BEFORE THE ARKANSAS SUPREME COURT

ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC.,
f/k/a JANSSEN PHARMACEUTICA, INC.
and/or JANSSEN, LP; and
JOHNSON & JOHNSON, INC.
Appellants

VS. **NO. 12-1058**

STATE OF ARKANSAS, *ex rel.*
DUSTIN McDANIEL, Attorney General,
Appellee

On Appeal from the Circuit Court of Pulaski County
Honorable Timothy D. Fox, Circuit Judge

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

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IDENTITY AND INTERESTS OF *AMICI CURIAE*

The interests of the Washington Legal Foundation and the Allied Educational Foundation are set forth more fully in the accompanying motion for leave to filed this brief.

Amici support each of the arguments raised by Appellants in their brief. *Amici* write separately to focus exclusively on issues related to the trial court's entry of a $1.2 billion judgment for alleged violations of the Arkansas Medicaid Fraud False Claims Act (MFFCA), A.C.A. §§ 20-77-901 *et seq*. *Amici* are concerned that the judgment below, if affirmed by this Court, will create tremendous uncertainty among regulated entities in the healthcare field and will make it extremely difficult for them to remain in business in Arkansas without exposing themselves to massive liabilities based on nothing more than good-faith disagreements or misunderstandings regarding regulatory requirements.

As interpreted by the trial court, the MFFCA authorizes damage claims against regulated entities based on virtually anything they say, regardless how tangential those statements are to claims filed under Medicaid. Even more troublesome, the trial court's interpretation eliminates any clear standards for determining the number of times that regulated entities violate the MFFCA, thereby exposing them to potentially unlimited damage awards under the

MFFCA's minimum statutory penalty of $5,000 per offense. *Amici* believe that this atextual interpretation of the MFFCA raises serious due process and free speech concerns under both the Arkansas and U.S. Constitutions.

STATEMENT OF THE CASE

Amici adopt by reference the Statement of the Case set forth in the brief of Appellants.

In brief, Appellant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen") is authorized by the federal Food and Drug Administration (FDA) to market Risperdal, a prescription antipsychotic medication widely administered by doctors in Arkansas and elsewhere. Arkansas recognizes Risperdal's significant value in treating patients with schizophrenia and other conditions, and it has reimbursed the cost of Risperdal under its Medicaid Program since the medication was first approved by FDA almost 20 years ago. FDA has established detailed rules regarding the labels for Risperdal and other prescription drugs, including a requirement that the labels include a "Warnings" section that discloses serious health hazards associated with use of the drug.

Arkansas contends that the Warnings section of the Risperdal label did not properly disclose all risks associated with its use. It filed suit under the MFFCA, alleging that the nondisclosure constituted "false statement[s] or representation[s]

of a material fact" in violation of A.C.A. § 20-77-902(8). In particular, it alleged that at various times between November 2002 and June 2006, the Warnings section failed to include warnings for cerebrovascular events (*i.e.*, strokes) in the elderly with dementia, diabetes, hyperglycemia, weight gain, and hyperprolactinemia.[1]

Arkansas adopted the MFFCA in 1993 to "eliminate fraud in the Arkansas Medicaid Program" and to "protect the integrity of the program." Acts 1993, No. 1299, § 16.[2] As currently drafted, the MFFCA prohibits persons from engaging in 11 enumerated activities; it authorizes the Attorney General to institute an action "for a civil penalty and restitution" against violators. A.C.A. § 20-77-902. Knowingly making "false statement[s] or representation[s] of a material fact" under specified circumstances – the claim asserted by Arkansas in this case – is

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[1] Throughout that period, the Risperdal label included risk information about each of these five conditions, but the information was not included in the Warnings section of the label until some months after November 2002: March 2003 for the risk of cerebrovascular events in the elderly with dementia, November 2003 for the risks of diabetes and hyperglycemia, and after June 2006 – the end date for the State's claim – for weight gain and hyperprolactinemia.

[2] The focus on eliminating Medicaid fraud is self-evident from the first two words of the title of the MFFCA, the "*Medicaid Fraud* False Claims Act."

the eighth of the 11 enumerated prohibitions.

Arkansas's suit contended both that the Risperdal label was knowingly "false" and that it met an additional requirement for § 902(8) liability: the label's allegedly false statements must be made "[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). It contended that 21 C.F.R. § 201.57(e) (2002), an FDA regulation that set forth the required contents of the Warnings section of prescription drug labels, was an "applicable federal . . . regulation" within the meaning of § 902(8)(B), even though the regulation did not address Medicaid fraud issues and was issued by FDA, an agency that has no oversight responsibility for the Medicaid program.[3]

The MFFCA further provides that a person or entity found to have violated § 902 shall be liable to Arkansas for: (1) full restitution; (2) a civil penalty of not less than $5,000 or more than $10,000 "for each violation"; and (3) three times the amount of all payments "found to have been fraudulently received from the

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[3] FDA substantially revised its regulations regarding the formatting of prescription drug labels after the period at issue in this lawsuit. The prescribed contents of the Warnings section of such labels are now set forth in 21 C.F.R. § 201.57(c).

Arkansas Medicaid program." A.C.A. § 20-77-903(a)(1). Arkansas has issued no regulations that clarify the meaning of the phrase "applicable federal . . . regulation" in § 902(8)(B) or the phrase "each violation" in § 903(a)(1).

The trial court agreed with Arkansas that 21 C.F.R. § 201.57(e) (2002) was an "applicable" federal regulation within the meaning of § 902(8)(B), and it entered judgment on a jury verdict that the nondisclosure of risk information in the Warnings section of the Risperdal label constituted "false statement[s] or representation[s] of a material fact." The trial court further determined that a new violation of § 902(8) occurred each time that Risperdal was filled or refilled by an Arkansas Medicaid patient during the 2002-2006 period. It calculated the $1.2 billion MFFCA judgment against Appellants by multiplying the number of fills and refills by the MFFCA's $5,000-minimum-per-offense civil penalty. The trial court made no finding that Appellants had defrauded the Arkansas Medicaid program or that the State had suffered any damages; indeed, Arkansas made no such claims.

In denying Appellants' motions for directed verdict and for judgment notwithstanding the verdict, the trial court *inter alia* rejected their contentions that: (1) the MFFCA judgment violated their rights to due process of law under the

U.S. and Arkansas Constitutions because the MFFCA was overly vague as applied to them; and (2) the MFFCA, by punishing their speech with respect to the health risks associated with use of Risperdal, violated their free speech rights under the U.S. and Arkansas Constitutions.

SUMMARY OF ARGUMENT

The language and history of the MFFCA indicate that the statute was adopted for the purpose of preventing persons from obtaining funds from the Arkansas Medicaid Program by fraudulent means. Arkansas does not allege that either Janssen or Johnson & Johnson (its corporate parent) defrauded the State, or that there was anything improper about the reimbursement payments made by the Medicaid Program to the numerous pharmacies and others who dispensed Risperdal to Arkansas consumers in accordance with a doctor's prescription. Under those circumstances, the MFFCA is inapplicable to this case. The statute does not authorize Arkansas to seek massive fines from a pharmaceutical company simply because it believes that the company should have affixed stronger safety warnings to a prescription drug. Even if a State is permitted to second-guess FDA's labeling determinations (and Appellants have argued forcefully that States may not do so), there is no indication that that was Arkansas's purpose in adopting the MFFCA.

The operative provision of the MFFCA, § 902(8), prohibits persons from knowingly making "false statement[s] or representation[s] of a material fact" under circumstances specified in the provision. Arkansas does not allege that the Risperdal label was "false" under any commonly understood definition of that word. Arkansas alleges that Janssen was required by federal law to include certain risk information in the Warnings section of its Risperdal label and that it failed to do so. Even if that allegation were correct, the use of a label that provides inadequate risk information does not make the label "false." The label might arguably be deemed "false" if Janssen had stated, "The risks identified in the Warning section are the *only* health risks associated with use of Risperdal." Not only did Janssen make no such claim, however, but it also identified the health risks in question in other portions of the product label.

Moreover, § 902(8) does not prohibit *just any* false statement; rather, it is limited to false statements made under the very limited circumstances described in Subparts (A) and (B). A fair reading of those subparts makes clear that they focus on false statements made by entities for the purpose of obtaining unwarranted Medicaid payments. Because Janssen did not make statements on its labeling for that purpose, those statements are not subject to § 902(8). Arkansas argues that § 902(8)(B) sweeps more broadly, noting that the word "Medicaid" appears

nowhere in Subpart (B). But the subpart states explicitly that it applies only to information required pursuant to "applicable" rules, regulations, etc., and Arkansas's proffered interpretation of the subpart (that it applies to *any* information required by federal or state law) fails to account for the word "applicable."

Even less tenable is the trial court's conclusion that § 903(a)(1) of the MFFCA authorizes imposition of 238,874 statutory penalties on Appellants, one for each of the Risperdal prescriptions filled or refilled by a Medicaid patient in Arkansas between 2002 and 2006. The statute authorizes a civil penalty of between $5,000 and $10,000 "for each violation," and Arkansas has presented no plausible argument that counting the number of prescriptions in any way tracks Janssen's alleged misconduct. Janssen does not write or fill Risperdal prescriptions. Moreover, the Warnings section of the Risperdal label is contained in the product's "package insert" and thus generally is not provided to consumers when they receive Risperdal at their drugstore. Arkansas alleges that Janssen's offense was the making of "false statement(s) or material misrepresentation(s)," yet it never explains how Janssen can be said to have uttered a statement by virtue of a consumer's receipt of a product that does not contain the statement in question.

In any event, Appellants cannot constitutionally be made subject to § 902(8) as interpreted by the trial court. It is a fundamental principle of our legal system, protected by the Due Process Clauses of the U.S. and Arkansas Constitutions, that laws regulating persons or entities must give fair notice of the conduct that is forbidden, and of the punishment that may be meted out to those who violate the law. A law is unconstitutionally vague under due process standards if it does not give a person of ordinary intelligence fair notice of what is prohibited. *Arkansas Tobacco Control Bd. v. Sitton*, 357 Ark. 357, 362, 166 S.W.3d 550, 553 (2004). A reasonable person reading § 902(8) would not understand that he could be held liable for $1.2 billion in damages under the facts of this case.

In particular, a reasonable person would not understand a prohibition against making "a false statement or misrepresentation of a material fact" to include truthful but allegedly misplaced disclosure of risk information on his product's label. Nor would he understand "applicable" federal regulations to refer to any and all federal regulations, even ones having nothing to do with Medicaid fraud and ones issued by an agency with no oversight authority over Medicaid. Nor would he understand that he could be charged with making a false statement every time his product was filled or refilled by an Arkansas Medicaid patient even though the statement in question was not attached to the product being dispensed.

Indeed, if Arkansas were constitutionally permitted to apply vague laws of this nature in the manner being espoused by the State in this case, every firm engaged in healthcare delivery within the State would face the possibility of a bankrupting judgment every time it issued a truthful yet allegedly incomplete report.

The judgment should be overturned for the additional reason that it was imposed in violation of Appellants' free speech rights under the U.S. and Arkansas Constitutions. It cannot seriously be denied that Appellants are being sanctioned for the content of their speech, the sort of sanction that routinely is subject to exacting First Amendment scrutiny. Arkansas responds that the First Amendment (and Article II, Section 6 of the Arkansas Constitution) are inapplicable here, because the jury determined that the speech in question was false, and false speech is not entitled to constitutional protection. That response is wrong on two counts. First, it simply is not true that the jury determined that the Risperdal label was false in any constitutional sense. The trial court did not require the jury, as a prerequisite to a finding of liability, to find that anything stated on the label was provably false. Rather, it was sufficient for the jury to find that the Warning section of the label failed to include risk information that, according to Arkansas, should have been included.

Second, the U.S. Supreme Court has explicitly rejected the claim that speech

categorically loses all First Amendment protection the moment a State determines that the speech is false. Rather, the Court has explained, false claims may be categorically banned only in conjunction with "evidence that the speech was used to gain a material advantage" – as when the speech is used to secure funds through fraud. *United States v. Alvarez*, 132 S. Ct. 2537, 2548 (2012). In the absence of a claim by Arkansas that Janssen acted fraudulently or gained any advantage as a result of its label, it is incumbent on Arkansas to demonstrate that the major sanctions it is attempting to impose on Appellants' speech can withstand First Amendment scrutiny.

Even if the Court applies the less-exacting *Central Hudson* test (a review standard often applied to commercial speech that does no more than propose a commercial transaction), the MFFCA judgment imposed by the trial court violates Appellants' free speech rights. In particular, Arkansas has not shown that its interest in ensuring the full disclosure of a prescription drug's risk information could not have been achieved through injunctive relief or a vastly smaller monetary penalty.

ARGUMENT

I. THE MFFCA PERMITS ARKANSAS TO COMBAT MEDICAID FRAUD, NOT TO POLICE THE LABELS OF PRESCRIPTION DRUGS

The Medicaid Fraud False Claims Act (MFFCA) was enacted in 1993 to "eliminate fraud in the Arkansas Medicaid Program" and to "protect the integrity of the program." Acts 1993, No. 1299, § 16. It authorizes the State's Attorney General to seek civil penalties and restitution from those who have defrauded the program. A.C.A. § 20-77-902. Nothing in the language, purposes, or history of the MFFCA authorizes the sort of action that the Attorney General is pursuing here: an action to impose massive civil penalties because he believes that Janssen inadequately disclosed risk information on its Risperdal label between 2002 and 2006.

Arkansas' suit relies on § 902(8), the eighth of 11 enumerated activities that the MFFCA bars providers of goods or services to the Medicaid Program from engaging in. Section 902(8) provides that a person shall be liable to Arkansas for a civil penalty or restitution if he or she:

> 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) With respect to the condition or operation of any institution, facility, or entity in order that the institution, facility, or entity may

> qualify either upon initial certification or upon recertification as a hospital, rural primary care hospital, skilled nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity for which certification is required; or
>
> (B) With respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements.

Arkansas asserts that 21 C.F.R. § 201.57(e) (2002), the FDA regulation governing the formatting of safety warnings on prescription drugs during 2002-2006, is an "applicable federal . . . regulation" within the meaning of § 902(8)(B). It further asserts that failure to adhere to the FDA regulation's formatting requirements constitutes the making of "a false statement or representation of a material fact" within the meaning of § 902(8). Neither assertion is well taken.

A. Janssen's Allegedly Improper Formatting of Risk Information Does Not Meet the MFFCA's Definition of a "False Statement or Representation of a Material Fact"

The factual basis for Arkansas's assertion that the Risperdal label contained "false statement[s] or representation[s]" is summarized at Pages 42-46 of Arkansas's Response in Opposition to Defendants' Motion for Judgment Notwithstanding the Verdict (hereinafter "Ark. Response"). Arkansas pointed to evidence that the Warnings section of the Risperdal label contained no warning for cerebrovascular events in the elderly with dementia from November 2002 to March 2003; contained no warning for diabetes or hyperglycemia from November

2002 to November 2003; and contained no warning for weight gain or hyperprolactinemia from November 2002 to June 2006. Ark. Response 46.[4] Arkansas claims that the failure to include such warnings, despite Janssen's knowledge that an association existed between use of Risperdal and each of the five conditions, rendered the Warnings section of the Risperdal label "false" within the meaning of § 902(8). *Id.* The trial court denied the Motion for Judgment Notwithstanding the Verdict on the basis of that understanding of § 902(8).[5]

Arkansas's claim is based on an implausible interpretation of § 902(8). The "first rule" in considering the meaning and effect of a statute "is to construe it just as it reads, giving the words their ordinary and usually accepted meaning in common language." *DaimlerChrysler Services North America, LLC v. Weiss*, 360 Ark. 188, 193, 200 S.W.3d 405, 407 (2004) (quoting *Faulkner v. Arkansas Children's Hospital*, 347 Ark. 941, 952, 69 S.W.3d 393, 400 (2002)). In the

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[4] Arkansas does not contest, however, that other sections of the Risperdal label contained risk information regarding these five conditions throughout the relevant time period.

[5] The question of the correct application and interpretation of an Arkansas statute is a question of law, which this Court decides *de novo*. *Broussard v. St. Edward Mercy Health System, Inc.*, 2012 Ark. 14, __, 386 S.W.3d 385, 388.

context of public pronouncements, the word "false" means "intentionally untrue," as in "false testimony." *Webster's New Collegiate Dictionary* (1981). Thus, § 902(8) permits imposition of a civil penalty only if Arkansas can point to "intentionally untrue" statements in the Risperdal label. Arkansas has not done so. While Arkansas asserts that the Warnings section of the Risperdal label failed to include all risk information known to Janssen, such an omission does not render the Warnings section "false" or "intentionally untrue" based on the ordinary and usually accepted meaning of those terms.

Arkansas points to an FDA regulation, 21 C.F.R. § 201.57(e) (2002), in support of its assertion that the Warnings section of the Risperdal labeling contained "false statement[s] or representation[s]." That regulation provided, in pertinent part:

> "Warnings": Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

Arkansas asserts that Janssen violated the regulation by failing to revise its label after obtaining evidence of an association between Risperdal and "serious hazards" posed by the five relevant conditions. Ark. Response at 50-52. But the issue under

the MFFCA is not whether Janssen violated the regulation; the issue is whether statements in the Warnings section of the label were "false." Indeed, after asserting in one breath that Janssen violated the regulation, Arkansas asserts in the next breath that the alleged violation is not the basis for its claim that Janssen is sanctionable; rather, it insists, the relevant violation was a § 902(8) "false" statement – a statement whose falsity consisted of failing to disclose risk information that "was required to be disclosed under applicable federal law." *Id.* at 51-52.[6] But the dissemination of a Warnings section that omitted the risk information cited by Arkansas is not rendered any more "false" or "intentionally untrue" simply because federal regulations arguably required inclusion of the

[6] Arkansas's reluctance to rely directly on the alleged violation of the FDA regulation is understandable. Federal law provides that only the United States may enforce the Federal Food, Drug, and Cosmetic Act and regulations issued pursuant thereto. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Accordingly, were the Court to view this action as an effort to enforce FDA regulations, it would be preempted. It is worth noting in this regard that FDA itself has never determined that the Risperdal labeling violated 21 C.F.R. § 201.57(e) (2002).

information.

B. The FDA Regulation Governing the Formatting of Prescription Drug Labels Is Not an "Applicable" Federal Regulation within the Meaning of the MFFCA

Section 902)(8) does not prohibit *just any* false statement; rather, it is limited to false statements made under the very limited circumstances described in Subsections (A) and (B). In asserting that the allegedly false statements in the Risperdal label are sanctionable under the MFFCA, Arkansas relies on § 902(8)(B), which applies the prohibition to false statements made "[w]ith respect to information required pursuant to *applicable* federal and state law, rules, regulations, and provider agreements" (emphasis added). Arkansas asserts that one such federal regulation is 21 C.F.R. § 201.57(e) (2002), the FDA regulation that specifies risk information to be included in the Warnings section.

Arkansas's reading of § 902(8)(B) is implausible because it fails to account for the word "applicable." Section 902(8)(B) does not encompass information required by any and all federal regulations; rather, it encompasses only the information required by "applicable" regulations. Arkansas does not explain how § 201.57(e) is "applicable" to any subject matter encompassed by the MFFCA.

Indeed, it is self evident that the formatting of risk information on the label of FDA-approved prescription drugs has no relevance to subject matters that the

Arkansas legislature sought to address when it adopted the MFFCA. As the Court has stressed repeatedly, "[T]he ultimate rule of statutory construction is to give effect to the intent of the General Assembly." *DaimlerChrysler*, 360 Ark. at 194, 200 S.W.2d at 408. A fair reading of § 902(8) makes clear that the General Assembly's principal focus was on an entity's false statements made for the purpose of obtaining necessary certifications or recertifications to operate a healthcare facility and that its intent was to prevent entities from obtaining unwarranted Medicaid payments. Subsection (A) addresses false statements regarding "the conditions or operations" of the healthcare facility made for the purpose of obtaining certifications or recertifications. Subsection (B) goes on to encompass false statements made with respect to information required by "applicable federal and state law, rules, regulations, and provider agreements." Within the context of § 902(8), the most logical interpretation of Subsection (B) is that the word "applicable" limits the subsection's coverage to laws, rules, regulations, or provider agreements that have some application to certification or recertification of a healthcare facility, or at the very least, some application to efforts to obtain Medicaid payments. There is no other plausible explanation regarding why the legislature would have combined Subsections (A) and (B) in the same statutory provision. Moreover, the word "applicable" becomes mere

surplusage if, as Arkansas asserts, Subsection (B) applies to *every* law that requires a regulated entity to supply information.[7]

Any doubt regarding the meaning of the statutory language is eliminated by resort to other interpretive tools. Where the meaning of statutory language is not clear, the Court looks not only to the language of the statute but also its "subject matter, the object to be accomplished, the purpose to be served, the remedy provided, the legislative history, and other appropriate means that shed light on the

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[7] In any event, Appellants cannot constitutionally be made subject to § 902(8) as interpreted by the trial court. It is a fundamental principle of our legal system, protected by the Due Process Clauses of the U.S. and Arkansas Constitutions, that laws regulating persons or entities must give fair notice of the conduct that is forbidden, and of the punishment that may be meted out to those who violate the law. A law is unconstitutionally vague under due process standards if it does not give a person of ordinary intelligence fair notice of what is prohibited. *Arkansas Tobacco Control Bd. v. Sitton*, 357 Ark. 357, 362, 166 S.W.3d 550, 553 (2004). A reasonable person reading § 902(8) would not understand that he could be held liable under the facts of this case, or that he could be assessed a $1.2 billion penalty for his conduct. *See BMW of N. Am., Inc. v. Gore*, 577 U.S. 559, 574 (1996).

subject." *DaimlerChrysler*, 360 Ark. at 194, 200 S.W.2d at 408. Each of those guideposts points decisively to the conclusion that the FDA regulation governing the formatting of prescription drug labels is not one that the General Assembly had in mind when it referenced "applicable" federal regulations.

Most importantly, as noted above, the General Assembly's stated purpose in adopting the Medicaid Fraud False Claims Act in 1993 was to "eliminate fraud in the Arkansas Medicaid Program" and to "protect the integrity of the program." Acts 1993, No. 1299, § 16. That stated purpose is served by prohibiting false statements that could result in healthcare providers receiving funds to which they are not entitled in light of their failure, *inter alia*, to comply with laws and regulations governing certification of their facilities. But that anti-fraud purpose is not served by sanctioning drug manufacturers for inadequate disclosure of risk information on product labels – particularly where, as here, Arkansas does not allege that the inadequate disclosure resulted in any improper payments being made by the Arkansas Medicaid Program. Indeed, the labeling regulation in question, § 201.57(e) (2002), does not address Medicaid fraud issues at all and was issued by FDA, an agency with no oversight responsibility for the Medicaid program.

The inapplicability of § 902(8) to this case is further demonstrated by

examining the subject matter of the other ten prohibitions set forth in § 902. Each of those ten prohibitions focuses on a specific aspect of the process by which healthcare providers submit claims to Medicaid or beneficiaries receive services covered by Medicaid. *See, e.g.*, § 902(1) (false statements in "any application for any benefit or payment under the Arkansas Medicaid program"); § 902(5) (presenting a Medicaid claim for a physician's service, knowing that "the individual who furnished the service was not licensed as a physician"); § 902(9)(A) (charging the Medicaid Program "at a rate in excess of the rates established by the state"). A well-established canon of statutory construction – *noscitur a sociis* (a word should be given meaning by the words around it)[8] – indicates that the legislature did not intend § 902(8) to regulate statements with respect to information required by federal regulations that have nothing to do with Medicaid fraud. Given the other ten prohibitions' exclusive focus on aspects of the

[8] As the U.S. Supreme Court has explained, "The maxim *noscitur a sociis*, that a word is known by the company it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress." *Jarecki v. G.D. Searle & Co.*, 367 U.S. 303, 307 (1961). *See also Hanley v. Arkansas State Claims Comm.*, 333 Ark. 159, 166-67, 970 S.W.2d 197 (1998).

process by which healthcare providers submit claims for payment to the Medicaid Program, it is highly unlikely that the General Assembly intended § 902(8) to regulate statements made in a context wholly unrelated to Medicaid claims. Instead, *noscitur a sociis* indicates that the legislature intended the word "applicable" to limit the reach of § 902(8)(B) to those federal regulations that are applicable to a healthcare provider's eligibility for Medicaid payments. Arkansas cannot plausibly assert that 21 C.F.R. § 201.57(e) relates to eligibility for Medicaid payments, given that the Risperdal label's allegedly deficient disclosure of risk information did not render Risperdal ineligible for Medicaid reimburse-ment. Accordingly, the *noscitur a sociis* canon indicates that § 201.57(e) is not an applicable federal regulation and thus does not fall within the scope of § 902(8).

Finally, the conduct of the Attorney General's office since the 1993 enactment of the MFFCA suggests that, until recently, the Attorney General believed that the MFFCA applied only to Medicaid fraud. In the years following enactment of the MFFCA (and its criminal law counterpart, A.C.A. § 5-55-111),[9] the Attorney General initiated a fair number of enforcement proceedings under one or both laws against healthcare providers who were alleged to have defrauded the

[9] The criminal statute contains a provision, A.C.A. § 5-55-111(8), that is virtually identical to § 902(8).

Arkansas Medicare Program. *See, e.g.*, *Dilday v. State*, 369 Ark. 1, 250 S.W.3d 217 (2007); *Blackwell v. State*, 338 Ark. 671, 1 S.W.3d 399 (1999). *Amici* have not, however, uncovered even a single case – prior to the instant lawsuit – in which the Attorney General sought to invoke either statute against an entity alleged to have made false statements with respect to information required by laws unrelated to payments under the Medicaid program. That enforcement history strongly suggests that, in the years immediately following the enactment of the MFFCA, executive branch officials in Arkansas understood § 902(8) and the remainder of the MFFCA to apply solely to Medicaid fraud.

The trial court's MFFCA liability standards create tremendous uncertainty among regulated entities in the healthcare field, particular the many hospitals that conduct business in Arkansas. Those standards make it very difficult for them to remain in business in Arkansas without exposing themselves to massive liabilities based on nothing more than good-faith disagreements or misunderstandings regarding regulatory requirements. For example, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 110 Stat. 1936, is one of many laws governing the day-to-day activities of healthcare providers. HIPAA requires them to maintain extensive records regarding every patient they treat. The decision below raises the possibility that each such record could form the basis for a

§ 902(8) claim against the healthcare provider, even when the record would not be viewed as "false" under the ordinary and usually accepted meaning of that word and even though most HIPAA records play no part in requests for Medicaid payments. The decision below suggests that § 902(8) comes into play whenever the provider's statement is made with respect to information "required" by federal law, a description that applies to virtually all HIPAA documents. If the decision below is affirmed, providers will have no guidance that will enable them to ensure that their statements do not run afoul of § 902(8).

II. THE TRIAL COURT'S IMPOSITION OF 238,874 STATUTORY PENALTIES WAS NOT AUTHORIZED BY § 903(a)(1)

The MFFCA provides that a person or entity found to have violated § 902 shall be liable to Arkansas for: (1) full restitution; (2) a civil penalty of not less than $5,000 or more than $10,000 "for each violation"; and (3) three times the amount of all payments "found to have been fraudulently received from the Arkansas Medicaid program." A.C.A. § 20-77-903(a)(1). Arkansas does not contend that anyone has suffered losses as a result of Appellants' allegedly inadequate risk disclosures, nor that Appellants fraudulently received any payments from the Medicaid Program; accordingly, § 903(a)(1)'s civil penalty provision is the only possible basis for recovery from Appellants under the

MFFCA. The trial court determined that every occasion on which Risperdal was dispensed to an Arkansas consumer during 2002-2006 constituted a separate offense for purposes of § 903(a)(1)'s "for each violation" provision. It thus calculated Appellants' MFFCA liability ($1.2 billion) by multiplying the number of Risperdal prescriptions and refills for Medicaid recipients (238,837) by the MFFCA's $5,000-minimum-per-offense civil penalty.

That calculation is inconsistent with § 903(a)(1). The statute authorizes a $5,000 civil penalty "for each violation," and neither the trial court nor Arkansas has come forward with a plausible theory that would explain how Appellants could be deemed to have committed a new violation of § 902(8) (*i.e.*, to have uttered a new false statement with respect to information required by FDA regulations) each time Risperdal is dispensed to an Arkansas consumer. For one thing, the label or "package insert" for Risperdal (the detailed document in which FDA has mandated that the "Warnings" section be included) is generally not provided to consumers along with the drug.[10] Thus, Janssen cannot be deemed to have made any sort of statement, let alone a false statement, when Risperdal is

[10] The medical information on the package insert is sufficiently complex that it is generally considered to be beyond the understanding of most consumers. The package insert is primary targeted at medical professionals.

dispensed. The MFFCA prohibits false statements, not the sale of drugs.

Moreover, Janssen neither writes nor fills Risperdal prescriptions. Rather, Janssen sells Risperdal to wholesalers, who in turn supply it to licensed pharmacies. Risperdal is dispensed only after doctors write prescriptions for their patients, and the patients bring the prescriptions to their pharmacists, who in turn seek reimbursement for the cost of drugs provided to individuals covered by Medicaid. Given that Janssen plays no role in the drug-dispensing process, there is no plausible basis for asserting that it commits a new violation of the MFFCA each time Risperdal is dispensed.

Arkansas contends that the Medicaid Program needs accurate labeling information so that it can "alert Arkansas doctors about Warnings on the label – *i.e.*, to follow up with individual doctors about individual Medicaid patients' use of a drug to caution the doctors about possible side effects, monitoring that may be necessary with the patient, contraindications, and the like." Ark. Response at 18. But Arkansas essentially concedes that it would not have altered its policies toward Risperdal if the risk information had been included in the Warnings section throughout 2002-2006, and it does not contend that the subsequent inclusion of that information has caused any alterations in Medicaid policy. The MFFCA authorizes an award of restitution in those instances in which violations of the

MFFCA cause injury, but in this instance the allegedly inadequate risk disclosure did not injure Arkansas and did not prevent it from supplying alerts to Arkansas doctors that it would otherwise have disseminated. Under those circumstances, § 903(a)(1) authorizes Arkansas to impose a civil penalty of between $5,000 and $10,000 for a violation of § 902(8), but it does not authorize Arkansas to multiply the civil penalty hundreds of thousands of times by claiming fictitious separate violations that bear no relationship to the conduct actually engaged in by Appellants.[11]

Finally, Arkansas's attempt to impose a massive penalty under § 903(a)(1) is inconsistent with statutory language demonstrating the legislature's desire to avoid excessive penalties. After setting forth permissible fines and penalties for violating the MFFCA, § 903(a) provides, "The court may assess not more than two (2) times

[11] The trial court determined that the allegedly inadequate risk disclosure in the Risperdal label somehow rendered the drug ineligible for Medicaid reimbursement. Appellants' brief demonstrates conclusively that that determination is incorrect as a matter of federal law. Moreover, even if Arkansas were correct regarding ineligibility for reimbursement (and it is not), it fails to explain how such ineligibility transforms every prescription of Risperdal into a separate false statement in violation of the MFFCA.

the amount of damages which the state sustained because of the act of the person." A.C.A. § 20-77-903(a)(2). Arkansas does not contend that it sustained any damages as a result of Appellants' allegedly inadequate risk disclosure. While § 903(a)(2) most likely does not bar Arkansas from assessing the $5,000-to-$10,000 civil penalty in cases in which the State sustained no damages, it provides strong evidence that the legislature sought to avoid excessive MFFCA penalties and thus did not authorize the Attorney General to rely on § 903(a)(1)'s "for each violation" language to impose massive penalties.

III. THE MFFCA JUDGMENT VIOLATES APPELLANTS' FREE SPEECH RIGHTS

Arkansas has imposed a $1.2 billion sanction on Appellants under the MFFCA as a result of their speech; that is, as a result of the statements that Janssen included in the Risperdal label. That burden on their speech rights violates their constitutional rights to free speech, regardless what standard of review the Court ultimately determines should governs this case.

Arkansas's principal response to Appellants' free speech claims is that the First Amendment (and Article II, Section 6 of the Arkansas Constitution) are inapplicable here, because the jury determined that the speech in question was false, and false speech is not entitled to constitutional protection. Ark. Response

33-37. That response is wrong on two counts.

First, it simply is not true that the jury determined that the Risperdal label was false in any constitutional sense. The trial court did not require the jury, as a prerequisite to a finding of liability, to find that anything stated on the label was provably false. Rather, it was sufficient for the jury to find that the Warnings section of the label failed to include risk information that, according to Arkansas, should have been included. As explained above, a statement is not "false" simply because it includes some, but not all, risk information for a prescription drug. In the absence of a finding that the Warnings section of the Risperdal label clearly implied that it included *all* risk information, the failure to include all such information does not constitute a false statement of fact. As the U.S. Supreme Court has repeatedly stressed, a statement is not deemed "false" for First Amendment purposes unless a reasonable listener would understand the speech to convey a statement of fact that is provably false. *See, e.g., Hustler Magazine, Inc. v. Falwell*, 485 U.S. 46, 57 (1988).[12]

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[12] Moreover, the Court has held that "an appellate court has an obligation to make an independent examination of the whole record to make sure that the judgment does not constitute a forbidden intrusion on the field of free expression." *Bose Corp. v. Consumers Union*, 466 U.S. 485, 499 (1984). Accordingly, it would

Second, the U.S. Supreme Court has explicitly rejected the claim that speech categorically loses all First Amendment protection the moment a State determines that the speech is false. Rather, the Court has held, false claims may be categorically banned only in conjunction with "evidence that the speech was used to gain a material advantage" – as when the speech is used to secure funds through fraud. *United States v. Alvarez*, 132 S. Ct. 2537, 2548 (2012).[13] In the absence of a claim by Arkansas that Janssen acted fraudulently or gained any advantage as a result of its label, it is incumbent on Arkansas to demonstrate that the major sanctions it is attempting to impose on Appellants' speech can withstand First Amendment scrutiny.

Arkansas asserts that the Risperdal label is "commercial speech," that such speech is entitled to a reduced level of constitutional protection, and that it is entitled to prohibit all false or misleading commercial speech. Ark. Response at

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be inappropriate for this Court to defer to the trial court's determinations of falsity.

[13] The Court explained:

> [T]here are instances in which the falsity of speech bears upon whether it is protected. Some false speech may be prohibited even if analogous true speech could not be. . . . But [this opinion] rejects the notion that false speech should be in a general category that is presumptively unprotected.

Id. at 2646-47.

33-37. To the contrary, the speech at issue here should not be classified as commercial speech; and even if it were so classified, Arkansas's $1.2 billion civil penalty could not withstand First Amendment scrutiny under any relevant standard of review.

The U.S. Supreme Court has made clear that "commercial speech," while entitled to a substantial degree of constitutional protection, is afforded a somewhat lower level of First Amendment protection than is speech that is noncommercial in nature. *See, e.g., Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 562-63 (1980). In general, "commercial speech" is defined as "speech which does no more than propose a commercial transaction." *Virginia State Bd. of Pharm. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976). The speech at issue here – the Risperdal label – does not meet that definition. Janssen does not disclose risk information for the purpose of proposing a commercial transaction with anyone. Indeed, it is well understood that the potential purchasers of Risperdal (patients in need of antipsychotic medication) generally neither receive nor read the "package insert" that contained the statements at issue, so one cannot plausibly argue that Janssen included risk information on its label for the purpose of persuading patients to purchase its product. The fact that the statements were made in connection with a profit-

seeking venture is insufficient to classify the statements as commercial speech. Fully protected speech is not transformed into commercial speech merely because the speaker is hoping to profit from his speech. *See, e.g., Bd. of Trustees of State University of New York v. Fox*, 492 U.S. 469, 482 (1989) (explaining that "[s]ome of our most valued forms of fully protected speech are uttered for a profit. *See, e.g., New York Times Co. v. Sullivan*, 376 U.S. 254 (1964).").

Moreover, even if the Risperdal label qualified as commercial speech, the U.S. Supreme Court has made clear that restrictions on commercial speech are entitled to "heightened" First Amendment review when, as here, the restrictions are content-based – that is, they are being imposed based on Arkansas's disapproval of the message being conveyed. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2664 (2011).

Ultimately, however, it matters little what standard of review the Court applies to Arkansas's restrictions on Janssen's speech because those restrictions cannot withstand First Amendment scrutiny even if this Court applies the somewhat relaxed standard of review applicable to commercial speech. At a minimum, the U.S. Supreme Court requires that the government prove that its speech restriction "directly advances" a "substantial government interest" and is "narrowly tailored" to achieve a reasonable "fit" between its stated goals and the

means used to achieve them. *Central Hudson*, 447 U.S. at 566. As with fully-protected speech, the burden of justifying restrictions on commercial speech rests squarely with the government regulator. *Thompson v. W. States Medical Center,* 535 U.S. 357, 373 (2002).

Arkansas has not demonstrated that it satisfies the narrow tailoring test. It is seeking to impose a $1.2 billion sanction on Appellants under the MFFCA for speech that failed to fully disclose Risperdal risk information in a timely manner – contending that Janssen should have included the information in the Warning section of Risperdal's label, as opposed to the other sections where it appeared, throughout the 2002-2006 period. Yet, Arkansas has presented no evidence suggesting that a sanction anywhere approaching the magnitude of the $1.2 billion MFFCA judgment is necessary in order to ensure timely disclosures. Indeed, Arkansas has not even presented evidence suggesting that an injunction ordering timely disclosures of risk information discovered in the future – unaccompanied by any civil penalty – would not be fully effective. In sum, the MFFCA judgment cannot withstand scrutiny under even the relaxed *Central Hudson* standard of review and accordingly must be vacated on First Amendment grounds.

CONCLUSION

Amici curiae respectfully request that the Court reverse the judgment of the trial court entered pursuant to the MFFCA.

Respectfully submitted,

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