

APPEAL NO. 35500

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

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

Appellee,

v.

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

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

Appellants.

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF
APPELLANTS**

Forrest H. Roles (WV Bar No. 3162)
Mark A. Carter (WV Bar No. 4316)
DINSMORE & SHOHL LLP
900 Lee Street
Huntington Square, Suite 600
Charleston, WV 25301
(304) 357-0924

Attorneys for Amicus Curiae

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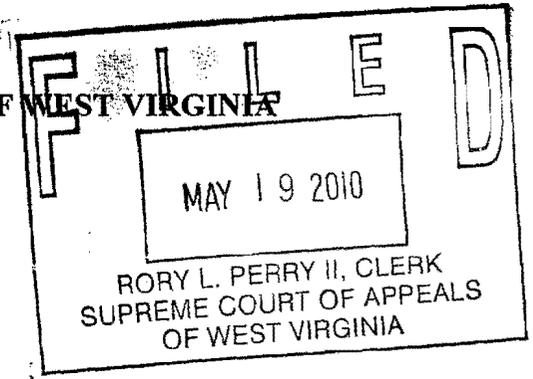


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**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF
APPELLANTS**

INTERESTS OF *AMICUS CURIAE*

The interests of the Washington Legal Foundation (WLF) are set out more fully in the accompanying motion for leave to file this brief.

WLF is a non-profit public interest law and policy center with supporters in all 50 states, including many in West Virginia. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government. In particular, WLF has devoted substantial resources to promoting free speech rights regarding matters of public interest, appearing before numerous federal courts in cases raising First Amendment issues. *See, e.g., Nike v. Kasky*, 539 U.S. 654 (2003).

For more than 30 years, WLF has worked actively to ensure that patients have access to the latest medical advances, particularly where the patients are critically ill and have limited treatment options. *See, e.g., Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 552 U.S. 1159 (2008). WLF's members include physicians who seek to receive all relevant information about the risks and benefits of FDA-approved products, and medical patients who want their doctors to have such information. Toward that end, WLF has worked to protect the First Amendment rights of its members to receive medical information from as broad a perspective as possible. It opposes efforts by government regulators to suppress competing points of view regarding risks and benefits of available medications, where there is a reasonable scientific basis for those points of view. Instead, it believes that health care and consumer welfare is best served by permitting

trained physicians to hear from multiple points of view and to use that information to make informed choices in the best interests of their patients.

WLF has litigated actively to ensure that government regulators respect First Amendment rights when attempting to restrict what health care providers may say about their products and what doctors and patients may hear. For example, WLF successfully challenged, on First Amendment grounds, Food and Drug Administration (FDA) restrictions on manufacturer dissemination of peer-reviewed medical journal articles that contain information about potential uses of FDA-approved drugs. As a result of that litigation, FDA is permanently enjoined from restricting such dissemination, even when the drug uses discussed in the journal articles have not been approved by FDA. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

In connection with its “DDMAC Watch” program, since 2005 WLF has been monitoring Warning Letters issued by FDA (through its Division of Drug Marketing, Advertising, and Communications, or DDMAC). When DDMAC sends a Warning Letter to a drug company employing legally deficient or ill-advised theories, WLF sends a response letter that identifies the deficiencies. To date, WLF has issued 53 such letters to DDMAC.

WLF is concerned that the decision below, if allowed to stand, will be detrimental to public health because it will deter pharmaceutical companies from speaking out on matters of public interest. The circuit court exhibited little or no understanding of the important First Amendment issues raised by this case. If the decision below is allowed to stand, the exercise of free speech rights will be chilled considerably, depriving doctors and patients of the robust discussion of matters of public interest that is vital to ensuring optimal health care.

STATEMENT OF THE CASE

Appellants appeal from a judgment imposing \$4.5 million in civil penalties under the West Virginia Consumer Credit and Protection Act (the “Consumer Protection Act”). The State of West Virginia filed the action based on: (1) a November 10, 2003 letter sent by Appellant Janssen Pharmaceutica Products L.P. (“Janssen”) to doctors (including some doctors in West Virginia) regarding Risperdal, an anti-psychotic drug manufactured by Janssen; and (2) a three-by-five-inch, 14-page promotional “file card” distributed by Janssen to doctors beginning in August 2003 regarding Duragesic, a patch manufactured by Janssen that, when applied to the skin, delivers a continuous dose of the narcotic pain medicine fentanyl. West Virginia alleged, *inter alia*, that the letter and file card contained false or misleading information.

At all times in connection with this litigation, Appellants have asserted that the statements contained in the letter and file card were truthful, and they put forth substantial evidence of truthfulness in opposition to West Virginia’s 2008 motion for partial summary judgment.¹ The circuit court nonetheless granted that motion in August 2008. *See* August 19, 2008 Opinion and Order on the Parties’ Motions for Summary Judgment (“Opinion and Order”). The circuit court noted that: (1) a Warning Letter issued by DDMAC in April 2004 stated that the November 10, 2003 letter from Janssen to doctors regarding Risperdal contained false and misleading statements, and Janssen did not seek any sort of administrative appeal from that letter; and (2) a Warning Letter issued by DDMAC in September 2004 stated that the Duragesic file card contained false and misleading statements, and Janssen did not seek any sort of

¹ That motion focused solely on the issue of whether Janssen made false or misleading statements in connection with the letter or file card.

administrative appeal from that letter either. The circuit court determined that FDA is “uniquely qualified” to make determinations regarding the truthfulness of statements made by drug manufacturers and thus that it would “giv[e] deference to the FDA’s findings and actions pertaining to the communications at issue.” Opinion and Order at 29, 32. The court determined that “giving deference” to FDA’s findings entailed entering judgment against Appellants as a matter of law on the issue of whether Janssen’s statements were “false or misleading” within the meaning of the Consumer Protection Act. *Id.* at 32.

The circuit court went on to determine that once it found (in deference to the Warning Letters) that Janssen’s statements were false or misleading, Appellants were not entitled to any First Amendment protection from civil penalties under the Consumer Protection Act. *Id.* at 33-35. The court said its no-First-Amendment-protection finding applied regardless whether Janssen’s speech was evaluated under the intermediate scrutiny normally applicable to commercial speech or (as Appellants asserted) under a strict scrutiny test. *Id.* at 34-35.

The circuit court then conducted a one-day bench trial on September 9, 2008, at which all of Appellants’ evidence regarding the truthfulness of Janssen’s statements was admitted without objection. On February 25, 2009, it issued a Final Order assessing \$4.5 million in civil penalties against Appellants. The court reiterated its summary judgment conclusion that Janssen’s statements were “false or misleading” as a matter of law (because the DDMAC Warning Letters had deemed the statements false and misleading) and thus that Appellants were not entitled to any First Amendment protection from liability under the Consumer Protection Act. Final Order at 30.

SUMMARY OF ARGUMENT

WLF agrees with Appellants that this Court should reverse the circuit court's judgment and order judgment in their favor, for each of the reasons set forth in Appellants' Brief. WLF writes separately to focus on the substantial and important First Amendment issues raised by this case. The judgment entered against Appellants constitutes a flagrant violation of their First Amendment rights to address matters of substantial public interest.

First, even if the circuit court were correct that the DDMAC Warning Letters constituted an official FDA determination that Janssen's statements were false and misleading (and it was not correct, as Appellants cogently demonstrate), the U.S. Supreme Court has repeatedly held that findings by government officials regarding the need for speech regulation are *not* entitled to deference when challenged under the First Amendment in judicial proceedings. Rather, the burden of proof in those proceedings remains at all times on government officials to demonstrate the factual predicate for any speech regulation. Moreover, even if DDMAC's actions could be deemed adjudicatory in nature (and they cannot), Appellants would still be entitled under the First Amendment to an independent review in the West Virginia courts of all issues relevant to their claims of constitutional protection.

Second, the circuit court ignored First Amendment case law that requires heightened First Amendment scrutiny when the speech being regulated touches upon matters of public concern. The circuit court's determination that Janssen's statements did not involve matters of public concern (Final Order at 32-37) cannot survive the "red face" test. WLF can think of few matters of greater public concern than the issues addressed by Janssen's statements: the safety and effectiveness of FDA-approved drugs. The First Amendment permits the imposition of financial

penalties only after a court has determined *both* that the statements in question were false or misleading *and* that Janssen acted in reckless disregard for the truth of the statements.

Third, the circuit court misapplied established First Amendment case law in determining that a speaker is not entitled to any First Amendment protections once it is determined that his speech is false or misleading. If the circuit court's determination were correct, a government agency could avoid all First Amendment review of its speech restrictions simply by branding as "false or misleading" any speech to which it objected, and then demanding deference for its determination in any subsequent court proceeding. Case law does not permit First Amendment restraints to be so easily evaded.

ARGUMENT

I. THE CIRCUIT COURT'S DECISION TO PROVIDE ABSOLUTE DEFERENCE TO DDMAC'S "FALSE OR MISLEADING" DETERMINATION IS CONTRARY TO ESTABLISHED FIRST AMENDMENT CASE LAW

Appellants have contended throughout these proceedings that statements contained in the November 10, 2003 letter to doctors concerning Risperdal and in the "file card" concerning Duragesic were entirely truthful. Yet, Appellants have been denied a full and fair opportunity to demonstrate the truthfulness of those statements in any judicial proceeding. The circuit court barred Appellants from litigating truthfulness, concluding that it should give conclusive deference to assertions in the DDMAC Warning Letters that the November 10 letter and the file card contained false or misleading statements. The decision to grant deference to the DDMAC letters is contrary to established First Amendment case law and (as explained in Part I.C of Appellants' Brief) effected a gross violation of Appellants' First Amendment rights.

Federal courts have long recognized that the First Amendment, subject only to narrow

and well-understood exceptions, does not countenance governmental control over the content of messages conveyed by private individuals. *See, e.g., Texas v. Johnson*, 491 U.S. 397, 414 (1989). While the courts have occasionally upheld content-based speech restrictions, they have always imposed on the government a heavy burden of demonstrating the necessity of such restrictions. *See, e.g., Ashcroft v. ACLU*, 542 U.S. 656, 665 (2005) (“When plaintiffs challenge a content-based speech restriction, the burden is on the government to prove that the proposed alternatives will not be as effective as the challenged statute.”); *Burson v. Freeman*, 504 U.S. 191, 198 (1992). As Justice Stevens recently noted:

We have repeatedly held that “[d]eference to a legislative finding” that certain types of speech are inherently harmful “cannot limit judicial inquiry when First Amendment rights are at stake,” reasoning that “the judicial function commands analysis of whether the specific conduct falls within the reach of the statute and if so whether the legislation is consonant with the Constitution.”

Morse v. Frederick, 551 U.S. 393, 443 n.6 (2007) (Stevens, J., dissenting) (quoting *Landmark Communications, Inc. v. Virginia*, 435 U.S. 829, 843, 844 (1978)).

Even when the challenged speech is deemed “commercial speech” – that is, speech that does no more than “propose a commercial transaction,” *Bd. of Trustees v. Fox*, 492 U.S. 469, 473 (1989) – courts have made clear that it is the regulators who bear the burden of justifying their content-based speech restrictions. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 770 (1993) (“[T]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it.”); *Thompson v. Western States Medical Center*, 535 U.S. 357, 373 (2002). The evidentiary burden is not light. For example, the government’s burden of showing that a commercial speech regulation advances a substantial government interest “in a direct and material way . . . ‘is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a

restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree.” *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfield*, 507 U.S. at 770-71).

In *Edenfield*, the Supreme Court struck down a Florida ban on direct solicitation of clients by CPAs, despite a determination by Florida regulatory officials that such solicitation presented a grave danger of inducing fraud. The Supreme Court refused to defer to that determination and struck down the ban because Florida officials had introduced no evidence at trial demonstrating that solicitation would lead to fraud. *Edenfield*, 507 U.S. at 771. Similarly, in *Rubin*, the Supreme Court refused to defer to the determination of federal alcoholic beverage regulators that a ban on beer labels disclosing alcohol content was necessary to prevent “strength wars” (wherein beer manufacturers would keep increasing the alcohol content of their products, in order to be able to advertise that their product was “strongest”). The Court held that regulators seeking to uphold the ban in the face of a First Amendment challenge were required to present to the courts their evidence regarding the likelihood of “strength wars.” *Rubin*, 514 U.S. at 487-490.

In none of the cases in which the U.S. Supreme Court has addressed First Amendment challenges to restrictions on commercial speech has the Court so much as suggested that it was willing to defer to government determinations regarding the truthfulness of the speech at issue, the need for speech restrictions, or their likely effectiveness. Such willingness would be inconsistent with the language quoted above. The burden of demonstrating that harms are “real” and that commercial speech restrictions alleviate those harms to “a material degree” would amount to nothing if the government could meet that burden simply by seeking deference to

government fact-finding.

The circuit court's "false or misleading" finding was based entirely on its decision to accord absolute deference to statements contained in the DDMAC Warning Letters, a decision that directly conflicts with First Amendment case law. As this Court has recognized, "whenever there is a First Amendment defense to actions under state law, the state court is required to be a judge of both the facts and the law." *Maynard v. The Daily Gazette Co.*, 191 W. Va. 601, 603, 447 S.E.2d 293, 295 (1994). Given that West Virginia introduced *no* evidence in support of its Consumer Protection Act claim other than the two Warning Letters issued by DDMAC, the circuit court could not possibly have ruled in West Virginia's favor other than by according absolute deference to DDMAC's letters. As explained above, such deference is entirely unwarranted in First Amendment cases.

Appellants have demonstrated at length that Janssen's interactions with DDMAC with respect to the two Warning Letters did not constitute adjudicative proceedings. But even if the interactions had been adjudicative in nature, the First Amendment would still require that Appellants be afforded an opportunity in these proceedings to contest any findings supposedly made by FDA. The First Amendment protects the right of a party to *de novo* appellate review within the judiciary of findings respecting his speech rights, and these West Virginia court proceedings have provided Appellants with their first opportunity to obtain judicial review of the "findings" that the State of West Virginia contends were made by FDA.

The U.S. Supreme Court held in *Bose Corp. v. Consumers Union of the United States, Inc.*, 466 U.S. 485 (1984), that a court reviewing findings in a First Amendment case has an obligation "to 'make an independent examination of the whole record' in order to make sure that

“the judgment does not constitute a forbidden intrusion on the field of free expression.” 466 U.S. at 499 (quoting *New York Times Co. v. Sullivan*, 376 U.S. 254, 284-286 (1964)). The Court held that that obligation “is equally applicable” regardless of the nature of the forum from which judicial review is sought. *Id.*

Independent appellate/judicial review of key factual findings in First Amendment cases is well established. *Bose* explained that such review is constitutionally mandated and has long-standing antecedents at common law:

The requirement of independent appellate review reiterated in *New York Times v. Sullivan* is a rule of federal constitutional law. It emerged from the exigency of deciding concrete cases; it is law in its purest form under our common-law heritage. It reflects a deeply held conviction that judges – and particularly Members of this Court – must exercise such review in order to preserve the precious liberties established and ordained by the Constitution.

Bose, 466 U.S. at 510-11.

The precise contours of the requirement of independent judicial review have not yet been firmly established. But *Bose* was quite clear that there is one area in which the requirement of independent judicial review should take precedence over any doctrine of deference: review of “special facts that have been deemed to have constitutional significance.” *Id.* at 505. After describing several categories of speech that traditionally have been deemed to merit no First Amendment protection (including fighting words, incitement to riot, obscenity, and child pornography), the Court explained the importance of careful appellate scrutiny of any assertion that challenged speech falls into one of those unprotected categories:

In each of these areas, the limits of the unprotected category, as well as the unprotected character of particular communications, have been determined by the judicial evaluation of special facts that have been deemed to have constitutional significance. In such cases, the Courts have regularly conducted an independent review of the record both to be sure

that the speech in question actually falls within the unprotected category and to confine the perimeters of any unprotected category within acceptably narrow limits in an effort to ensure that protected expression will not be inhibited. Providing triers of fact with a general description of the type of communication whose content is unworthy of protection has not, in and of itself, served sufficiently to narrow the category, nor served to eliminate the danger that decisions by triers of fact may inhibit the expression of protected ideas.

Id. at 504-05.

The circuit court explicitly held that Janssen's speech fell into a category (false and misleading speech) that it deemed unprotected by the First Amendment. Opinion and Order at 33-35. DDMAC's correspondence made no mention of the First Amendment, so any DDMAC "findings" must have been based on a similar conclusion. Accordingly, *Bose* dictates that this Court should undertake *de novo* review of the facts to determine whether Janssen's speech is entitled to any First Amendment protection; it further dictates that the circuit court erred in declining to undertake such a review.

Even in the context of commercial speech, the U.S. Supreme Court has looked to independent appellate/judicial review as an important safeguard against an unwarranted holding that the challenged speech merits no constitutional protection. *See Illinois ex rel. Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 621-22 (2003) (in a challenge to Illinois's efforts to regulate commercial – and allegedly fraudulent – solicitations, the Court said that Illinois's assertions that the defendant's speech was constitutionally unprotected because it was fraudulent would be subject to "[e]xacting proof requirement" at trial, and that "[a]s an additional safeguard responsive to First Amendment concerns, an appellate court could independently review the trial court's findings."). Given that most if not all of the speech at issue in this case is fully protected speech that is entitled to significantly greater First Amendment protection than is commercial

speech,² the circuit court's adoption of a deferential standard of review cannot be squared with *Madigan*'s endorsement of independent review of findings that speech is constitutionally unprotected because it is false or misleading.

The U.S. Supreme Court on several occasions has ruled that whether a libel defendant has acted with "actual malice" is a "special fact" that is deemed to have "constitutional significance" – and thus is subject to independent review. *See, e.g., Harte-Hanks Communications, Inc. v. Connaughton*, 491 U.S. 657, 685-86 (1989); *Bose*, 466 U.S. at 510-11.³ Similarly, whether a defendant's activities should be deemed noncommunicative in nature – and thus outside the ambit of the First Amendment – is a special fact subject to independent review. *Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston*, 515 U.S. 557, 567 (1995).⁴ And whether a defendant's speeches to civil rights supporters in Mississippi constitute "fighting words" – a category of speech to which the First Amendment does not apply – is also a special fact subject to independent judicial review. *NAACP v. Claiborne Hardware Co.*, 458 U.S. 886, 927-28 (1982).⁵

² *See Part II, infra.*

³ A libel defendant who has disseminated false information with "actual malice" has engaged in speech outside the protection of the First Amendment. *Id.*

⁴ The trial court made a factual finding that a parade organized by the defendants did not convey any messages and thus was not subject to First Amendment protection. The U.S. Supreme Court undertook an independent appellate review of that finding and ultimately reversed. *Id.* at 568-69.

⁵ Where "the trier of fact has had the opportunity to observe the demeanor of the witness" and uses those observations to make credibility determinations, courts review those determinations under a "clearly erroneous" standard, even when the determinations qualify as "special facts" for First Amendment purposes. *Harte-Hanks*, 491 U.S. at 688; *Hurley*, 515 U.S. at 567. But credibility determinations could not have played a role in any "findings" issued by

In sum, the circuit court erred as a matter of federal constitutional law when it provided absolute deference to DDMAC's "false and misleading" determination. Providing such deference was improper even if one assumes, contrary to fact, that FDA had conducted an adjudicatory proceeding and the circuit court was merely reviewing FDA's adjudicatory findings.

II. HEIGHTENED FIRST AMENDMENT SCRUTINY IS REQUIRED WHEN, AS HERE, THE REGULATED SPEECH TOUCHES UPON MATTERS OF PUBLIC CONCERN

West Virginia contends that the restrictions it seeks to impose on Appellants' speech are, at most, subject to an intermediate level of First Amendment scrutiny because the speech is mere "commercial speech" – it does no more than "propose a commercial transaction." *Bd. of Trustees v. Fox*, 492 U.S. at 473. There is substantial reason to question that characterization of Janssen's speech. For example, it sent the November 10, 2003 Risperdal letter to physicians not for the purpose of generating sales but because it was required by FDA to write to physicians to inform them of FDA-mandated changes in the product labeling.

But even if Janssen's speech can properly be characterized as "commercial" in nature, the circuit court erred in failing to apply a heightened level of First Amendment scrutiny to West Virginia's regulation of that speech. Information regarding the safety and effectiveness of pharmaceuticals generally, and of atypical antipsychotics and pain medications in particular, is a matter of significant public interest. Patients and doctors need that information to make

FDA, because FDA did not conduct a hearing or examine any witnesses. Neither, for that matter, did the circuit court have an opportunity to examine the demeanor of witnesses; it dispensed with all live witnesses in its one-day trial.

informed choices regarding treatment options.⁶ The First Amendment interests of American society in promoting uninhibited speech on an issue increases when, as here, the issue is one of significant public interest.

For example, when those seeking to disseminate information have been challenged by a party asserting an interest in nondissemination, the Supreme Court has consistently resolved such disputes by reference to whether the information involved a matter of public interest. *See, e.g., Smith v. Daily Mail Publishing Co.*, 443 U.S. 97, 103 (1979); *New York Times Co. v. United States*, 403 U.S. 713 (1971) (*per curiam*) (publication of Pentagon Papers over objections of federal government justified in part by the fact that the papers included information of great public concern). In *Bartnicki v. Vopper*, 532 U.S. 514 (2001), the Court held that the First Amendment prevented individuals whose illegally intercepted telephone conversations had been broadcast on a radio station from suing the radio station, in large measure because the conversations involved “information of public concern.” 532 U.S. at 534. Similarly, the First Amendment right of government employees to speak freely (without fear of discipline by their employers) hinges largely on the public importance of the matters addressed. *See Pickering v.*

⁶ The circuit court’s suggestions to the contrary, Final Order at 32-36, are wholly unpersuasive and merit little response. In support of its conclusion that Janssen’s speech did not involve matters of public concern, the circuit court relied on *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749 (1985). That case involved a credit reporting agency that sent a credit report regarding a business to five of its subscribers. The business sued for defamation, alleging that the credit report included false information. The Supreme Court held that the credit report was not a matter of public interest (and thus not entitled to heightened First Amendment protection) but rather was “solely in the individual interest of the speaker and its specific business audience.” *Id.* at 762. The contrast between the speech at issue in *Dun & Bradstreet* and the speech at issue here could not be more stark. Janssen distributed its letter and file card to hundreds of thousands of physicians, each of whom had a strong interest in receiving the type of safety and effectiveness information conveyed by Janssen.

Bd. of Education, 391 U.S. 563, 566 (1968).

In *Thornhill v. Thompson*, 310 U.S. 88 (1940), the Supreme Court rejected an effort to prevent speech by an entity that wished to speak out on an issue of public importance. The case involved labor picketing that sought “to advise customers and prospective customers” regarding labor conditions “and thereby to induce such customers” to change their purchase decisions. *Thornhill*, 310 U.S. at 99. Despite Alabama’s claim that information being conveyed by picketers was false, the Court overturned an injunction against the picketing because the First Amendment bars the government from “impair[ing] the effective exercise of the right to discuss freely industrial relations which are *matters of public concern*.” *Id.* (emphasis added). The Court reasoned, “Free discussion concerning the conditions in industry and the causes of labor disputes [is] indispensable to the effective and intelligent uses of the process of popular government to shape the destiny of modern industrial society.” *Id.* at 103. Similarly, free discussion concerning an issue of life-changing importance to medical patients is in jeopardy if the federal government is permitted to prevent speech by companies and individuals wishing to discuss the issue in good faith.

Because of the importance of open discussion on matters of public concern, there is considerable First Amendment case law to support the proposition that the First Amendment provides full protection even to *false* speech, and even when uttered in a commercial setting. For example, U.S. Supreme Court Justice Stephen Breyer opined, without contradiction by his colleagues in a case arising in a commercial context, that “speech on matters of public concern needs ‘breathing space’ – potentially incorporating certain false or misleading speech – in order to survive.” *Nike, Inc. v. Kasky*, 539 U.S. 654, 676 (2003) (Breyer, J., dissenting from dismissal

of writ of certiorari). That breathing space should include a prohibition against the imposition of penalties against a speaker in cases of this sort unless there is a finding both that the speech was false and that the speaker acted with knowledge of falsity or else in reckless disregard of the truth. *See New York Times v. Sullivan*, 376 U.S. 254 (1964) (imposing a heightened, “reckless disregard” standard to allegedly false statements contained in a paid newspaper advertisement). The Supreme Court arrived at that heightened standard of review based on its recognition of a “profound national commitment to the principle that debate on *public issues* should be uninhibited, robust, and wide open.” *Id.* at 270.

The circuit court dismissed Appellants’ arguments regarding the public importance of the matters they were discussing, concluding that a statement is not exempt from being labeled false or misleading merely because there existed (and continues to exist) a “legitimate scientific debate” regarding the correct answer. Opinion and Order at 28. That conclusion misses the point of the First Amendment protection to which Appellants are entitled. The existence of a “legitimate scientific debate” may not provide debate participants *carte blanche* to say whatever they want without regard to truth or falsity. But because society has a vested interest in encouraging free and open discussion of important scientific/medical questions, the courts have repeatedly afforded full First Amendment protections to such speech, thereby significantly limiting the circumstances under which the speaker can be sanctioned.

The circuit court refused to accord fully protected, noncommercial status to Janssen’s speech even though it was not uttered as part of a proposal to engage in a commercial transaction, seemingly because Janssen had an economic motive for its speech. But economic motive is insufficient to transform fully protected speech into commercial speech. *See Citizens United v.*

Federal Election Comm'n, 130 S. Ct. 876, 899 (2010) (“First Amendment protection extends to corporations”); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 67 (“[T]he fact that Youngs has an economic motivation for mailing the pamphlets would clearly be insufficient by itself to turn the materials into commercial speech.”).

The circuit court erred in failing to provide heightened First Amendment protection to Janssen’s speech on matters of public concern. At the very least, the circuit court should not have imposed punitive sanctions on Appellants without first determining not only that the speech was false but also that it was uttered with actual malice, *i.e.*, reckless disregard for the truth or falsity of the speech.

III. THE CIRCUIT COURT ERRED IN DENYING ALL FIRST AMENDMENT PROTECTION TO APPELLANTS ONCE IT DETERMINED THAT JANSSEN’S SPEECH WAS FALSE OR MISLEADING

The circuit court declined even to consider Appellants’ First Amendment claims. Once it determined that Janssen’s statements were false and misleading as a matter of law (based its on absolute deference to the statements contained in the DDMAC Warning Letters), the circuit court concluded that the First Amendment provided Appellants with no protection from the imposition of penalties under the Consumer Protection Act:

This Court finds that irrespective of whether the strict scrutiny test or intermediate scrutiny test under the First Amendment is applied to the defendants’ labeling, the determination of whether or not it is misleading is the controlling issue. The Court finds the First Amendment does not protect misleading labeling and/or advertising from civil penalties under the Consumer Protection Act.

Opinion and Order at 34-35.

As explained above, it was clear error for the circuit court to suggest that speech restrictions otherwise subject to strict scrutiny are absolved of all First Amendment analysis if the

speech at issue is found to be misleading. But even if the penalties imposed on Janssen's speech are ultimately deemed to be subject only to intermediate scrutiny, the judgment below must be reversed in light of the circuit court's fundamental misunderstanding of the U.S. Supreme Court's framework for analyzing restrictions on commercial speech.

That framework was first set forth in *Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557 (1980). Under the four-part *Central Hudson* test, courts consider as a threshold matter whether the commercial speech concerns unlawful activity or is *inherently* misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not inherently misleading, then the challenged speech regulation violates the First Amendment unless government regulators can establish that: (2) they have identified a substantial government interest; (3) the regulation "directly advances" the asserted interest; and (4) the regulation "is no more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566.

The circuit court sought to avoid application of Parts 2 through 4 of the *Central Hudson* test by declaring Janssen's statements false or misleading. But that effort was based on a basic misunderstanding of Part 1 of the *Central Hudson* test. Part 1 refers to speech that can be proven false under some objective standard; for example a claim that a drug has been approved for marketing by FDA when it has not been so approved. The allegations at issue here are not of that nature; rather, DDMAC criticized Janssen's speech on the grounds that it *might* mislead some doctors and consumers because it did not fully disclose all information that DDMAC deemed necessary to a full understanding of Risperdal's and Duragesic's risks and benefits. The Warning Letter concerning Risperdal stated:

- * Although Janssen's November 10, 2003 letter enclosed the new, FDA-approved revised labeling for Risperdal (which warned of a class-wide association between atypical antipsychotics and diabetes), the letter was misleading (in suggesting that Risperdal might not be associated with diabetes) by mentioning studies that had found no association between Risperdal and diabetes.
- * Janssen's November 10, 2003 letter failed explicitly to call attention to the fact that the new product labeling (which was enclosed with the letter and thus was easily reviewable by doctors receiving the letter) had been revised to communicate new information regarding the potential consequences of hyperglycemia and the recommendation of regular glucose control monitoring.

The Warning Letter concerning Duragesic stated:

- * The Janssen "file card" had reported on a study conducted by Simpson, *et al.*, which found that Duragesic was effective in treating chronic back pain and improved the quality of sleep; DDMAC did not suggest that Janssen had inaccurately reported on the study, but it questioned the usefulness of the study because it was "open-label" (*i.e.*, all the study participants knew that they were using Duragesic);
- * Other studies cited by the "file card," while accurately reported, similarly failed to satisfy the high standards that, DDMAC asserted, must be met before the results of the study could be reported to doctors;
- * The Janssen "file card" reported on data compiled by DAWN (the Drug Abuse Warning Network) showing that there were fewer reported cases of abuse of Duragesic than of other listed opioid products. Although DDMAC did not question the accuracy of Janssen's report on the DAWN data and although the "file card" included numerous caveats regarding the significance of the DAWN data, DDMAC concluded that the report on the DAWN data was false or misleading because it could suggest to readers that Duragesic is less abused than other opioid drugs – a suggestion DDMAC deemed not fully supported by the DAWN data.

A review of the charges contained in the DDMAC Warning Letters thus makes clear that

DDMAC was not asserting that the November 10, 2003 letter and the file card were false or "inherently misleading" in the sense that they contained provably false assertions. Rather, DDMAC was simply asserting a position that Janssen had failed to strike a proper balance in presenting the risks and benefits of its products. First Amendment commercial speech case law

is clear that under those circumstances, commercial speech can at most be deemed “potentially” misleading and is entitled to the intermediate level of protection provided by all four parts of the *Central Hudson* test.

For example, the U.S. Supreme Court in *In re R.M.J.* rejected the claim of State regulators that certain forms of legal advertising could be banned on prophylactic grounds, holding that:

Misleading advertising may be prohibited entirely, but the States may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive. . . . [T]he remedy in the first instance is not necessarily a prohibition but preferably a requirement of disclaimers or explanation. . . . Although potential for deception . . . is particularly strong in the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception.

In re R.J.M., 455 U.S. 191, 203 (1982).

Similarly, when DDMAC complained that Janssen (accurately) reported on medical studies that DDMAC deemed insufficiently rigorous, *In re R.J.M.* makes clear that the *Central Hudson* test protected Janssen from any assertion that its reporting was inherently misleading (and thus entitled to no First Amendment protection whatsoever). The First Amendment protected Janssen’s right to report on those studies (provided only that it included sufficient disclaimers to minimize the potential that readers would be misled). If West Virginia seeks to sanction Janssen for potentially misleading West Virginia physicians, it has an obligation to demonstrate that its sanctions can survive all four parts of the *Central Hudson* test.

In its brief opposing the petition for review by this Court, the State of West Virginia attempted to obfuscate the issue by asserting that First Amendment case law recognizes only two categories of “misleading” commercial speech – “actually misleading” speech and “inherently

misleading” speech – and that both are prohibited by the Consumer Protection Act. W.Va. Opp. Br. at 9.⁷ That is not how misleading speech has been categorized in First Amendment case law. *Central Hudson* and its progeny distinguish between, on the one hand, false and “inherently” misleading commercial speech (which is not entitled to First Amendment protection), and on the other hand speech that merely is “potentially” misleading (which is entitled to First Amendment protection under all four parts of the *Central Hudson* test). Janssen’s speech was at most “potentially” misleading.

The circuit court failed to conduct any sort of First Amendment analysis before imposing an onerous sanction on Appellants, because it erroneously concluded that a finding that Janssen’s speech was “misleading” rendered the First Amendment inapplicable. That error provides an additional compelling ground for reversing the judgment below.

⁷ West Virginia identified the “two types of misleading commercial statements” as follows: (1) “A commercial statement is *actually misleading* when recipients have actually been misled by it”; and (2) “A commercial statement is *inherently misleading* when the information is inherently likely to mislead, irrespective of whether anyone was actually misled.” *Id.*

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court reverse the circuit court's judgment and order judgment be entered in favor of Appellants.

Respectfully submitted,



Forrest H. Roles (WV Bar No. 3162)
Mark A. Carter (WV Bar No. 4316)
DINSMORE & SHOHL LLP
900 Lee Street
Huntington Square, Suite 600
Charleston, WV 25301
(304) 357-0924

Attorneys for Amicus Curiae

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this ____ day of May, 2010, copies of the foregoing amicus curiae brief of the Washington Legal Foundation were deposited in the U.S. Mail, first-class postage pre-paid, addressed as follows:

Frances A. Hughes
Chief Deputy Attorney General
State Capitol Building
Charleston, WV 25305

Barry M. Hill
Anapol Schwartz Weiss Cohan Feldman & Smalley
89 12th Street
Wheeling, WV 26003

Rebecca A. Betts
Allen Guthrie & Thomas, PLLC
500 Lee Street, East, Suite 800
P.O. Box 3393
Charleston, WV 25333-3394

Brian C. Anderson
O'Melveny & Myers LLP
1625 Eye Street, NW
Washington, DC 20006-4001



Mark A. Carter