UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	CIVIL ACTION NO. 01-12257-PBS
	MDL NO. 1456
THIS DOCUMENT RELATES TO: CLASS 1 JOHNSON & JOHNSON	

MEMORANDUM AND ORDER

September 3, 2010

Saris, U.S.D.J.

I. Introduction

Johnson & Johnson, Centocor, Inc., and Ortho Biotech Products, LP ("J&J") pursuant to Fed. R. Civ. P. 56 have filed two motions for summary judgment against the members of Class 1, one against Class 1 residents of Massachusetts [Docket No. 6667] and a second against all other members of Class 1 [Docket No. 6671]. Following briefing and a hearing, J&J's motion for summary judgment against Class 1 residents of Massachusetts is **DENIED** and J&J's motion for summary judgment against all other members of Class 1 is **ALLOWED-IN-PART** and **DENIED-IN-PART**.

II. Background

Plaintiffs brought this action in 2001 alleging that various pharmaceutical manufacturer defendants had unlawfully and fraudulently inflated the Average Wholesale Price ("AWP") of

their drugs. Because of the massive size of the case, the Court divided the case into two tracks: Track 1, a "fast track," involving five defendants, and Track 2, a "regular track." The Court certified three classes against the Track 1 defendants. The first class, Class 1, is a nationwide class of natural persons who made, or who incurred an enforceable obligation to make, a co-payment for numerous Medicare Part B covered drugs based on the drug's AWP (the "Medicare Part B Co-Payment Class"). In re Pharm. Indus. Average Wholesale Price Litig., 233 F.R.D. 229, 230 (D. Mass. 2006). The second class, Class 2, is a class of all third-party payors ("TPPs") who made reimbursements for numerous Medicare Part B covered drugs purchased in Massachusetts, or who made reimbursements for the drugs and have their principal place of business in Massachusetts, based on the drug's AWP (the "Third-Party Payor MediGap Supplemental Insurance Class"). Id. at 231. The final class, Class 3, is a class of: 1) all persons who made, or who incurred an enforceable obligation to make, a payment for drugs purchased in Massachusetts, including persons who paid coinsurance (co-payments proportional to the reimbursed amount) where such coinsurance was based upon use of AWP as a pricing standard; and 2) all third-party payors who made reimbursements for drugs purchased in Massachusetts, or who made reimbursements for drugs and have their principal place of business in Massachusetts,

based on contracts expressly using AWP as a pricing standard (the "Consumer and Third Party Payor Class for Medicare Part B Drugs Outside of the Medicare Context"). Id. All three classes contained subclasses for each defendant, including a subclass for J&J. Id. at 230-31. The relevant J&J drugs were Procrit, which is used to treat severe anemia, including anemia in AIDS and cancer patients, and Remicade, which is used to treat rheumatoid arthritis, Crohn's disease, and other conditions. Id. at 232; In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 54, 57 (D. Mass. 2007). All three classes have the same class counsel.

The class at issue here is Class 1, the Medicare Part B Co-Payment Class. The class was certified as a nationwide class because the Court held there would be no individual issues of knowledge, causation, and reliance. In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 82, 85 (D. Mass. 2005). The residents of nine states - Alabama, Alaska, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Montana, and Virginia - were excluded from Class 1 on the grounds that the consumer protection statutes in those states do not permit class actions. In re Pharm. Indus. Average Wholesale Price Litig., 233 F.R.D. at 230. The claims of residents of all other states and the District of Columbia are governed by the consumer protection statutes of their respective jurisdictions. Id. at 230-31. In particular,

the claims of Massachusetts residents are governed by Mass. Gen. Laws Ch. 93A. Id. at 230.

Two sets of class representatives were initially designated to represent the interests of the J&J subclass. James and Therese Shepley were designated to represent the J&J subclass with respect to Procrit; Larry Young on behalf of the estate of Patricia Young was designated to represent the J&J subclass with respect to Remicade. Subsequently, the class representatives withdrew and Mrs. Jimmie Austed has been proposed to serve in their place.[1]

The parties filed cross-motions for summary judgment with respect to Classes 1 and 2 in March 2006. The Court construed the term "average wholesale price" in the Balanced Budget Act of 1997 according to its plain meaning to include discounts and rebates. In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d 277, 287-88 (D. Mass. 2006). The Court granted defendants' summary judgment motion with respect to all Medicare Part B drugs furnished in 2004 because it found that when Congress passed the Medicare Prescription Drug Improvement and Modernization Act ("MMA") in 2003, it understood that "AWP was different than average sales price and was not reflective of

[1] Based on the plaintiffs' proffer, I find that Austed is an adequate class representative. J&J has yet to have the full allotted time to review Austed's medical records. In the event that J&J believes, following a complete review, that Austed is not an adequate class representative, J&J may file a motion for reconsideration and have her ousted.

actual prices in the marketplace." Id. at 288. The Court denied the parties' motions in all other respects.

In November and December of 2006, the Court conducted a Track One bench trial, which was limited to claims by Classes 2 and 3, the Third-Party Payor MediGap Supplemental Insurance Class and the Consumer and Third Party Payor Class for Medicare Part B Drugs Outside of the Medicare Context. At trial, the Court heard testimony from plaintiffs' expert, economist Dr. Raymond Hartman, that payors understood that there was a significant spread between a provider's drug acquisition cost and the drug's AWP, "on the order of 0%-25% over the class period." In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 89. Hartman used a 30% yardstick as a conservative estimate of the outer limit of payors' expectations of the difference between what was reported and what was actually paid. Id. at 87. This spread was due to a 20 to 25 percent formulaic markup from the Wholesale Acquisition Cost ("WAC") to AWP that "the market understood and expected" in addition to "some discounting from WAC" of which "payors were aware." Id. at 40, 91-92. Dr. Hartman further testified that the government had similar expectations, informing the Court that "government [and] policy makers" expected that "AWP did not exceed the average sales price by more than 30 percent." Id. at 40.

The Court issued its Findings of Fact and Conclusions of Law

in June 2007. In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20. Accepting Dr. Hartman's testimony about markups, the Court found that Dr. Hartman's 30% yardstick was a reliable measure of marketplace and government expectations. Id. at 92. The Court found that while any spread violated the plain meaning of the Medicare statute, spreads within that expected range were generally not unfair or deceptive under Chapter 93A. Id. at 32.

The Court rejected plaintiffs' theory that Class 2 Medi-Gap payors should be allowed to recover based on a per se liability theory. Id. at 97. Plaintiffs argued that per se liability should apply to Class 2 because their co-payments were set by statute, and urged the Court to reach this conclusion based on the Federal Trade Commission Act, regulations published by the Massachusetts Attorney General, and the Medicare statute. Id. at 82. The Court rejected the plaintiffs' arguments on the ground that the statutes and regulations did not apply to the defendants' conduct because the defendants did not advertise their prices to consumers and the Medicare statute was not a consumer protection statute within the meaning of the Massachusetts Attorney General's regulations. Id. at 84-85.

As a general matter, the Court found that "defendants unfairly and deceptively caused to be published false AWPs (or their formulaic counterparts: false WACs 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." Id. at 94. While the Court found

> 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.

Id. at 95. In addition, "[w]hile 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." Id.

The Court individually examined each drug's history to determine if the relevant defendant had violated Chapter 93A. The Court applied a three-factor analysis. The first and "most important inquiry asks: were there egregious [AWP] spreads above the 30% yardstick expected in the industry? In particular, I focus on the extent and duration of the spreads to evaluate egregiousness." Id. at 101-02. The second factor was an examination of

> the company's history of creating the spread. Did the manufacturer actually increase the AWP and/or list price, as opposed to just increasing the spread through discounts and rebates? Creating the spread by increasing the AWP comes at no cost to the pharmaceutical company and places the full financial burden of the spread on the payor and patient. This approach to expanding the spread is strong evidence of

> unethical conduct. Also relevant to this analysis is the legitimacy of the list price from which the markup is derived: Is it a real list price at which substantial sales were made or an unfair and deceptive price used to jack up the AWP? Finally, evidence that an AWP increase was intended to thwart Congress's change in reimbursement rates will constitute evidence of unethical behavior.

Id. at 102.

The final factor was whether "the defendant engage[d] in a proactive scheme to market the [AWP] spread to doctors by encouraging them to purchase drugs because of their profitability rather than their therapeutic qualities." Id. at 102.

The Court added that "[t]he weight given to each of these factors depends on the particular circumstances of each manufacturer and each drug for each year; no single factor is necessarily determinative, but the size and duration of a mega-spread is the most significant factor." Id.[2]

Evaluating Procrit, the Court found J&J's conduct "troubling." Id. at 104. In particular, J&J "actively marketed the spread on Procrit." Id. at 103. "J&J fully understood the Medicare reimbursement system and its impact on physician choices," and worked hard to "preserve positive economics for physicians." Id. at 55. J&J was actively concerned that the

[2] The First Circuit later affirmed the Court's framework for assessing liability under Chapter 93A, including its three-factor analysis, and also found that there was sufficient evidence for the Court to accept and use Dr. Hartman's testimony regarding the 30% yardstick. In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 183-86 (1st Cir. 2009).

government would find out about the spreads for their drugs and reduce reimbursement amounts accordingly and was likewise concerned that the public would find out about the spreads, which could lead to a "public relations issue." Id. As such, J&J took action to make sure neither the public nor the government discovered the truth. Id. Nevertheless, J&J "actively encouraged their sales representatives to market the spread on Procrit to physicians," and its sales force were instructed to sell Procrit by highlighting the potential for profit. Id. at 55-56.

Most significantly, after not raising its AWP from 1991 through 1996, J&J raised its list prices by approximately 5% in 1997 and 1998, exactly counteracting the reduction in Medicare reimbursement being implemented at that time. Id. at 103. J&J further raised its AWPs in 2000-2002. Id.

Despite J&J's spread-marketing campaign, however, the spreads on Procrit were consistently below Dr. Hartman's 30% liability yardstick, and usually below 25%. Id. at 104. Dr. Meredith Rosenthal acknowledged that Procrit was one of the drugs for which AWP-based reimbursement "seems to work well because the AWP closely tracks the" Average Sales Price ("ASP"). Id. Considering all three factors, the Court found that while J&J's conduct was "troubling," it did not violate Chapter 93A. Id.

The Court found that "[t]he story for Remicade is somewhat

similar." Id. J&J also marketed the spread on Remicade to physicians. Id. J&J's sales force would go through worksheets with physicians that highlighted the difference between their acquisition cost and AWP and calculated their "estimated margin per vial," "estimated revenue per patient," and "estimated monthly revenue from REMICADE." Id. at 58. One slide presentation "contained an audible 'Ka-Ching' sound on the slide showing the profit potential of Remicade." Id. at 104 n.84.

The Court found that Remicade's WAC-to-AWP spread was 30%, rather than the customary 20% or 25%. Id. at 57. However, J&J did not discount Remicade to physicians. Id. As a result, Remicade's "AWP closely tracked ASP throughout the period, and the spreads were all at or about 30%." Id. at 104. Thus, as to Remicade, "there were no secret or deceptive spreads." Id. Although the Court said it was a "close call," it rejected plaintiffs' argument that Remicade should be subject to a different expectations threshold of 25% because the greater WAC-to-AWP spread violated payor expectations. Id. Balancing the factors under consideration, the Court found that J&J had not violated Chapter 93A with respect to Remicade. Id.

Two weeks after the Court issued its Findings of Fact and Conclusions of Law, at a pre-trial conference involving another defendant, the plaintiffs' attorney asked the Court whether Dr. Hartman's 30% liability yardstick applied to the claims by

consumers in Class 1. Hr'g Tr. 8-9 July 3, 2007. The Court responded that it did apply to Class 1. Id. at 9-11. Plaintiffs' counsel argued that a different standard should apply to consumers "because there's no evidence that they had any knowledge of the so-called industry norm of 20, 25 percent." Id. at 10. The Court responded that "I ruled to the contrary and I don't accept that position. And, I thought it was clear. If not, I'm making it clear now." Id. at 11.

The defendants in Track One moved for an entry of judgment pursuant to Fed. R. Civ. P. 54(b), which the Court granted. The Court explained that its judgment in favor of J&J was appropriate under Chapter 93A with respect to Classes 2 and 3 because the spreads of Procrit and Remicade "never substantially exceeded the range of spreads generally expected by the industry and government." Schau Decl. Ex. 2 at 5. The Court entered judgment against Class 1 "for the same reason." Id.

On December 19, 2007, one of plaintiffs' attorneys, Donald E. Haviland, Jr., filed a Notice of Appeal on behalf of Larry Young and Therese Shepley. Schau Decl. Ex. 3. The rest of class counsel did not join in the Notice of Appeal. Id. Later, after the Court removed Haviland as class counsel, the remaining class counsel were granted leave to pursue the appeal. Schau Decl. Ex. 4.

The First Circuit decided the appeal by Young and Shepley on

September 28, 2009. In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 231 (1st Cir. 2009). The court vacated the Class 1 judgment and remanded the case because it "lack[ed] a clear understanding of both the scope of the district court's judgment and the reasons for the judgment." Id. at 237. It invited the Court to provide "additional explanation of its judgment." Id.

The First Circuit noted that the bench trial adjudicated only the claims of Classes 2 and 3, and not Class 1, that the Class 1 representatives did not participate in the trial, and the imposition of the trigger was based on the Court's findings as to the expectations of Classes 2 and 3, not Class 1. Id. at 236. The First Circuit noted that the judgment against Class 1 could not have been entered based on the Court's findings at trial because "the Class 1 plaintiffs were not represented before the court in the previous trial" and because some of the states in which Class 1 members resided contained jury trial rights. Id. Likewise, judgment could not have been entered pursuant to Rule 56 because the Court had not made its findings "with any deference to the Class 1 plaintiffs' potential evidence." Id.

The court made clear, however, that its concern about jury trial rights was inapplicable to Class 1 residents of Massachusetts because Chapter 93A does not provide the right to a jury trial. Id. at 237. The First Circuit also stated that its

decision should not be interpreted necessarily to require a trial of the Class 1 consumer claims in other states, or to preclude this Court from granting judgment in favor of J&J based on a properly framed motion for summary judgment. Id. The court stated that Class 1 plaintiffs should be allowed to make a proffer of evidence concerning their "expectations with respect to reasonable spreads" between average selling prices and AWP. Id.

At trial, the consumers who testified on behalf of Class 3 testified that they had never heard of AWP. In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 38. Likewise, both of the initial class representatives, Mr. Young and Mr. Shepley, testified at their depositions that they were not familiar with AWP. Schau Decl. Ex. 12 at 61; Schau Decl. Ex. 13 at 29. Plaintiffs have presented evidence that the consumer members of Class 1 had the same expectations with regard to reasonable spreads between ASP and AWP as the consumer members of Class 3 who testified at trial: because both sets of consumers had no knowledge of AWP whatsoever, they had no expectations with regard to reasonable spreads between ASP and AWP. However, they expected their costs to be related to the actual acquisition costs of their drugs. Pls.' Combined Opposition 10.

III. Discussion

A. Summary Judgment Standard

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" Barbour v. Dynamics Research Corp., 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). "To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990); see also Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986).

"Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who 'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.'" Barbour, 63 F.3d at 37 (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986)). "There must be 'sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted.'" Rogers, 902 F.2d at 143 (quoting Anderson, 477 U.S. at 249-50). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36.

B. Relevant Inquiry

The Court has already found, and plaintiffs concede, that there was a marketplace expectation of spreads between ASP and AWP, with an outer limit of approximately 30%, and that the government shared the market's understanding of spreads in that range. The spreads on Procrit were always within that range, and usually less than 25%. The spreads on Remicade hovered very near the top of that range throughout the class period. Plaintiffs and J&J agree that the consumers that make up Class 1 knew nothing about AWP. As such they were unaware of, and had no expectations regarding, the spreads between ASP and AWP.

This lack of knowledge played a critical role in the Court's decision to certify a nationwide class of consumers, as there was "no separate factual issue regarding the knowledge and reliance of each class member." In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 82. Likewise, in determining its choice of law analysis, the Court noted that "there is no indication that different definitions of reliance and causation will matter" as a result of consumers' uniform state of knowledge. Id. at 85.

Plaintiffs called two consumer witnesses at trial, and both testified they had never heard of AWP. Likewise, the initial J&J class representatives testified at their depositions that they had no knowledge of AWP. Defendants note that, as such,

consumers never formed any expectations with respect to reasonable spreads.

J&J argues that since the consumers' co-payment was fixed by regulation or statute, it stands to reason that the liability yardstick for Class 1 should be based on what the Health Care Financing Administration ("HCFA") and Congress knew and expected when they selected AWP as the reimbursement benchmark, not what consumers knew and expected.

The Court's decisions have been in keeping with this understanding. In the Court's summary judgment ruling in 2006, the Court granted summary judgment against Class 1 with respect to all drugs furnished in 2004 because when Congress enacted the Medicare Modernization Act in 2003, Congress clearly understood that AWP was different than ASP and was not reflective of actual prices in the marketplace. In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d at 288.

The plaintiffs argue that the Court cannot impute the knowledge of HCFA and Congress to the consumer members of Class 1. Plaintiffs are correct that the Court cannot impute the government's knowledge to consumers, but their argument misses the mark. The expectations of government are not the relevant standard for determining unfairness because those expectations are imputed to the consumer; instead, the expectations of government are the relevant standard because it was the violation

of those expectations that has the potential to make J&J's conduct unfair and deceptive. While reporting AWPs that were not the actual average acquisition cost of their drugs violated the literal terms of the Medicare statute, the inflation of J&J's AWPs triggers liability under consumer protection statutes only where the inflation is unfair or deceptive. And to the degree that AWPs were within the range of government expectations, they do not weigh in favor of finding J&J's conduct unfair and deceptive.

Still, in limited circumstances, a drug company's conduct, taken as a whole, may still be considered unfair and deceptive even when the spread is within the thirty percent yardstick. J&J notes that, at the bench trial, the Court found that the other factors under consideration, price manipulation and spread marketing, cut against J&J, but nevertheless found that J&J had not violated Chapter 93A. While it is true that the Court, in balancing all the relevant considerations, held this way, and would do so again at a bench trial concerning Class 1, it is not the case that a jury must find the same way.

J&J responds by arguing that even if conduct such as "marketing the spread" is "somehow 'unfair'" (it is, and the Court has already so held), it is not legally actionable if it does not cause consumers to suffer a cognizable loss. J&J argues that as long as the plaintiffs were paying no more than what the

government expected, they did not suffer a cognizable loss.

But as to both Remicade and Procrit, J&J engaged in conduct that a jury could find unfair, in violation of government expectations, and the cause of a cognizable loss. The Court accepted Dr. Hartman's 30% yardstick, a conservative estimate of the outside limits of government expectations, as a factual matter. While a jury must take into account government expectations, a jury could find this estimate too conservative specifically in the context of Procrit. The government certainly did not expect J&J to raise its AWP by 5% in 1997 and 1998, directly counteracting the government's attempts to limit reimbursement. A jury might reasonably conclude that this, along with J&J's marketing of the spread, made J&J's actions unfair and deceptive, and might find the resulting financial loss as a result of the 5% bump-up an appropriate measure of damages.

Likewise, with respect to Remicade, the government certainly did not expect J&J to use a 30% markup between WAC and AWP, a practice otherwise unheard of in the industry and 5%-10% more than what the experts at trial testified was normal. In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 104. A jury might reasonably conclude that this, along with J&J's marketing of the spread, made J&J's actions unfair and deceptive, and might find the resulting financial loss as a result of the increased WAC to AWP spread an appropriate measure

of damages.

Whether these losses were the product of unfair or deceptive conduct sufficient to impose liability under a consumer protection statute like Chapter 93A is determined by the three-factor analysis adopted by the Court, which includes a factor considering the size and duration of the spreads.

C. Class 1 residents of Massachusetts

It is undisputed that consumers had no spread-related expectations. The yardstick for determining the first factor of the Court's analysis, the size and duration of the spread, must thus be measured by reference to what the government knew, not what consumers knew. Plaintiffs have made no new proffer of evidence about Class 1 that would alter the Court's balancing under its three-factor analysis. This is hardly surprising since class counsel has remained the same, and the class representative is a newly added Medicare beneficiary. As proceeding to a bench trial as to the members of Class 1 in Massachusetts would result in the same outcome, there is no reason to hold such a trial. J&J has filed a summary judgment motion against the Massachusetts members of Class 1, which I must deny because the determination is necessarily a factual one. However, it makes sense to enter judgment for J&J based on the record before the Court in the bench trial. I will do so within 30 days unless an objection is filed to this procedure.

D. Other States

As an initial matter, when the Court certified Class 1 in 2006, it included consumers claiming under the South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-10, and the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101. Since then, the South Carolina Supreme Court and the Tennessee Supreme Court have ruled that their states' respective acts do not allow class actions. Dema v. Tenet Physician Servs.-Hilton Head, Inc., 678 S.E.2d 430, 434 (S.C. 2009); Walker v. Sunrise Pontiac-GMC Truck, Inc., 249 S.W.3d 301, 308-11 (Tenn. 2008). Plaintiffs concede that, as a result, the residents of South Carolina and Tennessee must be dismissed from Class 1. As such, the Court allows J&J's summary judgment motion as to the members of Class 1 that are residents of South Carolina and Tennessee.

1. States with no jury trial rights

The Massachusetts consumer protection statute is considered one of the broadest consumer-protection statutes in the country, a fact that plaintiffs have conceded. At the Track One trial, the Court assessed defendants' liability under the consumer-oriented provisions of § 9 of Chapter 93A. In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 80-82, 93-94. The Court's rulings made at the Track One trial would thus be the same at any future bench trial applying any other consumer protection statute. Plaintiffs concede that the consumer

protection statutes of Illinois, Nebraska, and New Hampshire do not provide a right to a jury trial. Given that the Court would rule against plaintiffs at a trial under any of these statutes, I will enter judgment for J&J against the residents of these states based on the record before the Court in the bench trial within 30 days unless an objection is filed.

Plaintiffs likewise concede that § 17200 of California's Business & Professional Code provides no right to a jury trial. As the Court would rule in the same manner as it did at the Track 1 trial, judgment for J&J on these claims is appropriate. Further, plaintiffs concede that § 1770 of California's Civil Code, plaintiff's sole additional cause of action under California law, is inapplicable to the conduct at hand, as the Court has already found in the context of Classes 2 and 3. In re Pharm. Indus. Average Wholesale Price Litig., 252 F.R.D. 83, 95 (D. Mass. 2008). As such, the Court will enter judgment for J&J against the residents of California based on the record before the Court in the bench trial within 30 days unless an objection is filed.

Likewise, plaintiffs concede that under North Carolina's consumer protection statute, it is the court that determines whether the defendant's acts or practices are deceptive or unfair. As the Court has already found that J&J's conduct was not sufficiently deceptive or unfair to trigger liability under

Chapter 93A, and that conclusion would remain the same at a trial as to Class 1 under North Carolina's statute, the Court will enter judgment for J&J against the residents of North Carolina based on the record before the Court in the bench trial within 30 days unless an objection is filed.

Finally, plaintiffs concede that Ohio's consumer protection statute requires that the challenged practice previously have been declared deceptive or unconscionable by prior rule or court decision, and Utah's consumer protection statute requires that the specific practice must previously have been declared to violate the statute. Plaintiffs further concede that no such rulings or decisions have been made. The Court thus allows J&J's motion for summary judgment as to the residents of Ohio and Utah.

2. States with jury trial rights

All other states whose residents are members of the class have consumer protection statutes that provide a jury trial right. J&J argues that summary judgment is nonetheless appropriate in all states for various reasons.

J&J argues that it is entitled to summary judgment in all the remaining states that require proof of actual injury: Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Idaho, Kansas, Maryland, Michigan, Missouri, New Jersey, New Mexico, New York, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Washington, Wisconsin, and Wyoming. Based on the

30% yardstick, J&J argues that Class 1 was not damaged by the defendants as a matter of law, and were likewise not damaged by J&J's other unfair conduct. As discussed above, J&J's attempts to counteract Medicare's attempt to limit reimbursement and its use of an oversized spread between AWP and WAC may well have caused plaintiffs actual injury. Viewing the facts in the light most favorable to the plaintiffs, a jury could well conclude that Class 1 suffered an actual loss (the approximately five percent spread in both cases) and, applying the three-factor test discussed by the Court, that J&J's conduct was deceptive and unfair.

J&J argues that it is entitled to summary judgment in all the remaining states that require proof of reliance: Arizona, Indiana, Maryland, Michigan, Minnesota, Oregon, Pennsylvania, South Dakota, and Wyoming. To support its argument, J&J notes that Class 1 consumers did not individually rely upon published AWPs when they made their statutory co-payments. However, Medicare beneficiaries necessarily relied on the price quoted to them in making co-payments.

The Court ruled that consumers in Class 3 who were beneficiaries of sophisticated TPPs could not prove reliance because "the knowledge of the TPP is imputed to the consumer." In re Pharm. Indus. Average Wholesale Price Litig., 252 F.R.D. at 97. J&J argues that Class 1 stands in the same relationship to

the government as Class 3 consumers stand with respect to TPPs. But Class 1 consumers are more akin to Class 2 TPPs. As the Court noted, the issue of reliance is

> largely beside the point [with respect to Class 2 TPPs] because the TPPs were contractually required to pay all or part of a Medicare beneficiary's co-payment, which is statutorily based on the AWP published in the industry publications. In other words, the Medigap Class TPPs are required, by contract, to rely on the AWPs in reimbursing for the co-payments made by Medicare beneficiaries.

Id. at 96-97. "Defendants make a strained argument that Medicare's knowledge of mega-spreads should be imputed to the TPPs in the Medigap Class. However, Medicare was not the agent of the TPPs that had contracts to reimburse beneficiaries, and Medicare did not set or approve drug prices." Id. at 97 n.11.

Similarly, the consumers in Class 1 were required to rely on AWPs in the sense that their co-payments were statutorily based on J&J's published AWPs. Medicare was nevertheless not the agent of the consumers in Class 1, nor did Medicare set or approve drug prices. It is because Medicare beneficiaries were required by federal regulation and statute to pay 20% of a price based on AWP that the Court held that there were "no separate factual issue[s] regarding the knowledge and reliance of each class member" in certifying a nationwide Class 1. In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 82. "[I]n 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." Id. at 85. As a matter of law, then, a jury would be instructed to find Class 1 to satisfy the requirement of reliance.

J&J argues that summary judgment is required in the remaining states that, like Massachusetts, prohibit both "unfair" and "deceptive" conduct: Connecticut, Florida, Hawaii, Maryland, Missouri, Oklahoma, Rhode Island, Vermont, Washington, West Virginia, Wisconsin, and Wyoming. In support, J&J notes the Court's language that the "defendants' actions cannot be said to be unfair . . . within the meaning of Chapter 93A so long as the spread stayed generally within th[e] expected range." In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 32. But this language came in discussing the Court's rejection of plaintiffs' position with respect to Class 2 that it was unfair and deceptive to have any spread between ASP and AWP. Were the Court to have accepted the 30% yardstick as a bright-line generalized legal conclusion, the Court would not have needed to do an in depth analysis of J&J's conduct under its three-part test, as it did. Of course, in determining whether the defendants' conduct violated Chapter 93A, the Court regarded the extent and duration of spreads above the expectations yardstick as "the most important inquiry." Id. at 101-02. But there are yards and yards of difference between "the most

important inquiry" and the only inquiry, and a jury may find J&J's conduct, such as increasing its AWP to counteract government attempts to limit reimbursement and using an inflated WAC to AWP spread, unfair and deceptive, based on its own factual conclusions regarding those factors and the relevant expectations as to the size of spreads.

J&J argues that summary judgment is required in the remaining states where consumer protection statutes prohibit only "false, misleading, or deceptive" acts and practices, but not practices that are "unfair" or "unconscionable:" Arizona, Colorado, Delaware, District of Columbia, Indiana, Michigan, Minnesota, Nevada, New York, North Dakota, Oregon, Pennsylvania, and South Dakota. J&J argues that in deception-only states, the factors considered by the Court, other than the size and duration of the spreads, are irrelevant. This is a tougher question which may merit a closer examination of the caselaw construing "deceptive." But a jury may very well conclude that J&J's actions, such as secretly inflating AWP to circumvent Congress' changes in reimbursement, made J&J's conduct "deceptive."

J&J argues that summary judgment is required in states that prohibit only "unconscionable" practices: Arkansas, Florida, Idaho, Kansas, New Jersey, New Mexico, and Texas. J&J cites Kansas' definition of unconscionable acts as typical, and scoffs at the notion that any jury could find J&J liable under such a

standard. But Kansas' definition includes a prohibition against taking "advantage of the inability of the consumer reasonably to protect the consumer's interests because of the consumer's . . . ignorance." Kan. Stat. Ann. § 50-627(b). But as J&J argues so vociferously, the consumers of Class 1 had no concept of AWP, and had no understanding of how the prices for their drugs were being determined, and fabricated, by J&J. This lack of knowledge was an essential aspect of its scheme to market its drugs to doctors on the basis of their profitability. In so doing, J&J exploited sick patients' ignorance not only to inflate the price of its drugs to higher levels, but also to alter doctors' medical recommendations. A reasonable jury could find this conduct unconscionable.

Finally, J&J argues that summary judgment must be granted in those states that require misrepresentations to be material: Connecticut, District of Columbia, Hawaii, Kansas, Maryland, Michigan, New Jersey, New York, Pennsylvania, Texas, and Vermont. J&J cites Michigan's definition of a "material" misrepresentation as typical: a misrepresentation is material if it is important to a transaction or affects the consumer's decisions. Laura v. DaimlerChrysler Corp., 711 N.W.2d 792, 794 (Mich. Ct. App. 2006). Reporting an inflated AWP, one that is not the same as the actual average price, in violation of the Medicare statute is a misrepresentation. Of course, whether that inflated AWP was

within the range of government expectations is relevant to the determination of whether the defendant's conduct was unfair or deceptive, but a false price is a misrepresentation regardless. A price is, of course, important to a transaction. As such, as a matter of law, a jury would be instructed that J&J made material misrepresentations as they affected the size of the co-payment.

ORDER

J&J's motion for summary judgment against Class 1 residents of Massachusetts [Docket No. 6667] is **DENIED** and J&J's motion for summary judgment against all other members of Class 1 [Docket No. 6671] is **ALLOWED-IN-PART** and **DENIED-IN-PART**. For the reasons stated in this opinion, the Court will also enter judgment against the Class 1 residents of the states specified above within 30 days unless there is an objection to the procedure made within that time. J&J shall likewise inform the Court whether there is a challenge to the class representative within 30 days.

/s/ Patti B. Saris

PATTI B. SARIS
United States District Judge