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SUPREME COURT OF ARKANSAS

No. CV-12-1058

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA, INC., AND/OR JANSSEN, LP; AND JOHNSON & JOHNSON, INC. APPELLANTS V. STATE OF ARKANSAS APPELLEE	**Opinion Delivered** March 20, 2014 APPEAL FROM THE PULASKI COUNTY CIRCUIT COURT [NO. CV2007-15345] HONORABLE TIMOTHY DAVIS FOX, JUDGE REVERSED AND DISMISSED IN PART; REVERSED AND REMANDED IN PART.

KAREN R. BAKER, Associate Justice

This appeal stems from litigation regarding Risperdal (risperidone). Risperdal is a second-generation, or atypical, antipsychotic medication developed in 1993 by the appellants, Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc. and/or Janssen, LP, and Johnson & Johnson ("Janssen"). Risperdal is considered to be highly beneficial in treating schizophrenia patients and allowing them to return to more productive lives.

Risperdal was approved by the Food and Drug Administration ("FDA") and put on the market in 1994.[1] The development of Risperdal and other second-generation antipsychotics was a tremendous breakthrough for this arena. The first-generation

[1]The Arkansas Medicaid Program has approved Risperdal for reimbursement since 1994.

antipsychotics were riddled with side effects, including severe neuroleptic effects, similar to Parkinson's disease. The State's expert, psychiatrist Dr. William Wirshing, compared the introduction of Risperdal to the advent of the antibiotic penicillin in the 1950s and labeled Risperdal as a "godsend." Further, Wirshing testified that second-generation antipsychotics are among the most powerful disease modifiers in all of modern medicine and that psychiatrists felt it was a "miracle drug" because it did not have the serious side effects of first-generation antipsychotics.

In 2000, the FDA requested that all drug manufacturers of second-generation antipsychotics provide any information that the companies had regarding weight gain and diabetes associated with the antipsychotics. Janssen responded in August 2000, but the FDA did not take action until September 2003. In September 2003, the FDA notified Janssen and all other drug manufacturers producing second-generation antipsychotics to add a class warning to their labels about diabetes. Janssen did not agree with the FDA's assessment that all second-generation antipsychotics required the same warning and corresponded with the FDA regarding modification of its label. In addition to the class warning, the FDA required all second-generation antipsychotic-drug manufacturers to send a letter to all health-care providers nationwide (referred to in the pharmaceutical industry as a "Dear Doctor Letter" ("DDL")) to advise of the label change.

On November 10, 2003, Janssen sent its DDL stating that the FDA had requested all manufacturers of second-generation antipsychotics, including Risperdal, to include a class-warning label regarding hyperglycemia and diabetes mellitus in their product labeling and to

enclose updated prescribing information for Risperdal. The November 10, 2003 DDL included the diabetes class-warning label and additional statements regarding Risperdal. The DDL stated in pertinent part:

> November 10, 2003
>
> Dear Healthcare Provider,
>
> The Food and Drug Administration (FDA) has requested all manufacturers of atypical antipsychotics to include a warning regarding hyperglycemia and diabetes mellitus in their product labeling. In addition to Janssen, the FDA made this request to the following manufacturers:
>
> AstraZeneca — Seroquel® (quetiapine)
> Bristol-Myers Squibb — Abilify™ (aripiprazole)
> Eli Lilly and Company — Zyprexa® (olanzapine)
> Novartis — Clozaril® (clozapine)
> Pfizer — Geodon®(ziprasidone)
>
> In an effort to keep you updated with the most current product information available for the management of your patients, enclosed please find updated prescribing information for RISPERDAL®(risperidone).
>
> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.
>
> For additional information about RISPERDAL or any other Janssen product, please call 1-800-JANSSEN (526-7736) from 9AM to 5PM EST, Monday through Friday.
>
> Sincerely,
> Ramy Mahmoud, MD
> Vice President CNS Medical Affairs
> Janssen Pharmaceutica, Inc.

The DDL cited eight references in support of its position.

On April 19, 2004, in response to Janssen's November 10, 2003 DDL, the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") sent a "DDMAC Warning Letter" (hereinafter "Warning Letter") to Janssen, directing Janssen to cease dissemination of any promotional materials contained in the information in the DDL and to also submit a plan of action to disseminate accurate and complete information. The "Warning Letter" stated in pertinent part:

WARNING LETTER

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a "Dear Healthcare Provider" (DHCP) Letter for Risperdal®(risperidone) disseminated by Janssen Pharmaceutica, Inc. on November 10, 2003. DDMAC has concluded that the DHCP letter is false or misleading in violation of Sections 502(a) and 201(n)of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. 352(a) and 321(n)), because it fails to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling (PI), minimizes the risk of hyperglycemia-related adverse events, which in extreme cases is associated with serious adverse events including ketoacidosis, hyperosmolar coma, and death, fails to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible, and misleadingly claims that Risperdal is safer than other atypical antipsychotics.

Although Janssen disagreed with the DDMAC's position and asserted that scientific evidence supported its 2003 DDL, Janssen followed the DDMAC's directive and sent a corrective letter with information about Risperdal, relating to hyperglycemia and diabetes, to the recipients of its DDL letter.[2] On July 21, 2004, Janssen sent a corrective letter to

[2]Although Janssen followed the Warning Letter's directive, it also objected to the Warning Letter and corresponded with the DDMAC on the following dates: April 19, April

health-care providers. The corrective letter, titled "IMPORTANT CORRECTION OF DRUG INFORMATION," stated in part as follows:

> The Food and Drug Administration's (FDA) Division of Drug, Marketing, Advertising, and Communications (DDMAC) has asked us to contact you because Janssen Pharmaceutica Products, L.P. recently received a Warning Letter concerning the promotion of Risperdal ® (risperidone). This letter provides important corrective information about Risperdal relating to hyperglycemia and Diabetes Mellitus.
>
> The Warning Letter concludes that Janssen disseminated a Risperdal Dear Health Care Provider (DHCP) dated November 10, 2003 that omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act ["FDCA"].
>
> Specifically, the Warning Letter stated that the DHCP letter omitted important information regarding hyperglycemia and diabetes, including the potential consequences and the recommendation of regular glucose control monitoring that was added to the approved product labeling for Risperdal; minimized the potentially fatal risks of hyperglycemia-related adverse events such as ketoacidosis, hyperosmolar coma and death; minimized the importance of blood glucose monitoring; suggested that Risperdal did not increase the risk of diabetes, contradicting the Warning in the revised product labeling; and made misleading claims suggesting that Risperdal has a lower risk of hyperglycemia and diabetes than other atypical anti-psychotics without adequate substantiation which is inconsistent with the Prescribing Information for Risperdal.
>
> In order to provide you with complete and accurate information regarding hyperglycemia and Diabetes Mellitus relative to Risperdal, please be advised that the Risperdal Prescribing Information was updated with the addition of the Warning in November 2003:
>
> WARNINGS
>
> **Hyperglycemia and Diabetes Mellitus**
>
> > Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical

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28, May 24, June 8, June 28, and July 26, 2004.

> antipsychotics including RISPERDAL®. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical anti-psychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical anti-psychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

On October 14, 2004, the DDMAC closed the matter, citing to Janssen's multiple letters of correspondence on the matter, without taking any further action. The October 14, 2004 letter from the DDMAC stated as follows:

> This letter responds to Johnson & Johnson Pharmaceutical Research and Development, L.L.C.'s (J&JPRD) letters on behalf of Janssen Pharmaceutica Products L.P. (Janssen) dated July 26, June 28, June 8, May 24, April 28, and April 19, 2004. These letters are regarding corrective actions taken in response to the Division of Drug Marketing, Advertising, and Communications' (DDMAC) serious concerns, voiced in its Warning Letter of April 19, 2004 regarding Janssen's dissemination of a Dear Healthcare Provider (DHCP) letter for Risperdal (risperidone). In addition, reference is made to DDMAC's May 27 and June 16, 2004 supplemental correspondences.
>
> DDMAC reviewed Janssen's DHCP Letter, dated November 10, 2003, and concluded that it was false or misleading in violation of the Federal Food, Drug, and Cosmetic

> Act (Act). In its correspondence, J&JPRD indicated that it had discontinued all promotional materials for Risperdal containing same or similar claims, issued a corrective DHCP letter (Important Correction of Drug Information Letter) to 754,000 healthcare providers, and issued an alternative DHCP letter that was posted on FDA's MedWatch website.
>
> In light of the aforementioned actions taken by J&JPRD regarding Risperdal's promotional materials, DDMAC considers this matter closed.

Subsequent to the DDMAC closing the matter, the Attorney General became involved with Risperdal litigation in early 2007. Justin Allen, Chief Deputy Attorney General at that time, testified that the Attorney General's office became interested in second-generation antipsychotic litigation, including Risperdal, when it was approached in early 2007 by outside law firms and other states' Attorney General offices.

In November 2007, the State filed suit against Janssen alleging violations of the Arkansas Medicaid Fraud False Claims Act ("MFFCA"), Ark. Code Ann. §§ 20-77-902 (Repl. 2001), alleging that Janssen knowingly made false statements or representations of material fact in its Risperdal label in violation of the MFFCA, specifically Ark. Code Ann. § 20-77-902(8)(B). The State also alleged violations of the Arkansas Deceptive Trade Practices Act ("DTPA"), Ark. Code Ann. § 4-88-107 (Repl. 2003), by Janssen's November 10, 2003 DDL distribution to Arkansas healthcare providers for making false, deceptive, or unconscionable statements in its promotion letter. The circuit court found that the alleged violations occurred between December 1, 2002, and June 30, 2006.

The State's theory of the case was that Janssen failed to comply with a federal labeling requirement, 21 C.F.R. § 201.57(e) (2002). The State further theorized that the alleged labeling violations triggered a violation of the MFFCA when the Arkansas Medicaid program

paid for reimbursement of Risperdal prescriptions. With regard to the MFFCA, the circuit court found that there were 238,874 Risperdal prescriptions filled and/or refilled during the 2002–2006 time frame. The State proceeded with its theory that these violations were actionable under § 20-77-902(8)(B).

As for the DTPA, the State's theory was that Janssen's 2003 DDL violated the DTPA, and it submitted the number of healthcare providers in Arkansas that had received the DDL as violations. The total number of DDL copies to healthcare providers in Arkansas was 4,569 and was the basis for the number of violations under the DTPA.

After a twelve-day jury trial, the jury found that Janssen had violated the MFFCA and the DTPA. The circuit court conducted a civil-penalties hearing and found that 238,874 prescriptions had been filled during the December 2002 to June 2006 time period, and that each constituted a violation under the MFFCA. The circuit court imposed the minimum statutory fine of $5,000 per violation for a total of $1,194,370,000. With regard to the DTPA violations, the circuit court found that, based on the jury's verdict, there were 4,569 violations, the number of copies of the DDL sent to healthcare providers, and imposed a $2,500 fine per violation for a total of $11,422,500. Janssen made timely directed-verdict, JNOV, and new-trial motions on both claims. This appeal followed.

We note that in a companion case, *Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. State*, 2014 Ark. 126, we address the attorney's fees and costs award.

From the denial of those motions, Janssen presents four issues on appeal: (1) the circuit court erred as a matter of law when it entered judgment on the State's MFFCA claim; (2)

the circuit court erred as a matter of law when it entered judgment against the defendants on the State's DTPA claim; (3) the civil penalties violate the excessive-fines and due-process clauses of the Arkansas and United States Constitutions; and (4) the judgment violates the First Amendment of the United States Constitution and the Free Speech Provision of the Arkansas Constitution.[3]

MFFCA

For its first point on appeal, Janssen alleges that the circuit court erred as a matter of law when it entered judgment on the State's MFFCA claim against Janssen. Janssen asserts four bases for this point on appeal: (a) the circuit court's interpretation of the MFFCA was erroneous, overbroad, and untenable; (b) the Federal Food Drug and Cosmetic Act preempts the State's MFFCA claim; (c) the State failed to prove the core elements of MFFCA liability; and (d) the MFFCA and special-verdict forms do not support liability for 238,874 MFFCA violations.

Interpretation of MFFCA

For its first basis for reversal on its MFFCA claim, Janssen asserts that the circuit court

[3]We also note that the following amicus curiae briefs were filed on behalf of: 65 Arkansas Legislators; AARP; Arkansas State Chamber of Commerce; Former FDA Commissioner Dr. Donald Kennedy; Pharmaceutical Research and Manufacturers of America; States of South Carolina, Alaska, Arizona, California, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, and Washington; The Public Citizen, Inc.; and Washington Legal Foundation and Allied Educational Foundation.

erred in its interpretation of Ark. Code Ann. § 20-77-902(8)(B) because the alleged conduct does not fall within the MFFCA. Accordingly, Janssen asserts that the circuit court interpreted the provision in an overbroad and untenable manner and urges us to reverse the circuit court's judgment.

The State responds that the circuit court correctly interpreted the MFFCA, claiming that reimbursement funds paid for allegedly mislabeled Risperdal prescriptions fall squarely within the MFFCA. The State contends that Janssen's actions violated subsection (8)(B) when it failed to comply with the FDA labeling requirements of 21 C.F.R. § 201.57(e), and that liability is proper because the Risperdal prescriptions at issue were paid for through the Arkansas Medicaid Program.

Janssen's first point on appeal requires us to interpret the statute at issue. We review issues of statutory interpretation de novo because it is for this court to decide what a statute means. *Cooper Realty Inv., Inc. v. Ark. Contractors Licensing Bd.*, 355 Ark. 156, 134 S.W.3d 1 (2003). While we are not bound by the circuit court's ruling, we will accept that court's interpretation of a statute unless it is shown that the court erred. *Id.* When dealing with a penal statute, this court strictly construes the statute in favor of the party sought to be penalized. *Id.*

Turning to our review of the statute before the us, "[t]he 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." *Potter v. City of Tontitown*, 371 Ark. 200, 209, 264 S.W.3d 473, 481 (2007). However, "when a statute is ambiguous, . . . we

must interpret it according to the legislative intent, and its review becomes an examination of the whole act." *Johnson v. Dawson*, 2010 Ark. 308, at 5, 365 S.W.3d 913, 916; *see also MacSteel Div. of Quanex v. Ark. Okla. Gas Corp.*, 363 Ark. 22, 30, 210 S.W.3d 878, 883 (2005) (observing "that this court will not read into a statute a provision that simply was not included by the General Assembly")). "The basic rule of statutory construction is to give effect to the intent of the legislature." *Dep't of Human Servs. & Child Welfare Agency Review Bd. v. Howard*, 367 Ark. 55, 62, 238 S.W.3d 1, 6 (2006). Additionally, in construing any statute, we place it beside other statutes relevant to the subject matter in question and ascribe meaning and effect to be derived from the whole. *Lawhon Farm Servs. v. Brown*, 335 Ark. 272, 984 S.W.2d 1 (1998). Statutes relating to the same subject must be construed together and in harmony, if possible. *Jester v. State*, 367 Ark. 249, 239 S.W.3d 484 (2006).

We first review the applicable statute, Ark. Code Ann. § 20-77-902(8)(B):

> A person shall be liable to the State of Arkansas, through the Attorney General, for a civil penalty and restitution if he or she:
>
> > (8) 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:
> >
> > > (B) With respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements;

Id.

In reading subsection (8)(B), as it is codified, a person is held liable to the state of Arkansas if he or she knowingly makes a false statement or representation of a material fact with respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements. We read this language as ambiguous and are unable

to ascertain when liability occurs with regard to the MFFCA. Therefore, we turn to the entire subsection 8(A)–(B):

> A person shall be liable to the State of Arkansas, through the Attorney General, for a civil penalty and restitution if he or she:
>
> (8) 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 conditions 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, 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[.]

Ark. Code Ann. § 20-77-902 (8)(A)–(B).

On review, subsection (8)(B) is inharmonious with subsection (A). First, subsection (A) provides that a person shall be liable to the State of Arkansas 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 with respect to the conditions 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, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity for which certification is required. In sum, under (8)(A), during the certification or recertification of a nursing home or similar facility named in the statute, if a person makes a false statement or misrepresentation of material fact, the statute

is triggered.

However, subsection (8)(B) provides that a person is liable to the State "if he or she knowingly makes a false statement or representation of a material fact . . . with respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements." What the General Assembly may have intended by this language is unclear because we cannot determine which "federal and state law, rules, regulations, and provider agreements" are "applicable." The question that arises is whether subsections (A) and (B) are to be read together or whether the provisions stand alone to create separate prohibitions. Thus, Ark. Code Ann. § 20-77-902(8)(B) is open to more than one interpretation and because reasonable minds could disagree as to its meaning, we cannot say that it is "clear and unambiguous" on its face. In light of this ambiguity, we turn to the statute's legislative history. *See Harrell v. State*, 2012 Ark. 421, ___ S.W.3d ___. In reviewing the legislative history, by Act 1299 of the 1993 Regular Session of the 79th General Assembly, the General Assembly enacted Ark. Code Ann. § 20-77-901 et seq., the MFFCA, including section 20-77-902. However, the language in Act 1299, § 2 differs from the language that was codified at § 20-77-902. Act 1299 provides in part:

> SECTION 2. Liability for certain acts.
>
> (a) A person shall be liable to the State of Arkansas, through the Attorney General, for a civil penalty and restitution if he:
>
> > (8) 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 with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify either upon initial certification or upon recertification as a hospital, rural primary care hospital, skilled nursing

> facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity for which certification is required or with respect to information required pursuant to applicable federal and state law, rules, regulations and provider agreements[.]

Act of Apr. 23, 1993, No. 1299, § 2, 1993 Ark. Acts 4282, 4283.

In comparing the General Assembly's language to the codified version, it is apparent that the language of the General Assembly was substantially altered by the Arkansas Code Revision Commission (ACRC). When Act 1299 was codified, subsection (a)(8) was separated into two separate stand-alone provisions–subsections (8)(A) and (8)(B)– substantially altering the meaning of subsection (a)(8).

Act 1299 § 2(a)(8) in its original form was one sentence that provides liability to persons or entities, that, while acquiring certification or recertification for operation of its facilities either: 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 or 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 with respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements. Stated differently, liability is triggered when either a false statement or a misrepresentation is made regarding the conditions or operations of an institution during certification or recertification *or* when during the certification or recertification process a false statement or misrepresentation of material fact is made regarding applicable federal and state law, rules, regulations, and provider agreements. The language "knowingly makes a false statement or representation of a material fact with respect to information required pursuant to applicable federal and state

law, rules, regulations, and provider agreements" was not intended to be a separate stand-alone liability provision.

Pursuant to Ark. Code Ann. § 1-2-303(d)(1)(A)–(S) (Repl. 2008), the ACRC, in the process of codifying the Acts, is permitted to make certain corrections to spelling, grammar, and clerical errors. However, § 1-2-303(d)(1) specifically provides that "the commission shall not authorize any change in the substance or meaning of any provision of the Arkansas Code or any act of the General Assembly. The bureau shall not change the substance or meaning of any provision of the Arkansas Code or any act of the General Assembly." Ark. Code Ann. § l-2-303(d)(1). Further, Ark. Code Ann. § l-2-303(d)(2) provides that except for the clerical-type changes specifically listed in subsection (d)(1): "the wording, punctuation, and format of sections of acts shall appear in the Arkansas Code *exactly as enacted* by the General Assembly." *Id.* (emphasis added).

Here, the ACRC substantively altered Act 1299 in its codification, which became § 20-77-902(8)(A)–(B), in a manner that rendered its meaning ambiguous by calling into question whether (A) and (B) were stand-alone provisions. The Arkansas Code prohibits such a substantive change. *See Harrell supra*; *Porter v. Ark. Dep't of Health & Human Servs.*, 374 Ark. 177, 182–83, 286 S.W.3d 686, 691 (2008). Thus, the Act controls. Accordingly, we must rely on the original wording of Act 1299. *Id.* Reading subsection (8) as one sentence, we hold that the subsection provides that a person shall be liable to the State of Arkansas, through the Attorney General, for a civil penalty and restitution if he 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 with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify either upon initial certification or upon re-certification as a hospital, rural primary care hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity for which certification is required or with respect to information required pursuant to applicable federal and state law, rules, regulations and provider agreements. As is apparent from this reading, the word "applicable" refers to the certification process and laws applicable to the process.

Accordingly, we reverse the circuit court's order denying Janssen's motion for directed verdict and dismiss the State's claim under the MFFCA as Janssen is indisputably not a healthcare facility and applying for certification or re-certification as described in the statute. Hence, the statutory provision is not applicable. As we have reversed and dismissed the State's MFFCA claim, we need not address Janssen's remaining arguments for reversal on its first point.

DTPA

For its second point on appeal, Janssen asserts that the circuit court erred when it entered judgment against Janssen on the State's DTPA claim. Janssen asserts two bases for reversal under this point: (a) the circuit court erroneously admitted the 2004 DDMAC "Warning Letter" and (b) the State's DTPA claim is preempted by federal law.

2004 DDMAC "Warning Letter"

For its first basis for reversal under its second point, Janssen contends that the circuit

court erred when it admitted the "Warning Letter" in the State's DTPA claim against Janssen. Janssen contends that the letter was hearsay and inadmissible under Rule 801 of the Arkansas Rules of Evidence, that it does not fall within an exception to the hearsay prohibition, and that it is inadmissible under Rule 803(8)(iv) because the "Warning Letter" was the result of a special investigation of a particular complaint, case, or incident. Janssen asserts that the State relied almost exclusively on the content of the letter to prove its claim under the DTPA. It further asserts that the prejudice of this outweighs any value that the letter may have added. In sum, Janssen contends that the letter is hearsay, that it does not fall within one of the exceptions to hearsay, and that it should have been excluded from the evidence under Rule 803(8)(iv).

The State responds that Janssen has mischaracterized its argument and that the letter was admissible under Rule 803(8) as it was part of an ongoing, routine investigation by the DDMAC and was part of the records, reports, or data compilations of the DDMAC resulting from an investigation made pursuant to authority granted by law. Citing to *Omni Holding & Development Corp. v. 3D.S.A., Inc.*, 356 Ark. 440, 156 S.W.3d 228 (2004), and *Archer-Daniels-Midland Co. v. Beadles Enterprises, Inc.*, 367 Ark. 1, 238 S.W.3d 79 (2006), the State contends that the letter was admissible and the circuit court did not err.

First, we will review the applicable DTPA statute, Ark. Code Ann § 4-88-107(a)(10), "Deceptive and Unconscionable Trade Practices," which provides in pertinent part:

> (a) Deceptive and unconscionable trade practices made unlawful and prohibited by this chapter include, but are not limited to, the following:
>
> (10) Engaging in any . . . unconscionable, false, or deceptive act or practice in

business, commerce, or trade[.]

In support of its position that Janssen had violated the DTPA, the State introduced, over Janssen's objection, the "Warning Letter," which stated in pertinent part:

WARNING LETTER

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a "Dear Healthcare Provider" (DHCP) Letter for Risperdal®(risperidone) disseminated by Janssen Pharmaceuitca, Inc. on November 10, 2003. DDMAC has concluded that the DHCP letter is false or misleading in violation of Sections 502(a)and 201(n)of the Federal Food, Drug, and Cosmetic Act (Act) 21 U.S.C. 352(a) and 321(n) because it fails to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling (PI), minimizes the risk of hyperglycemia-related adverse events, which in extreme cases is associated with serious adverse events including ketoacidosis, hyperosmolar coma, and death, fails to recommend regular glucose control monitoring to identify diabetes mellitus as soon as possible, and misleadingly claims that Risperdal is safer than other atypical antipsychotics.

Whether the "Warning Letter" was admissible requires us to review the circuit court's evidentiary ruling. Circuit courts have broad discretion, and a circuit court's ruling on the admissibility of evidence will not be reversed absent an abuse of that discretion. *Advanced Envtl. Recycling Techs., Inc. v. Advanced Control Solutions, Inc.*, 372 Ark. 286, 275 S.W.3d 162 (2008). On appeal, we will not reverse a circuit court's ruling on the admission of evidence absent an abuse of discretion nor will we reverse absent a showing of prejudice. *See Grummer v. Cummings*, 336 Ark. 447, 986 S.W.2d 91 (1999); *Edwards v. Stills*, 335 Ark. 470, 984 S.W.2d 366 (1998). A circuit court abuses its discretion when it makes a decision that is arbitrary or capricious. *See Phelan v. Discover Bank*, 361 Ark. 138, 205 S.W.3d 145 (2005). Moreover, the balancing of probative value against prejudice is a matter left to the sound discretion of the circuit court, and its decision on such a matter will not be reversed absent

a manifest abuse of that discretion. *See Grummer*, *supra*.

Turning to the Arkansas Rules of Evidence (2013), Rule 801(c) defines hearsay as a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted. Rule 802 further provides that "[h]earsay is not admissible except as provided by law or by these rules." Rule 803(8) provides in pertinent part:

> The following are not excluded by the hearsay rule, even though the declarant is available as a witness:
>
> > (8) Public Records and Reports. To the extent not otherwise provided in this paragraph, records, reports, statements, or data compilations in any form of a public office or agency setting forth its regularly conducted and regularly recorded activities, or matters observed pursuant to duty imposed by law and as to which there was a duty to report, or factual findings resulting from an investigation made pursuant to authority granted by law. The following are not within this exception to the hearsay rule:
> > . . .
> >
> > (iv) factual findings resulting from special investigation of a particular complaint, case, or incident[.]

Ark. R. Evid. R. 803.

In other words, while "factual findings resulting from an investigation made pursuant to authority granted by law" are admissible, factual findings "resulting from special investigation of a particular complaint, case, or incident" are not admissible. *Id*.

In reviewing the admissibility of the "Warning Letter," we first turn to the two cases relied on by the State in support of its position that we should affirm the circuit court. For two reasons, neither of those cases is helpful to our analysis: (1) the cases did not address the admissibility or inadmissibility of evidence pursuant to Rule 803(8)(iv) and (2) the cases do

not discuss the circumstances surrounding the government-issued warning letter or report involved in each particular case.

Omni Holding was a replevin action between a lessor and lessee of airplanes and damaged and switched plane parts. The circuit court admitted Federal Aviation Association ("FAA") inspection reports, and on appeal, Omni argued that the FAA reports were hearsay evidence that had been admitted without any foundational proof by a records custodian to show that the reports were true public records. As a corollary argument, Omni contended that each FAA document amounted to expert opinion evidence that was not subject to cross-examination and, thus, Omni was denied its right to confront witnesses. Omni did not assert that the reports were hearsay pursuant to Rule 803(8)(iv). We affirmed the circuit court and held that the reports clearly fell within the Rule 803(8) exception: "A review of all three [FAA] reports reveals that each document was signed and verified by an FAA employee. All three reports, entitled 'Comparison Contrast of Relative Findings,' are findings resulting from investigations made pursuant to authority granted to the FAA by law. They clearly fall within the Rule 803(8) exception and do not fall within any of the five exclusions to that rule." *Omni Holding*, 356 Ark. 440, 459, 156 S.W.3d 228, 242 (2004). Although our holding cited *infra* references Rule 803(8)(iv), Omni did not challenge the admissibility on 803(8)(iv) grounds, and other than our language cited above, we did not address Rule 803(8)(iv) and the circumstances surrounding the FAA inspection reports.

Next, we turn to *Archer-Daniels-Midland* ("ADM"). In *ADM*, Beadles operated a hog-finishing farm and purchased soybean meal from ADM. Beadles asserted that ADM was

aware that its soybean meal was contaminated with dioxin but did not warn Beadles. Beadles subsequently sold his hogs and attempted to ship the hogs, but the shipment was halted by the purchaser who stated that he had received "an official notification" of the alleged contamination. Beadles sued, claiming that ADM had failed to inform him of the contamination that resulted in the death of his hogs. After a bench trial, the circuit court found ADM liable for fraud. ADM appealed, and the court of appeals reversed. We took the case on Beadles's petition for review.

On appeal, the letter at issue was "a statement and warning sent out by the FDA under its duty to protect the public from consuming adulterated food. Further, the letter, which was addressed to feed mill operators, stated that recipients of contaminated soybean meal were to discontinue use of the soybean meal and to hold any remaining soybean meal and feed made from that soybean meal." *Archer-Daniels-Midland*, 367 Ark. 1, 10, 238 S.W.3d 79, 86–87. Beadles asserted that the letter was *admissible* pursuant to Ark. R. Evid. Rule 803(8). In affirming the circuit court, we agreed with Beadles and held that the letter was admissible pursuant to Rule 803(8). Yet, our opinion did not discuss Rule 803(8)(iv), and other than using the language discussed *infra* regarding the letter from the FDA, we did not address the circumstances surrounding the FDA letter. Accordingly, neither *Omni* nor *ADM*, is applicable in this case.

However, our court of appeals' opinion in *McCorkle Farms, Inc. v. Thompson*, 79 Ark. App. 150, 84 S.W.3d 884 (2002), is helpful to our analysis. In *McCorkle*, the court of appeals addressed the admissibility of the conclusions regarding an investigation by the Arkansas State

Plant Board's Pesticide Committee in a crop-damage case. In *McCorkle*, complaints had been lodged, an investigation conducted, and report provided to the Board. McCorkle sought to exclude the report as inadmissible evidence pursuant to Rule 803(8)(iv) and the court of appeals agreed:

> The Plant Board report resulted from a "special investigation of a particular complaint" and is not excepted from the hearsay rule. Ark. R. Evid. 803(8)(iv); *Swart v. Town & Country Home Center*, 2 Ark. App. 211, 619 S.W.2d 680 (1981); *Wallin v. Insurance Co. of N. Am.*, 268 Ark. 847, 596 S.W.2d 716 (Ark. App. 1980).
> . . . .
>
> Because several complaints were made . . . the Plant Board conducted a hearing. Thus, the hearing before the Plant Board was a special investigation of a particular complaint, case, or incident under Rule 803(8)(iv). The hearing before the Plant Board was a special investigation of a particular complaint, case, or incident under Rule 803(8)(iv) [and not a routine investigation].
>
> . . . .
>
> This distinction may be illustrated by the example of a public agency charged with monitoring water quality in the state's rivers. If the agency, in fulfillment of its routine duties, tests the water in a flooding river (i.e., resulting from a particular incident, namely, the flood), the factual findings of those tests would be admissible in a civil trial as within the public records or reports exception to the hearsay rule. If, however, the agency conducts an investigation in response to a complaint that someone is dumping material into a river, the factual results of that investigative report would be inadmissible pursuant to Rule 803(8)(iv). *See Daniels v. Tew Mac Aero Servs., Inc.*, 675 A.2d 984 (Me.1996).
>
> The preceding illustration highlights one of the primary underpinnings of the Rule 803(8) exception, namely, the assumption that routine reports by public officials in their official duties will be prepared properly. *Daniels*, *supra* (discussing the advisers' note to identical Maine R. Evid. 803(8)). That assumption may be suspect when a public official prepares a special report in response to a particular complaint, case, or incident as opposed to merely carrying out routine duties. There may be a greater likelihood that a special report will be influenced by persons interested in the outcome. This is true where the complaining party is not presented an opportunity to be heard at the administrative hearing. The 803(8)(iv) exception guards against the risk of people using public agency investigations as a litigation tool by banning as evidence

> at the trial the factual findings contained in special reports that result from particular complaints, cases, or incidents. *Daniels*, *supra*. Another reason supporting the conclusion that the Board's report is not within the Rule 803 exceptions is that where the drafters wished to make judicially-found facts admissible, they did so expressly. *See* Ark. R. Evid. 803(22) (pertaining to judgments of previous conviction) and Ark. R. Evid. 803(23) (pertaining to judgments as to personal, family, or general history, or boundaries).

McCorkle Farms, 79 Ark. App. 150, 159–61, 84 S.W.3d 884, 889–90 (2002).

Additionally, *Crockett v. City of Billings*, 761 P.2d 813 (Mont. 1988), lends support to our discussion. The Montana Supreme Court held that Rule 803(8)(iv), identical to our Rule, specifically excludes factual findings such as the reasonable-cause finding of the employment commission which directly results from an investigation of a particular complaint of discrimination as it was a finding in a specific investigation and was inadmissible. In *Stevenson v. Felco Industries, Inc.*, 216 P.3d 763 (Mont. 2009), citing to *Crockett*, the Montana Supreme Court revisited its Rule 803(8)(iv), identical to our Rule, and discussed the prejudicial nature of government-issued reports as evidence in litigation. The court explained:

> Many courts have expressed concern that reports issued by governmental agencies, because of their "official" nature, may cause a jury to give the evidence inordinate weight. *Johnson v. Ford Motor Co.*, 988 F.2d 573 (5th Cir.1993). Additionally, courts have observed that reports prepared by a disinterested governmental agency pursuant to a legal obligation carry a " badge of trustworthiness." *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594 (8th Cir. 2005). In *Fowler v. Firestone Tire & Rubber Co.*, 92 F.R.D. 1 (N.D. Miss.1980), the court, in refusing to admit a government report out of concern that the jury would give it inordinate weight, stated, "any probative value the evidence might have would be far outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." *Fowler*, 92 F.R.D. at 2.
>
> In 2003, an article in the *Tort Trial & Insurance Practice Law Journal* noted that "undue prejudice 'arises from the inordinate weight that a jury is likely to give to the probable cause determination reached by a government fact-finding body.'" *James E. Robinson, Challenging Admissibility and Use of Government Investigative Reports*, 38 Tort & Ins. L.J. 887, 901 (2003). Similarly, a note entitled *The Trustworthiness of Government Evaluative*

> *Reports Under Federal Rule of Evidence 803(8)(C)*, published in the Harvard Law Review (96 *Harv. L. Rev.* 492, 495 (1982)) explained that "[b]ecause the report has the government's endorsement, the jury might give it too much weight."

Stevenson, 216 P.3d 763, 771–72.

We also find support for the position that the "Warning Letter" was the result of a special investigation of a particular complaint, case, or incident, from the Arkansas Trial Handbook for Lawyers, which states:

> One of the primary underpinnings of the Ark. R. Evid. 803(8) exception is the assumption that routine reports by public officials in their official duties will be prepared properly. That assumption may be suspect when a public official prepares a special report in response to a particular complaint, case, or incident as opposed to merely carrying out routine duties. There may be a greater likelihood that a special report will be influenced by persons interested in the outcome. This is true where the complaining party is not presented an opportunity to be heard at the administrative hearing. The Ark. R. Evid. 803(8)(iv) exception guards against the risk of people using public agency investigations as a litigation tool by banning as evidence at the trial the factual findings contained in special reports that result from particular complaints, cases, or incidents. It is only the "factual findings" resulting from an investigation that come within the public records and reports hearsay exception of Ark. R. Evid. 803(8).

3A *Trial Handbook for Arkansas Lawyers* § 73:1 (2013-2014 ed.)(internal citations omitted).

Additionally, the FDA manual supports that the "Warning Letter" was part of a special investigation of a particular complaint, case or incident. The FDA Manual states:

> A Warning Letter is informal and advisory. It communicates the agency's position on a *matter*, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued.[4]

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[4]Further, we note that the testimony of the State's pharmacist, Laura Plunkett, supports that the "Warning Letter" was the result of a special investigation because she testified repeatedly the "Warning Letter" was in response to the 2003 DDL. Plummet testified:

> JANSSEN'S ATTORNEY: What specifically in the [2003 DDL] is this warning letter

http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/ucm176870.htm#SUB4-1-10 (emphasis added).

Turning to Janssen's specific evidentiary issue, we find the reasoning from *McCorkle* applicable to Janssen's case and our review of the 803(8)(iv) issue. Here, the "Warning Letter" stemmed from the investigation into the 2003 DDL and the particular information cited in the letter. The October 14, 2004 DDMAC letter closing the matter states: "These letters are regarding corrective actions taken in concerns, voiced in its Warning Letter of April 19, 2004 regarding Janssen's dissemination of [the 2003] Dear HealthCare Provider (DHCP) letter for Risperdal." The investigation was not, as the State alleges, part of routine record keeping and admissible under Rule 803(8). The letter was sent in response to a specific issue and special investigation regarding the 2003 DDL.

Finally, as argued by Janssen, we note that for evidence to be admissible, it must be

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	in response to, Doctor?
WITNESS PLUNKETT:	It's in response to the specific language within the . . . [2003] "Dear Doctor" letter.
. . .	
JANSSEN'S ATTORNEY:	Now what complaints--did the FDA have any complaints specifically with respect to the citations Dr. Mahmoud and Janssen put in their [2003] letter?
WITNESS PLUNKETT:	Yes. They -- the FDA points out that the citations to the study are, in some cases, a misrepresentation of what some of the data actually says. So, again, FDA is finding the information in the letter to be either misleading or untrue.

more probative than prejudicial. *See* Ark. R. Evid. 403. "A good definition of 'unfair prejudice' is found in the advisory committee's commentary to Fed. R. Evid. 403, which describes it as an 'undue tendency to suggest decision on an improper basis." *Berry v. State*, 290 Ark. 223, 233, 718 S.W.2d 447, 453 (1986). Here, the "Warning Letter" was highly prejudicial. "Reports issued by governmental agencies, because of their 'official' nature, may well carry inordinate weight in the minds of jurors." *Boude v. Union Pac. R. Co.*, 277 P.3d 1221, 1225 (Mont. 2012)(internal citations omitted). The "Warning Letter" was referred to repeatedly throughout the trial; in closing arguments alone it was mentioned at least fifteen times.

Based on the preceding discussion, we interpret Rule 803(8)(iv) to exclude the "Warning Letter" as inadmissible and prejudicial. The "Warning Letter" was part of a special investigation of a particular complaint, case, or incident and falls directly within the parameters of the prohibited hearsay from 803(8)(iv), and it is also more prejudicial than probative. Accordingly, based on our standard of review, we hold that the circuit court abused its discretion in admitting the letter and reverse and remand the DTPA claim to the circuit court.[5]

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[5]We note that while the dissent states, "Nothing at all in the record before us evidences that the letter resulted from any special investigation of a 'particular complaint, case or incident[,]'" we disagree. The "Warning Letter" itself specifically states that it is in response to a specific incident, the 2003 DDL. The "Warning Letter"states in pertinent part:

> The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a "Dear Healthcare Provider" (DHCP) Letter for Risperdal®(risperidone) disseminated by Janssen Pharmaceutica, Inc. on November 10, 2003.

As we have reversed and dismissed the MFFCA claim, and reversed and remanded the DTPA claim, we do not reach Janssen's remaining points on appeal.

Reversed and dismissed in part; reversed and remanded in part.

HANNAH, C.J., and CORBIN and DANIELSON, JJ., concur in part and dissent in part.

PAUL E. DANIELSON, Justice, concurring in part and dissenting in part. I wholeheartedly agree with the majority in its reversal and dismissal of the State's MFFCA claim; it is only because I reach that conclusion in a slightly different fashion that I respectfully concur in part. Because I disagree with the majority's conclusion that the DDMAC letter constituted inadmissible hearsay, I respectfully dissent in part.

With respect to the State's MFFCA claim, I believe that the language of Arkansas Code Annotated § 20-77-902(8) is plain and unambiguous. While the State would have this court read subsection (8)(B) standing alone, we simply cannot do so, as a "statute must be analyzed in its entirety and meaning given to all portions." *Commercial Printing Co. v. Rush*, 261 Ark. 468, 473, 549 S.W.2d 790, 793–94 (1977). As explained in one authority:

This language specifically identifies the particular matter under investigation.

Further, although the dissent states that our "position is belied by the DDMAC's mission, which is to 'protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated[,]'" we disagree. While the mission statement explains the DDMAC's general purpose, it is not helpful to the case before us. Rule 803(8)(iv) carefully makes the distinction between general matters and specific matters. Here, the DDMAC's mission does not alter the fact that the "Warning Letter" was in response to a specific incident and inadmissible under Rule 803(8)(iv).

Finally, we note that, although the dissent would find that the "Warning Letter" was admissible, the dissent fails to address the probative value of the letter versus its prejudicial effect under Rule 403.

> A statute is passed as a whole and not in parts or sections and is animated by one general purpose and intent. Consequently, each part or section should be construed in connection with every other part or section to produce a harmonious whole. Thus, it is not proper to confine interpretation to the one section to be construed.

2A *Sutherland Statutory Construction* § 46:5 (7th ed. 2013) (internal footnote omitted).

Subsection (8) of the instant statute is composed of two parts, (A) and (B), and provides that

> [a] person shall be liable to the State of Arkansas, through the Attorney General, for a civil penalty and restitution if he or she:
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> . . . .
>
> (8) 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 conditions 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, 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.

Ark. Code Ann. § 20-77-902(8). When (A) and (B) are read together, there is simply no question in my mind that the "information" referenced in part (8)(B) means any information required pursuant to laws or regulations applicable to the certification or recertification of "any institution, facility, or entity," other than with respect to the conditions or operations of the institution, facility, or entity. Because the State's MFFCA claim is not encompassed within section 20-77-902(8), I agree with the majority that the circuit court's judgment should be reversed and the State's claim dismissed.

I, however, would affirm the circuit court's denial of Janssen's motion in limine with respect to the State's claim under the ADTPA, as I cannot say that the circuit court abused

its discretion in admitting the DDMAC letter over Janssen's objections. Assuming that the instant letter was hearsay, it is apparent to me that the DDMAC warning letter falls clearly within the public-records exception set forth in Ark. R. Evid. 803(8). While Janssen avers that the letter is the result of a "special investigation of a particular complaint, case, or incident," which would preclude its admissibility as an exception to hearsay, I disagree, as I see nothing in the instant record to substantiate such a claim.

There appears to be no dispute that the FDA is a regulatory agency or that the DDMAC is responsible for reviewing and regulating the advertising of, or information pertaining to, prescription drugs pursuant to the FDA's regulatory authority. The warning letter, then, seems to me to unquestionably constitute either a "matter[] observed pursuant to duty imposed by law and as to which there was a duty to report" or "factual findings resulting from an investigation made pursuant to authority granted by law." Ark. R. Evid. 803(8). Nothing at all in the record before us evidences that the letter resulted from any special investigation of a "particular complaint, case, or incident." Ark. R. Evid. 803(8)(iv). To the contrary, it appears that the warning letter was merely the result of the agency's routine duties of reviewing and regulating the information on, and advertising of, drugs such as Risperdal.

Janssen's motion in limine to exclude the DDMAC letter contended that the letter was the result of a special investigation of a particular incident—the mailing of the 2003 DDL. But that argument is belied by the DDMAC's mission, which is to

> protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive

> surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.

FDA, The Office of Prescription Drug Promotion (OPDP) (formerly Division of Drug Marketing, Advertising and Communications—DDMAC), http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm (last updated Mar. 6, 2014). If it is the DDMAC's responsibility to monitor or surveil prescription-drug advertising or information, then I think it can hardly be said to conduct a "special investigation" each time it fulfills its routine duty.

It is for this reason that I believe Janssen's reliance on the court of appeals' opinion in *McCorkle Farms, Inc. v. Thompson*, 79 Ark. App. 150, 84 S.W.3d 884 (2002), is misplaced. In *McCorkle*, the court of appeals drew just this distinction between findings issued as a matter of routine as opposed to those issued in response to a specific complaint:

> This distinction may be illustrated by the example of a public agency charged with monitoring water quality in the state's rivers. If the agency, in fulfillment of its routine duties, tests the water in a flooding river (i.e., resulting from a particular incident, namely, the flood), the factual findings of those tests would be admissible in a civil trial as within the public records or reports exception to the hearsay rule. If, however, the agency conducts an investigation in response to a complaint that someone is dumping material into a river, the factual results of that investigative report would be inadmissible pursuant to Rule 803(8)(iv). *See Daniels v. Tew Mac Aero Servs., Inc.*, 675 A.2d 984 (Me. 1996).

79 Ark. App. at 160, 84 S.W.3d at 889. To that end, *McCorkle* actually supports affirming the circuit court's denial of Janssen's motion in limine, contrary to Janssen's claims otherwise.

Here, there is simply no evidence before us that DDMAC was investigating a particular

complaint, case, or incident.[6] Accordingly, it is clear to me that the DDMAC letter was admissible as a public-records exception to hearsay under Ark. R. Evid. 803(8), in light of the fact that the DDMAC was charged with the responsibility of monitoring and regulating all prescription-drug information. *See, e.g.*, *Archer-Daniels-Midland Co. v. Beadles Enters., Inc.*, 367 Ark. 1, 238 S.W.3d 79 (2006) (holding that a letter statement and warning sent out by the FDA, whose duty was to protect the public from consuming adulterated food, was admissible under Rule 803(8)). We have been resolute that our circuit courts are accorded wide discretion in evidentiary rulings, and we will not reverse such rulings absent a manifest abuse of discretion. *See Mays v. St. Pat Props.*, 357 Ark. 482, 182 S.W.3d 84 (2004). Because I cannot say that the circuit court manifestly abused its discretion in denying Janssen's motion in limine to exclude the DDMAC letter, I would affirm the circuit court's ruling, and I respectfully dissent on this basis.

HANNAH, C.J., and CORBIN, J., join.

O'Melveny &Myers, LLP, by: *Charles C. Lifland* (California), *Stephen D. Brody* and *Walter Dellinger* (Washington DC);

Drinker Biddle & Reath LLP, by: *Thomas F. Campion* (New Jersey), *Edward M. Posner*, *Gregg W. Mackuse* (Pennsylvania); and

Friday, Eldredge & Clark, LLP, by: *James M. Simpson*, *Laura H. Smith*, *Robert S. Shafer*,

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[6]Whether the DDMAC's warning letter was informal or not has no bearing on the matter, in my opinion; the fact that such a letter merely communicates the agency's position on a matter, as opposed to a legal conclusion, further reinforces my conclusion that such a letter is not the product of a "special investigation." Clearly the DDMAC letter found that Janssen's DDL was in violation of federal law; however, the finding that it did so in no way compels me to conclude that there was a special investigation. Nor does Ms. Plunkett's testimony compel me to reach such a conclusion. As I read the colloquy between Ms. Plunkett and counsel, it seems to reference the FDA's own complaints or issues with the DDL, rather than complaints made to the agency by an external entity or individual.

and *Martin A. Kasten*, for appellants.

Dustin McDaniel, Att'y Gen., by: *Bradford J. Phelps*, Chief Deputy Att'y Gen.;
Kellogg, Huber, Hansen, Todd, Evans & Figel, PLLC, by: *David C. Frederick*, *Derek T. Ho*, and *Caitlin S. Hall*; and
Bailey Perrin Bailey PLLC, by: *Fletcher V. Trammell*, *Robert W. Cowan*, *Justin C. Jenson*, and *Elizabeth W. Dwyer*, for appellee.

Mitchell, Williams, Selig, Gates & Woodyard, P.L.L.C., by: *Sherry P. Bartley* and *Brian A. Pipkin*, for amicus curiae Arkansas State Chamber of Commerce in support of appellants.

Richard A. Samp, Washington Legal Foundation; and
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Branch, Thompson, Warmath & Dale, P.A., by: *Robert F. Thompson*; and
Michael J. Gottlieb, for amicus curiae 65 Arkansas Legislators in support of appellees.

Quattlebaum, Grooms, Tull & Burrow, PLLC, by: *Steven W. Quattlebaum* and *E.B. Chiles, IV*; and
Arnold & Porter, LLP, by: *Robert N. Weiner*, *Jeffrey L. Handwerker*, and *Sarah M. Harris*, for amicus curiae Pharmaceutical Research and Manufacturers of America in support of appellants.

Hon. Alan Wilson, Att'y Gen., *Robert Cook*, Solicitor General, *J. Emory Smith*, Deputy Solicitor General, South Carolina; and
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Health Law Associates, by: *Charles R. Hicks*, for amicus curiae former FDA Commissioner Dr. Donald Kennedy.

Scott L. Nelson and *Allison M. Zieve*, Public Citizen Litigation Group;
Lavey & Burnett, by: *John L. Burnett*; and
Annabelle Imber Tuck for amicus curiae Public Citizen, Inc., in support of appellee.