230 F.R.D. 61, RICO Bus.Disp.Guide 10,925, Med & Med GD (CCH) P 301,677
(Cite as: 230 F.R.D. 61)

United States District Court,
D. Massachusetts.
In re PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION.

CIV.A. No. 01–12257.
MDL NO. 1456.
Aug. 16, 2005.

Background: Consumers and third-party payors (TTPs) brought suit against pharmaceutical manufacturers alleging that manufacturers fraudulently inflated drug prices by misstating average wholesale prices (AWPs) of their drugs in industry publications. Plaintiffs asserted violations of the Racketeer Influenced and Corrupt Organizations Act (RICO), common law civil conspiracies to violate state consumer protection laws, state fraud laws, and state Medicare anti-kickback laws. Plaintiffs moved to certify three nationwide classes.

Holdings: The District Court, Saris, J., held that:
(1) associations whose members were patients who made co-payments for drugs under Medicare Part B lacked standing to serve as class representatives for such patients;
(2) TPPs could not serve as adequate or typical representatives of patients who made co-payments for drugs under Medicare Part B;
(3) predominance requirement for class certification was not satisfied with respect to proposed class of TPPs that paid MediGap supplemental insurance for drug co-payments made by Medicare Part B beneficiaries;
(4) predominance requirement was not satisfied with respect to proposed nationwide class of third-party payors (TPPs) that paid for physician-administered drugs outside the context of Medicare Part B and consumers that made percentage-based co-payments for drugs under their private insurance plans; and
(5) predominance requirement was not satisfied with respect to proposed nationwide class of TPPs and consumers asserting state consumer protection law claims, and proposed nationwide class of TPPs and consumers asserting claims under RICO.

Motion granted in part and denied in part.

West Headnotes

[1] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Numerosity requirement for class certification was satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed nationwide class of patients who made co-payments for drugs under Medicare Part B, based on plaintiffs' statement there were an estimated 40 million Medicare beneficiaries, many of whom co-paid for drugs covered by Medicare. Fed.Rules Civ.Proc.Rule 23(a)(1), 28 U.S.C.A.

[2] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Commonality requirement for class certification was satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed nationwide class of patients who made co-payments for drugs under Medicare Part B; numerous common factual issues included whether the AWPs for the drugs were misrepresented, whether that misrepresentation was intentional, whether it was done with a fraudulent intent, and whether it proximately caused harm to consumers. Fed.Rules Civ.Proc.Rule 23(a)(2), 28 U.S.C.A.

[3] Associations 41 20(1)

41 Associations
41k20 Actions by or Against Associations
41k20(1) k. In general. Most Cited Cases

Generally speaking, associations do not have standing to seek monetary damages for injuries to their members.

[4] Associations 41 20(1)

41 Associations
41k20 Actions by or Against Associations
41k20(1) k. In general. Most Cited Cases

To establish standing on behalf of its members, an association must show: (1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

[5] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Associations whose members were patients who made co-payments for drugs under Medicare Part B lacked standing to serve as class representatives for such patients in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs) under typicality provision of class action rule, insofar as class members sought to recover monetary damages. Fed.Rules Civ.Proc.Rule 23(a)(3), 28 U.S.C.A.

[6] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Named plaintiffs who were third-party payors (TPPs) could not serve as adequate or typical representatives of patients who made co-payments for drugs under Medicare Part B, particularly those who did not have supplemental health insurance, in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs); there might be defenses unique to TPPs not applicable to consumers, and there might be conflict between TPPs and Medicare Part B beneficiaries with respect to settlements. Fed.Rules Civ.Proc.Rule 23(a)(3, 4), 28 U.S.C.A.

[7] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Predominance requirement for class certification was satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed nationwide class of patients who made co-payments for drugs under Medicare Part B; common factual issues predominated since typical Medicare Part B beneficiary by statute paid a percentage of AWP as co-pay, and differences in state consumer laws were not so significant that they caused individual legal issues to predominate. Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

[8] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Superiority requirement for class certification was satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed nationwide class of patients who made co-payments for drugs under Medicare Part B; it would be cost effective to focus the litigation involving proposed class in one forum, and one case would promote a uniformity of results appropriate for a nationwide reim-

bursement program. Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

[9] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Union health benefits fund satisfied typicality and adequacy requirements for class representation as named plaintiff in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed class of third-party payors (TPPs) that paid MediGap supplemental insurance for drug co-payments made by Medicare Part B beneficiaries; although fund did not pay the full 20% coinsurance payment in all cases, its underlying legal theory and its motivations were similar to those of the other TPP class members that made full payments. Fed.Rules Civ.Proc.Rule 23(a)(3, 4), 28 U.S.C.A.

[10] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Predominance requirement for class certification was not satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed class of third-party payors (TPPs) that paid MediGap supplemental insurance for drug co-payments made by Medicare Part B beneficiaries; although there appeared to be no factual differences with respect to reliance or causation, plaintiffs did not show that legal differences among state consumer protection statutes did not predominate over common legal questions. Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

[11] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Predominance and superiority requirements for class certification were satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to statewide class of third-party payors (TPPs) that paid MediGap supplemental insurance for drug co-payments made by Medicare Part B beneficiaries; common issues predominated under Massachusetts consumer protection statute, and management issues were not insuperable because damages are formulaic. Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.; M.G.L.A. c. 93A, § 1 et seq.

[12] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Predominance requirement for class certification was not satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed nationwide class of third-party payors (TPPs) that paid for physician-administered drugs outside the context of Medicare Part B and consumers that made percentage-based co-payments for drugs under their private insurance plans; plaintiffs asserted their claims under state consumer protection laws which had substantially varying standards and burdens. Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

[13] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

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Predominance requirement for class certification was not satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed nationwide class of third-party payors (TPPs) and consumers asserting state consumer protection law claims, and proposed nationwide class of TPPs and consumers asserting claims under the Racketeer Influenced and Corrupt Organizations Act (RICO) and state common law conspiracy claims. 18 U.S.C.A. § 1961 et seq.; Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

[14] Federal Civil Procedure 170A 182.5

170A Federal Civil Procedure
170AII Parties
170AII(D) Class Actions
170AII(D)3 Particular Classes Represented
170Ak182.5 k. Consumers, purchasers, borrowers, and debtors. Most Cited Cases

Superiority requirement for class certification was not satisfied in suit against pharmaceutical manufacturers alleging that they fraudulently inflated drug prices by misstating average wholesale prices (AWPs), with respect to proposed nationwide class of third-party payors (TPPs) and consumers asserting state consumer protection law claims, and proposed nationwide class of TPPs and consumers asserting claims under the Racketeer Influenced and Corrupt Organizations Act (RICO) and state common law conspiracy claims. 18 U.S.C.A. § 1961 et seq.; Fed.Rules Civ.Proc.Rule 23(b)(3), 28 U.S.C.A.

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MEMORANDUM AND ORDER RE: MOTION FOR CLASS CERTIFICATION

SARIS, District Judge.

I. INTRODUCTION

In this proposed massive class action, thirteen plaintiffs claim that forty-two defendant pharmaceutical manufacturers fraudulently and grossly inflate the prices to consumers of many drugs by misstating the "Average Wholesale Prices" ("AWPs") of their drugs in industry publications. These overstated AWPs allegedly cause beneficiaries of the Medicare Part B program, other consumer-patients, and third-party payors ("TPPs"), such as private health insurers, private health and welfare plans, and self-insured employers, to overpay for prescription drugs.

In this stage of the litigation, plaintiffs seek to certify three nationwide classes encompassing consumers and TPPs who allegedly paid inflated prices for 132 brand-name and generic prescription drugs on the basis of published, fraudulent AWPs.[FN1] Seventeen of the drugs at issue are reimbursed under Medicare Part B. The three proposed classes are the "physician-administered class," "the self-administered and specialty pharmacy class," and the "RICO class for self-administered and specialty drugs." The proposed class period is 1991 to the present.

> FN1. This motion encompasses 132 of the 321 drugs identified in the Second Amended Master Consolidated Complaint ("SAMCC"). The Court divided this multi-district litigation into two tracks, fast-track ("Track One") and normal-track ("Track Two"). Plaintiffs seek certification of three classes covering all of the Track One defendants' drugs named in the SAMCC. The Track One defendants are AstraZeneca PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P. and AstraZeneca U.S. ("AstraZeneca"); Bristol–Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc. ("the BMS Group"); GlaxoSmithKline, P.L.C., SmithKline Beecham, P.L.C., and GlaxoWellcome, Inc. ("the GSK Group"); Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products, L.P., McNeil–PPC, Inc., and Ortho Biotech ("the Johnson & Johnson Group"); and the Schering–Plough Corporation and Warrick Pharmaceuticals Corporation ("the Schering Plough Group").

Defendants argue that the proposed classes, involving millions of people and 11,000 TPPs, should not be certified because common factual and legal issues do not predominate and the classes are not manageable. They highlight

differences among the plaintiffs, among the defendants, among the 132 identified drugs (the "AWPIDs"), and among methods of reimbursement.

Plaintiffs allege violations of RICO, 18 U.S.C. § 1962(c), claiming that each manufacturer was engaged in an unlawful racketeering enterprise with each of four pharmacy benefit managers ("PBMs")—AdvancePCS; Caremark, Rx, Inc.; Express Scripts, Inc.; and Medco Health Solutions, Inc. (Count II). They also assert common law civil conspiracies to violate state consumer protection laws, state fraud laws, and state Medicare anti-kickback laws (Count IX). Finally, they claim that defendants committed fraud under state consumer protection laws by sending the AWPs to third party publishers (Count IV).[FN2]

FN2. Count I of the SAMCC, which alleged a RICO enterprise involving three publishers (Thompson Medical Economics, publisher of the Drug Topics Red Book; First Data Bank ("FDB"), publisher of the Blue Book; and Facts & Comparisons, Inc., publisher of the Medi–Span Master Drug Data Base), was dismissed. *In re Average Wholesale Price Litig.*, 307 F.Supp.2d 196, 203–05 (D.Mass.2004). The plaintiffs are not pressing Count III, seeking declaratory relief pursuant to 28 U.S.C. § 2201. Counts V to VIII and X pertain to the alleged Together Card Rx conspiracy to violate the antitrust laws, and are proceeding on Track Two of this litigation.

***66** Plaintiffs propose a two-phase trial, with issues of liability, causation, and aggregate (or per drug) damages adjudicated in Phase I by a jury, and issues of individualized damages for each class member adjudicated in Phase II. Plaintiffs describe Phase II as an administrative process, albeit one in which defendants may challenge class members' proofs of claims, if necessary, in a jury trial.

After hearing and review of the extensive briefing, the reports of the parties' experts,[FN3] and the report of independent expert Ernst R. Berndt, a professor of applied economics at the Sloan School of Management, Massachusetts Institute of Technology, I rule as follows: (1) the association plaintiffs do not have standing to assert claims of consumer-beneficiaries who make co-payments under Medicare Part B or who make private co-insurance payments for physician-administered drugs under private health insurance plans; (2) TPPs are not adequate or typical class representatives for Medicare Part B consumers; (3) a nationwide class of Medicare Part B beneficiaries meets the remainder of the requirements of Fed.R.Civ.P. 23(a) and 23(b)(3); (4) plaintiffs may amend the SAMCC to propose individual class plaintiffs who are Medicare Part B beneficiaries; (5) the Court ***DENIES*** the motion to certify a **nationwide** class of TPPs that provide MediGap-type supplemental insurance but certifies a **statewide** class in Massachusetts; (6) the Court ***DENIES*** the motion to certify a **nationwide** class of TPPs and consumers that pay for physician-administered drugs outside the Medicare Part B context but certifies a **statewide** class in Massachusetts; (7) the motion to certify nationwide classes of TPPs and consumers paying for self-administered drugs is ***DENIED***.[FN4]

FN3. The parties filed over twenty-two boxes of exhibits in relation to this motion, in addition to dozens of briefs and expert reports.

FN4. The Court has addressed the same scheme in numerous prior decisions. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172 (D.Mass. May 13, 2003); *Montana v. Abbot Labs.*, 266 F.Supp.2d 250 (D.Mass. June 11, 2003); *In re Pharm. Indus. Average Wholesale Price Litig.*, 309 F.Supp.2d 165 (D.Mass. Jan.9, 2004); *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F.Supp.2d 190 (D.Mass. Jan.9, 2004); *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F.Supp.2d 196 (D.Mass. Feb.24, 2004); *In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F.Supp.2d 187 (D.Mass. June 10, 2004); *In re Pharm. Indus. Average Wholesale Price Litig.*, 339 F.Supp.2d 165 (D.Mass. Sept.30, 2004); *Massachusetts v. Mylan Labs.*, 357 F.Supp.2d 314 (D.Mass. Feb.4, 2005).

II. PROPOSED CLASSES

Plaintiffs seek certification of the following classes, with respect to the drugs identified in the SAMCC, Attachment A, for defendants AstraZeneca, the BMS Group, the GSK Group, the Johnson & Johnson Group, and the Schering Plough Group:

[1] Physician–Administered Drugs Class (Medicare Part B Co–Pay and Private System Physician–Administered Drugs)

All persons or entities in the United States and its territories who (i) paid all or a portion of the co-insurance under Medicare Part B for an AWPID during the Class Period, and/or (ii) reimbursed another for a physi-

cian-administered AWPID under a contract that expressly uses AWP as a pricing standard, along with all individual persons who paid coinsurance (i.e., co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.

[2] Self–Administered and Specialty Pharmacy Drugs Class (Third–Party and Co–Payor Class for Self–Administered Drugs)

All persons or entities in the United States and its territories who reimbursed another for any self-administered AWPID, or for any AWPID which was distributed through a specialty pharmacy, under a contract that expressly uses AWP as a pricing standard, along with all individual persons who paid coinsurance (i.e., co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who ***67** make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.

The foregoing class is further subdivided into the following subclasses:

(a) brand-name sub-class; and

(b) generic the sub-class [sic]

[3] RICO Class for Self–Administered and Specialty Drugs

All persons or entities in the United States and its territories who reimbursed another for any self-administered AWPID, or for any AWPID which was distributed through a specialty pharmacy, under a contract with Caremark, AdvancePCS, Express Scripts and/or Medco (or their predecessors), which contract expressly uses AWP as pricing [sic] standard, along with all individual persons who paid coinsurance (i.e. co-pays proportional to the reimbursed amount) under such contracts for such AWPIDs. Excluded from the Class are those who make flat co-pays and those whose co-pay was reimbursed by an insurer or other third party.

The foregoing class is further subdivided into the following subclasses:

(a) brand-name sub-class; and

(b) generic the sub-class [sic]

(Am. Mot. for Class Cert. 3–4.)

III. FACTUAL BACKGROUND

For background about the structure of the pharmaceuticals market, the Court has relied on the expert reports of the parties, the tutorials on the structure of the pharmaceutical markets, and the excellent report written by Professor Ernst Berndt.[FN5] As is appropriate on a motion for class certification, the Court has generally treated the allegations of the SAMCC as true, but has also peered behind the SAMCC to determine what issues are susceptible to resolution via class treatment. *See* *Waste Mgt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 298 (1st Cir.2000).

FN5. Professor Berndt's report, which provides substantially more detail than this Order about the structure and history of the pharmaceuticals market, is available on the electronic docket at entry number 1384. He supplemented this report with a short memorandum on August 9, available at entry number 1639. The Court also received the reports of plaintiffs' experts, Dr. Raymond Hartman, an economist and a director at Greylock McKinnon Associates litigation consulting firm with extensive teaching and research experience; Professor Stephan Schondelmeyer, an economist at the University of Minnesota who is head of the Department of Pharmaceutical Care & Health Systems; and Professor Richard Frank, a professor of health economics at Harvard Medical School; and the reports of defendants' experts, Steven Young, the Managing Director of Huron Consulting Group's Healthcare and Higher Education Consulting practice; Dr. Eric Gaier, a partner at Bates White, a professional services firm that specializes in economic analysis; Dr. Robert Navarro, a pharmacist, an expert in pharmacy benefit managers, and president of the consulting firm NavarroPharma LLC; and Professor Halbert White, a professor in economics at the University of California, San Diego, who specializes in econometrics. The Court also attended a two-day tutorial hearing presented by plaintiffs' expert Dr. Meredith Rosenthal, an assistant professor of Health Economics and Policy at the Harvard School of Public Health, and defendants' experts Professor Fiona Scott Morton of the Yale School of Management (who spoke on a DVD tutorial but not at the hearing) and Dr.

Gregory Bell, a Group Vice President at the Charles River Associates consulting firm.

A. AVERAGE WHOLESALE PRICE AND THE SPREAD

Throughout the class period, from 1991 to the present, AWP has been the pricing benchmark for most pharmaceutical sales in the United States. (Hartman Decl. attach. D ¶¶ 29–30; Schondelmeyer ¶ 36.) It is akin to a sticker price for automobiles, setting the pricing baseline. (Hartman Decl. attach. D n.1.) Private publications such as the Drug Topics Red Book, the First Data Bank Blue Book, and the Medi–Span Master Drug Data Base list the AWPs. For each drug, the publications list one or more eleven-digit National Drug Code numbers ("NDCs"), which convey information such as dosage, package size, and manufacturer; each NDC of a drug may have its own AWP.[FN6]

FN6. For example, Appendix A to the SAMCC lists 40 different NDCs for the compound Dextrose, manufactured by B. Braun McGaw, with AWPs ranging from $15.98 to $2,032.32.

Dr. Berndt states:

> To knowledgeable industry observers, it has long been widely understood that in ***68** the U.S. pharmaceutical industry, the term "average wholesale price" [AWP] is a misnomer: it is not a measure of prices generally paid by wholesalers to manufacturers, it is not a measure of prices frequently paid by retail or mail order pharmacies to wholesalers, nor is it some average of these.

(Berndt ¶ 14.) Nonetheless, "real and understandable" confusion still remains, even within the industry, as to what AWP is. (Berndt ¶ 81.) Mockingly referred to as "Ain't What's Paid," AWP has been defined in the literature in various ways. (Berndt ¶ 16 (citing Bill Alpert, *Hooked on Drugs: Why do Insurers Pay Such Outrageous Prices for Pharmaceuticals?*, Barrons, June 1996, at 3).) For example, according to the American Society of Consultant Pharmacists' website, First Data Bank stated as late as 2000 that AWP is "the average wholesale price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC). The operative word is average." (Berndt ¶ 78.) Other recent documents continue to state that AWP is an actual average of prices (Berndt ¶ 80), even as government reports and other sources have stated that AWP is not an accurate measure of wholesale prices (Berndt ¶¶ 65–67).

Related to the AWP is a drug's Wholesale Acquisition Cost ("WAC"), which also is listed in publications.[FN7] WAC is understood to be the price at which a pharmaceutical firm typically sells a drug to wholesalers. (Berndt ¶ 15.) The WAC for single-source drugs correlates with the AWP over the life of a drug.[FN8] Typically, the AWP for a brand-name, self-administered drug is 20% or 25% above WAC. (Schondelmeyer ¶ 89; Berndt ¶ 15.) In the generic drug context the relationship is less predictable, with AWPs sometimes reaching 50% to 100% above WAC. (Schondelmeyer ¶ 92.)

FN7. Some defendants claim that they send data items other than WACs to publishers (such as Wholesale List Prices, "WLPs," in the case of Bristol–Myers Squibb), but these appear to be functional equivalents of WAC.

FN8. A multi-source drug, as opposed to a single-source drug, is a drug for which generic versions exist. *See* 42 U.S.C. § 1396r–8 (defining multi-source drugs in the context of the Best Prices rebate program). The parties have noted that in other contexts there is a difference between a generic drug and a multi-source drug, but that the difference is irrelevant to this case.

In almost every sale of prescription drugs, reimbursement from the government or TPP is based on AWP, WAC, or a discount from one of these numbers (e.g., AWP minus 15%). As plaintiffs' expert Hartman states, "The AWP, or its formulaic equivalent the WAC (Wholesale Acquisition Cost), is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs." (Hartman Rebuttal ¶ 3.) However, manufacturers actually sell drugs to providers like pharmacies and doctors at prices far below AWP and WAC. This creates a "spread" between the price healthcare providers pay to acquire drugs from wholesalers or manufacturers (the average acquisition cost, "AAC") and the reimbursement rate paid by TPPs, the government, and consumers making co-insurance payments or paying the entire cost of a drug. This spread can reach into the hundreds of dollars and thousands of percentage points:

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Drug	2001 Red Book AWP	Determined Actual AWP	Difference	Spread
-Acetylcysteine	$ 35.87	$ 21.90	$ 13.97	64%
-Acyclovir	$1047.38	$ 349.05	$ 698.33	200%
-Amikacin Sulfate	$ 995.84	$ 125.00	$ 870.84	697%
-Calcitriol (Calcijex)	$1390.66	$1079.00	$ 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%

***69**

In re Pharm. Indus. Average Wholesale Price Litig., 263 F.Supp.2d at 178 (quoting Complaint ¶ 190).

The gravamen of the fraudulent scheme alleged in the SAMCC is that defendant manufacturers send publishers their AWPs (or their WACs), knowing that TPPs and government payors consider them indicators of prices to providers. Defendants know that class members will make reimbursement payments based on those prices. In fact, plaintiffs allege, for the 321 identified drugs, the AWPIDS, AWPs are neither the true average prices charged by wholesalers nor the price measure "expected" by the market (e.g., AWP minus 16% to 33% is the cost to providers). Instead, defendants (or wholesalers) sell a drug to retailers at a *net* price often significantly below the expected "AWP minus 16% to 33%" threshold by utilizing hidden discounts, off-invoice rebates, free samples, education grants, and other promotional means that are not reflected in the list price. Defendants do so to increase their market share or sales, at a cost to the end-payor. Under plaintiffs' theory, class members have been defrauded by intentionally false misrepresentations as to AWP that permit retailers and intermediaries like PBMs to retain the benefits of price reductions. Plaintiffs allege that the scheme led to huge profits for drug companies and doctors at the expense of insurers and their beneficiaries.

B. REIMBURSEMENT FOR DRUGS

An analysis of the methods of drug reimbursement is essential to understanding the viability of the three proposed classes, which reflect two significantly different methods of distributing drugs. First, physician-administered drugs (mostly brand-name drugs) are generally sold to consumer-patients by physicians, who are reimbursed by the government Medicare Part B program and by private sector TPPs. Consumer-patients typically make "co-insurance" payments for these drugs, meaning they pay a portion of the cost of the drug based on a percentage of AWP, rather than a flat co-payment. The plaintiffs seek to include in the proposed class only consumer-patients who make co-insurance payments, not those who make flat co-payments.

Second, self-administered drugs (both brand-name and generic) are typically bought by a consumer through a retail or mail-order pharmacy, which is then sometimes reimbursed by a TPP or PBM. Again, consumers who make percentage-based co-payments (but not those who make flat co-payments) are included in the proposed class. I address the different reimbursement schemes separately below.

1. Medicare Part B Coverage for Physician–Administered Drugs

Medicare spent a large and rapidly growing amount on prescription drugs throughout the class period. In 1998,

Medicare spent $3.3 billion on prescription drugs. (Schondelmeyer ¶ 44.) This number grew to $8.4 billion by 2002. (*Id.*)

While Medicare generally did not cover the cost of self-administered prescription drugs during the proposed class period, it did cover some physician-administered drugs, including chemotherapies, inhalation therapies, end-state renal disease drugs, oral cancer drugs, and drugs used following organ transplants.[FN9] ***70** (SAMCC ¶ 144; Berndt ¶ 88.) Medicare Part B provided prescription coverage for approximately 450 drugs during this period.[FN10] (Berndt ¶ 88.) This set of drugs, known as "specialty pharmacy products," includes many brand-name drugs for which no effective therapeutic competition exists, making them very expensive—some cost more than $10,000. (Berndt ¶¶ 89, 93.) Thirty-five of these drugs accounted for 90% of Medicare Part B spending on drugs. (Berndt ¶ 87.) Seventeen of the 132 drugs at issue in this litigation were reimbursed under Medicare Part B. (Rosenthal 4.)

FN9. About half of all cancer patients are covered by Medicare. (Berndt ¶ 89.)

FN10. The Medicare statute has since been amended to add a more extensive prescription drug benefit. No one has briefed the effect of the statute on the class, which is defined as 1991 to the present. I will not address its impact here.

AWP was the basis for drug reimbursement under Medicare Part B for most of the proposed class period. Under the fee-for-service program, Medicare Part B reimburses for drugs based on formulae set by federal statute and federal regulations.[FN11] *See, e.g.*, 42 U.S.C. §§ 1395u(*o*), 13951(s); 42 C.F.R. § 405.517. From 1992 to 1997, reimbursement for single-source brand-name drugs was set at the lesser of the estimated acquisition cost ("EAC") or AWP.[FN12] 42 C.F.R. § 405.517 (amended Nov. 2, 1998; Jan. 7, 2004; Nov. 15, 2004). The EAC was supposed to be measured through surveys conducted by regional Medicare administrators (termed "carriers"), who were to determine the usual and customary charge ("U & C") for a geographic area. *Id.* However, the carriers never conducted the surveys, and instead relied on AWPs. (Rosenthal 7.) For multi-source generic drugs, reimbursement was set at the lower of EAC or the "Maximum Allowable Cost" ("MAC"), where MAC is defined as the median of the AWPs of all generic forms of a drug. 42 C.F.R. § 405.517 (amended Nov. 2, 1998; Jan. 7, 2004; Nov. 15, 2004).

FN11. Approximately 88% of patients in Medicare participate in the traditional, fee-for-service Medicare system. (Bell 18–19.) The other 12% participate in Medicare + Choice, a managed care system administered by commercial insurers. (*Id.*)

FN12. Prior to 1992, reimbursement was based on the "reasonable charge" amount. (Berndt ¶ 92.) Regional carriers would examine the amount billed by a physician and pay it if it was deemed reasonable.

On January 1, 1998, the relevant statute and regulation were amended. Reimbursement for single-source drugs was changed to the lesser of (1) the billed charge on the Medicare claim form or (2) 95% of AWP. 42 U.S.C. § 1395u(*o*) (amended Dec. 8, 2003); 42 C.F.R. § 405.517. Reimbursement for generic drugs was changed to the lower of (1) the median of the AWPs of all generic forms of a drug or (2) the AWP of the least expensive brand-name drug. 42 U.S.C. § 1395u(*o*) (amended Dec. 8, 2003); 42 C.F.R. § 405.517. From January 1, 2004 to January 1, 2005, drugs were generally reimbursed at 85% of AWP, although reimbursement for certain drugs is particularly described in the applicable regulation. 42 U.S.C. § 1395u(*o*); 42 C.F.R. § 414.707. Since January 1, 2005, reimbursement for both single-source and multi-source drugs has been based on the Average Sales Price (the actual average manufacturer's sales price) of a drug as reported by manufacturers. 42 C.F.R. § 414.904 (for single-source drugs, "[t]he average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product").

Because the carriers never conducted the surveys of EACs, AWP became the basis for most Medicare reimbursement. (Rosenthal 7.) The government utilized the AWPs listed in the pricing publications, which follow defendants' pricing instructions.[FN13]

FN13. There may have been some variability from AWP in the basis for payment, since the seventeen regional carriers have the ability to change reimbursement in some situations. The number of regional carriers varied over the class period. There were thirty-five in 1991, and there are seventeen today. (Young ¶ 169.) Carriers may institute a "Least Costly Alternative" ("LCA")

> plan, wherein reimbursement for a particular drug may not be higher than that for a competitor drug. (Bell 34.) Such a plan was instituted by certain carriers for AstraZeneca's drug Zoladex, with the result being that reimbursement varied around the country, with some regions not basing reimbursement on Zoladex's AWP. (Bell 35; AstraZeneca Surreply at 2–3.) LCA started in 1997 in two states, and by 2002 had spread to forty states. (Schondelmeyer ¶ 41.) However, these variations appear to have been rare, and defendants have identified only the LCA plan for Zoladex as creating significant variation.

***71** Medicare pays 80% of the allowed amount of a covered drug, and the beneficiary is responsible for paying the other 20%. 42 U.S.C. § 13951(a)(1)(S). Many beneficiaries have purchased private "MediGap" (or "wrap around") insurance, which pays all or some of this 20% co-payment. (Bell 35.) In 2000, approximately 85% of the approximately 40 million persons in Medicare had this supplemental insurance coverage for co-payments. (*Id.*) The proposed physician-administered class seeks to include health plans that provided MediGap insurance. Almost all health plans provide coverage for Medicare co-payments, so there is substantial overlap in membership among the classes. (Young Decl. ¶ 18.) There are more than four million Medicare enrollees who do not have this supplemental MediGap insurance coverage and must pay their own coinsurance for Part B covered drugs. (Rosenthal 5.)

The benchmarks for Medicare Part B reimbursement were based on AWP even though the Department of Health and Human Services and other agencies have disclosed over the years that pharmacies' and providers' acquisition costs were typically less than AWP. (Berndt ¶ 65.) Moreover, various publications disclosed that physicians were able to purchase many of the Medicare Part B outpatient drugs at prices considerably less than AWP. (Berndt ¶ 97.) In Dr. Berndt's words, the existence of a spread "has not been a secret, at least to active observers and health care participants." (Berndt ¶ 65.) However, the parties dispute whether the government and industry were aware of the magnitude of the spread, and when they reasonably should have been aware of the spread.

2. *The Private Reimbursement System for Self–Administered and Physician–Administered Drugs*

TPPs include traditional insurance companies, health maintenance organizations ("HMOs"), other forms of ERISA plans, self-insured employers, and union benefit funds.

The system of private reimbursement by TPPs is complex and its characteristics vary depending on factors such as: (a) whether drugs were administered by a physician or were self-administered; (b) whether a PBM was used; and (c) whether a drug was a single-source, brand-name drug or a multi-source, generic drug.

a. *Self–Administered Drugs*

In a typical single-source, self-administered drug transaction, a retailer, usually a pharmacy, purchases a drug from a wholesaler or manufacturer. The retailer sells the drug to a consumer-patient who has a prescription from a doctor. If the patient has prescription coverage through his employer, union or other entity, the retailer checks to see if the drug is on the formulary for the patient's insurance plan. If the drug is on the formulary, the patient usually pays a copayment, either based on a percentage of AWP or a flat copayment. The remainder of the payment is made by either a TPP or a PBM on behalf of the TPP. The patient self-administers the drug (e.g., by taking the pill).

i. *PBMs*

PBMs are the 800–pound gorillas of pharmaceutical reimbursement. They serve as middlemen, assisting TPPs in implementing their drug prescription programs. At least since the mid–1990s, PBMs have become pervasive in the market, as claims administrators, benefits advisors, and full-service providers (including mail-order and sometimes retail pharmacies). Some PBMs during the class period were stand-alone entities, while others were owned by managed care organizations (like Aetna and Anthem), retail pharmacies, grocery chains, wholesalers, or drug manufacturers. (Berndt ¶ 127.)

According to Dr. Berndt, "[a]n important implication of the patterns of diversified ownership and heterogenous scale and scope of operations among PBMs is that commercial information regarding common negotiable contractual terms, such as rebates, discounts, audit rights, fee structure, penalties, risk assignment***72** and other services offered is widely dispersed." (Berndt ¶ 133.) Plaintiffs' expert, Hartman, points out there is a lack of pricing transparency with respect to the precise details of PBM rebate contracts with manufacturers. (Hartman Decl. attach. C ¶ 24.) However, while the terms of a specific contract may be secret, "general knowledge concerning what is negotiable and what is the range of terms typically offered is widespread." (Berndt ¶ 134.)

Contracts between a health insurer, health plan, or self-insured employer and a PBM tend to be highly individualized, the result of negotiations that determine the best match of services for the plan. (Navarro ¶ 16.) At their most basic, PBMs may simply handle the administration of claims processing. This is how PBMs originally came about in the late 1980s. Over time, PBMs gained the capacity to handle more aspects of pharmaceutical reimbursement, including pharmacy network administration, formulary design and management, manufacturer rebate negotiation, drug utilization review (to determine whether a patient's prescriptions may interact), physician communication and education (including formulary compliance incentives), mail-order pharmacy services, generic substitution plans, and assumption of risk (a PBM may contract to pay for some or all of the reimbursement of pharmaceuticals, or to do so after the plan pays a certain amount). (Bell 43; Navarro ¶ 20; Gaier Surreply ¶ 38.)

Generally speaking, a PBM does not directly purchase or take possession of a drug from a manufacturer, but rather acts as an intermediary (except with regard to the relatively small number of prescriptions dispensed through mail-order pharmacies). (Berndt ¶ 132; Schondelmeyer ¶ 76.) PBMs help to streamline administration, to enhance competition among parties providing products or services, such as pharmacies and drug manufacturers, and to create incentives for manufacturers to lower costs. These strategies can reduce pharmacy program costs by 25% to 30%. (Navarro ¶ 21.)

A TPP may purchase these services from a PBM or perform equivalent functions in-house. A TPP considering the use of a PBM will typically send out a request for proposals, describing its goals. Usually, several PBMs bid for these TPP contracts. Throughout the process, TPPs are commonly advised by benefits consulting companies like Segal Company, Towers Perrin and Mercer. In virtually all instances, self-insured employers and union benefit funds retain consultants to represent them in negotiations with PBMs, and five of the six named union benefit funds in this action used such consultants. (Young ¶ 64; Navarro ¶ 59.)

By 1999, 90% of HMOs contracted with a PBM, and today 95% of all patients with drug coverage obtain benefits through a PBM. (Young ¶ 104.) In 2001, PBMs handled 1.5 billion of the 3 billion prescriptions filled and 80% of the money spent on prescriptions. (Schondelmeyer ¶ 76; Hartman Decl. attach. C ¶ 22.) The top three PBMs alone handled 1 billion of the prescriptions. (Schondelmeyer ¶ 76.)

Using ordinary discounts, rebates, and chargeback policies, brand-name pharmaceutical manufacturers have offered a variety of price reductions to PBMs in return for favorable placement on a client's formulary, the attainment of market share or volume targets, or the realization of other contractually specified goals. (Berndt ¶ 15.)

Turning to the nitty-gritty, in a typical transaction, a PBM will charge its client TPP an administrative fee (in the neighborhood of $.30 to $.40), a dispensing fee (around $2.50), and a drug price based on a percentage of AWP (e.g., AWP minus 13%). (Rosenthal 15–16.) The PBM, which has a contract with a pharmacy network, then pays the pharmacy the dispensing fee ($2.50), sometimes an administrative fee, and a lower drug reimbursement (AWP minus 15%; or, more typically, the same price expressed as a percentage over WAC). (Rosenthal 15–17.) The PBM pockets the difference between what it receives from its client and what it pays the pharmacy (here, 2% of AWP plus the administrative fee if not paid to the pharmacy). (Rosenthal 16; Hartman Decl. attach. E ¶ 12.) In simplified form, a typical transaction, as described by Advance PCS, a PBM, looks like this: (Rosenthal Tutorial Ex. 23.)

***73** The PBM-insurer contract determines whether a rebate that a

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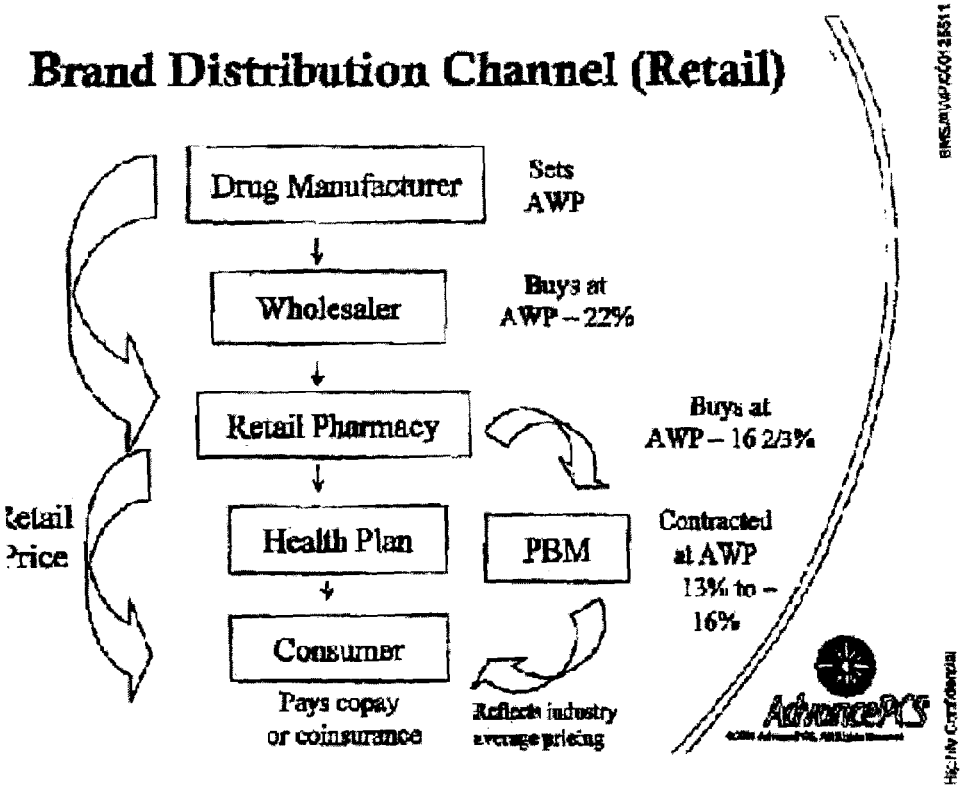
(Cite as: 230 F.R.D. 61)



manufacturer gives a PBM (based on sales or formulary placement) is passed through to the insurer and whether data about the size of the rebate is available to the insurer.[FN14] Some contracts provide that part of the rebates will be passed through to the insurer. Industry sources report that PBM clients typically receive 70% to 90% of the manufacturer rebates, or an average of $1.00 per claim, although the percentage varies from 0% to 100%. (Berndt ¶¶ 158, 160.) Many contracts provide that none of the rebate will be passed through but give the insurer the right to audit the PBM. (Navarro ¶¶ 43–44.) Other contracts provide that the amount of the rebate will be kept confidential from the insurer.

> FN14. Employers may also contract directly with manufacturers for the provision of rebates, bypassing PBMs. (Navarro ¶ 77 (citing example of John Deere).)

These rebates sometimes form a larger share of PBMs' revenue than do administrative fees from insurers or self-insured employers. (Schondelmeyer ¶ 76.) Manufacturers generally give larger rebates for drugs for which there are competitors, since the PBM may threaten to include only a competitor drug on the formulary if it does not receive a rebate.

Typically, a PBM attempts to restrict its plan's beneficiaries to a certain network of pharmacies. (Navarro ¶¶ 28–30.) By doing so, the PBM is able to stimulate competition among pharmacies that want to be included in its network, and in that way drive drug prices down. A PBM may negotiate several contracts with its pharmacy network to coincide with several different plans offered to employers. At various times in the class period, large HMOs, such as Kaiser Permanente, owned and operated their own networks of pharmacies. (Bell 45.)

ii. *Pharmacies*

The contract between a PBM and a pharmacy network dictates the terms by which ***74** the PBM pays for drugs. The contract usually specifies that the payment will be at the lowest of several alternatives, but according to plaintiffs the vast majority of transactions are made at AWP minus a discount, which typically is about 15% on branded pharmaceuticals and 13% to 25% on generics. (Rosenthal 16.) The reimbursement paid also varies by pharmacy, since pharmacies in geographic areas with little competition have more leverage to demand higher reimbursement.

(Navarro ¶¶ 29–30.)

In the brand-name context, a pharmacy contracts with a manufacturer, sometimes using a wholesaler as an intermediary (although this is less common for large pharmacy chains), for the purchase of drugs. The invoice price usually refers to WAC, rather than to AWP, and pharmacies typically acquire the drug at or around WAC. (Young ¶ 52.) It is important for the manufacturer to sell to the wholesaler at a price that allows both for the wholesaler's take (usually 2%) and for the pharmacy to earn a profit from selling to TPPs and consumers at AWP minus 13% to 18%. (Berndt ¶¶ 22, 24–27.) Therefore, according to plaintiffs, insurers generally expect that retailers are purchasing the self-administered, brand-name drugs at a range of AWP minus 16% to 33% (net of rebates). (Hartman Decl. ¶ 33.) In most situations, the pharmacy has little ability to refuse to carry a drug, because there are no competitor drugs. As Dr. Berndt stated,

> In most cases, the retail pharmacy cannot freely substitute between different patient-protected single-source brands, unless explicit permission is first obtained from the prescribing physician. This inability to stimulate price competition among single-source brands means that when negotiating with [a] branded manufacturer, the pharmacies have little bargaining power, and are essentially price takers.
>
> (Berndt ¶ 42.)

Pharmacies play a greater role in determining the spread for generic self-administered drugs than for brand-name drugs because a pharmacy has far greater leverage over drug choice in the former category. The multi-source arena differs from the single-source arena in that several manufacturers are producing the same product, usually in one name-brand form and several generic forms. The pharmacy is in the driver's seat, choosing which manufacturer's version of the compound to sell. Although reimbursement for recently launched generics references AWP, PBMs and insurers often use MAC pricing generally on their formularies. The MAC price is a single, set price that the PBM or insurer announces it will pay, and it is often based on the median or mean of the AWPs of several different manufacturers' versions of a drug. The pharmacy then decides which version of the generic to use. (Berndt ¶¶ 41, 56.) Sometimes TPPs use the public sector MACs used for Medicaid. A substantial portion of commercial payors have developed their own MAC lists and schedules that are proprietary and kept confidential. (*Id.* ¶ 58.)

Generic manufacturers compete to provide the generic version of a drug used by a particular pharmacy or pharmacy chain. A recent study demonstrates the continuing profitability to pharmacies of dispensing generic drugs—with gross margins growing rapidly for new multi-source drugs after 1997. (Berndt ¶¶ 40–41.) In the multi-source context, large spreads between the actual acquisition cost and AWP are common. (Berndt ¶ 47; Schondelmeyer ¶ 92.) Some of the highest spreads alleged in the SAMCC are from the multi-source context:

Defendant	Multisource Drug	RedBook AWP	DOJ Determined Actual AWP	Percentage Spread
Abbott	Sodium Chloride	$670.89	$ 3.22	20,735%
Baxter	Dextrose	$928.51	$ 2.25	41,167%
Baxter	Sodium Chloride	$928.51	$ 1.71	54,199%
Boehringer Group	Leucovorin Calcium	$184.40	$ 2.76	6,581%
B. Braun	Sodium Chloride	$ 11.33	$ 1.49	660%
BMS Group	Etoposide (Vepesid)	$136.49	$34.30	298%
Dey	Albuterol Sulfate	$ 30.25	$ 9.17	230%
Immunex	Leucovorin Calcium	$137.94	$14.58	846%
Pharmacia	Etoposide	$157.65	$ 9.47	1,565%
Sicor Group	Tobramycin Sulfate	$342.19	$ 6.98	4,802%
Watson	Vancomycin HCL	$ 70.00	$ 3.84	1,567%

***75** (SAMCC ¶ 187.) Because a TPP typically saves substantial money by paying for generics instead of brand-names, "the third party payor is less likely to quibble over whether the pharmacy is pocketing a larger margin for generics than for brands." (Berndt ¶ 52.)

b. *Physician–Administered Drugs*

Fewer players are at the table in a typical private sector transaction for a physician-administered drug.[FN15] A typical transaction involves a patient with cancer, or another serious disease requiring long-term care, arriving at her doctor's office to receive an injection. The doctor administers the injection of the oncology drug, often with separate drugs to counteract the side effects of the oncology drug. The doctor has purchased the oncology drug either directly from the manufacturer or through an intermediary physician group purchasing organization. The doctor bills the patient's insurance plan according to its formulary (usually found on a fee schedule). The plan reviews the claim (a process that costs around $45 per claim) and then pays the doctor. (Berndt ¶ 195.) According to plaintiffs' experts Hartman and Rosenthal, payments to physicians for physician-administered drugs and related services are predominantly based on AWP. (Rosenthal 10.) Defendants' expert Young disagrees, opining that the payments are negotiated as part of the overall physician fee schedule involving both drugs and services and that TPPs do not consider the providers' acquisition costs to be relevant. Dr. Berndt views the record as "unsettled" on this point. (Berndt ¶ 98.)

> FN15. It is not clear how many physician-administered drugs are involved. Plaintiffs claim there are fifteen physician-administered drugs and seventeen Medicare Part B drugs. Defendants state that there are thirty-five physician-administered drugs but they do not disclose how many are covered by Medicare Part B.

In the SAMCC, plaintiffs quote dozens of documents from defendants demonstrating an aggressive marketing of the spread to doctors (e.g., ¶ 347 ("Currently, physician practice can take advantage of the growing disparity between Vepesid's list price (and, subsequently, the Average Wholesale Price) and the actual acquisition cost when obtaining reimbursement ....") (quoting the BMS Group)), including many charts demonstrating how much better the spreads were on a particular defendant's drugs than on its competitors' (e.g., ¶¶ 238, 239 ("[O]ffices ... can increase their profit margin greatly by purchasing ZOLADEX") (quoting AstraZeneca)) with titles such as "Profit Maximization—It's in the Bag" (accompanying a medicine marketed in a premixed bag) (¶ 398 (quoting the GSK Group)).

There are several salient differences between the physician-administered and self-administered contexts. First, no pharmacies, retail or mail-order, generally are involved in the physician-administered context because the physician dispenses and administers the drug. While specialty pharmacies have recently begun to provide specialized delivery and administration services on a "high cost and high touch" basis (Berndt ¶ 100), these pharmacies make up a small percentage of the market, and their significance during the majority of the class period is unclear. (Young ¶ 32; Berndt ¶¶ 99, 103, 188.) Rebates to specialty pharmacies are rare because many physician-administered drugs are single-source and are the only products in their therapeutic classes. (Berndt ¶ 103.)

Second, PBMs are generally not involved in this arena, both because the administration of claims ordinarily requires individualized, specialized attention rather than rote processing, and because the percentage of the drug market involving physician-administered drugs is relatively small (no more than 11% of total prescription costs in 2002, and less than that previously). (Berndt ¶¶ 100, 137, 187.)

***76** Third, the amounts of money involved tend to be higher per transaction, often in the neighborhood of $5,000 to $250,000 per patient per year. (Rosenthal 10.) Therefore, the total amount of co-insurance payments by consumers may be significant.

Because doctors are involved as both retailers and as prescribing physicians, manufacturers, realizing the purchasing power of physicians, provide them with rebates, leading to large profits for the doctors on the prescription and administration of certain drugs. These profits now allegedly comprise a large percentage of these doctors' income; according to Hartman, two-thirds of the income of practice-based oncologists comes from the mark-up on injectable drugs. (Hartman Rebuttal ¶ 68.) Some experts have commented that "the financial incentives created by this profitability played a large and problematic role in prescribing decisions" from 1998–2003 because "prescribers responded to these high margins by tending towards administering more (and more expensive) drugs than might be medically necessary or optimal for the health of the patient." (Schondelmeyer ¶ 45 (citing expert panel

members cited in Stephen W. Schondelmeyer & Marian V. Wrobel, *Medicare and Medicaid Drug Pricing: Strategy to Determine Market Prices* 7 (2004).))

Because physician-administered drug reimbursement has been based on a five-digit "J–Code" system, which does not differentiate for strength, dosage and packaging (unlike NDCs), the issue of pricing transparency becomes an "order of magnitude larger" in this context. (Berndt ¶ 199).

> In summary, when medical benefit expenditure data are poorly monitored and "tracking patient data is nearly impossible", and when this is widely known, possibilities for mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit.
>
> (Berndt ¶ 191.)

Approximately 70% of physician-administered drugs are administered and reimbursed as a medical service rather than as a prescription benefit, typically resulting in higher reimbursement because of the difficulty of separating costs. (Berndt ¶¶ 104, 108.) Because doctors must incur the costs of administration and inventory for these drugs, most plans provide for an administration fee separate from the cost of the drug.

IV. RULE 23 STANDARD

Rule 23(a) sets forth several prerequisites to a class action. A class may be certified only if:

> (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representatives will fairly and adequately protect the interests of the class.

Fed.R.Civ.P. 23(a). Plaintiffs seek to certify a class pursuant to Rule 23(b)(3), which provides that an action may be maintained only if, additionally,

> the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action.
>
> Fed.R.Civ.P. 23(b)(3).

A court may certify a class on certain issues, like liability. *See* Fed.R.Civ.P. 23(c)(4)(A). The need for individualized damage proceedings does not ordinarily defeat predominance where there are still disputed common issues as to liability. *Tardiff v. Knox County*, 365 F.3d 1, 6–7 (1st Cir.2004). "Failing some practical solution allowing full resolution of all class damage claims in a single case, the court could enter ***77** a judgment of liability, leaving class members to pursue damage claims in separate law suits." *Id.; see also In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 141 (2d Cir.2001) (listing solutions to individual damage issues, such as "bifurcating liability and damage trials with the same or different juries ... [and] decertifying the class after the liability trial and providing notice to class members concerning how they may proceed to prove damages").

A district court must determine whether a proposed class meets the exacting prerequisites established by Rule 23. *Smilow v. Southwestern Bell Mobile Sys., Inc.*, 323 F.3d 32, 38 (1st Cir.2003). In "determinating the propriety of a class action, the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met." *Mowbray*, 208 F.3d at 298 (quoting *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178, 94 S.Ct. 2140, 40 L.Ed.2d 732 (1974) (internal citation omitted)). However, "a district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case." *Mowbray*, 208 F.3d at 298; *see also Tardiff*, 365 F.3d at 4–5 ("It is sometimes taken for granted that the complaint's allegations are necessarily controlling; but class action machinery is expensive and in our view a court has the power to test disputed premises early on if and when the class action would be proper on one premise but not another.").

V. CLASS ONE: PHYSICIAN–ADMINISTERED DRUGS

The first proposed nationwide class encompasses

physician-administered drugs paid for by (1) consumers making co-insurance payments pursuant to Medicare Part B; (2) TPPs providing private supplemental (MediGap) insurance to cover all or part of the Medicare Part B co-payments; (3) consumers making co-insurance payments for physician-administered drugs pursuant to private plans provided by TPPs; and (4) TPPs paying for these drugs outside the Medicare context. Plaintiffs allege that defendants caused the class injury by fraudulently inflating AWPs in violation of state consumer protection laws. [FN16]

FN16. Plaintiffs propose certifying a class under the following laws: Ala.Code § 8–19–5(27); Alaska Stat. § 45.50.471; Ariz.Rev.Stat. § 44–1522, subd. A; Ark.Code § 4–88–107(a); Cal. Civ.Code § 1770, Cal. Bus. & Prof.Code § 17200; Colo.Rev.Stat. § 6–1–105(1); Conn. Gen.Stat. § 42–110b(a); 6 Del.Code § 2513(a); D.C.Code § 28–3904; Fla. Stat. Ann. § 501.204(1); Ga.Code Ann. § 10–1–393(a); Haw.Rev.Stat. § 481A–3(a); Idaho Code § 48–603; 815 Ill. Comp. Stat. 505/2; Ind.Code § 24–5–0.5–3(a); Iowa Code § 714.16.2(a); Kan. Stat. Ann. § 50–626(a); Ky.Rev.Stat. § 367.170(1); La.Rev.Stat. § 51:1405; Me.Rev.Stat. tit. 5, § 207; Md. Com. Law Code §§ 13–303, 13–301; Mass. Gen. L. ch. 93A, § 2; Mich. Comp. Laws § 445.903; Minn.Stat. § 325D.44; Miss.Code Ann. § 75–24–5(1); Mo.Rev.Stat. § 407.020.1; Mont.Code § 30–14–103; Neb.Rev.Stat. § 59–1602; Nev.Rev.Stat. § 598.0915; N.H.Rev.Stat. § 358–A:2; N.J.Rev.Stat. § 56:8–2; N.M. Stat. § 57–12–3; N.Y. Gen. Bus. Law § 349(a); N.C. Gen.Stat. § 75–1.1(a); N.D. Cent.Code § 51–15–02; Ohio Rev.Code § 1345.02(a); Okla. Stat. tit. 15, §§ 752(13); Or.Rev.Stat. § 646.608(1); Pa. Stat. tit. 73, § 201–2(4); R.I. Gen. Laws §§ 6–13.1–2, 6–13.1–1(5)(xiii) and (xiv); S.C.Code § 39–5–20(a); S.D. Codified Laws § 37–24–6; Tenn.Code Ann. § 47–18–104(a); Tex. Bus. & Com.Code § 17.46(a); Utah Code § 13–11–4(1); Vt. Stat. tit. 9, § 2453; Va.Code § 59.1–200; Wash. Rev.Code § 19.86.020; W. Va.Code § 46A–6–104; Wis. Stats. § 100.18(1); and Wyo. Stat. § 40–12–105(a). (Mem. in Support, App. B.)

A. PHYSICIAN–ADMINISTERED CLASS OF MEDICARE PART B BENEFICIARIES

With respect to the physician-administered class, the Court first addresses the claims of the proposed class of Medicare Part B beneficiaries who themselves make co-payments.

1. *Numerosity*

[1] Plaintiffs state that there are an estimated 40 million Medicare beneficiaries, many of whom have co-paid for drugs covered by Medicare. Defendants have not challenged the numerosity requirement.

2. *Commonality*

[2] "A class has sufficient commonality 'if there are questions of fact and law which are common to the class.' " *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1019 (9th Cir.1998) ***78** (quoting Rule 23(a)(2)). "The threshold of 'commonality' is not high. Aimed in part at 'determining whether there is a need for combined treatment and a benefit to be derived therefrom,' the rule requires only that resolution of the common questions affect all or a substantial number of the class members." *Jenkins v. Raymark Indus., Inc.*, 782 F.2d 468, 472 (5th Cir.1986).

> All questions of fact and law need not be common to satisfy the rule. The existence of shared legal issues with divergent factual predicates is sufficient, as is a common core of salient facts coupled with disparate legal remedies within the class.

Hanlon, 150 F.3d at 1019. "The test or standard for meeting the Rule 23(a)(2) prerequisite is qualitative rather than quantitative; that is, there need be only a single issue common to all members of the class. Therefore, this requirement is easily met in most cases." 1 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 3.10 (4th ed.2002).

Here, there are numerous common factual issues: whether the AWPs and/or WACs for the AWPIDs were misrepresented, whether that misrepresentation was intentional, whether it was done with a fraudulent intent, and whether it proximately caused harm to consumers. Defendants have not challenged the commonality requirement.

3. *Typicality and Standing*

Defendants challenge plaintiffs' claim that the named plaintiffs are typical representatives for the Medicare Part B class, arguing that no named individual plaintiff purchased drugs under Medicare Part B, that association plaintiffs are inadequate representatives because they cannot recover damages, and that the United Food and Commercial Workers Unions & Employees Midwest

Health Benefits Fund ("UFCW") as a co-insurer under Medicare Part B is subject to unique defenses. Plaintiffs concede that no individual class member has paid for drugs under Medicare Part B, but argue that the associations and UFCW possess claims typical of the class.[FN17]

> FN17. In the SAMCC, plaintiffs name two individual plaintiffs who purchased drugs under the Together Rx Card Program, but do not allege that these individuals purchased physician-administered drugs or paid based on AWP.

Rule 23(a)(3) provides that a class action may be maintained only if the claims of the representative parties are typical of the claims of the class.

> Typicality determines whether a sufficient relationship exists between the injury to the named plaintiff and the conduct affecting the class, so that the court may properly attribute a collective nature to the challenged conduct. In other words, when such a relationship is shown, a plaintiff's injury arises from or is directly related to a wrong to a class, and that wrong includes the wrong to the plaintiff. Thus, a plaintiff's claim is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory.

In re Am. Med. Sys., Inc., 75 F.3d 1069, 1082 (6th Cir.1996) (quoting 1 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 3.13 (3d ed.1992)) (holding that district court erred by failing to probe issue of whether class representatives' claims were typical even of "each other, let alone a class"); *see also In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 686 (S.D.Fla.2004) (finding that representatives were typical of plaintiffs all subject to overcharge for drug even though members paid for overcharge in different ways). "The typicality requirement 'is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals.' " *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir.2004) (citation omitted). "Typicality, as with commonality, does not require 'that all putative class members share identical claims.' " *Id.* at 531–32 (citation omitted). "Although [the plaintiffs] may not have suffered identical damages, that is of little consequence to the typicality determination when the common issue of liability is shared." ***79***In re Lorazepam & Clorazepate Antitrust Litig.*, 202 F.R.D. 12, 28 (D.D.C.2001) (quoting *Lewis v. Nat'l Football League*, 146 F.R.D. 5, 9 (D.D.C.1992)) (finding representatives' claims typical despite the fact that some class members bought directly whereas others bought from agents or wholesalers at various rates in multitude of contracts).

No individual Medicare Part B consumer-patients have been proposed as class representatives, so the key question is whether an association with members who are patients meets the typicality requirement. In affidavits, association plaintiffs claim that their members make co-payments under Medicare Part B. (*See, e.g.,* Aff. of N.Y. Statewide Senior Action Counsel ¶ 4; Aff. of Citizen Action of N.Y. ¶ 4.) In the SAMCC, each association seeks only injunctive and declaratory relief and does not seek monetary relief on behalf of its members. Defendants do not challenge the standing of the associations to seek equitable relief,[FN18] but do contend that they cannot adequately represent class members asserting damage claims.

> FN18. Defendants challenge the standing of one association to seek any relief because at a deposition, the deponent could not provide members' names. However, defendants do not challenge the standing of the other associations on this ground.

"[S]tanding ... frequently appear[s] as [a] threshold requirement[ ] for the maintenance of federal class actions and must be considered in addition to the requirements of Rule 23 when deciding whether a particular action may be certified." 7AA Charles A. Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure* § 1785.1 (3d ed.2005); *see also Prado–Steiman v. Bush*, 221 F.3d 1266, 1279 (11th Cir.2000) ("[I]t is well settled that prior to the certification of a class, and technically speaking before undertaking any formal typicality or commonality review, the district court must determine that at least one named class representative has Article III standing to raise each class subclaim."); *Bano v. Union Carbide Corp.*, 361 F.3d 696, 713–16 (2d Cir.2004) (rejecting claims of association to be class representative on standing grounds). *Cf. Payton v. County of Kane*, 308 F.3d 673, 680 (7th Cir.2002) ("[There is a] long-standing rule that, once a class is properly certified, statutory and Article III standing requirements must be addressed with reference to the class as a whole, not simply with reference to the individual named plaintiffs.").

[3][4] Generally speaking, associations do not have standing to seek monetary damages for injuries to their members. To establish standing on behalf of its members, each association must show:

> (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

United Food & Commercial Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 553, 116 S.Ct. 1529, 134 L.Ed.2d 758 (1996) (quoting *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343, 97 S.Ct. 2434, 53 L.Ed.2d 383 (1977)). Most courts have held that associations do not have standing to seek damages on behalf of their members where both the fact and stated extent of injury would require individualized proof. *See Bano*, 361 F.3d at 715 ("[W]e know of no Supreme Court or federal court of appeals ruling that an association has standing to pursue damages claims on behalf of its members."); *Irish Lesbian & Gay Org. v. Giuliani*, 143 F.3d 638, 650 n. 5 (2d Cir.1998) ("An association generally cannot seek relief in damages for injuries to its members because unless the alleged injury is common to its entire membership, and shared by all to an equal degree, both the fact and extent of injury would require individualized proof." (citation omitted)); *Playboy Enters., Inc. v. Pub. Serv. Comm'n of P.R.*, 906 F.2d 25, 35–36 (1st Cir.1990) (holding that an association has no standing to sue on behalf of its members when seeking monetary relief to compensate its members' injuries).

[5] The key question, then, is whether an association may serve as a class representative for class members seeking to recover monetary damages. Allowing an association to be a class representative presents substantial advantages in cases like this one, in that associations likely have the motivation ***80** and resources to continue to act as representatives through the course of a multi-year litigation, as compared to elderly cancer patients, whose declining health may impair their ability to participate actively. Nonetheless, in *Bano*, the Second Circuit rejected this argument, stating:

> If the involvement of individual members of an association is necessary, either because the substantive nature of the claim or the form of the relief sought requires their participation, we see no sound reason to allow the organization standing to press their claims, even where it seeks to do so as a putative class representative.

361 F.3d at 715. While the associations may have standing to press any class claims for non-monetary relief, plaintiffs have not moved to certify under Fed.R.Civ.P. 23(b)(2).[FN19] The associations lack standing to serve as class representatives under Rule 23(b)(3).

> FN19. The defendants have also argued that plaintiff associations do not have standing to pursue a claim under approximately half of the state consumer protection statutes.

[6] This leaves only the TPP as a named representative. Some courts have held that the claims of consumer and third-party class representatives are typical of the claims of all class members notwithstanding variations in the amount of damages. *See Terazosin Hydrochloride*, 220 F.R.D. at 688. Here, plaintiffs argue that the TPP is typical in that its claims arise from the same course of conduct that gives rise to the claims of the absent class members. However, defendants assert that some TPPs (like those that purchased the drugs themselves) had extensive knowledge of AWP inflation and agreed to provide the insurance with open eyes; further, there may be defenses unique to TPPs not applicable to consumers (e.g., statute of limitations). "While it is settled that the mere existence of individualized factual questions with respect to the class representative's claim will not bar class certification, class certification is inappropriate where a putative class representative is subject to unique defenses which threaten to become the focus of the litigation." *Baffa v. Donaldson, Lufkin & Jenrette Sec. Corp.*, 222 F.3d 52, 59 (2d Cir.2000) (citation omitted) (holding that professional stock broker's superior knowledge and sophistication made her atypical representative for class of investors).

There is also concern about a possible conflict between TPPs and Medicare Part B beneficiaries with respect to possible settlements, given the different economic interests of the groups. Whether this concern is properly characterized as typicality or adequacy—the two inquiries frequently overlap—I am concerned that TPPs will not serve as adequate and typical representatives of Medicare beneficiaries, particularly those who do not have supplemental health insurance.

Because the requirement of Rule 23(a)(3) has not been met, the Court declines at this time to certify a class of Medicare Part B consumers. *See generally* Fed.R.Civ.P. 23 advisory committee's note to 2003 amendments ("The provision that a class certification 'may be conditional' is deleted. A court that is not satisfied that the requirements of Rule 23 have been met should refuse certification until they have been met."). The plaintiffs have identified indi-

viduals who could serve as additional class representatives and request an opportunity to amend the SAMCC to name them. Because this would further protect class interests, plaintiffs may move to amend in 60 days. *See Manual for Complex Litigation* (Fourth) § 21.26 (2004) (where replacement of a class representative is necessary, "courts generally allow class counsel time to make reasonable efforts to recruit and identify a new representative"). Plaintiffs must establish that there is an individual class representative with standing to sue each defendant.

The Track One defendants have supplemented their submissions by showing that in *Swanston v. Tap Pharm. Prods., Inc.*, No. CV2002–004988 (Ariz.Super.Ct.), a parallel proposed class action this Court remanded to the Arizona state court, the named class representative made no payments based on AWP and was therefore not a member of the class he sought to represent. Defendants point to this as proof that extensive individual inquiry is necessary to determine class membership. Arguably, class representatives***81** who were fully reimbursed suffered no injury. *See In re Relafen Antitrust Litigation*, 221 F.R.D. 260, 270–71 (D.Mass.2004) (excluding from the class all end payors who were reimbursed in full for all drug purchases). To address this issue, when plaintiffs amend the complaint to propose individual class representatives, they shall allege facts demonstrating typicality and adequacy of the class representatives and disclose the documents demonstrating that the proposed class representatives made co-insurance payments (at least in part) under Medicare Part B based on AWP. Because plaintiffs state that they have individuals waiting in the wings, the Court will continue to address the other certification requirements.

4. ***Adequacy***

"The adequacy inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997).

> The [adequacy] rule has two parts. The moving party must show first that the interests of the representative party will not conflict with the interests of any of the class members, and second, that counsel chosen by the representative party is qualified, experienced, and able to vigorously conduct the proposed litigation.

Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir.1985). "The conflict that will prevent a plaintiff from meeting the Rule 23(a)(4) prerequisite must be fundamental, and speculative conflict should be disregarded at the class certification stage." *Visa Check*, 280 F.3d at 145.

While the Court must defer ruling on individual representatives, the Court is satisfied that counsel is qualified. Counsel has conducted numerous class actions, and recently brought the Lupron suit, which raises similar drug-pricing issues, to a settlement. *See In re Lupron Mkting. & Sales Practices Litig.*, 228 F.R.D. 75 (D.Mass.2005).

5. ***Predominance***

[7] "The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem*, 521 U.S. at 623, 117 S.Ct. 2231. "Predominance is a test readily met in certain cases alleging consumer or securities fraud or violations of antitrust laws." *Id.* at 625, 117 S.Ct. 2231. "Where ... common questions predominate regarding liability, then courts generally find the predominance requirement to be satisfied even if individual damages issues remain," for "[t]he individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3)." *Smilow*, 323 F.3d at 40; *see also Tardiff*, 365 F.3d at 6–7 (noting that individuals subject to allegedly illegal strip search may have individual damages from emotional distress, lost wages, and medical treatment, but that these damages issues do not defeat initial certification); *Carnegie v. Household Int'l, Inc.*, 376 F.3d 656, 661 (7th Cir.2004) (affirming RICO class certification and suggesting procedural mechanisms available at later stage to cope with issues of whether particular members were defrauded and extent of individual damages).

Similarly, "where common issues otherwise predominated, courts have usually certified Rule 23(b)(3) classes even though individual issues were present in one or more affirmative defenses," for "[i]f ... evidence later shows that an affirmative defense is likely to bar claims against at least some class members, then a court has available adequate procedural mechanisms." *Smilow*, 323 F.3d at 39–40; *see also Mowbray*, 208 F.3d at 296 ("Although a necessity for individualized statute-of-limitations determinations invariably weighs against class certification under Rule 23(b)(3), we reject any per se rule that treats the presence of such issues as an automatic disqualifier."); *Tardiff*, 365 F.3d at 5 (noting that potential that some strip searches were legal would not defeat initial class certification, since class members likely could be grouped by likelihood that reason for arrest justified strip search); *Visa Check*, 280 F.3d at 137–39 (holding that

defense that individual plaintiffs may have mitigated damages by urging customers to use forms of payment other than defendants' cards did not cause individual issues to predominate).

***82** In cases involving fraudulent statements or misrepresentations, courts generally favor certification where the misrepresentations were materially uniform, but deny certification where they varied from transaction to transaction. *See* *Moore v. PaineWebber, Inc.*, 306 F.3d 1247, 1253–56 (2d Cir.2002) (stating that Third, Fourth, Fifth, Sixth, and Seventh Circuits follow this approach, with some variation); *In re LifeUSA Holding, Inc.*, 242 F.3d 136, 145–46 (3d Cir.2001) (decertifying class because the "plaintiffs assert claims arising not out of one single event or misrepresentation, but claims allegedly made to over 280,000 purchasers by over 30,000 independent agents where the District Court found that the sales presentations (hence the alleged misrepresentations) were neither uniform nor scripted").

Defendants have spent little time challenging the predominance of factual issues with respect to consumers who co-pay for physician-administered drugs under Medicare Part B. Here, common factual issues predominate since a typical consumer by statute simply pays a percentage of AWP as a co-pay. There is therefore no separate factual issue regarding the knowledge and reliance of each class member.

Defendants' primary challenge to the physician-administered drug class centers on the fact that each state consumer protection law has different legal standards. Differences in legal issues do not necessarily preclude class certification under Rule 23(b)(3). "As long as a sufficient constellation of common issues binds class members together, variations in the sources and application of [law] will not automatically foreclose class certification under Rule 23(b)(3)." *Mowbray*, 208 F.3d at 296; *see also* *Hanlon*, 150 F.3d at 1022–23 (holding that "the idiosyncratic differences between state consumer protection laws [were] not sufficiently substantive to predominate over the shared claims"). However, "[i]n a multi-state class action, variations in state law may swamp any common issues and defeat predominance." *Klay v. Humana, Inc.*, 382 F.3d 1241, 1261 (11th Cir.2004); *see also* *Amchem*, 521 U.S. at 624, 117 S.Ct. 2231 (observing that "[d]ifferences in state law ... compound ... the disparate questions undermining class cohesion in this case").

Choice of Law

Plaintiffs argue that individual legal issues do not predominate because this Court need only apply the laws of the states where the Track One defendants have their principal places of business, where they made the misrepresentations as to drug prices. To analyze the predominance challenge, this Court must first determine what law applies. *See* *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1189 (9th Cir.2001). The parties have agreed on the application of Massachusetts choice of law rules.[FN20]

FN20. Defendants note that it may be appropriate to apply the choice of law rules of each transferor court, *see* *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 141–42 (E.D.La.2002); Larry Kramer, *Choice of Law in Complex Litigation*, 71 N.Y.U. L.Rev. 547 (1996), but neither party has pursued the issue.

Taking a functional approach, Massachusetts courts look to the Restatement (Second) of Conflict of Laws ("Restatement") in determining choice of law issues. *Bushkin Assoc., Inc. v. Raytheon Co.*, 393 Mass. 622, 473 N.E.2d 662, 670 (1985). Restatement § 148, entitled "Fraud and Misrepresentation," most closely matches the claim and will be applied here.[FN21] Under that section, the most ***83** significant factor is where the plaintiff acted in reliance on a defendant's representation. Restatement § 148 at cmt. g ("In weighing these factors, the place where a plaintiff acted in reliance on defendant's representations is more important than the place where the defendant made or the plaintiff received the representations.").

FN21. This section provides:

> (2) When the plaintiff's action in reliance took place in whole or in part in a state other than that where the false representations were made, the forum will consider such of the following contacts, among others, as may be present in the particular case in determining the state which, with respect to the particular issue, has the most significant relationship to the occurrence and the parties:
>
> (a) the place, or places, where the plaintiff acted in reliance upon the defendant's representations,
>
> (b) the place where the plaintiff received the representations,

> (c) the place where the defendant made the representations,
>
> (d) the domicil, residence, nationality, place of incorporation and place of business of the parties,
>
> (e) the place where a tangible thing which is the subject of the transaction between the parties was situated at the time, and
>
> (f) the place where the plaintiff is to render performance under a contract which he has been induced to enter by the false representations of the defendant.
>
> Restatement (Second) of Conflict of Laws § 148 (1971).

Even though the defendants made the alleged misrepresentations in the states of their principal places of business when sending the AWPs to publishers, the Restatement § 148 factors point to applying the laws of the home states of the class members. The class members purchased physician-administered drugs in reliance on the published AWPs in states where they were receiving treatments from their physicians, typically their places of residence. Three of the significant contacts in § 148—the place of action in reliance, the place where misrepresentations were received, and the place of plaintiff's domicile—call for application of the law of the home state of each consumer. The conclusion that the home state of the consumer has a more significant relationship to the alleged fraud than the place of business of the defendant is in accordance with the principles of Restatement § 6,[FN22] since state consumer protection statutes are designed to protect consumers rather than to regulate corporate conduct. *See Relafen,* 221 F.R.D. at 277 ("[T]he primary aim of ... consumer protection laws generally ... is compensating consumers, not policing corporate conduct."); *Lyon v. Caterpillar, Inc.,* 194 F.R.D. 206, 216 (E.D.Pa.2000) ("[S]tate consumer protection acts are designed to protect the residents of the states in which the statutes are promulgated.").

> FN22. Section 6, which is generally applicable, *see Bushkin,* 473 N.E.2d at 670, provides:
>
> the factors relevant to the choice of the applicable rule of law include
>
> (a) the needs of the interstate and international systems,
>
> (b) the relevant policies of the forum,
>
> (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
>
> (d) the protection of justified expectations,
>
> (e) the basic policies underlying the particular field of law,
>
> (f) certainty, predictability and uniformity of result, and
>
> (g) ease in the determination and application of the law to be applied.
>
> Restatement (Second) of Conflict of Laws § 6 (1971).

Courts have generally rejected application of the law of a defendant's principal place of business to a nationwide class. *See In re Bridgestone/Firestone, Inc.,* 288 F.3d 1012, 1018 (7th Cir.2002) (applying Indiana lex loci delicti rule and stating that "[s]tate consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules"); *Relafen,* 221 F.R.D. at 277–78 (holding in antitrust case that Massachusetts and Pennsylvania choice of law rules would require that court apply law of state where consumers' purchases were made, rather than law of defendant's principal place of business); *Lyon,* 194 F.R.D. at 211–21 (applying Pennsylvania choice of law rules and Restatement to reject plaintiffs' argument that one state's law applied to nationwide claims). Thus, while it is tempting to apply the consumer protection laws of the states where defendants have their principal places of business to promote uniform results and the ease of managing a class, under the Restatement, the laws of the home states of the consumers govern.

Having smelled victory on the choice-of-law issue, defendants expect a knock-dead punch on their argument that the differences among the state consumer laws are so significant that they cause individual issues to predomi-

nate. Indeed, in a double-dare at oral argument, they waxed that no court in the nation has successfully certified a nationwide consumer class for litigation (as opposed to settlement) purposes.

Plaintiffs urge the court to deal with the differences among the states' laws by grouping the claims of class members from states with similar laws for trial. The First Circuit has approved of the use of grouping, as have numerous other circuits. *See* *Mowbray*, 208 F.3d at 296–97; *Relafen*, 221 F.R.D. at 278–87; *Klay*, 382 F.3d at 1262 ("[I]f the applicable***84** state laws can be sorted into a small number of groups, each containing materially identical legal standards, then certification of subclasses embracing each of the dominant legal standards can be appropriate."); *Hanlon*, 150 F.3d at 1022–23; *In re The Prudential Ins. Co. of Am. Sales Practices Litig.*, 148 F.3d 283, 315 (3d Cir.1998); *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 741–42 (5th Cir.1996) (accepting that grouping may be feasible but rejecting its application in the case at hand). It is true, however, that "when dealing with variations in state laws, the same concerns with regards to case manageability that arise with litigation classes are not present with settlement classes, and thus those variations are irrelevant to certification of a settlement class." *Warfarin*, 391 F.3d at 529 (but acknowledging grouping of state laws as a method to make a litigation class manageable).

Courts should look at how issues are likely to play out in the context of the case to see what individual issues are likely to arise, and what state law differences are irrelevant and may be ignored. *See* *Mowbray*, 208 F.3d at 296–97 ("Under either [grouping's] rule, the factual proffer will be largely the same ...."); *Relafen*, 221 F.R.D. at 279 n. 17 ("Yet with the exception of the variation discussed below, such differences [in state law] prove largely irrelevant.").

However, the burden is on plaintiffs to demonstrate "through an extensive analysis" that grouping is feasible. *Castano*, 84 F.3d at 742; *see also* *Zinser*, 253 F.3d at 1189–90 (stating that plaintiff seeking certification of nationwide class to which the law of forty-eight states potentially applies "bears the burden of demonstrating 'a suitable and realistic plan for trial of the class claims' " (citation omitted)); *In re Paxil Litig.*, 212 F.R.D. 539, 545 (C.D.Cal.2003) (holding that plaintiffs failed to meet their burden of showing that variances within each grouping were nonmaterial because in some cases plaintiffs' groupings were unsupported and the characterizations of others were "simply and outright wrong"); *Lyon*, 194 F.R.D. at 218–21 (rejecting four-part grouping of consumer fraud acts due to insufficient analysis, and reviewing caselaw rejecting similar groupings).

Providing the Court with a detailed fifty-state survey, which plaintiffs have not contested, defendants point to the following differences among the state consumer protection laws. Under Iowa law cited by plaintiffs, consumers may not bring claims. *See* *Molo Oil Co. v. River City Ford Truck Sales, Inc.*, 578 N.W.2d 222, 228 (Iowa 1998).[FN23] Under the laws of Alabama, Alaska, Georgia, Kentucky, Louisiana, Mississippi, and Montana, there is no right to bring a class action to enforce the consumer protection statutes. *See* Ala.Code § 8–19–10(f); Alaska Stat. § 45.50.531(b) (repealed provision that had allowed class actions); Ga.Code Ann. § 10–1–399(a); *Arnold v. Microsoft Corp.*, No. 00–CI–00123, 2001 WL 193765, at *6 (Ky.Cir.Ct. July 21, 2000); La.Rev.Stat. Ann. § 51:1409(A); Miss.Code Ann. § 75–24–15(4); Mont.Code Ann. § 30–14–133(1). Consumers in these states may be excluded out of hand. The states of Kansas, Missouri, New Jersey, Oregon, Washington, Alabama, Alaska, California, Georgia, Indiana, Maine, Massachusetts, Mississippi, Texas, and Wyoming possess special notice provisions for bringing consumer protection claims. *See* Kan. Stat. Ann. § 50–634(g); Miss.Code Ann. § 75–24–15(2); *Pointer v. Edward L. Kuhs Co.*, 678 S.W.2d 836, 842 (Mo.Ct.App.1984); N.J. Stat. Ann. § 56:8–20; Or.Rev.Stat. § 646.638(2); Wash. Rev.Code Ann. § 19.86.095; Ala.Code § 8–19–10(e); Alaska Stat. § 45.50.535(b)(1); Cal. Civ.Code § 1782; Ga.Code Ann. § 10–1–399(b); Ind.Code Ann. § 24–5–0.5–5(a); Me.Rev.Stat. Ann. Tit. 5, § 213(1–A); Mass. Gen. Laws ch. 93A, § 9(3); Tex. Bus. & Com.Code Ann. §§ 17.505, 17.5051; Wyo. Stat. Ann. §§ 40–12–109, 40–12–102(a)(ix). Plaintiffs have not alleged that they have complied with any notice provisions. While most states allow a plaintiff to give notice subsequent to the case being filed, others require dismissal of the complaint. Unless plaintiffs give evidence of compliance with the ***85** notice provisions, these states will be excluded.

> FN23. Defendants also urge that Puerto Rico does not allow private actions. However, Puerto Rico is not listed in plaintiffs' appendix as one of the jurisdictions in which they seek to bring a claim.

For the remaining states, defendants flag differences in requirements for establishing reliance, proximate cause, scienter, damages, and statutes of limitations, but in the context of the claims of consumer-patients under Medicare Part B, these variations in legal standards are unlikely to be

material. Significantly, plaintiffs have wisely noted that they are pressing only the theory that defendants intentionally made fraudulent misrepresentations of AWP.[FN24] Therefore, different standards governing scienter do not present individual issues. Defendants point to no state where the intentional, fraudulent acts alleged would be permitted under the consumer protection statute. States do have different definitions of reliance and proximate cause. *Compare* *Philip Morris, Inc. v. Angeletti*, 358 Md. 689, 752 A.2d 200, 235 (2000) ("Reliance by consumers would also seem to be a necessary precondition to awarding restitution or damages pursuant to the statutory consumer protection provisions pleaded by Respondents.") *with* *Izzarelli v. R.J. Reynolds Tobacco Co.*, 117 F.Supp.2d 167, 176 (D.Conn.2000) ("Under CUTPA, if the message is false, then it is a deceptive act without inquiry into whether the consumer actually believed the message or whether the consumer acted reasonably in relying on it."). However, in this context, where consumers (elderly people with cancer or another serious disease) make a percentage co-payment based on the stated AWP, there is no indication that different definitions of reliance and causation will matter or cannot be resolved as a matter of law prior to trial. Thus, the common legal and factual issues predominate over the individual ones.

FN24. (Corrected Plaintiffs' Reply Mem. in Support of Class Cert. at 23 n. 71.)

6. *Superiority*

[8] Rule 23(b)(3) requires a class action to be "superior to other available methods for the fair and efficient adjudication of the controversy." "In adding 'predominance' and 'superiority' to the qualification-for-certification list, the Advisory Committee sought to cover cases 'in which a class action would achieve economies of time, effort, and expense, and promote ... uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results.' " *Amchem*, 521 U.S. at 615, 117 S.Ct. 2231 (citation omitted). "[A] class action has to be unwieldy indeed before it can be pronounced an inferior alternative—no matter how massive the fraud or other wrongdoing that will go unpunished if class treatment is denied—to no litigation at all." *Carnegie*, 376 F.3d at 661.

With respect to Medicare Part B consumer patients making co-payments, it is cost effective to focus the litigation in one forum, and one case will promote a uniformity of results appropriate for a nationwide reimbursement program. However, from a manageability point of view, it is appropriate to have subclasses of consumers for the drugs of each manufacturer group. Therefore, there will be five subclasses, one for each Track One group. The Court defers deciding whether to hold a separate trial with respect to each manufacturer group.

Plaintiffs provided the Court with a brief summary of the issues to be decided at each phase. The Court is satisfied that as to the Medicare Part B beneficiary class, a class action is a superior method to resolve the dispute. Defendants have not identified any plausible individual issues that will arise with regard to these class members other than their proofs of damages, which may entail reviewing documents to determine whether each patient was required to pay a percentage-based co-pay and whether each has supplemental insurance. These damages calculations will be largely formulaic. Even if some corroboration and individualized attention is necessary, it is unrealistic to expect millions of beneficiaries across the nation to repeatedly prove these claims. The number of drugs at issue in the Medicare Part B context is limited to about seventeen, so even if deciding spreads by individual NDCs is necessary, it would not be unmanageable.

B. PHYSICIAN–ADMINISTERED CLASS OF THIRD–PARTY PAYORS THAT PAY MEDICARE PART B SUPPLEMENTAL INSURANCE

Plaintiffs seek to certify a class of TPPs that pay MediGap supplemental insurance ***86** for co-payments made by Medicare Part B beneficiaries.

[9] Defendants do not challenge numerosity under Fed.R.Civ.P. 23(a), a requirement I find is met, but do challenge typicality. The issue is whether UFCW is a typical representative for the TPP class of payors that pay Medicare supplemental insurance. While defendants argue that UFCW does not pay the full 20% coinsurance payment in all cases, UFCW's underlying legal theory and its motivations are similar to those of the other TPP class members that make full payments. Thus, I find that UFCW meets the typicality and adequacy requirements.

[10] Again, the common factual issues (as outlined in the previous section) predominate, in that the TPPs are required by contract to supplement Medicare drug co-payments. Some TPPs may have greater sophistication with respect to the existence of spreads because they purchase self-administered drugs, but there is no evidence that TPPs purchase physician-administered drugs or know of the mega-spreads that exist for these drugs. In any event, the reimbursement rate is set by statute, not negotiation.

Therefore, there appear to be no factual differences with respect to reliance or causation that predominate over the common issues. Defendants have not pressed an extensive predominance challenge in this context regarding factual issues.

Rather, defendants challenge class certification with respect to these TPPs primarily on the ground that the legal differences among the state consumer protection statutes predominate over the common legal questions. Plaintiffs have not examined which state consumer protection statutes, if any, permit corporations, unions or other entities to bring such class actions. It is apparent that many do not, and those that do have widely varying requirements. *See, e.g.*, *Scully Signal Co. v. Joyal*, 881 F.Supp. 727, 741 (D.R.I.1995) (holding that corporations may not bring suits); *Zine v. Chrysler Corp.*, 236 Mich.App. 261, 600 N.W.2d 384, 392 (1999) (allowing corporations to bring claims only if they made purchase for their own use); *Nelson v. Lusterstone Surfacing Co.*, 258 Neb. 678, 605 N.W.2d 136, 141 (2000) (limiting application to acts that affect public interest); Tex. Bus & Com.Code § 17.45(4) (allowing only businesses with assets of less than $25 million to bring suits). Plaintiffs have not proposed feasible groupings of these statutes, as would be necessary to proceed. Accordingly, the motion to certify a nationwide class is denied without prejudice.

[11] However, the Court will certify a statewide class of TPPs that pay supplemental insurance covering Medicare Part B co-payments under Mass. Gen. Laws ch. 93A. Under Chapter 93A, no notice is required prior to a corporate suit, *see* *Nader v. Citron*, 372 Mass. 96, 360 N.E.2d 870, 874 (1977), and corporations may bring class action claims, *see* Mass. Gen. Laws Ann. ch. 93A, § 11 (West 2005). Chapter 93A does not require a showing of reliance to state a claim. *See id.* (allowing claims by anyone who has been injured "as a result of" unfair or deceptive business practices); *Heller Fin. v. Ins. Co. of N. Am.*, 410 Mass. 400, 573 N.E.2d 8, 13 (1991) ("[W]hile [the plaintiff] need not show actual reliance on the misrepresentation, the evidence must warrant a finding that a causal relationship existed between the misrepresentation and the injury.").

From a superiority point of view, it makes sense to try this case with the Medicare Part B beneficiaries' trial, and management issues are not insuperable because damages are formulaic: TPPs paying MediGap-type supplemental insurance paid some or all of the 20% copayment, which in turn was based on AWP. *See* *Klay*, 382 F.3d at 1259–60 ("Particularly where damages can be computed according to some formula, statistical analysis, or other easy or essentially mechanical methods, the fact that damages must be calculated on an individual basis is no impediment to class certification."). In addition, the trial of a statewide class will provide important information for an accurate evaluation of claims under other states' laws. *Cf.* *Bridgestone/Firestone*, 288 F.3d at 1020 ("Once a series of decisions or settlements has produced an accurate subset of the claims ... the others in that subset can be settled or resolved at an established price.").

***87 C. THIRD–PARTY PAYOR PHYSICIAN–ADMINISTERED CLASS (NON–MEDICARE PART B)**

[12] Plaintiffs seek to include as part of the physician-administered class all TPPs that pay for physician-administered drugs outside the context of Medicare Part B and consumers that make percentage-based co-payments for these drugs under their private insurance plans. Defendants do not dispute that the class meets the numerosity/commonality/typicality/adequacy requirements of Fed.R.Civ.P. 23(a), and I find that it does.[FN25] However, defendants do argue that individual factual and legal issues predominate over common ones because (1) each TPP had a different level of knowledge regarding the spread; and (2) each TPP negotiated separate agreements with doctors or groups of doctors. Plaintiffs argue that the key factual issue, the use of AWP, is common to the entire class because most drug reimbursements in physician-administered contracts are based on AWP. (Hartman Rebuttal ¶ 21(b).) Studies show that the percentage discount off of AWP in the physician-administered context mostly varies from 0 to 10%, *with an average reimbursement of 98% of AWP*. (Rosenthal 10.)

> FN25. The parties did not separately address whether a TPP can serve as a typical representative of its own plan beneficiaries in the context of non-Medicare Part B physician-administered drugs. Unlike in the Medicare Part B context, here the TPP serves as the intermediary for its plan beneficiaries in negotiating with providers over reimbursement rates, and no conflict is immediately apparent. Plaintiffs have not taken the position that these plan beneficiaries could prevail even if their plans do not. In the absence of a challenge, or better briefing, I do not dwell on the point.

Plaintiffs rely heavily on their expert, Hartman, to show liability and aggregate damages based on the com-

mon use of AWP. In evaluating a motion for class certification, one of the thorniest issues is deciding the weight to be accorded an expert's opinion. "The question for the district court at the class certification stage is whether plaintiffs' expert evidence is sufficient to demonstrate common questions of fact warranting certification of the proposed class, not whether the evidence will ultimately be persuasive." *Visa Check*, 280 F.3d at 135. "[T]he Court's inquiry is limited to whether or not the proposed methods [for computing damages] are so insubstantial as to amount to no method at all." *Klay*, 382 F.3d at 1259 (citation omitted) (alteration in original). Plaintiffs need not "have selected a particular econometric model for demonstrating impact (or proving damages) at the class certification stage." *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 155 (3d Cir.2002). However, it is not permissible to use methods such as averaging damages to sweep individual issues under the judicial rug. *Bell Atl. Corp. v. AT & T Corp.*, 339 F.3d 294, 304–05 (5th Cir.2003) (finding that large number of independent factors that would affect what, if any, damages were suffered by each class member could not be approximated into an average damages amount).

Hartman believes that providers like doctors are natural targets of the AWP scheme because they have the power to move market share. (Hartman Decl. Exec. Summ.) Acknowledging that TPPs typically expect that AWP is larger than the average sales price ("ASP") by a "reasonably predictable amount" (Hartman Decl. ¶ 10), Hartman intends to calculate the spreads for the drugs allegedly subject to the AWP scheme and compare those spreads to "but for" spreads, that is, spreads for comparable drugs that are unaffected by the AWP scheme and fraud.[FN26] As a cross-check, he will compare the calculated "but for" spread with industry-wide surveys. In addition, under the "revealed preferences" method, Hartman will calculate the expected spread by examining the contracts for the drugs affected by the alleged fraud to determine what the parties expected the spread between AWP and the ASP to be, and compare that expected ***88** spread with the actual spread. (Hartman Rebuttal ¶ 50 ("Simply stated, economic agents reveal their preferences, and implicitly the information they relied on, by their actual market decisions and behavior.").) Hartman estimates that the range of actual reimbursement rates in TPP contracts with providers in the self-administered context was AWP minus 13% to 17% (Hartman Decl. ¶ 30(g)); Young uses the range of AWP minus 14% to 18% (Young ¶ 134). In the physician-administered context, the range is AWP minus 0% to 10%. (Rosenthal 10.) Hartman terms his overall approach the "yardstick method" because he intends to determine what the market reasonably expected the spread to be on average (e.g., AWP is 25% above the average sales price, ASP), and compare this number to the actual spread (e.g., AWP is 100% above ASP) to calculate aggregate class-wide damages.[FN27] (Berndt ¶ 212.)

> FN26. Dr. Berndt notes that Hartman proposes using a "multiple regression analysis" to "attempt in a more sophisticated statistical manner to control for factors other than the manufacturer's alleged illegal behavior" in choosing comparator drugs (Berndt ¶ 217), but that "it is unclear to [Berndt] at this time precisely how Dr. Hartman plans to proceed" with this analysis (Berndt ¶ 218).

> FN27. Hartman identifies a range of expected ASPs of 20% to 23% below AWP generally in his rebuttal declaration. (Hartman Rebuttal 63.) In his original declaration he varies the ranges of expected spreads depending on who moves market share. He identifies the yardsticks—the percentage amounts that TPPs believe ASPs are below AWPs—in the PBM context as being 16% to 33% for single source drugs, and 10% to 20% for multiple source drugs, and in the physician-administered context as being 0% for Medicare and 18% to 33% for the private drugs. (Hartman Decl. ¶ 33.)

Hartman does not go into much detail on how to apportion individual damages in Phase II, but he proposes using each TPP's actual contract reimbursement rate (e.g., AWP minus 15%) to determine what rate the TPP would have paid in the but-for world, on the assumption that the actual contract rate takes into account the knowledge and market power of each TPP. (Hartman Decl. attach. F ¶ ¶ 4–5; Hartman Rebuttal ¶¶ 54, 58, fig. 1–C.) In other words, weaker market participants tend to reimburse at AWP minus 14%, and stronger, more knowledgeable participants tend to reimburse at AWP minus 18%. (Hartman Rebuttal ¶ 58 ("While it is true that the Class includes payors characterized along a variety of dimensions which result in a variety of discounts off AWP and therefore a variety of reimbursement rates ... reimbursement rates have been found to be consistently within 14%–18% off AWP. This finding argues for the same shaped distribution and the same location on the distribution for the favored payors, the least favored payors and the average payor, relative to the artificially inflated AWP ....").) He then would measure the difference between each TPP's but-for

payment and the payment that TPP made in the actual world to calculate damages.

Hartman has performed these calculations for several drugs by way of example. Based on his preliminary information, he calculates the "but-for" spread between AWP and ASP in the physician administered context as being in the range of 18% to 33%. (Hartman Decl. ¶ 33.) Under Medicare Part B, he calculates the but-for spread as 0% because it is set by law. Under Hartman's calculation, Vepesid, an injectable, physician-administered drug, demonstrated actual spreads that range from a low of 291% in 2002:Q1 to a high of 24,249% in 2001:Q3. (Hartman Decl. ¶ 37.) Hartman assumes that reimbursement was made on average at AWP minus 15%. (Hartman Decl. ¶ 37, Table 3A.) After calculating a but-for AWP, his calculations result in $158 million in aggregate overcharges for this NDC for the period from 1997 to 2002. (Hartman Decl. ¶ 37.)

Defendants disagree with Hartman's contention that AWP is the driving force behind reimbursement in the physician-administered context, and claim that individual issues predominate. They argue that insurers individually negotiate physician fee schedules with doctors or doctor groups, which often have strong leverage depending on the specialty and geographic location of the practice, and that insurers vary dramatically in sophistication and knowledge about the spreads. Further, defendants argue that it is difficult to disaggregate the "bundle" of negotiated services in order to separate drug reimbursement costs from the fees for administration of the drugs. The most common interdependency is between reimbursement for the drug and reimbursement to the physician for the act of administration, with the former ***89** representing a net subsidy for the latter. (Gaier ¶ 62.)

Numerous courts have held that the need to examine individual negotiations or individual contracts to determine injury weighs against class certification, for it requires an unwieldy examination of each transaction to decide if there is proximate cause. *See* *Robinson v. Tex. Auto. Dealers Assoc.*, 387 F.3d 416, 423–25 (5th Cir.2004) (reversing certification of class of consumers whose sales contracts contained a tax as a line item separate from the cash price because determining whether a particular consumer negotiated based on the cash price or the bottom line required individual evaluation); *Klay*, 382 F.3d at 1263–1266 (reversing certification of breach of contract claims by doctors claiming defendants programmed computers to automatically underpay in some situations, where determination of whether doctor was underpaid required an individual evaluation of each contract and each transaction); *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 187–90 (3d Cir.2001) (affirming denial of certification where determination of whether class member was injured in particular instance would require evaluation of circumstances of trade, including whether a better price than that obtained by the agent was available based on each class member's characteristics and order specifications); *Poulos v. Caesars World, Inc.*, 379 F.3d 654, 664–66 (9th Cir.2004) (affirming denial of certification on causation grounds where establishing injury would depend on showing that individual class members were fooled by electronic machines resembling poker games into thinking that machines were programmed to follow random odds of winning at poker); *Lienhart v. Dryvit Sys., Inc.*, 255 F.3d 138, 148–49 (4th Cir.2001) (reversing certification where determination of liability would depend on whether in each case third parties both received and followed installation instructions from defendant).

In defendants' view, these variables—i.e., market power of doctors and sophistication and market power of TPPs—show why "a common course of conduct is not sufficient to establish liability of the defendant to any particular plaintiff." *Moore v. PaineWebber, Inc.*, 306 F.3d 1247, 1251 (2d Cir.2002) (holding that liability could not be established by proof of a central, coordinated fraudulent scheme where misrepresentations were not materially uniform because "each plaintiff must prove that he or she personally received a material misrepresentation, and that his or her reliance on this misrepresentation was the proximate cause of his or her loss"); *compare id. with Carnegie*, 376 F.3d at 662–63 (holding that class consisting of persons allegedly defrauded by failure of banks and tax preparers to reveal that tax preparer was engaged in self-dealing was properly certified because RICO fraud claims could be separated into common liability claims and individual injury claims).

Defendants' expert Stephen Young, who is not an economist but has industry experience as a consultant, attacks Hartman's expert methodology by arguing that (A) most commercial payors did not negotiate with physicians based on their drug acquisition costs, and even if they did they did not premise those negotiations on the view that AWP was a "signal" of acquisition costs; (B) the reimbursement attributable to a particular physician-administered drug, and the rationale for that reimbursement, cannot be assessed without a consideration of

the entire fee schedule of negotiated services; (C) because of the use of the "J–Codes", the analysis of physician-administered drugs will require significant individual inquiry in a manual process to determine the reimbursement level; and (D) unlike in retail pharmacy reimbursement, AWP is not consistently referenced in contracts for the reimbursement of physician-administered drugs. (Young Sur–Reply ¶ 4.) Young also states that the use of J–Codes in the generic context is particularly nettlesome because one J–Code covers all NDCs from multiple manufacturers.[FN28] (*Id.* ¶ 44.)

> FN28. Plaintiffs hotly contend that Young has submitted material that is misleading, unreliable and so false as to be sanctionable. In particular, they contend that Young misrepresented that contracts were not based on AWP, and that forty-nine percent of the contracts he relied on did not even include a fee schedule. Further, they disagree that it will be too difficult to cross-walk between the "J–Codes" used in physician-administered transactions and NDCs. This shrill debate between Hartman and defendants' experts, Young and White, about the reliability of the underlying data and problems of sample bias is the kind of technical dispute that should not be resolved in a motion for class certification. Rather, it should be the subject of a *Daubert* hearing. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

***90** While not critiquing the use of a yardstick in the physician-administered context, the independent expert, Berndt, expresses concern with Hartman's analysis because of the poor quality of the data available. He cites "accounting ambiguities" concerning whether physician-administered drugs were covered as medical or drug benefits and a J–Code classification system that "obfuscated true transaction[ ] prices and utilization" in concluding that "the quality of general information concerning actual prices for physician-administered services is likely to have been very poor." (Berndt ¶ 228.) He also points out that the "high touch, high cost" characteristics of physician-administered drugs imply that the statistical variance from any sample of information could be "very high." (Berndt ¶ 229.) To exacerbate the difficulties in deciphering the data, the literature in the public domain is not helpful in the area of generic drugs administered by physicians. (Berndt ¶ 229.) In a follow-up memorandum, Dr. Berndt states that he expects that the cross-walking between the five-digit J–Code and the eleven-digit NDC code that will be necessary to track actual physician-administered drug utilization and unit prices "is more likely to be feasible and reliable for the more recently introduced and typically more expensive biotech physician-administered drugs, and much less likely to be feasible and reliable for older, and in particular, multi-source off-patent and generic products." (Berndt Mem. of Aug. 9, 2005 at 2.) He adds that cross-walking will be less feasible for reimbursements made prior to 2000. (*Id.*)

The important question in a class certification context is whether after a sneak preview of the issues, the expert approach appears fundamentally flawed—an issue usually vetted more fully at a *Daubert* hearing based on a more detailed record.[FN29] The present record suggests concerns about the feasibility of using the yardstick methodology in the physician-administered context. How will plaintiffs find reliable comparator drugs to derive the but-for spread? How difficult is it to get reliable survey data on spreads in light of the ambiguities created by J–Codes and the overall lack of pricing transparency? However, it is inappropriate at this stage of the proceedings to determine on the merits whether Young's analysis of the quality of the data or the market is better than Hartman's. Based on the current cold record, I conclude that Hartman's but-for methodology for calculating damages on an aggregate class-wide basis, while preliminary, is not so insubstantial as to preclude class certification.

> FN29. Track One defendants have filed a motion to strike the Declaration of Raymond S. Hartman under *Daubert.* That motion is ***DENIED*** without prejudice.

The next question is how individual and common legal issues affect predominance. Plaintiffs have asserted claims under state consumer protection laws without demonstrating that those statutes cover corporations. The Court explained in the previous section that many such laws do not cover corporations and others have substantially varying standards and burdens. Therefore, predominance is satisfied only for a statewide class under Massachusetts law, Chapter 93A.

Finally, pursuant to Fed.R.Civ.P. 23(b)(3), this Court must determine whether a class is a superior vehicle for resolving plaintiffs' claims. A key factor in making this determination is manageability, which focuses on pragmatic concerns. Defendants argue that Phase II will consume years of jury time because each defendant will have

the right to a jury trial on its affirmative defenses. Further, defendants argue that because of different levels of knowledge, each TPP would have to prove its expectation as to the spread and the damages suffered as a result of the alleged fraud. The First Circuit approves of the use of bifurcation in class trials, especially where the individual issues are not overly complex. *See* *Smilow*, 323 F.3d at 41; *Tardiff*, 365 F.3d at 6–7. Nonetheless, the court ***91** must be careful to avoid certifying a class where

> [c]ommonality among class members on issues of causation and damages can be achieved only by lifting the description of the claims to a level of generality that tears them from their substantively required moorings to actual causation and discrete injury.

In re Fibreboard Corp., 893 F.2d 706, 712 (5th Cir.1990).

The Court is concerned that the proposed bifurcated trial may prove to be unmanageable, given that Phase II appears to require a separate individualized proceeding for each TPP. While Hartman's yardstick methodology may demonstrate average injury to the class and aggregate damages, the TPPs' injuries vary based on their individual expectations of the price and their reimbursement rates. While Hartman mentions using actual contract reimbursement rates in Phase II, plaintiffs have not adequately explained how each class member will show where its expectation as to the spread between AWP and ASP falls within the 18% to 33% range (and hence damages) absent an individual trial.[FN30] The methodology in Phase II is still abstract. While this is not fatal at this preliminary stage, *Klay*, 382 F.3d at 1259, plaintiffs will have to provide more details in order to survive a *Daubert* challenge.

> FN30. Bifurcation of a trial must be carefully crafted to avoid violating the Seventh Amendment by subjecting jury determinations made at the first phase to reevaluation at the second phase. *See* *Blyden v. Mancusi*, 186 F.3d 252, 268, 271 (2d Cir.1999) (reversing judgments in favor of two plaintiffs because the first jury found that there had been illegal "reprisals" generally by the defendants and the second jury was asked to specify whether particular acts were illegal reprisals against particular plaintiffs); *Matter of Rhone–Poulenc Rorer Inc.*, 51 F.3d 1293, 1303 (7th Cir.1995) (reversing certification where first jury was to determine whether defendants acted negligently generally in failing to screen blood for HIV and second jury was to determine damages and defenses such as proximate cause and comparative negligence, because findings pertinent to defenses necessarily overlapped with findings pertinent to liability).

Additionally, plaintiffs admit that defendants may be entitled to a jury trial on defenses such as when, if ever, individual TPPs had sufficient knowledge to trigger the statute of limitations and whether the market power of the doctors with whom a TPP dealt was an intervening cause of damages, breaking the causal chain. To further complicate matters, the allegations span a decade, requiring individualized inquiries concerning each TPP in different time periods. While it is conceivable that a method such as grouping categories of class members (as suggested by the First Circuit in *Tardiff*) may be feasible—particularly since the number of TPPs covering physician-administered drugs in Massachusetts would be a small subset of the national class—plaintiffs have failed to explain why class certification is superior if an extensive separate trial will be needed for each TPP at the damages phase.

However, the need for individualized proceedings on damages does not necessarily defeat class certification because the Court has the authority to certify a class for liability only pursuant to Rule 23(c)(4)(A) and decertify the class for damages. This approach is a logical option if plaintiffs' Phase II methodology does not survive a *Daubert* motion. Because the Court will have to try the claims that defendants fraudulently inflated AWPs of physician-administered drugs in the Medicare Part B trial, it makes sense to try the common claims involving the physician-administered drugs together in one trial with subclasses for each manufacturer.

Therefore, the motion to certify a class of TPPs and consumers paying for physician-administered drugs is ***ALLOWED*** with respect to claims under Chapter 93A involving drugs priced at a discount off of AWP. In the context of generic physician-administered drugs reimbursed through private TPPs, plaintiffs have not provided an adequate description of how the scheme or the but-for yardstick could work with generic pricing based on a commercial MAC. MAC varies from payor to payor, from contract to contract, and in some instances, from transaction to transaction. (Gaier Surreply ¶ 53.) Accordingly, generics will be considered only to the extent that the price in the contract between the TPP and physician is expressly predicated on AWP.

***92 VI. CLASSES TWO AND THREE: STATE LAW AND RICO CLAIMS PERTAINING TO SELF–ADMINISTERED DRUGS**

[13] Plaintiffs seek to certify third-party payor and consumer classes in the area of self-administered drugs and specialty pharmacy drugs. The proposed second class includes the state consumer protection law claims; the proposed third class includes the RICO claims and the state common law conspiracy claims. While not disputing that the proposed classes satisfy the Rule 23(a) factors, defendants strenuously argue that the individual issues involving each TPP and consumer class member far outweigh any commonality among the class members' claims.

Plaintiffs' core contention is that each PBM enters into an agreement with each manufacturer to defraud TPPs and consumers. In RICO parlance, this unlawful relationship is the RICO "enterprise." 18 U.S.C. § 1962(c). Under the common law claims, the agreement to defraud constitutes the conspiracy. Plaintiffs allege that manufacturers typically give PBMs secret rebates that are not disclosed to TPPs. Even if they are aware that some rebates exist, TPPs are not cognizant of the size of the rebates.[FN31] Because PBMs typically gain a large share of revenue from rebates from manufacturers, sometimes more than they do from administrative fees from insurers (Schondelmeyer ¶ 76), their financial interest lies in their relationship with drug manufacturers. This accounts for plaintiffs' allegation that there is a conspiracy between the drug manufacturers and the PBMs at the expense of their TPP clients.

> FN31. It is worth noting that the Congressional Budget Office recently conducted a study on whether PBMs and manufacturers should be forced to disclose the true acquisition price of drugs, and decided that in the situation of a partial oligarchy, as exists where several patent-protected products are competing for market share, secrecy is beneficial to competition. (Berndt ¶ 164.) This is because manufacturers would not give certain purchasers large discounts if that would mean that all purchasers would demand the same discounts. (Berndt ¶¶ 163–64.) Berndt notes that some economists believe secrecy also helps prevent implicit collusion on price among oligarchical manufacturers (Berndt ¶ 150), and that the FTC "has reinforced the conclusion that mandated increased cost transparency is likely to increase rather than decrease consumers' prices" (Berndt ¶ 163). Plaintiffs disagree with this line of reasoning.

Circuits have formulated different standards for evaluating predominance for proposed classes under RICO. *See* *Poulos*, 379 F.3d at 666 n. 3 (noting circuit split). The Fifth Circuit has adopted a presumption against certification of RICO cases. *See* *Sandwich Chef of Tex., Inc. v. Reliance Nat'l Indem. Ins. Co.*, 319 F.3d 205, 219 (5th Cir.2003). The Seventh Circuit disagrees. *See* *Carnegie*, 376 F.3d at 663. Circuits also disagree on the certifiability of nationwide classes involving claims of fraud where reliance must be proved. *Compare* *Sandwich Chef*, 319 F.3d at 205 ("Fraud actions that require proof of individual reliance cannot be certified [under Rule 23(b)(3)] ....") *with* *Prudential Ins.*, 148 F.3d 283 at 315 ("[T]he presence of individual questions as to the reliance of each investor does not mean that the common questions of law and fact do not predominate.") (citation omitted).

Plaintiffs emphasize that the First Circuit differs from other circuits in that it is not necessary to prove direct reliance on misrepresentations to establish liability. *See* *Systems Mgt., Inc. v. Loiselle*, 303 F.3d 100, 104 (1st Cir.2002) ("[C]riminal fraud under the federal statute does not require 'reliance' by anyone: it is enough that the defendant sought to deceive, whether or not he succeeded."); *Carnegie*, 376 F.3d at 662 (stating that Second, Fourth, and Fifth Circuits require direct reliance); *Summit Props. Inc. v. Hoechst Celanese Corp.*, 214 F.3d 556, 560 n. 16 (5th Cir.2000) (noting that Third, Sixth, Seventh, Eighth, and Eleventh Circuits also require direct reliance); *cf.* *Bank of China, N.Y. Branch v. NBM L.L.C.*, 545 U.S. 1138, 125 S.Ct. 2956, 162 L.Ed.2d 886 (2005) (granting petition for writ of certiorari on the question of whether "civil RICO plaintiffs alleging mail and wire fraud as predicate acts must establish 'reasonable reliance' "). In *Loiselle*, the First Circuit held that underpaid workers could recover damages against their employer, a cleaning company that had filed false invoices with a college being cleaned. 303 F.3d at 101–103. The defendant admitted that but-for its false invoices, ***93** the college would have insisted that the defendant comply with the prevailing wage laws. *Id.* at 103. The defendant contended, however, that it never made false statements to the workers, nor did the workers rely on defendant's false statements to the college. *Id.* The First Circuit held that direct reliance on such statements is not required by the RICO statute; however, it stated that it was essential that plaintiffs show proximate cause, for

> proximate cause—largely a proxy for foreseeability—is not only a general condition of civil liability at common law but is almost essential to shape and delimit a rational

remedy: otherwise the chain of causation could be endless.

Id. at 104. *Compare id. with* *Sandwich Chef*, 319 F.3d at 222–23 (holding that "a RICO predicate act 'visited upon a third person' is generally too remote to permit a recovery from a person who complains of injury flowing from that act," with narrow exception for "direct and contemporaneous result [s]"). "Reliance is doubtless the most obvious way in which fraud can cause harm, but it is not the only way." *Loiselle*, 303 F.3d at 104.

Applied to this case, *Loiselle* establishes that the plaintiff class members need not have heard or directly relied on the AWPs sent by defendants to the publishers (which are the fraudulent acts alleged by the SAMCC). However, class members must still demonstrate a link between defendants' sending the AWPs to publishers and the injury class members suffered.

Young argues that Hartman's analysis of the methodology for calculating class injury and aggregate damages is fundamentally flawed in the PBM context because of the significant variation in contractual terms in PBM–TPP agreements, particularly with respect to rebates. (Young Decl. ¶¶ 211–12.) According to Young, payors either (a) do not delegate the rebate process to the PBM; (b) delegate a portion of that authority and retain the right to obtain rebates directly from the manufacturer; or (c) delegate the authority to the PBM and negotiate what portion will be retained by the PBM as an administrative fee and what portion the TPP will receive. (Young Decl. ¶ 213.) For payors that do elect to delegate all or part of the process of negotiating with manufacturers for rebates, the level of rebate pass-through varies widely, from 0% to 100%. (Young Decl. ¶ 214.) Some TPPs also elect to obtain a guaranteed rebate per script. (Young Decl. ¶ 214.) One study demonstrated that on average, 79% of rebates were passed through to the TPP. (Young Decl. ¶ 214.)

Plaintiffs raise two arguments to demonstrate that certification is appropriate despite these differences among class members. First, they argue that defendants' conduct impacted the baseline from which negotiations were made, thereby injuring all members of the class. The cases plaintiffs cite employing this "baseline-impact" reasoning are primarily antitrust cases, a key distinction because it may be assumed in those cases that by preventing competition in a typical market defendants have raised prices to all purchasers. *See, e.g.*, *Linerboard*, 305 F.3d at 151–52 ("If, in this case, a nationwide conspiracy is proven, the result of which was to increase prices to a class of plaintiffs beyond the prices which would obtain in a competitive regime, an individual plaintiff could prove fact of damage simply by proving that the free market prices would be lower than the prices paid and that he made some purchases at the higher price."); *Klay*, 382 F.3d at 1256; *Lorazepam*, 202 F.R.D. at 29–30 ("[W]hen a defendant is alleged to have participated in a nationwide price-fixing conspiracy, impact will presumed as a matter of law, and the predominance requirement of Fed.R.Civ.P. 23(b)(3) will be satisfied."); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 344–46 (E.D.Mich.2001); *Terazosin*, 220 F.R.D. at 696–97; *In re Auction Houses Antitrust Litig.*, 193 F.R.D. 162, 166 (S.D.N.Y.2000) ("Price fixing conspiracies, at least to the extent they succeed in fixing prices, almost invariably injure everyone who purchases the relevant goods or services.").

Here, plaintiffs do not allege an antitrust conspiracy to fix prices, but rather allege a conspiracy between each PBM and each manufacturer, which allegedly defrauded TPPs by providing PBMs with secret rebates and by inflating AWPs to obtain favorable formulary placement. (Hartman Decl. attach.***94** E ¶ 12.) Defendants argue that the PBM, wholesale, and pharmacy markets for the procurement of prescription drugs are highly-competitive; therefore, unlike in a price fixing conspiracy, "payors can leverage this competition to dissipate the effects of the alleged AWP scheme." (Gaier ¶ 31.) Payors could simply switch to a competitor PBM if they were not receiving competitive prices. (Gaier ¶ 32.) Supporting this theory, the FTC has repeatedly stated that competition among PBMs is vigorous (a point with which Professor Berndt agrees).[FN32] (Berndt ¶¶ 206, 209.) This means that knowledge of the availability of rebates would be widespread because of the marketing by PBMs. Hartman disagrees that PBMs are competitive with each other. (Hartman Rebuttal ¶ 65.) He points to (disputed) evidence that some PBMs have substituted higher cost drugs in the mail-order context and that post-contractual self-dealing is prevalent among PBMs (Hartman Decl. attach. C ¶¶ 23–26) to support his theory that PBMs substitute higher cost drugs on their formularies to obtain higher rebates or greater AWP-based administrative fees (Hartman Decl. attach. E ¶ 12). This debate cannot be resolved on this record. Even assuming a conspiracy between PBM and manufacturers, the anti-trust "base-line impact" paradigm, while analogous, does not neatly match the allegations here because the key allegation in the SAMCC is that pharmaceutical companies compete (not conspire) with one another for market share by boosting the AWP of competitive drugs or offering rebates. The Court would have to look at each arrangement

between the PBM and the manufacturer with respect to each TPP for each AWPID to determine whether there was a fraudulent relationship that had a baseline impact on the drug reimbursement rates paid by the TPP.

> FN32. Mr. Navarro, one of defendants' experts, states that PBMs were competitive throughout much of the class period. (Navarro 9.)

Second, Plaintiffs rely on the Hartman yardstick methodology as a method of calculating aggregate class damages. They assert they can prove through the economic theory of revealed preferences, through the comparison method, and through surveys that TPPs expected the spread between AWP and AAC or ASP to be no more than 33% for brand-name drugs. Plaintiffs assert that with these methods they can prove that the fraud was the proximate cause of injury (inflated price) even for those with bargaining power and sophistication. (Hartman Rebuttal ¶¶ 50–53, 55, 58.) Using the yardstick, plaintiffs assert they can calculate aggregate class damages or damages per drug.

Here, however, the yardstick methodology has a flaw because, among other things, Hartman does not explain how it takes into account pass-through rebates paid to the TPPs. In the physician-administered context, any rebates were kept by the doctor. In the self-administered context, rebates often flow back to the TPP through the PBMs. Many TPP class members pay AWP minus 14% to 18% for a particular drug minus the negotiated pass through of the manufacturer's rebate plus fees. (Bell 55–56.) In Hartman's original declaration, he stated that "[r]eview of PBM contracts in discovery materials produced to date suggests that such rebates may not be shared with TPPs." (Hartman Decl. ¶ 30(d).) In his reply affidavit, Hartman addresses this issue as to the pass-throughs by asserting that "manufacturer data and/or payor data can be used to calculate rebates actually paid to TPPs" in the Phase II damages trials:

> [T]he analysis of overcharges in reimbursement rates can be extended to explicitly account for rebates. Actual manufacturer data and/or payor data can be used to calculate rebates actually paid to third-party payors per unit of drug reimbursed. Absent the AWP scheme, it is presumed that such unit rebates would be reduced .... At the Damages Phase of this litigation, I will calculate the extent to which rebates were paid and the extent to which those rebate payments changed in the but-for world, to the extent allowed by the data and by the availability of appropriate yardsticks. However, it should be noted that if I ignore the change in rebates, the calculation of overcharges based upon reimbursement***95** rates ... and actual rebates alone will be conservative to Defendants.

(Hartman Rebuttal Decl. ¶ 60.) This preliminary and tentative solution is unsatisfactory because the aggregate damages per drug calculated in Phase I are likely to be too high unless the pass-through rebates are taken into account when measuring the reimbursement rates paid by TPPs. (Gaier ¶¶ 55–56.) Additionally, Hartman's bald explanation for how he would address rebates contradicts in part his stated position that "[n]or are [manufacturers] fully informed of the extent to which the PBMs share rebates with their client TPPs." (Hartman Decl. attach. C ¶ 25(a).) In addition, even where there are no pass-through rebates, the audit rights possessed by some TPPs would affect the expected spreads.

Applying the predominance requirement to the common and individual issues discussed, the Court finds that common issues do not predominate. While establishing the background of the alleged fraud and the defendants' conduct will involve substantial common issues, there are significant issues which are not common. The contractual relationship between each TPP and each PBM may commonly reference AWP as the benchmark, but there the similarity ends because the contracts provide different bundles of services and rebates. There are also different levels of sophistication and knowledge among the TPPs. Because of the variability in TPPs' contracts with PBMs, plaintiffs are unable to show that each TPP class member paid more than it would have in the absence of the fraud via common proof. Significantly, many putative TPP class members (including those covering roughly 25% of persons with private insurance) purchased drugs themselves and therefore had first hand knowledge of the acquisition costs for drugs. (Young Decl. ¶¶ 5, 153.)

[14] Finally, even if Hartman's methodology could be fine-tuned, the class of all 11,000 TPPs is not manageable. It is true that many cases state that the need for an individualized damage proceeding need not always preclude class certification. However, most of those cases involve damages calculable according to a formula or template. *See* *Smilow*, 323 F.3d at 40 ("Common issues predominate where individual factual determinations can be accomplished using computer records, clerical assistance, and objective criteria—thus rendering unnecessary an evidentiary hearing on each claim."); *Klay*, 382 F.3d at 1260 ("Of course, there are also extreme cases in which computation

of each individual's damages will be so complex, fact-specific, and difficult that the burden on the court system would be simply intolerable ....").

As in the physician-administered context, damage determinations would necessitate individual jury trials in which defendants can assert defenses and challenge the TPP's actual expectations of the range. The issues are more complicated in this context given the complex web of participants, and the higher level of understanding of this market in general. This would not be the simple administrative proceeding before a master suggested by plaintiffs.

Holding 11,000 individual damages trials in Part II is a management nightmare, and class certification is not a superior method for resolving the fraud claims of each TPP. Many TPPs (unlike the sick elderly in the first class) are well-heeled corporations (Aetna, Cigna, Blue Cross/Blue Shield companies) able to defend their interests if they believe they have been defrauded. Plaintiffs assert that thousands of Taft–Hartley funds do not have the resources to devote to the preparation of the case on an individualized basis, but I have no "sorting hat" to cluster the plans.

Essentially, I am persuaded that the individual issues of each TPP will overwhelm the common questions and render the class action inefficient. The argument that this would be a manageable class is too large a pill to swallow. *See* *In re Sch. Asbestos Litig.*, 789 F.2d 996, 1011 (3d Cir.1986) (stating that "manageability is a serious concern" where class pressed claims against fifty defendants for "[i]n a sense, a whole industry is on trial," but allowing case to proceed with the caveat that certification was conditional); *Robinson*, 387 F.3d at 426 (reversing certification where district court "adopted a figure-it-out-as-we-go-along approach" to dealing ***96** with the fact that several hundred defendants would each offer an individualized defense).

I inject one last point: I have inadequate information about specialty pharmacies to certify a class involving reimbursements by TPPs for drugs sold by them.

Accordingly, I ***DENY*** the motion to certify classes two and three.

VII. *ORDER*

For the reasons stated above, I order the following:

(1) The motion to certify a nationwide class of Medicare Part B beneficiaries is deferred pending plaintiffs' proposed amendment to add individual class representatives. I will then certify the nationwide class (except in those states where class actions are not authorized or notice was not given) if adequate individual class representatives are found.

(2) The motion to certify a nationwide class of TPPs that pay MediGap supplemental insurance to cover Medicare co-payments is ***DENIED***, but the Court will certify a statewide class under Mass. Gen. Laws ch. 93A.

(3) The motion to certify a nationwide class of TPPs and consumers paying for physician-administered drugs in the private context based on AWP is ***DENIED***, but the Court will certify a statewide class for brand-name drugs and those generic drugs for which reimbursement was explicitly based on AWP, not MAC pricing.

(4) The motion to certify a nationwide class of consumers and TPPs paying for self-administered drugs is ***DENIED***.

(5) Plaintiffs shall file their proposed amendment adding individual class members within sixty days of the date of this opinion, together with supporting documentation. Any depositions shall take place within thirty days of the amendment. Any challenge to adequacy or typicality shall be filed within forty-five days of the amendment. Any opposition shall be filed fourteen days later. There will be no replies, sur-replies, supplemental replies, letter briefs, motions to strike, or similar subterfuges for more briefing opportunity. The parties are limited to twenty pages per side. There shall be no individual briefs by each defendant. The parties shall be reasonable with respect to any appendices. The same brief and page limitations apply to any motion for reconsideration.

(6) Plaintiffs shall propose a class certification order consistent with this decision within sixty days of the date of this opinion. The Court intends to issue one order certifying the class.

D.Mass.,2005.
In re Pharmaceutical Industry Average Wholesale Price Litigation
230 F.R.D. 61, RICO Bus.Disp.Guide 10,925, Med & Med GD (CCH) P 301,677

230 F.R.D. 61, RICO Bus.Disp.Guide 10,925, Med & Med GD (CCH) P 301,677
(Cite as: 230 F.R.D. 61)

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