APPEAL NO. 35500

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

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SUPREME COURT OF APPEALS
OF WEST VIRGINIA

STATE OF WEST VIRGINIA, EX REL.,
DARRELL V. McGRAW, JR.,
ATTORNEY GENERAL,

Appellee,

v.

JOHNSON & JOHNSON and JANSSEN
PHARMACEUTICA PRODUCTS L.P.,

Appellants.

On Appeal From The Circuit Court
of Brooke County, Civil Action No.
04-C-156

BRIEF OF APPELLEE

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I. Nature of the case

The plaintiff is the State of West Virginia by its attorney general, Darrell V. McGraw, Jr. The defendants are Jansen Pharmaceutica Products L.P and its parent company, Johnson & Johnson, the manufacturers of Risperdal, a prescription drug in a class of drugs known as atypical antipsychotics, and Duragesic, a prescription pain patch containing the narcotic Fentanyl.

The state's complaint seeks to require the defendants to pay civil monetary penalties for violating the West Virginia Consumer Credit and Protection Act, W.Va. Code, §46A-1-101 *et seq*. ("WVCCPA"), and specifically for violating §46A-6-104 of the Act, which prohibits unfair or deceptive acts or practices in the conduct of any trade or commerce. The WVCCPA (§46A-7-11) authorizes the attorney general to bring such an action and for imposition of civil penalties of no more than $5,000 for each violation.

The state claims that the defendants, as part of their commercial enterprise of selling prescription drugs in West Virginia, violated the WVCCPA in the following ways.

(1) The defendants sent a misleading November 2003 Dear Healthcare Provider ("DHCP") letter concerning Risperdal to 3,900 doctors in West Virginia.

(2) The defendants' sales representatives had 400 personal meetings with West Virginia doctors in which the message delivered by the sales representative was consistent with the misleading November 2003 Risperdal letter.

(3) Between August 2003 and September 2004 the defendants distributed a misleading Duragesic file card to 50 doctors in West Virginia.[1]

---

[1] In the pharmaceutical industry and in FDA parlance, the term "file card" or "professional file card" is used to describe a promotional brochure for a prescription drug product, typically with a fold-out, multi-page design, that is distributed to physicians, pharmacists, and other health care providers. Summary

(4) The defendants' sales representatives had 100 personal meetings with West Virginia doctors in which the message delivered by the sales representative was consistent with the misleading Duragesic file card.[2]

The trial court determined that the Risperdal DHCP letter and Duragesic File card are misleading as a matter of law and granted partial summary judgment to the state on this issue.

A bench trial was conducted on the remaining issues, following which the trial court granted judgment to the state and imposed civil penalties of $500 for each of the 3,900 Risperdal DHCP letters, $500 for each of the 50 Duragesic file cards, $5,000 for each of the 400 Risperdal sales meetings, and $5,000 for each of the 100 Duragesic sales meetings. These total $4,475,000 for 4,450 violations of the WVCCPA.

II. Argument Summary

A. Risperdal

The defendants' main Risperdal argument is that they were cut off from presenting evidence contrary to the scientific findings in the FDA's Risperdal Warning Letter by the trial court's finding that the defendants' DHCP letter is misleading as a matter of law.

This argument is a red herring, because the Warning Letter makes no scientific findings. It merely recites the previously-made FDA diabetes risk label requirement for Risperdal and refers to the scientific information the FDA considered in arriving at the requirement. The diabetes risk label requirement had been sent to the defendants seven months before the Warning Letter. Thus, what the defendants are really asking for is an opportunity to contest the validity of the FDA's diabetes labeling requirement for Risperdal.

Judgment Order, p.8. The Duragesic file card of concern in the present case is a 16-page, full-color sales brochure with a folding design. State's trial exhibit 100.

[2] The defendants stipulated to the number of letters, file cards, and sales meetings.

However, a state court is precluded by deference, preemption, or both from allowing a collateral attack on an FDA drug safety labeling requirement that would invalidate, modify, or render it ineffective. Thus the defendants' experts were offered to support a proposition the trial court could not entertain.

The defendants had options they could have pursued for the purpose of contesting the FDA's diabetes label requirement. They could have petitioned the FDA commissioner for administrative review, or they could have filed suit against the FDA under the federal Administrative Procedures Act. They chose to do neither.

The Risperdal DHCP letter is inherently misleading as a matter of law, without any reliance whatsoever on the FDA Warning Letter, because the DHCP letter (1) represents that Risperdal has less diabetes risk than other atypical antipsychotic drugs, which is contrary to the FDA's label requirement for Risperdal, (2) omits the blood sugar monitoring information required by the FDA to be included in Risperdal's label, which conceals information deemed by the FDA to be important to physicians in monitoring the health of their patients, (3) eviscerates the FDA-mandated diabetes label requirements by indicating that Risperdal has no more risk of causing diabetes than taking nothing, (4) gives the impression that its contents are FDA-approved by its salutation of "Dear Healthcare provider" and other means, and (5) does not contain disclaimers to the effect that its substance is not FDA-approved, and representations in it are contrary to the FDA's label requirements for Risperdal.

B. Duragesic

As with Risperdal, the trial court did not give preclusive effect to the Duragesic Warning Letter. The trial court's finding that the Duragesic file card is misleading as a matter of law is supported by specific federal regulations that prohibit representations made in the file card and

by facts that were all in existence before the Warning Letter was sent. There is nothing the defendants' Duragesic experts could say that would change the regulations or the facts that are apparent from the face of the file card in comparison to the Duragesic's FDA-mandated label.

DAWN (Drug Abuse Warning Network) is a federal program operated by a sister agency to the FDA under the Secretary of Health and Human Services. FDA regulations prohibit making a comparative safety claim for a drug unless the claim is supported by a well-controlled study. DAWN has no controls, and it is not a study. It is a surveillance system operated by the federal government to collect data. Nonetheless, the file card makes a comparative safety claim for Duragesic based on DAWN data, and in doing so represents (1) that DAWN data is scientific proof that Duragesic is safer than its competitors, which is not true; (2) that DAWN data can be used to support the comparison made, which is prohibited by law; and DAWN data represents clinical experience, which is not true. For these reasons, and others discussed *infra*, the file card is misleading as a matter of law, without any consideration of the Warning Letter.

The defendants could have petitioned the FDA commissioner for review of the Duragesic Warning Letter, and if unsatisfied with the result, could have obtained judicial review under the Administrative Procedures Act. The defendants, however, did not select this option.

C. First Amendment

The Risperdal DHCP letter and Duragesic file card are misleading commercial publications and are therefore entitled to no First Amendment protection.

D. Penalty

The trial court conducted a detailed factual analysis under the five-factor test recommended by the defendants in determining an appropriate penalty. The defendants violated the WVCCPA

4,450 times, and the aggregate penalty imposed for these violations is only 20% of what is legislatively authorized and is well within the reasonable range of the trial court's discretion.

III. Facts

A. Risperdal Facts

Risperdal is a prescription drug in a class of prescription drugs known as atypical antipsychotics ("Atypicals").

In a letter dated September 11, 2003, the FDA informed the defendants of its decision to require a uniform, class-wide revision of the labels for all Atypicals, including Risperdal, to include new diabetes risk information.

> After reviewing the available data pertaining to the use of atypical antipsychotic medications and diabetes mellitus adverse events, we have concluded that the product labeling for all atypical antipsychotics should be updated to include the information about these events.
>
> ...we believe the safe use of Risperdal can be enhanced by informing prescribers and patients about these events. Increased attention to the signs and symptoms of diabetes mellitus may lead to earlier detection and appropriate treatment, and thus reduce the risk for the most serious outcomes.[3]

The letter goes on to specify the exact text required by the FDA for this new Risperdal label requirement.

> Hyperglycemia, in some cases extreme and associated with ketoacidosis ... coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL®.
>
> ... epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics...
>
> Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia ...

[3] Defendants' trial exhibit 63.

> In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of the suspect drug.

The defendants were dissatisfied with the FDA's decision to require this change to Risperdal's label, and they wrote the FDA saying so in a September 26, 2003, letter. This letter cites literature purporting to show that Risperdal has a lower risk of diabetes than some other Atypicals,[4] and it proposes a considerably milder diabetes risk label change for Risperdal.[5]

Despite not having received approval from the FDA in response to their request to treat Risperdal differently, the defendants took it upon themselves to create a letter containing their position – contrary to the FDA's label requirement – that Risperdal is not associated with an increased risk of diabetes. The defendants sent this letter, dated November 10, 2003, to 754,000 doctors, pharmacists, and others involved with prescribing drugs. The letter includes the following.

> In an effort to keep you updated with the most current product information available for the management of your patients, enclosed please find updated prescribing information for RISPERDAL (risperidone).
>
> 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[1-8] 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* then some other studied atypical antipsychotics.[6] (Emphasis added)

The defendants' followed up on this November 2003 letter by sending sales representatives to meet with prescribers in West Virginia and repeat the unapproved promotional claims for Risperdal made in the letter.

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[4] This is the same literature the defendants would later offer in the present case in asking the trial court to invalidate the FDA's decision requiring a diabetes risk change to Risperdal's label. Defendant's April 8, 2008, motion for partial summary judgment as to Risperdal, pp. 4-5.

[5] The defendants' letter and proposed changes are set out on pp. 8-9 of the trial court's final order.

[6] Final order at p. 13.

The letter uses the salutation, "Dear Health Care Provider." A "Dear Health Car Provider" (DHCP) letter is not a routine matter. As the FDA stated with respect to the defendants' November 2003 Risperdal DHCP letter to 754,000 recipients:

> "The health-care community relies on DHCP letters for accurate and timely information regarding serious risks and associated changes in labeling and the dissemination of this letter at a time critical to educating health care providers is a serious public health issue."

The defendants acknowledged this in responding to the FDA Warning Letter, saying they

> "agree... with DDMAC that the healthcare community relies on Dear Healthcare Provider Letters (DHCP) to provide accurate and timely information regarding serious risks and changes in labeling." [7]

When the FDA recognized what the defendants had said in the DHCP letter, it took action by sending the defendants a Warning Letter dated April 19, 2004, stating that the promotional DHCP letter contains multiple representations and omissions that are false or misleading under FDA regulations.[8] The Warning Letter indicates that the defendants' DHCP letter, among many other shortcomings, (1) fails to state that the diabetes risk label requirement for Atypicals is class-wide, with no exception for Risperdal, (2) minimizes the risk of hyperglycemia-related adverse events, and (3) omits the FDA's recommendation for regular glucose monitoring of patients taking Risperdal. The Warning Letter directs the defendants to submit a written plan of action designed to disseminate accurate and complete information to those who had received the DHCP letter. The Warning Letter shows its teeth by concluding with "Failure to correct the violations...may result in FDA regulatory action, including seizure or injunction without further notice."

The defendants responded to the Warning Letter by writing to the FDA, saying they disagree with the FDA as to Risperdal's safety relative to other Atypicals, and pointing to the eight

[7] State's trial exhibit 16.
[8] State's trial exhibit 3.

articles they claim support their position. However, in a move that, if accepted by the FDA, would avoid the risk of more serious, far-reaching, and punitive regulatory action, the defendants offered to settle the matter with the FDA by sending a corrective letter to those to whom the DHCP letter had been sent.[9]

In its response, the FDA stuck by its guns by (1) declining to reevaluate its class-wide diabetes risk information requirement, (2) reiterating its view that the November 2003 DHCP letter is "false or misleading" and contains "serious violations," and (3) rejecting the defendants' proposed corrective letter.[10]

The defendants then sent the FDA a revised, proposed corrective letter. The FDA rejected this second effort as well, but delineated changes that would make it acceptable. The defendants acquiesced to the changes. The final version of the corrective latter was mailed in July 2004, stating:

> Dear Health Care Provider:
>
> The Food and Drug Administration's (FDA) Division of Drug, Marketing, Advertising, and Communications (DDMAC) has asked us to contact you because Janssen Pharmaceutica Products, L.P. recently received a Diabetes risk information Letter concerning the promotion of Risperdal® (risperidone). This letter provides important corrective information about Risperdal relating to hyperglycemia and Diabetes Mellitus.
>
> The Diabetes risk information Letter concludes that Janssen disseminated a Risperdal Dear Health Care Provider (DHCP) dated November 10, 2003 that omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act.
>
> Specifically, the Diabetes risk information Letter stated that the DHCP letter omitted important information regarding hyperglycemia and diabetes, including the potential consequences and the recommendation of regular glucose control monitoring that was added to the approved product labeling for Risperdal; minimized the potentially fatal risks of hyperglycemia-related adverse events such as ketoacidosis, hyperosmolar coma

[9] A corrective letter is one that meets the requirements of 21 CFR 200.5. This also applies to the Duragesic corrective letter discussed *infra*. The defendant's letter is their trial exhibit 87.
[10] State's trial exhibit 15.

> and death; minimized the importance of blood glucose monitoring; suggested that Risperdal did not increase the risk of diabetes, contradicting the Diabetes risk information in the revised product labeling; and made misleading claims suggesting that Risperdal has a lower risk of hyperglycemia and diabetes than other atypical antipsychotics without adequate substantiation which is inconsistent with the Prescribing Information for Risperdal. [11]

The Corrective Letter was sent to the 754,000 healthcare professionals to whom the DHCP letter had been sent, including 3,900 in West Virginia, and was posted to the FDA's website. This concluded the FDA's regulatory action regarding the Risperdal DHCP letter.[12] The FDA has not changed Risperdal's diabetes labeling requirement, it is today as it was in 2004.[13]

B. Duragesic Facts

J&J began distributing a 16-page, full color Duragesic file card to physicians in August 2003. Between August 1, 2003 and September 27, 2004, the defendants distributed 109,891 Duragesic File cards nationally, including 50 in West Virginia. The defendants' sales representatives made 100 Duragesic sales calls on doctors in West Virginia during this time period, delivering a message consistent with the file card.[14]

On September 2, 2004, the FDA sent the defendants a Warning Letter, stating that multiple representations and omissions in the promotional file card are false or misleading under FDA regulations, including (1) the claim that Duragesic had a lower potential for abuse compared to other narcotics, (2) using Drug Abuse Warning Network ("DAWN") data to make a safety comparison to other narcotics, (3) stating Duragesic has a favorable side-effect profile without supporting information, (4) stating Duragesic is associated with less constipation, nausea, and vomiting than oral opioids without supporting information, (5) citing three studies that do not support the statements for which the studies are cited, and (6) suggesting that patients taking

[11] The final version of the "Risperdal Corrective Letter" is State's trial exhibit 6.
[12] State's trial exhibit 21.
[13] Trial court's summary judgment order at p.12.
[14] Trial Evidence Stipulation No. 3.

Duragesic will experience improved social or physical functioning without supporting evidence.[15]

The specific facts relied upon by the state to demonstrate that the Duragesic file card contains false and misleading information are contained in the Duragesic argument section of this brief *infra.*

The defendants responded to the Duragesic Warning Letter, stating disagreement with it and referring to articles claimed to support the file card, but also saying that the defendants would discontinue distribution of the file card and other promotional activities containing the same or similar messages.[16] The FDA replied, indicating that the proposed corrective action is inadequate, and a Corrective Letter would be needed.[17] The defendants submitted a proposed corrective letter, the FDA accepted it, and it reads as follows.

> Dear Healthcare Professional:
>
> The Food and drug Administration's (FDA) Division of Drug, Marketing, Advertising, and Communications (DDMAC) has asked us to contact you because Janssen Pharmaceutica Product L.P. received a Diabetes risk information Letter on September 2, 2004 concerning a promotional file card for DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM).
>
> The Diabetes risk information Letter concluded that a promotional file card distributed by Janssen made false or misleading claims about the abuse potential and adverse event profile of the drug and included unsubstantiated effectiveness claims for DURAGESIC, in violation of the Federal Food, Drug and Cosmetic Act.
>
> Specifically, the Diabetes risk information Letter stated that the promotional item falsely or misleadingly suggested that DURAGESIC had a lower potential for abuse compared to other opioid products, which could encourage an unsafe use of the product, potentially resulting in serious or life-threatening hypoventilation. The Diabetes risk information Letter also stated that the promotional file card falsely or misleadingly suggested that DURAGESIC is associated with less gastrointestinal adverse events than oral opioids. Lastly, the Diabetes risk information Letter stated that the promotional item contained claims of effectiveness for chronic back pain, and improvement in

[15] State's trial exhibit 102.
[16] Defendants' trial exhibit 215.
[17] Defendants' trial exhibits 216, 218

activities of daily living, quality of sleep, physical and social functioning, which were not supported by substantial evidence or clinical experience.

Therefore, we direct you to the reverse side of this document for a copy of the Boxed Diabetes risk information for DURAGESIC (Fentanyl transdermal system), Information on Drug Abuse and Dependence and Indications and Usage, and the accompanying full Prescribing Information for DURAGESIC.

The corrective letter was sent in February 2005 to 109,891 health care professionals who had received the file card,[18] and the letter was posted to the FDA's website. This concluded the FDA's regulatory action.[19] There has been no change to Duragesic's FDA-mandated prescribing information that is relevant to issues in the present case since the corrective letter was sent.[20]

C. Facts relevant to penalty amount

1. Financial information [21]

Johnson & Johnson earnings and balance sheet in billions of dollars

Year	2003	2004	2005	2006	2007
Total Sales	$41.862	$47.348	$50.514	$53.324	$61.095
Gross Profit	$29.686	$33.926	$36.560	$38.267	$43.344
Net Earnings	$7.197	$8.509	$10.411	$11.053	$10.576
Total Assets	$48.263	$53.317	$58.025	$70.556	$80.954
Shareholders Equity	$26.869	$31.813	$37.871	$39.318	$43.319

Johnson & Johnson sales of Risperdal, Duragesic, and all pharmaceuticals in billions of dollars.

Year	2003	2004	2005	2006	2007
Risperdal	$2.512	$3.05	$3.552	$4.183	$4.697
Duragesic	$1.63	$2.083	$1.585	$1.295	$1.164

[18] State's trial exhibit 111.
[19] Defendants' brief at p. 10.
[20] Final order at p.26.
[21] This information is taken from J&J Annual Reports to Stockholders and is undisputed.

All Pharmaceuticals	$19.517	$22.128	$22.322	$23.267	$24.866

2. The defendants had prior notice, in the form of previous FDA Warning Letters, not to be misleading in promoting Risperdal and Duragesic. [22]

a. Before the defendants mailed the November 2003 Risperdal DHCP letter, the FDA had sent the defendants a Warning Letter charging an earlier Risperdal promotion as being false or misleading under FDA regulations.[23]

b. Before the defendants distributed the Duragesic file card, the FDA had sent the defendants *two* Warning Letters charging earlier Duragesic promotions as being false or misleading under FDA regulations.[24]

3. The defendants knew they could not trust themselves

The defendants predicted that if manufacturers draft their own letters to physicians regarding the diabetes label change, each will put its own misleading spin on the information. The defendants wrote in an October 27, 2003, letter to the FDA that they "strongly believe ... physicians may receive inconsistent, misleading and inaccurate information..." if manufacturers are free to draft their own communications.[25]

4. Trial court findings

The trial court's findings of fact regarding the defendants' willful conduct with regard to the Risperdal DHCP letter are set out a page 25-27 infra, and its findings as to Duragesic in this context are set out on page 33-34.

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[22] The FDA's Regulatory Procedures Manual (August 1997) considers a Warning Letter as "Prior Notice" of conduct that is in violation of the laws enforced by the FDA. Defendants' trial exhibit 71, chapter 10, subchapter entitled "Prior Notice."
[23] State's trial exhibit 17.
[24] State's trial exhibits 106 and 107.
[25] Defendants' trial exhibit 66. The substance of this letter is quoted in its entirety in the trial court's final order at p.11.

IV. Argument

A. Risperdal discussion

1. The defendants' main appeal point is a red herring

The defendants say the intended purpose of the scientific evidence regarding Risperdal that they wanted to put on in the trial court is impeachment of the scientific determinations in the Risperdal Warning Letter. However, the Warning Letter makes no scientific determinations. Rather, the Warning Letter is based on the FDA's prior decision to require a label change for Risperdal and the scientific information upon which *that* labeling decision is based.

The defendants are effectively asking this court to allow them to invalidate an FDA labeling requirement, intended to promote safer use of Risperdal, by directing the trial court to conduct a de novo review of the scientific basis for an FDA labeling requirement. A state court cannot do this.

a. The FDA's Risperdal Warning Letter does not make scientific determinations

The trial court could not have given preclusive effect to scientific determinations in Risperdal Warning Letter, because this letter does not make any. The scientific points discussed in the Warning Letter are those underlying, and incorporated into, the FDA's public health policy decision to require Risperdal's label to (1) contain specific diabetes risk information and (2) to be identical to the label of all other Atypicals with regard to diabetes risks. The FDA had conveyed Risperdal's new label requirements to defendants some seven months before the Warning Letter was sent.[26] The Warning Letter's reliance on the scientific evidence considered by the FDA in arriving at its label change requirement, as opposed to making any

[26] FDA's September 11, 2003, letter, which is defendants' trial exhibit. 63.

new scientific determinations of its own, is illustrated by the following excerpts from the Warning Letter.

Opening paragraph on page 1

> The Division of Drug, Marketing, Advertising, and Communications (DDMAC) has reviewed a 'Dear Healthcare Provider (DHCP) Letter for Risperdal... disseminated by Janssen... on November 10, 2003. DDMAC has concluded that the DHCP letter is false or misleading in violation of Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act...because it fails to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling (PI)...

First full paragraph on page 2:

> In response to post-marketing reports of diabetes mellitus, including some cases that resulted in hospitalization and/or death, FDA evaluated the risk of the development of diabetes mellitus in patients treated with atypical antipsychotics.
>
> This evaluation included a thorough review from a number of sources, including clinical trial data, spontaneous post-marketing reports, epidemiological studies, published case series, published clinical pharmacology studies, published preclinical studies, and unpublished studies for clozapine, olanzapine, risperidone [Risperdal], quetiapine, ziprasidone, and aripiprazole.
>
> Based on this review, and given the severity of the events reported and the potential to identify those events at an earlier stage with additional monitoring, FDA determined to require the addition of language to the Diabetes risk information section of the PI for all atypical antipsychotics regarding the risk of hyperglycemia and diabetes.

First paragraph on page 3:

> The DHCP letter fails to communicate the fact that information regarding the potential consequences of hyperglycemia and the recommendation of regular glucose control monitoring was added to the PI for Risperdal.

Middle of page 3:

> This statement [in the defendant's DHCP letter] suggests that Risperdal does not increase the risk of diabetes, contradicting the revised PI...

Middle of second paragraph on page. 4:

> FDA's conclusion regarding the lack of evidence to support a ranking of risk among the atypical antipsychotics is reflected in the following statement from the Diabetes risk

information section of the PI for Risperdal: 'Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.'

b. The point the defendants wish to make cannot be made without invalidating the FDA's label requirements for Risperdal

The point the defendants want to try to prove is that Risperdal has less risk of causing diabetes than other Atypicals. They cast this as disagreement with the Warning Letter, but it is actually disagreement with the FDA's label requirement itself. The letter's science is the label's science, and the former cannot be invalidated without invalidating the latter.

c. A state court cannot invalidate an FDA drug labeling requirement by allowing it to be collaterally attacked by the drug's manufacturer

(1) A state court should decline, based on deference, to invalidate an FDA drug safety labeling requirement

Judgments as to safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and are entitled to deference. *Zeneca v. Shalala*, 213 F.3d 161 (4th Cir. 2000), *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995), *Henley v. FDA*, 77 F.2d 616, 621 (2d Cir. 1996).

"Congress has entrusted ... FDA with authority to make such expert policy judgments ... [and to make] subtle scientific judgments about a drug's risks and benefits." *Public Citizen Health Research Group v. Commissioner, Food & Drug Admin.*, 740 F.2d 21, 28 (D.C. Cir. 1984). Because courts are "... not expert on the medical and scientific issues which must be explored in order to produce accurate labeling, the assignment of that function to the FDA is sensible and proper." *United States v. Diapulse Corporation,* 457 F.2d 25, 29 (2d Cir. 1972).[27]

[27] To the same effect: "[T]he intent behind the [FDCA] was to give the agency primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise", *Rutherford v. United* States, 806 F.2d 1455, 1461 (10th Cir. 1986). "A district court is not empowered to evaluate the actual safety and effectiveness of a drug product. That determination is committed to the FDA due to its superior access to technical expertise." *United States v. Undetermined Quantities of Various Articles*, 675 F.2d 994, 1000 (8th Cir. 1982).

The FDA has authority to issue labeling rules under 21 U.S.C. 352 and 355 and has done so. Deference [to a federal agency] ... is warranted "when it appears that Congress delegated authority to the agency to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Gonzalez v. Oregon*, 546 U.S. 243, 255-56 (2006) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 226-227 (2001).

The FDA is charged with "promot[ing] the public health by promptly and efficiently reviewing [drug manufacturers'] clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protect[ing] the public health by ensuring that . . . drugs are safe and effective." 21 U.S.C. § 393(b)(1), (b)(2)(B).

Those filing amicus briefs for the defendants in the present case agree.

> The FDA is the expert federal agency charged by Congress with ensuring that drugs are safe and effective. Product Liability Advisory Council's amicus brief in *Wyeth v. Levine*.[28]
>
> The centerpiece of FDA's expert weighing of risks and benefits is the medicine's labeling ... By providing a coordinated set of instructions to physicians, including diabetes risk information and contraindications calibrated to the best scientific evidence, FDA achieves a balance in communicating information about the benefits and risks of a drug. PhRMA's amicus brief in Wyeth in *Wyeth v. Levine*.[29]
>
> As the Court has explained, '[t]he determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations . . . within the peculiar expertise' of FDA. *Weinberger v. Bentex Pharms. Inc.*, 412 U.S. 645, 654 (1973). 'Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background.' *Id.* Thus, federal courts of appeals have repeatedly held that ... drug ... labeling [is] squarely within the primary scope of FDA's regulatory authority. Washington Legal Foundation's amicus brief in *Wyeth v. Levine*.[30]

(2) A state court is preempted from invalidating an FDA drug safety labeling requirement

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[28] http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-1249_PetitionerAmCuPLAC.pdf
[29] http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-1249_PetitionerAmCuPhRMABIO.pdf
[30] http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-1249_PetitionerAmCuWLFAmeColofEmgncyPhy.pdf

The exclusivity of the FDA's jurisdiction to determine the contents of a drug's labeling can be recognized by deferring to it, as indicated above, and therefore it might not be necessary to reach a preemption analysis. Nonetheless, preemption in this regard will be explored.

State law is preempted when "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U. S. 132, 373 U.S. 142-143 (1963), or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidomtz,* 312 U.S. 52, 67 (1941). Also see *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714-716 (1985).

Plain and simple, the defendants are asking to be allowed to offer evidence for the purpose of showing that the FDA's Risperdal diabetes label requirement is wrong. Assuming the defendants were to get what they are asking for, and assuming that the trial court were to find that the defendants have the better side of the argument, there would be 49 states with the FDA-approved label for Risperdal in force, and West Virginia standing alone permitting a weaker label. Even if there might be a way to comply with federal and West Virginia law without violating one or the other, this result would nonetheless be hopelessly and irreconcilably at odds with Congressional intent to have a uniform national drug labeling policy under the auspices of the FDA, and defendants' amicus PhRMA agrees:

> A court that permits state law to override [the] FDA ...cannot fully anticipate the ripple effects of its decision through the entire regulatory structure.[31]

This is precisely the concern addressed by this court in *Morgan v. Ford Motor Company*, 680 S.E.2d 77 (2009), in finding that piecemeal collateral attacks could "eviscerate ... unitary federal regulation."

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[31] PhRMA amicus brief in *Colaccico v. Apotex*, page12, http://druganddevicelaw.net/Colacicco%20materials/Colacicco%203d%20Cir%20PhRMA%20amicus.pdf

In *Wyeth v. Levine*, 555 U.S. ___ (2009), the court held that federal law does not preempt a state law tort claim based on an inadequate warning in a prescription drug's label. In reaching this decision, the *Wyeth* court observed that a manufacturer generally may not change a drug label without FDA approval, but there is an exception permitted when the change adds or strengthens a warning to improve drug safety. The general rule, *i.e.,* that a manufacturer is bound to comply with FDA-mandated drug labeling, applies in the present case, because it does not involve a manufacturer's effort to improve drug safety by adding stronger diabetes risk information, but rather an effort to increase sales by diluting the FDA-required label.

Defendants' amicus PhRMA again agrees:

> Congress delegated to the Agency broad responsibility to 'protect the public health' by ensuring that prescription drugs are safe and that the label contains appropriate 'directions for use and cautionary statements.' 21 U.S.C. § 353(b)(2). Among other things, FDA's labeling regulations require warnings that allow physicians to use the drug safely... 21 C.F.R. §§ 201.100(c)(1); 201.56; 201.57; 314.70; 601.12. All these requirements fall within the 'proper bounds' of FDA's delegated authority and can preempt state law.[32]

The state has been unable to find – and challenges the defendants to find – a single case holding that a state court has authority to invalidate an FDA requirement as to the minimum risk information that must be included in a drug's label.

d. Invalidating an FDA drug safety label requirement is incompatible with the WVCCPA

W.Va. Code, § 46A-6-101 states:

> The legislature hereby declares that the purpose of this article is to complement the body of federal law governing unfair competition and unfair, deceptive and fraudulent acts or practices in order to protect the public and foster fair and honest competition. It is the intent of the Legislature that, in construing this article, the courts be guided by the interpretation given by the federal courts to the various federal statutes dealing with the same or similar matters. To this end, this article shall be liberally construed so that its beneficial purposes may be served.

[32] *Id* at page 8

The trial court put it this way:

> ... state standards should not be weaker than those provided by federal law, because weaker standards would not comport with the legislative directive to interpret the Consumer Protection Act liberally to accomplish its purposes, one of which is to penalize those who violate it, and pharmaceutical makers can have no legitimate expectation of more lenient requirements under West Virginia law than they are already subject to under federal law. It is also unlikely that the legislature intended to provide less protection in the area of prescription drugs to West Virginia consumers than the rest of the country is entitled to under federal law.[33]

e. The defendants know a state court cannot invalidate an FDA drug safety labeling requirement

What would the defendants be saying to this court, if the state were claiming that the defendants violated the WVCCPA by sending information to doctors that had been specifically *approved* by the FDA for inclusion in Risperdal's label? The state's prediction is they would be saying what they said earlier in this case:

> The FDA's authority over prescription drugs is both comprehensive and pervasive. Congress has charged the agency with reviewing all available scientific evidence and determining precisely how the risks and benefits of a prescription drug must be conveyed on its label/package inserts. The agency's authority also extends to the marketing of prescription drugs...The FDA balances ***twenty factors*** to determine whether a pharmaceutical company's communications to doctors... about its prescription drug is fair, or false and misleading... There is no justification for interpreting the CCPA expansively to require either additional or varying state-law-based requirements on top of the specific and comprehensive requirements imposed under federal law with its comprehensive authority and specialized expertise.[34] (Emphasis in original)

f. Defendants' experts have nothing to say that is relevant to any issue in the case

The defendants' Risperdal expert opinions and other scientific evidence were offered for the purpose of showing that the FDA's Risperdal diabetes risk label requirements are wrong, but these experts have nothing to say that bears on the case, because the court cannot permit a collateral attack on the validity of the FDA label requirements. The defendants might argue that

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[33] Trial court's summary judgment order at p. 18.

[34] Pages 17-18 of defendants' brief in support of motion for summary judgment.

their experts could also offer opinions that information in the DHCP letter is not misleading, but the basis for this would be that the information is not misleading because it is scientifically correct, which gets back to trying to prove the FDA' label requirement is erroneous. This is circular and goes nowhere.

2. The defendants had alternative means to address their disagreement with the FDA over Risperdal's labeling, but chose not to take advantage of them

a. Federal Administrative Procedures Act

The federal Administrative Procedures Act, 5 U.S.C. § 701 *et seq.* (APA), entitles a party claiming to have been adversely affected by federal agency decision to judicial review of the decision. 5 U.S.C. § 702. The standard of review of agency action under the APA is whether the agency's decision is arbitrary or capricious, 5 U.S.C. 706 (2)(A), and the court in an APA case is not empowered to substitute its judgment for that of the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe,* 401 U.S. 402, 416 (1971).

If the agency action being challenged is, as it would have been here, an FDA decision to require a drug's label to include safety information, 21 CFR 201.80 comes into play:

> The labeling shall be revised to include warning information as soon as there is *reasonable evidence of an association* of a serious hazard with a drug; *a causal relationship need not have been proved.* (Emphasis added)

The defendants could have availed themselves of the APA to challenge the FDA's decision to require Risperdal's label to include the class-wide diabetes risk information, but they did not. Perhaps they did not think they could prove that the FDA lacks reasonable evidence to support the label change requirement or acted capriciously in requiring its application to Risperdal. Perhaps they had business reasons. Regardless, for whatever reason, the defendants chose not to go this route, and they could have. They were not without a remedy.

Furthermore, *the defendants could have filed an APA action against the FDA, challenging the class-wide rule's applicability to Risperdal, after the present case was filed, and they could*

have asked to have the present case stayed pending resolution of the APA case. The FDA announced the class-wide diabetes risk label change to the defendants in 2003, and the present case was filed in 2004. APA claims are subject to the general six-year statute of limitations contained in 28 U.S.C. § 2401(a).[35]

b. Petition for review by the FDA commissioner

The defendants could have obtained administrative reconsideration of the FDA's required changes to Risperdal's label by availing themselves of the procedure available under 21 CFR 10.33:

> The [FDA] Commissioner may ... reconsider a matter ... on the petition ... [for] reconsideration of part of all of a decision of the Commissioner... submitted... no later than 30 days after the date of the decision.

This regulation does not require the decision for which reconsideration is requested to be a final one, but the Commissioner's decision on such a petition is final agency action and is reviewable in federal court. 21 CFR 10.45(d). The defendants therefore could have availed themselves of the FDA's administrative review process to obtain reconsideration of the Risperdal and Duragesic Warning Letters, and if unsatisfied, could have gone on to an APA action.

c. The defendants created their own problem

The defendants complain, "Neither before nor after the warning letters were issued was any administrative or judicial hearing held..." [36] The reason is that the defendants did not ask for either, despite the fact that they had the unilateral ability to obtain both.

3. The Risperdal DHCP letter is misleading as a matter of law

a. Analysis of the letter

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[35] The defendants still had time to file an APA action when they were making the same arguments being made now on appeal to the trial court in conjunction with summary judgment proceedings in 2008.
[36] Defendants' brief at p. 20.

The Risperdal DHCP letter begins with the salutation "Dear Healthcare Provider", and the defendants stipulate that this was intentional.[37] As indicated *supra* at pages 4-5, the defendants and the FDA agree that recipients of Dear Healthcare Provider letters rely on DHCP to provide "accurate and timely information regarding serious risks and changes in labeling." The Risperdal DHCP letter was therefore unquestionably designed by the defendants to be accepted by its recipients as providing accurate information about the diabetes risk information being required by the FDA to be added to Risperdal's label.

The first paragraph of the DHCP letter, which has no subject line, says the FDA directed the letter sent to inform doctors of new risk information.

> "The Food and Drug Administration (FDA) has requested all manufacturers of atypical antipsychotics to include diabetes risk information regarding hyperglycemia and diabetes mellitus in their product labeling.

A person reading this, absent a disclaimer to the contrary, is lead to believe that what follows is FDA-approved, or at least is not contrary to FDA label requirements. The letter continues:

> In an effort to keep you updated with the most current product information available for the management of your patients...

This logically leads one to believe, given the reference to the FDA in the first paragraph, that "the most current product information" is approved, or at least not rejected, by the FDA.

Next the letter next groups Risperdal's competitors in the atypical antipsychotic marketplace in a prominent list, but excludes Risperdal. This graphically sets the stage for distinguishing Risperdal's diabetes risk from the others in the text that follows:

> 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[1-8] 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

[37] Trial evidence stipulation no. 3.

suggests that RISPERDAL® is associated with a *lower risk of diabetes* then some other studied atypical antipsychotics. (Emphasis added.)

This is patently misleading, when compared to the diabetes risk information required by the FDA to be included in Risperdal's label, and when compared with what the FDA specifically instructed the defendants to say to physicians about Risperdal's label change.[38]

In summary, the DHCP is inherently misleading as a matter of law for the following reasons.

1. The DHCP letter indicates that Risperdal has less diabetes risk than other atypical antipsychotic drugs, which is *contrary to the FDA's label requirement for Risperdal.*

2. The DHCP letter omits the blood sugar monitoring information required by the FDA to be included in Risperdal's label, which *conceals information deemed by the FDA to be important to physicians in monitoring the health of their patients.*

3. The DHCP letter *eviscerates the FDA-mandated diabetes label requirements by indicating that Risperdal has no more risk of causing diabetes than taking nothing.*[39]

4. The DHCP *gives the impression that its contents are FDA-approved* by its salutation of "Dear Healthcare provider" and other means discussed *supra.*

5. The DHCP letter *does not contain disclaimers* to the effect that:

- its substance is not FDA-approved, and
- views expressed in it are contrary to the FDA's label requirements for Risperdal.

b. The facts that make the DHCP letter misleading were in place before the Warning Letters came into existence

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[38] The DHCP uses the term "suggests," which under FDA regulations in 21 CFR 202.1(e)(6) is indistinguishable from, and interchangeable with, "represents." The trial court held "The FDA truth-in-communications standards applicable to communications between pharmaceutical companies and health care providers... treat the words 'suggestion' and 'representation' as being synonymous. The court declines to hold that 'suggest' as used in the November 2003 Risperdal letter insulates the claims that follow from being misleading." Summary judgment order at p. 23.

[39] "... a body of evidence ... suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients..."

The question of whether the DHCP letter is inherently misleading as a matter of law is determination for this court to make on a de novo basis, and it does not matter a whit how the defendants characterize the means by which the trial court came to this conclusion.[40] All the facts showing the DHCP letter is misleading were in place before the FDA's Warning Letter was written. No opinion from the defendants' experts that can change these facts, and no reliance need be placed on the Warning Letter or the Corrective Letter to establish them. This applies with equal force to the Duragesic file card.

4. An inherently misleading publication violates the WVCCPA

This court has recognized that inherently misleading statements are within the purview of the Consumer Protection Act.

> ...where the language of ... a solicitation is on its face, misleading ... such solicitation is in contravention of [WVCCPA] as a matter of law, and a circuit court is authorized to determine without resort to extrinsic evidence that the West Virginia Consumer Credit and Protection Act ... [has] been violated, *SER McGraw v. Imperial Marketing,* 203 W. Va. 203, 506 S.E.2d 799 (1998)
>
> The issue is: whether defendant, in its solicitation efforts in West Virginia . . . engaged in conduct which is calculated to or likely to, deceive and misrepresent ... and thereby violate [the WVCCPA]." SER McGraw v. Imperial Marketing, *Id.*
>
> "...where the possibility of deception is self-evident, extrinsic evidence is not necessary for a finding that materials are misleading." *SER McGraw v. Imperial Marketing,* 196 W.Va. 346, 472 S.E.2d 792 (1996), quoting from *Zauderer v. Office of Disciplinary Counsel,* 471 U.S. 626, 652-53 (1985).

5. Importation of FDA regulations to provide legal standards to determine if information published by a prescription drug manufacturer is misleading under the WVCCPA is appropriate and fair to the defendants

The WVCCPA has no standards of its own for determining whether prescription drug advertising or communications between drug manufacturers and doctors are misleading.

[40] The nature of the defendants' arguments invites an analytical methodology error. The defendants' focus on the trial court's reasoning process suggests that this is where the review on appeal should begin, but this is the wrong starting point. De novo appellate review of whether the defendants' publications are misleading as a matter of law starts with the publications themselves.

However, the WVCCPA does instruct West Virginia courts to be guided by federal law dealing with the same or similar matters. W.Va. Code, §46A-6-101(1). The trial court appropriately imported the federal regulations as guidelines on this background, reasoning as follows.

> In this instance, federal law provides comprehensive and detailed criteria, designed by federal regulators with specific expertise in the field, who are charged with national regulation of the prescription drug industry, that address the exact circumstances of the case at hand.
>
> State standards for determining what is misleading should not be more stringent than federal standards, because more rigorous standards would be in jeopardy of impermissibly conflicting with federal law ... However, state requirements that parallel federal requirements and do not impose a duty on pharmaceutical makers that is different from, or in addition to, federal requirements are permissible, even if state law provides a remedy, *e.g.*, damages or penalties, not found in its federal counterpart. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).
>
> ... use of federal standards to determine what is misleading in prescription drug communications under state law offers consistency to pharmaceutical makers and avoids the risk these companies will be required to meet different standards in different states as to what they can and cannot say in communicating information about their products
>
> Accordingly, based on state law, federal law, fundamental fairness to the defendants, and principles of judicial economy, the court finds the determination of whether statements or omissions in (1) prescription drug advertising and (2) prescription drug communications from a pharmaceutical company to health care providers are false or misleading under the West Virginia Consumer Protection Act should be determined by reference to the federal standards in 21 CFR 202.

Under federal regulations in 21 CFR 202.1(e)(6), a communication from a drug maker to health care providers is false or misleading if it "contains a representation or suggestion not approved or permitted for use in the labeling ..." This is precisely what the DHCP letter does.

6. The trial court did not base its determination that the DHCP letter is misleading on FDA's Warning Letter or Corrective Letter

Despite saying in its final order that the summary judgment finding that the DHCP letter is misleading as a matter of law would not be revisited, the trial court effectively did so anyway

and made it clear that its conclusion that the DHCP letter is misleading is not based on the FDA Warning Letter or the Corrective Letter.

> The Court finds the November 2003 Risperdal Letter modifies the FDA's mandated language and conveys a message to healthcare professionals that is materially inconsistent with the critical aspects of the diabetes risk diabetes risk information, which the FDA had instructed all manufacturers of atypical antipsychotic medications, including the defendants, to send out to the healthcare community.[41]
>
> ... the defendants' wording of its November 2003 Risperdal Letter was deliberately constructed to circumvent the FDA's mandated diabetes risk information for an increased risk of diabetes, and deliberately constructed to mislead healthcare professionals who rely on this type of information when prescribing medication for their patients.[42]
>
> ... defendants willfully mailed out its November 2003 Risperdal Letter suggesting that Risperdal had a lower risk of causing diabetes than other atypical antipsychotic drugs, and had no risk of causing diabetes when compared to taking nothing. The defendants mailed out the letter even though the FDA had not approved this language and directed defendants to send out the class-wide diabetes risk information. The defendants intentionally sent out the November 2003 Risperdal Letter containing false or misleading information inconsistent with the risk information prescribed by the FDA.[43]
>
> ... the Court rejects the defendants' argument that they believed their scientific data was accurate, and the FDA was wrong in requiring it to add the diabetes risk information. The companies who manufacture prescription drugs do not make their own rules as to what can be said about the risks and benefits of their products; but rather, the FDA makes these decisions to provide the necessary information for healthcare providers to determine which prescription medication is best suited for their patients.[44]
>
> The [Risperdal] letter does not suggest or represent that there is a difference of opinion between Janssen and the FDA, that there is a legitimate scientific debate as to the truth of the statements in the letter that the FDA did not approve, or that Janssen is expressing its opinion, as opposed to stating facts.[45]
>
> ... the defendants willfully forwarded the November 2003 Risperdal Letter and made sales calls concerning Risperdal, which contained false or misleading health information, to West Virginia healthcare providers in order to make its medication Risperdal more appealing for sale.[46]

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[41] Final order at 12.
[42] Final order at 13.
[43] Final order at 50.
[44] Final order at 60.
[45] Summary judgment order at 24.
[46] Final order at 51.

... defendants' conduct was dishonest in that it attempted to circumvent the required risk language to make its medication more appealing for sale then other atypical antipsychotic medications.[47]

... the ... letter ... contained language that misled and circumvented the FDA's concerns while attempting to place defendants' medication in the best light possible.[48]

... the defendants' false or misleading promotional materials are...endangering West Virginia citizens' ... health and lives. Healthcare professionals rely on the medical information circulated by prescription drug manufacturers. [49]

...the promotional materials attempt to make Risperdal ... more marketable and attractive than other medications that treat similar ailments, so that healthcare professionals are more likely to consider prescribing Risperdal ...[50]

Janssen drafted the letter to prescribers that would ultimately be dated November 10, 2003. The company did not seek FDA approval of this letter before sending it to prescribers, and the defendants have not offered evidence of a reason why they could not have done so. The letter omits the need to monitor patients receiving Risperdal for symptoms of hyperglycemia, despite the fact that this was one of the principal reasons cited by the FDA for the letter. The letter also suggests or represents that (1) taking Risperdal has no more risk of diabetes than taking nothing and (2) Risperdal has less risk of diabetes some other atypical antipsychotics. *Neither of these statements was approved by the FDA, and neither is contained in the revised prescribing information that was approved by the FDA.* The letter does not suggest or represent that there is a difference of opinion between Janssen and the FDA, that there is a legitimate scientific debate as to the truth of the statements in the letter that the FDA did not approve, or that Janssen is expressing its opinion, as opposed to stating facts. *The letter also does not point out that the unapproved statements and omission conflict with, or are at least different from, the FDA-approved revised prescribing information.* (Emphasis added)[51]

B. Duragesic discussion

1. The Duragesic file card is misleading as a matter of law

a. Duragesic's FDA-approved prescribing information

Duragesic is a very strong narcotic that can cause death. Its FDA-approved (and required) prescribing information includes the following.

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[47] Final order at 61.
[48] Final order at 36.
[49] Final order at 31.
[50] Final order at 31.
[51] Summary judgment order at 24.

DURAGESIC® contains a high concentration of a potent Schedule II opioid agonist, Fentanyl.

Schedule II opioid substances which include Fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone *have the highest potential for abuse and associated risk of fatal overdose* due to respiratory depression.

Fentanyl can be abused and is subject to criminal diversion. *The high content of Fentanyl in the patches* (DURAGESIC®) may be a particular target for abuse and diversion.

...

DURAGESIC® should ONLY be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance...

A Schedule II drug is one with an accepted medical use but also with a high potential for abuse that may lead to severe psychological or physical dependence. 21 U.S.C. 812(b)(2). Duragesic's risk of causing death from a single dose has been emphasized by the FDA.

For patients who are not opioid-tolerant, the amount of Fentanyl in one Fentanyl patch of the lowest strength is large enough to cause ... death.[52]

b. Step-by-step guide to the file card

The Duragesic file card uses a combination of graphics, headlines, and text to paint a picture of a relatively benign medication that will improve the quality of life for anyone with aches and pains. The cover says, "1,360 loaves and counting... Work, uninterrupted", followed by a photograph of two hands kneading bread with "Duragesic" superimposed, and then "Life, uninterrupted." Apparently a person who switches to Duragesic can start making 1,360 loaves of bread at a stretch pain-free.

The next page says "Long lasting efficacy... Up to 72 hours of uninterrupted pain relief per patch. Nothing here about one patch can kill you. To the right of this is the statement, "... patients ... would recommend it." Are we selling narcotics or refrigerators? Flip to the next

[52] FDA Public Health Advisory, June 18, 2008.
http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm048721.htm

page, and the hands and bread reappear, accompanied by headlines touting significant improvement in physical and social functioning for people on Duragesic, but no mention that the FDA has only approved it for people who have been taking narcotics so long that they have become tolerant of them. Then comes a photograph of a fellow playing pool with "Game uninterrupted" superimposed. Apparently Duragesic improves your pool game.

Next is the page using DAWN information, but more about this later. After the DAWN page comes, "What to tell patients about applying the patch," accompanied by illustrations and text explaining how to put the thing on, but no suggestion that the doctor might also want to mention that once you get it on, it could kill you if you are not careful. The risk information is then crammed into two pages in small type face, followed by a finishing page featuring return of the hands and bread, along with headlines reading, "Helps patients think less about their pain," and redux of "Improvements in physical and social functioning."

Returning to the portion of the file card dealing with DAWN, there is a prominent claim that Duragesic has a "Low reported rate of mentions in DAWN data," followed by "Source: Drug Abuse Diabetes risk information Network (DAWN) database." The chart in the file card immediately below the claim of "Low reported rate of mentions in DAWN data," shows these "mentions" as Hydrocodone (Vicodin and Percocet) 21,567, Oxycodone (Oxycontin)) 18,409, Methadone 10,725, and Fentanyl (Duragesic patch and other forms of Fentanyl administration) 710 mentions.[53] The obvious intent is to suggest that Duragesic is safer than Percocet, Vicodin, Oxycontin, and Methadone. However, the FDA-mandated prescribing information for Duragesic groups it with all other Schedule II narcotics as a class of drugs with the "highest potential for

[53] These numbers may not be entirely legible on the copy of the file card in the appellate record. The numbers themselves, as opposed to their significance or lack thereof, are not disputed and are easy to read in the FDA Duragesic Warning Letter.

abuse and associated risk of fatal overdose" and does not distinguish, or suggest there is a basis for distinguishing, Duragesic as having less risk of harm or abuse than the others.

c. The safety claim made for Duragesic in comparison to other narcotics in inherently misleading

The FDA's Duragesic Warning Letter says "Duragesic is not as widely prescribed as other opioid products." This is something the FDA is certainly qualified to know, and its veracity has never been questioned by the defendants. It is the type of readily verifiable, non-controversial information of which a court may take judicial notice,[54] as did the trial court in finding that the safety comparison made to other opioids in the file card is not weighted for differences in the number of prescriptions written for each of the drugs, which in itself could account for all of the differences in the "mentions," and there is no disclaimer to this effect.

By combining Fentanyl delivered by a Duragesic patch with other Fentanyl delivery methods, the file card suggests that Duragesic is safer than other Schedule II narcotics, simply because its active ingredient is Fentanyl. This is at odds with Duragesic's prescribing information, stating, "Duragesic has a high concentration of ...Fentanyl ..." It is also misleading when the fact that one Duragesic patch with the lowest dose of Fentanyl can be fatal is considered.

All of the information on the DAWN page is presented under a heading of "*Proven clinical experience*," (emphasis added), giving the impression that:

[54] A "court may take judicial notice of facts 'not subject to reasonable dispute' because such facts are 'generally known' or 'capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.' " *In re: Bayer Corp. Combination Aspirin Products Marketing and Sales Practices Litigation*, 2010 U.S. Dist. LEXIS 31021 (E.D.N.Y. 2010), quoting 5B Wright & Miller § 1357at 376, citing to supporting decisions, and taking judicial notice of facts set forth on the FDA website, because they are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."

• DAWN data are scientific proof that Duragesic is safer than its competitors in the pain relief market, which is not true;

• DAWN data can be used to support the comparison made, which prohibited by FDA regulation; and

• DAWN data represents clinical experience, which is not true.

DAWN is a public health surveillance system that monitors drug-related hospital emergency department visits and drug-related deaths to track the impact of drug use and abuse in the United States.[55] DAWN is operated by the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA is required by law to collect data for DAWN under 42 U.S.C. 290aa-4. SAMHSA and the FDA are two of the eleven operating divisions of the Department of Health and Human Services, the principal federal agency for protecting the health of Americans.[56]

DAWN collects data related to recent drug use from emergency department records from its participating hospitals. The criteria for inclusion in DAWN are intentionally broad and simple. Thousands of drugs and other substances of all types are included in DAWN. These include illegal drugs of abuse, prescription and over-the-counter medications, dietary supplements, non-pharmaceutical inhalents, and alcohol. Because DAWN cases are defined broadly, DAWN captures many different types of drug-related cases, including drug abuse and misuse, suicide attempts, overmedication, adverse reactions, accidental ingestions, malicious poisoning, underage drinking, detoxification, and homicide by drugs. DAWN only collects data from emergency departments.[57]

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[55] https://dawninfo.samhsa.gov
[56] http://www.hhs.gov.
[57] https://dawninfo.samhsa.gov/collect/collect_qas.asp#1. The court may take judicial notice of this noncontroversial, general information about DAWN. *Bayer Corp. Combination Aspirin Products Marketing and Sales Practices Litigation*, footnote 54 *supra*.

A comparative safety claim made in promotional material for a prescription drug, such as the one made in the file card for Duragesic by reference to DAWN, is prohibited by law, unless it is supported by a "well-controlled study" under 21 CFR 201.57(g)(4) which states:

> ... any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies as defined in 314.126 ...[58]

21 CFR 314.126 in turn provides specific, detailed requirements that must be satisfied to meet the legal definition of an "adequate and well-controlled" study that can be used to support a comparative safety claim in drug promotion. 21 CFR 314.126 requires a study, in order to be a "well-controlled study," to include at least one of five types of controls:

- placebo control (test drug is compared with an inactive preparation),
- dose-comparison control (at least two doses of the test drug are compared),
- no treatment control (test drug is compared with no treatment),
- active treatment control (test drug is compared with known effective therapy),
- historical control (results of treatment with the test drug are compared with experience in comparable patients or populations).

DAWN does not meet the legal definition of a "well-controlled study" because it is not a study at all, but rather a data collection program, and even if one assumes it could be called a study, it has no controls resembling the type required by 21 CFR 314.126, because DAWN does not compare *treatment* with Duragesic to anything, and all of the approved categories of control require a *treatment* comparison.

[58] 21 CFR 201.57 is long and has many subheadings. The provision quoted above is apparently "(g)(4)" but this might not be right. The quoted provision is approximately two-thirds of the way through 201.57.

File cards are prescription drug labeling under 21 CFR 202.1(1)(2): "... file cards...published for use by medical practitioners ...containing drug information supplied by the manufacturer...are hereby determined to be labeling..." [59]

A communication from a prescription drug maker to health care providers is false or misleading under FDA regulations contained in 21 C.F.R. 202.1(e)(6) if it "uses literature... or references that purport to support an advertising claim but in fact do not support the claim or have no relevance to the claim".[60] Accordingly, DAWN data cannot be used, as a matter of law under 21 CFR 201.57(g)(4) and 21 CFR 314.126, as used in the Duragesic file card, *i.e.,* as the sole support for a comparative safety claim. The FDA's September 2004 Duragesic Warning Letter says:

> The DAWN data cannot provide the basis for a valid comparison among these products [Duragesic, Percocet, Vicodin, Oxycontin, and Methadone]. As you know, DAWN is not a clinical database. Instead it is a national public health surveillance system that monitors drug-related emergency department visits and deaths.

This is a legal reminder from the FDA that DAWN, a surveillance database maintained by a sister federal agency, is not a "well-controlled study" and therefore cannot be used as sole support for a comparative safety claim.[61] The trial court noted that it "can clearly understand the FDA's reasoning that DAWN data do not support the comparisons the defendants attempt to

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[59] This regulatory definition of labeling was approved in *Kordel v. U.S.*, 335 U.S. 345, 349 (1948), holding that a label is written information attached to the product container, while labeling includes material that does not physically accompany the product.

[60] Other specific types of representations deemed false or misleading under 21 C.F.R. 202.1(e)(6) include a communication that

- "contains a representation or suggestion not approved or permitted for use in the labeling that a drug is ..., safer, has fewer or less incidents of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience";
- "contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience"; and
- "uses a quote or paraphrase out of context to convey a false or misleading idea".

[61] "DDMAC Warning Letters... represent the best and most authoritative statement of FDA's own views on the law." (Quoting amicus Washington Legal Foundations as cited on page 36 *infra.*)

bestow upon the reader." [62] While the determination that use of DAWN data to make a comparative safety claim is impermissible is established by FDA regulations, the confirmatory legal position in the Warning Letter is comforting.

The trial court's independently found as follows.[63]

> The Court concludes that defendants intentionally sent the Duragesic File Card out to healthcare providers before submitting the file card to the FDA for consideration and approval. The defendants intended the language and format of the file card. The defendants knew the law under the FDA regulations and the federal Food, Drug & Cosmetic Act, which prohibits false or misleading statements about prescription drugs, and it knew from the regulations what kind of statements were prohibited. The defendants were twice put on notice by previous warning letters that is promotional materials for Duragesic contained false or misleading statements; however, the defendants sent out another promotional materials that contained false or misleading statement.
>
> The Court concludes the defendants' willfully created the Duragesic File Card and made sales calls concerning Duragesic which contained false or misleading health information. The defendants then willfully sent the false or misleading file card to West Virginia healthcare providers in order to make its medication Duragesic more appealing for sale. The Court concludes that defendants violated the "willful" element of the WVCCPA in regards to Duragesic.

d. The case is about the law, not science

The defendants are asking to be allowed to use expert opinions to the effect that the use of DAWN data to support the comparative safety claim in the file card is justified, but a court cannot find the law wrong based on an expert's opinion. The defendants say the case is about science, but it is not. It is about the law, failure to obey it, and the consequences. The law is that DAWN is not a study, much less a well-controlled one, and the law is that a comparative safety claim for a drug cannot be made unless it is supported by a well-controlled study. The very reason for the existence of these FDA regulations is to prevent manufacturer's from coming up with statistics drawn from unreliable sources and using them to support drug safety or benefit

[62] Final order at p. 24.
[63] Final order at pp. 48-49.

claims that can mislead the doctors who prescribe their drugs and the people who take them. The regulations gave the defendants, who have an entire division devoted to regulatory compliance, fair notice that they cannot base a comparative safety claim on DAWN, but they did it anyway, and they did it intentionally.[64] This is indefensible.

e. The file card is misleading as a matter of law under the WVCCPA

Having determined that the file card contains false or misleading information under federal law, taking the next step by finding that the file card also violates West Virginia law embodied in the WVCCPA's prohibition against unfair or deceptive acts contained in W.Va. Code, §46A-6-104, is relatively easy. The WVCCPA includes the following as prohibited acts and omissions.

> Disparaging the goods, services or business of another by false or misleading representation of fact; §46A-6-102(7)(H).
>
> The ... use ... of any deception ... 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. §46A-6-102(7)(M),
>
> 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. §46A-6-102(7)(N)

The file card violates §46A-6-102(7)(H), because it makes a false or misleading claim, based solely and illegally on DAWN, regarding the safety of Duragesic in comparison to other pain medications made by other manufacturers. The card violates §46A-6-102(7)(M) and §46A-6-102(7)(N) because it illegally uses the DAWN database to support a comparative safety claim, falsely indicates that DAWN data is scientific proof of the claim, makes a comparative safety claim that is not justified when compared to FDA-approved prescribing information for

[64] Defendants stipulated that the file card is in form, format, and content as they intended it to be. Trial evidence stipulation no. 3.

Duragesic, and deceptively suggests that Duragesic is safer than its competitors simply because its active ingredient is Fentanyl, as opposed to a different narcotic.

Additionally, in light of the foregoing, if not standing alone, the entire format and tenor of the file card are designed deliver a misleading sales message that gives the impression that Duragesic has marvelous improvement in quality of life benefits, while understating the risks of this extremely potent and potentially lethal drug delivery device. An advertisement should be analyzed not only in its specifics, but also in its entirety, and an advertisement that conveys an unjustified overall impression of drug superiority is misleading. *American Home Products*, 98 F.T.C. 136, 374 (1981), *aff'd*, 695 F.2d (3d Cir. 1982).

C. The defendants' arguments that the Warning Letters and Corrective Letters are inadmissible do not present a genuine issue for the court

Determination of whether the defendants' publications are misleading does not hinge on the Warning Letters. The defendants treat these letters as if they are the only evidence that their publications are misleading, but, as previously mentioned, all the facts showing the publications are misleading were in existence before the Warning Letters were created, and they contain no new, independent scientific factual findings.

These letters were generated by the FDA as the first and last steps in regulatory enforcement actions regarding Risperdal and Duragesic. As such, *they are legal documents*, and they can be considered for their legal consequences in addressing questions of law, and this is a completely different analysis than would be performed under the Rules of Evidence.[65] The extensive review of FDA documents in *Colaccico v. Apotex,* 521 F.3d 253 (2008), illustrates the point.

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[65] The defendants' theory that the Corrective Letters are subsequent remedial measures within the meaning of WVRE 407 is wrong. A remedial measure under 407 is one if taken sooner might have prevented an earlier occurrence, but a corrective letter cannot exist without something to correct, so it is impossible for a corrective letter to make it less likely that the misleading letter it corrects would have been published. In short, Rule 407 is inapplicable.

The trial court wisely considered these letters for legal purposes in addressing preemption potential, stating the following.

> A West Virginia state court, when presented with the issue of whether a manufacturer has published misleading information regarding one of its prescription drugs in an action brought by the attorney general for civil penalties under the WVCCPA, should determine what, if any, position or action the FDA has taken with regard to the publication. If the FDA has approved the publication, the court may be preempted from making, or allowing, a contrary finding...
>
> On the other hand, this Court finds that when the FDA makes a determination that a prescription drug advertisement is misleading, and a cause of action is brought in state court that coincides with the FDA's findings, then the FDA does not preempt a state's consumer protection laws. A cause of action under this scenario is not an obstacle to the FDA's regulatory objectives, and it allows the State to maintain the important function of protecting the welfare of its citizenry.

The letters can be used to ascertain the FDA's legal position and the FDA's interpretation of its own rules in developing the legal framework within which to decide if the defendants' publications are misleading. As the Washington Legal Foundation, one of the amici for the defendants says, "DDMAC Warning Letters... represent the best and most authoritative statement of FDA's own views on the law."[66]

D. The Risperdal letter and Duragesic file card are misleading commercial publications, and as such they are not entitled to First Amendment protection

1. The First Amendment does not protect inherently misleading commercial publications.

The First Amendment does not protect misleading commercial speech, as is indicated in *Central Hudson Gas & Electric v. Public Service Commission*, 447 U.S. 557 (1980):

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading.

[66] Washington Legal Foundation, Legal Backgrounder, August 10, 2007. http://www.wlf.org/upload/08-10-07friede.pdf.

This court agreed in *SER McGraw v. Imperial Marketing*, 196 W.Va. 346, 472 S.E.2d 792 (1996), a case brought by the attorney general for civil penalties under the WVCCPA.

> ... step one in the Central Hudson test: 'for commercial speech to come within [First Amendment protection], it at least must ... not be misleading.'
>
> ...we agree with the circuit court's findings that SCI's solicitations ... were misleading and deceptive. We therefore need to go no farther in our analysis since upon the finding of deceptive solicitation there is nothing ... protected under the First Amendment. *Id.* at 361.

The principle is stated in its simplest terms in *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995), "[T]he government may freely regulate commercial speech that ... is misleading. 515 U.S. at 623-24. Information is misleading under *Central Hudson* if it is inherently likely to mislead, irrespective of whether anyone was actually mislead. *Joe Conte Toyota, Inc. v. Louisiana Motor Vehicle Commission,* 24 F.3d 754 (5th Cir. 1994). This is in harmony with §46A-6-102(7)(M) of the WVCCPA, which makes it a deceptive business practice to "... use ... misrepresentation, or the concealment ... of any material fact ... whether or not any person has in fact been misled, deceived or damaged thereby."

2. Cases involving a restriction on a class of speech are in a different category for First Amendment purposes than cases where the specific speech in issue has been determined to be misleading

The defendants agree in principal that an inherently misleading commercial publication receives no First Amendment protection, stating at page 29 of their appeal petition brief, "inherently misleading statements ... lose constitutional protection." However, they seem to lose track of this, citing case-after-case turning on whether a restriction on speech that could include both protected and unprotected speech is enforceable, as opposed to the issue in the

present case, *i.e.,* application of the First Amendment to inherently misleading commercial speech.[67]

If the trial court's decision that the publications are inherently misleading is affirmed, the only remaining First Amendment issue is whether the publications are commercial. If so, they receive no First Amendment protection.

3. The Duragesic file card is a commercial publication

The Duragesic file card is a full-color sales brochure that is unarguably a commercial advertising piece. Saying more about this would be to say less. All one has to do is look at it.

4. The Risperdal letter is a commercial publication

a. Janssen says the Risperdal letter is promotional

Janssen Vice President Mahmoud categorized the Risperdal letter as a promotional piece in the Risperdal corrective letter that he signed.[68]

> The ... FDA ... has asked us to contact you because Janssen Pharmaceutica Products, L.P. recently received a Diabetes risk information Letter concerning the *promotion of Risperdal®* (risperidone). This letter provides important corrective information about Risperdal relating to hyperglycemia and Diabetes Mellitus. (Emphasis added).
>
> The Diabetes risk information Letter concludes that Janssen disseminated a Risperdal Dear Health Care Provider...letter dated November 10, 2003 that omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act.

b. The goal of the DHCP letter was to increase sales of Risperdal

The trial court ripped into the defendants' meretricious claim that the DHCP letter is something other than a tool to sell more Risperdal.

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[67] The defendants seem to be unwilling to confront this distinction, even though it is made in cases they cite, *e.g., In Re R. M. J.*, 455 U.S. 191 (1982): " ...the Court has made clear ... that regulation - and imposition of discipline - are permissible where the particular advertising is inherently likely deceive..."

[68] Summary judgment order at p.6

> ... the defendants willfully forwarded the November 2003 Risperdal Letter and made sales calls concerning Risperdal, which contained false or misleading health information, to West Virginia healthcare providers *in order to make its medication Risperdal more appealing for sale*.(emphasis added)[69]
>
> ... defendants' conduct was dishonest in that it attempted to circumvent the required risk language to make its medication *more appealing for sale then other atypical antipsychotic medications.* (Emphasis added)[70]
>
> ... the ... letter ... contained language that misled and circumvented the FDA's concerns while attempting to place defendants' medication in the best light possible.[71]
>
> ...the defendants' promotional materials are commercial speech aimed at specific healthcare professionals in order to make Risperdal and Duragesic more marketable.[72]
>
> ... defendants' promotional materials were issued solely in the individual interest of marketing its medication, Risperdal ..., to its business audience of healthcare professionals.[73]
>
> The private citizens of West Virginia were not privy to the defendants' disagreement with the FDA's diabetes risk information label requirement, but could have potentially borne the cost of defendants' decision to provide false or misleading health labeling, advertisements, and sales calls.[74]

The trial court also found as a matter of fact that the defendants' intention in wording the Risperdal letter was not to invoke scientific debate on a public issue, but rather to influence physicians to prescribe more Risperdal:

> ... the defendants' wording of its November 2003 Risperdal Letter was deliberately constructed to circumvent the FDA's mandated diabetes risk information for an increased risk of diabetes, and deliberately constructed to mislead healthcare professionals who rely on this type of information when prescribing medication for their patients.[75]
>
> ... the defendants' promotional materials are commercial speech aimed at specific healthcare professionals in order to make Risperdal and Duragesic more marketable.[76]

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[69] Final order at 49.
[70] Final order at 61.
[71] Final order at 36.
[72] Final order at 36.
[73] Final order at 37.
[74] Final order at 37.
[75] Final order at 60.
[76] Final order at 36.

The final order makes these additional findings of fact at page 31:

> ... the defendants' false or misleading promotional materials are...endangering West Virginia citizens' ... health and lives. Healthcare professionals rely on the medical information circulated by prescription drug manufacturers.
>
> ...the promotional materials attempt to make Risperdal ... more marketable and attractive than other medications that treat similar ailments, so that healthcare professionals are more likely to consider prescribing Risperdal ...

The summary judgment order at page 21 finds:

> The Risperdal letter ... [is] a part of the defendants' activities related to selling their goods, which in this instance are prescription drug products.

c. The FDA classified the Risperdal letter as promotional material

The FDA Risperdal Diabetes risk information Letter states:

> DDMAC requests that Janssen immediately cease the dissemination of *promotional materials for Risperdal* that contain claims the same as or similar to those described above and provide a plan of action to disseminate accurate and complete information to the audience(s) that received the *violative promotional materials* ...
>
> It is your responsibility to ensure that *your promotional materials for Risperdal* comply with each applicable requirement of the Act and FDA implementing regulations. (Emphasis added)[77]

d. The defendants are attempting to overcome the facts by recasting the Risperdal letter as a scientific white paper on a matter of public concern

The defendants' retrospective claim that the purpose of the Risperdal letter was to contribute to a scientific debate of national public interest, made well after the letter was sent to 3,900 West Virginia doctors and 400 follow-up sales calls were made, is no more than a cover story someone came up with to try to avoid responsibility for not telling the doctors what the FDA told the defendants to tell them. The trial court dealt with this as follows in the summary judgment order says at 24:

[77] Final order at 19, quoting from the FDA's Risperdal Diabetes risk information Letter. The diabetes risk information letter is appropriately considered here for the purpose of considering the FDA's expressed view in determining the legal question of whether the publication is commercial.

> The [Risperdal] letter does not suggest or represent that there is a difference of opinion between Janssen and the FDA, that there is a legitimate scientific debate as to the truth of the statements in the letter that the FDA did not approve, or that Janssen is expressing its opinion, as opposed to stating facts.

The final order contains the following findings of fact in this regard.[78]

> ...defendants' promotional materials were not disseminated to the public through the channels of national or local media, (i.e., television, radio, newspapers,) but were rather mailed to a specifically targeted audience of healthcare professionals. This marketing campaign confined the false or misleading message to healthcare professionals with the apparent hope of persuading these physicians to prescribe Risperdal ... to their patients.[79]
>
> The defendants' promotional materials are private advertisements, labeling, and sales calls that were sent by defendants to specific healthcare professionals. The defendants' promotional materials were not directly available for public consumption, and were not published nor delivered from any other media outlet. Rather, the labels, advertisements, and sales calls were made to specifically targeted healthcare professionals through the mail, telephone, and in person.[80]
>
> Likewise, it cannot be said that defendants' promotional materials involve any "strong interest in the free flow of commercial information" as the statements were sent specifically to healthcare professionals with the intention of persuading those physicians to prescribe the medications to their patients. It does not appear the promotional materials were ever intended to be physically placed in the hands of the patients.[81]
>
> The Court concludes that defendants' promotional materials are not matter of public concern because the language of the materials does not concern the debate over an appropriate diabetes risk information, nor were the promotional materials intended to persuade the public ...
>
> Furthermore, the Court concludes that defendants' statements were not issued for the purposes of debate on public issues. In regards to Risperdal, the defendants were required by the FDA to send specific diabetes risk information concerning the increased risk of diabetes. While the defendants attempted to debate the diabetes risk information directly with the FDA (which was unsuccessful on all but one sentence), the Risperdal cover letter and labeling were mailed without language describing the defendants' disagreement with the FDA's position. In fact, the cover letter and labeling stated no issues of debate but instead contained language that misled and circumvented the

[78] These findings might be appropriately classified as mixed findings of law and fact.
[79] Final order at 37.
[80] Final order at 34.
[81] Final order at 35.

FDA's concerns while attempting to place defendants' medication in the best light possible.[82]

...the promotional materials...fail...to address any debate between the company and the governing agency.[83]

...defendants' promotional materials do not contain a public issue.[84]

5. Even a true statement can be misleading if it omits information needed to keep it from being so

As recognized long ago in *United States v. 95 Barrels of Vinegar,* 265 U.S. 438 (1924):

> Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute [FDCA] is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act. 265 U. S. at p. 443.[85]

This is consistent with inclusion of "The ... omission of any material fact ... in connection with the ... advertisement of any goods" as an unfair business practice in §46A-6-102(7)(M) of the WVCCPA.

If everything in the case is stripped away except (1) the DHCP letter's failure to include a disclaimer to the effect that the FDA did not approve distinguishing Risperdal's diabetes risk from that of other Atypicals, and (2) the Duragesic file card's failure to include a disclaimer indicating that the comparative safety claim made by reference to DAWN is not FDA-approved, both publications are misleading on these bases alone under §46A-6-102(7)(M), even if what the publications say is assumed to be true.

6. Adoption of the defendants' First Amendment position could render the FDA ineffective in controlling prescription drug labeling

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[82] Final order at 35.
[83] Final order at 36.
[84] Final order at 32.
[85] To the same effect: *Space Shoe Corp. v. FTC*, 304 F.2d 270,272 (2nd Cir. 1962).

The defendants' First Amendment argument can be read as advocating a shield for pharmaceutical companies that allows them to say whatever they please about a drug's risks and benefits, even if contrary to FDA public health policy decisions. If such a proposition were valid, it would consume the FDA's regulatory authority and give drug makers an open field to make any claim they unilaterally deem to be based on a reliable source.

The FDA has made the same observation:

> "... we note that your argument, taken to its logical conclusion, would necessitate the abolishment of ... the new drug approval process ... because it would allow the marketing of human drug products without regard to whether such products meet ... applicable statutory standards for legal marketing. ... [T]he determination ... that the labeling for your product is false or misleading obviates the need ... to address the other three prongs of *Central Hudson*..."[86]

E. The defendants' preemption argument is legally, factually, and logically defective

The defendants base their preemption challenge on something that never happened, *i.e.,* that the trial court ruled "Janssen had a duty to challenge DDMAC's allegations if it wanted to preserve its right to deny those allegations in any later state enforcement actions."[87] The trial court made no such ruling. The trial court did comment, as does this brief above, that the defendants had the Administrative Procedures Act available for Risperdal, and they had the FDA internal regulatory review procedure available for Risperdal and Duragesic, but converting observations as to the availability of avenues of redress into a ruling that such avenues must be pursued is quite a stretch.

The defendants also appear to be making the quizzical argument that deference to the FDA is preempted. The U.S. Supreme court aptly described such an argument years ago: the "fallacy is

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[86] October 27, 2008, letter to Gary Balkema, President, Bayer HealthCare LLC from Deborah M. Autor, Esq., Director, FDA Compliance Center for Drug Evaluation and Research. http://www.fda.gov/ICECI/EnforcementActions/Diabetes risk informationLetters/2008/ucm1048456.htm. The defendants have three amicus briefs on their side. It is only fair to let the FDA weigh in on a subject.

[87] Defendants' brief in support of petition for appeal at 22.

made apparent by the mere statement of the proposition." *First National Bank in St. Louis v. Missouri*, 263 U.S. 640, 660 (1924) (Cited for language only)

The state's position is that the court should defer to the FDA with respect to its public health policy decision regarding Risperdal's label, and it is the state's position that FDA regulations prohibit using DAWN to support a comparative safety claim for Duragesic.

The defendants are the ones who want to upset the FDA apple cart. They are the ones who want this court to allow invalidation of an FDA drug safety label requirement. They are the ones asking not to have FDA regulations applied to the Duragesic file card.

F. The trial court employed accepted legal standards and gave due regard to the facts in arriving at a civil penalty that is reasonable under the circumstances

1. The trial court used the five-factor test advocated by the defendants for determining an appropriate penalty.

Both sides recommended in their trial briefs use in this case of the five-factor analysis employed by federal courts in assessing penalties under the FTC Act, and the trial court accepted. These factors, as articulated in *United States v. Reader's Digest Ass'n*, 662 F.2d 955, 967 (3d Cir. 1981), are (1) the good faith or bad faith of the defendant; (2) injury to the public, (3), the Defendant's ability to pay; (4) the desire to eliminate the benefits derived by a violation, and (5) the necessity or desirability of vindicating the authority of the agency involved. While not every factor may be relevant or applicable to a particular case, the factors nonetheless provide guidance to the Court in the formulation of an appropriate civil penalty.[88]

The trial court proceeds over the following ten pages of the final order to consider each factor separately, in detail, and make factual findings as to it. These factual findings and the penalty based on them are reviewed under an abuse of discretion standard and are entitled to "great

[88]Final order at page 57

deference" and not overturned unless "clearly erroneous". *CMC Enterprise v. Ken Lowe Management Co.,* 206 W.Va. 414, 418, 525 S.E. 2d 295 (1999).

2. The trial court's finding of injury to the public is based on extensive federal precedent to the effect that harm to the public occurs *as a matter of law* when misleading information reaches members of the public

The trial court held at page 63 of its final order:

> While the parties stipulated to the fact that no evidence was presented that any West Virginia consumer or healthcare provider relied on, was misled, or sustained harm as a result of the Risperdal Letter or Duragesic File card, this Court concludes the ruling in *Reader's Digest* takes consideration of the great potential of harm that arises from the false or misleading promotional materials. In this case, the potential for harm is even greater because the potential damage is a physical injury. Therefore, for the purposes of determining an appropriate civil penalty, the Court concludes as a matter of law that whenever false or misleading promotional materials that concern health is delivered to the public, or its healthcare providers, that such promotional materials in and of itself cause harm and injury.[89, 90]

3. The trial court specifically and unequivocally explained that it did *not* consider the defendants' efforts to get the FDA to change its positions as having any bearing on the amount of the civil penalty

> ... the *Noerr-Pennington* doctrine bars no evidence from this case because the Court has not based any findings of culpability or wrongdoing on the defendants' disagreement with the FDA ... The Court has ... based no penalty on the defendants' decision to contest the FDA's findings. Additionally, the defendants have not identified any specific evidence it believes should be limited under the *Noerr-Pennington* doctrine.[91]
>
> The court does not in this opinion, nor did it in its summary judgment order, make a finding that defendants' act of asking the FDA for an exception constitutes culpable conduct as to either liability for a penalty or as to the amount of a penalty. Culpability does not lie in asking for an exception for Risperdal, but rather in proceeding as if an

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[89] The court's finding of injury to the public as a matter law does not violate the parties' pretrial stipulation No. 2, because the stipulation by its own terms does not apply to legal issues such as the intention, purpose, effect, and/or meaning of statutes, regulations, rules, court decisions, or other sources of law.

[90] As noted by the trial court, this finding of public harm as a matter of law is supported by a line of analogous federal decisions, including *United States v. Reader's Digest*, 662 F.2d 955, 966-967 (3d Cir. 1981), cert denied, 455 U.S. 908 (1982), *U.S. v. National Financial Services*, 98 F.3d 131 (4th Cir. 1996), *United States v. Mac's Muffler Shop, Inc.*, 1986 U.S. Dist. LEXIS 18108, 25 ERC (BNA) 1369 (U.S.D.C. N.D. Ga. 1986).

[91] The final order states at page 73:

> exception had been granted, when it had not been. Similarly, the court does not in this opinion, nor did it in its summary judgment order, attach culpability to the defendants' requests, made after the Duragesic and Risperdal Diabetes risk information Letters were issued by the FDA, to persuade the FDA to change its position as to the scientific determinations the FDA had made as to the risks and benefits of Risperdal and/or Duragesic. The defendants' efforts to get the FDA to reverse its scientific findings are relevant as part of the history showing that the FDA refused to change its position, but these efforts themselves have not been found to be culpable conduct, and the defendants are not being penalized for making them.[92]

4. Vindication of the interests of West Virginia consumers is a rational consideration appropriately weighed along with other factors in determining an appropriate penalty

Vindication of West Virginia consumers might not fit neatly into the FTC five-factor test, but the test is being borrowed from federal law for guidance, not because it is binding. As this court pointed out in *SER Johnson & Johnson v. Karl,* 647 S.E. 2d 899, 913 (2007):

> Pharmaceutical manufacturers spend millions to make millions more. They are pushing their products onto the general public like never before. Consequently, consumers need more protection.
>
> ...prescription drug manufacturers ... benefit financially from the sales of prescription drugs and ... consumers ...bear the significant health risks of using those drugs...

A principal objective of the attorney general in bringing this case is vindication of West Virginia citizens' "right to be free from companies promoting false or misleading prescription drug information that could have a negative impact on their health and lives."[93] It is indeed unfortunate that the defendants believe the interests of the people who pay dearly for their products are not worthy of being taken into account.

5. The penalty amount assessed in this case is within the trial court's range of reasonable discretion

a. The starting point is unimportant if the end point is appropriate

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[92] Footnote 40 to the final order.
[93] Final order at 68.

The trial court's statement that it will determine "whether the penalty should be $5,000 or less" simply paraphrases the WVCCPA, where it says the court may assess a civil penalty of no more than $5,000 for a violation of the Act. There is no basis for reading anything into such a benign statement, and if the amount of the penalty under the WVCCPA is reasonable, the court's starting point for arriving at it is insignificant. Nonetheless, if one assumes that the trial court meant to indicate that the starting point for assessing the penalty is the maximum, which some courts have termed the top-down method, this has substantial support.[94] The court in *U.S. v Gulf Park Water Company, Inc. et al.,* 14 F. Supp. 2d 854, 858, (1998), explains:

> Some courts use the 'top-down' method of penalty calculation, in which the court begins at the statutory maximum, and adjusts downward ... Other courts use the 'bottom-up' method of penalty calculation, in which the court begins the penalty calculation using the defendant' economic benefit of noncompliance, and adjusts upward or downward considering the factors.

b. The penalty is not excessive

The most significant factor influencing the size of the aggregate penalty is the number of violations, and the defendants on appeal do not challenge the trial court's decision that each letter, each file card, and each sales call is a separate violation of the WVCCPA. The distinction made by the trial court between mailing on the one hand, and direct solicitation of West Virginia health care professionals by the defendants' sales representatives on the other, is consistent with this court's pronouncement in *SER McGraw v. Imperial Marketing* 196 W. Va. 346, 472 S.E.2d 792 (1996):

> ...we agree that mail solicitations generally subject the consumer to a lesser degree of coercion than face-to-face or even telephone solicitations, see *Shapero v. Kentucky Bar Ass'n, 486 U.S. 466, 475-476, 100 L. Ed. 2d 475, 108 S. Ct. 1916 (1988)*

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[94] The "top-down" methodology is required by *Atlantic States Legal Foundation v Tyson Foods,* 897 F.2d 1128 (11th Cir. 1990), and it is favored in *U.S. v. B.& W. Investment Properties*, 38 F.3d 362 (7th Cir. 1994), and *P.I.R.G. v Powell Duffryn,* 913 F.2d 64 (3d Cir.1990).

The trial court found that the defendants acted in bad faith, obviously not accepting the testimony of the defendants' witnesses presented to convince the court to the contrary. The defendants' appeal brief does not mention the ability-to-pay factor, and the state assumes this indicates the defendants are not challenging the use of this criterion.

The circuit court evaluated the totality of its penalty assessment process on pages 72-73 of the final order:

> The Court has conducted a five-factor analysis to ensure the civil penalty was proportionate to the violating acts. Also, the Court concludes the civil penalty is not exclusively punitive in nature, and the Court's calculation of the civil penalty was substantially lower than the maximum civil penalty the West Virginia Legislature has authorized courts to assess under the WVCCPA....
>
> The Court finds the determined civil penalty in the present case is below the maximum authorized by the operative statute, and is the product of a five-factor balancing test that gives consideration to the purpose of the WVCCPA and the violations committed by the defendants.

A statutory penalty that is less than the maximum allowed by the enabling statute does not contravene the Excessive Fines Clause. *U.S. v. Mackby*, 221 F.Supp.2d 1106 (N.D.Cal. 2002),[95] and the penalty in the present case is only 20% of the maximum. The state invites the court review illustrative recent fines and penalties paid by pharmaceutical and medical device manufacturers for comparison purposes.[96]

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[95] To the same effect: *Balice v. U.S. Dept. of Agric.*, 203 F.3d 684, 699 (9th Cir. 2000) (holding that a $225,500 fine did not violate the Eighth Amendment where the maximum fine was $528,000, notwithstanding the lack of monetary loss to the government); *Ghaith R. Pharaon v. Board of Governors of the Fed. Reserve Sys.*, 135 F.3d 145, 156 (D.C. Cir. 1998) (holding that a $37 million penalty did not violate the Excessive Fines Clause because 'the penalty is proportional to his violation and well below the statutory maximum [of $111.5 million]'); *United States v. Emerson*, 107 F.3d 77, 79 (1st Cir. 1997) (holding that 'a fine one-half the size of that permitted by the relevant statute, assessing $5,000 for each of [defendant's] thirty-seven admitted violations rather than the statutory maximum of $10,000 per violation ... though substantial, is constitutionally permissible'); *Untied States v. Advance Tool Co.,* 902 F.Supp. 1011, 1018 (finding that an award of $365,000 as a civil penalty under the FTCA did not violate the Eighth Amendment where the maximum penalty was over $3.4 million, notwithstanding the Government's failure to prove any actual damages).

[96] $86 million, Topamax, Johnson & Johnson

V. Conclusion

The defendants were fairly found to have violated the Consumer Protection Act 4,450 times, and an appropriate penalty was assessed. Judgment should be affirmed.

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http://www.justice.gov/opa/pr/2010/April/10-civ-500.html

$185 million, Trileptal, Novartis
http://online.wsj.com/article/SB10001424052748703906204575026963160833710.html

$296 million, defibrillators, Boston Scientific
Boston Scientific settles defibrillator investigation for $296 million

$355 million, Zoladex, Astra Zeneca
http://news.bbc.co.uk/2/hi/business/3008440.stm

$520 million, Seroquel, Astra Zeneca,
http://www.nytimes.com/2009/10/30/business/30drug.html?_r=1

$634.5 million, Oxycontin, Purdue
http://www.cnbc.com/id/18591525/

$650 million, Vioxx and Zocor, Merck
http://www.brandweeknrx.com/2008/02/merck-to-pay-mo.html

$875 million, Lupron, Takeda and Abbot
http://www.nytimes.com/2001/10/04/business/2-drug-makers-to-pay-875-million-to-settle-fraud-case.html

$1.4 billion, Zyprexa, Lilly
http://medheadlines.com/2009/02/06/eli-lilly-gets-14b-fine-for-zyprexa-off-label-marketing/

$1.19 billion + $550 million, Neurontin, Pfizer
http://bloomberg.com/apps/news?pid=20601109&sid=a4yV1nYxCGoA&pos=10

$2.3 billion, Bextra and other drugs, Pfizer
http://www.businessweek.com/bwdaily/dnflash/content/sep2009/db2009092_913433.htm

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APPEAL NO. 35500

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

JOHNSON & JOHNSON and JANSSEN PHARMACEUTICA PRODUCTS L.P.,

Appellants,

v.

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

Appellee.

CERTIFICATE OF SERVICE

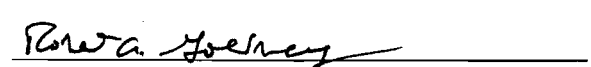
Date of Service: June 16, 2010

Type of Service: Regular U.S. Mail.

Persons served: **Rebecca A. Betts and Debra C. Price**, Allen Guthrie & Thomas, 500 Lee Street East, Suite 800, P.O. Box 3394, Charleston, West Virginia 25333; and **Brian C. Anderson**, O'Melveny & Meyers, 1625 Eye Street, NW, Washington DC 20006.

Items served:

1. Brief of Appellee
2. State's Motion for Leave to Substitute Color Version of Exhibit for Black and White Version



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