

APPEAL NO. 35500

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

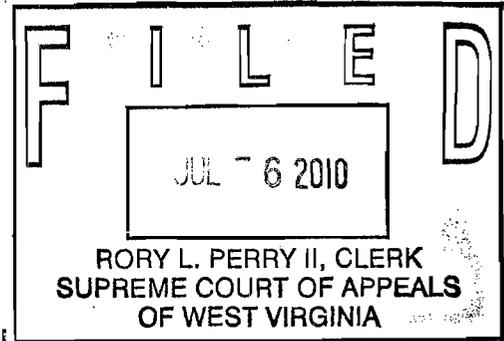
STATE OF WEST VIRGINIA, EX REL.,  
DARRELL V. McGRAW, JR.,  
ATTORNEY GENERAL,

*Appellee,*

v.

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

*Appellants.*



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

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**APPELLANTS' REPLY BRIEF**

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JULY 6, 2010

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## INTRODUCTION

As Janssen and Johnson & Johnson explained in their opening brief, remand, at a minimum, is required in this case. The arguments raised by the State in its brief reinforce that result.

## ARGUMENT

### I. THE CIRCUIT COURT'S MISAPPLICATION OF ISSUE PRECLUSION COMPELS A REVERSAL AND REMAND.

As Janssen explained in its opening brief, the circuit court erred in giving preclusive effect to two “informal and advisory” warning letters, because those warning letters are not judgments and did not result from any actual litigation. (*See* Janssen Br. at 20-26.) In its brief, the State has elected not to take issue with this point, and in fact now concedes that Janssen is correct: a warning letter cannot give rise to issue preclusion. (*See* State Br. at 13 (“The trial court could not [give] preclusive effect to the scientific determinations in [the] Risperdal Warning Letter, because this letter does not make any.”).) Instead, the State now suggests an entirely new theory that was never raised, litigated, or addressed below. (*See infra* Part II.) A fair analysis of the issue preclusion point warrants a remand. Because the State has now conceded that warning letters cannot give rise to issue preclusion, at a minimum, remand is required.

### II. THE STATE'S NEW THEORY FAILS.

#### A. The State Misstates The Circuit Court's Ruling.

The circuit court's decision was based on the two warning letters which it erroneously held were preclusive and which the State now concedes were not preclusive. In place of the argument it pursued below, the State now contends that the circuit court did not award judgment

based on the warning letters. (*See id.* at 3, 25-26, 36-37.) That contention is contradicted by the record.

Contrary to its position before this Court, the State made clear to the circuit court below that it was urging the circuit court to treat the warning letters as preclusive, and even included a subsection to its summary judgment brief captioned “The FDA’s Risperdal and Duragesic Warning Letters are final FDA determinations that the defendants made misleading statements about these products.” (*See State’s S.J. Br.* at 20.) The State also contended that Janssen “allowed the Warning Letters to become final with respect to FDA findings that Jansen violated federal law by making false or misleading statements” by agreeing to issue what the State terms “corrective” letters rather than administratively appealing the warning letters. (*Id.*)

The State took precisely the same position in opposing Janssen’s cross-motion for partial summary judgment, arguing that it was relying on “[t]he conclusiveness of FDA determinations [in warning letters] that both promotional pieces at issue are misleading.” (*See State’s Opp’n to Mot. for S.J.* at 9.) As the State summarized, its “proof of misleading statements begins, and – if the court accepts their **binding** effect – ends with these FDA findings [in the warning letters].” (*Id.* (emphasis added).)

The circuit court adopted the State’s argument and held that it would give “deference to the FDA’s findings and actions pertaining to the communications at issue.” (S.J. Order. at 32.) In denying Janssen’s motion to reconsider the summary judgment order, the circuit court reiterated that its summary judgment ruling relied on its determination that “the FDA’s warning letters were not informal and advisory,” but instead “constitute[d] mandatory FDA action and the FDA’s official judgment as to the matters addressed in the letters.” (*See Order Concerning Mot. to Reconsider* at 2-3 (quoting S.J. Order).) The court then stated that it had given

“deference to the FDA’s findings” on “whether a communication is false or misleading” and would “not revisit the correctness of the FDA’s scientific findings.” (*See id.* at 3 (quoting S.J. Order).) Summary judgment was therefore warranted, the court reasoned, because it accepted “the FDA’s findings and actions concerning whether Janssen’s statements were false or misleading.” (*Id.* at 4 (emphasis added).) The State’s current contention, that the circuit court “did not give preclusive effect to” the warning letters (State Br. at 3), is simply incorrect.

Because the State now concedes that the warning letters are not preclusive, a reversal of the judgment below is required. The State admits that the “trial court could not [give] preclusive effect to the scientific determinations in [the] Risperdal Warning Letter, because this letter does not make any.” (*Id.* at 13.) The State similarly admits that the Duragesic warning letter “contain[s] no new, independent scientific findings.” (*Id.* at 36.) The State concedes what the law dictates: the warning letters do not have any preclusive effect and they do not support judgment against Janssen. The warning letters were the only basis for the circuit court’s judgment that Janssen’s communications were false and misleading. Reversal of the circuit court’s decision is therefore required.

**B. The State Did Not Argue Its New Theory Below and Janssen Had No Opportunity To Contest It There.**

Rather than defending the grounds it argued below or the substance of the circuit court’s decision, the State now asserts that the circuit court’s ruling was based not on the warning letters, but on the FDA-approved labels for Risperdal and Duragesic. The State’s new theory, argued for the first time on appeal, is that Janssen’s statements were false or misleading under the West Virginia Consumer Credit and Protection Act (“CCPA”) not because they were *actually* false or misleading, but because they were inconsistent with the FDA-approved product labels and regulations. (*See, e.g.*, State Br. at 3 (contending that the statements in the November 10, 2003

Risperdal letter were false or misleading because the letter contained statements that are “contrary to the FDA’s label requirement for Risperdal” and “omit[ted] the blood sugar monitoring information required by the FDA to be included in Risperdal’s label”).) Because the State never raised its new label theory in the circuit court, Janssen had no opportunity to address it or to present any lay or expert testimony – or any other evidence – in response. Likewise, because the State did not raise its label theory in the circuit court, the circuit court had no occasion to address the theory or to consider the evidence in light of it.

Fairness alone requires a remand in light of the State’s shift in position. The State’s speculative assertion that the same judgment would have been rendered if this case had been litigated under the State’s new label theory (rather than the warning-letter theory the State prevailed upon below but now abandons) is no basis for affirming a judgment of \$4,475,000. *Cf. Riggs v. W. Va. Univ. Hosp., Inc.*, 221 W. Va. 646, 654, 656 S.E.2d 91, 99 (2007) (applying judicial estoppel to prevent attempt by plaintiffs “post-verdict to re-define their claims” where “the jury was not instructed on [the new theory], Appellants did not request such an instruction and the verdict form utilized by the jury did not include findings on [the new theory]”). As Chief Justice Davis wrote in that case,

Rule 8(e)(2) [of the West Virginia Rules of Civil Procedure] does not sanction sandbagging a party by asserting a post-trial legal theory of recovery that was never raised in the pleadings, nor expressly or impliedly consented to by the parties. This situation is an affront to the integrity of the judicial process, not just the adversely affected party. Consequently, it is appropriate to reaffirm the integrity of the court by applying the doctrine of judicial estoppel to such conduct.

*Id.* at 674, 656 S.E.2d at 119 (Davis, C.J., concurring).

In this circumstance, the State’s new theory should not be considered by this Court. If considered, however, this case must at the very least be remanded so that it can be tried and an

adequate record developed on the terms newly raised by the State. The circuit court's judgment should be vacated, Janssen must have the opportunity to defend against the State's new theory, and the circuit court should have the chance to consider whether the law and the evidence support the State's contentions.

**C. There Is No Legal Or Factual Basis For The State's New Theory.**

**1. No State Or Federal Law Supports The State's New Theory.**

No judicial decision construes the CCPA (or any other law) to prohibit truthful, non-misleading statements about a prescription drug on the ground that they vary from the contents of the FDA-approved label, and the State's new theory has no legal basis. The CCPA prohibits "deceptive" conduct, which is defined to include "false" or "misleading" statements. *See* W. Va. Code § 46A-6-102(7) & 104. A statement about a prescription drug is not "false," "misleading," or "deceptive" simply because it varies from the precise wording of an FDA-approved label or omits one of the warnings contained in the label. Rather, a statement is only "false," "misleading," or "deceptive" if it asserts something that is provably false, or if it would lead a reasonable person in the intended audience (in this case, doctors) to believe something that is untrue. *See* Federal Trade Commission, 1983 Policy Statement on Deception, *available at* <http://www.ftc.gov/bcp/policystmt/ad-decept.htm> (statement is "deceptive" if it "is likely to mislead" a "reasonable consumer").

The State now contends that the FDA's approval of a prescription drug label constitutes conclusive proof that any statement a manufacturer makes about its prescription drug that is in any way inconsistent with the label is "misleading" as a matter of law, even if the specific statement challenged has no actual tendency to mislead anyone. (*See, e.g.*, State Br. at 15, 19-20.) As the U.S. Supreme Court recently explained, however, information about a prescription

drug is not misleading (that is, “misbranded”) under federal law simply because it diverges from the FDA-approved label. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1197 (2009). Rather, the question of whether product information is misleading depends on the relevant science. *See id.* And to make the determination, even the FDA’s belief that product information is misleading “is *not* conclusive” because federal law “contemplates that federal juries will resolve most misbranding claims.” *See* 129 S. Ct. at 1197 (emphasis added). Thus, not even a case involving a manufacturer who unilaterally altered the *label itself* would be conclusively resolved by the FDA’s labeling decisions. Rather, the altered label’s adequacy would present a question of *fact*, which would focus on the scientific basis for the challenged alteration. *See id.* Moreover, an FDA-approved label cannot be accorded preclusive effect because it is no more a “judgment” that resulted from “actual litigation” than the warning letters on which the circuit court relied. (*See* Janssen Br. at 21-26.) *See also* Franklin D. Cleckley, Robin J. Davis, & Louis J. Palmer, Jr., *Litigation Handbook on West Virginia Rules of Civil Procedure* § 8(c) at 200 (3rd ed. 2008) (“The central inquiry on collateral estoppel is whether a given issue has been actually litigated by the parties in the earlier suit.”). The State’s new theory has no legal foundation.

**2. There Is No Support For The State’s New “Label” Argument In The Evidentiary Record.**

As three of the State’s arguments on appeal make clear, there is no support for the State’s new argument in the evidentiary record.

*First*, the State insists that the November 10, 2003 Risperdal letter was “false” or “misleading” as a matter of law because it “eviscerates the FDA-mandated diabetes label requirements by indicating that Risperdal has no more risk of causing diabetes than taking nothing.” (*See* State Br. at 23 (emphasis omitted).) But the letter (which was sent exclusively to medical professionals) merely indicates what “a body of evidence from published peer-reviewed

epidemiology research suggests” (*see* Janssen Br. at 8), and the State has offered no expert to testify that a reasonable doctor would construe that statement as the State now advocates. Nor does the State suggest that the statement is itself untrue or that it mischaracterizes the research to which it refers. Rather, the State challenges the statement as inconsistent with the new warning in the Risperdal label. But that warning in the label states simply that hyperglycemia-related events have “been reported in patients treated with atypical antipsychotics including RISPERDAL” while making it clear that little is known about the relationship between atypical antipsychotics generally and glycemic events due to the existence of several “confounders” that prevent definitive causal conclusions. (*See* Ex. to Janssen Br.) Thus, the label simply alerts doctors to a *potential* issue, which the November 10, 2003 letter itself did. (*See id.*) There is therefore no basis for the State’s assertion that Janssen’s letter “*eviscerated*” the label or suggested anything that was “false” or “misleading” as a matter of law. The most the State can say is that Janssen’s statement was not taken verbatim from the FDA-approved label. This does not satisfy the CCPA’s requirement that the State prove that Janssen’s letter was false or misleading.

*Second*, the State asserts that the November 10, 2003 Risperdal letter “omits 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” (*see* State Br. at 23 (emphasis omitted)). But there is no evidence that Janssen concealed anything. In fact, the entire revised label, with FDA prescribed diabetes warning, was enclosed with the letter. The State simply argues that, as a matter of law, the letter was “misleading” because it did not repeat that information, irrespective of whether it would, in fact, mislead any reasonable prescriber (a proposition for which the State offered no evidence). The

State thus contends that a truthful, non-misleading statement about a prescription drug is “false” or “misleading” whenever it fails to include *all* of the information contained in the FDA-approved label. This contention fails as an evidentiary matter under the CCPA.

*Third*, with respect to the Duragesic claim, the State contends that a statement that Duragesic has a “[l]ow reported rate of mentions in DAWN data” in the file card was misleading *per se* because, according to the State, *federal regulations* prohibit “[a] comparative safety claim” that is not “supported by a ‘well-controlled study,’” (See State Br. at 32.) The State refers to no evidence that the statement in the file card was false or misleading. Instead, the State argues that FDA regulations require comparative safety claims to be “supported by a ‘well-controlled study’ under 21 CFR 201.57(g)(4),” which in turn requires that the “well-controlled study” meet the requirements promulgated by the FDA in 21 C.F.R. § 314.126. (*Id.*) The State, arguing for its new theory, contends that Janssen’s alleged violation of these FDA regulations preclude it from defending the truth of the statements in the file card and render them false or misleading under the CCPA. (State Br. at 34 (“The defendants say the case is about science, but it is not. It is about the law . . . .” (referring to FDA regulations)).)

DAWN refers to the Drug Abuse Warning Network, which compiles data on emergency room admissions related to different narcotic drugs. On the same page that the Duragesic file card references the DAWN data, the file card lists the limitations to DAWN data in bullet points, telling doctors: the data does not distinguish Duragesic from other forms of fentanyl, which is the narcotic pain reliever Duragesic delivers; the data only include events that led to admission in an emergency department; and the data does not include information on the severity of the events, or whether the events led to hospital admission. (See Janssen Br. at 11.) The State did not address the clear qualifications that accompanied the statement it challenges with testimony or

evidence below and it offers no argument for finding the statement misleading in its brief beyond the assertion that it violated FDA regulations, which was not raised at the summary judgment stage. Nor can the State deny that fentanyl had a “[l]ow reported rate of mentions in DAWN data,” or point to evidence suggesting that a reasonable doctor would have drawn broader conclusions than the DAWN data would permit. The State offered no expert testimony suggesting how a reasonable doctor would have interpreted the file card, and this Court cannot sit as a trier of fact in the State’s evidentiary vacuum to find that a reasonable doctor would have been misled in the face of Janssen’s clear disclosures.

The CCPA requires the State to adduce evidence to satisfy the false or misleading standard. It has not done so in this case, whether under the theory it advanced in the circuit court or under the new argument it raises on appeal.

**3. The State’s New Legal Argument Is Preempted By Federal Law.**

Even if there were evidence in the record below supporting the State’s new theory, the State’s argument would be preempted by federal law, because it is a naked attempt to use State law to enforce FDA regulations. The State argues that the circuit court’s judgment should be upheld because a violation of an FDA regulation renders a statement false or misleading as a matter of law under the CCPA. (State Br. at 24.) The State specifically argues that the Court should import “FDA regulations to provide legal standards to determine if information published by a prescription drug manufacturer is misleading under the CCPA.” (*See id.*) As noted, in contending that the Duragesic file card is false or misleading as a matter of law, the State relies *exclusively* on FDA regulations, and directly asserts that the file card’s supposed false or misleading nature is “established by FDA regulations.” (*See id.* at 33 (contending that “DAWN 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”); *id.* at 34 (“that use of DAWN data to make comparative safety claims is impermissible is established by FDA regulations”).) The same is true of the State’s claim that the Risperdal letter is false or misleading under the CCPA. The State asserts that the Risperdal letter was false or misleading under the CCPA because it was “contrary to the FDA’s label requirement for Risperdal,” omitted “blood sugar monitoring information required by the FDA to be included in Risperdal’s label,” and “eviscerates the FDA-mandated diabetes label requirements.” (*Id.* at 3.)

But federal law provides that the federal government – and only the federal government – may enforce federal drug labeling law, and specifically prohibits attempts to use state law to enforce federal drug labeling law. The FDA’s organic statute (the U.S. Food, Drug, and Cosmetic Act, or “FDCA”) provides “all such proceedings for the enforcement, or to restrain violations, of this Act [the FDCA] shall be by and in the name of the United States.” 21 U.S.C. § 337(a). As the U.S. Supreme Court has explained, § 337(a) “leaves no doubt that” that the federal government has the exclusive authority to “file suit for noncompliance” with FDA regulations adopted under it. *See Buckman Co. v. Pls.’ Legal Committee*, 531 U.S. 341, 349 n.4 (2001) (finding state lawsuit preempted where premised on notion that defendant defrauded FDA in getting medical device approved).

Because the State’s new theory turns exclusively on whether Janssen violated the FDCA or FDA regulations adopted under it (without regard to whether Janssen’s statements were actually false or misleading), it is preempted. *See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (“[T]he plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*). For a state-law claim to survive, then, the claim must be premised on conduct that . . . would give rise to a recovery under state

law *even in the absence of the FDCA.*” (second emphasis added)). See also *PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (dismissing state law false advertising and deceptive trade practices claims brought on grounds that products were sold without proper FDA approval because the claims “represent[] an impermissible attempt to enforce the FDCA through a private right of action”); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994) (“violations of the FDCA do not create private rights of action”). Cf. *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 2009 U.S. Dist. LEXIS 58697, \*\*24-25 (C.D. Cal. June 17, 2009) (“[T]ruthful off-label promotion of drugs does not violate . . . state consumer protection laws. Rather, it violates the FDCA. But the law is very clear in that only the federal government, and not a private plaintiff, may enforce the FDCA.”). The State presented no evidence that the Risperdal letter or Duragesic file card are false or misleading under the standards of the CCPA. To impose liability based on alleged violations of the FDCA alone would be preempted.

**4. Both the Circuit Court’s Ruling and the State’s New Theory Violate the First Amendment.**

The State secured a judgment below – without presenting evidence that the substance of Janssen’s speech is misleading – by urging the circuit court to defer to DDMAC’s “finding” to this effect. Having now abandoned that approach, on appeal the State again seeks to evade the need to prove Janssen’s speech is misleading, this time by arguing it can punish speech made without prior approval by the government, even if the statements were made in good faith and “even if what the publications say *is assumed to be true.*” (State Br. at 43 (emphasis added).)

The law is clear, however, that statements on a matter of public concern, which can relate to “any matter of political, social or other concern of the community,” *Connick v. Meyers*, 461 U.S. 138, 146 (1983), can only be punished if the State establishes actual malice by proving the

speaker knew its statements were false or spoke with reckless disregard of the statements' falsity. (See Janssen Br. at 33-41.) Statements about the safety and efficacy of drugs and medical devices (even by commercially-interested parties) address matters of public concern. See, e.g., *TMJ Implants, Inc. v. Aetna, Inc.*, 498 F.3d 1175, 1185-86 (10th Cir. 2007) (bulletins explaining why insurers classified medical device as experimental were statements on a matter of public concern although insurers were not media defendants and bulletins concerned economic interests of insurers and their customers). There was no finding of actual malice below. Indeed, all of the evidence shows that Janssen's statements were reasonable as a matter of science and made with the good faith belief that they were true. The State offered no proof to the contrary. The First Amendment does not permit imposition of a civil penalty on this record.

There is no merit to the State's argument "the trial court's decision that the publications are inherently misleading" wiped out Janssen's First Amendment rights. (State Br. at 39.) First, nowhere in any of its opinions did the circuit court make any finding that Janssen's statements were "inherently" misleading. Second, and more important, Janssen's statements are not inherently misleading. Inherently misleading speech is a narrowly-defined class of commercial speech which is deprived of constitutional protection if it is shown to make *no* worthwhile contribution to the marketplace of ideas. *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 504 n. 22, (1984); *In re R.M.J.*, 455 U.S. 191, 203-04 (1982). And a statement is only inherently misleading if either "the particular method by which the information is imparted to consumers is inherently conducive to deception and coercion," *Peel v. Att'y Regis. & Discip. Comm'n of Ill.*, 496 U.S. 91, 112 (1990); (Marshall, J., and Brennan, J. concurring), or it is devoid of intrinsic meaning and therefore can only deceive, *Peel*, 496 U.S. at 112; *Joe Conte Toyota, Inc. v. Louisiana Motor Vehicle Commission*, 24 F.3d 754, 756 (5th Cir. 1994). The

State has no evidence to satisfy either prong here, and instead argues simply that it needs no such evidence. (See State Br. at 43.) The State is mistaken.

The arguments that Janssen's speech is inherently misleading fall into one of three categories: that a reader might assume Janssen's statements were government approved, that they might interpret the statements as making affirmative claims of product superiority, or the statements are inherently misleading merely because they are not government approved. (*Id.* at 23) As the record is devoid of evidence of what a reasonable physician would assume about or infer from the letter, established case law makes clear the State's mere allegations in this respect do not make Janssen's statements inherently misleading. In both *Ibanez v. Fla. Dep't of Bus. & Prof. Reg.*, 512 U.S. 136, 145 n. 10 (1994), and *Peel*, 496 U.S. at 101, for example, the Supreme Court conceded that someone might read the statements and infer that the certifications were government approvals, but held that this did not make them inherently misleading. Similarly, while the State contends the letter could be read as making affirmative claims of product superiority, (State Br. at 23), what it actually says is that while additional research is needed, ***there is evidence*** suggesting Risperdal does not cause diabetes or poses less of a risk of doing so than some other medications. This statement is not inherently misleading. It is not devoid of intrinsic meaning, as the cited studies contain evidence suggesting these possible conclusions. The possibility that someone ***might*** impute more meaning to a statement than it actually says makes the statement, at most, potentially misleading, not inherently misleading. *Peel*, 496 U.S. at 101; *Ibanez*, 512 U.S. at 145.

Finally, the fact that the FDA has made a decision as to what it will ***require*** be said about a subject ***on a product label*** does not mean that anything else said on that subject ***in places other than the label*** is inherently misleading. See, e.g., *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C.

Cir. 1999) (rejecting argument by FDA that any health claim it believes lacks significant scientific support is inherently misleading). If adopted, the unprecedented position advanced by the State, dictated by its desire to avoid having to prove Janssen's statements are misleading, would effectively prohibit drug companies from engaging in *any* speech about their products other than reprinting the product labels. The State has not attempted to articulate any substantial interest that would be directly advanced by the ban it advocates. Furthermore, the only interest the State has ever suggested is advanced is that of protecting consumers from false and misleading statements. (See State Br. at 37-44.) Given that the State's proposed ban would prohibit even statements that are "assumed to be true" (*id.* at 43), the sweeping prohibition the State now urges is far broader than reasonably necessary to address that interest. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980) (State must show regulation of commercial speech is no more restrictive than reasonably necessary to directly advance a substantial state interest).

The State's argument, that any statement about a pharmaceutical that goes beyond the four corners of its FDA-approved label is inherently misleading as a matter of law without regard to its truthfulness, rests on the assumption that the public cannot be trusted to evaluate information from any source other than the FDA. In *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (drug compounding services), *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (alcohol price advertising), and *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (alcohol strength advertising), the Court struck down laws that, without regard to truthfulness, banned advertising on certain subjects due, in whole or part, to concerns that consumers might misuse that information. In striking down all three bans, the Court made clear that "[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of

its misuse if it is freely available, that the First Amendment makes for us.” *Thompson*, 535 U.S. at 375, (quoting *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)). If anything, the position the State advances here is more infirm than the bans invalidated in decisions such as *Thompson*, which were limited to advertisements. Here, the standard proposed not only embraces advertising, but extends to *any* speech by pharmaceutical companies about their products, even presenting data at scientific conventions. It is patently overbroad, and would violate the First Amendment.

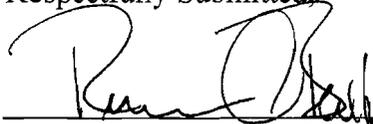
### CONCLUSION

For these reasons and those set forth in Janssen’s opening brief, the Court should reverse the circuit court’s judgment and remand.

July 6, 2010

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Respectfully Submitted,



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## CERTIFICATE OF SERVICE

I, Rebecca A. Betts, counsel for defendants-appellants Johnson & Johnson and Janssen Pharmaceutica Products, L.P., hereby certify that service of the **Appellants' Reply Brief** was made upon counsel for plaintiff-appellee on July 6, 2010, by depositing a true copy in the United States mail, addressed as follows:

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