

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**CHARLESTON DIVISION**

WEST VIRGINIA DEPARTMENT OF HEALTH AND  
HUMAN RESOURCES, BUREAU FOR MEDICAL  
SERVICES,

Plaintiff,

v.

CIVIL ACTION NO. 2:09-cv-01542

KATHLEEN SEBELIUS, et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER**

This is a lawsuit by the West Virginia Department of Health and Human Resources (“DHHR”) challenging the withholding of federal Medicaid payments. Named as defendants are the following parties: Kathleen Sebelius, the Secretary of the United States Department of Health and Human Services (the “Secretary”), in her official capacity; the United States Department of Health and Human Services (“HHS”); Charlene Frizzera, the Acting Administrator of the Centers for Medicare and Medicaid Services, in her official capacity; and the Centers for Medicare and Medicaid Services (“CMS”).<sup>1</sup> On October 29, 2009, the Departmental Appeals Board (“DAB”)

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<sup>1</sup> As of the date of this Memorandum Opinion and Order, Sylvia Burwell is the HHS Secretary and Andy Slavitt is the Acting Administrator of CMS. When a public officer who has been sued in her official capacity resigns, that officer’s successor is automatically substituted as a party, pursuant to Federal Rule of Civil Procedure 25(d). This substitution is automatic and does not require a court order. Fed. R. Civ. P. 25(d). In light of the Court’s disposition of the present motions, the Court finds it unnecessary to direct the Clerk to docket the substitution of Secretary Burwell and Acting Administrator Slavitt as parties to this action.

of HHS issued a ruling sustaining a disallowance of federal financial participation by CMS. On December 23, 2009, DHHR filed a complaint for judicial review of that decision, representing final agency action, pursuant to the Administrative Procedure Act (“APA”). (ECF No. 1.) Currently pending before the Court are the parties’ cross motions for summary judgment. (ECF Nos. 29 and 30.) For the reasons discussed herein, Defendants’ Motion for Summary Judgment, (ECF No. 29), is **GRANTED** and Plaintiff’s Motion for Summary Judgment, (ECF No. 30), is **DENIED**.

## *I. Background*

### **A. Statutory and Regulatory Framework**

Medicaid is a cooperative federal-state program established for the purpose of “providing federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons.” *Harris v. McRae*, 448 U.S. 297, 301 (1980). The Medicaid Act is located in Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* The Act is designed to allow federal and state governments to “jointly share the cost of providing medical care to eligible low-income and disabled individuals.” *Va. Dep’t of Med. Assistance Servs. v. Johnson*, 609 F. Supp. 2d 1, 2 (D.D.C. 2009) (citing 42 U.S.C. §§ 1396 and 1396b). Although participation in the Medicaid program is voluntary, every state has elected to participate and administer that program pursuant to broad federal requirements and the terms of its own state Medicaid plan. *See* 42 U.S.C. §§ 1396, 1396a. Congress has enumerated a number of conditions to regulate state receipt of these funds, and each state wishing to receive federal Medicaid funds is “required to submit a plan for medical assistance, and the Secretary of the Department of Health and Human Services (“HHS”) must approve the plan before funds are disbursed.” *W. Va. Dep’t of Health and Human*

*Res. v. Sebelius (West Virginia I)*, 649 F.3d 217, 219 (4th Cir. 2011) (citing 42 U.S.C. § 1396-1). Once the Secretary approves a state plan, the state becomes generally eligible to receive federal matching funds. These funds, defined as “federal financial participation” (“FFP”), are designed to cover a percentage of the amounts “expended . . . as medical assistance under the State plan.” 42 U.S.C. § 1396b(a)(1).

FFP grant amounts are based on a given state’s Federal Medical Assistance Percentage (“FMAP”), which is the percentage of the state’s medical assistance expenditures for which federal reimbursement is available. *Id.* § 1396d(b); *see also* 42 C.F.R. § 433.10. Although federal Medicaid funding is often denoted as reimbursement, it actually operates as a series of advance payments. *See* 42 U.S.C. 1396b(d); *Solomon v. Califano*, 464 F. Supp. 1203, 1204 (D. Md. 1979). At the beginning of every quarter, each participating state submits an estimate to the CMS, in whom the Secretary has delegated the authority to review such submissions, of allowable Medicaid expenditures for that quarter. 42 U.S.C. § 1396b(d)(1). In turn, CMS disburses to that state, in advance, an amount equal to the FMAP of the state’s estimation “of the total amount expended during such quarter as medical assistance under the State plan.” *Id.* § 1396b(a)(1). Because the federal funds are paid out in advance, the Medicaid statute builds adjustments into each quarterly disbursement, and the amount received must be “reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section . . . for any prior quarter.” *Id.* § 1396b(d)(2)(A).

Overpayments may be withheld from future advances or, in the event of a dispute over a disallowance, may be retained by the state at its option pending resolution of the dispute. *Id.* § 1396b(d)(5). When a state discovers that it has made an overpayment, it has one year to attempt

to recover such payment.<sup>2</sup> Once this time period expires, the Secretary is entitled reduce, or make disallowances to, the state's FFP payment to reflect the overpayment. *Id.* § 1396b(d)(2)(C). The federal government's right to collect overpaid funds in the form of FFP disallowances "operates independent of a state's recovery of funds wrongfully disbursed." *West Virginia I*, 649 F.3d at 219; *see also* 42 U.S.C. § 1396b(d)(2)(C) (noting that once recoupment period expires, the Secretary is to make an appropriate adjustment "whether or not recovery was made"). As the Fourth Circuit noted in a companion case to the present litigation, "[t]he sine qua non of a proper disallowance is an overpayment." *Id.* at 224 (citing 42 U.S.C. § 1396b(d)(2)(A)).

The Social Security Act uses the term "overpayment" in "two related senses." (ECF No. 24 (DAB Decision No. 2185) at 8.) Within § 1396b(d)(2)(C), the term refers to payments made by a state Medicaid program "to a provider which is in excess of the amount that is allowable for services furnished" under Title XIX. 42 C.F.R. § 433.304. Because these types of overpayments are based on expenditures that are not allowable under the statute in the first place, CMS is entitled to recoup the share of federal money expended in an unauthorized way. *See West Virginia I*, 649 F.3d at 224–25 (noting that CMS is entitled to disallow portions of future funding to recoup overpayments where a third party "cause[s] 'the amount paid by a Medicaid agency to a provider [to be] in excess of the amount that is allowable [under the Medicaid Act].'" (quoting 42 C.F.R. § 433.304)).

Overpayment is also discussed in 42 U.S.C. § 1396b(d)(3), which provides that:

The pro rata share to which the United States is equitably entitled, as determined by the Secretary, of the net amount recovered during any quarter by the State or any political

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<sup>2</sup> The statute was amended in 2010 to increase the state's recoupment period to one year. At all times relevant to the instant litigation, however, the time limit was sixty days. *See West Virginia I*, 649 F.3d at 219 n.1. The amendment is not relevant to this case, however, as it is undisputed that CMS did not seek to make adjustments until well over a year after the overpayments were discovered. (*See, e.g.*, ECF No. 1 at 7–8.)

subdivision thereof with respect to medical assistance furnished under the State plan shall be considered an overpayment to be adjusted under this subsection.

42 U.S.C. § 1396b(d)(3)(A).

The DAB, the HHS body which reviews CMS disallowance determinations, has determined that this statutory provision “‘applies in instances . . . where a State has recouped benefits that have been correctly paid to recipients,’” and further that “‘the types of ‘recoveries’ covered by [Section 1396b(d)(3)] are not ‘qualified in any way.’” (ECF No. 24 at 19.)

## **B. Factual Background**

The current Medicaid dispute revolves around funds recovered by the State of West Virginia pursuant to a 2004 settlement agreement with Purdue Pharma L.P. (“Purdue”) and other pharmaceutical manufacturing companies. On June 11, 2001, West Virginia, acting through its Attorney General, filed a state court complaint against Purdue and other manufacturers of OxyContin alleging violations of the West Virginia Consumer Credit and Protection Act (“WVCCPA”), common law continuing public nuisance, unjust enrichment, indemnity, negligence, medical monitoring, and violations of the West Virginia Antitrust Act. (ECF No. 1 at 6–7.) These allegations centered on the defendants’ efforts to market the prescription drug OxyContin. Specifically, West Virginia alleged that the defendants “‘manufactured, promoted, and marketed OxyContin for the management of pain by making misrepresentations or omissions regarding the appropriate uses, risks, and safety of OxyContin.” (ECF No. 24, Ex. 6 at 42–43.)

The state alleged that this deceptive marketing campaign rendered “‘physicians, pharmacists, and patients” unable to properly evaluate the risks associated with the drug and consequently caused the State to spend “‘millions of dollars each year” on two types of expenditures: (1) excessive prescription costs; and (2) services and programs to treat the

“deleterious health effects” caused by OxyContin. (*Id.*; *see also* ECF No. 31 at 5 (state court defendants’ improper marketing “resulted in the State incurring costs for ‘excessive and unnecessary’ OxyContin prescriptions and for health care services to diagnose and treat the adverse consequences of OxyContin use”).)

The original complaint was later modified in two significant ways. First, in response to the defendants’ motion to dismiss the lawsuit, West Virginia amended the complaint to add three state agency plaintiffs responsible for paying for OxyContin prescriptions on behalf of eligible citizens. (ECF No. 24, Ex. 6 at 94–125.) The amended complaint named the DHHR (which administers the state Medicaid program through its Bureau for Medical Services), the West Virginia Bureau of Employment Programs (“BEP”) (which administered the West Virginia Worker’s Compensation System)<sup>3</sup>, and the West Virginia Public Employees Insurance Agency (“PEIA”) (which administers the health insurance program for state, county, and municipal employees). (*Id.* at 94; ECF No. 31 at 6; ECF No. 1 at 2.) Second, the State dropped several claims, such that at the time of settlement there were only two counts remaining: (1) a claim under the WVCCPA; and (2) a public nuisance claim. (*See* ECF No. 1 at 7.) Throughout the administrative proceedings, the parties have referred to these two claims as Count I and Count II, respectively, and the Court will adopt that terminology.

Originally, West Virginia sought to recover the same “restitution and reimbursement” damages on both counts. These damages included (1) all OxyContin prescription costs incurred by the state agencies as a result of the defendants’ conduct; (2) all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences

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<sup>3</sup> West Virginia has since transitioned to a system of private insurance for the provision of workers’ compensation, regulated by the state Insurance Commissioner. W. Va. Code §§ 23–1–1(e), 23–2c–1 to –24.

associated with OxyContin use (including addiction); and (3) all prescription costs incurred by consumers related to OxyContin. (ECF No. 24, Ex. 6 at 55–56, 59.) Over the course of the litigation, however, West Virginia began to pursue different damage theories for the different claims. Specifically, the state sought damages in the form of reimbursement for prescription expenditures with respect to Count I, and in the form of substance abuse and treatment expenditure reimbursement with respect to Count II.<sup>4</sup>

The parties agreed to settle the case on November 4, 2004. (ECF No. 1 at 7.) Under the terms of the settlement agreement, signed on December 15, 2004, West Virginia agreed to release the defendants from all claims in exchange for a payment of \$10 million, to be made in four equal installments. (ECF No. 24, Ex. 7 at 105.) The settlement provided for the sum to be paid to the Consumer Protection Fund of the office of the Attorney General and “used (subject to a determination of attorney’s fees and expenses by the Court) in conformity with the [court’s] Final Order.” (*Id.* at 106–07.) That court order required the plaintiffs to pay their attorney’s fees out of the proceeds of the settlement and apportioned the remaining settlement funds to be used for (1) accredited continuing medical education programs directed at the use, abuse, and diversion of prescription drugs; (2) law enforcement training, education, and funding relating to abuse and diversion of prescription drugs; and (3) community based drugs and diversion education programs. (ECF No. 24, Ex. 2 at 9.)

West Virginia did not report the settlement to CMS, and the agency did not become aware of the settlement proceeds until 2007. At that time, CMS notified DHHR that it would be

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<sup>4</sup> This bifurcation is undisputed by the parties and appears in several documents that were part of the DAB record. The clearest articulation of the damages theories is perhaps an internal memorandum between the state’s lawyers, circulated on September 27, 2004, and providing a table describing the damages theories for each count. (ECF No. 24, Ex. 7 at 81–82.)

disallowing \$4,143,075 in FFP on the basis that this figure represented the federal government's proper share of the OxyContin settlement. (*Id.* at 4–6.) CMS classified these funds as overpayments, and determined its appropriate share by “equitably distributing” \$5.5 million of the settlement fee to DHHR and then multiplying that total by West Virginia's FMAP. (*Id.* at 4.) DHHR promptly appealed CMS's disallowance determination to the DAB on September 7, 2007. (ECF No. 24 at 46–49.) DHHR made several arguments against the validity of the disallowance, but primarily asserted that the settlement proceeds were not overpayments within the meaning of the relevant statutory framework, and thus that CMS was not entitled to disallow any share of those proceeds. (*See id.* at 46–48; *id.* at 78–86.)

### **C. Procedural History**

#### **1. DAB Decision No. 2185**

On July 14, 2008, the DAB issued a ruling, DAB Decision No. 2185. (*Id.* at 7–28.) The DAB affirmed CMS's general authority to disallow FFP to recoup the federal government's share of the OxyContin settlement proceeds, (*id.* at 7), but provided alternative legal justifications for that authority. Specifically, it concluded that CMS was entitled to make the disallowance that it did “under either section 1903(d)(2) of the Act, section 1903(d)(3) of the Act, or OMB Circular A-87's provision regarding applicable credits.”<sup>5</sup> (*Id.* at 16.)

In recognition of the two distinct damages theories pursued in the underlying litigation, the DAB divided the settlement proceeds into two corresponding portions. As to Count I, the DAB determined that the federal government was entitled to the share of the settlement proceeds that represented reimbursement for Medicaid expenditures on OxyContin prescriptions by the authority

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<sup>5</sup> The DAB consistently refers to the Medicaid Act according to its placement in the Social Security Act, Title XIX (i.e. Section 1903), rather than by its official codification at 42 U.S.C. § 1396.



of both 42 U.S.C. §§ 1396b(d)(2) and 1396b(d)(3). (*Id.*) To the extent those expenditures represented “excessive and medically unnecessary” prescription costs, they were not allowable under the Medicaid Act, and thus represented FFP overpayments within the meaning of § 1396b(d)(2). (*Id.* at 19.) Further, to the extent they represented allowable medical expenditures because used on valid OxyContin prescriptions, they were recoverable by the federal government under § 1396b(d)(3). The underlying litigation was brought, at least in part, on behalf of the state Medicaid program to recover expenditures made on behalf of that program, rendering the proceeds resulting from the settlement of such a claim a “recover[y] . . . by the State . . . with respect to medical assistance.” (*Id.* at 19–20.) As such, the DAB determined that the federal government was entitled to recover its equitable pro rata share. (*Id.*)

With respect to Count II, the DAB determined that the federal government’s share was authorized by § 1396b(d)(3) alone. (*Id.* at 20.) Because that damages theory sought reimbursement for substance abuse treatment costs, and those costs generally count as allowable “medical assistance,” the expenditures did not represent unauthorized expenditures. (*Id.* at 22.) However, as above, the settlement proceeds, recovered pursuant to a lawsuit calculated in some degree to recover Medicaid expenditures, qualified as a recovery within the meaning of § 1396b(d)(3). The DAB reasoned that:

Given this clear and substantial connection between count II’s reimbursement claim and the settlement, we find that the State’s receipt of the settlement proceeds constituted a ‘recover[y] . . . by the State . . . with respect to medical assistance’ for OxyContin-related substance abuse treatment. Consequently, CMS was authorized under section 1903(d)(3) to claim the federal government’s ‘equitable share’ of the recovery that relates to count II of the amended complaint.

(*Id.*)

Alternatively, the DAB determined that CMS was entitled to disallow the FFP at issue, as to both counts of the underlying litigation, because the entire settlement represented an “applicable credit” as defined by OMB Circular A-87, which sets cost principles to govern the receipt of federal funds. (*Id.* at 23.) The circular requires that a recipient of federal funds make a report to the federal government any time it obtains outside funds in an area in which the recipient receives federal funding, in order to allow the federal government to share in the cost saving created by such funds. (*See id.* (“If the award recipient obtains funds that offset or reduce an expense item allocable to the federal award, then the recipient must share that cost reduction with the federal government.”).) Given the direct relationship between the underlying litigation and the state Medicaid program, the DAB found that “there is a sufficient basis for finding that receipt of the settlement proceeds effectively reduced the State’s overall costs of providing Medicaid-covered medical or health services . . . Absent a disallowance, that cost reduction or savings would accrue to the State alone.” (*Id.* at 24.) As such, the DAB determined the federal government was entitled to a share of the proceeds as applicable credits.

Ultimately, however, while comprehensively upholding CMS’s authority to recoup the federal share of the settlement at issue, the DAB determined that CMS had not adequately articulated its method for calculating what that federal share should be. (*Id.* at 27.) In particular, the original calculation failed to explain “why more than one-half of the settlement proceeds were distributed to Medicaid, when there were two other named plaintiffs . . . on whose behalf the plaintiffs sought ‘reimbursement.’” (*Id.*) The DAB remanded the case to CMS to recalculate the disallowance and explain “the criteria and methods used by CMS to calculate the disallowance amount.” (*Id.* at 28.) The DAB further instructed CMS to “give DHHR a reasonable opportunity

to submit additional evidence and argument about what would constitute an appropriate or equitable distribution of the OxyContin settlement proceeds to Medicaid.” (*Id.* at 27.)

## **2. DAB Decision No. 2278**

On remand, CMS followed these instructions and afforded DHHR an opportunity to provide “data driven, supportable, and documented” evidence in support of calculating the disallowance. (ECF No. 24, Ex. 7 at 8.) As will be discussed in more detail below, DHHR did not take advantage of this opportunity, submitting only a letter and one-page table, on November 12, 2008, indicating state Medicaid expenditures for “opioid” substance abuse treatment for the calendar year 2000. (*Id.* at 9–11.) As DHHR admits, this letter noted that “its expenditure data did not differentiate between treatment for OxyContin abuse and treatment for abuse of other kinds of opioids (such as heroin or methadone).” (ECF No. 31 at 7.) When CMS requested more specific information to help with its calculation, DHHR noted that CMS already had everything it needed based on the letter and prior discovery between the parties. (ECF No. 24, Ex. 7 at 13.)

CMS ultimately recalculated the disallowance to be \$4,099,452. (*Id.* at 4–7.) CMS based this disallowance upon “the material the DHHR provided to CMS on November 12, 2008 and the documents the DHHR earlier supplied during the course of informal discovery.” (*Id.* at 5.) A central feature of the methodology employed by CMS was an allocation of the settlement based on the two types of damages/reimbursement the state sought in the underlying litigation (as described above, prescription costs for Count I and substance abuse treatment costs for Count II). (*Id.* at 5–6.) In general, CMS determined the proportion of the settlement attributable to each count, divided the settlement proceeds accordingly, and then determined Medicaid’s appropriate share of each portion.

More specifically, CMS began by determining, using data provided by the state itself, the amount of OxyContin expenditures the state sought as reimbursement for each count. For Count I, CMS used the deposition testimony of the state's expert on damages, Daniel Selby, as well as the exhibits attached to his deposition, to determine total OxyContin expenditures for each of the named plaintiff state agencies between the years 2000 and 2002. (*Id.*) Based on that information, CMS determined that the state expended a total of \$21,096,689.37, and that \$12,463,638.94 of that total (59.079%) represented DHHR Medicaid expenditures. (*Id.*) As for Count II, CMS relied on two pieces of evidence: (1) a damages estimate on a pre-trial form submitted by West Virginia in the underlying litigation, which stated that the Behavioral Health Service bureau of DHHR, an entity not reimbursed by federal Medicaid, expended \$2,000,000 on OxyContin substance abuse treatment annually; and (2) the table DHHR submitted in its November 12, 2008 letter to CMS, indicating that the state Medicaid program spent \$1,786,757.08 on undifferentiated opioid substance abuse in the year 2000. (*Id.*) CMS extrapolated these expenditures over the three-year period between the same 2000-2002 timeframe that CMS used to calculate its pro rata share under Count I, and determined that “[s]ubstance abuse treatment costs associated with OxyContin for years 2000–2002 totaled \$11,360,271.24.” (*Id.* at 5.) DHHR Medicaid expenditures represented 47.184% of this total.

Based on these calculations, CMS determined that the state sought \$32,456,960.61 in total damages—\$21,096,689.37 (or 64.999% of the total) pursuant to Count I and \$11,360,271.24 (35.001%) pursuant to Count II. (*Id.* at 6.) Accordingly, CMS allocated the \$10 million settlement proportionally to the two counts: \$6,499,900 (\$21,096,689.37 multiplied by 64.999%) to Count I and \$3,500,100 (\$11,360,271.24 multiplied by 35.001%) to Count II. (*Id.*) CMS then

multiplied these figures by the proportion of expenditures attributable to DHHR, as defined above, to determine the total Medicaid share of each type of expenditure. At this step, Medicaid was allocated \$3,840,075.92 (\$6,499,900 multiplied by 59.079% Medicaid share) of the Count I proceeds and \$1,651,487.18 (\$3,500,100 multiplied by 47.184% Medicaid share) under Count II. (*Id.*) Finally, CMS multiplied the total Medicaid share for each count by the FMAP (74.65% at the time) to arrive at the federal government's total share of the settlement. (*Id.*) This yielded a total of \$2,866,616.68 for Count I, \$1,232,835.18 for Count II, and a total federal recovery of \$4,099,451.86.<sup>6</sup> CMS did not account for the fact that the State paid \$3,333,333 in court-ordered attorney's fees out of the settlement proceeds.

DHHR appealed the revised determination to the DAB on March 20, 2009, arguing that the CMS determination was arbitrary and capricious for three primary reasons: (1) on Count I, it failed to account for damages claims on behalf of a fourth plaintiff, the class of West Virginia consumers on whose behalf the state Attorney General initiated a *parens patriae* action; (2) on Count II, it ignored the State's litigation strategy by relying on evidence not utilized by the State and not considering the evidence the State actually relied upon; and (3) as to both counts, it failed to take into account the cost of litigation, namely the award of attorney's fees. (ECF No. 24, Ex. 1 at 34.) In its Decision No. 2278, the DAB reaffirmed CMS's authority to claim a share of the settlement proceeds, rejected Plaintiff's first two contentions, and upheld as reasonable CMS's general calculation method. (ECF No. 24 at 29–30.)

However, as to the third contention, it agreed with the plaintiff and found that “based on the particular circumstances of this case, we have determined to require deduction of the plaintiffs’

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<sup>6</sup> CMS then rounded this number up to arrive at a total disallowance of \$4,099,452.

attorney's fees (totaling \$3,333,333) from the gross settlement amount (\$10 million) prior to calculation of Medicaid's share of the settlement." (*Id.* at 41–42.) The DAB calculated the appropriate disallowance to be \$2,732,968 by subtracting the attorney's fee award from the \$10 million settlement total, and then applying the CMS methodology to the new starting number of \$6,666,667. (*Id.* at 44.) West Virginia subsequently filed the present complaint before this Court seeking review of the final decision of the DAB.<sup>7</sup> (ECF No. 1.)

### 3. Federal Court Proceedings

By Order of this Court entered July 27, 2010, the instant case was stayed pending the Fourth Circuit's review in *West Virginia I*, 649 F.3d 217 (4th Cir. 2011). (ECF No. 21.) In that case, as in this one, the West Virginia Attorney General proceeded against a pharmaceutical manufacturer on behalf of state agencies, including DHHR, responsible for paying prescription costs under various state programs. *West Virginia I*, 649 F.3d at 219–20. West Virginia claimed that the defendants fraudulently inflated the reimbursement values of certain drugs, in violation of the WVCCPA, and that these inflation tactics artificially increased the amount the state agencies were required to pay for prescriptions. *See id.* at 220.

Ultimately the case settled, but West Virginia did not report the settlement proceeds to CMS. Nonetheless, in similar fashion as this case, CMS discovered the settlement and disallowed what it determined to be the federal share of the proceeds. *Id.* There, as here, West Virginia argued that CMS lacks the statutory authority to make a disallowance based on state receipt of settlement proceeds because these proceeds are not overpayments to "providers," within the

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<sup>7</sup> A final decision by the DAB, upholding a CMS disallowance determination, is subject to review as final agency action under the Administrative Procedure Act. *See Kansas Health Policy Auth. v. U.S. Dep't of Health and Human Servs.*, 798 F. Supp. 2d 162, 165 n.5 (D.D.C. 2011)(citing *New Mexico Dep't of Info. Tech. v. U.S. Dep't of Health and Human Servs.*, 577 F. Supp. 2d 347, 351 (D.D.C. 2008)).

meaning of 42 C.F.R. § 433.304, and West Virginia correspondingly lacked any duty to recoup such funds. *Id.* at 224. The Fourth Circuit rejected that argument. Emphasizing that the “sine qua non of a proper disallowance is an overpayment,” that court held that “the Medicaid Act plainly authorizes CMS to disallow payments to a state when that state overpays a provider, regardless of whether the state has recovered from a provider or a third party—or, indeed, recovered from anyone at all.” *Id.* at 224. The decision affirmed CMS’s ability to make Medicaid disallowances to recoup the federal share of settlement proceeds recovered by a state pursuant to claims brought on behalf of its Medicaid program.

## ***II. STANDARD OF REVIEW***

Rule 56(c) of the Federal Rules of Civil Procedure provides that a court shall grant summary judgment “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, shows that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). When parties files cross-motions for summary judgment, the trial court must consider each motion separately and view the facts relevant to each in the light most favorable to the nonmoving party. *Mellen v. Bruting*, 327 F.3d 355, 363 (4th Cir. 2003). Each moving party bears the burden of showing that there is no genuine issue of material fact and that he is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Normally, Rule 56(e) requires the nonmoving party to go beyond the pleadings and by its own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial. *Id.* at 324.

However, where summary judgment is sought in a case reviewing final agency action, “Rule 56(c) does not apply because of the limited role of a court reviewing that administrative record.” *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89 (D.D.C. 2006). “In this context, summary judgment becomes the ‘mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.’” *Ohio Valley Envtl. Coal. v. Hurst*, 604 F. Supp. 2d 860, 879 (S.D. W. Va. 2009) (quoting *Mainella*, 459 F. Supp. 2d at 90).

The Administrative Procedure Act constrains the district court’s scope of review in such cases and provides that a reviewing court shall set aside agency actions, findings of fact, and conclusions of law only when they are “arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law.” 5 U.S.C. § 706(2)(A). The APA further provides that the district court must set aside any agency findings and conclusions that are “unsupported by substantial evidence . . . [appearing] on the record of an agency hearing.” *Id.* at § 706(2)(E).

The arbitrary and capricious standard is a “highly deferential standard which presumes the validity of the agency’s action.” *Nat. Res. Def. Council v. U.S. Envtl. Prot. Agency*, 16 F.3d 1395, 1400 (4th Cir. 1993). When applying it, a court is limited to the task of reviewing whether the deciding body “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action, including a ‘rational connection between the facts found and the choice made.’” *Kreis v. Sec’y of the Air Force*, 406 F.3d 684, 686 (D.C. Cir. 2005) (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). While a “searching and careful inquiry of the record” is required, this inquiry is primarily educational, to allow the court to assess the agency’s decision-making process. *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177,



192 (4th Cir. 2009); *see also Ethyl Corp. v. Env'tl. Prot. Agency*, 541 F.2d 1, 36 (D.C. Circ. 1976) (district court scrutiny of the record designed to allow it to “comprehend the meaning of the evidence relied upon and the evidence discarded; the questions addressed by the agency and those bypassed; the choices open to the agency and those made”). Ultimately, the court’s review of the administrative record “is intended to inform it of the propriety of the agency’s decision, not to enable the court to make its own decision,” *W. Va. Dep’t of Health and Human Res. v. U.S. Dep’t of Health and Human Servs.*, 899 F. Supp. 2d 477, 482 (S.D. W. Va. 2012), and a court is not empowered to substitute its judgment for that of the agency. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971).

The agency’s factual conclusions must be supported by substantial evidence, or “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consol. Edison Co. v. Nat’l Labor Relations Bd.*, 305 U.S. 197, 229 (1938). A court must uphold a decision that has “substantial support in the record as a whole” even if it might have decided differently as an original matter. *AT&T Wireless PCS, Inc. v. City Council of Va. Beach*, 155 F.3d 423, 430 (4th Cir. 1998) (quoting *NLRB v. Grand Canyon Mining Co.*, 116 F.3d 1039, 1044 (4th Cir. 1997)).

### ***III. DISCUSSION***

#### **A. Scope of Current Dispute**

In *West Virginia I*, the Fourth Circuit concluded its opinion by noting that, as the result of a settlement agreement with a pharmaceutical manufacturer, “West Virginia received federal Medicaid funding in excess of that authorized by statute. The federal government is entitled to recoup the overage.” 649 F.3d at 225–26. The parties no longer dispute that the same is true of

the instant case. Although Plaintiff's complaint, filed prior to the Fourth Circuit decision, alleged several assignments of error on the part of the DAB in upholding the CMS disallowance determination, the parties, by their more recent summary judgment briefing, now agree that that case resolved Plaintiff's legal contentions as to CMS's constitutional and statutory authority to disallow settlement proceeds at all. (*See* ECF No. 33 at 1; ECF No. 31 (Pl.'s Mem. Supporting its Mot. for Summ. J.) at 1 ("At issue before the Court is whether the Center [sic] for Medicare and Medicaid Services (CMS) properly calculated a disallowance against West Virginia's Federal Medicaid funds."))

Plaintiff did not respond to Defendants' summary judgment motion, nor did it reply to Defendants' response to Plaintiff's summary judgment motion, in which the defendants contended that "the DHHR's summary judgment motion abandons at least five of the seven 'assignments of error' set forth in its complaint challenging the legal basis for the disallowance." (ECF No. 33 at 2.) As such, as formulated in the plaintiff's motion, the "only issue before this Court is whether CMS was arbitrary and capricious in reaching the amount of the disallowance." (ECF No. 31 at 9.) Specifically, the only argument that Plaintiff pursues in light of the decision in *West Virginia I* is that the CMS disallowance calculation, as well as the decision of the DAB to uphold it, was arbitrary and capricious for failing to account for the class of West Virginia consumers on whose behalf, DHHR argues, the underlying litigation against Purdue was commenced pursuant to the Attorney General's *parens patriae* authority. (ECF No. 31 at 10.)

**B. “Some Reasonable Basis” Review of Calculation Methodology**

With respect to the issue currently before the Court—the method of calculating an overpayment award to which the federal government is lawfully entitled—this Court is once again guided by the Fourth Circuit’s decision in *West Virginia I*. As noted above, the court in that case determined that the federal government’s authority to recoup Medicaid overpayments through disallowances is not determined by a state’s actual recovery of such overpayments. In the context of a disallowance based on a state’s receipt of settlement proceeds, this means that the actual division of the settlement proceeds, including their specific allocation to the state Medicaid program, is irrelevant for purposes of determining the appropriate federal share. *See id.* at 219 (noting that “the federal government’s right to collect overpaid funds operates independent of a state’s recovery of funds wrongfully disbursed”). So long as the underlying lawsuit was brought in some manner to recover Medicaid expenditures, the federal government is entitled to recover the share of such expenditures that it determines to be overpayments. *See* 42 U.S.C. § 1396b(d)(2)(A) (describing the HHS Secretary’s authority to adjust quarterly Medicaid disbursements “to the extent of any overpayment or underpayment *which the Secretary determines* was made under this section” (emphasis added)); *id.* at § 1396b(d)(3)(A) (entitling the federal government to recover, as an overpayment, the “pro rata share to which the United States is equitably entitled, *as determined by the Secretary,*” of amounts recovered by a state with respect to medical assistance covered by its Medicaid plan (emphasis added)).

As to the actual calculation of that share, the *West Virginia I* court, recognizing the difficulties associated with determining after the fact the extent to which litigation underlying a

settlement was actually brought on behalf of a state Medicaid program<sup>8</sup>, “fully endorse[d]” the DAB’s review of the CMS calculation, in which it noted that “absent complete or perfect information, an allocation need only have some reasonable basis.” *West Virginia I*, 649 F.3d at 225.

Here, a review of the underlying state court litigation reveals that West Virginia’s ultimate theories of liability and damages were far from a picture of clarity, and that CMS had a reasonable basis for excluding damages on the part of individual consumers and allocating the federal Medicaid share the way it did. The Court agrees with the DAB that CMS’s disallowance calculation was reasonable in light of the record before it. As such, the DAB’s decision to uphold that calculation, particularly with the modification that attorney’s fees should be factored into the disallowance, was neither arbitrary nor capricious.

### **C. Analysis**

At the time West Virginia and the plaintiff agencies in the underlying state court litigation settled their claims, two causes of action remained viable. West Virginia no longer challenges the fact that both were asserted, to some degree, to recover expenditures made by the state Medicaid program. The first, Count I, was for violation of the WVCCPA based on allegations that the defendants “made untrue, deceptive or misleading representations of material facts to, and omitted and/or concealed material facts from, the State and citizens of West Virginia in marketing

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<sup>8</sup> In the absence of a judgment setting forth a specific dollar amount of recovery on each asserted claim, CMS faces a difficult task in determining the extent to which generalized settlement proceeds reflect recovery on behalf of a state Medicaid program. In the instant case, as in *West Virginia I*, the fact of settlement injects some amount of guesswork into that calculation because settlement proceeds do not necessarily reflect the actual damages theories pursued and the extent to which those theories are based on harm suffered by specific entities. In order to convert such settlement proceeds into a Medicaid share, the state’s underlying legal claims must be scrutinized in order to determine the theory of recovery actually sought (and, accordingly, the portion of the recovery that would have been properly allocable to its Medicaid program upon judgment) with the ultimate objective of translating that underlying theory of recovery into an appropriate Medicaid allocation of settlement proceeds.

and promotional campaigns and materials . . . regarding the appropriate use and safety of OxyContin.” (ECF No. 24, Ex. 6 at 54.) As damages, the state sought reimbursement for expenditures made on OxyContin prescriptions and as a result of the defendants’ deceptive marketing campaign. (ECF No. 24, Ex. 4 at 112 (state legal memorandum filed shortly before the scheduled trial date asserting that “as a result of the deceptive practices of the defendant in marketing its product, the plaintiffs actually incurred substantial expense just by paying for the product itself”).) The second, Count II, was a public nuisance claim alleging that as a result of defendants’ marketing campaign and that campaign’s promotion of widespread addiction and substance abuse, the “State has suffered economic harm in the expenditure of massive sums of monies.” (ECF No. 24, Ex. 6 at 59.)

DHHR now alleges that Count I was brought by the Attorney General, pursuant to his *parens patriae* authority, on behalf of all West Virginia consumers who had purchased OxyContin promoted by the defendants.<sup>9</sup> The DAB rejected this argument for two primary reasons. First because it determined it not to be “evident from the record that the State was, at the time of settlement, seeking damages on behalf of individual consumers.” (ECF No. 24, Ex. 1 at 35.) Second, even assuming the state was pursuing such a theory, “DHHR has provided no valid estimate of those damages.” (*Id.*) The record demonstrates that the DAB’s basis for rejecting DHHR’s arguments on this count was sound.

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<sup>9</sup> “The power to sue as *parens patriae*—literally, parent of the country—is ‘inherent in the supreme power of every State.’” *West Va. ex rel. Morrissey v. Pfizer, Inc.*, 969 F. Supp. 2d 476, 492 (S.D. W. Va. 2013) (quoting *Mormon Church v. United States*, 136 U.S. 1, 57 (1890)). “[*P*]arens patriae is a standing doctrine under which a state may under proper circumstances sue on behalf of its citizens when a separate quasi-sovereign interest also is at stake.” *United States v. Johnson*, 114 F.3d 476, 481 (4th Cir. 1997) (citing *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 600–01 (1982)).

First, and most obviously, West Virginia consumers are not listed as plaintiffs in the complaint, in either its original or amended form. Moreover, to the extent DHHR argues that the class of consumers are represented by the Attorney General's presence as party to the litigation, there is no specific indication, in either version of the complaint, that the Attorney General was exercising his *parens patriae* authority or bringing suit on behalf of West Virginians as a whole. To the contrary, when describing the parties to the litigation in the original complaint, West Virginia defined the State's interest in the lawsuit as an employer and health insurer, (ECF No. 24, Ex. 6 at 44), and as a provider of social programs to combat substance abuse and addiction, (*id.* at 45). When defining the Attorney General's specific interest in the lawsuit, West Virginia merely stated that "[t]his suit concerns matters of state-wide interest. Darrell V. McGraw, Jr. is the Attorney General of the State of West Virginia . . . and is duly authorized by the Constitution and the statutes of the State of West Virginia to pursue this action." (*Id.* at 44.) Given the express opportunity to define the parties to the litigation, as well as the Attorney General's basis for pursuing the action, the state simply made no reference to *parens patriae* or participation by the citizenry as a whole. Instead, the state's interest was clearly framed in terms of its own expenditures.

Further, as described above, the state eventually amended the complaint to add the plaintiff state agencies out of a concern that several causes of action would not be viable without the presence of these agencies as parties. (*Id.* at 91 (court order noting that adding the state agencies as plaintiffs "makes the Motion to Dismiss the common law claims moot").) In the amended complaint, the state noted that the various state agencies, along with the Attorney General, would be referred to collectively as "'the State' or the 'State of West Virginia.'" (*Id.* at 94.) This

amendment, effected for the specific purpose of establishing the presence of the appropriate parties to pursue the claims in the complaint, did not make any mention of West Virginia consumers as a class. Again, the class of plaintiffs was defined as the state of West Virginia, and there was no indication that the state was pursuing the lawsuit on behalf of its consumers. A good indication of West Virginia's conception of the lawsuit at the time it was filed is the very first paragraph of the complaint, which begins by asserting that the "State of West Virginia spends hundreds of millions of dollars each year to provide or pay for health care and other necessary services and programs on behalf of indigents and other eligible citizens, including payments for the prescription drug OxyContin." (*Id.* at 42.)

However, it is true, as DHHR argued before the DAB, that, as lawsuits evolve, a party's actual method of proving its case can differ somewhat from allegations asserted in an initial complaint. (*See* ECF No. 24 at 76 ("[A]t the end of the day there can be a significant difference between the *allegata* and the *probata*.")) And it is also true that, whether the class of consumers was an actual party to the litigation or not, there is plenty in the record to indicate that, at the time of the settlement, West Virginia was at least trying to pursue, as damages, reimbursement for OxyContin purchases by individual consumers not covered by state-funded insurance plans. For example, in its original complaint, West Virginia asserted that it was seeking to recover, among other things, "restitution and reimbursement for all the costs consumers have incurred in excessive and unnecessary prescription costs related to OxyContin." (ECF No. 24, Ex. 6 at 44.) As the case progressed, and West Virginia's theory of liability solidified, it became clear that the measure of damages the state sought with respect to Count I was confined to "reimbursement for expenditures on OxyContin prescriptions." (ECF No. 31 at 5.)

As to precisely which types of expenditures the state sought reimbursement for, there is contradictory evidence in the record but the state's pre-trial form, submitted less than a month before trial, provides some evidence that individual consumer purchases were on the table. That form stated that one of the issues for trial was whether "the Plaintiffs and West Virginians have suffered an 'ascertainable loss' as a result of Defendants' use or employment of these unfair or deceptive acts or practices." (ECF No. 24, Ex. 6 at 188.) That same form further provided that the state plaintiffs in the case "seek restitution of purchase price for all OxyContin which was purchased by consumers in the State of West Virginia." (*Id.* at 195.) Other evidence of West Virginia's intention to pursue this damages claim exists in the record before the DAB. (*See* ECF No. 24, Ex. 7 at 79 (state expert testifying that state's intent was to attempt to recover prescription spending beyond that expended by the state agencies); *id.* at 81–82 (internal memoranda between state lawyers differentiating between, on the one hand, damages sought by the state and attorney general, including purchases by the "State citizenry," and those sought by the state agency plaintiffs on the other).)

However, there are a number of instances in the state's documents in which the state speaks of the WVCCPA suit as being an effort to recover expenditures by state agencies only, with no mention of citizen consumers. (*See* ECF No. 24, Ex. 6 at 43 (state alleging that, as the result of the defendants' conduct, "the State spends millions of dollars each year to pay for excessive prescription costs and to pay health care and medical costs and provide necessary services and programs on behalf of indigents and other eligible citizens who have used or will use OxyContin"); *id.* at 160 (state lawyer confirming, at a pre-trial hearing, the court's suggestion that the state intended to prove its WVCCPA suit by showing that "the State ended up having to pay" as the



result of defendants' deceptive marketing practices); *id.* at 162 (state lawyer again confirming, at same hearing, that the state's theory of liability on Count I was that "[o]ur state paid . . . a lot of money"); *id.* at 187 (opening paragraph of the state's pre-trial form describing the lawsuit as seeking to recover "amounts spent by the Plaintiff agencies to purchase [OxyContin] on behalf of third-parties for whom it was obligated to do so" as well as "amounts expended in combating the public nuisance created by OxyContin".)

Thus, at the time the case settled, the state's measure of damages under Count I was at best ambiguous. Although its reimbursement claim for OxyContin prescriptions paid for by the plaintiff state agencies was clearly articulated, its further intent to recover prescription expenditures on behalf of the entire class of West Virginia consumers was more vague. This likely stemmed from the fact, noted by the DAB, that unlike with respect to its state agency claims, West Virginia was never able to articulate an accurate and reliable method to calculate consumer losses, either in the state court litigation or in the proceedings before the DAB. The speculative nature of the state's damages estimates on this theory, especially when contrasted with the state's concrete data supporting agency damages, provides further support for CMS's decision to exclude consumer losses when making its disallowance determination.

Over the course of the state court litigation, West Virginia made it clear that, with respect to Count I, the reimbursement it was seeking was in the form of expenditures, measured by the cost incurred by the purchaser, on OxyContin prescriptions (whether that purchaser be the state as an insurer or an individual consumer without state-provided insurance). (*See* ECF No. 24, Ex. 6 at 43–44 (seeking reimbursement and restitution from defendants based on "costs the State has incurred in paying excessive and unnecessary prescription costs related to OxyContin," "costs

expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use,” and “costs consumers have incurred in excessive and unnecessary prescription costs related to OxyContin”); *id.* at 195 (noting the state’s intention at trial to “seek restitution of purchase price for all OxyContin which was purchased by consumers in the State of West Virginia”); ECF No. 24, Ex. 4 at 112–14 (arguing that under state’s WVCCPA theory, plaintiffs suffered “ascertainable loss” simply by “paying for [OxyContin] itself” and that primary remedy sought included “monies paid by the state and restitutionary relief”).)

Consistent with that theory, West Virginia was able to produce concrete OxyContin expenditure data on behalf of each plaintiff state agency. Estimates of such expenditures appear in the original complaint, (*see* ECF No. 24, Ex. 6 at 51–53), and by the time of settlement West Virginia had adduced even more specific expenditure data. Specifically, West Virginia was able to produce evidence showing each state agency’s expenditures on OxyContin in particular, broken down year-by-year, during the time period relevant to the lawsuit. (*See* ECF No. 24, Ex. 7 at 15–27.) Such evidence fits directly with West Virginia’s theory as to Count I: the defendants created a deceptive market for OxyContin, advertising it as a product that it actually was not, and the state and its consumers suffered harm for purposes of that statute every time they paid for a prescription of the falsely advertised product. (*See* ECF No. 24, Ex. 6 at 160–62; *id.* at 111–14.) DHHR argues that the appropriate measure of damages is “what the consumers spent on the product,” (ECF No. 31 at 14), and the data provided with respect to the state agencies directly reflects this.

With respect to individual consumer losses, however, the evidence in the record paints a different picture. West Virginia was simply unable to come up with any data indicating how much consumers had actually spent on OxyContin, as differentiated from how much money the

defendants in the case were able to make on the drug as the result of their sales efforts in the state. Before this Court, as before the DAB, DHHR argues that the ultimate damages award the state was seeking under Count I was \$100,169,345.65, which as the state admits represents Purdue's direct sales numbers, or "the amount of money that Purdue Pharma made on sales of Oxycontin to West Virginians." (*Id.*; see also ECF No. 24, Ex. 6 at 195 (state pre-trial form representing that, "[a]ccording to internal 'direct sales' documents provided by the Purdue defendants in discovery, their earnings alone totaled \$100,169,345.65, for the period 1996 through 2002").) As the DAB recognized, the record does not provide any further explanation as to the derivation of this figure, and there are reasons to doubt that an undifferentiated accounting of a pharmaceutical manufacturer's total sales revenue for a given drug is equivalent to the amount paid for such prescription drugs by individually insured retail consumers.<sup>10</sup>

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<sup>10</sup> The DAB rejected the validity of the \$100 million estimate on the following well-reasoned basis:

In their complaint and elsewhere, the plaintiffs, including the State (in its *parens patriae* capacity), characterized their damages as reimbursement for "expenditures" or costs incurred for OxyContin or OxyContin-related substance abuse treatment. Accordingly, DHHR demands that CMS account for individual consumers' "losses"—a term that we construe to mean actual expenditures or payment obligations incurred by those consumers. In support of that demand, DHHR points to section VIII of its October 8, 2004 Pre-Trial Form. On its face, that document contains no estimate of losses sustained by individual consumers, only a statement that Purdue's "sales revenue" or "earnings" from its West Virginia operations totaled \$100,169,345.65 from 1996 through 2002. DHHR does not explain how, or from what sources, this figure was derived, and the available evidence suggests that the figure does not, in fact, represent consumers' "losses." In particular, a September 27, 2004 legal memorandum prepared by the plaintiffs' attorneys states that the \$100 million figure represented sales revenue to Purdue "as opposed to what was paid by the state and its citizenry (or their various private third party payors), as the latter would be impossible to calculate without knowing what each drug store charged." "Therefore," says this memorandum, "it is difficult to categorize these as 'actual damages' on behalf of the entire State citizenry."

Another difficulty with the \$100 million figure is that it relates to years for which the plaintiffs were not seeking damages.

(ECF No. 24 at 35–36 (citations omitted).)

As is noted below, the DAB's discussion with respect to the time period involved is not entirely accurate as it misstates the applicable limitations period. Nonetheless, it is undisputed that under the correct limitations period, the \$100 million figure still includes sales numbers for at least some years for which the state was not seeking, and could not have sought, damages.

For one, sales revenues by a pharmaceutical manufacturer do not directly correlate to the purchase price actually expended by individual consumers of that drug because such manufacturers do not sell their product directly to individual consumers.<sup>11</sup> Moreover, with respect to West Virginia consumers with private, third party insurers (as opposed to state-provided insurance), a significant part of the aggregate purchase price for prescription drugs will be paid for by those private insurers rather than the individual consumer directly. *See West Virginia I*, 649 F.3d at 220 (“Assuming the patient is insured, the pharmacist submits a claim for reimbursement for the drug purchase to the patient’s health-insurance program.”); *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 71 (D. Mass. 2005) (describing the procedure by which an individual with private insurance is reimbursed for her prescription drug purchases, and noting that in the typical transaction, where the drug is covered by that private insurance plan, “the patient usually pays a copayment, either based on a percentage of [average wholesale price] or a flat copayment. The remainder of the payment is made by either a [third party provider] or a [pharmacy benefit manager] on behalf of the [third party provider].”). And while West Virginia

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<sup>11</sup> The actual means by which prescription drugs are eventually distributed to consumers, and pursuant to which third-party insurance providers in turn cover prescription drug purchases at the consumer level is a highly complex process that is beyond the scope of either this case or the underlying state court litigation. *See generally In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005) (providing a general discussion of drug pricing and reimbursement procedures). For present purposes, however, the important takeaway is that prescription drugs are typically distributed through a multifaceted supply chain, with actors at each level of that chain pursuing their own measure of profit margin. *See id.* at 69–76. Accordingly, the direct sales revenue of a pharmaceutical manufacturer, situated at the top of that supply chain will not reflect, at least directly, the aggregate retail purchase price paid by individual consumers at the bottom of that supply chain for a given prescription drug. *See New England Carpenters Health Benefits Fund v. First Databank, Inc.*, 244 F.R.D. 79, 82 (D. Mass. 2007) (“Manufacturers typically sell drugs to wholesalers on the basis of [wholesale acquisition cost.] Wholesalers sell drugs to retail pharmacies based on [wholesale acquisition cost] plus or minus a factor that generates a margin for the wholesaler . . . Although retailers buy pharmaceuticals on the basis of [wholesale acquisition cost], they get reimbursed by [third party providers] and consumers for branded drugs based on [a different metric].”). Given the many actors involved and the multitude of factors that determine the ultimate price a given consumer will pay at the counter for a prescription drug, the manufacturer’s total sales revenue, without more, is simply not the accurate measure of consumer expenditures (representing consumer losses on West Virginia’s theory) that West Virginia now represents it to be.

clearly sought damages on behalf of the state agencies that provided insurance for covered individual purchasers of OxyContin, and at least arguably sought damages on behalf of individual West Virginia consumers as a whole, there is no indication in the record that West Virginia ever sought recovery on the basis of expenditures made by any private insurance company.

The lawyers for the state acknowledged the disconnect between the direct sales number and the state's consumer damages theory in an internal memorandum, prepared close to the time of the scheduled trial and noting that the \$100 million figure "represents what Purdue sold as opposed to what was paid by the state and its citizenry (or their various private third party payors), as the latter would be impossible to calculate without knowing what each drug store charged." (ECF No. 24, Ex. 7 at 81.) Thus, in light of the fact that, at least in the pre-trial form, the state expressly sought restitution of the "purchase price for all OxyContin which was purchased by consumers in the State of West Virginia," (ECF No. 24, Ex. 6 at 195), the reference to the \$100 million figure appears aimed at providing context for more specific expenditures actually made by state agencies or individual consumers rather than as an independent estimate of damages.

However, although the state was able to provide further, specific hard data for expenditures made by the agency plaintiffs, it never came forward with anything else tending to prove actual expenditures made by individual consumers. Instead, it appears that DHHR attributes the entire difference between the \$100 million figure and the specific data on agency expenditures to expenditures by individual consumers. Putting aside the lack of congruence between direct sales numbers, on the one hand, and consumer expenditures on the other, DHHR's proposed allocation ignores West Virginia's repeated admissions that it simply did not have, and did not need as a matter of prosecuting its case, the information necessary to accurately quantify any individual

consumer expenditures, much less any evidence differentiating such expenditures from expenditures made by private insurance companies on such consumers' behalf. (See ECF No. 24, Ex. 7 at 81 (internal memorandum, prepared close to the settlement date, noting that it would be "impossible" to calculate purchase price paid by the state and its citizens for OxyContin "without knowing what each drug store charged"); ECF No. 24, Ex. 6 at 139 (state counsel stating that state did not intend to prove its case "patient by patient"); *id.* at 151 (counsel noting that state doesn't keep data on individual OxyContin purchases and would incur considerable difficulty and expense in producing it); (ECF No 24, Ex. 4 at 111 (state court memorandum resisting defendant's attempt to compel information about individual consumer patients because it was "irrelevant to the plaintiff's claims" and unable to be produced "without violating state and federal laws ensuring the privacy of the individual patients involved").)<sup>12</sup>

Thus, it is simply not the case, as DHHR continues to argue, that the state was "prepared to prove" \$100,169,345.65 in damages for violations of the WVCCPA. (ECF No. 24, Ex. 1 at 39.) That figure does not fit within the theory of damages West Virginia pursued during the litigation because it does not represent costs expended by individual consumers of OxyContin. It

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<sup>12</sup> In its summary judgment briefing before this Court, DHHR argues that the \$100 million figure is the appropriate measure of actual damages under the WVCCPA. (ECF No. 31 at 14.) It also argues, however, that the DAB was arbitrary and capricious for failing to consider the possibility of statutory damages, which DHHR now appears to argue would have provided a "valid estimate of damages relating to the consumer damages." (*Id.* at 16.) West Virginia never raised this argument before the DAB, and its sole evidence that the statutory damages theory was pursued in the state court litigation is that an internal memorandum between the state's lawyers mentioned the availability of statutory penalties to the AG for each violation of the WVCCPA. (*Id.*) However, even if statutory damages were considered, DHHR's cited memorandum mentions the state's intent to seek the maximum penalty "for each prescription." (ECF No. 24, Ex. 7 at 81.) Thus, any statutory damages argument would require quantifying some measure of individual OxyContin purchases, and it remains the case that West Virginia has never provided any evidence of *how many* individual consumers purchased *how many* prescriptions of OxyContin. As noted above, it consistently maintained that "[w]e have a marketing case . . . we're not going to prove it, patient by patient." (ECF No. 24, Ex. 6 at 139.) Thus, even if statutory damages were considered, such consideration would not change the fact that West Virginia never provided a way to accurately measure the proper amount of such damages. The \$100 million figure by definition refers to direct earnings by the manufacturer and thus provides no basis for calculating an award of statutory damages based on individual consumer purchases.

does not differentiate between revenues received by the manufacturer (which are often paid to the manufacturer not by the consumer but by either wholesale distributors or retail pharmaceutical providers) and actual purchase prices paid by retail purchasers; nor does it detail the complex procedure by which a manufacturer's wholesale revenues are derived in a way that would allow the DAB or this Court to draw a reliable comparison between such revenues and consumer expenditures. Further, it does not differentiate between expenditures made by West Virginia citizens, on whose behalf West Virginia claims it was seeking to recover, and those made by private insurance companies, expenditures by whom the state never indicated its intent to recover. Moreover, even if direct sales by Purdue were an appropriate starting point for calculating the state's losses with respect to OxyContin prescriptions, the \$100 million figure is inappropriate because, as the DAB noted, it "relates to years for which the plaintiffs were not seeking damages."<sup>13</sup> (ECF No. 24 at 36.) The fact that the \$100 million figure represented at least some sales figures from outside the applicable statute of limitations period is further evidence that it was meant to serve as a reference point to compare actual expenditures incurred rather than as an independent measure of damages.

This conclusion is bolstered by the deposition testimony of Daniel Selby, the state's expert on damages, who asserted that the state agency OxyContin expenditures were "the only specific pay orders I know of," that "the first-line prayer will be to get what the State has paid," that, with

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<sup>13</sup> In its opinion, the DAB mistakenly noted that West Virginia has a two-year statute of limitations for claims brought under the WVCCPA. As DHHR correctly points out, the WVCCPA utilizes a four-year statute of limitations. W. Va. Code. § 46A-5-101(1). Nonetheless, even under the appropriate statute of limitations, the \$100 million figure would still include at least some sales from before the applicable period, as DHHR admitted in its briefing before this Court. (ECF No. 31 at 15 n.6 ("Admittedly, the 1996 to 1997 year would not be covered. Therefore a *pro rata* share is applicable).) As such, the DAB's ultimate conclusion is still supported, and the undifferentiated \$100 million direct sales figure still stands in contrast to the figures supporting the state agency expenditures, which represented actual expenditures and were broken down year-by-year.

respect to the defendants' direct sales numbers, "I'm not aware of what counsel will do," and that he would only testify as to the gross sales numbers "if [he] can get an accurate picture of what those numbers are." (ECF No. 24, Ex. 7 at 79.) Mr. Selby's testimony indicates that while the state was prepared to provide specific evidence as to the damages incurred by the state agencies, it was not prepared, without further information, to prove the nature of the remaining expenditures contributing to the \$100 million figure in any concrete way. The uncertainty the state's lead damages expert expressed towards the \$100 million figure demonstrates that the figure was simply not a workable estimate of losses actually suffered by the state and its citizens.

Such was the state of West Virginia's lawsuit at the time it settled, as it appears in the record before the DAB. West Virginia was pursuing two causes of action that clearly sought reimbursement for state expenditures on OxyContin prescription and treatment costs. With respect to Count I, the state's damages theory clearly sought to recover West Virginia's *expenditures* on OxyContin prescriptions. As to precisely which expenditures the state sought to recover, the record is not dispositive. Clearly they were sought on behalf of the plaintiff state agencies, but, as documented above, there are also references to purchases by all West Virginia consumers. However, this class was not included as a plaintiff to the litigation, either directly or through the Attorney General. Moreover, the state, in contrast to its showings with respect to state agency prescription expenditures, was not able to provide any specific data documenting individual consumer expenditures other than a reference to the defendants' total OxyContin sales revenue in West Virginia, which the state itself acknowledged did not represent "what was paid by the state and its citizenry." (ECF No. 24, Ex. 7 at 81.)

On this record, the DAB concluded that:



Because there is no hard evidence that the State was seeking damages on behalf of individual West Virginia consumers at the time of the OxyContin settlement, and because DHHR failed to furnish information that would enable CMS (or the Board) to place a value on any claim for reimbursement of consumers' losses, we hold that CMS acted reasonably in allocating the settlement proceeds among only the three named state agency plaintiffs.

(ECF No. 24 at 36.) Given the ambiguity described above with respect to whether the claims were being pursued on behalf of the class of consumers and, if so, the appropriate way to calculate such damages, CMS had a reasonable basis to exclude such consumer claims when calculating its disallowance. As such, the Court does not find that the DAB's decision to affirm that disallowance was arbitrary and capricious.<sup>14</sup>

This determination is bolstered by the fact that this case has already been remanded for the sole purpose of allowing CMS to make a revised disallowance determination. Specifically, in its first decision, the DAB ordered that "CMS shall give DHHR a reasonable opportunity to submit additional evidence and argument about what would constitute an appropriate or equitable distribution of the OxyContin settlement proceeds to Medicaid." (ECF No. 24 at 27.) In

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<sup>14</sup> The same is true of the DAB decision to affirm the CMS disallowance with respect to Count II. Although DHHR does not assert this argument in its summary judgment briefing and appears to have abandoned it, DHHR's initial complaint before this Court alleged that the "reasons for the disallowance and procedures utilized by CMS to determine it" are arbitrary and capricious in part for "[d]isregarding other State agencies, such as the Department of Military Affairs from the allocation of settlement proceeds." (ECF No. 1 at 12-13.) This argument appears to be made with respect to a single reference in West Virginia's pre-trial form, which asserted Count II damages on behalf of the West Virginia Department of Public Safety (an agency whose full name is the West Virginia Department of Public Safety and Military Affairs ("DMAPS")), in the amount of \$2,833,112. (ECF No. 24, Ex. 6 at 195-96.) DHHR made the same argument before the DAB, which rejected it based on three considerations: (1) DHHR failed to provide any concrete evidence of damages to DMAPS during the remand period; (2) in contrast to the agencies considered in CMS's disallowance calculations, DMAPS was never a plaintiff to the state court litigation; and (3) the lack of evidence that the DMAPS-related costs listed in the pre-trial form were even substance abuse related. (ECF No. 24 at 38.) Given the fact that these costs appear to attribute the entire yearly cost of incarceration for each prisoner who was under the influence of OxyContin at the time of his offense to substance abuse treatment costs recoverable under Count II, (*see* ECF No. 24, Ex. 7 at 97), there was certainly room for CMS to question the validity of the \$2.8 million figure. In the absence of more reliable and quantifiable damages with respect to DMAPS, an agency that was not made a party to the underlying state court litigation, CMS had a reasonable basis to determine that the litigation was not brought on its behalf and to allocate the settlement proceeds accordingly. The Court thus determines that the DAB's decision to uphold CMS's disallowance with respect to Count II, to the extent it is even being challenged here, was not arbitrary and capricious.

response to this ruling, CMS offered DHHR the opportunity to submit additional evidence that would clarify DHHR's theory of the underlying litigation, quantify the specific expenditures sought to be reimbursed in that litigation, and allow CMS to better calculate Medicaid's proper share of the settlement proceeds. (ECF No. 24, Ex. 7 at 8 (letter from a CMS assistant regional administrator to DHHR encouraging the agency to submit "any evidence and argument that you wish CMS to consider in reassessing the amount of the disallowance").)

In response to this invitation, DHHR responded, on November 12, 2008, with a two-page letter and a one-page attachment documenting DHHR expenditures on all opioid substance abuse treatment in the year 2000. (*Id.* at 9–11.) This document was intended to address the substance abuse related damages West Virginia sought pursuant to Count II of the underlying litigation. However, it did not differentiate between expenditures based on OxyContin treatment and treatment for other opioid substances like heroin, methadone, or morphine. (*Id.* at 9.) Nor did West Virginia make any attempt to provide further information as to DHHR's proper share of the Medicaid expenditures sought pursuant to Count I. Notably in light of its arguments before the DAB and this Court, it did not argue that expenditures by the class of West Virginia citizen consumers should be factored into the Count I calculation.

CMS responded by affording DHHR another opportunity to make its case and supplement the record, this time specifically requesting that DHHR "please provide to CMS both summary level information and all supporting data addressing both liability theories for the entire period of covered conduct." (*Id.* at 12.) To this, DHHR simply responded that "all data addressing the Count One overpayment/reimbursement claim has long since been in your possession" and that with respect to Count II, DHHR's November 12 letter had provided "precisely" the information

requested by CMS. (*Id.* at 13.) The second letter did not further break down DHHR’s opioid substance abuse numbers into OxyContin-specific expenditures and again did not address the damages theory associated with Count I.

DHHR’s desired disposition of this case is that this Court remand the case to allow for a “calculation or reimbursement that accounts for the losses consumers suffered and for the statutory penalties to which the Attorney General is entitled.” (ECF No. 31 at 16.) DHRR has already had ample opportunity to make its case for what the proper disallowance in this case should be. The evidence adduced to date simply provides no convincing indication that West Virginia was pursuing a theory of consumer losses, with reference to either statutory or actual damages, that could in any way be quantified. The fact that it did not use the remand period to present any additional evidence, save a one-page printout as to substance abuse expenditures (a proffer that CMS dutifully incorporated into its ultimate damages calculation) suggests that consumer expenditure evidence supporting DHHR’s Count I theory simply does not exist. On such a record, the DAB’s decision to affirm CMS’s disallowance calculation, discounted by over \$1 million to account for a court-ordered award of attorneys’ fees, was not arbitrary and capricious.<sup>15</sup>

#### ***IV. Conclusion***

For the reasons discussed above, the Court **FINDS** no grounds on which to set aside the decision of the DAB. Accordingly, the Court **GRANTS** Defendants’ Motion for Summary

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<sup>15</sup> It is true that DHHR proposed alternative methodologies for calculating the disallowance, as it apparently failed to do in the *West Virginia I* litigation. (*See* ECF No. 24, Ex. 1 at 53–57.) However, all three of its proposed methodologies use the \$100 million direct sales figure as the starting point for Count I damages. (*Id.*) As the Court has extensively detailed in this opinion, that number contrasts sharply with the detailed expenditure data forwarded on behalf of the plaintiff state agencies, and is not an accurate representation of the losses suffered by individual consumers as the result of purchasing OxyContin.

Judgment, (ECF No. 29), **DENIES** Plaintiff's Motion for Summary Judgment, (ECF No. 30), **DISMISSES** this case, and **DIRECTS** the Clerk to remove this action from the Court's docket.

**IT IS SO ORDERED.**

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER:        March 22, 2016



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THOMAS E. JOHNSTON  
UNITED STATES DISTRICT JUDGE