IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

September 2010 Term

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**SUPREME COURT OF APPEALS**
**OF WEST VIRGINIA**

No. 35500

STATE OF WEST VIRGINIA EX REL.
DARRELL V. MCGRAW, JR., ATTORNEY GENERAL,
Plaintiff Below, Appellee

v.

JOHNSON & JOHNSON and
JANSSEN PHARMACEUTICA PRODUCTS, L.P.,
Defendants Below, Appellants

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Appeal from the Circuit Court of Brooke County
The Honorable Martin J. Gaughan, Judge
Civil Action No. 04-C-156

REVERSED AND REMANDED

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The Opinion of the Court was delivered PER CURIAM.

JUSTICE MCHUGH disqualified.
JUDGE ABOULHOSN sitting by temporary assignment.

SYLLABUS BY THE COURT

1. "Appellate review of a partial summary judgment order is the same as that of a summary judgment order, which is *de novo*." Syl. Pt. 1, *West Virginia Department of Transportation, Division of Highways v. Robertson*, 217 W. Va. 497, 618 S.E.2d 506 (2005).

2. "'A motion for summary judgment should be granted only when it is clear that there is no genuine issue of fact to be tried and inquiry concerning the facts is not desirable to clarify the application of the law.' Syllabus Point 3, *Aetna Casualty & Surety Co. v. Federal Insurance Co. of New York*, 148 W. Va. 160, 133 S.E.2d 770 (1963)." Syl. Pt. 2, *Ramey v. Contractor Enterprises, Inc*., 225 W. Va. 424, 693 S.E.2d 789 (2010).

3. "Collateral estoppel will bar a claim if four conditions are met: (1) The issue previously decided is identical to the one presented in the action in question; (2) there is a final adjudication on the merits of the prior action; (3) the party against whom the doctrine is invoked was a party or in privity with a party to a prior action; and (4) the party against whom the doctrine is raised had a full and fair opportunity to litigate the issue in the prior action." Syl. Pt. 1, *State v. Miller*, 194 W. Va. 3, 459 S.E.2d 114 (1995).

4. "For issue or claim preclusion to attach to quasi-judicial determinations of administrative agencies, at least where there is no statutory authority directing otherwise, the prior decision must be rendered pursuant to the agency's adjudicatory authority and the procedures employed by the agency must be substantially similar to those used in a court. In addition, the identicality of the issues litigated is a key component to the application of administrative *res judicata* or collateral estoppel." Syl. Pt. 2, *Vest v. Board of Education*, 193 W. Va. 222, 455 S.E.2d 781 (1995).

Per Curiam:

The State of West Virginia, by its Attorney General, Darrel V. McGraw, Jr., ("the State"), sued Appellants Johnson & Johnson and Janssen Pharmaceutica Products, L.P. (jointly "the Appellants") under the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-1-101 to -139 (2006) ("Consumer Protection Act"). The State asserts that the Appellants communicated false and misleading information to healthcare providers in West Virginia regarding two pharmaceutical drugs manufactured and distributed by the Appellants. The Circuit Court of Brooke County, West Virginia, entered partial summary judgment in favor of the State on the primary issue of whether certain statements and omissions contained in the Appellants' communications were false and misleading. Following a bench trial on the remaining issues, the circuit court entered final judgment in favor of the State and assessed a civil penalty of $4,475,000 against the Appellants.

On appeal, the Appellants argue that the circuit court erred in entering partial summary judgment against them because, in so doing, the circuit court treated two informal and advisory warning letters issued by the federal Food and Drug Administration ("FDA") as legal determinations that the parties are precluded from relitigating. Alternatively, the Appellants contend that the circuit court's reliance on those warning letters is preempted by federal law and violates their First Amendment free speech rights. The Appellants additionally raise several assignments of error relating to the evidence considered at the

bench trial and the circuit court's method of assessing the civil penalty. Having considered the briefs of the parties,[1] oral argument, and the record in this case, the Court concludes that the circuit court erred in finding that the Appellants' communications to healthcare providers were false and misleading as a matter of law. The circuit court's order entering partial summary judgment is therefore reversed, and the case is remanded for further proceedings consistent with this opinion.

## I. FACTS

Janssen Pharmaceutica Products L.P. ("Janssen"), a pharmaceutical company, is a subsidiary of Johnson & Johnson. At issue in this case are representations Janssen made to healthcare providers in West Virginia concerning two of its drugs: Risperdal, an antipsychotic drug used to treat schizophrenia, and Duragesic, a narcotic pain relief medication that is administered through a patch worn on the patient's skin. Both drugs have been approved by, and their distribution is regulated by, the FDA.

### A. Risperdal

Risperdal, known generically as risperidone, is among a class of antipsychotic drugs known as "atypical antipsychotics." Atypical antipsychotics are linked as a class

[1]The Court also acknowledges the contributions of the three amici curiae in this case, Pharmaceutical Research and Manufacturers of America, the Product Liability Advisory Counsel, Inc., and Washington Legal Foundation, each of which filed a brief in support of the Appellants.

because they significantly reduce the occurrence of certain side-effects, called extrapyramidal side-effects, that plagued the earlier generation of antipsychotic drugs. In 1993, the FDA approved Risperdal for use in managing various psychotic disorders, including schizophrenia.

In the late 1990s, research emerged indicating an increased risk of hyperglycemia and Type II diabetes among patients taking atypical antipsychotics. At the request of the FDA, Janssen provided it with clinical data on Risperdal that, Janssen asserts, indicated that Risperdal was not associated with "alterations in glycemic control." In addition, Janssen undertook its own studies regarding the issue by convening a panel of twenty-five experts. That panel unanimously agreed that "convincing evidence" existed to show that risperidone's effect on glucose metabolism was lower than other atypical antipsychotic drugs.

In the summer of 2003, several new studies were released concerning the connection between atypical antipsychotics and hyperglycemia. The studies indicated that the risk of diabetes mellitus (chronic hyperglycemia) was increased among patients using atypical antipsychotics as compared to other classes of antipsychotics. However, other studies suggested differences among the drugs within the class of atypical antipsychotics. The Appellants contend that these studies indicated that the risk posed by Risperdal was less

than the risk posed by certain other atypical antipsychotics, and no greater than the risk posed by typical antipsychotics.

Following the release of these various studies, the FDA directed all manufacturers of atypical antipsychotics, as a class, to add a warning to their drug package insert labels regarding the increased risk of hyperglycemia, diabetes mellitus and ketoacidosis, a serious complication of diabetes that can lead to a coma or death. In addition, the FDA determined that all patients treated with atypical antipsychotics should be monitored for hyperglycemia. After receiving this directive, Janssen responded to the FDA that it did not believe a warning was necessary for Risperdal. Nevertheless, despite its disagreement, Janssen cooperated with the FDA's request and developed a new warning label that, after some modifications, the FDA approved.

On November 10, 2003, Janssen mailed the revised warning label to prescribers of Risperdal, including healthcare providers in West Virginia, along with a cover letter. The cover letter explained that the FDA had requested that all manufacturers of atypical antipsychotic drugs include a warning with their product regarding an increased risk for hyperglycemia and diabetes mellitus. The letter then states:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes

> when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.

(Footnotes omitted). The letter omits any mention of the need to monitor patients receiving atypical antipsychotics for symptoms of hyperglycemia. Janssen addressed this letter with the salutation "Dear Healthcare Provider."

Later that same month, the FDA contacted Janssen and requested that it send out a formal letter to healthcare providers, known as a "Dear Doctor" or "Dear Healthcare Provider" letter ("DHCP letter"), informing them of the revised label. DHCP letters are used in the pharmaceutical world to timely advise healthcare professionals of changes in drug labeling and risks associated with drugs. In response, Janssen sent the FDA a copy of its November 10, 2003, letter (the "Risperdal DHCP letter"), which it had already disseminated to the healthcare community, suggesting that the letter was sufficient to meet the FDA's request.

Several months later, in April 2004, the Director of the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") issued a "warning letter" to Janssen. In that warning letter, DDMAC stated that it found the information contained in Janssen's Risperdal DHCP letter to be "false and misleading" in violation of sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 352(a) & 321(n).

Specifically, DDMAC asserted that the Risperdal DHCP letter failed to disclose material information regarding the addition of the new warning to the drug's product labeling,[2] minimized potential risks associated with "hyperglycemia-related adverse events," and "misleadingly claims that Risperdal is safer than other atypical antipsychotics." Furthermore, DDMAC noted that the DHCP letter "fails to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible." DDMAC concluded its warning letter by requesting that Janssen cease to distribute the Risperdal DHCP letter, and "provide a plan of action to disseminate accurate and complete information to the audience(s) that received the violative promotional materials."

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[2]As the circuit court recognized in its summary judgment order, federal law distinguishes between a drug "label" and drug "labeling." A "label" pertains solely to the information placed directly on a drug package, 21 U.S.C. § 321(k), while

> "[l]abeling" is defined by statute as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C § 321(m). Thus, labeling "embraces advertising or descriptive matter that goes with the package in which the articles are transported," *Kordel v. United States*, 335 U.S. 345, 350, 69 S.Ct. 106, 93 L.Ed. 52 (1948), in addition to any label that may be placed directly on a pill bottle.

*Colacicco v. Apotex Inc.*, 521 F.3d 253, 258 n. 1 (3d Cir. 2008), *vacated on other grounds*, ___ U.S. ___, 129 S. Ct. 1578 (2009). "Labeling" that accompanies a drug is not limited to materials physically transported with the drug, but rather includes "all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article." *V. E. Irons, Inc. v. U.S.*, 244 F.2d 34, 39 (1st Cir. 1957), *cert. denied*, 77 S. Ct. 1383 (1957).

Janssen responded to DDMAC by indicating that it disagreed with DDMAC's findings, and asserting that its statements contained in the Risperdal DHCP letter were scientifically correct. Nevertheless, on July 21, 2004, after several rounds of modifications by the FDA, Janssen voluntarily distributed another DHCP letter, entitled "IMPORTANT CORRECTION OF DRUG INFORMATION" (the "Risperdal corrective letter"), which informed healthcare providers that Janssen had received a warning letter from the FDA. In addition to reciting DDMAC's concerns with the Risperdal DHCP letter, the Risperdal corrective letter also set forth the material information concerning the increased risk of diabetes and hyperglycemia that had been left out of the original letter. Following Janssen's dissemination of the Risperdal corrective letter, DDMAC closed the matter without taking any further action.

### B. Duragesic

The second drug at issue in this case, Duragesic, delivers a continuous dose of fentanyl, a narcotic pain medication, through a patch applied to a patient's skin. Duragesic was approved by the FDA in 1991 to treat chronic pain.

In August 2003, Janssen began distributing a "file card," or small color booklet, containing promotional information on Duragesic. Around this same time, Janssen sales representatives made calls to physicians delivering a message consistent with that

contained in the file card. Physicians in West Virginia received both file cards and phone calls.

Among other things, the file card contains information regarding Duragesic's alleged benefits over other pain medications, including claims that Duragesic reduces certain common side-effects and that Duragesic is comparatively less susceptible to being abused than other pain medications. The file card repeatedly directs the reader to "[p]lease see important safety information, including Boxed Warning," and the final two pages of the file card contain an FDA-mandated boxed warning regarding instances in which Duragesic is contraindicated.

Shortly after Janssen began distributing the Duragesic file card, it sent a copy to the FDA pursuant to 21 C.F.R. § 314.81(b)(3)(i), which requires submission of promotional labeling to the FDA at the time of initial dissemination. On September 2, 2004, DDMAC sent a warning letter to Janssen stating that the Duragesic file card "makes false or misleading claims about the abuse potential and other risks of the drug, and includes unsubstantiated effectiveness claims for Duragesic" in violation of section 502(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(a). Specifically, DDMAC cited the following representations contained in the file card: (1) Janssen's claim that Duragesic has a lower potential for abuse compared to other narcotics, based on its low rate of "mentions"

in the Drug Abuse Warning Network ("DAWN") database;[3] (2) Janssen's claim that Duragesic has a "favorable side-effect profile" (fewer gastrointestinal side-effects, low rates of constipation, vomiting and nausea, and fewer problems for patients with cancer); and (3) Janssen's improved patient outcome claims relating to the drug's effectiveness (implying that patients taking Duragesic will experience improved social and physical functioning, or improved work activity). With regard to each of these claims, DDMAC indicated that the research relied upon by Janssen to make the claim was insufficient or inappropriate.

In the warning letter, DDMAC concluded that "the file card thus misbrands Duragesic in violation of the [Federal Food, Drug and Cosmetic] Act. 21 U.S.C. § 352(a)." It requested that Janssen immediately stop distributing the cards and submit a plan for disseminating corrective information.

Janssen responded to DDMAC by contesting the assertions contained in the warning letter, and submitting detailed references to the medical literature that it believed supported its assertions. Despite its disagreement, however, Janssen also complied with DDMAC's requests, and in February 2005, it sent a corrective DHCP letter (the "Duragesic corrective letter"). Once again, Janssen titled its letter "IMPORTANT CORRECTION OF

[3] DAWN is a national public health surveillance system that monitors and compiles data from drug-related emergency room visits. DAWN is operated by the federal Substance Abuse and Mental Health Services Administration, a division of the federal Department of Health and Human Services, which is required by federal law to collect the DAWN data.

DRUG INFORMATION," and informed the reader of the FDA's warning letter and its assertions. On the back of the corrective letter, Janssen provided the standard warning information required to be distributed with Duragesic. With the issuance of this corrective letter, the FDA closed the matter.

## II. PROCEDURAL HISTORY

In August 2004, the State sued the Appellants in the Circuit Court of Brooke County, West Virginia, alleging violations of the Consumer Protection Act. The Act makes it unlawful to engage in "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce" in West Virginia. W. Va. Code § 46A-6-104.

The State alleged that, as part of their commercial activities in West Virginia, the Appellants repeatedly and willfully issued deceptive and misleading communications to healthcare providers regarding Risperdal and Duragesic. The State's allegations pertaining to Risperdal are based entirely on the statements and omissions contained in Janssen's Risperdal DHCP letter and are the same statements and omissions relied on by DDMAC in the Risperdal warning letter. Similarly, the State's allegations pertaining to Duragesic are based on the Appellants' statements and omissions in the Duragesic file card and, again, are the same statements and omissions relied on by DDMAC in its Duragesic warning letter.

In its complaint, the State sought an injunction preventing the Appellants from disseminating deceptive and misleading information in West Virginia in the future, and sought monetary damages as provided for by the Consumer Protection Act. Specifically, the State sought a $5,000 civil penalty for each alleged violation, i.e. each deceptive and misleading communication willfully made to a healthcare provider in West Virginia.

In the spring of 2008, the parties filed cross-motions for partial summary judgment. On August 19, 2008, the circuit court entered an opinion and order denying the Appellants' motion and granting the State's motion. The circuit court found that, based on the FDA's prior determinations, the Appellants had, as a matter of law, made false and misleading statements with respect to Risperdal and Duragesic in violation of the Consumer Protection Act. After denying a motion to reconsider filed by the Appellants, the circuit court conducted a bench trial on the remaining issues in the case: whether the Appellants' false and misleading statements were made repeatedly and willfully, as required under the Consumer Protection Act for the assessment of a civil penalty, and if so, the number of violations that occurred and the appropriate penalty amount for each violation.

At the bench trial, conducted on September 8, 2009, the State presented no witnesses, stipulated to the competency of the Appellants' witnesses and waived its right to cross-examine them, stipulated to the admissibility of the Appellants' exhibits, and submitted a written brief in lieu of opening and closing arguments. The Appellants submitted exhibits

and expert witness testimony via affidavit. The Appellants argued that their evidence showed that their statements were not actually false or misleading and, therefore, that they had not *willfully* disseminated false and misleading information.

On February 25, 2009, the circuit court entered a final order with findings of fact and conclusions of law. In that order, it reaffirmed its prior ruling that the statements were false and misleading as a matter of law, and ruled that the Appellants had made those statements repeatedly and willfully. The circuit court then found that each Risperdal DHCP letter and Duragesic file card sent by the Appellants to healthcare providers in West Virginia, as well as each phone call made by the Appellants' representatives, constituted a separate violation of the Consumer Protection Act. Based on the evidence presented, the circuit court concluded that the Appellants had committed 4,450 violations of that Act and, after applying a five-part test to determine the appropriate penalty amount, it assessed a $5000 penalty for each phone call and a $500 penalty for each item mailed. Thus, the circuit court assessed a total civil penalty of $4,475,000 against the Appellants.

## II. STANDARD OF REVIEW

"Appellate review of a partial summary judgment order is the same as that of a summary judgment order, which is *de novo.*" Syl. Pt. 1, *W. Va. Dept. of Transp., Div. of Highways v. Robertson*, 217 W. Va. 497, 618 S.E.2d 506 (2005). "'A motion for summary judgment should be granted only when it is clear that there is no genuine issue of fact to be

tried and inquiry concerning the facts is not desirable to clarify the application of the law.' Syllabus Point 3, *Aetna Casualty & Surety Co. v. Federal Insurance Co. of New York*, 148 W. Va. 160, 133 S.E.2d 770 (1963)." Syl. Pt. 2, *Ramey v. Contractor Enters., Inc*., 225 W. Va. 424, 693 S.E.2d 789 (2010).

## III. DISCUSSION

As previously noted, the Consumer Protection Act makes it unlawful to engage in "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce . . . ." W. Va. Code § 46A-6-104. To enforce the provisions of this Act, the attorney general may bring a civil action to restrain a defendant from engaging in such unfair or deceptive acts. *Id.* at § 46A-7-107. If the attorney general can prove that a defendant has engaged in a course of repeated and willful violations of the Act, then a court may assess a civil penalty of no more than five thousand dollars for each violation. *Id.* at § 46A-7-111(2).

The Act defines "trade or commerce" as "the advertising, offering for sale, sale or distribution of any goods or services" that directly or indirectly affects West Virginia citizens. *Id.* at § 46A-6-102(6). In defining "unfair methods of competition and unfair or deceptive acts or practices," the Act sets forth a non-exhaustive list of prohibited activities, which includes, in relevant part:

> (E) Representing that goods or services have . . . characteristics, . . . uses, [or] benefits . . . that they do not have . . . ;
>
> . . .
>
> (H) Disparaging the goods . . . of another by false or misleading representation of fact;
>
> . . .
>
> (L) Engaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding;
>
> (M) The act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby;
>
> (N) Advertising, printing, displaying, publishing, distributing or broadcasting . . . any statement or representation with regard to the sale of goods . . . which is false, misleading or deceptive or which omits to state material information which is necessary to make the statements therein not false, misleading or deceptive;"

*Id.* at §§ 46A-6-102(7)(E), (H), (L), (M) & (N).[4]

In the instant case, neither party disputes that the Appellants engaged in commerce in West Virginia, as defined by the Consumer Protection Act. The questions before the circuit court, therefore, were (1) whether the Appellants engaged in "unfair or

[4]In a 2005 amendment to West Virginia Code § 46A-6-102, the Legislature changed the numbering and lettering of the relevant subsections, without changing their substance. Although the State filed this case before this amendment, the Court here cites to the subsections as they are currently designated.

deceptive acts or practices" when Janssen disseminated the Risperdal DHCP letter and the Duragesic file card to healthcare providers in West Virginia and, if so, then (2) whether Janssen's distribution of these materials constituted a "course of repeated and willful violations." *See* W. Va. Code § 46A-6-104; W. Va. Code § 46A-7-111(2). In granting the State's motion for partial summary judgment, the circuit court ruled that the first question could be decided as a matter of law, while the second question was an issue of fact to be decided at trial. It then ruled, as a matter of law, that Janssen's statements and omissions in the Risperdal DHCP letter and the Duragesic file card were false and misleading and, thus, constituted "unfair or deceptive acts or practices." *See* W. Va. Code § 46A-6-104.

In reaching this conclusion, the circuit court relied on federal law. Initially, it noted that the Consumer Protection Act does not contain specific guidelines for determining whether a representation is misleading in the context of communications between a prescription drug companies and physicians. Under the Consumer Protection Act, however, "courts [are to] be guided by the interpretation given by the federal courts to the various federal statutes dealing with the same or similar matters." W. Va. Code § 46A-6-101(1).[5] The circuit court, therefore, looked for guidance from the Federal Food Drug and Cosmetic

[5]As set forth by the Legislature, the purpose of the Consumer Protection Act "is to complement the body of federal law governing . . . unfair, deceptive and fraudulent acts or practices in order to protect the public and foster fair and honest competition." W. Va. Code § 46A-6-101(1). To this end, the Legislature directs courts to be "guided by the interpretation given by the federal courts to the various federal statutes dealing with the same or similar matters." *Id.* Courts are to liberally construe the Act "so that its beneficial purposes may be served." *Id.*

Act, 21 U.S.C. §§ 301 to -399 ("FDCA"), the federal law governing the labeling and advertising of prescription drugs.

Among other things, the FDCA prohibits the misbranding of any drug in interstate commerce. 21 U.S.C. § 331(b). As relevant to this case, a drug is considered "misbranded" if "its labeling is false or misleading in any particular." *Id.* at § 352(a). The term "labeling" is construed broadly to encompass not only the label affixed to a drug container, but also other material accompanying the drug, including advertisements. *Kordel v. U.S.*, 335 U.S. 345, 350 (1948); 21 U.S.C. § 321(m) (2009); 21 C.F.R. § 202.1(l)(2) (2008).

As the agency charged with enforcing the FDCA, the FDA has promulgated regulations that set forth specific standards for prescription drug labeling and advertising. *See* 21 U.S.C. § 371. Under these regulations, "advertisements" include, among other things, letters and file cards containing drug information "which are disseminated by or on behalf of [the drug] manufacturer." 21 C.F.R. § 202.1(l)(2). The FDA's regulations provide that "[a]ll advertisements for any prescription drug . . . shall present a true statement of information in brief summary relating to side effects, contraindications . . . and effectiveness." *Id.* at § 202.1(e)(1).

> An advertisement does not satisfy the requirement that it present a "true statement" of information in brief summary relating to side effects, contraindications, and effectiveness if:

> (i) It is false or misleading with respect to side effects, contraindications, or effectiveness; or
>
> (ii) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug . . . ; or
>
> (iii) It fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement.

*Id.* at § 202.1(e)(5).

To assist in determining whether the information contained in an advertisement is false or misleading, the FDA promulgated extremely specific and detailed guidelines. 21 C.F.R. §§ 202.1(e)(6) & (7). For example, an advertisement is false or misleading if it "[c]ontains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, . . . safer, has fewer, or less incidence of, or less serious side effects or contradindications than has been demonstrated by substantial evidence . . . ." *Id.* at § 202.1(e)(6)(i). Similarly, an advertisement may be false or otherwise misleading if it "[c]ontains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions," or if it "[u]ses the concept of 'statistical significance' to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results." *Id.* at §§ 202.1(e)(7)(i) & (ii).

In the instant case, the circuit court concluded that the question of whether the Appellants' statements or omissions in their communications to West Virginia healthcare providers were false or misleading under the Consumer Protection Act should be determined by reference to the federal regulations governing whether drug advertisements are false and misleading under the FDCA.[6] Rather than considering this question to be an issue of fact for determination by a fact finder, however, the circuit court held that the issue could be decided as a matter of law on summary judgment.

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[6]While concluding that it should look to the FDCA for guidance, the circuit court acknowledged that, typically, only the United States is entitled to enforce an action under the FDCA. 21 U.S.C. § 337(a). As such, claims brought to enforce violations of the FDCA by any party other than the United States are generally preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). A cause of action brought under a state statute, such as the Consumer Protection Act, however, is not an action to enforce the FDCA so long as it "is premised on conduct that would give rise to liability under traditional common law principles." *In re Bayer Corp. Combination Aspirin Prods. Mktg. and Sales Practices Litig.*, 701 F. Supp. 2d 356, 369 (E.D. N.Y. 2010). On the other hand, if a defendant's conduct "would not expose it to liability but for the FDCA, 'then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*.'" *Id.* (*quoting Lefaivre v. KV Pharm. Co.*, 2010 WL 59125, at *3 (E.D. Mo. January 5, 2010)).

In the instant case, the State alleges that the Appellants disseminated false and misleading drug information to healthcare providers, an area traditionally subject to state law liability. The State is not simply alleging that the Appellants violated the FDCA by, for example, failing to provide the mandated warning information required by the FDA in Risperdal labeling. Rather, the State maintains that this alleged failure resulted in false and misleading information actually being disseminated to providers in West Virginia. Thus, the State's claims are not federally preempted by the FDCA and, in fact, the case provides an instance in which "[t]he FDCA and the state law consumer protection statutes serve complementary, though somewhat overlapping, roles." *In re Bayer Corp.*, 701 F. Supp. 2d at 370-71.

In concluding that the statements and omissions at issue are false and misleading as a matter of law, the circuit court relied on the FDA's communications with Janssen regarding the two drugs. Specifically, the circuit court reasoned that, in issuing the warning letters, the FDA had determined that certain statements and omissions contained in the Risperdal DHCP letter and the Duragesic file card were false and misleading in violation of the FDCA. The circuit court ruled that "the warning letters sent by the FDA were not informal or advisory by [sic] rather required [Janssen to take] mandatory action." It found that Janssen could have administratively appealed the FDA's determination but chose not to do so. Instead, Janssen acquiesced to the FDA's demands by issuing the respective corrective letters. Thus, the circuit court reasoned, Janssen waived its opportunity to contest the FDA's characterization of its representations. Finally, the circuit court concluded that the contents of the corrective letters–which simply restated the allegations contained in the warning letters–constituted "mandatory FDA action and the FDA's official judgment as to the matters addressed in the letters," because the FDA had directed Janssen to issue those letters and because the letters became part of the drugs' official "labeling" once they were mailed to healthcare providers and made public on the FDA's website.[7]

In other words, the circuit court found that, through the warning letters and corrective letters, the FDA had issued an official determination that certain statements and

[7]The circuit court stated in a footnote, without further explanation, that although it was granting preclusive effect to the "FDA corrective letters" in this case, such letters may not necessarily be preclusive in all cases.

omissions in the Risperdal DHCP letter and the Duragesic file card were false and misleading under the FDCA. Because the circuit court had already decided that it should look to the FDCA to determine whether a statement regarding a prescription drug is false and misleading under the Consumer Protection Act, it ruled that it would give "deference to the FDA's findings and actions pertaining to the communications at issue." Consequently, because the FDA had determined that the Appellants' statements and omissions were false under the FDCA, the circuit court ruled, as a matter of law, that the same statements and omissions were false and misleading under the Consumer Protection Act.

The Appellants contend that the circuit court erred by giving preclusive effect to DDMAC's determination that their Risperdal and Duragesic statements were false and misleading. They point out that, pursuant to the FDA's own guidelines, warning letters are merely "informal and advisory" and do not constitute a final judgment of the FDA. The Appellants further assert that, despite the circuit court's finding to the contrary, they did not have the ability to administratively appeal the allegations contained in those warning letters and, thus, were never afforded the opportunity to defend against the FDA's informal determinations. This Court agrees.[8]

[8]The Appellants additionally challenge the circuit court's entry of partial summary judgment on federal preemption and free speech grounds. The Court's decision on issue preclusion, however, renders consideration of the Appellants' alternative arguments unnecessary.

The doctrine of collateral estoppel, or issue preclusion,[9] "forecloses the relitigation of 'issues that were actually litigated in an earlier suit even though the causes of action [in the former and subsequent proceedings] are different.'" *Peters v. Rivers Edge Mining, Inc.*, 224 W. Va. 160, 177, 680 S.E.2d 791, 808 (2009) (*quoting Mellon-Stuart Co. v. Hall*, 178 W. Va. 291, 298-99, 359 S.E.2d 124, 131-32 (1987)). Specifically, the doctrine of collateral estoppel will bar the relitigation of an issue, thereby giving preclusive effect to the prior determination of that issue, if four conditions are met:

> (1) The issue previously decided is identical to the one presented in the action in question; (2) there is a final adjudication on the merits of the prior action; (3) the party against whom the doctrine is invoked was a party or in privity with a party to a prior action; and (4) the party against whom the doctrine is raised had a full and fair opportunity to litigate the issue in the prior action.

Syl. Pt. 1, in part, *State v. Miller*, 194 W. Va. 3, 459 S.E.2d 114 (1995). Here, no preclusive effect can be given to the FDA's determination that the statements and omissions in the Risperdal DHCP letter and Duragesic file card are false and misleading, because the FDA did not render a "final adjudication on the merits" on this issue, nor did the Appellants have an opportunity to fully and fairly litigate the question. *See id.*

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[9]Recently, this Court noted that the doctrine of collateral estoppel "is often more descriptively referred to as 'issue preclusion.' " *State ex rel. Taylor v. Janes*, 225 W. Va. 329, ___, 693 S.E.2d 82, 88 (2010) (*citing Yeager v. U.S.*, ___ U.S. ___, 129 S. Ct. 2360, 2367 n. 4 (2009)).

Although collateral estoppel may be applied to quasi-judicial determinations of administrative agencies, this Court has always been wary of so doing. *See Page v. Columbia Natural Res., Inc.*, 198 W. Va. 378, 393, 480 S.E.2d 817, 832 (1996) ("[W]e are of the opinion that only rarely, if at all, will administrative proceedings provide the same full and fair opportunity to litigate matter as will a judicial proceeding . . . ."). Consequently, the Court has held that,

> [f]or issue or claim preclusion to attach to quasi-judicial determinations of administrative agencies, at least where there is no statutory authority directing otherwise, the prior decision must be rendered pursuant to the agency's adjudicatory authority and the procedures employed by the agency must be substantially similar to those used in a court. In addition, the identicality of the issues litigated is a key component to the application of administrative *res judicata* or collateral estoppel.

Syl. Pt. 2, *Vest v. Bd. of Educ.*, 193 W. Va. 222, 455 S.E.2d 781 (1995). A review of the FDA's determinations in the instant case clearly indicates that neither of these prongs are met here.

A close examination of the FDA's actual determinations is required in considering their sufficiency under *Vest*. Here, the FDA's determinations that Janssen had violated the FDCA were issued in the form of warning letters. Pursuant to the FDA's Regulatory Procedures Manual, a "warning letter" is

> a correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more

> products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the Act.

FDA Regulatory Procedures Manual, Exhibit 4-1 at § 4.1 (March 2004). The purpose of warning letters is to give the recipient "an opportunity to take voluntary and prompt corrective action before [the FDA] initiates an enforcement action." FDA Regulatory Procedures Manual § 4-1-1. The letters, therefore, are "informal and advisory." *Id.* They communicate the FDA's position on a matter, but do not commit the agency to taking enforcement action. *Id.*

Importantly, the FDA "does not consider Warning Letters to be final Agency action on which it can be sued." *Id.* Rather, if a recipient of a warning letter fails to comply with the requested corrective actions, the FDA can, but is not obligated to, proceed with an enforcement action by requesting that the Department of Justice initiate a civil suit seeking an injunction or seizure of products, or a criminal suit seeking penalties, including fines and imprisonment. *See* 21 U.S.C. §§ 332-34.[10] Therefore, under the FDA's own regulations, its

[10]Since the events at issue in this lawsuit, Congress has authorized an additional enforcement mechanism in cases concerning direct-to-consumer advertising. Specifically, the Secretary of Health and Human Resources, which oversees the FDA, is now allowed to assess civil money penalties for direct-to-consumer advertisements that are false or misleading without (continued...)

determination that a drug company has violated the FDCA, when stated in a warning letter, is not a final agency action or decision on that issue.

Clearly, in issuing warning letters, the FDA is not acting pursuant to any adjudicatory authority, nor does it employ any due process procedures similar to those accorded defendants in courts of law. *See Vest,* 193 W. Va. 222, 455 S.E.2d 781, Syl. Pt. 2. Rather, in issuing a warning letter, the FDA, acting pursuant to its *regulatory* authority, attempts to remedy a perceived violation through informal means. No hearing is provided prior to the issuance of the letters, nor is the recipient notified of the alleged violations. Indeed, the purpose of the warning letters is to provide such preliminary notification, thereby giving the alleged violator an opportunity to resolve the problem in an informal manner before actual adjudication takes place. Accordingly, the warning letters cannot be considered quasi-judicial determinations by the FDA and, thus, are not subject to collateral estoppel under West Virginia law.

This conclusion is further supported by the findings of federal courts from around the country, which have similarly held that FDA warning letters do not constitute adjudications on the merits. In a federal case considering false advertising claims under the

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[10](...continued)
instituting a lawsuit. *See* 21 U.S.C. § 333(g) (2009). The statute, however, guarantees certain procedural safeguards, including written notice and an opportunity for a hearing, to protect the entities against which a penalty is being assessed. *Id.* at § 333(g)(2).

Lanham Act, 15 U.S.C. § 1125, the district court found that FDA warning letters did not constitute a final determination of whether a drug company had engaged in misbranding. *Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 947 (E.D. Wis. 2008). In so holding, the district court summarized other federal court holdings on this matter:

> Indeed, several courts have recognized that letters such as those cited here do not constitute an official agency determination. *See Herman*, 150 F.3d at 662 ("An agency action is not final if it is only 'the ruling of a subordinate official,' or 'tentative.' The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.") (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 796-97, 112 S.Ct. 2767, 120 L. Ed. 2d 636 (1992)); *see also Dietary Supplemental Coalition, Inc. v. Sullivan*, 978 F.2d 560, 562-63 (9th Cir. 1992) ("'[T]he type of informal letter issued by the FDA . . . does not constitute . . . formal or final agency action . . . .' ") (*quoting Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1377 (9th Cir.1983)), *cert. denied*, 508 U.S. 906, 113 S. Ct. 2333, 124 L. Ed.2d 245 (1993); *Genendo Pharmaceutical N.V. v. Thompson*, 308 F. Supp. 2d 881, 885 (N.D . Ill. 2003) (statements of agency officials below the Commissioner "do not rise to the level of final agency action–even when they are contained in warning letters or other official regulatory correspondence.); *Summit Tech. Inc.*, 922 F. Supp. at 306 ("regardless of any warning letters that the FDA may have sent to defendants, it is clear that the FDA has not completed this investigation.").

*Id.* Thus, federal district courts from around the country agree that warning letters are not final agency action.

Moreover, in *Wyeth v. Levine*, ___ U.S. ___, 129 S. Ct. 1187 (2009), the United States Supreme Court recently noted that "because [the Food, Drug and Cosmetic Act] contemplates that federal juries will resolve most misbranding claims, *the FDA's belief that a drug is misbranded is not conclusive*." *Id.* at 1198 (emphasis added). Because the FDA issues warning letters prior to any adjudication of an alleged violation, such letters, by their nature, simply set forth the FDA's *belief* that an FDCA violation has occurred and are not conclusive. *See id.* In the instant case, therefore, the FDA's positions, as set forth in the Risperdal and Duragesic warning letters, were not a final adjudications on the merits by that agency, but rather informal and advisory notifications to Janssen that the FDA believed that Janssen's communications violated the FDCA.

While the lack of a final adjudication on the merits is, by itself, sufficient to prevent the application of issue preclusion to the FDA's determinations, such application is rendered even more egregious because the Appellants did not have the opportunity to fully and fairly litigate the issue. Indeed, the circuit court clearly erred in finding that Janssen could have, but chose not to, formally appeal the findings in those letters. Specifically, in its summary judgment order, the circuit court indicated that Janssen could have "institute[d] administrative proceedings to challenge the Warning Letter on scientific, First Amendment, or other grounds." For this proposition, the circuit court cited to 21 C.F.R. § 10.33 which states: "[t]he Commissioner may at any time reconsider a matter . . . on the petition of an interested person." *Id.* at § 10.33(a). That regulation then continues: "[a]n interested person

may request reconsideration of part or all of a decision of the Commissioner . . . ." *Id.* at § 10.33(b). In this case, however, the warning letters were not a "decision of the Commissioner." Rather, the warning letters were issued by the Director of DDMAC, not the Commissioner. Therefore, this regulation is inapplicable, as there is no "decision of the Commissioner" for which Janssen could request reconsideration. *See id.*

Furthermore, because warning letters do not constitute "final agency action," they are not susceptible to judicial review and, thus, Janssen could not have initiated a civil lawsuit to challenge the validity of the letters. *See* FDA Regulatory Procedures Manual § 4-1-1 ("FDA does not consider Warning Letters to be final Agency action on which it can be sued."). Without a final agency action, recipients of warning letters cannot sue the FDA because they cannot establish a sufficiently imminent injury and, as such, their claims are not ripe. *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983).

Accordingly, the circuit court erred in giving preclusive effect to the FDA's determinations that Janssen had violated the FDCA through its statements and omissions in the Risperdal DHCP letter and the Duragesic file card. The FDA's belief that such violations occurred did not constitute a final adjudication on the merits and Janssen did not have the opportunity to fully and fairly litigate those issues. *See Vest*, 193 W. Va. 222, 455 S.E.2d 781, Syl. Pt. 2.

## IV. CONCLUSION

In sum, the FDA's *belief*, as expressed in the warning letters and subsequent corrective letters, that Janssen violated the FDCA is not sufficient to establish, as a matter of law, that the Appellants' communications to healthcare providers were actually false and misleading in violation of the Consumer Protection Act. It is fundamental that every defendant is entitled to defend themselves against allegations of misconduct. *See* Syl. Pt. 3, *In re Charleston Gazette FOIA Request*, 222 W. Va. 771, 671 S.E.2d 776 (2008) ("'The due process of law guaranteed by the State and Federal Constitutions, when applied to procedure in the courts of the land, requires both notice and the right to be heard.' Syllabus Point 2, *Simpson v. Stanton*, 119 W. Va. 235, 193 S.E. 64 (1937)."). Whether Janssen's statements and omissions in the Risperdal DHCP letter and the Duragesic file card are actually false and misleading under the FDCA, and thus constitute "unfair or deceptive acts or practices" under the Consumer Protection Act, is a question of fact to be decided by a finder of fact. The State, therefore, must present evidence that Janssen's specific statements and omissions do, in fact, violate the relevant laws, and the Appellants are entitled to present evidence to the contrary.

For these reasons, the Court reverses the order granting partial summary judgment entered on August 19, 2008, vacates the final order entered on February 25, 2009,[11]

[11]Because the circuit court erred in granting the State's motion for partial summary judgment, this Court need not reach the assignments of error pertaining to alleged evidentiary errors (continued...)

and remands the action to the Circuit Court of Brooke County, West Virginia, for further proceedings consistent with this opinion.

Reversed and Remanded.

[11](...continued)
during the bench trial and alleged errors in assessing the civil penalty.