IN THE CHANCERY COURT OF RANKIN COUNTY, MISSISSIPPI
20TH CHANCERY COURT DIVISION

In the Matter of:	)	
	)	
MISSISSIPPI MEDICAID PHARMACEUTICAL AVERAGE WHOLESALE PRICE LITIGATION	)	**MASTER DOCKET NO. 65586-65632, 66312, 66313, 66314**
	)	
This Document Relates to:	)	
	)	
State of Mississippi vs. Sandoz, Inc.;	)	**No. 65622**

OPINION

This case involves allegations that Sandoz caused to be published inflated "Average Wholesale Prices" (AWPs) for the drugs manufactured by Sandoz which resulted in the Mississippi Division of Medicaid (DOM) reimbursing pharmacies at an inflated price, all allegedly in violation of the Mississippi Consumer Protection Act; the Mississippi Medicaid Fraud Control Act and common law fraud.

Medicaid is a joint Federal-State program that was established by Congress in 1965 for the purpose of providing medical assistance to financially needy patients, including the poor, the disabled and pregnant women. The Federal Agency responsible for Medicaid is the Center for Medicare and Medicaid Services (CMS) formerly known as the Health Care Financing Administration (HCFA). CMS is part of the Federal Department of Health and Human Services (HHS) which establishes regulations governing the administration of the Medicaid Program.

Mississippi voluntarily chose to participate in the Medicaid Program. Prescription drugs are a covered benefit in the Mississippi Medicaid Program. When Congress established the Medicaid Program in 1965, state participation was conditioned upon compliance with various federal regulations and guidelines.

The Mississippi Legislature initially established the Medicaid Commission to administer the Mississippi Medicaid Program. In 1984, the Mississippi Supreme Court declared the Medicaid Commission to be unconstitutional, and in response, the Legislature created the Division of Medicaid (DOM) to administer the Mississippi Medicaid Program from 1984 to the present.

Mississippi paid for the prescription drugs dispensed to individuals covered by the Medicaid Program by reimbursing pharmacies that dispensed drugs to eligible Medicaid patients and requested a reimbursement payment from DOM for the prescription drugs.

Sandoz is a corporation organized and existing pursuant to the laws of Colorado that engages in the business of manufacturing, marketing and selling generic drugs. Sandoz, Inc. was known as Geneva Pharmaceuticals, Inc., until the company changed its name to Sandoz, Inc., in 2003. Sandoz does not manufacture brand name drugs, but rather manufactures generic drugs exclusively. Sandoz' participation in the Medicaid program is governed by the provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA'90). In

order to qualify its drugs for participation in Medicaid, Sandoz voluntarily entered into a Form Rebate Agreement with HHS, and agreed to pay rebates at the Federal Statutory Rate. Once qualified, Sandoz' drugs were eligible for reimbursement by State Medicaid Agencies, including DOM.

From January 1, 1991, through October 20, 2005, (the relevant damage period claimed by the State) Mississippi paid pharmacies dispensing Sandoz' prescription drugs to recipients of the State's Medicaid Program the lesser of: (1) the Federal Upper Limit (FUL), if applicable, plus a reasonable dispensing fee; (2) the usual and customary charge to the general public (U&C); or (3) the estimated acquisition cost (EAC) plus a reasonable dispensing fee.

As required by Federal Law, Mississippi DOM, like all other states, had a "State Plan" that was approved by CMS. DOM's State Plan defined the scope of the services provided, how they were paid and other aspects of its Medicaid Program. Mississippi's Reimbursement Formula for prescription drugs was included in its State Plan. Any changes to the reimbursement rate for prescription drugs in Mississippi's State Plan had to be approved by CMS.

According to CMS, which oversees Medicaid for the Federal Government, the dispensing fee is to be paid to pharmacists for dispensing drugs covered by the Medicaid Program and should be determined separately from a drug's ingredient cost reimbursement levels. From January 1, 1991, through March, 2002, the DOM paid a

dispensing fee of $4.91 per prescription (except for a short lived $.25 increase in the dispensing fee from August 1, 1991, through September 30, 1992). From April, 2002, through June, 2005, the dispensing fee was $3.91. From July, 2005, through October, 2005, the dispensing fee for multiple-source generic drugs was $4.91.

CMS regulations directed CMS to set Federal Upper Limit (FUL) reimbursement rates at one hundred fifty percent (150%) of the lowest published price, when three (3) or more manufacturers of a particular drug product were available in the market place. If at least three (3) manufacturers of a particular drug were not available in the market a place, a FUL could not be set.

CMS required DOM to submit for approval its State Plans defining the scope of services provided, how they were paid and other aspects of Mississippi's Medicaid program. For all drugs (brand and generic) covered by Medicaid for which there was not a FUL, Federal Regulations required DOM to make findings and assurances every three (3) years that its payments did not exceed, in the aggregate, the lower of (1) U&C or (2) EAC plus a reasonable dispensing fee.

U&C is defined in DOM's Provider Manuals as the price the pharmacy would charge a member of the general public without insurance coverage (i.e. the price to the pharmacy's cash customers).

Under the "lesser" of reimbursement methodology, DOM could

never pay more than EAC plus a reasonable dispensing fee for Sandoz prescription drugs.

Federal Regulations define EAC as DOM's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." From 1991-2000, DOM applied an identical definition: "MEAC is defined as the Division's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." From 2002-2005, DOM's State Plan defined MEAC as "the Division's best estimate of the actual purchase price generally and currently paid by providers for a drug, identified by National Drug Code[1] (NDC) number, marketed or sold by a particular manufacturer or labeler."

For approximately the first 20 years of its existence, the State's Medicaid Program limited pharmacy reimbursement to a closed formulary of approximately 1,500-1,800 prescription drugs. DOM decided which drugs would be covered by its Medicaid Program and DOM used its own codification system for assigning names and prices to drugs. Pharmacy providers submitted paper claims for reimbursement to DOM by mail, and DOM processed these reimbursement

[1]NDCs are unique product identifiers for drugs. Each NDC is an 11-digit three segment number which identifies the labeling (i.e. company), product and trade package size. A given Sandoz drug may have several NDCs corresponding to different dosages and package sizes.

claims manually. During this same time period, the vast majority of claims for prescription drugs were reimbursed by DOM at U&C. Although the AWP for a particular drug played a role in the reimbursement process during the early years of Medicaid, the vast majority of pharmaceutical reimbursements were made at U&C by DOM.

DOM's coverage and reimbursement for pharmaceutical drugs changed dramatically when Congress enacted the Omnibus Budget Reconciliation Act of 1990 (OBRA'90).

When Congress enacted OBRA'90, DOM was obligated to cover all prescription drugs manufactured by any pharmaceutical company that entered into a Rebate Agreement with the Federal Government and qualified to participate in the Medicaid Program. The enactment of OBRA'90 required DOM to cover approximately 65,000 prescription drugs identified by NDCs, which represented a substantial increase in the volume of pharmaceutical reimbursements by DOM.

By 1999, approximately 600,000 Mississippians received Medicaid benefits and roughly 900 pharmacies - virtually every pharmacy in the State - dispensed drugs to Medicaid recipients. Following the enactment of OBRA'90, the number of pharmacy claims submitted to DOM for reimbursement exceeded 1,000,000 per month.

As a practical matter, DOM was required to replace its manual billing system for reimbursement of pharmaceutical drugs with a much more complicated electronic one covering thousands of NDCs.

Although the record before the Court is substantially in

conflict as to whether, as a practical matter, DOM could have surveyed participating pharmacies in the State for the purpose of accurately determining a pharmacist's estimated acquisition cost (EAC) for a particular drug, the record is clear that DOM undertook no such formal survey, and the Court concludes that because of the constantly changing prices for drugs on virtually a daily basis, obtaining this accurate information was virtually impossible considering DOM's lack of resources.

In order to handle the increased volume of reimbursement claims submitted by pharmacies, DOM contracted with third party fiscal agents, Electronic Data Systems (EDS) and subsequently Affiliated Computer Systems (ACS) to process and pay these claims.

From 1980 forward, Mississippi has included a drug manufacturer's AWP as part of its ingredient cost reimbursement formula for prescription drugs.

During most of the 1980's, the Mississippi ingredient cost reimbursement formula (as opposed to dispensing fee reimbursement) was the lesser of EAC (defined as the drug's AWP) plus a dispensing fee, or U&C. Mississippi revised its reimbursement formula to include FULs plus a dispensing fee effective January 1, 1988.

From 1988, through October, 2005, DOM reimbursed for prescription drugs at the lesser of (1) FUL plus a dispensing fee; (2) EAC plus a dispensing fee; or (3) the U&C charge. From May 1, 1990, to March 31, 2002, EAC was defined by statute as AWP minus

ten percent (10%). From April 1, 2002, to June 30, 2005, EAC was defined to be AWP minus twelve percent (12%). From July 1, 2005, until October 20, 2005, (the end of the State's damage period) EAC was defined to be (1) the lesser of AWP minus twelve percent (12%) or wholesale acquisition cost (WAC) plus nine percent (9%) for brand name drugs and single source generic drugs, and (2) AWP minus twenty-five percent (25%) for multiple source generic drugs. In 2004, the Legislature removed AWP from the statute and revised EAC to be "EAC as determined by the Division" of Medicaid.

Sandoz, like all drug manufacturers participating in the Medicaid Program, reports its AWPs and its Wholesale Acquisition Costs (WACs) to First Data Bank (FDB) which in turn publishes these drug manufacturers' AWPs and WACs and furnishes this information to subscribers. Throughout the relevant damage period, Mississippi's fiscal agents (EDS and ACS) subscribed to First Data Bank, and utilized Sandoz' AWPs published in FDB to determine EAC for purposes of ingredient cost reimbursement to pharmacies.

Although the evidence before the Court is sharply disputed on many points, it is undisputed, and Sandoz acknowledges that the AWPs that it reported to FDB and that FDB published and furnished to DOM's fiscal agents, never represented the net average wholesale prices that Sandoz received for the sale of a particular drug to a pharmacy or a wholesaler. Other than the fact that Sandoz' AWPs as reported to and published by FDB, were always substantially higher

than true net average wholesale prices paid by pharmacies and wholesalers for Sandoz' drugs; there is no predictable relationship between the average wholesale price Sandoz reported for its drugs and the actual price Sandoz received for the sale of its drugs. It is also undisputed that throughout the relevant damage period, FDB published the identical AWPs that it received from Sandoz and DOM relied upon Sandoz' AWPs as published by FDB to determine EAC for purposes of reimbursing pharmacies for the ingredient cost of Sandoz' drugs.

On October 20, 2005, Mississippi Attorney General Jim Hood filed a Complaint against approximately eighty-six (86) drug companies (including Sandoz) in the Chancery Court of the First Judicial District of Hinds County, Mississippi. According to the Complaint, the action was commenced in the public interest in behalf of Plaintiff, the State of Mississippi, and its citizens pursuant to the Mississippi Consumer Protection Act, the Mississippi Medicaid Fraud Control Act (MFCA) and the Attorney General's common law authority to represent its citizens.

The Complaint alleges that the drug companies' conduct of reporting inflated AWPs caused Mississippi to overpay excessive amounts for prescriptions dispensed to recipients of the State's Medicaid Program. The Complaint also alleges that drug manufacturers created, widened and marketed the difference or "spread" between the prices of their drugs and the inflated AWPs

they reported in order to increase market share and profit.

The Defendant pharmaceutical companies removed the action to Federal Court, but it was remanded back to the Chancery Court of the First Judicial District of Hinds County on September 17, 2007. On September 16, 2008, the action was severed and transferred, including Mississippi's case against Defendant Sandoz, Inc. (Sandoz) which consented to venue in Rankin County, Mississippi.

On October 22, 2010, the State filed a Second Amended Complaint against Sandoz. The Second Amended Complaint contained allegations similar to those in the original Complaint, which was incorporated by reference, including (1) that the action was commenced on behalf of Mississippi and its citizens; (2) that Sandoz caused Mississippi to overpay excessive amounts by reporting inflated AWPs; (3) that its conduct violated the Mississippi Consumer Protection Act and the Mississippi Medicaid Fraud Control Act; and (4) that its conduct constituted common law fraud.

On April 4, 2011, Mississippi's case against Sandoz, *State of Mississippi vs. Sandoz, Inc.*, Docket No. 65622, proceeded before this Court as a non jury trial.

THE MEANING OF AWP

The primary issue of fact to be determined by this Court is the parties' understanding of the phrase "Average Wholesale Price" or AWP, as this phrase was used for purposes of pharmaceutical reimbursement by the Mississippi Division of Medicaid. Much of the

record before this Court contains the parties' competing positions with regard to Sandoz' and the State's understanding of the meaning of AWP.

In support of its position that the State understood and relied on the fact that Sandoz' AWPs meant just what the phrase says "Average Wholesale Prices", or the average of those prices that a wholesaler received from the sale of Sandoz' drugs to pharmacies; the State relies upon the plain meaning of the phrase; the testimony of Ms. Helen Wetherbee, the Executive Director of the Division of Medicaid from 1991 to 1999; the testimony of the State's expert, Dr. Gerald Anderson and the definitions of the phrase AWP as contained within various publications from First Data Bank from 1991 through 2003. The State also directs the Court's attention to the fact that DOM was obligated by Federal and State Law to reimburse pharmacies for its ingredient costs at a pharmacy's Estimated Acquisition Costs (EAC) of its drugs, and utilizing a meaningless AWP published by FDB for Sandoz' drugs would have violated its statutory obligations.

In support of Sandoz' position that its published AWPs were never intended to reflect the average prices retail pharmacies paid to wholesalers for Sandoz' drugs, Sandoz relies upon the testimony of its experts; the testimony of Mr. Jack Lee, Director of Pharmacy for DOM from 1997 to 2001; and various articles and publications, including Reports from the Office of Inspector General (OIG) within

the Department of Health and Human Services concluding that published AWPs do not accurately reflect a drug manufacturer's true average wholesale prices. Rather than reflecting an accurate average of its wholesale prices, Sandoz contends that its published AWPs were merely a suggested list price or reference price primarily designed to assure that its newly launched drugs would be designated as generic as opposed to brand. Finally, Sandoz argues that the State and DOM must have known that its published AWPs were not true net average wholesale prices for its drugs because DOM and the Legislature set a pharmacy's ingredient reimbursement at a discounted AWP.

Although the evidence presented by Sandoz and the State is in direct opposition as to the parties' understanding of the meaning of Sandoz' published average wholesale prices, some evidence is undisputed which sheds light on Sandoz' intent and the State's understanding of Sandoz' published AWPs:

- Sandoz maintained exclusive control over its AWPs published by First Data Bank throughout the relevant time frame;
- From 1991 through 2003, First Data Bank consistently defined Sandoz' AWPs as the average price paid by the pharmacy to the wholesaler for a particular drug;
- First Data Bank never defined Sandoz' AWPs as a manufacturer's suggested "sticker" price, list price or

reference price;

- DOM and its fiscal agents relied upon Sandoz' published AWPs that appeared in First Data Bank for the purpose of reimbursing pharmacies its ingredient cost of drugs;
- Federal regulations required DOM to reimburse pharmacies, in the aggregate, at the lesser of (1) U&C or (2) EAC plus a reasonable dispensing fee; therefore, under the "lesser" of reimbursement methodology, DOM could never pay more that EAC plus a reasonable dispensing fee for Sandoz prescription drugs;
- Federal regulations and DOM consistently defined EAC as DOM's "best estimate" of the price generally and currently paid by providers (pharmacists) for a drug marketed or sold by a particular manufacturer;
- Sandoz knew that DOM along with approximately forty-five (45) other State Medicaid Agencies utilized its published AWPs to satisfy DOM's statutory requirement to reimburse pharmacy providers at EAC for its ingredient costs;
- Sandoz' published AWPs were meaningless and worthless to DOM with regard to fulfilling its obligation to reimburse ingredient costs at EAC;
- Sandoz' published AWPs relied upon by DOM always exceeded the true average wholesale prices pharmacies paid to wholesalers for Sandoz' drugs;

- The best and most efficient way for DOM to obtain accurate pricing information for Sandoz drugs was for Sandoz to accurately report AWPs at true average wholesale transaction prices; and
- The AWPs Sandoz submitted to FDB on which Mississippi Medicaid relied to determine EAC were not prices any pharmacy provider paid for its drugs - in fact, they were not prices at all - otherwise, if they had been, the State' reimbursement system would have worked as intended.

In order for this Court to accept Sandoz' vague definition of AWP, Sandoz must convince this Court to depart from the plain meaning of the words "Average Wholesale Price (AWP)" and instead, pronounce that AWP is a technical term of art that essentially has no meaning. Sandoz' interpretation of AWP asks this Court to ignore fundamental rules of law which require Courts to interpret words according to their plain meaning and avoid a construction that would render any term meaningless. *Jones v. GMC*, 2007 U.S.Dist. LEXIS 40267 (S.D. Miss. June 1, 2007)(Citing *Davis v. Miller*, 32 So. 871, 873 (Miss. 1947); *Lamb Const. Co. v. Renova*, 573 So.2d 1378, 1384 (Miss. 1990); *State ex rel. Pair v. Burroughs*, 487 So.2d 220, 226 (Miss. 1986); *State v. Russell*, 185 Miss. 13 (Miss. 1939). Additionally, Courts refrain from establishing a technical term of art (as Sandoz proposes here) when there is

conflicting expert testimony regarding the definition of the term. *Commonwealth of Mass. V. Blackstone Valley Electric Co.*, 67 F.3d 981, 986 (1st Cir. 1995). A departure from the plain meaning of a term (Average Wholesale Price) is only warranted when the term has a "well-defined" understanding within the relevant field in which it is used. *Corning Glass Works v. Brennan*, 417 U.S. 188, 201-02 (1974). In the instant case, Sandoz' proposed vague definition of the term Average Wholesale Price is anything but "well defined."

FDB's definitions of AWP were significant. FDB represented to its customers that the pricing information it provided was "the most comprehensive and in-depth information" available. According to DOM's former Executive Director, Helen Wetherbee, FDB was "the national standard, the gold standard" on which Mississippi's Medicaid Program relied to meet its statutory pharmacy reimbursement obligations. Ms. Wetherbee believed that FDB was "the best possible way ... to serve the Medicaid Program and get prompt, accurate information with respect to pharmacy product pricing." According to Ms. Wetherbee, she believed that DOM's pharmacy staff was aware of FDB's definition of AWP, and further, that DOM's understanding was consistent with FDB's definitions during her tenure as Director of the Division of Medicaid.

For every NDC assigned to a drug it manufactures, Sandoz had exclusive control in setting an AWP and a WAC for these drugs.

Although there is no proof that Sandoz was aware of

Mississippi's specific reimbursement methodology, the evidence taken as a whole does establish that Sandoz was aware that programs such as Mississippi Medicaid reimbursed pharmacy providers by using the AWPs and WACs Sandoz reported to FDB.

It also appears from the evidence as a whole that Sandoz felt that offering substantial "spreads" to customers (the difference in the actual transaction price that a pharmacy pays for a particular drug and the AWP Sandoz caused to be published in FDB) was important to its customers, and that Sandoz utilized this "spread" as a marketing tool. Sandoz frequently provided price quotes for its drugs to retail pharmacies by listing not only the net price that retail pharmacies would pay for a particular drug, but also listing Sandoz' published AWP and WAC for the particular drug. In fact, Sandoz advised one customer in 1992 "we offer substantial margins between acquisition costs and AWP for your profit potential." Sandoz also prepares internal price lists comparing side-by-side drug costs, AWPs and WACs and distributes these internal price lists to the sales and marketing departments.

Sandoz did nothing to communicate to DOM or any other State Medicaid Agencies the true transaction prices that pharmacies were paying for Sandoz' drugs and Sandoz never advised DOM or other State Medicaid Agencies that its pharmacy customers paid substantially less than Sandoz' published AWPs. In fact, it appears from the evidence before the Court that Sandoz never

advised DOM or other State Medicaid agencies that its published AWPs were not true average wholesale prices paid for its drugs.

STANDARD OF REVIEW FOR STATE'S STATUTORY CLAIMS

The State has asserted causes of action against Sandoz under the Mississippi Consumer Protection Act and the Mississippi Medicaid Fraud Control Act. In construing and interpreting a statute, the "pole star of guidance" is legislative intent as determined from the statute as a whole using the language in it. *Quitman County v. Turner*, 18 So.2d 122, 124 (Miss. 1944); *Clark v. State ex rel. Miss. State Med. Ass'n*, 381 So.2d 1046, 1048 (Miss. 1980). "Whether the statute is ambiguous, or not, the ultimate goal of this Court in interpreting a statute is to discern and give full effect to the legislative intent." *Allred v. Yarbrough*, 843 So.2d 727, 729 (Miss. 2003), (Quoting *City of Natchez v. Sullivan*, 612 So.2d 1087, 1089 (Miss. 1992).

The statutory text is the best evidence of legislative intent. The plain meaning of the statutory text is to be applied, and there is no room for construction or interpretation unless it is ambiguous or silent as to a particular issue. *In re Guardianship of Duckett* 1991 So.2d 1165, 1182 (Miss. 2008). The words and the phrases in the statute are to be used according to their common, ordinary and usual meaning. *Pearl River Valley Water Supply District v. Hinds County*, 445 So.2d 1330, 1334 (Miss. 1984); *Miss. Code Ann*. Sect. 1-3-65 (West 2010).

In addition to the language used in a statute, Courts also look at the statute's historical background, subject matter, purposes and objectives to be accomplished in order to ascertain legislative intent. *Clark*, 381 So.2d at 1048. In interpreting a statute, unintended and unjust results are to be avoided, and an "unwise purpose will not be imputed to the Legislature when a reasonable construction is possible." *Zeigler v. Zeigler*, 164 So.2d 768, 769 (Miss. 1935); *Quitman County*, 18 So.2d at 124.

MISSISSIPPI'S CONSUMER PROTECTION ACT

The relevant provisions of Mississippi's Consumer Protection Act, appear as follows:

Section 75-24-5 provides:

> "(1) Unfair methods of competition affecting commerce and unfair or deceptive trade practices in or affecting commerce are prohibited. Action may be brought under Section 75-24-5(1) only under the provision of Section75-24-9.
>
> (2) Without limiting the scope of subsection (1) of this section, the following unfair methods of competition and unfair or deceptive trade practices or acts in the conduct of any trade or commerce are hereby prohibited:
>
> ...
>
> (e) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have;
>
> ...

> (k) Misrepresentations of fact concerning the reason for, existence of, or amounts of price reductions;"

The State alleges Sandoz violated Section 75-24-5(1) which prohibits "unfair methods of competition affecting commerce and unfair or deceptive trade practices in or affecting commerce". The State also alleges that Sandoz violated Section 75-24-5(2)(e)(k) by "representing that goods ... have characteristics ... they do not have" and making "misrepresentations of fact concerning the reason for, existence of, or amounts of price reductions" and that this conduct constitutes unfair or deceptive trade practices under the statute.

Although Mississippi's Consumer Protection Act (CPA) does not define what an "unfair or deceptive trade practice" is, the purpose of the CPA is "to protect the citizens of Mississippi from deceptive and unfair trade practices." *Holman v. Howard Wilson Chrysler Jeep, Inc.*, 972 So.2d 564, 572 (Miss. 2008).

Mississippi's CPA creates an "Office of Consumer Protection" within the Attorney General's Office and vests in this Office administrative and enforcement authority. (Section 75-24-1). Administrative regulations promulgated by the Office of Consumer Protection provide that they are to "be liberally construed and applied to promote the general purposes and policies of the act." (Section 3-1-4:3.) Although the State argues that Sandoz' conduct is in violation of certain rules enacted by the Office of Consumer

Protection pursuant to Mississippi's Consumer Protection Act, it does not appear that the rules relied upon by the State were ever adopted.

In the Rules of Consumer Protection available on WestLaw and LEXIS, the "effective date" field is blank. Additionally, the Mississippi Administrative Procedure Law (MAPL) (Section 25-43-1 at et seq.), designates the Secretary of State's Office as the official Registrar for the Rules of Mississippi State Agencies and as the Publisher of the Mississippi Administrative Code cited in Plaintiff's Conclusions of Law. The Administrative Procedure of Law requires that the Secretary of State keep all filed rules open to the public for inspection. (Section 25-43-2.101.) Sandoz has submitted to the Court a Certificate from the Secretary of State confirming that the Secretary of State's Log does nor reflect the adoption of the rules relied upon by the State. Therefore, the Court declines to consider rules which have never been statutorily adopted by the Offices of Consumer Protection.

However, interpretations given by the Federal Trade Commission (FTC) and Federal Courts to the analogous Federal Statute are intended to guide Mississippi Courts in applying the Consumer Protection Act. (Section 75-24-3(c).) Federal regulations closely resemble the Office of Consumer Protection's Prohibitions against misrepresenting prices, and the Court concludes that Sandoz violated those prohibitions. (16 C.F.R. Section 233.3(a).) FTC

regulations regarding advertisements for reductions off list prices maintain that a particular list price "will not be deemed fictitious if it is the price at which substantial (that is not isolated or insignificant) sales are made" but that one "significantly in excess of the highest price at which substantial sales in the trade area are made" is misleading. *In re: Giant Food, Inc.*, 61 F.T.C. 326 (1962).

The United States Supreme Court has determined that a particular act or practice is deceptive or unfair if it has the capacity of tendency to deceive. *FTC v. Raladam Co.*, 316 U.S. 149, 152 (1942). In construing the advertisement provisions under the FTC, the Ninth Circuit Court of Appeals concluded that the statute "is violated if it induces the first contact through deception, even if the buyer later becomes fully informed before entering the contract." *Resort Car Rental System, Inc. V. FTC*, 518 F.2d 962 (9th Cir. 1975).

A particular act may not be "deceptive" but nevertheless be "unfair" in violation of the FTC. The United States Supreme Court has applied the following Sperry factors developed by the FTC to determine whether a particular act is "unfair" under the Federal statute: (1) Whether it offends a public policy established by statute, and common law or otherwise; (2) "Whether it is immoral, unethical, oppressive or unscrupulous"; or (3) "Whether it causes substantial injury to consumers, or competitors or other

businessmen."

This Court has previously rejected Sandoz' contention in its Motion for Summary Judgment that the State is not a "consumer" for purposes of Mississippi's Consumer Protection Act. (See, March 30, 2011, Order adopting Report and Recommendation No. 31). This Court now reaffirms its earlier finding that the State is, in fact, a "consumer" for purposes of the Consumer Protection Act. This Court also reaffirms its earlier ruling rejecting Sandoz' argument that the State is prohibited from seeking compensatory damages under Section 75-24-15 because the State did not consume the drugs purchased by DOM.

Significantly, Courts involved in virtually identical AWP litigation in other jurisdictions have applied similar State Consumer Protection Acts and rejected identical arguments as Sandoz asserts here. Specifically, the Idaho Court involved in similar AWP litigation addressed an identical argument as that raised by Sandoz as follows:

> "[G]iven the remedial nature of the ICPA, such a narrow reading of the IDAPA definition of consumer as purchaser is inappropriate. The Defendants' argument taken to its logical extension, would lead to the situation in which neither the State, nor Medicaid recipients could qualify as 'consumers' because the State does not actually consume the drugs and the Medicaid recipients do not pay for them. Here it is apparent that the State is the ultimate purchaser in the chain of distribution and the one directly affected by the alleged manipulation of the AWP." *Idaho v. Alpharma, USPD, Inc.*, No. CV-0C-0701847 (Id. Dist. Ct. Aug. 31, 2007.) See also, *Kentucky v. Alpharma, USPD, Inc.*, No. 04-CI-1487, Franklin Cir. Ct. Order Jan. 19, 2011.

In addition to the Idaho and Kentucky Courts identified above, other Courts involving similar AWP litigation have concluded that reporting inflated AWPs to First Data Bank in a similar manner as Sandoz did in this case, violates those State's Consumer Protection Acts which contain nearly identical language. See 73 Pa. Statutes Sections 201-4, 201-3; Accord Mississippi Code Annotated Section 75-24-9, 75-24-5; *Common Wealth of Pennsylvania v. Bristol- Myers Squibb Co.*, No. 212 M.D. 2004 (Pa. Commw. Ct. Sept. 10, 2010); *Commonwealth of Pennsylvania v. Johnson & Johnson*, No. 212 M.D. 2004 (Pa Commw. Ct. Dec. 7, 2010). In fact, a Kentucky Court found Sandoz liable for conduct identical to that at issue in this case under a virtually identical consumer protection statutory provision. *Commonwealth of Kentucky v. Astrazeneca*, No. 04-CI-1487 (Ky. Cir. Ct. Feb. 18, 2010).

This Court concludes that Sandoz' submission of AWPs to FDB that have no predictable relationship to what customers pay for its drugs while knowing Mississippi relied on this information in determining EAC is an unfair and deceptive trade or practice within the meaning of Mississippi's Consumer Protection Act. Therefore, the Court finds that the State of Mississippi is entitled to relief pursuant to the terms of the Mississippi Consumer Protection Act.

CLAIMS ASSERTED UNDER
THE MISSISSIPPI MEDICAID FRAUD CONTROL ACT

Plaintiff alleges that Sandoz violated three (3) substantive provisions of the MFCA: the false claims, anti-kickback and

conspiracy provisions. (Sections 43-13-213, 207 and 2011.) For each of these violations, Plaintiff seeks relief under the MFCA's Civil Penalties Provision. The relief sought by the Plaintiff is contained within the Civil Liability Provision of the MFCA:

> "[a] health care provider or vendor committing any act or omission in violation of this article shall be directly liable to the state and shall forfeit and pay to the state a civil penalty equal to the full amount received, plus an additional civil penalty equal to triple the full amount received." (Section 43-13-225(1).)

Section 225 is not a general damages provision. Rather, this Section provides that a provider or vendor of Medicaid benefits shall forfeit "the full amount received" from the State in violation of MFCA. Sandoz argues that since it did not receive any payments from the State as a result of its misconduct, it cannot be liable for the civil penalties set forth in Section 225 of the MFCA.

It is instructive to compare the "full amount received" language of the MFCA to the civil recovery provision of the Federal FCA, which establishes a penalty based on the "amount of damages which the Government sustained." 31 U.S.C. Section 3729(a)(1). The MFCA calculates penalties on the basis of what the Defendant received from the State, while the FCA focuses on what the Government lost.

Under the FCA, a Defendant that did not gain any money from its unlawful conduct could still be liable for a penalty based on

losses incurred by the Government as a result of such conduct. The MFCA, however, does not provide for recovery beyond the amount the Defendant has improperly received.

In 2006, 2007 and 2010, the Mississippi Legislature considered Bills that would have replaced the "full amount received" language with language that permits recovery for the "amount of damages that the State sustains because of the act of that person." H.B. 249 Miss. 2006; S.B. 2279 (Miss. 2007); H.B. 1165 Miss. 2010. The fact that the Mississippi Legislature considered such a change, demonstrates its recognition that the existing penalty provision was limited to the amount a provider or vendor received and thus required an amendment if it was to also cover the amount of the State's loss.

It is undisputed that Sandoz never received any monies from DOM. In the opinion of the Court, the fact that Sandoz never received any money from DOM, prohibits the State from recovering from Sandoz an "amount received" by Sandoz as a result of its alleged violations of the Medicaid Fraud Control Act.

The Court therefore concludes that the State has failed to meet its burden of proving that it is entitled to recover from Sandoz the civil penalties contained within Section 43-13-225(1).

In addition to finding that the State's claims under the False Claims Act fail as a result of the State not being entitled to recover from Sandoz the civil penalties contained within Section

43-13-225(1), the Court also concludes that the State cannot establish liability under the False Claims Provision of the MFCA.

The False Claims Provision of the MFCA provides that "[a] person shall not make, present or cause to be made or presented a claim for Medicaid benefits, knowing the claim to be false, fictitious or fraudulent." Mississippi Code Annotated Section 43-13-213. An essential element of the State's claim under the False Claims Provision of the MFCA is that Sandoz "make, present, or cause to be made or presented" a claim for Medicaid benefits. (Section 43-13-213).

In the case before the Court, it is clear that Sandoz never submitted any claim for Medicaid reimbursements to the DOM. Instead, the evidence is undisputed that a pharmacy would submit a claim for drug reimbursement to the DOM without any involvement from Sandoz in the claims process. There is no evidence before the Court that Sandoz participated in any way in the claims process, such as by assisting pharmacies in submitting their claims.

The issue as to whether Sandoz "ma[de], or cause(d) to be made or presented" a claim for Medicaid benefits pursuant to Section 43-13-213, was before this Court on Sandoz' Motion for Summary Judgment Dismissing Plaintiff's Statutory Claims. In holding that there existed a genuine issue of material fact as to whether Sandoz caused to be submitted a false claim for Medicaid benefits, this

Court relied primarily upon Judge Saris' decision in the Multi-District AWP litigation which concluded that a drug manufacturer such as Sandoz satisfied similar statutory language by causing false claims to be presented, even though the drug manufacturer did not directly participate when presenting the claims. *In re: Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Sup.2d 12, 16 (D. Mass. 2007). In adopting the Special Master's Report and Recommendation No. 31, this Court concluded:

> "According to Judge Saris, '[m]ost courts agree, the FCA covers indirect billing of the federal government.' Judge Saris noted the allegations made by the government against the drug manufacturers in *In re: Pharm. Indus. Average Wholesale Price Litig.*, (which are virtually identical to the allegations made by the State in this case) and concluded "the submission by doctors and pharmacists of false pharmaceutical claims to Medicare and Medicaid was not only a foreseeable and substantial factor in the government's loss, but also it was 'an intended consequence of the alleged scheme of fraud.'" (491 F.Sup.2d at 16)." (R&R No. 31 at 10-11).

Since the entry of this Court's Order adopting R&R No. 31, Judge Saris has reconsidered whether a drug manufacturer's conduct in reporting false AWPs and WACs to FDB, for which the Massachusetts Division of Medicaid relied in reimbursing pharmacies, creates liability under Prong 1 of the Massachusetts False Claims Act. Prong 1 of the Massachusetts False Claims Act prohibits any person from "knowingly cause[ing] to be presented, a false or fraudulent claim for payment or approval." (Mass. Gen.

Laws Ch. 12 Section 5B(1)). After noting that the Massachusetts False Claims Act is modeled after the "similarly worded" Federal False Claims Act (31 U.S.C. Section 3729 (a)(1)), Judge Saris determined that Prong 1 of the Massachusetts False Claims Act, which contains virtually identical language to the language prohibiting false claims in the Mississippi False Claims Act, does not create liability for a drug manufacturer who publishes a false or fraudulent AWP/WAC but does not participate in the claims reimbursement process. In finding no liability under Prong 1 of the Massachusetts Medicaid False Claims Act, Judge Saris stated:

> "The false WACs provided to MassHealth by Warrick (drug manufacturer) through FDB did not pass through pharmacists to be 'presented' to MassHealth. ... The pharmacists submitted claim forms electronically to MassHealth's fiscal agent (Unisys or ACS) using the Pharmacy Online Processing System. Those claims forms included the U&C price for the drug purchased, but they did not contain WACs or Average Wholesale Prices (AWPs). The claim traveled electronically, through a network switch to an agent's server, where it caused, among other things, a pricing file to be brought up. The pricing files in the claims at issue here included the false WACs obtained from the FDB.
>
> ...
>
> The claims submitted by the pharmacy contained a National Drug Code (NDC) assigned by Warrick, that determined which pricing file was activated for comparison purposes." (2011 U.S. Dist. LEXIS 46293 at 4-5).

After discussing the virtually identical arguments made by the State of Massachusetts as are made here by the Plaintiff in this

case, Judge Saris concluded "there is no precedent supporting the Commonwealth's [Massachusetts's] argument that the Defendant's conduct falls within that contemplated in Prong 1 of the MFCA." Therefore, Judge Saris found as a matter of law that a drug manufacturer's conduct in causing false and fraudulent AWPs and WACs to be published in the FDB which are ultimately relied upon for reimbursement by a Division of Medicaid does not create liability under a Medicaid False Claims Act prohibition of submitting a false claim or "causing to be made" a false claim.

Just as in the Massachusetts case before Judge Saris, Mississippi's DOM prescription reimbursement process involved pharmacies submitting claims to DOM and not Sandoz. The claims submitted by pharmacies were submitted to DOM's fiscal agent. The claim forms included the U&C price for the drugs purchased, but they did not contain WACs or AWPs.

For the reasons set forth above, this Court concludes that Sandoz' conduct of reporting false and fraudulent AWPs to FDB which were ultimately relied upon by DOM for pharmaceutical reimbursement does not create liability under the False Claims Provision of the MFCA.

CLAIMS ASSERTED UNDER COMMON LAW FRAUD

The State alleges causes of action under Mississippi common law fraud. "Fraud is committed by deliberately misleading another by acts, words, or at times, by silence." *United States v. May*,

199 F.Supp.2d 536, 538 (S.D. Miss. 2002).

Under Mississippi Law, in order to establish common law fraud, the State must prove by clear and convincing evidence (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) his intent that it should be acted on by the person in a manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) the hearer's reliance on its truth; (8) the hearer's right to rely thereon; and (9) the hearer's consequent and proximate injury. *Trim v. Trim*, 33 So.3d 471, 478 (Miss. 2010); *Allen v. Mac Tools, Inc.*, 671 So.2d 636, 642 (Miss. 1996); *Gardner v. State*, 108 So.2d 592, 594 (Miss. 1959).

"A statement of representation may be 'false' or 'fraudulent' when it constitutes a half truth or effectively conceals a material fact, with intent to defraud." "A 'material fact' is a fact that would be important to a reasonable person in deciding whether to engage or not engage in a particular transaction." "To act with 'intent to defraud' means to act knowingly and with the specific intent to deceive, ordinarily for the purpose of causing some financial loss to another or bringing about some financial gain to one's self." *United States v. Means*, 695 F.Supp. 288, 292-293 (S.D. Miss. 1988).

The Court concludes that Sandoz made a representation by submitting its AWPs to FDB with the intent that FDB publish this

information to third parties such as DOM. The evidence is undisputed that from January 1, 1991, through October 20, 2005, Sandoz reported AWPs for its products to FDB with the intent that FDB would publish this information to Medicaid agencies such as DOM and/or their fiscal agents. The evidence also establishes that Sandoz knew that Medicaid agencies such as DOM relied upon the AWPs that Sandoz reported to FDB.

When Sandoz reported its AWPs to FDB, Sandoz knew the reported and ultimately published AWPs were not prices any of its customers actually paid for Sandoz' drugs. Sandoz submitted its AWPs to FDB with the intent of inducing Medicaid agencies such as DOM to rely on its AWPs in paying pharmacies for Sandoz' drugs. DOM reasonably relied on the information contained within the Sandoz' published AWPs.

Sandoz argues that because certain State employees testified that they believed that Sandoz' published AWPs were not true average wholesale prices received by Sandoz for its drugs, therefore, the State did not rely upon the falsity of Sandoz' published AWPs. First, "there is a very strong presumption ... that public officers have properly discharged the duties of their office and performed faithfully those matters with which they are charged. Stated in another way, the Courts will presume, in the absence of evidence to the contrary, that public officers have not culpably neglected or violated their official duties and have not

acted illegally in the doing of any official act." *Harris v. Harrison County Bd. Of Supervisors*, 366 So.2d 651, 652. Furthermore, "there is a presumption that public officers perform their duties in the manner required by law and it is the responsibility of any person challenging the validity of an official, or an official act to show the invalidity by clear proof." *Massachusetts v. Mylan Labs.*, 608 F.Supp.2d 127, 149-152.

In *Mylan Labs.*, Judge Saris rejected an identical argument as that being made by Sandoz by concluding that scattered and sporadic knowledge of isolated government employees "provides no silver bullet for the Defendants" that would allow them to escape fraudulent liability. (*Id.* at 151-152.) Furthermore, the Defendants in *Mylan Labs., Supra* also argued (as Sandoz argues here) that the Defendant's submission of Average Manufacturer Prices (AMPs) to the State absolved them of any fraudulent conduct. After discussing the difficulty of "reverse engineering" of AMPs to make them of any use to the Massachusetts' Division of Medicaid, Judge Saris found that "even if you didn't need Einsteinian quantitative skills to discover fraud, the Commonwealth's failure to [reverse engineer AMPs] does not equate to government knowledge or approval" of the fraud.

Sandoz' conduct caused Mississippi to overpay for its prescription drugs and as a result, Mississippi sustained proximate injury and damages as a result of Sandoz reporting false and

inflated AWPs.

The Court therefore concludes that the State has met its burden of proving by clear and convincing evidence that Sandoz engaged in common law fraud with regard to its reporting false, fraudulent and inflated AWPs.

SANDOZ' CONSTITUTIONAL ARGUMENTS

For the reasons set forth in this Court's Order adopting Special Master's Report and Recommendation No. 29, this Court finds that the Attorney General's Second Amended Complaint alleging that Sandoz engaged in common law fraud and violated the Medicaid Fraud Control Act and the Mississippi Consumer Protection Act, is not an attempt to unconstitutionally usurp the Legislature's statutory authority. Therefore, this Court is not prohibited from adjudicating this case or controversy by virtue of either the separation of powers or the political question doctrines.

DAMAGES AWARDED TO PLAINTIFF, STATE OF MISSISSIPPI

The State's damage expert, Mr. Sauls testified that as a result of DOM relying upon inflated AWPs, DOM overpaid for pharmaceutical reimbursements in the total sum of $$23,954,618.00. Included within this amount was Mr. Sauls' calculation that when DOM reimbursed on the basis of the usual and customary (U&C) charge, it paid both the U&C amount and a dispensing fee. However, Mississippi has never paid a dispensing fee in addition to the U&C amount. The effect of this error was to overstate Mr. Saul's

compensatory damage computation by $293,000.00, and the Court concludes that this amount should be deducted from Mr. Sauls' calculation in determining the compensatory damages that the State is entitled to recover. After correcting for the error, the Court accepts the State's expert's testimony as to the amount that the State overpaid to Sandoz during the relevant damage period.

The Court therefore concludes that as a result of Sandoz' conduct which violates the Mississippi Consumer Protection Act and Mississippi's common law fraud, the State is entitled to recover from Sandoz as compensatory damages the total sum of $23,661.618.00.

In addition to recovering compensatory damages from Sandoz, the Mississippi Consumer Protection Act permits the Court to award to the State/Attorney General, a sum not to exceed $10,000.00 per violation of the Consumer Protection Act, upon the Court's finding that the Defendant knowingly and willfully used an unfair deceptive trade practice prohibited by the CPA. Having previously found that Sandoz knowingly and willfully committed an unfair or deceptive trade practice as prohibited by the Consumer Protection Act, the Court finds that it is appropriate to award a civil penalty pursuant to the provisions of Section 75-24-19(1)(b).

Neither the statute nor any Mississippi case defines what a "violation is" for purposes of the penalty set forth in Section 75-24-19(1)(b). However, case law construing the penalty provision

of the Federal FCA makes clear, the number of violations should be determined by the conduct of the Defendant, and not the conduct of other parties. *United States v. Borenstein*, 423 U.S. 303, 313 (1976).

Having considered all of the evidence before the Court, along with case law interpreting the "per violation" provision of the Federal FCA, the Court concludes that the "per violation" language in Section 75-24-19(1)(b) should be the number of occasions that Sandoz improperly set an AWP during the relevant damage period from January 1, 1991, through October 20, 2005. Specifically, the Court concludes that during the State's alleged damage period, Sandoz set improperly inflated AWPs on 2,699 occasions, and therefore, Sandoz has committed 2,699 violations for purposes of Section 75-24-19(1)(b). (See *Johnson & Johnson*, 2004 W.L. 5599972 at *1n.3; *Bristol-Myers Squibb Co.*, No. 212 M.D. 2004, Slip Op.¶3n).

Considering all of the evidence submitted by the parties, the Court concludes and hereby awards to the State a civil penalty in the amount of $1,000.00 per violation of the Consumer Protection Act committed by Sandoz with the total civil penalty award being $2,699,000.00.

The Court has previously concluded that Sandoz' conduct in knowingly reporting inflated AWPs to the FDB with the knowledge that DOM and other State and Medicaid agencies relied upon these false and fraudulent AWPs for pharmaceutical reimbursement purposes

constitutes common law fraud. Therefore, the Court concludes that the State is entitled to recover punitive damages arising out of Sandoz' fraudulent conduct.

After considering all of the evidence submitted by the parties, the Court concludes that the State is entitled to recover from Sandoz the total sum of $11,830,809.00 or fifty percent (50%) of the compensatory damages incurred by the State, as punitive damages.

The Mississippi Consumer Protection Act makes no provision for the awarding of prejudgment interest in behalf of the State or against Sandoz. In addition to violating Mississippi's Consumer Protection Act, this Court has concluded that Sandoz' conduct violated the tort of Mississippi common law fraud.

Under Mississippi Law, prejudgment interest is not allowable on common law fraud claims when the claims are not liquidated. See *Upchurch Plumbing, Inc. v. Greenwoood Utils. Comm'n*, 964 So.2d 1100, 1117 (Miss. 2007)(en banc) holding that prejudgment interest is only available in tort actions in limited circumstances namely, where (1) the amount due is liquidated when the claim was originally made or (2) the denial of a claim is frivolous or in bad faith.

The Court concludes that the claims at issue in this cause were not liquidated, and therefore, the State is not entitled to recover prejudgment interest.

Finally, the State of Mississippi is hereby granted an injunction against Sandoz, Inc. pursuant to Section 75-24-9 of the Mississippi Consumer Protection Act, and Sandoz, Inc. is hereby enjoined from violating the Consumer Protection Act, Section 75-24-1, et seq. as those violations are more fully set forth in this Opinion.

Sandoz, Inc. is assessed all costs in this matter.

SO ORDERED, this the 2nd day of September, 2011.

CHANCELLOR THOMAS L. ZEBERT
SENIOR STATUS JUDGE