendency to influence the [Government's] actions, by inflating . . . the amount of the [Government's] payment." Id.

VAC's complaint thus satisfies Allison Engine's intent and materiality requirements. As such, it has stated a proper claim for relief under 31 U.S.C. § 3729(a)(2).

3. Specificity

The Defendants also argue that VAC's complaint fails to satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b) because it fails to identify with specificity any false claims for payment or allege facts from which the existence of false claims could be inferred. This Court has ruled extensively on the required level of specificity for a complaint to satisfy Rule 9(b) under the circumstances of this MDL. See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d at 390-91; In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d at 171-72; In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d at 208-11; In re Pharm. Indus.

Average Wholesale Price Litig., 263 F. Supp. 2d at 194.

Specifically, this Court has held that a plaintiff must "state the specific drugs sold by each defendant by alleging the fraudulent scheme, specifying the alleged fraudulent AWP figures for each drug, and attaching exhibits to the complaint to demonstrate the spread for each drug." In re Pharm. Indus.

Average Wholesale Price Litig., 478 F. Supp. 2d at 172. VAC has done that here.

The Complaint alleges that Defendants engaged in a fraudulent scheme involving tens of thousands of Medicaid claims, over a thousand NDCs, and reimbursements of billions of dollars from Medicaid over the course of a decade. (Compl. ¶¶ 1-289.) Defendants reported false and inflated AWPs and WACs for certain drugs knowing that Medicaid relied on these prices to set reimbursement rates. (Id. ¶¶ 3-4, 46-47, Ex. 1-A, Ex. 1-B, Ex. 1-C.) As a result, Medicaid paid excessive reimbursement for Defendants' drugs which induced Defendants' customers to purchase their drugs. (Id. ¶¶ 3-5.)

The Complaint specifically lists the drugs at issue by Defendant, labeler code, name, dosage, and NDC. (Id. Ex. 1-A.) The Complaint specifically sets out the fraudulent AWP and WAC figures for each drug. (Id. Ex. 1-B, Ex. 1-C.) Finally, the Complaint specifically demonstrates the spread of each drug, both as a raw dollar amount and as a percentage, by comparing the published figures with VAC's contract price. (Id.) This is

sufficient to satisfy the pleading requirements of Fed. R. Civ. P. 9(b).

4. Statute of Limitations

Finally, the Defendants argue that all of VAC's claims based on transactions prior to May 21, 2002 are time-barred because they occurred more than six years before the Complaint was filed, and thus fall afoul of the FCA's six-year statute of limitations. See 31 U.S.C. § 3731(b). Defendants argue that the Complaint does not relate back to earlier complaints. Their arguments fail. VAC's original complaint was filed in 2000, but it did not assert any claims against the Defendants in this case. In 2001, VAC filed a First Amended Complaint, naming Mylan and Schein as defendants and specifying numerous drugs. Additional defendants and additional drugs were added in the Second Amended Complaint, filed in 2002, and in the Third Amended Complaint, filed in 2005. After the United States declined to intervene in this case, VAC filed the instant Amended Severed Complaint in 2008.

This Court has already held in this MDL that pursuant to Fed. R. Civ. P. 15(c)(1)(A) an amended complaint filed by the government relates back to the relator's original *qui tam* complaint. In re Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d 389, 397-98 (D. Mass. 2007) ("The unique structure of the FCA supports the government's position that the government's complaint should be treated as an amended complaint

that relates back to the relator's complaint under Rule 15(c)(1)."). As "the FCA contemplates a direct link between the interest of the relator, who is always acting 'in the name of the Government,' and the government in every *qui tam* suit," this applies equally to amended complaints filed by the relator. Id. Although the Defendants argue that relation back is unavailable to relators, they provide no justification for not giving relators the same rights as the government in whose name they act.

Defendants argue that allowing relation back here would violate their due process rights under the Fifth Amendment to the United States Constitution. However, any delay in unsealing the case was caused by the Government exercising its right to obtain lawful extensions of the seal to investigate what is an incredibly large and complex scheme. The Defendants have produced no evidence that the extensions were improper or prejudicial, and they have provided no evidence that they were harmed in their ability to gather evidence or prepare their defense. Furthermore, "[w]hile in some circumstances egregious delay may be sufficiently prejudicial to trigger due process concerns," the due process clause is certainly not coextensive with an enacted statute of limitations, and "this record is insufficient to address any constitutional concerns." Id. at 399.

As such, the claims in relator's instant complaint relate back to the date of the earlier complaint in which the specific drugs were first identified. Amendments which "involve[] the same alleged pricing scheme for the same drug against the same defendant" properly relate back to the earlier complaint. In re Pharm. Indus. Average Wholesale Price Litig., 2007 WL 4287572, at *3 (D. Mass. Dec. 6, 2007). Although Defendants argue that relation back should be determined on an NDC-by-NDC basis, a drug-by-drug analysis is the appropriate standard. Although different NDCs have certain different characteristics, such as package size and dosage strength, the fact that the drug, defendant, and the overall scheme are the same makes any new NDC "sufficiently related" to relate back to claims in earlier complaints regarding other NDCs of the same drug. Id.

Defendants make a final point of arguing that the tolling provision of the FCA cannot be invoked by the relator. 31 U.S.C. § 3731 provides that otherwise time-barred claims may be brought within "3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances." 31 U.S.C. § 3731(b)(2). Defendants argue that because this provision speaks to discovery by an "official of the United States," it applies only to suits by the government, and they cite to numerous courts that have agreed with this argument, the apparent majority view. See United

States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 725 (10th Cir. 2006) (holding that the provision “was not intended to apply to private qui tam relators at all”); United States ex rel. Amin v. George Washington Univ., 26 F. Supp. 2d 162, 172 (D.D.C. 1998) (holding that the provision “only applies to cases in which the government intervenes”); United States ex rel. Thistlethwaite v. Dowty Woodville Polymer, Ltd., 6 F. Supp. 2d 263, 265 (S.D.N.Y. 1998) (same); United States ex rel. Sanders v. N. Am. Bus Indus., Inc., 546 F.3d 288, 293, 296 (4th Cir. 2008) (same, and collecting cases).

VAC replies, however, with numerous courts that have held that the provision applies to relators as well. One line of cases allows relators to invoke the tolling provision, but bases the beginning of the period on the relator’s own knowledge. See United States ex rel. Malloy v. Telephonics Corp., 68 Fed. Appx. 270, 273 (3d Cir. 2003) (holding that relators may invoke the tolling provision and basing the tolling period’s start on the relator’s own knowledge); United States ex rel. Hyatt v. Northrop Corp., 91 F.3d 1211, 1213-18 (9th Cir. 1996) (same). A second line of cases allows relators to invoke the tolling provision, but bases the beginning of the period on the knowledge of the relevant government official. See United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Amer., Inc., 474 F. Supp. 2d 75, 82-89 (D.D.C. 2007) (explaining the three-way split, collecting cases, and adopting the third view); United States ex rel.

Salmeron v. Enter. Recovery Sys., Inc., 464 F. Supp. 2d 766 (N.D. Ill. 2006) (adopting the third view); United States ex rel. Gonzalez v. Fresenius Med. Care N. Am., 2008 WL 4277150, at *7-8 (W.D. Tex. Sept. 2, 2008) (same).

While the issue is debatable, this last line of cases seems most consistent with the language of the statute. 31 U.S.C. § 3731(b) does not expressly limit the tolling provision to the Government. Although the awareness of "the official of the United States charged with responsibility to act in the circumstances" determines the beginning of the tolling period, there is nothing about this trigger which suggests that a relator cannot invoke the tolling provision. Section 3730 makes clear that both the Attorney General and private persons may bring actions under the FCA. 31 U.S.C. § 3730(a)-(b). If the government does not intervene, "the person who initiated the action shall have the right to conduct the action." Id. § 3730(c)(3). As the relator has the right to conduct the action, the relator has the right to invoke the provisions of the statute, including the tolling provision.

Where the drafters of the FCA deemed it necessary, they drew distinctions as to what occurs "[i]f the Government proceeds with the action," "[i]f the Government elects not to proceed with the action," and "[w]hether or not the Government proceeds with the action." Id. § 3730(c). The very next provision after the tolling provision specifically applies only "[i]f the Government

elects to intervene." Id. § 3731(c). The drafters of the FCA knew how to delineate between the rights and responsibilities of the Government and of private parties acting on its behalf. As they chose not to limit the tolling provision to the Government, the statute gives the benefit of the tolling provision to relators as well. For the same reason, the tolling period is started by the knowledge of "the official of the United States charged with responsibility to act in the circumstances," not the relator. The language of the statute supports no other meaning. As the court in Pogue reasoned, the section

unambiguously applies to relators. . . . [T]he three-year statute of limitations is to be measured, as the statute says, from the date the relevant government official knows or should know of the facts relevant to the cause of action. . . . The other cases to consider the issue have asserted that the plain words of § 3731(b) are somehow ambiguous, then turned to legislative history and congressional intent in an effort to give those words different meaning. But the legislative history and congressional intent are perfectly harmonious with the words used by Congress, which the Court today gives their plain effect.

Pogue, 474 F. Supp. at 85.

That being said, the government arguably should have made further inquiry into the spreads for generic drugs based on the 1997 OIG report. See In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 78-79. Nevertheless, the application of the provision to this case is better handled on a motion for summary judgment. See In re Pharm. Indus. Average Wholesale Price Litig., 2007 WL 4287572, at *4.

B. The Individual Motions

Three individual motions to dismiss have also been filed by (1) Barr Pharmaceuticals, Inc., (2) Ivax Corporation, and (3) Alparma, Inc., Alparma USPD Inc., Barre-National, Inc., and Barre Parent Corporation ("the Moving Alparma Defendants"), claiming that they are merely parent companies and not appropriate defendants.

VAC responds with evidence that Barr Pharmaceuticals, Inc., Ivax Corporation, and the Moving Alparma Defendants have claimed to manufacture and market pharmaceutical products in their SEC filings. (Mem. in Opp. to Def. Barr Pharmaceuticals, Inc.'s Mot. to Dismiss [Docket No. 62] 3; Mem. in Opp. to Def. Ivax Corporation's Mot. to Dismiss [Docket No. 63] 3-4; Mem. in Opp. to the Moving Alparma Defendants' Mot. to Dismiss [Docket No. 61] 3.) This is sufficient evidence to support the claim that these Defendants are proper parties at this stage. See Massachusetts v. Mylan Labs., Inc., 2009 WL 607434, at *2 n.1 (Mar. 11, 2009).

ORDER

Defendants' joint motion to dismiss [Docket No. 34] is **DENIED**. The individual motions to dismiss [Docket Nos. 29, 31, 37] are **DENIED**.

S/PATTI B. SARIS
United States District Judge

Publisher Information

**Note* This page is not part of the opinion as entered by the court.
The docket information provided on this page is for the benefit
of publishers of these opinions.**

1:08-cv-10852-PBS VEN-A-CARE v. Actavis Mid Atlantic, LLC et al
Patti B. Saris, presiding
Date filed: 05/21/2008
Date of last filing: 10/02/2009

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