H

United States District Court,
D. Massachusetts.
In re PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION.
This Document Relates To:
City of **New York** et al
v.
Abbott Laboratories, et al. Civ. Action No. 04-cv-06054, et al.
County of Nassau
v.
Abbott Laboratories, et al. Civ. Action No. 05-cv-10179.

MDL No. 1456.
Civil Action No. 01-12257-PBS.
April 2, 2007.

MEMORANDUM AND ORDER

SARIS, U.S.D.J.

***1** New York City and forty-two New York counties bring these lawsuits against fifty pharmaceutical manufacturers and subsidiaries alleging Medicaid fraud in violation of the federal Best Prices Statute, 42 U.S.C. § 1369r-8 and state statutory and common law. The counties claim that the manufacturers reported artificially inflated prices for prescription drugs to various drug-pricing compendia, causing the state of New York to overpay providers for drugs purchased through the state's Medicaid program. Because the counties are obligated under New York law to reimburse the state for fifty percent of its Medicaid drug costs, they allege injury as a result of defendants' fraud.

The Attorney General of the state of New York filed a brief as Amicus Curiae. Defendants [FN1] have moved to dismiss the Consolidated Complaint ("CC"), filed by New York City and forty-one of the counties, and the Amended Complaint, filed individually by New York's Nassau County ("NCAC"), under Fed.R.Civ.P. 12(b)(6), 9(b) and 8(a). The parties have agreed to joint briefing of the issues. This opinion will address the cross-cutting issues raised in the joint briefing. Twenty-one defendants have also filed separate memoranda in support of the motion to dismiss, raising issues specific to each defendant. Those issues will be addressed in subsequent orders.

FN1. The named defendants include: Abbott Laboratories, Inc.; Alpha Therapeutics; Agouron Pharmaceuticals, Inc.; Amgen, Inc.; AstraZeneca Pharmaceuticals L.P.; AstraZeneca US; Aventis Behring; Aventis Pharmaceuticals Inc.; Barr Laboratories, Inc.; Baxter Health Care Corp.; Bayer Corporation; Berlex Laboratories, Inc.; Biogen, Inc.; Boehringer Ingelheim Corp.; Bristol-Myers Squibb Co.; Chiron Corp.; Dey L.P.; EMD, Inc.; Eli Lilly and Co.; Endo Pharmaceuticals, Inc.; Ethex Corp.; Forest Pharmaceuticals Inc.; Fujisawa Healthcare, Inc.; Genentech, Inc.; Genzyme Corp.; GlaxoSmithKline P.L.C.; Hoffman-La Roche, Inc.; Immunex Corp.; Ivax Corp.; Ivax Pharmaceuticals Inc.; Janssen Pharmaceutical; Johnson & Johnson; Key Pharmaceuticals, Inc.; King Pharmaceuticals; MedImmune, Inc.; Merck & Co., Inc.; Mylan Laboratories, Inc.; Novartis Pharmaceuticals Corp .; Organon Inc., USA; Ortho Biotech; Ortho-McNeil Pharma-

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

ceuticals; Par Pharmaceuticals; Pfizer Inc.; Pharmacia Corp.; Purdue Pharma, L.P.; Reliant Pharmaceuticals; Sanofi-Synthelab, Inc.; Schering-Plough Corp.; Serono, Inc.; SmithKline Beecham Corp. D/B/A GlaxoSmithKline; Takeda Pharmaceuticals N.A., Inc.; TAP Pharmaceutical Products, Inc.; Teva Pharmaceuticals Industries, Inc.; Warrick Pharmaceuticals Corp.; Watson Pharmaceuticals, Inc.; and Wyeth.

After hearing and review of the briefs, the Court ***ALLOWS IN PART*** and ***DENIES IN PART*** the motion to dismiss Counts III, VI, VII and VIII of the Consolidated Complaint and Counts IV, VII, VIII and IX the Nassau Complaint. The Court ***ALLOWS*** the motion to dismiss all other counts.

I. Background

Plaintiffs' claims form part of the massive Average Wholesale Price ("AWP") Multi-district litigation ("MDL") pending in this Court, and largely duplicate those brought by New York's Suffolk County in a related lawsuit.[FN2] *See County of Suffolk v. Abbott Labs., Inc,* 339 F.Supp.2d 165 (D.Mass.2004) ("*Suffolk I* "); *County of Suffolk v. Abbott Labs., Inc,* 2004 WL 2387125 (D.Mass. Oct. 26, 2004) ("*Suffolk II* "); *see also* Memorandum and Order (MDL Docket No. 1482, Apr. 8, 2004) ("*Suffolk III* "). The Court assumes close familiarity with that lawsuit, as well as the alleged drug pricing schemes discussed in its previous AWP MDL decisions. *See In re Pharm. Indus. Average Wholesale Price Litig .,* 263 F.Supp.2d 172 (D.Mass.2003) (Saris, J.) ("*Pharm.I* "); *In re Pharm. Indus. Average Wholesale Price Litig.,* 309 F.Supp.2d 165 (D.Mass.2004) (Saris, J.) ("*Pharm.II* "); *In re Pharm. Indus. Average Wholesale Price Litig.,* 307 F.Supp.2d 190 (D.Mass.2004) (Saris, J.) ("*Pharm.III* "); *In re Pharm. Indus. Average Wholesale Price Litig.,* 307 F.Supp.2d 196 (D.Mass.2004) (Saris, J.) ("Pharm.IV"); *In re Pharm. Indus. Average Wholesale Price Litig.,* 321 F.Supp.2d 187 (D. Mass. June 10, 2004) ("*Pharm.V* "); *In re Pharm. Indus. Average Wholesale Price Litig.,* 230 F.R.D. 61 (D.Mass.2005) (Saris, J.) ("*Pharm.VI* ") (providing background to the structure of the pharmaceutical market); *In re Pharm. Indus. Average Wholesale Price Litig.,* 2006 U.S. Dist. LEXIS 80083 (D.Mass. Nov. 2, 2006) ("*Pharm.VII* "); *see also Commonwealth of Massachusetts v. Mylan Labs., Inc.,* 357 F.Supp.2d. 314, 318 (D.Mass.2005) (Saris, J.).[FN3]

> FN2. The plaintiffs bring claims under 42 U.S.C. § 1396r-8, the federal "Best Prices" statute; (CC Count I; NCAC Count II); failure to comply with state medicaid rebate provisions in violation of N.Y. Soc. Serv. L. § 367(A)(7)(d) (CC Count II; NCAC Count III); obtaining public funds through false statements in violation of N.Y. Soc. Serv. L. § 145-b (CC Count III; NCAC Count IV); violations of New York Department of Health regulations 18 N.Y.C.R.R. § 515.2(b)(4) & (5) (CC Count IV; NCAC Count V); breach of contract (CC Count V; NCAC Count VI); unfair trade practices in violation of N.Y. Gen. Bus. L. § 349 (CC Count VI; NCAC Count VII); common law fraud (CC Count VII; NCAC Count VIII); and unjust enrichment (CC Count VIII; NCAC Count IX). Individual plaintiff Nassau County's claims largely track those of the consolidated plaintiffs, though it brings an

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

additional RICO count alleging a manufacturer-publisher racketeering enterprise in violation of 18 U.S.C. § 1962(C) (NCAC Count I). For the sake of convenience, this opinion will refer to the consolidated plaintiffs and Nassau county collectively as "plaintiffs" or "counties," unless otherwise indicated.

FN3. Particularly useful summaries found in *Pharm. I,* 263 F.Supp.2d AWP scheme), and *Pharm. IV,* 307 F. alleged Best Prices scheme). This of the factual background are at 178-80 (describing alleged Supp.2d at 196-97 (describing dispute involves aspects of New York's Medicaid program. For a more detailed discussion of the New York Medicaid system, *see Suffolk I,* 339 F.Supp. at 174-75.

A. Medicaid Reimbursement

***2** The federal government pays approximately fifty percent of Medicaid's share of prescription drug costs. *See* 42 U.S.C. § 1396d(b). Responsibility for the remaining fifty percent is apportioned among state and local authorities according to state law. *See id.* In New York, the state reimburses providers directly for the total share of prescription drug costs attributable to both state and local government. N.Y. Soc. Serv. Law § 367-b. By statute, each county is then billed for twenty-five percent of the total costs (or fifty percent of the state's costs) for prescription drugs associated with county residents. N.Y. Social Services Law § 368-a; *see also id.* § 367-b(6).[FN4] Collectively, the New York county Medicaid programs paid in excess of $13 billion between 1997 and 2003 for the prescription drugs at issue in these lawsuits. (CC ¶ 2.)

FN4. Under the original state Medicaid scheme, counties paid providers directly. However, in 1978 the New York Legislature revised the statutory scheme governing the administration of Medicaid. Under N.Y. Soc. Serv. L. § 367-a, local social services districts no longer paid providers directly, but instead reimbursed the state. The new scheme did not alter the counties' financial obligations, but only the manner in which providers are reimbursed.

There are two components of the price the New York Medicaid program pays for prescription drugs. The first (the "AWP" component) is the price of the drug, initially paid by the state directly to providers, such as retail pharmacies. This price is determined by a formulary set by state law, and is based on wholesale pricing data supplied by the manufacturer to various drug pricing compendia. *See Suffolk I,* 339 F.Supp.2d at 174 (describing state drug reimbursement methodologies). The second component of a drug's price (the "Best Prices" component) consists of a rebate that manufacturers remit directly to the states, pursuant to mandatory agreements between the manufacturers and the Secretary of Health and Human Services, acting "on behalf of the states." *See* 42 U.S.C. § 1396r-8 (establishing rebate program); *see also Pharm. V,* 321 F.Supp.2d at 195-97 (describing program). These rebate agreements require manufacturers to provide the federal government with accurate "Best Prices" for their prescription drugs (defined as the lowest price paid by any purchaser), which are then used to compute a rebate based upon a federal statutory formula. *See*

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

42 U.S.C. § 1396r-8. In New York, the state is required to share this rebate with the counties on a pro rata basis. (CC ¶ 103.)

Actual manufacturer pricing information is considered proprietary, so the Medicaid program relies on "average" or "estimated" wholesale pricing data supplied by each manufacturer. These lawsuits allege that defendants fraudulently reported inaccurate pricing information as to both the AWP and Best Prices components, causing the counties to overpay for pharmaceuticals. *See, e.g., Pharm. VI,* 230 F.R.D. at 67-77 (describing the alleged fraud). They bring these lawsuits to recover these overpayments, in addition to treble damages and additional monetary and equitable relief.

B. Medicaid Administration

In New York, the Department of Health ("DOH" or "department") has been designated "as the single state agency to supervise the administration" of the state's Medicaid program. N.Y. Soc. Serv. Law § 368-a(1). DOH is empowered to impose sanctions for unacceptable practices relating to Medicaid, 18 N.Y.C.R.R. § 515.3, and to bring civil actions to recover Medicaid overpayments. N.Y. Soc. Serv. Law § 145-b(2); 18 N.Y.C.R.R. § 518.5(c).

***3** Recent legislation has created a new Office of Medicaid Inspector General within DOH to coordinate enforcement activities and conduct investigations of suspected Medicaid fraud. *See* N.Y. Soc. Serv. Law 145-b(5) (added July 26, 2006). Under federal law, DOH is required to refer allegations of suspected fraud and abuse to the state Medical Fraud Control Unit within the Office of the Attorney General for investigation and possible civil or criminal prosecution. 42 C.F.R. § 455.15(a). In addition, the Attorney General may bring civil actions to recover damages for Medicaid fraud under New York Executive Law § 63(12).

New York City and each county in New York state have been constituted as "local social services districts." N.Y. Soc. Serv. L. § 61. Subject to the supervision of DOH, each district "shall furnish medical assistance to the persons eligible therefor who reside in its territory." *Id.* § 365(1). Both state and federal governments contemplate a role for these districts in the administration and oversight of the Medicaid program. *See, e.g.,* 42 U.S.C. § 1396a; N.Y. Soc. Serv. Law 145-b. Accordingly, each district has its own fraud and overpayments unit, determines Medicaid eligibility, and performs other important functions related to the program. (*See* CC ¶ 115.) These districts may bring civil actions to recover damages for Medicaid fraud. *See* N.Y. Soc. Serv. Law § 145-b(2) ("[T]he local social services district or the state shall have a right to recover civil damages."). However, the district may retain a share of any recovery only if DOH has approved the litigation as a "demonstration program" under Part C, § 5 of the Act of April 12, 2005, ch. 58, N.Y. Laws 2043, at 2118. DOH has approved the counties' litigation now before the Court. (*See* Exh. B to Cicala Dec., Docket No. 2463, Apr. 17, 2006.)

II. Discussion

A. Implied Causes of Action

1. Standard of Review

For purposes of defendants' motion to dismiss under Rule 12(b)(6), the Court takes as true "the well-pleaded facts as they appear in the complaint, extending [the] plaintiff every reasonable inference in his

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

favor." *Coyne v. City of Somerville,* 972 F.2d 440, 442-43 (1st Cir.1992) (citing *Correa-Martinez v. Arrillaga-Belendez,* 903 F.2d 49, 51 (1st Cir.1990)). A complaint should not be dismissed under Fed.R.Civ.P. 12(b)(6) unless "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Roeder v.. Alpha Indus., Inc.,* 814 F.2d 22, 25 (1st Cir.1987) (quoting *Conley v. Gibson,* 355 U.S. 41, 45-46 (1957)).

2. 42 U.S.C. § 1396r-8

Plaintiffs allege that defendants failed to accurately report "Best Prices" as required under 42 U.S.C. § 1396r-8. New York is a participant in the federal Best Prices rebate program, in which manufacturers are obligated to report accurate pricing information, inclusive of cash and volume discounts, free goods, and various other provider rebates. *See* 42 U.S.C. § 1396r-8. Plaintiffs allege that defendants knowingly violated Section 1396r-8 when they improperly excluded routine discounts, rebates, free samples and other inducements from their calculation of Best Prices, thereby decreasing the rebates to the counties. Plaintiffs contend that there is an implied cause of action under Section 1396r-8 through which they may recover the difference between the rebates received and what the rebates should have been had defendants accurately reported Best Prices. FN5

FN5. This is not new ground. In light of the Court's previous decisions holding that the statute supplies no such remedy, plaintiffs concede they press the claim only to preserve it for appeal. (Pls.' Consol. Opp. to Defs.' Mot. to Dismiss, at 4 n. 10.)

***4** To determine the existence of an implied cause of action, "[t]he judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right, but also a private remedy. Statutory intent on this latter point is determinative." *Alexander v. Sandoval,* 532 U.S. 275, 286-87 (2001). As this Court explained in *Suffolk I,* 339 F.Supp.2d at 177, the counties cannot "point to any provisions [in the rebate statute] demonstrating a Congressional intent to create a remedy." Accordingly, Section 1396r-8 does not support a cause of action for the counties. *Id.* (no implied cause of action under Best Prices statute); *Mylan Labs,* 357 F.Supp.2d at 325-26 (same).

Count I of the Consolidated Complaint and Count II of Nassau County's Amended Complaint therefore fail to state a claim.

3. N.Y. Soc. Serv. Law § 367-a(7)(d)

Plaintiffs further allege that defendants' failure to accurately report Best Prices violates N.Y. Soc. Serv. Law § 367-a(7)(d). The statute empowers the state to enter into manufacturer rebate agreements where none exist under federal law, otherwise incorporates the federal manufacturer rebate agreements, and provides that DOH will reimburse Medicaid recipients for covered drugs under the terms of that agreement. *See id.* Defendants, and the New York Attorney General as Amicus, take the position that the statute does not create a private cause of action.

Section 367-a(7)(d) does not expressly provide the counties with a remedy for a manufacturer's submission of false pricing data. Under New York law, "[t]o imply a private right of action when not expressly provided by statute, plaintiffs must prove (1) they are members of the class for whose benefit the statute was enacted; (2) a

private right of action would promote the legislative purpose; and (3) creation of such a right of action would be consistent with the legislative scheme." *Masters v. Wilhelmina Model Agency,* 2003 U.S. Dist. LEXIS 698, at *19 (S.D.N.Y. Jan. 17, 2003) (citing *Sheehy v. Big Flats Community Day,* 73 N.Y.2d. 629, 633 (1989)).

"Even where the recognition of a private cause of action might arguably promote one aspect of a statute's legislative goals, the greater concern is the 'consistency of doing so with the purposes underlying the legislative scheme.' " *Hudes v. Vytra Health Plans Long Island, Inc.,* 295 A.D.2d 788, 789 (N.Y.App.Div.2002) (quoting *Sheehy,* 73 N.Y.2d at 629); *see also Mark G. v. Sabol,* 93 N.Y.2d 710, 720 (N.Y.1999) (avoiding unwarranted interference with the legislative scheme is the "most critical" factor in determining whether a private cause of action exists).

Where a "statute carries its own potent official enforcement mechanism," a court should not imply a private right of action. *Uhr v. East Greenbush Cent. Sch. Dist.,* 94 N.Y.2d 32, 40 (N.Y.1999) (no implied right of action where, inter alia, statute expressly provided for enforcement and administration by the Commissioner of Education); *see, e.g., Carrube v. N.Y. City Transit Auth.,* 291 A.D.2d 558 (N.Y.App.Div.2002) ("With regard to the third prong of the *[Sheehy]* test, if a provision or body of law has a potent official enforcement mechanism, the Legislature contemplated administrative enforcement and there is no private right of action.").

***5** Here, plaintiffs' claims fail because recognition of an implied cause of action on the part of the counties under Section 367-a(7)(d) would be inconsistent with the enforcement mechanisms prescribed in New York's Medicaid scheme. The New York legislature has expressly authorized DOH (not the counties) to bring civil actions to recover Medicaid overpayments made to a provider under the state rebate statute. *See* N.Y. Soc. Serv. Law § 367-a(10)(d) ("The department [DOH] may bring and maintain an action ... for any claimed overpayments made to the provider.").

Where the legislature intends to vest enforcement powers in both the state and local social services districts, it does so expressly. *See* N.Y. Soc. Serv. Law 145-b (empowering "local social services districts or the state" to bring suit to recover public funds obtained by fraud); *Id.* § 369 (allowing county to file lien on interest in trust to recover cost of medical assistance). Here, the legislature's silence as to the counties' enforcement authority indicates that the counties have no remedy under the statute.

Accordingly, Section 367-a(7)(d) does not support a cause of action for the counties. Count II of the Consolidated Complaint and Count III of Nassau County's Amended Complaint are therefore dismissed.

4. New York Department of Health Regulations 18 N.Y.C.R.R. §§ 515.2(b)(4) & 5

Likewise, plaintiffs may not recover on the basis of New York City Department of Health Regulations, 18 N.Y.C.C.R. §§ 515.2(b)(4) & (5). The regulations provide that "[c] onversion of a medical payment, or any part of such payment, to a use or benefit other than for the use and benefit intended by the medical assistance program" is an "unacceptable practice." 18 N.Y.C.C.R. § 515.2(b)(4). The regulations

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

further define "unacceptable practice" to include "offering or paying either directly or indirectly any payment (including any kickback, bribe, ... rebate or discount), whether in cash or in kind, in return for purchasing, ... ordering or recommending any medical care, services or supplies for which payment is claimed," unless "the discount or reduction in price is disclosed to the client and reflected in the claim." 18 N.Y.C.R.R. § 515.2(b)(5).

The regulations prohibiting "unacceptable practices" relating to Medicaid do not create an implied right of action for the counties. Instead, the regulations empower *DOH* to bring "sanctions," typically against providers, which include suspension from the Medicaid program for a reasonable time, censure, or conditional or limited participation in the program. *Id.* § 513(a). In addition, the "*department* may also require the repayment of overpayments determined to have been made as a result of an unacceptable practice." *Id.* § 513(b) (emphasis added). The regulations set out in detail the guidelines and procedures applicable to the imposition of sanctions, *see id.* §§ 515.4-515.6, and authorize *DOH* (not the counties) to bring civil proceedings to recover any overpayment only if it "would be more efficient or effective or in the best interests of the program." *See id.* § 518.5(c). To imply a cause of action permitting the counties to recover under these regulations would be inconsistent with this regulatory scheme. *See, e.g., Sheehy,* 73 N.Y.2d. at 633.

***6** Further, as amicus curiae, DOH has taken the position that the regulations do not supply a cause of action to the counties. The department, speaking on behalf of the New York Commissioner of Health, is entitled to substantial deference by this Court with respect to the interpretation of these regulations. (*See* Br. for the Attorney General of New York as Amicus Curiae, at 15 n. 7. (citing *Cortlandt Nursing Care Center v. Whalen,* 46 N.Y.2d 979, 980 (N.Y.1979) ("[T]he commissioner's interpretation of a [Medicaid] regulation is 'controlling and will not be disturbed in the absence of weighty reasons.' Unless the [DOH's] determination is arbitrary and capricious, it must be sustained.") (citations omitted)). In light of the discussion above, the DOH's interpretation is neither arbitrary nor capricious.

Count IV of the Consolidated Complaint and Count V of the Nassau Complaint are dismissed.

B. Other State Law Claims

1. Breach of Contract

Plaintiffs also allege that as a result of defendants' submission of false Best Prices, defendants breached their rebate agreements with the Secretary of Health and Human Services. The counties assert that they may recover for this breach as third party beneficiaries of those agreements. In *Suffolk I,* the Court determined that the counties were not third party beneficiaries of the rebate agreements, explaining:

> While [the county] is in a class of 'government agencies paying for drugs under Medicaid,' the [Model Rebate Agreement, or] MRA specifically defines 'the 50 states" as the parties to be benefitted. There is no 'clear indication' that counties (as opposed to states) were in the class of intended beneficiaries from the vantage point of either the pharmaceutical manufacturers or the federal government or in the text of the MRA.

339 F.Supp.2d at 179.

Plaintiffs now urge the Court to reconsider that decision, arguing that the Court should have looked beyond the four corners of the rebate agreement to the broader statutory and regulatory scheme in determining whether the counties were intended beneficiaries, in particular because of the "peculiarity of relations among the parties here." (Pls.' Consol. Opp. at 28.) Plaintiffs ultimately contend that a determination of the parties' intent to benefit the counties raises a factual question inappropriate for disposition at this stage.

Plaintiffs' contention that the Court should look beyond the face of the agreement to discern an intent to benefit the counties does not save them. "[T]o show the possibility of a fact dispute regarding intent, [the county] *must first show a clear indication on the face of the contract* of an intent either to benefit [the county] or to benefit a class that includes [the county]." *Suffolk I,* 339 F.Supp.2d at 178 (emphasis added). The circumstances surrounding the agreement, including the statutory and regulatory environment in which it arises, may inform third-party beneficiary analysis when the agreement itself is ambiguous, but may not substitute for a clear lack of intent in the text of the agreement itself. *See, e.g., Klamath,* 204 F.3d at 1211; *Sanders v. Bressler,* 03-CV-5283 (DRH), 2006 U.S. Dist. LEXIS 8352, at *18 (E.D.N.Y. Feb 10, 2006)("Where the contract is clear and unambiguous on its face, the courts must determine the intent of the parties from within the four corners of the instrument.").

***7** Because there is no indication of an intent to benefit the counties on the face of the rebate agreements, plaintiffs may not recover as third-party beneficiaries. *See Suffolk I,* 339 F.Supp.2d at 178. Count V of the Consolidated Complaint and Count VI of the Nassau Complaint are dismissed.

2. Unfair Trade Practices

Plaintiffs also bring claims alleging that defendants' conduct constituted an unfair trade practice under New York's consumer protection statute, General Business Law § 349. The statute provides monetary relief for any person injured by reason of "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 349.

"A plaintiff asserting a Section 349 claim 'must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act.' " *In re Rezulin Prods. Liab. Litig.,* 390 F.Supp.2d 319, 336-337 (S.D.N.Y.2005) (quoting *Stutman v. Chem. Bank,* 95 N.Y.2d 24, 29 (2000)); *see also Maurizio v. Goldsmith,* 230 F.3d 518, 522 (2d Cir.2000) (a practice is "consumer-oriented" under Section 349 if it results in "harm to the public interest") (citation omitted). Here, plaintiffs satisfy the first two elements, at least with respect to their AWP claims, by adequately alleging that defendants' conduct was materially misleading and "consumer-oriented." *See Suffolk I,* 339 F.Supp.2d at 182 (county satisfies first two elements of Section 349 with respect to AWP claims).

In *Suffolk I,* the Court reserved decision on whether Section 349 permits recovery for counties' payments to the state based on AWPs submitted by defendants pending clarification of the statute's "actual injury" requirement in *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc.,* 3

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

N.Y.3d 200 (N.Y.2004). In *Blue Cross,* several third party payors sued tobacco companies under Section 349 alleging that the companies engaged in deceptive practices designed to mislead the public about the harmful and addictive effects of smoking, causing the payors to overpay for subscribers' medical expenses. *Id.* at 203-04. The issue before the state's highest court was whether Section 349 abrogated the common law rule that "an insurer or third party payer of medical expenditures may not recover derivatively for injuries suffered by its insured." *Id.* at 206. The court found that it did not, explaining that "[a] lthough [the insurer] actually paid the costs incurred by its subscribers, its claims are nonetheless indirect because the losses it experienced arose wholly as a result of smoking related illnesses suffered by those subscribers"; in such circumstances, "the insurer's sole remedy is in equitable subrogation." *Id.* at 206-07. Accordingly, the court concluded that "a third party payor has no standing to bring an action under *General Business Law § 349* because its claims are too remote." *Id.* at 208.

***8** Defendants maintain that the counties' injuries are "entirely derivative" of those suffered the state, and therefore not cognizable under Section 349. Plaintiffs and the New York Attorney General counter that because the counties are obligated by state statute to bear a portion of the costs of Medicaid reimbursement, they are directly injured by the alleged AWP scheme and thus have standing to sue under Section 349.

"An injury is indirect or derivative when the loss arises solely as a result of injuries sustained by another party." *Blue Cross,* 3 N.Y.3d at 208. Because a local social services district "pays money to and receives money from the State, following State requirements which set the applicable reimbursement rate" it is, in a sense, "an indirectly-harmed party." *See Suffolk I,* 339 F.Supp.2d at 176. Nonetheless, there are significant differences between an indirectly-injured insurance carrier and a county acting as Medicaid payor. In *Blue Cross,* smokers were directly injured when they suffered smoking-related injuries as a result of defendant tobacco companies' deceptions; in turn, the third party payors were indirectly injured when they paid claims related to the smokers' illnesses pursuant to their obligations under insurance agreements. Here, by contrast, the counties were injured in tandem with the state when both overpaid for Medicaid reimbursements based on defendants' deceptive pricing submissions. Although the method and timing of payment may differ, the state's losses were not distinct from those suffered by the counties under the statutory scheme. *But see County of Erie,* Index No.2005-2439, at *28 (dismissing a county's Section 349 claims based on defendant manufacturers' AWP/Best Prices scheme because "the County ... is as remote a party as the private insurer in *Blue Cross,* " reasoning that "in effect, [a county] is the insurer of the poorest citizens").

Moreover, the relationship at issue in *Blue Cross,* that between an insured and his carrier, is a contractually-negotiated risk sharing arrangement for which the common law provides an established remedy: equitable subrogation. *See* 3 N.Y.3d at 206. The relationship at play here is quite different. The counties bear an independent legal duty to reimburse for residents' Medicaid costs based on AWP. *See* N.Y. Soc. Serv. Law 365(1)(a) ("[E]ach public welfare district shall furnish medical assistance to the persons eligible therefor who

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

reside in its territory ...."); *see also id.* § 62(1) ("[E]ach public welfare district shall be responsible for the assistance and care of any person who resides in or is found in its territory and who is in need of public assistance ."); *id.* § 368-a (providing for partial state reimbursement "the expenditures made by social services districts for medical assistance for needy persons"). Because the counties are obligated under state law to pay a portion of Medicaid reimbursement costs, their injuries are not derivative of the state's within the meaning of *Blue Cross.* As such, the counties may recover under Section 349 for those overpayments caused by defendants' deceptive pricing submissions.

3. Unjust Enrichment

***9** Plaintiffs have alleged that defendants were unjustly enriched because they improperly retained rebate funds that should have gone to the plaintiffs as a result of defendants' submission of inaccurate Best Prices. They therefore have asserted a sufficient "substantive connection" between defendants' conduct and their own loss to support standing with respect to Best Prices/unjust enrichment claims.

In New York, unjust enrichment "applies in situations where no legal contract exists, 'but where the person sought to be charged is in possession of money or property which in good conscience and justice he should not retain, but should deliver to another.' " *Indyk v. Habib Bank Ltd.,* 694 F.2d 54, 57 (2d Cir.1982) (quoting *Matarese v. Moore-McCormack Lines, Inc.,* 158 F.2d 631, 634 (2d Cir.1946)).

> The essential inquiry in any action for unjust enrichment or restitution is whether it is against equity and good conscience to permit the defendant to retain what is sought to be recovered.... Generally, courts will look to see if a benefit has been conferred on the defendant under mistake of fact or law, if the benefit still remains with the defendant, if there has been the otherwise a change of position by the defendant, and whether the defendant's conduct was tortious or fraudulent.

Paramount Film. Distrib. Corp. v. State, 30 N.Y.2d 415, 421 (N.Y.1972) (citations omitted). "The enrichment may either be the receipt of money or its equivalent or by being saved from expense or loss." *Baratta v. Kozlowski,* 94 A.D.2d 454, 464 (N.Y.App.Div.1983). In *Suffolk I,* the Court observed:

> "[l] eaving aside the thorny issue of whether Suffolk may recover from Defendants to the extent that the AWP fraud boosted their sales, the Court notes that Suffolk's claim that Defendants were 'saved from expense' when they fraudulently underpaid Best Prices rebates to the State, and consequentially Suffolk, suffices to state a claim."

339 F.Supp.2d at 181.

Defendants move to dismiss plaintiffs' unjust enrichment claims arguing that under New York law such a claim, "which is a quasi-contract claim, requires some type of direct dealing or actual substantive relationship with a defendant." *Redtail Leasing Inc. v. Belleza,* 1997 WL 603496, at *8 (S.D.N.Y. Sept. 30, 1997). However, as this Court observed in related proceedings, "unjust enrichment does not require any contractual or fiduciary relationship among the parties," nor does it "require that a defendant receive direct payments from a plaintiff." *Mylan Labs,* 357 F.Supp.2d at 324; *see Cox,* 8 A.D.3d at 40-41 ("Plaintiffs allegations that Microsoft's de-

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

ceptive practices caused them to pay artificially inflated prices for its products state a cause of action for unjust enrichment.... It does not matter whether the benefit is directly or indirectly conveyed.").

Next, defendants argue that any attempt to assert unjust enrichment claims based on Best Prices reporting is barred as a matter of law by the rebate agreements. Defendants contend that under New York law "[t]he existence of a valid and enforceable written contract governing a particular subject matter ordinarily precludes recovery in quasi contract *[i.e.,* unjust enrichment] for events arising out of the same subject matter." *MacDraw, Inc. v. CIT Group Equip. Fin.,* 157 F.3d 956, 964 (2d Cir.1998) (citing, inter alia, *U.S. East Telecomms., Inc. v. U.S. West Communications Services, Inc.,* 38 F.3d 1289, 1296 (2d Cir.1994)). Cases cited by defendants stand for the unremarkable proposition that a party may not avoid the express terms of a contract-even a contract with a third party-by pleading a cause of action in unjust enrichment. *See, e.g., Granite Partners, L.P. v. Bear, Stearns & Co.,* 17 F.Supp.2d 275, 311 (S.D.N.Y.1998). While the express terms of the rebate agreements may ultimately preclude recovery, plaintiffs may assert unjust enrichment as an alternative theory of recovery.

***10** Defendants argue that plaintiffs' unjust enrichment claims should be subject to the particularity requirements of Fed.R.Civ.P. 9(b). While some courts have required particularity for unjust enrichment claims premised entirely on fraudulent conduct, *see Ramapo Land Co., Inc. v. Consolidated Rail Corp.,* 918 F.Supp. 123, 128 (S.D.N.Y.1996), here plaintiffs could, at least conceivably, state a claim for unjust enrichment based in quasi-contract or a tort other than fraud *(i.e.,* negligent misrepresentation). As such, the unjust enrichment claims are not necessarily subject to Rule 9(b).

Defendants further contend that plaintiffs' claims are deficient even under Fed.R.Civ.P. 8(a). That rule sets forth the bare requirements of notice pleading, under which a plaintiff need only make "a short and plain statement of the claim showing that the pleader is entitled to relief." In *Suffolk II,* 2004 WL 2387125, at *2-3, the Court dismissed the counties' unjust enrichment/Best Prices claims as to certain defendants because "[w]ith respect to most companies, [the county had] not tied the Best Prices claims to any particular drugs, discounts or other company specific practices which would support an inference of misrepresenting Best Prices." However, the Court sustained such claims against those defendants that had "set forth at least minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for any specific drug; *or* (2) any information showing a company-wide scheme to misstate Best Prices." *Id.* at *3 (emphasis added) (citing *Educadores Puertoriquenos en Accion v. Hernandez,* 367 F.3d 61, 66-67 (1st Cir.2004)).

Here, with respect to most defendants, the counties have "not tied the Best Prices claims to any particular drugs, discounts or other company specific practices which would support an inference of misrepresenting Best Prices." *Suffolk II,* 2004 WL 2387125, at *2-3. Instead, the counties have relied on general, though as yet unproven, allegations of Best Prices misreporting, either by Congress or various law enforcement agencies. *(See, e.g.,* Exh. D to CC.) This is insufficient. However, the allegations are sufficient against Biogen (for

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

Amevive, Zeralin and Avonex only), GlaxoSmithKline (for Paxil and Flonase only), Merck (for Zocor only), Pfizer (for Lipitor only), and TAP Pharmaceuticals (for Lupron only) because the plaintiffs have alleged specific information of Best Prices misreporting as to particular drugs. Defendants' motion is allowed as to the remaining defendants' Best Prices/unjust enrichment claims.

4. N.Y. Soc. Serv. Law § 145-b

Plaintiffs also bring claims under N.Y. Soc. Serv. Law § 145-b alleging that defendants obtained public funds by means of false statements. Section 145-b(1) provides in relevant part:

> (a) It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, *on behalf of himself or others,* to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.
>
> ***11** (b) ... “[S]tatement or representation” includes, but is not limited to: a claim for payment made to the state, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment, financial information whether in a cost report or otherwise, health care services available or rendered, and the qualifications of a person that is or has rendered health care services.
>
> (c) ... [A] person, firm or corporation has attempted to obtain or has obtained public funds *when any portion of the funds from which payment was attempted or obtained are public funds, or any public funds are used to reimburse or make prospective payment to an entity from which payment was attempted or obtained.*

(emphasis added). Significantly, the statute expressly empowers “the local social services district or the state” to initiate civil actions, and provides for treble damages. *Id.* § 145-b(2).[FN6]

> FN6. The statute was amended in July of 2006 to coordinate state and local enforcement activities. *See* N.Y. Soc. Serv. Law § 145-b(5). This Section does not affect the standing of a local social services district to bring suit under the statute. *See* *Suffolk I,* 339 F.Supp.2d at 180.

Defendants move to dismiss the counties' claims under Section 145-b for failure to state a claim, contending that the AWP scheme alleged falls outside the reach of this statute because defendants have not directly “obtain[ed] payments from public funds.” Defendants argue that they did not violate the law because any public funds expended as a result of the publication of inflated AWPs went to providers, and not to defendants.

In *Suffolk I,* the Court held that Section 145-b encompasses the AWP scheme alleged by plaintiffs

> because Defendants attempted to obtain, ‘on behalf of’ providers, payment from public funds through means of reporting false data (the AWP' s) that served as the basis for the claims of the providers. Alternatively, ... Defendants arguably obtained public funds when public funds

were used to reimburse providers, from whom defendants obtained payment.

339 F.Supp.2d at 179-81. However, the Court dismissed Suffolk County's Best Prices claims "because Suffolk ha[d] not provided any support for the notion that Section 145-b encompasses statements made to lower payments made *to* the state, as opposed to statements made to receive payments *from* the state." *Id.* at 180 (Emphasis added). After full consideration, the Court declines to revisit the ruling in *Suffolk I.*

Plaintiffs have alleged that defendants received public funds within the meaning of the statute when they fraudulently manipulated wholesale prices in order to increase Medicaid reimbursements to providers. Defendants actively marketed these "spreads" in order to induce providers and other intermediaries in the distribution chain to select their products over those of competitors. Though the providers may in fact have pocketed the spread, defendants realized the benefit of their fraud in the form of increased sales and market share, inclusion of their drugs in various formularies, and exclusivity arrangements with wholesalers and other providers. Moreover, under the definition of "obtain," a party receives public funds if it receives payment from any entity that is reimbursed from such funds. *See* N.Y. Soc. Serv. Law § 145-b (1)(c). These allegations state a cause of action under Section 145-b. *See County of Erie v. Abbott Labs, et al.,* C.A. No.2005-2439, at *28 (N.Y.Sup.Ct. Sept. 7, 2006) (pharmaceutical manufacturers' AWP fraud states a cause of action under Section 145-b); *see also People v. Brooklyn Psychosocial Rehab. Inst.,* 185 A.D.2d 230, 234 (N.Y.App. Div.2d Dep't 1992) (where defendant made false statements that resulted in public payments which "inured to [his] benefit," though indirectly, he obtained public funds within meaning of Section 145-b); *Kurianski v. Baghai-Kermani,* Index No. 42931/92, at *4 (N.Y.Sup.Ct. Sept. 29, 1998) (doctor peddling prescriptions for controlled substances without a medical purpose obtained public funds under Section 145-b even though payments went to providers because the "State loses the same amount of money, and the Medicaid system suffers the same level of abuse, whether the payments are receive by the perpetrator of the fraud or by a third party").

***12** Therefore, defendants' motions to dismiss Count III of the consolidated complaint and Count IV of the Nassau Complaint are denied as to plaintiff's AWP claims. However, plaintiffs' Best Prices claims are dismissed because there is no indication that the statute was intended to target false statements made to lower payments to the states. *See Suffolk I,* 339 F.Supp.2d at 180.

5. Fraud

Plaintiffs charge fraud on the basis of N.Y. Social Services Law § 366-b. That statute provides that

> any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing services or merchandise, or who knowingly submits false information for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining authorization of furnishing services or merchandise under this title, shall be guilty of a Class A misdemeanor....

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

However, this statute does not supply a cause of action to plaintiffs. *See County of Erie,* Index No.2005-2439, at *25. Instead, it provides a criminal penalty for Medicaid fraud. The only civil remedy available to the counties under the New York Medicaid scheme is provided by Section 145-b. Accordingly, fraud claims based on Section 366-b are dismissed. *See Sheehy,* 73 N.Y .2d. at 633.

Defendants also move to dismiss plaintiffs' fraud claims under state common law on the ground that New York does not recognize a cause of action for fraud where reliance is by a third party to the alleged misrepresentation.

> In order to sustain a cause of action for common law fraud, the plaintiff must establish with sufficient particularity that the defendant "(1) made a material false statement; (2) knowing that the statement was false; (3) acting with intent to defraud; that plaintiff (4) reasonably relied on the false representation and (5) suffered damage proximately caused by the defendant's actions."

N.B. Garments (Pvt.) Ltd, v. Kids Int'l Corp., No. 03-8041, 2004 U.S. Dist. LEXIS 3774, at *7 (S.D.N.Y. March 10, 2004) (quoting *Morris v. Castle Rock Entm't, Inc.,* 246 F.Supp.2d 290, 296 (S.D.N.Y.2003)). Defendants argue that because the counties are third parties to the alleged misrepresentations, which were relied upon by the state when it made reimbursements with no input from the counties, they cannot satisfy the element of reasonable reliance.

Plaintiffs respond that third-party reliance is sufficient to support a claim of common law fraud in New York where plaintiffs were injured as a direct and immediate consequence of a misrepresentation to a third party. In *Suffolk I,* the Court dismissed the county's common law fraud counts because "a plaintiff does not establish the reliance element of fraud for purposes of ... New York law by showing only that a third party relied on a defendant's false statement." 339 F.Supp.2d at 180 (citing *Cement & Concrete Workers Dist. Council Welfare v. Lollo,* 148 F.3d 194, 196 (2d Cir.1998)). However, the Court recognized that an alternative line of cases permit recovery based on third-party reliance. *Id.* at 181 (citing *N.B. Garments (Pvt.) Ltd, v. Kids Int'l Corp.,* No. 03-8041, 2004 U.S. Dist. LEXIS 3774, at *9-12 (S.D.N.Y. March 10, 2004)).

***13** Plaintiffs now urge this Court to reconsider the holding in *Suffolk I,* particularly in light of the decision in *County of Erie,* Index No.2005-2439, at *15-17, which held that the alternative *Eaton* line of cases recognizing third-party reliance in fraud compelled recognition of plaintiff county's AWP/Best Prices fraud claims.

In *Eaton,* 83 N.Y. at 34-35, New York's highest court held that a misrepresentation made to one party, which the maker intends to be communicated to and influence a third party, is actionable in fraud by the third party if he relies on the misrepresentation to his detriment. The court explained:

> If A. casually or from vanity makes a false or exaggerated statement of his pecuniary means to B. or even if he does so with the intent to deceive and defraud B. and B. communicates the statement to C. who acts upon it, A. cannot be held as for a false representation to C. But if A. makes the statement to B. for the purpose of being communicated to C. or intending that it shall reach and influence him, he can be so held.

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

Id. Contrary to this view, a more recent line of cases culminating in the Second Circuit's decision in *Lollo,* 148 F.3d at 196, have held that "a claim of fraud will not lie when premised on the reliance of a third party." *Id.* at 197 (citations omitted).FN7

FN7. One court explains the development of this conflict as follows:

> By way of history, about a century after the *Eaton* line of cases, without any reference to binding authority from their parent court, lower New York state courts began to hold that common law fraud was not cognizable when based on the reliance of a third-party (hereinafter referred to collectively as "the *Garelick* line"). Then, the snowball effect began to take further hold, and courts in this district cited exclusively to the *Garelick* line (without reference to the *Eaton* line) to conclude that in New York "a claim of fraud will not lie when premised on reliance of a third-party." And, to make matter's [sic] worse, the Second Circuit followed this conclusion, with reliance on the *Garelick* line (still, without citation to or discussion of the *Eaton* line).
>
> *N.B. Garments,* 2004 U.S. Dist. LEXIS 3774, at *3 (citations omitted).

Since the decision in *Lollo,* New York's courts have reaffirmed the principle that third-party reliance is, in certain circumstances, actionable in fraud. For example, in *Securities Investor Protection Corp. v. BDO Seidman, LLP,* New York's highest court reiterated the "general and unremarkable principle that liability for fraud can be imposed through communication by a third party," provided the plaintiff justifiably and directly relied on the fraud. 95 N.Y.2d 702, 710 (N.Y.2001) (declining, however, to impose liability for fraud where plaintiff did not know of defendants' statements but instead relied on third party's independent evaluation of those statements) (citing *Tindle v. Birkett,* 171 N.Y. 520 (N.Y.1902)).

Third party reliance on fraud is also cognizable under New York law where there is a sufficient causal connection between a defendant's fraud and a plaintiff's injury. *See, e.g., Desser v. Schatz,* 182 A.D.2d 478, 479-80 (N.Y.App.Div.1992) (where defendant fraudulently induced bank to issue satisfaction of a mortgage, wrongfully extinguishing plaintiff's interest, reliance by the bank, "to the clear detriment of plaintiff, is manifest, and it is of no moment, in this context, that the false representation was not made directly to [the] plaintiff" (citing *Eaton,* 83 N.Y. at 31)). Fraud exists "where a false representation is made to a third party, resulting in injury to the plaintiff." *Buxton Mfg. Co. v. Valiant Moving & Storage,* 239 A.D.2d 452, 455 (N.Y.App.Div.1997) (liability for fraud imposed where subcontractor was directly injured as a result of defendant's misrepresentation to a third party that the subcontractor had been paid in full (citing *Eaton,* 83 N.Y. at 31)); *cf.* W. Prosser, *The Law of Torts* § 108, at 714 (4th Ed.1971) (explaining that the reliance element of fraud is essentially causation-in-fact).

***14** By contrast, cases refusing to recognize third party reliance on fraud generally "present[ ] a risk of far-flung liability for inchoate or unintended injuries." *Union*

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

Carbide Corp. v. Montell N.V., 9 F.Supp.2d 405, 412-13 (S.D.N.Y.1998). The *Union Carbide* court explained that where a third party "effectively acts as proxy for both sides to an exchange," one party may bring a claim in fraud against the other for misrepresentations made to the third party proxy; however, "indirect reliance is insufficient when a plaintiff's injury is an unintended or remote consequence of a defendant's misrepresentations; i.e., when the theory of fraud presented is far removed from the usual, transactional context."

Here, the question is whether a fraud claim is cognizable where the state relied on the defendants' submission of false AWP pricing information to the detriment of the counties. Plaintiffs claim that defendants submitted fraudulent wholesale pricing data to publishers, intending that the information would be relied on by Medicaid payors to calculate provider reimbursements. Plaintiffs contend that the state relied on the accuracy of that information when making payments to providers, and the counties were injured when they overpaid for prescription drugs purchased through the program. Under New York law, because the misrepresentations relied on by the state caused the counties direct harm, plaintiffs' claim of fraud is viable.

Similarly, with respect to their Best Prices claims, plaintiffs have alleged third party reliance on fraud which caused them harm. Again, Defendants' alleged failure to accurately report Best Prices directly and foreseeably harmed plaintiffs when the defendants failed to remit the full amount due under the terms of the Best Prices statute and the rebate agreements.

As a result, plaintiffs have adequately stated a claim for fraud under New York law. However, to succeed, plaintiffs must plead these claims with particularity.

6. *Rule 9(b)*

Defendants also move to dismiss the counties' Section 349, Section 145-b, and fraud claims under Fed.R.Civ.P. 9(b), arguing that the counties fail to allege sufficient facts to satisfy the heightened pleading standard applicable to counts sounding in fraud. Because Section 145-b "applies to 'false statements,' 'deliberate concealments,' or 'other fraudulent schemes or devices[ ]' Rule 9(b) applies to this claim." *Suffolk II,* 2004 U.S. Dist. LEXIS 21448, at *2 (citing *United States v. Karvelas,* 360 F.3d 220, 227-28 (1st Cir.2004)). In addition, "most courts have also held that it is appropriate to require 'specificity' in pleading a violation of Section 349." *Id.* at *3 (collecting cases). Rule 9(b) provides that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." *See Daly v. Llanes,* 30 F.Supp.2d 407, 414 (S .D.N.Y.1998).

a. AWP claims

In *Pharm. I,* the Court held that in light of the detailed fraudulent scheme alleged, the plaintiffs' AWP allegations were sufficient with respect to "any drug identified in the complaint together with the allegedly fraudulent AWP published by a named defendant for that drug." 263 F.Supp.2d at 194. The Court stated that to satisfy the strictures of Rule 9(b), "plaintiffs [must] clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *Id.; see also Pharm. IV,* 307 F.Supp.2d at 209 (D.Mass.2004) ("In light of the allegations

and concessions concerning an industry-wide practice of inflating AWP's, the Court rejects arguments that Plaintiffs must allege a specific spread for each drug, so long as sufficient facts were alleged to infer a fraudulent scheme by each particular Defendant manufacturer (i.e., government investigations concerning that company, internal company documents, specific alleged fraudulent spreads on other drugs manufactured by that company and the like).”). Subsequent MDL decisions have added a requirement that the complaint allege a good faith estimate of an “actual” market price from which the spread may be calculated. *See Suffolk II,* 2004 WL 2387125, at *4; *see also* Order, MDL Docket No. 1482, at *2.

***15** Here, in the complaints and attached exhibits, the plaintiffs set out, among other things, (1) the specific defendants' drugs (listed by National Drug Code) paid for by the counties in the year 2000 (or, for Nassau County, in 2004) (2) an actual “average wholesale price” for each drug computed on the basis of actual market data,[FN8] (3) the allegedly fraudulent AWP listed for each drug, and (4) a “spread” representing the difference between the estimated actual and reported AWP. (*See* Exhs. A & B to CC; Exhs. A & B to NCAC.) In addition, plaintiffs have alleged the amount of money that the counties spent on drugs manufactured by each defendant. They have also cited numerous federal and state government reports and investigations, along with other evidence that each defendant intentionally inflated wholesale pricing data as part of a business strategy to market the resulting spread to providers.

> FN8. Plaintiffs derived “actual” market prices from information provided by Ven-A-Care of the Florida Keys, Inc., a licensed pharmacy. These prices were available to thousands of pharmacies across the nation who participate in the McKesson/Servall program, and provide a more reliable benchmark for actual prices than the methodology employed by Suffolk. *(See, e.g.,* Pl. Opp. to Def. Chiron's Motion to Dismiss at 2 n. 4; Pls.' Opp. to Def. Amgen's Motion to Dismiss at 2 & n. 4.) The plaintiffs contend that Rule 9(b) is satisfied because their “AWP allegations rest not on ‘industry average’, but on a comparison of reported AWPs against actual market prices for defendants' drugs.” The Court agrees.

Mindful of the complexity of the scheme, the Court concludes that the plaintiffs have satisfied Rule 9(b) with respect to those drugs (1) specifically identified in the complaint as (2) purchased by the counties in any year subject to this lawsuit along with (3) an allegedly fraudulent AWP calculated on a good faith basis, together with a spread. *See also Steinke,* 432 F.Supp.2d at 1089. Thus for those drugs listed in the Exhibits identified above, plaintiffs have complied with Rule 9(b).

Defendants point out that many of plaintiffs' allegations concerning wholesale pricing fraud are premised on the submission of an alternative data point for average drug prices, either “Wholesale Acquisition Cost” (“WAC”) or an equivalent listing. The plaintiffs state that the case is not about the 20-25% mark up between WAC and AWP. (CC §§ 7-8.) Given the formulaic relationship between WAC and AWP, no more particularity is required.[FN9] Defendants' motion to dismiss is denied.

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

FN9. The exhibits attached to the complaint list thousands of drugs. Only those drugs for which the plaintiffs have alleged a spread greater than the 20-25% mark up between WAC and AWP survive.

i. Physician-Administered Drugs

Defendants contend that physician-administered drugs ("PADs") FN10 are reimbursed based on actual cost, not AWP, and that such drugs should therefore be excluded from these lawsuits. *See* N.Y. Soc. Serv. Law § 367-a (9)(a) (setting reimbursement "for drugs provided by medical practitioners *and claimed separately* by the practitioners, [at] the actual cost of the drugs to the practitioners") (emphasis added). Plaintiffs respond that it is only where a claim for a PAD is submitted by a practitioner outside of a hospital or clinic setting, that reimbursement is at actual cost.

FN10. For a list of PADs contained in the complaints, see Pls.' Consol. Mem. in Support of the Motion to Dismiss at 27 n. 21.

Plaintiffs assert that "[w]here hospitals and clinics submit claims for PADs, Medicaid reimbursement is made based on AWP. Many drugs also classified as PADs may be self-administered, and in that case also they are reimbursed based on AWP." (Pls.' Corrected Surreply at 16.) In support of this contention, plaintiffs cite to the individual Reply Brief of defendant Medimmune, in which Medimmune concedes that the PAD Synagis "is distributed both by physicians, who are statutorily required to be reimbursed at actual cost, and by Assignment of Benefit Distributors, who are reimbursed at AWP minus a percentage." (Medimmune Rep. at 3.) They also point to the Lupron Settlement Agreement, which resolved allegations that defendant TAP Pharmaceuticals inflated AWP for Lupron, another PAD. (*See* Exh. A to TAP's Supp. Mem. in Support of Defs.' Motion to Dismiss.)

***16** Rule 9(b) requires more. Plaintiffs have not alleged specific drugs reimbursed based on AWP, or made specific allegations in the complaint with respect to PADs. Absent such information, plaintiffs allegations are insufficient to support an inference of fraud.

However, prior to June 9, 1994, PADs were reimbursed based on AWP. *See* N.Y. Soc. Serv. Law § 367-a (9)(a) (1994 amendments). These drugs survive if plaintiffs have otherwise met rule 9(b)'s requirements. Accordingly, PADs purchased after June 9, 1994 are dismissed from the complaints as to all causes of action.

ii. Drugs Reimbursed at the Federal Upper Limit

Defendants also seek to exclude certain classes of drugs not reimbursed on the basis of AWP. New York reimburses providers for multisource or generic drugs that have at least three suppliers at the Federal Upper Limit ("FUL"). *See* N.Y. Soc. Serv. Law § 367-a(9)(b)(i). Federal regulations provide that a drug's FUL is set by the Centers for Medicaid and Medicare Services ("CMS") at "150% of the published price for the least costly therapeutic equivalent"-where the "published price" is defined by "publishing compendia" and certain other criteria are satisfied. *See* 42 C.F.R. § 447.332. CMS's FUL price "is based on all listings contained in current editions of published compendia of cost information for drugs available for sale nationally." 42 C.F.R. § 447.332, subd. (a)(1)(ii). Plaintiffs allege that by fraudulently overstating a drug's least costly

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

price, on average by in excess of 150% of the defendants' actual price, defendants caused plaintiffs to overpay for generic and multisource drugs calculated on the basis of FUL.

The method for calculating FUL is disputed. Defendants contend that the regulations defining FUL are directed to CMS, and therefore impose no legal obligation on defendants to accurately state their "least costly" price for any drug. The parties have failed to explain the FUL reimbursement system clearly, and plaintiffs have generally not specified which defendants stated false "published prices," what the false prices published were, for which drugs, and what spread resulted. Plaintiffs claim they have this information and therefore should replead it. As such, these claims based on drugs reimbursed on the basis of FUL are dismissed without prejudice. However, the consolidated plaintiffs have adequately alleged specific FUL pricing manipulation by Alpharma (Clobetasol only), Barr (Chlordiazepoxide only), the Boehringer Group (Furosemide and Prednisone only), Endo (Selegiline, Captopril-HCTZ, and Carbidopa/Levo only), Ethex (Doxazosin Mesylate only), and the Ivax Group (Buspirone only)). These claims for these drugs survive.

b. Best Prices/Rebate Claims

In *Suffolk II,* the Court determined that the county's Best Prices claims fell "woefully short" under Rule 9(b) because the county had failed to "tie [ ] the Best Prices claims to any particular drugs, discounts or other company-specific practices which would support an inference of misrepresenting Best Prices." 2004 WL 2387125, at *6. Here, Plaintiffs appear to concede that their generalized allegations of widespread violations of the Best Prices statute and rebate agreements, standing alone, are insufficient to satisfy Rule 9(b)'s particularity requirements. Nonetheless, plaintiffs assert that this Court's ruling in *Mylan Labs,* sustaining Best Prices claims against Mylan, Barr, Duramed, Ivax, Warrick, Watson, Schein, Teva, Par, Dey, Ethex, Pureoac, and Roxane under Rule 9(b) should in itself provide sufficient evidence of Best Prices fraud with respect to those defendants. Likewise, the plaintiffs point to an investigation commenced in April 2004 by the Senate Finance Committee against Johnson & Johnson, AstraZeneca, Bristol-Myers Squibb, Novartis, Eli Lilly and Co., Aventis, Boehringer Ingelheim, Forest, Sanofi-Synthlabo, and Eisai as sufficient evidence of Best Prices violations. However, absent particularized allegations concerning each defendants' allegedly fraudulent reporting of Best Prices for specific drugs, plaintiffs have failed to carry their burden under Rule 9(b). Accordingly, plaintiffs' Best Prices/fraud claims are dismissed without prejudice to replead with more specificity at a later date.

***17** However, plaintiffs' Best Prices claims survive with respect to Biogen (for Amevive, Zeralin and Avonex only), GlaxoSmithKline (Paxil and Flonase only), Merck (Zocor only), Pfizer (Lipitor only), and TAP Pharmaceuticals (Lupron only) because they have alleged Best Prices misreporting with respect to the specific drugs identified.

C. RICO Claims

Finally, plaintiff Nassau County alone resurrects allegations that defendants' AWP scheme constitutes a "manufacturer-publisher enterprise" in violation of the federal racketeering statute, 18 U.S.C. § 1962(c). Claims of this sort were dismissed under Fed.R.Civ.P.

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

12(b)(6) and 9(b) in this Court's prior decisions in *Pharm. I,* 263 F.Supp.2d at 184, *Pharm. IV,* 307 F.Supp.2d at 204, and *Suffolk I,* 339 F.Supp.2d at 175. The counties' claims fare no better here.

Plaintiffs have failed to demonstrate that the manufacturers and publishers comprised an association-in-fact for the purpose of engaging in racketeering activity. *See United States v. Turkette,* 452 U.S. 576, 580 (1981). Among other things, as in *Pharm. IV.,*

> the participants, as described, do not share a common purpose more specific than that common to many human endeavors, the reaping of a profit. The publishers are indifferent as to whether the AWP spread exists or not; their financial interest lies in earning money through selling books listing numbers. The spread is irrelevant to their financial well being.

307 F.Supp.2d at 204. Further, plaintiffs rely on substantially the same facts in support of their allegations that the publishers knew of defendants' fraud that were deemed insufficient in *Pharm. IV. See id.*

To be sure, discovery in the MDL class litigation has revealed a more active role for some publishers than initially alleged; for example some publishers convert WACs into AWPs. However, there are no allegations regarding how the application of a formulaic mark up from wholesale acquisition cost to AWP was motivated by a common fraudulent purpose. This complaint has largely recycled the old RICO allegations. The Nassau Complaint thus fails to state a claim under Section 1962(c), and defendants' motion to dismiss Count I of that complaint is allowed.

ORDER

For the reasons stated, defendants' motion to dismiss (Docket No. 2200) Counts I, II, IV and V of the Consolidated Complaint and Counts I-III, V, and VI of the Nassau Complaint is ***ALLOWED.*** The motion to dismiss Counts III, VI, VII and VIII of the Consolidated Complaint and Counts IV, VII, VIII and IX of the Nassau Complaint is ***ALLOWED IN PART*** and ***DENIED IN PART.***

D.Mass.,2007.
In re Pharmaceutical Industry Average Wholesale Price Litigation
Not Reported in F.Supp.2d, 2007 WL 1051642 (D.Mass.), RICO Bus.Disp.Guide 11,263, Med & Med GD (CCH) P 302,071

END OF DOCUMENT

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.