2012 WL 1449053 (Ark.Cir.) (Trial Motion, Memorandum and Affidavit)
Circuit Court of Arkansas.
Sixth Division
Pulaski County

STATE OF ARKANSAS, Ex Rel. Dustin Mcdaniel, Attorney General, Plaintiff
v.
Ortho-Mcneil-JANSSEN Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutics Inc., and/or Janssen, LP and Johnson & Johnson, Inc., Defendants

No. CV07-15345.
April 3, 2012.

Brief in Support of Defendants' Motion for Directed Verdict

Defendants Ortho-McNeil-Janssen Pharmaceuticals, Inc. [1] ("Janssen") and Johnson & Johnson (erroneously named as Johnson & Johnson, Inc.) (collectively, "Defendants"), by and through their attorneys, hereby submit this brief in support of their Motion for Directed Verdict.

I. SUMMARY OF ARGUMENT

Plaintiff, the State of Arkansas (the "State"), has asserted two claims against Defendants. For its first, the State claims Defendants violated the Arkansas Medicaid Fraud False Claims Act ("MFFCA"), A.C.A. §§ 20-77-901 to-911, by distributing an FDA-approved package insert, or product label, for Risperdal® (the "Risperdal package insert" or the "package insert") because certain disclosures in the package insert were misplaced or "inadequate." For the second, the State claims that Defendants violated the Arkansas Deceptive Trade Practices Act ("DTPA"), A.C.A. §§ 4-88-101 to-115, when Janssen delivered or mailed a November 10, 2003 letter to certain Arkansas healthcare professionals (the "November 2003 mailing").

II. THE STATE'S EVIDENCE

A. As to the November 2003 mailing.

The State's expert, Dr. William Wirshing, testified that every statement in the November 2003 letter was true. On re-direct examination, however, he testified that although the statements in the November 2003 letter were true, one sentence in the letter now strikes him as misleading. He explained that the sentence, which refers to a "body of evidence from published peer-reviewed epidemiology research [1-8] ," suggested that (1) every one of the referenced citations supported the statements about the risk of hyperglycemia and diabetes made in the letter; and (2) the referenced citations constituted all available data addressing the risk of hyperglycemia and diabetes, and that no other data or evidence existed. Dr. Wirshing did not offer any opinion about whether other healthcare professionals would reach the same conclusion; in fact, he conceded that others might well disagree with him. He did not attempt to buttress his impression by saying that it was an "opinion" or that it was rendered with any degree of "certainty."

Dr. Wirshing also testified about whether the statement he considered to be misleading was made "knowingly." He testified that he knew Dr. Ramy Mahmoud, whom he described as a very capable and well-qualified epidemiologist. Dr Wirshing then expressed his opinion that Dr. Mahmoud believed that all of the statements in the letter were true.

With respect to RIS-USA-113, Dr. Wirshing testified that the results of 113 — a single study — did not support the statements in the letter. He also testified, however, that the body of scientific literature identified as the basis for the statements in the letter did, in fact, support the statements. And he testified that Risperdal in fact causes less weight gain — substantially less weight gain — than most of the other second generation antipsychotics then on the market, including Zyprexa, Clozaril, and Seroquel. Even after his review of the topline and "final" results of 113, Dr. Wirshing's opinion about the differences in risk between Risperdal and other drugs remained the same. In other words, 113 did not change his opinion about Risperdal's association with weight gain and related metabolic side effects.

B. As to the Risperdal Package Insert.

Dr. Wirshing and Dr. Laura Plunkett testified that certain statements in the package insert concerning risks associated with Risperdal should have been moved to different parts of the package insert and that one of those statements should have been worded somewhat differently. In particular, Dr. Wirshing testified that statements about cerebrovascular risks, hyperprolactinemia, and metabolic risks — all of which appeared in the package inserts before November 2002 — should have been moved to the "Warnings" section of the package insert. But Dr. Wirshing also testified that every statement in every package insert was truthful, that Janssen submitted every package insert to the FDA, and that the FDA approved each package insert. He acknowledged that the placement of risk information is something that pharmaceutical manufacturers discuss with the FDA.

1. Cerebrovascular risks in the elderly with dementia.

Information about cerebrovascular risks in **elderly** patients with dementia was included in the Postintroduction Reports section of the Risperdal package insert prior to November 2002. Additional information was added to the Warnings section of the package insert in March 2003. Dr. Wirshing testified that Janssen first received data that contained a safety "signal" in 1997 or 1999, in the results from trial RIS-USA-63. Dr. Wirshing testified that the March 2003 warning was predicated on the results of RIS-USA-63, that Janssen had submitted the full results of RIS-USA-63 to the FDA, and that Janssen and the FDA engaged in a back-and-forth discussion about appropriate changes to the package insert. Further, Dr. Wirshing testified that Janssen informed doctors about these risks well before information was added to the Warnings section in March 2003. Indeed, Dr. Wirshing testified that he spoke to doctors about such risks on behalf of Janssen.

2. Hyperprolactinemia.

The Risperdal package insert has always included information about hyperprolactinemia, which was set forth in the Precautions section. Dr. Wirshing testified that the information in the package insert about hyperprolactinemia was true. Nevertheless, Dr. Wirshing testified that, in his opinion, the package insert was inadequate because: (l)the discussion about hyperprolactinemia should have been in the Warnings section of the package insert, not the Precautions section; and (2) the package insert did not explicitly state that Risperdal caused greater prolactin elevation than other antipsychotics. [2] But he also testified that Janssen never denied that Risperdal causes greater prolactin elevation than other antipsychotics. Moreover, Dr. Wirshing testified that Risperdal's association with hyperprolactinemia and its related side effects were known to healthcare providers, and that the available data about Risperdal and hyperprolactinemia were known to the FDA. Finally, Dr. Wirshing testified that the FDA later decided to combine the Warnings and Precautions sections into one section — "Warnings and Precautions" — because healthcare professionals did not find the distinction between the two sections to be meaningful. Indeed, he acknowledged that he and other healthcare professionals reviewed both the Warnings and Precautions sections of the package insert.

3. Metabolic risks.

Dr. Wirshing acknowledged that information about metabolic risks — weight gain, hyperglycemia, and diabetes — was included in the Adverse Reactions and Postintroduction Reports sections of the package insert prior to November 2002.[3] Additional information about these risks was added to the package insert in October 2003, pursuant to the FDA's request for a class warning. Dr. Wirshing's only criticism was that such information was not included in the Warnings section before October 2003. He testified that the weight gain associated with Risperdal — a gain of six pounds over the first eight or ten weeks that then plateaus — is much less than the weight gain associated with other second generation antipsychotics ("SGAs") such as Zyprexa[4] or Clozaril. And, unlike other SGAs that have direct diabetogenic effects, Risperdal's propensity to cause diabetes is almost entirely the result of an increase in risk associated with gaining weight. In other words, Risperdal has a primary effect on weight gain, and that weight gain represents the mechanism of action by which the medicine is then associated with an increased risk of diabetes. Even after considering the results of RIS-USA-113, Dr. Wirshing opined that Risperdal causes substantially less weight gain than Zyprexa, Clozaril, and Seroquel.

Dr. Plunkett also offered her opinion that the Risperdal package insert should have included a "warning" about the risk of diabetes. Dr. Plunkett did not provide any analysis or reasoning to support her conclusion. She also did not offer this opinion to a reasonable degree of scientific certainty.

Both Dr. Wirshing and Dr. Plunkett testified that they disagreed with the FDA's October 2003 "class warning" because they believed that the warning should have included information specific to each drug and its differential risk. And both experts ranked the most commonly used SGAs, testifying that Risperdal causes much less weight gain than Zyprexa, Clozaril, and Seroquel.

III. APPLICABLE STANDARD

A motion for a directed verdict must be granted when there is no substantial evidence to support a jury verdict. *Pope v. Overton*, 2011 Ark. 11, at 3,__ S.W.3d__. Substantial evidence is evidence "of sufficient force and character to compel a conclusion one way or the other with reasonable certainty," without resorting to "suspicion or conjecture." *Schubert v. Target Stores, Inc.*, 2010 Ark. 466, at 3,__S.W.3d__(internal citation omitted). Where the evidence does not enable fair-minded persons to reach different conclusions, a jury question is not presented, and a directed verdict must be granted. *Pope*, 2011 Ark. 11, at 3; *see also Minor v. Chase Auto Fin. Corp.*, 2010 Ark. App. 670, at 3.

IV. ARGUMENT

A. Defendants Are Entitled to a Directed Verdict on the State's MFFCA Claim.

Defendants are entitled to a directed verdict on the State's MFFCA claim because it is (1) preempted by federal law; (2) not supported by any evidence, let alone substantial evidence; and (3) barred by the statute of limitations.

1. The State's MFFCA claim is preempted by federal law.

The State's expert, Dr. Wirshing, conceded that there was no false statement in the Risperdal package insert. He took issue, however, with the wording of one of the discussions of Risperdal's risks, and with the placement of the different risk disclosures within the package insert. For example, he contended that the discussion of hyperprolactinemia risks should have contained additional information and should have been placed in the "Warnings" section, rather than in "Precautions." The State's "package insert" claim, then, is not really about "false statements," but about compliance with federal prescription drug labeling law.

But only the federal government — the FDA and the Department of Justice — may enforce that federal law. *See* 21 U.S.C. § 337(a) ("[P]roceedings for the enforcement, or to restrain violations, of this chapter [of the FDCA] shall be by and in the name of the United States."); *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 726 n.14 (D. Md. 2006)

("The [FDA] has enforcement power over false and misleading labels. 21 U.S.C. § 352. To the extent that Plaintiff relies solely on the false label argument to find a Lanham Act violation ... such a claim is essentially a mislabeling claim, which is within the jurisdiction of the FDA and thus would be precluded."). The U.S. Supreme Court has explained that Section 337(a) "leaves no doubt that" the federal government has the exclusive authority to "file suit for noncompliance" with the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001); *see also Mut. Pharm. Co. v. Watson Pharm., Inc.*, No. CV 09-5700, slip op. 2009 WL 3401117, at *5 (CD. Cal. Oct. 19, 2009) (unpublished) ("Plaintiffs' contentions concerning the product labels and inserts are even weaker, both because the evidence of confusion is weaker and because disputes concerning the content of those labels and inserts falls even more squarely within the primary jurisdiction of the FDA.").

Section 337(a) preemption aside, to the extent the State's MFFCA claim is based on the contention that Janssen misrepresented or withheld information from the FDA, that claim also is preempted by federal law. *Buckman Co.*, 531 U.S. at 348 ("Given this analytical framework, we hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law."); *see also id.* at 347 ("Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied."' (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))). As it turns out, the State's claim is largely a claim about "withholding" from the FDA the topline results of RIS-USA-113 and the preliminary report from ERI.

Finally, the State's effort to penalize the use of the FDA-approved package insert is an obstacle to the achievement of one of the principal objectives of federal drug labeling law — the effective and uniform regulation of prescription drug labeling nationwide. [5] It is therefore barred by the doctrine of "obstacle" preemption. *25 Residents of Sevier Cnty. v. Ark. Highway & Transp. Comm* % 330 Ark. 396, 399-400, 954 S.W.2d 242, 243 (1997) (recognizing that conflict preemption operates "where state law stands as an obstacle to the accomplishment of the full purposes and objectives of a federal statute"); *see also AT&T Mobility LLC v. Concepcion*,__ U.S. _, 131 S. Ct. 1740, 1753 (2011) (recognizing that state law is preempted by federal law when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

In this action, the Arkansas Attorney General argues that the FDA-approved Risperdal package insert should have had more or different warnings regarding certain of the side effects that may be associated with Risperdal treatment, or that the package insert should have displayed some of these warnings more prominently, in a different section of the package insert. There may well be state attorneys general and juries in other states with different views about the warnings that should have appeared in the Risperdal package insert, or about the placement of those warnings within the package insert. The imposition of different labeling requirements in different states, enforced by the imposition of massive penalties, however, is entirely inconsistent with the congressional purpose of ensuring nationwide uniformity. *See, e.g., Lofton v. McNeil Consumer & Specialty Pharms.*, _ F.3d _, No. 10-10956, 2012 WL 579772, at *8 (5th Cir. Feb. 22, 2012) ("allowing] the state court[s] to interject varying views on what disclosures are sufficient" would interfere with the FDA's regulation of labels and potentially result in "over-disclosure problems"). [6]

When Defendants made the "obstacle preemption" argument earlier, the State based its opposition, in substantial part, on *Wyeth v. Levine*, 555 U.S. 555 (2009). There is nothing in *Wyeth*, however, that suggests the State's claim here would not be preempted. In *Wyeth*, the plaintiff received a direct injection of an anti-nausea medication that resulted in gangrene and the eventual amputation of her arm. She sued Wyeth, claiming it knew but failed to warn that this method of administering the medicine was more dangerous than other methods. The U.S. Supreme Court first rejected Wyeth's "impossibility" preemption defense, concluding it was possible for Wyeth to comply with the FDA's regulation and with the demands of the state tort suit because Wyeth could have proactively strengthened its label and sought the FDA's approval after the fact. *Id.* at 573. The Court then held that under the specific facts presented in *Wyeth*, individual personal injury product liability suits like Ms. Levine's did not obstruct the purposes and objectives of federal drug labeling regulations. *See id.* at 581 ("In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling.").

There is, however, a vast difference between the obstructive impact of individual personal injury actions, such as the *Wyeth* action, and actions, such as this one, brought by a state attorney general challenging the use, in his state, of an FDA-approved

package insert. *Wyeth* did not hold that attempts by state attorneys general to penalize pharmaceutical manufacturers for the use of an FDA-approved package insert would not be preempted. Indeed, the *Wyeth* court specifically "recognize[d] that some state-law claims might well frustrate the achievement of congressional objectives." *Id.* at 581. Moreover, when concluding that Ms. Levine's state-law tort claim was not preempted, the *Wyeth* court relied on the fact that Congress was familiar with state-law personal injury actions, but did not expressly preempt them when amending the FDCA. *See id.* at 574-75. There is, however, no similar indication that Congress meant to allow state attorneys general to require that package inserts approved by the FDA be modified before they are used in their states, or to seek enormous penalties for a manufacturer's use of an FDA-approved package insert. Until very recently, no state had attempted to do what Arkansas tries to do here. In short, federal preemption of a suit brought by a state seeking to engage in "regulation by penalization" is neither considered nor controlled by *Wyeth*.

It could not be clearer that the State's MFFCA claim is preempted by federal law.

2. The State failed to introduce evidence, let alone substantial evidence, of each element of its MFFCA claim.

The State's MFFCA claim is based on the alleged violation of a single provision of that statute which imposes liability on a person who "[k]nowingly makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact ... [w]ith respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements." A.C.A. § 20-77-902(8)(B). As the plain text of the statute makes clear, to prove its claim, the State must establish (1) a false statement or representation (2) knowingly made by Defendants (3) as to "information required" for the Arkansas Medicaid program (4) that was material to the Arkansas Medicaid program. Defendants are entitled to a directed verdict on the State's MFFCA claim because the State did not present any evidence, let alone substantial evidence, to meet its burden on each element of the claim.

a. There is no evidence Defendants made a false representation.

The State presented no evidence that Janssen made a false representation in the Risperdal package insert. In fact, the State's expert, Dr. Wirshing, testified that not a single page of the Risperdal package insert contained a "lie" or anything he believed to be "false." He simply disagreed with the placement within the package insert of such truthful information — and, in the case of hyperprolactinemia, with the failure to add a statement about the differences among medicines. In addition, the State presented no evidence from which a jury could conclude that Arkansas Medicaid ever even received a copy of the Risperdal package insert.

The State has not even established that the challenged parts of the Risperdal package insert were false "statement[s]." Rather, the evidence shows that the statements about diabetes, weight gain, hyperprolactinemia, and other side effects on which the State's MFFCA claim rests were based on extensive medical research and information as to the use of Risperdal for over a decade. Opinions that are based on scientific evidence cannot amount to false representations. *See, e.g.*, *Moore v. Keith Smith Co.*, 2009 Ark. App. 361, at 9 (affirming the entry of summary judgment on a claim for fraud because "the alleged misrepresentation was an expression of opinion"); *McDonagh v. Bergan*, No. 03 C-146, 2003 WL 21798735, at *3 (N.D. 111. July 25, 2003) ("The alleged statements are not capable of being proven true or false .... [D]isagreements of this type amongst medical professionals should be settled by discussion and research in the medical community, not by the courts."). [7]

b. There is no evidence Defendants acted "knowingly."

Even if there was evidence of a false statement or misrepresentation by Defendants, there is no evidence that it was "knowingly" made. "'[K]nowingly' means that the person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information." A.C.A. § 20-77-901(4). The State has not introduced any evidence that Defendants made any representations with knowledge that they were false or with reckless disregard of their truth or falsity. Notably, neither of the State's experts testified that RIS-USA-113 or ERI rendered any statement in the package insert "false."

c. There is no evidence Defendants' alleged false representation or misrepresentation related to "information required" by Arkansas Medicaid.

Likewise, the State did not present any evidence that establishes that Janssen made false representations to Arkansas Medicaid as to "information required" by the Medicaid program. Ms. Ford testified that the only condition for a pharmaceutical manufacturer to participate in the Arkansas Medicaid program is to obtain FDA approval for the prescription drug and to execute a federal rebate agreement. *See* 42 U.S.C. § 1396r-8(a) (requirement for rebate agreement); *see also Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003) ("[Medicaid] impose[s] a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements either with the Secretary or, if authorized by the Secretary, with individual States, to provide rebates on their Medicaid sales of outpatient prescription drugs."); *Iowa Dep't of Human Servs. v. Ctrs. for Medicare & Medicaid Servs.*, 576 F.3d 885, 886 (8th Cir. 2009) ("The [Medicaid] program requires drug manufacturers to enter into rebate agreements with the Secretary in order for their drugs to be eligible for Medicaid reimbursement."). And there was no testimony that Defendants were ever in violation of these requirements. Significantly, there is no evidence that the State requires submission of the package insert. Simply put, while its MFFCA claim is premised on alleged misrepresentations in the Risperdal package insert, the State failed to present any evidence that the Risperdal package insert constitutes "information required" to be submitted to Arkansas Medicaid. The State has, therefore, failed to satisfy the second element of its MFFCA claim.

d. There is no evidence that Defendants' alleged false statements or misrepresentations were material.

Not only did the State fail to present any evidence that the challenged statements in the Risperdal package insert were material to a single coverage or payment decision of the Arkansas Medicaid program, the evidence unequivocally established that they were entirely immaterial. The MFFCA plainly states that any alleged misrepresentation by a defendant must be "material" to Arkansas Medicaid. A.C.A. § 20-77-902(8)(B).

Arkansas courts have defined materiality in similar contexts of alleged fraud and misrepresentation as follows:

To prove materiality of a misrepresentation, it is only necessary to show the misrepresented fact was a material influence on the decision; it must have been a substantial factor, but it is not necessary that it was the paramount or decisive inducement.

S. Equip. & Tractor Co. v. K&K Mines, Inc., 272 Ark. 278, 279-80, 613 S.W.2d 596, 597 (1981). Materiality thus is something of sufficient importance to alter the conduct or decision of another. *See, e.g.*, *Kessler v. Nat'I Enters., Inc.*, 238 F.3d 1006, 1015 (8th Cir. 2001) (applying Arkansas law) (plaintiffs would not have purchased time-share interest if they had known it did not come with hotel amenities and parking); *Nicholson v. Simmons First Nat'I Corp.*, 312 Ark. 291, 297, 849 S.W.2d 483, 487 (1993) ("[Plaintiff] offered no proof on how [Defendants'] false statements in any way impaired his contract rights or decisions in this matter.").

The State failed to introduce any evidence that Arkansas received or considered information in the Risperdal package insert. Pamela Ford, a state employee from the Medicaid Pharmacy Program, testified generally that the Pharmacy Program typically reviews warnings and contraindications in package inserts and considers whether to develop educational materials for Arkansas physicians. But Ms. Ford did not provide any testimony that was specific to the Risperdal package insert. She did not say, for example, whether the Arkansas Medicaid Pharmacy Program sent any "educational" letters after "warnings" were added to the Risperdal package insert in March and October 2003. Indeed, the State offered no evidence whatsoever about any use, by Medicaid, of a Risperdal package insert. The State offered no evidence that Risperdal package inserts were ever reviewed or considered in connection with any decision, at any time, about coverage or payment for the medicine. In fact, Ms. Ford conceded that the entire "Janssen" file at Arkansas Medicaid consisted of two letters received in 2009, related to pricing. *See, e.g.*, *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2010 WL 2649513 (E.D. La. June 29, 2010); *In re Rezulin Prods. Liab. Litig.*, 524 F. Supp. 2d 436 (S.D.N.Y. 2007).

In addition, Dr. Wirshing, testified that the package insert is not the only piece of information considered by a prescribing physician. According to Dr. Wirshing, prescribing based solely on the information contained in the package insert does not constitute "best practices." Further, Dr. Wirshing testified that healthcare professionals who prescribed antipsychotics should have been aware, prior to 2002, that Risperdal was associated with the risks complained of here. Indeed, the State of Arkansas undertook an independent program to review the use of antipsychotics to treat **elderly** patients. That program, referred to as the Medicaid Medication Management Project (the "M3 Project"), included an educational component that informed healthcare providers about a number of risks associated with Risperdal, including several of the risks at issue here. The State offered no proof that the issues about which it complains — the placement and the wording of certain risk disclosures — were material to Arkansas prescribers, given their multiple sources of information and preexisting knowledge about the side effects of the medicine.

There is no evidence, and clearly no substantial evidence, that the Risperdal package insert, or the "warnings" in particular, was material in any respect to a single action or decision by Arkansas Medicaid. The State failed to introduce any evidence that Arkansas Medicaid received or considered the Risperdal package insert. Further, the fact that Arkansas Medicaid was independently and fully aware of Risperdal's side effects, but repeatedly decided not to subject Risperdal to a prior authorization requirement, is fatal to the State's MFFCA claim.

3. The State's entire MFFCA claim is barred by the statute of limitations.

An MFFCA claim must be filed no more than five years after the date on which the alleged violation is committed. A.C.A. § 20-77-908(b). The State's expert, Dr. Wirshing, testified that "warnings" about metabolic risks and hyperprolactinemia should have been included in the very first label, in 1994, and that a "warning" about the risk of cerebrovascular adverse events ("CVAE") and increased mortality should have been added to the label in 1997 or 1999. The statute of limitations thus began to run on the State's MFFCA claim when the initial Risperdal package insert was disseminated in 1994 or when the CVAE "warning" should have been added in 1997 or 1999. Because the alleged violation occurred more than five years prior to the initiation of this action, the State's entire MFFCA claim is time barred.

Although the package insert was used from 1994 through the initiation of this action in 2007, the State's MFFCA claim is based on the same alleged inadequacies throughout the entire period.[8] The State's MFFCA claim thus is time barred in its entirety because Arkansas does not recognize a "continuing violation" exception to the bar of the statute of limitations. *See, e.g., Gunn v. Farmers Ins. Exch.*, 2010 Ark. 434, at 9, ___ S.W.3d___ ("This court does not recognize a continuing tort theory. Because all of the actions which form the essence of her complaint occurred more than three years prior to the filing of her complaint, [plaintiff's] tortious interference claim against [defendant] is time barred." (citation omitted)); *Chalmers v. Toyota Motor Sales, USA, Inc.*, 326 Ark. 895, 906, 935 S.W.2d 258, 264 (1996) ("[W]e have specifically rejected the continuing-tort theory of tolling the statute of limitations as inconsistent with the General Assembly's intent in stating that limitations begin to run at 'the date of the wrongful act complained of and no other time.' As the evidence clearly shows, the wrongful acts which the [plaintiffs] complain of began in the early to mid 1980s." (citations omitted)).

For instance, the Arkansas Supreme Court has held that the continued use of misappropriated trade secrets does not give rise to a new cause of action with a new time of accrual for each successive infraction. *Quality Optical of Jonesboro, Inc. v. Trusty Optical, LLC*, 365 Ark. 106, 110, 225 S.W.3d 369, 372 (2006) ("[Appellant's argument rests on a 'continuing tort' theory. Appellant argues that a new statute of limitations time period should commence with each successive infraction. This is not the law."); *see also Williams v. Edmondson*, 257 Ark. 837, 848-49, 520 S.W.2d 260, 267 (1975) ("The continuing tort theory best addresses itself to the General Assembly who has the responsibility for establishing the public policy on that issue."). In addition to the case law, the fact that the MFFCA specifies that a claim may be brought no later than five years after the alleged violation occurred, A.C.A. § 20-77-908(b), but does not contain a "continuing violation" provision allowing the State to recover on an otherwise time-barred claim, is compelling evidence that the State may not recover under such circumstances.

Because the State's MFFCA claim is based on the exact same alleged inadequacies in the 1994-1999 Risperdal package inserts, and Arkansas does not recognize the "continuing tort" theory, the entire MFFCA claim is barred by the statute of limitations.

B. Defendants Are Entitled to a Directed Verdict on the State's DTPA Claim.

Defendants are entitled to a directed verdict on the State's DTPA claim because it is (1) not supported by any evidence, let alone substantial evidence; (2) preempted by federal law; and (3) barred by the statute of limitations.

1. The State failed to introduce evidence, let alone substantial evidence, of each element of its DTPA claim.

To prevail on its DTPA claim, the State must prove (1) Defendants used deception, fraud, or false pretense in connection with the sale or advertisement of Risperdal and (2) that such deception, fraud, or false pretense was material. A.C.A. § 4-88-108(1). To meet the first element, the State may show either (1) that Defendants "[k]nowingly [made] a false representation as to the characteristics" or "benefits ... of goods or services or as to whether goods are ... of a particular standard, quality, grade, style or model," *id.* § 4-88-107(a)(l), or (2) that Defendants engaged in an unconscionable, false, or deceptive trade practice in connection with the November 2003 mailing, *id.* § 4-88-107(a)(10).[9] An unconscionable, false, or deceptive trade practice is one that actually deceives or is likely to deceive the intended audience.[10] *See FTC v. Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003) (To establish liability for a deceptive trade practice, "the FTC must establish that (1) there was a representation; (2) the representation was likely to mislead customers acting reasonably under the circumstances; and (3) the representation was material." (citations omitted)); *see also Curtis Lumber Co. v. La. Pac. Corp.*, 618 F.3d 762, 779 (8th Cir. 2010) (relying on cases discussing the FTCA to interpret the DTPA and observing that "many courts have defined trade practices as deceptive if they are likely to deceive or have a capacity to deceive a reasonable consumer"); *Forever Green Athletic Fields*, 2011 Ark. App. 347, at 18,__S.W.3d__(noting that one element of a claim under the DTPA is a "deceptive consumer-oriented act or practice which is misleading in a *material* respect" (emphasis added)). Janssen is entitled to a directed verdict on the State's DTPA claim because the State failed to present sufficient evidence to meet its evidentiary burden on each element of its claim.

a. There is no evidence to support the existence of an actionable representation.

The State did not introduce any evidence of a false statement or misrepresentation by Defendants. The kinds of statements contained in the November 2003 letter — statements about what is suggested by the still-incomplete scientific literature — are not actionable representations.

The evidence and the plain language of the November 2003 mailing show that Janssen expressed its opinion as to the conclusions that could be drawn from the then-published peer-reviewed epidemiological literature, all of which Janssen identified in the November 2003 mailing. Indeed, Janssen's disclosure of the sources upon which its opinion was based-enabling any reader of the November 2003 letter to draw his or her own conclusions — coupled with its inclusion in the mailing of the revised Risperdal package insert and its statement that "confirmatory research is still needed," plainly show that Janssen's explanation of Risperdal's association with diabetes constituted Janssen's judgment as to the significance of the scientific evidence it had identified.

Opinions that are based on scientific evidence cannot amount to false representations. *See, e.g.*, *Moore*, 2009 Ark. App. 361, at 9 (affirming the entry of summary judgment on a claim for fraud because "the alleged misrepresentation was an expression of opinion"); *McDonagh*, 2003 WL 21798735, at *3 ("The alleged statements are not capable of being proven true or false .... [D]isagreements of this type amongst medical professionals should be settled by discussion and research in the medical community, not by the courts."); *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 496 (5th Cir. 2000) (holding, under analogous Lanham Act, 15 U.S.C.A. § 1125(a): "Bald assertions of superiority or general statements of opinion cannot form

the basis of Lanham Act liability. Rather the statements at issue must be a 'specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact."' (citations omitted)).

In addition, the State's expert, Dr. Wirshing, testified that the statements in the November 2003 letter were true. He acknowledged that the letter (1) implied that additional research was still needed to address the issue, (2) did not suggest that every article ever written was cited, and (3) listed all of the published, peer-reviewed epidemiological studies available at the time. There was no "false" statement.

b. There is no evidence to support a finding that Defendants acted "knowingly."

A person acts "knowingly" when he or she has actual knowledge of the falsity or acts in deliberate ignorance or reckless disregard of the truth or falsity of the challenged statement. *See, e.g.*, A.C.A. § 20-77-901(4). The State's expert, Dr. Wirshing, agreed that Dr. Mahmoud, the Janssen epidemiologist who signed the letter, was very capable and very well qualified. And Dr. Wirshing testified that, in Dr. Wirshing's opinion, Dr. Mahmoud believed that the statements made in the November 2003 letter were true. No reasonable jury could conclude in the face of this testimony from the State's expert witness that Defendants "knowingly" made deceptive statements in the letter.

c. There is no evidence that the November 2003 mailing actually deceived or was likely to deceive Arkansas physicians.

To prevail on its DTPA claim, the State must show that the November 2003 mailing actually deceived or was likely to deceive its intended audience. *Forever Green Athletic Fields, Inc.*, 2011 Ark. App. 347, at 18 (stating that a DTPA claim requires "a deceptive consumer-oriented act or practice"); *see also Curtis Lumber Co.*, 618 F.3d at 779 ("Along the lines of the Federal Trade Commission's definition of deception, many courts have defined trade practices as deceptive if they are likely to deceive or have a capacity to deceive a reasonable consumer." (citations omitted)). To determine whether the challenged conduct satisfies this standard, courts have looked to guidelines published by the Federal Trade Commission ("FTC"), as the DTPA is based on the FTC Act. *See Curtis Lumber*, 618 F.3d at 779 ("Because 'deceptive act or practice' is not defined in any Arkansas statute, regulation, or opinion, we look elsewhere. Arkansas is one of many states that enacted a deceptive and unfair trade practices act, or a 'little FTC act,' in the 1960s or 1970s") (applying Arkansas law). In particular, the FTC Policy Statement on Deception states that "a practice or representation directed to a well-educated group, such as a prescription drug advertisement to doctors, would be judged in light of the knowledge and sophistication of that group." FTC Policy Statement on Deception at 2 (Oct. 14, 1983). The relevant audience for the State's DTPA claim is Arkansas physicians and healthcare prescribers because the November 2003 mailing was addressed and sent only to physicians.

The State was thus required to present evidence that the November 2003 mailing actually deceived or was likely to deceive Arkansas physicians — a burden that it has failed to satisfy. The State did not present any evidence about the knowledge or sophistication of Arkansas physicians, nor did it present any facts that demonstrate that the mailing, with its disclosure of the supporting scientific literature, actually deceived or was likely to deceive physicians. *See, e.g.*, *Cytyc Corp.*, 12 F. Supp. 2d at 300 ("In the actual statement, contained in a press release, Cytyc identified the specific screening site, and the numbers of positive cases diagnosed with the pap smear and with ThinPrep. The inclusion of such specific evidence means that this statement could not be found to be misleading.").

d. Lack of evidence of materiality.

To prevail on its DTPA claim, the State must prove that the November 2003 mailing was material to Arkansas physicians and other healthcare professionals. *Forever Green Athletic Fields*, 2011 Ark. App. 347, at 18 (noting that one element of a claim under the DTPA is a "deceptive consumer-oriented act or practice which is misleading in a *material* respect" (emphasis added)); *see also* A.C.A. § 4-88-108(2) (liability may be imposed in certain instances for "[t]he concealment, suppression, or

omission of any *material* fact with intent that others rely upon the concealment, suppression, or omission" (emphasis added)); FTC Policy Statement on Deception at 2 (Oct. 14, 1983) ("[T]he representation, omission, or practice must be a 'material' one. The basic question is whether the act or practice is likely to affect the consumer's conduct or decision with regard to a product or service."); *Tashman*, 318 F.3d at 1277 (To establish liability for a deceptive trade practice, "the FTC must establish that (1) there was a representation; (2) the representation was likely to mislead customers acting reasonably under the circumstances; and (3) the representation was material." (citations omitted)). The DTPA does not define materiality, but the FTC stated in its 1983 Policy Statement on Deception that a material claim is one that is "likely to affect" a party's "conduct or decision with regard to a product or service." FTC Policy Statement on Deception at 2 (Oct. 14, 1983). In the analogous context of common law fraud, which requires a showing of "a false representation of a material fact," *Nicholson*, 312 Ark. at 296, 849 S.W.2d at 486, the Supreme Court of Arkansas has explained that to prove materiality of a misrepresentation, one must "show the misrepresented fact was a material influence on the decision; it must have been a substantial factor, but it is not necessary that it was the paramount or decisive inducement," *Southern Equipment & Tractor Co.*, 272 Ark. at 280, 613 S.W.2d at 597. The case law confirms that materiality is something of substantial importance to change the conduct of another. *See, e.g.*, *Kessler v. Nat'I Enters., Inc.*, 238 F.3d 1006 (8th Cir. 2001) (applying Arkansas law) (plaintiffs would not have purchased time-share interest if they had known it did not come with hotel amenities and parking); *Nicholson*, 312 Ark. at 297, 849 S.W.2d at 487 ("[Plaintiff] offered no proof on how [Defendants'] false statements in any way impaired his contract rights or decisions in this matter.").

The State has failed to present any evidence that the November 2003 mailing was material to physicians or even impacted physicians' conduct in any way. It has not identified even one Risperdal prescriber who would have changed his or her prescribing decision if the November 2003 mailing had not contained the challenged statements about Risperdal's association with diabetes. Without any evidence to the contrary, the November 2003 letter cannot be found "material" to Arkansas healthcare professionals.

2. The State's DTPA claim is preempted by federal law.

The State's DTPA claim rests on the April 2004 warning letter's characterization of the November 2003 mailing as "false or misleading in violation of Sections 502(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act," Trial Ex. P822, and certain inferences drawn by Dr. Wirshing from one sentence in the November 2003 letter.

Dr. Wirshing, after first admitting the statements in the letter were not false — that they were supported by the science to which the November 2003 letter cited — said, on re-direct, that one sentence in the letter was "misleading." In particular, he said that he read the November 2003 letter to say that (1) all eight of the studies to which the letter cited supported all of the statements in the letter and (2) there was no evidence other than the eight published peer-reviewed epidemiological studies about the metabolic effects of antipsychotics. There is, however, no way to read the letter the way Dr. Wirshing now claims to read it. The letter indicates that support for its statements can be found in the eight studies to which it cites — but it most certainly does not say that each and every study supports the statements in the letter. And the letter clearly refers only to "published peer-reviewed epidemiological studies."

The State is left, then, with the 2004 DDMAC letter. The State relies primarily on the words "false or misleading" in the April 2004 DDMAC letter, ignoring its statement that its conclusion was based on federal law and federal standards. The federal standards, however, are different from Arkansas DTPA standards — and the conclusions in the DDMAC letter with respect to federal standards are not probative of violations of the DTPA.

Moreover, any claim based on the conclusions in the 2004 warning letter is preempted/barred by federal law. As explained above, regardless of the name placed on it by the plaintiff, a claim for alleged violations of the FDCA, such as the one here, is expressly precluded by federal law. *See* 21 U.S.C. § 337(a) ("[P]roceedings for the enforcement, or to restrain violations, of this chapter [of the FDCA] shall be by and in the name of the United States."). The FDA's preliminary conclusion that the November 2003 letter was "false or misleading" was made in the context of the FDCA, not the DTPA, and was based on a comparison of the statements in the letter to the language of the FDA-approved Risperdal package insert and the FDA's interpretation of

its labeling regulations. The FDA is the lone governmental entity empowered to take action with respect to the determination communicated in the subject warning letter. *See, e.g.*, *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 726 n.14 (D. Md. 2006) ("The [FDA] has enforcement power over false and misleading labels. 21 U.S.C. § 352. To the extent that Plaintiff relies solely on the false label argument to find a Lanham Act violation ... such a claim is essentially a mislabeling claim, which is within the jurisdiction of the FDA and thus would be precluded."). [11]

3. The State's DTPA claim is barred by the statute of limitations.

A claim for violation of the DTPA must be filed no more than five years after the date on which the alleged violation is committed. A.C.A. § 4-88-115. The State's DTPA claim is based on the dissemination of the November 2003 mailing and the presentation sales calls that occurred during the period from November 10, 2003 to July 21, 2004. Although the State's DTPA claim was based on alleged violations that occurred no later than July 21, 2004, the State did not raise a claim arising from the November 2003 mailing or the presentation sales calls until its Second Amended Complaint, which was filed on July 15, 2011 — approximately two years after the five-year limitations period had run.

The State has failed to demonstrate that its DTPA claim based on the November 2003 mailing and presentation sales calls from November 10, 2003 through July 21, 2004 "relates back" to the date of the filing of the original Complaint, and thus cannot avoid the bar of the statute of limitations. Under Arkansas law, a claim relates back only when it arises out of the same "conduct, transaction, or occurrence" from which a claim in the earlier pleading arose. *See* ARCP Rule 15(c)(1); *Ray & Sons Masonry Contractors v. U.S. Fid. & Guar. Co.*, 353 Ark. 201, 208-09, 114 S.W.3d 189, 193-94 (2003). Although its original Complaint contained a reference to the November 2003 mailing in the background section, there is nothing in the original Complaint that allows relation back. The State did not advance any claims in the original Complaint, DTPA or otherwise, that arose out of the November 2003 mailing or the presentation sales calls; in fact, the original Complaint did not contain a single reference to the November 2003 mailing or the presentation sales calls in the "Allegations" section, which set forth the basis for the State's claims. Likewise, the State's First Amended Complaint, filed on April 29, 2010, did not include any claims arising out of the November 2003 mailing or the presentation sales calls. Because the State waited until July 15, 2011 to advance a cause of action based on the November 2003 mailing and the presentation sales calls, the State's DTPA claim is untimely and Janssen is entitled to a directed verdict on this claim.

C. The State Introduced No Evidence, Let Alone Substantial Evidence, on Which the Jury Could Determine that Johnson & Johnson Is Liable for the Purported Violations of the MFFCA and the DTPA.

Johnson & Johnson is a holding company; it owns stock in separately incorporated operating companies such as Janssen. In other words, Johnson & Johnson is a separate corporate entity that has no operations of its own. Thus, to impose liability on Johnson & Johnson, the State must show that Johnson & Johnson (1) was directly involved in the conduct that gives rise to the State's claims, (2) is secondarily liable because it acted in a way that warrants piercing the corporate veil, or (3) for purposes of its DTPA claim only, is subject to imputed liability pursuant to A.C.A. § 4-88-113(d)(1). The State has not presented evidence as to even one of these alternatives.

First, the State presented no evidence that Johnson & Johnson was involved in the alleged wrongdoing that gives rise to the State's claims. The State's MFFCA claim is based on alleged inadequacies in the Risperdal package insert, while its DTPA claim is based on allegedly misleading statements in the November 2003 letter. The State has presented no evidence that Johnson & Johnson was directly involved with either the Risperdal package insert or the November 2003 mailing.

Second, the State failed to present any evidence that supports piercing the corporate veil to impose secondary liability on Johnson & Johnson for the conduct in which Janssen allegedly engaged. Arkansas courts widely agree that it is a "nearly universal rule that a corporation and its stockholders are separate and distinct entities, even though a stockholder may own the majority of the stock." *K.C. Props. of N. W. Ark, Inc.*, v. *Lowell Inv. Partners, LLC*, 373 Ark. 14, 32, 280 S.W.3d 1,15 (2008). To pierce the

corporate veil, the plaintiff must demonstrate that the corporate form has been illegally **abused** to its injury. *Don G. Parker, Inc. v. Point Ferry, Inc.*, 249 Ark. 764, 768, 461 S.W.2d 587, 590 (1971) (refusing to disregard corporate form where plaintiff was unable to prove there was an "illegal **abuse** of the corporate structure to the detriment of [plaintiff]"); *see also Quinn-Matchet Partners, Inc. v. Parker Corp., Inc.*, 85 Ark. App. 143, 149, 147 S.W.3d 703, 707 (2004) (refusing to disregard the corporate form because plaintiff did not prove the corporate form was **abused** for illegitimate purposes and the corporation adhered to corporate formalities). Further, "[p]iercing the fiction of a corporate entity should be applied with great caution." *Banks v. Jones*, 239 Ark. 396, 399, 390 S.W.2d 108, 110 (1965). Indeed, when Arkansas courts have pierced the corporate veil, the defendant generally has engaged in fraud or deception in connection with the corporate existence. *See, e.g.*, *Anderson v. Stewart*, 366 Ark. 203, 208, 234 S.W.3d 295,298-99 (2006). The State has failed to present any evidence that Johnson & Johnson was engaged in fraud or deception in connection with the corporate form; it thus may not be held secondarily liable for any alleged violations of the MFFCA or the DTPA by Janssen.

Finally, the State did not present any evidence that liability should be imputed to Johnson & Johnson under the DTPA. As an initial matter, and for the reasons set forth above, the State did not introduce any evidence on which the jury could find Janssen liable under the DTPA; thus, there is no basis on which to impute liability. In any event, the State did not present any evidence that Johnson & Johnson "knew or reasonably should have known of the existence of the facts by reason of which" Janssen could be found liable. A.C.A. § 4-88-113(d)(1).

Notably, all the State said in opposition to Johnson & Johnson's motion for summary judgment was that a sales representative in another case in another state referred to Janssen as a "division" rather than as a "subsidiary" of Johnson & Johnson and that a lawyer employed by Johnson & Johnson provided legal advice to Janssen. The State, however, has not presented even this "evidence" to the jury in this case. Thus, it has not met its burden as to Johnson & Johnson.

D. The State Failed to Provide Any Basis on Which the Court Could Impose Penalties Under the MFFCA and the DTPA.

Although the DTPA and the MFFCA authorize a court to award civil penalties, the State has not provided the Court with a basis *in this case* on which to award penalties, especially the enormous amount sought by the State here, because (1) the State did not introduce sufficient proof of the number of alleged violations for either its MFFCA claim or DTPA claim, (2) the MFFCA does not permit imposition of penalties in the absence of damages, and (3) the amount requested, if awarded, would violate the Excessive Fines and Due Process protections of the U.S. and Arkansas Constitutions. [12]

1. An award of civil penalties for the use of an FDA-approved package insert would be unprecedented and inappropriate.

The State seeks penalties in connection with two documents, the Risperdal package insert and the November 2003 letter. It is clear from the State's presentation, however, that both the package insert and the letter fall within the purview of and are subject to regulation by the FDA. Dr. Wirshing testified that the FDA, which oversees prescription drug labeling, has time and again concluded that the Risperdal package insert was sufficient. The FDA has never stated that the Risperdal package insert was deficient or that Janssen should have updated it to add any warnings earlier. Similarly, the FDA, after reviewing the November 2003 mailing, deemed a corrective letter the only remedy necessary. Janssen sent this letter in July 2004, and the FDA decided not to pursue any other remedies.

2. The State did not introduce sufficient proof of the number of alleged violations for either its MFFCA claim or its DTPA claim.

The MFFCA authorizes a civil penalty "of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation," A.C.A. § 20-77-903(a)(1), while the DTPA imposes an upper limit on the exercise of the Court's

discretion — the penalty may not exceed "ten thousand dollars ($10,000) per violation," A.C.A. § 4-88-113(a)(3). Both, however, impose upon the State an obligation to establish the number of violations. Arkansas courts have repeatedly held that "damages" may not be based on speculation, conjecture, or surmise. *Optical Partners, Inc. v. Dang*, 2011 Ark. 156,__S.W.3d__. This applies with even more force to penalties. [13]

a. There is no evidence of the number of violations associated with the State's MFFCA claim.

The State may not recover civil penalties under the MFFCA because, not only has it failed to show a violation of the MFFCA, it has failed to present evidence of the number of alleged violations. *See* A.C.A. § 20-77-903(a)(l) (authorizing a civil penalty "for each violation"). The State presented evidence of the number of Risperdal prescriptions reimbursed by Arkansas Medicaid from November 20, 2002 through June 30, 2006, but the act of filling prescriptions for Risperdal is not a valid basis for penalties. Reimbursement for Risperdal prescriptions cannot serve as the basis for civil penalties in this action.

The State says that the act that is a "violation" of the MFFCA is the misplacement or the wording of certain of the warnings in the Risperdal package insert. There is no separate "violation" each time the package insert is distributed. Moreover, the undisputed evidence is that a package insert does *not* accompany each Risperdal prescription. Further, it would be wholly inappropriate to award the State civil penalties for Medicaid fraud based on the Risperdal package insert when, as here, the State did not offer any evidence that (1) Janssen submitted — or was required to submit — the Risperdal package insert to the Arkansas Medicaid program, or (2) Arkansas Medicaid used or considered the Risperdal package insert when it paid claims for reimbursement for the cost of Risperdal prescriptions. [14]

Even if prescriptions were an appropriate basis for the number of violations, which they are not, the State did not present any evidence that a single claim for reimbursement of a Risperdal prescription was a false claim. The State's witness, Ms. Ford, only testified that Janssen satisfied the requirements to be a covered outpatient drug, reimbursable through Arkansas's Medicaid Program. In other words, Arkansas Medicaid was *required* to reimburse for all of the prescriptions; they simply cannot constitute violations of the MFFCA. For sure, allowing the State to recover for each Risperdal prescription reimbursed by Arkansas Medicaid would run counter to the purpose of the MFFCA: "to help recover public funds and Medicaid moneys that have been *wrongfully misappropriated* and will otherwise be lost forever ...." S.B. 838, 88th Gen. Assemb., Reg. Sess. (Ark. 2011) (emphasis added). The State may not seek penalties for each Risperdal prescription reimbursed by Arkansas Medicaid.

b. There is no evidence that each sales presentation between November 10, 2003 and July 21, 2004 constitutes a violation of the DTPA.

The State also did not demonstrate that the number of letters sent to Arkansas physicians plus the number of presentation sales calls between November 10, 2003 and July 21, 2004 is a proper measure of the number of violations for the State's DTPA claim. *See* A.C.A. § 4-88-113(a)(3) (imposing a civil penalty "per violation"). First, Amanda Proffitt, a former Janssen sales representative, testified that letters were delivered, rather than mailed, to some Arkansas physicians.

Second, the State did not make any effort to determine whether physicians upon whom Janssen's sales representatives called on from November 10, 2003 through July 21, 2004 had already received the November 2003 letter in the mail. Thus, to "count" the number of presentation sales calls, as well as the number of mailings, would be to double- and triple-count the "violations." Awarding a penalty for multiple deliveries of the same letter over-counts the violations. *See, e.g.*, *Walnut Creek Manor v. Fair Emp't &Hous. Comm'n*, 814 P.2d 704, 721 (Cal. 1991) ("'[T]he number of violations is to be determined by the number of persons to whom the misrepresentations were made, and not by the number of separately identifiable misrepresentations involved."' (quoting *People v. Superior Court*, 507 P.2d 1400, 1404 (Cal. 1973))); *State ex rel. Corbin v. United Energy Corp.*, 725 P.2d 752, 759 (Ariz. Ct. App. 1986) (affirming trial court and noting that "[t]he judge ruled that there could be only one violation of the consumer fraud act for each consumer, regardless of the number of misrepresentations made to each consumer").

Third, Ms. Proffitt testified that the November 2003 letter was discussed, shown, or distributed only on one presentation sales call to each Arkansas physician upon whom the sales representative called after November 10, 2003. There is no basis, then, for penalties based on the erroneous assumption, employed by the State's witness, Mr. Woodlock, that the letter was presented on *every* sales call during the period from November 10, 2003 to July 21, 2004. [15] An award of penalties for both "mailings" and "presentation sales calls" would be improper.

3. There is no basis for penalties under the MFFCA in the absence of damages.

The MFFCA prohibits an assessment of penalties in the absence of damages. Specifically, the statute provides the following "[f]ines and penalties":

(a)(1) It shall be unlawful for any person to commit any act proscribed by § 20-77-902, and any person found to have committed any such act or acts shall be deemed liable to the State of Arkansas, through the Attorney General, for full restitution and for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation....

A.C.A. § 20-77-903(a)(l). The statute then provides the following limitation:

(2) The court may assess not more than two (2) times the amount of damages which the state sustained because of the act of the person.

Id. at § 20-77-903(a)(2). The statute is clear, then, that any assessment by the Court [16] is limited to two times the amount *of damages*. Such a limitation is necessary to satisfy the constitutional constraints on the imposition of penalties because neither the Due Process Clause nor the Excessive Fines Clauses of the U.S. and Arkansas Constitutions permit an enormous award of penalties where the State sustained no damages. At trial, the State did not even attempt to prove any damages, let alone damages that are the result of Defendants' alleged MFFCA violations. Thus, the State's MFFCA claim must fail.

4. There is no constitutionally permissible basis for civil penalties on this record.

The penalty requested is facially violative of the Due Process and Excess Fines Clauses of the U.S. and Arkansas Constitutions.

a. The Due Process Clause bars the State's request for civil penalties on this record.

Civil penalty awards are subject to constitutional due process considerations. *See generally BMW of N. Am. v. Gore*, 517 U.S. 559, 572-73 (1996) (economic penalties that a state imposes, "whether the penalties take the form of legislatively authorized fines or judicially imposed punitive damages, must be supported by the State's interest in protecting its own consumers and its own economy"). Arkansas courts engage in a thorough and independent evaluation of the civil penalty using the constitutional guideposts set forth by the U.S. Supreme Court in *BMW of North America v. Gore*, 517 U.S. 559, 575 (1996). *See Allstate Ins. Co. v. Dodson*, 2011 Ark. 19, at 29. As explained in *BMW*, the court must evaluate (1) the degree of reprehensibility; (2) the disparity between the harm or potential harm suffered by the plaintiff and the punitive damage award; and (3) the difference between this remedy and civil penalties authorized or imposed in comparable cases. With respect to reprehensibility, additional considerations include "whether the harm caused was physical as opposed to economic; the tortious conduct evinced an indifference to or a reckless disregard of the health or safety of others; the target of the conduct had financial vulnerability; the conduct involved repeated actions or was an isolated incident; and the harm was the result of intentional malice, trickery, or deceit, or mere accident." *Id.* at 30 (quoting *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408,419 (2003)).

In this case, the harm the State alleges Janssen caused is economic, not physical, in nature. Further, the State has produced no evidence that Janssen acted in a reckless, intentional, or malicious manner. That is, there is no evidence that the package insert

was the product of malice or intentional wrongdoing, or that the letter was anything but a good-faith communication about important medical and scientific issues. This factor demonstrates that a substantial penalty award would run afoul of the Due Process Clause. Moreover, a substantial penalty award would stand in stark contrast to any supposed harm to the State where the State has conceded that it suffered *no* harm whatsoever. Finally, a substantial penalty award would not be consistent with awards in comparable cases. *See, e.g.*, *Reader's Digest*, 662 F.2d at 960 & n.3 (upholding penalty of $ 1,750,000 for 16,100,820 violations, or 11 cents per violation); *United States v. Nat 7 Fin. Servs., Inc.*, 98 F.3d 131 (4th Cir. 1996) ($550,000 penalty for unfair debt collection practices equaled $1 per violation).

The "searching review" that the Constitution requires favors Janssen on each of the *BMW* factors. *See Jim Ray, Inc. v. Williams*, 99 Ark. App. 315, 322-23, 260 S.W.3d 307, 311-12 (Ark. Ct. App. 2007) (concluding that penalty award was unconstitutionally excessive where party's conduct was not "particularly egregious"). *Cf. Holiday Inn Franchising, Inc. v. Hotel Assocs., Inc.*, 2011 Ark. App. 147, at 23-25,__S.W.3d__(upholding damages award where party's conduct demonstrated a significant degree of reprehensibility); *Hudson v. Cook*, 82 Ark. App. 246, 262-63, 105 S.W.3d 821, 831 (2003) (upholding penalty award where party's actions were "intentional and premeditated").

b. The Excessive Fines Clause bars the State's request for civil penalties on this record.

Civil penalty awards are subject to the prohibition of excessive fines contained in both the U.S. and Arkansas Constitutions. U.S. Const. amend. VIII ("Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted."); Ark. Const. art. II, § 9 ("[N]or shall excessive fines be imposed ...."). In determining whether the Excessive Fines Clause has been violated, the inquiry under state and federal law is the same: whether the forfeiture is "grossly disproportional to the gravity of a defendant's offense." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998); *see also Delta Sch. of Commerce, Inc. v. Harris*, 310 Ark. 611, 616-17, 839 S.W.2d 203, 206-07 (1992) (considering cases construing U.S. Constitution's Excessive Fines Clause because the excessive fines provision of both constitutions are virtually identical).

Weighing the evidence in light of this constitutionally mandated proportionality test, the imposition of substantial civil penalties would be excessive in violation of the U.S. and Arkansas Constitutions. The proportionality analysis must take into account, first, the position of the FDA with regard to the challenged statements in the Risperdal package insert and the November 2003 mailing. The FDA has never challenged the Risperdal package insert or asserted that it was "inadequate." Its repeated approval of the Risperdal package insert — multiple times over more than a decade — demonstrates that a substantial penalty assessed against Janssen would be excessive under Arkansas and federal law. *See Advocat, Inc. v. Sauer*, 353 Ark. 29, 52, 111 S.W.3d 346, 359 (2003) (holding that "an award of $63 million in punitive damages shocks the conscience of this court as a civil penalty"). As for the November 2003 mailing, although the FDA did take issue with certain of the statements in the November 2003 letter, it saw no need for an enforcement action. Instead, it sent an informal warning letter, and it marked its file "closed" when Janssen sent the July 2004 corrective letter.

Second, the proportionality analysis must give substantial weight to the fact that the State presented no evidence of actual deception, no evidence of any personal injury, and no evidence of any financial loss. A substantial civil penalty in a case such as this — a case involving no federal enforcement action, no deception, no harm, no loss, and no criminal intent — surely would be grossly disproportionate. *See Bajakajian*, 524 U.S. at 339 (relying on the fact that "[t]he harm that respondent caused was also minimal"); *cf. Walton v. Scott*, 247 Ark. 268, 272, 445 S.W.2d 97, 98-99 (1969) ("Perhaps a case might arise — especially one raising no issue of criminal intent — when the amount of the penalty might fairly and reasonably be said to be excessive."). [17]

Finally, it would be unconstitutional to impose even the minimum MFFCA penalty based on the evidentiary record the State has put before the Court. *U.S. ex rel. Birkart Globistics GmbH & Co.*, 2012 WL 488256, at *1 (E.D. Va. Feb. 14, 2012) (holding that $5,000 minimum penalty under federal False Claims Act violated Excessive Fines Clause where it resulted in a penalty of $50,248,000).

E. A Liability Verdict and the Imposition of Civil Penalties Would Violate the Free Speech Protections Afforded to Janssen Under the Federal and State Constitutions.

The State seeks to penalize Janssen for (1) the statements it made in the November 2003 letter regarding the conclusions that could be drawn from the scientific evidence relating to the metabolic side effects associated with antipsychotic treatment, and (2) statements in the FDA-approved Risperdal package insert regarding certain risks that may be associated with Risperdal treatment. Regardless of how they are characterized or classified, Janssen's statements are protected by the First Amendment to the U.S. Constitution and by Article II, Section 6 of the Arkansas Constitution.

Speech on matters of public concern is protected by the First Amendment. *Snyder v.Phelps*, _ U.S. _, 131 S. Ct. 1207, 1215 (2011) (holding that state law cause of action seeking to impose liability on speech on a matter of public concern must satisfy requirements of First Amendment). Speech involves a matter of "public concern" if it relates to "any matter of political, social or other concern to the community." *Connick v. Myers*, 461 U.S. 138, 146 (1983). Statements on scientific and medical research — the type of statements at issue here — are matters of public concern. *See, e.g., Bd. of Trs. of Leland Stanford Jr. Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991); *McMillan v. Togus Reg'l Office, Dep't of Veteran Affairs*, 294 F. Supp. 2d 305, 317 (E.D.N.Y. 2003), *aff'd* 120 F. App'x 849 (2d Cir. 2005). Accordingly, these statements are entitled to the full protection of the First Amendment. And, under First Amendment precedent, the State was required to prove, by clear and convincing evidence, that Defendants believed the statements were false when made or that Defendants made the statements with reckless disregard for whether they were false. *See Ill. ex rel. Madigan v. Telemarketing Assocs.*, 538 U.S. 600, 620 n.10 (2003); *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 342, 348-50 (1974). [18]

Even if this Court does not classify Janssen's statements as relating to matters of "public concern," they remain subject to the protections of the First Amendment as "commercial speech." *See Sorrell v. IMS Health Inc.*, _ U.S. _, 131 S. Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment."); *id.* at 2667 ("As in previous cases, however, the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied."); *id.* at 2653 ("Under a commercial speech inquiry, it is the State's burden to justify its content-based law as consistent with the First Amendment.").

The State seeks to penalize Defendants because it disagrees with the content of Janssen's statements in the November 2003 letter and the Risperdal package insert. In such circumstances, there must be a heightened judicial scrutiny. As explained in *Sorrell*, "[t]he First Amendment requires heightened judicial scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys." 131 S. Ct. at 2664 (quotation marks and citations omitted). The *Sorrell* court also recognized that "[a] consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue. That reality has great relevance in the fields of medicine and public health, where information can save lives." *Id.* (internal quotation marks and citations omitted); *id.* at 2670 ("The more benign and, many would say, beneficial speech of pharmaceutical marketing is also entitled to the protection of the First Amendment. If pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive. Absent circumstances far from those presented here, the fear that speech might persuade provides no lawful basis for quieting it."); *id.* at 2671 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.... These precepts apply with full force when the audience, in this case prescribing physicians, consists of sophisticated and experienced consumers." (quotation marks and citations omitted)).

Regardless of the burden of proof imposed, the State has not carried its burden. It certainly did not prove, by clear and convincing evidence, that Janssen believed its statements were false when it made them or that Janssen made the statements with reckless disregard for whether they were false; it did not even prove, by a preponderance of the evidence, that Janssen's statements were either literally false or actually misleading. *See Sorrell*, 131 S. Ct. at 2659. To the contrary, neither of the State's experts disputes the factual accuracy of a single page of the package insert, and Dr. Wirshing testified that there was scientific support for each of the statements in the November 2003 letter.

V. CONCLUSION

For all the foregoing reasons, Defendants respectfully request the Court grant their Motion for Directed Verdict.

Respectfully submitted,

Dated: April 3, 2012.

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Footnotes

1 On June 22, 2011, Ortho-McNeil-Janssen Pharmaceuticals, Inc. changed its name to Janssen Pharmaceuticals, Inc.

2 Dr. Wirshing did not offer these opinions to a reasonable degree of medical or scientific or any other certainty.

3 Dr. Wirshing also testified that the package insert disclosed that Risperdal caused significant weight gain in subjects in clinical trials. In fact, the package insert, in a section entitled "Weight Changes," reported "a statistically significantly greater incidence of weight gain for RISPERDAL® (18%) compared to placebo (9%)." Trial Ex. P656.

4 Dr. Wirshing said the weight gain associated with Zyprexa was 11.8 kg, which he calculated to be about 22 pounds. 11.8 kg, however, is actually about 26 pounds.

5 Ensuring uniformity of prescription drug labeling throughout the United States is one of the principal purposes of the FDCA and the FDA's prescription drug labeling regulations. *See* Proposed Labeling for Oral Aspirin-Containing Drug Prods., 50 Fed. Reg. 51,400, 51,403 (Dec. 17, 1985) (codified at 21 C.F.R. pt. 201) ("FDA has a well-established policy of promoting uniformity in the area of labeling.").

6 Other courts have reached this conclusion in similar cases. *See, e.g., Prohias v. AstraZeneca Pharm., L.P.*, 958 So. 2d 1054 (Fla. Dist. Ct. App. 2007) (stating that claim that FDA-approved drug label violated the Florida Deceptive and Unfair Trade Practices Act conflicted with federal law and therefore was preempted); *see also, e.g., Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (holding, for false advertising claims, that "representations by [defendant] that comport substantively with statements approved as accurate by the FDA cannot supply the basis for [plaintiff's] claims"); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144-45 (S.D.N.Y. 1987) ("In unfair competition actions under state statutory or common law, it has been consistently ruled that compliance with FDA warning requirements is a complete defense ....").

7 At bottom, the State's MFFCA case is about "withholding" from the FDA the topline results of RIS-USA-113 and the preliminary report from ERI. The State's claim under the MFFCA, however, is based on Section 20-77-902(8)(B), which requires an affirmative representation. A.C.A. § 20-77-902(8)(B) ("Knowingly makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact...."). A separate provision of the MFFCA, which is not a basis for the State's claim, applies to alleged omissions. *See, e.g.*, A.C.A. § 20-77-902(3) (establishing liability for one who "knowingly conceals or fails to disclose that event....").

8 The Court rejected the State's argument that its claim was saved by the discovery rule when it permitted the State to pursue only those alleged violations occurring within five years of the filing of the complaint. In any event, the State did not present any evidence that the discovery rule should apply to its MFFCA claim. In addition, the State did not plead or prove fraudulent concealment.

9 Both A.C.A. § 4-88-108(1), which deals with affirmative statements, and A.C.A. § 4-88-108(2), which deals with omissions, require proof of materiality. There is no "omissions" claim under A.C.A. § 4-88-107(a)(10), and, even if there were, it would require proof of materiality. To permit an omissions claim to proceed under the DTPA without proving materiality would read out A.C.A. § 4-88-108(2). *Ward v. Doss*, 361 Ark. 153,159, 205 S.W.3d 767, 770 (2005) ("Our review becomes an examination of the whole act. We reconcile provisions to make them consistent, harmonious, and sensible in an effort to give effect to every part.").

10 Although Arkansas appellate courts have not addressed the issue to date, Defendants believe that the State cannot show that the November 2003 letter was "likely to deceive" without proving that at least some of the physicians to whom the letter was addressed actually were deceived and, thus that proof of "actual deception" is required in a case in which the statements are challenged after the fact. Even if proof of actual deception is not required, the State did not introduce any evidence that Arkansas physicians or other healthcare professionals were likely to be deceived by the November 2003 mailing.

11 The State's reliance on the DDMAC letter is particularly inappropriate because, after completing a full investigation of the November 2003 mailing, DDMAC decided not to take any action against Janssen — despite all of the remedies available to it. *See generally* FDA Regulatory Procedures Manual § 4-1-1 ("The Warning Letter was developed to correct violations of the statutes or regulations. Also available to the agency are enforcement strategies which are based on the particular set of circumstances at hand and may include sequential or concurrent FDA enforcement actions such as recall, seizure, injunction, administrative detention, civil money penalties and/or prosecution to achieve correction.").

12 The State's evidence, such as it is, would not support an award of substantial penalties, if the factors from *United States v. Readers' Digest Association* are applied, as they should be. 662 F.2d 955, 967 (3d Cir. 1981) (the *Reader's Digest* factors include: (1) the good faith or bad faith of the defendants; (2) the injury to the public; (3) the desire to eliminate the benefits derived from a violation; (4) the necessity of vindicating the authority of a regulatory agency; and (5) the defendants' ability to pay). If this motion is not granted, and penalties are, in fact, to be considered, Defendants respectfully request the opportunity to brief the penalties issues.

13 The State also failed to introduce any evidence on which the Court could determine penalties pursuant to A.C.A. § 4-88-202, even if applicable, which it is not.

14 Further, substantial civil penalties under the MFFCA based on each Risperdal prescription reimbursed by Medicaid would be improper because the risks that the State alleges were inadequately disclosed in the Risperdal package insert are rare — occurring in a fraction of one percent of patients. Thus, there is no justification for the imposition of a penalty for each prescription.

15 Mr. Woodlock's calculations are flawed for other reasons as well. When doing his count, he did not eliminate duplicate sales call records. And, he did not make any effort to eliminate presentation sales calls on health care professionals who did not prescribe Risperdal, or did not prescribe at all.

16 There can be no dispute that the court assesses the amount of both restitution and penalties. *Id.* at § 20-77-903(e) ("For actions under this subchapter, whether tried by the court or the jury, the restitution and penalty shall be fixed by the court.").

17 Additionally, it would be improper to impose substantial civil penalties under either the MFFCA or the DTP A because at the time this lawsuit was initiated, and to the best of Janssen's knowledge, no other court had ever imposed a penalty, much less such a massive penalty, for the alleged inadequacy of an FDA-approved package insert or a "Dear Health Care Provider" letter. *See generally State v. Am. Recycling Techs., Inc.*, No. CV040832985, 2009 WL 1532330, at *6 (Conn. Super. Ct. May 5, 2009) (imposing a civil penalty of $50,000 for the violation of unfair trade practices act and solicitation of charitable funds act after the court concluded "that this is the first case in Connecticut construing the SCFA, and that defendant conceivably could have been uncertain of the applicability of some of its provisions to it").

18 The First Amendment requires clear and convincing evidence that a challenged statement was made with knowledge that it was false or with reckless disregard for whether it was false in *any* challenge to First Amendment-protected speech regarding matters of public concern. Although this proof requirement is often imposed in defamation cases, it is not an element of a defamation cause of action. Rather, it is a proof requirement designed to ensure that speech worthy of First Amendment protection is not chilled. *See New York Times Co. v. Sullivan*, 376 U.S. 254, 277-78 (1964) (explaining the need for clear and convincing proof of knowing falsehood or reckless disregard by reference to the need to guarantee robust public debate about matters of public concern).

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