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SUPREME COURT OF ARKANSAS

No. CV-17-788

Opinion Delivered: November 2, 2017

ARKANSAS DEPARTMENT OF CORRECTION AND WENDY KELLEY, IN HER OFFICIAL CAPACITY AS DIRECTOR OF THE ARKANSAS DEPARTMENT OF CORRECTION
APPELLANTS

V.

STEVEN SHULTS
APPELLEE

APPEAL FROM THE PULASKI COUNTY CIRCUIT COURT, SEVENTEENTH DIVISION
[NO. 60CV-17-4931]

HONORABLE MACKIE M. PIERCE, JUDGE

AFFIRMED IN PART; REVERSED AND REMANDED IN PART.

COURTNEY HUDSON GOODSON, Associate Justice

Appellants, the Arkansas Department of Correction and Wendy Kelley, in her official capacity as Director of the Arkansas Department of Correction ("ADC"), appeal from the Pulaski County Circuit Court's order requiring the ADC to provide appellee Steven Shults with the pharmaceutical package inserts and labels for its supply of midazolam, one of the drugs in the State's execution protocol. For reversal, the ADC argues that the lethal-drug information requested by Shults is confidential and not subject to disclosure under the Method of Execution Act ("MEA"), Arkansas Code Annotated section 5-4-617 (Supp. 2015). In the alternative, the ADC contends that, even if the information is not confidential under the MEA, it is still required to redact certain information from the drug labels to protect the confidentiality of sellers and suppliers in the chain of distribution. We affirm in part and reverse and remand in part.

Shults, an Arkansas resident and attorney, filed a complaint against the ADC on September 7, 2017, after it refused to provide him with public records pertaining to the State's supply of midazolam pursuant to his Arkansas Freedom of Information Act ("AFOIA") request. According to the allegations in the complaint, Shults submitted an AFOIA request to the ADC on August 21, 2017, seeking, in part, documents and records held by the agency after May 1, 2017, containing "the name of chemicals or substances intended or considered for use in lethal injection executions, manufacturer/compounder, concentration, expiration date(s) and/or lot numbers of all chemicals or substances intended or considered for use in executions currently in the possession of the ADC." On August 24, 2017, the ADC responded to the request by providing records revealing that on August 4, 2017, Kelley had acquired 4 vials of midazolam, a drug listed in its execution protocol. The ADC refused, however, to disclose the package inserts or labels for the newly acquired supply of midazolam because, it stated, these documents could be used to identify the sellers or suppliers of the drug in violation of the MEA. Shults alleged that the ADC's interpretation of the MEA was in violation of the clear language of the statute and of his rights under the AFOIA, that the ADC was not substantially justified in its refusal to provide the requested records, and that he was entitled to unredacted copies of the drug labels and package inserts.

On September 18, 2017, the ADC filed a motion to dismiss the complaint under Arkansas Rules of Civil Procedure 12(b)(1), 12(b)(6), and 12(b)(8) or, alternatively, for a stay of the proceedings pending the final resolution of a related case filed by Shults. The ADC argued that Shults had failed to state an AFOIA claim because the records he sought

were specifically exempted from public disclosure by the MEA. According to the ADC, the lethal-drug labels and package inserts readily identify the drug manufacturers, who are also sellers and suppliers that are protected by the confidentiality provisions in the MEA. The ADC further argued that interpreting these provisions to include manufacturers comports with both legislative intent and public policy. In the alternative, the ADC asserted that, even if the circuit court concluded that Shults had stated a cognizable AFOIA claim, the court should order information such as lot and batch numbers to be redacted from the drug labels because it could lead to the identification of downstream sellers and suppliers.

In support of its motion, the ADC attached the affidavit of Rory Griffin, the deputy director of Health and Correctional Programs with the ADC. Griffin stated that the ADC had attempted to comply with both the disclosure and confidentiality provisions of the MEA in response to past AFOIA requests; however, even when the ADC had provided redacted copies of lethal-drug labels and package inserts, some recipients had been able to determine the identity of the drug manufacturers by comparing the redacted labels and inserts to publicly available information. Griffin indicated that this is because each manufacturer's labels and package inserts are unique with respect to format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance. Given the unique character of drug labels and package inserts, Griffin stated that the only way for the ADC to comply with the confidentiality provisions of the MEA is to decline disclosure of these records entirely. In addition to the fact that the labels and inserts reveal the identity of the manufacturer, Griffin asserted that the lot and batch numbers on the drug labels can be used to trace the drug through the distribution and supply chain all the way to the end user,

which in this case is the ADC. Thus, Griffin averred that the MEA absolutely prohibits the ADC from disclosing this information when responding to AFOIA requests.

A hearing was held on Shults's complaint on September 19, 2017, and on September 22, 2017, the circuit court entered an order denying the ADC's motion to dismiss and granting Shults's request that he be provided with the unredacted midazolam labels and package inserts. The court disagreed with the ADC's interpretation of section 5-4-617 of the MEA, finding that the General Assembly did not intend to protect the identity of manufacturers of drugs used in the ADC's lethal-injection protocol. The ADC filed a notice of appeal the same day, and on September 27, 2017, this court granted its request for an emergency stay of the order pending appeal. We also granted Shults's motion to expedite the appeal.

The ADC argues that the circuit court erred by ordering it to provide Shults with copies of the midazolam labels and package inserts because these records are not subject to disclosure under the MEA's confidentiality provisions. Thus, the issue presented on appeal is strictly one of statutory interpretation.

We review issues of statutory interpretation de novo, as it is for this court to determine the meaning of a statute. *Dep't of Ark. State Police v. Keech Law Firm, P.A.*, 2017 Ark. 143, 516 S.W.3d 265. However, in the absence of a showing that the circuit court erred, its interpretation will be accepted as correct on appeal. *Hendrix v. Alcoa, Inc.*, 2016 Ark. 453, 506 S.W.3d 230.

The primary rule of statutory interpretation is to give effect to the intent of the legislature. *Keep Our Dollars in Independence Cnty. v. Mitchell*, 2017 Ark. 154, 518 S.W.3d

64. We first construe the statute just as it reads, giving the words their ordinary and usually accepted meaning in common language. *Id.* Statutory language is ambiguous if it is open to two or more constructions, or if it is of such obscure or doubtful meaning that reasonable minds might disagree or be uncertain as to its meaning. *Dickinson v. SunTrust Nat'l Mortg. Inc.*, 2014 Ark. 513, 451 S.W.3d 576. When a statute is ambiguous, we must interpret it according to legislative intent, and our review becomes an examination of the whole act. *Id.* In conducting this review, we reconcile statutory provisions to make them consistent, harmonious, and sensible in an effort to give effect to every part. *Id.*

The MEA's confidentiality provisions relied upon by the ADC are contained in Arkansas Code Annotated section 5-4-617(i) and (j):

> (i)(1) The procedures under subdivision (g)(1) of this section, the implementation of the procedures under subdivision (g)(1) of this section, and the identities of the entities and persons who participate in the execution process or administer the lethal injection are not subject to disclosure under the Freedom of Information Act of 1967, § 25-19-101 et seq.
> (2) The department shall keep confidential all information that may identify or lead to the identification of:
> (A) The entities and persons who participate in the execution process or administer the lethal injection; and
> (B) The entities and persons who compound, test, sell, or supply the drug or drugs described in subsection (c) of this section, medical supplies, or medical equipment for the execution process.
> (3) The department shall not disclose the information covered under this subsection in litigation without first applying to the court for a protective order regarding the information under this subsection.
> (j) The department shall make available to the public any of the following information upon request, so long as the information that may be used to identify the compounding pharmacy, testing laboratory, seller, or supplier is redacted and maintained as confidential:
> (1) Package inserts and labels, if the drug or drugs described in subsection (c) of this section have been made by a manufacturer approved by the United States Food and Drug Administration;
> (2) Reports obtained from an independent testing laboratory; and

> (3) The department's procedure for administering the drug or drugs described in subsection (c) of this section, including the contents of the lethal-injection drug box.

The ADC contends that the drug labels and package inserts at issue here could not be disclosed under the confidentiality provisions in subsections (i) and (j) because they could lead to the identification of lethal-drug sellers and suppliers. More specifically, the ADC argues that lethal-drug manufacturers are protected by the plain language of these confidentiality provisions because they "sell" or "supply" lethal-injection drugs—such as midazolam— to distributors and place the drugs into the stream of commerce. The ADC therefore asserts that, because it presented evidence to show that even redacted copies of these records could lead to the identification of the midazolam's manufacturer, it was justified in refusing to provide the records to Shults.

As the ADC argues, the definitions of both "seller" and "supplier" could be interpreted to include a manufacturer. *See, e.g.*, *Black's Law Dictionary* (10th ed. 2014) (defining a "seller" as "someone who sells or contracts to sell goods" and a supplier as a "business engaged, directly or indirectly, in making a product available to consumers). However, the term "manufacturer" also has its own distinct meaning and is defined as "[a] person or entity engaged in producing or assembling new products." *Id*. Thus, it is unclear from the plain language in the confidentiality provisions of the statute whether the legislature intended for drug manufacturers to be included within the terms "seller" or "supplier."

A review of the entire statute, however, reveals that the legislature explicitly referred to a "manufacturer" of lethal drugs in two different subsections. *See* Ark. Code Ann. § 5-4-617(d)(1) & (j)(1). As the circuit court found, this demonstrates that the legislature was aware of the differences between the terms "manufacturer," "seller," and "supplier" and

that it could have easily included "manufacturer" among the entities whose identity was confidential for purposes of the MEA had it intended to do so. We have repeatedly held that we will not read into a statute language that was not included by the legislature. *E.g.*, *Mitchell*, *supra*; *Scoggins v. Medlock*, 2011 Ark. 194, 381 S.W.3d 781; *Potter v. City of Tontitown*, 371 Ark. 200, 264 S.W.3d 473 (2007).

Furthermore, we agree with the circuit court that, under the ADC's interpretation of the statute, subsection (j)(1) would be rendered meaningless. This subsection expressly states that "so long as the information that may be used to identify the compounding pharmacy, testing laboratory, seller, or supplier is redacted and maintained as confidential," the ADC "shall make available to the public . . . [p]ackage inserts and labels, if the drug or drugs . . . have been made by a manufacturer approved by the United States Food and Drug Administration." If the ADC's argument is correct that manufacturers are included within the terms "seller" or "supplier" and that disclosure of even redacted labels and inserts would lead to the identification of those manufacturers, then these records would never be disclosed to the public despite the express mandate to the contrary in this subsection. In addition, this interpretation would defeat the purpose of section 5-4-617(d)(1), which requires that the ADC use drugs that are made by an FDA-approved manufacturer. As the circuit court noted, the public has no way to verify whether the ADC is complying with that requirement if drug manufacturers are protected by the confidentiality provisions in the statute. Thus, the ADC's position would violate our rule of construction that we interpret a statute in such a way as to give effect to every provision. *Dickinson*, *supra*.

The ADC's argument that protecting the identity of manufacturers supports the State's interest in carrying out death sentences is also unpersuasive. As the ADC asserts, the General Assembly adopted the confidentiality provisions of the MEA "to address the problem of drug shortages." Act of April 6, 2015, No. 1096, § 1(b), 2015 Ark. Acts 4932. However, the evidence presented in this case demonstrated that many manufacturers of lethal-injection drugs already prohibit the use of these drugs in executions and that these manufacturers often have contracts in place with their distributors that prevent the downstream sale of the drugs to prison officials. It is therefore the confidentiality of the sellers and suppliers of these drugs to the ADC that the confidentiality provisions were intended to protect.

We interpret AFOIA liberally to promote free access to public information. *Keech Law Firm*, *supra*. In addition, we interpret any exemptions to AFOIA narrowly and in favor of disclosure. *Id.*; *Ark. State Police v. Wren*, 2016 Ark. 188, 491 S.W.3d 124. Based on the foregoing principles, we conclude that the circuit court was correct in determining that the identity of drug manufacturers is not protected under the confidentiality provisions of section 5-4-617, and we affirm this ruling.

The ADC also argues, however, that even if we agree with the circuit court that the confidentiality of manufacturers is not protected under the statute, it is still required to redact certain information such as lot, batch, and/or control numbers that could lead to the identification of other sellers and suppliers in the chain of distribution. We agree.

Pursuant to section 5-4-617(j), if package inserts and drug labels are made available to the public, any information that could be used to identify the seller or supplier must be

redacted and maintained as confidential. The ADC presented evidence through Griffin's affidavit that drug labels contain unique identifying information in the form of lot and/or batch numbers that can be used by the manufacturer to trace the drug through the distribution and supply chain, all the way to the end user. The ADC's argument is also supported by FDA regulations, which require that drug labels contain information revealing "the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product[.]" 21 C.F.R. § 210.3(b)(11) (2011).

While Shults disputes the ADC's claim, he has provided no evidence to refute it. At the hearing, the circuit court agreed with the ADC that Griffin's testimony with regard to the lot, batch, and/or control numbers was unrebutted, and the court further indicated that it believed that Griffin's testimony was correct. Despite this discussion, the circuit court then stated in its order that there were *no* facts before it to indicate that the package inserts and labels would identify the sellers and suppliers. This finding is clearly contrary to the unrefuted evidence presented by the ADC.

Accordingly, because disclosure of information such as lot, control, and/or batch numbers could lead to the identification of the seller and/or supplier of the midazolam, the ADC is correct that it is required to redact and maintain this information as confidential under section 5-4-617(j). We therefore reverse that portion of the circuit court's order requiring disclosure of the unredacted records and remand for the court to determine, based on the evidence presented by the parties, which information must be redacted on the midazolam labels and/or package inserts at issue. Due to the expedited status of this appeal, we order the mandate to issue within three days of this opinion unless a petition for

rehearing is filed. If a petition for rehearing is filed, any response will be due on an expedited basis to be set by the clerk.

Affirmed in part; reversed and remanded in part.

KEMP, C.J., and WOOD, WYNNE, and WOMACK, JJ., concur in part and dissent in part.

JOHN DAN KEMP, Chief Justice, concurring in part and dissenting in part. I join the majority's holding that the circuit court was correct in determining that the identity of the drug manufacturers is not protected under the confidentiality provisions of Arkansas Code Annotated section 5-4-617 (Supp. 2015).

I respectfully dissent from the majority's decision to reverse that portion of the circuit court's order requiring disclosure of the unredacted records, pursuant to Arkansas Code Annotated section 5-4-617(j) (Supp. 2015), and to remand for the circuit court to determine which information must be redacted on the midazolam labels and package inserts. In my view, this issue has already been decided by the circuit court.

Arkansas Code Annotated section 5-4-617(j) provides,

> (j) *The department shall make available to the public any of the following information upon request, so long as the information that may be used to identify the compounding pharmacy, testing laboratory, seller, or supplier is redacted and maintained as confidential:*
>
> (1) *Package inserts and labels, if the drug or drugs described in subsection (c) of this section have been made by a manufacturer approved by the United States Food and Drug Administration*;
>
> (2) Reports obtained from an independent testing laboratory; and
>
> (3) The department's procedure for administering the drug or drugs described in subsection (c) of this section, including the contents of the lethal-injection drug box.

(Emphasis added.)

In the case at bar, the Arkansas Department of Correction (ADC) presented an affidavit of Rory Griffin, an ADC employee, that "ADC declined to provide copies of the package insert and label for the recently-acquired midazolam" because he believed that the sellers and suppliers would be identified. The circuit court ruled,

> [T]he court holds the AMEA [Arkansas Method of Execution Act] does not make the identity of manufacturers of FDA-approved drugs used in the lethal injection method-of-execution ("MOE") protocol confidential. *The court further finds that there are no facts before the court that the package inserts and labels of lethal injection drugs manufactured by FDA-approved manufacturers would identify (i) the entities and persons who participate in the execution process, (ii) the identities of persons who administer the lethal injection drugs, or (iii) the compounder, testing laboratory, seller, or supplier of the lethal injection drugs.*

(Emphasis added.) In making this determination, the circuit court found that the evidence before it was not compelling. ADC had the burden of proving that the records were exempt from disclosure. *See Young v. Rice*, 308 Ark. 593, 596, 826 S.W.2d 252, 254 (1992) ("[T]he keeper of the requested records [] has the burden of proving the records are exempt from disclosure"). Clearly, the circuit court found that ADC had not met its burden. Thus, I cannot say that the circuit court erred in determining that the unredacted records must be provided. To remand to the circuit court for a second determination on this issue is wholly unnecessary. Accordingly, I would affirm the circuit court's ruling on this point.

WYNNE, J., joins.

SHAWN A. WOMACK, Justice, concurring in part and dissenting in part. I concur with the majority's holding that, to the extent the labels and package inserts of midazolam are subject to disclosure, the circuit court erred in ordering that the Arkansas Department of Correction ("ADC") disclose the documents without redacting the lot, control, and batch numbers. The affidavit of Rory Griffin stated that these numbers may be

used to identify the proximate sellers and/or suppliers of midazolam. Even Shults does not contest that the Method of Execution Act ("MEA") requires the ADC to refuse disclosure of information that "may identify or lead to the identification of" these entities. *See* Ark. Code Ann. § 5-4-617(i)(2) (Supp. 2015). The circuit court was not entitled to accept the unsupported conjecture of Shults that this information would not lead to identification over the affidavit of the ADC that it would.

I write separately to dissent from the majority's conclusion that manufacturers are not included in the general confidentiality provision of the MEA protecting those who "sell" or "supply" drugs "for the execution process." Ark. Code Ann. § 5-4-617(i)(2)(B). The majority opinion faithfully recounts our principles of statutory interpretation, but I believe that it too eagerly discards the clear "ordinary and usually accepted meaning" of the statutory terms and reaches a contrary result by relying on two unpersuasive factors it finds in an "examination of the whole act."

As the definitions set out in the majority demonstrate, manufacturers fall squarely within the commonly understood meanings of both seller and supplier. Pharmaceutical manufacturers exist to sell or supply drugs, and the ADC intends to use these drugs "for the execution process." The majority's observation that "manufacturer" has a more specific meaning separate from "seller" or "supplier" does not negate the fact that manufacturers are commonly understood to "sell" and "supply" as written in the statute. To hold otherwise is to find ambiguity in any statute using a general term for an activity rather than a list of specific terms for entities engaging in that activity. General terms—no less than specific

terms—should be "accorded their full and fair scope," not "arbitrarily limited." Antonin Scalia & Bryan A. Garner, *Reading Law: An Interpretation of Legal Texts* 101 (2012).

Even admitting the ambiguity claimed by the majority, the two factors identified in the rest of the MEA to exclude manufacturers from the general confidentiality provision are unpersuasive. First, the majority notes that the legislature used the term "manufacturer" in two subsections of the MEA; this is used to support the inference that the legislature knew how to say manufacturer when it meant manufacturer. That inference would be warranted, however, only if the circuit court or the majority were comparing like sections. If the legislature had kept its "compound, test, sell, or supply" language in the general confidentiality provision but in another section granted a different protection to entities who "compound, test, sell, supply, *or manufacture*" drugs, the majority would be absolutely correct to read manufacturers out of the general "sell" and "supply" in the confidentiality provision. But that is not the case here. The two uses of manufacturer in the MEA are each in identical instances of the fixed phrase "made by a manufacturer approved by the United States Food and Drug Administration." Ark. Code Ann. § 5-4-617(d)(1), (j)(1). This is not the legislature denying that manufacturers are sellers and suppliers; it is instead the legislature using the specific term where the general one would be inaccurate. The federal regulatory approval referred to in these subsections only applies to manufacturers, and therefore mirroring the federal regulatory language makes eminent sense.

The second factor cited by the majority to exclude drug manufacturers from the common understanding of entities selling or supplying drugs is the assertion that including manufacturers in the confidentiality provision would render subsection (j)(1) of the MEA

meaningless. This ignores the structure of the provision, however. On its face, the subsection is a contingent requirement. The ADC must disclose the specified materials, but only if that disclosure can be performed without imperiling the confidentiality of protected entities. The majority asserts that the subsection would be surplusage if manufacturers were intended as a protected entity because any portion of the labels or package inserts would reveal the manufacturer of the drugs and therefore the specified materials would never be disclosed. It is an unwarranted logical leap, however, to assume that the legislature had that information at the time of drafting. As the ADC argued before the circuit court and on appeal, the legislature's inclusion of section (j)(1) can be read harmoniously with the common understanding of manufacturers as sellers or suppliers. At the time of enactment, the legislature could have reasoned that labels and package inserts would not identify manufacturers after being stripped of logos, names, and other obvious identifying information. After experience has taught that no amount of redaction will prevent identifying the manufacturer of a drug from these materials, however, the legislature's safety valve operated as intended and the ADC must refuse disclosure.

I would hold that manufacturers are included in the MEA confidentiality provision protecting those who sell or supply drugs used for the execution process. Because any portion of the labels or package inserts requested by Shults would identify the manufacturer, I would reverse the circuit court's order that the ADC must produce the documents. If any materials are to be disclosed, however, I agree with the majority's analysis that the lot, control, and batch numbers must be redacted to protect the indisputably shielded proximate

sellers and/or suppliers of the midazolam. Therefore, I respectfully concur in part and dissent in part.

WOOD, J., joins.

Leslie Rutledge, Att'y Gen., by: *Lee P. Rudofsky*, Solicitor Gen.; *Nicholas J. Bronni*, Deputy Solicitor Gen.; and *Jennifer L. Merritt*, Sr. Ass't Att'y Gen., for appellants.

Williams & Anderson PLC, by: *Philip E. Kaplan*, *Heather G. Zachary*, and *Alec Gaines*, for appellee.