



UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____))
IN RE PHARMACEUTICAL INDUSTRY) M.D.L. No. 1456
AVERAGE WHOLESALE PRICE) Civil Action No. 01-12257-PBS
LITIGATION))
_____)

MEMORANDUM AND ORDER

February 24, 2004

Saris, U.S.D.J.

I. INTRODUCTION

In this massive proposed class action, Plaintiffs allege that forty-two pharmaceutical companies fraudulently overstate the published "average wholesale prices" ("AWP") of many of their prescription drugs, which results in inflated payments for such drugs by consumers and beneficiaries of the federal Medicare Part B program (through co-payments), private health and welfare plans, health insurers, self-insured employers and other end-payers for prescription drugs.¹ They have identified 321 drugs

¹ The Amended Complaint names eleven plaintiffs, including five ERISA-qualified employee benefit plans, a voluntary employee benefit plan and five associations. It names the following companies as defendants (corporate groupings are separated by semicolon): Abbott 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



with allegedly inflated prices.

On May 13, 2003, the Court allowed in part a motion to dismiss the original master consolidated complaint. See In re Pharm. Indust. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 178-80 (D. Mass. 2003) (Saris, J.) (Pharm. I). The Court assumes close familiarity with that opinion, which sets forth the factual background of the allegations as well as the appropriate legal standards. In response to that opinion, Plaintiffs have filed a 297-page amended master consolidated complaint ("AMCC"), which asserts violations of the federal racketeering statute, eleven consumer fraud statutes and the antitrust laws.² Again,

Group," which includes Boehringer Ingelheim Corp., Ben Venue Laboratories Inc. and Bedford Laboratories; B. Braun of America, 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 includes GlaxoSmithKline, P.L.C., SmithKline Beecham Corp., and Glaxo Wellcome, Inc.; Hoffman-LaRoche, Inc.; Immunex Corp.; "The Johnson and Johnson Group," which includes Johnson & Johnson, Centocor, Inc., Janssen Phamarceutical Products, L.P., McNeil-PPC, Inc., and Ortho Biotech; Novartis Pharmaceuticals Corp.; 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.; TAP Pharmaceutical Products, Inc.; and Watson Pharamaceuticals, Inc.

² The Amended Master Consolidated Complaint (the "AMCC") pleads causes of action under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1962(c), (d); Section 16 of the Clayton Act, 15 U.S.C. § 26; the Sherman Act, 15 U.S.C. § 1; the antitrust statutes of 22 states; state consumer protection statutes of 11 states; and civil conspiracy



the Defendant pharmaceutical manufacturer companies move to dismiss.

After hearing, the Court ALLOWS IN PART and DENIES IN PART the motion to dismiss the claims that the pharmaceutical companies violated the Racketeer Influenced and Corrupt Organizations Act ("RICO") and antitrust law. Among other things, the Court holds that Plaintiffs have set forth sufficient facts to state claims concerning: (1) the alleged RICO enterprises between the pharmaceutical manufacturers and four pharmacy benefit managers ("PBM's") with the common objective of promoting fraudulent AWP's; (2) the alleged price-fixing conspiracy of the Together Card Program Defendants in violation

law. The AMCC also seeks declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. Plaintiffs bring this action on behalf of themselves and two classes:

[1] The AWP Payor Class:

All persons or entities who, for purposes other than resale and during the Class Period, paid any portion of the purchase for a prescription drug manufactured by a Defendant Drug Manufacturer (as identified in Appendix A) at a price calculated by reference to the published AWP during the Class Period.

[2] Sub-Class: The PBM Third-Party Payor Class:

All Third-Party Payors that, during the Class Period, contracted with a PBM to provide to its participants a prescription drug manufactured by a Defendant Drug Manufacturer and identified in Appendix A.

(¶ 595.)



of the antitrust laws; and (3) RICO claims involving multi-source drugs.

II. DISCUSSION

Plaintiffs allege three primary paradigms that accomplish this fraud. First, Plaintiffs allege that each Defendant artificially raises its published AWP's to benefit medical providers (like doctors). The "spread" between the actual cost of the drug and the AWP encourages providers to use that Defendant's drugs at the expense of the beneficiaries of Medicare Part B who make co-payments.³ Second, Plaintiffs allege that each Defendant increases AWP's and provides other fraudulent kickbacks, discounts and rebates to encourage pharmacy benefit managers to put its drugs on their formularies. Third, Plaintiffs allege that certain Defendant manufacturers participate in an antitrust and RICO conspiracy through a discount drug program, the Together Rx Program. The Defendants use this program to "raise, fix, maintain and/or stabilize the AWP of the Together Card Drugs," thereby raising the prices paid by the elderly, uninsured participants as well as by non-participants who also pay for those drugs based on AWP.

A. RICO

³ The Defendants do not address separately this paradigm, but they make arguments under Rule 9(b) in the context of the second paradigm that are applicable to both the first and second paradigms.



Plaintiffs allege that Defendants engaged in a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c) by establishing the fraudulent AWP pricing scheme through the use of interstate mails and wire communications. 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."⁴ See Libertad v. Welch, 53 F.3d 428, 441 (1st Cir. 1995). While pleadings are to be construed liberally, "a greater degree of specificity is required in RICO cases." Bessette v. Avco Fin. Servs., Inc., 130 F.3d 439, 443 (1st Cir. 2000).

Defendants argue that the RICO claims must be dismissed for five reasons: (1) Plaintiffs do not plead a viable enterprise; (2) Defendants did not conduct or participate in the conduct of any enterprise; (3) Defendants' actions were not the proximate cause of the Plaintiffs' injuries; (4) Plaintiffs failed to allege facts sufficient to satisfy Federal Rule of Civil Procedure 9(b); and (5) Plaintiffs' multi-source drug allegations

⁴ 18 U.S.C. § 1962(c) (2000) 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



do not make sense.

1. Enterprises

Plaintiffs allege two types of enterprises. The first type is the Manufacturer-Publisher enterprise between each drug manufacturer and each of the publishers printing the AWP data. The second type is the Manufacturer-Pharmacy Benefit Manager enterprise between each drug manufacturer and each PBM. Each type of enterprise will be discussed separately.

(a) The Manufacturer - Publisher Enterprises (Count I ¶¶ 624 - 628)

In Count I, Plaintiffs claim that the Defendant drug manufacturers engaged in an illegal pattern of racketeering activity wherein each manufacturer formed a separate association-in-fact enterprise with each of the companies that published the AWP's, and that each manufacturer conducted the affairs of its enterprises. The complaint identifies Thomson Medical Enterprise, First DataBank, Inc. and Facts & Comparisons, Inc. as the publishers. (¶ 622.) For example, Plaintiffs allege an enterprise between Abbott and Thomson Medical, which "is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWP's", (b) "selling, purchasing, and administering" [drugs with AWP's to plaintiffs]



and (c) "deriving profits from these activities." (¶ 628(a).)

Defendants argue that these allegations do not suffice to plead an association-in-fact enterprise under the tests established by the First Circuit. See Pharm. I, 263 F. Supp. 2d at 182. 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; (2) whether there is systematic linkage, such as overlapping leadership, structured or financial ties or continuing coordination; (3) whether there is a common communication network for sharing information on a regular basis; (4) whether the associates hold meetings and sessions where important discussions take place; (5) whether the associates wear common colors, signs or insignia to make the group identifiable; and (6) whether the group conducted common training and instruction. See id.

According to the AMCC, each manufacturer-publisher enterprise "has a systematic linkage because there are contractual relationships, financial ties, and continuing coordination of activities" between the participants and a "common communication network" through which the participants "share information on a regular basis." (See, e.g., ¶ 628.) The primary communication between the participants in each alleged enterprise is the sending of the allegedly fraudulent AWP's by



the manufacturer to the publisher for publication. (§ 625.) The AMCC alleges that the publishers know of the fraudulent nature of the reported AWP's (§ 626), but they publish the information anyway. The AMCC alleges that "each one of the Publishers was aware of the Defendant Drug Manufacturers' AWP scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme." (§ 212.) Finally, according to the AMCC, "[e]ach of the enterprises has the common purpose of perpetuating use of the AWP's": the manufacturers wish to push the spread to increase their market share, and the publishers have an economic incentive to publish without question the prices reported "because if they did not, the manufacturers could easily revert to the other methods of publishing prices or the publishers would have to independently investigate the AWP at significant expense." (§ 624.)

These allegations of an association-in-fact enterprise fall short in two ways. An enterprise must be "a group of persons associated together for a common purpose of engaging in a course of conduct." United States v. Tourette, 452 U.S. 576, 580 (1981). 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.

Further, Plaintiffs do not cite sufficient facts to support the allegation that the publishers know of the fraudulent nature of the AWP's they publish. Plaintiffs rely on surveys by unnamed publishers undertaken prior to 1992 regarding unnamed drugs, but the allegations in the complaint relate to behavior beginning in 1991. They also point to reports on AWP inflation by Congressional bodies and government agencies, and a recent lawsuit brought by Defendant Dey seeking to force publishers to publish the AWP it reports rather than the true price of its drugs, after publishers lowered its AWP's following a Texas prosecution of Dey for AWP fraud. While some of these factors may support an inference that some publishers may have been aware of concerns by governmental entities about inflated AWP's, they are insufficient to draw a reasonable inference that each of the publishers knew of the fraudulent nature of the AWP's for the identified drugs.

Plaintiffs further insist that "each of the manufacturer-publisher enterprises has a common purpose of perpetuating the use of AWP's as a benchmark for reimbursement in the pharmaceutical industry" (§ 624), thus skirting the issue of whether the publishers knew of the fraud. It is true that the use of AWP as a pricing benchmark may be a common objective, and the members of an enterprise do not have to share all objectives



so long as they have one in common. See, e.g., United States v. London, 66 F.3d 1227, 1244 (1st Cir. 1995) (holding that there was a common or shared purpose animating the enterprise, a bar, check-cashing business and an individual engaged in gambling: profiting from the bookmakers who were engaged in illegal gambling). However, without a shared illegal purpose to defraud, the shared innocent objective of using AWP as a published benchmark would not support a claim of a RICO enterprise. See Blue Cross v. Smithkline Beecham Clinical Labs., Inc., 62 F. Supp. 2d 544, 549 (D. Conn. 1998) (dismissing RICO complaint for insufficient allegations of a common purpose to defraud).

Second, even if the common "reaping-a-profit" objective were to suffice, the AMCC contains only conclusory allegations concerning systematic linkages and ascertainable structures. Essentially, Plaintiffs have merely parroted language from Pharm. I dismissing a similar claim in the initial master complaint. The only systematic linkage or structured or financial ties described with some detail in the AMCC are the contracts for the publishing of the AWP's; there are no allegations of a common command structure or any considered response to evolving conditions. Allegations of a common communication network beyond the sending of AWP information to be published are barebones: there are no common communications alleged beyond those that would be exchanged by parties to an arms-length contract. The



Plaintiffs do not attempt to allege the remaining factors (meetings, joint training, etc.) relevant to a determination of whether an association-in-fact existed. The publishers' printing of fraudulent AWP's under a contract with the manufacturers does not constitute an enterprise.

(b) The Manufacturer - PBM Enterprises
(Count II ¶¶ 651 - 661)

In Count II, Plaintiffs allege multiple associations-in-fact, each consisting of: (1) a PBM that, acting as a middleman between drug manufacturers and end-payors, administered purchases of a defendant manufacturer's drugs and billed end-payors based on the reported AWP and (2) a defendant drug manufacturer. (¶ 651.) The four named PBM's are: Advance PCS, serving 75 million health plan members; Caremark Rx, Inc., with \$5.6 billion in revenues in 2001; Express Scripts, Inc., the third-largest PBM in America; and Medco Health Solutions, Inc., a wholly-owned subsidiary of Merck. (¶ 650.) For example, the AMCC alleges an Abbott-Caremark Rx Enterprise. (¶ 661(a).)

According to Plaintiffs, PBM's, with the knowing assistance of the manufacturers, have engaged in hidden profit-making schemes falling into three general categories: (1) garnering rebates and other "soft dollars from drug manufacturers that the PBM's, to a large extent, keep without disclosing to the health plans the true amounts of the rebates"; (2) pocketing "secret



spreads" between actual drug costs and the prices charged to health plans and their members; and (3) keeping "secret discounts" provided by the drug manufacturers in association with the PBM's mail-order operations. (§ 654.)

The paradigms here are somewhat different from the paradigm in the Medicare Part B context, discussed in Pharm. I. First, the AMCC alleges that the PBM benefits because it pockets the spreads between the published AWP's for brand-name drugs, which it uses to calculate the rates it charges to end-payors (e.g., AWP minus 13 percent), and the actual prices which it pays the retail pharmacies (e.g., AWP minus 15 percent). (See § 171.) Second, there is a "spread" in PBM mail-order operations in which the PBM acts as a pharmacy between the published AWP price and the actual acquisition cost. (Id.) Finally, the PBM pockets spreads in the mail-order context in which a third-party "repackager" is used between the rates charged to end-payors and the rates paid to the repackagers. (Id.)

The "spreads" motivate the PBM's to put the brand-name drug on a formulary: the greater the AWP inflation, the greater the profit to the PBM from the spread. (Id.) Each manufacturer benefits from a spread because it encourages PBM's to sell that manufacturer's drug, rather than a competitor's.

Alleged communications between PBM's and the manufacturers include, *inter alia*: (1) marketing materials about the AWP's for



brand-name drugs sent from manufacturers to PBM's; (2) written representations of the AWP's sent by the manufacturers; (3) "thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant drug manufacturer's drug on a particular PBM's formulary"; and (4) written communications, including checks, relating to rebates, kickbacks and other financial inducements. (§ 666(a)-(i).)

Additionally, salespersons from manufacturers regularly meet with PBM's in order to promote their products and the fraudulent AWP scheme. (§§ 664, 667(e).) Plaintiffs allege that Defendants controlled, *inter alia*, the setting of the AWP's, the distribution of marketing material used to inform the PBM's of the benefits of using AWP's, and the affairs of the PBM's by providing rebates and administrative fees in exchange for the PBM's use of a particular manufacturer's AWP's. (§ 667.)

These allegations provide a plausible common fraudulent purpose (a falsely-inflated AWP) and describe systematic linkages, common communication networks, and regular meetings among associates. It is true that Plaintiffs have not alleged specific communications for each enterprise, but courts have recognized that relaxation of pleading requirements is permitted where information is in a defendant's sole possession. See, e.g., Efron v. Embassy Suites (P.R.) Inc., 223 F.3d 12, 16 (1st Cir. 2000). Such relaxation is particularly appropriate here



where most of the Defendants have conceded that AWP's represent only an "undiscounted sticker price" that has no direct relation to the actual average price they charge for their drugs and that this is a widespread pricing and reporting practice. Pharm. I, 263 F. Supp. 2d at 180.

**2. Conduct or Participate in the Conduct
(Manufacturer - PBM Enterprises)**

Defendants argue that the AMCC makes insufficient allegations that each manufacturer conducted or participated in the conduct of the manufacturer - PBM enterprises. The "conduct or participate in the conduct" portion of § 1962(c) "requires some participation in the operation or management of the enterprise itself." Reves v. Ernst & Young, 507 U.S. 170, 176 (1993). "An enterprise is 'operated' not just by upper management but also by lower-rung participants in the enterprise who are under the direction of upper management. An enterprise also might be 'operated' or 'managed' by others 'associated with' the enterprise who exert control over it as, for example, by bribery." Id. at 184 (footnote omitted). See United States v. Shifman, 124 F.3d 31, 36 (1st Cir. 1997) (holding that debtor who referred persons to loan shark in exchange for debt relief or fees conducted or participated in the conduct of loan sharking enterprise); Aetna Cas. Sur. Co. v. P & B Autobody, 43 F.3d 1546, 1559 (1st Cir. 1994) (holding that operation or management test

