

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESAL PRICE) M.D.L. No. 1456
LITIGATION) Civil Action No. 01-12257-PBS
)
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)
THIS DOCUMENT RELATES TO)
01-CV-12257-PBS)
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)

MEMORANDUM AND ORDER

November 1, 2007

Saris, U.S.D.J.

Plaintiffs seek multiple damages based on this Court's finding of a violation of Chapter 93A against two defendants, AstraZeneca and Bristol-Myers Squibb ("BMS"). See In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 103, 105-08 (D. Mass. 2007). The Court found that defendants grossly inflated the Average Wholesale Prices ("AWPs") of certain expensive physician-administered drugs ("PADs"). To recap, I found:

The overwhelming evidence at trial established that AWPs are fictitious and are rarely, if ever, prices paid by doctors for PADs or by pharmacies for [self-administered drugs or SADs]. Nonetheless, defendants argue that they had no intent to deceive the patients or payors who ultimately paid for their products when they caused their AWPs to be published in the compendia. The manufacturers have emphasized that both the government and [third-party payors or TPPs] understood that AWP was a fictitious number and were not deceived by the published AWP.

It is true that by the late 1990's most sophisticated TPPs and the government understood that AWP did not represent a true average of wholesale prices, but that

there was a spread of 20 or 25 percent between the AWP and wholesale list (or acquisition) price. However, this knowledge does not exonerate defendants.

I find that the defendants unfairly and deceptively caused to be published false AWP (or their formulaic counterparts: false [wholesale acquisition costs] or [wholesale list prices]) knowing that TPPs and the government did not understand the extent of the mega-spreads between published prices and true average provider acquisition costs. Moreover, defendants knew that neither the government nor the TPPs could do much to change the AWP reimbursement benchmark because they were locked into the nationwide reimbursement scheme established by statute or contract.

Unscrupulously taking advantage of the flawed AWP system for Medicare reimbursement by establishing secret mega-spreads far beyond the standard industry markup was unethical and oppressive. It caused real injuries to the insurers and the patients who were paying grossly inflated prices for critically important, often life-sustaining, drugs. Defendants caused these injuries by not reporting a true average wholesale price, that approximated provider actual acquisition costs or was within well established industry expectations (i.e., the Hartman 30 percent "speed limit"). Instead, the spreads were as high as 1,000%. This is exactly the sort of false and misleading information for which Chapter 93A is intended to provide relief. See [OIG Compliance Program Guidance for Pharmaceutical Manufacturers](#), 68 Fed. Reg. 23,731 at 23,733 (May 5, 2003) (specifying, at the end of the class period, that manufacturers are under a legal duty not to submit "false, fraudulent, or misleading information" where "reimbursement by Medicare and Medicaid[] for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly . . . failed to generate or report such information completely and accurately").

While I find that the mega-spreads prior to 2001 were deceptive as well as unfair, I also find that once the cat was out of the bag, and the mega-spreads became widely known, the conduct was still egregious under the unfairness prong of Chapter 93A because neither the TPPs nor the government could move quickly or effectively to fix the problem. In retrospect, at least, it has become clear that the Medicare statute itself created a perverse incentive by pegging the

nationwide reimbursement for billions of drug transactions a year to a price reported by the pharmaceutical industry, thus putting the proverbial pharmaceutical fox in charge of the reimbursement chicken coop. The different pharmaceutical companies unfairly took advantage of the system by setting sky high prices with no relation to the marketplace.

While establishing mega-spreads itself constitutes egregious misconduct, marketing those spreads so that doctors would choose a drug based on profit rather than therapeutic value is particularly outrageous and unethical. Even the industry understood that spread-marketing violated industry standards. Both BMS and [Johnson & Johnson] instructed their sales teams that the spread should not be a promotional or marketing tool, although these instructions were often ignored. Moreover, in 2003, the OIG belatedly issued guidelines condemning this practice. *Id.* at 23,737 ("If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated."). Although these guidelines were issued at the end of the class period, they defeat any notion that the federal government's failure to change the AWP pricing benchmark signaled acquiescence in spread-marketing or the reporting of mega-spreads.

Throughout the class period, the pharmaceutical industry understood that if the size of the spreads and the marketing of the spreads became public, a public relations nightmare would ensue. As such, the manufacturers insisted on confidentiality in physician contracts and lobbied to undermine government surveys. See In re Lupron Mktg. & Sales Practices Litig., 295 F. Supp. 2d 148, 168 n.19 (D. Mass. 2003) (pointing out that "[i]f everything [about Lupron] was known to everybody, why did defendants emphasize secrecy?").

Significantly, the defendants well understood the devastating impact the mega-spreads had on old and sick patients required to make co-payments they could ill afford, and set up programs to help some needy patients by subsidizing their costs. The spiraling drug costs incurred by third-party payors and the government, however, were never a concern.

491 F. Supp. 2d at 94-96.

A. Knowing and Willful

Because defendants' conduct in publishing false AWP's was deceptive and unfair, I must determine whether there was a knowing or willful violation of the Act, and, if so, whether to double or treble the damages under Mass. Gen. Laws ch. 93A, §9(3A). See Grand Pac. Fin. Corp. v. Brauer, 57 Mass. App. Ct. 407, 421-22, 783 N.E.2d 849, 863 (App. Ct. 2003). Chapter 93A requires multiple damages if a fact-finder determines that a "willful or knowing violation" occurred." Anderson v. Comcast Corp., 500 F.3d 66, 74 (1st Cir. 2007). To establish a "willful or knowing" violation, there must be some evidence that defendant had a subjectively culpable state of mind. See Anthony's Pier Four, Inc. v. HBC Assocs., 411 Mass. 451, 475, 583 N.E.2d 806, 821-22 (1991).

B. Class Two

Class 2 consists of third-party payors ("TPPs") in Massachusetts that reimburse Medicare beneficiaries for their statutory twenty percent coinsurance obligations under Medicare, known as Medigap insurance or supplemental insurance. See 42 U.S.C. §1395u(o).

Both defendants protest that the government knew that AWP was not a true price. While the government had the lawful authority to conduct surveys to determine actual provider costs and did not do so, there was no persuasive evidence in this record that the government actually knew about, or approved, the mega-spreads between the published prices and the true average

provider acquisition costs. The lack of effective government oversight does not excuse defendants' conduct.

I conclude that defendants' conduct was both knowing and willful because they knew that Medicare beneficiaries, and thus their insurers, were locked by statute into paying twenty-percent of grossly inflated phony AWP, which bore no relation to any average of wholesale prices in the marketplace.

C. Multiple Damages for Class 2

Because the conduct was willful, I must award multiple damages. Trebling the damages is tempting. Astrazeneca "marketed the spread" in a strategy that sold its drug Zoladex based on its profitability to the doctor's office; this violated industry standards and was unethical. The evidence of marketing the spread was clearcut and the damage to sick and old beneficiaries inevitable. On the other hand, Astrazeneca was locked in a competitive battle with TAP, which sold the more expensive drug Lupron (a therapeutic equivalent) using the same marketing strategy. While two wrongs don't make a right, Astrazeneca was not the first to start the unlawful spread-marketing. Moreover, it tried to alleviate the impact of its conduct by providing free drugs to consumers, and initiating alternative methods for selling drugs directly to TPPs through a program, which unfortunately turned out to be unsuccessful. Given these mitigating factors, I will only double the damages.

BMS raises a different issue because it didn't actually publish a false AWP, but instead published a wholesale list price

("WLP"), knowing it would be marked up by the publishing company by at least 20-25%, the standard industry mark-up. Thus, it knew that it was important for the wholesale list price to be an accurate price. Based on guidelines from the Federal Trade Commission and caselaw, I found that so long as BMS was selling a substantial number of drugs at list price, it did not engage in unfair or deceptive conduct. However, the caselaw was sparse as to the meaning of substantial. I find that BMS's conduct was willful and knowing when less than ten percent of its sales were made within 5% of the list price, and the spreads were huge. In these situations, BMS knew that the published wholesale list price was not an accurate price and was deceptive and unfair. Accordingly, with respect to Class 2, I find that BMS's conduct was willful with respect to the following drugs in the listed years:

For Taxol, in 2002, less than 1 percent of sales were made at list price while spreads reached over 500%. With respect to Cytoxan, by 1999 only 6 percent of sales were made at WLP, and the spread reached 676%. Similarly, in 2001, only 7 percent of sales were made at WLP, and the spread reached 171%. With respect to Rubex, in 1998 only 7 percent of sales were made at WLP while spreads exceeded 200% and in 2002 no sales were made at WLP and the spread was 54%.

In the exercise of my discretion, I will double the damages, rather than treble them, because there was little evidence that BMS actually marketed the spread, and it also had a program for

the poor.

D. Class Three

With respect to Class 3, I find that the conduct was not knowing and willful, although it was unfair. In contrast to Class 2 where defendants ignored a clear statutory standard, the TPPs adopted AWP in their contracts as the predominant pricing benchmark. The TPPs were not locked into that benchmark by a statutory scheme, and most were either sophisticated players (like Blue Cross Blue Shield) or smaller plans that hired consultants or the larger TPPs to negotiate their contracts. Defendants' culpability must be measured in light of the plaintiffs' knowledge. Again, there was little to indicate that any TPP understood the true size of these mega-spreads particularly in the beginning of the class period; however, once they knew, as they plainly did by the tail end of the 1990's, they did nothing to mitigate and continued to negotiate contracts on the basis of AWPs they understood were inflated. In any event, plaintiffs cannot prove a knowing and willful violation of Chapter 93A where defendants believed TPPs knew about the spreads and did nothing. In the end, the true victims may well have been the beneficiaries of those plans who had to make larger co-insurance and/or premium payments.

E. Warrick

Warrick has produced undisputed evidence that its unfair and deceptive conduct in inflating the AWP for albuterol did not cause Class 2 any damages because of the methodology for

calculating Medicare reimbursement for multi-source drugs based on a median. Accordingly, I order entry of judgment in favor of Warrick.

ORDER

Astrazeneca

I award damages for Class 2 against Astrazeneca of single damages with prejudgment interest through August 1, 2007 of \$3,467,267. To double the damages, I add \$2,090,103. The total award for Class 2 is \$5,557,370.00.

I award damages for Class 3 of \$7,384,499.00 (including prejudgment interest).

The total award against Astrazeneca is \$12,941,869.00 for Classes 2 and 3.

Bristol-Myers Squibb

I award single damages for Class 2 for Bristol-Myers Squibb of \$309,267 (including prejudgment interest). To account for the doubling, I add \$275 for Rubex in 1998, \$14,401 for Cytosin in 1999, \$8,856 for Cytosin in 2001, \$13 for Rubex in 2002, and \$55,745 for Taxol in 2002. This sums to a doubling amount of \$79,290. The total award for Class 2 is \$388,557.00.

I award damages for Class 3 of \$307,037 (including prejudgment interest).

The total award against BMS is \$695,594.00 for Classes 2 and 3.

Pursuant to Fed. R. Civ. P. 54(b), I order entry of separate judgment with respect to Classes 2 and 3 (the Massachusetts

classes). This is without prejudice to plaintiffs' motion to certify national classes of residents who live outside Massachusetts. This motion shall be filed within twenty-one (21) days.

S/PATTI B. SARIS
United States District Judge

Publisher Information

**Note* This page is not part of the opinion as entered by the court.
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1:01-cv-12257-PBS Citizens for Consume, et al v. Abbott Laboratories,, et al
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Sue Miles (Plaintiff)

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Sandoz, Inc. (Consolidated Defendant)

Sandoz, Inc. (Defendant)

Sandoz, Inc. (Intervenor Defendant)

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Hoechst Marion Roussel, Inc. (Consolidated Defendant)
Aventis Pharma TERMINATED: 10/26/2004 (Consolidated
Defendant)
Aventis Pharmaceuticals Inc. (Defendant)
Hoescht Marion Roussel, Inc. (Defendant)
Sanofi-Synthelabo, Inc. TERMINATED: 10/26/2004 (Defendant)
Z.L.B. BEHRING (Intervenor Defendant)
Sandoz, Inc. (Defendant)

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Sandoz, Inc. (Defendant)
Sandoz, Inc. (Intervenor Defendant)

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Takeda Pharmaceuticals North America, Inc. (Defendant)

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Ethex Corporation (Defendant)

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Ethex Corporation (Defendant)
Ethex Corporation (Consolidated Defendant)
Schering-Plough, Corp (Defendant)

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Warrick Pharmaceuticals Corporation (Consolidated Defendant)

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(Defendant)

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Nancy M Bonnell 1275
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repres United Food & Commercial Workers Unions and Employers Midest
enting Health Benefits Fund (Consolidated Plaintiff)

repres Abbott Laboratories (Consolidated Plaintiff)

Action Alliance of Senior Citizens of Greater Philadelphia
(Consolidated Plaintiff)
All Plaintiffs (Plaintiff)
Arizona, State of (Consolidated Plaintiff)
Carpenters & Millwrights of Houston and Vicinity Welfare Trust Fund,
Board of Trustees, Individually and on behalf of all others similarly
situated (Consolidated Plaintiff)
Citizens for Consumer Justice (Plaintiff)
Colorado Progressive Coalition (Plaintiff)
Commonwealth of Kentucky (Consolidated Plaintiff)
Commonwealth of Pennsylvania (Consolidated Plaintiff)
Congress of California Seniors (Plaintiff)
Connecticut Citizen Action Group (Plaintiff)
County of Chautauqua (Plaintiff)
County of Chenango (Consolidated Plaintiff)
County of Cortland (Consolidated Plaintiff)
County of Dutchess (Consolidated Plaintiff)
County of Lewis (Consolidated Plaintiff)
County of Nassau (Consolidated Plaintiff)
County of Onondaga (Consolidated Plaintiff)
County of Ontario (Consolidated Plaintiff)
County of Orleans (Consolidated Plaintiff)
County of Oswego (Consolidated Plaintiff)
County of Rockland (Consolidated Plaintiff)
County of Schenectady (Consolidated Plaintiff)
County of Schuyler (Consolidated Plaintiff)
County of Seneca (Consolidated Plaintiff)
County of Westchester (Consolidated Plaintiff)
County of Wyoming (Consolidated Plaintiff)
Essex County (Consolidated Plaintiff)
Florida Alliance for Retired Americans (Plaintiff)
Government Employees Hospital Association (Consolidated Plaintiff)
Gray Panthers of Sacramento (Plaintiff)
Health Action of New Mexico (Plaintiff)
Health Care For All (Plaintiff)
International Union of Operating Engineers, Local No. 68 Welfare
Fund (Consolidated Plaintiff)
Maine Consumers for Affordable Health Care (Plaintiff)
Massachusetts Senior Action Council (Plaintiff)

Masspirg (Plaintiff)
Minnesota Senior Federation (Plaintiff)
National Automatic Sprinkler Industry Welfare Fund (Intervenor
Plaintiff)
New Jersey Citizen Action (Plaintiff)
New York State Wide Senior Action Council (Plaintiff)
North Carolina Fair Share (Plaintiff)
Oregon Health Action Campaign (Plaintiff)
Oregon State Public Interest Research Group (Plaintiff)
Pennsylvania Alliance For Retired Americans (Plaintiff)
Pipefitters Local 537 Trust Funds (Plaintiff)
Rice & Thompson (Plaintiff)
State of Arizona (Consolidated Plaintiff)
State of California (Plaintiff)
State of Connecticut (Plaintiff)
State of Florida (Consolidated Plaintiff)
State of Florida (Plaintiff)
State of Mississippi (Consolidated Plaintiff)
State of Montana (Plaintiff)
State of Nevada (Consolidated Plaintiff)
State of Nevada (Plaintiff)
State of Nevada/State of Montana (Plaintiff)
State of New York (Plaintiff)
State of Ohio (Consolidated Plaintiff)
State of South Carolina (Consolidated Plaintiff)
Suffolk County (NY) (Plaintiff)
The City of New York (Consolidated Plaintiff)
The City of New York and Captioned New York Counties (Plaintiff)
The County of Columbia (Consolidated Plaintiff)
The County of Erie (Consolidated Plaintiff)
The County of Ulster (Consolidated Plaintiff)
The People of the State of Illinois (Plaintiff)
Twin Cities Baker Workers Health & Welfare Fund (Consolidated
Plaintiff)
United Food & Commercial Workers Unions and Employers Midest
Health Benefits Fund (Consolidated Plaintiff)
United Senior Action of Indiana, Inc. (Plaintiff)
United States, ex rel. (Consolidated Plaintiff)
Ven-A-Care of the Florida Keys Inc. (Consolidated Plaintiff)
Ven-A-Care of the Florida Keys, Inc. (Consolidated Plaintiff)
Ven-A-Care of the Florida Keys, Inc. (Plaintiff)
Vermont Public Interest Research Group (Plaintiff)
West Virginia Citizen Action (Plaintiff)
Wisconsin Citizen Action (Plaintiff)
Betty Sicher (Plaintiff)
Constance Thompson (Plaintiff)
Edward West (Consolidated Plaintiff)
Harold Bean (Plaintiff)
Henry D. McMaster (Consolidated Plaintiff)
Jack Douglas (Plaintiff)
Joan S. Lee (Plaintiff)
John Bennett (Plaintiff)
John V. Digel (Consolidated Plaintiff)
John B. Rice (Plaintiff)

Kimberly K. Hoover (Intervenor Plaintiff)
Leroy Townsend (Consolidated Plaintiff)
Pearl Munic (Plaintiff)
Robert J. Swanston (Plaintiff)
Roberta S. Starks (Intervenor Plaintiff)
Ronald E. Turner (Consolidated Plaintiff)
Shirley Geller (Consolidated Plaintiff)
Sue Miles (Plaintiff)
T. Mark Jones (Consolidated Plaintiff)
T. Mark Jones (Plaintiff)
Zachary T. Bentley (Consolidated Plaintiff)
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(fax) shanin.specter@klinespecter.com (All Plaintiffs)
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Ivax Pharmaceuticals, Inc. (Consolidated Defendant)

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Astrazeneca Pharmaceuticals LP (Defendant)

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 State of Nevada/State of Montana (Plaintiff)
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 State of California (Plaintiff)
 Ven-A-Care of the Florida Keys, Inc. (Consolidated Plaintiff)
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Colorado Progressive Coalition (Plaintiff)

Congress of California Seniors (Plaintiff)

Florida Alliance for Retired Americans (Plaintiff)

Health Care For All (Plaintiff)

Massachusetts Senior Action Council (Plaintiff)

Masspirg (Plaintiff)

Minnesota Senior Federation (Plaintiff)

New Jersey Citizen Action (Plaintiff)

New York State Wide Senior Action Council (Plaintiff)

Pennsylvania Alliance For Retired Americans (Plaintiff)

Vermont Public Interest Research Group (Plaintiff)

West Virginia Citizen Action (Plaintiff)

Wisconsin Citizen Action (Plaintiff)

Jason Bruno Dickstein repres Baxter Healthcare Corp. (Consolidated Defendant)

Shapiro Morin & Oshinsky enting

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Teva Pharmaceutical USA (Consolidated Defendant)
Teva Pharmaceuticals USA, Inc. (Defendant)
Boehringer Ingelheim International GMBH (Consolidated Defendant)
Bill L Bryant, Jr. Akerman Senterfitt-Tallahassee FL 106 E. College Ave Tallahassee, FL 32301 850-224-9634 850-325-2528 (fax) Assigned: 12/06/2006
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Boehringer Ingelheim Pharmaceuticals, Inc. (Consolidated Defendant)
Boehringer Ingelheim Roxane, Inc (Consolidated Defendant)
C H Boehringer Sohn (Consolidated Defendant)
Pharma-Investment Limited (Consolidated Defendant)

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