## IN THE COMMONWEALTH COURT OF PENNSYLVANIA

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 d/b/a GlaxoSmithKline; Pfizer, Inc.; Pharmacia Corporation; Contoor, Inc.; Ethicon, Inc.; Janssen Pharmaceutical Products, L.P.; McNeil-PPC, Inc.; Ortho Biotech, Inc.; Ortho Biotech Products; L.P.; McNeil-PPC, Inc.; Ortho Biotech, Inc.; Ortho-McNeil Pharmaceutical, Inc; Amgen, Inc.; Immunex Corporation; Bristol-Myers Squibb Company; Baxter International Inc.; Baxter Healthcare Corporation; Boehringer Ingelheim Corporation; Boehringer Ingelheim Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.; Aventis Behring, L.L.C.; Hoechst Marion Roussel, Inc., Boehringer Ingelheim Corporation; Warrick Pharmaceuticals Corporation; Schering Sales Corporation; Schering Sales Corporation; Chering Sales Corporation; Dey, Inc.; Defendants	Commonwealth of Pennsylvania, Plaintiff	:
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.; Schering-Plough : Corporation; Warrick Pharmaceuticals : Corporation; Schering Sales : Corporation; Dey, Inc., :	V.	No. 212 M.D. 2004
	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	
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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 BRISTOL-MYERS SQUIBB COMPANY

## TABLE OF CONTENTS

I. BACKGROUND	6
A. Opening	
D. History	0
B. History	
1. Average Wholesale Price – Origin & Evolution	
2. Plaintiff Agencies a. DPW/Pennsylvania Medicaid	13
b. Department of Aging/PACE 3. BMS	
C. Procedural History	
II. BMS' CHALLENGE TO STATUTORY INJUNCTION	
A. Summary of BMS' Argument.	
B. Sufficiency of Evidence	
1. Contentions	
2. Analysis	
C. Alleged Irreparable Harm to Others	36
1. Alleged Irreparable Harm to Innocent Third Parties	
a. Contentions	
b. Analysis	
i. Waiver	
ii. Failure of Proof	39
iii. Modification of Injunction	
iv. Failure of Legal Support	42
2. Alleged Procedural Defect	
a. Contentions	47
b. Analysis	47
3. Alleged Interference with Statutory/Regulatory Schemes	49
a. Contentions	49
b. Analysis	
4. Alleged Irreparable Harm to BMS	53
a. Contentions	53
b. Analysis	54

5. Alleged Commerce Clause Violation	57
a. Contentions	
b. Analysis	
6. Balancing the Harm	
a. Contentions	
b. Analysis	
D. Alleged Lack of Urgent Necessity	63
1. Alleged Inconsistency in the Decision	
a. Contentions	
b. Waiver	
c. Standard for Injunction under CPL	
d. Urgent Necessity	
2. Alleged Lack of Ongoing Injury	
a. Contentions	
b. Analysis	
3. Alleged Failure to Provide Meaningful Relief	
a. Contentions	
b. Analysis	
i. Waiver	
ii. AWP Confusion	
iii. OIG Reports, Surveys and Price Audits	
iv. AMPs and ASPs	
v. Conclusion	
4. Alleged Harm Compensable by Monetary Damages	
a. Contentions	
b. Analysis	
0. 7 mary \$15	
E. Alleged Lack of Clear Right to Relief	96
1. Alleged Inconsistency with Jury Verdict	
a. Contentions	
b. Analysis	
2. Alleged Lack of Fraudulent or Deceptive Conduct	
a. Contentions	
b. Analysis	
3. Alleged Inconsistency of Decision with <u>MDL 2007</u> Opinion	
a. Contentions	
b. Analysis	
4. Alleged Lack of Proof of Overpayment	
a. Contentions	
b. Analysis	
5. Alleged Lack of Proof of Spread Marketing	
a. Contentions	110

b. Analysis	118
III. BMS' CHALLENGE TO STATUTORY RESTORATION	120
A. Alleged Lack of Statutory Basis for Restoration	120
1. Contentions	
2. Analysis	
B. Alleged Inconsistency with Dismissal of Unjust Enrichment Claim.	124
1. Contentions	
2. Analysis	
C. Alleged Absence of Overpayment	126
1. Contentions	
2. Analysis	
D. Alleged Flawed Damage Estimate	129
1. BMS Contentions	
a. Drugs Not in the Case	129
b. Challenge to "But For" Methodology	
c. Rebates	
2. Analysis	130
a. Generally	130
b. Drugs Not in the Case	
c. Challenge to "But For" Methodology	133
d. Rebates	
E. Alleged Inconsistency with Jury Verdict	136
1. Contentions	136
2. Analysis	137
F. Alleged Impropriety of Award in Suit on behalf of DPW and PACE.	138
1. Contentions	138
2. Analysis	
IV. OTHER EVIDENTIARY ISSUES	144
V. BMS' REQUEST FOR STAY	145
A. Generally	
B. Likely to Prevail on Merits	145
C. Irreparable Injury without Stay	148

D. Stay Not Harm Other Parties	148
E. Stay Not Adversely Affect Public	149
F. Conclusion	149
VI. COMMONWEALTH'S CHALLENGE TO VERDICT ON	
COMMON LAW CLAIMS	150
A. Standards for Analyzing Motions for JNOV and New Trial	
B. Elements of Negligent Misrepresentation Claim/Section 552 of the	
Restatement (Second) of Torts	151
C. Preliminary Matters	154
D. JNOV – Negligent Misrepresentation	
1. Waiver	
a. Contentions	
b. Analysis	156
2. Merits	
a. Entitlement to JNOV based on the sufficiency of the evid	lence157
i. Contentions	157
ii. Analysis	158
b. JNOV "as a matter of law"	162
i. Contentions	162
ii. Analysis	163
c. Practical Considerations	165
E. New Trial – Negligent Misrepresentation	166
1. General, non-particularized evidence regarding knowledge	167
a. Contentions	167
b. Analysis	167
2. Reasonable reliance evidence	169
a. Contentions	
b. Analysis	
3. Evidence beyond the relevant time period	171
a. Contentions	
b. Analysis	
4. Evidence of wrongful conduct	
a. Contentions	
b. Analysis	
5. Practical Considerations	176

F. Conspiracy – Motions for JNOV and New Trial	176
1. Contentions	176
2. Analysis	
a. Waiver	
b. Merits	
3. Alleged Evidentiary Errors	
VII. COMMONWEALTH'S REQUEST FOR MODIFICATION	
OF DECISION REGARDING CPL	
A. Contentions	
1. Costs	
2. Attorney Fees	
3. Civil Penalties	
B. Analysis	186
1. Costs	
2. Attorney Fees	
3. Civil Penalties	
VIII. CONCLUSION	190

### 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 Bristol-Myers Squibb Co. (BMS), 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 BMS, reported or contributed to the reporting of inflated AWPs for certain specified drugs that are published in commercial publications and that these inflated prices caused overpayment by DPW and PACE, which relied on these reported prices.

Central among the Commonwealth's claims is that the published AWPs for BMS' 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 BMS 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 BMS, market this spread in order to gain market share over a competitor's drug.

The Commonwealth's suit against Defendant BMS, which asserted claims of common law fraud or misrepresentation and civil conspiracy, as well as violations of the Unfair Trade Practices and Consumer Protection Law (CPL),<sup>1</sup> culminated in a five-week jury trial. After the close of evidence, issues relating to

<sup>&</sup>lt;sup>1</sup> Act of December 17, 1968, P.L. 1224, <u>as amended</u>, 73 P.S. §§201-1-201-9.3.

the Commonwealth's claims of fraud or misrepresentation and civil conspiracy were submitted to the jury, while issues relating to the statutory claims were submitted to the trial judge for non-jury decision.

Ultimately, the jury returned a verdict in favor of BMS on the common law claims. Shortly thereafter, the trial judge issued a Decision Awarding Injunction and Restoration (Decision) against BMS, finding that BMS violated the CPL. As to the remedy for the CPL violations, the Decision provided for injunctive relief, which essentially restrains BMS from contributing to the reporting of inflated AWPs for its drugs and from creating, marketing or promoting the spread for its drugs. In addition, the trial judge ordered BMS to restore to the Commonwealth the amount of \$27,617,952.

Both the Commonwealth and BMS filed post-trial motions. For its part, the Commonwealth seeks judgment *non obstante veredicto* (JNOV) or, alternatively, a new trial on its negligent misrepresentation and civil conspiracy claims as well as modification of the trial judge's Decision on its statutory claims, to provide for relief in addition to that granted by the trial judge.

On the other hand, BMS challenges the Court's determinations that it violated the CPL. It therefore requests the Court vacate its Decision awarding injunctive relief and restoration.

For the following reasons, we deny the Commonwealth's post-trial motions. In addition, we decline BMS' request to vacate the award of injunctive

relief and restoration; however, as explained more fully below, we modify the injunction.

#### **B.** History

#### **1.** Average Wholesale Price – Origin & Evolution

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.

Since the late 1960s, nearly every branded prescription drug sold in the United States has an AWP, which is published in commercial pricing compendia like Red Book, First DataBank, and Medispan. <u>See In re Pharm. Indus.</u> <u>Average Wholesale Price Litig.</u>, 491 F. Supp. 2d 20 (D. Mass. 2007), <u>aff'd</u>, 582 F.3d 156 (1st Cir. 2009), <u>cert. dismissed sub. nom.</u>, <u>AstraZeneca Pharm. LP v.</u> <u>Blue Cross Blue Shield of Massachusetts</u>, <u>U.S.</u>, 131 S.Ct. 60 (2010) (<u>MDL 2007</u>). 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 facilitate use in the computer-dominated reimbursement systems, such as those used by the Plaintiff Agencies. <u>See</u> BMS Trial, Notes of Testimony (N.T.), 8/24/10, at 1903-04 (Thomas Snedden, Director of PACE); 2020 (Dr. Terri Cathers, Director of Pharmacy for the Fee-for-Service Program of DPW's Office of Medical Assistance Programs). The federal government used AWP as the pricing benchmark for Medicare reimbursement until the 2005 effective date of the Medicare Prescription Drug, Improvement & Modernization Act of 2003.<sup>2</sup> <u>MDL 2007</u>. By statute and regulation, it has also been the pricing benchmark used by the Plaintiff Agencies for Medicare Part B and Medicaid drug reimbursements.

Neither the federal government's Centers for Medicare and Medicaid Services (CMS) (and its predecessor, the Healthcare Finance Administration, also known as 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. <u>Id.</u>

Initially, AWP was, in fact, the average price charged by wholesalers to providers, like doctors and pharmacies. N.T., 8/16/10, at 673-75. It was derived from the markup charged by wholesalers over their actual acquisition cost, sometimes called the "wholesale acquisition cost" or "WAC." <u>Id.</u> at 675. 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.

<sup>&</sup>lt;sup>2</sup> <u>See</u> Pub. L. No. 108-173, 117 Stat. 2066.

Dr. Comanor testified WAC (or in BMS' case, "Wholesale List Price," or WLP) is a conventional term that signifies the price paid by the wholesalers before discounts. N.T., 8/16/10, at 672. In contrast, the AWP is the average wholesale price, which is the basis under which most reimbursement payments are made to pharmacies and other providers. <u>Id.</u> at 682.

Originally, the AWP was 20-25% higher than the WAC/WLP because that reflected the typical costs at the outset of the distribution process of pharmaceuticals. <u>Id.</u> at 675-76. However, competition and improved efficiency forced wholesale prices to decrease. <u>Id.</u> at 676. Eventually, the markup was eliminated in the market, so that prices paid to wholesalers approached WAC/WLP values. <u>Id.</u>

BMS often sold its branded drugs to wholesalers at WLP less 2%, reflecting a prompt pay discount. N.T., 8/19/10, at 1370 (Zoltan Szabo, BMS' Vice President of Global Pricing). In addition, through various arrangements with wholesalers, BMS offered high volume purchasers, such as Group Purchasing Organizations (GPOs), significant discounts off the WLPs for its drugs. Id. at 1380-85. BMS also offered substantial discounts below its WLPs to long term care pharmacies such as Omnicare, resulting in higher volume sales of BMS drugs, and, as a direct result, an increased market share for BMS. Id. at 762, 764-770; PX-8962; PX-8963.

It is undisputed that wholesalers' profit margins were very thin or nonexistent. N.T., 8/19/10, at 676 (Comanor) ("there's essentially no difference

between the manufacturer's price and the wholesaler's price because of the improved efficiency of the wholesaler.") From all these circumstances the trial judge inferred that an actual average of wholesale prices for BMS branded drugs was below WAC/WLP. Evidence to the contrary was rejected, and the trial judge declined to draw inferences favorable to BMS.<sup>3</sup>

Despite the greatly reduced prices in sales from wholesalers to pharmacies, BMS and manufacturers of other branded drugs did not change the process for determining and reporting AWP. <u>Id.</u> at 678. Indeed, pharmaceutical manufacturers, including BMS, understood the AWPs for their branded drugs would be subject to a markup of approximately 25 percent over their reported WACs/WLPs. <u>Id.</u> at 678; 683-86. Thus, despite market changes, the AWPs continued to be set equal to the WAC/WLP plus an established markup. <u>Id.</u> In other words, although the market changed, the mechanism by which AWPs were set did not change, so there became an increasing disconnect between reality and price-setting. <u>Id.</u> at 680-81. In reality, AWP "was not the actual price that [a] pharmacist purchased the drug." N.T., 8/26/10, at 2421 (Love). This resulted in AWP being a "fictitious number." N.T., 8/24/10, at 2072 (Cathers).

The trial judge found no believable evidence that any Pennsylvania pharmacy or physician ever paid full AWP to acquire BMS branded drugs. Nevertheless, for years the Plaintiff Agencies reimbursed Pennsylvania pharmacies

 $<sup>^3</sup>$  The Commonwealth's damage 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 conservative estimate which understated the amounts of restoration.

and other providers at full AWP for BMS 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 escape an AWP-dominated reimbursement regime.

BMS recognized that AWPs were "the legacy of a distribution system which ceased to exist in the early 1980s," and were previously used to represent the price at which wholesalers sold drugs to pharmacies and physicians. PX-491. BMS also understood that AWPs continue to play a pivotal role in the overall prescription drug pricing and reimbursement systems. <u>Id.</u> BMS further understood the high costs of reimbursement for prescription drugs by public payors placed pressure on state budgets. <u>See</u> PX-548; PX-580.

In addition, BMS recognized that general confusion existed over AWP. <u>See</u> PX-491 ("The media often refers to AWP as the cost of the drug. Generally implying that this is the amount that manufacturers charge.") Indeed, at times there was confusion among BMS executives and employees regarding AWP. <u>See, e.g.</u>, N.T., 8/19/10, at 1418, 1460-62 (testimony of Rose Crane, former BMS President of U.S. Primary Care, regarding her belief that AWP was a price paid by wholesalers); N.T., 8/11/10, at 324 (testimony of Paul Norris, BMS' Regional Business Director for the Northeast Region, Oncology Division, that some BMS employees within the global marketing organization believed AWP was "representative of the price that we sold the product.")

Further, while the testimony of DPW and PACE witnesses reveals they had some knowledge that AWP represented a flawed reimbursement benchmark, their testimony also showed they did not definitively understand the extent of the inaccuracy as it pertained to the BMS branded drugs at issue here. These witnesses never testified they knew WAC/WLP represented a price that providers actually paid for BMS drugs and, in any event, there was evidence that providers paid less than WAC/WLP. The testimony of DPW and PACE witnesses shows that although they knew problems existed within the existing AWP system, substantial confusion existed, and they lacked an awareness of an actual average of wholesale prices for BMS branded drugs. More importantly, DPW and PACE witnesses did not have an accurate estimate of acquisition costs in a format suitable for calculating the tens of thousands of claims they receive each day.

Also, BMS emphasized it reported WLPs for its branded drugs to the pricing compendia, rather than AWPs, and sought to distinguish itself in that regard from the conduct of other defendant pharmaceutical manufacturers who reported AWPs; nevertheless, BMS understood, expected and intended that the pricing compendia would apply a standard markup to its WLPs to derive an AWP. <u>See</u> N.T., 8/19/10, at 1374-76, 1385-86 (Szabo); N.T., 8/17/10, at 1019-20 (Douglas Soule, Senior Territory Representative for BMS); PX-491; N.T., 8/11/10, at 158-162, 170-71, 173, 189-92, 194-95, 198-99, 218-19, 220-21, PX-133, PX-487, PX-478, PX-474, PX-476 (Denise Kaszuba, BMS Senior Pricing Analyst/Associate Manager of Pricing Support); N.T., 8/11/10, at 247-49 (Norris); N.T., 8/16/10, at 678 (Comanor).

### 2. Plaintiff Agencies

As noted above, the Commonwealth, through its Attorney General, filed this action on behalf of DPW and PACE.<sup>4</sup> 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 has agreed to assume. <u>See N.T., 8/24/10, at 2017, 2021; Eastwood Nursing & Rehab.</u> <u>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. <u>Eastwood Nursing</u>.</u>

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:

> Medicaid covers the poorest of the poor in Pennsylvania and the sickest of the sick. Roughly today two-thirds are children. Many of those children are either very poor or very ill. We cover the blind, the disabled. And it's at a

<sup>&</sup>lt;sup>4</sup> The Commonwealth also initially brought claims on behalf of the Pennsylvania Employees Benefits Trust Fund (PEBTF), but later sought to discontinue those claims against Defendant BMS. The Court permitted the discontinuance of the PEBTF claims with regard to BMS early in the trial.

hundred percent of the federal poverty level, so these people are very poor and desperately need good quality health care coverage and pharmacy benefits, and that's what the Medicaid program provides.

N.T., 8/24/10, at 2017.

With regard to prescription reimbursement, Pennsylvania Medicaid processes roughly 30,000 claims per <u>day</u>, which are submitted electronically. The Medicaid fee-for-service program covers approximately 25,000 national drug codes (NDCs).

Pennsylvania Medicaid benefits are delivered through two systems: the "fee-for-service" system and the managed care system. In Pennsylvania, 42 counties operate under the fee-for-service program. These counties are located in the center and the northern tier of the state (configured in a "T" formation). The fee-for-service program reimburses providers on a "claim-by-claim" basis." N.T. 8/24/10, at 2032.

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. <u>Id.</u> DPW reimburses these MCOs on a monthly, fixed fee basis per recipient.<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> 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 restoration was calculated based on the different reimbursement system in the mandatory managed care zones.

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" for DPW reimbursement is AWP, which is listed in the national pricing compendia, including First DataBank, Red Book and Medispan. The national pricing compendia receive their data from drug manufacturers. <u>Id.</u> at 2022.

The reimbursed formula for Medicaid is fixed by state regulation. Between 1991 and 1995, DPW reimbursed providers at 100% of AWP. From 1996 through 2004, DPW reimbursed providers at a rate of AWP-10%. <u>Id.</u> at 2025-26.

### **b.** Department of Aging/PACE

PACE provides a comprehensive prescription drug benefit to qualified, older Pennsylvania residents throughout all of the state's 67 counties. PACE is available to Pennsylvania residents, aged 65 or older, with limited incomes. PACE eligibility requirements are based on income, residency and age.

PACE is funded through revenue generated by the Pennsylvania Lottery. PACE has an annual budget that exceeds \$200 million, approximately 96-97% of which is used to pay for prescription drugs for its beneficiaries. 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 10<sup>th</sup> grade education, who has four or five different disease states, and who takes five or six prescription medications daily.

PACE reimburses providers for a drug's ingredient cost and a dispensing fee. When a pharmacy fills a PACE beneficiary's prescription, it collects a small co-payment from the beneficiary and bills PACE, which, in turn, reimburses the pharmacy for the balance of the prescription price.

Because of the complex administration of the PACE program, claims are handled and processed electronically. To that end, Snedden credibly explained:

[O]ur foremost concern with the PACE program is [to] make sure that people don't get medications that are inappropriate for them, that the dose might be too high, the duration too long, the mix of medications could cause them to be hospitalized. So the pharmacy, when the prescriptions are presented, they have to be input by the pharmacist into a computer, which comes into the PACE main frame, where they are scanned and checked to ensure that there won't be any drug misadventure. All of that happens within about one second from the time the pharmacist inputs prescriptions. There's just no practical way you could do that in a paper environment.

N.T., 8/24/10, at 1903.

Approximately 300 drug companies have participated in the PACE program, and PACE covers roughly 30,000 drugs.

PACE's reimbursement formula is fixed by statute. AWP is the "price basis" upon which PACE reimburses pharmacies. N.T., 8/24/10, at 1913. PACE initially reimbursed providers at 100% of AWP. After 12 years of reimbursing providers at 100% of AWP, the statutory reimbursement rate changed to AWP-10%. In 2003, PACE's reimbursement formula changed to AWP-12%. PACE uses the pricing publication Red Book.

#### **3. BMS**

Defendant BMS is a Delaware corporation engaged in the business of manufacturing, distributing, marketing and selling brand-name pharmaceutical drugs.

The specific BMS branded drugs at issue in this case are: Etopophos, Vepesid, Avapro, Blenoxane, Buspar, Cefzil, Coumadin, Cytoxan, Glucophage, Monopril, Monopril HCT, Paraplatin, Plavix, Pravachol, Rubex, Serzone, Sustiva, Taxol, Tequin, Videx, Zerit, and Abilify.

Most 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 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 small 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 government. <u>See 42 U.S.C. §1395*l*</u>; <u>MDL 2007</u>, 491 F. Supp. 2d at 33. Patients or someone on their behalf (such as an insurer) are responsible for a 20% co-payment. <u>Id</u>. 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). <u>See MDL 2007</u>, 491 F. Supp. 2d at 33-34.

There are no generic drugs involved in this case.

BMS sells its branded drugs to wholesalers or specialty distributors at a price around the drug's WLP, as discussed more fully elsewhere. In turn, these wholesalers sell BMS branded drugs to providers, such as pharmacies and physicians. In some instances, BMS sells its branded, Medicare Part B injectable drugs directly to physicians.

#### **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. <u>See Commonwealth ex rel. Pappert v. TAP Pharm. Prods., Inc.</u>, 885 A.2d 1127 (Pa. Cmwlth. 2005) (<u>TAP II</u>); <u>Commonwealth ex rel. Pappert v. TAP Pharm.</u><u>Prods., Inc.</u>, 868 A.2d 624 (Pa. Cmwlth. 2005) (<u>TAP I</u>).

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 <u>TAP I</u>, we sustained the defendant pharmaceutical companies' preliminary objections challenging the sufficiency of the factual averments in the Commonwealth's original complaint, but 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 <u>TAP II</u>, 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, which they did.

This case then proceeded through a lengthy period of robust discovery administered in part by a discovery master. Counsel for BMS served as liaison counsel for all remaining defendants. 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 BMS' motion so that only BMS would be involved in the August 9, 2010 jury trial.<sup>6</sup>

After final pretrial conference, the trial judge issued an order indicating his intention to submit issues related to the Commonwealth's fraud and misrepresentation and civil conspiracy claims to the jury. The judge also indicated he would render a non-jury decision on the Commonwealth's unjust enrichment and CPL claims.<sup>7</sup> Additionally, shortly before trial, the trial judge disposed of 18 motions *in limine*, filed by the Commonwealth and BMS.

<sup>&</sup>lt;sup>6</sup> Approximately three weeks prior to trial, BMS filed a motion for partial summary judgment, which the trial judge denied on the grounds it would unreasonably delay final pretrial conference and trial. The trial judge noted the relevant pleadings closed in 2006, and BMS did not assert it was precluded from filing the motion earlier. The judge entered his order without prejudice to renew after the close of the Commonwealth's case or after the close of evidence.

<sup>&</sup>lt;sup>7</sup> Prior to trial, the Commonwealth moved to amend its complaint to add the drug Abilify to the BMS branded drugs already at issue in the case.

Trial commenced as scheduled on August 9 and continued over the ensuing five weeks. More than a dozen witnesses testified, prior testimony by more than 20 witnesses was read or presented by videotape, and over 300 exhibits, many voluminous, were received.

In addition to numerous trial rulings, at the close of the Commonwealth's case-in-chief, the trial judge granted BMS' motion for compulsory non-suit on the Commonwealth's unjust enrichment claim on the ground the Commonwealth did not identify any fund to which a common-law equitable remedy would apply.

Consistent with the pretrial order, following the close of evidence the trial judge submitted issues relating to the Commonwealth's claims of negligent misrepresentation, fraudulent misrepresentation and civil conspiracy to the jury. Additionally, issues relating to the Commonwealth's claims under the CPL were submitted to the trial judge for non-jury decision.

Ultimately, the jury returned verdicts in favor of BMS on the Commonwealth's claims for negligent and fraudulent misrepresentation. <u>See</u> Verdict Form, Phase I (Attachment A). More specifically, the jury answered "no" to the question of whether BMS was liable for negligent misrepresentation or fraudulent misrepresentation. Based on its response to these questions, the jury did not answer questions concerning causation. Additionally, the jury did not answer any questions relating to civil conspiracy, to damages or to outrageous conduct.

The next day, the trial judge heard oral argument on the Commonwealth's claims under the CPL. Shortly thereafter, the judge issued his Decision, finding BMS violated the CPL by engaging in unfair or deceptive practices. See Decision Awarding Injunction and Restoration of 9/10/10 (Attachment B).

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 addition, he added sufficient explanation so that the parties could understand why he did not follow the jury verdict and how he calculated restoration amounts.

In particular, the trial judge acknowledged the jury verdicts finding neither negligent misrepresentation nor fraudulent misrepresentation. However, the trial judge concluded that a different standard applied in a CPL enforcement action. <u>See Weinberg v. Sun Co., Inc.</u>, 565 Pa. 612, 777 A.2d 442 (2001). Specifically, the judge indicated that, unlike claims for common law fraud or misrepresentation, 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 under Section 4 of the CPL, 73 P.S. §201-4. <u>See MDL 2007</u>; see also Com. v. Parisi, 873 A.2d 3 (Pa. Cmwlth. 2005) (CPL to be liberally construed to effectuate legislative goal of consumer protection).

Ultimately, the trial judge issued a perpetual injunction restraining BMS from: contributing in any manner, directly or indirectly, to the reporting to DPW or to PACE of inflated AWPs for BMS drugs; and, contributing in any manner, directly or indirectly, to the creation, promotion or marketing of spreads for BMS drugs that are reimbursed by DPW or PACE.

In addition, pursuant to Section 4.1 of the CPL,<sup>8</sup> 73 P.S. §201-4.1, the trial judge directed BMS to restore to the Commonwealth money in the amount of \$27,617,952. To that end, the trial judge credited the damage methodology set forth in Exhibits 6A, 6B and 6C of the revised report of Commonwealth damage expert Frederick R. Warren-Boulton, Ph.D., for the period 1991 through 2004, with one exception. Specifically, the trial judge credited only that portion of the testimony of BMS expert Gregory K. Bell, Ph.D., that Dr. Warren-Boulton's estimates were inflated by inclusion of drugs not in the case. To account for this problem, the trial judge reduced Dr. Warren-Boulton's estimates by 40%.

The trial judge further found BMS willfully used practices declared unlawful by the CPL; however, the trial judge determined he lacked sufficient information to calculate civil penalties; as such, he declined to award any civil penalties under Section 8(b) of the CPL, 73 P.S. §201-8(b). The trial judge credited Dr. Warren-Boulton's civil penalty methodology that assumed a CPL violation occurred each time the reported AWP changed for a BMS drug, and assessing each violation at \$1000. However, the trial judge indicated Dr. Warren-Boulton's calculations were not limited to the period 1991-2004 for which restoration was awarded and could be inflated by drugs not in the case. As such,

<sup>&</sup>lt;sup>8</sup> Added by the Act of November 24, 1976, P.L. 1166, <u>as amended</u>.

the trial judge declined to award civil penalties. The trial judge also declined to award any sums under Section 9.2 of the CPL,<sup>9</sup> 73 P.S. §201-9.2.

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 BMS filed post-trial motions. For its part, the Commonwealth seeks JNOV or, alternatively, a new trial on its negligent misrepresentation and civil conspiracy claims as well as modification of the Decision under the CPL to include an award of civil penalties, costs and attorney's fees.

On the other hand, BMS challenges the trial judge's findings that it violated the CPL and, therefore, requests the Court vacate its Decision awarding injunctive relief and restoration under the CPL.

# II. BMS' CHALLENGE TO STATUTORY INJUNCTION A. Summary of BMS' Argument

Through its Brief in Support of Its Motion for Post-Trial Relief or in the Alternative for a Stay, BMS asks this Court to change the Decision by vacating both the injunction and the order of restoration. BMS argues there is no evidence to support the relief granted, and it is inconsistent with the jury's conclusion that BMS was not liable for negligent misrepresentation or fraud. Specifically, it

<sup>&</sup>lt;sup>9</sup> Section 9.2 was added by the Act of November 24, 1976, <u>as amended</u>.

contends the proposed injunction should be vacated for the following 15 primary reasons (with numerous sub-arguments):

- It will cause irreparable harm to innocent third parties.
- It is procedurally defective and violates due process.
- It interferes with the legislative and regulatory scheme.
- It will cause BMS irreparable harm.
- It unconstitutionally interferes with interstate commerce.
- Greater harm will come from entering the injunction than not entering it.
- It is not justified by any urgent necessity since, as the Court acknowledges in its Decision, the Commonwealth was not damaged after 2004.
- There is no threat of ongoing injury.
- The proposed injunction will not give the Commonwealth any information it does not already have.
- Even if they were harmed, DPW and PACE could be adequately compensated by monetary damages.
- The Decision is inconsistent with the jury's verdict.
- BMS' conduct is not in fact fraudulent or deceptive, or even unfair.
- The Decision is inconsistent with Judge Saris' decision in <u>MDL 2007</u> on which the Court relies.

- There is no proof of causation because pharmacies are not overpaid.
- There is no proof that would support an injunction against marketing the spread because the practice makes no sense in the context of this case.

BMS' Br. in Support of its Mot. for Post-Trial Relief or in the Alternative for a Stay at 8-9 (BMS' Br.).

Of particular concern, BMS asserts, is the harm the injunction will cause to innocent third parties, including patients who rely on BMS drugs. BMS maintains the proposed injunction requires it to take steps to ensure the AWPs for its drugs are equal to their acquisition costs. It contends pharmacies will refuse to stock BMS drugs if they will lose 12 to 14 percent on every drug, which is the percentage below AWP that PACE and DPW currently reimburse pharmacies for drugs.

#### **B.** Sufficiency of Evidence

#### **1.** Contentions

BMS begins by reciting the common law elements necessary to obtain permanent injunctive relief. It then argues there is no proof that would justify the relief awarded here. Specifically, BMS maintains there was no proof that it made any misrepresentation to the Plaintiff Agencies. It contends there was no proof that DPW or PACE relied on anything BMS said or did. In fact, BMS asserts, Thomas Snedden, the Director of PACE, affirmatively testified he did not rely on BMS, and he was not defrauded or deceived by BMS. N.T., 8/24/10, at 1936-38, 2005-2006. BMS maintains all present and former DPW and PACE employees testified they knew AWPs were not acquisition costs. <u>See</u> N.T., 8/24/10, at 1914; N.T., 8/24/10, at 2057-60; N.T., 8/26/10, at 2420-22; N.T., 8/30/10, at 2736; N.T., 8/30/10, at 2763-64; N.T. 8/30/10, at 2791-93; N.T., 8/31/10, at 2994. BMS argues there was overwhelming and unrebutted testimony and documents demonstrating DPW and PACE knew what acquisition costs were. <u>See</u> DX 1, DX 3-6, DX 8-12, DX 405, DX 482, DX 501, DX 514, DX 551, DX 553, DX 558, DX 564. BMS asserts the reimbursement formulas used by the Plaintiff Agencies were the product of choice, not any fraud or deception.

In addition, BMS maintains there was unrebutted testimony that pharmacies were not overpaid. BMS argues the Commonwealth's own expert agreed pharmacies are not overpaid. N.T., 8/16/10, at 853 (Comanor). BMS contends there is no proof here that it caused the Commonwealth any harm.

For these reasons alone, BMS argues, the Decision should be vacated. It maintains an award under the CPL is improper where no evidence exists to support it. <u>See, e.g., Braccia v. Arlington Capital Mortg. Corp.</u>, Civ. Action No. 08-1370, 2009 WL 3756351, at \*12 (E.D. Pa. Nov. 9, 2009); <u>Sheikh v. Travelers</u> <u>Pers. Ins. Co.</u>, Civ. Action No. 06-1477, 2007 WL 2571451, at \*4 (E.D. Pa. Aug. 31, 2007).

#### 2. Analysis

The remedy of entry of judgment in a party's favor is proper only where a party successfully challenges the sufficiency of the evidence. On the other

hand, the remedy of a new trial is proper when the verdict rendered by the trial court indicates the trial court abused its discretion when weighing the evidence. <u>Morin v. Brassington</u>, 871 A.2d 844 (Pa. Super. 2005). "This distinction is crucial and is repeated *ad nauseum* by the appellate courts of this Commonwealth in both civil and criminal cases." <u>Id.</u> at 851. Here, BMS does not ask for a new trial.

A sufficiency analysis must begin by accepting the credibility and reliability of all evidence, viewed in the light most favorable to the verdict winner regardless of whether the losing party thinks the evidence was believable.  $\underline{Id.}^{10}$ 

"In Pennsylvania, a permanent injunction will issue if the party establishes [a] clear right to relief. The party need not establish either irreparable harm or immediate relief, as is necessary when seeking a preliminary injunction, and a court may issue a final injunction if such relief is necessary to prevent a legal wrong for which there is no adequate redress at law." <u>Bd. of Revision of Taxes,</u> <u>City of Phila. v. City of Phila.</u>, <u>Pa. \_\_\_</u>, <u>4</u> A.3d 610, 627 (2010) (citations and quotations omitted).

<sup>&</sup>lt;sup>10</sup> Alternatively, a claim that the verdict was against the weight of the evidence concedes that the evidence presented by the verdict winner was sufficient to satisfy the elements of the cause of action but contends the evidence was unreliable and untrustworthy to such a degree that a verdict based on it would shock one's sense of justice, and, therefore, a new trial would be necessary to cure the injustice. <u>Morin v. Brassington</u>, 871 A.2d 844 (Pa. Super. 2005). Further, under the standard of review for challenges to the weight of the evidence, this Court is under no obligation to view the evidence in a light most favorable to the verdict winner. <u>Id.</u>

Here, however, the remedy of injunctive relief is explicitly provided by statute. Specifically, 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, <u>he may bring an action in the name of the</u> <u>Commonwealth against such person to restrain by</u> <u>temporary or permanent injunction the use of such</u> method, act or practice.

73 P.S. §201-4 (footnote omitted) (emphasis added). By the plain terms of the statute, the Attorney General must prove: 1) that a person is using or about to use a practice declared unlawful by the CPL; and 2) that proceedings would be in the public interest.

Although BMS relies on the common law elements necessary to obtain an injunction, the basis for the injunction entered here is statutory. As a result, BMS' arguments lack merit. This point is discussed in more detail below.

The proper analysis is set forth in <u>Commonwealth v. Burns</u>, 663 A.2d 308 (Pa. Cmwlth. 1995), a case involving a post-trial challenge to a permanent injunction under the CPL. There, 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.

Review of the record here reveals ample support for the trial judge's determinations that BMS 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 his determinations that BMS violated the CPL, <u>see</u> Section 3 of the CPL, 73 P.S. §201-3, ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce as defined by subclauses (i) through (xxi) of clause (4) of section 2 of this act … are hereby declared unlawful), the trial judge had a duty to issue an injunction to restrain BMS' unlawful practices.

More specifically, similar to Judge Saris' decision in <u>MDL 2007</u>, the trial judge first determined BMS engaged in unfair or deceptive practices by contributing to the reporting of inflated AWPs for its drugs to the Plaintiff Agencies. The record clearly supports this determination. To that end, as in <u>MDL 2007</u>, BMS claimed to be unique among drug manufacturers in that it did not directly report AWPs or suggested AWPs to the pricing compendia. However, as in <u>MDL 2007</u>, the trial judge here determined BMS knew, expected, and intended that when it reported a price, the publications would predictably calculate an AWP that was 20 to 25 percent higher than BMS' WLP. <u>See N.T.</u>, 8/19/10, at 1374-76, 1385-86 (Szabo); N.T., 8/17/10, at 1019-20 (Soule); PX-491; N.T., 8/11/10, at 158-162, 170-71, 173, 189-92, 194-95, 198-99, 218-19, 220-21, PX-133, PX-487, PX-478, PX-474, PX-476 (Kaszuba); N.T., 8/11/10, at 247-49 (Norris); N.T., 8/16/10, at 678 (Comanor); <u>see MDL 2007</u>, 491 F. Supp. 2d at 60. As in <u>MDL 2007</u>, the evidence was sufficient to conclude that BMS could affect, and at times

fully control, the AWP for its drugs. Id. at 60-61.

In addition, similar to <u>MDL 2007</u>, the trial judge determined BMS contributed to or participated in the promotion or marketing of spreads for its Medicare Part B drugs. Review of the record also discloses ample support for this determination. <u>See</u> N.T., 8/11/10, at 303 (Norris); N.T., 8/17/10, at 1004-05 (Soule); PX-399; N.T., 8/17/10, at 1010-11; PX-211; <u>see also N.T., 8/12/10</u>, at 487 (Peterson) (regarding Lynx2OTN); PX-111; PX-8869 (AWP price report); N.T., 8/12/10, at 488-89, 490-93 (AWP price report showing Oncology Therapeutics Network Corporation (OTN) dispensing unit price and AWP based on selected modifier), 493 (spread-difference between amount of reimbursement and amount paid).

In short, contrary to BMS' contentions, the trial judge's determinations that BMS violated the CPL by engaging in unfair or deceptive practices are supported by substantial evidence. Based on these determinations, the trial judge was duty-bound to issue an injunction to restrain BMS' unlawful practices.

BMS' remaining arguments regarding the alleged lack of sufficient evidence to support the award of injunctive relief are addressed throughout this opinion, where appropriate. However, there are four important points to make here. First, regarding deception, the trial judge gave greater weight to evidence regarding confusion about AWP, and he rejected as not credible evidence suggesting that AWP was a term of art, widely known outside the pharmaceutical

industry to be derived from a formulaic relationship of known proportions over WAC/WLP.

Second, also regarding deception, the trial judge rejected BMS' contentions regarding "government knowledge." Some evidence was not credible, some documentary evidence was given little weight, and the trial judge declined to draw inferences favorable to BMS. This is especially true of testimony by Thomas Snedden on this point, whose credibility was compromised by his demeanor, bias, and strong tendency to agree with whoever was questioning him.

Third, as to reliance, the trial judge rejected BMS' contentions regarding "government choice." Most importantly, 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. The rejection was also based on the limited weight given documentary evidence and the refusal of the trial judge to draw inferences favorable to BMS on this issue. 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.

Fourth, as to causation, the trial court accepted the expert opinion of the Commonwealth's liability and causation expert, Dr. William Comanor, that the Plaintiff Agencies were harmed by enhanced price discrimination by the drug manufacturers, including BMS. The enhanced price discrimination took the form of different pricing/rebate schemes for public and private payors, resulting in public payors, such as DPW and PACE, paying more than private payors. The trial judge rejected the testimony of pharmacist David Smith, relied upon by BMS, as not credible based on demeanor.

Further, the two unreported federal district court cases cited by BMS do not compel a different result. Specifically, in <u>Sheikh</u>, a federal trial court dismissed a private plaintiff's CPL claim against an automobile insurance company based on the company's alleged failure to pay benefits where the court determined the company acted properly in cancelling the policy prior to an accident for which the plaintiff sought benefits.

In <u>Braccia</u>, a federal trial court rejected a private plaintiff's CPL claim against a mortgage company where the court determined the plaintiff did not prove reliance or injury as a result of an alleged misrepresentation that occurred when the plaintiff sought to obtain a residential mortgage.

Clearly, <u>Sheikh</u> and <u>Braccia</u> are distinguishable on their facts. Neither case involved an Attorney General enforcement action under the CPL's catchall provision where, as explained below, the burden of proof is relaxed. Also, unlike in <u>Sheikh</u> and <u>Braccia</u> the evidence supports a determination that BMS violated the

CPL by engaging in deceptive conduct (as further explained below) and that DPW and PACE suffered harm in the form of overpayments as a result of that violation.

# C. Alleged Irreparable Harm to Others 1. Alleged Irreparable Harm to Innocent Third Parties a. Contentions

BMS next asserts that today DPW reimburses pharmacies at the lower of AWP-14% or WAC+7%. 55 Pa. Code §1121.56(a)(1)(i). PACE currently reimburses pharmacies at AWP-12%. <u>See</u> Section 509(6) of the State Lottery Law.<sup>11</sup> BMS contends the undisputed evidence at trial showed these formulae were developed over a period of years after careful negotiation with pharmacies in an effort to arrive at an amount that would ensure patients' access to care. <u>See</u> DX-501.

BMS maintains that while the proposed injunction prohibits it from contributing in any manner, directly or indirectly, to the reporting to DPW or PACE of inflated AWPs for its drugs, the undisputed evidence showed BMS does not report AWPs to the pricing compendia. Rather, BMS reports a list price that the pricing compendia mark up by 20-25% to arrive at an AWP. N.T., 8/11/10, at 215, 221-22. BMS argues the proposed injunction would require it to ask the pricing services to make the AWPs for its drugs equal to the list prices. BMS contends that if the pricing compendia were willing to do this, the AWPs for BMS drugs would be equal to their list prices. BMS maintains there was extensive,

<sup>&</sup>lt;sup>11</sup> Act of August 26, 1971, P.L. 351, <u>as amended</u>, 72 P.S. §3761-509(6). Section 509 was added by the Act of November 21, 1996, P.L. 741.

unrebutted trial testimony – by witnesses for both sides – that pharmacies acquire drugs at or near list price. It asserts if AWPs were made equal to list prices, the regulatory and statutory provisions cited above would be unaffected by the injunction, and pharmacies would immediately lose at least 12-14% on every BMS drug they acquired.

BMS argues that, as its expert Dr. Fiona Scott-Morton pointed out, if pharmacies were placed in a position where they lost 12-14% on every BMS drug, they would simply refuse to stock BMS drugs. N.T., 9/2/10, at 3456-58. BMS contends this would not only harm pharmacies; it would also harm patients who would not have access to BMS drugs. It argues some of these drugs are of critical importance in treating serious illnesses.

BMS contends the potential harm to innocent third parties is a critical factor that courts should consider in deciding whether to grant injunctive relief. <u>See Weinberger v. Romero-Barcelo</u>, 456 U.S. 305, 312 (1982); <u>accord Bradley v.</u> <u>Pittsburgh Bd. of Educ.</u>, 910 F.2d 1172, 1175 (3d Cir. 1990). Indeed, it argues, courts refused to grant injunctive relief where interested parties were or could have been adversely affected. <u>See Weinberger; North Jersey Media Grp., Inc. v.</u> <u>Ashcroft</u>, 308 F.3d 198, 229 (3d Cir. 2002).

## **b.** Analysis

#### i. Waiver

BMS never raised an issue of alleged harm to others in such a way as to alert the trial judge to consider it in rendering the Decision. <u>See</u> BMS' Proposed

Findings of Fact and Conclusions of Law, filed 7/26/10 (pretrial); N.T., 9/9/10, at 3890-92 (after jury verdict, BMS closing on CPL). Also, there was no credible evidence offered by BMS as to the alleged harm to others in the context of an injunction. Indeed, BMS offered no evidence other than that applicable to the common law causes of action. <u>See id</u>. Therefore, this issue of alleged irreparable harm to others and its numerous sub-contentions are waived.

In a footnote to its Motion for Post-Trial Relief or Stay, BMS contends that "neither the Court nor the Plaintiff ever suggested entry of this type of injunction prior to September 10, 2010." Mot. at 2, n.1. This contention is a canard, for several reasons. First, contrary to BMS' assertions, BMS had ample notice of the Commonwealth's request for injunctive relief, which was specifically requested in the Commonwealth's corrected amended complaint. Count XXVII of the corrected amended complaint included a request that the Court enter "an Order permanently enjoining each and every Defendant from continuing the deceptive and/or unfair acts or practices complained of herein, and requiring corrective measures." Corrected Am. Compl. at p. 215, ¶¶ 3, 11.

Second, both the Commonwealth and the trial judge repeatedly raised issues regarding injunctive relief prior to and during the course of the trial. <u>See</u> N.T., 8/2/10, at 68 (mentioned at the pre-trial conference by the Commonwealth's counsel when discussing the claims set forth in the complaint); N.T., 8/10/10, at 96 (mentioned by the Commonwealth's counsel); N.T., 8/26/10, at 2365 (mentioned by the trial judge), 2370 (mentioned by the Commonwealth's counsel prior to the start of BMS' case-in-chief).

Also, the trial judge raised the injunction issue during closing arguments on the Commonwealth's CPL claims, and a discussion occurred regarding the type of injunctive relief sought. <u>See N.T.</u>, 9/9/10, at 3860.

Third, BMS' position throughout trial was to defend both the common law claims and the statutory claims in the same way, without additional issues or evidence related to the statutory claim. <u>Compare</u> BMS' Proposed Findings of Fact and Conclusions of Law, filed 7/26/10 (*pretrial*), Conclusion #31 ("The Commonwealth is thus unable to meet its burden of proving a violation of the [CPL] for the same reasons outlined with respect to its common law fraud claim."), <u>with</u> N.T., 9/9/10, at 3892-3894 (*after jury verdict*, during BMS' closing on CPL claim, "the statutory claim fails for the very same reasons the jury found against the Commonwealth [on the common law claims].").

As such, BMS received ample notice that the Commonwealth sought and the trial judge was considering injunctive relief, but, consistent with its pretrial strategy, it did not present additional evidence or defenses to challenge the entry of such relief. By failing to present evidence or defenses at trial, BMS did not properly preserve an affirmative defense of harm to others.

#### ii. Failure of Proof

In addition, BMS' irreparable-harm-to-others contentions are not supported by credible evidence. Accordingly, they fail for factual reasons. As discussed below, BMS presented no believable evidence showing pharmacies would drop out of these programs as a result of the injunction. Instead, opinion

evidence to the contrary was accepted. Also, BMS' argument that DPW recipients or PACE claimants will suffer if it cannot charge the Plaintiff Agencies the fictitious AWPs for its drugs, is entirely speculative.

The record does not support BMS' assertions that the proposed injunction will cause irreparable harm to innocent third parties, namely, pharmacies, which would not stock BMS drugs, and patients, who would be deprived access to BMS drugs. Significantly, the trial judge rejected as not credible the testimony of BMS' experts, Drs. Bell and Scott-Morton, upon which BMS bases its assertions. With regard to Dr. Bell, the trial judge rejected his testimony based on demeanor and on bias because of his strong financial relationship with BMS. N.T., 9/1/10, at 3114-15, 3217-24. The trial judge rejected the testimony of Dr. Scott-Morton based on demeanor. In any event, neither of BMS' expert witnesses expressed opinions on the impact on pharmacies or patients that would result from requiring BMS to cease reporting or contributing to the reporting of inflated AWPs for its drugs.

Regarding the alleged effects of the proposed injunction on patients, BMS asserts some of its drugs are of critical importance in treating serious illnesses. However, BMS cites no record evidence to support its argument that the proposed injunction would have the effect of preventing patients from obtaining necessary medications or the actual effects on patients if that occurred.

## iii. Modification of Injunction

Further, BMS views the injunction as requiring it to exercise some degree of control over the pricing compendia, which, it argues, would likely not comply with a request to change AWPs for BMS products.<sup>12</sup> BMS references the testimony of Kay Morgan, a former First DataBank employee whose deposition from a different case was *excluded* by the trial judge here. <u>See N.T., 8/31/10, at 2967</u>. BMS complains the exclusion was improper.<sup>13</sup> BMS asserts Morgan testified regarding First DataBank's refusal to publish Average Sales Prices (ASPs) for other drug manufacturers. BMS argues it would have attempted to prove this fact if it had received notice of the requested relief. BMS' Br. at 12, n.8.

Contrary to BMS' claim of surprise, BMS had ample notice of the request for injunctive relief. This notice is more fully discussed above.

<sup>&</sup>lt;sup>12</sup> BMS relies on the testimony of its employee Denise Kaszuba, who had responsibility for managing the publication of the price lists and who requested that the pricing compendia increase the markup factor on BMS' oncology products in 1992, which MediSpan and First DataBank declined to do. N.T., 8/11/10, at 138-39, 140, 164-165. BMS also highlights that Dr. Bell opined BMS did not control the 20 to 25% markup of list price to AWP.

The opinion of Dr. Bell and the testimony of Denise Kaszuba on this point were rejected by the trial judge. As explained above, the trial judge here, like Judge Saris in <u>MDL 2007</u>, determined BMS knew, expected and intended that when it reported a price, the publications would predictably calculate an AWP that was 20% to 25% higher than BMS' WLP. As in <u>MDL 2007</u>, the evidence was sufficient to conclude that BMS could affect, and at times fully control, the AWP for its drugs. <u>MDL 2007</u>, 491 F. Supp. 2d at 60-61.

<sup>&</sup>lt;sup>13</sup> Morgan's deposition testimony was not received into evidence. <u>See</u> N.T., 9/1/10, at 3142-45; N.T., 8/31/10, at 2967 (trial judge sustaining the Commonwealth's objection to the admission of Morgan's deposition testimony). For the reasons stated on the record, there was no error in this ruling.

More importantly, this Court can modify the terms of the injunction awarded against BMS so that it more closely resembles the injunction awarded against Johnson & Johnson Defendants, following the second trial in this case. Specifically, in that decision, the trial judge issued an injunction, which, among other things, restrained Johnson & Johnson Defendants from contributing, directly or indirectly, to the reporting to DPW and PACE of inflated AWPs without also arranging for the transmission to the agencies of current, accurate estimated acquisition costs, such as Average Manufacturers Prices (AMPs) or ASPs, for each of their branded drugs in a format equivalent to that in which AWPs are reported to the agencies, or in another format acceptable to the agencies. Thus, as modified, the injunction would not require the pricing compendia to make the AWPs for BMS drugs equal to WACs/WLPs; rather, it would require BMS to transmit current, accurate estimated acquisition cost data to DPW and PACE in an appropriate format so as to allow these agencies to make informed decisions based on accurate data when developing their reimbursement formulae.

#### iv. Failure of Legal Support

In addition, BMS' harm-to-others contentions fail as a matter of law because this is not a relevant consideration in determining whether to issue a statutory injunction. As discussed more thoroughly below, "[w]hen the Legislature declares certain conduct to be unlawful, it is tantamount to calling it injurious to the public." <u>Pennsylvania Pub. Util. Comm'n v. Israel</u>, 356 Pa. 400, 406, 52 A.2d 317, 321 (1947). Such conduct cannot be permitted to continue. Id.

Also, the cases cited by BMS do not compel the result it seeks. More specifically, in Weinberger, the U.S. Supreme Court considered "whether the Federal Water Pollution Control Act<sup>[14</sup>] [FWPCA] requires a district court to enjoin immediately all discharges of pollutants that do not comply with the [FWPCA]'s permit requirements or whether the district court retains discretion to order other relief to achieve compliance." Id. 456 U.S. at 306-07. There, the district court found the Navy violated the FWPCA by discharging ordnance into the sea during its weapons-training exercises without first obtaining a required permit. However, the Court declined to enjoin the Navy's training operations; rather, it simply ordered the Navy to apply for a permit. The court reasoned the Navy's "technical violations" were not causing any "appreciable harm" to the quality of the water, and an injunction would cause grievous harm to the Navy's military preparedness and therefore to the Nation. Id. at 310. On appeal, however, the First Circuit reversed, directing the district court to enjoin all training activities until the Navy obtained the required permit. It concluded the traditional equitable balancing of competing interests was inappropriate where there was an absolute statutory duty to obtain a permit.

On further appeal, however, the U.S. Supreme Court reversed. Initially, the Court acknowledged the fundamental principle that an injunction is an equitable remedy that does not issue as of course. The Court reviewed the established principles governing the award of equitable relief in federal courts. The Court explained the essential bases for injunctive relief are irreparable injury and inadequacy of legal remedies. The Court stated that, where the plaintiff and

<sup>&</sup>lt;sup>14</sup> 86 Stat. 816, <u>as amended</u>, 33 U.S.C. §§1251-1376.

the defendant advance competing claims of injury, a court must balance the competing claims and consider the effect on each party of the granting or withholding of the requested relief. The Court explained that, although "particular regard" should be afforded to the public interest, "[t]he grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law." <u>Id.</u> at 313. Finally, the Court stated:

Of course, Congress may intervene and guide or control the exercise of the courts' discretion, but we do not lightly assume that Congress has intended to depart from established principles. ... <u>Unless a statute in so many</u> words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.

Id. (citation omitted) (quoting Porter v. Warner Holding Co., 328 U.S. 395, 398 (1946)) (emphasis added).

Applying these principles, the Court concluded the purpose of the FWPCA--to restore and maintain the integrity of the Nation's waters--would not be undermined by allowing the Navy's statutory violation to continue during the permit application process because the ordnance was not polluting the water. The Court determined an injunction against all discharges was not the only means of ensuring compliance with the FWPCA; it found nothing in the statute that suggested Congress intended to deny courts their traditional equitable discretion.

Unlike the FWPCA, at issue in <u>Weinberger</u>, here the CPL specifically contemplates issuance of an injunction as the primary form of relief in an action brought by the Attorney General in the public interest. 73 P.S. §201-4. Moreover, unlike in <u>Weinberger</u>, where the facts indicated the Navy committed "technical violations" that did not cause "appreciable harm," here BMS' unlawful and deceptive business practices violate the primary purpose of the CPL, which is to "protect citizens from unfair or deceptive practices [and] to benefit the public at large by eradicating unfair or deceptive business practices." <u>Chatham Racquet</u> <u>Club v. Commonwealth by Zimmerman</u>, 541 A.2d 51, 59 (Pa. Cmwlth. 1988) (citation omitted); <u>see also Commonwealth by Creamer v. Monumental Props.</u>, 459 Pa. 450, 329 A.2d 812 (1974) (CPL is to be construed liberally to effectuate its purpose of ensuring fairness in market transactions and placing sellers and consumers on equal ground). In addition, BMS' unlawful practices directly harmed DPW and PACE by causing them to overpay for BMS drugs.

Further, BMS' reliance on the Third Circuit's decision in <u>Bradley</u> is misplaced. BMS cites <u>Bradley</u> for the proposition that a "district court should consider the effect of the issuance of a preliminary injunction on other interested persons and the public interest." <u>Id.</u> 910 F.2d at 1175. In <u>Bradley</u>, the Third Circuit considered "the propriety of [a] district's court's denial, <u>without a hearing or findings of fact or conclusions of law</u>, of [a teacher's] <u>motion for preliminary injunction</u> preventing … school officials from banning … a teaching methodology she favored, and retaliating against her for using and advocating [that methodology]." <u>Id.</u> at 1174 (emphasis added). Ultimately, the Third Circuit held

the district court erred in failing to provide any basis for dismissal of the request for preliminary injunctive relief without a hearing.

Aside from the obvious factual distinctions between <u>Bradley</u> and this case, BMS offers no clear explanation as to how <u>Bradley</u> applies here. Specifically, the case presently before this Court involves the grant of a clearly-defined, statutorily-authorized permanent injunction issued after an extensive trial. <u>Bradley</u>, on the other hand, involved dismissal of a request for preliminary injunctive relief without a hearing or any explanation for the dismissal. Thus, <u>Bradley</u> does not advance BMS' position.

In addition, BMS' citation to <u>North Jersey Media</u> is puzzling. <u>North</u> <u>Jersey Media</u> involved a suit by media groups seeking access to certain "special interest" deportation hearings involving persons who the U.S. Attorney General determined might have connections to or knowledge of the September 11, 2001 terrorist attacks. <u>Id.</u> 308 F.3d at 199. The district court found in favor of the media groups, and issued a preliminary injunction preventing the U.S. Attorney General from denying access to the hearings. On appeal, however, a divided panel of the Third Circuit reversed, holding the district court did not adequately consider evidence concerning the potential threat to national security posed by allowing access to the hearings.

While BMS cites <u>North Jersey Media</u> for the proposition that an injunction should not go "beyond providing relief to plaintiffs," the language quoted by BMS is actually found in a dissenting opinion in the case. <u>Id.</u> at 229

(Scirica, J., dissenting). In any event, as with <u>Weinberger</u> and <u>Bradley</u>, discussed above, aside from the glaring factual distinctions between this case and <u>North</u> <u>Jersey Media</u>, BMS offers no explanation as to how the case applies here, particularly in light of the fact that it did not involve a statutorily authorized injunction.

## 2. Alleged Procedural Defect

#### a. Contentions

BMS next maintains that, because the Decision does not take into account the effects of the injunction, it is procedurally defective. BMS argues that, before granting or denying an injunction, a court must provide clear notice of the conduct to be enjoined, and an opportunity for all affected parties to be heard. <u>See Allegheny v. Milk Control Comm'n</u>, 417 Pa. 22, 207 A.2d 838 (1965) (lower court's denial of injunction was erroneous "in the absence of a hearing, answer of proper motions filed and opportunity for the parties to be heard"). BMS argues that here the Commonwealth did not even ask for the relief the trial judge awarded. It contends, therefore, the proposed injunction violates fundamental principles of due process, including notice and an opportunity to be heard. <u>Pa. Bankers Ass'n v.</u> Pa. Dep't of Banking, 598 Pa. 313, 956 A.2d 956 (2008).

## **b.** Analysis

Due process requires a person be provided notice and an opportunity to be heard prior to an adjudication affecting that person's rights. <u>Fountain Capital</u> <u>Fund, Inc. v. Pa. Secs. Comm'n</u>, 948 A.2d 208 (Pa. Cmwlth. 2008). It does not, however, confer an absolute right to be heard. <u>Id.</u> Due process is a right that a party may waive. <u>Id.</u>

BMS' arguments fail. As discussed above, the Commonwealth raised a claim for injunctive relief in its corrected amended complaint, as well as before and during the trial in this matter. In addition, the issue of injunctive relief was raised at the closing arguments on the Commonwealth's CPL claims, and a discussion occurred regarding the type of injunctive relief sought.

Further, at trial BMS was on notice as to the specific conduct that was the target of the request for injunctive relief. In particular, at oral argument on BMS' motion for compulsory non-suit, the trial judge inquired about the Commonwealth's theory on its conspiracy claim. <u>See N.T.</u>, 8/26/10, at 2353. In response, the Commonwealth identified four components to its theory of conspiracy, two of which, inflation of AWP, and creation, promotion or marketing of spreads, <u>see id.</u> at 2354, involve the specific conduct restrained by the trial judge through his award of injunctive relief.

Additionally, when charging the jury on the Commonwealth's conspiracy claim, the trial judge utilized a proposed contention point for charge submitted by the Commonwealth, which stated: "Plaintiff agencies assert that Bristol-Myers Squibb combined or agreed with one or more drug companies or others to do all of the following: To cause to be reported inflated wholesale prices for their prescription drugs; to create and maintain spreads between their reported average wholesale prices and the actual prices charged for their drugs ....." See

N.T., 9/8/10, at 3787 (emphasis added); Plaintiff's Proposed Jury Instructions, No. 27, served 8/31/10. Because BMS received the contention in writing days before the close of evidence, and because the trial judge specifically mentioned the type of conduct that was ultimately restrained in his instructions to the decision-maker on the common law claims, BMS had ample notice of the type of conduct that was the target of the request for relief.

In short, it is clear that BMS received notice and an opportunity to be heard on the Commonwealth's claim for injunctive relief during the course of the five-week trial in this matter. Therefore, no due process violation occurred.

# 3. Alleged Interference with Statutory/Regulatory Schemes a. Contentions

BMS further asserts if the Plaintiff Agencies had been given an opportunity to consider the relief ordered, they may have opposed it. BMS observes that Thomas Snedden testified PACE could not reduce drug reimbursement to actual acquisition cost without raising the dispensing fee to \$10 – something that can only be done by the Legislature. N.T., 8/24/10, at 1976-78. BMS asserts DPW made clear that its reimbursement formula is designed to "assure the availability to MA clients of high quality pharmacy services, equal to that of the general population in the same geographic regions, at the best possible prices." DX-501 at p. 3. BMS notes the Commonwealth affirmatively contended that obtaining changes in the reimbursement formulas is an arduous process at best. N.T., 9/9/10, at 3782.

BMS asserts additional testimony showed DPW's actions are constrained by the Independent Regulatory Review Commission (IRRC), which considers proposals for changes in reimbursement after receiving input from various stakeholders, including the General Assembly, the Governor and the pharmacies. <u>See</u> N.T., 8/26/10, at 2457-61; 8/30/10, at 2570-72 (Love); N.T., 8/30/10, at 2735-36, 2740 (Yearsley); DX-500; DX-501 at p.6; DX-699 at PA 501104; DX-804. It argues the IRRC rejected DPW's efforts to lower reimbursement in the past. N.T., 8/26/10, at 2483; DX-500. BMS contends the proposed injunction upsets the delicate balance, which the IRRC, the General Assembly, the Governor and PACE established over the years.

BMS further asserts a court should not issue an injunction when it would "interfere with the exercise of … discretionary powers" by other arms of government. Jones v. Bonner, 523 A.2d 849, 850 (Pa. Cmwlth. 1987). Here, BMS maintains, as recently as 2008, DPW decided not to sponsor a proposal to lower reimbursement by 2% from AWP-14% to AWP-16% because "the overall savings that were estimated did not outweigh the costs of disruption to providers and access." N.T., 9/1/10, at 3097 (Cathers). BMS argues the proposed injunction effectively trumps that 2008 determination and lowers reimbursement (at least on BMS drugs) to an amount significantly below pharmacy acquisition cost.

BMS contends the proposed injunction also threatens to harm the Commonwealth in other ways. It asserts the Commonwealth is required by federal law to establish reimbursement rates that will ensure access. 42 U.S.C. §1396a(30)(A); 42 C.F.R. §447.204. BMS argues that if patients in Pennsylvania

do not have access to BMS drugs, the federal funding the Commonwealth receives for its Medicaid program could be jeopardized. It maintains the Commonwealth currently receives approximately 65% of its funding for the Medicaid program from the federal government. BMS contends it would cause a major financial crisis for the Commonwealth, not to mention a health crisis for the recipients of Medicaid, if that funding were denied.

#### **b.** Analysis

BMS did not invite the fact-finder to consider any of these contentions during trial. <u>See</u> N.T., 9/9/10, at 3890-92 (closing arguments on CPL claim). Accordingly, they are waived.

Further, BMS' arguments fail on the merits. As with several other arguments advanced by BMS, its arguments on this point begin with a mischaracterization of the language of the injunction.

As noted, the injunction as currently formulated restrains BMS from, among other things, "[c]ontributing in any manner, directly or indirectly, to the reporting to [DPW] or to [PACE] of inflated [AWPs] for [BMS] drugs ...." Decision at 2. The trial judge's action in enjoining BMS from contributing to the reporting of fictitious prices in no way results in the alleged harm suggested by BMS. Also, if the Court modifies the injunction to more closely resemble the injunction issued against Johnson & Johnson Defendants, as explained above, it would simply require BMS to provide DPW and PACE with current, accurate estimated acquisition costs, in a useful format for each of their branded drugs. No change in the current AWP reporting would be needed.

There is no reason in this record or in common sense to support the claim that the Plaintiff Agencies would oppose the receipt of useful, accurate pricing data. This is the data for which the AWPs were intended as a proxy. This is particularly true if, as BMS asserts, the Agencies are unable to adequately defend their positions when proposing changes to their reimbursement rates because of the lack of clear information on estimated acquisition costs.

Most importantly, the trial judge rejected BMS' contentions that the reimbursement levels utilized by the Plaintiff Agencies are the product of "choice." BMS' assertions on this point are based on the premise that DPW and PACE employees were concerned with ensuring access (i.e., protecting pharmacy participation) to their respective programs. To the extent DPW and PACE witnesses testified to concerns over access, however, the trial judge rejected this testimony as not credible because it was at odds with the accepted expert testimony of Dr. Warren-Boulton, who explained in detail that no access problem existed (i.e., pharmacies leaving the network), even when reimbursement rates *decreased*. See N.T., 8/25/10, at 2173-78 (regarding DPW program); 2178-79 (regarding PACE program); see also N.T., 8/25/10, at 2204, 2212-13, 2219-20.

## 4. Alleged Irreparable Harm to BMS

#### a. Contentions

BMS next contends the proposed injunction will cause it irreparable harm. BMS asserts that if, as a result of the injunction, pharmacies refuse to stock its drugs, it will effectively be out of business in Pennsylvania. It argues an injunction that prevents a company from engaging in otherwise lawful activity is constitutionally invalid. <u>See Commonwealth ex rel. Davis v. Van Emberg</u>, 464 Pa. 618, 347 A.2d 712 (1975) (injunction must be narrowly tailored to avoid restraining lawful activities); <u>see also Commonwealth v. Zasloff</u>, 8 A.2d 801, 803 (Pa. Super. 1939), <u>aff'd</u>, 338 Pa. 457, 13 A.2d 67 (1940) (government edict that prevents "innocent transactions" violates due process).

BMS also maintains the proposed injunction will affect its business outside of Pennsylvania. BMS argues it does not report prices solely for use by the Plaintiff Agencies; rather, it reports list prices to national pricing services, which publish those prices on a nationwide basis. At this point, BMS asserts, it is unknown how the pricing services would react to a request by BMS that they change the way they report AWPs. BMS argues if the pricing services were unable, or refused, to limit any changes to Pennsylvania, the impact would be felt nationwide.

BMS also asserts other states, in an effort to ensure access to their Medicaid beneficiaries, established reimbursement formulas based on AWP. N.T., 8/25/10, at 2192-93 (Warren-Boulton). It contends private payors, located throughout the country, also have contracts with providers based on AWPs. N.T.,

8/16/10, at 682-83, 690-92 (Comanor); N.T., 8/25/10, at 2205-07 (Warren-Boulton). BMS argues that if, as a result of the trial judge's order, the pricing services decided to change the way they calculate AWPs, modification of regulations and statutes and the renegotiation of contracts nationwide would be required.

#### **b.** Analysis

As with the rest of its harm-to-others arguments, BMS does not indicate where in the record these concerns were preserved at trial. Accordingly, the argument is waived.

Also, BMS cites no record evidence to support its speculative assertions of harm to BMS. Accordingly, it failed to prove its contentions.

Additionally, BMS' contentions mischaracterize the terms and intended effect of the injunction. Moreover, as with the injunction entered after trial against Johnson & Johnson Defendants, the injunction against BMS can be modified to prohibit BMS from: contributing, directly or indirectly, to the reporting to DPW and PACE of inflated AWPs without also arranging for the transmission to the agencies of current, accurate estimated acquisition costs, such as AMPs or ASPs, for each of their branded drugs in a format equivalent to that in which AWPs are reported to the agencies, or in another format acceptable to the agencies and, promoting and/or marketing of spreads for branded drugs reimbursed by DPW and PACE (thereby eliminating the prohibition on <u>creation</u> of spread). This would limit the effect of the proposed injunction to the two Pennsylvania agencies, and it would moot BMS' unsupported "parade of horribles."

Further, BMS fails to support its contentions with applicable legal authority; rather, the authority upon which BMS relies is distinguishable. In <u>Van</u> <u>Emberg</u>, the Pennsylvania Supreme Court considered the validity of an injunction that prohibited the proprietor of an adult bookstore from engaging in "any business activity at the premises." <u>Id.</u> at 619, 347 A.2d at 713. In that case, a court of common pleas initially granted an *ex parte* injunction prohibiting any business activity. No record of the proceeding was made. After hearing, the common pleas court entered a second decree continuing the injunction and specifying the defendants were enjoined from distributing in any manner "the book, papers, magazines and all other materials and exhibits referred to in the testimony taken in this matter." <u>Id.</u> at 620, 347 A.2d 713. Vacating the grant of the injunction, the Supreme Court explained:

The ex parte injunction enjoined defendants from '... operating any business activity at the premises.' The later decree issued after the hearing was not much more specific. The record indicates that there was a variety of books, magazines and other items, not established to be obscene, sold in this store. There is no basis in the record before us upon which the chancellor could have found that every item in the store was obscene and all sales properly enjoinable. The injunction is manifestly invalid on its face because of its failure to specify with particularity what materials were obscene and to limit its mandate to affect only those so designated. <u>The broad</u> prohibition of this decree, enjoining all business activity, cannot be upheld.

This Court stated in <u>Collins v. Wayne Iron Works</u>, 227 Pa. 326, 330, 76 A. 24, 25 (1910): 'The entry of an injunction is, in some respects, analogous to the publication of a penal statute. It is a notice that certain things must be done or not done . . .. Such a decree should be as definite, clear and precise in its terms as possible . . ..'

The dissemination of printed material is one of the most zealously protected rights accorded by the United States Constitution and the Pennsylvania Constitution. In some circumstances specific publication may be enjoined because they do not enjoy constitutional protection. However, a blanket prohibition against the dissemination of all 'books, papers, magazines and all other materials' cannot be tolerated.

Id. at 623-25, 347 A.2d at 715-16 (emphasis added) (citations and footnotes omitted).

Clearly, this is not a case like <u>Van Emberg</u>. Unlike the broad prohibition on all business activity condemned by the Supreme Court in <u>Van</u> <u>Emberg</u>, the language of the injunction here is sufficiently specific as to the conduct prohibited, and does not broadly prohibit BMS from conducting all business activity. Indeed, the trial judge here tailored his injunction so as to prohibit two discrete unlawful and deceptive business practices, which violated Pennsylvania law.

In addition, BMS' reliance on <u>Zasloff</u>, a 1939 Superior Court decision, is misplaced. There, the Superior Court declared unconstitutional the former Fair Sales  $Act^{15}$  in response to a challenge by an individual who was

<sup>&</sup>lt;sup>15</sup> Act of July 1, 1937, P.L. 2672, <u>formerly</u> 73 P.S. §§201-207.

charged with violating a provision that prohibited a retailer from selling any merchandise at less than his cost. The Pennsylvania Supreme Court affirmed, stating: "the right of an owner of property to fix the price at which he will sell it is an inherent attribute of the property itself, and as such within the protection of the 14th Amendment …." Zasloff, 338 Pa. at 459, 13 A.2d at 69.

BMS' reliance on <u>Zasloff</u> is unavailing given that it involved a statute that preceded the CPL, which the Supreme Court invalidated. Further, the underlying conduct at issue in <u>Zasloff</u>, which simply involved a retailer's sale of merchandise at a cost less than he paid, is far different from the unlawful and deceptive conduct, which the trial judge determined BMS employed here.

#### **5. Alleged Commerce Clause Violation**

#### a. Contentions

BMS next maintains the injunction unconstitutionally interferes with interstate commerce in two ways. First, BMS argues the injunction impermissibly acts as a direct regulation on interstate commerce by prohibiting BMS from marketing WAC to AWP spreads. BMS contends the injunction inappropriately uses Pennsylvania law to alter "industry-wide practices that thousands of companies, pharmacies and physicians nationwide have relied on to structure their business dealings for more than 40 years." BMS' Br. at 17.

In addition, BMS argues the injunction constitutes a form of "economic protectionism," which benefits Pennsylvanians at the expense of non-Pennsylvanians. Specifically, BMS argues the injunction relieves the Plaintiff Agencies of the burden of negotiating discounts from industry-standard drugs and redistributes the burden to payors in the rest of the country.

#### **b.** Analysis

This argument fails for several reasons. First and foremost, BMS did not raise any issue regarding the Commerce Clause of the U.S. Constitution before the trial judge. Therefore, this issue is waived.

Second, as to the merits, the Commerce Clause of the U.S. Constitution enumerates to "the Congress [the] Power ... to regulate Commerce ... among the several States." U.S. CONST. art. I, § 8, cl. 3. The U.S. Supreme Court interprets the Commerce Clause as containing "an implicit or 'dormant' limitation on the authority of the States to enact legislation affecting interstate commerce." <u>Healy v. Beer Inst., Inc.</u>, 491 U.S. 324, 326 n.1 (1989). The dormant Commerce Clause "prohibits economic protectionism-that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." <u>New Energy Co. of Indiana v. Limbach</u>, 486 U.S. 269, 273 (1988) (citations omitted). In sum, since Congress possesses plenary power to regulate commerce among the states, states are prohibited from passing laws that discriminate against interstate commerce. <u>Indianapolis Power & Light Co. v. Pa. Pub. Util. Comm'n</u>, 711 A.2d 1071 (Pa. Cmwlth. 1998).

Courts apply a two-tiered approach when analyzing whether state economic regulation violates the Commerce Clause:

When a state statute directly regulates or discriminates against interstate commerce, or when its

effect is to favor in-state economic interests over out-ofstate interests, we have generally struck down the statute without further inquiry. When, however, a statute has only indirect effects on interstate commerce and regulates evenhandedly, we have examined whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.

Brown-Foreman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573, 579 (1986); see also Empire Sanitary Landfill v. Dep't of Envtl. Res., 546 Pa. 315, 684 A.2d 1047 (1996); Kerbeck Cadillac Pontiac, Inc. v. State Bd. of Vehicle Mfrs., Dealers & Salespersons, 854 A.2d 663 (Pa. Cmwlth. 2004).

In <u>Healy</u>, the U.S. Supreme Court further explained:

The principles guiding this assessment ... reflect Constitution's special concern both with the the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres. Taken together, our cases concerning the extraterritorial effects of state economic regulation stand at a minimum for the following propositions: First, the "Commerce Clause ... precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State," ... and, specifically, a State may not adopt legislation that has the practical effect of establishing "a scale of prices for use in other states." Second, a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature. The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State. Third, the practical effect of the statute must

be evaluated not only by considering the consequences of the statute itself, but also by <u>considering how the</u> <u>challenged statute may interact with the legitimate</u> <u>regulatory regimes of other States and what effect would</u> <u>arise if not one, but many or every, State adopted similar</u> <u>legislation.</u> Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State. And, specifically, <u>the</u> <u>Commerce Clause dictates that no State may force an</u> <u>out-of-state merchant to seek regulatory approval in one</u> <u>State before undertaking a transaction in another</u>.

<u>Healy</u>, 491 U.S. at 335-37 (citations and footnotes omitted). The cases cited by BMS all involve instances of a court interpreting legislative action. None of the cases involve review of the terms of an injunction to determine if it violates the Commerce Clause. The Commerce Clause itself is directed at legislative power, enumerating power vested in the U.S. Congress. The dormant Commerce Clause implicitly identifies the limits of states in impacting interstate commerce.

Third, if the injunction is modified to conform to the injunction issued after Johnson & Johnson Defendants' trial, no Commerce Clause violation is evident. This is because BMS will be able to comply with the injunction in a manner in current industry-wide use: reporting ASPs for its drugs. This has been a statutory requirement of all Medicare Part B drugs of all drug manufacturers nationwide since January 1, 2005. Also, because of settlement in the related Lupron litigation, reporting of ASPs has been a matter of Consent Agreement between the Commonwealth and TAP Pharmaceuticals, another Defendant in this case. See Def. TAP Pharmaceutical Products, Inc.'s Mem. in Support of its Mot.

For Summ. J. at 4; Ex. 6, ¶17 (TAP agreed to report ASP data for all of its products reimbursed by Pennsylvania Medicaid).<sup>16</sup> Given this nationwide statutory change, and the existing reporting situation involving a co-Defendant, a commerce clause violation under a modified injunction is unclear at best.

## 6. Balancing the Harm

#### a. Contentions

BMS further argues that, in contrast to the harm that would follow from the injunction, no harm would result from refusing to grant relief. As discussed more fully below, BMS contends that the Plaintiff Agencies already have all the information they need to set appropriate reimbursement rates. BMS asserts witness after witness from the Plaintiff Agencies testified the current reimbursement levels (including payments for the drugs and the dispensing fees) are appropriate. <u>See</u> N.T., 8/30/10, at 2794-95 (Nardone); N.T., 8/31/10, at 2061-62 (Cathers); N.T., 8/24/10, at 1975-78, 1994-96 (Snedden). BMS further contends no court in any other AWP case granted an injunction of the type ordered here. It asserts the proposed injunction is unprecedented and unnecessary, and greater injury will result from entering than refusing to enter the injunction.

<sup>&</sup>lt;sup>16</sup> This Court can take judicial notice of TAP's motion for summary judgment, which included TAP's settlement agreement (and was filed on August 26, 2010, while the trial involving BMS was still ongoing). <u>Cf. Lycoming Cnty. v. Pa. Labor Relations Bd.</u>, 943 A.2d 333 (Pa. Cmwlth. 2007) (Commonwealth Court may take judicial notice of pleadings and judgments in other proceedings where appropriate).

#### **b.** Analysis

BMS' argument fails for several reasons. First, although BMS baldly asserts greater harm will result from upholding the grant of the injunction rather than denying it, BMS provides no explanation *from the record* of the harm that would result. This is not surprising given that, at trial, BMS presented no clear proof of the alleged harm that would result from the grant of any injunctive relief.

In addition, although BMS asserts that testimony by DPW and PACE witnesses confirmed that these Agencies have the information needed to set appropriate reimbursement rates, the record does not support this assertion. As explained in detail below, the testimony revealed significant confusion over the various pricing benchmarks used in the pharmaceutical industry and the import of each of these benchmarks as they relate to estimated acquisition costs for BMS branded drugs. Much of the testimony relied upon by BMS on this issue was given little weight by the trial judge, because the DPW and PACE witnesses, particularly Mr. Snedden, appeared biased in favor of supporting their past decision-making.

Also, as explained above, the trial judge rejected BMS' contentions that the reimbursement levels utilized by the Plaintiff Agencies were the product of "choice" by these agencies. BMS' assertions on this point are based on the premise that DPW and PACE employees were concerned with ensuring access to their respective programs. To the extent DPW and PACE witnesses testified to concerns over access, however, the trial judge rejected this testimony as not credible because it was at odds with the accepted expert testimony of Dr. Warren-Boulton, who explained in detail that no access problem existed, even when

reimbursement rates *decreased*. <u>See</u> N.T., 8/25/10, at 2173-78 (regarding DPW program); 2178-79 (regarding PACE program); <u>see also</u> N.T., 8/25/10, at 2204, 2212-13, 2219-20.

Further, while BMS asserts a grant of injunctive relief is unprecedented, it makes no effort to discuss or compare other judicial opinions granting relief in AWP-related litigation with a case brought under a statutory scheme like the CPL, which expressly authorizes the Attorney General to seek injunctive relief to restrain CPL violations where such proceedings are in the public interest.

#### **D.** Alleged Lack of Urgent Necessity

## **1. Alleged Inconsistency in the Decision**

#### a. Contentions

BMS next argues an injunction should be denied where there is no urgent necessity to avoid an injury that cannot be compensated by damages. It contends that the Decision recognizes there is no urgent necessity that cannot be compensated by monetary damages because the trial judge refused to award restitution after 2004, which is an obvious acknowledgement that the Commonwealth did not suffer harm after 2004.

#### b. Waiver

As with the preceding issue, the issue of alleged lack of urgent necessity (and its four sub-contentions) was not brought to the attention of the fact-finder before entry of the non-jury Decision. <u>See N.T.</u>, 9/9/10, at 3890-92 (during

BMS' closing on CPL claim, "the statutory claim fails for the very same reasons the jury found against the Commonwealth [on the common law claims]."). These arguments simply were not made during the closing, or at any other time during trial. Further, no affirmative evidence was offered on any of these points. The issue and its subparts are therefore waived.

## c. Standard for Injunction Under CPL

Moreover, for the following reasons lack of urgent necessity (and its four sub-contentions) are not elements of the Commonwealth's proof for an injunction in the public interest under the CPL. Rather, the Commonwealth must prove a violation of the CPL.

The remedy of injunctive relief here is explicitly 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, <u>he may bring an action in the name of the</u> <u>Commonwealth against such person to restrain by</u> <u>temporary or permanent injunction the use of such</u> <u>method, act or practice.</u>

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,<sup>17</sup> <u>formerly</u> 31 P.S. §20.4). As an obvious corollary, where a statute authorizes restoration when an injunction 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 <u>Burns</u>, 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 <u>Israel</u>. In <u>Israel</u>, the Public Utility Commission filed suit in Dauphin County Common Pleas Court (sitting as Commonwealth Court)

<sup>&</sup>lt;sup>17</sup> Act of July 7, 1994, P.L. 421, <u>as amended</u>. The Food Act, <u>formerly</u> 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.

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,<sup>18</sup> 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 act, matter, or thing herein prohibited or declared to be unlawful; \* \* \* then and in every such case <u>the</u> <u>commission may institute in the court of common pleas</u> 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 <u>thereto</u> ....

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. <u>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.</u>

<sup>&</sup>lt;sup>18</sup> <u>Formerly</u> Section 903 of the Act of May 28, 1937, P.L. 1053, <u>as amended</u>, 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.

In <u>Commonwealth v. Pittsburgh & Connellsville</u> <u>Railroad Co.</u>, 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 <u>an injunction may issue to prevent wrongs of a repeated and continuing character</u>, or which occasion damages which are estimable only by conjecture and not by any accurate standard. \* \* \* <u>Besides this, where the right invaded is secured by statute</u> ... there is generally no question of the amount of damage, but simply of the right.'

<u>Id.</u> 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.

<u>Id.</u> at 409, 52 A.2d at 321 (emphasis added). <u>Israel</u> stands for the proposition that, for purposes of injunctive relief, statutory violations constitute irreparable harm <u>per</u> <u>se</u>. Although <u>Israel</u> 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 AWP litigation decision in <u>Commonwealth of Kentucky ex rel. Conway v. Alpharma USPD, Inc.</u> 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). 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 that consumer protection statute, Judge Shepherd wrote: "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." <u>Id</u>., 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 BMS 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 BMS violated the CPL, the trial judge had a duty to issue an injunction to restrain BMS' unlawful practices. <u>Israel</u>.

#### d. 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 BMS' 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).

Our Supreme Court holds that the mere fact that an illegal practice has been abandoned does not necessarily render a controversy moot. <u>Tamagno v.</u> <u>Waiters & Waitresses Union, Local No. 301</u>, 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." <u>Id</u>. at 461, 96 A.2d at 147.

Similarly, in <u>Commonwealth v. Percudani</u>, 844 A.2d 35 (Pa. Cmwlth.), <u>amended on reconsideration by</u>, 851 A.2d 987 (Pa. Cmwlth. 2004) (<u>Percudani II</u>), 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, <u>Percudani II</u> 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. <u>Percudani II</u>, 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.

<u>Id.</u>

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.[<sup>19</sup>]

<sup>&</sup>lt;sup>19</sup> The Court in <u>Percudani II</u> provided the following string citation in support of its conclusion: <u>See Commonwealth by Zimmerman v. Nat'l Apt. Leasing Co.</u>, 519 A.2d 1050 (Pa. Cmwlth. 1986) (where Commonwealth alleged that apartment leasing company wrongfully **(Footnote continued on next page...)** 

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. <u>Whether</u> the [AG] 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 [AG'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 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

## (continued...)

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).

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.

<u>Percudani II</u>, 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 also disagreed with the majority's interpretation of the CPL, stating:

The [CPL] authorizes the [AG] to institute an action to enjoin an unfair trade method, act or practice "[w]henever the [AG] ... has reason to believe that any person *is using or is about to use*" this practice. 73 P.S. § 201-4. The [AG] asserts that this provision authorizes his action against [the appraiser], who is out of the business of appraising real estate and will be for at least the next five years. Stated otherwise, the [AG] sees no distinction between "has used" in the past, "is using" in the present or "about to use" in the future. However, the only way to read the actual words of the [CPL] is that

past conduct that is no longer continuing cannot support a complaint.

The distinction between "has used," "is using" and "is about to use" has been given effect in precedent interpreting an unfair trade practice statute very similar to Pennsylvania's [CPL]. In State ex rel. McLeod v. Brown, 278 S.C. 281, 294 S.E.2d 781 (1982), the defendants contended that the state attorney general could not pursue an action against them because they had voluntarily ceased the conduct cited in the complaint. The South Carolina Supreme Court rejected this defense because the unfair trade practice statute expressly authorized actions against a person who "has used" an unlawful practice. Brown, 294 S.E.2d at 782-783. Indeed, the South Carolina statute authorized the state attorney general to seek civil penalties as well as injunctive relief for violations that had occurred in the past but had discontinued.

In sum, the words "is using or is about to use" have a meaning separate from "has used." We must enforce the actual language used by the General Assembly in the [CPL], and we must not insert words that are not there under the principle *expressio unius est exclusio alterius*. The allegation that [the appraiser] may have engaged in an unfair trade practice in the past, but is no longer, cannot support an action under the [CPL]. The [AG] cannot aver that [the appraiser] "is using" or "is about to use" an unfair method of doing real estate appraisals. By virtue of the … consent order, [the appraiser] is barred from doing *any* real estate appraisals, whether fair or unfair.

<u>Percudani II</u>, 844 A.2d at 51-53 (Leavitt, J., dissenting) (emphasis in original) (footnotes omitted).

Of further note, 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). ...

<u>Percudani II</u>, 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, <u>and</u> 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 <u>Hershey Chocolate Corp. v. Federal Trade</u> <u>Commission</u>, 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) ("[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); United States v. W.T. Grant Co., 345 U.S. 629, 632 (1953) (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, <u>Percudani</u>; (2) cessation of the alleged offending conduct does not, in and of itself,

bar a claim for injunctive relief, <u>Hershey Chocolate</u>; <u>id.</u>; 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 BMS' position. While it asserts the record contains no proof of an ongoing threat of injury, there is also no evidence that BMS, in fact, ceased all its offending conduct and promised not to renew it. To the contrary, BMS contended that all past activity was lawful and it did nothing wrong.

Moreover, BMS continues to report WLPs to the pricing compendia, which in turn continue to report fictitious AWPs to the Plaintiff Agencies. Also, there was no believable evidence that BMS intended to permanently change any marketing or reporting practice without a court order. In this regard, there was no believable evidence that BMS 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 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 Attorney General for further proceedings in the public interest, pursuant to section 4.

73 P.S. §201-5. 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. <u>See</u> 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 BMS did not utilize 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. Also, the decision not to award statutory restoration after 2004 is in no way inconsistent with the trial judge's grant of injunctive relief. First, BMS fails to acknowledge the structure of the CPL as it relates to Attorney General enforcement actions. Based on the plain language of Section 4.1 of the CPL, a grant of injunctive relief is a prerequisite to an award of restoration. See 73 P.S. §201-4.1. There is no authority to the contrary. Thus, upon finding violations of the CPL, the trial judge was authorized to grant injunctive relief, which, in turn, provided him with discretion to also award restoration.

In addition, the decision not to award statutory restoration post-2004 was based on a number of considerations, including changes in the statutory and regulatory reimbursement formulae for the Plaintiff Agencies, which occurred after 2004, and the passage of the federal Medicare Prescription Drug, Improvement and Modernization Act, which took effect in January 2005. In short, no inconsistency exists between the grant of injunctive relief and the award of statutory restoration for a closed period.

## 2. Alleged Lack of Ongoing Injury

#### a. Contentions

BMS further maintains the Commonwealth did not demonstrate a current threat of an ongoing injury so as to justify the grant of injunctive relief. It contends that, at the Commonwealth's request, the trial judge barred evidence of any conduct after 2008. As a result, BMS asserts, no evidence of any ongoing injury appears of record. For the same reason, BMS argues, it was deprived the opportunity to show the Commonwealth no longer suffers from any injury it may

79

have incurred in the past. BMS maintains where, as here, no threat of ongoing injury is shown, an injunction should be denied as there is nothing to enjoin. <u>See Christoffel v. Shaler Area Sch. Dist.</u>, 430 A.2d 726 (Pa. Cmwlth. 1981); <u>Weichert Co. of Pa., Inc. v. Long & Foster Real Estate, Inc.</u>, Dkt. No. 03-00849, 2005 WL 6195331 (C.P. Montgomery 2005).

## **b.** Analysis

Although another defendant group which proceeded to a separate trial raised this issue in its pretrial memorandum, BMS did not.<sup>20</sup> Moreover, BMS did not alert the trial judge to consider this contention at any time before the Decision.

Regardless of waiver, the contention lacks merit, for the reasons discussed in the preceding section of this opinion.

## **3. Alleged Failure to Provide Meaningful Relief**

## a. Contentions

BMS also asserts that the Plaintiff Agencies have all the information they need to determine appropriate reimbursement rates. BMS argues that DPW

<sup>&</sup>lt;sup>20</sup> Johnson & Johnson Defendants, another group of defendants that proceeded to separate trial, specifically raised a defense in opposition to the Commonwealth's request for injunctive relief in their pre-trial memorandum. <u>See</u> J&J Defs.' Pre-Trial Mem., 7/26/10, at p. 51, ¶22 ("<u>Plaintiff is not entitled to injunctive relief against the J&J Defendants</u> where the undisputed evidence is that the J&J Defendants ceased providing suggested AWPs to Publishers or anyone else, including third-party payors, in 2004.") (Emphasis added). That Johnson & Johnson Defendants specifically raised a defense to the request for injunctive relief shows other defendants in this case knew the Commonwealth sought injunctive relief. For this additional reason, BMS cannot credibly claim surprise regarding the request for and award of injunctive relief.

and PACE have access to the Health and Human Services Office of the Inspector General (OIG) reports that summarize the results of surveys concerning pharmacy acquisition costs. <u>See</u> N.T., 8/24/10, at 1972-74 (Snedden); N.T., 8/26/10, at 2421-22, 2424, 2426-27, 2473, 2480-84 (Love). Further, BMS contends that from time to time the Commonwealth conducted its own surveys or audits to determine actual acquisition costs, and can continue to do so in the future.

BMS argues the Commonwealth also has access to every piece of information BMS has in its possession, custody or control regarding actual acquisition costs of pharmacies and doctors. BMS maintains it calculates the following types of relevant pricing information in the regular course of its business: WLPs (prices at which BMS sells to wholesalers, which, according to testimony by a BMS witness, are very close to what retail pharmacies pay for drugs), N.T., 8/31/10, at 2842-43 (Larkin)); AMPs (prices determined in accordance with regulatory requirements that reflect net prices, after discounts, of products destined for the retail class of trade; they are slightly below list prices – and, therefore, below pharmacy acquisition costs – because they reflect prompt pay discounts and discounts to mail order pharmacies), N.T., 8/31/10, at 2852-55, 2872-73); and, (3) ASPs (prices for physician administered drugs calculated pursuant to regulatory requirements and published on the internet), N.T., 8/31/10 at 2851-52).

BMS contends the Commonwealth already has access to all of these prices; thus, it asserts that there is nothing more it can provide. Also, BMS asserts that it is not involved in transactions between wholesalers and retail pharmacies;

therefore, it is not in a position to provide those prices other than to estimate generally that they are close to list prices, which BMS provides. N.T., 8/11/10, at 282-83 (Norris). In fact, BMS argues the Commonwealth has greater access to pharmacy acquisition costs because it can audit pharmacies, and BMS cannot.

BMS maintains where, as here, an injunction would not provide meaningful relief, it should not be issued. As noted above, BMS contends that the only practical means BMS has to comply with the injunction is to ask the pricing services to make the AWPs for BMS drugs equal to WACs/WLPs.

## **b.** Analysis

### i. Waiver

BMS did not invite the trial judge to consider that any injunction would be incapable of providing meaningful relief because of the structure of the drug pricing system. <u>See</u> N.T., 9/9/10, at 3890-92 (closing argument on CPL claim). Accordingly, this contention is waived.

Also, on the merits we reject BMS' argument that the injunction will provide no meaningful relief because the Plaintiff Agencies have all of the information they need to set appropriate reimbursement rates. There are two general reasons for this conclusion. First, the trial judge found that there is much confusion regarding AWPs and actual provider acquisition costs. Second, the trial judge found that the information available to Plaintiff Agencies is not useful because of format, timing, and ambiguity and because it does not cover each National Drug Code (NDC).

82

## ii. AWP Confusion

Regarding AWP confusion, the trial judge found that the pricing system utilized in the pharmaceutical industry is very complicated, <u>see</u>, <u>e.g.</u>, N.T., 8/16/10, at 712-13, 722 (Comanor). As a result, confusion over the meaning and import of each of the various pricing values, seriously hindered, if not completely prevented, the efforts of DPW and PACE to discover current, accurate estimated acquisition costs in a useful format for BMS drugs.

For example, with regard to her understanding of AWP, former, longtime DPW employee Suzanne Love, who had significant involvement in pharmaceutical reimbursement, testified as follows (with emphasis added):

Q. Okay. Was it also your -- do you agree with the description in this proposed regulation that AWP is a misnomer? It is actually the manufacturer's suggested list price?

A. It was my understanding that the AWP received from the pricing service was determined by the manufacturer.

\* \* \* \*

Q. ... You used AWP throughout your time at DPW, correct?

A. Yes.

Q. Did you understand it to be an actual average of wholesale prices?

A. It was always my understanding that the AWP that was reported by our pricing service represented the price identified by the manufacturer. It was my understanding that that was not the actual price that the pharmacist purchased the drug. Q. Okay. Now, do you have a --

A. But I didn't have anything to prove that.

Q. Didn't have anything to prove what?

A. That it wasn't the actual price that the pharmacist paid.

Q. Okay. Did you -- <u>how did you obtain the</u> <u>understanding that it -- that the published AWP was not</u> <u>the price that the pharmacist paid</u>?

A. <u>Day-to-day discussions</u>, rumors, things like that.

Q. With whom?

A. Pharmacists, the pharmacy association.

N.T., 8/26/10, at 2420-21. Further, with regard to her understanding of WAC/WLP, Love testified (with emphasis added):

Q. ... You knew at this time that the WAC, the published WAC was closer to the pharmacists' actual acquisition cost than the published AWP, isn't that correct?

A. <u>It's hard for me to say that I knew this. I mean, you hear these things in discussions, you read articles here and there that suggest that it would be closer.</u>

Q. All right. I didn't mean that you had a moral certainty. I just meant that you had some sort of information that would suggest to you that WAC would be closer to actual acquisition cost than –

A. I had -- I'm sorry.

Q. I guess you can finish. Go ahead, answer.

A. I didn't mean to interrupt. I, <u>I had anecdotal</u> information that it was closer to actual acquisition cost.

N.T., 8/26/10, at 2472.

In addition, as to her knowledge of the various pricing benchmarks,

Dr. Terri Cathers, Director of Pharmacy for the Fee-for-Service Program of DPW's

Office of Medical Assistance Programs testified (with emphasis added):

Q. Now I want to talk about up through 2008. Can you tell the jury about your understanding of AWP while you were with Pennsylvania Medicaid up through 2008. What was your understanding of AWP?

A. <u>Well, AWP is -- is not easily understood. I mean</u> we've seen AMP today, we've seen WAC today, we've heard about actual acquisition cost, and we've heard about AWP.

But I don't -- I don't know what any of these prices actually mean, where they come from, and I don't know anybody who does, other than the manufacturers who have to have some sort of method for coming up with these prices. But that's unknown to all of us.

Q. Okay. And it has been?

A. Absolutely. It has been unknown as -- forever.

Q. Okay. But there was a suggestion in this case that, you know, some of the manufacturers may hand over a WAC. If some -- if a manufacturer -- first of all, how many manufacturers do you deal with?

\* \* \* \*

A. ... Over 300.

Q. Okay. And we already said there's 25,000 different drugs?

A. Yes.

Q. 30,000 claims a day?

A. Yes.

Q. <u>Okay</u>. So if one of these manufacturers or a couple of them gave you a paper of WAC, what their WAC was, could you -- what could you do with that information?

A. Nothing. By the time the paper reaches my desk it's potentially old data, and what is a piece of paper going to do for a large computer infrastructure that requires system coding to look at a claim when it comes in and pay it appropriately. It would not be efficient, it would not be accurate, and it would not be timely.

Q. Okay. So it wouldn't be accurate. Would it be current?

A. It would not be accurate, timely –

Q. It wouldn't be current, right?

A. Right.

Q. And it wouldn't be efficient?

A. That's right.

\* \* \* \*

Q. Okay. <u>Are you privy to AMP, or is that a secret figure</u>?

A. <u>Oh, that's very secretive.</u> <u>Only CMS and the</u> manufacturers have access to the AMP. The state Medicaid programs do not see that price nor is it made available publicly.

## \* \* \* \*

Q. Okay. Did Pat DeHart [who worked in BMS' state government affairs department] ever offer to show you ASP?

A. <u>No.</u> And in fact I had asked about the pricing, and I don't -- she brought like some glossy card. She didn't leave it with me. <u>It gave me zero information</u>. There was nothing that on there said, oh, yeah, this drug is so high cost because it was -- whatever. There was no explanation. So I was like, okay. Well, you know, just another empty request.

\* \* \* \*

A. <u>AMP is calculated by the drug manufacturers, and it is</u> what the wholesaler would pay to the manufacturer for the drug. It is not acquisition cost for the pharmacies to buy the drug. <u>AMP</u> has nothing to do with the pharmacy's ability to buy the drug or the price at which the providers would pay.

And AMP ... it definitely did not increase at the same rate as the AWP. And obviously that's by design. Because if the manufacturer is paying rebates against AMP, well, wouldn't you want AMP to be lower so you don't pay higher rebates? It seems to make sense to me if I were them.

N.T., 8/24/10, at 2023-24, 2027, 2037, 2041.

Further, although much of his testimony was rejected, Thomas Snedden, Director of PACE, provided the following credible testimony regarding pricing (with emphasis added):

Q. What would you like to pay?

A. <u>I'd like to pay whatever the price is that pharmacists</u> <u>are paying for the product.</u> And that price can vary, depending on whether it's independent pharmacy, chain pharmacy, institutional pharmacy, nursing home pharmacy, and then pay them a fair and reasonable fee to dispense that medication over and above the price that they pay for the medication. Q. So do I have it right you would like to pay the actual price paid by the pharmacists and then pay them a dispensing fee?

A. <u>Yes. We call it the actual acquisition cost.</u> Plus a dispensing fee.

Q. <u>Have you ever had success getting the actual</u> <u>acquisition cost getting paid by the reimbursement</u> <u>program?</u>

A. Not for the PACE program.

\* \* \* \*

Q. So does PACE get AMP data from the manufacturers?

A. Yes, we do.

Q. You get it pursuant to that contract they sign?

A. Pursuant to the statute and the contract, yes.

Q. And what does the contract say to PACE about what you can do with those AMPs?

A. The statute and the contract require us to keep that data confidential.

Q. Can you use that data for reimbursement?

A. <u>No.</u>

Q. Have you always kept that data confidential?

A. Very much so.

\* \* \* \*

Q. Why do you want to know real prices?

A. <u>I want to make sure the program is reimbursing fairly</u> to providers so that they take good care of the PACE enrollment.

Q. <u>Have you ever gotten real transaction prices from any</u> <u>drug manufacturer?</u>

A. Not outside of AMPs.

Q. Have you ever gotten any from BMS?

A. <u>No.</u>

Q. You said not outside of AMPs. That's the calculated price that they created?

A. Right. Right.

\* \* \* \*

Q. <u>Have they shown you any real transaction prices to</u> <u>any customer?</u>

A. <u>No.</u>

N.T., 8/24/10, at 1915, 1921, 1925-26 (emphasis added).

Thus, the testimony of DPW and PACE witnesses revealed that even if they had some anecdotal information about the various pricing values used in the pharmaceutical industry, they did not have sufficient information to accurately estimate provider acquisition costs for BMS' branded drugs. Further, while the testimony of these witnesses reveals they had some knowledge that AWP was a flawed value, their believable testimony also shows they did not fully understand the extent of the inaccuracy for the branded drugs at issue here. <u>See, e.g.</u>, N.T., 8/31/10, at 3031 (Radke) (explaining he was unaware that manufacturers had a formula for computing AWP).

Additionally, these witnesses never testified they knew that WAC/WLP represented a price that providers actually paid for BMS drugs, and, in any event, there was credible evidence that providers paid less than WAC/WLP. N.T., 8/16/10, at 762-70; PX-8962, PX-8963 (Comanor). In sum, the testimony of the DPW and PACE representatives shows that, although they knew problems existed within the AWP-based reimbursement system, it is also clear that substantial confusion existed, such that these witnesses lacked an awareness of the actual average of wholesale prices for specific BMS branded drugs.<sup>21</sup>

The trial judge rejected BMS' assertion that it had an inferior understanding about actual provider acquisition costs for its branded drugs. Instead, the trial judge determined BMS had vastly superior knowledge regarding the pricing environment for its drugs, including the reimbursement component of the pricing environment. <u>See</u> PX-491 (BMS June 2002 presentation on "Average Wholesale Price (AWP)"); PX-375, also identified as Bates # BMS 1237476 (1999 PowerPoint presentation by consulting firm Charles River Associates to BMS executives regarding marketing of BMS drug Paraplatin), N.T., 9/1/10, at 3217-3224 (description of PX-375 by Bell); <u>see also</u> PX-8951 (BMS company e-mail indicating BMS "understood the different [pricing] policies they could adopt.

<sup>&</sup>lt;sup>21</sup> Although not relevant to this trial, there was also substantial, credible evidence received in the subsequent trial of Johnson & Johnson Defendants regarding confusion about AWP.

They could adopt a policy which says low AWP, keep the prices stable and not pay much rebates. <u>And an alternative is the last one, high AWP/aggressive rebates.</u> <u>And that was the choice</u>." N.T., 8/16/10, at 756-59 (Comanor describing PX-8951). Evidence to the contrary was rejected as less credible.

## iii. OIG Reports, Surveys and Price Audits

More importantly, the OIG reports, surveys and price audits upon which BMS relies are not communicated to the Plaintiff Agencies in a format suitable for use with the tens of thousands of computer-based claims submitted to the Plaintiff Agencies each day. In other words, unlike the price information purchased from the pricing compendia, the OIG reports, surveys and price audits are not automatically updated to be current, and they are not provided in a digital format. Instead, information in the OIG reports, surveys and price audits are static, stale, and analog-style.

In addition, testimony revealed that the OIG reports and audits available to DPW and PACE are of limited value to these agencies in assisting them in ascertaining current provider acquisition costs for BMS branded drugs in Pennsylvania. Specifically, the OIG reports were based on national surveys, which did not include Pennsylvania; therefore, these reports were of limited value to Agency employees in attempting to determine the prices paid for drugs by other third-party payors in Pennsylvania. The trial judge also afforded little weight to these reports because they: (1) lacked clarity as to whether the reports included BMS branded drugs; (2) appeared to have included generic drugs, which have much higher spreads than branded drugs, and which were not at issue in this case; (3) reported varying percentages off AWP, making it difficult to gain clarity as to what figure represented an actual average of wholesale prices; and (4) did not cover all the drugs in the case. Also, while the Plaintiff Agencies have the authority to conduct audits, the limited resources of these agencies, coupled with the limited useful information provided, greatly restricted the practical value of these audits. N.T., 8/24/10, at 1923-25 (Snedden); 2058-60, 2075-76, 2110-12 (Cathers). Further, while BMS often referred to the PriceWaterhouseCoopers study, the value of the findings produced by this study were also limited because of the study's self-recognized limitations. <u>See</u> DX-514 at p.7.

#### iv. AMPs and ASPs

As to the AMPs, these are values calculated by the drug manufacturers which are not based on prices paid by providers; rather, AMPs are based on prices paid by wholesalers. N.T., 8/24/10, at 2041 (Cathers). AMPs are used for rebates, not for reimbursement. <u>See id</u>. Moreover, the underlying data is not shared with the Plaintiff Agencies. <u>Id</u>. at 2027. AMP data cannot be used for reimbursement. N.T., 8/24/10, at 1921 (Snedden).

Regarding the ASPs available for download on the internet since 2005, BMS does not contend, nor can it contend, that these prices are available for <u>all</u> of its branded drugs. These prices are available only for Medicare Part B drugs administered by a physician. There is no believable evidence in this case that digital, downloadable ASPs are available for each of the self-administered drugs which comprise the bulk of the drugs addressed in this trial.

#### v. Conclusion

In sum, like Judge Saris in <u>MDL 2007</u>, the trial judge determined the limited government knowledge in this case does not exonerate BMS. <u>See MDL 2007</u>, 491 F.Supp.2d at 94. Instead, similar to Judge Saris, the trial judge determined that BMS contributed to the publication of false AWPs for its branded drugs, knowing the government did not understand the extent of the spread between published prices and true average provider acquisition costs. <u>Id.</u>

Moreover, like Judge Saris in <u>MDL 2007</u>, the trial judge determined that BMS knew that the Plaintiff Agencies could not do much to change the reimbursement benchmark because they were locked into a reimbursement regime established by statute or formal regulation. <u>Id.</u> at 94-95; N.T., 8/16/10, at 687-88, 703-04 (Comanor); <u>see also Alpharma USPD, Inc.</u>, slip op. at 4 (denying post-trial motions of drug manufacturer found guilty of violating consumer protection statute by manipulating AWPs; rejecting "government knowledge" and "government choice" arguments; "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.").

Thus, public payors like DPW and PACE are less "nimble" than private payors such as pharmacy benefits managers, when it comes to their ability to change reimbursement rates. N.T., 8/16/10, at 687-88, 703-04 (Comanor).

93

BMS' conduct exploited the flaws inherent in this system, which discriminates against public payors. <u>Id.</u> at 695, 721, 741, 756-61

Also, 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.

Finally, the language of the proposed injunction against BMS can be tailored to conform to the language in the order granting injunctive relief against Johnson & Johnson Defendants. Such a modification would require BMS to arrange for the transmission to DPW and PACE of current, accurate estimated acquisition costs, such as AMPs or ASPs, for each of its branded drugs, in a format equivalent to that in which AWPs are reported to DPW or PACE, or in another format acceptable to DPW and PACE. With this modification, the injunction will have the effect of conveying accurate estimated cost information so that DPW and PACE no longer need to speculate regarding estimated acquisition costs, a target for which they must aim under federal law.

## 4. Alleged Harm Compensable by Monetary Damages a. Contentions

BMS further argues whatever hypothetical harm the Commonwealth might suffer in the future could be compensated by money damages. In fact, BMS

contends, the Commonwealth sought monetary damages; as such, it asserts, injunctive relief is inappropriate here.

#### **b.** Analysis

BMS did not invite the fact-finder to consider this contention at any time during trial. <u>See</u> N.T., 9/9/10, at 3890-92 (closing on CPL claim). Accordingly, it is waived.

Even on the merits the contention fails. As with several of its other arguments, BMS' assertions on this point are improperly premised on the common law standards for injunctive relief rather than on the statutory scheme at issue here. As explained above, as the primary remedy in an enforcement action by the Attorney General, the CPL contemplates an action for temporary or permanent injunctive relief to restrain CPL violations. 73 P.S. §201-4. Further, the plain language of the CPL states, whenever a court issues a permanent injunction, it may order restoration. See 73 P.S. §201-4.1. Thus, under the CPL, the grant of injunctive relief is a prerequisite to an award of restoration of money in a suit by the Attorney General. In other words, the statutory remedies are not mutually exclusive; rather, they are primary and secondary.

More particularly, Section 4.1 of the CPL states:

<u>Whenever any court issues a permanent injunction</u> 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 <u>restore</u> to any person in interest <u>any moneys</u> 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).

Based on a "plain meaning" interpretation of Section 4.1 of the CPL, a court may only order restoration when it grants a permanent injunction to prevent violations of the CPL as authorized in Section 4. BMS' arguments do not acknowledge the CPL's statutory scheme. BMS' contentions are improperly premised on the common law standards for a grant of injunctive relief, which are inapplicable here. Thus, BMS' arguments fail.

### E. Alleged Lack of Clear Right to Relief

BMS next contends the Commonwealth did not demonstrate a clear right to relief. In support, it advances five contentions: (1) the trial judge's Decision is inconsistent with the jury verdict; (2) BMS' conduct is not fraudulent or deceptive; (3) the trial judge's decision is inconsistent with the <u>MDL 2007</u> decision; (4) there is no proof of causation because pharmacies were not overpaid; and, (5) there is no proof that supports an injunction against marketing the spread.

These contentions appear no different than BMS' initial challenge to the sufficiency of the evidence supporting an injunction. With an eye to completeness, however, we will address them again in more detail.

# 1. Alleged Inconsistency with Jury Verdict

## a. Contentions

BMS asserts the trial judge found BMS' conduct was "unfair or deceptive;" however, the trial judge did not explain his decision. Moreover, BMS contends that there is no basis on which the Court could conclude the Commonwealth demonstrated a "clear right to relief" as required for issuance of an injunction.

BMS argues the only viable "unfair or deceptive practice" at issue here is the CPL's catchall provision. It asserts the provision only applies to instances of fraud or deception, not unfairness. See 73 P.S. 201-2(4)(xxi).<sup>22</sup>

BMS observes that some uncertainty exists in the case law as to whether the General Assembly's addition of the term "deceptive" to the catchall provision in 1996 eliminates the need to prove every element of fraud. Specifically, BMS points out the Superior Court requires proof of fraud when establishing a CPL catchall claim, while the Commonwealth Court does not. Compare Booze v. Allstate Ins. Co., 750 A.2d 877 (Pa. Super. 2000) (private action) with Commonwealth by Corbett v. Manson, 903 A.2d 69 (Pa. Cmwlth. 2006) (action in the public interest). In any event, BMS contends, this Court never held reliance is not required.

 $<sup>^{22}</sup>$  Prior to 1996, the catch-all provision did not contain the phrase "or deceptive", but merely read, "Engaging in any other fraudulent conduct which creates a likelihood of confusion or of misunderstanding." In 1996, the General Assembly modified the catch-all provision to add the phrase "or deceptive" so that it now reads "Engaging in any other fraudulent *or deceptive* conduct which creates a likelihood of confusion or of misunderstanding". Section 2(4)(xxi) of the CPL (emphasis added).

BMS further notes that in <u>Manson</u>, this Court "applied the more relaxed standard, but only to establish that the word 'deceptive' included a 'should have known' negligence standard." BMS' Br. at 25-26. BMS argues the jury here applied this standard when it rejected the Commonwealth's negligent misrepresentation claim. In fact, it contends the trial judge recognized this fact at argument on the CPL claim. As a result, BMS asserts the jury's verdict in its favor on the negligent misrepresentation claim bars the Commonwealth from recovering on its CPL claims under principles of collateral estoppel and <u>res judicata</u>.

BMS further argues, even if the reliance requirement is relaxed in an enforcement action by the Attorney General, the Commonwealth's claim is still barred because BMS defended on grounds other than reliance in presenting its case to the jury. Among other things, BMS notes, it argued it should not be found liable because it only reported truthful prices, and there was sufficient record evidence for the jury to decide the case on that basis. BMS maintains the Court cannot assume the jury decided in favor of BMS based solely on the reliance element, as opposed to whether there was even an initial misrepresentation.

BMS cites several cases, including <u>Beckert v. Warren</u>, 497 Pa. 137, 439 A.2d 638 (1981) and <u>Beacon Theatres</u>, Inc. v. Westover, 359 U.S. 500 (1959), in support of its contention that where, as here, there is a trial involving both legal claims and equitable claims, the legal claim should be decided first and the adequacy of the relief it provides assessed.

BMS further asserts that the jury's findings are dispositive on factual issues common to the legal and equitable issues in order to avoid producing an inconsistent result and to protect the right to a jury trial. See, e.g., Wade v. Orange Cnty. Sheriff's Office, 844 F.2d 951, 954 (2d Cir. 1988). BMS argues the trial judge is not free to disregard the jury's determination of the legal claims when issuing a subsequent ruling on any equitable claims. It asserts this is particularly true where, as here, the Commonwealth objected to a special verdict on the elements of the legal claim, and the trial judge sustained that objection.

In sum, BMS argues the trial judge's disregarding of the jury's verdict would deprive BMS of its constitutional right to a jury trial under the Pennsylvania Constitution, <u>see</u> PA. CONST. art. 1, § 6, and would violate principles of <u>res</u> judicata and collateral estoppel.

#### **b.** Analysis

At the outset, we acknowledge BMS' point that the Commonwealth initially based its CPL claims on four alleged unfair or deceptive practices aside from its claim under the catchall provision. BMS argues none of these other subsections apply here. In fact, at closing argument on the statutory claims, BMS argued the Commonwealth did not offer evidence in support of the four subsections other than the catchall. N.T., 9/9/10, at 3883-84. In its rebuttal, the Commonwealth did not contest BMS' assertion. Further, in its brief in opposition to BMS' post-trial motions, the Commonwealth does not refute this assertion; rather, it focuses its discussion on the applicability of the catchall provision. Thus,

we agree with BMS that the Commonwealth abandoned any CPL claims other than those that fall within the catchall provision.

As to the merits, there is no inconsistency between the jury's verdict and the trial judge's determinations under the CPL. The jury answered "no" when asked whether BMS was liable for negligent misrepresentation, Question 1. <u>See</u> Attachment A. The jury also answered "no" when asked whether BMS was liable for fraudulent misrepresentation, Question 3. <u>Id</u>. The jury did not answer any other questions. Thus, the jury did not answer any questions regarding causation, conspiracy, amount of financial harm or liability for outrageous conduct, Questions 2, 4, 5, 6, 7, and 8. <u>Id</u>. Further, the jury was not asked to decide, and did not decide, the factual issues in the Commonwealth's CPL claim. <u>Id</u>.

The test for deceptive conduct under Section 2(4)(xxi) of the CPL is essentially whether the conduct has the tendency or capacity to deceive, which is a lesser, more relaxed standard than that for fraud or negligent misrepresentation. <u>Commonwealth ex rel. Corbett v. Peoples Benefit Servs., Inc.</u>, 923 A.2d 1230, 1236 (Pa. Cmwlth. 2007); <u>Manson</u>. In short, the Commonwealth must establish the acts or practices are capable of being interpreted in a misleading way. <u>Peoples Benefits Servs</u>. Here, the trial judge determined that AWP is a fictitious price that can mislead both ordinary and sophisticated consumers as to the actual acquisition cost for the branded drugs at issue. Moreover, as discussed elsewhere, the record is clear that significant confusion existed regarding the use of the AWP in the reimbursement system.

Thus. regardless of the jury's verdict on liability for misrepresentation, the trial judge could find in the CPL action that BMS engaged in "deceptive conduct [fictitious or deceptive pricing scheme] which creates a likelihood of confusion or of misunderstanding" within the meaning of Section 2(4)(xxi) of the CPL (catchall provision). See In re Pharm. Indus. Average Wholesale Price Litig. (MDL 2010), 738 F. Supp. 2d 227 (D. Mass. 2010) (in states where consumer protection statutes prohibit deception only, including Pennsylvania, a fact-finder may well conclude that contributing to inflated, fictitious AWPs to circumvent changes in reimbursement constitutes "deceptive conduct").

Also, in awarding a permanent injunction in the public interest under Section 4 of the CPL, the standard to be applied by the court is different from the standard applied in a private action for damages under Section 9.2 of the CPL,<sup>23</sup> or a common law action for fraudulent or negligent misrepresentation. <u>See Weinberg</u> (private actions under Section 9.2 of the CPL distinguished in *dicta* from enforcement actions by the Attorney General under Section 4 to restrain unlawful conduct). In <u>Weinberg</u>, the Supreme Court determined a private plaintiff, who was not actually deceived or influenced by a defendant's false advertisement, cannot recover under Section 9.2 of the CPL on the ground that the false advertisement might deceive a substantial segment of the public. The more relaxed standard applies only in enforcement actions by the CPL. <u>Id.</u>

<sup>&</sup>lt;sup>23</sup> Added by the Act of November 24, 1976, P.L. 1166.

Regardless of the effect of the Supreme Court's decision in <u>Weinberg</u>, this Court interpreted the "catchall" language in Section 2(4)(xxi) of the CPL on several occasions. In <u>Commonwealth v. Percudani</u>, 825 A.2d 743 (Pa. Cmwlth. 2003) (<u>Percudani I</u>), this Court determined the General Assembly's addition of the language "or deceptive conduct" signaled an approval of a less restrictive interpretation of the catchall provision; thus, the Commonwealth need not prove the common law elements of fraud to establish a violation of the catchall provision.

In <u>Manson</u>, which followed <u>Percudani I</u>, this Court recognized the test for deceptive conduct under Section 2(4)(xxi) of the CPL "is whether the conduct <u>might be deceptive to the ordinary consumer, a lesser offense than fraudulent</u> <u>conduct</u> ...." <u>Manson</u>, 903 A.2d at 74 (emphasis added); <u>see also Peoples Benefit</u> <u>Servs.</u> (an act or practice is unfair or deceptive if it has the capacity or tendency to deceive; neither the intention to deceive nor actual deception need be established. Rather, the plaintiff needs only to show the acts or practices are capable of being interpreted in a misleading way). These cases have the effect of eliminating the common law state of mind element (either negligence or intent to deceive), and of softening or eliminating the common law reliance and causation elements implicated in actual deception.

Further, in <u>Pennsylvania Department of Banking v. NCAS of</u> <u>Delaware, LLC</u>, 995 A.2d 422 (Pa. Cmwlth. 2010) (<u>en banc</u>), this Court cited <u>Percudani I</u> and <u>Peoples Benefit Services</u>, and we determined the Attorney General sufficiently stated a claim for deceptive conduct under Section 2(4)(xxi) of the CPL against the defendants, operators of cash advance centers in Pennsylvania. More specifically, the Attorney General averred the defendants offered a loan product (line of credit) to Pennsylvania consumers at an excessive rate of interest. Although the loan product appeared to charge simple interest on the cash advances that corresponded to an annual percentage rate of 5.98%, the added monthly participation fee of \$149.50 essentially resulted in a "real interest rate" of 368%.

In <u>NCAS</u>, this Court again observed neither intention to deceive nor actual deception must be proven; and, it need only be shown that the acts or practices are capable of being interpreted in a misleading way. "The test for the court is to determine the overall impression arising from the totality of what is said, as well as what is reasonably implied ...." <u>NCAS</u>, 995 A.2d at 444 (quoting <u>Peoples Benefit Servs.</u>, 923 A.2d at 1236).

Additionally, in <u>Seldon v. Home Loan Services, Inc.</u>, 647 F. Supp. 2d 451 (E.D. Pa. 2009), the U.S. District Court for the Eastern District of Pennsylvania predicted the Pennsylvania Supreme Court would conclude that a plaintiff alleging deceptive conduct under the catchall provision in Section 2(4)(xxi) of the CPL need not allege the elements of common law fraud. <u>See id.</u> at 468-70.

As a result of the foregoing, it is clear that even if the jury found that BMS did not make a misrepresentation, the jury was not asked to find (and could not find without instructions) whether BMS engaged in deceptive conduct under the CPL. This is a different standard. <u>Peoples Benefit Servs.</u>; <u>Manson</u>; <u>Percudani</u>

103

<u>I</u>. Thus, the jury verdict does not preclude a finding of deceptive conduct by the trial judge on the statutory claims.

As a further result of the foregoing discussion, it is clear that the stateof-mind elements necessary for a common law misrepresentation claim are not prerequisites for a statutory claim under the CPL catchall provision. Therefore, any jury decisions in favor of BMS on state-of-mind elements are irrelevant to the CPL claim.

Also, BMS' conduct was material, as it impacted a nonmalleable reimbursement system to which the Plaintiff Agencies were chained by statute and regulation. Stated differently, because 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, regardless of the jury verdict.

Additionally, the jury verdict does not preclude the trial judge's findings regarding reliance. The CPL does not expressly require proof of reliance. Also, the recent cases in this area compel the conclusion that in an action in the public interest under the catchall provision of the CPL, either there is no reliance element, or it is softened from the common law reliance standard. <u>Id.; see also MDL 2007</u>. Therefore, even assuming the jury found there was no reliance (as that term was defined in instructions), it would not preclude a different determination by the trial judge on the statutory claim.

Further, the Commonwealth proved that BMS' actions caused it to overpay for BMS' branded drugs. As discussed elsewhere, the trial judge accepted the opinion of the Commonwealth's liability and causation expert, Dr. Comanor, on this element. The jury did not answer any question regarding causation, so the trial judge's determination cannot be in conflict with the verdict.

Finally, while BMS correctly contends that legal matters must be determined prior to equitable matters, <u>Beacon Theatres</u>; <u>Beckert</u>, as discussed above, the issues considered by the jury were distinct from the CPL claims considered by the trial judge. Therefore, the jury verdict on common law claims has no preclusive effect on the statutory claims, and there is no affront to BMS' constitutional right to a jury trial.

## 2. Alleged Lack of Fraudulent or Deceptive Conduct a. Contentions

BMS next asserts, even if the issue of deceptive conduct was not conclusively decided by the jury, there is no basis for the trial judge to find BMS acted deceptively. BMS contends the issue of whether conduct is fraudulent or deceptive cannot be determined in a vacuum. It points out that Pennsylvania, like most states, looks to FTC policies and decisions to assist in interpreting the CPL. <u>Monumental Props</u>. BMS notes the FTC, in its Policy Statement on Deception, states: "If a representation or practice affects or is directed primarily to a particular group, the [FTC] examines reasonableness from the perspective of that group." FEDERAL TRADE COMM'N POLICY STATEMENT ON DECEPTION (1983) (Appended to In the Matter of Cliffdale Assocs., Inc., 103 F.T.C. 110 (1984)).

Here, it argues, the Commonwealth had to show persons at DPW and PACE who were responsible for making reimbursement decisions would reasonably believe that AWP was an indication of actual acquisition cost. <u>See Arizona Cartridge Remanufacturers Ass'n.</u>, Inc v. Lexmark Int'l, Inc., 290 F. Supp. 2d 1034 (N.D. Cal. 2003). BMS contends no witness from DPW or PACE testified they thought AWP was an acquisition cost during the relevant time period, much less at the time to which the injunction applies.

#### **b.** Analysis

BMS' arguments fail. Clearly, BMS engaged in or contributed to a scheme of fictitious or deceptive pricing, which falls under the CPL's catchall provision. Indeed, BMS does not seriously dispute that essentially no one paid the fictitious AWPs for BMS drugs.

In addition, while the testimony of the DPW and PACE witnesses reveals they had some knowledge that AWP-based reimbursement was flawed, their testimony also shows substantial confusion over AWP. Thus, they did not understand the extent of the inaccuracy, they did not have a better proxy for estimated provider acquisition cost, and they were chained to an AWP-based reimbursement system by law. The trial judge's determinations in this regard are consistent with those of other courts dealing with AWP litigation. <u>MDL 2007</u>; <u>Alpharma USPD, Inc</u>.

Also, BMS' conduct did not affect just "sophisticated" reimbursement professionals at DPW and PACE. Rather, it also affected reasonable consumers, such as Medicare Part B drug recipients who paid co-payments of 20% of AWPbased reimbursement price. <u>See MDL 2007</u>, 491 F. Supp. 2d at 33, <u>citing 42</u> U.S.C. §1395*l*.

Further, even accepting BMS' intended target audience argument, see Arizona Cartridge (where alleged deceptive business practice is targeted to sophisticated purchaser, question of whether it is misleading will be viewed from vantage point of members of targeted group), this does not alter the conclusion that BMS' conduct was deceptive to the audience. To that end, several other groups involved in buying, selling, and reimbursing pharmaceuticals must also be included in this audience. More particularly, it is appropriate to include BMS employees and corporate officers charged with setting the company's prices. It is also appropriate to include others involved in the establishing drug reimbursement formulae, such as legislators and regulators at IRRC. A target audience would also include providers, such as pharmacy benefit managers, pharmacists and doctors. Because the record reveals confusion among most of these groups, a determination of deception is still appropriate even if the audience is not viewed as simply the "reasonable consumer." See, e.g., N.T., 8/19/10, at 1418, 1460-62 (testimony of Rose Crane, former BMS President of U.S. Primary Care, regarding her belief that AWP was a price paid by wholesalers); N.T., 8/11/10, at 324 (testimony of Paul Norris, BMS' Regional Business Director for the Northeast Region, Oncology Division, that BMS employees within the global marketing organization believed that AWP was "representative of the price that we sold the product."); N.T., 8/23/10, at 1656-57, 1663 (testimony of BMS Vice President of Federal Government Affairs Michael Carozza referring to PX-777, which included

testimony of oncologist Dr. Harvey Golomb before Congressional committee stating that oncologists "routinely pay full AWP for drugs"), <u>id.</u> at 1771 (Carozza referring to PX-413, which related to U.S. Senate Finance Committee's lack of knowledge of markup used to arrive at AWP), <u>id.</u> at 1790-92.

# 3. Alleged Inconsistency of Decision with <u>MDL 2007</u> Opinion a. Contentions

BMS next argues the trial judge relied on the <u>MDL 2007</u> decision in concluding BMS' conduct was unfair or deceptive. However, the trial judge overlooked that part of Judge Saris' decision where she found spreads of 30% or less were not unfair or deceptive, taking into account, "all the facts and circumstances to determine whether the statutory violation involves unfair or deceptive conduct." <u>MDL 2007</u>, 491 F. Supp. 2d at 83. BMS contends Judge Saris found no liability for spreads of 30% or less because "it is undisputed that the market understood and expected a 20 to 25 percent formulaic markup from WAC to AWP." <u>Id.</u> at 91.

BMS maintains the undisputed record of "government knowledge" here is even more compelling than the record knowledge in the <u>MDL 2007</u> decision. It argues, not only did the Commonwealth know the difference between WAC and AWP, but DPW now uses WAC in its reimbursement formula. BMS contends that while it disagrees with much of Judge Saris' opinion in <u>MDL 2007</u>, there is no principled basis under which the trial judge could rely on that opinion, but selectively reject what Judge Saris called her "30 percent speed limit." <u>Id.</u> at 95. In connection with the jury instructions, BMS further asserts that the trial judge relied on Judge Saris to apply a plain meaning interpretation to the DPW regulation and the PACE statute to instruct the jury that AWP means an average price that a wholesaler charges a retailer. However, BMS argues, the issue before Judge Saris was whether AWP in the Medicare statute should be interpreted without reference to the way that term is used by the pricing services. BMS maintains the explicit references to AWP in the "pricing services" in the Pennsylvania statute and regulation bar a plain meaning interpretation here.

BMS also argues that even if a plain meaning interpretation is applied, it does not follow that any AWP that exceeds acquisition cost is deceptive or unfair. It points out that Judge Saris found that spreads less than 30% were not deceptive or unfair notwithstanding her plain meaning interpretation of the Medicare statute. <u>Id.</u> at 97. BMS maintains she found that whether an AWP was deceptive or unfair depended on what people understood, not the statutory definition.

BMS contends that if the 30% "speed limit" is applied here, there can be no liability under the CPL for any self-administered drugs because it was undisputed that self-administered drugs were sold at list price, which is always within 30% of AWP. It asserts the Commonwealth's witnesses Gregory Hamilton and Dr. Comanor admitted this fact. BMS argues its expert, Dr. Gregory Bell, further showed this fact through a detailed statistical analysis that the Commonwealth did not challenge. BMS maintains the Commonwealth also conceded the point relating to self-administered drugs at oral argument on the statutory claim, but nevertheless contended that "injectables" exceeded the 30% limit. It argues Dr. Bell testified that injectables (Medicare Part B pharmaceuticals) were less than 1% of the claims, and the Commonwealth's counsel conceded that they were less than 2%. Needless to say, concerns surrounding less than 2% of all claims do not provide a "statutory basis" for issuing an injunction regarding all AWPs.

Furthermore, BMS asserts there is no systematic proof of what the spreads were for Medicare Part B pharmaceuticals. BMS contends Dr. Warren-Boulton assumed all drugs, including injectables, were acquired at WAC + 2%, which would result in spread of less than 30%. In addition, as noted, BMS reported the ASPs of all injectables to CMS, which publishes them on the internet, since 2004.

# **b.** Analysis

We reject BMS' assertion that the Decision is inconsistent with the decision in <u>MDL 2007</u> because the trial judge chose to ignore the 30% "speed limit" portion of Judge Saris' opinion. In short, BMS did not present credible expert testimony that a 30% "speed limit" was appropriate here. Thus, because the record on liability and causation in this case differs from the record in <u>MDL 2007</u> in that regard, there is no inconsistency between the decisions.

Like Judge Saris, the trial judge concluded the fact that Pennsylvania was slow to change its reimbursement system does not negate causation. <u>MDL</u>

<u>2007</u>, 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 <u>all</u> branded drugs, credibly characterized as "egregious" by the Commonwealth's liability and causation expert, Dr. Comanor. N.T., 8/16/10, at 761. 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. <u>Id.</u> at 756-62.

In addition, BMS' reliance on the testimony of its expert, Dr. Bell, is inappropriate. This is because the trial judge expressly rejected that testimony. Decision of September 10, 2010, n. 2 ("The Court accepts as credible only that part of the testimony of Gregory K. Bell, Ph.D., that the damage estimates of Dr. Warren-Boulton are inflated by the inclusion of drugs not in this case."). BMS fails to explain its reliance on testimony it knows has been rejected.

Further, we reject BMS' contentions that the trial judge erred in applying a plain meaning approach to his construction of the relevant statute and regulation. The trial judge recently explained his plain meaning analysis in an opinion resolving a motion *in limine* filed by Johnson & Johnson Defendants. He explained, in relevant 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 <u>Commonwealth v. TAP Pharmaceutical Products, Inc.</u>, 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. <u>See also [People ex rel. Spitzer v. Pharmacia Corp.</u>, 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).

Thus, in a recent opinion in this litigation, the trial judge provided a thorough and detailed explanation of its decision to utilize the plain meaning construction of the relevant statute and regulation in the BMS trial. BMS advances no persuasive argument that warrants revisiting this interpretation.

# 4. Alleged Lack of Proof of Overpayment

# a. Contentions

BMS further asserts that even if the Commonwealth need not prove reliance in an enforcement action, it still must prove causation. BMS cites this Court's decision at the preliminary objection stage of this litigation for the proposition that the Commonwealth "must prove 'money lost as a result of a violation' to obtain monetary relief under § 201-4.1." BMS' Br. at 33-34 (quoting <u>TAP II</u>, 885 A.2d at 1139-40). BMS cites <u>Weiler v. SmithKline Beecham Corp.</u>, 53 Pa. D. & C. 4th 449 (C.P. Phila. 2001) for the proposition that relaxation of standards under the catchall does not obviate the need to prove a causal connection between the deceptive conduct and the harm alleged.

Here, BMS argues, in the absence of any alleged "violation" by BMS, the Commonwealth cannot prove it would have paid any provider any less. BMS notes DPW and PACE witnesses acknowledged, irrespective of what AWPs were, the total amount paid for drug reimbursement and dispensing fees would have been the same. Essentially, BMS asserts DPW and PACE witnesses conceded that if DPW and PACE reimbursed providers at an amount closer to actual acquisition cost than AWP for its drugs, the Plaintiff Agencies would have had to correspondingly increase the amount of the dispensing fees paid in order to offset the lower reimbursement for drug ingredient costs.

# **b.** Analysis

In <u>TAP II</u>, this Court, in an *en banc* decision, explained:

[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. <u>Hence, if the Court were to conclude that the Defendants' conduct</u> <u>constitutes a violation of the Law, and the</u> <u>Commonwealth establishes the loss of money as a result</u> <u>of the conduct, the Commonwealth may prevail in its</u> <u>claims</u>.

<u>Id.</u> at 1139-40 (emphasis added). As explained in greater detail above, the record clearly supports the trial judge's determination that BMS engaged in unfair or deceptive acts or practices within the meaning of the CPL's catchall provision.

Further, the Commonwealth proved causation of harm through the opinion of its expert on liability and causation, Dr. Comanor. Dr. Comanor believably opined that the Plaintiff Agencies were harmed by enhanced price discrimination by the drug manufacturers, specifically including BMS, on all drugs. 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. N.T., 8/16/10, at 729-31, 765-62. In particular, Dr. Comanor described a conscious decision by BMS executives to increase prices so that public payors paid more, while increasing rebates to private payors, so that they did not suffer from price increases. <u>Id</u>. at 746-62; PX-8951 (BMS pricing document describing "high AWP/aggressive rebate policy").

In addition, contrary to BMS' implications that the Commonwealth did not offer a theory of harm, based on the accepted testimony and opinions of Dr. Comanor regarding liability, and Dr. Warren-Boulton regarding the computation of losses, the Commonwealth established it could have paid providers less absent BMS' violations in reporting inflated, fictitious AWPs for its drugs.

Consequently, the Commonwealth established a causal relationship between BMS' violations of the CPL and the overpayments by DPW and PACE based on the fictitious prices.

Further contrary to BMS' assertions, the relevant inquiry here is not whether pharmacies were overpaid generally, but whether the Plaintiff Agencies overpaid for BMS drugs based on fictitious and deceptive pricing (the inflated AWPs).<sup>24</sup> The pharmacies did not set the fictitious AWPs for BMS drugs. Quite simply, BMS contributed to fictitious and deceptive prices for its drugs, which caused the Plaintiff Agencies to pay more for them than the true market prices.

Finally, we discern no merit in BMS' assertions based on total provider reimbursement. This is a variant of the "government choice" contention which was rejected by the trial judge. The evidence referenced by BMS involved 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.

<sup>&</sup>lt;sup>24</sup> While not controlling here, this distinction was even more apparent in the second trial involving Johnson & Johnson Defendants. Believable evidence in that trial established that providers, such as pharmacies, were overpaid by public payors, but underpaid by private payors.

# 5. Alleged Lack of Proof of Spread Marketing a. Contentions

As a final point, BMS asserts the second clause of the proposed injunction prohibits it from marketing the spread. However, BMS argues there is no proof it had a company policy that permitted marketing the spread. In fact, it contends, it prohibited spread marketing.

In addition, BMS argues, even if the record contains scant evidence that it marketed the spread with regard to physician-administered drugs, as numerous witnesses testified the concept of spread marketing does not even make sense with respect to self-administered drugs because pharmacies have to stock all branded self-administered drugs, and BMS does not discount to retail pharmacies.

## **b.** Analysis

As explained above, similar to Judge Saris' decision in <u>MDL 2007</u>, the trial judge determined BMS contributed to or participated in the promotion or marketing of spreads on physician-administered Medicare Part B branded drugs, sometimes referred to as "injectables." This determination is amply supported by the record. Thus, the record supports a determination that BMS marketed the spread to physicians on physician-administered drugs. As Judge Saris explained:

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

<u>In re Pharm. Indus. Average Wholesale Price Litig.</u>, 520 F. Supp. 2d 267, 271 (D. Mass. 2007) (emphasis added). The trial judge here made the same determinations. As to BMS witness testimony regarding instructions against marketing the spread, the trial judge did not believe these instructions were enforced.

Of further note, with regard to the specific evidence of BMS' spreadmarketing in the record before her, Judge Saris in <u>MDL 2007</u> explained:

> [P]laintiffs presented substantial evidence suggesting that BMS was marketing the spread. ... [T]here is one significant piece of spread marketing evidence that applies to all the BMS drugs at issue here. OTN offered customers an online "Cost Differential" report for BMS drugs. (*See* PX 219.) The site prompted the customer to input a variety of information, including their AWP reimbursement percentage. The site would then display, by regimen, the reimbursement rate, acquisition cost, and "AWP Cost Differential" (equivalent to the spread) for the requested drugs. (*Id.* at 134-36.)

MDL 2007, 491 F. Supp.2d at 62.

The record here contains nearly identical proof that BMS marketed the spread on its physician-administered Medicare Part B branded drugs. <u>See</u> PX-111 (Lynx2OTN); PX-8869 (AWP Price Report); N.T., 8/12/10, at 475-76, 48388, 488-91, 493 (Peterson) (AWP price report shows OTN dispensing unit price and AWP based on selected modifier; acknowledging that spread is the difference between amount of reimbursement and amount paid). Therefore, the record contains substantial evidence to support the trial judge's determination that BMS marketed or promoted spreads.

# **III. BMS' CHALLENGE TO STATUTORY RESTORATION**

Like Johnson & Johnson Defendants, BMS also challenges the trial judge's award of restitution under the CPL. Among other things, BMS asserts the award of restitution should be vacated because: there is no statutory basis for restitution; the trial judge's decision to award restitution is inconsistent with his decision to dismiss the unjust enrichment claim; there is no proof of causation because pharmacies were not overpaid; Dr. Warren-Boulton's damage estimate is not a proper basis for restitution because it is flawed; restitution is inconsistent with the jury's verdict; and restitution under Section 4.1 of the CPL is not appropriate in a suit on behalf of DPW and PACE.

## A. Alleged Lack of Statutory Basis for Restoration

### **1.** Contentions

In its first argument, BMS points out the trial judge awarded \$27.6 million in restitution under Section 4.1 of the CPL, which 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 any 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).

First, BMS argues, if this Court vacates the proposed injunction, there will be no basis for any restitution and thus that part of the trial judge's order must be vacated as well.

BMS further asserts it will not be possible to modify the AWP portion of the injunction in a way that will avoid irreparable harm to innocent third parties. Any relief that would result in pharmacies losing money on prescription drugs would cause pharmacies not to stock them. As a result, there is no way to eliminate the irreparable harm to innocent third parties without also eliminating the basis for restitution.

In addition, BMS argues, even if the Court vacates only the first paragraph of the injunction relating to AWPs, restitution under Section 4.1 must be limited to money "acquired by means of any violation of the [A]ct." 73 P.S. §201-4.1. Thus, if the Court vacates the AWP portion of the injunction, but continues in place the prohibition against marketing the spread, any "restitution" must be limited to restitution or disgorgement of money acquired from marketing the spread. Therefore, because the proof at trial established that spread marketing never occurred with respect to brand name self-administered drugs, and more than 98% of the claims relate to self-administered drugs, restitution cannot exceed \$540,000.

In addition, BMS argues restitution under Section 4.1 is an equitable remedy only available where the defendant acquired money as a result of a violation of the CPL. <u>See Commonwealth ex rel. Corbett v. Ted Sopko Auto Sales & Locator</u>, 719 A.2d 1111 (Pa. Cmwlth. 1998) (restitution under CPL is an equitable remedy). The record clearly shows BMS did not acquire anything. It simply sold drugs at a list price to wholesalers, who, in turn, sold those drugs to providers. Those providers, not BMS, acquired any overpayment made by DPW or PACE.

#### 2. Analysis

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, review 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. <u>Middletown Twp. v. Lands of Stone</u>, 595 Pa. 607, 939 A.2d 331 (2007).

In the preceding section we discussed at length and rejected BMS' challenge to the basis for the injunction. It need not be repeated here.

Nevertheless, BMS argues, even assuming it violated the CPL, there is no statutory basis for ordering restitution because it is not possible to modify the

AWP portion of the injunction in a way that will avoid irreparable harm to innocent third parties.

In a preceding section, we rejected BMS' arguments that the injunction will allegedly cause irreparable harm to others. We concluded that the arguments were waived because they were not raised during trial, that the arguments lack merit because the expert evidence on which they were based was rejected by the trial judge, that the arguments lack merit because the record does not support BMS' factual assertions, that the arguments lack a legal foundation, and that if the injunction is modified to conform to the injunction entered after the second trial involving Johnson & Johnson Defendants, BMS' arguments become moot.

BMS further argues that if the Court vacates the AWP portion of the injunction, but continues the prohibition against marketing the spread, restitution cannot exceed \$540,000. Because we will not vacate the AWP portion of the injunction, no further discussion is needed.

BMS next argues restitution is an equitable remedy only available where the defendant acquired money as a result of a CPL violation. BMS asserts it did not acquire anything; it simply sold its drugs at list price to wholesalers; who, in turn, sold them to providers.

Section 4.1 of the CPL permits the court, in its discretion, to order restoration. Although BMS continually characterizes the remedy as "restitution,"

123

that word does not appear in the text of Section 4.1. 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 <u>TAP II</u> rejected BMS' 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.

<u>Id.</u> at 1139-40 (emphasis added). In accord with <u>TAP II</u>, the Court *again* rejects BMS' argument that statutory restoration is not an appropriate remedy because it did not acquire any money as a result of any CPL violation.

# **B.** Alleged Inconsistency with Dismissal of Unjust Enrichment Claim

# **1.** Contentions

BMS asserts the trial judge granted nonsuit dismissing the Commonwealth's unjust enrichment claim because there was no proof BMS received any money as a result of the alleged scheme. BMS argues restitution under Section 4.1 of the CPL is no different from the remedy for unjust enrichment. In either case, the remedy cannot be imposed without proof the defendant "acquired" money by means of unlawful conduct. Therefore, BMS argues, the trial judge's order for monetary restoration cannot be reconciled with his decision to dismiss the unjust enrichment claim, which was based on the fact that the Commonwealth did not present any evidence regarding an amount unjustly retained by BMS.

#### 2. Analysis

"Unjust [e]nrichment is an equitable doctrine." <u>TAP II</u>, 885 A.2d at 1137. "Under the doctrine, the law implies that a contract exists when a party is found to have been unjustly enriched; the doctrine requires the offending party to pay the plaintiff the value of the benefit he has conferred on the defendant." <u>Id.</u> "A party alleging that a defendant has been unjustly enriched must establish the following: (1) plaintiff conferred a benefit on the defendant; (2) the defendant appreciated the benefit; and (3) acceptance and retention by the defendant of the benefits, under the circumstances, would make it inequitable for the defendant to retain the benefit without paying for the value of the benefit." <u>Id.</u>

"Further, a defendant need not have accepted and appreciated the benefit intentionally; instead, the focus remains on the question of whether the defendant has been unjustly enriched." <u>Id.</u> (citation omitted). "Additionally, the plaintiff bears the burden of establishing either that the defendant wrongfully secured the benefit or passively received a benefit that it would be unconscionable to retain." <u>Id.</u>

In <u>TAP II</u>, this Court noted the Commonwealth did not plead any facts showing DPW and PACE conferred any direct benefit on the defendants. <u>Id.</u>

Nevertheless, the Commonwealth contended that its reimbursement did confer a benefit on defendants, an increase in market share. In the BMS trial, however, the Commonwealth failed to quantify this benefit or to explain how it could be valued.

Conversely, as discussed above, in <u>TAP II</u> this Court determined that restoration under Section 4.1 of the CPL does not require that the money restored originate from payments made to a defendant. Consequently, where, as here, the Commonwealth establishes a violation of the CPL, which resulted in a loss of money to the Commonwealth, the Commonwealth may prevail on its restoration claims under Section 4.1 of the CPL. <u>Id.</u> Therefore, in accord with <u>TAP II</u>, the Court rejects BMS' argument.

## **C. Alleged Absence of Overpayment**

#### **1.** Contentions

BMS next contends restitution is improper because no overpayment occurred. It asserts PACE Director Snedden, Commonwealth's expert, Dr. Comanor, as well as BMS' experts, Drs. Bell and Scott-Morton, all agreed that pharmacies were not overpaid. Where there is no overpayment, BMS argues, there can be no basis for restitution.

BMS again asserts statutory restitution under Section 4.1 of the CPL is no different from the common law remedy for unjust enrichment. The Commonwealth must prove causation to obtain restitution. <u>See Commonwealth by</u> <u>Packel v. Ziomek</u>, 352 A.2d 235 (Pa. Cmwlth. 1976) (remedial compensation under CPL must be based on specific amount lost by aggrieved individuals);

126

<u>Weiler</u> (although catchall provision of CPL does not require proof of common law fraud, it does not obviate the need to establish a causal connection between the alleged deceptive conduct and the harm plaintiffs suffered). BMS asserts the Commonwealth failed to do so here.

Specifically, BMS argues the Commonwealth failed to present evidence in support of a claim for restitution, unjust enrichment or disgorgement under Section 4.1 of the CPL. BMS further argues the trial judge erred in relying on Dr. Warren-Boulton's damages calculation submitted in connection with the fraud claim. BMS contends the Commonwealth did not even attempt to argue this "damages" calculation supported a claim for restitution under the CPL. Thus, BMS contends it did not receive notice and an opportunity to be heard on this issue. <u>See Fiore v. Bd. of Fin. & Revenue</u>, 534 Pa. 511, 633 A.2d 1111 (1993) (procedural due process requires more than notice and hearing; it also protects the right to an orderly hearing adapted to the nature of the case).

#### 2. Analysis

In a previous section we explained at length why BMS' no-proof-ofpharmacy-overpayment contention lacked merit. That discussion need not be repeated. Because the Commonwealth established a violation of the CPL, which resulted in a loss of money, the Commonwealth can prevail on its restoration claims under Section 4.1 of the CPL. <u>TAP II</u>; <u>Northview Motors, Inc. v.</u> <u>Commonwealth ex rel. Zimmerman, 562 A.2d 977 (Pa. Cmwlth. 1989).</u> In addition, to the extent BMS relies on the testimony of PACE Director, Thomas Snedden, and of its experts, Drs. Bell and Scott-Morton, the arguments lack merit. The testimony of these witnesses on this point was rejected as in conflict with the more believable testimony of the Commonwealth's damages expert, Dr. Warren-Boulton. In particular, the testimony of Mr. Snedden on this point appeared to the trial judge to be biased in favor of supporting his past actions. The testimony of the BMS experts, Drs. Bell and Scott-Morton, was also rejected based on demeanor, and Dr. Bell was impeached based on his extensive financial relationship with BMS.

The single answer of the Commonwealth's liability and causation expert, Dr. Comanor, on which BMS relies, was given little weight for two reasons. First, it was an ambiguous answer. Second, Dr. Comanor was not asked to quantify overpayment to or from any party, and he did not express any opinion on this point. As a result, the trial judge viewed Dr. Comanor's answer as one of "no opinion" whether pharmacies were overpaid.

Moreover, BMS' procedural due process rights were not violated. BMS had adequate notice and fair opportunity during the five-week trial to be heard regarding the Commonwealth's statutory restoration claim. BMS received Dr. Warren-Boulton's damage calculations before trial, and its attorneys crossexamined him at length during trial. The trial judge did not restrict BMS from asking Dr. Warren-Boulton how his calculations related to the statutory claim for restoration. BMS' contentions on this issue lack any merit.

# D. Alleged Flawed Damage Estimate

# **1. BMS Contentions**

# a. Drugs Not in the Case

BMS contends there are significant flaws in the way Commonwealth's damages expert calculated damages. BMS recognizes that the trial judge acknowledged Dr. Warren-Boulton's damages included drugs not in the case and relied on BMS expert testimony to reduce damages by 40%.

However, BMS asserts its expert, Dr. Bell, testified that the amount of money the Commonwealth claims it spent on the drugs was inflated by 40%. BMS argues there is no way to determine how much the Commonwealth's damages were inflated by the inclusion of drugs not in the case.

# b. Challenge to "But For" Methodology

Like Johnson & Johnson Defendants, BMS argues the underlying concept of Dr. Warren-Boulton's damage calculation is flawed. He did not calculate the damages Plaintiff Agencies suffered as a result of BMS' conduct. Rather, he simply calculated the money the Commonwealth could have saved if Plaintiff Agencies decided to act another way. Specifically, Dr. Warren-Boulton calculated the amount of money Plaintiff Agencies could have saved had they employed the formula pharmacy benefit managers (PBMs) used to reimburse pharmacies.

Moreover, PBMs used the same AWPs that Plaintiff Agencies used. Dr. Warren-Boulton never explained how those AWPs were deceptive or unfair when DPW used them, but not when PBMs used them. In fact, DPW used a PBM for the managed care part of its business. That PBM (Eagle) reimbursed pharmacies at AWP – 16.5%, which was within the range used by Dr. Warren-Boulton in his damages analysis. However, DPW witnesses testified they knew what their own PBMs were paying, but decided not to expand their use of PBMs because, in the end, they paid less as a result of Medicaid rebates.

#### c. Rebates

Like Johnson & Johnson Defendants, BMS further argues this underscores another flaw in Dr. Warren-Boulton's analysis: he considered the reimbursement part of the PBM equation, but he did not consider the rebates. The Mercer report took rebates into account and concluded that DPW paid less than PBMs. BMS asserts the jury decided to consider the Mercer report, and it urges this Court to do so as well.

# 2. Analysis

#### a. Generally

If the record contains sufficient evidence to support an award of restoration under Section 4.1 of the CPL, the award will not be disturbed. <u>Northview Motors</u>. Issues of credibility and evidentiary weight are within the exclusive province of the trial judge. <u>Id.</u> Further, questions of credibility and resolution of testimonial conflicts are for the trial court. <u>Id.</u>

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." <u>Id.</u> 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. <u>Id.</u>

"The determination of damages is a factual question to be decided by the fact-finder." <u>Delahanty v. First Pennsylvania Bank</u>, 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." <u>Id.</u> "Thus, the law does not demand that the estimation of damages be completely free of speculation." <u>Id.</u> "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." <u>Id.</u> at 1258.

Here, the trial judge relied on the Commonwealth's damage expert, Dr. Warren-Boulton's Revised Expert Report, dated August 9, 2010 (Revised Boulton Rep.) to determine the amount of restoration. <u>See</u> Decision at 2, n.2. In particular, the trial judge accepted Dr. Warren-Boulton's damage methodology, excluding interest, using the national average for PBM payments as a benchmark for what the Plaintiff Agencies would have paid in the "but for" world for BMS branded drugs absent BMS' deceptive practices and fictitious AWPs. The national average for PBM payments is well above what is needed to ensure "access" through an adequate pharmacy network. Dr. Warren-Boulton explained the original intent of the federal legislation was to pay the actual acquisition costs. N.T., 08/25/10, at 2212. PBMs are able to negotiate much lower reimbursement rates than the Plaintiff Agencies. PBMs do not operate under the same institutional constraints as the Plaintiff Agencies. Id. at 2208. PBMs are not bound by determined formulae; rather, they are able to negotiate their own reimbursement rate for each drug. Id. As such, the fictitious AWPs adversely affect the Plaintiff Agencies to a much greater extent than the PBMs.

Further, the trial judge limited the restoration award to the years 1991 through 2004. <u>See</u> Revised Boulton Rep., Exs. 6A, 6B, 6C. This resulted in a total amount of \$46,193,174 for the years 1991 through 2004.

The trial judge's decision not to award statutory restoration post-2004 was based on a number of considerations, including changes in the statutory and regulatory reimbursement formulae for the Plaintiff Agencies, which occurred after 2004, and the passage of the federal Medicare Prescription Drug, Improvement and Modernization Act, which took effect in January 2005.

#### **b. Drugs Not in the Case**

The trial judge also accepted as credible a small portion of the testimony of BMS' expert, Dr. Bell. He testified the number of claims by the Plaintiff Agencies was approximately 40% less than the number of claims considered by the Commonwealth's damage expert, Dr. Warren-Boulton. <u>See</u> N.T., 09/01/10, at 3193-95. The trial judge accepted this testimony because it was

132

confirmed by his independent review of Paragraphs 620 through 636 of the corrected amended complaint (listing BMS drugs at issue) and of the demonstrative exhibits used during Dr. Comanor's direct testimony. Two of the demonstrative exhibits listed the drugs he considered. The trial judge's independent review confirmed that Dr. Comanor considered drugs not in the case. Further, the Commonwealth's damage expert, Dr. Warren-Boulton, relied on Dr. Comanor's expanded listing of BMS drugs. Therefore, the trial judge reduced the \$46,193,197 amount by 40%. The trial judge determined this amount to be \$27,617,952.

# c. Challenge to "But For" Methodology

Viewing the evidence in a light most favorable to the Commonwealth as the prevailing party on the CPL claim, the record supports the trial judge's discretionary determinations as to the amount of restoration. <u>Delahanty</u>. As discussed above, matters of credibility and evidentiary weight are for the factfinder. <u>Northview Motors</u>. The trial judge, as fact-finder in the CPL action, can choose which evidence to believe and which evidence to disregard. <u>Id.</u>

Here, the trial judge accepted Dr. Warren-Boulton's methodology and calculation of restoration. This testimony provides substantial evidence to support the amount of restoration.

The trial judge concluded that the fact of loss was clearly established. The best manner of computing loss was a matter properly reserved to the discretion of the trial judge. Also, BMS' contentions raise questions of credibility and weight of the evidence which are no longer appropriate matters for debate. Although BMS cites evidence that could support different determinations, the proper inquiry is whether there is substantial evidence supporting the findings actually made. Delahanty.

BMS complains that Dr. Warren-Boulton did not explain why AWPs were deceptive for the Plaintiff Agencies but not deceptive for PBMs. This complaint is of no moment, because another witness, the Commonwealth's liability and causation expert, Dr. Comanor, addressed this issue at length. He explained in detail the drug manufacturers' enhanced price discrimination under which there were different price/rebate schemes for public and private payors. He also explained how public payors, like the Plaintiff Agencies, paid more than the private payors, like PBMs. That this explanation came from a witness other than Dr. Warren-Boulton does not entitle BMS to relief.

BMS' arguments relating to DPW's knowledge of reimbursement rates paid by its PBMs are rejected as misleading at best. DPW contracts with managed care organizations, similar to PBMs, only in Pennsylvania's lower southeast and southwest regions, known as "mandatory care zones." N.T., 8/24/10, at 2032. DPW reimburses these managed care organizations on a monthly, fixed fee basis per recipient. This is an entirely different reimbursement system than the "fee-for-service" system in the remainder of Pennsylvania, which was the focus of this trial. The Commonwealth's damage expert's opinions, and the trial judge's restoration calculations, were based only on the fee-for-service reimbursement system. The trial judge reasonably declined to increase the complexity of the case by attempting to compare the two different reimbursement systems used by DPW.

#### d. Rebates

As to rebates, the trial judge rejected as not credible the opinion of BMS' experts, that Plaintiff Agencies, as public payors, actually pay less than private payors after receiving statutory rebates. Rather, the trial judge accepted as more credible the conflicting opinion of the Commonwealth's damage expert, Dr. Warren-Boulton, that rebates are unrelated to the Commonwealth's overpayment based on fictitious AWPs. N.T., 8/25/10, at 2168.<sup>25</sup>

Part of the reason for accepting Dr. Warren-Boulton's opinion derives from the asymmetrical relationship between reimbursements and rebates. Until recently, reimbursement was based on AWP; however, the Omnibus Budget Reconciliation Act of 1990<sup>26</sup> base rebates are a percentage of a different metric, average manufacturers price (AMP). The distinct methodologies for establishing reimbursements and for calculating base rebates are so different that it tended to corroborate Dr. Warren-Boulton's position.

BMS' arguments based on the Mercer report are nothing more than an improper attempt to reargue the trial judge's decision to favor the

 $<sup>^{25}</sup>$  This same point was made with much greater detail during the second trial involving Johnson & Johnson Defendants. N.T., 11/3/10, at 2414-30 (Warren-Boulton). That the same detailed testimony was not offered to a jury is understandable.

<sup>&</sup>lt;sup>26</sup> 104 Stat. 1388-143.

Commonwealth's damage expert over BMS' experts. This is because the Mercer report was primarily used by BMS' experts in the testimony about the effect of rebates. N.T., 9/1/10, at 3183-90 (Bell); N.T., 9/2/10, at 3314-15 (Scott-Morton). This testimony, however, was rejected. Although the jury asked for a copy of the Mercer report during deliberations, the jury never reached the issue of damages; therefore, the trial judge was not compelled to draw any conclusions about the significance of the report.

Considering the foregoing, we discern no merit in BMS' contentions on this issue.

#### E. Alleged Inconsistency with Jury Verdict

### **1.** Contentions

BMS next argues the Court cannot and should not disregard the jury's verdict in this case. If the jury, in taking all the evidence into account, found the Plaintiff Agencies chose to reimburse pharmacies at a higher rate than PBMs on the front-end, because they would receive more in rebates on the back-end, that is fatal to Dr. Warren-Boulton's damage calculation based on PBMs.

BMS urges that the trial judge's award of restitution effectively nullifies the jury's verdict and imposes liability and damages where the jury saw none. BMS argues the trial judge violated its Seventh Amendment right to a jury trial by making findings contrary to those of the jury on factual issues common to all claims. <u>See Roebuck v. Drexel Univ.</u>, 852 F.2d 715 (3d Cir. 1988); <u>Wade</u>.

Further, in its reply brief, BMS argues the jury returned a general verdict on negligent misrepresentation, which must be treated as a finding in favor of BMS on all elements of that claim, including causation and the fact that BMS made no material misrepresentation at all, not just a finding on the reliance element.

#### 2. Analysis

After careful review, we cannot locate where BMS suggested to the trial judge that the jury considered rebates as nullifying offsets in the *liability* part of the case, thereby constraining the fact-finding of the trial judge on the statutory claim. <u>See N.T.</u>, 9/9/10, at 3858-3901 (closing arguments on CPL claim). Indeed, the word "rebate" does not appear anywhere in that volume of the transcript. Given the tortured nature of the suggested inference, this is not surprising. In any event, BMS may not now raise new arguments to re-form the facts.

Moreover, BMS' argument makes no sense. The jury did not decide certain factual issues material to the CPL claim. <u>See</u> Attachment A. Of particular importance, the jury did not render a verdict on causation or on damages. <u>Id</u>. There is nothing in the instructions to the jury which invited them to consider any aspect of damages or offsets in their deliberations on *liability* for misrepresentation. Therefore, the amount of restoration ordered does not conflict with the jury verdict.

Further, as discussed more fully in the previous section addressing whether the injunction is in conflict with the jury verdict, the cases addressing the

137

CPL have the effect of eliminating the common law state of mind element necessary for claims of misrepresentation. <u>See Peoples Benefit Servs.</u>; <u>Manson</u>; <u>Percudani I</u>. Also, the cases have the effect of softening or eliminating the common law reliance and causation elements implicated in actual deception. <u>Id.</u> Simply, the issue of whether BMS' conduct violated the terms of the CPL was not submitted to the jury. Accordingly, there was no conflict when the trial judge decided that issue.

Consequently, the trial judge's injunction (Section 4 of the CPL), and restoration order (Section 4.1 of the CPL), were proper regardless of the jury's verdict.

# F. Alleged Impropriety of Award in Suit on behalf of DPW and PACE 1. Contentions

Like Johnson & Johnson Defendants, BMS contends restitution under Section 4.1 of the CPL is inappropriate in a suit on behalf of the Plaintiff Agencies. BMS' argument is as follows. The CPL is a consumer protection statute. However, there are no consumers involved in this case. Consumers who purchased drugs from pharmacies or had them injected by physicians made a fixed copayment irrespective of the AWP. <u>See</u> 55 Pa. Code §1101.63(b)(5)(i) (amount of co-payment paid to providers by Medicaid recipients for pharmacy services, drugs and over-the-counter medications); Section 519(d) of the State Lottery Law, 72 P.S. §3761-519(d) (co-payments for PACE claimants).<sup>27</sup> Section 4.1 of the CPL is

<sup>&</sup>lt;sup>27</sup> Section 519 was added by the Act of November 21, 1996, P.L. 741. It is clear that for a Medicare Part B covered drug, 80% of the cost is paid for by the government, and 20% is paid **(Footnote continued on next page...)** 

clearly designed to provide restitution to consumers who lose money as a result of CPL violations, not sophisticated entities like DPW and PACE. <u>See Commonwealth v. Ortho-McNeil-Jannsen Pharm., Inc.</u> 13 Pa. D. &. C. 5th 187 (C.P. Phila. 2010) (no fiduciary relationship existed between drug manufacturers and PACE, a sophisticated government entity, in a drug reimbursement case alleging false representations regarding effectiveness of particular drug).

BMS asserts that the Commonwealth is not suing on behalf of consumers. Rather, it is suing in its proprietary capacity on behalf of DPW and PACE. When the Commonwealth sues in its proprietary capacity to obtain damages, it must do so under Section 9.2 of the CPL (private actions), 73 P.S. §201-9.2. A plaintiff seeking money damages under Section 9.2 must prove reliance. <u>Hunt v. U.S. Tobacco Co.</u>, 538 F.3d 217 (3d Cir. 2008). Further, BMS argues the Commonwealth may only seek injunctive relief where it seeks to enforce the CPL on behalf of Pennsylvania consumers. <u>Lofton v. Diolosa</u>, No. 3:CV-05-1193, 2008 WL 2994823 (M.D. Pa. July 31, 2008) (unreported).

The irony of the case, BMS argues, is that it never sought to take advantage of AWPs. BMS contends it did not report AWPs, it did not manipulate AWPs, and it supported passage of the Medicare Modernization Act, which eliminated AWPs as a basis for reimbursement of injectibles under Medicare Part

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for by whoever is responsible for the co-payment. <u>MDL 2007</u>, 491 F. Supp. 2d at 33 (<u>citing</u> 42 U.S.C. §1395*l*). In addition, BMS incorrectly cites 72 P.S. §3761-519(d) as pertaining to PACE claimants. The section instead refers to PACE<u>NET</u> (Pharmaceutical Assistance Contract for the Elderly <u>Needs Enhancement Tier</u>) claimants.

B. Further, BMS never made any representations, much less misrepresentations, about AWPs to either DPW or PACE.

#### 2. Analysis

BMS' arguments do not address the plain language of the CPL. Accordingly, the arguments lack merit.

In its corrected amended complaint, the Commonwealth alleged that BMS engaged in deceptive conduct which creates a likelihood of confusion or misunderstanding within the meaning of Section 2(4)(xxi) of the CPL, 73 P.S. §201-(2)(4)(xxi). This conduct is declared unlawful under Section 3 of the CPL, 73 P.S. §201-3. The Attorney General also alleged that BMS' use of deceptive conduct was willful within the meaning of Section 8 of the CPL, 73 P.S. §201-8. The Attorney General further determined that proceedings to enjoin BMS' unlawful conduct were in the public interest. Corrected Am. Compl. at ¶671. Following a five-week trial, the trial judge determined the Commonwealth proved these allegations.

BMS is a "person" as defined by Section 2(2) of the CPL.<sup>28</sup> Where, as here, the Attorney General had reason to believe BMS engaged in deceptive acts or practices in violation of the CPL, the Attorney General could seek an injunction

<sup>&</sup>lt;sup>28</sup> Section 2(2) of the CPL defines "**person**" as "natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and <u>any other legal entities</u>." 73 P.S. §201-2(2) (emphasis by underline added).

under Section 4 of the CPL upon a determination that such proceedings would be 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 <u>only</u> rather than on behalf of a Commonwealth agency. As expressly authorized, the Commonwealth is the named Plaintiff here. Further, pursuant to Section 204(c) of the Commonwealth Attorneys Act, "[t]he Attorney General shall represent the Commonwealth and all Commonwealth agencies ... in any action brought by ... the Commonwealth or its agencies ...." 71 P.S. §732-204(c).<sup>29</sup> In this case, the Attorney General sued in the name of the Commonwealth on behalf of the Plaintiff Agencies, which he is authorized to do.

Other than referencing the general purpose of the CPL (to protect the public from fraud and unfair or deceptive business practices), BMS cites no precedential authority to support an interpretation of Section 4 that would bar the Attorney General from suing on behalf of the Plaintiff Agencies. Contrary to BMS' 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, the plain language of 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

<sup>&</sup>lt;sup>29</sup> Act of October 15, 1980, P.L. 950, <u>as amended</u>.

in section 4 above, the court may in its discretion direct that the defendant or defendants restore to any person in <u>interest</u> 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." A "person" under the CPL includes "corporations, trusts, partnerships, incorporated and unincorporated associations, and <u>any other legal entity</u>." Section 2(2) of the CPL, 73 P.S. §201-2(2) (emphasis added). BMS does not contend that the Plaintiff Agencies are illegal entities, nor does it contend that the Plaintiff Agencies do not satisfy the broad statutory definition of "person." Based on a common sense reading of the definition, as well as BMS' failure to argue otherwise, we conclude that the Plaintiff Agencies satisfy the definition of "person" as used in the phrase "any person in interest" 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 BMS' CPL violations. Consequently, under the plain language of Section 4.1, restoration is appropriate.<sup>30</sup>

<sup>&</sup>lt;sup>30</sup> 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" **(Footnote continued on next page...)** 

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.<sup>31</sup> Mississippi courts hold that the State of Mississippi is a "person" which can recover damages under that state's consumer protection statute. <u>Hood ex rel. State of Mississippi v. BASF Corp.</u>, 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

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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, <u>as amended</u>, 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.

<sup>31</sup> 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.

entity." Ky. Rev. Stat. Ann. §367.110(1).<sup>32</sup> In AWP litigation under the Kentucky Consumer Protection Act, the state recovered overpayments by the Kentucky Medicaid Program. <u>Alpharma USPD, Inc.</u>, 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. <u>State of Wisconsin v. Abbott</u> <u>Labs et al.</u>, No. 2010AP232-AC, 2011 WL 2039396 (Wis. App. Ct. 2011) (unpublished certification to Wisconsin Supreme Court).

For all these reasons we reject BMS' arguments that restoration to the Plaintiff Agencies is improper.

# **IV. OTHER EVIDENTIARY ISSUES**

BMS also raises various evidentiary challenges. These are mentioned at the end of footnotes in BMS' brief, usually without any analysis, case citations or discussion. While issue-spotting is great sport, without more it is wholly insufficient in a case of this complexity to preserve an issue for judicial review. These issues are waived. <u>See Pa. AFL-CIO by George v. Commonwealth</u>, 563 Pa. 108, 757 A.2d 917 (2000) (party waived claims that it made in passing in a footnote).

 $<sup>^{32}</sup>$  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.

#### **V. BMS' REQUEST FOR STAY**

## A. Generally

As alternative relief, BMS requests a stay of the injunction pursuant to Pa. R.A.P. 1732 (Application for Stay or Injunction Pending Appeal). BMS relies on three cases. <u>Reading Anthracite Co. v. Rich</u>, 525 Pa. 118, 577 A.2d 881 (1990) (relating to weighing the equities); <u>Pa. Pub. Util. Comm'n v. Process Gas</u> <u>Consumers Grp.</u>, 502 Pa. 545, 467 A.2d 805 (1983); <u>Witmer v. Dep't of Transp.</u>, <u>Bureau of Driver Licensing</u>, 889 A.2d 638 (Pa. Cmwlth. 2005).

The decision granting or denying a stay is within the trial court's discretion and will not be overturned absent a clear abuse of discretion. <u>Yatron v.</u> <u>Hamburg Area Sch. Dist.</u>, 631 A.2d 758 (Pa. Cmwlth. 1993).

To prevail on an application for stay pending appeal, a petitioner must satisfy the well-established factors set forth in <u>Process Gas</u>. The four factors considered in determining a request for entry of a stay are as follows: 1) the petitioner must make a strong showing that it is likely to prevail on the merits; 2) the petitioner has shown that without the requested relief, he or she will suffer irreparable injury; 3) the issuance of a stay will not substantially harm other interested parties in the proceedings; and, 4) the issuance of a stay will not adversely affect the public interest.

#### **B.** Likely to Prevail on Merits

BMS argues the first factor does not require a "strong showing" that it is "likely" to prevail, but rather a "substantial case" on the merits of the appeal, "at least where other equitable factors favor a stay." BMS' Br. at 43, 45; Reply Br. at 24. In other words, BMS suggests that the Court give less weight to the first factor based on the strength of the other three factors. <u>Witmer</u> (granting driver's unopposed application for supersedeas, which raised a legal question of first impression). When BMS addresses this factor, it generally asserts "there are substantial procedural and substantive legal issues raised by the Court's decision, which BMS has set forth above." BMS Brief, p. 45. More specifically, BMS claims there are no grounds for injunctive relief or restitution. <u>Id.</u>

In its Reply Brief, BMS argues that both the Commonwealth and the public have an interest in having the substantial legal issues raised by the appeal decided correctly on the merits. As novel and substantial issues in this case, BMS refers to whether the Commonwealth has to prove reliance when it proceeds on behalf of a state agency, whether a defendant can be liable for deceptive conduct when no one in the target audience was deceived and whether a court deciding a CPL claim can make findings inconsistent with the jury's verdict on the common law claims in a case.

To obtain a stay pending appeal, the petitioner must present more than appeal issues which are not frivolous, but rather must show that he is likely to prevail on the merits. <u>Young J. Lee, Inc. v. Dep't of Revenue, Bureau of State Lotteries</u>, 504 Pa. 367, 474 A.2d 266 (1983). However, the first factor is not inflexible. <u>Goslin v. State Bd. of Med.</u>, 937 A.2d 531 (Pa. Cmwlth. 2007). The court considers and weighs the first requirement relative to the other three criteria. <u>Process Gas</u>. "[I]n exercising its discretion to grant or deny a stay pending appeal, this Court may properly grant a stay, even when a litigant has presented a substantial case on the merits, if the litigant's showing with regard to the remaining three factors strongly supports the applicant's request." <u>Goslin</u>, 937 A.2d at 534.

We conclude BMS satisfies the first factor for the grant of a stay pending appeal. BMS raises at least six issues which have not been addressed by the Pennsylvania Supreme Court:

1) What is the meaning of the term "average wholesale price" in the controlling statute and regulation?

2) What is the meaning of the term "deceptive conduct" in the catchall provision of Section 2(4)(xxi) of the CPL?

3) What "audience" should be used in evaluating whether conduct is likely to deceive under the catchall provision of Section 2(4)(xxi) of the CPL?

4) Under what circumstances, if any, may an injunction be issued pursuant to Section 4 of the CPL based on past conduct?

5) May restoration be ordered under Section 4.1 of the CPL where no identifiable fund is retained by the defendant?

6) May restoration under Section 4.1 of the CPL be awarded to Commonwealth agencies, such as DPW and PACE?

Given these substantial legal issues, a stay may be appropriate. However, we must also evaluate the other Process Gas factors.

#### **C. Irreparable Injury without Stay**

BMS asserts irreparable harm will result to it without a stay. BMS essentially relies on arguments previously discussed in Sections II(C)(1), (4) above.

We conclude that BMS fails to satisfy this factor for the reasons discussed above. In short, credible evidence in the record does not support BMS' factual contentions and unwarranted assumptions. Also, if the injunction is modified to more closely resemble the injunction awarded against Johnson & Johnson Defendants, many of BMS' arguments become moot.

#### **D. Stay Not Harm Other Parties**

This portion of BMS' argument is similar to contentions discussed at length in Section II(C) above. Also, BMS contends that if the injunction is stayed, DPW and PACE will have the period pending the outcome of any appeal to study potentially necessary adjustments to their pharmacy reimbursement formulae in the event this Court is affirmed. BMS maintains the Commonwealth is not prejudiced by a stay and maintaining the <u>status quo</u>. In support of its proposition, BMS argues the jury's finding of lack of harm to DPW and PACE and the Commonwealth's acquiescence with a postponed effective date for the order granting the injunction. <u>Id.</u>

We conclude BMS failed to satisfy this factor, as discussed more fully in Section II(C) above. In short, BMS mischaracterizes the language of the injunction and the extent of the jury's verdict. Further, BMS' proofs regarding

148

government "choice" and access (pharmacy participation) were rejected on credibility grounds by the trial judge. Also, if the injunction is modified to more closely resemble the injunction issued against Johnson & Johnson Defendants, many of BMS' contentions become moot.

### E. Stay Not Adversely Affect Public

BMS' argument on this factor is the similar to the one advanced for the second factor, regarding irreparable harm.

As discussed more completely above, in <u>Israel</u>, the Supreme Court affirmed the trial court's opinion, which included the following: "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." <u>Id.</u> at 406, 52 A.2d at 321. Based on this reasoning, we determine that BMS failed to satisfy the no-public-harm factor needed to qualify for a stay pending appeal.

### **F.** Conclusion

Having concluded that BMS did not satisfy all factors needed to qualify for a stay pending appeal, we exercise our discretion by denying the request.

# VI. COMMONWEALTH'S CHALLENGE TO VERDICT ON COMMON LAW CLAIMS

Through its motions for post-trial relief, the Commonwealth seeks JNOV, or, in the alternative, a new trial, as to DPW's claim for negligent misrepresentation following the jury verdict in favor of BMS. The Commonwealth does not seek JNOV or a new trial on the Department of Aging/PACE's claim for negligent misrepresentation. In addition, the Commonwealth seeks JNOV on its claims for conspiracy on behalf of the Plaintiff Agencies or, in the alternative, a new trial on such claims.

## A. Standards for Analyzing Motions for JNOV and New Trial

This Court fully addressed the applicable standards for JNOV and new trial in <u>Department of General Services v. U.S. Mineral Products. Co.</u>, 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).

# B. Elements of Negligent Misrepresentation Claim/Section 552 of the Restatement (Second) of Torts

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. <u>Bortz v. Noon</u>, 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." <u>Id.</u> 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. <u>Id.</u>

In Bilt-Rite Contractors, Inc. v. The Architectural Studio, 581 Pa. 454,

866 A.2d 270 (2005), our Supreme Court discussed a trio of cases that comprised the Court's recent jurisprudence on the tort of negligent misrepresentation. The Court recognized that in each of these cases, it approvingly cited, but never formally adopted, Section 552 of the Restatement (Second) of Torts regarding negligent misrepresentation, which provides:

§ 552. Information Negligently Supplied For The Guidance Of Others

(1) One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

(2) Except as stated in Subsection (3), the liability stated in Subsection (1) is limited to loss suffered

(a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and

(b) through reliance upon it in a transaction that he intends the information to influence or knows that the recipient so intends or in a substantially similar

transaction.

(3) The liability of one who is under a public duty to give the information extends to loss suffered by any of the class of persons for whose benefit the duty is created, in any of the transactions in which it is intended to protect them.

RESTATEMENT (SECOND) OF TORTS: MISREPRESENTATION §552 (1977).

In <u>Bilt-Rite</u>, the Supreme Court held that a contractor could maintain a negligent misrepresentation claim against an architect for alleged misrepresentations in the plans upon which the contractor relied in submitting its bid for a school construction project. After a detailed examination of the language of Section 552 of the Restatement and cases interpreting that Section, the Court stated:

[W]e hereby adopt Section 552 as the law in Pennsylvania in cases where information is negligently supplied by one in the business of supplying information, such as an architect or design professional, and where it is foreseeable that the information will be used and relied upon by third persons, even if the third parties have no direct contractual relationship with the supplier of information. In so doing, we emphasize that we do not view Section 552 as supplanting the common law tort of negligent misrepresentation, but rather, as clarifying the contours of the tort as it applies to those in the business of providing information to others.

<u>Id.</u> at 482, 866 A.2d at 287. Ultimately, the Court held the contractor's claim fell within Section 552 and that neither the absence of privity between the contractor and the architect nor the economic loss doctrine barred the contractor's claim. With regard to the latter, the Court stated, "to apply the economic loss doctrine in the

context of a Section 552 claim would be nonsensical: it would allow a party to pursue an action only to hold that, once the elements of the cause of action are shown, the party is unable to recover for its losses. Thus, we hold that the economic loss rule does not apply to claims of negligent misrepresentation sounding under Section 552." <u>Id.</u> at 483-84, 866 A.2d at 288.

The facts of the present case fall within the parameters of Section 552 of the Restatement; however, the application of this Section, within the drug-pricing context, appears to be an issue of first impression in Pennsylvania.

#### **C. Preliminary Matters**

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. <u>Lahr v. City of York</u>, 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. <u>Id.</u>

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. <u>Hinkson v. Dep't of Transp.</u>, 871 A.2d 301 (Pa. Cmwlth. 2005).

## **D. JNOV – Negligent Misrepresentation**

The Commonwealth argues it is entitled to JNOV based on the sufficiency of the evidence and, separately, based on the law.

BMS disputes the Commonwealth's assertions, but, as a threshold matter, it asserts the Commonwealth did not properly preserve its right to seek JNOV based on the sufficiency of the evidence.

#### 1. Waiver

#### a. Contentions

BMS first argues the Commonwealth did not properly preserve its claim for JNOV based on the sufficiency of the evidence because it did not move for a directed verdict after the close of all the evidence.

The Commonwealth does not respond to this argument.

#### **b.** Analysis

In order to preserve its right to seek JNOV based on the sufficiency of the evidence, the Commonwealth was required to seek a directed verdict after the close of all the evidence. <u>U.S. Mineral Prods.</u>; see Pa. R.C.P. No. 226(b). By failing to do so, the Commonwealth waived its right to seek JNOV based on the sufficiency of the evidence. <u>Id.</u>

More specifically, in <u>U.S. Mineral Products</u>, this Court applied Pa. R.C.P. No. 227.1(b)(1), which states "post-trial relief may not be granted unless the grounds were raised at trial by some appropriate method, if available." <u>Id.</u> at 725. This Court then adopted the approach taken by our Superior Court, which "requires a motion for directed verdict during trial as a prerequisite to a post-trial motion for JNOV <u>based on the state of the evidence</u>." <u>Id.</u> (emphasis added). The Court explained "this approach has the salutary effect of submitting the issue to the trial judge for initial evaluation during trial, when the proofs are still fresh, and is consistent with past practice and with the current rule governing post-trial practice ....." <u>Id.</u> In <u>U.S. Mineral Products</u>, the Court concluded the plaintiff did not preserve its right to seek JNOV "by not ask[ing] the trial judge to consider a directed verdict on the first special interrogatory." <u>Id.</u>

Here, the Commonwealth sought a directed verdict after the close of its case-in-chief; however, it did not move for a directed verdict at the close of all the evidence, which is the appropriate time for seeking a directed verdict. See Pa. R.C.P. No. 226(b) (with emphasis added) ("[a]t the close of <u>all</u> the evidence, the trial judge may direct a verdict upon the oral or written motion of any party").<sup>33</sup> The Rules do not empower the trial court to grant a directed verdict earlier. Consistent with <u>U.S. Mineral Products</u>, the Commonwealth waived its right to seek JNOV based on the state of the evidence.

#### 2. Merits

## a. Entitlement to JNOV based on the sufficiency of the evidence

#### i. Contentions

The Commonwealth argues the "[e]vidence (both admitted and rejected) ... overwhelming[ly] ... establishe[s] that BMS made multiple misrepresentations of material fact with respect to their AWPs that were relied upon by [DPW] in reimbursing BMS drugs ....." Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 18, 20. The Commonwealth suggests BMS conceded the Commonwealth satisfied all the elements of a negligent misrepresentation claim except for reliance because BMS only challenged the reliance element in its closing argument to the jury.

 $<sup>^{33}</sup>$  On the other hand, BMS moved for a directed verdict after all the evidence was presented. N.T., 9/7/10, at 3537. The trial judge denied the motion. <u>Id.</u>

The Commonwealth argues that "legally" BMS should not have been able to challenge reliance using the evidence it presented. In particular, the Commonwealth asserts DPW had a legal obligation to abide by the pricing scheme set forth in statute, and it lacked the power to change the system. The Commonwealth maintains the trial judge erred in allowing evidence of generalized knowledge that AWPs do not constitute actual averages of wholesale prices. The Commonwealth argues this evidence was particularly confusing because the trial judge instructed the jury that DPW was required to reimburse providers for prescription drugs based on AWP.

The Commonwealth also argues that once the trial judge admitted this "general knowledge" evidence, the trial judge should have also allowed specific evidence that: state and federal authorities were only investigating a few companies from the hundreds of companies in the industry; some of the companies acknowledged wrongdoing; some companies were criminally prosecuted; and, some companies were ordered to provide actual average sales prices for their drugs.

#### ii. Analysis

Much of the Commonwealth's argument in support of its request for JNOV based on the state of the evidence asks this Court to address evidentiary issues, 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 §64:15 (footnotes omitted); see Drew v. Laber, 477 Pa. 297, 383 A.2d

158

941 (1978); <u>Broxie v. Household Fin. Co.</u>, 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); <u>see Drew</u>; <u>Henry Shenk Co. v. City of Erie</u>, 352 Pa. 481, 43 A.2d 99 (1945). Thus, the Commonwealth's 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 relate to 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>U.S. Mineral Prods.</u> A court may not vacate a jury's 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." <u>Birth Center v. St.</u> <u>Paul Cos., Inc.</u>, 567 Pa. 386, 398, 787 A.2d 376, 383 (2001) (citations omitted). The Court must view the evidence in the light most favorable to the verdict winner. <u>Id.</u> The Court must resolve any doubts in favor of the verdict winner. <u>Id.</u>

"A jury is entitled to believe all, part or none of the evidence presented .... A jury can believe any part of a witness' testimony that they choose, and may disregard any portion of the testimony that they disbelieve." <u>Estate of</u> <u>Hicks v. Dana Cos., LLC</u>, 984 A.2d 943, 961 (Pa. Super. 2009), <u>appeals denied</u>, \_\_\_\_\_ Pa. \_\_\_\_, \_\_\_\_, 19 A.3d 1051, 1052 (2011). The Commonwealth presented significant evidence tending to establish: (1) BMS contributed to reporting of false AWPs for its branded drugs, <u>see MDL 2007</u>; (2) BMS acted knowing the falsity of the AWPs reported for its branded drugs; and, (3) BMS 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, and a contrary jury verdict on these elements would compel close scrutiny.

However, there was sufficient evidence adduced at trial that could support a jury finding that the Plaintiff Agencies did not rely on the accuracy of reported AWPs. On the element of reliance, the trial judge instructed the jury in accordance with Section 17.240 [formerly 13.22] of the Pennsylvania Suggested Standard Jury Instructions (Civil), which states:

> <u>'Reliance' means a person</u> would not have acted (or <u>would not have failed to act</u>) as he or she did unless <u>he or she considered the misrepresentation to be true.</u> The appropriate test of reliance is whether the misrepresentation induced or influenced the course of conduct by the Plaintiff Agencies.

N.T., 9/8/10, at 3771-72 (emphasis added). Whether the party claiming to have been defrauded relied on a false representation is a question of fact. <u>Drelles v.</u> <u>Mfrs. Life Ins. Co.</u>, 881 A.2d 822, 840 (Pa. Super. 2005).

Here, the parties presented conflicting evidence on the factual issue of whether the Plaintiff Agencies relied on the false AWPs for BMS 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, BMS 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 jury may have found that the failure of the Plaintiff Agencies to change their conduct was caused by confusion or by legal or structural constraints rather than by a belief that the reported AWPs were true average wholesale prices. Further, the jury could have determined that such a circumstance did not constitute reliance as defined by the trial judge in the instructions.

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. <u>See MDL 2007</u>; <u>see also Alpharma USPD</u>, Inc., slip op. at 4-7, 11-12 (denying post-trial motions of drug manufacturer in AWP litigation under Kentucky Consumer Protection Act; rejecting "government knowledge" and "government choice" arguments by drug manufacturer; regardless of their personal knowledge or opinions about the proper meaning of AWP, state Medicaid officials were obligated to implement the law as written). In contrast, the common law tort of negligent misrepresentation which we presently address requires proof of classic reliance.

Where, as here, the evidence is conflicting on a material fact, a court should not enter JNOV. <u>U.S. Mineral Prods.</u> For all these reasons, we deny the request for JNOV based on the sufficiency of the evidence.

## b. JNOV "as a matter of law"

#### i. Contentions

The Commonwealth focuses on the reliance element of DPW's negligent misrepresentation claim. Citing <u>Scaife Co. v. Rockwell-Standard</u> <u>Corporation</u>, 446 Pa. 280, 285 A.2d 451 (1972), the Commonwealth asserts that whether reliance on an alleged misrepresentation is justified depends on whether the recipient knew or should have known the information supplied was false. The Commonwealth also cites <u>Siskin v. Cohen</u>, 363 Pa. 580, 70 A.2d 293 (1950), for the proposition that, "[w]here the means of obtaining information are not equal, the positive representations of the person who is supposed to possess superior means of information may be relied on." <u>Id.</u> at 584, 70 A.2d at 295 (quoting <u>Emery v. Third Nat'l Bank of Pittsburgh</u>, 314 Pa. 544, 548, 171 A. 881, 882 (1934)).

The Commonwealth then argues the jury's verdict is clearly against the weight of the evidence. The Commonwealth concedes BMS showed one or two representatives of DPW knew AWP was a misnomer, but BMS did not establish that the agency itself possessed such knowledge. The Commonwealth further argues BMS did not produce evidence that DPW definitively knew of the spreads for BMS drugs. The Commonwealth contends DPW justifiably relied on AWP because AWP was the only published price for BMS drugs.

The Commonwealth devotes a substantial portion of its brief to a discussion of precedent from federal courts and courts of other states. The ensuing discussion does not address the elements of a negligent misrepresentation claim, but instead addresses the following principles: (1) pricing information is

162

presumptively material; (2) advertised prices of any kind must be realistic; (3) it is not a defense to assert DPW should have known of the deception; (4) it is immaterial whether BMS itself published the deceptive prices; and, (5) the purported knowledge of one government agency may not be imputed to another agency of that government. For these reasons, the Commonwealth seeks JNOV "as a matter of law."

#### ii. Analysis

The Commonwealth incorrectly invites us 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, BMS. <u>U.S. Mineral Prods.</u>

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. <u>Scaife</u> and <u>Siskin</u> 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 <u>Scaife</u> and <u>Siskin</u>, 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 <u>Scaife</u> and <u>Siskin</u> 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 BMS' alleged violations of certain legal duties from an unidentified legal 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 on the common law claims, for

164

several reasons.

First, the Commonwealth cites no authority that establishes that the elements for claims brought under the CPL's catchall provision and claims for negligent misrepresentation are one in 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. <u>See Clark v. Pfizer, Inc.</u>, 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); <u>but see In re</u> <u>Neurontin Mktg., Sales Practices & Prods. Liab. Litig</u>, 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.

#### c. Practical Considerations

The Commonwealth devotes no discussion to the practical

implications of its request for JNOV on behalf of DPW on a theory of negligent misrepresentation. The jury did not reach questions about causation or damages. Accordingly, even if JNOV would be awarded on the liability issue, a new trial would be required to resolve unanswered jury questions of causation and damages.

Moreover, since DPW prevailed on the statutory claim and was awarded restoration for its losses, any award of damages for common law claims would likely be set-off against the statutory restoration amounts to protect against double recovery. Thus, while it is theoretically possible for DPW to recover more on retrial, the advisability of a new trial is unclear at best.

#### **E.** New Trial – Negligent Misrepresentation

The Commonwealth argues the trial judge made four general evidentiary errors that warrant a new trial. Specifically, it contends the trial judge erred in: admitting general, non-particularized evidence regarding the purported knowledge of DPW; refusing certain evidence that tended to show reasonable reliance; allowing evidence of conduct outside the relevant time period; and precluding certain evidence as cumulative.

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. <u>Cheng v.</u> <u>Se. Pa. Transp. Auth.</u>, 981 A.2d 371 (Pa. Cmwlth. 2009). Further, "[e]videntiary rulings that [do] not affect the verdict will not provide a basis for disturbing the jury's judgment." <u>Helpin v. Tr. of Univ. of Pa.</u>, 969 A.2d 601 (Pa. Super. 2009), <u>aff'd, \_\_\_\_</u> Pa. \_\_\_, 10 A.3d 267 (2010).

## **1.** General, non-particularized evidence regarding knowledge

#### a. Contentions

The Commonwealth first argues the trial judge erred in permitting BMS to present generalized evidence of "government knowledge" that AWP generally did not represent an actual average of wholesale prices because such evidence did not relate to the particularized fraud and misrepresentation at issue. The Commonwealth asserts the purported knowledge offered by BMS did not relate to BMS branded drugs or to specific BMS conduct. The Commonwealth contends this evidence was particularly confusing because the trial judge instructed the jury that DPW was required to reimburse providers for prescription drugs based on AWP. The Commonwealth asserts the only evidence the jury should have considered regarding DPW's knowledge should have been specific evidence relating to BMS drugs, BMS' AWPs and BMS' wrongful conduct, not DPW's general knowledge regarding AWP.

#### **b.** Analysis

While the Commonwealth asserts it repeatedly objected to the admission of evidence regarding generalized knowledge, for the most part it does not identify where in the record it preserved this issue. Given the massive trial record here, this lapse significantly impedes our ability to efficiently review the issue. The Commonwealth's failure to support its argument with record citations is fatal to its claim. Pa. R.C.P. No. 227.1(b)(2); Estate of Hicks (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, we disagree with the merits of Commonwealth's argument. The two exhibits identified by the Commonwealth, DX-551 and DX-553, are clearly relevant and admissible.<sup>34</sup> They relate to knowledge by persons at DPW with responsibility for the reimbursement of drugs that reported AWPs were not a true averages of wholesale prices. Such knowledge was relevant to the element of reliance. This is because under a common law definition of reliance, conduct must be predicated on a belief that a representation is true.

The Commonwealth's arguments go to the weight of the evidence, not its admissibility. The trial judge did not limit any attempts by the Commonwealth to present its "weight" arguments to the fact-finder. That the Commonwealth apparently failed to persuade the fact-finder to give little weight to this evidence is not a sufficient basis for post-trial relief.

<sup>&</sup>lt;sup>34</sup> The Commonwealth cites DX-553 as an example of what it considers improper "government knowledge" evidence. DX-553 was a survey of drug prices performed by Gerald Radke in the 1980s. The Commonwealth notes none of the drugs in the survey were BMS drugs. <u>See N.T., 8/24/10, at 2111-12</u>. The Commonwealth also cites DX-551, which BMS used during the cross-examination of Dr. Terri Cathers. It is a 1990 DPW/Medicaid memorandum which could demonstrate notice to those who wrote or received it that AWP was not representative of the actual acquisition cost of pharmaceuticals.

#### 2. Reasonable reliance evidence

#### a. Contentions

The Commonwealth next argues the trial judge erred in excluding relevant evidence regarding DPW's reasonable reliance on BMS' AWPs in the context of a statutory scheme that required reimbursement based on this value. The Commonwealth offers no record citations that identify where it offered any such evidence. Instead, it provides a general description of this evidence followed by a discussion as to how the trial judge precluded evidence of guilty pleas by officers of TAP and AstraZeneca, among others, investigations of BMS and other drug companies by Congress and the Department of Justice, and invocations of the Fifth Amendment by company executives and physicians (with whom the drug companies allegedly conspired). The Commonwealth contends that because the trial judge excluded this evidence, the jury heard a one-sided view of DPW's continued reliance on AWPs as a basis for drug reimbursement.

### **b.** Analysis

The Commonwealth's failure to identify where in the ponderous transcript the trial judge made his exclusionary rulings significantly interferes with our ability to efficiently review this assignment of error. The trial judge believes these rulings were explained on the record at the time they were made, often at the beginning of the morning or afternoon sessions, outside the presence of the jury. Given the number of issues the parties want addressed, it is an unreasonable burden for the trial judge to locate all the transcript references. For these reasons, the issue is waived. Pa. R.C.P. No. 227.1(b)(2); see Browne v. Commonwealth,

843 A.2d 429 (Pa. Cmwlth. 2004) (failure to effectively set forth argument on issue in brief in support of post-trial motions results in waiver).

As to the merits, the trial judge properly shielded the jury from such inflammatory evidence as guilty pleas and Fifth Amendment invocations by other drug companies (not BMS) and their employees. While this evidence may have some minimal probative value on conspiracy issues, the probative value was far outweighed by the tendency to inflame the jury. <u>See</u> Pa. R.E. 403. It was not an abuse of discretion to exclude this evidence.

Further, the trial judge allowed considerable evidence regarding DPW's confusion about real average wholesale prices and its reliance on published AWPs, discussed elsewhere in this opinion. Thus, the jury did not receive a one-sided view of the reliance issue. Under these circumstances, it is unclear how the excluded evidence may have produced a different result except by unfairly inflaming the jury.

Regarding investigations of BMS and other drug companies by Congress, the trial judge ruled multiple times on this evidence, and explained his reasons for excluding it on the record. <u>See, e.g.</u>, N.T., 9/1/10, at 3071 (sustaining legal relevance objection to another "Stark" letter, from Congressman Pete Stark, Ranking Member, Committee on Ways and Means); PX-827. No abuse of discretion is evident.

170

#### 3. Evidence beyond the relevant time period

#### a. Contentions

The Commonwealth also argues the trial judge's "most significant ... ruling" was the decision to admit documents from irrelevant time periods, both before 1991 and after 2008. Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 35. The Commonwealth argues it raised objections to the presentation of this evidence, but it does not identify where in the record it preserved these objections. The Commonwealth also notes the trial judge first began to sustain objections relating to timeframe during the Commonwealth's cross-examination of a BMS witness, pharmacist David Smith.

The Commonwealth argues, "[i]t was only at the end of the trial, during the charge conference, that the [trial judge] decided to charge the jury that evidence after 2008 should not be considered, although the [trial judge] allowed such evidence in at trial. The same ruling should have been made as to evidence prior to the relevant time period." <u>Id.</u> The Commonwealth asserts the trial judge's subsequent instruction did not cure the earlier error.

The Commonwealth argues the trial judge's error is compounded by decisions the Court made during discovery.<sup>35</sup> To that end, the Commonwealth notes the Court restricted it to discovery of documents within the relevant time period, while defendants, including BMS, were permitted to obtain information from DPW concerning its purported "knowledge" prior to and after the relevant

<sup>&</sup>lt;sup>35</sup> Discovery rulings were made by then-President Judge James Gardner Colins and later by President Judge Bonnie Leadbetter over several years.

time period. The Commonwealth maintains BMS had an unfair advantage at trial and was able to present a skewed record on "knowledge." It asserts DPW lacked the ability to present contrary evidence regarding BMS' conduct "behind the scenes" to conceal relevant knowledge because of the Court's discovery limitations. The Commonwealth argues the Court compounded this error by placing "rigid limitations" on it during discovery by requiring it to produce an authenticating witness for each late produced document it sought to use.<sup>36</sup>

#### **b.** Analysis

As with its preceding arguments, the Commonwealth fails to specify where it preserved objections at trial. The trial judge believes there were extensive on-the-record discussions about this issue, during which he explained his rationale. Because the failure to specify transcript references significantly impedes our review, the issue is waived. Pa. R.C.P. No. 227.1(b)(2); Estate of Hicks; Hinkson.

<sup>&</sup>lt;sup>36</sup> Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 7. Early in its brief, the Commonwealth spends considerable time identifying what it avers were multiple discovery violations by BMS and other defendants. <u>See</u> Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 5-7. The Commonwealth does not explain how this discussion ties into its claims for post-trial relief; however, the discussion seems to relate to the Commonwealth's claims regarding admission of evidence outside the relevant time period.

The Commonwealth argues BMS prevented it from reviewing relevant evidence by producing nine boxes of documents shortly before trial commenced. The Commonwealth argues the Court indicated it would sanction defendants for such discovery abuse. It asserts: "Plaintiffs went to trial against BMS fully expecting that the Court's discovery rulings would carry through to the trial proofs and evidentiary rulings thereon ...." Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 7. The Commonwealth contends the Court erred in not imposing sanctions against BMS for discovery violations. The Commonwealth argues the trial judge should have granted its motion *in limine* in which it sought an adverse inference based on BMS' late production of documents.

Further, the Commonwealth contends that counsel for BMS highlighted two documents from 1986 and 1990 during his closing argument; however, the Commonwealth did not raise any objection during closing argument. By failing to do so, the Commonwealth did not preserve this argument. <u>U.S.</u> <u>Mineral Prods.</u>, 598 Pa. at 347, 956 A.2d at 976 (failure to lodge objection to closing argument so as to afford trial judge a contemporaneous opportunity to take corrective action resulted in waiver).

Additionally, the Commonwealth's claim fails on its merits. Regarding evidence before 1991, when the Commonwealth's claim for restoration began, the argument goes to the weight rather than the admissibility of the evidence. The evidence was obviously admissible and relevant to the reliance element. As discussed above, the evidence tended to show notice to responsible persons at DPW that reported AWPs were not true averages of wholesale prices. The Commonwealth was free to argue to the jury that the evidence should be given less weight because it was remote in time. That the Commonwealth failed to persuade the fact-finder, however, does not justify a second opportunity to do so in a new trial.

As to evidence after 2008, the trial judge ruled that such evidence could inject collateral and unfairly confusing issues because it covered the period of heated national debate over health care reform. After the ruling, the trial judge consistently precluded evidence beyond 2008 when asked to do so by formal objection. Further, the trial judge provided the jury with a limiting instruction, directing it to consider evidence through 2008. <u>See N.T.</u>, 9/8/10, at 3767 ("As a

173

preliminary matter, the Plaintiff [A]gencies seek damages for the period 1991 through 2008. During the trial I limited the evidence to matters occurring through 2008. That's the evidence before you."); <u>Id.</u> at 3794 (identifying the period as "from 1991 through 2008, or you know, any lesser period within that, within that time frame that you find is appropriate.") "Generally, in the absence of extraordinary circumstances, a prompt and effective curative instruction which is directed to the damage done will suffice to cure any prejudice suffered by the complaining party. Moreover, juries are presumed to heed a court's curative instructions." <u>Mt. Olivet Tabernacle Church v. Edwin L. Wiegand Div.</u>, 781 A.2d 1263, 1275 (Pa. Super. 2001), <u>aff'd per curiam</u>, 571 Pa. 60, 811 A.2d 565 (2002) (citations and quotations omitted).

The Commonwealth also engages in an extensive discussion regarding BMS' alleged discovery violations. This Court previously rejected the Commonwealth's arguments that BMS violated discovery orders.<sup>37</sup> Further, contrary to the Commonwealth's assertions, it is not clear the Court erred in any of its discovery rulings. In addition, the Commonwealth does not explain how such alleged errors impact the outcome of the claim for negligent misrepresentation. Further, the Commonwealth does not explain how the Court's present decision should be shaped by these supposed violations.

<sup>&</sup>lt;sup>37</sup> BMS argues the Court repeatedly rejected the Commonwealth's assertions that BMS did not comply with its discovery obligations. For example, BMS notes President Judge Leadbetter rejected the Commonwealth's request for an order directing BMS to comply with prior orders. President Judge Leadbetter concluded the Commonwealth: did not specifically identify BMS' disclosure deficiencies; attempted to exceed prior rulings; and, had not yet "digested material already received." BMS' Br. at 4 (quoting Commonwealth Court Order of 6/14/10, at n.1). BMS notes the trial judge rejected a similar motion by the Commonwealth at trial. <u>Id.</u> (citing N.T., 8/16/10, at 640).

Both parties identify what they consider numerous acts of bad faith by the other with regard to the manner in which discovery proceeded. While discovery difficulties may have arisen, the parties had ample time to conduct discovery. Both parties labored under the same time constraints.

#### 4. Evidence of wrongful conduct

#### a. Contentions

As a final point to its arguments relating to alleged evidentiary errors, the Commonwealth asserts the trial judge erred in precluding certain evidence of BMS' wrongful conduct on grounds it was "cumulative," as in the case of evidence that mentioned BMS' wholly-owned subsidiary, Apothecon, or "irrelevant," as in the case of certain BMS branded drugs that faced generic competition. The Commonwealth asserts these rulings effectively precluded whole swatches of relevant evidence that Judge Saris admitted in her bench trial in <u>MDL 2007</u>, which involved BMS and some of the same drugs at issue here.

#### **b.** Analysis

This issue is not set forth in the argument section of the Commonwealth's brief; rather, it is raised in the Commonwealth's lengthy discussion of the applicable standard for a new trial. By not developing this argument with appropriate record citations or analysis, the Commonwealth waived it. <u>Browne</u>.

As to the merits of this claim, the trial judge did not exclude evidence relating to Apothecon as cumulative; rather, the trial judge excluded the evidence because it related to generic drugs, which were not at issue in this case. Also, the trial judge did not exclude evidence regarding drugs that faced generic competition; rather, he admitted such evidence to the extent offered by the parties.

With regard to the Commonwealth's statement that Judge Saris admitted similar evidence in <u>MDL 2007</u>, the trial before Judge Saris proceeded as a bench trial, not a jury trial. Unlike the trial judge in this case, Judge Saris was not concerned about protecting a jury from evidence that, even if relevant, could cause unfair prejudice, confusion of the issues or have a tendency to mislead the jury. Pa. R.E. 403.

#### **5. Practical Considerations**

As discussed above in relation to the Commonwealth's request for JNOV, a new trial on the common law negligent misrepresentation claim may have little or no positive effect on any ultimate recovery by the Commonwealth. This is because any damages recovered on common law claims may be set-off against the restoration award made on the statutory claim. Such a set-off may be required to prevent double recovery by DPW.

# F. Conspiracy – Motions for JNOV and New Trial 1. Contentions

The Commonwealth also seeks JNOV on its claims for conspiracy on behalf of the Plaintiff Agencies or, in the alternative, a new trial on such claims. Specifically, the Commonwealth challenges the trial judge's decision that allowed the jury to reach the conspiracy claim only upon the finding of an underlying tort. The Commonwealth asserts the trial judge should have permitted the jury to consider whether BMS engaged in a conspiracy to violate the CPL.

The Commonwealth maintains, "[d]espite the fact that the Court had ruled that BMS had violated the [CPL], neither the Court nor the jury was ever given an opportunity to render a verdict as to whether BMS had engaged in a civil conspiracy to violate the [CPL]." Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 33. The Commonwealth argues a civil conspiracy is a combination of two or more actors with a common purpose to do an unlawful act, and the trial judge found BMS engaged in unlawful acts under the CPL. Thus, the Commonwealth contends, JNOV is appropriate.

Notably, after setting forth its argument in support of JNOV on its conspiracy claim, the Commonwealth's entire discussion regarding its request for a new trial on this claim consists of only one sentence: "For the reasons set forth above, the Court should grant a new trial as to Plaintiffs' conspiracy claims." Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 36. Thus, the argument above forms the basis for the Commonwealth's requests for JNOV and a new trial.

BMS counters the Commonwealth's claim for conspiracy to violate the CPL is "newly minted." BMS asserts the Commonwealth changed its theory of conspiracy after the jury reached its verdict. BMS asserts the Commonwealth's complaints regarding conspiracy based on violations of the CPL are waived pursuant to Pa. R.C.P. No. 227.1(b).

177

#### 2. Analysis

#### a. Waiver

The Commonwealth waived its contention that the jury should have been permitted to consider its claim that BMS engaged in a conspiracy to violate the CPL. The Commonwealth never expressly identified a violation of the CPL as the predicate to its conspiracy claim.

Specifically, in response to questions from the trial judge seeking an explanation of its conspiracy theory, counsel for the Commonwealth did not mention a purported conspiracy to violate the CPL during oral argument on BMS' motion for compulsory non-suit on the conspiracy claim. <u>See N.T.</u>, 8/26/10, at 2353-54.

Similarly, counsel for the Commonwealth did not mention a purported conspiracy to violate the CPL during closing argument. See N.T., 9/7/10, at 3604-90 (Haviland), 3747-48 (Eichen). Further, the Commonwealth's proposed points for charge regarding its conspiracy contentions did not mention the CPL at all. Thus, the Commonwealth did not identify a claim for conspiracy to violate CPL at trial. Failure to do so results in waiver. See Broxie, 472 Pa. at 377, 372 A.2d at 743 ("in order to preserve for appellate review an issue concerning the correctness of a trial court's charge to the jury, the complaining party must submit a specific point for charge or make a timely, specific objection to the charge given.")

The Commonwealth points to one objection pertaining to the trial judge's charge to the jury on conspiracy. Specifically, at the charge conference,

counsel for the Commonwealth stated, "Conspiracy, I do object to the issue of whether or not the predicate act has to be one of fraud or something stronger than that." N.T., 9/7/10, at 3582. He further maintained the issue was a "wrongful act," and "[t]hat's what the conspiracy charge goes to. We are not suggesting negligence, per se, gets to it, but if they have committed a misrepresentation--" Id. The Commonwealth's counsel again insisted, "All I'm suggesting, the predicate doesn't have to be tort." Id. at 3583:2-16. Despite this vague objection, the Commonwealth never expressly identified violation of the CPL as the predicate to its conspiracy claim. Therefore, the Commonwealth's general objection was not sufficient to place the trial judge on notice regarding this theory.

In sum, the Commonwealth did not preserve a claim based on BMS' purported conspiracy to violate the CPL.<sup>38</sup> See Pa. R.C.P. No. 227.1(b)(1).

- (i) to inflate the average wholesale prices ("AWPs") for BMS drugs;
- (ii) to create or promote "spreads" for BMS drugs;

(iv) to conceal the truth about the acts or practices described in (i) through (iii) above.

## (Footnote continued on next page...)

<sup>&</sup>lt;sup>38</sup> The Commonwealth also complains the jury verdict form used by the trial judge differed from the proposed form it submitted by requiring an affirmative response to Questions 3 and 4 (fraudulent misrepresentation) before the jury could proceed to Question 5 (civil conspiracy).

The Commonwealth's proposed verdict form included three questions with subsections. The first two questions related to fraudulent misrepresentation and negligent misrepresentation. The third question asked, "Did defendant [BMS] <u>conspire or agree</u> with any other drug company or any other person or entity to do any of the following:

<sup>(</sup>iii) to maintain AWP-based reimbursement for drugs by public payers, like the Department of Public Welfare/Medicaid and the Department of Aging/PACE; or

#### **b.** Merits

The foregoing notwithstanding, in the interest of completeness we address the merits of the Commonwealth's post-trial motions regarding its conspiracy claim. We conclude the Commonwealth misunderstands the law.

Contrary to the Commonwealth's assertions, a claim for civil conspiracy does, in fact, require proof of a separate underlying tort as a predicate. <u>See Sprinturf, Inc. v. Southwest Recreation Indus., Inc.</u>, 281 F. Supp. 2d 784 (E.D. Pa. 2003). As the Third Circuit explained, "The rule that civil conspiracy may not exist without an underlying tort is a common one. Indeed, we are unaware of any jurisdiction that recognizes civil conspiracy as a cause of action requiring no separate tortious conduct." <u>Boyanowski v. Capital Area Intermediate Unit</u>, 215 F.3d 396, 405-06 (3d Cir. 2000) (citation and quotation omitted). Even the cases referenced by the Commonwealth involved underlying intentional torts. <u>See Phillips v. Selig</u>, 959 A.2d 420, 437 (Pa. Super. 2008) (affirming trial court's dismissal of interference with contract claims, thereby finding "no predicate cause of action exists upon which Appellants may assert claims for civil conspiracy"); Weaver v. Franklin Cnty., 918 A.2d 194, 202 (Pa. Cmwlth. 2007) (because

## (continued...)

Although the Commonwealth's proposed form differed from the one used by the trial judge, the Commonwealth ultimately agreed with the verdict form drafted by the trial judge. N.T., 9/7/10, at 3557 (responding with general agreement to trial judge's proposed verdict form). Moreover, the Commonwealth does not provide any record citation that corresponds with an objection to the verdict form. Thus, the Commonwealth waived any objection related to the verdict form.

"[p]laintiff cannot recover for the underlying torts of intentional infliction of emotional distress and libel, there can be no conspiracy as to them").

As to whether an intentional CPL violation could serve as the predicate to a conspiracy claim, the Commonwealth acknowledges that no other court addressed the validity of such a claim. <u>See</u>, <u>e.g.</u>, <u>Knipmeyer v. Bell Atl.</u> <u>Corp.</u>, 51 Pa. D. & C. 4th 225 (C.P. Phila. 2001) (although plaintiffs' complaint against public utility included claim for conspiracy to violate CPL, court dismissed complaint based on filed rate doctrine); <u>Westfield Grp. v. Campisi</u>, No. 2:02 CV 997, 2006 WL 328415 (W.D. Pa. Feb. 10, 2006) (mentioning claim of conspiracy to violate CPL without substantive discussion). Our independent research reveals no authority that clearly supports the Commonwealth's position.

For both of these additional merit-related reasons, the Commonwealth is not entitled to post-trial relief on its civil conspiracy claims.

#### **3. Alleged Evidentiary Errors**

As explained above, the Commonwealth contends evidentiary errors occurred at trial in four areas, which prejudiced its proof of conspiracy. These include: admission of general, non-particularized evidence of the purported "knowledge" of the Plaintiff Agencies; exclusion of evidence tending to show "reasonable reliance" by the Plaintiff Agencies; admission of evidence beyond the relevant time period; and, exclusion of certain evidence of BMS' wrongful conduct. The Commonwealth does not identify where in the record it preserved these evidentiary issues. For the most part, the Commonwealth also fails to specifically identify the evidence it believes was improperly admitted or excluded. Accordingly, this claim is waived.

More importantly, the Commonwealth does not persuasively explain how any of these alleged evidentiary errors resulted in prejudice regarding its conspiracy claim. To the limited extent that review of the claimed evidentiary errors is possible based on the deficiencies in the presentation of these issues, the Commonwealth's claims fail on their merits for the reasons stated in our analysis of the Commonwealth's request for a new trial on its negligent misrepresentation claim. Thus, the Commonwealth cannot prevail on its motion for a new trial on its conspiracy claim.

# VII. COMMONWEALTH'S REQUEST FOR MODIFICATION OF DECISION REGARDING CPL

#### **A.** Contentions

In his Decision regarding the CPL, the trial judge: (1) determined BMS violated the CPL by engaging in unfair or deceptive practices; (2) issued a perpetual injunction restraining BMS from engaging in these practices; (3) directed BMS to restore to the Commonwealth money in the amount of \$27,617,952, <u>see</u> Section 4.1 of the CPL; (4) found BMS willfully used practices declared unlawful by the CPL, <u>see</u> Section 8(b) of the CPL, but determined he lacked sufficient information to calculate civil penalties based on the evidence presented by the Commonwealth; and, (5) awarded no damages or reasonable attorney fees under Section 9.2 of the CPL.

With regard to civil penalties, the trial judge accepted as credible the civil penalty methodology set forth in Dr. Warren-Boulton's revised expert report, assuming a violation occurred each time the reported AWP changed for a BMS drug, and assessing each violation at \$1000. This was the most conservative methodology offered by the expert. The trial judge indicated, however, the expert's calculations were not limited to the period 1991-2004 for which restoration was awarded and could be inflated by drugs not in the case. Thus, the trial judge declined to adopt the calculations.

The Commonwealth now requests modification of the Decision by amending it to provide for costs, attorney fees, and civil penalties.

BMS counters the Commonwealth did not submit evidence for the relief it now seeks, such as a statement of costs or attorney fees, or a revised expert report with a proper calculation of civil penalties. Thus, BMS contends the Commonwealth is not entitled to the relief requested.

#### 1. Costs

The Commonwealth asserts an award of costs is proper under Section 4.1 of the CPL 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

183

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 BMS to justice.

The Commonwealth further maintains that the Court should consider both the Plaintiff Agencies' constrained fiscal abilities and the vulnerable citizens who benefit from these programs. The Commonwealth asserts an award of costs is appropriate to ensure the restoration awarded is not diminished by the effort expended in ending the illegal practices. Thus, the Commonwealth asks this Court provide "an award of reasonable costs under [Section 4.1 of the CPL] (providing an appropriate time for the Plaintiffs to submit a statement of costs for the Court's review and approval)." Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 38.

#### 2. Attorney Fees

The trial judge 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]." Pls.' Revised Mem. of Law in Support of Mot. for Post-Trial Relief Pursuant to Pa. R.C.P. 227.1 at 42 (citing <u>TAP II</u>).

The Commonwealth contends the trial judge found BMS violated the CPL. Pursuant to the 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 BMS employed acts or practices declared unlawful. 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.

#### **3. Civil Penalties**

The Commonwealth also points out Section 8 of the CPL provides for an award of civil penalties in actions brought under Section 4. It contends that in enacting the CPL, the General Assembly saw fit to provide for imposition of civil penalties in two separate and distinct circumstances: violation of an injunction issued under Section 4; and willful employment of unlawful acts or practices in actions brought under Section 4. <u>See</u> Sections 8(a), (b) of the CPL, 73 P.S. §201-8(a), (b). Indeed, by providing for civil penalties, the General Assembly intended to create an enforcement tool to be utilized to effectuate the CPL's purposes. <u>See</u> <u>Commonwealth by Packel v. Ziomek</u>, 352 A.2d 235 (Pa. Cmwlth. 1976).

According to the Commonwealth, civil penalties are appropriate here based on the trial judge's finding that BMS "willfully used practices declared unlawful by statute." Decision Awarding Injunction, filed September 10, 2010, at ¶3. The Commonwealth further asserts an award of civil penalties is consistent with orders issued by courts in Massachusetts, Kentucky and Wisconsin, which the Commonwealth's counsel referenced in his closing on the CPL claims. The Commonwealth also points out in <u>MDL 2007</u>, Judge Saris permitted a supplemental calculation of penalties after trial.

The Commonwealth relies on an attachment to its memorandum in support of its post-trial motions, which is another revised expert report from Dr. Warren-Boulton that includes new calculations of civil penalties that incorporate the trial judge's concerns regarding temporal limits and specific BMS drugs at issue in this case.

#### **B.** Analysis

#### 1. Costs

Generally, in a case under the CPL, a trial court's decision to award costs will not be disturbed absent abuse of discretion. <u>Neal v. Bavarian Motors</u>, <u>Inc.</u>, 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. <u>Wallace v. Pastore</u>, 742 A.2d 1090 (Pa. Super. 1999); <u>Com. ex rel. Corbett v. Ted Sopko Auto Sales & Locator</u>, 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. <u>Sternlicht v. Sternlicht.</u>, 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. <u>Dep't of Envtl. Prot. v.</u> <u>Bethenergy Mines, Inc.</u>, 563 Pa. 170, 758 A.2d 1168 (2000).

In general, costs are incident to a final judgment. <u>Novy v. Novy</u>, 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. <u>Clark v. Reardon</u>, 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). <u>See generally</u> 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. <u>Id</u>.

Substantively, however, where the proceeding is based on a statute, the right to recover costs must be found in the statute.<sup>39</sup> <u>Dep't of Transp., Bureau</u> <u>of Driver Licensing v. Rapp</u>, 589 A.2d 805 (Pa. Cmwlth. 1991).

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

<sup>&</sup>lt;sup>39</sup> 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. <u>Richmond v. Pa. Higher Educ. Assistance Agency</u>, 297 A.2d 544 (Pa. Cmwlth. 1972).

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 <u>restore</u> to any person in interest <u>any moneys</u> or property, real or personal, <u>which</u> <u>may have been acquired by means of any violation of this</u> <u>act</u>, 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]." <u>Id.</u> It is unclear how costs would qualify under this language.

We acknowledge that the title of this unconsolidated statutory provision is "Costs and Restitution." However, 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.

#### 2. Attorney Fees

Also, the provisions of the CPL governing enforcement actions by the Attorney General do not specifically authorize an award of attorney fees. <u>See</u> 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,<sup>40</sup> 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 Decision Awarding Injunction, filed September 10, 2010, ¶4. For this additional reason, the trial judge did not abuse his discretion in failing to award private action attorney fees to the Commonwealth.

#### **3. Civil Penalties**

Although the Commonwealth asks this Court to revisit the trial judge's decision regarding civil penalties, the record is deficient on this issue. The Commonwealth seeks to cure this deficiency by submitting supplemental materials

<sup>&</sup>lt;sup>40</sup> <u>Compare</u> New Jersey Consumer Fraud Act, N.J. Stat. Ann. §56:8-19 ("In all actions under this section, <u>including those brought by the Attorney General</u>, <u>the court shall also award</u> reasonable attorneys' fees, filing fees and reasonable costs of suit.") (Emphasis added.)

from Dr. Warren-Boulton as an attachment to its memorandum in support of its post-trial motions. It contends the attachment responds to the trial judge's concerns regarding the information submitted at trial.

The Commonwealth's belated submissions are clearly improper. Acceptance of these submissions at the post-trial stage would deprive BMS the opportunity to cross-examine Dr. Warren-Boulton on his supplemental materials or to provide alternative calculations of its own. Clearly, this Court cannot countenance the Commonwealth's attempt to supplement the trial record with new, extra-record materials. Unlike in <u>MDL 2007</u>, the Commonwealth's primary authority in support of its request for civil penalties, here the trial judge did not invite additional, post-trial submissions on the issue of civil penalties.<sup>41</sup>

For these reasons, we reject the Commonwealth's requests to modify the Decision.

#### **VIII. CONCLUSION**

For all the reasons discussed, we deny the Commonwealth's post-trial motions. For the most part, we also deny BMS' post-trial motions. However, pursuant to Pa. R.C.P. No. 227.1, we make two modifications. First, we modify Paragraphs 1(a) and (b) of the permanent injunction to enjoin the following conduct:

<sup>&</sup>lt;sup>41</sup> Notably, after the second trial in this case, which involved Johnson & Johnson Defendants, the trial judge accepted the Commonwealth's expert's calculation of civil penalties pursuant to Section 8(b) of the CPL, which was tailored to the period of 1991-2004 and properly included in the record.

(a) 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 Bristol-Myers Squibb 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; and,

(b) 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 Bristol-Myers Squibb branded drugs which are reimbursed by the Plaintiff Agencies.

The purpose of this modification is to more closely conform the BMS injunction to that issued after the second trial involving Johnson & Johnson Defendants. See Non-Jury Decision, filed December 7, 2010,  $\P$ 3(a).

Second, we modify the amount of restoration awarded in Paragraph 2 of the Decision Awarding Injunction from \$27,617,952 to \$27,715,904, to correct a clerical error.<sup>42</sup>

Finally, BMS' request for stay pending appeal is denied.

ROBERT SIMPSON, Judge

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

<sup>&</sup>lt;sup>42</sup> The amount of restoration awarded in Paragraph 2 of the September 10, 2010 Decision Awarding Injunction contained a mathematical error. The trial judge inadvertently failed to add amounts from Exhibit 6B from the Revised Expert Report of Frederick R. Warren-Boulton, Ph.D., despite the intention to do so, as stated in note 2. The amount inadvertently omitted was \$163,255, representing Federal Settlement NDCs for DPW, excluding interest, from 1991 through 2004, before 40% reduction. Accordingly, the Court molds the amount of the judgment on its own motion.

## 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 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	:
Derenualits	

# <u>O R D E R</u>

**AND NOW**, this 31<sup>st</sup> day of August, 2011, it is **ORDERED and DECREED** as follows:

1) Post-trial motions of the Commonwealth are **DENIED**; and

2) Post-trial motions of Bristol-Myer Squibb Co. are **GRANTED** in **part and DENIED in PART**. The motions are **GRANTED** only to the extent that Paragraphs 1 (a) and (b) awarding a permanent injunction are hereby **MODIFIED** to enjoin the following conduct:

(a) 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 Bristol-Myers Squibb 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,

(b) 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 Bristol-Myers Squibb branded drugs which are reimbursed by the Plaintiff Agencies.

In all other respects, the post-trial motions of Bristol-Myers Squibb Co. are **DENIED**; and

3) Request of Bristol-Myer Squibb Co. for a Stay Pending Appeal is **DENIED**; and

4) The Chief Clerk shall enter judgment in favor of the Commonwealth of Pennsylvania and against Bristol-Myers Squibb Co. in the amount of \$27,715,904.

ROBERT SIMPSON, Judge

### IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania,	:	
Plaintiff	:	
	:	
v.	:	No. 212 M.D. 2004
	:	
Bristol Myers Squibb Company, et al.,	:	
Defendant	nesiton	

#### <u>VERDICT FORM</u> PHASE I

question. If your answer is "no," do not answer question 4; instead, proceed to

**INSTRUCTIONS:** If you answer a question, please provide one answer. If you agree that each answer represents the vote of at least 10 jurors, sign below.

1. Is Defendant Bristol-Myers Squibb liable for negligent misrepresentation?

 $(1) \quad \text{Yes}$   $(2) \quad \text{No}$ 

If your answer to question 1 is "yes," please proceed to the next question. If your answer is "no," do not answer question 2; instead, proceed to question 3.

2. Was any negligent misrepresentation a cause of financial harm to the Plaintiff Agencies?

Please answer the next question.

3. Is Defendant Bristol-Myers Squibb liable for fraudulent misrepresentation?

(1) Yes 

If your answer to question 3 is "yes," please proceed to the next question. If your answer is "no," do not answer question 4; instead, proceed to question 5.

4. Was any fraudulent misrepresentation a cause of financial harm to the Plaintiff Agencies?

(1) Yes

L. Is Defendent Bristol-Myers Squibb liable for negligent (2) and the securation?

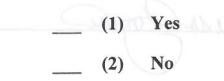
Only answer question 5 if you answered "yes" to both questions 3 and 4. If you did not answer "yes" to both questions 3 and 4, skip questions 5 and 6, and go directly to the instructions before question 7.

5. Is Defendant Bristol-Myers Squibb liable for conspiracy?

\_\_\_\_\_ (1) Yes \_\_\_\_\_ (2) No

If your answer to question 5 is "yes," please proceed to the next question. If your answer is "no," do not answer the next question; instead, proceed to question 7 and follow the instructions.

6. Was any conspiracy involving Defendant Bristol-Myers Squibb a cause of financial harm to the Plaintiff Agencies?



Only answer question 7 if you answered "yes" to both questions 1 and 2, or to both questions 3 and 4, or to both questions 5 and 6. If you did not answer "yes" to at least one of those pairs of questions, stop and return to the courtroom.

7. In what amount has conduct of Defendant Bristol-Myers Squibb, or a conspiracy involving Bristol-Myers Squibb, caused financial harm to the Plaintiff Agencies?

\$

Only answer question 8 if you answered "yes" to both questions 3 and 4, or to both questions 5 and 6. If you did not answer "yes" to at least one of those pairs of questions, stop and return to the courtroom.

8. Is Defendant Bristol-Myers Squibb liable for outrageous conduct?

(1) Yes

\_\_\_\_ (2) No

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After your verdict is signed by the jury foreperson, please return to the courtroom.

Jury Foreperson

Date:

Only answer question 8 if you answered "yes" to both questions 3 and 4, or to both questions 5 and 6. If you did not answer "yes" to at least one of those pairs of questions, stop and return to the courtroom.

8. Is Defendant Bristol-Myers Squibb liable for outrageous conduct?

# IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania, Plaintiff

v.

No. 212 M.D. 2004

Bristol-Myers Squibb Company, et al. Defendant

## DECISION AWARDING INJUNCTION and RESTORATION

AND NOW, this 10th day of September, 2010, after trial in the above-referenced matter, it is **ORDERED** and **DECREED** as follows:

1. Pursuant to Section 4 of the Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTPCPL), 73 P.S. §201-4, the Court finds that Defendant Bristol-Myers Squibb Company violated the statue by engaging in unfair or deceptive practices;<sup>1</sup> accordingly, a perpetual injunction is hereby issued restraining Defendant Bristol-Myers Squibb Company, its agents, attorneys, employees, and assigns, and each of them, from the following such acts:

<sup>&</sup>lt;sup>1</sup> The Court acknowledges the jury verdicts finding neither negligent misrepresentation nor fraudulent misrepresentation. The Court concludes, however, that the standard to be applied in a UTPCPL enforcement action is different. <u>See Weinberg v. Sun Company, Inc.</u>, 565 Pa. 612, 777 A.2d 442 (2001). Pursuant to this conclusion, the Court determines that 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 under Section 4 of the UTPCPL. <u>See In re Pharm. Indus. Average Wholesale</u> <u>Price Litig.</u>, 491 F.Supp.2d 20, 93-95 (D. Mass. 2007); <u>see also Com. v. Parisi</u>, 873 A.2d 3 (Pa. Cmwlth. 2005)(UTPCPL to be liberally construed to effectuate legislative goal of consumer protection).

(a) Contributing in any manner, directly or indirectly, to the reporting to the Pennsylvania Department of Public Welfare or to the PACE program of inflated average wholesale prices for Bristol-Myers Squibb drugs; and,

(b) Contributing in any manner, directly or indirectly, to the creation, 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 Bristol-Myers Squibb drugs which are reimbursed by the Pennsylvania Department of Public Welfare or by the PACE program; and

2. Pursuant to Section 4.1 of the UTPCPL, 73 P.S. §201-4.1, the Court directs that Defendant Bristol-Myers Squibb restore to the Commonwealth of Pennsylvania money in the amount of \$27,617,952;<sup>2</sup> and

3. Pursuant to Section 8(b) of the UTPCPL, 73 P.S. §201-8(b), the Court finds that Defendant Bristol-Myers Squibb willfully used practices declared unlawful by the statute, including the acts described in Paragraph 1; however, the

<sup>&</sup>lt;sup>2</sup> The Court accepts as credible the damage methodology excluding interest set forth in Exhibits 6A, 6B, and 6C of the Revised Expert Report of Frederick R. Warren-Boulton, Ph.D. (August 9, 2010), for the period 1991 through 2004, with one exception. The Court accepts as credible only that part of the testimony of Gregory K. Bell, Ph.D., that the damage estimates of Dr. Warren-Boulton are inflated by the inclusion of drugs not in this case. Therefore, the Court reduced Dr. Warren-Boulton's damage estimates by 40%.

Court has insufficient information to calculate civil penalties, and it therefore declines to award any;<sup>3</sup> and

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

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). The period for filing post-trial motions regarding the jury verdict and this non-jury decision shall commence with the filing of this Decision.

ROBERT SIMPSON, Judge

<sup>&</sup>lt;sup>3</sup> The Court accepts as credible the civil penalty methodology set forth at page 11 and Exhibit 9 of the Revised Expert Report of Frederick R. Warren-Boulton, Ph.D. (August 9, 2010), assuming a violation occurred each time the reported AWP changed for a Bristol-Myers Squibb Company drug, and assessing each violation at \$1000. The calculations, however, are not limited to the period 1991-2004 for which restoration is awarded and may be inflated by drugs not in the case. Accordingly, the calculations were not adopted by the Court.