[J-52B-2014] IN THE SUPREME COURT OF PENNSYLVANIA MIDDLE DISTRICT

CASTILLE, C.J., SAYLOR, EAKIN, BAER, TODD, MCCAFFERY, STEVENS, JJ.

COMMONWEALTH OF PENNSYLVANIA : No. 85 MAP 2011

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TAP PHARMACEUTICAL PRODUCTS, INC.; ABBOTT LABORATORIES; ASTRAZENECA PLC; ASTRAZENECA, HOLDINGS, INC.; ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; BAYER AG; BAYER CORPORATION; SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE; PFIZER, INC.; PHARMACIA CORPORATION; JOHNSON & JOHNSON; ALZA

CORPORATION; CENTROCOR, INC.; ETHICON, INC.; JANSSEN

PHARMACEUTICAL PRODUCTS, L.P.; MCNEIL-PPC, INC.; ORTHO BIOTECH, INC.; ORTHO BIOTECH PRODUCTS;

L.P.; ORTHO-MCNEIL

PHARMACEUTICAL, INC; AMGEN, INC.; IMMUNEX CORPORATION; BRISTOL-MYERS SQUIBB COMPANY; BAXTER INTERNATIONAL INC.; BAXTER HEALTHCARE CORPORATION; IMMUNO-U.S.. INC.; AVENTIS

PHARMACEUTICALS, INC.; AVENTIS BEHRING, L.L.C.; HOECHST MARION

ROUSSEL, INC., BOEHRINGER INGELHEIM CORPORATION:

BOEHRINGER INGELHEIM

PHARMACEUTICALS, INC.; BEN VENUE

LABORATORIES; BEDFORD

LABORATORIES; ROXANE

LABORATORIES; SCHERING-PLOUGH

CORPORATION; WARRICK

PHARMACEUTICALS CORPORATION; SCHERING SALES CORPORATION;

Appeal from the decision of the

Commonwealth Court (Opinion re Post-Trial Motions of the Commonwealth and Bristol-Myers Squibb Company) dated

8/31/11 at No. 212 MD 2004

ARGUED: May 7, 2013

RE-SUBMITTED: April 25, 2014

DEY, INC.

DONNA A. BOSWELL, ESQ., ANN M. VICKERY, ESQ., AND JOSEPH A.

YOUNG, ESQ.,

Intervenors

APPEAL OF: BRISTOL-MYERS SQUIBB

COMPANY

OPINION ANNOUNCING THE JUDGMENT OF THE COURT

DECIDED: June 16, 2014

MR. JUSTICE SAYLOR

This case is among a number of civil actions brought by state attorneys general against pharmaceutical companies nationwide challenging the propriety of prescription drug pricing, in particular, as it impacts third-party reimbursement for brand-name drug purchases subsidized by government social welfare programs. The Commonwealth has centered its claims upon alleged overpayments tied to the use of an industry benchmark figure known as "AWP" in government reimbursement formulas. While many issues of concern have been raised about the Commonwealth's approach to this litigation and the judgment it has obtained, our present decision to overturn the monetary component of that judgment is grounded on the Commonwealth's failure, by any measure, to offer a rational accounting for the billion dollars in rebate monies which Commonwealth agencies received from the drug manufacturers it has haled into court.

I. Background

A. General Overview

The Commonwealth's Department of Public Welfare ("DPW") and its Department of Aging ("DOA") each administer programs using public funds to subsidize purchases of prescription drugs by qualified persons with low incomes and/or disabilities. DPW

maintains a cost-sharing relationship with the federal government under Title XIX of the federal Social Security Act, 42 U.S.C. §§1396 to 1396w-5, also known as the Medicaid Act, to provide necessary medical care to indigent persons. See 62 P.S. §§441.1 to 449 (containing the enabling provisions for the Commonwealth's Medical Assistance Program). DOA operates the Pharmaceutical Assistance Contract for the Elderly ("PACE"), offering financial assistance in prescription drug purchases to low-income, elderly citizens.²

Per the relevant aspects of these programs, private entities, including physicians and pharmacies (herein termed "providers"), purchase branded drugs from wholesalers and administer and dispense them to program beneficiaries. The providers then submit claims to DOA and DPW, which tender reimbursement per statutory and regulatory formulas, respectively. See generally 72 P.S. §3761-509(6); 55 Pa. Code §1150.51.

In the salient time period (1991 through 2004), state statutes and regulations relied upon industry-reported figures -- average wholesale prices or "AWPs" -- as a key benchmark in these reimbursement formulas. <u>See</u> 72 P.S. §3761-502; 55 Pa. Code

Reimbursement formulas in fee-for-service programs encompass both payment and dispensing fee components. <u>See</u>, <u>e.g.</u>, <u>id.</u> §1121.55. Program beneficiaries in some instances may also be responsible for copayments. <u>See</u> <u>Commonwealth v. TAP Pharm. Prods.</u>, <u>Inc.</u>, 36 A.3d 1197, 1215 (Pa. Cmwlth. 2011). The numerical breakdown among these components is not particularly relevant to our disposition of this appeal; rather, our focus is upon the net cost to the government reimbursement programs involved here.

¹ The Commonwealth's Medical Assistance program encompasses both fee-for-service and managed care systems, but this case concerns only the former, whereby DPW reimburses providers for services and covered supplies on a claim-by-claim basis. <u>See, e.g.</u>, 55 Pa. Code §1150.51.

² The enabling statute for PACE is presently reposited in Chapter 5 of the State Lottery Law, Act of August 26, 1971, P.L. 351, No. 91 (as amended 72 P.S. §§3761-501 to 3761-522), since the program is funded by lottery proceeds.

§1121.2. AWPs were based upon price reports made by prescription drug manufacturers, including defendant Bristol Myers Squibb Company ("BMS"), to industry publishing services. See TAP, 36 A.3d at 1211 (explaining that "[s]ince 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" (citing In re Pharm. Indus. AWP Litig., 491 F. Supp. 2d 20, 32 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009))). Generally, drug manufacturers reported AWPs at 20 or 25 percent above wholesale acquisition costs ("WACs"), 3 or they simply transmitted their WACs to the publishers, which calculated the AWPs according to the same markup conventions. Despite the self-reporting dynamic, however, neither Congress, nor the Pennsylvania General Assembly, nor the Commonwealth executive branch provided a concrete definition for the AWP conception or otherwise sought to impose meaningful restrictions on their content.⁴

By 1991, there was a wealth of information available to state officials and to the public at large confirming that AWPs served as a "list" or "book" price, so that the term "average wholesale price" was (or had become) a misnomer. <u>See, e.g., State of Louisiana v. DHHS</u>, 905 F.2d 877, 880 (5th Cir. 1990) (reflecting a federal government agency's observation in the 1970s that "AWP data are frequently inflated" and "should"

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³ WACs are the prices at which a pharmaceutical company sells its products to wholesalers. BMS utilizes the term "Wholesale List Cost" or "WLC" as a synonym for the more conventional one which we employ here.

⁴ The inherent complexity and the need for some sort of pricing conventions in connection with reimbursements by DPW and DOA is evident when considering, for example, that the Medical Assistance program processes about 30,000 claims per day, covering approximately 25,000 national drug codes. See TAP, 36 A.3d at 1214; accord id. at 1211 ("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.").

not be equated with the estimated acquisition costs for a drug." (quoting 40 Fed. Reg. 34518 (Aug. 15, 1975))). The disconnect may have initially related to price incentive mechanisms utilized by drug manufacturers to enhance market share, such as discounts and rebates, and narrowing profit margins for wholesalers on account of increased efficiencies and intense competition. See Pharm. Indus. AWP Litig., 491 F. Supp. 2d at 33; TAP, 36 A.3d at 1213 (quoting a pharmaceutical company as recognizing that AWPs were "the legacy of a distribution system which ceased to exist in the early 1980s"); id. (asserting that "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").

Great controversy ensued concerning the degree to which state agencies apprehended the evolving AWP convention and whether providers were being overpaid because of its use in program reimbursement formulas. In response, the federal and state governments implemented various pricing reforms and cost-containment measures within reimbursement systems. For example, DPW and DOA eventually routinized a practice of discounting AWPs in the Medical Assistance and PACE reimbursement formulas, so that instead of paying the listed AWP price to providers, they paid a rate, for example, of AWP minus 10 percent ("AWP-10").6

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⁵ For a commonly repeated historical account of the evolution of AWPs, see <u>TAP</u>, 36 A.3d at 1212.

⁶ DPW reimbursed providers for the branded prescription drug component at 100 percent of AWP from 1991 through late 1996. <u>See TAP</u>, 36 A.3d at 1215; <u>see also</u> 72 P.S. §3762-303(h)(6) (superseded). From then through 2004, DPW reimbursed providers at a rate of AWP minus 10 percent. <u>See</u> 72 P.S. §3761-509(6) (superseded).

Under the PACE program's reimbursement formula, which is fixed by statute, DOA generally reimbursed providers for the branded prescription drug component at 100 percent of AWP until 1996. <u>See</u> 72 P.S. §3761-303(h)(6) (superseded). Thereafter, the (...continued)

In addition, since 1990, federal law has required that, for each brand-name drug, manufacturers must pay rebates to state Medicaid programs. See 42 U.S.C. §1396r-8. To enable the government to calculate those rebates, manufacturers must submit Average Manufacturer Prices ("AMPs") and "best prices" to the federal Center for Medicare and Medicaid Services ("CMS") on a regular basis. See id. §1396r-8(b)(3). AMPs are defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade [after deducting] customary prompt pay discounts." Id. §1396r-8(k)(1). "Best price" generally means the lowest price available from the manufacturer during the rebate period, inclusive of discounts and other rebates. Id. §1396r-8(c)(1)(C)(ii). The main rebate is calculated by multiplying the total units of a drug purchased under a state program in the rebate period by the greater of: 1) the difference between AMP and best price for the drug, or 2) a minimum rebate percentage of the AMP, currently 23.1 percent. See id. §1396r-8(c)(1). Additional rebates are provided, see, e.g., id. 1396r-8(c)(2), and states have the ability to impose others. The General Assembly also adopted a rebate system for PACE, very similar to the Medical Assistance regime, in 1991. See 72 P.S. §§3761-702 to 3671-707.

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These evolving discounts were attended by additional controversy, since they met opposition from pharmacies and pharmacy associations. <u>See, e.g., Rite Aid of Pa., Inc. v. Houstoun,</u> 171 F.3d 842 (3d Cir. 1999).

⁽continued...)

statutory reimbursement rate changed to AWP-10. <u>See</u> 72 P.S. §3761-509, Historical and Statutory Notes. In 2003, PACE's core reimbursement calculation changed to AWP-12. <u>See id.</u> §3761-509(6).

⁷ Indeed, in 1996, the Legislature amended the statute to establish the federal rebate calculation as a floor for rebates to PACE. See 72 P.S. §§3761-707.

Despite such measures, state attorneys general, among others, claimed pharmaceutical companies were manipulating price data to create a "spread" between prices actually paid by providers and the amount of reimbursement the providers obtained from government social welfare programs. See, e.g., State v. Abbott Labs., 829 N.W.2d 753, 759 (Wis. Ct. App. 2013) (discussing spread marketing in the context of a successful action by the State of Wisconsin against a drug manufacturer); AstraZeneca LP v. State, 41 So. 3d 15, 27 & n.8 (Ala. 2009) (same, in the setting of litigation by the State of Alabama against a drug manufacturer which ultimately was unsuccessful). Drug manufacturers were accused of "marketing the spread," to enhance their own market share over competitors, by encouraging physicians to prescribe their products based on profitable returns to their practices. See, e.g., id.⁸

The pharmaceutical companies offered many defenses, denying that they employed unethical marketing practices, with some also positing that they merely submitted accurate WACs to the pricing services and did not control the subsequent calculation and reporting of AWPs. See, e.g., TAP, 36 A.3d at 1214. The drug manufacturers also emphasized that state legislatures and agencies intentionally provide profits to providers to ensure access for program beneficiaries to the medications they need. See, e.g., id. at 1231. In all events, the companies maintained that it was well known among all associated with the industry that AWPs served only as a suggested list price establishing a basis for negotiation. See, e.g., AstraZeneca, 41 So. 3d at 29-33 (reasoning that Alabama could not have reasonably relied on alleged

⁸ The notion of "marketing the spread" is less consonant with dispensation of drugs from pharmacies than through physicians' practices, since pharmacists do not select particular prescription products for consumers. Nevertheless, plaintiffs in these actions have styled their claims to encompass reimbursements to pharmacies, often claiming collusive practices fostering indirect benefits.

fraudulent misrepresentations about AWPs by a pharmaceutical manufacturer, given that state officials knew of the disparity between AWP and WAC, they had ample data concerning actual drug acquisition costs by pharmacies, and the state nevertheless always utilized reimbursement formulas it deemed appropriate).

B. The Present Litigation

In 2004, the Commonwealth commenced the present litigation against BMS and thirteen other pharmaceutical companies on behalf of DPW and PACE, consistent with other actions referenced above. The Commonwealth claimed that the defendants engaged in deceptive practices between 1991 and 2008 by causing inflated AWPs for their brand-name drugs to be published in industry publications.⁹

The Commonwealth advanced three common-law causes of action, <u>i.e.</u>, negligent misrepresentation, fraud, and civil conspiracy; one equitable claim in the

⁹ The Commonwealth Court has provided the following elaboration on the scope of the Commonwealth's claims:

Most of the [Commonwealth's] claims . . . involve self-administered branded drugs, such as pills. . . .

A small percentage of the claims involve Medicare Part B drugs. These are injectable or infusible drugs which require administration by a physician. . . . Since 1992, reimbursement and co-payment for Medicare Part B drugs has been based on a formula which included an AWP factor (plus an allowance for other costs, such as a dispensing fee). See [Pharm. Indus. AWP Litig.], 491 F. Supp.2d at 33-34.

There are no generic drugs involved in this case.

TAP, 36 A.3d at 1216.

TAD 26 A 24 at 12

nature of unjust enrichment; and one statutory claim asserting multiple acts in violation of the Unfair Trade Practices Consumer Protection Law.¹⁰

In its most simplistic form, the Commonwealth contended that AWP, per the plain meaning of the words underlying the acronym, suggests that the figure is in fact an actual average price paid by providers to wholesalers. See Corrected Amended Civil Action Complaint, Commonwealth v. TAP Pharm. Prods., Inc., 212 M.D. 2004, at 145-46 ¶¶648-659. Given that AWPs are higher than providers' actual acquisition costs, the Commonwealth asserted that DPW and DOA were misled and that the agencies overpaid providers in reimbursements. See id.

BMS defended in a conventional manner, <u>inter alia</u>, denying any fraudulent conduct on its part and highlighting the information readily available to public officials contradicting the Commonwealth's assertions about AWPs. BMS also asserted that it was entitled to a setoff should any damages be awarded against it, <u>see</u> Answer and New Matter of BMS, <u>TAP</u>, 212 M.D. 2004, at 50 ¶956(z).

In response to the defendants' reliance on the claimed setoff, the Commonwealth filed a pretrial motion seeking to preclude evidence of rebates. According to the Commonwealth.

Rebates paid by the Defendants to Plaintiffs do no "offset" or eliminate their damages, are wholly irrelevant, and would inject issues that cause jury confusion and unfair prejudice to Plaintiffs. . . .

* * *

It is an undisputed fact that the Defendants, as are all prescription drug manufacturers, are required as a condition of their participation in Pennsylvania's Medicaid Program to

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¹⁰ Act of December 17, 1968, P.L. 1224 (as amended 73 P.S. §§201-1 to 201-9.3 (the "UTPCPL").

enter into contracts that obligate them to make . . . quarterly payments to Pennsylvania. These rebates are calculated by Center for Medicare and Medicaid Services ("CMS") based on what is known as the Average Manufacturer's Price ("AMP"). These rebates do not affect, in any way, the amount that Plaintiffs reimburse providers for a particular drug, which is based on AWP, not AMP. The converse is also true: Plaintiffs' reimbursement payments to providers do not affect the amount which a drug manufacturer pays in rebates. Thus, Defendants' (or any other manufacturer's) rebate payments to the Plaintiffs would be the same regardless of the AWP, or for that matter the WAC, that Defendants have set and reported to the pricing compendia such as First DataBank, Red Book, and Medi-Span.

Plaintiffs' Motion <u>In Limine</u> to Preclude Evidence of Rebates to "Offset" Plaintiffs' Damages, <u>TAP</u>, 212 M.D. 2004, at 1-3.

BMS responded that rebates go directly to the issue of whether the Commonwealth overpaid for drugs, since rebates lower the net cost of drugs to the programs. See 42 U.S.C. §1396r-8(b)(1)(B) (indicating, as a provision of the federal Medicaid statute, that amounts a state receives under the rebate program "shall be considered to be a reduction in the amount expended [by the state] for medical assistance."); cf. 72 P.S. §3761-709(b) (couching rebates relative to certain pharmaceutical programs as "a refund of expenditures"). Indeed, BMS stressed, "the whole purpose of the federally mandated rebate program was to ensure that the Commonwealth got the best prices in the marketplace." Defendant BMS's Memorandum in Opposition to Plaintiffs' Motion In Limine to Preclude Evidence of Rebates to "Offset" Plaintiffs' Damages, TAP, 212 M.D. 2004, at 2. More simply, BMS explained:

A rebate is nothing more than a type of discount. It is the net price a state actually pays. As such, "rebates may play a role in determining the correct amount of damages in the case" and may "mitigate [the states'] damages" In re

Pharmaceutical Industry Average Wholesale Price Litig., 457 F. Supp. 2d 65, 75 (D. Mass. 2006).

* * *

[D]ocumentary and testimonial evidence from the Commonwealth and its witnesses evince the integral role rebates played in cost reduction initiatives in medical assistance programs.

<u>Id.</u> at 3-4.

The trial court denied the Commonwealth's motion, and BMS was tried separately from the other corporate defendants, with the common-law and equitable claims being considered by the jury and the UTPCPL claim determined by the trial judge.

Interestingly, at trial, testimony from several of the Commonwealth's own witnesses substantially undermined certain of the allegations lodged in the complaint. For example, Thomas Snedden, long-term director for the PACE program, testified that he has known since 1987 that AWPs are not transaction prices, the markup of 20 to 25 percent is well known in the industry, and he had not in any fashion been deceived by BMS on the subject of AWP. See N.T., Aug. 24, 2010, at 1936, 1945. Mr. Snedden also testified that, since 1992, DOA has received AMP data and "detailed information about what a retailer is paying" from drug manufacturers, including BMS, id. at 1947-

The Commonwealth's own "paid fact witness" from the pharmaceutical industry, Gregory B. Hamilton, testified that "[e]veryone knew" the difference between WAC and AWP, including, presumably, in Mr. Hamilton's judgment, DPW and DOA. N.T., August 12, 2010, at 416-18, 429-30. Similarly, Gerald Radke, a former deputy secretary for Pennsylvania's Medical Assistance program, testified in the defense case that program staff referred to AWP as "Ain't What's Paid," since "everybody knew average wholesale price was not the price, it was the manufacturer's suggested list price." N.T., August 31, 2010, at 2994. Moreover, the Commonwealth's main expert witness on the liability side indicated that the Commonwealth agencies did not overpay pharmacies. See N.T., August 16, 2010, at 853 (testimony of economist William S. Comanor, PhD).

1948, and DOA has audited pharmacies for the last twenty years to obtain actual transaction prices for drugs. <u>See id.</u> at 1959, 1964.

As to rebates, Mr. Snedden engaged in the following discussion on crossexamination:

- Q. . . . There's been a lot of discussion in this trial that rebates are not calculated on AWPs, they're calculated on the AMP[s]. That's correct, isn't it?
- A. Yes, sir.
- Q. But rebates are money that the PACE program gets in the door from the drug manufacturers, correct?
- A. Yes, sir.
- Q. It's money they get in the door to offset what they spend reimbursing pharmacies in the program, correct?
- A. Yes, sir.
- Q. To say the two are completely unrelated and disconnected is not entirely accurate, is it?
- A. Well, I thought we were talking about the calculation as opposed to the cash flow.
- Q. Leaving aside the calculation.
- A. Right.
- Q. In other words, how you come up with the dollars, leaving that aside for a moment, the rebates themselves are entirely related to the utilization of those particular drugs in your program, correct?
- A. That's right. Yes, sir.

- Q. So, in that sense they're they're not unrelated, they're totally related, correct?
- A. Related in the sense that <u>it's an offset for the money that</u> <u>we spend on the AWP.</u>
- Q. Let's break it down and make it real simple. You reimburse a Plavix pill for a dollar, okay?
- A. \$5.
- Q. \$5. All right.
- A. It's expensive.
- Q. What would the rebate be, roughly?
- A. The rebate would be about a dollar 10 cents.
- Q. Okay. And when you look at your, the business of PACE, you would deduct that rebate amount from the \$5 to come up with what is my net cost for this particular reimbursement, true, you look at it that way?
- A. I actually look at it as a we call it a <u>refund of expenditure</u>. But it's in the aggregate. If I'm spending 20 million dollars a month for drugs, and I'm expecting that I'm going to get back somewhere close to five million of that.
- Q. Let's do it that way then. I'm happy with that.
- A. It goes drug by drug.
- Q. You probably don't take the time to just do it on a pill by pill or drug by drug basis?
- A. No.
- Q. But on an overall expenditure basis if you were going to expend 20 million dollars one month and you had a rebate coming at five million, you view that as an offset against [the] cost of reimbursement for the drugs, correct?

A. That's correct.

Q. It's just that's how you calculate that reimbursement to get to the five million dollars, uses an AMP number rather than the AWP number, correct?

A. That's correct.

Q. But, Mr. Snedden, from a practical financial standpoint of running your program, those rebates are extremely important to you, aren't they?

A. Can't overstate it.

Q. Those rebates you can't overstate. <u>It's those rebates that</u> you get from the manufacturer gives you a much better overall price for these pharmaceutical products, don't they?

A. That's correct.

- Q. The rebates that you get from the drug manufacturers like my client, Bristol-Myers, are in the 10s and 20s and 30s of millions of dollars, aren't they?
- A. That's correct.
- Q. We're not talking coupons, are we?
- A. No, sir.
- Q. We are talking multiple 10s of millions of dollars every single year, correct?
- A. Every quarter.

* *

Q. Has [the] one billion dollars in rebates that has been paid by the drug manufacturers to the PACE program, has that assisted the PACE program in its mission?

A. Very much so.

N.T., August 24, 2010, at 1966-1971 (emphasis added). According to Mr. Snedden, given such rebates, PACE reimburses for branded prescription drugs at a very substantial discount. See id. at 1971.¹²

As its damages expert, the Commonwealth presented testimony from economist Frederick R. Warren-Boulton, PhD. On the subject of rebates, the economist had only this to say:

[L]et's do one other little complication in this. All right? Which is rebates. Because the money doesn't just flow in the direction you'd expect. This is kind of like a backwash. All right? Most of the money is flowing down from the customers, the taxpayers or the customers down to the drug company, but then there's two little places where it kind of flows back again as well, and these are rebates.

* * *

In particular, there are three kinds of rebates that come back up to PACE and DPW. So we've got drugs I guess in black [as indicated on a demonstrative exhibit], we've got regular money in green, and we've got rebates in red. All right?

Now, what I want to focus on in my testimony today is going to be pretty narrow. I'm interested in this place right here. (descriptive gesture). Okay? All right. And I'm interested in what goes in and what comes out. And my damages are going to be dealing just with this issue.

* * *

The rebate -- and as I say, I'm sure you've heard a lot about rebates, but these rates are completely outside of where I'm going. I'm just in here. So what you can notice is there's no

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¹² Mr. Snedden also elaborated on his agency's concern with paying pharmacies enough to ensure program beneficiaries have access to the drugs they need, and that this has nothing to do with BMS. <u>See id.</u> at 1954.

little red arrow that goes in there, there's no little red arrow that comes out of it. <u>I'm kind of rebate-free</u>.

N.T., August 25, 2010, at 2166-2168 (emphasis added). Notably, after having attributed economic significance to rebates relative to DPW's and DOA's reimbursement payments, Mr. Warren-Boulton offered no economic rationale for excluding them entirely in his ensuing damages formulations. Mr. Warren-Boulton then summarized his views regarding what DPW and PACE should have paid providers in a "but for" world in which neither rebates nor institutional constraints (such as subjugation of social welfare programs to legislative prerogatives) had material significance. See id. at 2169-2226.

At the close of the Commonwealth's case, the trial court granted BMS's motion for a non-suit on the equitable claim of unjust enrichment. See TAP, 36 A.3d at 1217 (explaining that "the Commonwealth did not identify any fund to which a common-law equitable remedy would apply"). The jury returned general verdicts favorable to BMS on the fraud and negligent misrepresentation counts, and the civil conspiracy count went by the wayside. ¹³

Thereafter, the trial court issued its decision on the statutory claim, finding BMS violated the UTPCPL by engaging in unfair or deceptive practices. See TAP, No. 212 M.D. 2004, slip op. at 1 (Pa. Cmwlth. Sep. 10, 2010), reproduced in TAP, 36 A.3d at 1300-02. The court permanently enjoined BMS from: reporting, or contributing to the reporting of, AWPs to the Plaintiff Agencies; and promoting or marketing the spreads for its drugs that are reimbursed by DPW or PACE. See id. at 2. The court additionally awarded the Commonwealth restoration damages in the amount of \$27,617,952. See

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¹³ Given that it did not find fraud or misrepresentation, the jury did not reach this claim per its charge and the verdict slip. See TAP, 36 A.3d at 1218.

id. 14 The court acknowledged the defense verdict rendered by the jury, but it explained that the standard for a UTPCPL enforcement action differs from that applicable to common law actions. See id. at 1 n.1. It indicated, in this respect, that a plaintiff's knowledge of the inaccuracy of a representation, and a plaintiff's lack of reliance on such representation, while factors to be considered, are not complete defenses under Section 4 of the UTPCPL. See id.

BMS filed a motion for post-trial relief, arguing, inter alia, that: its conduct was not deceptive; the court's decision was inconsistent with the jury's verdict; there was no threat of ongoing injury to justify an injunction; restitution was improper since the Commonwealth failed to prove causation, inasmuch as BMS's complained-of actions did not result in the company acquiring any reimbursement monies; in any event, DPW and DOA made a policy choice to use an AWP-based formula to supply reimbursement at higher levels than private third-party payors so as to incentivize pharmacy participation in the government programs; and the damages amount was in error because it was based on a flawed methodology used by the Commonwealth's damages expert.¹⁵

In a published decision, a three-judge panel of the Commonwealth Court, consisting of the trial judge and two of his colleagues, denied BMS's post-trial motion "[f]or the most part." TAP, 36 A.3d at 1294. In particular, the court granted BMS's motion to the extent that it made some changes to the wording of the injunction, adding

¹⁴ The trial court nonetheless declined to award a civil penalty under Section 8(b) of the UTPCPL, <u>see</u> 73 P.S. §201-8(b), notwithstanding that it found that BMS's statutory violations were willful. The court explained that it lacked sufficient information to calculate the amount of such penalty. <u>See TAP</u>, No. 212 M.D. 2004, <u>slip op.</u> at 2.

¹⁵ The Commonwealth also sought post-trial relief and lodged an appeal; however, that appeal has been withdrawn, mooting its challenges to the Commonwealth Court's treatment. <u>See TAP</u>, 36 A.3d at 1275-94.

language clarifying that BMS is permitted to continue reporting AWPs so long as it also provides DPW and DOA with estimated acquisition costs, such as AMP, for each of its branded drugs. See id. at 1295. In addition, the Commonwealth Court sua sponte enlarged the restoration award to \$27,715,904 (an increase of \$97,952), due to a mathematical error in the prior calculation of the award. See id. at 1294-95 & n.42.

In explaining the decision, the Commonwealth Court established the theme that it viewed AWPs as a "fictitious price," serving as a "flawed reimbursement benchmark." TAP, 36 A.3d at 1213, 1253. The court summarized that the evidence showed that, although agency personnel knew that AWP-based reimbursement was flawed, they did not know the full extent of the inaccuracies involved. See id. at 1214. In terms of the testimony -- including that of the Commonwealth's own witnesses -- that state officials were not deceived, see supra note 11 and accompanying text, the court indicated that it was declining to draw "inferences" in BMS's favor. Id. at 1222. With respect to Mr. Snedden, the panel depicted his credibility as being compromised by "his demeanor, bias, and strong tendency to agree with whoever was questioning him." Id. at 1222. The court also developed that BMS's conduct affected individual clients of the government agencies because some of these persons paid copayments as a percentage of the inflated AWP numbers. See Id. at 1256.

The Commonwealth Court further parsed through BMS's additional challenges and made numerous other statements of law and fact. Of particular significance to our disposition, the court's treatment of the rebate issue was brief. In this regard, the court "accepted as more credible the . . . opinion of the Commonwealth's damage expert, Mr. Warren-Boulton, that rebates are unrelated to the Commonwealth's overpayment based

on fictitious AWPs." <u>TAP</u>, 36 A.3d at 1269 (quoting N.T., August 25, 2010, at 2168). Further, the court alluded to the difference in the formulas for payments versus rebates as supporting its conclusion. <u>See id.</u> ("The distinct methodologies for establishing reimbursements and for calculating base rebates are so different that it tended to corroborate Dr. Warren-Boulton's position.").

In its present arguments to this Court, BMS renews challenges it lodged in the Commonwealth Court. Most material to our treatment, BMS maintains that the Commonwealth's methodology in support of its damages claims was fundamentally flawed, when unrebutted defense evidence demonstrated that BMS paid DPW and DOA more than \$164 million in rebates in the relevant time period, an amount that far

To bolster its assessment in this regard, the Commonwealth Court added, by way of a footnote, that Mr. Warren-Boulton had discussed the point in greater detail in another, later bench trial against different drug manufacturers conducted in the Commonwealth Court. See TAP, 36 A.3d at 1269 n.25. While offering apologia to the effect that it was understandable "[t]hat the same detailed testimony was not offered to a jury" at the BMS trial, the Commonwealth Court cited no authority which would permit it to rely on evidence adduced at a distinct trial where the relevant witness was not subject to cross-examination by BMS's counsel.

Compounding such irregularities, the Commonwealth Court also expressly relied on a report from Mr. Warren-Boulton which had not been introduced or admitted into evidence at trial. See, e.g., TAP, 36 A.3d at 1267 ("Here, the trial judge relied on the Commonwealth's damage expert, Dr. Warren-Bouto's Revised Expert Report, dated August 9, 2010[,] . . . to determine the amount of restoration."); see also Letter of William F. Cavanaugh, Esquire, dated March 4, 2014 (explaining, on behalf of the Commonwealth and BMS, that "Dr. Warren-Boulton's revised expert report . . . was neither admitted into evidence at trial nor included as part of the record of this appeal.").

¹⁶ As further discussed below, in the relevant passage of Mr. Warren-Boulton's testimony, he did not say that rebates are unrelated in an economic sense to the asserted overpayments. In point of fact, he likened rebates to "backwash" relative to payments, and merely indicated that he intended to focus exclusively on the agencies' reimbursement payments to pharmacists to the exclusion of the rebates in his damages estimates. <u>See</u> N.T., August 25, 2010, at 2168.

exceeds the asserted "restoration." <u>See</u> Brief for BMS at 68 (citing, <u>inter alia</u>, N.T., Spetember 1, 2010, at 3200, reflecting unrebutted testimony from defense economist Gregory K. Bell to the effect that BMS paid rebates to DPW of \$102 million and to DOA of \$62 million in the relevant time period relative to subject drugs). In response, the Commonwealth merely relies upon the Commonwealth Court's rationale. <u>See</u> Brief for the Commonwealth at 70 ("There is ample evidence of record demonstrating that rebates have nothing whatsoever to do with inflated payments based on AWPs, or the valuation of such payments in the 'but for' world.").

II. Discussion

While on this record, we have concerns about the Commonwealth Court's credibility judgments, ¹⁷ we have elected to place our focus on the rebate question, since we regard it as a straightforward matter of law over which our review is plenary.

Finally, the Commonwealth Court's general allusions to Mr. Snedden's demeanor and bias are abstract, and its claim that Mr. Snedden merely agreed with anything the lawyers said is in substantial tension with the record of the proceedings – in point of fact, Mr. Snedden frequently provided detailed and sometimes passionate explanations for his responses. See N.T., August 24, 2010, at 1895-2010.

¹⁷ In particular, the Commonwealth Court's assessment of Mr. Snedden's testimony seems highly questionable. There can be no dispute that, per express statutory command, DOA was provided with BMS's AMP data throughout the relevant time period, see, e.g., 72 P.S. §3761-704(c), and that DOA had actual purchase data from audited pharmacies. With such information in hand, it is not clear why the Commonwealth Court did not believe Mr. Snedden when he said that he was not deceived by BMS or any other drug manufacturer providing its average manufacturer prices per the statute. Indeed, as BMS stresses, the informational aspect of the revised injunction imposed by the Commonwealth Court requires only that BMS provide DPW and DOA with the same AMP data which it has been providing to DOA for the last twenty years, so that it does not appear that, per the injunction, Mr. Snedden would gain any additional information in any event.

If it is not already clear from the above, we are disturbed by the Commonwealth's failure to account in this litigation for the billion dollars of rebate monies it has received from defendant drug manufacturers in the relevant time period. In the first instance, we find the Commonwealth's emphasis upon the use of different calculations in reimbursements versus rebates to be obfuscatory. The Commonwealth's own damages expert acknowledged that the rebates conventionally flowed like "backwash" relative to Commonwealth reimbursement payments, N.T., August 25, 2010, at 2166; Mr. Snedden elaborated on this point amply throughout a portion of his testimony which was not specifically rejected by the Commonwealth Court based on some undisclosed aspect of his demeanor, see N.T., August 24, 2010, at 1966-1971; and this Court is not in need of a body of evidence to apprehend that a rebate operates to reduce the net price of a Accord 42 U.S.C. §1396r-8(b)(1)(B) (indicating, as a provision of the commodity. federal Medicaid statute, that amounts a state receives under the rebate program "shall be considered to be a reduction in the amount expended [by the state] for medical assistance."); cf. In re Flonase Antitrust Litig., 284 F.R.D. 207, 224 n.16 (E.D. Pa. 2012) ("Rebates, of course, offset the net cost of a brand drug[.]"); In re Pharm. Indus. AWP Litig., 457 F. Supp. 2d 65, 75 (D. Mass. 2006) (commenting, at a median stage of prolix AWP litigation, on the potential role of rebates in mitigating damages). Were the rebates specified in terms of a fixed amount per pill - say one dollar - they would also rest upon a different "formula," but they would no less plainly serve to reduce the net price of reimbursements.¹⁸

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¹⁸ To the extent the Commonwealth suggests that DPW and DOA should always have had both a pure AMP or WAC-based pricing system and the substantial rebates required per federal and state law, it ignores its own failure to address the political hurdles involved in altering reimbursement formulas, see, e.g., N.T., August 25, 2010, at 2321 (reflecting Mr. Warren-Boulton's affirmation that he was not considering "the political process, the political donations, the lobbying, the industry lobbying," but, rather, (...continued)

Furthermore, the Commonwealth Court's satisfaction with the credibility of Mr. Warren-Boulton's testimony cannot insulate the mistreatment of rebates from reasonable scrutiny. We have already noted that the economist did not explain his tactic of ignoring rebates in any economic terms; rather, he only indicated that it was his choice to do so. See supra note 16. While we suppose that litigants might always wish to maximize recoveries, it is astonishing that -- based upon such insubstantial testimony -- the Commonwealth Court would permit the Commonwealth to accept a billion dollars in rebates relative to social welfare reimbursements while giving no credit to the payers.

The Commonwealth may have many grievances about how convoluted pricing has become in the pharmaceutical trade and various manipulative practices on the part of participant actors which may be masked by such complexity. Nevertheless, federal and state law have provided very specific remedial and compensatory measures -- laid squarely at the feet of drug manufacturers -- and, in the present case, the Commonwealth failed to so much as attempt to show that these were in any sense inadequate.

The Commonwealth Court might have cabined the ten-year course of this litigation by recognizing -- earlier on -- the significance of rebates to prices, and, failing that, it should have taken good guidance from the jury which was empaneled. By the Commonwealth's abject failure to account responsibly for rebates taken from the defendants it sued, it has proved no harm as a result of pharmaceutical-company

(continued...)

was merely addressing what might have been paid to pharmacies to ensure access in the abstract, free of any political considerations), and the fact that remedial measures including discounts from AWP and rebates were implemented in response to the drawbacks of industry conventions in the first instance.

pricing practices, and we decline to sustain any judgment in the circumstances as they have come before us here.¹⁹

IV. The Divided Disposition

Although the Justices supporting this opinion presently would bring this protracted litigation to a close, upon the response authored by Mr. Justice Baer, three other Justices have taken the position that the matter should be remanded to the Commonwealth Court for further consideration in light of our above analysis. Notably, this sort of impasse has yielded troubling results in previous cases. See, e.g., Schmidt v. Boardman, 608 Pa. 327, 11 A.3d 924 (2011) (equally divided Court, in relevant part) (upholding a multi-million dollar component of a jury award by operation of law in light of an equal division of the Court, even though no member of the Court believed that that component of the verdict should have been upheld). Solely in order to avoid an untenable result here, we will accede to the remand which Justice Baer proposes, on the terms which he has specified.

Parenthetically, we note that substantial concern has been expressed about the use by public agencies of outside counsel, with personal financial incentives, to spearhead litigation pursued in the public interest, including AWP litigation. See, e.g., Dayna Bowen Matthew, The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud, 40 U. MICH. J.L. REFORM 281 (2007). At the very least, close supervision is required in such relationships, and, of course, the state agencies in whose name the cause is pursued bear the ultimate responsibility for the sort of overreaching which we find to have occurred here.

¹⁹ Our judgment might have been different, and a deeper review of this record on the issue of deception might be appropriate had the Commonwealth restricted its damages claims, say, according to the time value of money between the time of its reimbursement of providers and its receipt of rebates. By failing to respond substantively to BMS's evidence that rebates greatly exceeded the "restorative" damages fashioned by the Commonwealth Court, however, the Commonwealth proved nothing injurious to its agencies resulting from the governing reimbursement/rebate regimes and the price reporting which occurred thereunder.

The order of the Commonwealth Court is vacated, and the matter is remanded per the terms of the responsive opinion of Justice Baer.

Opinion Announcing the Judgment of the Court.

Mr. Justice Stevens did not participate in the consideration or decision of this case.

Mr. Chief Justice Castille and Mr. Justice Eakin join the Opinion Announcing the Judgment of the Court.

Mr. Justice Baer files a concurring opinion in which Madame Justice Todd and Mr. Justice McCaffery join.