

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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NEW ENGLAND CARPENTERS HEALTH))
BENEFITS FUND, et al.,))
Plaintiffs,))
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v.)	CIVIL ACTION NO. 05-11148-PBS
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FIRST DATABANK, INC. and))
McKESSON CORPORATION,))
Defendants.))
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))
DISTRICT COUNCIL 37 HEALTH AND))
SECURITY PLAN, on behalf of))
itself and all others similarly))
situated,))
Plaintiff,))
))
v.)	CIVIL ACTION NO. 07-10988-PBS
))
MEDI-SPAN, a division of))
WOLTERS KLUWER HEALTH, INC.,))
Defendant.))
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MEMORANDUM AND ORDER

March 17, 2009

Saris, U.S.D.J.

I. Introduction

In these twin national class actions, plaintiffs assert that defendants First DataBank, Inc. ("FDB"), a drug pricing publisher, and McKesson Corporation, a drug wholesaler, engaged in a racketeering enterprise to fraudulently increase the published "average wholesale price" ("AWP") of over four hundred branded drugs by five percent from late 2001 to 2005 in violation

of 18 U.S.C. § 1962 and state law.¹ They also allege that Medi-Span, another publisher, negligently published the same false drug prices. The proposed settlement classes include third-party payors ("TPPs") and consumers who paid for drugs based on the fraudulently inflated prices during the time period.

This is the second proposed class settlement. After receiving numerous objections to the first proposed settlement from pharmacy groups and other third parties that were affected by it, as well as one consumer class member and one TPP class member, Blue Cross and Blue Shield of Michigan ("BCBS Michigan"), the Court rejected the proposed settlement on multiple grounds. Among other things, the Court was concerned that the proposal provided prospective relief only with no money for consumers or TPPs. The Court was also troubled by the proposal that over 8,000 National Drug Codes ("NDCs") for branded drugs were to be rolled back four percent, not just those 1,442 NDCs affected by the fraud.

Now, class plaintiffs and defendants move for final approval of the Amended and Restated Settlement Agreements with FDB and Medi-Span which effectively roll back the drug prices for over 400 branded drugs by four percent. The proposed class settlement agreement contains the following key provisions:

¹ Affected drugs include such popular medications as Lipitor, Claritin, Prozac, Nexium, Plavix, Allegra, Wellbutrin, Ambien, Prilosec, Zantac, Valtrex, Zyprexa, Celebrex, Imitrex, Risperdal, Seroquel, and Neurontin. (Third. Am. Compl. App. A.)

1. FDB and MediSpan will pay \$2.7 million into the settlement fund for the benefit of the settlement classes. This amount includes \$1.2 million, the amount defendant had agreed to pay in attorneys fees and expenses. Plaintiffs have waived their right to attorneys fees in this action. Recently, the plaintiffs resolved their claims with co-defendant McKesson for \$350 million. Accordingly, all class members will receive cash compensation from the combined settlement pool of \$352.7 million.

2. FDB and Medi-Span will roll back from 1.25 to 1.20 the wholesale average cost ("WAC") to AWP mark-up for all of the 1,442 NDCs affected by the fraudulent scheme.

3. FDB and Medi-Span will make the price adjustments about ninety days following this Court's final approval.

After a second notice was sent out about this new settlement, a fairness hearing was held on December 17, 2008. While class members filed only two objections, one by the National Automatic Sprinkler Industry Welfare Fund ("NASI") and one by BCBS Michigan, once again non-class members filed various objections, mostly focused on the provision of the settlement which effectively rolls back drug prices to the level before the fraudulent scheme began. Objectors include the National Community Pharmacists Association ("NCPA"), the National Association of Chain Drug Stores ("NACDS"), the Food Marketing Institute ("FMI"), the Long Term Care Pharmacy Alliance ("LTCPA"), the American Society of Consultant Pharmacists ("ASCP"), the Independent Pharmacy Cooperative ("IPC"), and the Pharmaceutical Care Management Association ("PCMA"). Additional

briefs were submitted after the hearing. There are no objections from consumers.

After a review of the objections, the Court certifies the proposed national settlement classes under Fed. R. Civ. P. 23(b)(2) and (b)(3), and approves the class settlements under Fed. R. Civ. P. 23(e) on the ground that they are fair, reasonable and adequate. However, I modify the agreement so that the rollback of drug prices will not go into effect until six months after the date of this order to alleviate the impact on independent and rural pharmacies.

II. Factual Background

The Court assumes familiarity with its previous Memorandum and Order, as well as certain facts established during the related multidistrict litigation. See In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007). A summary of the allegations (many of which defendants dispute) follows.

Almost all single-source brand-name pharmaceuticals are contractually reimbursed based on AWP, a pricing benchmark. (Third Am. Compl. ¶¶ 2, 4.) Despite its name, AWP is not an average of prices charged by wholesalers to providers (such as pharmacies and doctors) and it does not necessarily bear any relationship to any prices actually charged in the marketplace.

(Id. ¶ 42.) Rather, it is a price reported by drug manufacturers to publishing companies like FDB and Medi-Span. (Id.) TPPs and the government rely on the published AWP to reimburse providers. (Id. ¶¶ 3, 4.) Typically, a drug's wholesale acquisition cost or "WAC" was understood as the price wholesalers paid to purchase a drug from the manufacturer; the WAC was then marked up by a fixed percent to derive the AWP. (Id. ¶¶ 7, 37.) FDB represented that it surveyed wholesalers to ascertain the AWP, but this was untrue. (Id. ¶¶ 109, 119.)

Beginning in 2001, FDB and McKesson reached a secret agreement to raise the markup between WAC and AWP from its standard 20% to 25% for over four hundred drugs. (Id. ¶¶ 129.) McKesson communicated these new 25% WAC to AWP markups to FDB, which then published AWP's with the new markup. (Id.) To camouflage the scheme, McKesson and FDB agreed to effectuate price changes only when some other WAC-based price announcement was made by a drug manufacturer. (Id. ¶ 144.) McKesson has estimated that by 2002, 95% of all prescription drug manufacturers used the inflated 25% markup, and by 2004, 99% of all prescription drug manufacturers did so. (Id. ¶ 140.) The scheme ended on March 15, 2005, when FDB told its customers that it would "no longer survey drug wholesalers for information relating to" AWP. (Id. ¶ 159.)

The scheme resulted in higher profits for retail pharmacies that purchase drugs on the basis of WAC but are reimbursed on the

basis of AWP, a differential called "the spread". (Id. ¶ 2.) McKesson implemented the scheme in order to provide a greater "spread" to important retail pharmacy clients like Rite Aid as well as to its own pharmacy related businesses. (Id. ¶¶ 13, 141-42.)

Nearly all TPPs contract with pharmacy benefit managers ("PBMs") to assist in the reimbursement process. (Id. ¶ 64.) PBMs are the "800-pound gorillas of pharmaceutical reimbursement" and their relationships with TPPs are heavily negotiated and highly individualized. In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 71-72. TPPs negotiate drug pricing discounts with PBMs based on AWP, and PBMs, in turn, negotiate discounts with pharmacy networks based on AWP, although TPPs sometimes negotiate discounts with pharmacy networks directly. (Third Am. Compl. ¶¶ 64-65.) Typically, TPPs enter into contracts with PBMs to reimburse pharmacies for drugs at AWP minus approximately fifteen percent plus a dispensing fee. In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 72. Sometimes PBMs earn the difference between what they pay a retailer and what a TPP pays the PBM; other times, TPPs use PBMs merely as claims administrators. Id.

III. Discussion

1. The Standard

Rule 23(e)(2) establishes that a settlement must be fair, reasonable and adequate. The First Circuit has not established a

fixed test for evaluating the fairness of a settlement. In re Tyco Int'l, Ltd. Multidistrict Litig., 535 F. Supp. 2d 249, 259 (D.N.H. 2007). "Although the district court must carefully scrutinize the settlement, there is a presumption in favor of the settlement if the parties negotiated it at arms-length after conducting meaningful discovery." Id. See also Bussie v. Allmerica Fin. Corp., 50 F. Supp. 2d 59, 72 (D. Mass. 1999) ("Th[e] fairness determination is not based on a single inflexible litmus test but, instead, reflects [the court's] studied review of a wide variety of factors bearing on the central question of whether the settlement is reasonable in light of the uncertainty of litigation."). In this Circuit, many courts have relied on the factors set forth by the Second Circuit to determine the fairness of a settlement:

(1) the complexity, expense, and likely duration of the litigation; (2) the reaction of the class to the settlement; (3) the stage of the proceedings and the amount of discovery completed; (4) the risks of establishing liability; (5) the risks of establishing damages; (6) the risks of maintaining the class action through the trial; (7) the ability of the defendants to withstand a greater judgment; (8) the range of reasonableness of the settlement fund in light of the best possible recovery; (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation.

City of Detroit v. Grinnell Corp., 495 F.2d 448, 463 (2d Cir. 1974) (internal citations omitted); see In re Lupron Mktg. and Sales Practices Litig., 228 F.R.D. 75, 93-94 (D. Mass. 2005) (noting that Grinnell has supplied the "most commonly referenced

factors" and proceeding to apply them). Other courts have used pared down versions of the Grinnell list; one court has utilized a six-factor list, considering:

- (1) comparison of the proposed settlement with the likely result of litigation;
- (2) reaction of the class to the settlement;
- (3) stage of the litigation and the amount of discovery completed;
- (4) quality of counsel;
- (5) conduct of the negotiations; and
- (6) prospects of the case, including risk, complexity, expense and duration.

In re Compact Disc Minimum Advertised Price Antitrust Litig., 216 F.R.D. 197, 206 (D. Me. 2003). Another court has utilized an even slimmer, although fundamentally similar, five-factor list, considering:

- (1) risk, complexity, expense and duration of the case;
- (2) comparison of the proposed settlement with the likely result of continued litigation;
- (3) reaction of the class to the settlement;
- (4) stage of the litigation and the amount of discovery completed; and
- (5) quality of counsel and conduct during litigation and settlement negotiations.

In re Tyco Int'l, Ltd. Multidistrict Litig., 535 F. Supp. 2d at 259-60 (D.N.H. 2007). "Where the rights of third parties are affected, however, their interests too must be considered." In re Masters Mates & Pilots Pension Plan and IRAP Litig., 957 F.2d 1020, 1026 (2d Cir. 1992). Applying all these factors to the proposed settlement, I find that the settlement is fair and reasonable. With respect to the risks of litigation, the documentary evidence against FDB and McKesson strongly supports a

finding of liability with respect to both defendants.² However, you can't get blood from a stone. Whether considered on its own as "the ability of the defendants to withstand a greater judgment" or as part of the broader factor of "the likely result of continued litigation", because of FDB's limited finances and questionable insurance coverage,³ the \$2.7 million cash payment combined with the AWP rollback provisions constitutes a reasonable settlement of the claims. Dr. Raymond S. Hartman has predicted that the rollback will provide as much as \$1.03 billion in prospective savings to TPPs, insureds paying coinsurance and cash payees, although he acknowledges that amount is difficult to predict because many parties are likely to renegotiate their contracts. (Decl. of Raymond S. Hartman [Docket No. 642] ¶¶ 4(d), 7.) Still, even assuming the renegotiations will dissipate the value of the settlement, the rollback will have the added

² In 1998, Medi-Span merged with FDB. (Third Am. Compl. ¶ 97.) This merger was short lived as the Federal Trade Commission ordered a divestiture of the merger in 2001. (Id. ¶ 98.) As part of this divestiture, the government required FDB to provide Medi-Span with its pricing data for a number of years. (Id. ¶ 100.) Medi-Span, in turn, published the data alongside FDB. (Id.) Medi-Span, unlike McKesson or FDB, had a limited role in the scheme and any liability against it arises from its negligent misrepresentations of various AWP prices by relying on and publishing the WAC-to-AWP markup factor wrongfully manipulated by FDB and McKesson, as well as publishing inflated AWPs after FDB no longer provided this data. (Medi-Span Compl.) Plaintiffs have conceded that their case against Medi-Span is weaker than against FDB and is based upon one count of negligent misrepresentation. (Id.)

³ See Sealed Decl. of Thomas M. Sobol [Docket No. 121].

advantage of righting a wrong and providing greater transparency in drug pricing, a notoriously opaque business.

As for the details of the settlement process, it comes after extensive discovery and motion practice and heads off what would likely be complex, expensive, and lengthy, albeit probably successful, litigation. The quality of counsel on both sides and their conduct during the initial phases of litigation have been top-notch, and the settlement negotiations have been conducted diligently and at arms-length.

2. The Objections by Class Members

The reaction of the class has been almost entirely positive. Only two putative class members have objected. NASI objects to the \$1.2 million of attorneys' fees and expenses. However, this objection is now moot because Plaintiffs have waived attorneys' fees and expenses in this litigation, and have agreed to seek such fees solely in connection with the McKesson settlement.⁴

BCBS Michigan contends that the rollback of the AWP mark-up is of little or no value to class members. Plaintiffs' expert Raymond S. Hartman has predicted that the rollback may permit class members to purchase a large group of drugs at lower prices, with a total possible benefit in the billions. BCBS Michigan contends that AWP reductions are likely to generate no benefits for the TPP class because PBMs will simply renegotiate the

⁴ NASI also objects to \$160,000 in third-party fees. Plaintiffs have not justified these fees and do not seem to be pressing for them.

reimbursement contracts (many of which are at-will) with TPPs.

Plaintiffs respond to this criticism in three ways. First, according to Dr. Hartman, the rollback will have at least short term benefits until the contracts are renegotiated. In his view, these benefits will likely outweigh any potential benefits from litigation against FDB for the class of consumers and TPPs because FDB does not have sufficient resources to make a large monetary contribution. In rejecting the last settlement, I was greatly concerned that consumers and TPPs would not receive any compensation. While the prospective relief would aid future purchasers of drugs, it would not compensate past injured parties. While FDB's contribution is relatively small, it is something, and plaintiffs have provided a persuasive sealed analysis of FDB's lack of ability to pay a larger settlement amount. BCBS Michigan is the only TPP to object, and no consumers have objected.

Second, plaintiffs point out that even if subsequent renegotiations reduce the benefit of the rollback to TPPs, the rollback will eliminate the fraudulent mark-up and increase transparency in pricing. TPPs will now enter into negotiations with PBMs and wholesalers with knowledge that the differential between WAC and AWP is 1.20 and that it will stay at that level.

Third, it is undisputed that, going forward, the rollback will benefit consumers who make co-payments for the listed drugs based on AWP because the percentage payment will reduce the amount of the co-pay.

3. Objections from Non-Class Members

A veritable alphabet soup of non-class members object, complaining that there are flies in the settlement. The Court must consider the interests of any third parties that may be affected by the settlement. In re Masters Mates & Pilots Pension Plan and IRAP Litig., 957 F.2d at 1026.

NACDS, FMI, LTCPA, and ASCP object. NACDS consists of nearly two hundred chain community pharmacy companies that fill over seventy-one percent of the prescriptions dispensed in the United States. FMI represents 1,500 companies that operate 26,000 retail food stores, one third of which have in-store pharmacy departments. LTCPA and ASCP's members are pharmacies that serve the residents of long-term care facilities.

Their main concern is that both FDB and Medi-Span have announced plans to voluntarily roll back the AWP on thousands of NDCs beyond the 1,442 directly required by the proposed amended agreement. As stated earlier, the Court had rejected the first rollback of more than 8,000 NDCs in the first proposed settlement on the ground that there was no evidence that they were part of the fraudulent scheme. Objectors paint FDB and Medi-Span's voluntary rollback as a "collusive end-run" around the Court's concerns. In response, FDB and Medi-Span claim there "simply is no agreement or quid pro quo with Settlement Class Counsel or others concerning FDB's separate and independent editorial decisions regarding the future publication of" Blue Book AWP. (Supplemental Decl. of Sheila L. Birnbaum, Esq. [Docket No. 647])

¶ 10.) They point out that they have the editorial right to publish whatever drug prices they want as long as they are not making fraudulent misrepresentations.

Even if the Court infers that this rollback is the product of the earlier agreement between the parties, it was disclosed to the Court, and the Court has no interest in interfering with it. AWP has been exposed as a faux inflated price unrelated to actual drug prices. Reliance on AWP is a trap for unwary and unsophisticated TPP purchasers and results in consumers paying unwarranted co-payments. Not only do FDB and Medi-Span have the right to make these changes, but in my view, after eight years of this MDL, rolling back AWP or phasing them out as a pricing benchmark is in the public interest and to the benefit of the class.

Objectors also complain that FDB will independently discontinue publishing AWP data for all drugs in the Blue Book within two years following the rollback. However, this decision is not part of the settlement agreement. Just as with the rollback itself, even if I could stop FDB and Medi-Span, I would not do so.

Second, NACDS, FMI, PCMA, which represents PBMs, and other non-class members object that the proposed AWP rollback continues to be punitive to innocent non-parties and to threaten the viability of certain pharmacies because it will impose "very substantial transaction costs" and administrative burdens on retail drug chains and PBMs. As objectors concede, though, many

of the retail drug chains have already renegotiated their contracts with PBMs because they have been on notice for two years since October 2006 that there was likely going to be a rollback and "the vast majority (i.e. over 90%) of most PBMs' contracts contain adjustment provisions that operate to maintain the 'relative economics' of the agreement in the event of the kind of AWP changes contemplated by the proposed settlement." (Mem. of NACDS and FMI [Docket No. 619] 8; Objection by PCMA [Docket No. 612] 6.)

A more compelling case is made by IPC, the largest group purchasing organization for independent pharmacies. It submitted an amicus curiae brief stating that at a margin of 2.8%, many of its members "cannot absorb a 4-5% reduction in reimbursement for brand name pharmaceuticals, approximately 80% of prescription sales." (Brief of IPC [Docket No. 605] 7.)

While these concerns should be weighed, these pharmacies (both chain and independent) and PBMs, reimbursed on the basis of AWP, were unjustly enriched when drug prices were fraudulently inflated during the scheme, yet they have not been asked to disgorge their profits. None of the pharmacies protested the windfalls they received when prices were unilaterally inflated by five percent. Further, the pharmacies seem to have survived prior to the start of this fraudulent scheme, making it seem likely that they will survive after it has been undone. Accordingly, in weighing the equities, I do not find that any transactional costs on third parties that must renegotiate their

contracts are so unfair or disproportionate as to undermine the benefits of the settlement. Moreover, delaying implementation of the rollback for six months as requested by the NCPA (Objection and Opp'n of NCPA [Docket No. 610]) will mitigate the effect of the rollback on pharmacies. IPC's request for an eighteen month delay is excessive in light of the fact that the industry has been on notice for two years of the prospective relief.

Finally, objectors express concern that the settlement agreement provides for a data room which will give plaintiffs discoverable material concerning drug price reporting practices. Objectors complain that the data room will contain proprietary and confidential data of pharmacies. However, as I understand it, the data room will contain only non-privileged discoverable materials.

4. Accuracy of the NDCs

The NCPA filed a Johnny-come-lately objection that some NDCs have been improperly included in the settlement. The proposed settlement lists 1,442 NDCs. NCPA complains because the list includes 415 discontinued NDCs (or 29% of the 1,442). According to FDA regulations, a manufacturer may reuse an NDC even after it has ceased selling the product.⁵ The NCPA claims that

⁵ 21 C.F.R. § 207.35(b)(4)(ii) provides:
When a registrant has discontinued a drug product, its product code may be reassigned to another drug product 5 years after the expiration date of the discontinued product, or, if there is no expiration date, 5 years after the last shipment of the discontinued

"eliminating these NDCs from the list will prevent potential future harm flowing from possible reinstatement", but has not specified the harm that could be caused by allowing these fraudulently inflated NDCs to be rolled back. (Supplemental Reply of NCPA [Document 711] 2.) Given the possibility that these drugs could be reintroduced, their NDCs should be included in the rollback. The NCPA merely raises the specter that the class has not been properly informed of the scope of the injunctive relief because so many drugs have been discontinued. This argument is unpersuasive. NCPA's expert, Mr. Heckman, has not disputed that these drugs were fraudulently inflated. As such, the class has been properly informed that the only drugs subject to the rollback are the ones whose prices were inflated.⁶ This objection is much ado about nothing.

Second, NCPA complains about 369 NDCs which were not included in the earlier settlement list of 8,486 NDCs submitted with the 2006 Settlement Memorandum but which now appear in the new proposed settlement list of 1,442 NDCs. Plaintiffs respond that the vast majority of these drugs have been discontinued.

product into commercial distribution. Reuse of product codes may occur, under the specified conditions, regardless of the NDC, Product Code, and Package Code configuration used.

⁶ To the degree that there is concern that a listed NDC could at some point be reassigned to a new drug, the affected parties can petition the Court for appropriate relief.

NCPA seeks to eliminate 105 of these NDCs for reasons which are not entirely clear. According to plaintiffs, most of these have been discontinued or have no associated IMS sales data, suggesting that none have been sold. At the Court's suggestion, plaintiffs' expert met with NCPA's expert to discuss the data. While the parties were able to explain many of NCPA's concerns, NCPA complains that plaintiffs were not able to demonstrate their reasons for including thirty-eight of these NDCs and that forty-four were discontinued. In response, plaintiffs have introduced a declaration from their expert corroborating that these drugs are properly on the list and none of the defendants has objected. (Decl. of Renee Rushnawitz [Docket No. 715] ¶ 15.) NCPA has offered no evidence in rebuttal.

Plaintiffs seek sanctions because their expert fees necessitated by NCPA's objections ran over \$100,000. While I do worry that the motion was a ploy to delay implementation of the settlement, which it did by three months, I do not find the objection was in bad faith because the inclusion of discontinued NDCs may have legitimately triggered concern.

ORDER

I **CERTIFY** the proposed classes and **APPROVE** the Amended and Restated Settlement Agreements in both actions, with the one qualification that the rollback will go into effect no earlier than 180 days from the entry of the Final Judgment. I **DENY** the

request for sanctions against NCPA. Because the final order and judgment proposed by the parties earlier in the litigation is out-dated in both actions, the parties shall file a new form of judgment consistent with this order within one week

S/PATTI B. SARIS
United States District Judge