IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania, Plaintiff	:	
v.	:	No. 212 M.D. 2004
TAP Pharmaceutical Products, Inc.; Abbott Laboratories; AstraZeneca PLC; AstraZeneca, Holdings, Inc.; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Bayer AG; Bayer Corporation; SmithKline Beecham Corporation d/b/a GlaxoSmithKline; Pfizer, Inc.; Pharmacia Corporation; Johnson & Johnson; Alza Corporation; Centocor, Inc.; Ethicon, Inc.; Janssen Pharmaceutical Products, L.P.; McNeil-PPC, Inc.; Ortho Biotech, Inc.; Ortho Biotech Products; L.P.; Ortho-McNeil Pharmaceutical, Inc; Amgen, Inc.; Immunex Corporation; Bristol-Myers Squibb Company; Baxter International Inc.; Baxter Healthcare Corporation; Immuno-U.S., Inc.; Aventis Pharmaceuticals, Inc.; Aventis Behring, L.L.C.; Hoechst Marion Roussel, Inc., Boehringer Ingelheim Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.; Ben Venue Laboratories; Bedford Laboratories; Roxane Laboratories; Schering-Plough Corporation; Warrick Pharmaceuticals Corporation; Schering Sales Corporation; Dey, Inc., Defendants	:	Argued: May 9, 2011

BEFORE: HONORABLE BONNIE BRIGANCE LEADBETTER, President Judge
HONORABLE ROBERT SIMPSON, Judge (P)
HONORABLE BARRY F. FEUDALE, Senior Judge

OPINION
BY JUDGE SIMPSON **FILED: August 31, 2011**

OPINION re POST-TRIAL MOTIONS
of the COMMONWEALTH of PENNSYLVANIA
and JOHNSON & JOHNSON DEFENDANTS

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I. BACKGROUND

A. Opening

This complex original jurisdiction action, which comes before a panel of this Court for a third time, involves the pricing of pharmaceuticals reimbursed by the Pennsylvania Department of Public Welfare (DPW), which administers Pennsylvania's Medicaid program, and by the Department of Aging, which administers the Pharmaceutical Assistance Contract for the Elderly (PACE) program, based on Average Wholesale Price (AWP) between 1991 and 2008.

In particular, the Commonwealth, through its Attorney General, filed suit against numerous pharmaceutical companies, including defendant Johnson & Johnson and several of its current or former subsidiary operating companies[1] (collectively, "Johnson & Johnson Defendants"), which, the Commonwealth claimed, engaged in improper conduct that caused DPW and PACE (collectively, "Plaintiff Agencies") to pay inflated prices for pharmaceuticals the defendant pharmaceutical companies manufactured, marketed and sold. Among other things, the Commonwealth alleged the defendant pharmaceutical companies, including Johnson & Johnson Defendants, reported, or contributed to the reporting of, inflated AWPs for certain branded drugs which are published in commercial publications. These inflated prices caused damages to DPW and PACE, which relied on these reported prices.

[1] Those subsidiary companies are Alza Corporation, Centocor, Inc., Ethicon, Inc., Janssen L.P., McNeil-PPC, Inc., Ortho-Biotech, Inc., Ortho-Biotech Products, L.P., and Ortho-McNeil Pharmaceutical, Inc.

Central among the Commonwealth's claims is that the published AWPs for Johnson & Johnson Defendants' branded drugs are fictitious because they do not reflect an accurate average wholesale price charged by wholesalers to providers, including physicians and pharmacists. Because AWP was the predominant benchmark for reimbursement by government and third-party payors, including DPW and PACE, the Commonwealth asserted that Johnson & Johnson Defendants, and other pharmaceutical companies, inflated or contributed to the inflation of each drug's AWP to create a "spread" between a provider's actual acquisition cost and the fictitious, published AWP, and that pharmaceutical companies, including Johnson & Johnson Defendants, market this spread in order to sell more product.

The Commonwealth's suit against Johnson & Johnson Defendants, which asserted claims of common law fraud or misrepresentation, civil conspiracy and unjust enrichment, as well as violations of the Unfair Trade Practices and Consumer Protection Law (CPL),[2] culminated in a five-week non-jury trial.

Ultimately, the trial judge issued a Non-Jury Decision (Decision) in which he found in favor of Johnson & Johnson Defendants on the Commonwealth's common law claims. With regard to the CPL claims, the trial judge found Johnson & Johnson Defendants violated the CPL. As to the remedy for the CPL violations, the Decision provided for a grant of perpetual injunctive relief, which essentially restrains Johnson & Johnson Defendants from contributing to the reporting of inflated AWPs for their drugs and from marketing or promoting

[2] Act of December 17, 1968, P.L. 1224, as amended, 73 P.S. §§201-1-201-9.3.

the spread for their drugs. In addition, the trial judge ordered Johnson & Johnson Defendants to restore to the Commonwealth the amount of $45,283,562. Further, pursuant to Section 8(b) of the CPL, 73 P.S. §201-8(b), the trial judge found Johnson & Johnson Defendants willfully used practices declared unlawful by the CPL. Thus, in addition to restoration, the trial judge awarded civil penalties against Johnson & Johnson Defendants in the amount of $6,567,000.

Both the Commonwealth and Johnson & Johnson Defendants filed post-trial motions. For its part, the Commonwealth seeks judgment *non obstante veredicto* (JNOV) as to DPW's claim for negligent misrepresentation as well as both Plaintiff Agencies' claims for civil conspiracy. Alternatively, the Commonwealth seeks a new trial on its negligent misrepresentation and civil conspiracy claims for both Plaintiff Agencies as well as modification of the trial judge's Decision under the CPL to include an award of costs and attorney fees.

On the other hand, Johnson & Johnson Defendants challenge the trial judge's determinations that they violated the CPL. They therefore request the Court vacate the trial judge's Decision awarding injunctive relief and restoration.

For the following reasons, we deny the Commonwealth's post-trial motions. In addition, we decline Johnson & Johnson Defendants' request to vacate the award of injunctive relief and restoration.

B. Parties

1. Plaintiff Agencies

As noted above, the Commonwealth, through its Attorney General, filed this action on behalf of DPW and PACE.[3] A brief description of the roles of the Plaintiff Agencies is helpful.

a. DPW/Pennsylvania Medicaid

DPW administers Pennsylvania's Medicaid program. Medicaid is a joint state-federal funded program for medical assistance in which the federal government approves a state plan for the funding of medical services for the needy and then subsidizes a significant portion of the financial obligations the state agreed to assume. See Notes of Testimony (N.T.), 11/2/10, at 2196; Eastwood Nursing & Rehab. Ctr. v. Dep't of Pub. Welfare, 910 A.2d 134 (Pa. Cmwlth. 2006). Once a state voluntarily chooses to participate in Medicaid, the state must comply with the requirements of Title XIX of the Social Security Act, 42 U.S.C. §§1396-1396(q), and applicable regulations. Eastwood Nursing.

DPW provides medical benefits to the poor in Pennsylvania. N.T., 11/2/10, at 2184. According to Dr. Terri Cathers, who testified as designee for DPW, and who serves as the Director of Pharmacy for the Fee-for-Service Program of DPW's Office of Medical Assistance Programs:

[3] The Commonwealth also initially brought claims on behalf of the Pennsylvania Employees Benefits Trust Fund (PEBTF), but later sought to discontinue those claims against Johnson & Johnson Defendants. The trial judge permitted the discontinuance of the PEBTF claims with regard to Johnson & Johnson Defendants prior to trial.

> Medical Assistance is an entitlement program that is essentially awarded to those recipients who are a hundred percent of the federal poverty level. And it ensures access to quality health care, pharmacy benefits, and in some cases food stamps and cash as needed for the poor and indigent, the poorest folks in the state of Pennsylvania, many of which are children.

Id.

With regard to prescription reimbursement, because of the number of claims Pennsylvania Medicaid processes every day, claims are submitted electronically. Id. at 2193. The Medicaid fee-for-service program covers approximately 25,000 national drug codes (NDCs). Id. at 2188.

Pennsylvania Medicaid benefits are delivered through two systems: the "fee-for-service" system and the managed care system. Id. at 2184-85. In Pennsylvania, 42 counties operate under the fee-for-service program. Id. at 2185. These counties are located in the center and the northern tier of the state (configured in a "T" formation). Id. at 2185-86. The fee-for-service program reimburses providers for prescription drugs and pays a dispensing fee on a claim-by-claim basis. Id. at 2192-93.

Pennsylvania's lower southeast and southwest regions are known as "mandatory managed care" zones; nine managed care organizations (MCOs)

contract with DPW to provide Medicaid benefits and services. Id. at 2185. DPW reimburses these MCOs on a monthly, fixed fee basis per recipient. Id.[4]

DPW reimburses drug providers, like pharmacies, at the lesser of estimated acquisition cost, which is DPW's best estimate of the rate that ensures access to the provider, or a "usual and customary" charge, which is the amount a pharmacy would submit or charge a cash-paying customer.

The baseline value for DPW reimbursement is AWP, which is listed in the national pricing compendia, including First DataBank and Medispan. Id. at 2193.

The reimbursement formula for Medicaid is fixed by state regulation. Between 1991 and 1995, DPW reimbursed providers at 100% of AWP. Id. at 2195. From 1996 through 2004, DPW reimbursed providers at a rate of AWP-10%. Id.

b. Department of Aging/PACE

PACE provides a comprehensive prescription drug benefit to qualified, older Pennsylvania residents. Id. at 2060-61. PACE is available to Pennsylvania residents, aged 65 or older, with limited incomes. Id. PACE eligibility requirements are based on income, residency and age. Id.

[4] The Commonwealth's expert evidence on damages, and the trial judge's restoration calculations, were based only on the fee-for-service part of the program. No damages were calculated based on the different reimbursement system in the mandatory managed care zones.

PACE is funded through revenue generated by the Pennsylvania Lottery. Id. at 2064. PACE has an annual budget that exceeds $200 million, approximately 97% of which is used to pay for prescription drugs for its beneficiaries. Id. at 2066.

Thomas Snedden, who has served as the Director of PACE for over 25 years, gave partly credible testimony as to the program. He believably explained the typical PACE beneficiary is a 78-year-old, widowed female who lives alone in a private residence, who has less than a 10th grade education, and who has four or five chronic medical conditions. Id. at 2067.

PACE reimburses providers for a drug's ingredient cost and a dispensing fee. When a pharmacy fills a PACE beneficiary's prescription, it bills PACE, which, in turn, electronically reimburses the pharmacy for the prescription. Id. at 2069-71.

Because of the complex administration of the PACE program, the voluminous claims PACE receives are handled and processed electronically. Id. at 2071. PACE covers as many as 60,000 drugs. Id. at 2068-69. It reimburses providers for approximately 40,000 prescriptions each day. Id. at 2069.

PACE's reimbursement formula is fixed by statute. Id. at 2072. AWP is the basis upon which PACE reimburses pharmacies. Id. PACE initially reimbursed providers at 100% of AWP. Id. Beginning in 1996, the statutory reimbursement rate changed to AWP-10%. Id. In 2003, PACE's reimbursement

formula changed to AWP-20%. Id. PACE uses the pricing publication Red Book. Id. at 2087.

2. Johnson & Johnson Defendants

Defendant Johnson & Johnson is a New Jersey corporation. N.T., 10/18/10, at 127. Alza Corporation, Centocor, Inc., Ethicon, Inc., Janssen L.P., McNeil-PPC, Inc., Ortho-Biotech, Inc., Ortho-Biotech Products, L.P. and Ortho-McNeil Pharmaceutical, Inc. are or were subsidiary operating companies of Johnson & Johnson. Id. Johnson & Johnson Defendants engage in or did engage in the business of manufacturing, distributing, marketing and selling prescription drugs, some of which were reimbursed by the Plaintiff Agencies. Id. at 128.

The specific Johnson & Johnson branded drugs at issue in this case are: Procrit, Remicade, Topamax, Aciphex, Bicitra, Doxil, Duragesic, Elmiron, Erycette, Flexeril, Floxin, Floxin I.V., Grifulvin, Haldol, Haldol Decanoate, Levaquin, Monistat, Mycelex, Pancrease, Parafon, Polycitra, Propulsid, Regranex, Reminyl, Renova, Retin-A, Retin-A Micro, Risperdal, Spectazole, Sporanox, Terazol, Testoderm, Tolectin, Tylenol/COD, Tylox, Ultracet, Ultram, Urispas, Vascor and Viadur. Id. at 132-33.

The majority of the claims by the Plaintiff Agencies involve self-administered, branded drugs, such as pills. Self-administered, branded drugs are usually obtained from pharmacies, which are reimbursed for their cost through the Medicaid and PACE programs. During the period of the Plaintiff Agencies' claims, reimbursement for these drugs was based on estimated acquisition cost

paid by the pharmacies, for which some variation of AWP was a proxy. Pharmacies were also paid a dispensing fee.

A smaller percentage of the Plaintiff Agencies' claims here involve Medicare Part B drugs. These are injectable or infusible drugs which require administration by a physician. Eighty percent of the cost is reimbursed by the Plaintiff Agencies. See 42 U.S.C. §1395*l*; See In re Pharm. Indus. Average Wholesale Price Litig., 491 F.Supp.2d 20, 33 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009), cert. dismissed sub. nom., AstraZeneca Pharm. LP v. Blue Cross Blue Shield of Massachusetts, ___ U.S. ___, 131 S.Ct. 60 (2010) (MDL 2007). Patients or someone on their behalf (such as an insurer) are responsible for a 20% co-payment. Id. at 38-39 (discussing Johnson & Johnson Defendants). Since 1992, reimbursement and co-payment for Medicare Part B drugs has been based on a formula which included an AWP factor (plus an allowance for other costs, such as a dispensing fee). See id. at 33-34, 38.

There are no generic drugs involved in this case.

Johnson & Johnson acquired Defendant Centocor, Inc. after Centocor obtained federal approval to market Remicade® (infliximab), a Medicare Part B infusible drug. N.T., 10/18/10, at 128-29.

Defendant Ortho-Biotech Products, L.P. was a limited partnership. Id. at 131. During its existence, Ortho-Biotech Products was a wholly owned subsidiary of Johnson & Johnson. Id. Ortho-Biotech Products marketed branded

drugs, which included Procrit® (epoetin alfa), a Medicare Part B injectable drug. Id.

In December 2008, a new company, Centocor Ortho-Biotech, Inc. was created through a merger between Ortho-Biotech, Inc. and Centocor, Inc. Centocor Ortho-Biotech, Inc., f/k/a Centocor, Inc., is a wholly owned subsidiary of Johnson & Johnson.

Defendant Ortho-McNeil Pharmaceutical, Inc. (OMP) was formerly a wholly owned subsidiary of Johnson & Johnson. Id. OMP was formed through the merger of two other Johnson & Johnson subsidiaries, Ortho Pharmaceutical Corporation and McNeil Pharmaceutical. Id. at 131-32. OMP's drugs included Terezol, Terconazole, and Elmiron capsules. Id. at 132. OMP transferred its assets and liabilities to Janssen Pharmaceutica, Inc. and simultaneously changed its name to Ortho-McNeil-Janssen Pharmaceuticals, Inc. Id.

Defendant Janssen Pharmaceutical Products, L.P. was formerly a wholly owned subsidiary of Johnson & Johnson. Id. at 129. A Janssen predecessor was founded in Belgium as an independent company in 1953. Id. Johnson & Johnson acquired that company in 1961 and opened its first office in the United States in 1973. Id. Janssen was engaged in the manufacture and sale of branded anti-psychotic pharmaceutical products, including Risperdal. Id. at 129-30.

Defendant McNeil Consumer and Specialty Pharmaceuticals, a division of McNeil-PPC Inc., was a New Jersey corporation. Id. at 130. McNeil-PPC, Inc. is an indirect wholly owned subsidiary of Johnson & Johnson. Id. Through its McNeil Consumer and Specialty Pharmaceuticals Division, McNeil manufactures and sells a variety of 15 over-the-counter and branded prescription drugs. Id. McNeil's prescription drugs include Flexeril. Id.[5]

As discussed in more detail hereafter, Johnson & Johnson Defendants typically sell their pharmaceutical products to wholesalers, warehousing chains, and specialty pharmacies at or below a published list price sometimes referred to as wholesale acquisition cost, or WAC. Id. at 133-34. In turn, these wholesalers sell Johnson & Johnson branded drugs to providers, such as pharmacies and physicians.

Some Johnson & Johnson Defendants sell their branded Medicare Part B injectable drugs directly to physicians. Id. at 134. Other Johnson & Johnson Defendants sell self-administered drugs that are typically dispensed to patients by retail pharmacies or in hospitals. Id.

Johnson & Johnson Defendants report their WACs to pricing compendia and others. Id. at 134. Prior to 2004, certain Johnson & Johnson Defendants reported suggested AWPs that were generally 20% or 25% above WAC. Id. at 133.

[5] Additionally, Defendant Ethicon, Inc. is a New Jersey corporation, and Defendant Alza Corporation was a Delaware corporation. N.T., 10/18/10, at 128-29.

C. Procedural History

The initial procedural background to this complex litigation is set forth in this Court's two prior *en banc* decisions at the preliminary objection stage. See Commonwealth ex rel. Pappert v. TAP Pharm. Prods., Inc., 885 A.2d 1127 (Pa. Cmwlth. 2005) (TAP II); Commonwealth ex rel. Pappert v. TAP Pharm. Prods., Inc., 868 A.2d 624 (Pa. Cmwlth. 2005) (TAP I).

Briefly, in March 2004, the Commonwealth filed its original complaint against 14 pharmaceutical companies alleging the companies engaged in improper conduct that caused certain Commonwealth entities, including DPW and PACE, to pay inflated prices for various pharmaceuticals the companies manufacture, market and sell. In response, the companies filed preliminary objections. In TAP I, we sustained the defendant pharmaceutical companies' preliminary objections challenging the sufficiency of the factual averments in the Commonwealth's original complaint, but we granted the Commonwealth leave to amend.

Shortly thereafter, the Commonwealth filed a corrected amended complaint, to which the defendant pharmaceutical companies again filed preliminary objections. The Commonwealth's corrected amended complaint pled four causes of action: fraud or misrepresentation, civil conspiracy, unjust enrichment and violations of the CPL.

In TAP II, we overruled the defendant pharmaceutical companies' global preliminary objections that challenged the sufficiency of the corrected

amended complaint. We directed the defendant pharmaceutical companies to file answers to the amended complaint, which they did.

This case then proceeded through a lengthy period of robust discovery administered in part by a discovery master. By order, discovery closed on July 30, 2010.

In late-May 2010, the trial judge scheduled the case for jury trial in Northampton County on August 9, 2010. The pharmaceutical company defendants filed motions seeking separate trials.

After status conference with all remaining defendants, the trial judge granted in part, and deferred in part, the defendants' motion for separate trials. In particular, the trial judge granted Defendant Bristol-Myers Squibb Co.'s (BMS) motion so that only BMS would be involved in the August 9 jury trial. Ultimately, the Commonwealth's suit against BMS proceeded to a five-week jury trial, after which a jury returned verdicts in favor of BMS on the Commonwealth's common law claims. Consistent with his prior instructions, the trial judge issued a decision on the Commonwealth's CPL claims. In his decision, the trial judge determined BMS violated the CPL, and he awarded a perpetual injunction and restoration against BMS.

On the same day the trial judge issued his decision on the Commonwealth's CPL claims against BMS, he issued an order denying in part, and deferring in part, the remaining defendants' motion for separate trials. In

particular, the trial judge denied the motions for separate trials filed by Johnson & Johnson Defendants and TAP Pharmaceutical Products, Inc. and scheduled a jury trial involving those two defendants for October 18, 2010, in Northampton County.[6] Prior to final pretrial conference, TAP Pharmaceutical Products reached a settlement agreement with the Commonwealth. As a result, the second trial involved only the Commonwealth's claims against Johnson & Johnson Defendants.

After final pretrial conference for the trial involving Johnson & Johnson Defendants, the trial judge issued an order indicating his intention to submit issues related to the Commonwealth's common law claims to the jury. The trial judge also indicated he would render a non-jury decision on the Commonwealth's unjust enrichment and CPL claims. Shortly thereafter, the parties agreed to waive their right to a jury trial, thereby electing to proceed to non-jury trial. Prior to trial, the trial judge disposed of more than 20 motions *in limine*, filed by the Commonwealth and Johnson & Johnson Defendants. Of particular note, the trial judge issued a 13-page opinion denying Johnson & Johnson Defendants' Supplemental Motion *In Limine* to Preclude Reference to or Application of the Court's prior "Plain Meaning" Interpretation of AWP. In that opinion, the trial judge explained his interpretation of the term average wholesale price or AWP as set forth in the relevant statutory and regulatory provisions.

[6] Shortly before trial, the trial judge denied defendants' motions for partial summary judgment on the Commonwealth's conspiracy and common law fraud claims based on testimony received during the trial involving BMS, including testimony regarding Johnson & Johnson Defendants and other defendants.

Trial commenced as scheduled on October 18 and continued over the course of the ensuing five weeks. At trial, the parties presented 19 live witnesses. In addition, the parties read or played videotapes of prior testimony by more than 20 witnesses. Hundreds of exhibits, many voluminous, were also received.

Ultimately, the judge issued his Decision, finding in favor of Johnson & Johnson Defendants on the Commonwealth's unjust enrichment, misrepresentation/fraud and civil conspiracy claims. However, the trial judge found Johnson & Johnson Defendants violated the CPL by engaging in unfair or deceptive practices. See Non-Jury Decision, 12/7/10 (Attached as Appendix A). Consistent with Pa. R.C.P. No. 1038, the trial judge did not issue findings and conclusions, but he did dispose of all issues.

In particular, the trial judge stated the standard in an enforcement action applying the catch-all provision of the CPL is different than the standard applicable to common law fraud and misrepresentation claims. Commonwealth v. Manson, 903 A.2d 69 (Pa. Cmwlth. 2006); Commonwealth v. Percudani, 825 A.2d 743 (Pa. Cmwlth. 2003); see Weinberg v. Sun Co., Inc., 565 Pa. 612, 777 A.2d 442 (2001). Under this approach, a plaintiff's knowledge of the inaccuracy of a representation and a plaintiff's lack of reliance, while factors to be considered, are not necessarily complete defenses in an enforcement action brought in the public interest. See Manson; Percudani; see also MDL 2007 (in AWP litigation under unfair trade practice statute, private payors' knowledge that AWPs were not actual averages of wholesale prices did not shield drug manufacturers from liability). Cf. Helbros Watch Co. v. Federal Trade Comm'n, 310 F.2d 868 (D.C. Cir. 1962), cert.

denied, 372 U.S. 976 (1963) (fictitious pricing or fictitious pre-ticketing is illegal even if sophisticated purchaser knows price is fictitious).

Based on his findings that Johnson & Johnson Defendants violated the CPL, the trial judge issued a perpetual injunction. Specifically, the trial judge restrained Johnson & Johnson Defendants from contributing in any manner, directly or indirectly, to the reporting to the Plaintiff Agencies of inflated AWPs for Johnson & Johnson Defendants' branded drugs without also arranging for the transmission to the Plaintiff Agencies of current, accurate estimated acquisition costs, such as average manufacturers' prices (AMPs) or average sales prices (ASPs), for each of their branded drugs, in a format equivalent to that in which AWPs are reported to the Plaintiff Agencies, or in another format acceptable to the Plaintiff Agencies. The injunction also restrained Johnson & Johnson Defendants from contributing in any manner, directly or indirectly, to the promotion or marketing of spreads for their branded drugs that are reimbursed by the Plaintiff Agencies.

In addition, pursuant to Section 4.1 of the CPL,[7] the trial judge directed Johnson & Johnson Defendants to restore to the Commonwealth money in the amount of $45,283,562. In so doing, the trial judge accepted as credible the expert testimony in general, and the "PBM" (pharmacy benefit manager) damage methodology excluding interest in particular, of the Commonwealth's damage expert, Frederick R. Warren-Boulton, Ph.D. The trial judge calculated restoration

[7] Added by the Act of November 24, 1976, P.L. 1166, as amended, 73 P.S. §201-4.1.

using Dr. Warren-Boulton's suggested figures and preferred methodology for the period 1991 through 2004, subject to two exceptions.[8]

The trial judge further found Johnson & Johnson Defendants willfully used practices declared unlawful by the CPL. As a result, he awarded the Commonwealth civil penalties under Section 8(b) of the CPL, 73 P.S. §201-8(b), in the amount of $6,567,000.00. In so doing, the trial judge credited the civil penalty methodology set forth by Dr. Warren-Boulton, concluding a violation occurred each time the reported AWP changed for a Johnson & Johnson Defendant branded drug in this case during the period 1991-2004, and assessing each violation at $1,000. The trial judge declined to award any sums under Section 9.2 of the CPL, 73 P.S. §201-9.2.[9]

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[8] First, the trial judge subtracted $7,718.00, representing total "PBM" reimbursements for Viadur excluding interest (amounts set forth in Exhibits 7B and 7D attached to Warren-Boulton's Supplemental Report of September 30, 2010). See J&J Ex. 5814.

Second, although for the most part the trial judge rejected the testimony of Johnson & Johnson witness Ernest R. Berndt, Ph.D., the Court accepted his "PBM Damages Adjustment #3: Removal of First Data Bank's 5% Increase in AWP (DPW)," as set forth in J&J's Demonstrative Exhibit 45, for the years 2002, 2003, and 2004. This resulted in an additional reduction of damages in the amount of $7,908,532. The trial judge specifically rejected other proffered adjustments to the Warren-Boulton PBM methodology, and the trial judge accepted Dr. Warren-Boulton's explanation during direct and rebuttal testimony.

The only other portions of Dr. Berndt's testimony accepted related: 1) to the witness' concessions on cross-examination regarding confusion of Johnson & Johnson executives regarding AWP; 2) to the expert witness' inability to figure out a real average wholesale price for Johnson & Johnson drugs; and, 3) to his agreement that the Medical Assistance Program, with its high payment rates, is subsidizing pharmacies for accepting the discounted rates offered by private payors and giving them the latitude to submit lower bids on prescription contracts. The trial judge specifically rejected as not credible testimony by Dr. Berndt and others suggesting that the Plaintiff Agencies had knowledge of the prices paid for Johnson & Johnson Defendants' branded drugs which was superior to that enjoyed by those Defendants.

[9] Added by the Act of November 24, 1976, P.L. 1166.

Further, the trial judge rejected the affirmative defenses asserted by Johnson & Johnson Defendants that the Commonwealth was judicially estopped, and that the case presented a non-justiciable, political question.

As a final point, the trial judge indicated the Decision was not immediately effective and would not become effective until the completion of post-trial practice. See Pa. R.A.P. 311(a)(4).

Shortly thereafter, both the Commonwealth and Johnson & Johnson Defendants filed post-trial motions. For its part, the Commonwealth seeks JNOV as to DPW's claim for negligent misrepresentation as well as both Plaintiff Agencies' claims for civil conspiracy. Alternatively, the Commonwealth seeks a new trial on its negligent misrepresentation and civil conspiracy claims for both Plaintiff Agencies as well as modification of the trial judge's Decision under the CPL to include an award of costs and attorney's fees.

On the other hand, Johnson & Johnson Defendants challenge the trial judge's findings that they violated the CPL. Therefore, they request the Court vacate the trial judge's Decision awarding injunctive relief, restoration and civil penalties.

II. FINDINGS AND CONCLUSIONS: INFLATED "PRICES"

A. WAC and AWP – Generally

Throughout the period for which damages were awarded, Johnson & Johnson Defendants reported AWPs or suggested AWPs for each of their branded

pharmaceuticals. N.T., 10/18/10, at 133-34. No Defendant reported or suggested an AWP after 2004. Id. The AWPs were published by pricing compendia.

As explained in more detail hereafter, Johnson & Johnson Defendants typically sell their products to wholesalers, warehousing chains, or specialty distributors at or below a published price sometimes referred to as a wholesaler acquisition cost, or WAC. The Defendants report their WACs to pricing compendia and others. Id.

Prior to 2004, Johnson & Johnson Defendants reported suggested AWPs that were generally 20% or 25% above their WACs. Id. Johnson & Johnson Defendants expected that the AWP values they gave to the pricing compendia would be published to and used by third-party payors such as the Plaintiff Agencies when reimbursing for their pharmaceutical products.

The Defendants' reported WACs (wholesale acquisition costs) were inflated. Johnson & Johnson Defendants often sold their branded drugs to wholesalers at WAC less 2%, reflecting a prompt pay discount. PX-980n; PX-10052.004. Johnson & Johnson Defendants frequently sold their branded drugs to wholesalers at WAC less up to 2.9%. PX-10052.007. Specialty distributors of Remicade, a Centocor product, had the opportunity to get the 2% prompt pay discount plus an additional 1% to 1.5% discount off of WAC. Deposition of Ronald J. Krawczyk, 6/22/10, at 101; N.T., 10/20/10, at 719. Pharmacies and physicians purchasing Procrit, a product of Ortho Biotech, received discounts of

5% to 10% off WAC, while some high-volume purchasing physicians could obtain greater discounts off WAC. PX-982bb ¶15.

Where drug manufacturers offer discounts below WAC, it tends to increase spreads between the acquisition cost of the drugs paid by providers and the amount of reimbursement paid to providers. N.T., 10/26/10, at 1493 (Comanor). With larger spreads, higher quantities of drugs can be sold, which would be a benefit to the manufacturer. Id.

The published AWPs for Johnson & Johnson Defendants' branded pharmaceuticals were further inflated by the 20% to 25% markup over WAC (30% for Remicade). There was no connection between the reported AWP values and actual transactions in the market. In particular, there is no believable evidence that any Pennsylvania pharmacy or physician ever paid full AWP to acquire Johnson & Johnson Defendants' branded drugs. Thus, the published AWPs were fictitious prices. See MDL 2007, 491 F.Supp.2d 20, 105 (where 50% of sales made below stated price, the stated price is deemed fictitious).

Those writing Pennsylvania's reimbursement laws intended the phrase "average wholesale price" to mean what it plainly says, that is, an average of wholesale prices paid by providers. Trial Judge's Opinion of October 14, 2010 (attached as Appendix B), slip op. at 8. This conclusion is consistent with evidence received during the trial involving Johnson & Johnson Defendants. However, the AWPs for Johnson & Johnson Defendants' branded drugs were not an average of wholesale prices.

By reporting inflated WACs and reporting and suggesting fictitious AWPs for further publication and use, Johnson & Johnson Defendants materially contributed to a deceptive reimbursement system creating the likelihood of confusion, and in many cases actual confusion, for state legislators, state regulators, state reimbursement administrators, and patients who were responsible for co-payments toward drug reimbursements. The confusion regards the actual acquisition cost paid by providers for the reimbursed pharmaceuticals.

B. AWP System and Confusion – Findings

The AWP-based system for drug reimbursement is inherently a complicated system in which "average wholesale price" or "AWP" is the cornerstone of a larger pricing infrastructure. PX-980b. Because AWP is an inflated and fictitious price within a complicated system, its unclarified use creates a regime with a tendency to deceive those that must deal with the reimbursement system.

Since the late 1960s, almost every branded prescription drug sold in the United States has an average wholesale price, which is published in commercial compendia like Red Book, First DataBank, and Medispan. During the period covered by this lawsuit, AWP is provided in a current, digital format for each available branded pharmaceutical, in each dosage and packaging size. The digital format and the constantly updated value are essential for use in computer-dominated reimbursement systems, such as those used by Plaintiff Agencies. N.T., 11/2/10, at 2193, 2196 (Cathers).

AWP was the pricing benchmark used by the federal government for Medicare reimbursement until the 2005 effective date of the Medicare Prescription Drug, Improvement & Modernization Act of 2003.[10] MDL 2007. By statute and regulation, it has also been the pricing benchmark used by the Plaintiff Agencies for Medicare Part B and Medicaid drug reimbursements. N.T., 10/18/10, at 125-26.

Neither the federal government's Centers for Medicare and Medicaid Services (CMS) (and its predecessor, the Healthcare Finance Administration, "HCFA"), nor the Plaintiff Agencies regulate or set the AWPs; rather, they entrusted the pharmaceutical companies with the task of reporting the AWPs accurately to the publications. MDL 2007, 491 F. Supp. 2d at 32; N.T., 10/25/10, at 1261 (Crane); N.T., 10/27/10, at 1580 (Bohn).

Those writing Pennsylvania's laws governing reimbursement intended: 1) to use an easily ascertained estimate of providers' acquisition costs for pharmaceuticals; and 2) to integrate reimbursement into an existing industry system so the thousands of daily transactions could be processed efficiently. Opinion of October 14, 2010, slip op. at 7. Thus, those writing Pennsylvania's reimbursement laws sought a formula to give an easily ascertained, objective, accurate estimate of acquisition costs for pharmaceuticals, not a fictitious value unrelated to prices actually paid by providers. Id. at 7-8.

Further, those writing Pennsylvania's reimbursement laws intended the phrase "average wholesale price" to mean what it plainly says, that is, an

[10] See Pub. L. No. 108-173, 117 Stat. 2066.

average of wholesale prices paid by providers. Id. at 8. This conclusion is consistent with evidence received during the trial involving Johnson & Johnson Defendants. PX-980b; PX-1085n; N.T., 10/26/10, at 1309-10 (Ortiz); N.T., 11/2/10, at 2078 (Snedden).

Accordant with this intention, AWP initially was in fact the average price charged by wholesalers to providers, like doctors and pharmacies. MDL 2007, 491 F.Supp. 2d at 33. However, the market evolved.

In general, and on the specific topic of evolution of the AWP-based pricing system, the trial judge accepted the testimony of the Commonwealth's expert witness on liability and causation, Dr. William Comanor, currently Professor of Economics at UC Santa Barbara, and Professor of Health Services at UCLA, and Director of the research program of pharmaceutical economics and policy at UCLA.

Throughout the period in question, AWP was derived from the markup charged by wholesalers over their actual acquisition cost, sometimes called the "wholesale acquisition cost" or "WAC." N.T., 10/20/10, at 1423 (Comanor). WAC is a conventional term which signifies the acquisition price paid by the wholesalers before discounts. Id. In contrast, the AWP is the average wholesale price charged by wholesalers, which is the basis under which most reimbursement payments are made to pharmacies and other providers.

Originally, the AWP was 20-25% higher than WAC because that reflected the typical costs at the outset of the distribution process of pharmaceuticals. Id. at 1424. However, competition and improved efficiency forced down prices charged by wholesalers. Id. Eventually, the markup was eliminated in the market, so that the wholesaler-charged prices approached WAC values. Id.; see also, MDL 2007, 491 F.Supp.2d at 33.

As discussed above, Johnson & Johnson Defendants often sold their branded drugs to wholesalers at discounts of 2% or more below WAC. As a result, the WACs reported by Johnson & Johnson Defendants to the commercial compendia were not real wholesale acquisitions costs but were inflated.

Despite the greatly reduced prices in sales from wholesalers to pharmacies, Johnson & Johnson Defendants, and the manufacturers of other branded drugs, did not change the process for determining and reporting AWP. N.T., 10/20/10, at 1425 (Comanor). Thus, despite market changes, the AWP continued to be set equal to the WAC price plus an established markup. Id. In other words, the market changed, but the mechanism by which the AWP was set did not change, so there became an increasing disconnect between reality and price-setting. Id. By this process, AWP was further inflated over an already inflated WAC value. This resulted in AWP being "a fictitious number." N.T., 11/2/10, at 2197 (Cathers).

It is undisputed that wholesalers' profit margins were very thin or nonexistent. N.T., 10/20/10, at 1424 (Comanor) ("markup eliminated in the

market"). From all the above circumstances the trial judge inferred that a real average of wholesale prices for Johnson & Johnson branded drugs was below WAC. See PX-10052.005 (slide referring to sales from wholesalers to retailers: "The competitive wholesale market allows some large customers to purchase at WAC or less."). Evidence to the contrary was rejected as of lesser weight, and the trial judge declined to draw different inferences.[11]

There is no believable evidence that any Pennsylvania pharmacy or physician ever paid full AWP to acquire Johnson & Johnson Defendants' branded drugs. Nevertheless, for years the Plaintiff Agencies reimbursed Pennsylvania pharmacies and other providers at full AWP for Johnson & Johnson branded drugs. Gradually, the Plaintiff Agencies were able to convince other parties involved in setting reimbursement rates to lower rates to reflect discounts off AWP. Only recently was DPW able to partially escape an AWP-dominated reimbursement regime.

Johnson & Johnson Defendants understood that AWP was intended to represent the average price at which wholesalers sell drugs to physicians, pharmacies and other customers. PX-980b. Johnson & Johnson Defendants recognized AWP is considered a flawed pricing mechanism that, although not widely understood, plays a pivotal role in the overall prescription drug pricing and reimbursement systems. Id. Johnson & Johnson Defendants understood that

[11] The Commonwealth's damages expert, Dr. Frederick R. Warren-Boulton, whose opinions were accepted, calculated restoration based on an assumed acquisition cost of WAC plus 2%. He stated, however, that his was a conservative estimate. The trial judge agreed that it was a very conservative estimate which understated the restoration amounts.

inflated AWPs will increase the cost of prescription drugs to the commercial and public payors, putting additional pressure particularly on the state budgets. Id. In a January 9, 2001, letter, Robert G. Savage, Johnson & Johnson Company Group Chairman, responded to inquiries from Congressman Stark in part by indicating that "we agree that the governments' use of AWP as a benchmark for reimbursement may be an anachronism that bears reexamination." PX-10012. Johnson & Johnson Defendants understood that "AWP is not sustainable." PX-10020.20.

In addition, Johnson & Johnson Defendants knew that governments were confused about AWP. As referenced above, Johnson & Johnson Defendants knew that the flaws in the AWP pricing regime were not widely understood. PX-980b. In a February, 2002 e-mail, Shannon Salmon wrote to Alex Gorsky, then-President of Janssen Pharmaceutica, "Congress has tried to figure out how to address AWP under Medicare for at least 5 years." PX-1615.0001.

During his trial testimony, Alex Gorsky conceded that, in February 2002, there was a lot of confusion around AWP and AMP (average manufacture's price, used in rebate calculations) because it was a very complex system. N.T., 10/25/10, at 1152. AWP had been an issue for the entire industry and the government and the press, and there was confusion for some time. Id. at 1153. Later in 2002, it was Johnson & Johnson Defendants' perception that there was still confusion. Id. at 1154; N.T., 11/4/10, at 2694 (Scodari).

In a March, 2002 e-mail exchange between Brian Bastean, Strategic Account Manager for Ortho-McNeil Pharmaceutical, Inc. and Kay [Morgan] at First DataBank, Mr. Bastean wrote, "Thanks again-it never ceases to amaze me how confusing this price structure is but it is clear as to why very few understand it." PX-980ee.0004.

Indeed, at times there was confusion among Johnson & Johnson executives regarding AWP. As an example, in prior testimony accepted for the truth of the matter asserted, Rose Crane, former Company Group Chairperson of OTC and Nutritionals for Johnson & Johnson, stated that AWP is "an average wholesale price that we used when we did promotional items, so it has to be a real price I assume." N.T., 10/25/10, at 1232. The expert witness for Johnson & Johnson Defendants, Dr. Earnest R. Berndt, believably testified on cross-examination that he was not surprised that there was confusion even among Johnson & Johnson executives about AWP. N.T., 11/15/10, at 3998; see Non-Jury Decision, filed December 7, 2010, slip op. at 3-4, n.2 (although for the most part Dr. Berndt's testimony was rejected, certain parts were accepted as credible).

Interestingly, there was also significant information submitted to Judge Saris in MDL 2007 regarding "real and understandable confusion" about "the type of price AWP measures" from Dr. Berndt. N.T., 11/15/10, at 4005; see also id. at 3989-96, 4001-04. Unfortunately, Dr. Berndt did not include the same type of record analysis in his expert report in this case. Id. Dr. Berndt's reasons for not doing so were rejected. His failure to be as forthcoming in this trial until

confronted by the Commonwealth's counsel was disappointing, and this failure contributed to concerns about his objectivity.

Consistent with the understanding of Johnson & Johnson Defendants regarding AWP confusion, the Plaintiff Agencies were not aware of the formulaic relationship between WAC and AWP. N.T., 11/12/10, at 3769, 3735-36, (Love), id. at 3834, (Radke), and N.T., 11/2/10, at 2222-23, 2259, 2273 (Cathers). While those responsible for reimbursement programs at the Plaintiff Agencies knew there was a difference between AWPs and actual acquisition costs paid by providers, they did not know the extent of the inaccuracy. N.T., 11/2/10, at 2197-98 (Cathers); id. at 2090 (Snedden); N.T., 11/12/10, at 3616-17 (Love). Thus, the Plaintiff Agencies did not fully understand, and could not prove, the manner in which AWPs were inflated and the full extent of the inflation. Id. Also, they did not know a real average of wholesale prices for a given branded drug, and they did not have a better estimate of provider acquisition cost available in a current, digital format for each drug in the case. Id.

An example of the tendency of the AWP-based reimbursement system to confuse Pennsylvania state legislators and state regulators involves the role of the Independent Regulatory Review Commission (IRRC)[12] in reviewing and

[12] The current edition of The Pennsylvania Manual describes the Independent Regulatory Review Commission as follows:

> The Independent Regulatory Review Commission was created in June 1982 as a result of the Regulatory Review Act to provide oversight and review of all proposed and existing rules and regulations issued by all departments, boards, commissions, agencies, or other authorities of the Commonwealth, excluding the

(Footnote continued on next page…)

approving proposed changes in the levels of reimbursement. Suzanne Love, a former, long-time DPW employee who had significant involvement in pharmaceutical reimbursement, explained that the commissioners "frequently may not know anything about pharmaceuticals and pharmaceutical pricing. The whole process is just laden with all these technical terms that, you know, people get really confused about." N.T., 11/12/10, at 3620-21. She further testified that she attempted to simplify it so that the average person could understand the proposal. Id. This testimony illustrates that people with no technical background and no insider knowledge nevertheless participated significantly in setting Pennsylvania reimbursement levels. From all these circumstances the trial judge inferred that the regime was likely to cause confusion and that a fictitious price, AWP, was a cornerstone of that regime.

Of further interest was a portion of the testimony of Johnson & Johnson Defendants' expert witness, Dr. Berndt. Among other current positions, Dr. Berndt is a professor in Applied Economics at the MIT Sloan School of

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(continued…)

> Legislature, Fish and Boat Commission, and the Game Commissions, and any court, political subdivision, or municipal or local authority. IRRC is a channel for legislative oversight, a mechanism for comprehensive impact analysis, and a forum for public participation. IRRC is unique in that it is the only independent agency charged with reviewing regulations in the United States.
>
> The Commission also acts as a clearinghouse for complaints, comments, and other input regarding existing regulations, proposed regulations, and administrative procedures.

119 The Pennsylvania Manual 4-121 (2009), *available at* www.dgs.state.pa.us\publications.

Management, and a member of the affiliated faculty at Harvard-MIT Division of Health Sciences and Technology. J&J Demonstrative Ex. 1. Despite his qualifications, Dr. Berndt testified that he had "no clue" about a real average wholesale price for Johnson & Johnson Defendants' drugs. N.T., 11/15/10, at 4006. Further, he was not sure he could figure out a real average wholesale price for the drugs. Id. at 4006-07. The trial judge declined to infer that the responsible persons at the Plaintiff Agencies could do what an MIT healthcare economist could not do.

Given the foregoing findings regarding confusion, the trial judge rejected conflicting evidence that there was an industry/government-wide understanding regarding the meaning and use of AWP. Thus, the trial judge rejected as not credible evidence suggesting that AWP was a term of art, widely known to be derived from a formulaic relationship of known proportions over WAC.

C. CPL Violation

1. Tendency to Deceive

Because AWP is an inflated and fictitious value within a complicated system, and is not the price intended by those writing Pennsylvania's reimbursement laws, its unclarified use has a tendency to deceive those who must deal with the reimbursement system. These practices fall under the "catchall" provision in Section 2(4)(xxi) of the CPL as prohibited unfair or deceptive practices. 73 P.S. §201-2(4)(xxi). The unfair and deceptive practices may be restrained under Section 4 of the CPL, 73 P.S. §201-4, and restoration may be ordered under Section 4.1 of the CPL, 73 P.S. §201-4.1.

2. Materiality

Also, Johnson & Johnson Defendants' conduct was material, as it impacted a nonmalleable reimbursement system to which the Plaintiff Agencies were chained by statute and regulation. Stated differently, because at all relevant times the Plaintiff Agencies were required by law to reimburse according to some form of AWP, deceptive conduct as to that value was material as a matter of law and of fact.

3. "Government Knowledge"

a. Generally

For the most part, the trial judge rejected Johnson & Johnson Defendants' proposed findings of fact regarding "government knowledge" of DPW, Proposed Findings 34-46, and "government knowledge" of PACE, Proposed Findings 68-72. Some evidence was not credible, some documentary evidence was given little weight, and the trial judge declined to draw inferences favorable to Johnson & Johnson Defendants.

While some witnesses from the Plaintiff Agencies understood that there was a difference between AWPs and actual acquisition costs paid by providers during the period for which damages were awarded, they did not know the extent of the inaccuracy. They did not know an actual average of wholesale prices for a given branded drug, and they did not have a better estimate of provider acquisition cost available in a current, digital form for each drug in this case.

In contrast, Johnson & Johnson Defendants had vastly superior knowledge regarding the pricing environment for their drugs, including the reimbursement component of the pricing environment. PX-10020 (2/5/02, "AWP Medicare Update"); PX-10052 (8/11/03, "AWP Presentation").

b. "Government Knowledge" – Other Findings

(1) Radke Testimony

Johnson & Johnson Defendants rely heavily on the testimony of Gerald Radke, former Deputy Secretary of DPW for Medical Assistance. Most of his testimony was rejected as not credible based on demeanor and on bias. In particular, he expressed his friendship for defense counsel, Walter Cohen, Esq., and he confirmed that when he left DPW in 1991 he was mad. N.T., 11/12/10, at 3843-44. The only credible parts of his testimony were the following statements:

- Average wholesale price was fabricated, N.T., 11/12/10, at 3833.

- Mr. Radke had no clue how manufacturers made up average wholesale price. Id. at 3833-34.

- Mr. Radke was unaware of a formulaic relationship between WAC and AWP. Id. at 3834.

- J&J X-549, page 2 (6/2/86 memo from Radke to Cohen setting forth information of lower unit costs for drugs acquired by

> pharmacies from 11.73% to 20.28% below the current DPW estimated acquisition cost) was not a scientific study and was never used in furtherance of any regulatory action. Id. at 3836-37.

Regarding J&J X-549, the trial judge attached very little weight to this document for several reasons: 1) Mr. Radke's comments; 2) information on page 2 of the document referencing difficulties in obtaining information from chain pharmacies; 3) lack of clarity whether the drugs subject to cost "audits" were branded or generic drugs; and 4) lack of clarity whether any Johnson & Johnson Defendants' drugs in this case were subjects of the cost "audits." To the contrary, Mr. Radke's testimony about this document is consistent with Ms. Love's testimony about anecdotal evidence of pharmacy acquisition prices which were of limited value to DPW, as discussed more fully elsewhere.

As to J&J X-2090, Mr. Radke's testimony regarding this document was rejected as not credible. In particular, the trial judge specifically rejected his testimony that "Nobody in the business ever thought that AWP meant average wholesale price." N.T., 11/12/10, at 3831. This testimony is inconsistent with more believable testimony to the contrary. The document itself was given very limited weight because it fails to support a finding of full knowledge regarding the extent to which reported AWPs were inflated and regarding a more accurate estimate of a pharmacy's acquisition cost.

(2) Other DPW Evidence

Johnson & Johnson Defendants rely on various reports published by the Health and Human Services Office of the Inspector General (OIG). However, for the following reasons these exhibits were given little weight.

- 8/1984 OIG Report, J&J X-404, was given little weight because the field work did not include Pennsylvania. It was unclear that branded drugs were involved; it was unclear that Johnson & Johnson Defendants' drugs were involved; it was unclear that any drugs in this case were involved.

- 8/1989 OIG Report, J&J X-569, was given little weight because it did not involve a sample of prices from Pennsylvania, and it was unclear whether any Johnson & Johnson Defendants' drugs or drugs in this case were involved. Further, the study does not suggest a more reliable figure. It should also be noted that about a year after this report, the Omnibus Budget Reconciliation Act of 1990[13] (OBRA) was passed, which placed a four year moratorium on states' reimbursement policies. The moratorium expired on December 31, 1994. During this time, Plaintiff Agencies were not permitted to change reimbursement policies. Therefore, they were severely restricted in their reaction to information in the 1989 OIG Report.

[13] 104 Stat. 1388-143.

- In 1997, the OIG issued another report, J&J X-565. This was given little weight because Pennsylvania was not among the states selected for sampling, it was unclear that any branded drugs from Johnson & Johnson Defendants were involved, and it was unclear that any drugs at issue in this case were involved in the sampling.

- A similar OIG report was issued in 2001, J&J X-1806. This was given little weight because, again, none of the sampling was done in Pennsylvania, and because it was unclear that any of Johnson & Johnson Defendants' branded drugs or any drugs involved in this case were sampled.

- Also, an OIG report was issued in 2002, PX-10132. Because none of the sampling was done in Pennsylvania, because it was unclear that Johnson & Johnson Defendants' branded drugs were among the drugs sampled, and because it was unclear that any drugs involved in this case were sampled for price, this exhibit was given little weight.

- In J&J X-491, DPW compiled a list of the OIG's 1997 results on a state-by-state basis. This was given no weight because it was not useful information to DPW. N.T., 11/12/10, at 3634.

All these documents represent the type of non-Pennsylvania anecdotal information which was of limited or no use to DPW in establishing a different reimbursement scheme. Id. at 3633-34, 3678-79, 3769-70, 3770-71, 3780. Evidence and inferences to the contrary were rejected as not credible.

Johnson & Johnson Defendants also relied on J&J X-547, a 1990 memorandum from the Governor's Secretary of the Budget to the DPW Secretary of Legislative Affairs. The passage on which Johnson & Johnson Defendants rely refers to discounts equaling 50% or more off the average wholesale price of a drug. As this appears to be a reference to generic drugs, which are not in this case, and the trial judge declined to draw the inference that branded drugs were included in the reference, this exhibit was given no weight.

Johnson & Johnson Defendants also relied on J&J X-793, an affidavit signed by Suzanne Love in 1998 in connection with a lawsuit filed by Rite Aid challenging a new reimbursement schedule established in October, 1995. For the most part, the statements in this affidavit were given little weight because they were drafted by lawyers, not by the witness, N.T., 11/12/10, at 3644, and because the affidavit arose in a different context in a different lawsuit. Id. Moreover, Johnson & Johnson Defendants' reliance on paragraph 9 of that affidavit is misplaced because the witness was not asked about that portion of the affidavit and given no opportunity to explain her position.

Other parts of the affidavit were rejected as not credible because they were premised on protecting pharmacy participation, also referred to as "access."

The evidence in this regard is contradicted by the accepted opinion the Commonwealth's damages expert, Dr. Warren-Boulton, that access was never threatened, even at lower reimbursement rates. E.g., N.T., 11/3/10, at 2365-67, 2531-32; see also N.T., 11/2/10, at 2083 (Snedden), 2190-91, 2192 (Cathers).

Regarding documents used in conjunction with the September 1995 IRRC hearing, these documents were given little weight as to their contents. The exhibits were given more weight to illustrate confusion regarding use of AWPs in the reimbursement system.

Thus, J&J X-798 stated that "AWPs are routinely 25% higher than drug companies' listed direct prices," "average difference between pharmacies' cost and AWP-15%," "profit margin will still exist even at AWP-10%." Although those who were members of the IRRC were responsible for judging proposed regulations regarding reimbursement, they did not understand the process or the terms; therefore, Ms. Love simplified the process. The figures referenced above were meant as examples to explain that even a reduction of reimbursement rate would still leave profit margin for pharmacies. N.T., 11/12/10, at 3620-21, 3678-79. Moreover, the statement that "AWPs are routinely 25% higher than drug companies' listed direct prices" is inaccurate because the evidence in this case established that there was usually a 20% mark up for Johnson & Johnson Defendants' branded drugs. PX-10020.005.

Similarly, in J&J X-5840, the statement that "WAC is the price drug companies sell to wholesalers," was given little weight. This was because the

statement is inaccurate insofar as it fails to take account of a 2% prompt pay discount. Instead, Johnson & Johnson Defendants sold their branded drugs to wholesalers usually at WAC less 2%, PX-980n, PX-10052.004, and frequently at WAC less up to 2.9%, PX-10052.007. Partly on this basis, the trial judge determined that average manufacturers price was a more accurate estimate of provider acquisition cost than WAC. See N.T., 11/2/10, at 2102-03 (Snedden); PX-10020.0011.

Likewise, J&J X-26 was given little weight because of its limited scope, involving one Johnson & Johnson Defendant branded drug, and limited purpose, to challenge the pharmacists' claim that a reduced payment level would drive them out of business. N.T., 11/12/10, at 3626-27.

Johnson & Johnson Defendants also relied on a 1998 study on pharmacy dispensing costs from PriceWaterhouseCoopers. J&J X-1360. This exhibit was given very little weight because of the "Limitations of This Study," J&J X-1360 at page 7, and because of the circumstances surrounding its creation as described by Thomas Snedden and Suzanne Love. N.T., 11/2/10, at 2097-2100; N.T., 11/12/10, at 3688.

Johnson & Johnson Defendants also relied on DPW's ability to audit pharmacists. Evidence regarding audits was given no weight in this case for reasons explained by Suzanne Love, N.T., 11/12/10, at 3634-37, and Thomas Snedden, N.T., 11/2/10, at 2095.

Johnson & Johnson Defendants' Proposed Finding 46, that DPW was aware of the formulaic relationship between WAC and AWP, was specifically rejected. In addition to the testimony of Mr. Radke referenced above, the trial judge accepted the testimony of Suzanne Love, that she was unaware of a formulaic relationship between WAC and AWP, N.T., 11/12/10, at 3769, 3735-36, and the similar testimony by Dr. Terri Cathers. N.T., 11/2/10, at 2222-23, 2259, 2273.

(3) PACE Evidence

Johnson & Johnson Defendants relied heavily on the testimony of Thomas Snedden, Director of the Pennsylvania PACE Program. Based on demeanor, however, and his willingness to agree with almost every question asked by any attorney, only parts of his testimony were deemed credible. Also, to the extent he appeared biased toward defending his prior pronouncements and decisions, some of his testimony was given little weight.

Further, for the following reasons the trial judge rejected the proposed finding that Mr. Snedden understood the formulaic relationship between WAC and AWP. At one point, Mr. Snedden testified that he thought he understood a general relationship between WAC and AWP in that "the WAC was 20% less." N.T., 11/2/10, at 2088. He added, however, that until recently he was unaware that the markups could be higher, even up to 30%. Id. at 2088-89. On this point, the more credible evidence was the testimony of Suzanne Love, that she was unaware of a formulaic relationship between WAC and AWP (N.T., 11/12/10, at 3769, 3735-36), and the similar testimony of Dr. Terri Cathers (N.T., 11/2/10, at 2222-23, 2259, 2273), and of Mr. Radke (N.T., 11/12/10, at 3834).

The foregoing notwithstanding, the trial judge found that several statements by Thomas Snedden were believable. Thus, in addition to background information describing the PACE program, the following pieces of testimony regarding "government knowledge" or "government choice," together with inferences in favor of the Commonwealth, were accepted as credible:

- "The understanding of most people was that the average wholesale price was, in fact, the price that the pharmacy was paying to the wholesaler, and that they weren't paying anything less, and they weren't making any money on the ingredient side of the formula." N.T., 11/2/10, at 2078.

- Virtually all Pennsylvania pharmacies participate in the PACE program; pharmacy participation has always been sufficient to ensure adequate access; it never came to Mr. Snedden's attention that any pharmacists dropped out of the PACE program, even when reimbursement rates on the ingredient side dropped in 1996 and 2003. Id. at 2083.

- While Mr. Snedden knew that pharmacists were paying less than AWP, it was always hard to quantify the difference. Id. at 2090.

- Average manufacturer prices (AMPs), provided by drug manufacturers to PACE, were of limited value because: 1) the

underlying data is not provided; 2) AMPs are not provided on a drug-by-drug basis; and 3) AMP information may not be used in reimbursement methodology. Id. at 2102-03; see also id. at 2200-01 (testimony by Cathers that provision of average sales prices (ASPs) not usable by DPW because they are not current and not provided in digital format).

- Mr. Snedden tried unsuccessfully many times to alter the reimbursement formula. Id. at 2111-20.

Johnson & Johnson Defendants relied on OIG Reports, J&J X-404, 569, 565, 1806. For the reasons discussed above regarding DPW "government knowledge," the contents of these documents were given little weight.

Similarly, Johnson & Johnson Defendants relied on a 1998 PriceWaterhouseCoopers study, J&J X-1360. For the reasons discussed above in relation to DPW "government knowledge," this exhibit was given very little weight.

Johnson & Johnson Defendants also relied on audits performed of pharmacies by PACE. However, the audits were primarily for drugs on the generic side, and the audits were not really helpful in terms of reimbursement for branded drugs, which are the drugs in this case. N.T., 11/2/10, at 2095.

c. "Government Knowledge" – Conclusions

Unlike Judge Saris in MDL 2007, the trial judge rejected evidence that there was an industry/government-wide understanding regarding the meaning and use of AWP. Thus, the trial judge rejected as not credible evidence suggesting that "AWP" was a term of art, widely known to be derived from a formulaic relationship of known proportions over WAC. Instead, the trial judge determined that there was significant confusion regarding the derivation of AWPs. The trial judge also determined that Johnson & Johnson Defendants knew about the confusion and knew that the flaws in the AWP pricing regime were not widely understood.

Like Judge Saris, the trial judge determined the limited "government knowledge" in this case does not exonerate Johnson & Johnson Defendants. MDL 2007, 491 F.Supp.2d at 94. Instead, similar to Judge Saris, the trial judge determined that Johnson & Johnson Defendants caused to be published false AWPs, and their formulaic counterparts false WACs, knowing the government did not understand the extent of the spread between published prices and true average provider acquisition costs. Id.

4. Reliance/"Government Choice"

a. Generally

Regarding reliance, like Judge Saris the trial judge found that Johnson & Johnson Defendants knew that the Plaintiff Agencies could not do much to change the AWP reimbursement benchmark because they were locked into a reimbursement regime established by statute or formal regulation. Id. at 94-95;

N.T., 10/18/10, at 125-26; see also Commonwealth of Kentucky ex rel. Conway v. Alpharma USPD, Inc. et al., No. 04-CI-1487 (Franklin Cir. Ct., Div. 1, Jan. 19, 2011) (unpublished decision denying post-trial motions of drug manufacturer found guilty of violating Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§367.110-367.360), slip op. at 4 ("The civil servants who administered the Medicaid program during the relevant time frame came and went, and each had a differing level of knowledge, understanding and experience with regard to the application of these administrative regulations. Nevertheless, once the state's administrative regulation was adopted that required reimbursement based on the AWP reported by the manufacturer, the state was not free to disregard AstraZeneca's AWP.").

For the most part, the trial judge rejected Johnson & Johnson Defendants' proposed findings of fact regarding "government choice." Some evidence was not credible, some documentary evidence was given little weight, and the trial judge declined to draw inferences favorable to Johnson & Johnson Defendants.

Most importantly, the trial judge rejected the contention that the Plaintiff Agencies made deliberate policy decisions to reimburse at higher rates than other third-party payors to ensure pharmacy participation, also referred to as "access." Rather, the trial judge found more credible the opinions of the Commonwealth's damages expert, Dr. Warren-Boulton, that pharmacy participation was never threatened, even when reimbursement rates were reduced. The trial judge determined that in Pennsylvania the level of reimbursement and the

continuing reliance on formulae based on some form of AWP were the result of several factors: confusion over AWP; lack of a better proxy for provider acquisition costs; and, an inflexible reimbursement system where changes to laws and regulations came slowly, if at all.

b. "Government Choice" – Findings

For the most part, the trial judge rejected Johnson & Johnson Defendants' proposed findings of fact regarding "government choice" of DPW, Proposed Findings 47-65, and "government choice" of PACE, Proposed Findings 73-78. Some evidence was not credible, some documentary evidence was given little weight, and the trial judge declined to draw inferences favorable to Johnson & Johnson Defendants. Notably, the contention that the Plaintiff Agencies made deliberate policy decisions to reimburse at higher rates than other third-party payors was rejected as inconsistent with more credible evidence that pharmacy participation, also referred to as "access," was never threatened and that reimbursement rates were beyond the sole control of the Plaintiff Agencies.

Regarding the access issue, the trial judge accepted the expert opinion of Dr. Warren-Boulton that access was never threatened, even at lower reimbursement rates, N.T., 11/3/10, at 2365-67, 2531-32, and also the supporting testimony by Dr. Terri Cathers, N.T., 11/2/10, at 2190-91, 2192, and by Thomas Snedden, id. at 2083.

As to the Plaintiff Agencies' lack of sole control over reimbursement rates, the trial judge accepted as credible, and gave the most weight to, testimony

by Dr. Terri Cathers, N.T., 11/2/10, at 2195, 2196, 2197, testimony by Suzanne Love, N.T., 11/12/10, at 2692, 3710-21, and testimony by Thomas Snedden, N.T., 11/2/10, at 2111-20.

Johnson & Johnson Defendants relied on the testimony of Gerald Radke, former Deputy Secretary of DPW for Medical Assistance. As stated elsewhere, most of his testimony was rejected as not credible based on demeanor and on bias.

Similarly, J&J X-2090 was given very little weight because it fails to support a finding of full knowledge regarding the extent to which reported AWPs were inflated and regarding a more accurate estimate of a pharmacy's acquisition cost.

Johnson & Johnson Defendants also relied on J&J X-793, an affidavit signed by Suzanne Love in 1998 in connection with a lawsuit filed by Rite Aid challenging a new reimbursement schedule established in October 1995. For the most part the statements in this affidavit were given little weight because they were drafted by lawyers not by the witness, N.T., 11/12/10, at 3644, and because the affidavit arose in a different context in a different lawsuit. Id.

Johnson & Johnson Defendants reliance on the Third Circuit Court of Appeals' opinion in Rite Aid of Pennsylvania, Inc. v. Houstoun, 171 F.3d 842, 855 (3d Cir. 1999), was curious. That case did not involve a statutory claim for injunctive relief and restoration under Pennsylvania's CPL, and it is unclear

whether in that case there was testimony that DPW absolutely does not intentionally pay profits to providers. See N.T., 11/2/10, at 2203 (Cathers). Accordingly, the fact-finding discussed by the Third Circuit Court of Appeals, while interesting, was given no weight in this litigation.

Similarly, testimony that DPW intended to pay a profit to pharmacists or other providers was rejected in favor of testimony that DPW does not intentionally pay profits to providers. Id.

Johnson & Johnson Defendants relied heavily on the testimony of Thomas Snedden during cross-examination to support the conclusion that PACE made deliberate policy decisions to reimburse at higher rates than other third-party payors. However, the trial judge gave little or no weight to this testimony because of Mr. Snedden's demeanor and because he appeared biased toward defending his prior pronouncements and decisions. In addition, because of Mr. Snedden's tendency to agree with every question asked of him, much less weight was given to his responses to leading questions.

5. Causation

Also like Judge Saris, the trial judge concluded the fact that Pennsylvania was slow to change its reimbursement system does not negate causation. MDL 2007, 491 F.Supp.2d at 96. On causation of harm, however, the trial judge received different evidence than that submitted to Judge Saris. Here, evidence established that the Plaintiff Agencies were harmed not by so-called "mega-spreads" on Medicare Part B drugs, but by enhanced price discrimination

by the drug manufacturers on all branded drugs, credibly characterized as "egregious" by the Commonwealth's liability and causation expert, Dr. Comanor. N.T., 10/26/10, at 1494-95. The enhanced price discrimination took the form of different pricing/rebate schemes for public and private payors resulting in public payors, such as the Plaintiff Agencies, paying more than private payors. Id.

Dr. Comanor described two methods of price discrimination. However, only the second method was used in the calculation of restoration, and the trial judge therefore declined to make any findings regarding Dr. Comanor's first theory of price discrimination. See PX-10268 (slide used by Dr. Warren-Boulton during rebuttal: "No damages calculated as to Dr. Comanor's theory that J&J raised WAC with offsetting rebates to PBMs [pharmacy benefits managers]").

The method of price discrimination on which damages were calculated arose where private payors received *lower* rebates from drug manufacturers than public payors received. The private payors nevertheless paid no more than the economic value of the drug because the higher reimbursement rates paid by public payors subsidized the pharmacy overhead. N.T., 10/26/10, at 1493, 1495 (Comanor); PX-10052.0012 ("Cash and Medicaid subsidizes Managed Care").

In other words, the overpayment to providers by the Plaintiff Agencies allowed providers to accept lower reimbursement levels from private payors. This was described more fully as "overhead shifting" by the Commonwealth's damages expert, Dr. Warren-Boulton, whose opinions on this

point the trial judge also accepted. N.T., 11/3/10, at 2410-13, 2430-31; N.T., 11/16/10, at 4109-12. Further, these opinions were corroborated by opinions of some Johnson & Johnson Defendants' executives. E.g., PX-980ee.0001 ("Pharmacies create their own [reimbursement] problems by accepting poor reimbursement rates and then expect Medicaid to bail them out.") The Commonwealth's experts' opinions about "overhead shifting" were also corroborated by the opinion of Defendants' expert witness, Dr. Ernst Berndt. N.T., 11/15/10, at 4040-41; see Decision, slip op. at 3-4, n.2 (although for the most part Dr. Berndt's testimony was rejected, certain parts were accepted as credible).

Johnson & Johnson Defendants' complaints about Dr. Comanor's theories of liability and causation were rejected. First, they complained about the manner in which Dr. Comanor dealt with rebates. They were particularly critical of his theory that Johnson & Johnson Defendants paid *more* in rebates to private payors than to public payors. Second, relying on the testimony of their expert witness, Dr. Berndt, Johnson & Johnson Defendants asserted that Dr. Comanor is "just plain wrong," and that his charts showing price increases for their drugs fail to show net costs after rebates.

These complaints were rejected for several reasons. First and foremost, the trial judge rejected Johnson & Johnson Defendants' contentions regarding the use of rebates, as more fully discussed below. Almost as important, Johnson & Johnson Defendants' complaints are directed at Dr. Comanor's first theory of liability and causation (raising WAC prices with offsetting rebates to private payors). As stated above, however, the trial judge accepted, and restoration

was computed on, Dr. Comanor's second theory (overhead shifting). Under this alternate theory, it was assumed that private payors received *lower* rebates than public payors received. Johnson & Johnson Defendants' contentions do not mention, or even recognize, the "overhead shifting" theory. Third, for the most part the trial judge rejected the testimony on which Johnson & Johnson Defendants rely, especially the testimony of their expert, Dr. Berndt.

Nevertheless, around 2004, several major changes occurred to the reimbursement system in Pennsylvania. First, the 2003 Medicare Prescription Drug, Improvement & Modernization Act, enacted in 2003 and effective January 1, 2005, changed reimbursement for drugs or biologicals under Medicare Part B away from a system based on AWP to a system based on average sales price (ASP). Second, in 2005 the reimbursement rate for DPW changed to the lesser of AWP-14% or WAC + 7% based upon the lowest reported value in any of the three pricing compendia, plus a dispensing fee. N.T., 10/18/10, at 125-26. Accordingly, during this period the reimbursement regime significantly moved away from AWP reimbursement. The trial judge therefore decided that after 2004 actions of Johnson & Johnson Defendants regarding inflated "prices" were not as closely related to restoration amounts.

6. Restoration Amounts

a. Generally

As to the amount of restoration, larger spreads between a provider's acquisition cost and the level of reimbursement leads to higher profits for providers. N.T., 10/26/10, at 1493 (Comanor). Also, to the extent that drug

manufacturers can sell more product, that benefits the manufacturer. Id. The trial judge accepted one of Dr. Warren-Boulton's methodologies for calculating restoration, as described more fully in the Non-Jury Decision, filed December 7, 2010, slip op. at 3-4 n. 2.

b. Rebates – Findings

The trial judge rejected the argument of Johnson & Johnson Defendants that rebates paid to DPW and PACE should be set-off dollar for dollar against restoration in this case. The trial judge also rejected Johnson & Johnson Defendants' Proposed Findings 79 through 89 on this topic. There were several reasons for this position.

Primarily, the trial judge accepted as credible the opinion evidence of the Commonwealth's damages expert, Dr. Warren-Boulton. He testified that the rebate issue is essentially irrelevant to his calculation. N.T., 11/3/10, at 2441. After a lengthy explanation of his analysis, Dr. Warren-Boulton explained that in his opinion, inclusion of the OBRA rebates, including the base rebate (15.1% of AMP) and the Best Price rebate, would cause his calculation of damages to go higher. Id. at 2414-30. He reiterated this position during rebuttal testimony, N.T., 11/16/10, at 4109-12; PX-10268 ("No damages calculated as reduction in rebates to DPW/PACE because overhead shifting reduces Best Price rebate"); PX-10269 (Exhibit 16A). His opinions on this point were accepted.

Second, the position urged by Johnson & Johnson Defendants was at odds with the asymmetrical relationship between reimbursement and rebates.

Reimbursement is based on AWP; however, OBRA base rebates are a percentage of a different metric, average manufacturers price (AMP). The significance of this difference was demonstrated in PX-1615 (2/16/02 email from Joseph Scodari [world-wide chairman of J&J pharmaceuticals] to Gorsky: "if legislators are seriously considering this [changing rebate calculation basis from AMP to AWP] then they still don't understand what AWP is …."). The inference drawn from this exhibit was that the distinct methodologies for establishing reimbursement and for calculating base rebates are so different that it would be destructive to the system for the same methodology to be used for both.

Third, the evidence on which Johnson & Johnson Defendants relied was not credible. In particular, the testimony of Michael Hepburn, Senior Director of Government Contract Compliance for Ortho-McNeil Janssen Pharmaceuticals, was rejected as not credible. In addition to credibility determinations based on demeanor, Mr. Hepburn was impeached based on his limited experience and understanding of reimbursement issues. N.T., 11/8/10, at 2902-06. Indeed, counsel for Johnson & Johnson Defendants explained to the trial judge that Mr. Hepburn's testimony was related to rebates, "not the damages in this case." Id. at 2908. Further, Mr. Hepburn's testimony was inconsistent with the accepted opinions of Dr. Warren-Boulton.

Also, parts of the testimony of Thomas Snedden and Dr. Terri Cathers, which were relied upon by Johnson & Johnson Defendants to establish that rebates reduce the net prices that the Plaintiff Agencies paid for branded drugs, were rejected. This testimony was contrary to the expert opinion of Dr. Warren-Boulton. It was also contrary to the more believable testimony of Dr. Cathers that

there is no dollar for dollar relationship between reimbursement and rebates because of different methodology and because of the significant delay in receiving rebates. N.T., 11/2/10, at 2208-10.

D. Negligent Misrepresentation

Negligent misrepresentation requires proof of: (1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known its falsity; (3) with an intent to induce another to act on it; and, (4) which results in injury to a party acting in justifiable reliance on the misrepresentation. Bortz v. Noon, 556 Pa. 489, 729 A.2d 555 (1999). "The elements of negligent misrepresentation differ from intentional misrepresentation in that the misrepresentation must concern a material fact and the speaker need not know his or her words are untrue, but must have failed to make a reasonable investigation of the truth of these words." Id. at 501, 729 A.2d at 561. Moreover, as with any negligence action, there must be an existence of a duty owed by one party to another. Id.

The Commonwealth presented significant evidence tending to establish: (1) Johnson & Johnson Defendants contributed to reporting of false AWPs for their branded drugs, see MDL 2007; (2) Johnson & Johnson Defendants acted knowing the falsity of the AWPs reported for their branded drugs; and, (3) Johnson & Johnson Defendants acted with an intent that the Plaintiff Agencies use the false AWPs in any reimbursement scheme for the branded drugs. This evidence could satisfy several elements of proof.

However, the trial judge found that the Plaintiff Agencies did not rely on the accuracy of reported AWPs. On the common law element of reliance, Section 17.240 of the Pennsylvania Suggested Standard Jury Instructions (Civil) provides: "'Reliance' means a person would not have acted (or would not have failed to act) as he or she did unless he or she considered the misrepresentation to be true." Pa. SSJI (Civ) 17.240, formerly Pa. SSJI (Civ) 13.22. Comment 5 further explains as follows: "The appropriate test of reliance is whether the misrepresentation induced or influenced the plaintiff's course of conduct." Id. at Subcommittee Note (5). Whether the party claiming to have been defrauded relied on a false representation is a question of fact. Drelles v. Mfrs. Life Ins. Co., 881 A.2d 822 (Pa. Super. 2005).

Here, the parties presented conflicting evidence on the factual issue of whether the Plaintiff Agencies relied on the false AWPs for branded drugs. Specifically, the Commonwealth presented evidence that the Plaintiff Agencies could not deviate from the use of an AWP-based reimbursement methodology because use was mandated by law and because public payors are less nimble in responding to market changes. On the other hand, Johnson & Johnson Defendants presented evidence that the Plaintiff Agencies did not shift away from using AWP as the centerpiece for reimbursement, despite some knowledge that the reported values were inaccurate. The trial judge found that the failure of the Plaintiff Agencies to change their conduct was caused by confusion and by legal or structural constraints rather than by a belief that the reported AWPs were true averages of wholesale prices. Further, the trial judge determined that such a circumstance did not constitute reliance as classically defined. As a result of these

findings, the trial judge concluded that the Commonwealth failed to prove all the elements of negligent misrepresentation.

Notably, a claim under the CPL for "other deceptive conduct," does not expressly require proof that action or inaction is based on reliance that a representation is true. Other explanations for a plaintiff's conduct are considered. See MDL 2007; see also Alpharma USPD, Inc., slip op. at 12 ("Regardless of their personal knowledge or opinions about the proper meaning of AWP, these state [Medicaid] officials were obligated to implement the law as written.").

E. Conspiracy

The essential elements of a claim for civil conspiracy are: (1) a combination of two or more persons acting with a common purpose to do an unlawful act or to do a lawful act by unlawful means or for an unlawful purpose; (2) an overt act done in pursuance of the common purpose; and, (3) actual legal damage. Phillips v. Selig, 859 A.2d 420 (Pa. Super. 2008). Proof of malice, or an intent to injure, is also an essential part of a cause of action for conspiracy. Skipworth v. Lead Indus. Ass'n, Inc., 547 Pa. 224, 690 A.2d 169 (1997); Thompson Coal Co. v. Pike Coal Co.; 488 Pa. 198, 412 A.2d 466 (1974); Weaver v. Franklin Cnty., 918 A.2d 194 (Pa. Cmwlth. 2009); Goldstein v. Phillip Morris, Inc., 854 A.2d 555 (Pa. Super. 2004). This unlawful intent must be absent justification. Thompson Coal.

In Thompson Coal, our Supreme Court explained the test regarding the requisite intent as follows:

> Assume that what is done is intentional, and that it is calculated to do harm to others. Then comes the question, Was it done with or without "just cause or excuse"? If it was bona fide done in the use of a man's own property * * * such legal justification would * * * exist not the less because what was done might seem to others to be selfish or unreasonable. * * * But such legal justification would not exist when the act was merely done with the intention of causing temporal harm, without reference to one's own lawful gain, or the lawful enjoyment of one's own rights.

Id. at 211, 412 A.2d 466, 472 (quoting Rosenblum v. Rosenblum, 320 Pa. 103, 108-09, 181 A. 583, 585 (1935)). Proof of conspiracy must be made by full, clear and satisfactory evidence. Phillips.

The trial judge found the Commonwealth satisfied most of the elements required to prove conspiracy. Specifically, the trial judge determined Johnson & Johnson Defendants conspired with other defendants, as well as other groups not parties to this litigation, to inflate AWPs for their drugs, to maintain an AWP-based reimbursement for drugs by public payors, and to conceal the truth about these acts. The trial judge also determined Johnson & Johnson Defendants and others committed overt acts in pursuance of these common purposes resulting in actual legal damage to the Plaintiff Agencies.

However, the trial judge declined to infer malice from the circumstances. Indeed, the record supports a finding that, instead of acting with the sole intent to injure the Plaintiff Agencies, Johnson & Johnson Defendants acted in furtherance of their business interests. See, e.g., N.T., 10/26/10, at 1493 (testimony by Commonwealth's liability and causation expert, Dr. Comanor,

opining that drug manufacturers' pricing policies benefit the manufacturers because they can sell higher quantities of drugs). Because of this finding, the trial judge concluded that the Commonwealth failed to prove all the elements necessary for a civil conspiracy.

III. FINDINGS AND CONCLUSIONS: MARKETING THE SPREAD

Johnson & Johnson Defendants include two wholly-owned subsidiaries, Centocor, Inc. and Ortho Biotech Products, L.P. Johnson & Johnson Defendants have two Medicare Part B drugs at issue in this case, Procrit and Remicade. With the exception of opinion evidence, the evidence received regarding these two drugs was almost identical to that received by Judge Saris in MDL 2007. Not surprisingly, the trial judge made very similar findings to those of Judge Saris in MDL 2007, although the trial judge came to different conclusions based on different opinion evidence relating to liability, causation and damages.

A. Procrit®

Procrit is the brand name for epoetin alfa, which is used to treat severe anemia, including anemia in AIDS and cancer patients. N.T., 11/1/10, at 1764-66. Epoetin alfa is manufactured by Amgen, Inc. and licensed to Johnson & Johnson's Ortho Biotech for sale as Procrit. Id. Amgen also sells epoetin alfa under the brand name Epogen. Procrit and Epogen are identical, having exactly the same FDA-approved indications for use. Id. Under a licensing agreement, Amgen has the exclusive right to market epoetin alfa for use in the treatment of anemia in dialysis patients while Ortho Biotech has the exclusive right to market epoetin alfa for non-dialysis uses. Id. Physicians, however, are not subject to the terms of the

licensing agreement and may lawfully administer either brand of epoetin alfa to any patients they choose. Id. Consequently, Procrit and Epogen are sometimes in direct competition with each other.

Ortho Biotech introduced Procrit in January 1991, about 18 months after Amgen launched Epogen. Id. at 1766-67. Ortho Biotech set the WAC price and the AWP for Procrit equal to those already established for Epogen. Id. The published AWP for Procrit, like that of Epogen, was set 20% higher than the WAC price. Id.

After launching Procrit, Ortho Biotech offered discounts below the WAC price to non-dialysis providers in order to encourage physicians to use Procrit rather than Epogen. Id. at 1769-70. These discounts generally ranged from 5% to 10% off of the WAC price, although some high volume purchasing physicians could receive higher discounts. Id.; PX-982bb, ¶15. The WAC price and AWP price remained constant for the six years following Procrit's launch.

Johnson & Johnson Defendants fully understood the Medicare reimbursement system and its impact on physician choices. A 1993 memo emphasized that the "goal is to keep the physician 'whole' i.e. whole on the 80% as there is a fear that they will not be reimbursed on the remaining 20%." PX-1188.0005. A 1999 examination of reimbursement scenarios showed that a physician's profit per patient, for a 20-week course of Procrit, could range from a loss of $304 to a gain of $1,520 depending on the percentage of the copayment collected. PX-1195.0003. A 1996 McKinsey & Company consulting report for

Ortho Biotech quoted a doctor as stating that "[m]y practice makes $6-8,000 per month on Procrit." PX-1185.0014. The report advised that "[Ortho Biotech] must preserve positive economics for physicians." PX-1183.0034. Significantly, in 1997, when Medicare decided to change Part B reimbursement from 100% of AWP to 95% of AWP, Ortho Biotech responded by making its first price increase since the launch of Procrit. In February of 1997, Ortho Biotech increased the prices on the most popular unit of Procrit by 3.5% and then in January of 1998 increased the prices an additional 1.8%. PX-1088; PX-1089. The result was that physicians would receive essentially the same reimbursement amount for Procrit after Medicare reduced its reimbursement percentage of AWP.

While Johnson & Johnson Defendants worked to "preserve physician economics," there was serious concern at the company that the government would find out about the spreads and take action to reduce the reimbursement amounts. See PX-1188.0003. In 1998, Cathleen Dooley, then the Senior Director for Reimbursement and Health Policy, sent an e-mail about Medicare's reimbursement policy for Procrit in which she stated, "[r]ight now they do not know what the cost [of Procrit and Epogen] is for different providers." PX-1108.0001 She cautioned that the fact that patients were paying a copayment of a price much higher than the acquisition cost would be a "public relations issue." PX-1108.0002. She further noted that the only way that Medicare could determine Procrit's market price was "to require an invoice be submitted with each Medicare claim that is sent in. This would be very cumbersome ...." PX-1108.0001. Similarly, when Ortho Biotech considered taking a price increase in 1997 and 1998, it was concerned that raising the Procrit AWP above the Epogen AWP could "raise red flags" and "trigger a

price survey." PX-1111. Ortho Biotech recognized that if a survey were taken, "the reimbursement rate would be lowered," which would decrease the profit to providers. PX-1188.0003.

Despite these concerns, Johnson & Johnson Defendants actively encouraged their sales representatives to market the spread on Procrit to physicians. Evidence to the contrary was rejected. For example, Charles River Associates, a consulting firm, advised that the "Procrit sales force must provide compelling evidence that continuing with Procrit provides economic benefits." PX-1025o.0004. The consultants further encouraged Ortho Biotech to develop a spreadsheet that would model those economic benefits of Procrit. See PX-1025o.0005.

In at least one region, the sales representatives were receiving specific instructions on ways "to tactfully discuss how an office can profit from providing Procrit in the office." PX-1082.0001. In a 1996 memo to his sales team, Sales Manager John Hess emphasized that the "office needs to understand that there is profit associated with Procrit." Id. The memo then provides a chart showing a "return on equity for Procrit" and instructing the sales force to "ask for their real numbers" when "reviewing with a physician or office manager." Id. The memo also specifically quantifies the profits per patient for Medicare and non-Medicare patients over various time periods. PX-1082.0002. Mr. Hess also directed the sales representatives to be discreet in their use of the profit information, instructing them to "simply draw out the scenario on a piece of scratch paper asking for the office billing fee, injection fee, and acquisition fee based on medicare or non-

medicare." Id. The memo closes with an underlined directive: "Do not distribute this memo to your offices. This is for your information only!" Id.

The main Ortho Biotech office was also highlighting profit potential to physicians in a slide presentation created by an outside company. PX-1180. One slide asks, "Can you make money ? ? ? ?." PX-1180.0003. Another slide responds, "[d]rugs have paid well under part B." PX-1180.0008. The next slide explains the Medicare reimbursement at 95% of AWP and quotes the current AWP for Procrit. PX-1180.0009. The presentation concludes with the question "Should you give Procrit?" and the first reason supporting an affirmative answer is "Additional revenue." PX-1180.0011.

Later, Ortho Biotech apparently stated a policy prohibiting spread marketing, evidencing an understanding that spread marketing violated industry standards. The trial judge was not convinced the policy was enforced. Testimony about the policy from Johnson & Johnson Defendants' executives was not believable. This was essentially the same determination made by Judge Saris in MDL 2007, 491 F.Supp.2d at 95.

B. Remicade®

Centocor, Inc. launched Remicade in 1998 and Johnson & Johnson acquired Centocor in 1999. Remicade (infliximab) is used to treat rheumatoid arthritis, Crohn's disease, and other conditions. N.T., 10/19/10, at 462-64 (Hoffman). Remicade is administered to patients via intravenous infusion, which frequently takes place in a physician's office, but which may also take place in

hospital out-patient departments. Remicade has been a single-source drug from its inception in 1998 and throughout the period for which restoration was awarded, although it faces therapeutic competition in the treatment of rheumatoid arthritis. Id.

Centocor set the AWP for Remicade at a 30% markup over its WAC price. John Hoffman, Vice President of the strategic customer franchise at Centocor, explained why the 30% markup was chosen: "It was [a combination] of looking at what the payors would bear in terms of the price of the product; and … that it was going to be financially viable [for physicians]." Id. at 455-56. Throughout the period, Centocor maintained this 30% difference between WAC and AWP.

Centocor sold Remicade to specialty distributors, who in turn sold to physicians. Specialty distributors of Remicade had the opportunity to get the 2% prompt pay discount plus an additional 1% to 1.5% discount off of WAC. Deposition of Ronald J. Krawczyk, 6/22/10 at 101; N.T., 10/20/10, at 719. Thus, the specialty distributors were paying WAC less 3% to 3.5% to obtain Remicade.

Centocor pursued a strategy of marketing the spread to physicians. Evidence to the contrary was rejected. Centocor developed and implemented a Practice Management Program ("PMP") to educate physicians on buying, infusing, and billing for Remicade. Deposition of Laura Glassco, 9/1/05, at 20-21, N.T., 10/20/10, at 563. One of the PMP materials was a "Financial Impact Worksheet," which listed the AWP and allowed the physician to fill in her acquisition cost, the

percentage discount off AWP for reimbursement, her case load, and the number of vials per patient. PX 1103.0008. The worksheet then showed the physician how to calculate an "Estimated margin per vial," "Estimated revenue per patient," and "Estimated monthly revenue from REMICADE." Id.

Centocor also hosted PMP seminars, where sales representatives made presentations to groups of physicians explaining the profit potential of using Remicade given the AWP-based reimbursement. Senior Sales Executive Laura Glassco explained how she walked doctors through a PowerPoint presentation that illustrated the profitability:

> Basically I would share with the physician … that AWP was at that time the price that's shown here, [and] that Medicare reimbursement was AWP less 5 …. I then walked through with them the scenario which you see here of an example of a patient that might be a three-vial infused patient …. [I]f the cost of the drug was a certain amount, I show the cost of the drug to the physician and I compare that to what the reimbursement was from Medicare …. The last slide shows then the difference between what the physician paid for the drug and what the physician … gets reimbursed from … the Medicare carrier.

Deposition of Laura Glassco, 9/1/05, at 105-08, N.T., 10/20/10, at 587-89. One of the concluding slides showed that, assuming the drug is purchased at list price, the annual profit per patient on Remicade would be $2,293.41. PX-1121.0018.

Laura Glassco also forwarded an e-mail to her sales team, in which she praised one of the sales representatives for his "work in the field." PX-

1121.0001. In the forwarded email, the sales representative writes about how he explained reimbursement to the physician and walked through a "Medicare AWP example" showing the potential reimbursement. Id. He notes that "Dr. Kassan seemed so excited about getting started …." Id.

C. Conclusions

Like Judge Saris in MDL 2007, the trial judge determined that Johnson & Johnson Defendants marketed the spread for Procrit and Remicade, the Medicare Part B drugs. Also like Judge Saris, the trial judge here concluded that marketing the spread "so that doctors would choose a drug based on profit rather than therapeutic value is particularly outrageous and unethical." MDL 2007, 491 F.Supp.2d at 95. The trial judge determined this practice constitutes deceptive conduct which creates a likelihood of confusion or of misunderstanding, particularly among patients receiving the drugs. This is a violation of the CPL, which may be enjoined.

Additionally, like Judge Saris the trial judge determined that the pharmaceutical industry in general, and Johnson & Johnson Defendants in particular, understood that if the marketing of spreads became public, a public relations nightmare would ensue. Id. As such, the manufacturers insisted on confidentiality in physician contracts and lobbied to undermine government surveys. Id. at 95-96.

As to restoration, however, the trial judge's conclusions differed from those of Judge Saris. She predicated her conclusions of no liability for Procrit and

Remicade marketing on expert testimony that the spreads between AWPs and ASPs for these pharmaceuticals were consistent and predictable throughout the class period. Id. at 103-04. In contrast, as discussed more fully elsewhere, the trial judge here rejected evidence that there was an industry/government-wide understanding regarding the meaning and use of AWP, and the trial judge rejected as not credible evidence suggesting that AWP was known by the Plaintiff Agencies to be derived from a formulaic relationship of known proportions over WAC.

Instead, the trial judge determined that by marketing the spread, Johnson & Johnson Defendants were benefited by selling more of their branded pharmaceuticals. See N.T., 10/26/10, at 1493 (Comanor). The trial judge also determined that the Plaintiff Agencies were harmed by reimbursing for Johnson & Johnson Defendants' branded pharmaceuticals at a price significantly greater than providers' acquisition costs. As discussed more fully elsewhere, the trial judge accepted Dr. Warren-Boulton's methodology for calculating restoration and penalties.

IV. J&J GLOBAL CHALLENGE: JUDICIAL ESTOPPEL

A. Contentions

Johnson & Johnson Defendants assert the Commonwealth's claims are barred by judicial estoppel. Specifically, they maintain the Commonwealth successfully asserted in prior litigations that it intended its reimbursement rates to be more generous than those of other states or private payors to provide pharmacies a reasonable profit on ingredient cost. They argue the Commonwealth

is judicially estopped from taking the opposite position here because it now suits the Commonwealth's purposes in this litigation.

Johnson & Johnson Defendants contend that for decades the Commonwealth engaged in litigation concerning appropriate reimbursement levels under Medicaid. They maintain throughout these "reimbursement litigations,"[14] the Commonwealth, in defending DPW's reimbursement formula, unfailingly asserted before the deciding tribunals that its reimbursement for ingredient cost contains a built-in profit that compensates pharmacies beyond what they pay for merely purchasing a drug. Johnson & Johnson Defendants assert the Commonwealth should be judicially estopped from disavowing this position and maintaining the opposite to this Court – that the Commonwealth never intended to provide a profit in its ingredient cost-reimbursement and, therefore, should be awarded damages based on declining to seek lower reimbursement rates.

Johnson & Johnson Defendants assert over the last 30 years, government and pharmacist organizations sued the Commonwealth alleging its pharmacy reimbursement was unlawful. In response, the Commonwealth consistently argued its "generous" reimbursement for ingredient costs to

[14] Johnson & Johnson Defendants cite Pa. Pharmacists Ass'n v. Houstoun, 283 F.3d 531 (3d Cir. 2002); Rite Aid of Pa. v. Houstoun, 171 F.3d 842 (3d Cir. 1999); Pa. Pharmacists Ass'n v. Casey, 800 F. Supp. 173 (M.D. Pa. 1992); Pa. Pharmacists Ass'n v. Houstoun, No. Civ. A. 99-491, 2000 WL 730344 (E.D. Pa. June 7, 2000); Pa. Pharmacists Ass'n v. Dep't of Pub. Welfare, 733 A.2d 666 (Pa. Cmwlth. 1999); Dep't of Pub. Welfare v. Shalala, No. CV-95-237, 1996 WL 179572 (M.D. Pa. 1996); Dep't of Pub. Welfare v. HCFA, Dkt. No. A-95-65, 1996 WL 50989 (H.H.S.) (Departmental Appeals Board Jan. 26, 1996); Dep't of Pub. Welfare v. HCFA, Dkt. No. 91-113, 1992 WL 685317 (H.H.S.) (Departmental Appeals Board, March 18, 1992).

pharmacies was an intentional policy decision, and the Commonwealth's overall reimbursement rates were fair and reasonable. See, e.g., Rite Aid of Pa., 171 F.3d at 855 ("[DPW's] finding that at least 40 states discounted AWP by, on average, 10%, and that the eight large, non-government plans studied discounted AWP by at least 10% and, in some cases, discounted AWP by an even higher percentage, supported its determination that AWP-10% would allow pharmacies to maintain provision of care and earn a profit. Furthermore, the plans paid lower dispensing fees than the $3.50 previously offered by [DPW]. Thus, [DPW] was aware that with the revised rates, Pennsylvania's program would pay more than most states and more than those of other major Pennsylvania payors.")

In short, Johnson & Johnson Defendants argue the Commonwealth consistently and repeatedly argued before multiple tribunals that its ingredient cost deliberately contained an amount that paid pharmacists more than they paid for drugs. They assert judicial estoppel bars the Commonwealth from now seeking to recover monies paid to pharmacists based on lower reimbursement levels others were using or on pharmacists' actual acquisition costs.

B. Analysis

This issue was not raised by Bristol-Myers Squibb (BMS) in the first trial. Nevertheless, the trial judge in the second trial rejected this contention, which was raised in both a motion for compulsory non-suit and in proposed findings of fact and conclusions of law. After careful review, we discern no error in the trial judge's decisions on this point.

By way of background regarding the doctrine of judicial estoppel, the U.S. Supreme Court explained:

> Where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him. This rule, known as judicial estoppel, generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase.
>
> Although we have not had occasion to discuss the doctrine elaborately, other courts have uniformly recognized that its purpose is to protect the integrity of the judicial process, by prohibiting parties from deliberately changing positions according to the exigencies of the moment …. Because the rule is intended to prevent improper use of judicial machinery, judicial estoppel is an equitable doctrine invoked by a court at its discretion.
>
> Courts have observed that the circumstances under which judicial estoppel may appropriately be invoked are probably not reducible to any general formulation of principle[.] Nevertheless, several factors typically inform the decision whether to apply the doctrine in a particular case: First, a party's later position must be "clearly inconsistent" with its earlier position. Second, courts regularly inquire whether the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create "the perception that either the first or the second court was misled[.]" Absent success in a prior proceeding, a party's later inconsistent position introduces no risk of inconsistent court determinations, and thus poses little threat to judicial integrity. A third consideration is whether the party seeking to assert an inconsistent

> position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped.

New Hampshire v. Maine, 532 U.S. 742, 749-51 (2001) (citations and quotations omitted).

Further delineating the contours of the doctrine of judicial estoppel, this Court, speaking through Judge (now President Judge) Leadbetter, explained:

> With respect to judicial estoppel, we note that, as a general proposition, a party to an action is estopped from assuming a position inconsistent with his assertion in a previous action, if his assertion was successfully maintained. However, the doctrine only applies if the issues and the parties are the same in the subsequent action ….

Bergdoll v. Commonwealth, 858 A.2d 185, 194 (Pa. Cmwlth. 2004) (en banc), aff'd per curiam, 583 Pa. 44, 874 A.2d 1148 (2005) (citations and quotations omitted) (emphasis added). Indeed, "for the doctrine to apply, the issues and the parties have to be the same, and the inconsistent positions must be asserted in the same or subsequent phase of the same proceeding or in a subsequent proceeding involving the same parties." Phila. Suburban Water Co. v. Pa. Pub. Util. Comm'n, 808 A.2d 1044, 1061 (Pa. Cmwlth. 2002) (en banc) (emphasis added).

Here, the Commonwealth's trial against Johnson & Johnson Defendants is not a subsequent phase of the "reimbursement litigations" referenced by the Defendants. Nor is it a subsequent proceeding involving the same parties. Indeed, a review of the cases cited by Johnson & Johnson Defendants reveals the parties to the majority of those suits were various pharmacies or pharmacists

organizations and DPW, its Secretary or the Commonwealth. Johnson & Johnson Defendants were not parties to any of these suits. Because of the difference in the parties and the difference in the proceedings, judicial estoppel does not apply.

Moreover, a review of the Third Circuit's decision in Rite Aid of Pennsylvania, the primary case cited by the Defendants, reveals the issues in that case and the issues in the Commonwealth's current suit are not the same. Rite Aid of Pennsylvania concerned a procedural challenge by Rite Aid and the Pennsylvania Pharmacists Association to DPW's promulgation of revised regulations governing payment rates for prescription drugs to Medicaid recipients (changing the reimbursement formula from full AWP to AWP-10%, and the dispensing fee from $3.50 to $4.00). Clearly, this issue is distinct from the issues presented in the Commonwealth's trial against Johnson & Johnson Defendants, which involve whether they committed common law fraud, misrepresentation or violated the CPL by contributing to the reporting of inflated AWPs to DPW and PACE, or by promoting or marketing the spreads on its drugs that are reimbursed by DPW or PACE.[15]

[15] In addition, a review of the reported cases Johnson & Johnson Defendants cite in a footnote does not convince us that the issues in those cases and the case before us are the same. See Pa. Pharmacists Ass'n v. Houstoun (considering whether the Pennsylvania Pharmacists Association and various pharmacies could maintain a 1983 action against the Secretary of DPW challenging the reimbursement rates paid to pharmacies); Pa. Pharm. Ass'n v. Casey (considering whether the Commonwealth violated federal law when it lowered drug reimbursement rates); Pa. Pharm Ass'n v. Dep't of Pub. Welfare (considering whether the Commonwealth's reimbursement to pharmacists for prescription drugs purchased by Medicaid complied with federal law and regulations, and the issue of the pharmacists' standing to bring the suit); Pa. Pharm. Ass'n v. Dep't of Pub. Welfare (considering preliminary objections in a suit brought by pharmacists seeking to, among other things, enjoin DPW from permitting
(Footnote continued on next page…)

In addition, given the trial judge's findings regarding the significant confusion over AWP, we reject Johnson & Johnson Defendants' argument that it is clear that the Commonwealth knowingly asserted in earlier litigation that it intended its reimbursement rates to be more generous than other entities in order to provide pharmacists a reasonable profit on ingredient costs. Because it is clear that significant confusion regarding AWP existed among those responsible for the Commonwealth's reimbursement programs, we do not believe the Commonwealth is attempting to "play[] fast and loose with the judicial system by adopting whatever position suits the moment." Sunbeam Corp. v. Liberty Mut. Ins. Co., 566 Pa. 494, 500, 781 A.2d 1189, 1192 (2001) (internal quotations omitted). To the contrary, because of the abundance of evidence regarding confusion over AWP, application of the doctrine of judicial estoppel is problematic.

Finally, because judicial estoppel is an equitable doctrine invoked at a court's discretion, New Hampshire, we do not believe it is properly invoked by Johnson & Johnson Defendants, who come before the Court with unclean hands by virtue of their commission of deceptive acts and practices that run afoul of the

(continued…)

reimbursement of providers under a managed care program based on certain outpatient pharmacy rates).

Johnson & Johnson Defendants also cite two Department of Health and Human Services, Departmental Appeals Board decisions that involved disallowances by the Health Care Financing Administration of claims made by DPW under the federal Social Security Act. See Dep't of Pub. Welfare v. HCFA, Dkt. No. A-95-65, 1996 WL 50989 (H.H.S.) (Departmental Appeals Board Jan. 26, 1996); Dep't of Pub. Welfare v. HCFA, Dkt. No. 91-113, 1992 WL 685317 (H.H.S.) (Departmental Appeals Board, March 18, 1992). Clearly, these decisions do not concern the same issue presented in the trial involving Johnson & Johnson Defendants.

CPL. In re Adoption of S.A.J., 575 Pa. 624, 838 A.2d 616 (2003) (doctrine of unclean hands requires that party seeking equity act fairly and without fraud or deceit as to the controversy at issue).

V. J&J GLOBAL CHALLENGE: NON- JUSTICIABLE POLITICAL QUESTION

A. Contentions

Johnson & Johnson Defendants assert that judgment should be entered in their favor because the claims against them involve a non-justiciable political question.

They argue the current case involves more than merely interpreting the laws of Pennsylvania and determining the intent behind legislative and regulatory action. Rather, the pertinent legislative and regulatory bodies acted well within their constitutionally and legislatively granted powers when they enacted the reimbursement rates applicable for the Plaintiff Agencies. They assert these Agencies seek damages premised on what the Commonwealth would have paid if it based payments on lower reimbursement rates implemented by other states or private payors. In other words, the Commonwealth is asking the Court to approve reimbursement rates that Pennsylvania Medicaid could have adopted. They argue the evidence shows DPW, PACE, the IRRC and the General Assembly expressly considered and rejected these reimbursement formulae. Johnson & Johnson Defendants further assert that the Commonwealth is asking this Court to impose these judicially-crafted reimbursement rates retroactively by having them pay for the alleged shortfall.

In addition, Johnson & Johnson Defendants contend that by asking the Court to enjoin them from continuing the allegedly deceptive and unfair acts complained of, the Commonwealth would dramatically alter the amount of payments not only for pharmacies in connection with dispensing prescriptions to Medicaid patients, but also tens of thousands of industry participants nationwide—both private and public—that have structured their contracts around the AWP benchmark as it is and was, not as the Commonwealth alleges it should have been.

Also, Johnson & Johnson Defendants maintain these decisions cannot be made without a court undertaking a shadow administrative rulemaking process that the General Assembly expressly directed PACE and DPW to undertake in the first instance, reserving for itself the ultimate right to approve or disapprove. In short, Johnson & Johnson Defendants argue that this Court should decline to decide the case because of a "lack of judicially discoverable and manageable standards for resolving it; [and] the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion." Sweeney v. Tucker, 473 Pa. 493, 510, 375 A.2d 698, 706 (1977) (citation omitted).

B. Analysis

This legal issue was not raised by BMS in the first trial. Nevertheless, the trial judge in the second trial rejected this contention, which was raised in both a motion for compulsory non-suit and in proposed findings of fact and conclusions of law. For both factual and legal reasons, no error is evident.

Factually, this issue is a variant of the "government choice" contention advanced during trial. For reasons discussed at length above, the trial judge rejected many of the facts upon which Johnson & Johnson Defendants now rely. Thus, the trial judge rejected the contention that the Plaintiff Agencies made deliberate policy decisions to reimburse at higher rates than other third-party payors to ensure pharmacy participation, also referred to as "access." Rather, the trial judge found more credible the opinions of the Commonwealth's damages expert, Dr. Warren-Boulton, that pharmacy participation was never threatened, even when reimbursement rates were reduced. The trial judge determined that in Pennsylvania the level of reimbursement and the continuing reliance on formulae based on some form of AWP were the result of several factors: confusion over AWP; lack of a better proxy for provider acquisition costs; and, an inflexible reimbursement system where changes to laws and regulations came slowly, if at all.

Legally, "[t]o determine if a case or controversy constitutes a non-justiciable political question, the Court must ascertain 'whether the duty asserted can be judicially identified and its breach judicially determined, and whether protection for the right asserted can be judicially molded.'" Harris v. Kellogg, Brown & Root Servs., Inc., 618 F. Supp. 2d 400, 419 (W.D. Pa. 2009) (quoting Baker v. Carr, 369 U.S. 186, 198 (1962)).

Further, with regard to the political question doctrine, our Pennsylvania Supreme Court explained:

> As this Court noted in [*Sweeney*], a basic precept of our form of government is that the Executive, the

Legislature, and the Judiciary are independent, co-equal branches of government. Id. at 705. As we further noted, while the dividing lines among the three branches "are sometimes indistinct and are probably incapable of any precise definition[,]" under the principle of separation of the powers of government, no branch should exercise the functions exclusively committed to another branch. Id. The political question doctrine is generally considered to derive from the principle of separation of powers. Under the doctrine, the courts will not review the actions of another branch of government where the constitution entrusts those actions to that other branch. Id.

In evaluating whether there is a political question in a case such that a court should refrain from deciding, we are guided by the standards the U.S. Supreme Court discussed in [*Baker*], the seminal case in the area. In *Baker*, the High Court stated:

> Prominent on the surface of any case held to involve a political question is found a textually demonstrable constitutional commitment of the issue to a coordinate political department; or a lack of judicially discoverable and manageable standards for resolving it; or the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion; or the impossibility of a court's undertaking independent resolution without expressing lack of the respect due coordinate branches of government; or an unusual need for unquestioning adherence to a political decision already made; or the potentiality of embarrassment from multifarious pronouncements by various departments on one question.

Id. at 217, 82 S.Ct. 691, *quoted in Sweeney*, 375 A.2d at 706.

Council 13, Am. Fed'n of State, Cnty. & Mun. Employees, AFL-CIO v. Rendell, 604 Pa. 352, 370-71, 986 A.2d 63, 74-75 (2009).

We again reject the argument that this case presents a non-justiciable political question. As discussed at length above, the Commonwealth proved that Johnson & Johnson Defendants' business practices violated the CPL. Therefore: (1) the duty at issue can be judicially identified (refrain from deceptive conduct, such as contributing to fictitious prices which are key values in an inflexible, complicated reimbursement system); (2) a breach of that duty can be judicially determined; and, (3) protection for the right asserted can be judicially molded through issuance of an injunction and restoration. Therefore, this case simply does not present a non-justiciable political question.

Further, we reject the argument that this case lacks "judicially discoverable and manageable standards for resolving it." To the contrary, the legal and factual questions presented by this suit are of the type the judiciary is competent to resolve under the Constitution, and equipped to resolve as a practical matter. In adjudicating this case, the Court interprets and applies the CPL, a task commonly undertaken. In short, this suit involves legal, rather than political standards, and the Court possesses the criteria to adequately evaluate the claims before it. See, e.g., Gross v. German Found. Indus. Initiative, 456 F.3d 363 (3d Cir. 2006).

Moreover, Johnson & Johnson Defendants' contention that this case is impossible to decide "without an initial policy determination of a kind clearly for

nonjudicial discretion," is unsustainable. Under this factor, a political question is implicated if in deciding the case, a court would have to make a policy determination of the kind appropriately reserved for diplomatic-and thus Executive-discretion. See e.g., Aktepe v. United States, 105 F.3d 1400 (11th Cir. 1997) (case non-justiciable, in part, because the policy determination would be of a kind reserved for military discretion). A political question under the third factor "exists when, to resolve a dispute, the court must make a policy judgment of a legislative nature, rather than resolving the dispute through legal and factual analysis." Equal Employment Opportunity Comm'n v. Peabody W. Coal Co., 400 F.3d 774, 784 (9th Cir. 2005). As discussed above, resolution of the Commonwealth's suit proceeded through a careful legal and factual analysis rather than through a policy judgment. Thus, this assertion fails.

Of additional note, the U.S. District Court of Massachusetts considered and rejected a political question defense asserted by drug manufacturers in the context of AWP-related litigation in In re Lupron Marketing and Sales Practices Litigation, 295 F. Supp. 2d 148 (D. Mass. 2003). Lupron involved an action by cancer patients and health care plans, accusing drug manufacturers of conspiring to artificially inflate the price of Lupron in violation of the civil provisions of the Racketeer Influenced and Corrupt Organizations Act.[16] The drug manufacturers sought dismissal of the suit on the ground the case presented a non-justiciable political question. Specifically, they asserted:

> Congress has spent decades wrestling over the cost structure of the Medicare program and, despite being

[16] 18 U.S.C. §§1961-68.

> aware of the fact that the AWP for most prescription drugs does not reflect their actual cost, "has repeatedly, consciously, and intentionally left the current system in place, leading to the inescapable conclusion that Congress intends AWP to be higher than the cost charged to providers." Defendants accuse plaintiffs of now attempting an "end run around the political system" by trying to accomplish in the courts what they have failed to obtain in the political process. For the court to intervene and "second-guess" the decisions of Congress and the HHS regulators would, in the eyes of defendants, "be inappropriate and inadvisable."

Id. at 162 (citations omitted).

Rejecting this assertion, U.S. District Court Judge Richard G. Stearns explained:

> While an elegant doctrine, political question considerations have generally led to judicial abstention only in sensitive matters relating to national defense and only then in the rarest of cases. As Professor Tribe notes, the Supreme Court has invoked the political question doctrine only twice since *Baker v. Carr* to hold an issue nonjusticiable. [1 L.H. Tribe, *American Constitutional Law* 376 (3d ed.2000)]. *See Gilligan v. Morgan,* 413 U.S. 1, 93 S.Ct. 2440, 37 L.Ed.2d 407 (1973) (declining to evaluate the training of the Ohio National Guard); *Nixon v. United States*, 506 U.S. 224, 113 S.Ct. 732, 122 L.Ed.2d 1 (1993) (declining to entertain a challenge to the Senate's "sole authority" to determine impeachment trial procedures). Mere disagreement with a determination by Congress, even one with constitutional dimensions, is not normally a reason for a court to abstain on justiciability grounds. As Justice Marshall observed in *United States v. Munoz-Flores,* 495 U.S. 385, 390, 110 S.Ct. 1964, 109 L.Ed.2d 384 (1990), a case involving a challenged violation of the Origination Clause, "[t]he Government may be right that a judicial finding that Congress has passed an unconstitutional law might in some sense be said to entail a 'lack of respect' for Congress' judgment. But disrespect, in the sense the

> Government uses the term, cannot be sufficient to create a political question. If it were, *every* judicial resolution of a constitutional challenge to a congressional enactment would be impermissible."
>
> Moreover, I do not agree with the premise of defendants' argument that a judicial resolution of this case would entail any disrespect to the intent of Congress in structuring prescription drug reimbursement rates using the AWP as a benchmark. As defendants portray the Congressional purpose in setting the reimbursement rate at 95% of AWP, Congress meant to turn a blind eye to the inflated AWPs as a means of enticing physicians to treat Medicare patients. In other words, Congress deliberately invited the very fraud of which defendants are accused. As defendants describe it, "a determination that AWP must be set at the actual cost to providers would result in lower Medicare payment levels to physicians, prompting many of those physicians to stop treating Medicare patients because it is not cost-effective for them to do so." Defendants' Memorandum, at 32. The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual. It is far more likely that by setting the Medicare reimbursement rate below the AWP, Congress took a tentative step towards using Medicare's purchasing power as a means of driving down the cost of prescription drugs to the Medicare program. "Average," after all, means that in a competitive market, some prices will be higher and some lower than the median. Congress might reasonably have wished to put Medicare on the lower rung of the equation.

Id.at 162-63 (footnotes omitted).

A similar argument was also raised by drug companies at an early stage in the multi-district litigation in In re Pharmaceutical Industry Average Wholesale Price Litigation, 263 F. Supp. 2d 172 (D. Mass. 2003), in which

plaintiffs alleged that numerous drug manufacturers fraudulently overstated the published AWP of many of their prescription drugs. There, Judge Saris explained:

> Defendants concede that the "national average wholesale price" figures upon which Medicare Part B reimbursements and co-payments are based are not the *actual* average of wholesale prices they charge for their drugs. Nonetheless, pointing to legislative hearings and statements on AWPs, they contend that Congress knows that the AWPs they report represent only an "undiscounted sticker price" that has no direct relation to the actual average price they charge for their drugs, and that Congress has acceded to this widespread pricing and reporting practice.
>
> Drawing on the policies underpinning the political question doctrine, and urging "prudential abstention," defendants argue that it would be an unwarranted excursion into the legislative domain for this Court to hold defendants' practices unlawful when Congress has acquiesced in these practices. However, not every matter touching on politics is a political question. It goes without saying that interpreting congressional legislation is a recurring and accepted task for the federal courts. The fact that congressional hearings have been held, congressional reports generated, and executive branch statements on the AWP issued, without follow-up legislative action, does not mandate judicial retreat from this heartland task of construing statutory language.

Id. at 180-81 (citations, quotations and footnote omitted); see also Alpharma USPD, Inc. (on post-trial motions of drug manufacturer in AWP litigation for violation of Kentucky Consumer Protection Act, trial court rejected non-justiciable political question argument).

The fact that other courts have considered and rejected the political question doctrine in the context of AWP litigation, including litigation under

consumer protection statutes, provides further support for our conclusion that the doctrine does not bar the Commonwealth's right to relief here.

VI. J&J CHALLENGES TO CPL AWARDS

A. Plaintiff Agencies Not Consumers

1. Contentions

Johnson & Johnson Defendants argue that under Section 4 of the CPL, the Attorney General may bring suit to enjoin fraudulent or deceptive conduct where such proceedings are in the public interest. By its terms, they contend, Section 4 applies to suits on behalf of all members of the Commonwealth, or all consumers. The Defendants assert that here the Attorney General did not bring such an action; rather, he sued in his capacity as a representative of the Plaintiff Agencies, which are not the ordinary types of consumers the CPL was intended to protect. As such, Johnson & Johnson Defendants argue any claim on behalf of the Plaintiff Agencies is barred under Section 4.

2. Analysis

Johnson & Johnson Defendants' arguments ignore the statutory language at issue. Accordingly, their arguments lack merit. Section 4 of the CPL, which relates to "Restraining prohibited acts," states, as pertinent:

> Whenever the Attorney General … has reason to believe that any person is using or is about to use any method, act or practice declared by section 3 of this act to be unlawful, and that proceedings would be in the public interest, he may bring an action in the name of the Commonwealth against such person to restrain by temporary or permanent injunction the use of such method, act or practice.

73 P.S. §201-4.

The plain language of this section authorizes the Attorney General to seek an injunction in the name of the Commonwealth where he has reason to believe (1) a "person" is violating the CPL; and, (2) such proceedings are in the public interest. Here, the Commonwealth alleged and proved Johnson & Johnson Defendants' conduct violated the CPL, and proceedings to enjoin this unlawful conduct were in the public interest. As to the public interest, the trial judge awarded more than $45,000,000 to restore to the Commonwealth public funds paid because of violations of the CPL.

Johnson and Johnson Defendants are "persons" as defined by Section 2(2) of the CPL. See Section 2(2) of the CPL, 73 P.S. §201-2(2) (defining **"person"** as "natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entities.") Where, as here, the Attorney General had reason to believe Johnson & Johnson Defendants violated the CPL, the Attorney General could seek an injunction under Section 4 upon a determination that such proceedings were in the public interest.

Nothing in the plain language of Section 4 limits the Attorney General's right to seek injunctive relief to a suit on behalf of the Commonwealth or its consumers only rather than on behalf of a Commonwealth agency. As expressly authorized, the Commonwealth is the named Plaintiff. Further, pursuant to Section 204(c) of the Commonwealth Attorneys Act,[17] "[t]he Attorney General

[17] Act of October 15, 1980, P.L. 950, as amended.

shall represent the Commonwealth and all Commonwealth agencies … in any action brought by … the Commonwealth or its agencies ….” 71 P.S. §732-204(c). Here, the Attorney General sued in the name of the Commonwealth on behalf of the Plaintiff Agencies, which he is authorized to do.

Other than citing the general purpose of the CPL (to protect the public from fraud and unfair or deceptive business practices), Johnson & Johnson Defendants cite no authority to support an interpretation of Section 4 that would bar the Attorney General from suing on behalf of the Plaintiff Agencies. Contrary to Johnson & Johnson Defendants' contentions, we may not disregard the plain language of the CPL under the pretext of pursuing its spirit. 1 Pa. C.S. §1921(b).

Similarly, Section 4.1 does not preclude an award of restoration to the Plaintiff Agencies. That Section states:

> Whenever any court issues a permanent injunction to restrain and prevent violations of this act as authorized in section 4 above, the court may in its discretion direct that the defendant or defendants restore to any person in interest any moneys or property, real or personal, which may have been acquired by means of any violation of this act, under terms and conditions to be established by the court.

73 P.S. §201-4.1 (emphasis added).

Section 4.1 does not expressly restrict the restoration remedy to natural persons or to consumers. Instead, it refers to “any person in interest.” As noted above, a “person” under the CPL includes “any other legal entity.” Johnson & Johnson Defendants do not contend that the Plaintiff Agencies are illegal

entities, nor do they contend that the Plaintiff Agencies do not satisfy the definition of "person." Based on a common sense reading of the definition, as well as the Defendants' failure to argue otherwise, we conclude that the Plaintiff Agencies satisfy the definition of "person" as used in Section 4.1 of the CPL.

Moreover, the Commonwealth established its "interest" and the interest of its Agencies because of the loss of significant public moneys through Johnson & Johnson Defendants' CPL violations. Consequently, under the plain language of Section 4.1, restoration is appropriate.[18]

[18] Our conclusion would be the same even if we resorted to principles of statutory construction. When statutory language is not explicit, the intention of the General Assembly may be ascertained by considering the consequences of a particular interpretation. 1 Pa. C.S. §1921(c)(6). Further, in ascertaining legislative intent, the Statutory Construction Act requires a presumption that "the General Assembly did not intend a result that is absurd or unreasonable" as well as a presumption that "the General Assembly intends to favor the public interest as against any private interest." 1 Pa. C.S. §1922(1), (5).

Evaluating the consequences of a particular interpretation, we note that a construction under which a Commonwealth agency is not a "person" results in the inability of those agencies to recover restoration under Section 4.1, and to participate with general creditors under Section 9.1 of the CPL. Added by the Act of November 23, 1976, P.L. 1166, as amended, 73 P.S. §201-9.1. Thus, Commonwealth agencies harmed by violations of the CPL would have fewer remedies than other legal entity plaintiffs. Concomitantly, those violating the CPL have more limited liability if a Commonwealth agency is a victim. How such a construction is in the public interest is unclear.

The absurdity of a construction under which a Commonwealth agency is not a "person" is most evident with regard to suits in the public interest under Sections 4 and 4.1 of the CPL. If it is not a "person in interest," a Commonwealth agency could not recover past lost sums under Section 4.1. This is true even if suit brought in the public interest is successful and prospective injunctive relief is granted. In short, even where suit in the public interest is successful, a Commonwealth agency would have no retrospective remedy, only a prospective remedy. Such a result is indefensible, clearly not in the public interest, and inconsistent with our charge to liberally construe the CPL to achieve its objectives.

Our conclusion that the Commonwealth and its Agencies may be a "person in interest" entitled to restoration under Section 4.1 of the CPL is consistent with rulings elsewhere. The Mississippi version of the consumer protection statute defines "person" as including "any other legal entity." Miss. Code Ann. §75-24-3.[19] Mississippi courts hold that the State of Mississippi is a "person" which can recover damages under that state's consumer protection statute. Hood ex rel. State of Mississippi v. BASF Corp., No. 56863, 2006 WL 308378 (Miss. Ch. Ct. Jan. 17, 2006) (unpublished opinion). Similarly, the Kentucky Consumer Protection Act defines "person" to include "any other legal entity." Ky. Rev. Stat. Ann. §367.110(1).[20] In AWP litigation under the Kentucky Consumer Protection Act, the state and its Medicaid program come within the statutory definition of "person" entitled to recover because they actually purchased the drugs at issue. Alpharma USPD, Inc., slip op. at 8-9, 10. Also, in AWP litigation for violations of the Wisconsin consumer protection statute, the state recovered sums overpaid by its Medicaid program. State of Wisconsin v. Abbott Labs et al., No. 2010AP232-AC, 2011 WL 2039396 (Wis. App. Ct. 2011) (unpublished certification to Wisconsin Supreme Court).

Similarly, there is no language in Section 8(b) of the CPL, 73 P.S. §201-8(b), that bars the Commonwealth from obtaining an award of civil penalties

[19] Miss. Code Ann. §75-24-3 defines "person" to mean "natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entity." This is the same definition as that in the CPL.

[20] Ky. Rev. Stat. Ann. §367.110(1) defines "person" to mean "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations and any other legal entity." This is the same definition as that in the CPL.

for willful CPL violations against its Agencies. To the contrary, the Commonwealth is expressly authorized to recover civil penalties in an action brought in the public interest by the Attorney General under Section 4. Moreover, that provision specifically states that such civil penalties "shall be in addition to other relief which may be granted under sections 4 and 4.1 of this act." Id. This conclusion is consistent with results elsewhere in AWP litigation. Alpharma USPD, Inc.; Abbott Labs.

Thus, an award of civil penalties is ancillary to a suit for injunctive relief where a person, firm or corporation willfully violates the CPL. As discussed below, the trial judge's findings reveal Johnson & Johnson Defendants willfully violated the CPL. Therefore, an award of civil penalties is appropriate.

B. Challenge to Meaning and Application of "AWP"

1. Contentions

For several reasons, Johnson & Johnson Defendants assert that they did not violate the so-called "catchall provision" of the CPL, which proscribes engaging in "any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." Section 2(4)(xxi) of the CPL, 73 P.S. §201-2(4)(xxi). First, they challenge the trial judge's "plain meaning" interpretation of the Pennsylvania statute and regulation defining average wholesale price. They contend the overwhelming evidence at trial establishes that all industry participants understood AWP is a term of art, and the reported AWPs did not deceive anyone. Further, in their reply brief Johnson & Johnson Defendants highlight a fundamental inconsistency of the trial court's "plain meaning" construction: if

AWP was meant to be an actual average of wholesale prices, subsequent reimbursement formulae that used discounts off AWP would mean that the General Assembly intended pharmacists to be reimbursed at a level *below* what they paid to acquire the drugs. They assert such a legislative intention cannot be supported by the record.

Second, Johnson & Johnson Defendants contend that the likelihood of confusion or misunderstanding must be evaluated in terms of the target audience. They rely on Federal Trade Commission precedent and persuasive authority from other states. Because those in the industry were the target audience, and they understood the meaning, derivation and operation of AWP, there could be no likelihood of deception or misunderstanding.

Third, Johnson & Johnson Defendants urge the Court to adopt the position of some other states that do not apply their deceptive practices acts to sophisticated parties, like the Plaintiff Agencies.

Fourth, they contend that their use of industry-wide practices relating to pricing was not material to the decisions by the Plaintiff Agencies to use AWP as part of their reimbursement formulae.

Fifth, Johnson & Johnson Defendants challenge whether the Commonwealth proved the use of AWPs caused any harm. They assert that because the Plaintiff Agencies understood that AWPs were not actual averages of acquisition costs, no conduct by the Defendants caused the Plaintiff Agencies to

use AWP as part of their reimbursement formulae or caused any harm. To the contrary, the unrebutted testimony of David Smith, a pharmacist, established that pharmacies were not overpaid.

2. Analysis

a. "Plain Meaning" Construction of AWP

These same arguments were advanced by BMS during and after the first trial, and they are addressed at length in our opinion disposing of post-trial motions involving the first trial.

Shortly before the second trial, which involved Johnson & Johnson Defendants, the trial judge issued an opinion disposing of a motion *in limine* and construing the meaning of AWP as used in Pennsylvania's reimbursement laws. The trial judge adopted a "plain meaning" construction, explaining in part:

> Through its motion, Johnson & Johnson Defendants ask this Court to revisit its construction of the term AWP as explained to the jury in the first trial in Commonwealth v. TAP Pharmaceutical Products, Inc., which involved Defendant [BMS]. In arriving at a plain meaning interpretation, this Court relied, in part, on the opinion of U.S. District Court Judge Patti B. Saris in [MDL 2007], and on an earlier decision in the same case reported at 460 F.Supp.2d 277 (D. Mass. 2006) (MDL 2006).
>
> Johnson & Johnson Defendants take issue with this Court's reliance on Judge Saris' opinion because in the case before her, Judge Saris was interpreting the federal Medicare statute; here, however, the Court is construing Pennsylvania law. Johnson & Johnson Defendants assert that Pennsylvania law defines AWP with reference to the

national pricing compendia, which [DPW and PACE] knew differed from average transaction prices.

* * * *

Mindful of the evidence presented at the first trial involving BMS, the Court concludes that those writing Pennsylvania laws governing reimbursement intended: 1) to use an easily-ascertained estimate of acquisition costs for pharmaceuticals; and 2) to integrate reimbursement into an existing industry system so the thousands of daily transactions could be processed efficiently. Thus, those writing Pennsylvania's reimbursement laws sought a formula to give an easily-ascertained, objective, accurate estimate of acquisition costs for pharmaceuticals, not a fictitious value allowing reimbursement unrelated to prices actually paid by providers.

The Court further concludes that those writing Pennsylvania's reimbursement laws intended the phrase "average wholesale price" to mean what it plainly says, that is, an average of wholesale prices paid by providers. See Narberth Borough v. Lower Merion Twp., 590 Pa. 630, 915 A.2d 626 (2007) (the primary and favored indicator of the Legislature's intention is the plain language of the statute under scrutiny).

The reference to published prices was not intended to modify the accuracy of the average price phrase; rather, the reference to published prices was intended to establish a widely-available third-party source of average prices. Establishing such a source relieves the Plaintiff Agencies of legal mandates to ascertain, by alternative methods, estimated acquisition costs. Extensive evidence was received at the BMS trial about such methods. See also [People ex rel. Spitzer v. Pharmacia Corp., 895 N.Y.S.2d 682, 687-88 (N.Y. Sup. Ct. 2010)] (describing New York's prior requirement for the state to conduct its own wholesale pricing survey). In short, the reference to published prices does not change the plain meaning of the cost to be ascertained.

> This construction utilizes the plain meaning of the phrase "average wholesale price" and also explains the reference to published prices. This construction thereby acknowledges all the language at issue, consistent with principles of statutory construction. Most importantly, this construction is consistent with legislative intent, described above.
>
> In addition, this construction is consistent with Judge Saris' "plain meaning" construction of the term "AWP" in the 1994 Medicaid statute. MDL 2007; MDL 2006. As the DPW regulation is part of the same joint federal-state Medicaid Program, this Court's interpretation is consistent with the rule of statutory construction that statutes are to be construed in harmony with the existing law and as part of a general and uniform system of jurisprudence. Trigona v. Lender, 926 A.2d 1226 (Pa. Cmwlth. 2007); Northern Tier Solid Waste Auth. v. Dep't of Revenue, 860 A.2d 1173 (Pa. Cmwlth. 2004).
>
> Further, the construction is consistent with that of another state court. See State of Hawai'i v. Abbott Labs. et. al., No. 1CC 06-1-000720 (1st Cir. Haw., Aug. 1, 2010) (August 1, 2010, Order of the Honorable Gary W.B. Chang, First Circuit Court of the State of Hawai'i: "The Court holds that the term 'AWP' as used in the Hawaii Medicaid reimbursement formula, in relation to the instant action, is the average price charged by wholesalers to their wholesale customers, such as pharmacies and physicians. This is based upon the Court's construction, as a matter of law, of all legal authorities that bear upon this definition. The definition of 'AWP' is not a question of fact for the jury to decide. It is a question of law for this Court to decide ….")).

Commonwealth v. TAP Pharm. Prods., Inc et al., (Pa. Cmwlth., No. 212 M.D. 2004, filed October 14, 2010) (Simpson, J.); slip op. at 2-3, 7-10 (footnotes omitted).

Significantly, the trial judge's conclusion was consistent with evidence received during the trial involving Johnson & Johnson Defendants. PX-980b; PX-1085n; N.T., 10/26/10, at 1309-10 (Ortiz); N.T., 11/2/10, at 2078 (Snedden).

As discussed more fully above, the trial judge rejected the contention that AWP was a term of art, widely known to be derived by a formulaic mark-up over WAC. Rather, the trial judge determined that there was confusion about AWP, that Johnson & Johnson Defendants knew there was confusion about AWP, that the Plaintiff Agencies were not aware of the formulaic relationship between WAC and AWP, and that while those responsible for reimbursement programs at the Plaintiff Agencies knew there was a difference between AWPs and actual acquisition costs paid by providers, they did not know the extent of the inaccuracy. Thus, the Plaintiff Agencies did not fully understand, and could not prove, the manner in which AWPs were inflated and the full extent of the inflation. Also, they did not know a real average of wholesale prices for a given branded drug, and they did not have a better estimate of provider acquisition cost available in a current, digital format for each drug in the case.

Regarding the asserted "fundamental inconsistency" involving reimbursement rates with discounts off AWP, this argument has no merit in light of the trial judge's findings regarding AWP confusion. As explained in depth above, the trial judge found that the unclarified use of AWPs has a tendency to deceive those dealing with the reimbursement system. We highlight the role of the IRRC in particular.

b. Target Audience

Further, given the trial judge's findings regarding AWP confusion, contentions involving the target audience understanding of AWP have no merit. The trial judge found confusion about AWP among executives of Johnson & Johnson Defendants, those with responsibility for reimbursement at the Plaintiff Agencies, legislators, and regulators and others responsible for setting reimbursement levels. The trial judge determined that the unclarified use of AWPs in the complex and inflexible reimbursement system had a tendency to deceive those who must deal with the system.

c. Sophisticated Parties

Citing several cases from other jurisdictions, Johnson & Johnson Defendants assert the CPL should not apply to the Plaintiff Agencies because they are not ordinary consumers; rather, they are sophisticated parties that were not likely to misunderstand or be confused by AWPs. We reject this argument.

The federal and state cases cited by Johnson & Johnson Defendants do not compel the conclusion they seek. Although some of the cases state that deceptive practices statutes are intended to protect ordinary consumers rather than sophisticated parties, the cases are factually distinguishable; none of these cases involve AWP or pharmaceutical pricing litigation. See M&T Mortg. v. White, 736 F. Supp. 2d 538 (E.D. NY 2010) (denying defendants' motions for summary judgment on real estate purchasers' claims under New York Deceptive Practices Act, N.Y. Gen. Bus. Law §349, where materials issues of fact existed); Fleetwood v. Stanley Steemer Int'l, Inc., 725 F. Supp. 2d 1258 (E.D. Wash. 2010) (granting

franchisor's motion for summary judgment on franchisee's claim under Washington's Consumer Protection Act, Wash. Rev. Code Ch. 19.36, where franchisee did not show any unfair deceptive act or practice occurred); see also Griggs v. State Farm Lloyds, 181 F.3d 694 (5th Cir. 1999) (granting summary judgment in favor of insurer on insured's claims under Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code Ann. §§17.41-17.63, where insured did not show misrepresentation of material fact and insured was "unusually" sophisticated customer); Fed. Deposit Ins. Corp. v. Fox Creek Holding, LLC, No. 1:09-CV-00480-E-ELJ-LMB, 2010 WL 2667336 (D. Idaho July 2, 2010) (granting summary judgment on commercial mortgagee's claim that mortgagor's method of computing interest on loan violated Idaho Consumer Protection Act, Idaho Code Ann. §§48-601-48-619, where it was unclear that method of computing interest was deceptive or unfair trade practice and commercial mortgagee was sophisticated entity); Golden Needles Knitting & Glove Co., Inc. v. Dynamic Mktg. Enters., Inc., 766 F. Supp. 421 (W.D. N.C. 1991) (granting plaintiff's motion for summary judgment on defendant's counterclaim under Florida's Deceptive and Unfair Trade Practices Act, Fl. St. Ann. §§501-201-501.213, arising from commercial contract dispute because Florida's Deceptive and Unfair Trade Practices Act applies only to consumer transactions, not sophisticated commercial transactions); Rhino Linings USA, Inc. v. Rocky Mountain Rhino Lining, Inc., 62 P.3d 142 (Colo. 2003) (*en banc*) (reversing judgment in favor of dealer on dealer's claims under Colorado Consumer Protection Act, Colo. Rev. Stat. Ann. §6-1-101-6-1-115, where dealer did not establish defendant manufacturer engaged in deceptive practice and any alleged deceptive practice did not have a significant impact on the consuming public but instead was private in nature); Carcano v. JBSS, LLC, 684 S.E.2d 41

(N.C. Ct. App. 2009) (granting summary judgment on plaintiff real estate investor's claim against defendant co-investors under North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §75-1.1, where plaintiff did not show defendants' acts rose to the level of deceptive trade practices, or that any alleged deceptive act or practice affected "commerce").

Significantly, Johnson & Johnson Defendants cite no Pennsylvania cases which hold the CPL applies only to ordinary consumers rather than sophisticated parties.

Unlike the cited cases, the case presently before this Court involves the highly complex area of pharmaceutical pricing and the AWP-based reimbursement system, which sophisticated parties, including executives of Johnson & Johnson Defendants and their own expert, recognized was confusing. Further, none of the cases cited involve an enforcement action by an attorney general in the public interest. Rather, they all involve suits by private consumers or businesses.

Additionally, a conclusion that the CPL applies to the Plaintiff Agencies is directly supported by the decision of Judge Saris in MDL 2007, which also involved AWP litigation under a state consumer protection statute. In MDL 2007, Judge Saris held the sophisticated plaintiffs, including Blue Cross/Blue Shield of Massachusetts, a non-profit organization, and certain entities that provide health and welfare benefits to union workers, could bring AWP-related claims against pharmaceutical manufacturers under the Massachusetts Consumer

Protection Act.[21] See also Alpharma USPD, Inc.; Abbott Labs. Thus, the trial judge's decision here is consistent with case law in the AWP area.

Finally, in light of the varied practices covered by the CPL and the myriad factual scenarios that could be implicated, the argument in support of a bright-line rule that the CPL never applies to sophisticated parties is problematic.

For all these reasons, we reject the assertions that, as a matter of law, the CPL only applies to ordinary consumers and can never apply to sophisticated parties.

d. Materiality

The contention of Johnson & Johnson Defendants regarding an alleged lack of materiality is unsustainable. As explained above, Johnson & Johnson Defendants' conduct was material, as it impacted a nonmalleable reimbursement system to which the Plaintiff Agencies were chained by statute and regulation. Stated differently, because at all relevant times the Plaintiff Agencies were required by law to reimburse according to some form of AWP, deceptive conduct as to that value was material as a matter of law and of fact.

e. Causation of Harm

We discern no merit in Johnson & Johnson Defendants' contentions that the Commonwealth failed to prove that their conduct caused harm. As discussed above, the believable evidence established that the Plaintiff Agencies

[21] Mass. Gen. Laws ch. 93A, §2.

were harmed by enhanced price discrimination by the drug manufacturers on all branded drugs, credibly characterized as "egregious" by the Commonwealth's liability and causation expert, Dr. Comanor. The enhanced price discrimination took the form of different pricing/rebate schemes for public and private payors in which AWP was a cornerstone.

The method of price discrimination on which restoration was calculated arose where private payors received *lower* rebates from drug manufacturers than public payors received. The private payors nevertheless paid no more than the economic value of the drug because the higher reimbursement rates paid by public payors subsidized the pharmacy overhead. N.T., 10/26/10, at 1493, 1495 (Comanor); PX-10052.0012 ("Cash and Medicaid subsidizes Managed Care").

In other words, the overpayment by Plaintiff Agencies allowed providers to accept lower reimbursement levels from private payors. This was described more fully as "overhead shifting" by the Commonwealth's damages expert, Dr. Warren-Boulton. Further, these opinions were corroborated by opinions of some Johnson & Johnson Defendants' executives. E.g., PX-980ee.0001 ("Pharmacies create their own [reimbursement] problems by accepting poor reimbursement rates and then expect Medicaid to bail them out.") The Commonwealth's experts' opinions about "overhead shifting" were also corroborated by Defendants' expert witness, Dr. Ernst Berndt. N.T., 11/15/10, at 4040-41.

The testimony of David Smith, the pharmacist who stated that pharmacies were not overpaid for branded drugs, was rejected as inconsistent with the credible evidence outlined above.

C. Injunction Improper

1. Contentions

Johnson & Johnson Defendants also challenge the propriety of the injunction entered by the trial judge, raising several arguments. First, they contend the injunction is moot under United States v. W.T. Grant Co., 345 U.S. 629 (1953), because there is no reasonable expectation that the wrong will be repeated. They highlight the fact that Johnson & Johnson Defendants stopped reporting or suggesting AWPs to the pricing compendia in 2004. Further, AMPs have been provided to PACE since 1991, and ASPs for Medicare Part B drugs have been publicly available for download for the past six years. They also contend it is "undisputed" that there is no marketing of the spread by Johnson & Johnson Defendants.

Next, relying on the common law elements necessary for permanent injunctive relief, Johnson & Johnson Defendants contend that the injunction is unnecessary. Because no restoration was awarded for any period after 2004, there can be no urgent necessity to avoid an injury that cannot be compensated by damages. Also, there is no evidence of future noncompliance.

In an argument not previously raised, Johnson & Johnson Defendants also assert that the injunction impermissibly burdens their commercial free speech rights, contrary to the protections of the First Amendment.

2. Injunction Moot

We reject the argument that the injunction is moot because there is no reasonable expectation that the wrong will be repeated. There are several factual reasons for this conclusion.

The trial judge enjoined the following conduct:

> (i) Contributing in any manner, directly or indirectly, to the reporting to the Pennsylvania Department of Public Welfare or to the PACE program (Plaintiff Agencies) of inflated average wholesale prices (AWPs) for Johnson & Johnson Defendants' branded drugs, without also arranging for the transmission to the Plaintiff Agencies of current, accurate estimated acquisition costs, such as average manufacturers' prices (AMPs) or average sales prices (ASPs), for each of their branded drugs, in a format equivalent to that in which AWPs are reported to the Plaintiff Agencies, or in another format acceptable to the Plaintiff Agencies; and,
>
> (ii) Contributing in any manner, directly or indirectly, to the promotion or marketing of "spreads" (the difference between the price at which a drug is reimbursed to a provider and the acquisition price of the drug paid by the provider) for Johnson & Johnson Defendants' branded drugs which are reimbursed by the Plaintiff Agencies ….

Non-Jury Decision of December 7, 2010, ¶3(a), Slip op. at 3 (emphasis added).

Our Supreme Court holds that the mere fact that an illegal practice has been abandoned does not necessarily render a controversy moot. Tamagno v. Waiters & Waitresses Union, Local No. 301, 373 Pa. 457, 96 A.2d 145 (1953). In particular, the fact that the defendants had for two years obeyed a permanent injunction did not justify vacation of the injunction. "[E]ven though the defendant may give assurance that he will not err again it is for the court to say whether the complainant should be compelled to accept such assurance instead of insisting upon the continuance of the injunctive relief which he has obtained." Id. at 461, 96 A.2d at 147. Johnson & Johnson Defendants do not discuss this authority.

Moreover, whether or not Johnson & Johnson Defendants stopped reporting or suggesting AWPs to the pricing compendia, they continue to report inflated WACs for their drugs. Also, the pricing compendia continue to report fictitious AWPs for Johnson & Johnson Defendants' branded drugs. Further, the Plaintiff Agencies still have reimbursement formulae which contain some form of AWP. While the cessation of directly reporting or suggesting fictitious AWPs is an improvement, the conduct of Johnson & Johnson Defendants still contributes to the reporting of fictitious values to the Plaintiff Agencies. The trial judge determined that such unclarified conduct violated the CPL.

To clarify the reported AWPs, the trial court referenced transmission to the Plaintiff Agencies of current, accurate estimated provider acquisition costs, such as AMPs or ASPs, in a format equivalent to that in which AWPs are reported. This last qualification is important, although Johnson & Johnson Defendants do not address it. It contemplates a current digital value for each NDC.

Believable testimony established that the AMPs and ASPs now available to Plaintiff Agencies do not satisfy the format requirement. Thus, Thomas Snedden testified that the AMPs provided by drug manufacturers to PACE were of limited value because the underlying data is not provided, and AMPs are not provided on a drug-by-drug basis. N.T., 11/2/10, at 2102-03. Similarly, Dr. Cathers testified that ASPs are not usable by DPW because they are not current and not provided in digital format. Id. at 2200-01.

Interestingly, Johnson & Johnson Defendants do not dispute that they internally maintain ASPs for all their drugs, but this information has not been shared with the Plaintiff Agencies. At trial, Catherine Tak-Piech, Johnson & Johnson's Vice President of Outcomes Research and Health Economics, testified ASP data exists for *all* Johnson & Johnson drugs, and Johnson & Johnson Defendants did not experience a problem with the reporting of ASP data. N.T., 10/18/10, at 271, 284-85. Because of the availability of ASPs for each branded drug, the trial judge believed that it would not be burdensome for Johnson & Johnson Defendants to comply with the injunction.

As for the contention that it is "undisputed" that there is no marketing of the spread by Johnson & Johnson Defendants, nothing could be further from the truth. The Commonwealth strongly challenges this contention. Although this issue is discussed at length above, the following summary is useful here.

Consistent with Judge Saris' decision in MDL 2007, the trial judge determined the record contained sufficient evidence that Johnson & Johnson

Defendants marketed the spread for their Medicare Part B drugs Procrit® (licensed to and sold by Ortho Biotech),[22] and Remicade® (sold by Centocor).[23] Also like Judge Saris, the trial judge concluded that marketing the spread "so that doctors would choose a drug based on profit rather than therapeutic value is particularly outrageous and unethical." MDL 2007, 491 F.Supp.2d at 95. The trial judge determined this practice constitutes deceptive conduct which creates a likelihood of confusion or of misunderstanding, particularly among patients receiving the drugs. This is a violation of the CPL, which may be enjoined.

Further, although Ortho Biotech apparently stated a policy prohibiting spread marketing, the trial judge was not convinced the policy was enforced. The trial judge rejected testimony about the policy from Johnson & Johnson Defendants' executives. This is essentially the same determination made by Judge Saris in MDL 2007, 491 F.Supp.2d at 95. Similarly, the trial judge determined Centocor pursued a strategy of marketing the spread to physicians, and he rejected evidence to the contrary.

In short, the record contains substantial evidence to support the trial judge's findings that Johnson & Johnson Defendants marketed spreads for their branded Medicare Part B drugs. These findings support the trial judge's determination that this practice constituted deceptive conduct that creates a likelihood of confusion or of misunderstanding, particularly among patients

[22] See PX-1025o.0004-.0005; PX-1082.0001-.0002; PX-1180; PX-1180.0003; PX-1180.0008-.0009; PX-1180.0011.

[23] N.T., 10/20/10, at 563, 587-89 (testimony of Laura Glassco regarding Centocor's "Practice Management Program"); PX-1103.0008; PX-1121.0018; PX-1121.0001.

receiving the drugs. Thus, the trial judge correctly determined this constitutes a violation of the CPL, which may be enjoined.

For these factual reasons, there is no merit in the contention that the injunction is moot.

3. Injunction Unnecessary

a. Contentions

Johnson & Johnson Defendants assert the injunction is unnecessary. Legally, they rely on case law addressing the common law elements necessary for permanent injunctive relief. Factually, they interpret the trial judge's refusal to award restoration after 2004 as proof that there is no urgent necessity to avoid an injury that cannot be compensated by damages. Also, they point to their good faith in establishing a policy against marketing the spread. They claim the record lacks evidence that Johnson & Johnson Defendants are reasonably certain to repeat conduct determined to be impermissible.

In contrast, the Commonwealth asserts that the common law elements necessary for permanent injunctive relief do not control a statutory injunction to restrain a violation of law. Rather, a plaintiff must only prove a clear right to relief.

b. Standard for Injunction Under CPL

The remedy of injunctive relief here is not a common law-based remedy; rather, it is provided by statute. Section 4 of the CPL, which relates to "Restraining prohibited acts," states, as pertinent:

> Whenever the Attorney General … has reason to believe that any person is using or is about to use any method, act or practice declared by section 3 of this act to be unlawful, and that proceedings would be in the public interest, he may bring an action in the name of the Commonwealth against such person to restrain by temporary or permanent injunction the use of such method, act or practice.

73 P.S. §201-4 (emphasis added). This provision sets forth no express elements for injunctive relief beyond: 1) a person is believed to be using or about to use a practice declared unlawful by the CPL, and 2) proceedings would be in the public interest.

Commentators observe that where a statute authorizes a court to issue an injunction restraining a person from violating the statute, relief is available without regard to the adequacy of a remedy at law. 15 STANDARD PA. PRACTICE 2D, §83:245 (citing former Section 4 of the Food Act,[24] formerly 31 P.S. §20.4). As an obvious corollary, where a statute authorizes restoration when an injunction

[24] Act of July 7, 1994, P.L. 421, as amended. The Food Act, formerly 31 P.S. §§ 20.1 to 20.18, was repealed effective January 24, 2011, by the Act of November 23, 2010, P.L. 1039. The material is now found in the Food Safety Act, 3 Pa. C.S. §§ 5721 to 5737, as added in 2010 and effective January 24, 2011. 3 Pa. C.S. § 5725(b) provides, in addition to proceeding under any other remedy available at law or in equity for a violation of the Act, or a rule or regulation adopted or any order issued under the Act, the Secretary of Agriculture may assess specified civil penalties.

issues, the existence of the additional restoration remedy does not diminish the availability of the injunction. Section 4.1 of the CPL, 73 P.S. §201-4.1. To hold otherwise would produce an absurd result. In these ways, statutory provisions may alter the elements needed to obtain a statutorily authorized injunction.

Consistent with this analysis, in Commonwealth v. Burns, 663 A.2d 308 (Pa. Cmwlth. 1995), a case involving a post-trial challenge to a permanent injunction under the CPL, this Court accepted the Attorney General's argument that whenever a violation of a statute is found, such violation constitutes irreparable harm *per se*, and injunctive relief is appropriate. The only issue therefore is whether the record adequately supports the findings and conclusions.

This analysis is also consistent with the leading case on this issue, our Supreme Court's decision in Pennsylvania Public Utility Commission v. Israel, 356 Pa. 400, 52 A.2d 317 (1947). In Israel, the Public Utility Commission filed suit in Dauphin County Common Pleas Court (sitting as Commonwealth Court) seeking to enjoin a transportation company from operating taxicabs because the company did not possess a certificate of public convenience as required by statute. Notably, Section 903 of the Public Utility Law,[25] then in effect, provided, as pertinent:

> Whenever the commission shall be of opinion that any person * * * is violating, or is about to violate, any provisions of this act; or has done, or is about to do, any

[25] Section 903 of the Act of May 28, 1937, P.L. 1053, as amended, formerly 66 P.S. §1343 (emphasis added). A substantially similar provision is now codified at Section 502 of the Public Utility Code, 66 Pa. C.S. §502.

> act, matter, or thing herein prohibited or declared to be unlawful; * * * then and in every such case the commission may institute in the court of common pleas of Dauphin County, injunction, mandamus, or other appropriate legal proceedings, to restrain such violations of the provisions of this act, or of the regulations, or orders of the commission, and to enforce obedience thereto ….

The operators of the transportation company challenged the commission's request for a preliminary injunction, asserting, because there was no allegation of irreparable injury, no preliminary injunction could issue. Adopting and quoting from the well-reasoned opinion of the Honorable Robert E. Woodside, Jr., our Supreme Court stated:

> At the hearing the Commonwealth … made a prima facie showing that the defendants are operating taxicabs in violation of law. The argument that a violation of law can be a benefit to the public is without merit. When the Legislature declares certain conduct to be unlawful it is tantamount in law to calling it injurious to the public. For one to continue such unlawful conduct constitutes irreparable injury.
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> * * * *
>
> In Commonwealth v. Pittsburgh & Connellsville Railroad Co., 1854, 24 Pa. 159, 160, 62 Am. Dec. 372, the Court said:
>
> 'The argument that there is no 'irreparable damage,' would not be so often used by wrongdoers, if they would take the trouble to observe that the word 'irreparable' is a very unhappily chosen one, used in expressing the rule that an injunction may issue to prevent wrongs of a repeated and continuing character, or which occasion damages which are estimable only by conjecture and not by any accurate standard. * * * Besides this, where the right invaded is secured by statute

> … there is generally no question of the amount of damage, but simply of the right.'

Id. at 406-07, 52 A.2d at 321.

Ultimately, the Court concluded:

> When the provisions of the Public Utility Commission Law are being violated the Legislature provided for the Commission to come before this Court, and prevent the violation by obtaining an injunction. When the right to such injunction is clear, as it is here, under the undisputed facts, it is our duty to issue a preliminary injunction.

Id. at 409, 52 A.2d at 321 (emphasis added). Israel stands for the proposition that, for purposes of injunctive relief, statutory violations constitute irreparable harm per se. Although Israel concerned the irreparable harm criterion for issuance of a preliminary injunction, it is helpful here because it involved a scenario in which an agency, which was statutorily authorized to obtain an injunction to restrain statutory violations, was granted such an injunction upon proof that a clear statutory violation occurred.

Further support for our conclusion that the common law criteria for a permanent injunction do not apply here can be found in the recent decision in Alpharma USPD, Inc. In that decision, Franklin Circuit Court Judge Phillip J. Shepherd denied post-trial motions of a drug manufacturer which was found to have violated the Kentucky Consumer Protection Act by manipulating and falsely reporting AWPs for its drugs reimbursed by the Kentucky Medicaid Program. Discussing the standard for injunctive relief under the statute, Judge Shepherd stated, "KRS 367.190 authorizes the issuance of injunctive relief upon proof of a

violation, without demonstration of irreparable injury, inadequate remedies at law, or other common law requirements for an injunction." Id., slip op. at 16.

As discussed more fully above, our review of the record here reveals ample support for the trial judge's determinations that Johnson & Johnson Defendants violated the CPL by engaging in unfair or deceptive acts or practices within the meaning of the "catchall provision" in Section 2(4)(xxi) of the CPL, 73 P.S. §201-2(4)(xxi) ("Engaging in any other … deceptive conduct which creates a likelihood of confusion or of misunderstanding."). Based on the trial judge's determinations that Johnson & Johnson Defendants violated the CPL, the trial judge had a duty to issue an injunction to restrain Johnson & Johnson Defendants' unlawful practices. Israel.

c. Urgent Necessity

Based on the foregoing discussion, we do not believe that proof of "urgent necessity to avoid an injury that cannot be compensated by damages" is an element of the Commonwealth's proof under Section 4 of the CPL. Nevertheless, there are additional reasons why we discern no merit in the Defendants' position on this issue. Specifically, we conclude: 1) that an injunction can issue to restrain future conduct based on prior unlawful activity; 2) that cessation of the offending conduct does not, in and of itself, bar a claim for injunctive relief; and 3) the Court may consider whether the offending conduct is likely to reoccur absent the grant of an injunction.

Section 4 of the CPL, which relates to "Restraining prohibited acts," states, as pertinent:

> Whenever the Attorney General … has reason to believe that any person is using or is about to use any method, act or practice declared by section 3 of this act to be unlawful, and that proceedings would be in the public interest, he may bring an action in the name of the Commonwealth against such person to restrain by temporary or permanent injunction the use of such method, act or practice.

73 P.S. §201-4 (emphasis added).

In Commonwealth v. Percudani, 844 A.2d 35 (Pa. Cmwlth.), amended on reconsideration by, 851 A.2d 987 (Pa. Cmwlth. 2004), this Court considered whether under Section 4 the Attorney General could seek to enjoin future conduct based on past violations of the CPL where the alleged offending conduct ceased prior to the Attorney General's filing of the complaint.

Factually, Percudani involved a complaint in equity filed by the Attorney General against various defendants alleging CPL violations that arose out of the defendants' construction, sale and mortgage of residential homes. Pertinent here, the Attorney General averred one of the defendants, a certified appraiser, misled consumers by issuing inflated appraisals of their homes. As a result, the Attorney General sought to enjoin the appraiser from committing further CPL violations. The defendants, including the appraiser, filed preliminary objections to the Attorney General's complaint.

In particular, the appraiser sought dismissal of the suit on the grounds the Attorney General lacked standing to pursue the action, and this Court lacked subject matter jurisdiction over the suit. Specifically, the appraiser argued that prior to the filing of the suit, he entered into a consent agreement with the State Bureau of Professional and Occupational Affairs in which he agreed to surrender his appraisal license and agreed not to seek reinstatement for at least five years. The appraiser asserted Section 4 of the CPL authorized the Attorney General to bring suit against any person who is believed to be "*using or is about to use*" any deceptive act or practice, but did not permit an action based on past acts or practices. Percudani, 844 A.2d at 45 (emphasis in original). The appraiser asserted:

> the Legislature's use of the present tense limits the Commonwealth's ability to pursue violations of the [CPL] to ongoing deceptive acts or practices. In essence, [the appraiser] claims that because he cannot perform appraisals by virtue of the consent order, which was entered prior to the filing of the Commonwealth's complaint, he cannot presently use or in the near future use allegedly deceptive acts or practices. Therefore, there is nothing that the Commonwealth can prohibit nor can he be held accountable for his past conduct. He argues that the [CPL] does not create a cause of action against those who cannot presently or in the future use deceptive acts or practices.

Id.

Rejecting this argument, a divided panel of this Court, speaking through Senior Judge Jiuliante, stated:

> Our research has uncovered several cases in which the Commonwealth had sought to enjoin future conduct based on past acts. Consequently, case law indicates that

the Commonwealth may pursue violations of the Law based on past illegal activities.[26]

In his reply brief, [the appraiser] cites *Eugene Dietzgen Co. v. FTC*, 142 F.2d 321 (7th Cir. 1944), to suggest that since the consent order has stopped the allegedly unfair practice, the object of the [AG's] action, namely an injunction to prevent further violations of the [CPL], is unnecessary. Notwithstanding, the propriety of the actual issuance of an injunction against [the appraiser] is premature inasmuch as presently before the Court are [d]efendants' preliminary objections. Whether the Commonwealth is able to sustain its burden of proof and the appropriateness of any remedy imposed is a matter to be heard at another time.

Furthermore, if we adopted [the appraiser's] interpretation of Section 4 of [CPL] and limited the Commonwealth's actions to ongoing activities, the purpose of the [CPL] would be frustrated. As even [the appraiser] points out, a party could simply avoid liability under the [CPL] by discontinuing its actions even after

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[26] The Court in Percudani provided the following string citation in support of its conclusion: See Commonwealth by Zimmerman v. Nat'l Apt. Leasing Co., 519 A.2d 1050 (Pa. Cmwlth. 1986) (where Commonwealth alleged that apartment leasing company wrongfully withheld security deposits, it was sufficient that Commonwealth believe that a violation of Law *occurred* in order to set forth cause of action against company); see also Frishman v. Dep't of State, Bureau of Prof. & Occupational Affairs, 592 A.2d 1389 (Pa. Cmwlth. 1991) (where petitioner entered into a consent decree with Commonwealth in action arising under the Law and admitted to participating in vehicle odometer rollback scheme, State Board of Vehicle Manufacturers, Dealers and Salespersons was not precluded from revoking petitioner's salesperson's license or imposing civil penalty); Commonwealth by Preate v. Pa. Chiefs of Police Ass'n, Inc., 572 A.2d 256 (Pa. Cmwlth. 1990) (Commonwealth's complaint alleged that association held itself out to be a charitable organization and solicited contributions for itself and other entities); Northview Motors, Inc. v. Commonwealth by Zimmerman, 562 A.2d 977 (Pa. Cmwlth. 1989) (evidence was sufficient to support restitution award to consumers who were damaged by auto dealer that violated Law by misleading consumers about the price and quality of the vehicles); Commonwealth by Biester v. Luther Ford Sales, Inc., 430 A.2d 1053 (Pa. Cmwlth. 1981) (action by Commonwealth against automobile seller for nondisclosure that vehicle *sold* was flood damaged was remanded for imposition of restitution and civil penalties consistent with the Law).

> proceedings are commenced and claim that the matter is moot. Such an interpretation would do little in the way of preventing unfair or deceptive acts or practices and compensating injured consumers. In ascertaining legislative intent, we may consider the consequences of a particular interpretation and may presume that the legislature did not intend a result that is absurd or unreasonable. 1 Pa.C.S. § 1921(c) and § 1922; *Pennsylvania State Police, Bureau of Liquor Control Enforcement v. McCabe*, 163 Pa.Cmwlth. 11, 644 A.2d 1270 (1993). To allow a party to avoid liability for its actions by merely discontinuing its conduct would render the penalty provisions of the [CPL] meaningless in their application.

Percudani, 844 A.2d at 45-46 (emphasis added). Thus, the panel majority (Senior Judge Jiuliante and Judge Cohn-Jubelirer) held the Attorney General could seek an injunction against the appraiser despite the lack of a current threat of ongoing injury because of the underlying consent order, which restrained the appraiser from conducting appraisals.

In a dissenting opinion, Judge Leavitt disagreed that the Attorney General could seek an injunction against the appraiser where the professional licensing body previously restrained the appraiser from engaging in the alleged unlawful conduct. Judge Leavitt's dissenting opinion also briefly explained how this issue would be addressed under the Federal Trade Commission Act (FTC Act), 15 U.S.C. §§41-58, the federal law upon which the CPL is modeled. Specifically, Judge Leavitt stated:

> The parties are in agreement that the [CPL] is modeled on the … FTC Act …. The FTC Act includes the language "has used," and, in this respect, FTC case law precedent has limited value to this controversy. Nevertheless, the FTC may not issue a cease and desist

> order to restrain a practice long discontinued and where there is no reason to believe it will be renewed. *Rodale Press, Inc. v. Federal Trade Commission*, 407 F.2d 1252 (D.C.Cir.1968); *Marlene's Inc. v. Federal Trade Commission*, 216 F.2d 556 (7th Cir.1954). The result is different where the defendant claims the right to renew the practice. *Stanley Laboratories v. Federal Trade Commission*, 138 F.2d 388 (9th Cir.1943). …

Percudani, 844 A.2d at 53, n.6 (Leavitt, J., dissenting) (emphasis added). Thus, the FTC cannot issue a cease and desist order to restrain prior unlawful conduct where the conduct ceased, and where there is no reasonable probability that the conduct will reoccur.

With regard to the FTC's power to issue a cease and desist order where the offending conduct ceased, in Hershey Chocolate Corp. v. Federal Trade Commission, 121 F.2d 968, 971-72 (3d Cir. 1941) (footnotes omitted), the Third Circuit explained:

> [T]he petitioners contend that the order is invalid in that the practices ordered ceased were discontinued shortly before the complaint was issued …. The [FTC] would have no power at all if it lost jurisdiction every time a competitor halted an unfair practice just as the [FTC] was about to act. The practice may have been discontinued but without the [FTC's] order it could be immediately resumed. Likewise the [FTC's] power would be limited indeed if it were restricted to enjoining unfair acts of competitors only as evidenced in the past. To be of any value the order must proscribe the method of unfair competition as well as the specific acts by which it has been manifested. In no other way could the [FTC] fulfill its remedial function.

See also Beneficial Corp. v. Fed. Trade Comm'n, 542 F.2d 611, 617 (3d Cir. 1976) (citations omitted) (emphasis added) ("[T]his and other courts have held that at least where a discontinued deceptive trade practice could be resumed, the prior practice may be the subject of a cease and desist order."); Fleet v. U.S. Consumer Council, Inc., 95 B.R. 319, 339 (E.D. Pa. 1989) (citations omitted) ("[W]e shall issue an injunction enjoining [d]efendants … from continuing to engage in deceptive and unconscionable commercial practices …. Even though [the corporate defendant] is and has been out of business for over five years, it is clearly not an impossibility that either [the corporate defendant], under different management, or [its chief operating officer], under a different corporate guise, could attempt to resume a like business again.") (citing City of Mesquite v. Aladdin's Castle, Inc., 455 U.S. 283, 289 (1982)); W.T. Grant Co. (defendant's voluntary cessation of activity does not render request for injunctive relief moot because otherwise defendant would be free to return to his old ways)); People ex rel. Spitzer v. Applied Card Sys., Inc., 805 N.Y.S.2d 175, 179 (N.Y. App. Div. 2005) ("To the extent that respondents voluntarily discontinued [their conduct] … such voluntary discontinuance of fraudulent or deceptive practices will not bar the issuance of an injunction to prevent future practices.")

The rules that can be synthesized from the above authority are: (1) an injunction can issue to restrain future conduct based on prior unlawful conduct, Percudani; (2) cessation of the alleged offending conduct does not, in and of itself, bar a claim for injunctive relief, Hershey Chocolate; Percudani; and, (3) the Court should consider whether the alleged offending conduct is likely to reoccur absent the grant of an injunction.

Applying the principles gleaned from the authority outlined above, we reject Johnson & Johnson Defendants' position. While Johnson & Johnson Defendants assert the record contains no proof of an ongoing threat of injury, there is also no evidence that Johnson & Johnson Defendants, in fact, ceased all their offending conduct and promised not to renew it. To the contrary, Johnson & Johnson Defendants contended that all past activity was lawful and they did nothing wrong.

Moreover, Johnson & Johnson Defendants continue to report inflated WACs to the pricing compendia, which in turn continue to report fictitious AWPs to the Plaintiff Agencies. Also, there was no believable evidence that Johnson & Johnson Defendants intended to permanently change any marketing or reporting practice without a court order. In this regard, there was no believable evidence that Johnson & Johnson Defendants would make more transaction pricing information available in a usable format to the Plaintiff Agencies without a court order. Thus, issuance of a perpetual injunction under Section 201-4 of the CPL was proper.

In addition, the CPL contains a more formal mechanism by which an alleged offender can provide assurance that such conduct has, in fact, ceased and will not be renewed. Specifically, Section 5 of the CPL (relating to "Assurances of voluntary compliance"), states:

> In the administration of this act, the Attorney General may accept an assurance of voluntary compliance with respect to any method, act or practice deemed to be violative of the act from any person who has engaged or was about to engage in such method, act or practice. Such assurance may include a stipulation for voluntary payment by the alleged violator providing for the restitution by the alleged violator to consumers, of

> money, property or other things received from them in connection with a violation of this act. Any such assurance shall be in writing and be filed with the court. Such assurance of voluntary compliance shall not be considered an admission of violation for any purpose. Matters thus closed may at any time be reopened by the [AG] for further proceedings in the public interest, pursuant to section 4.

73 P.S. §201-5 (footnote omitted). Thus, a voluntary compliance agreement, which must be filed with the court, is the formal mechanism by which a party can assure its alleged offending conduct ceased and will not reoccur.

Indeed, TAP Pharmaceutical Products, Inc., a former defendant in this suit, entered into such an agreement in connection with its settlement of the related Lupron litigation. As part of its settlement, TAP agreed to report ASP data for *all* of its products reimbursed by Pennsylvania Medicaid. See Def. TAP Pharmaceutical Products, Inc.'s Mem. in Support of its Mot. For Summ. J. at 4; Ex. 6, ¶17. As such, the type of agreement contemplated by Section 5 of the CPL is not unfamiliar to the drug companies in the context of this litigation.

Because there is a specific CPL provision to ensure a voluntary permanent cessation of conduct, and Johnson & Johnson Defendants have not utilized the available procedure, the non-CPL cases they cite do not control. Absent the filing of such an enforceable agreement, an injunction should remain in effect to restrain the unlawful conduct.

4. First Amendment

Johnson & Johnson Defendants argue the injunction which prohibits them from contributing in any manner, directly or indirectly, to the promotion or marketing of spreads, contravenes their commercial free speech rights by enjoining truthful and factually accurate statements.

This issue was not raised by BMS in the first trial. In fact, the issue was not raised by Johnson & Johnson Defendants in the second trial. In particular, Johnson & Johnson Defendants did not raise a First Amendment issue in their pre-trial memoranda, at the pre-trial conference, in their motion for compulsory non-suit, in their proposed findings of fact and conclusions of law, or at closing argument. See Pa. R.C.P. No. 227.1(b)(1). In their brief in support of post-trial motions, Johnson & Johnson Defendants do not identify where they raised this issue prior to or during trial. See Pa. R.C.P. No. 227.1(b)(2). Failure to raise this issue before or during trial deprived the Commonwealth of an opportunity to respond to this claim and precluded development of a factual record on this issue. As such, Johnson & Johnson Defendants did not properly preserve this claim.

Even if not waived, this claim fails for several reasons. The trio of cases cited by Johnson & Johnson Defendants involved challenges to legislative action, not the grant of an injunction. See Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002) (involving challenge to provisions of Food and Drug Administration Modernization Act of 1997, 111 Stat. 2328, 21 U.S.C. §3539); 44 Liquormart Inc. v. Rhode Island, 517 U.S. 484 (1996) (involving challenge to Rhode Island statute); Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976) (involving challenge to validity of

Virginia statute). Johnson & Johnson Defendants cite no authority that indicates these cases apply to a grant of injunctive relief.

Nevertheless, assuming commercial free speech protections apply to the terms of an injunction, no First Amendment violation occurred here. As to the analytical framework employed in resolving a commercial free speech challenge, our U.S. Supreme Court stated:

> Although commercial speech is protected by the First Amendment, not all regulation of such speech is unconstitutional. See [Virginia State Bd. of Pharmacy.] In [Central Hudson Gas & Electric v. Public Service Commission of New York, 447 U.S. 557 (1980),] we articulated a test for determining whether a particular commercial speech regulation is constitutionally permissible. Under that test we ask as a threshold matter whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, however, we next ask "whether the asserted governmental interest is substantial." [Id. at 566.] If it is, then we "determine whether the regulation directly advances the governmental interest asserted," and, finally, "whether it is not more extensive than is necessary to serve that interest." *Ibid.* Each of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional.

Thompson, 535 U.S. at 367 (emphasis added).

Here, the trial judge enjoined Johnson & Johnson Defendants from contributing to the promotion or marketing of spreads for their branded drugs that are reimbursed by the Plaintiff Agencies. By promoting and marketing spread,

Johnson & Johnson Defendants sought to induce doctors and other providers to purchase Medicare Part B branded drugs based on the drugs' profitability. The trial judge determined that such conduct violates the CPL, which prohibits, among other things, fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding. In short, the promotion or marketing of spread violates the CPL.[27] Therefore, it is unlawful. As such, this conduct is not entitled to commercial free speech protection. Thompson.

Further, even in we applied the three-prong Central Hudson test, the injunction granted is valid. First, the asserted governmental interest is substantial in that elimination of spread marketing helps to ensure providers choose to purchase and prescribe Johnson & Johnson branded drugs based on their therapeutic value rather than their profitability. In addition, the restraint of spread-marketing helps to conserve the Plaintiff Agencies' limited resources so that these resources are not depleted through overpayment for Johnson & Johnson branded drugs.

Second, the elimination of spread-marketing directly advances these governmental interests by reducing the instances where providers purchase and prescribe drugs based on the drugs' profitability. Also, the restraint of spread-marketing assists in conserving valuable governmental resources by reducing overpayments for branded drugs that are reimbursed by the Plaintiff Agencies.

[27] Of further note, in 2003 the federal Office of Inspector General issued guidelines condemning spread marketing.

Third, the prohibition on spread-marketing, which is carefully tailored to apply to Johnson & Johnson branded drugs that are reimbursed by the Plaintiff Agencies, is not more extensive than necessary to serve the governmental interests at issue here.

D. Restoration Improper

1. Contentions

Johnson & Johnson Defendants contend that the Commonwealth did not establish a basis for an award of restoration under Section 4.1 of the CPL, 73 P.S. §201-4.1. First, they contend that because there is no basis for an injunction under Section 4 of the CPL, there is no basis for the trial judge's award of restitution under Section 4.1.

Moreover, like BMS, Johnson & Johnson Defendants argue that restitution is not permitted where, as here, the Defendants did not "acquire" any funds from the Plaintiff Agencies. Rather, the Plaintiff Agencies reimbursed providers such as pharmacies for the branded drugs involved.

In addition, like BMS, Johnson & Johnson Defendants contend that there was no evidence of any "overpayment" to providers by the Plaintiff Agencies. Like BMS, Johnson & Johnson Defendants refer to evidence provided by their expert witness and to a response during cross-examination given by the Commonwealth's liability and causation expert, Dr. Comanor, that he had no opinion whether pharmacists were overpaid. N.T., 10/26/10, at 1548. Johnson &

Johnson Defendants also contend that there was no overpayment to providers when rebates paid to the Plaintiff Agencies are taken into account.

Johnson & Johnson Defendants also object to the amounts awarded as restoration. These objections are addressed separately below.

2. Analysis – Generally

These challenges to the legal basis for restoration and the amounts of restoration are meritless. The challenges are similar, if not identical, to those raised by BMS. For the reasons discussed in our opinion denying the post-trial motions of BMS, we reject these similar challenges.

The accepted testimony from the Commonwealth's expert witnesses provides a sufficient legal basis for the award of restoration pursuant to Section 4.1 of the CPL. As discussed in the previous section, the factual and legal bases for the injunction are present.

Section 4.1 of the CPL authorizes a court issuing a permanent injunction to also use its discretion to order restoration. By the clear terms of the statute, the remedy is discretionary. Therefore, once a restrainable violation of the CPL is established, review of an ancillary award of restoration is limited to the deferential abuse of discretion standard.

An abuse of discretion exists where the trial court reached a conclusion which overrides or misapplies the law, or when the judgment exercised

is manifestly unreasonable, or the result of partiality, prejudice, bias or ill-will. Middletown Twp. v. Lands of Stone, 595 Pa. 607, 939 A.2d 331 (2007).

3. No Basis for Injunction

In the foregoing discussion we reviewed the trial judge's findings and conclusions regarding: fictitious AWP prices; confusion about the meaning and derivation of AWPs and the lack of a better proxy for estimated provider acquisition cost; the tendency to mislead caused by the unclarified use of fictitious AWPs in a complicated reimbursement system; materiality of AWPs to reimbursement by Plaintiff Agencies; "government knowledge;" reliance and "government choice;" causation; restoration amounts; and, marketing the spread. In addition, we reviewed the propriety of the statutory injunction entered on the Commonwealth's suit in the public interest pursuant to Section 4 of the CPL. For all the reasons previously discussed, we conclude there was a basis for entry of the statutory injunction. Concomitantly, we conclude there was a basis for the trial judge to also exercise his discretion in awarding restoration under Section 4.1 of the CPL.

4. J&J Not "Acquire" Funds

Like BMS, Johnson & Johnson Defendants contend that they did not acquire any funds from the Plaintiff Agencies. Rather, the Plaintiff Agencies paid providers. Because Johnson & Johnson Defendants did not acquire funds from the Plaintiff Agencies, they contend that no basis for common law restitution exists. Also, Johnson & Johnson Defendants urge this Court to overrule its prior *en banc* decision in TAP II in which we determined that restoration under Section 4.1 of the

CPL does not require that the money restored originate from payments made to a defendant.

Section 4.1 of the CPL permits the court, in its discretion, to order restoration. Although Johnson & Johnson Defendants continually characterize the remedy as "restitution," that word does not appear in the text of Section 4.1 of the CPL. While the statutory remedy is of an equitable nature, the fact that the General Assembly chose a word different than "restitution" suggests that it did not intend the remedy to be exactly the same.

Consistent with this general observation, an *en banc* panel of this Court in TAP II rejected this same argument:

> [A]s the Commonwealth argues, the [CPL], while providing for recovery of damages, does not specifically require that the damages sought arise from payment made directly to a defendant. [Section 4.1] provides that a court may order a defendant to restore any money lost as a result of a violation. 73 P.S. §201-4.1. Hence, if the Court were to conclude that the Defendants' conduct constitutes a violation of the [CPL], and the Commonwealth establishes the loss of money as a result of the conduct, the Commonwealth may prevail in its claims.

Id. at 1139-40 (emphasis added). In accord with TAP II, we again reject the argument that statutory restoration is not an appropriate remedy because Johnson & Johnson Defendants did not acquire any money as a result of any CPL violation.

5. No Evidence of "Overpayment"

Johnson & Johnson Defendants' contention that there is no evidence that there was any "overpayment" to pharmacists for any DPW and PACE drugs is wildly inaccurate. The extensive testimony of the Commonwealth's damages expert, Dr. Warren-Boulton, both initially and on rebuttal, explains in detail both the fact and the amount of overpayment by Plaintiff Agencies. This testimony was accepted by the trial judge.

Moreover, the relevant inquiry here is whether the Plaintiff Agencies overpaid for drugs based on fictitious and deceptive pricing. The pharmacies did not set the fictitious AWPs. Quite simply, Johnson & Johnson Defendants contributed to fictitious and deceptive prices for their drugs, which caused the Plaintiff Agencies to pay more for them. See MDL 2007 (fictitious AWP caused end payors to pay more than they would have if defendants reported a true AWP).

Also, to the extent Johnson & Johnson Defendants rely on the rejected opinions of their expert, Dr. Berndt, or the rejected testimony of their pharmacist witness, David Smith, their contentions lack merit.

Like BMS, Johnson & Johnson Defendants contend that the Commonwealth's liability and causation expert, Dr. Comanor, could not give an opinion on cross-examination as to whether the Plaintiff Agencies made overpayments to pharmacies for drugs. For the same reasons BMS' argument was rejected, we reject it again here.

Johnson & Johnson Defendants further rely on rebates paid to the Plaintiff Agencies to support their contention regarding lack of evidence of overpayment. However, for reasons discussed more fully elsewhere, the trial judge rejected Johnson & Johnson Defendants' approach to rebates. Instead, the trial judge accepted the opinion testimony of Dr. Warren-Boulton that the inclusion of OBRA rebates, including the base rebate (15.1% of AMP) and the Best Price rebate, would cause the calculation of restoration amounts to go *higher*. N.T., 11/3/10, at 2414-30. He reiterated this position during rebuttal testimony. N.T., 11/16/10, at 4109-12; PX-10268; PX-10269.

6. Challenge to Warren-Boulton's PBM Model

a. Contentions

Like BMS, Johnson & Johnson Defendants challenge the methodology of the Commonwealth's damages expert, Dr. Warren-Boulton. Johnson & Johnson Defendants contend that Dr. Warren-Boulton did not properly construct "but for" worlds. For example, in one of Dr. Warren-Boulton's "but for" worlds, the Plaintiff Agencies decide to reimburse at the same levels as PBMs. However, in reality, the level of PBM reimbursement was always known to the Plaintiff Agencies, and they chose not to reimburse at those levels. Accordingly, the "but for" worlds constructed by Dr. Warren-Boulton cannot be considered true measures of "but for" damages.

They also complain Dr. Warren-Boulton ignored real-world political considerations in constructing his "but for" analysis. Finally, Johnson & Johnson Defendants contend the trial judge erred in failing to adjust Dr. Warren-Boulton's

calculations for improperly including claims that were not based on AWP and for including differences in dispensing fees which are entirely unaffected by AWP and Johnson & Johnson Defendants' conduct.

b. Analysis – Generally

These challenges to the amounts of restoration are meritless. The trial judge accepted Dr. Warren-Boulton's methodology and calculations. This testimony provides substantial evidence to support the amount of restoration.

The law does not require that proof of damages conform to the standard of mathematical exactness. James Corp. v. N. Allegheny Sch. Dist., 938 A.2d 474 (Pa. Cmwlth. 2007). "The law simply requires the claim be supported by a reasonable basis for the calculation." Id. at 494. If the facts afford a reasonably fair basis for calculating the amount to which the plaintiff is entitled, such evidence cannot be disregarded as legally insufficient. Id.

"The determination of damages is a factual question to be decided by the fact-finder." Delahanty v. First Pennsylvania Bank, 464 A.2d 1243, 1257 (Pa. Super. 1983). A fact-finder "may make a just and reasonable estimate of the damages based on relevant data, and in such circumstances, may act on probable and inferential, as well as direct and positive proof." Id. "Thus, the law does not demand that the estimation of damages be completely free of speculation." Id. "Where the amount of damage can be fairly estimated from the evidence, the recovery will be sustained even though such amount cannot be determined with entire accuracy." Id. at 1258.

The trial judge concluded that the fact of loss was clearly established. Therefore, the best manner of computing loss was a matter properly reserved to the discretion of the fact-finder. Also, Johnson & Johnson Defendants' contentions raise questions of credibility and weight of the evidence which are no longer appropriate matters for debate. Further, their reliance on the testimony of their expert, Dr. Berndt, is misplaced, because for the most part the trial judge rejected that testimony. Non-Jury Decision of December 7, 2010, ¶3(b), n. 2.

c. Global Challenges to "But For" Methodology

Regarding the global challenge to the way in which Dr. Warren-Boulton constructed his "but for" worlds, the trial judge rejected the "government knowledge" argument advanced by Johnson & Johnson Defendants. As the "government knowledge" contention was a premise of the "but for" methodology challenge, its rejection is fatal to the challenge. Moreover, Johnson & Johnson Defendants did not ask Dr. Warren-Boulton about the public availability of PBM reimbursement rates he used, nor did they establish the availability of this information through any other credible source.

Similarly, the trial judge rejected the "government choice" argument advanced by Johnson & Johnson Defendants. Instead, the trial judge determined reimbursement rates were beyond the sole control of the Plaintiff Agencies. As this "government choice" contention was also a premise for the challenge to the "but for" methodology, its rejection is fatal to the challenge.

d. Real-World Factors

Dr. Warren-Boulton's statements on cross-examination during his rebuttal testimony do not require that all his testimony be ignored. He was cross-examined on "real-world" considerations, particularly the level of dispensing fees included as part of the reimbursement formulae. N.T., 11/16/10, at 4124-25.

This cross-examination was a rehash of testimony regarding "government choice," involving the interrelated drug and dispensing fee components of the "chosen" reimbursement formulae. As discussed elsewhere, the trial judge rejected the contention that the Plaintiff Agencies made deliberate policy decisions to reimburse at higher rates than other third-party payors to ensure pharmacy participation, also referred to as "access." Rather, the trial judge found more credible the opinions of Dr. Warren-Boulton that pharmacy participation in the drug reimbursement programs was never threatened, even when reimbursement rates were reduced. The level of reimbursement and the continuing reliance on formulae based on some form of AWP were the result of several factors: confusion over AWP; lack of a better proxy for true provider acquisition costs; and, an inflexible reimbursement system where changes to laws and regulations came slowly, if at all.

Under these circumstances, the contention of Johnson & Johnson Defendants relating to real-world factors is another improper attack on the trial judge's credibility and fact-finding determinations.

e. Improper Inclusions

Johnson & Johnson Defendants also complain that Dr. Warren-Boulton improperly included claims not based on AWP and dispensing fee reimbursements. However, the trial judge rejected these arguments insofar as he rejected the expert testimony of Dr. Berndt, upon which they were based. N.T., 11/15/10, at 3937-39. Instead, the trial judge expressly accepted Dr. Warren-Boulton's rebuttal testimony on these points. N.T., 11/16/10, at 4088-89, 4095-98, 4099-4105, Non-Jury Decision of December 7, 2010, ¶3(b), n. 2.

Thus, Johnson & Johnson Defendants' contentions on these points are nothing more than an improper attempt to reweigh the evidence and revisit expert witness credibility determinations.

7. Restoration Before 1997

a. Contentions

Johnson & Johnson Defendants argue, even if an award of restitution is generally proper, restitution is unavailable prior to February 2, 1997. Specifically, they assert the General Assembly did not amend the CPL's catchall provision, upon which the trial judge based his finding of liability, to include the language "or deceptive" (in addition to fraudulent) conduct until December 1996, and the amendment did not take effect until February 2, 1997. Johnson & Johnson Defendants contend there is no indication the General Assembly intended the amendment to apply retroactively. Further, they maintain, prior to the amendment, a plaintiff bringing a claim under the CPL's catchall provision had to prove all the elements of common law fraud. Johnson & Johnson Defendants assert that the

trial judge ruled the Commonwealth did not prove common law fraud here; therefore, no damages should be awarded for any conduct before February 2, 1997.

b. Waiver

This issue was not raised in the first trial involving BMS. Further, the issue was not raised in the second trial involving Johnson & Johnson Defendants.

In particular, Johnson & Johnson Defendants did not raise this argument in their pre-trial memoranda, at the pre-trial conference, in their motion for compulsory nonsuit, in their proposed findings of fact and conclusions of law, or at closing argument. See Pa. R.C.P. No. 227.1(b)(1). Indeed, in their brief in support of post-trial motions, Johnson & Johnson Defendants do not identify where they raised this issue prior to or during trial. See Pa. R.C.P. No. 227.1(b)(2). Failure to raise this issue before or during trial deprived the Commonwealth of an opportunity to respond to this claim and precluded development of a record on this issue. As such, Johnson & Johnson Defendants did not properly preserve this claim. Id.[28]

E. Civil Penalties Improper

1. Contentions

Johnson & Johnson Defendants contend that there was no evidence in the record to support the trial judge's finding of willful violation of the CPL and its imposition of penalties. In addition, they contend the trial judge erred in counting penalties on the basis of changes to each national drug code (NDC), which

[28] If, however, the defense is not waived, and if it is deemed meritorious, the amount of restoration awarded would be reduced from $45,283,562.00 to $34,768,221.00.

compounds violations by counting changes to variable strengths of drugs rather than just counting each time the price changed for a drug. These contentions have no merit.

Section 8(b) of the CPL, 73 P.S. §201-8(b),[29] applies to an action brought under Section 4 of the CPL, dealing with suits brought in the public interest. Where the court finds that a firm or corporation has willfully used a practice declared unlawful, the Commonwealth may recover civil penalties.

In his Non-Jury Decision, the trial judge stated: "the Court finds that Johnson & Johnson Defendants willfully used practices declared unlawful by the [CPL] …." The judge specifically accepted as credible the civil penalty methodology set forth in Exhibit 15 of the Supplemental Report of September 30,

[29] Section 8(b) of the CPL provides:

> (b) In any action brought under section 4 of this act, if the court finds that a person, firm or corporation is willfully using or has willfully used a method, act or practice declared unlawful by section 3 of this act, the Attorney General or the appropriate District Attorney, acting in the name of the Commonwealth of Pennsylvania, may recover, on behalf of the Commonwealth of Pennsylvania, a civil penalty of not exceeding one thousand dollars ($1,000) per violation, which civil penalty shall be in addition to other relief which may be granted under sections 4 and 4.1 of this act. Where the victim of the willful use of a method, act or practice declared unlawful by section 3 of this act is sixty years of age or older, the civil penalty shall not exceed three thousand dollars ($3,000) per violation, which penalty shall be in addition to other relief which may be granted under sections 2 and 4.1 of this act.

73 P.S. §201-8(b).

2010, by the Commonwealth's damages expert, Dr. Warren-Boulton. PX-10229; Non-Jury Decision of December 7, 2010 at ¶3c, Note 3. The trial judge awarded $6,567,000.00 in civil penalties pursuant to Section 8(b) of the CPL, 73 P.S. §201-8(b).

2. Evidence of Willfulness

In awarding penalties, the trial judge relied in part on the opinion of the Commonwealth's liability and causation expert, Dr. Comanor. He described "exploitation by drug companies like J&J, and this exploitation takes the form of enhanced price discrimination. In particular, the public payors subsidized pharmacy overheads to the advantage of private payors, as indeed acknowledged in that J&J slide [PX-10052]." N.T., 10/26/10, at 1495; see also id. at 1482-84. Significantly, he then opined, "The actions of the drug manufacturers like J&J to take advantage of the public payors was a conscious decision on their part." N.T., 10/26/10, at 1495 (emphasis added). Together with the evidence discussed above regarding AWP System and Confusion, this constitutes substantial evidence supporting the determination that Johnson & Johnson Defendants' actions were willful.

3. Changes to NDCs

As for the amount of the penalties, the trial judge accepted the opinion testimony of Dr. Warren-Boulton. N.T., 11/3/10, at 2402-07. The methodology approved was the most conservative approach offered by the expert witness.

Notably, this approach is consistent with the approach employed by the trial judge in Abbott Laboratories. There, trial judge rejected an approach to quantifying forfeitures which was premised on each AWP-based reimbursement of the defendant pharmaceutical company's drugs. Instead, the trial judge adopted a more conservative approach focused on AWP changes reported to pricing compendia as a basis for calculating forfeitures under the Wisconsin consumer protection statute, and he valued each forfeiture at $1000.

Johnson & Johnson Defendants' challenge to the counting of penalties on the basis of changes to NDCs does not warrant post-trial relief, for several reasons. First, the challenge was not raised at any time before the non-jury award was entered; therefore, it is waived. Second, Johnson & Johnson Defendants offered no evidence in support of the challenge. Even now, Johnson & Johnson Defendants do not offer a different positive number as a basis for computing penalties. Third, this challenge clearly goes to the weight to be given the expert opinion rather than its competence. As such, it is an improper attempt to revisit credibility determinations made by the trial judge.

Having found no merit in the arguments of Johnson & Johnson Defendants, their motion for post-trial relief is denied and dismissed.

VII. COMMONWEALTH DEMAND FOR JNOV

A. Contentions

The Commonwealth seeks JNOV in favor of DPW on the issue of negligent misrepresentation and in favor of both Plaintiff Agencies on the issue of civil conspiracy.

In what appears to be argument cut from its brief in support of post-trial motions after the BMS trial, the Commonwealth contends that JNOV in favor of DPW on the claim of negligent misrepresentation is appropriate based upon evidence (both admitted and rejected) because of the breach of duty by Johnson & Johnson Defendants and because of DPW's reasonable reliance on the statute governing reimbursement. The Commonwealth also complains about evidentiary rulings which hindered it from proving guilty pleas and settlements by other drug manufacturers but which permitted Johnson & Johnson Defendants to attack reliance with broad, non-specific evidence relating to "government knowledge."

The Commonwealth also argues that DPW is entitled to JNOV on the claim of negligent misrepresentation as a matter of law. In this regard, the Commonwealth makes the following points: pricing information is presumptively material; advertised prices of any kind must be realistic; it is no defense to assert that DPW should have known of the deception; it does not matter that Johnson & Johnson Defendants did not publish the deceptive prices themselves; and, the purported knowledge of one government agency may not be imputed to another agency of that government. These points are largely supported by cases from federal courts and the courts of other states.

As to the civil conspiracy claims of the Plaintiff Agencies, the Commonwealth assumes the trial judge rejected these claims because he improperly required an underlying tort as an object of the conspiracy. Because any wrongful act may be the object of a civil conspiracy, and Johnson & Johnson Defendants committed a wrongful act when they violated the CPL, the Commonwealth satisfied its burden with respect to the civil conspiracy claims.

Johnson & Johnson Defendants first argue that the Commonwealth failed to conform with Pa. R.C.P. No. 227.1(b)(2) because it repeatedly fails to "state how the grounds were asserted in pre-trial proceedings or at trial."

Regarding the negligent misrepresentation claim, Johnson & Johnson Defendants contend the evidentiary rulings did not hinder the Commonwealth's ability to prove reliance. They also point out that the Commonwealth fails to give citations to the transcript in support of its evidentiary rulings complaints.

Johnson & Johnson Defendants further assert that the negligent misrepresentation claim failed on its merits. First, they assert the claim is barred by the economic loss doctrine.

Next, they contend the Commonwealth failed to establish the elements of negligent misrepresentation. In particular, they argue that there was no misrepresentation by Johnson & Johnson Defendants, that the Plaintiff Agencies did not justifiably rely on any misrepresentations, that the alleged

misrepresentation was immaterial, and that the Commonwealth cannot establish causation.

Finally, Johnson & Johnson Defendants argue that they owed no duty to the Commonwealth. They point out that no statute imposes a duty to affirmatively report actual averages of wholesale prices. In addition, they did not track actual retail acquisition prices from wholesalers or have knowledge of those prices which was superior to that of the Plaintiff Agencies.

Regarding the civil conspiracy claims, Johnson & Johnson Defendants contend that the Commonwealth failed to prove actual malice, that is, a specific intent to injure the plaintiff, which is an essential element of the claim. The Commonwealth's own proof showed that drug manufacturers were motivated by the prospect of increased income, a legitimate business purpose.

B. Analysis

1. Generally

This Court fully addressed the applicable standards for JNOV and new trial in Department of General Services v. U.S. Mineral Products. Co., 927 A.2d 717 (Pa. Cmwlth. 2007), aff'd, 598 Pa. 331, 956 A.2d 967 (2008), stating:

> Preliminarily, we set forth the guiding principles when considering motions for JNOV and new trial. The criteria for granting these mutually exclusive types of post-trial relief are different.
>
> Judgment notwithstanding the verdict may be entered on two bases: where the movant is entitled to judgment as a matter of law, and/or where the evidence is

> such that no two reasonable persons could disagree the verdict should have been rendered for the movant. On the first basis, a court reviews the record and concludes that even with all factual inferences decided adverse to the movant, the law nonetheless requires a verdict in movant's favor. On the second basis, the court reviews the evidentiary record and concludes the evidence is such that a verdict for the movant is beyond peradventure. Judgment notwithstanding the verdict should not be entered where the evidence is conflicting on a material fact, and a reviewing court is required to consider the evidence, together with all reasonable inferences, in a light most favorable to the verdict winner.
>
> In order to obtain a new trial, however, the moving party must demonstrate in what way trial error caused an incorrect result. Our analysis of whether [p]laintiffs are entitled to a new trial follows a two step process. First, we must decide whether one or more mistakes occurred at trial. Second, if we conclude a mistake occurred, we must determine whether the mistake is a sufficient basis for granting a new trial. The harmless error doctrine underlies every decision to grant or deny a new trial. A new trial is not warranted merely because some irregularity occurred during the trial or another trial judge would have ruled differently; the moving party must demonstrate prejudice resulting from the mistake. In addition, a new trial based on weight of the evidence issues will not be granted unless the verdict is so contrary to the evidence as to shock one's sense of justice. A mere conflict in testimony will not suffice as grounds for a new trial. In ruling on a motion for new trial, the court must review all the evidence.

Id. at 723 (citations omitted).

Much of the Commonwealth's argument based on the evidence asks this Court to address evidentiary rulings, which are not the proper subject of a motion for JNOV. Indeed, in deciding a motion for JNOV, a court "is confined to

consideration of those things appearing on the entire record as it existed at the close of trial ….” 10 STANDARD PA. PRACTICE 2D §64:14 (footnotes omitted); see Drew v. Laber, 477 Pa. 297, 383 A.2d 941 (1978); Broxie v. Household Fin. Co., 472 Pa. 373, 372 A.2d 741 (1977). “The record may not be added to by the insertion of evidence that should have been admitted, or diminished by the elimination, as inadmissible, of evidence that had been.” 10 STANDARD PA. PRACTICE 2D §64:15 (footnotes omitted); see Drew; Henry Shenk Co. v. City of Erie, 352 Pa. 481, 43 A.2d 99 (1945). Thus, the Commonwealth’s evidentiary arguments are improperly raised in the context of a motion for JNOV. We discuss the Commonwealth’s arguments relating to evidentiary issues below as they impact the Commonwealth’s motion for new trial.

As to the arguments appropriately raised, in order to grant JNOV based on the sufficiency of the evidence, a court must review the evidentiary record and conclude the evidence is such that a verdict for the movant is beyond peradventure. U.S. Mineral Prods. A court may not vacate a fact finding unless “the evidence was such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant.” Birth Center v. St. Paul Cos., Inc., 567 Pa. 386, 397-98, 787 A.2d 376, 383 (2001). The Court must resolve any doubts in favor of the verdict winner. Id.

The Commonwealth incorrectly invites this Court to draw factual inferences in its favor. Our review of a request for JNOV, however, requires us to examine the record by drawing all factual inferences in a light most favorable to the verdict winner on the common law claims, Johnson & Johnson Defendants.

U.S. Mineral Prods.

2. Negligent Misrepresentation

The Commonwealth's arguments for JNOV fail for both factual and legal reasons. Factually, as more fully described above, the Commonwealth failed to prove common law reliance. In other words, the Commonwealth failed to prove that the Plaintiff Agencies refrained from changing their reimbursement schemes because they believed the reported AWPs were true averages of wholesale prices paid by providers. Instead, the trial judge determined that in Pennsylvania the level of reimbursement and the continuing reliance on formulae based on some form of AWP were the result of several factors: confusion over AWP; lack of a better proxy for provider acquisition costs; and, an inflexible reimbursement system where changes to laws and regulations came slowly, if at all. Because the Commonwealth failed to prove an element of the negligent misrepresentation claim, it cannot prevail on its request for JNOV.

Moreover, the Commonwealth's position fails legally. As to the law, the Commonwealth initially cites Pennsylvania authority, but then shifts its argument to an exhaustive discussion of case law from other jurisdictions.

Regarding Pennsylvania law relied upon by the Commonwealth, the cases are clearly distinguishable. See Scaife Co. v. Rockwell-Standard Corp., 446 Pa. 280, 285 A.2d 451 (1972); Siskin v. Cohen, 363 Pa. 580, 70 A.2d 293 (1950). These cases involved claims for fraudulent misrepresentation in which reliance was contested, but in both cases the jury found for the plaintiffs. Thus, in both

cases the prevailing plaintiffs were entitled to all favorable inferences when the verdicts were reviewed. That is not the situation here.

To the extent the Commonwealth relies on Scaife and Siskin for the proposition that reliance is established as a matter of law where one party has greater access to information than the other party, the position is unsustainable. In both cases the Supreme Court reiterated the principle that where the means of obtaining information are not equal, a person may rely on the positive representations of one who possesses superior means of information. However, the principle is one that informs the fact-finder's determination, not one that requires a finding of reliance as a matter of law. Indeed, in both Scaife and Siskin, the Supreme Court ultimately deferred to the fact-finder's findings where the issue of reliance was disputed. Here, we reach a result consistent with Scaife and Siskin by denying the Commonwealth's request to alter the fact-finder's resolution of the disputed issue of reliance.

Regarding law from other jurisdictions, the Commonwealth essentially asks us to presume it established reliance and causation based on alleged violations of certain legal duties from an unidentified source. The Commonwealth advocates this position in a lengthy section of its argument that relies exclusively on federal cases as well as cases from other states.

The Commonwealth's argument appears to be based on three premises: (1) the more relaxed standard applicable in a statutory enforcement action by the Attorney General under the CPL also applies to a negligent

misrepresentation claim; (2) federal standards under the FTC Act apply to a common law negligent misrepresentation claim; and, (3) causation and reliance were established by application of a "fraud on the market" theory of liability. These arguments do not compel JNOV relief for several reasons.

First, the Commonwealth cites no authority that establishes that the elements for claims brought under the CPL's catch-all provision and claims for negligent misrepresentation are the same. In the absence of authority, or further explanation, we reject the Commonwealth's attempt to trump the elements of a common law claim with an analysis based on statutory construction.

Second, although cases interpreting the FTC Act may be helpful in analyzing a CPL claim, the application of those cases to a common law tort claim is far less apparent and is not explained by the Commonwealth.

Third, the Commonwealth did not present proof consistent with the recently explained fraud on the market theory. See Clark v. Pfizer, Inc., 990 A.2d 17 (Pa. Super. 2010) (in securities fraud, plaintiffs establish causation and reliance on a class wide basis through aggregate, statistical proof of harm); but see In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig, 618 F. Supp. 2d 96 (D. Mass. 2009) (Saris, J.) (fraud on the market theory has not been adopted outside the securities fraud context). Moreover, at trial the Commonwealth did not assert causation and reliance could be presumed based on such theory. Thus, even if the Commonwealth's arguments can now be construed as raising such a claim, this claim is waived.

For all these reasons, we decline the invitation to grant JNOV on the negligent misrepresentation claim.

3. Civil Conspiracy

The Commonwealth's request for JNOV on the civil conspiracy claims fails because the Commonwealth failed to establish an essential element of conspiracy, actual malice. This failure of proof is discussed earlier in the opinion.

Failure to clearly prove malice precludes a grant of JNOV in favor of the Commonwealth. See Thompson Coal (where facts indicated defendant acted to advance legitimate business interests rather than solely to injure plaintiffs, defendant was entitled to summary judgment on conspiracy claim); Rutherfoord v. Presbyterian-Univ. Hosp., 612 A.2d 500, 509 (Pa. Super. 1992) (ex-employee's civil conspiracy claim failed based on his acknowledgment that he lost his employment because defendant wanted to terminate as many employees as it could, thereby negating any specific intent to injure plaintiff); see also Zafarana v. Pfizer Inc. 724 F. Supp.2d 545 (E.D. Pa. 2010) (dismissing conspiracy claim against Pfizer, Pharmacia and Upjohn, in case alleging the companies improperly marketed their drugs for off-label uses, where plaintiffs did not aver sole purpose of conspiracy was to injure, but rather allegations indicated intent was to maximize profits); Bro-Tech Corp. v. Thermax, Inc., 651 F.Supp.2d 378, 419 (E.D. Pa. 2009) (where plaintiffs' entire case was built on theory that defendants acted for their business advantage and benefit, plaintiffs could not maintain a civil conspiracy claim because "plaintiffs' evidence belies the notion that [d]efendants acted without a business motive, but purely out of malice."); WM High Yield Fund v.

O'Hanlon, No. Civ. A. 04-3423, 2005 WL 1017811, at *14 (E.D. Pa. Apr. 29, 2005) (civil conspiracy claim failed where plaintiffs acknowledged defendants' intent was to "raise new capital to fund [the] growth" of a nonparty corporation, thereby negating "malice solely to injure [p]laintiffs"); Lackner v. Glosser, 892 A.2d 21 (Pa. Super. 2006) (where evidence in business dispute did not show defendants acted with intent to injure plaintiff, trial court properly granted summary judgment in defendants' favor on conspiracy claim).

VIII. COMMONWEALTH DEMAND FOR NEW TRIAL

A. Contentions

Similar to the arguments raised in support of post-trial relief after the BMS trial, the Commonwealth relies on three types of alleged error in evidentiary rulings to support its demand for a new trial on DPW's claim for negligent misrepresentation and on the civil conspiracy claims of both Plaintiff Agencies.

First, the Commonwealth decries the admission of general, non-particularized evidence of "government knowledge" of AWPs, without any showing that the evidence was relevant to Johnson & Johnson Defendants' drugs or Johnson & Johnson Defendants' specific conduct at issue in the case. The Commonwealth offers a lone citation to the record, N.T., 11/12/10, at 3616-17. No objection is raised on these pages.

Second, the Commonwealth complains that the trial judge refused its proof of certain evidence that "tended to show [the Plaintiff Agencies'] reasonable reliance on the investigations, prosecutions, settlements and guilty pleas

concerning J&J and its co-conspirators." Plaintiffs' Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 9 (emphasis in original). The Commonwealth does not include any citations to the record to support this argument.

Third, the Commonwealth assigns error in the receipt of evidence that was outside the relevant time period. The Commonwealth does not include any citations to the record to support this argument.

As to the admitted "government knowledge" evidence, Johnson & Johnson Defendants respond that the Commonwealth does not identify specifically the evidence in question, does not identify where it preserved its objections, does not recite any legal principle that would have permitted the trial judge to exclude the evidence, and does not attempt to show that any potential for prejudice outweighed its probative value.

Regarding the excluded evidence of "reasonable reliance," Johnson & Johnson Defendants highlight the Commonwealth's failure to identify the evidence in question and to indicate where it preserved objections. The Defendants suggest that the evidence at issue must be the deposition testimony of two doctors who asserted the Fifth Amendment during depositions in an unrelated case regarding their alleged billing for free samples of a drug not sold by Johnson & Johnson Defendants. N.T., 11/3/10, at 2343-47. They also assert that exclusion of the irrelevant evidence was not an abuse of discretion and that the evidence has nothing to do with reliance on Johnson & Johnson Defendants' AWPs.

B. Analysis

The purpose of post-trial motions is to give the trial court an opportunity to review and reconsider its earlier rulings and correct its own errors before an appeal is taken. Lahr v. City of York, 972 A.2d 41 (Pa. Cmwlth. 2009). Post-trial motions should be granted only when the moving party suffered prejudice as a result of the trial court's clear error. Id.

Post-trial relief is governed by Pa. R.C.P. No. 227.1, which provides, as pertinent:

> (a) After trial and upon the written Motion for Post-Trial Relief filed by any party, the court may
>
> > (1) order a new trial as to all or any of the issues; or
> >
> > (2) direct the entry of judgment in favor of any party; or
> >
> > (3) remove a nonsuit; or
> >
> > (4) affirm, modify or change the decision; or
> >
> > (5) enter any other appropriate order.
>
> (b) Except as otherwise provided by Pa. R.E. 103(a), post-trial relief may not be granted unless the grounds therefor,
>
> > (1) if then available, were raised in pre-trial proceedings or by motion, objection, point for charge, request for findings of fact or conclusions of law, offer of proof or other appropriate method at trial; and

> (2) are specified in the motion. The motion shall state how the grounds were asserted in pre-trial proceedings or at trial. Grounds not specified are deemed waived unless leave is granted upon cause shown to specify additional grounds.

Failure to specify how the grounds for relief were asserted at trial or in pre-trial proceedings results in waiver of those issues. Hinkson v. Dep't of Transp., 871 A.2d 301 (Pa. Cmwlth. 2005).

In evaluating these assignments of error, we are mindful that the admission or exclusion of evidence are matters within the sound discretion of the trial court, and will not be disturbed absent a clear abuse of discretion. Cheng v. Se. Pa. Transp. Auth., 981 A.2d 371 (Pa. Cmwlth. 2009).

The Commonwealth's failure to indicate where in the ponderous transcript the trial judge made his erroneous rulings interferes with our ability to efficiently review the request for a new trial. Given the number of issues the parties want addressed, it is an unreasonable burden for the trial judge to locate transcript references. For this reason, the request for a new trial should be deemed waived. Pa. R.C.P. No. 227.1(b)(2); Estate of Hicks v. Dana Cos., LLC, 984 A.2d 943 (Pa. Super. 2009), appeals denied, ___ Pa. ___, 19 A.3d 20, 21 (2011) (appellants' failure to cite to the place in the record where they objected to trial court's preclusion of evidence resulted in waiver); Hinkson (failure to specify in a post-trial motion how the grounds for relief were asserted at trial, or in pre-trial proceedings, will result in a waiver of those grounds).

Moreover, the Commonwealth's arguments fail on the merits. As to admitted evidence of "government knowledge," the trial judge took into consideration the specificity of the evidence in deciding credibility and weight. This consideration is detailed earlier in this opinion. Accordingly, prejudice to the Commonwealth is unclear in the absence of a more specific reference to items of evidence.

With regard to invocation of the Fifth Amendment by persons not employed by Johnson & Johnson Defendants, the trial judge acted within his broad discretion in excluding evidence with no apparent probative value that carried a significant risk of confusion. Pa. R.E. 403. This is especially true given the unfocused and impenetrable explanation of relevance from the Commonwealth's counsel. See N.T. 11/3/10 at 2343-44. Also, because the Commonwealth's conspiracy claim failed for other reasons, the exclusion of this evidence could not be prejudicial to that claim.

As to the evidence before and after the time period covered by the Commonwealth's claimed damages, no abuse of discretion is apparent. Having heard much of the same type evidence in the first trial, the trial judge, sitting as fact-finder in this trial, was capable of sorting the wheat from the chaff. Moreover, as more fully discussed in our companion opinion regarding the trial involving BMS, evidence arising before 1991 was relevant to the issue of reliance. Further, there can be no prejudice from evidence of occurrences after 2008. This is because the trial court did not award restoration after 2004, when structural changes in the law altered the reimbursement landscape.

IX. COMMONWEALTH DEMAND FOR MODIFICATION

A. Contentions

In arguments almost identical to those involving the BMS trial, the Commonwealth also asks the Court to modify the non-jury award in two ways: add an award of costs pursuant to Section 4.1 of the CPL, 73 P.S. §201-4.1; and, add an award of reasonable counsel fees pursuant to Section 9.2 of the CPL, 73 P.S. §201-9.2.

The Commonwealth asserts an award of costs is proper given the trial judge's finding that the Commonwealth proved entitlement to injunctive relief based on violations of the CPL. The Commonwealth maintains this Court should exercise its discretion and award costs because the Commonwealth incurred significant costs in prosecuting this matter and an award of costs is an integral part of restoration. The Commonwealth contends that while restoration of moneys illegally acquired through CPL violations restores those harmed to a financial status that existed prior to the violations, it does not address the costs involved in obtaining such relief. It argues that absent an award of costs restoration falls short of its core goal. Without a concomitant award of costs, the restoration award would be reduced by the expenditures incurred in obtaining the injunction. In other words, absent an award of costs, the Plaintiff Agencies have to bear the financial burden of bringing Johnson & Johnson Defendants to justice.

In addition, the Commonwealth notes that as part of the trial judge's Decision, he did not award reasonable attorney fees pursuant to Section 9.2 of the CPL; however, the trial judge did not elaborate on why attorney fees were not

awarded. The Commonwealth asserts Section 9.2 of the CPL directly applies to the Plaintiff Agencies "due to their unique posture in this action as 'persons' under [this section]." Plaintiffs' Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. No. 227.1 at 35 (citing TAP II).

The Commonwealth contends the trial judge found Johnson & Johnson Defendants violated the CPL. Pursuant to these findings, the trial judge issued a permanent injunction. As a result, there is *prima facie* evidence for purposes of Section 9.2 of the CPL that Defendants employed acts or practices declared unlawful by Section 3. Because this Court previously determined the Plaintiff Agencies are "persons" within the meaning of the CPL, an award of attorney fees is permissible under the CPL. Thus, the Commonwealth seeks modification of the decision to include attorney fees.

Johnson & Johnson Defendants urge that we deny the modification request because the Commonwealth distorts the language of the CPL and conflates separate and distinct statutory provisions.

Regarding costs, Johnson & Johnson Defendants highlight that neither Section 4 (relating to suits in the public interest to enjoin violations of the CPL) nor Section 4.1 (relating to an award of restoration where an injunction is entered) expressly provide for an award of costs. Moreover, "costs" do not satisfy the statutory language that permits restoration. In contrast, Section 9.2 of the CPL (relating to private actions) expressly permits recovery of costs and reasonable

attorney fees, demonstrating that the General Assembly knew how to provide for the recovery of these items but chose not to do so for suits in the public interest.

As to attorney fees, Johnson & Johnson Defendants argue that because the Commonwealth did not prove a claim under Section 9.2 (relating to private actions), it may not recover attorney fees under that provision. Defendants remind us that the Commonwealth did not prove any losses for individual consumers, and the Plaintiff Agencies are not entitled to proceed under Section 9.2 because they did not purchase pharmaceuticals for "personal, family or household purposes," as required by that provision. Moreover, relying on Toy v. Metropolitan Life Insurance Co., 593 Pa. 20, 928 A.2d 186 (2007), and similar cases, Johnson & Johnson Defendants contend that plaintiffs in private actions must prove all the elements of common law fraud, and the Commonwealth here did not prove reliance or causation.

B. Analysis

Generally, in a case under the CPL, a trial court's decision to award costs will not be disturbed absent abuse of discretion. Neal v. Bavarian Motors, Inc., 882 A.2d 1022 (Pa. Super. 2005). Likewise, an award of attorney fees and the imposition of civil penalties are also within the trial court's discretion. Wallace v. Pastore, 742 A.2d 1090 (Pa. Super. 1999); Com. ex rel. Corbett v. Ted Sopko Auto Sales & Locator, 719 A.2d 1111 (Pa. Cmwlth. 1998).

Further, parties to litigation are responsible for their own costs unless otherwise provided by agreement of the parties, some other recognized exception,

or statutory authority. Sternlicht v. Sternlicht, 822 A.2d 732 (Pa. Super. 2003). Generally, a litigant cannot recover counsel fees or costs from an adverse party unless the legislature expressly authorized such an award. Dep't of Envtl. Prot. v. Bethenergy Mines, Inc., 563 Pa. 170, 758 A.2d 1168 (2000).

In general, costs are incident to a final judgment. Novy v. Novy, 324 Pa. 362, 188 A. 328 (1936). In the absence of a statute requiring them to be paid when the services are performed, costs must be paid only after the action is terminated by judgment or discontinuance. Clark v. Reardon, 1 Pa. D. & C. 270 (C.P. Lancaster 1921).

Procedurally, the Commonwealth is not precluded from filing a bill of costs after judgment (although the type of costs recoverable is likely far less expansive than envisioned by the Commonwealth). See generally, 25A STANDARD PA. PRACTICE 2D §§127:35-127:44; 127:82-127:89. The costs will thereafter be taxed by a procedure which allows all parties to be heard. Id.

Substantively, however, where the proceeding is based on a statute, the right to recover costs must be found in the statute.[30] Dep't of Transp., Bureau of Driver Licensing v. Rapp, 589 A.2d 805 (Pa. Cmwlth. 1991).

[30] This rule may be contrasted with the Statute of Gloucester, which remains in effect as part of the common law of Pennsylvania, and which authorizes the recovery of full costs where damages are recovered in a common-law forum and where such damages are recoverable at common law. Richmond v. Pa. Higher Educ. Assistance Agency, 297 A.2d 544 (Pa. Cmwlth. 1972).

Section 4.1 of the CPL, the statutory provision at issue here, provides:

> Whenever any court issues a permanent injunction to restrain and prevent violations of this act as authorized in section 4 above, the court may in its discretion direct that the defendant or defendants restore to any person in interest any moneys or property, real or personal, which may have been acquired by means of any violation of this act, under terms and conditions to be established by the court.

73 P.S. §201-4.1 (emphasis added).

The plain language of Section 4.1 does not provide for an award of costs in an enforcement action by the Attorney General. Moreover, while the provision speaks to restoration of moneys, it limits restoration to moneys "acquired by means of any violation of [the CPL]." Id. It is unclear how costs would qualify under this language.

We acknowledge that the title of this unconsolidated statutory provision is "Costs and Restitution." Nevertheless, we decline the invitation to depart from the plain language of the text.

More significantly, the language used in Section 4.1 differs from the language used in Section 9.2(a) of the CPL, which expressly provides for an award of costs in private actions under the CPL. Presumably, if the General Assembly intended to permit costs in an enforcement action by the Attorney General, it would have expressly provided for such an award as it did in Section 9.2. The absence of such language from Section 4.1 leads to the conclusion that the Attorney General is not entitled to costs in a CPL enforcement action. The

Commonwealth cites no authority to the contrary, and our research fails to disclose any case that awarded costs in an Attorney General enforcement action since the enactment of Section 4.1 in 1976.

Also, the provisions of the CPL governing enforcement actions by the Attorney General do not specifically authorize an award of attorney fees. See Sections 4, 4.1 of the CPL, 73 P.S. §§201-4, 201-4.1. While an award of attorney fees is permissible in a private action under the CPL, the trial judge only granted relief under the statutory provisions for suits in the public interest. Because the CPL does not authorize an attorney fee award in an Attorney General enforcement action,[31] the Commonwealth is not entitled to attorney fees here.

Further, the Commonwealth did not prove damages under Section 9.2; therefore, the trial judge expressly declined to award any sums under Section 9.2 of the CPL. See Non-Jury Decision, filed December 7, 2010, ¶3(d). For this additional reason, the trial judge did not abuse his discretion in failing to award private action attorney fees to the Commonwealth.

[31] Compare New Jersey Consumer Fraud Act, N.J. Stat. Ann. §56:8-19 ("In all actions under this section, including those brought by the Attorney General, the court shall also award reasonable attorneys' fees, filing fees and reasonable costs of suit.") (Emphasis added.)

X. CONCLUSION

For all the reasons discussed, post-trial relief is denied both to the Commonwealth and to Johnson & Johnson Defendants. The Chief Clerk shall enter the Non-Jury Decision, filed December 7, 2010, as a final order.

ROBERT SIMPSON, Judge

Judges Cohn Jubelirer, Leavitt and Brobson did not participate in the decision in this case.

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania, Plaintiff	:	
v.	:	No. 212 M.D. 2004
TAP Pharmaceutical Products, Inc.; Abbott Laboratories; AstraZeneca PLC; AstraZeneca, Holdings, Inc.; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Bayer AG; Bayer Corporation; SmithKline Beecham Corporation d/b/a GlaxoSmithKline; Pfizer, Inc.; Pharmacia Corporation; Johnson & Johnson; Alza Corporation; Centocor, Inc.; Ethicon, Inc.; Janssen Pharmaceutical Products, L.P.; McNeil-PPC, Inc.; Ortho Biotech, Inc.; Ortho Biotech Products; L.P.; Ortho-McNeil Pharmaceutical, Inc; Amgen, Inc.; Immunex Corporation; Bristol-Myers Squibb Company; Baxter International Inc.; Baxter Healthcare Corporation; Immuno-U.S., Inc.; Aventis Pharmaceuticals, Inc.; Aventis Behring, L.L.C.; Hoechst Marion Roussel, Inc., Boehringer Ingelheim Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.; Ben Venue Laboratories; Bedford Laboratories; Roxane Laboratories; Schering-Plough Corporation; Warrick Pharmaceuticals Corporation; Schering Sales Corporation; Dey, Inc., Defendants	:	

O R D E R

AND NOW, this 31st day of August, 2011, it is **ORDERED and DECREED** as follows: the post-trial motions are **DENIED**. The Chief Clerk shall enter the Non-Jury Decision of December 7, 2010, as a **FINAL ORDER**. Moreover, the Chief Clerk shall enter **JUDGMENT** in favor of the Commonwealth of Pennsylvania and against Johnson & Johnson Defendants in the amount of $51,850,562.00, representing restoration and civil penalties.

_____

ROBERT SIMPSON, Judge

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania, Plaintiff	:	
v.	:	No. 212 M.D. 2004
Johnson & Johnson; Alza Corporation; Centocor, Inc.; Ethicon, Inc.; Janssen Pharmaceutical Products, L.P.; McNeil-PPC, Inc.; Ortho Biotech, Inc.; Ortho Biotech Products; L.P.; Ortho-McNeil Pharmaceutical, Inc., et al. Defendants	:	Argued: October 18, 2010

BEFORE: HONORABLE ROBERT SIMPSON, Judge

OPINION NOT REPORTED
MEMORANDUM OPINION
BY JUDGE SIMPSON

FILED: December 7, 2010

NON-JURY DECISION

AND NOW, this 7th day of December, 2010, after non-jury trial in the above-captioned matter involving the Johnson & Johnson Defendants, it is **ORDERED** and **DECREED** as follows:

1. On Count XXVIII of the Corrected Amended Complaint (Unjust Enrichment), the Court enters a verdict in favor of the Johnson & Johnson Defendants and against the Plaintiff; and

2. On Count XXIX of the Corrected Amended Complaint (Misrepresentation/Fraud), the Court enters a verdict in favor of the Johnson & Johnson Defendants and against the Plaintiff; and

3. On Count XXX of the Corrected Amended Complaint (Violation of the Pennsylvania Unfair Trade Practice and Consumer Protection Law), the Court takes the following actions:

a. Pursuant to Section 4 of the Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTPCPL), 73 P.S. §201-4, the Court finds that Johnson & Johnson Defendants violated the statute by engaging in unfair or deceptive practices;[1] accordingly, a perpetual injunction is hereby issued restraining Johnson & Johnson Defendants, their agents, attorneys, employees, and assigns, and each of them, from the following such acts:

---

[1] The standard in an enforcement action applying the catch-all provision of the UTPCPL is different than the standard applicable to common law fraud and misrepresentation claims. Commonwealth v. Manson, 903 A.2d 69 (Pa. Cmwlth. 2006); Commonwealth v. Percudani, 825 A.2d 743 (Pa. Cmwlth. 2003); see Weinberg v. Sun Company, Inc., 565 Pa. 612, 777 A.2d 442 (2001). Under this approach, a plaintiff's knowledge of the inaccuracy of a representation and a plaintiff's lack of reliance, while factors to be considered, are not necessarily complete defenses in an enforcement action brought in the public interest. See Manson; Percudani; see also In re Pharm. Indus. Average Wholesale Price Litig., 491 F.Supp.2d 20, 93-95 (D. Mass. 2007) (in AWP litigation under unfair trade practice statute, private payers' knowledge that AWPs were not actual averages of wholesale prices did not shield drug manufacturers from liability); cf. Helbros Watch Co. v. Federal Trade Comm'n, 310 F.2d 868 (D.C. Cir. 1962), cert. denied, 372 U.S. 976 (1963) (fictitious pricing or fictitious pre-ticketing is illegal even if sophisticated purchaser knows price is fictitious).

(i) Contributing in any manner, directly or indirectly, to the reporting to the Pennsylvania Department of Public Welfare or to the PACE program (Plaintiff Agencies) of inflated average wholesale prices (AWPs) for Johnson & Johnson Defendants' branded drugs, without also arranging for the transmission to the Plaintiff Agencies of current, accurate estimated acquisition costs, such as average manufacturers' prices (AMPs) or average sales prices (ASPs), for each of their branded drugs, in a format equivalent to that in which AWPs are reported to the Plaintiff Agencies, or in another format acceptable to the Plaintiff Agencies; and,

(ii) Contributing in any manner, directly or indirectly, to the promotion or marketing of "spreads" (the difference between the price at which a drug is reimbursed to a provider and the acquisition price of the drug paid by the provider) for Johnson & Johnson Defendants' branded drugs which are reimbursed by the Plaintiff Agencies; and

b. Pursuant to Section 4.1 of the UTPCPL, 73 P.S. §201-4.1, the Court directs that Johnson & Johnson Defendants restore to the Commonwealth of Pennsylvania money in the amount of $45,283,562.00;[2] and

[2] The Court accepts as credible the expert testimony in general, and the "PBM" damage methodology excluding interest in particular, as set forth in Revised Exhibit 12 (Department of Public Welfare) and Exhibit 13 (PACE), of Plaintiff's damage expert, Frederick R. Warren-Boulton, Ph.D. Damages are calculated using his suggested figures and preferred methodology for the period 1991 through 2004, with two exceptions.
(Footnote continued on next page...)

c. Pursuant to Section 8(b) of the UTPCPL, 73 P.S. §201-8(b), the Court finds that Johnson & Johnson Defendants willfully used practices declared unlawful by the statute, including the acts described in Paragraph 3(a); accordingly, in addition to amounts to be restored, the Court awards civil penalties against the Johnson & Johnson Defendants in the amount of $6,567,000.00;[3] and

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(continued...)

First, the Court subtracts $7,718.00, representing total "PBM" reimbursements for Viadur excluding interest (amounts set forth in Exhibits 7B and 7D attached to Warren-Boulton's Supplemental Report of September 30, 2010). See J&J Exhibit 5814.

Second, although for the most part the Court rejects the testimony of Johnson & Johnson witness Ernest R. Berndt, Ph.D., the Court accepts his "PBM Damages Adjustment #3: Removal of FDB's 5% Increase in AWP (DPW)," as set forth in J&J's Demonstrative Exhibit 45, for the years 2002, 2003, and 2004. This results in an additional reduction of damages in the amount of $7,908,532.00. The Court specifically rejects other proffered adjustments to the Warren-Boulton PBM methodology, and the Court accepts Warren-Boulton's explanation during direct and rebuttal testimony.

The only other portions of Berndt testimony accepted relate: 1) to the witness' concessions on cross-examination regarding confusion of Johnson & Johnson executives regarding AWP; 2) to the expert witness' inability to figure out a real average wholesale price for Johnson & Johnson drugs; and 3) to his agreement that the Medical Assistance Program, with its high payment rates, is subsidizing pharmacies for accepting the discounted rates offered by private payers and giving them the latitude to submit lower bids on prescription contracts. The Court specifically rejects as not credible testimony by Berndt and others suggesting that the Plaintiff Agencies had knowledge of the prices paid for Johnson & Johnson Defendants' branded drugs which was superior to that enjoyed by those Defendants.

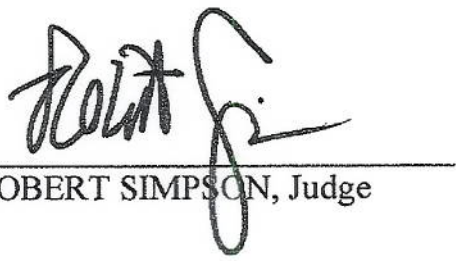
[3] The Court accepts as credible the civil penalty methodology set forth in Exhibit 15 of Warren-Boulton's Supplemental Report of September 30, 2010, Plaintiff's Exhibit 10229, concluding that a violation occurred each time the reported AWP changed for a Johnson & Johnson Defendant branded drug in this case during the period 1991-2004, and assessing each violation at $1,000.00.

d. The Court awards no damages or attorneys' fees pursuant to Section 9.2 of the UTPCPL, 73 P.S. §901-9.2; and

e. The Court rejects the following affirmative defenses offered by the Johnson & Johnson Defendants: Plaintiff is judicially estopped, and the case presents a non-justiciable political question.

4. On Count XLIII of the Corrected Amended Complaint (Civil Conspiracy), the Court enters a verdict in favor of the Johnson & Johnson Defendants and against the Plaintiff; and

5. This Decision is not immediately effective and shall not become effective until the completion of post-trial practice. See Pa. R.A.P. 311(a)(4).



ROBERT SIMPSON, Judge

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania, Plaintiff	:	
v.	:	No. 212 M.D. 2004
TAP Pharmaceutical Products, Inc.; Abbott Laboratories; AstraZeneca PLC; AstraZeneca, Holdings, Inc.; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Bayer AG; Bayer Corporation; SmithKline Beecham Corporation d/b/a GlaxoSmithKline; Pfizer, Inc.; Pharmacia Corporation; Johnson & Johnson; Alza Corporation; Centrocor, Inc.; Ethicon, Inc.; Janssen Pharmaceutical Products, L.P.; McNeil-PPC, Inc.; Ortho Biotech, Inc.; Ortho Biotech Products; L.P.; Ortho-McNeil Pharmaceutical, Inc; Amgen, Inc.; Immunex Corporation; Bristol-Myers Squibb Company; Baxter International Inc.; Baxter Healthcare Corporation; Immuno-U.S., Inc.; Aventis Pharmaceuticals, Inc.; Aventis Behring, L.L.C.; Hoechst Marion Roussel, Inc., Boehringer Ingelheim Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.; Ben Venue Laboratories; Bedford Laboratories; Roxanne Laboratories; Schering-Plough Corporation; Warrick Pharmaceuticals Corporation; Schering Sales Corporation; Dye, Inc., Defendants	:	

BEFORE: HONORABLE ROBERT SIMPSON, Judge

OPINION NOT REPORTED

MEMORANDUM OPINION
BY JUDGE SIMPSON **FILED: October 14, 2010**

On September 30, 2010, before the trial scheduled to begin October 18, 2010, Defendants Johnson & Johnson, ALZA Corporation, Centocor, Inc., Ethicon, Inc., Janssen L.P., McNeil-PPC, Inc., Ortho Biotech, Inc., Ortho Biotech Products, L.P., and Ortho-McNeil Pharmaceutical, Inc. (Johnson & Johnson Defendants) filed a Supplemental Motion *In Limine* to Preclude Reference to or Application of the Court's prior "Plain Meaning" Interpretation of AWP. Plaintiff responded on October 12, 2010.

Contentions

Through its motion, Johnson & Johnson Defendants ask this Court to revisit its construction of the term AWP as explained to the jury in the first trial in Commonwealth v. TAP Pharmaceutical Products, Inc., which involved Defendant Bristol-Myers Squibb Co. (BMS). In arriving at a plain meaning interpretation, this Court relied, in part, on the opinion of U.S. District Court Judge Patti B. Saris in In re Pharmaceutical Industry Average Wholesale Price Litigation, 491 F.Supp.2d 20, 94 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009), cert. dismissed sub. nom., AstraZeneca Pharmaceuticals LP v. Blue Cross Blue Shield of Massachusetts, ___ U.S. ___ (U.S., No. 09-1069, filed September 28, 2010) (MDL 2007), and on an earlier decision in the same case reported at 460 F.Supp.2d 277 (D. Mass. 2006) (MDL 2006).

Johnson & Johnson Defendants take issue with this Court's reliance on Judge Saris' opinion because in the case before her, Judge Saris was interpreting the federal Medicare statute; here, however, the Court is construing Pennsylvania law. Johnson & Johnson Defendants assert that Pennsylvania law defines AWP with reference to the national pricing compendia, which the

Pennsylvania Department of Public Welfare and the Pennsylvania Department of Aging (Plaintiff Agencies) knew differed from average transaction prices. In support, Johnson & Johnson Defendants rely primarily on a recent decision issued by a New York trial court. See People ex rel. Spitzer v. Pharmacia Corp., 895 N.Y.S.2d 682 (N.Y. Sup. Ct. 2010). Johnson & Johnson Defendants assert that in Spitzer the New York court expressly distinguished Judge Saris' "plain meaning" interpretation of AWP because, unlike the federal statute, the New York statute defined AWP with reference to the pricing compendia. Johnson & Johnson Defendants contend the same reasoning applies here.

Plaintiff counters that a plain meaning approach as used in the jury charge in the BMS trial is appropriate. That is, "under the plain meaning canon of statutory construction, I instruct you that the term "average wholesale price" used in those laws means the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies." BMS Trial, 9/8/10 Notes of Testimony (N.T.) at 3768. Plaintiff points out that, contrary to Johnson & Johnson Defendants' assertions, this Court's interpretation was not based primarily on Judge Saris' opinion. Indeed, Plaintiff notes that in the BMS trial, Plaintiff also cited this Court to the ruling of Judge Gary Chang of the First Circuit Court of the State of Hawai'i, who reached the same result as Judge Saris. Plaintiff further contends this Court's ruling on the plain meaning of AWP is consistent with Pennsylvania law and is also consistent with the rulings of Judges Saris and Chang, who were resolving related questions. Thus, Plaintiff maintains, there is no reason for this Court to reconsider its "plain meaning" interpretation.

Discussion

1) Question of Law

The issue raised by the parties, which concerns the proper interpretation of AWP, is one of statutory construction, which presents a pure question of law. See Diehl v. Workers' Comp. Appeal Bd. (I.A. Constr.), ___ Pa. ___, ___ A.3d ___ (Dkt. No. 26 WAP 2009, filed September 29, 2010). In resolving this issue, we are guided by the settled principles set forth in the Statutory Construction Act, including the primary maxim that the object of statutory construction is to ascertain and effectuate legislative intent. 1 Pa. C.S. §1921(a). Further, every statute shall be construed, if possible, to give effect to all its provisions. Id.; Nationwide Mut. Ins. Co. v. Fleming, ___ Pa. ___, 992 A.2d 65 (2010). Additionally, we are mindful that "when the words of a statute are clear and free from all ambiguity, the letter of it is not to be disregarded under the pretext of pursuing its spirit." 1 Pa. C.S. §1921(b). It is only when "the words of the statute are not explicit" on the point at issue that resort to statutory construction is appropriate. 1 Pa. C.S. §1921(c); Malt Beverage Distributors Ass'n v. Pa. Liquor Control Bd., 601 Pa. 449, 974 A.2d 1144 (2009).

2) Law

Pennsylvania laws govern the rates of reimbursement by the Department of Public Welfare (DPW) (Pennsylvania Medicaid) and the Pharmaceutical Assistance Contract for the Elderly (PACE), a program administered by the Department of Aging.

Specifically, Section 509 of the State Lottery Law (Law)[1] requires the PACE program to reimburse based on the average wholesale cost, plus a dispensing fee. In turn, Section 502 defines "Average wholesale cost," (which, under the Law, is synonymous with "Average wholesale price") as "[t]he cost of a dispensed drug based upon the price published in a national drug pricing system in current use by the Department of Aging as the average wholesale price of a prescription drug in the most common package size." 72 P.S. §3761-502; see also 6 Pa. Code §22.2.

Additionally, Section 1121.2 of DPW's regulations, 55 Pa. Code §1121.2, defines "AWP" as "[t]he average wholesale price for a drug as found in the Department's pricing service publication."

3) Ambiguity

The parties here advance competing interpretations regarding the meaning of AWP as set forth in statute and regulation. Specifically, Plaintiff advances a plain meaning interpretation (i.e., the average price at which wholesalers sell drugs to physicians and pharmacies), focusing primarily on the use of the term "AWP" in the relevant statutory and regulatory provisions. On the other hand, Johnson & Johnson Defendants concentrate on references to the national pricing compendia. Thus, Plaintiff emphasizes the initial portion of the statutes and regulations, while Johnson & Johnson Defendants focus on the latter portion. Because the parties offer conflicting interpretations of the relevant statutory and regulatory provisions, the term AWP is ambiguous. See, e.g., Malt

[1] Act of August 26, 1971, P.L. 351, as amended, 72 P.S. §3761-502.

Beverage Distribs. (statute is ambiguous where parties offered conflicting, but plausible interpretations).

4) Statutory Construction

"As in all cases where a latent ambiguity in [a] statute exists, we resort to the canons of statutory construction to discover the Legislature's intent." Id. 463, 974 A.2d at 1153.

When statutory language is not explicit, the intention of the Legislature may be ascertained by considering, among other matters, the mischief to be remedied, the object to be attained, other statutes on the same or similar subjects, the consequences of a particular interpretation, and administrative interpretations of the statute. 1 Pa. C.S. §1921(c) (3)-(6), (8).

Further, in ascertaining legislative intent, the Statutory Construction Act "requires a presumption that the [Legislature] did not intend a result that is absurd or unreasonable" as well as a presumption that "the [Legislature] intends to favor the public interest as against any private interest." 1 Pa. C.S. §1922(1), (5).

a) Plaintiff's Position

Applying these principles to the statutory and regulatory language at issue, we note, both provisions define AWP by reference to the prices contained in the national drug compendia used by the Plaintiff Agencies. Plaintiff's interpretation gives primacy to the term AWP as used in those provisions, but the interpretation does not explain the remainder of the statutory and regulatory

language, which define AWP with reference to the industry's drug pricing compendia.

b) J&J Position

On the other hand, the interpretation advanced by Johnson & Johnson Defendants "appears to boil down to the remarkable proposition that the Legislature delegated responsibility for ... drug reimbursement to the pharmaceutical industry, and that drug manufacturers were thereafter free to report whatever prices and obtain whatever level of reimbursement they desired." Spitzer, 895 N.Y.S. 2d at 693. Clearly, this would lead to an absurd result, and would favor a private, rather than public interest, which we must presume the Legislature did not intend. 1 Pa. C.S. §1922(1), (5). It is also noteworthy that there is no known judicial acceptance of this position.

c) Conclusions

This Court must give effect to all of a statute's provisions. See 1 Pa. C.S. §1921(a). Accordingly, unlike the parties here who each focus on one phrase to the exclusion of the other, we will try to reconcile both phrases of the reimbursement language.

Mindful of the evidence presented at the first trial involving BMS, the Court concludes that those writing Pennsylvania laws governing reimbursement intended: 1) to use an easily-ascertained estimate of acquisition costs for pharmaceuticals; and 2) to integrate reimbursement into an existing industry system so the thousands of daily transactions could be processed efficiently. Thus, those writing Pennsylvania's reimbursement laws sought a formula to give an

easily-ascertained, objective, accurate estimate of acquisition costs for pharmaceuticals, not a fictitious value allowing reimbursement unrelated to prices actually paid by providers.

The Court further concludes that those writing Pennsylvania's reimbursement laws intended the phrase "average wholesale price" to mean what it plainly says, that is, an average of wholesale prices paid by providers. See Narberth Borough v. Lower Merion Twp., 590 Pa. 630, 915 A.2d 626 (2007) (the primary and favored indicator of the Legislature's intention is the plain language of the statute under scrutiny).

The reference to published prices was not intended to modify the accuracy of the average price phrase; rather, the reference to published prices was intended to establish a widely-available third-party source of average prices. Establishing such a source relieves the Plaintiff Agencies of legal mandates to ascertain, by alternative methods, estimated acquisition costs. Extensive evidence was received at the BMS trial about such methods. See also Spitzer, 895 N.Y.S.2d at 687-88 (describing New York's prior requirement for the state to conduct its own wholesale pricing survey). In short, the reference to published prices does not change the plain meaning of the cost to be ascertained.

This construction utilizes the plain meaning of the phrase "average wholesale price" and also explains the reference to published prices. This construction thereby acknowledges all the language at issue, consistent with principles of statutory construction. Most importantly, this construction is consistent with legislative intent, described above.

In addition, this construction is consistent with Judge Saris' "plain meaning" construction of the term "AWP" in the 1994 Medicaid statute. MDL 2007; MDL 2006.[2] As the DPW regulation is part of the same joint federal-state Medicaid Program, this Court's interpretation is consistent with the rule of statutory construction that statutes are to be construed in harmony with the existing law and as part of a general and uniform system of jurisprudence. Trigona v. Lender, 926 A.2d 1226 (Pa. Cmwlth. 2007); Northern Tier Solid Waste Auth. v. Dep't of Revenue, 860 A.2d 1173 (Pa. Cmwlth. 2004).[3]

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[2] The Court rejects the suggestion by Johnson & Johnson Defendants that Judge Saris later retreated from her pronouncement. This suggestion is not supported by the clear language in either of Judge Saris' opinions on this topic.

[3] Also, this Court's interpretation is consistent with other legislation on the same subject, including the 2003 Medicare Prescription Drug, Improvement and Modernization Act. In MDL 2007, Judge Saris provided the following helpful background regarding this federal legislation:

> In passing the 2003 Act, Congress decided to phase out the use of AWP in Medicare reimbursement. On July 15, 2003, the House Committee on Ways and Means issued a report stating that "[t]he term 'AWP' is not defined in statute or regulation, but generally, AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." H.R. Rep. No. 108-178, pt. 2, at 194 (2003). However:
>
> AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices. Congress is now able to adopt an alternative basis for payment that will more accurately reflect actual acquisition costs for physicians. This will ensure that Medicare no longer bases its payments on prices that do not reflect prices otherwise available through market incentives and transactions.
>
> *Id.* at 197-98.
>
> On December 8, 2003, the 2003 Act was enacted. Section 303 of the 2003 Act required that reimbursements for drugs and

(Footnote continued on next page...)

Further, the construction is consistent with that of another state court. See State of Hawai'i v. Abbott Labs. et. al., No. 1CC 06-1-000720 (1st Cir. Haw., Aug. 1, 2010) (August 1, 2010, Order of the Honorable Gary W.B. Chang, First Circuit Court of the State of Hawai'i: "The Court holds that the term 'AWP' as used in the Hawaii Medicaid reimbursement formula, in relation to the instant action, is the average price charged by wholesalers to their wholesale customers, such as pharmacies and physicians. This is based upon the Court's construction, as a matter of law, of all legal authorities that bear upon this definition. The definition of 'AWP' is not a question of fact for the jury to decide. It is a question of law for this Court to decide ....")).

This construction is somewhat inconsistent with the New York court's decision in Spitzer. However, the Spitzer decision is not persuasive here, for several reasons. First, the decision in Spitzer was rendered in a different procedural posture: before trial on cross-motions for summary judgment. The current decision is rendered after the benefit of a full jury trial.

(continued...)

> biologicals furnished on or after January 1, 2005 be based on either a competitive acquisition program or an average sales price. *See* 42 U.S.C. § 1395u(*o*) (2006) (outlining reimbursements for drugs or biologicals under Medicare B); *id.* §§ 1395w-3, 1395w-3b (establishing and defining requirements of competitive acquisition programs); *id.* § 1395w-3a (defining average sales price payment methodology). ...

MDL 2007, 460 F.Supp.2d 277, 283-84 (emphasis added, footnote omitted). Thus, under the Medicare Prescription Drug, Improvement and Modernization Act, accurate reporting became a requirement. As a result, this federal legislation supports this Court's conclusion that AWP must reflect an objective, accurate estimate of the acquisition cost for pharmaceuticals rather than a fictitious price.

Second, and more importantly, the decision in Spitzer is in tension with Pennsylvania law, which holds that questions of statutory construction are issues of law, not issues of fact. Diehl; see also Hawai'i v. Abbott Labs. (construction of "AWP" is question of law for court, not question of fact for jury).

Third, this Court rejects the import of the decision in Spitzer, which bases a meaning of "AWP" on a factual determination of "the industry standards and reasonable expectations of market participants at the time of the Legislature's decision to base reimbursement on industry published AWP's." Spitzer, 895 N.Y.S.2d at 695. As the Spitzer court suggests, industry standards and reasonable expectations may be different for:

- different types of drugs (physician-administered drugs v. self-administered drugs, as discussed during the BMS trial); and

- drugs produced by different manufacturers (drugs from Bristol-Myer v. drugs from Squibb, before consolidation of the companies, as discussed during the BMS trial); and

- different drugs from the same manufacturer (depending on clinical indications, as discussed during the BMS trial); and

- the same drug at different price levels (priced above or within a 20%-25% mark-up range, or priced above or below a drug's economic value, as discussed during the BMS trial); and

- the same drug at different times in its marketing cycle (monopolistic branded drugs v. branded drugs with alternate branded drugs of similar therapeutic value v. generic drugs, as discussed during the BMS trial); and,

- the same drug under different payment terms (considering prompt payment and other discounts, as discussed during the BMS trial); and

- the same drug depending on the reimbursing party (private v. public payors, as discussed during the BMS trial).

Moreover, it is unclear how, if at all, a "whatever the pharmaceutical company was reporting consistent with industry standards and expectations when the AWP statute was enacted [1994]" analysis will take into account new generations or classes of drugs developed thereafter. These circumstances were discussed during the BMS trial.

Respect for these multiple factual distinctions is appropriate at the summary judgment stage; however, subjugating a legal interpretation to these intricacies permits an absurd complexity for a fairly straightforward term. There is nothing in Pennsylvania's laws that evince an intent for such a potentially inaccurate, inconsistent and unpredictable reimbursement system as possible under the Spitzer decision. The Court presumes such an unworkable and unreasonable result was not intended.[4]

[4] For similar reasons, the Court is not persuaded by that small part of a Wisconsin trial court's decision on summary judgment made available by Johnson & Johnson Defendants. Wisconsin v. Abbott Labs., No. 04-CV-1709 (Dane County Cir. Ct. May 20, 2008)

Further, the Court declines the invitation of Johnson & Johnson Defendants to adopt the purported agency interpretations of AWP under a deference approach, for legal and factual reasons. Legally, courts need not give deference to an agency where, as here, its construction frustrates legislative intent. Velocity Express v. Pennsylvania Human Relations Com'n, 853 A.2d 1182 (Pa. Cmwlth. 2004). Factually, the Court rejected much of the evidence from the BMS trial on which the Johnson & Johnson Defendants currently rely. In particular, the Court gave little or no weight to the testimony of Thomas Snedden, Director of the PACE program from the late 1980s, because of his demeanor and because he appeared biased toward defending his prior pronouncements and decisions. Also, the purported DPW interpretation of the term AWP as a "misnomer" and a "list price" was rejected as insufficiently specific and in conflict with legislative intent.

For all the reasons stated, the Johnson & Johnson Defendants' Supplemental Motion *in Limine* to Preclude Reference to or Application of the Court's Prior "Plain Meaning" Interpretation of AWP is denied.

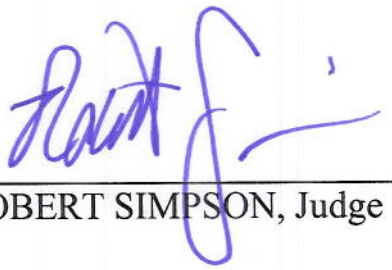
ROBERT SIMPSON, Judge

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania, Plaintiff	:	
v.	:	No. 212 M.D. 2004
TAP Pharmaceutical Products, Inc.; Abbott Laboratories; AstraZeneca PLC; AstraZeneca, Holdings, Inc.; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Bayer AG; Bayer Corporation; SmithKline Beecham Corporation d/b/a GlaxoSmithKline; Pfizer, Inc.; Pharmacia Corporation; Johnson & Johnson; Alza Corporation; Centrocor, Inc.; Ethicon, Inc.; Janssen Pharmaceutical Products, L.P.; McNeil-PPC, Inc.; Ortho Biotech, Inc.; Ortho Biotech Products; L.P.; Ortho-McNeil Pharmaceutical, Inc; Amgen, Inc.; Immunex Corporation; Bristol-Myers Squibb Company; Baxter International Inc.; Baxter Healthcare Corporation; Immuno-U.S., Inc.; Aventis Pharmaceuticals, Inc.; Aventis Behring, L.L.C.; Hoechst Marion Roussel, Inc., Boehringer Ingelheim Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.; Ben Venue Laboratories; Bedford Laboratories; Roxane Laboratories; Schering-Plough Corporation; Warrick Pharmaceuticals Corporation; Schering Sales Corporation; Dey, Inc., Defendants	:	

O R D E R re: Johnson & Johnson Defendants' Supplemental Motion *in Limine* to Preclude Reference to or Application of the Court's Prior "Plain Meaning" Interpretation of AWP

AND NOW, this 14th day of October, 2010, upon consideration of Johnson & Johnson Defendants' Supplemental Motion *in Limine*, and response thereto, it is **ORDERED** and **DECREED** as follows: the Motion is **DENIED**, for the reasons stated in the foregoing opinion.



ROBERT SIMPSON, Judge