

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY )  
AVERAGE WHOLESale PRICE ) M.D.L. No. 1456  
LITIGATION ) Civil Action No. 01-12257-PBS  
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**MEMORANDUM AND ORDER**

May 13, 2003

Saris, U.S.D.J.

**I. INTRODUCTION**

In this proposed class action, plaintiffs allege that numerous pharmaceutical companies fraudulently overstate the published "average wholesale price" ("AWP") of many of their prescription drugs, which results in inflated payments for such drugs by beneficiaries of the federal Medicare Part B program (through beneficiary co-payments), private health and welfare plans, and other end-payors.<sup>1</sup>

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<sup>1</sup> The complaint names the following companies as defendants (corporate groupings are separated by semicolon): Abbot Laboratories; Amgen, Inc.; "AstraZeneca," which includes, Zeneca, Inc., AstraZeneca US, and AstraZeneca Pharmaceuticals L.P.; "The Aventis Group," which includes, Aventis Pharmaceuticals, Inc., Hoechst Marion Roussel, Inc., and Aventis Behring, LLC; "Baxter," which includes, Baxter International Inc. and Baxter Healthcare Corporation; Bayer Corp.; "The Boehringer Group," which includes, Boehringer Ingelheim Corp, Ben Venue Laboratories, Inc., and Bedford Laboratories; B. Braun Medical Inc.; "The BMS Group" which includes, Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc.; Dey, Inc.; "The Fujisawa Group" which includes, Fujisawa Healthcare, Inc. and Fujisawa U.S.A., Inc.; "The GSK Group" which

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The Master Consolidated Complaint asserts claims under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C §§ 1964(c) (Counts I-IV), and the consumer protection statutes of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, and Washington (Count V). Plaintiffs also seek declaratory relief on the claim that reporting AWP's above the actual average wholesale price for various drugs is unlawful. (Counts VI and VII.)<sup>2</sup> The plaintiffs bring this action on behalf of themselves and two Classes: Class One, the Medicare Part B co-payor class,<sup>3</sup> and Class Two, the third-party payor class.<sup>4</sup>

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includes, GlaxoSmithKline, P.L.C., SmithKline Beecham Corp., and Glaxo Wellcome, Inc.; Hoffman-La Roche, Inc.; Immunex Corp.; "The Johnson & Johnson Group" which includes, Johnson & Johnson, Centocor, Inc. and Ortho Biotech; Merck & Co., Inc.; Pfizer, Inc.; "The Pharmacia Group" which includes, Pharmacia Corp. and Pharmacia & Upjohn, Inc.; "The Schering-Plough Group" which includes, Schering-Plough Corp. and Warrick Pharmaceuticals Corp.; "The Sicor Group," which includes, Sicor, Inc., Gensia, Inc., and Gensia Sicor Pharmaceuticals, Inc.; and Watson Pharmaceuticals, Inc.

<sup>2</sup> The Judicial Panel on Multidistrict Litigation ordered all related cases transferred to this District for coordinated and consolidated pre-trial proceedings.

<sup>3</sup> Class One includes: "All persons or entities who, for purposes other than resale and during the Class Period, paid for the purchase of a prescription drug manufactured by a Defendant Drug Manufacturer, which payment constituted a contribution toward the Medicare Part B co-payment." (¶ 333.) Counts I and II assert claims on behalf of Class One members only with respect to Medicare Part B covered drugs.

<sup>4</sup> Class 2 Two includes: "All Third-Party Payors that, during the Class Period, contracted with a PBM or other

Acknowledging that their AWP's represent only "undiscounted sticker prices," and not actual average wholesale prices, defendants have jointly moved to dismiss on the following grounds: (1) that the court should abstain because this dispute involves a legislative question; (2) that the plaintiffs fail to allege viable RICO enterprises; and (3) that the state law claims are preempted by the Medicare Act, 42 U.S.C. § 1395-1395qqq, and the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001-1461. Individual defendants have raised company-specific grounds for dismissal.

After hearing and extensive briefing, the Court **ALLOWS** the motion to dismiss the RICO claims and **DENIES** the motion to dismiss the state claims on preemption grounds. The Court also dismisses (1) all the association plaintiffs on the ground they lack standing, (2) all claims regarding drugs that are not identified by name with a specified fraudulent AWP, and (3) certain companies from which no plaintiff claims to have purchased a drug with an inflated AWP. The dismissal will go into effect in 30 days if there is no motion to amend.

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intermediary to, based on a "discount" off of AWP, provide to its participants a brand name prescription drug manufactured by a Defendant Drug Manufacturer." (¶333) Counts III and IV are brought on behalf of Class Two members against some of the defendants for unlawful conduct associated with brand name prescription drugs.

## II. STANDARD OF REVIEW

Generally, for purposes of a motion to dismiss the Court takes as true "the well-pleaded facts as they appear in the complaint, extending [the] plaintiff[s] every reasonable inference in [their] 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[s] can prove no set of facts in support of [their] claim which would entitle [them] 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)). As to the RICO claims, the Court is mindful of the First Circuit's instruction that while "the pleadings should generally be construed liberally . . . a greater level of specificity is required in RICO cases." Bessette v. Avco Fin. Servs., Inc., 230 F.3d 439, 443 (1st Cir. 2000) (citing Garita Hotel Ltd. P'ship v. Ponce Fed. Bank., 958 F.2d 15, 17 & n. 1 (1st Cir. 1992)).

## III. FACTUAL BACKGROUND

The consolidated class action complaint alleges the following facts, many of which are in dispute.

Medicare is the federal insurance program that pays for the medical care of persons 65 and older. See 42 U.S.C. §§ 1395 -

1395qqq. The Medicare program is administered by the Center for Medicare and Medicaid Services ("CMS"), which is under the authority of the Secretary of Health and Human Services. Medicare Part B establishes an insurance program to pay for physicians' services. See id. at §§1395j-1395w. Medicare generally does not cover the cost of prescription drugs that a beneficiary self-administers (for example, by swallowing the drug). It does cover approximately 450 outpatient drugs, including ones that are administered by a doctor, and certain oral anti-cancer drugs. (Compl. ¶ 143.)

Through the Medicare Part B program, the federal government reimburses health care providers, such as physicians, for up to 80 percent of the allowable cost of certain prescription drugs that they administer directly to patients. The remaining 20 percent is paid by the Medicare Part B beneficiary, as a co-payment. 42 U.S.C. § 13951(o); (Compl. ¶ 149.) The drug reimbursement rates are based on "the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological." 42 C.F.R. § 405.517; see also 42 U.S.C. § 1395u(o) ("...the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.").

In setting reimbursement rates, the Medicare program uses the AWP's generated by the pharmaceutical industry. There are no

regulations describing how AWP's are to be calculated, nor any regulatory process for approving them. Pharmaceutical companies do not report AWP's directly to the federal government, but instead send their pricing information to independent publishing companies that compile the data and publish the AWP's in trade publications, which are then used by the government, as well as private health plans.<sup>5</sup> The publishing companies do not independently review the figures for accuracy. The figures are not filed with the CMS.

The pharmaceutical companies vastly overstate the AWP's of many drugs in the data they provide to the trade publications. For example, for one drug called "Acyclovir," defendant Abbott Laboratories reports an AWP to the "Red Book" publication of \$1047.38, while the actual average wholesale price is only \$349.05. In some instances the reported AWP is more than 10,000 percent higher than the actual AWP. The following table, drawn from the complaint (¶ 190), provides just a sampling of AWP overstatements by Abbott:

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<sup>5</sup> The major publications include the Drug Topics Red Book (the "Red Book"), American Druggist First Databank Annual Director of Pharmaceuticals, Essential Director of Pharmaceuticals ("the Blue Book) and the Master Drug Database. These books report AWP's for various dosages of thousands of prescription drugs.

Drug	Abbott's 2001 Red Book AWP	DOJ Determined Actual AWP	Difference	Spread
Acetylcysteine	\$35.87	\$21.90	\$13.97	64%
Acyclovir	\$1,047.38	\$349.05	\$698.33	200%
Amikacin Sulfate	\$995.84	\$125.00	\$870.84	697%
Calcitriol (Calcijex)	\$1,390.66	\$1,079.00	\$311.66	29%
Cimetidine Hydrochloride	\$214.34	\$35.00	\$179.34	512%
Clindamycin Phosphate	\$340.52	\$75.35	\$265.17	352%
Dextrose	\$239.97	\$3.91	\$236.06	6,037%
Dextrose Sodium Chloride	\$304.38	\$1.93	\$302.45	15,671%
Diazepam	\$28.50	\$2.03	\$26.47	1,304%
Furosemide	\$74.52	\$14.38	\$60.14	418%
Gentamicin Sulfate	\$64.42	\$.51	\$63.91	12,531%
Heparin Lock Flush	\$38.30	\$13.60	\$24.70	182%
Metholprednisolone Sodium Succinate	\$34.08	\$2.30	\$31.78	1,382%
Sodium Chloride	\$670.89	\$3.22	\$667.67	20,735%
Tobramycin Sulfate	\$150.52	\$2.94	\$147.58	5,020%
Vancomycin Hydrochloride	\$382.14	\$4.98	\$377.16	7,574%

The complaint alleges by name more than 100 drugs, from numerous pharmaceutical companies, with inflated AWP's.

This overstatement in the reporting creates a "spread," as seen in the table above, between the actual cost of a drug to a health care provider, and the reimbursement paid to the provider by the federal government. It also inflates the co-payments made by consumers. Defendants actively market this "spread" to providers, who are encouraged to buy drugs from defendants at the highly "discounted" actual prices, and are urged to keep the reimbursement and co-payment spreads for themselves. This

practice increases sales and a drug manufacturer's market share of the drug.

For some defendants, the AWP scheme is not the only mechanism used to create the artificial "spreads." Another method involves the provision of "free samples" to health providers who are sometimes encouraged to bill their customers for the samples as they would any other drug. This "free sample" scheme lowers the providers' overall costs while not reducing the amount they receive in reimbursements from the federal government, or co-payments from consumers, which remain tied to the reported AWPs. Other fraudulent pricing practices include off-invoice pricing, phony consulting fees, as well as debt forgiveness, rebates, and grants. All of these incentives were designed to lower the providers' net cost of purchasing the drugs.

Plaintiff union and employee health benefit plans contract with drug plan managers, known as Pharmacy Benefit Managers ("PBMs"), which operate as intermediaries between the pharmaceutical companies and the private health plans. These PBMs set prices on their formularies - their drug fee lists - based on the AWP figures reported in the same trade publications used by the Medicare program, less a certain percentage discount. Again, defendants market the same pricing and reporting "spread" to PBMs that they do to individual health care providers serving

Medicare patients. The PBMs are offered drugs at highly "discounted" actual prices while charging the private health plans fees based on the inflated AWP. The PBMs benefit by keeping the "spread" for themselves and the pharmaceutical companies benefit because PBMs are drawn to keeping on their formularies drugs from those companies offering the most lucrative "spreads."

#### IV. DISCUSSION

##### A. Prudential Abstention

Defendants concede that the "national average wholesale price" figures upon which Medicare Part B reimbursements and co-payments are based are not the actual average of wholesale prices they charge for their drugs. Nonetheless, pointing to legislative hearings and statements on AWP, they contend that Congress knows that the AWP they report represent only an "undiscounted sticker price" that has no direct relation to the actual average price they charge for their drugs, and that Congress has acceded to this widespread pricing and reporting practice.<sup>6</sup>

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<sup>6</sup> Plaintiffs' dispute defendants' claim that the government has acquiesced in defendants' practices with respect to AWP. Most recently, plaintiffs have submitted as "supplemental authority" a document prepared by the Department of Health and Human Services, Office of the Inspector General, titled "Compliance Program Guidance for Pharmaceutical Manufacturers" (dated April 2003), which contains the following statement: "[I]t is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one

Drawing on the policies underpinning the political question doctrine, and urging "prudential abstention," defendants argue that it would be an unwarranted excursion into the legislative domain for this Court to hold defendants' practices unlawful when Congress has acquiesced in these practices. See generally Warth v. Seldin, 422 U.S. 490, 499-500, 95 S.Ct. 2197, 2205 (1975) (discussing limitations on judicial intervention that involve matters of "judicial self-governance."); Baker v. Carr, 369 U.S. 186, 210, 82 S.Ct. 691, 706 (1961) (noting that the political question doctrine operates as a prudential limitation on the courts review of other branches of government; it is "primarily a function of the separation of powers").

However, "not every matter touching on politics is a political question." Japan Whaling Ass'n v. Am. Cetacean Soc'y, 478 U.S. 221, 229-30, 106 S.Ct. 2860, 2865-66 (1986). "It goes without saying that interpreting congressional legislation is a recurring and accepted task for the federal courts." Id.; see also Bureau of Alcohol, Tobacco and Firearms v. Fed. Labor Relations Auth., 464 U.S. 89, 98 n. 8, 104 S.Ct. 439, 445 n. 8 (1983) (observing that "deciding what a statute means" is "the quintessential judicial function"); United States v. 29 Cartons of \*\*\* An Article of Food, 987 F.2d 33, 38 (1st Cir 1993) (same).

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purpose is to manipulate the 'spread' to induce customers to purchase its product." Id. at 27.

The fact that congressional hearings have been held, congressional reports generated, and executive branch statements on the AWP issued, without follow-up legislative action,<sup>7</sup> does not mandate judicial retreat from this heartland task of construing statutory language. Cf. Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 306, 108 S.Ct. 1145, 1154 (1988) (indicating "reluct[ance] to draw inferences from Congress' failure to act.").

The primary authority on which defendants rely for their prudential abstention argument, Stephenson v. Shalala, 87 F.3d 350 (9th Cir. 1996), is not on point. In Stephenson, the Ninth Circuit upheld the Secretary's interpretation of a statutory provision that health providers charge certain Medicare hospital patients a reasonable fee, relying, in part, on Congressional acquiescence in her interpretation. Id. at 356-57. The Stephenson Court exercised its duty to interpret the statute at issue there by applying appropriate canons of construction: the case is not an example of a court abstaining from statutory construction. See id.

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<sup>7</sup> Defendants make much of the fact that Congress enacted legislation barring the Secretary of Health and Human Services from "directly or indirectly decreas[ing] the rates of reimbursement" for drugs covered by Part B until the Comptroller General studied the issue of medical drug reimbursement, Medicare, and Medicaid and Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. No. 106-554, §429(c), 114 Stat. 2763 (2000). However, the study was completed in September 2001.

I decline to dismiss the action on prudential abstention grounds.

**B. RICO Allegations**

**1. The Enterprise Requirement**

Plaintiffs allege that defendants engaged in a pattern of racketeering activity by accomplishing the fraudulent AWP pricing scheme through the use of interstate mails and wire communications in violation of 18 U.S.C. § 1962(c).<sup>8</sup> Defendants argue that the RICO claims must be dismissed because plaintiffs do not allege a viable RICO enterprise.<sup>9</sup>

To state a RICO claim under § 1962(c), a plaintiff must allege four elements: "(1) conduct; (2) of an enterprise; (3) through a pattern; (4) of racketeering activity." See Libertad v. Welch, 53 F.3d 428, 441 (1st Cir. 1995).

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<sup>8</sup> 18 U.S.C. § 1962(c) provides:

It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . .

<sup>9</sup> Defendants also argue that the claims should be dismissed because plaintiffs cannot demonstrate violations of the mail and wire fraud statutes, and because the plaintiffs' injuries were not caused directly by the conduct of any of the defendants. However, I do not discuss these arguments in light of the dismissal for failure to allege an enterprise.

The term "enterprise" is defined by the statute:

"enterprise" includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.

18 U.S.C § 1961(4). In interpreting the RICO "enterprise" requirement, the Supreme Court has explained that "[t]here is no restriction upon the associations embraced by the definition: an enterprise includes any union or group of individuals associated in fact." United States v. Turkette, 452 U.S. 576, 580, 101 S.Ct. 2524, 2527 (1981). The enterprise concept is not unbounded, however, because an enterprise must be "an entity for present purposes a group of persons associated together for a common purpose of engaging in a course of conduct." Id. at 583, 101 S.Ct. at 2528 (emphasis added). An enterprise is "proved by evidence of an ongoing organization, formal or informal, and by evidence that the various associates function as a continuing unit." Id. "While 'enterprise' and 'pattern of racketeering activity' are separate elements of a RICO offense, proof of these two elements need not be separate or distinct but may in fact 'coalesce.'" United States v. Patrick, 248 F.3d 11, 19 (1st Cir. 2001) (citing Turkette, 452 U.S. at 583, 101 S.Ct. at 2528).

"[T]wo or more legal entities can form or be part of an association-in-fact RICO enterprise." (first emphasis added) United States v. London, 66 F.3d 1227, 1243 (1st Cir. 1995); see

also River City Markets, Inc. v. Fleming Foods West, Inc., 960 F.2d 1458, 1462 (9th Cir. 1992) ("Virtually every business contract can be called an 'association in fact.'"); VNA Plus, Inc. v. Apria Healthcare Group, Inc., 29 F. Supp.2d 1253, 1259 (D. Kan. 1998) ("It is well established that no formal legal entity is required to create a RICO enterprise -- an informal association between two contracting businesses will suffice."); cf. Cedric Kushner Promotions v. King, 533 U.S. 158, 163, 121 S.Ct. 2087, 2091 (2001) (an association-in-fact enterprise can be comprised of only a corporation and its principal owner).

To make a claim out under RICO, the First Circuit has "consistently held that the same entity cannot do 'double duty' as both the RICO Defendant and the RICO Enterprise." Libertad, 53 F.3d at 442 (citing Miranda v. Ponce Fed. Bank, 948 F.2d 41, 44-45 (1st Cir. 1991)); see also Cedric Kushner Promotions, 533 U.S. at 161, 121 S.Ct. at 2090 (2001) (holding that the same party cannot serve as both the RICO defendant and the RICO enterprise).

Some circuits have held that a RICO enterprise must exhibit an "ascertainable structure distinct from that inherent in the conduct of a pattern of racketeering activity." Patrick, 248 F.3d at 18 (quoting United States v. Bledsoe, 674 F.2d 647, 665 (8th Cir. 1982)). The First Circuit, however, has declined to define a criminal enterprise under 18 U.S.C. § 1962(c) as

requiring an ascertainable structure. See Patrick, 248 F.3d at 18. Instead, to establish an association in fact enterprise, plaintiff must show that the associated groups "constitute a larger unit, over and above their separate structures and operations." Libertad, 53 F.3d at 442.

The First Circuit has considered several factors in determining whether a RICO association-in-fact enterprise has been properly asserted: (1) whether the associates have a common purpose, see id. at 442-443; (2) whether there is "systematic linkage, such as overlapping leadership, structured or financial ties or continuing coordination," id. at 443; (3) whether there is a common communication network for sharing information on a regular basis, see id. at 444; (5) whether the associates hold meetings and sessions where important discussions take place, see Patrick, 248 F.3d at 19; (6) whether the associates wear common colors, signs or insignia to make the group identifiable, see id.; and (7) whether the group conducted common training and instruction, see id. None of these factors is dispositive.

## **2. The AWP Enterprises (¶¶ 346-350)**

Plaintiffs allege twenty-one separate "AWP Enterprises," each consisting of a single defendant pharmaceutical company and all the medical providers that prescribe its drugs with a reported AWP. The complaint describes these enterprises as "associations-in-fact consisting of (a) various and independent

medical providers who prescribed Covered Drugs for which a Defendant Drug Manufacturer reported an AWP, and (b) a Defendant Drug Manufacturer, including its directors, employees, and agents." (Compl. ¶ 346.) As one example of this type of enterprise, it alleges "The Abbott Provider Enterprise is an association-in-fact consisting of the various and independent medical providers who prescribed Covered Drugs for which Abbot reported an AWP, and Defendant Abbott, including its directors, employees and agents." (¶ 350.) The providers are those who sought co-payments from members of Class One (¶ 347.) Further, the providers, according to the complaint, are aware not only of the drug manufacturers' scheme, but are also "aware of the involvement of other similarly-situated providers in that fraudulent and unlawful scheme." (¶ 348.)

Plaintiffs essentially allege that each enterprise takes a hub-and-spoke design, with an individual drug manufacturer at the center dealing independently with each individual provider as the spoke. Put another way, plaintiffs allege that a doctor in Massachusetts and a doctor in Minnesota are part of the same RICO enterprise if they both prescribe Abbot's drug Acyclovir and collect a co-payment based on its AWP. The common purpose, according to plaintiffs, is that universal elixir -- greed.

Defendants argue that this hub-and-spoke configuration fails to allege a RICO enterprise. In an analogous context, the

Supreme Court has rejected a similar alleged hub-and-spoke conspiracy which had a pattern of separate spokes meeting at the common center without "the rim of the wheel to enclose the spokes." See Kotteakos v. United States, 328 U.S. 750, 769, 66 S.Ct. 1239, 1250 (1946) (holding that hub-and-spoke conspiracy in which one person arranged fraudulent loans from the Federal Housing Authority for eight different people constituted not one but eight separate conspiracies, each requiring its own proof for conviction). The Court cautioned against confusing "the common purpose of a single enterprise with the several, though similar, purposes of numerous separate enterprises of like character." Id.

Most courts have found that complaints alleging hub-and-spoke enterprises fail to satisfy the RICO enterprise requirement. See VanDenBroeck v. CommonPoint Mortg. Co., 210 F.3d 696, 700 (6th Cir. 2000) (rejecting a RICO enterprise involving defendant bank and a series of sub-lenders with whom the bank associated, because there were no allegations of a mechanism by which this group "conducted its affairs or made decisions"); New York Auto. Ins. Plan v. All Purpose Agency & Brokerage, Inc., 97-CV-3164, RICO Bus. Disp. Guide 9611, 1998 WL 695869 at \*6 (S.D.N.Y. Oct. 6, 1998) (rejecting a hub-and-spoke enterprise in which auto-insurer conspired with individual clients to provide them lower insurance rates, without any

evident association between the clients; stating "Such a series of discontinuous independent frauds is not an 'enterprise.' Each is a single two-party conspiracy."); First Nationwide Bank v. Gelt Funding, Corp., 820 F.Supp. 89, 98 (S.D.N.Y. 1993) (holding that hub-and-spoke scheme is not an enterprise); Blue Cross and Blue Shield of Ala. v. Caremark, Inc., 98-CV-1285, RICO Bus. Disp. Guide 9828, 1999 WL 966434 at \*8 (N.D. Ill. 1999) (rejecting enterprise theory in RICO insurance-fraud claim involving health providers because "[p]laintiffs fail to allege how this large and geographically diverse group of almost 3,000 independent physicians and entities acted in concert with one another . . . there is no indication that the individual [providers] were even aware of each other's existence."); Blue Cross of Cal. v. Smithkline Beecham Clinical Labs., Inc., 62 F. Supp.2d 544, 551-53 (D. Conn. 1998) (rejecting proposed enterprise consisting of insurer and, among others, thousands of doctors, where there was no evidence doctors were even aware of alleged kickback scheme). But see Fidelity Funding of Cal., Inc. v. Reinhold, 79 F.Supp.2d 110, 126 (E.D.N.Y. 1997) ("[Plaintiff] has alleged in it's Complaint a 'hub-and-spoke' arrangement, where Micro and Maxum served as the twin hubs and other defendants . . . served as the spokes. Whether or not this alleged arrangement adequately constitutes a non-RICO

conspiracy . . . it is sufficient to constitute a RICO enterprise." ).

Plaintiffs rely heavily on In re Managed Care Litig., 185 F. Supp.2d 1310 (S.D. Fla. 2002). There the plaintiffs alleged several enterprises consisting of each of the defendant managed care insurance companies together with "the [d]efendant's health plans, and the primary physicians, medical specialists, medical laboratories, hospitals, outpatient centers, pharmacies, [and] home health agencies who contract with the [d]efendant." Id. at 1323. The district court found that a RICO enterprise existed because these associates actually constituted a "network" of inter-related health care providers, and moreover that the defendants had promoted the association as a "network" to plaintiffs, who complained of misrepresentations in their insurance coverage. See id.

Here, however, plaintiffs have not alleged an association in fact between a specific pharmaceutical company and a specific medical care provider (or a specific network of providers), that forms a continuing unit with a common purpose. Rather, they assert a series of enterprises, each consisting of hundreds or thousands of medical care providers whose only relationship to each other is that they all prescribe a covered drug with an AWP. Plaintiffs point out correspondence and other communications among the members of each of these alleged AWP enterprises,

including instructions from the pharmaceutical companies to the doctors concerning how to facilitate and conceal the alleged racketeering scheme. (See ¶¶ 161, 162, 175, 349.) Most of the mass marketing documents concern efforts by the companies to market "the spread" - between their actual prices and their reported AWP's - directly to the individual providers. (See ¶¶ 200, 213, 262, 296, 297, 303, 320, 349.) The documents as described do not allege a network among all the members of these alleged enterprises.

The complaint makes no allegation that all doctors who prescribe a pharmaceutical company's drug have associated together with each other and the drug company as an entity with a common fraudulent purpose, or that there is any common communication network, decision-making process, or organizational structure. The allegation that each provider was aware that there were likely other providers engaged in parallel schemes is insufficient to establish an association-in-fact RICO enterprise. In short, to use the Supreme Court's parlance, there was no rim to connect the spokes. At best, there were multiple and separate enterprises of like character. In sum, I conclude that plaintiffs have failed to allege facts that establish the RICO enterprise requirement through the "AWP Enterprises."

**3. Pharmacy Benefit Managers ("PBM") Enterprises  
(¶¶ 429-431)**

Next, plaintiffs allege the existence of Pharmacy Benefit

Manager Enterprises ("PBM Enterprises"), comprised of each individual drug manufacturer and all the Pharmacy Benefit Managers that exploit the "spread" between the reported AWP and the actual price of covered drugs. Sixteen different PBM enterprises are named. Each of the PBM Enterprises is said to be comprised of an individual drug company at the hub (i.e. Abbot, Amgen, etc.) and a number of unnamed pharmacy benefit managers as spokes. Again, however, the complaint fails to allege facts which would support an entity consisting of all the PBMs joined with a drug company in a common purpose.

**4. Publisher Enterprises (¶¶ 375-77, 402-404)**

The "Publisher Enterprises" present an even weaker theory. Plaintiffs allege that the Publisher Enterprises were associations-in-fact comprised of each of the defendants and the publishers that reported their AWP. There is no allegation that the publishing companies even benefitted from the "spread" scheme other than by the profits generated for publishing data provided to them. Again, plaintiffs identify each of these hub-and-spoke enterprises by the name of a pharmaceutical company (e.g. "Abbot - Publisher Enterprise," etc.) and claim that these enterprises consist of the company and each of the major publishers that reported the AWP provided to them by the company as the spokes. Twenty-one such enterprises are named. The same twin problems of

connectedness and common purpose arise with respect to these enterprises.

**5. Third-Party Payor / Victim Enterprises  
(¶¶ 351, 378, 405, 432)**

The Class Two plaintiffs allege that their employee health benefit plans are "enterprises" which were victimized when they made fraudulently inflated payments for drugs, based on defendants' falsely inflated AWP's. (¶ 359.) The third-party payor plaintiffs are the Board of Trustees of Carpenters and Millrights of Houston and Vicinity Welfare Trust Fund, Teamsters Health & Welfare Fund of Philadelphia, Twin Cities Bakery Workers Health and Welfare Fund, and United Food and Commercial Workers Unions and Employees Midwest Benefits Funds. Plaintiffs contend that these third-party payors satisfy the RICO enterprise requirement because they are "victim enterprises." This "victim enterprise" theory requires a different legal analysis.

The major purpose of RICO is to protect legitimate business enterprises from infiltration by racketeers. See Turkette, 452 U.S. at 591, 101 S.Ct. at 2532. The enterprise element may be satisfied by alleging a legitimate enterprise that was victimized by a racketeering scheme. See Aetna Cas. Sur. Co. v. P & B Autobody, 43 F.3d 1546, 1558 (1st Cir. 1994) (holding that an insurance company that was victim of racketeering activity involving company insiders satisfied enterprise requirement of RICO); United States v. Boylan, 898 F.2d 230, 243 (1st Cir. 1990)

(finding that the Boston Police Department was a victim enterprise because its affairs were interfered with through racketeering in the form of bribes), cert. denied, 498 U.S. 849, 111 S.Ct. 139 (1990).

To succeed in their RICO claim, however, plaintiffs must show not just the existence of a victim-enterprise, but that defendants "conduct[ed] or participat[ed], directly or indirectly, in the conduct of such enterprises affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

The Supreme Court has explained that "to conduct or participate, directly or indirectly, in the conduct" of an enterprise, "one must participate in the operation or management of the enterprise itself." Reves v. Ernst & Young, 507 U.S. 170, 185, 113 S.Ct. 1163, 1173 (1993). "[R]ICO liability is not limited to those with a formal position in the enterprise, but some part in directing the enterprise's affairs is required." Id. at 179, 113 S.Ct. at 1170 (footnote omitted, emphasis in original). Operation of the enterprise is not limited to its formal managers or employees because "[a]n enterprise might be 'operated' or 'managed' by others 'associated with' the enterprise who exert control over it as, for example, by bribery." Id. at 184, 133 S.Ct. at 1173. In Aetna the First Circuit found that defendants who, with the cooperation of two inside Aetna appraisers, had processed false insurance claims,

had exercised control over the victim insurance company:

[Defendants] caused the Aetna appraisers to approve false claims and conduct their appraisals in a manner contrary to Aetna's business practices and caused Aetna to pay out large sums of money on false claims. The evidence was sufficient to support a finding that [defendants] exerted control over the enterprise, if not by bribery . . . then at least by other methods of inducement.

Aetna, 43 F.3d at 1560.

Plaintiffs allege that the false inflation of AWP's caused the third-party payor victim-enterprises to pay more for prescription drugs than they otherwise would have paid. However, there is no allegation of infiltration of the third party payors, of cooperation by insiders, or of inducement of insiders, by bribery or any other covert means. The reporting of inflated AWP's to independent trade publications, which in turn resulted in the payment of inflated drug prices predicated on those prices, does not constitute "operation or management" of the third-party payor health programs within the meaning of § 1962(c). See In re Smithkline Beecham Clinical Labs., Inc., 108 F. Supp.2d 84, 100 (D. Conn. 1999) ("[A]lthough [defendant's] alleged fraudulent billing practices may have victimized the physicians' offices, hospitals, and laboratories, that does not suffice to establish that [defendant] 'operated or managed' the affairs of each of these alleged enterprises.") (emphasis in original); but see Liberty Mut. Ins. Co. v. Diamante, 138 F. Supp.2d 47, 61 (D.

Mass. 2001) ("It is not a sine qua non of liability that an employee of the innocent enterprise be a knowing participant in the racketeering activity.").

This analysis applies to the alleged third-party payor publisher enterprises as well. (Compl. ¶¶ 378, 405.) While the defendants contracted with the publishing companies and paid money to the publishing companies for their services, such transactions are inadequate to show that defendants exercised "control" over the third party payor enterprises as that term is used in the RICO statute. Moreover, in no sense could the publishing companies be considered victim enterprises as they were not harmed by the fraud.

#### **V. PREEMPTION OF STATE LAW CLAIMS**

Plaintiffs also bring state law claims under the consumer protection statutes of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, and Washington. (¶ 452.) Defendants argue that these claims are preempted by both the Medicare statute and by ERISA.

##### **A. Medicare**

The federal Medicare Act preempts the state consumer fraud causes of action "if and only if Congress intended it to do so." Mass. Med. Soc'y v. Dukakis, 815 F.2d 790, 791 (1st Cir. 1987) (Breyer, J.). Reviewing preemption doctrine, the First Circuit set forth the following framework:

Congress might show that it intends to preempt state law by explicitly withdrawing the power of states to regulate within certain fields. Or, Congress might implicitly withdraw the states' power to regulate by creating a regulatory system so pervasive and complex that it leaves 'no room' for the states to regulate. Congress might also enact a law such that 'compliance with both federal and state regulations is a physical impossibility,' in which case the state statute must yield. Finally, the Supreme Court has noted that, even in the absence of a direct conflict, a state law violates the supremacy clause when it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'

Id. (citations omitted). The guiding principle throughout the preemption analysis is Congressional intent. See Cal. Fed. Sav. & Loan Ass'n v. Guerra, 479 U.S. 272, 280, 107 S.Ct. 683, 689 (1987).

Defendants acknowledge that the Medicare statute does not explicitly preempt the state consumer protection statutes. See, e.g., Mass. Ass'n. of Health Maint. Org. v. Ruthhardt, 194 F.3d 176, 179 (1st Cir. 1999) (involving an express preemption provision). Nonetheless, defendants argue that the Medicare system is so extensive and complex that it preempts the entire field of consumer protection laws as they relate to billing for medical treatment related to Medicare. Defendants further contend that allowing state consumer fraud claims to go forward would stand as an obstacle to the accomplishment of the Medicare system envisioned by Congress.

When Congress legislates in a field which the States have traditionally occupied, like medical fee regulation, "courts must presume that Congress has not preempted state power to act unless that was Congress's 'clear and manifest purpose.'" Mass. Med. Soc'y, 815 F.2d at 791 (citing Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, 67 S.Ct. 1146, 1152 (1947)); see also generally Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 719, 105 S.Ct. 2371, 2378 (1985) ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern.").

The issue in Mass. Med. Soc'y was whether the Medicare Act preempted a state law that banned health providers from charging patients for the balance of their fee not covered by Medicare. The First Circuit rejected a Supremacy Clause challenge even though there was evidence that Congress intended to permit the practice of balance billing. The language is helpful:

To prevail, MMS must show that Congress intended to create an "option" in the strong sense of that word: that Congress intended to create a legal *right* to balance bill, a right immune from significant state interference. MMS cannot win by showing only that Congress failed to disturb a preexisting legal status quo that happened to permit doctors to balance bill. We cannot infer from Congress's simple failure to disturb an existing practice that Congress meant to grant that practice the status of a right, immune from state regulation.

Mass. Med. Soc'y, 815 F.2d at 792. Other circuits have agreed.

See Penn. Med. Soc'y v. Marconis, 942 F.2d 842, 849 (3d Cir. 1991) (holding that the Medicare Act did not preempt state legislation regulating billing practices); Med. Soc'y of the State of N.Y. v. Cuomo, 976 F.2d 812, 816 (2d Cir. 1992) (holding that "regulation of public health and the cost of medical care are virtual paradigms of matters traditionally within the police powers of the state."). See also Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 256, 104 S.Ct. 615, 626 (1984) (finding no preemption of state tort suit for damages stemming from leakage of nuclear power plant, despite exclusive federal regulation of nuclear safety).

Here, the fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their AWP's cannot be read as a clear and manifest intention to grant immunity from state regulation of such fraudulent practices. Because there is no evidence of a clear and manifest intent to preempt the entire field of state regulation of fraudulent medical billing practices, claims based on state consumer protection statutes that allege such practices are not preempted. Cf. Hofler v. Aetna US Healthcare of California, Inc., 296 F.3d 764, 768 (9th Cir. 2002) ("Because Congress did not clearly manifest any intention to convert all state tort claims arising from the administration of Medicare benefits into federal questions, we hold that the Medicare

program does not completely preempt state tort law claims." ).  
Further, the Medicare statute supports plaintiffs' position that  
there was no legislative intent to preempt supervision of the  
compensation of a person providing health services. See 42  
U.S.C. § 1395.<sup>10</sup>

Defendants also argue that the state law claims conflict  
with or are an obstacle to the Medicare program, and thus must be  
preempted. "A conflict exists when it is impossible to comply  
with both state and federal law, or if the state law is an  
obstacle to the accomplishment of the full purposes and  
objectives of Congress in enacting the federal legislation."  
Penn. Med. Soc'y, 942 F.2d at 848 (citing Schneidewind v. ANR  
Pipeline Co., 485 U.S. at 300, 108 S.Ct. at 1150-51).

The maintenance of these consumer protection claims against  
defendants will not actually conflict with the operation of the  
federal program. Compare Cox v. Shalala, 112 F.3d 151, 154 (4th

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<sup>10</sup> The opening provision of the Act states that:

Nothing in this subchapter shall be construed  
to authorize any Federal officer or employee  
to exercise any supervision or control over  
the practice of medicine or the manner in  
which medical services are provided, or over  
the selection, tenure, or compensation of any  
officer or employee of any institution,  
agency, or person providing health services;  
or to exercise any supervision or control  
over the administration or operation of any  
such institution, agency, or person.

42 U.S.C. § 1395.

Cir. 1997) (holding that North Carolina's Wrongful Death Act conflicted with the Medicare Act to the extent that it capped the amount of money that Medicare could recover for medical expenses it paid in connection with the provision of medical services to a Medicare beneficiary who died as a result of malpractice; because the Medicare statute entitled the program to complete compensation, the state law presented an actual conflict and was therefore preempted). Neither will the action require state courts to construe complex federal regulations. Compare Congress of Cal. Seniors v. Catholic Healthcare West, 87 Cal. App. 4th 491, 508, 104 Cal. Rptr.2d 665, 667 (2001) (holding that extensive and complex federal law governing cost reporting by hospitals precluded a claim that hospital's including certain anti-union expenses in annual Medicare cost reports constituted an unfair business practice under state law).

Defendants protest that to allow state consumer fraud claims in this context will permit state courts, one-by-one, to construe the meaning of "national average wholesale prices" as it is used in the statute, and that that will defeat the goal of uniform application of federal laws. To be sure, the need for uniformity in enforcement is an important goal which should be considered in determining preemption. As the Supreme Court has pointed out in a different context, complying with a federal "regulatory regime in the shadow of 50 states' tort regimes will dramatically

increase the burdens facing regulated entities." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349-350, 121 S.Ct. 1012, 1018 (2001).

However, state courts frequently construe terms in federal laws in order to adjudicate causes of action based in state law, and the Supreme Court has pointed out that it is the ultimate decision-maker on federal questions arising out of state court. See Merrell Dow Pharms., Inc. v. Thompson, 478 U.S. 804, 810, 106 S.Ct. 3229, 3233 (1986) (recognizing that state court will be required to construe federal law to determine viability of state negligence claim, and that uniformity might be compromised, but holding that remand was nonetheless required because of lack of jurisdiction); see also J.A. Jones Constr. Co. v. City of New York, 753 F.Supp. 497, 505 (S.D.N.Y. 1990) ("A state court will have to determine the scope of the EPA Procurement Regulations in order to decide this [contract] case, but there is no doubt that that court will fulfill its 'constitutional obligation . . . to uphold federal law.'").

The circuit courts have routinely held that state prohibitions on balance billing did not conflict with or create an obstacle to the accomplishment of the federal Medicare program. See, e.g., Mass. Med. Soc'y, 815 F.2d at 796 ("We . . . conclude that the Massachusetts balance billing ban does not pose a significant 'obstacle,' constitutionally speaking, to any

congressional 'purpose' or 'objective' in the Medicare Act." ). They so held despite the fact that their decision meant that different state laws might produce significant differences across states in terms of how much doctors could be compensated for their treatment of Medicare-covered patients. See id. at 794-95 (noting that states would be unlikely to provide supplemental regulation that would harm their own citizens' ability to participate in the Medicare program).

Defendants argue that preemption is required by the Supreme Court's holding in Buckman. In that case, plaintiffs brought a state fraud-on-the-agency tort claim against a consulting firm that made fraudulent statements to the FDA to obtain regulatory approval for the marketing of a medical device that injured plaintiffs. The Court held that "plaintiff's state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." Buckman, 531 U.S. at 348, 121 S.Ct. at 1017. Allowing the state-law based "fraud-on-the-FDA" theory to go forward, the Court held, would unduly interfere with the FDA's "statutorily required judgment" concerning the approval of devices and would "inevitably conflict with the FDA's responsibility to police fraud consistent with the Administration's judgment and objectives." Id. at 349-350, 121 S.Ct. 1017-1018. Unlike the FDA in Buckman, CMS does not make a discretionary judgment with respect to the statutorily defined

Medicare Part B reimbursement rates, and does not approve the AWP's. Therefore, the decision of the pharmaceutical companies, not an agency action, is alleged to cause plaintiffs' harm. Cf. Green v. Fund Asset Mgmt., L.P., 245 F.3d 214, 223 n. 7 (3rd Cir. 2001) (holding plaintiffs' claims not preempted because, "[u]nlike the plaintiffs in Buckman, the plaintiffs in the case at bar allege not fraud against a federal agency, but rather violations of state and federal securities laws"); see also Caraker v. Sandoz Pharms. Corp., 172 F.Supp.2d 1018, 1039 n. 17 (S.D. Ill. 2001) ("Courts have generally read Buckman's specific holding rather narrowly.") (citing Green).

Accordingly, I find that the Medicare statute does not preempt the state causes of action.

#### **B. ERISA Preemption**

Class Two, the third-party payor class, is comprised of employee health benefit plans that assert state law claims against the defendant pharmaceutical companies. Defendants argue that the state claims are preempted by ERISA under the Supremacy Clause. U.S. Const. art. VI.

ERISA is a comprehensive statutory scheme that governs private employee benefit plans, including both pension and welfare plans. Section 514(a) of the statute, ERISA's general preemption provision, states that ERISA "shall supersede any and all state laws insofar as they . . . relate to any employee

benefit plan" covered by the statute, 29 U.S.C. § 1144(a), although preemption stops short of "any law of any state which regulates insurance." § 514(b)(2)(A), 29 U.S.C. § 1144(b)(2)(A). "When state-law claims 'relate to' ERISA plans, those claims are transmuted into ERISA claims." Carpenters Local Union No. 26 v. United States Fid. & Guar. Co., 215 F.3d 136, 139 (1st Cir. 2000) (citing 29 U.S.C. §1144(a)).

A law relates to a covered employee benefit plan for purposes of §514(a) "if it has a connection with or a reference to such a plan." Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 97, 103 S.Ct. 2890, 2900 (1983); Cal. Div. of Labor Standards Enforcement v. Dillingham Constr. N.A., Inc., 519 U.S. 316, 324, 117 S.Ct. 832, 837 (1997). Preemption does not occur, however, "if the state law has only a tenuous, remote, or peripheral connection with covered plans, as is the case with many laws of general applicability." New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 661, 115 S.Ct. 1671, 1680 (1995) (citing District of Columbia v. Greater Washington Bd. of Trade, 506 U.S. 125, 130 n. 1, 113 S.Ct. 580, 583 n. 1 (1992)). The "starting presumption" is "that Congress does not intend to supplant state law." Id. at 654, 115 S.Ct. at 1676.

In Carpenters, the First Circuit analyzed the scope of ERISA preemption under § 514(a) in the context of a suit brought by an

ERISA plan against a third party. Holding that ERISA did not preempt the trustees of an ERISA plan from bringing a claim against a surety for payments owed the fund under a state statute generally authorizing such suits, the Carpenters Court reasoned:

ERISA preemption proscribes the type of alternative enforcement mechanism that purposes to provide a remedy for the violation of a right expressly guaranteed and exclusively enforced by the ERISA statute. Those state laws which touch upon enforcement but have no real bearing on the intricate web of relationships among the principal players in the ERISA scenario (e.g., the plan, the administrators, the fiduciaries, the beneficiaries, and the employer) are not subject to preemption on this basis. . . . The Massachusetts bond statute does not constitute a proscribed alternate enforcement mechanism. By the same token, it has no other meaningful nexus with ERISA; it does not, for example, interfere with the administration of covered employee benefit plans, purport to regulate plan benefits, or impose additional reporting requirements. Last -- but far from least -- it regulates an area of the law traditionally thought to be the states' preserve: enforcing contracts under state law for the citizenry's protection.

215 F.3d at 141 (citations omitted).

Other circuits have also held that an ERISA plan may bring a claim as plaintiff against a third party, where the cause of action is based on statutory or common law of general applicability. See LeBlanc v. Cahill, 153 F.3d 134, 138 (4th Cir. 1998) (holding that ERISA does not preempt "a state common law cause of action for fraud, pressed by a pension plan subject

to ERISA, against a third party who is neither a fiduciary nor a party in interest with respect to the plan . . . ."); Airparts Co., Inc. v. Custom Benefit Servs. of Austin, 28 F.3d 1062, 1065 (10th Cir. 1994) (holding that ERISA plan trustees' common law fraud claims against consultant to plan was not preempted: "[I]f there is no effect on the relations among the principal ERISA entities - the employer, the plan, the plan fiduciaries, and the beneficiaries - there is no preemption. . . . [A]ctions that affect the relations between one or more of these plan entities and an outside party similarly escape preemption."); Operating Eng'rs Health and Welfare Trust Fund v. JWJ Contracting Co., 135 F.3d 671, 678-79 (9th Cir. 1998) (holding that ERISA plan trustees are not preempted from bringing a claim under state statute authorizing action against surety who failed to pay money owed to plan); Trs. for Michigan Laborers' Health Care Fund v. Seaboard Sur. Co., 137 F.3d 427, 429 (6th Cir. 1998) (holding that a claim brought by ERISA plan trustees' under state law against employer's surety was not preempted); Geller v. County Line Auto Sales, Inc., 86 F.3d 18, 22-23 (2d Cir. 1996) (finding no preemption for ERISA plan trustees' common law fraud claim against employer, a non-fiduciary of the plan, who misreported a non-employee as eligible for plan coverage); Trs. of the AFTRA Health Fund v. Biondi, 303 F.3d 765, 781 (7th Cir. 2002) (holding that ERISA plan trustees' common law fraud action against

participant who misrepresented marital status in order to maintain ex-wife's health coverage was not preempted).

The issue in the case at bar is whether a fraud claim, pressed by an ERISA plan against a third party pharmaceutical company under state consumer protection statutes involving payments the plan made to its pharmacy benefit manager, is preempted. According to the complaint, health plans typically contract with PBMs so that the plan's participants can obtain brand name drugs from the PBMs. In these contracts, the drugs are typically priced at the AWP less a percentage discount. Under the above case law, the plaintiffs' claim is not preempted. Plaintiffs here do not seek an alternative state-law mechanism for the enforcement of their rights with respect to the terms of their ERISA plans. Nor does this dispute require the Court to determine whether plan fiduciaries behaved fraudulently with respect to the plans. The consumer protection statutes at issue here are laws of general application and do not single out ERISA plans by reference or for special treatment.

Defendants argue that the state law claims are preempted because the Court will have to evaluate and interpret the terms of the ERISA plans to determine defendant's liability under the state law claims, as well as the amount of damages. Only by referring to these plans, they argue, can the Court determine whether reimbursement for prescription drugs for a particular

employer was based on AWP and the amount of reimbursement that was required. A state law claim is preempted when "the Court's inquiry must be directed to the plan" to resolve the claim. Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 139-40, 111 S.Ct. 478, 485 (1990); Hampers v. W.R. Grace & Co., Inc., 202 F.3d 44, 52 (1st Cir. 2000) (holding that "a cause of action 'relates to' an ERISA plan when a court must evaluate or interpret the terms of the ERISA-regulated plan to determine liability under a state law cause of action.")

Plaintiffs argue that the Court need not evaluate or interpret the terms of the ERISA plans to determine liability, and that the Court need only interpret the terms of the contract between the plan and the PBM. The complaint seeks damages for the spread between the drug price charged by the PBM and the fair AWP, and does not appear to be asking for amounts that can only be reimbursed by interpreting the plan documents. While there may be some damage theories that are preempted (for example, whether the plans cover co-payments), the Court need not determine that issue at this early stage of the proceedings.

Because the consumer protection statutes do not have a sufficient "connection to" the employee benefit plans and do not refer to ERISA plans, there is no ERISA preemption.

## VI. MISCELLANEOUS

### A. Filed Rate Doctrine

Two defendants argue that the complaint must be dismissed under the filed rate doctrine, which limits attacks outside the regulatory process on rates filed with federal regulatory agencies. See Town of Norwood v. New England Power Co., 202 F.3d 408, 415 (1st Cir. 2000). "It is the filing of the tariffs, and not any affirmative approval or scrutiny by the agency, that triggers the filed rate doctrine." Id. at 419 (emphasis in original); see also Square D Co. v. Niagara Frontier Tariff Bureau, Inc., 476 U.S. 409, 417, 106 S.Ct. 1922, 1927 (1986) (upholding the "stringent rule" of the filed rate doctrine pertaining to rates that had not been vetted at a formal hearing because they had been "duly submitted" and "filed" under the terms of the Interstate Commerce Act); Fla. Mun. Power Agency v. Fla. Power & Light Co., 64 F.3d 614, 616 (11th Cir. 1995) (noting that the Supreme Court "has emphasized the limited scope of the filed rate doctrine to preclude damage claims only where there are validly filed rates.").

Pharmaceutical companies do not "file" their AWP's with any federal regulatory agency. Rather, the pharmaceutical companies publish their wholesale pricing information in independent, publicly available trade publications that are used by the government and others to implement the statutorily defined

reimbursement rates. The "filed rate" doctrine is thus inapplicable here.

**B. Government Action Doctrine**

Borrowing from antitrust caselaw, two defendants argue that plaintiffs' claims that they were injured must be dismissed under the so-called "government action" doctrine. Under that doctrine, the courts have barred plaintiffs from collecting damages that resulted from government action, such as legislation, that was induced by the organized effort of defendants. See Sandy River Nursing Care v. Aetna Cas., 985 F.2d 1138, 1147 (1st Cir. 1993) (holding that plaintiffs were barred from recovering damages that resulted from legislation raising workers compensation insurance rates, which plaintiffs claimed were passed in response to an illegal economic boycott and price-fixing by defendants); see also Eastern R.R. Presidents Conference v. Noerr Motor Freight Inc., 365 U.S. 127, 145, 81 S.Ct. 523, 533 (1961) (holding that trucking industry plaintiffs were barred from recovering damages from railroad industry defendants who had orchestrated widespread anti-trucking campaign resulting in anti-trucking legislation).

This doctrine is inapplicable to the case at bar because plaintiffs do not claim that the harm they suffer stems from the AWP system as Congress has established it, but rather from the

defendants' fraudulent statements about their average wholesale prices.

### **C. Standing**

Several, but not all, of the individual defendant motions raise standing issues. Defendants do not dispute that all of the individual named plaintiffs have standing because each plaintiff claims to have purchased at least one covered drug. However, several pharmaceutical companies correctly argue that the individually named plaintiffs do not have standing to bring suit against them because no plaintiff claims to have purchased their drug. See Allen v. Wright, 468 U.S. 737, 751, 104 S.Ct. 3315, 3324 ("The requirement of standing . . . has a core component derived directly from the Constitution. A plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief.").

Plaintiffs contend that a named plaintiff who has purchased one drug from one of the defendants can serve as a class representative, pursuant to Fed. R. Civ. P. 23, in a class of all persons who made purchases of covered drugs from any defendant, even those companies against which no named plaintiff claims to have made a purchase. However, under long standing caselaw, "[a] named plaintiff cannot acquire standing to sue by bringing his action on behalf of others who suffered injury which would have

afforded them standing had they been named plaintiffs . . . .  
Standing cannot be acquired through the backdoor of a class  
action." Allee v. Medrano, 416 U.S. 802, 828-29, 94 S.Ct. 2191,  
2207 (1974); see also O'Shea v. Littleton, 414 U.S. 488, 494, 94  
S.Ct. 669, 675 (1974) (same).

Some courts have carved out an exception to the standing  
requirement in cases in which all defendants are juridically  
related in a manner that suggests that a single resolution of the  
dispute would be expeditious. See La Mar v. H&B Novelty & Loan  
Co., 489 F.2d 461, 466 (9th Cir. 1973) (discussing juridical  
linkage doctrine). "Post-La Mar cases from other courts have  
suggested that if all the defendants took part in a similar  
scheme that was sustained either by a contract or conspiracy, or  
was mandated by a uniform state rule, it is appropriate to join  
as defendants even parties with whom the named class  
representative did not have direct contact." Payton v. County of  
Kane, 308 F.3d 673, 679 (7th Cir. 2002) (collecting cases); cf.  
Alves v. Harvard Pilgrim Health Care, Inc., 204 F.Supp.2d 198,  
205 (holding that named plaintiff who had a claim against one  
ERISA plan could represent class of plaintiffs against other  
ERISA plans that he did not have a claim against, where the plans  
were all administered by the same employer and the gravamen of  
the challenge was to general practices of the employer that  
affected the plans). "[A] common commercial practice," however,

is not enough to establish juridical linkage. La Mar, 489 F.2d at 470.

Defendants argue that in the present case there is no allegation of corporate, contractual, conspiratorial, or other legal connection to establish juridical linkage between all the defendants. I agree that the allegations in the complaint are insufficient to support a claim of standing under the doctrine of juridical linkage with respect to defendants from which no plaintiff has purchased a drug. Indeed, the primary thrust of plaintiffs' theory is that the companies competed with one another by offering inflated AWP's. The doctrine of juridical linkage is not indefinitely elastic so as to permit an industry-wide challenge on the basis of the conduct of select companies.

For present purposes, however, I decline defendants' invitation to determine whether a plaintiff who purchased one drug from a given company has standing to represent a class of others who purchased a different drug or drugs from the same company. Those allegations fit better into the juridical linkage claim, and the issue will be decided at a later stage in the litigation. See Ortiz v. Fibreboard Corp., 527 U.S. 815, 831, 119 S.Ct. 2295, 2307 (1999) ("[C]lass certification issues are . . . 'logically antecedent' to Article III concerns . . . . Thus the issue about Rule 23 certification should be treated first, 'mindful that [the Rule's] requirements must be interpreted in

keeping with Article III constraints . . . .") (citations omitted).

Finally, defendants also assert that none of the association plaintiffs has alleged sufficient facts to establish standing under Article III. See United States v. AVX Corp., 962 F.2d 108, 116 (1st Cir. 1992) (holding that an association must establish that "at least one of [its] members possesses standing to sue in his or her own right."); Guckenburger v. Boston Univ., 957 F. Supp. 306, 320-21 (D. Mass. 1997) (same). None of the associations alleges specific members who purchased a specific drug from a specific company. Instead, the allegations in the complaint and accompanying affidavits contain only bare bones assertions and empirically non-verifiable conclusions unsupported by specific facts concerning any injury-in-fact on the part of one of its members. See AVX Corp., 962 F.2d at 117 (holding that association did not have standing to press suit on behalf of its members where "the members are unidentified; their places of abode are not stated; the extent and frequency of . . . [their injury] is left open to surmise. In short, the asserted injury is not anchored in any relevant particulars."). Thus, all the associations are **DISMISSED** as party plaintiffs.

**D. Fed. R. Civ. P. 8 and 9(b)**

Defendants argue that the complaint fails to meet either the heightened pleading standards for fraud set forth in Fed. R. Civ.

P. 9(b) or even the notice pleading standards of Fed. R. Civ. P. 8, because it makes fraud claims based on some Medicare covered drugs, brand name drugs and generic multi-source drugs without identifying the drug and specifying the fraudulent published AWP.

The Court **DENIES** defendants' motion to dismiss with respect to any drug identified in the complaint together with the allegedly fraudulent AWP published by a named defendant for that drug. However, to the extent the complaint seeks to encompass all "brand name drugs" (§§ 166, 333), named drugs without a specific fraudulent AWP, or generic multi-source drugs<sup>11</sup>, the motion to dismiss is **ALLOWED**. In the event any such amendment is filed, plaintiffs shall 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.

#### **E. Fraudulent Concealment**

Defendants argue that plaintiffs failed to allege fraudulent concealment with specificity. See J. Giels Band Empl. Ben. Plan v. Smith Barney Shearson, Inc., 76 F.3d 1245, 1255 (1st Cir. 1996) (holding that plaintiffs have the burden under Rule 9(b) to

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<sup>11</sup> In their sur-reply (Docket No. 33), plaintiffs provide particular allegations with respect to generic multi-source drugs. However, these allegations are not in the complaint, and as defendants point out, multiple source drugs do not fit the paradigm described in the complaint.

plead with particularity the facts giving rise to fraudulent concealment). As that issue only affects the amount of damages, I do not address it now.

**F. Multi-Source/Generic Drugs**

I allow the motion to dismiss all multi-source generic drugs from the complaint, because plaintiffs have not framed their claims to include such drugs. However, it is unclear from the complaint and briefing which drugs are in fact multi-source or generic, and therefore which claims or defendants are affected by this ruling. If plaintiffs wish to encompass a theory that captures multi-source generic drugs, they should move to amend.

**G. Detritus**

I decline to address the other arguments for dismissal either because they are without merit or because a ruling has been rendered unnecessary in light of the above conclusions of law.

**ORDER**

For the foregoing reasons, I order as follows:

1. The omnibus motion to dismiss is **ALLOWED** with respect to the RICO claims (Counts I, II, III, and IV), **DENIED** with respect to the claims for declaratory and other relief pursuant to 28 U.S.C. §§ 2201, 2002 (Counts VI and VII), and **DENIED** with respect to claims brought under the state consumer protection statutes (Count V). The Court **ALLOWS** the motion to dismiss with respect

to any drugs that the complaint fails to identify both with respect to name of the drug and the allegedly fraudulent published AWP for the drug. (Docket Nos. 215, 185, 188, 203, 205, 211.)

2. The motions to strike certain paragraphs from the complaint (Docket No. 184) are **DENIED**.

3. The motion for a more definite statement (Docket No. 185) is **DENIED**.

4. I dismiss all associations as plaintiffs.

5. I dismiss Abbott, Baxter, Boehringer, BMS, Braun, Smithkline, Immunex, Johnson & Johnson, Pharmacia, Schering-Plough, and Warrick with respect to the Class One claims only.

6. I dismiss Amgen, Bayer, Hoffmann LaRoche, Merck, Pfizer, Sicor, and Johnson and Johnson with respect to both the Class One and Class Two claims.

7. The dismissals are without prejudice to a motion to amend to cure any defects.

8. The dismissals in this Order will go into effect in 30 days unless a motion to amend is filed.

9. Discovery shall begin forthwith on the pending non-dismissed claims.

10. A scheduling conference shall be held for all non-dismissed claims at 3 p.m. on June 18, 2003.

A handwritten signature in cursive script that reads "Patti B Saris". The signature is written in black ink and is positioned above a horizontal line.

PATTI B. SARIS  
United States District Judge