CV-17-788

IN THE SUPREME COURT OF ARKANSAS

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

v. No. CV-17-788

STEVEN SHULTS APPELLEE

ON APPEAL FROM THE CIRCUIT COURT
OF PULASKI COUNTY, ARKANSAS
THE HONORABLE MACKIE PIERCE

ABSTRACT, BRIEF, AND ADDENDUM OF APPELLANTS

LESLIE RUTLEDGE
Arkansas Attorney General

By: LEE P. RUDOFSKY (2015015)
Solicitor General
NICHOLAS J. BRONNI (2016097)
Deputy Solicitor General
JENNIFER L. MERRITT (2002148)
Senior Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Telephone: (501) 682-1319
Facsimile: (501) 682-2591
Lee.Rudofsky@ArkansasAG.gov
Nicholas.Bronni@ArkansasAG.gov
Jennifer.Merritt@ArkansasAG.gov

Attorneys for Appellants

Table of Contents

Informational Statement

I. ANY RELATED OR PRIOR APPEAL

Ark. Dept. of Correction, et al. v. Steven Shults, Arkansas Supreme Court No. CV-17-261; *Ark. Dept. of Correction, et al. v. Steven Shults*, Arkansas Supreme Court No. CV-17-267; and *Ark. Dept. of Correction, et al. v. Steven Shults*, Arkansas Supreme Court No. CV-17-544.

II. BASIS OF SUPREME COURT JURISDICTION

See Jurisdictional Statement.

(___) Check here if **no** basis for Supreme Court Jurisdiction is being asserted, *or* check below all applicable grounds on which Supreme Court Jurisdiction is asserted.

(1) ___ Construction of Constitution of Arkansas
(2) ___ Death penalty, life imprisonment
(3) ___ Extraordinary writs
(4) ___ Elections and election procedures
(5) ___ Discipline of attorneys
(6) ___ Discipline and disability of judges
(7) _X_ Previous appeal in Supreme Court
(8) ___ Appeal to Supreme Court by law

III. NATURE OF APPEAL

(1) _X_ Administrative or regulatory action
(2) ___ Rule 37
(3) ___ Rule on Clerk
(4) ___ Interlocutory appeal
(5) ___ Usury
(6) ___ Products liability
(7) ___ Oil, gas, or mineral rights
(8) ___ Torts

(9) ___ Construction of deed or will
(10) ___ Contract
(11) ___ Criminal

This is an appeal of an order entered by the Pulaski County Circuit Court requiring the Arkansas Department of Correction to disclose lethal-drug package inserts and labels in response to a FOIA request. The circuit court required disclosure of those records despite undisputed evidence that doing so would identify or lead to the identification of a seller or supplier in violation of the Arkansas Method of Execution Act, Ark. Code Ann. § 5-4-617(i)(2)(B). This Court granted the State's emergency motion for an immediate stay of the circuit court's order. The State now appeals on the merits.

IV. IS THE ONLY ISSUE ON APPEAL WHETHER THE EVIDENCE IS SUFFICIENT TO SUPPORT THE JUDGMENT?

No.

V. EXTRAORDINARY ISSUES

(X) appeal presents issue of first impression,
(__) appeal involves issue upon which there is perceived inconsistency in the decisions of the Court of Appeals or Supreme Court,
(__) appeal involves federal constitutional interpretation,
(X) appeal is of substantial public interest,
(X) appeal involves significant issue needing clarification or development of the law, or overruling of precedent,
(X) appeal involves significant issue concerning construction of statute, ordinance, rule, or regulation.

VI. CONFIDENTIAL INFORMATION

(1) Does the appeal involve confidential information as defined by Sections III(A)(11) and VII(A) of Administrative Order 19?

___ Yes _X_ No

(2) If the answer is "yes," then does this brief comply with Rule 4-1(d)?

___ Yes ___ No

Jurisdictional Statement

1. The issue of law raised on appeal is as follows: Does the Method of Execution Act prohibit the Arkansas Department of Correction from disclosing in response to a FOIA request pharmaceutical package inserts and box labels that may identify or lead to the identification of sellers or suppliers of lethal-injection drugs?

2. I express a belief, based on a reasoned and studied professional judgment, that this appeal raises the following questions of legal significance for jurisdictional purposes: This case presents a question of first impression regarding whether the Method of Execution Act's confidentiality provisions apply to all sellers and suppliers in the distribution chain. The appeal is of substantial public interest due to the competing interests of the State in maintaining its lethal-drug supply and the public in accessing records under FOIA. The scope of the Method of Execution Act's confidentiality provisions is an important issue needing clarification or development of the law. Finally, the appeal involves a significant issue concerning the construction and application of State statutes.

/s/ Jennifer L. Merritt
Jennifer L. Merritt
Senior Assistant Attorney General

Points on Appeal

The lethal-drug information requested by Shults is confidential and not subject to disclosure.

A. The Method of Execution Act expressly requires the ADC to maintain the confidentiality of lethal drug sellers and suppliers.

Ark. Code Ann. § 5-4-617(i)(2)(B) & (j).

Hammerhead Contracting & Dev., LLC v. Ladd, 2016 Ark. 162, 489 S.W.3d 654.

B. Manufacturers "sell" and "supply" lethal drugs in the distribution chain.

Hammerhead Contracting, 2016 Ark. 162, 489 S.W.3d 654.

Mosley Mach. Co. v. Gray Supply Co., 310 Ark. 214, 833 S.W.2d 772 (1992).

C. The State's interpretation of the statute gives full effect to all of its provisions and is consistent with legislative intent.

Act 1096 of 2015, *codified at* Ark. Code Ann. § 5-4-617.

State v. Colvin, 2013 Ark. 203, 427 S.W.3d 635.

D. As a matter of public policy, lethal-drug confidentiality provisions should apply to all sellers and suppliers in the chain, including the original manufacturers.

Kelley v. Johnson, 2016 Ark. 268, 496 S.W.3d 346.

E. The confidentiality provision in the Method of Execution Act trumps the FOIA.

Bd. of Trustees for the City of Little Rock Police Dep't Pension & Relief Fund v. Stodola, 328 Ark. 194, 942 S.W.2d 255 (1997).

F. Even if the identity of lethal-drug manufacturers is not confidential under the Method of Execution Act, the ADC still must redact certain information from drug labels to protect the confidentiality of other sellers and suppliers in the chain of distribution.

21 U.S.C. § 360eee-1.

21 C.F.R. § 210.3(b)(11).

Table of Authorities

Cases **Page**

Statutes and Rules

Other Authorities

Abstract

Hearing on FOIA Complaint
September 19, 2017
(R. 147)

SENIOR ASSISTANT ATTORNEY GENERAL JENNIFER MERRITT FOR THE ARKANSAS DEPARTMENT OF CORRECTION DEFENDANTS:

The State moves to dismiss the Complaint under Rule 12(b)(1), 12(b)(6), as well as 12(b)(8). And, alternatively, the State requests a stay of this case pending the final resolution of a related case filed by Mr. Shults against the same Defendants that involves the same factual and legal issues that is currently pending before the Supreme Court of Arkansas.

In terms of the Motion to Dismiss, the State has first moved on the grounds of sovereign immunity. And I will admit to the Court that the sovereign immunity defense is somewhat tied into the 12(b)(6) defense because sovereign immunity is the rule. And unless an exception to sovereign immunity applies, the State is absolutely immune from suit in state courts.

Mr. Shults apparently concedes that a complaint that does not state a valid claim for an illegal or unconstitutional act is barred by sovereign immunity. None of the other exceptions could possibly apply in this case. So an illegal or (R. 151) unconstitutional act has to be shown, or the complaint is barred. So, in other words, a complaint against a state agency that fails to state a cognizable legal claim and fails under 12(b)(6) also fails under 12(b)(1). The State is immune because the

Complaint fails to state a valid claim. Mr. Shults also recognizes in his Response that sovereign immunity is the rule, and that this exception is the only one that applies.

The Court should hold that the Complaint here fails to overcome the ADC's sovereign immunity because it does not state a cognizable FOIA claim. There's one claim in this case; it's a FOIA claim. Shults seeks records under the FOIA that cannot be disclosed, under any circumstances, under a completely separate act, the Method of Execution Act, which the legislature passed in 2015.

This was an amendment to the Method of Execution Act for a number of purposes. It codified a new lethal-drug protocol. And with relevance to this specific case, the legislature codified for the very first time a number of very strong confidentiality provisions that protect the identity of a number of people who (R. 152) are involved with the lethal-injection process; everyone from sellers and suppliers of drugs, to testers of drugs, the executioner, any other person who is involved. A broad swath of individuals who are involved in the execution process are absolutely confidential under Arkansas Code Annotated § 5-4-617(i)(2). That provision states, "The department shall keep confidential" – that is mandatory, "shall" – "all information that may identify or lead to the identification of the entities and persons who test, sell, or supply the drug or drugs for the execution process."

So that is a very broad confidentiality provision. In the State's view, this isn't even really a FOIA case. This is a case under the Method of Execution Act. And the Plaintiff bears a burden of showing and pleading that he is entitled to the records that he seeks under the Method of Execution Act.

This Complaint specifically alleges an entitlement to two different kinds of information that is subject to the confidentiality provision in 5-4-617. First, Mr. Shults seeks disclosure of lethal (R. 153) drug labels. So, literally, the label on a vial of injectable medicine that identifies the manufacturer of the drug, other information, as well as package inserts. So the package inserts are those tiny little pieces of paper that are stuck into drug boxes. When you open them up, they are big. They've got a lot of information about warnings and contraindications and the like. Those documents are unique to each manufacturer. Each manufacturer of a drug has its own unique style, format, diction, color scheme, logos, and the like. So those documents identify who a seller or supplier of that drug is; and that's the ADC's position.

The parties have stipulated outside of court. Mr. Gaines and I exchanged some emails the other day. We don't dispute the facts that are alleged in the Complaint, with regard to the specifics of Mr. Shults's FOIA request, or the ADC's response. We've stipulated as to the authenticity and admissibility of the exhibits that were attached to Mr. Shults's Complaint, as well as the exhibits that

the State has introduced. So the only issue for the Court today is a legal one. And that is whether the Method of (R. 154) Execution Act bars the ADC from releasing the lethal-drug labels and package inserts in response to FOIA requests. ADC believes that these records are clearly within the scope of the confidentiality provisions of the Method of Execution Act, and, therefore, cannot be disclosed in response to a FOIA request or otherwise.

When construing the Method of Execution Act, of course, the Court's main goal is to give effect to the intent of the legislature. So the first rule of statutory construction is to construe a statute just as it reads, giving the words their ordinary and usually-accepted meaning in common language. Under the MEA, the ADC is required to keep confidential information that may identify or lead to the identification of entities – that is plural – entities who sell or supply drugs for the execution process. Another provision in 5-4-617, subsection (j), reiterates that any information that may be used to identify a seller or supplier must be maintained as confidential. So the statute is clear that the identity of drug sellers and suppliers is (R. 155) confidential. And I really don't think there is any dispute among the parties about that.

What is really the precise issue before the Court today is whether a drug manufacturer is a seller or a supplier of lethal drugs that is afforded confidentiality under the Method of Execution Act. If a manufacturer is a seller, as the ADC

contends, then the Court must deny the relief requested by Mr. Shults because it is undisputed that disclosure of lethal-drug labels and package inserts would reveal the manufacturer's identity due to the unique characteristics of each manufacturer's packaging and labeling information. And there are actually two affidavits in the record before the Court that establish those facts. And those facts are undisputed from Deputy Director Rory Griffin.

The MEA does not define seller or supplier. So the Court needs to look to the ordinary and usually-accepted meaning of those two terms. And I've cited the Court to Black's Law Dictionary online, which clearly says that a "seller" is "one who sells anything" and a "supplier" is a "party supplying (R. 156) goods or services." So under the ordinary and usually-accepted meaning of those terms, a manufacturer must be a seller or supplier because otherwise those drugs would never be in the stream of commerce. I don't think that manufacturers are in the business of giving away their drugs. And even if they were giving them away and weren't selling them, they would still be supplying them. They are the initial seller and supplier in the chain of supply. The Arkansas Supreme Court has also recognized for well over a century that manufacturers do sell or supply their products in the stream of commerce.

THE COURT: I'll take judicial notice of that fact, that manufacturers, if they didn't, they wouldn't manufacture because they would make no money. So I'm clear on that point.

MS. MERRITT: So manufacturers are then sellers or suppliers, as the Court has taken judicial notice. (R. 157).

THE COURT: I will not take judicial notice that manufacturers are sellers or suppliers within the statute. I will simply take judicial notice of the fact that manufacturers sell their product, but I don't take judicial notice of the fact that seller and supplier as utilized in the MEA equates to manufacturer. They don't necessarily mean the same thing in my mind. GM manufactures automobiles, but they don't sell them in Arkansas. They supply them to dealers through a distribution network, who in turn sell; those are the sellers, the dealer. The manufacturer is GM in Detroit or whichever facility manufactures the automobile, which they in turn sell through a distribution network, who then in turn – you know, and supplies and sells, that type of thing.

MS. MERRITT: Yes, Your Honor. I agree with Your Honor's description there. The MEA applies to sellers and suppliers –

THE COURT: Suppliers. It does. (R. 158).

MS. MERRITT: – so whether the Court views it as a seller or a supplier, I believe, and it's the ADC's position in this case, that a manufacturer is indeed a seller and/or a supplier.

THE COURT: I understand your position and I'm not trying to quibble with you. I'll take judicial notice of the fact that manufacturers have to sell their product in commerce in order to stay in business. If they weren't making money, they wouldn't be there long, so, but are they sellers and suppliers as delineated in the MEA? That I don't know. I'll wait and hear both sides of the argument before I decide that.

MS. MERRITT: Very well, Your Honor. Thank you. Our view, of course, is that the MEA does cover a seller or supplier – any seller or supplier. It does not say the ADC's proximate supplier. It does not say the direct supplier of the drug. What it does say, is it applies to the entities – which is plural – who sell or supply drugs. So it is our position that a manufacturer is clearly a seller or supplier under the plain (R. 159) language of the statute. The legislature could have written the statute in a way that did apply only to the ADC's immediate, proximate seller or supplier, but they did not choose to do that.

This interpretation also best reconciles the Method of Execution Act's confidentiality and disclosure provisions. So there are confidentiality provisions and there are some disclosure provisions in the Method of Execution Act. Our

interpretation best reconciles those two provisions, and gives effect to the legislature's clear intent to keep all lethal-drug seller and supplier information confidential.

Act 1096 of 2015, which adopted these confidentiality provisions for the first time, is very clear that its purpose was to address the problem of lethal-drug shortages; that is Section 1 of the new act. The Supreme Court of Arkansas held in *Kelley vs. Johnson* that the confidentiality provisions in the MEA furthered that purpose as a matter of public policy that was within the sole realm of the legislature to decide, whether that was good policy or not. Again, legislative intent is the benchmark (R. 160) for this Court when interpreting the statute.

As evidenced by the affidavits of Deputy Director Griffin, the ADC does know from recent experience that any disclosure of lethal-drug labels and package inserts does identify a seller or supplier in violation of the MEA due to the unique format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance of all of that information. Mr. Griffin's affidavit explains in great detail how last year when the ADC produced redacted drug labels and package inserts, – what the ADC did was take out manufacturer names, manufacturer logos, manufacturer addresses, any other information that the ADC believed would or could be used to identify the manufacturer, which, again, in its view, is a seller or a supplier under the Act. The ADC redacted all of that information in an attempt to

be as open as it could and comply with the disclosure as well as the confidentiality provisions in the Method of Execution Act.

The ADC released that information to Mr. Shults in 2016, as well as a number of media outlets in response to different FOIA requests. And the folks who received that (R. 161) information very easily went online and Googled the different drug manufacturers, and very easily identified who those manufacturers were, published the names of those manufacturers in AP news articles and the like. And some of those manufacturers actually later intervened or attempted to file amicus briefs in different litigation that was ongoing at the time about the constitutionality of other provisions of this Method of Execution Act, the drug protocol, and the like.

So given these well-documented difficulties that the Department has in finding a lethal-drug supplier – somebody who would be willing to sell these drugs to the Department of Correction – as well as the well-documented efforts of manufacturers to keep their products out of the hands of corrections officials like the ADC, a construction of the MEA's confidentiality provisions to include manufacturers is really necessary, in our view, in order to honor the legislative intent of adopting these provisions.

We've cited the Court, again, to records in federal court cases that demonstrate how the manufacturers got involved in litigation in an (R. 162)

attempt to stop the State from using their drugs. And that is exactly the situation that the legislature was trying to avoid in adopting the MEA.

So for these reasons, we think the Court should hold as a matter of law that drug manufacturers are sellers or suppliers entitled to protection under the Method of Execution Act, and that the ADC must keep confidential any information that may identify them. And that includes withholding requests for those documents from production and response to FOIA requests.

Under longstanding precedent, in the event of a conflict – so we have this very open public-records law over here, adopted, you know, a half century ago; and then we have the Method of Execution Act over here on the other side, which was adopted just a few years ago in response to a very specific and well-documented problem. The MEA controls in the event of a conflict with the FOIA because the MEA is both the more specific provision that deals specifically with disclosure of lethal-drug information as well as confidentiality of that information. It's also the more recent statute. So if there is a conflict, (R. 163) the MEA has to trump the FOIA.

So, in our view, Mr. Shults does not have any right to this information that he seeks under the FOIA. And for that reason, the Court should grant the State's Motion to Dismiss under Rule 12(b)(1) as well as Rule 12(b)(6) and dismiss the Complaint with prejudice. (R. 164).

[ABSTRACTOR'S NOTE: Argument regarding the State's motion to dismiss under Ark. R. Civ. P. 12(b)(8) based on the pendency of another action or, alternatively, to stay proceedings pending the appeal in *Shults I* is not abstracted here. The State is not appealing the circuit court's rulings on these issues. (R. 164-66).]

The last point that I would like to make is, even if the Court disagrees on everything else, I would ask that the Court find that the ADC was substantially justified in its position. If the Court does find a FOIA violation, the ADC is facing a mandatory confidentiality provision in the Method of Execution Act. It has done all that it could in the past to provide information that it thought it could provide, and still satisfy the statutory confidentiality provisions, and that backfired in the past. And so this time, the ADC believes it absolutely just cannot give anything because if it discloses any portion of the drug labels or package inserts, it would reveal the identity of the manufacturer, which is a seller or supplier in the stream of commerce of drugs. So the ADC's interpretation is certainly reasonable, even if the (R. 167) Court were to rule against the ADC in this particular matter. And so we would ask that the Court find that the ADC's position was substantially justified, as well as stay any disclosure order so that we could appeal if needed.

FOR THE PLAINTIFF, MR. ALEC GAINES: First, I'll address the State's sovereign immunity argument. It's our opinion that sovereign immunity is not

applicable to FOIA. FOIA contains an express waiver of sovereign immunity. Without that waiver, FOIA would be worthless. You wouldn't be able to sue the State to get the documents you're looking for. So in that regard, I don't think sovereign immunity is an applicable defense here.

The State went into the merits of the (R. 168) case to argue that this case should be dismissed under 12(b)(6). And, again, I'm not sure that's an appropriate vehicle to do that. I will go into our argument on the AMEA.

As Ms. Merritt pointed out, the narrow issue before the Court is whether a seller or supplier includes a manufacturer. And the State has taken the position that everybody in the chain of distribution is a seller or a supplier for the purposes of the AMEA. And we disagree with that.

From our point of view, the AMEA expressly requires production of labels and package inserts that could be used to identify manufacturers, as long as those labels and package inserts protect the confidentiality of the seller or supplier of the drugs to the ADC. And in our opinion, that means the proximate seller or supplier.

ADC on the other hand, of course, has taken the position that manufacturers of these products – midazolam in this case – are included in the prohibition. And, specifically, their position is there is no difference in a manufacturer and a seller or supplier for statutory purposes. And again, that seller/supplier includes (R. 169) everyone in the chain of distribution.

Now, Ms. Merritt seemed to state that the AMEA is a specific statute here, but we would argue that FOIA's a specific statute. The AMEA provides an exemption, a FOIA exemption. So the statute should be interpreted under FOIA. And the FOIA, as you're well aware, must be liberally construed in favor of disclosure. If a statute fails to specify records kept out of the public domain, then the privacy must yield to openness. And FOIA exemptions must be narrowly construed in a manner that favors disclosure. Less than clear or ambiguous exemptions must be interpreted in favor of disclosure. So keeping the FOIA in mind, there are a couple of provisions that are applicable here.

And the first is the section (c) of the AMEA. Again, 5-4-617. And this is the section that identifies the drug options available to the ADC for lethal injection. For this particular request, of course, we are talking about the ADC's supplies of midazolam. The ADC previously supplied labels and package inserts for vecuronium bromide in response to an earlier FOIA request, and produced unredacted copies of the inserts for potassium (R. 170) chloride as ordered by Judge Griffen in *Shults I*, as well as redacted copies of the package inserts [sic].

Next, section (d)(1). This section requires ADC to obtain the drugs identified in section (c) through a reputable source. Through ADC's response to Mr. Shults's FOIA request, which is Exhibit B to the Complaint, we know that we are dealing with drugs approved by the FDA.

So the next relevant subsection is (i)(2). I would note that section (i)(1) specifically exempts certain records from FOIA. So to the extent legislature meant to exempt records from FOIA, it knew how to do that, it chose not to. But we aren't dealing with (i)(1), we're dealing with (i)(2). This is the section the ADC cited in its FOIA response to Mr. Shults.

In relevant part, it reads, "The department shall keep confidential all information that may identify or lead to the identification of the entities or persons who sell or supply the drug or drugs described in subsection (c) for the execution process." By all accounts, these drugs are not for the execution process until (R. 171) they come into the hands of the ADC. The manufacturers expressly prohibit their use for executions, and prohibit their distributors from selling to departments of correction.

Finally subsection (j)(1), deals with the information which the department shall make available to the public as long as the information that may be used to identify the – "the" seller or supplier – is redacted and maintained as confidential. The "the" is important here because that would only identify the proximate seller or supplier. It doesn't say "any," it says "the."

So what's included in the information that must be available to the public? Package inserts and labels of the drug or drugs in subsection (c) of this section have been made by a manufacturer approved by the FDA.

Now, clearly, AMEA's statutory scheme is intended to ensure drugs being used to carry out lethal injections are manufactured by legitimate and federal-government-approved sources. And can only be construed to protect the confidentiality of (R. 172) the direct source of the drugs being sold or supplied to the ADC by specifically including the manufacturer separate from the restrictions on identification of sellers and suppliers. The ADC's argument that manufacturer is embraced with the seller/supplier must fail.

And the Supreme Court decision in *Kelley v. Johnson* is in line with that interpretation. In that case, the Court recognized and approved the statutory confidentiality requirements, but the Court was careful to confine its analysis to only the seller or supplier of the drugs to ADC, just as the statute mandates. The case contains no reference to maintaining confidentiality of the manufacturer. And, indeed, the justification given by the Court for the confidentiality provision, which is ensuring the ADC continues to have a source for securing execution drugs, makes no sense if applied to the manufacturers. There is no need for Arkansas to protect the name of the manufacturers because everyone knowns there are a limited number of manufacturers of these execution drugs. And the manufacturers have unequivocally stated they do not want their drugs being used for (R. 173) executions.

There are a couple of problems with the ADC's interpretation. And, again, there are important to consider in conjunction with statutory interpretation under FOIA. First, disclosure of the manufacturer is not prohibited by statute. It is only the seller or supplier that is protected. It's FOIA response says the ADC must keep confidential all information that may identify entities that sell or supply the drugs for execution purposes. Yet instead of providing any evidence the labels or package inserts can be used to identify the actual seller or supplier, ADC states news outlets in the past have been able to compare labels to publicly identify the manufacturer, which it has incorrectly been labeled as a seller or supplier.

In fact, the ADC has represented to Judge Griffen, in *Kelley v. Johnson*, that the only entity identified by labels and package inserts are manufacturers. And in that case, the ADC asked for a protective order. And in its pleading, it said that if the Court determines to allow discovery into the identify of drug sources, it should enter an attorneys-eyes-only protective order that (R. 174) requires only disclosure of information that may reveal the identity of manufacturers of the drugs, such as unredacted package inserts, product warnings, and box labels. So, again, they asserted in their brief that the only entity that can be identified by these labels and package inserts are the manufacturers.

The second problem with ADC's argument is the statutory language. The term "manufacturers" is used several times in this section; notably, (d)(1)

and (j)(1). Had the legislature intended to limit information that could be used to identify the manufacturer, it would not have used that – it would have used that term elsewhere to exempt the information.

More importantly, such an interpretation renders (j)(1) meaningless. Under ADC's interpretation, there is no right to the package inserts and labels to confirm these drugs are coming from manufacturers approved by the FDA, despite clear language saying that that is public information. Stated otherwise, if the legislature meant to keep manufacturer labels and package inserts a secret, (j)(1) would not be in the AMEA to begin with. (R. 175)

The absurdity of ADC's position is highlighted if you look at section (j) and insert "manufacturer" for seller or supplier. In that case, this section would mandate that the ADC must disclose packaging inserts and labels if the drug is made by the FDA-approved manufacturer, but not if the packaging inserts and labels will allow identification of the manufacturer. As ADC has noted, the package inserts and labels will always allow identification of the manufacturer. So that interpretation reads that subsection out of the statute. And that is a clear violation of the fundamental rules of statutory interpretation. And, further, FOIA states that disclosure is appropriate where the language is ambiguous or less than clear.

In our opinion, the only reasonable way to interpret the AMEA under normal statutory construction, much less the favorable construction under FOIA, is that the legislature did not intend to include manufacturers within the term "sellers" or "suppliers." Those terms refer to, in ADC's words, the ADC's immediate supplier or proximate middleman of the drug. Simply put, the labels and (R. 176) package inserts will not identify the person or entity that directly sold these packages to ADC.

I'd like to address Rory Griffin's affidavit, if I can real quick. We agreed on the authenticity of that affidavit, but we did not agree with the content of it. (R. 177).

[ABSTRACTOR'S NOTE: Argument regarding Shults's motion to strike portions of Rory Griffin's affidavit, which the circuit court denied, and the State's motion to dismiss under Ark. R. Civ. P. 12(b)(8) based on the pendency of another action or, alternatively, to stay proceedings pending the appeal in *Shults I* is not abstracted here. The circuit court's rulings on these issues are not before this Court on appeal. (R. 178-79).]

In regard to Ms. Merritt's argument that the ADC had substantial justification to deny our FOIA request, we disagree. It's not reasonable, in light of the clear statutory language, and we think we're entitled to fees eventually.

DEFENDANTS' REPLY BY MS. MERRITT:

I'd like to reply to just a few points that were made by my friend, Mr. Gaines. First of all, I submit to the Court that the two different provisions of the Method of Execution Act – the confidentiality provision on the one hand under § 5-4-617(i)(2)(B), and then on the other hand, the disclosure provision under subsection (j)(1) – are easily reconciled. Subsection (j)(1), as Mr. Gaines mentioned to the Court, it talks about certain information that the department must make available to the public, but only, quote, "so long as the information that may be (R. 180) used to identify the compounding pharmacy, testing laboratory, seller, or supplier is redacted and maintained as confidential." Then it goes on to talk about package inserts and labels.

So when we're looking at it in practice, the ADC has a box of a vial of injectable medicine. Any one box is only going to have one label. That one label on that box of drugs will only identify one entity, one manufacturer, one seller, one supplier. So that provision is entirely consistent with subsection (i)(2)(B), which requires the ADC to maintain the confidentiality for all entities – which is plural – that sell or supply execution drugs.

The second point that I'd like to make is –

THE COURT: Let me ask, when I read a sentence like that, it – you know, "The department shall keep confidential all information that may identify or lead to

the identification of the entities and persons who" – and then it lists who those entities and persons are – "compound, test, sell, or supply the drug or drugs described in subsection (3) of this (R. 181) section." Why didn't the legislature simply insert the word "manufacturer" there?

MS. MERRITT: I don't have evidence in this record, Judge. I do have over a century of precedent from the Arkansas Supreme Court that really uses those terms interchangeably.

THE COURT: But you've got what you argue is a specific statute that the legislature set out to specifically address certain issues. And a huge issue that they left the barn door wide open on is manufacturer. I mean, they use the word in the statute. It's not like they're not familiar with it. When you look at (d)(1), they talk about drugs approved by USFDA and made by a manufacturer approved by USFDA.

Then we go down to (j)(1), and they say, "The department shall make available the following information so long as it may be used" – you know – "provide the information upon request, so long as the information that may be used to identify the compounding pharmacy, testing lab, seller, or supplier is redacted and maintained (R. 182) as confidential."

And then the very next subsection, "Package inserts and labels, if the drug or drugs described in subsection (c) of this section have been made by a manufacturer

approved…." Why didn't they put manufacturer in (j)? I mean, we wouldn't be here had they done that, but they didn't.

MS. MERRITT: I certainly wish the legislature would have been more specific in the terms. Again, I think the courts have used those terms interchangeably, the common understanding of sellers and suppliers.

THE COURT: But they wanted to be specific here. That was your words. You said we have a specific statute versus a general statute. We have a recently enacted statute versus one that has been in existence for years. They knew what the issues were, presumably. I can't speak for them, but, you know, all I can do is interpret what they've given me here. And they left out a key word that's the crux of the (R. 183) issue here, not once, but twice in this statute. Maybe three times if you, you know – they could have just added another subsection and said, "Also, the manufacturer shall kept confidential." They didn't do that.

MS. MERRITT: That's right, Your Honor. It says, "seller or supplier." And all I can reiterate is that everyone knows that a manufacturer must sell or supply drugs. So under the common understanding of the word, you know, longstanding precedent from the Arkansas Supreme Court, that really does kind of use those terms interchangeably. Certainly, it could have been more artfully drafted, more specifically drafted, but it's our position that a manufacturer is a seller or supplier, so it should be covered by those confidentiality provisions.

There's one other issue about drug labels. So Mr. Gaines said there's absolutely nothing on any of these documents that would identify the ADC's proximate (R. 184) supplier, and that's not true. There are unique identifying numbers on each actual label that's on the lethal-drug vial, lot numbers, batch numbers, things like that, that Mr. Rory Griffin has testified. And it's undisputed, unrefuted, that those numbers can be used to trace back through the supply chain, a drug.

I think the Court could take judicial notice that the purpose of those is really for an issue such as a contamination or a recall. It's meant to be able to track the drug all the way from the supplier, all the way down to the hands of the consumer. So those specific lot numbers and batch numbers certainly can be used, may be used to identify the actual proximate supplier or seller to the ADC. And that specific information on the drug label is absolutely confidential, even under (j)(1). Mr. Griffin is a 25-year veteran in the healthcare industry. He is a registered nurse. He is a health services administrator, administrator of medical and dental (R. 185) services, a deputy director. And part of his job is to – he's a nurse. So he well knows what drug labels are for, what information on drug labels is for, and he also does know that in his experience and his practice a drug manufacturer is a seller or supplier in the chain. Mr. Shults certainly could have offered his own evidence, but did not on those points.

Finally, the suggestion that the ADC voluntarily turned over lethal-drug package inserts and redacted labels in response to *Shults I*, and is therefore barred from raising this issue again, is absolutely false on the public record. Judge Griffen ordered the ADC to immediately – within 30 minutes of the conclusion of a hearing that ended after 5:00 p.m. – turn over this information, and threatened the ADC and counsel with contempt of court. So ADC did what it could to comply with Judge Griffen's order. It immediately filed a Notice of Appeal, filed an emergency petition for a stay, but did go ahead and turn over the package insert and a redacted label that did redact the lot (R. 186) number and batch number, in violation of Judge Griffen's order, but did so under threat of contempt of court, and pursuant to a court order. So, certainly, that was not a voluntary disclosure of that information. And if the Court does look at the information that Mr. Shults attached to his Response to the Motion to Dismiss, the record is very clear that the Petition for Emergency Stay in *Shults I* that the Supreme Court granted, was with regard to the entire disclosure order. It was not solely with regard to the issue about lot numbers and batch numbers. The ADC sought an immediate and emergency stay of the entire disclosure order, and the Supreme Court granted the relief as requested.

PLAINTIFF'S REPLY BY MR. GAINES: Your Honor, I think you put your finger directly on the point here. Again, there's no point in section (j)(1) if

ADC does not have to disclose the labels and inserts. They would identify the manufacturer. If the legislature wanted to exempt manufacturers from disclosure, they would have been put in here (R. 187) specifically in section (i)(2)(B). So there's one simple solution to that. They didn't mean to exempt manufacturers. That's the only way we think that statute can be read. And, again, this is a FOIA case, and the statute must be liberally construed, and unless the exemption is clear, the statute must be liberally construed in favor of disclosure.

In regards to the lot/batch numbers, there's no evidence that that information could be used to identify the end user, none whatsoever.

THE COURT: How can you tell me that?

MR. GAINES: Well, first, there's no evidence in the record that –

THE COURT: I do have evidence in the record. I have the affidavit that's unrefuted – Mr. Griffin –

MR. GAINES: – we have moved to strike portions of that Affidavit.

THE COURT: I understand, but I haven't stricken it, so – and I've read it. And, you know, I'm going to tell you, I think the gentleman is correct. Now, that's just my layperson's opinion, and he has given me unrefuted testimony (R. 188) under oath that that, in fact, is the case.

MR. GAINES: Well, there's no evidence in the record that they obtained those drugs in the normal distribution chain.

THE COURT: – and, you know, that, too. You know, I've got a lot of issues here that are not answered, but you-all are asking me to rule on a Motion to Dismiss, stays, you know, et cetera. And some of this information that you're asking me – or some of the things that you're asking me to do, I don't know that I have the necessary information to be able to make that call. So, you know, I have what I have.

And I'll tell you-all for the record, I did not look at any of Judge Griffen's rulings or anything until after I had gone through everything you have submitted me, in this case, and formulated my own opinions about what I thought things should be, or not, or whatever. Then I read Judge Griffen's orders and the pleadings in that case, so that I would not be swayed or persuaded one way or the other, and would look at it in – in my mindset (R. 189) with based upon what you had given me, then I looked at Judge Griffen's orders.

And I'll tell you, you know, some of the things that he decided, I had made up my mind the same way, but I have – you know, I have some issues with some of it. And one of them is the label. That's why they put those on there. Ms. Merritt's correct. I mean, it is for a recall purpose.

If they just stuck that stuff out there, and there's no way to get it back, and they manufacture a bad drug, how can the manufacturer ever recall it or do anything to protect quality later on down the line – if people are dying because

they've suddenly discovered there's a reason for that, and that's the drug that we manufactured – without that identifying information?

And I'm no pharmacist, but I have some experience in this issue, and some personal experience in this very issue. So I don't know how to get around that. And I can't ignore it because I think Ms. Merritt's correct. So, you know, there's an issue there.

Now, does it identify sellers that sold these drugs? That, I don't know. You know, if they came (R. 190) from London, as you argued, maybe not. Maybe – you know, if they came from someone that happened to get a supply some way that not in the ordinary course of commerce in drug distribution, sales, and supplies, I don't know. But I don't know any of that. So –

MR. GAINES: That's an important thing that you don't know. And the burden is on the State to show the exemption applies. If evidence is missing, that's on the State, not on Mr. Shults. I would note that I agree with you that the lot and batch numbers are used for recall purposes, but in our opinion – we're not experts, we don't have an expert witness. State didn't have an expert witness; they have a nurse, who does not have intricate – you know, intricate knowledge of the pharmaceutical (R. 191) process. It's our opinion that – it was Judge Griffen's opinion – that the lot and batch numbers do not identify the end – it doesn't go through the distribution process. It just shows in which lot and batch of the

manufacturer's original process those drugs came from. It doesn't show where they went after.

THE COURT: Now, Mr. Gaines, you're telling me that if a drug manufacturer puts a lot and batch number on there, and when they sell that to a seller or supplier, that they don't keep up with the lot and batch number of that drug that they sold to that particular entity that is selling and in the business of supplying that drug – so that they can, again, go back – what if they've got it in their storeroom and they haven't sold it all, they know where to go to get that bad drug back, in case they need that recall.

MR. GAINES: Again, I'm not an expert in this field, but it's our opinion that wouldn't go through the entire chain of distribution to allow the manufacturer to identify exactly where that drug came from, but the point, (R. 192) also –

THE COURT: – you know, if that seller subsequently sells to another seller or another supplier down the road, and they subsequently sell, what record-keeping is required for that lot and batch number to be tracked throughout all this process? I have no idea.

MR. GAINES: Understood. And I don't, either. I would tell you this, if the State didn't want that lot and batch number out there, they can simply redact it from the label, and still produce redacted copies of the label and unredacted copies of the insert, which has no lot and batch numbers on them.

COURT'S RULING: All right. As I said, you know, I went through this. I – I read it briefly (R. 193) yesterday. I thought I would have more time than I did here at the office. So I took it home last night. And I sat and read everything that you-all had given me and then I started going through Ark. Code Annotated § 5-4-617, the MEA. When I went through that, I made notes. And I noted that, specifically, the legislature, in paragraph (d)(1), talked about a manufacturer approved by the FDA.

And then under (i)(2)(B), they don't mention a manufacturer when they talk about the entities that would be kept confidential. "The entities and persons who." And then they delineate who those entities and persons are. "Compound, test, sell, or supply the drug or drugs described in subsection (c) of this section."

Then, they go down to (j), "The department shall make available." That's mandatory, as I understand the Supreme Court's interpretation of the word. "To the public any of the following information upon request, so long as the information that may be used to identify" – again "the compounding pharmacy." The same as goes back up to (i)(2). "Testing laboratory" goes back up to (b), the test. "Seller or supplier." "Sell or supply the drug or drugs is (R. 194) redacted and maintained as confidential."

So they specifically delineate in both of those sections "the entities and persons who" and then they describe them specifically. Nowhere in there is the

word "manufacturer" used. And the legislature could have easily inserted that word. They do not.

Then you go to (j)(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 USFDA." So they could have, and they probably should have if, you know, they want to accomplish what the State argues, but they didn't. And you're asking me to read into this statute something that is not there. And I cannot do that.

So I do not find that "seller" or "supplier" equates to manufacturer. So the exemption there does not apply.

And I think that if I interpret the reading of (j)(1) as the State would argue, it makes that provision meaningless. And I don't think that I can do that, either.

As I told you, I read Judge Griffen's the paperwork as it relates to, I'll call it, *Shults I*, after reading your pleadings and documents (R. 195) and the statute. And I find Judge Griffen's opinion to be very well-written, very concise, and it is applicable.

And so I'm going to order the State to supply – and, again, the other thing the legislature could have done, had they wanted to remove from the package inserts and labels, the lot and batch numbers, they didn't do that. And they could have. So I'm going to order that it be provided. (R. 196-97). What if just say this,

what if I order you to turn it over by next Thursday. That'll give you a little over a week to make your application for stay.

And, again, I understand the Plaintiff wants (R. 198) it, and I've ruled that you're entitled to it. I am not inclined to dismiss under 12(b)(8), nor am I inclined to stay this proceeding waiting on ruling in *Shults I*. You know, I have good attorneys, very bright people, that understand that, you know, I've made a ruling, but you-all certainly have your right to challenge that, and I expect you to do so. You know, so that's no surprise, and I'll let the Supreme Court make the final call on that issue. But that's the way I see it today.

MS. MERRITT: Thank you, Your Honor. And can I confirm, the Court is ordering complete, unredacted disclosure of the label, as well?

THE COURT: Yes, ma'am.

MS. MERRITT: So we do need to disclose lot (R. 199) and batch numbers under the Court's order?

THE COURT: Yes, ma'am. (R. 200).

Statement of the Case

This expedited appeal involves the proper scope and application of confidentiality provisions in the Arkansas Method of Execution Act, Ark. Code Ann. § 5-4-617 ("MEA"), that require the Arkansas Department of Correction ("ADC") to maintain the confidentiality of lethal drug sellers and suppliers.

The FOIA request. Plaintiff-Appellee Steven Shults is an attorney with no apparent connection to death-penalty litigation or death-row inmates. He is not a prisoner facing a scheduled execution, nor does he represent a prisoner facing a scheduled execution. Shults has submitted weekly FOIA requests to the ADC seeking, among other things, records related to the Department's lethal-drug supply. (Add. 5-10). The FOIA request at issue here, dated August 21, 2017, specifically requested documents or records in any form (including photos or copies of labels on drug bottles, packaging, or inserts) containing the following information about all drugs intended for use in judicial executions: drug name, manufacturer, concentration, expiration date(s), and lot numbers. (Add. 8).

ADC's response. ADC provided Shults with information and records revealing that the Department had recently acquired a supply of bulk-manufactured, FDA-approved midazolam, a drug listed in its execution protocol. (Add. 11, 130-31). ADC informed Shults that it was in possession of pharmaceutical package inserts and labels for the midazolam that were potentially responsive to his request.

(Add. 11). But ADC explained that those records were exempt from FOIA disclosure under the Arkansas Method of Execution Act, Ark. Code Ann. § 5-4-617 ("MEA") because, under that provision, ADC is required to "keep confidential all information that may identify or lead to the identification of . . . the entities . . . who . . . test, sell, or supply the drug or drugs . . . for the execution process." (Add. 11) (quoting Ark. Code Ann. § 5-4-617(i)(2)(B)). ADC acknowledged that, while the MEA generally requires disclosure of "[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," ADC may only disclose such documents where "the information that ***may be used*** to identify the . . . seller, or supplier is redacted and maintained as confidential." (Add. 11) (quoting Ark. Code Ann. § 5-4-617(j)-(j)(1)). ADC explained that this Court had recently sustained the constitutionality of the MEA in *Kelley v. Johnson*, 2016 Ark. 268, 496 S.W.3d 346, and that ADC was required to fully comply with the confidentiality provisions of the law. (Add. 11).

ADC explained to Shults that, consistent with the MEA's broad prohibition on the disclosure of all information that may identify or lead to the identification of entities that sell or supply drugs for the execution process and the requirement that any package inserts and labels be redacted to maintain that confidentiality, ADC had determined that it was prohibited from disclosing the drug package inserts and

labels that potentially would be responsive to his request. (Add. 11). ADC explained that, based on its previous experience disclosing inserts and labels, along with a detailed comparison of such documents used by different drug manufacturers, production of those records would identify or lead to the identification of the suppliers and sellers of those drugs. (Add. 11).

ADC noted that it had previously disclosed labels and inserts that redacted manufacturer logos, addresses, and other information which the ADC believed could be used to identify sellers or suppliers. (Add. 12). But, despite those efforts, news outlets were able to compare the redacted inserts and labels with publicly-available (unredacted) information and readily discern the identity of the drugs' suppliers and sellers. (Add. 12) (identifying three examples of news reports publishing the names of the manufacturers of the drugs in ADC's possession after production of redacted package inserts and labels). Such identification despite ADC's efforts at redaction was "unsurprising" "[g]iven variations in format, style, diction, font, organization, grammar, and spelling between the labels and inserts used by various manufacturers[.]" (Add. 12). As a result, it is not possible to redact the labels or package inserts in a manner that would—as required by the Method of Execution Act—maintain confidentiality." (Add. 12).

In order to provide Shults with as much information as possible, ADC confirmed that its recent purchase was of bulk-manufactured, FDA-approved

midazolam with an expiration date of January 2019. (Add. 11). ADC also provided URL information for a number of websites where Shults could find package inserts and labels for *all* FDA-approved drugs, including the recently-acquired injectable midazolam. (Add. 12).

The lawsuit.[1] Shults filed suit on September 7, 2017, alleging that the ADC violated the FOIA and the Method of Execution Act by failing to provide him with copies of the package inserts and labels for the newly-acquired midazolam. (Add. 1). Shults requested that the circuit court hold a prompt hearing and enter an order finding that ADC violated the FOIA through improper interpretation of Ark. Code Ann. § 5-4-617(j)(1), that ADC was not substantially justified in its refusal to provide the records as requested, and that Plaintiff is entitled to unredacted copies of lethal drug labels and package inserts. (Add. 3).

ADC moved to dismiss the Complaint, arguing that Shults failed to state a valid FOIA claim because the information he seeks is confidential under the MEA. (Add. 23, 83). ADC also submitted the Affidavit of Rory Griffin, who is the Department's Deputy Director for Health and Correctional Programs with 25 years of experience in ADC's healthcare system. (Add. 106). Deputy Director Griffin explained why it is impossible for the ADC to disclose drug package inserts and

[1] The same factual and legal issues that are presented in this case are also the subject of another FOIA lawsuit that Shults filed in March 2017 in Pulaski County Circuit Court No. 60CV-17-1419, which is currently pending before this Court on appeal in Supreme Court No. CV-17-544 ("*Shults I*").

labels in a way that complies with the MEA's confidentiality provisions. (Add. 107-09). Deputy Director Griffin also testified that "[d]rug labels not only reveal the identity of the manufacturer, which is the initial 'seller' or 'supplier' of the drug into the stream of commerce," but "also contain unique identifying information in the form of lot and/or batch numbers that may be used to trace the drug through the distribution chain, all the way from the manufacturer through its supply chain and to the end user, which in this case is the ADC." (Add. 109). "Accordingly, the MEA absolutely prohibits the ADC from disclosing lot and/or batch numbers in response to FOIA requests." (Add. 109).

The FOIA hearing. The circuit court held a hearing on September 19, 2017. The circuit court took judicial notice that drug manufacturers sell or supply their products in the stream of commerce. (Ab. 6). The circuit court also credited the undisputed testimony of Deputy Director Griffin that lot and batch numbers appearing on drug labels can be used to identify sellers and suppliers in the distribution chain. (Ab. 24-26). But the court ultimately ruled in favor of Shults and ordered unredacted disclosure of the requested package insert and label because the legislature did not specifically include the terms "manufacturer," "lot number," or "batch number" in the MEA's confidentiality provisions. (Ab. 28-30; Add. 133-36). ADC filed a notice of appeal (Add. 137) and obtained an emergency stay of the disclosure order from this Court.

Argument

This case presents a straightforward question of law: Whether documents that identify or could lead to the identification of lethal-drug sellers and suppliers—including the manufacturers that "sell" and "supply" those drugs into the stream of commerce—are subject to disclosure under the FOIA. On de novo review, this Court should hold that such records are absolutely confidential under the MEA and reverse the circuit court's disclosure order.

I. Standards of review

The question of the correct application and interpretation of an Arkansas statute is a question of law which this Court reviews de novo. *Hammerhead Contracting & Dev., LLC v. Ladd*, 2016 Ark. 162, at 6, 489 S.W.3d 654, 658-59; *see also Ark. State Police v. Wren*, 2016 Ark. 188, at 3, 491 S.W.3d 124, 126; *Pulaski Cty. v. Ark. Democrat-Gazette, Inc.*, 370 Ark. 435, 439, 260 S.W.3d 718, 720 (2007). On review of an issue of statutory interpretation, this Court is not bound by the decision of the circuit court. *Fox v. Perroni*, 358 Ark. 251, 256, 188 S.W.3d 881, 885 (2004) (citing *Bryant v. Weiss*, 335 Ark. 534, 983 S.W.2d 902 (1998)). A circuit court's factual findings that underpin its legal conclusions are reviewed under an abuse-of-discretion standard. *Ark. Lottery Comm'n v. Alpha*

Mktg., 2013 Ark. 232, at 6, 428 S.W.3d 415, 419 (citing *Ark. Dep't of Envtl. Quality v. Oil Producers of Ark.*, 2009 Ark. 297, at 5, 318 S.W.3d 570, 572-73).

Courts liberally interpret the FOIA in favor of disclosure. *Fox*, 358 Ark. at 256, 188 S.W.3d at 885. But courts should also remain "aware of the need for a balancing of interests to give effect to what we perceive to be the intent of the General Assembly." *Pulaski Cty.*, 370 Ark. at 440, 260 S.W.3d at 721. "In doing so, a common sense approach must be taken." *Id*. (citing *Bryant v. Mars*, 309 Ark. 480, 830 S.W.2d 869 (1992)). In any event, this case is not about the interpretation of the FOIA, but rather about the interpretation of certain provisions of the Method of Execution Act passed by the General Assembly in 2015. *See* Ark. Act 1096 of 2015.

II. The lethal-drug information requested by Shults is confidential and not subject to disclosure.

On the undisputed facts, disclosure of lethal-drug package inserts and labels would identify or lead to the identification of sellers or suppliers of those drugs in violation of the Method of Execution Act, Ark. Code Ann. § 5-4-617(i)(2)(B). The circuit court took judicial notice that, manufacturers are "sellers" or "suppliers" in the chain of distribution. This Court should hold, as a matter of law, that manufacturers therefore fall within the plain terms of the MEA's confidentiality provisions. Interpreting the confidentiality provisions of the MEA to include

manufacturers, moreover, comports with both legislative intent and public policy. Given the specific confidentiality afforded this information under the MEA, it is not subject to disclosure under the FOIA as a matter of law. This Court should therefore reverse the decision of the circuit court and dismiss.

A. The Method of Execution Act expressly requires the ADC to maintain the confidentiality of lethal drug sellers and suppliers.

This Court applies rules of statutory construction in order to "give effect to the intent of the legislature." *Hammerhead Contracting*, 2016 Ark. 162, at 7, 489 S.W.3d at 659. "The first rule of statutory construction is to construe a statute just as it reads, giving the words their ordinary and usually accepted meaning." *Id.* As discussed below, the plain language of the MEA requires the ADC to maintain the confidentiality of lethal drug sellers and suppliers.

The Arkansas General Assembly amended the Method of Execution Act in 2015, in part, "to address the problem of drug shortages." Ark. Act 1096 of 2015, § 1(a). In addition to adopting a new drug protocol, Act 1096 included new nondisclosure provisions providing that "[t]he department shall keep confidential all information that may identify or lead to the identification of . . . [t]he entities and persons who compound, test, sell, or supply the drug or drugs . . . for the execution process." Ark. Code Ann. § 5-4-617(i)(2)(B). The act permits the ADC to disclose package inserts and labels for bulk-manufactured, FDA-approved

drugs upon request, ***but only if*** "information that may be used to identify" a "seller" or "supplier" "is redacted and maintained as confidential." Ark. Code Ann. § 5-4-617(j)-(j)(1). Thus, when construing the statute just as it reads, it clearly affords confidentiality to any seller or supplier of lethal-injection drugs.

B. Manufacturers "sell" and "supply" lethal drugs in the distribution chain.

As discussed above, the confidentiality provisions in the MEA are broadly worded to apply to any seller or supplier of lethal drugs. *See* Ark. Code Ann. § 5-4-617(i)(2)(B) & (j)(1). The MEA does not define the terms "seller" or "supplier," so this Court affords those words their ordinary and usually accepted meaning. *Hammerhead Contracting*, 2016 Ark. 162, at 7, 489 S.W.3d at 659. According to Black's Law Dictionary, a "seller" is "[o]ne who sells anything" and a "supplier" is a "party supplying services or goods." *See* http://thelawdictionary.org/seller/ and http://thelawdictionary.org/supplier/ (last visited Oct. 4, 2017). And this Court has recognized for well over a century that manufacturers "sell" or "supply" their products in the stream of commerce. *See, e.g.*, *Mosley Mach. Co. v. Gray Supply Co.*, 310 Ark. 214, 833 S.W.2d 772 (1992) (discussing implied duties and warranties running from "the manufacturer-seller in a sales contract" to the purchaser); *Crow v. Fones Bros. Hardware Co.*, 176 Ark. 993, 4 S.W.2d 904 (1928) (using terms "manufacturer," "seller," and "supplier" interchangeably);

Jeffries v. State, 52 Ark. 420, 12 S.W. 1015 (1890) (holding that, "as in all commercial transactions, [a] manufacturer may sell by his agents").

Under the plain meaning of the MEA, a drug manufacturer is a seller or supplier in the lethal-drug distribution chain. Public records available here in Arkansas—filed by some of the manufacturers of Arkansas's lethal drugs, no less—demonstrate that lethal-drug manufacturers "sell" or "supply" them to distributors and place the drugs into the stream of commerce. *See infra* Part II.D. Indeed, the circuit court below took judicial notice that drug manufacturers sell or supply their products in commerce. (Ab. 6). As a result, this Court should conclude as a matter of law that drug manufacturers are sellers and/or suppliers within the scope of the MEA's confidentiality provisions.

C. The State's interpretation of the statute gives full effect to all of its provisions and is consistent with legislative intent.

In construing any statute, this Court places it beside other relevant provisions and "ascribe[s] meaning and effect to be derived from the whole." *State v. Colvin*, 2013 Ark. 203, at 7, 427 S.W.3d 635, 640. "Statutes relating to the same subject must be construed together and in harmony, if possible." *Id.* The stated purpose of Act 1096 was to help remedy the problem of lethal-drug shortages. Ark. Act 1096 of 2015, § 1(b). To that end, the legislature afforded complete confidentiality to drug sellers and suppliers as well as entities and persons who

compound and test drugs (along with others involved in the execution process). Ark. Code Ann. § 5-4-617(i)(2) & (j). While the MEA does contemplate disclosure of redacted package inserts and labels for drugs made by FDA-approved manufacturers (which includes the midazolam at issue here), that disclosure provision mandates that the ADC "redact[] and maintain[] as confidential" all "information that may be used to identify" any "seller" or "supplier." Ark. Code Ann. § 5-4-617(j)-(j)(1).

As established by the affidavits of ADC Deputy Director Rory Griffin, the *only* way to reconcile the MEA's mandatory confidentiality and disclosure provisions under the undisputed facts of this case is for the ADC to decline disclosure altogether of package inserts and labels for its recently-acquired midazolam. Based on recent experience, ADC knows that any disclosure short of complete and wholesale redaction would lead to the identification of the seller or supplier of the ADC's midazolam based on the unique format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance of the package insert and label in the ADC's possession. (Add. 34-36, 107-09). It is an undisputed fact in this case that news reporters published the names of lethal-drug manufacturers—including the manufacturer of ADC's previous supply of midazolam—despite the ADC's redaction of all of the obvious identifying information on the package inserts and labels (such as manufacturer name, logo,

address, and the like). (Add. 12, 34, 107-08). That prior experience demonstrates that it is simply not possible for the ADC to redact the requested package insert and label of the midazolam in a way that would protect the confidentiality of the seller or supplier of the drug as required by the MEA. The ADC's interpretation is the only possible way to reconcile the various MEA provisions on the undisputed facts of this case.

D. As a matter of public policy, lethal-drug confidentiality provisions should apply to all sellers and suppliers in the chain, including the original manufacturers.

Public policy is best served by an interpretation of the MEA's confidentiality provisions that includes manufacturers. In sustaining the constitutionality of the MEA's confidentiality provisions in *Kelley v. Johnson*, the Court observed that the General Assembly has declared, as a matter of public policy, that capital murder may be punishable by death. 2016 Ark. 268, at 26, 496 S.W.3d 346, 363, *cert. denied sub nom. Johnson v. Kelley*, 137 S. Ct. 1067 (2017). The Court also recognized that the State "has a legitimate interest in carrying out a sentence of death in a timely manner," and the General Assembly adopted the confidentiality provisions of the MEA "[i]n aid of that process." *Kelley*, 2016 Ark. 268, at 26, 496 S.W.3d at 363 (quoting *Baze v. Rees*, 553 U.S. 35, 61 (2008)). This Court should similarly interpret the MEA's confidentiality provisions in this case with that public policy in mind.

The *Kelley v. Johnson* Court specifically noted the "undisputed affidavits" offered by the ADC in that case that "demonstrate[d] ADC's own obstacles to acquiring the drugs and the unwillingness of suppliers to sell the drugs to a department of correction." *Id.* at 25, 496 S.W.3d at 362. It was an undisputed fact in *Johnson* that the ADC's supplier of the drugs it had at that time "agreed to provide them only on the condition of anonymity, and that supplier is no longer inclined to sell the drugs to ADC." *Id.* The undisputed evidence in that case also established "that manufacturers prohibit distributors from selling the drugs to departments of correction." *Id.* This Court observed that, "[g]iven the practical realities of the situation," public disclosure of the identity of suppliers of drugs for lethal injections would frustrate the State's ability to carry out lawful sentences. *Id.* at 25-26, 496 S.W.3d at 362-63. The Court noted further that "[t]he General Assembly has determined that there is a need for confidentiality" and "[t]he question whether the enactment is wise or expedient is a matter exclusively for the General Assembly to decide." *Id*. at 26, 496 S.W.3d at 363.

Public records in another case filed by the prisoners demonstrate why the broadest possible construction of the MEA's confidentiality provisions is required to protect the ADC's lethal-drug supply. In a subsequent challenge to the MEA brought by the same prisoners in *Johnson* in a federal-court case styled *Jason McGehee, et al. v. Asa Hutchinson, et al.*, in the U.S. District Court for the Eastern

District of Arkansas, Case No. 4:17-cv-00179-KGB, two lethal-drug manufacturers sought leave to file an *amicus* brief in support of the prisoners' case. *See* Mtn. for Leave by Fresenius Kabi USA, LLC, and West-Ward Pharmaceuticals Corp. (Apr. 13, 2017) in Case No. 4:17-cv-00179-KGB (DE 42). In their supporting brief, the manufacturers objected to the State of Arkansas's use of their drugs in lethal injections "despite the Manufacturers' implementation of distribution protocols to prevent this[.]" *Id.*, DE 43 at 2.

Fresenius Kabi, which manufactures most of the potassium chloride in the United States, averred that "[i]f the State of Arkansas has obtained Fresenius Kabi-manufactured potassium chloride to use in capital punishment—as appears to be the case—it would have been contrary to and in violation of the company's contractual supply-chain controls." *Id.* at 4. Fresenius Kabi specifically referenced (and attached as an exhibit to its federal-court filing) a redacted label and package insert previously produced by the ADC in response to FOIA requests to show that the ADC's potassium chloride "originated from Fresenius Kabi[.]" *Id.*

West-Ward explained that it appeared to be the manufacturer of the State's midazolam based on another redacted label and package insert previously disclosed by the ADC. *Id.* at 5. Like Fresenius Kabi, West-Ward detailed the various efforts it has undertaken to keep its drugs out of the hands of departments of correction for use in capital punishment, including the implementation of

"distribution controls to ensure that the drugs are not used in connection with lethal-injection protocols, including instructing that such medicines be sold only to pre-authorized customers who agree not to sell them to departments of correction, other entities that intend to use them for lethal injection, secondary distributors, or retail pharmacies." *Id.* West-Ward complained that the ADC's acquisition of its midazolam for use in capital punishment violated those "contractual controls." *Id.* at 5-6.

An interpretation of the MEA's confidentiality provisions in a way that includes drug manufacturers would further the express purpose of the MEA—to help the ADC acquire the drugs that are necessary for it to perform its legal duty and carry out lawful sentences. Absent such an interpretation, drug manufacturers will continue to be publicly identified in published news reports and will continue to interject themselves into litigation in an effort to halt the State's use of their drugs for capital punishment. In addition, public pressure from anti-death-penalty advocates likely would lead manufacturers to implement even more distribution controls that would, as a practical matter, make it impossible for the State to acquire the drugs in its lethal-injection protocol. *See Glossip v. Gross*, 135 S. Ct. 2726, 2733 (2015) (discussing the "practical obstacle" to lethal injection that emerged when "anti-death-penalty advocates pressured pharmaceutical companies to refuse to supply the drugs used to carry out death sentences"). This Court

should not sanction such a result, which would obliterate the stated purpose for the MEA's confidentiality provisions.

E. The confidentiality provision in the Method of Execution Act trumps the FOIA.

The intent of the General Assembly in adopting broad confidentiality provisions in Act 1096 of 2015 would be thwarted if the ADC is forced to disclose package inserts and labels that identify lethal-drug sellers and suppliers in response to FOIA requests. Both the MEA and the FOIA govern disclosure of public records in response to citizen requests, so they are in *pari materia* and must be construed harmoniously, if capable of reconciliation. *Bd. of Trustees for the City of Little Rock Police Dep't Pension & Relief Fund v. Stodola*, 328 Ark. 194, 200, 942 S.W.2d 255, 258 (1997).

The MEA is a specific statute that concerns the disclosure of lethal-drug package inserts and labels in response to citizen requests. Ark. Code Ann. § 5-4-617(j)(1). The FOIA relates to disclosure of public records generally. *See* Ark. Code Ann. §§ 25-19-101 *et seq.* "A general statute must yield when there is a specific statute involving the particular subject matter." *Stodola*, 328 Ark. at 201, 942 S.W.2d at 258. In addition, the fact that Act 1096's confidentiality and disclosure provisions were enacted in 2015, long after the FOIA, is a factor to which this Court has given credence in statutory interpretations. *Id.* (citing

Donoho v. Donoho, 318 Ark. 637, 639, 887 S.W.2d 290, 291 (1994); *Moore v. McCuen*, 317 Ark. 105, 876 S.W.2d 237 (1994); *Uilkie v. State*, 309 Ark. 48, 827 S.W.2d 131 (1992)).

Under these principles of statutory construction, this Court should reverse the trial court's decision that the lethal-drug package inserts and labels requested by Shults are subject to disclosure under the FOIA. While both the MEA and the FOIA deal with disclosure of public records, when the records requested relate to lethal-injection drugs (or other information covered by the MEA), § 5-4-617(j)(1) controls. *See id.* The clear intent behind § 5-4-617, as expressed by the General Assembly's legislative findings in Section 1 of Act 1096 of 2015, is to address the problem of lethal-drug shortages by affording confidentiality to all participants in the process, including drug sellers and suppliers. Section 5-4-617 is the more specific, and the more recent, statute governing disclosure of records regarding lethal-injection drugs. It therefore controls under longstanding precedent, and the circuit court reversibly erred in concluding otherwise.

F. Even if the identity of lethal-drug manufacturers is not confidential under the Method of Execution Act, the ADC still must redact certain information from drug labels to protect the confidentiality of other sellers and suppliers in the chain of distribution.

The MEA expressly requires the ADC to maintain confidentiality of "all information that may identify or lead to the identification of" the "entities and

persons" who sell or supply lethal drugs. Ark. Code Ann. § 5-4-617(i)(2)(B). And the MEA also requires "information that may be used to identify" sellers or suppliers to be "redacted and maintained as confidential" prior to responding to public records requests. Ark. Code Ann. § 5-4-617(j)(1). Regardless of whether the MEA renders confidential information about a drug *manufacturer*, it cannot be honestly disputed that, ***at the very least***, § 5-4-617(i)(2)(B) and (j) require redaction of any information on a drug label or package insert that ***could potentially*** lead to the identification of the ***seller*** or ***supplier*** of the drug.

The circuit court's order violates the MEA's mandatory confidentiality provisions by compelling disclosure of unique identifying information on lethal-drug labels. (Add. 135). As Griffin's undisputed testimony established—which the circuit court credited and agreed with at the FOIA hearing (Ab. 24-26)—those labels contain information such as lot, batch, and/or control numbers that may be used to identify ADC's seller and/or supplier (Add. 109). As a result, that unique identifying information is absolutely confidential and cannot be disclosed pursuant to the MEA, Ark. Code Ann. § 5-4-617(i)(2)(B) and (j).

Federal law supports this conclusion. FDA regulations require that lot numbers, control numbers, and/or batch numbers on drug labels reveal "**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)

(emphases added). Federal law also requires all drug manufacturers, repackagers, wholesale distributors, and dispensers in the pharmaceutical distribution supply chain to use these unique product identifiers on ***each drug label*** and to provide transaction information, transaction history, and a transaction statement for ***each transaction*** in commerce. 21 U.S.C. § 360eee-1; *see also* 21 C.F.R. § 211.130(c) (requiring drug labels to identify the product with a lot or control number "that permits determination of the history of the manufacture and control of the batch").

The circuit court's order compelling ADC to disclose lethal-drug lot and batch numbers ignores the undisputed facts and federal law. The evidence before the circuit court demonstrated that disclosure of the lot and batch numbers on the lethal-injection drug label at issue here would allow the recipient to track the product through the stream of commerce. Thus, on the undisputed facts and in light of federal drug-labeling laws, it is very likely that manufacturers and/or their wholesalers could use these numbers to identify the seller or supplier that provided the midazolam to ADC.

On de novo review, this Court should reverse the circuit court's unnaturally narrow interpretation of the MEA's confidentiality provisions. The circuit court reasoned that lot and batch numbers are not confidential under the MEA because the legislature did not specifically protect that information. (Ab. 29). But that ruling ignores the plain language of the MEA, which twice forbids disclosure of

information that ***may*** lead to identification of sellers and suppliers. Ark. Code Ann. § 5-4-617(i)(2) and (j). Because the statute broadly protects not only information that actually identifies a seller or supplier, but also information that ***may*** allow someone to identify a seller or supplier, this Court should reverse the circuit court's order compelling disclosure of lot and batch numbers. These indicia should plainly be redacted as confidential under the MEA prior to any disclosure of a drug label.

Conclusion

For the foregoing reasons, the Court should reverse and dismiss. Lethal-drug package inserts and labels identify sellers or suppliers and are confidential under the MEA. Such documents are not subject to disclosure under the FOIA. ***At a minimum, the Court should reverse the circuit court's order requiring disclosure of lot and batch numbers on lethal-drug labels***.

Respectfully submitted,

LESLIE RUTLEDGE
Arkansas Attorney General

By: */s/ Jennifer L. Merritt*

LEE P. RUDOFSKY (2015015)
Solicitor General
NICHOLAS J. BRONNI (2016097)
Deputy Solicitor General
JENNIFER L. MERRITT (2002148)
Senior Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Telephone: (501) 682-1319
Facsimile: (501) 682-2591
Lee.Rudofsky@ArkansasAG.gov
Nicholas.Bronni@ArkansasAG.gov
Jennifer.Merritt@ArkansasAG.gov

Attorneys for Appellants

Certificate of Service

I hereby certify that on this 6th day of October, 2017, I electronically filed the foregoing via the eFlex electronic filing system, which shall send notification of the filing to any participants. I also certify that I will serve a paper copy of the brief within five calendar days upon the following:

Honorable Mackie Pierce
Pulaski County Circuit Judge
401 W. Markham St., Suite 360
Little Rock, Arkansas 72201

Philip E. Kaplan, Esq.
Heather Goodson Zachary, Esq.
Alec Gaines, Esq.
WILLIAMS & ANDERSON PLC
111 Center Street, Suite 2200
Little Rock, Arkansas 72201

/s/ Jennifer L. Merritt
Jennifer L. Merritt

Certificate of Compliance

I hereby certify that I have submitted and served on opposing counsel (except for incarcerated pro se litigants) unredacted and, if required, redacted PDF documents that comply with the Rules of the Supreme Court and Court of Appeals. The PDF documents are identical to the corresponding parts of the paper documents from which they were created as filed with the Court. To the best of my knowledge, information, and belief formed after scanning the PDF documents for viruses with an antivirus program, the PDF documents are free of computer viruses. A copy of this certificate will be submitted with the paper copies filed with the Court and has been served on all opposing parties.

/s/ Jennifer L. Merritt
Jennifer L. Merritt

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
_____ DIVISION

STEVEN SHULTS PLAINTIFF

v. CASE NO: _____

ARKANSAS DEPARTMENT OF CORRECTION; DEFENDANTS
WENDY KELLEY, in her Official Capacity

COMPLAINT

Steven Shults, for his Complaint against the Arkansas Department of Correction ("ADC") and Wendy Kelley, in her official capacity as director of the ADC, states:

1. This case is an appeal from denial of rights guaranteed under the Arkansas Freedom of Information Act ("AFOIA"), and it is brought pursuant to Ark. Code Ann. § 25-19-107(a).

PARTIES, JURISDICTION, AND VENUE

2. Plaintiff, Steven Shults, is a resident of the State of Arkansas, and brings this action in his capacity as a citizen entitled to request and receive certain public records under the AFOIA. Ark. Code Ann. § 25-19-101, et seq.

3. Defendant Arkansas Department of Correction ("ADC") is a "department, agency, or institution of the" State of Arkansas and is subject to the AFOIA's requirements of providing access to certain public records upon request.

4. Defendant Wendy Kelley is the director of the ADC, and she is being sued in her official capacity because she has administrative control over certain records that form the basis for this lawsuit, making her the "custodian" of those records within the meaning of the AFOIA. Ark. Code Ann. § 25-19-103(1)(A).

5. Jurisdiction and venue are proper in this Court, as ADC is "a department, agency, or institution of the" State of Arkansas. *See* Ark. Code Ann. § 25-19-107(a).

STATEMENT OF FACTS

6. On August 21, 2017, Plaintiff submitted a Freedom of Information Act Request to the ADC via e-mail. Attached as Exhibit 1 to the Complaint is the Affidavit of Steven Shults. Exhibit A to Exhibit 1 is the August 21, 2017, AFOIA request. In his Request, Plaintiff sought, in part, information relating to the ADC's supply of drugs intended for use in lethal injection executions. *Id.*

7. On August 24, 2017, ADC provided a response to the August 21, 2017 AFOIA request. ADC provided records revealing that Director Wendy Kelley acquired 40 vials of midazolam, a drug listed in its execution protocol, on August 4, 2017. Ex. 1, Ex. B.

8. ADC refused to disclose the package inserts or labels for the newly-acquired supplies of midazolam as required by the AFOIA and Arkansas Method of Execution Act ("AMEA") because it took the position it is "prohibited from disclosing the pharmaceutical package inserts and labels" because the labels could be used to identify the sellers or suppliers of the drugs to ADC. *Id.*

9. ADC's interpretation is in violation of the clear language of the statute, and renders portions of the AMEA, Ark. Code Ann. § 5-4-617(j)(1) in particular, meaningless.

COUNT 1: VIOLATION OF THE AFOIA

10. ADC has violated Plaintiff's rights under the AFOIA and AMEA by failing to provide records of lethal injection drug product labels and package inserts, documents that are "public records" under the Arkansas FOIA and *specifically* subject to disclosure under the AMEA. Ark. Code Ann. §§ 25-19-105; 5-4-617.

11. In the context of these records, the AMEA *specifically* requires ADC to disclose the very materials requested by Plaintiff in this action: the "[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 . . . ." Ark. Code Ann. § 5-4-617(j)(1).

12. ADC's stated reason for refusing to produce the requested records is contrary to the plain meaning of the AMEA and constitutes a violation of the AFOIA. Furthermore, ADC's stated reason for refusing to produce are contrary to established ADC policies and procedures regarding disclosure of package inserts and labels. *See* Ex. 1, Ex. C.

13. ADC does not have substantial justification to refuse to disclose the requested records to the Plaintiff.

REQUEST FOR RELIEF

14. Plaintiff requests and is entitled to a hearing on this matter within seven (7) days of the date of this application. *See* Ark. Code Ann. § 25-19-107(b). Given the execution of prisoners has been scheduled for November 9, 2017, Plaintiff respectfully requests the Court expedite this matter.

15. Plaintiff, through undersigned counsel, reserves the right to seek reasonable attorney's fees and costs from the Arkansas Claims Commission upon successful completion of this matter. See Ark. Code Ann. § 25-19-107(e)(2)(B).

WHEREFORE, the Plaintiff, Steven Shults, prays that this Court will hold a hearing and enter an Order finding Defendant violated the AFOIA through improper interpretation of Ark. Code Ann. § 5-4-617(j)(1), that Defendant was not substantially justified in its refusal to provide the records as requested, and that Plaintiff is entitled to unredacted copies of product labels and inserts and all such additional relief as is necessary and proper.

WILLIAMS & ANDERSON PLC
111 Center Street, Suite 2200
Little Rock, Arkansas 72201
Telephone: 501-372-0800
Facsimile: 501-372-6453

/s/ Alec Gaines
Philip E. Kaplan (AR68026)
pkaplan@williamsanderson.com
Heather G. Zachary (AR2004216)
hzachary@williamsanderson.com
Alec Gaines (AR2012277)
againes@williamsanderson.com

Attorneys for Steven Shults

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
_____ DIVISION

STEVEN SHULTS — PLAINTIFF

v. CASE NO: _____

ARKANSAS DEPARTMENT OF CORRECTION;
WENDY KELLEY, in her Official Capacity — DEFENDANTS

AFFIDAVIT OF STEVEN SHULTS

I, Steven Shults, am competent to testify, have personal knowledge regarding the statements contained in this affidavit, and do hereby state and verify the following:

1. I am a resident of the State of Arkansas.

2. On August 21, 2017, I submitted a Freedom of Information Act Request to the Arkansas Department of Correction ("ADC") via e-mail.

3. Specifically, I sent the records request to Solomon Graves, ADC's Public Information Officer and Legislative Liaison, at Solomon.Graves@arkansas.gov with the subject line "FOIA Request."

4. In my Request, I sought, in part, information relating to the ADC's supply of drugs intended for use in lethal injection executions.

5. A true and correct copy of the records request and accompanying e-mail is attached to my affidavit as Exhibit A.

6. In response to this request, ADC provided me with records on August 24, 2017, revealing that it had acquired 40 vials of midazolam, a drug listed in its execution protocol. A true and correct copy of this email and the accompanying response is attached to my affidavit as Exhibit B.

7. ADC refused to disclose to me the package inserts or labels for the newly-acquired supplies of midazolam because it took the position it is "prohibited from disclosing the pharmaceutical package inserts and labels" because the labels could be used to identify the sellers or suppliers of the drugs to ADC.

8. In response to a Freedom of Information Act request made on October 24, 2016 (substantially similar to my August 21, 2017, request), on October 27, 2016, ADC provided me with records, including package inserts and product labels for prior supplies of Midazolam, Potassium Chloride, and Vecuronium Bromide that were in ADC's possession at the time, but apparently not subject to the same prohibitions claimed in ADC's response to my August 21, 2017, request. A true and correct copy of my request and the accompanying response is attached to my affidavit as Exhibit C.

9. I declare under penalty of perjury under the laws of the United States of America that the above information is true and correct to the best of my knowledge.

Steven Shults

STATE OF ARKANSAS)
)
COUNTY OF PULASKI)

The above named appeared personally before me on this 6th day of September, 2017, and swore that the above statement is true and correct to the best of his knowledge and belief.

Robin Brady
NOTARY PUBLIC

My Commission Expires:

10-12-2026

NOTARY PUBLIC ARKANSAS
ROBIN D. BRADY
No. 12350861
LONOKE COUNTY
Commission Expires 10-12-2026

Jennifer Armour

From: Robin Brady <RBrady@shultslaw.com>
Sent: Monday, August 21, 2017 10:09 AM
To: 'solomon.graves@arkansas.gov'
Cc: 'jim.depriest@arkansas.gov'; Steve Shults
Subject: FOIA Request
Attachments: 2017-08-21 Letter from Steven Shults to Solomon Graves re FOIA Request.pdf

Attached is a letter of this date to you from Steve Shults, making a Freedom of Information Act request. Please respond by August 24, 2017.

Thank you.

Robin Brady
Office Manager
SHULTS LAW FIRM, LLP
200 West Capitol Avenue, Suite 1600
Little Rock, AR 72201-3621
Phone: (501) 375-2301
Fax: (501) 375-6861
www.shultslaw.com

SHULTS LAW FIRM, LLP

Attorneys at Law
200 West Capitol Avenue, Suite 1600
Little Rock, Arkansas 72201-3621
Telephone (501) 375-2301 Facsimile (501) 375-6861
www.shultslaw.com

August 21, 2017

VIA EMAIL (solomon.graves@arkansas.gov)

Mr. Solomon Graves
Public Information Officer
Arkansas Department of Correction
P.O. Box 8707
Pine Bluff, AR 71611-8707

Re: FOIA Request

Dear Mr. Graves:

I am a citizen of Arkansas. Under the Arkansas Freedom of Information Act (FOIA), Ark. Code Ann. §§ 25-19-101 to -110, I request copies of the following public records held by the Arkansas Department of Correction (the "ADC") relating to the execution of prisoners. Please include any public records held by the ADC, regardless of who created them.

I am requesting all records produced from May 1, 2017, through the date of your response. In particular, I request:

1. Copies of any inventories or logs of the following substances: thiopental sodium, sodium thiopental, pancuronium bromide, potassium chloride, pentobarbital, pentobarbital sodium, phenobarbital, nembutal, nembutal sodium, rocuronium bromide, midazolam, hydromorphone, brevital, diazepam, amobarbital, secobarbital, potassium acetate, etomidate, amidate or any other chemical or substance acquired for the purpose of anything relating to lethal injections by the ADC.

2. The expiration dates and beyond-use dates of all chemicals or substances intended or considered for use in lethal injection executions in the possession of the ADC.

3. Documents or records in any form (including, but not limited to: labels on drug bottles, packaging, or inserts) containing any of the following: 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.

4. All documents or correspondences (including, but not limited to: emails, faxes, letters, memos of telephone calls), whether internal or external, relating to attempts by the ADC to acquire compounded or manufactured chemicals or substances intended or considered for use in lethal injection executions.

5. All documents or correspondences (including, but not limited to: emails, faxes, letters, memos of telephone calls), whether internal or external from or with manufacturers of chemicals or substances intended or considered for use in lethal injection executions.

6. All correspondences (including, but not limited to: emails, faxes, letters, memos of telephone calls, notes of meetings), whether internal or external, between any ADC employee or agent and any other person or entity, or in the ADC's possession even if not a party to the correspondence, regarding the following substances: thiopental sodium, sodium thiopental, pancuronium bromide, potassium chloride, pentobarbital, pentobarbital sodium, phenobarbital, nembutal, nembutal sodium, rocuronium bromide, midazolam, hydromorphone, brevital, diazepam, amobarbital, secobarbital, potassium acetate, etomidate, amidate or any other chemical or substance considered or intended for the purpose of anything relating to lethal injections by the ADC.

7. Any correspondences between the ADC and any other party, including both internal and external communications, regarding any considered, proposed, or current execution protocols, regulations, guidelines, checklists, notes, or other documents that instruct or direct the carrying out of an execution.

8. All documents or correspondences, whether internal or external, regarding proposed, intended or considered changes in execution protocols, including switches to new lethal injection drug combinations, gasses, or other methods of execution. This includes, but is not limited to: any research, any payments to or contracts with experts, any and all emails or notes of meetings or calls, and any scholarship or documents in the ADC's possession bearing on execution methods.

9. All documents and correspondences (including, but not limited to: emails, faxes, letters, memos of telephone calls), whether internal or external, by or with manufacturers, compounding pharmacies or pharmacists, or other parties, where the party has refused to produce chemicals or substances and/or has requested that the ADC not use its products or substances for the purpose of executions.

If the ADC does not maintain certain requested public records, please let me know who does, and include the proper custodian's name and address.

Please let me know in advance if there will be any charge to me for obtaining these public records.

Please respond to this request by email no later than August 24, 2017, as required by Ark. Code Ann. § 25-19-105(e) and Op. Att'y Gen. 2000-059.

If you deny any of this request, please cite each specific exemption on which you rely to refuse to release the information, provide a detailed description of why the exemption applies, and notify me of the appeal procedures available to me under the law. As required by the FOIA, please provide redacted documents wherever non-exempt

information is commingled with exempt information. Please detail to the fullest extent possible the subject and volume of any withheld information.

Please send all documents to me by email as soon as possible at: sshults@shultslaw.com. Thank you in advance for your prompt compliance with this request.

Yours truly,

Steven Shults

SS

cc: Mr. Jim DePriest (via email --jim.depriest@arkansas.gov)

Jennifer Armour

From: Solomon Graves <Solomon.Graves@arkansas.gov>
Sent: Thursday, August 24, 2017 5:30 PM
To: Steve Shults
Cc: Jim Depriest; Robin Brady
Subject: Fwd: FOIA Request
Attachments: 2017-08-21 Letter from Steven Shults to Solomon Graves re FOIA Request.pdf; ATT00001.htm

Mr. Shults,

First, the ADC has determined that its pharmaceutical logs and a reimbursement request are responsive to your FOIA request. Copies of the relevant portions of those logs and the reimbursement request are attached in response to your FOIA request.

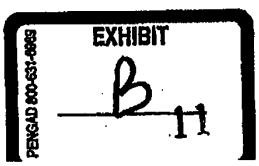
Secondly, the following are the expiration or beyond-use dates of all chemicals or substances intended or considered for use in lethal injections executions in the possession of the ADC:

Potassium Chloride - August 2018
Vercuronium Bromide - March 2018
Midazolam - January 2019

Unless a specific date is given, it is understood that the expiration or beyond-use date is the last day of the month.

Next, ADC has determined that it is in possession of pharmaceutical package inserts and labels for bulk-manufactured drugs approved by the United States Food and Drug Administration that are potentially responsive to your request. ADC has determined that the package inserts and labels are exempt from the FOIA disclosure under the Arkansas Method of Execution Act, Ark. Code Ann. § 5-4-617. Under that provision, ADC is required to "keep confidential all information that may identify or lead to the identification of . . . the entities . . . who . . . test, sell, or supply the drug or drugs . . . for the execution process." Ark. Code Ann. § 5-4-617(i)(2)(B). And while the Method of Execution Act generally requires ADC to disclose "[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," ADC may only do so where "the information that may be used to identify the . . . seller, or supplier is redacted and maintained as confidential." Ark. Code Ann. § 5-4-617(j)(1) (emphasis added). The Arkansas Supreme Court has sustained the Method of Execution Act's constitutionality, and ADC is required to comply with both the spirit and letter of that law. See Kelley v. Johnson, 2016 Ark. 268, 496 S.W.3d 346 (2016).

Consistent with the Method of Execution Act's broad prohibition on the disclosure of all information that may identify or lead to the identification of entities that test, sell, or supply drugs for the execution process and the requirement that any package inserts and labels be redacted to maintain that confidentiality, ADC has determined that it is prohibited from disclosing the pharmaceutical package inserts and labels that would potentially be responsive to your request. Indeed, based on our previous experience disclosing labels and inserts and a detailed comparison of various inserts and labels used by different manufacturers, ADC has determined that it would be impossible to disclose the inserts and labels that are potentially responsive to your request while simultaneously maintaining as confidential the identity of the suppliers and sellers of those drugs.



Previously, in response to FOIA requests, ADC has produced labels and inserts that redacted manufacturer logos, addresses, and other information which the ADC believed could be used to identify suppliers and sellers. Despite that, ews outlets were able to compare the redacted inserts and labels to publicly-available (unredacted) information and readily discern the identity of the drugs' suppliers and sellers. For example, we note the following published news reports:

- http://bigstory.ap.org/article/5f4ef9172ded4399a6123b25dbd1de4b/pfizer-says-its-blocking-use-drugs-lethal-injections (reporting the name of the manufacturer of ADC's previous supply of potassium chloride);

- http://bigstory.ap.org/article/83c83b81d76e40f58eba25b715c112a7/apnewsbreak-arkansas-execution-drug-made-pfizer-company (describing how Associated Press reporters compared a redacted drug label produced by ADC to information submitted to the National Institutes of Health to identify the manufacturer); and

- https://www.nytimes.com/2015/09/23/us/arkansas-objections-raised-over-use-of-drugs-in-executions.html?_r=1 (identifying the "company that appears to have made a drug that Arkansas purchased for lethal injections . . . after The Associated Press obtained redacted photographs of the containers and related items through a Freedom of Information Act request").

Given variations in format, style, diction, font, organization, grammar, punctuation, and spelling between the labels and inserts used by various manufacturers, a news outlet's ability to identify the suppliers and sellers is unsurprising. As a result, it is not possible to redact the labels or package inserts in a manner that would—as required by the Method of Execution Act—maintain confidentiality.

Package inserts and labels for all FDA-approved sources of injectable drugs are widely available on the Internet. For example, package inserts, labels, and other drug information are available on the following websites:

- https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
- https://druginfo.nlm.nih.gov/drugportal/
- http://druginserts.com/

The publicly-available drug information for injectable drugs should provide you with all of the information you seek about the drugs in ADC's possession.

Finally, the ADC has determined that is not in possession of any responsive documents related to:

- Question 4;
- Question 5;
  Question 7;
  Question 8; and
- Questions 9

Please let me know if you have any further questions.

Solomon Graves
ublic Information Officer & Legislative Liaison Arkansas Department of Correction
Office: 870-267-6205
Cell: 870-643-1922
Fax: 870-267-6244
Solomon.Graves@arkansas.gov<mailto:Solomon.Graves@arkansas.gov>
http://ADC.arkansas.gov

Sent from my iPad

Begin forwarded message:

From: Robin Brady <RBrady@shultslaw.com<mailto:RBrady@shultslaw.com>>
Date: August 21, 2017 at 10:09:09 AM CDT
To: "'solomon.graves@arkansas.gov<mailto:solomon.graves@arkansas.gov>'"
<solomon.graves@arkansas.gov<mailto:solomon.graves@arkansas.gov>>
Cc: "'jim.depriest@arkansas.gov<mailto:jim.depriest@arkansas.gov>'"
<jim.depriest@arkansas.gov<mailto:jim.depriest@arkansas.gov>>, Steve Shults
<SShults@shultslaw.com<mailto:SShults@shultslaw.com>>
Subject: FOIA Request

Attached is a letter of this date to you from Steve Shults, making a Freedom of Information Act request. Please respond by August 24, 2017.

Thank you.

Robin Brady
Office Manager
SHULTS LAW FIRM, LLP
200 West Capitol Avenue, Suite 1600
Little Rock, AR 72201-3621
Phone: (501) 375-2301
Fax: (501) 375-6861
www.shultslaw.com<http://www.shultslaw.com/>

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SEVENTEENTH DIVISION

STEVEN SHULTS — PLAINTIFF

v. CASE NO: 60CV-17-4931

ARKANSAS DEPARTMENT OF CORRECTION;
WENDY KELLEY, in her Official Capacity — DEFENDANTS

PLAINTIFF'S TRIAL BRIEF

I. INTRODUCTION

The instant action involves Defendant Arkansas Department of Correction's ("ADC") violation of the Arkansas Freedom of Information Act ("AFOIA") with respect to Plaintiff's request for public records, as described below. The following facts and proceedings prompted this AFOIA action.

Plaintiff Steven Shults is a citizen of the State of Arkansas. He is a Little Rock-based attorney, and a partner in the law firm of Shults & Brown, LLP. Respondent ADC controls and manages the Arkansas prison system pursuant to Ark. Code. Ann. § 12-27-101, *et seq*, and it administers lethal injection executions. Respondent Wendy Kelley, in her Official Capacity as Director of the ADC, is the "custodian" of records responsive to Plaintiff's AFOIA requests pursuant to Ark. Code Ann. § 25-19-103(1)(A).

On August 21, 2017, Plaintiff submitted an AFOIA request to the ADC via e-mail. Complaint, Ex. 1, Ex. A. In his Request, Plaintiff sought, in part, information relating to the ADC's supply of drugs intended for use in lethal injection executions. *Id.*

In response to the August 21, 2017, request, ADC provided records on August 24, 2017, revealing that it had acquired 40 vials of midazolam, a drug listed in its execution protocol. *Id.*,

Ex. B. However, ADC refused to disclose the package inserts or labels for the newly-acquired supplies of midazolam. *Id.* For the reasons stated below, ADC has violated the AFOIA by refusing to disclose the package inserts and labels. Plaintiff seeks production of all responsive documents as well as all other proper relief to which he may be entitled under the AFOIA.

II. STANDARD OF REVIEW

Under the AFOIA, "any citizen of the State of Arkansas" may seek access to disclosure of public records, except those specifically exempted. Ark. Code Ann. § 25-19-105(a). Under Ark. Code Ann. § 25-19-107(a), "[a]ny citizen" denied rights granted under the FOIA may appeal "to the Pulaski County Circuit Court or to the circuit court of the residence of an aggrieved party, if an agency of the state is involved."

The legislative purpose of the AFOIA was to ensure "public business" is conducted in an "open and public manner." Ark. Code Ann. § 25-19-102. As such, the Act is to be liberally construed in favor of disclosure. *See Nabholz Construction Corp. v. Contractors for Public Protection Ass'n,* 371 Ark. 411, 414 (2007); *Fox v. Perroni*, 358 Ark. 251, 256 (2004). It has long been recognized by the Arkansas Attorney General's Office that the AFOIA is "one of the strongest sunshine acts in the nation." *See* Arkansas Freedom of Information Handbook, 10th ed. (December 2001), at 2 (statement of Mark Pryor, former Attorney General). For nearly fifty years, it has been a well-settled law that the AFOIA was "passed wholly in the public interest and is to be interpreted liberally." *Laman v. McCord,* 245 Ark. 401, 405, 432 S.W.2d 753, 755 (1968).

In an early appellate decision interpreting the AFOIA, *Laman v. McCord*, 245 Ark. 401, 432 S.W.2d 753 (1968), the Arkansas Supreme Court observed that "statutes enacted for the public benefit are to be interpreted most favorably to the public" and in doing so concluded that

the Arkansas FOIA was passed "wholly in the public interest and is to be liberally interpreted to the end of its praiseworthy purposes may be achieved." *Id.* at 755. Since this early decision, the Court has remained committed to a "liberal interpretation" of the AFOIA. *See, e.g., Commercial Printing Co. v. Rush*, 261 Ark. 468, 549 S.W.2d 790, 793 (1977); *Sebastian County Chapter of Am. Red Cross v. Weatherford*, 311 Ark. 656, 846 S.W.2d 641, 644 (1993); *Johninson v. Stodola*, 316 Ark. 423, 872 S.W.2d 374, 275 (1994). That liberal interpretation means that, "whenever the legislature fails to specify that any records in the public domain are to be excluded from inspection . . . then privacy must yield to openness and secrecy to the public's right to know the status of its own affairs." *Ragland v. Yeargan,* 288 Ark. 81, 85, 702 S.W.2d 23, 25 (1986). Following this, AFOIA exemptions are to be narrowly construed "in a manner that favors disclosure." *Young v. Rice,* 308 Ark. 593, 826 S.W.2d 252 (1992). Additionally, "[a] statutory provision for nondisclosure [under the AFOIA] must be specific" and "less than clear or ambiguous exemptions will be interpreted in a manner favoring disclosure." *Thomas v. Hall*, 2012 Ark. 66, at *5, 399 S.W.3d 387, 390.

Because there is a presumption in favor of disclosure, an entity or custodian claiming an exemption under the AFOIA must carry the burden of establishing that the exemption applies and justifying the nondisclosure of information. *See, e.g., Orsini v. State,* 340 Ark. 665, 13 S.W.3d 167 (2000).

A record is subject to the Freedom of Information Act when (1) it is possessed by an entity covered by the act, (2) the record falls within the act's definition of public record, and (3) disclosure of the record is not be exempted by the act or other statutes. *Legislative Joint Auditing Comm. v. Woosley*, 291 Ark. 89, 91 (1987) (*citing* Watkins, *Access to Public Records Under the Arkansas Freedom of Information Act,* 37 Ark.L.Rev. 741 (1984)).

Here, Plaintiff sought records from the ADC, a State agency. The records sought included information about drugs to be used in lethal injection executions. Among those requested records were package inserts and labels for 40 vials of midazolam to be used in upcoming executions. The Arkansas Execution Act mandates disclosure of package inserts and labels by ADC. Ark. Code Ann. § 5-4-617(j)(1), and the exemptions cited by ADC do not apply to exempt the records from disclosure. For these reasons, Plaintiff is entitled to judgment and an Order finding Defendant violated the AFOIA through improper interpretation of Ark. Code Ann. § 5-4-617(j)(1).

III. ARGUMENT

A. Plaintiff has a legal right to the disclosure of records sought in Plaintiff's Request, and ADC has a legal duty to make such records available.

The documents sought by Plaintiff's Request pertain to one of the drugs used in the lethal injection executions performed by ADC. The records therefore document the activities of ADC, a public office. Consequently, they are public records within the meaning of AFOIA to the extent kept by ADC, and if not made otherwise exempt from the definition of "public record" under one of the Act's exemptions.

In general, the Arkansas Method of Execution Act ("AMEA") expressly requires ADC to disclose "[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 . . . " Ark. Code Ann. § 5-4-617(j)(1).

As ADC acknowledged in its Response, ADC is in possession of pharmaceutical package inserts and labels. Complaint, Ex. 1, Ex. B. ADC correctly acknowledges that the department is under a statutory duty to "make available to the public any of the following information upon request", provided that "information that may be used to identify the . . . seller, or supplier is

redacted and maintained as confidential." *Id.* (*citing* Ark. Code Ann. § 5-4-617(j)). However, ADC determined that although the AMEA generally requires ADC to disclose "[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," ADC may only do so where "the information that ***may be used*** to identify the . . . seller, or supplier is redacted and maintained as confidential." Ark. Code Ann. § 5-4-617(j)(1) (emphasis added)." Complaint, Ex. 1, Ex. B.

ADC went on to state that:

> [I]t is prohibited from disclosing the pharmaceutical package inserts and labels that would potentially be responsive to your request. Indeed, based on our previous experience disclosing labels and inserts and a detailed comparison of various inserts and labels used by different manufacturers, ADC has determined that it would be impossible to disclose the inserts and labels that are potentially responsive to your request while simultaneously maintaining as confidential the identity of the suppliers and sellers of those drugs.
>
> Previously, in response to FOIA requests, ADC has produced labels and inserts that redacted manufacturer logos, addresses, and other information which redacted information the ADC believed could be used to identify suppliers and sellers. Despite that, news outlets were able to compare the redacted inserts and labels to publicly-available (unredacted) information and readily discern the identity of the drugs' suppliers and sellers . . . As a result, it is not possible to redact the labels or package inserts in a manner that would—as required by the Method of Execution Act—maintain confidentiality.

Id.

ADC's interpretation of the statute is flawed. Even if the ADC were correct that it could refuse to disclose the product inserts and labels---notwithstanding the directive that this information "shall be made available to the public"---the given justification, to protect the "seller" or "supplier", is not at issue here. The relevant confidentiality provision of Ark. Code Ann. § 5-4-617 makes confidential any information leading to the identification of "entities and persons who *participate* in the execution process or administer the lethal injection" and "the entities and persons who *compound, test, sell, or supply*" lethal injection drugs. Ark. Code Ann.

§ 5-4-617(j) (emphasis added). Under the plain language of the statute, Ark. Code Ann. § 5-4-617 does not make confidential the identities of the *manufacturers* of lethal injection drug products. In fact, the relevant provision of the statute fails to mention drug manufacturers by name, despite referring to manufacturers by name elsewhere in the statute's text. *See, e.g.,* Ark. Code Ann. § 5-4-617(d).

By the clear language of Ark. Code Ann. § 5-4-617(j)(1), the Legislature has already balanced the competing interests and determined that the public has a clear right to view package inserts and labels, provided that the identity of the "seller, or supplier is redacted and maintained as confidential." The Legislature's decision *not* to include language providing an exemption for "manufacturers" speaks to and makes clear its intent *not* to provide an exemption under the AFOIA and AMEA for disclosure of information that could identify the manufacturer.

Accordingly, to support its decision withholding the labels on the basis that they allow identification of the "manufacturer," ADC must show that the manufacturer itself is the "seller" or "supplier" of the drugs to the ADC. Such proof is unlikely, given the fact that for the past several years, various departments of correction have received letters from pharmaceutical companies each of which vigorously demand that its life-saving drugs should not be used to execute a prisoner, and given the fact that an ADC official submitted an affidavit as recently as October 14, 2015, stating the difficulties the ADC encountered in its attempt to procure execution drugs. Complaint, Ex. 1, Ex. C. The pharmaceutical industry has categorically and unanimously turned its back on the lethal injection, and every FDA-approved manufacturer of the drugs currently used in executions in the USA has made statements opposing the practice and put distribution controls in place to prevent prisons buying their drugs for this purpose. Erik Eckholm, *Pfizer Blocks the Use of Its Drugs in Executions*, N.Y. TIMES, May 13, 2016, at A1,

available at https://www.nytimes.com/2016/05/14/us/pfizer-execution-drugs-lethal-injection.html (last accessed September 14, 2017). Thus, even if disclosure of product labels and inserts allows the public or "news outlets" to infer the identity of the manufacturer, these inserts would not reveal the identities of the "seller" or "supplier" – i.e.: the other entities in the supply-chain, such as drug distributors and wholesalers, retail pharmacies, or persons who participate directly in the execution process. Finally, if ADC's assertion is to believed that its newly-acquired supplies of midazolam were "bulk-manufactured and FDA-approved," then the requested package inserts and product labels would not reveal the "persons who compound" the drug, because pharmaceutical compounding consists of a wholly different type of drug preparation activity than bulk-manufacturing.

The Arkansas Supreme Court's decision in *Kelley v. Johnson*, 2016 Ark. 268, 496 S.W.3d 346, bolsters the conclusion that the confidentiality provisions of the AMEA are not applicable to prevent identification of the manufacturer of the drug, but merely to the supplier or provider of the drugs to the ADC. Specifically, the court noted that the purpose of the confidentiality provision was to combat the obstacles ADC had encountered with acquiring the drugs -- that "the current supplier of the drugs agreed to provide them only on the condition of anonymity" and that "manufacturers prohibit distributors from selling the drugs to departments of correction." *Id.* at *25, 496 S.W.3d at 362. Accordingly, it is clear from the Supreme Court's decision that ensuring the confidentiality of the non-supplying *manufacturer* was not part of its consideration.

Because ADC's cited exemption does not support its decision to withhold drug product labels and package inserts, Plaintiff has a right to this record, and ADC has a duty to permit inspection and copying under the Arkansas Freedom of Information Act.

B. The public interest strongly weighs in favor of the disclosure of the public records Plaintiff seeks.

Pharmaceutical package labels and inserts provide critical information about a given drug product. Product labels disclose the strength and size of the vial; package inserts provide information about a given drug products' components, indications, usage, and potential contraindications. These records critically ensure that a product in question was produced by a Food and Drug Administration-approved manufacturer and produced according to Current Good Manufacturing Practice regulations, and therefore the existence of these records act as a stamp of good quality for a drug product. Ark. Code Ann. § 5-4-617(j)(1) seemingly mandates that package inserts and labels be produced for this very reason -- to allow the public to verify the State of Arkansas is obtaining lethal injection drugs from legitimate sources.

ADC implicitly recognized this function in its October 27, 2016, response to Plaintiff's October 24, 2016, AFOIA requests. *See* Complaint, Ex. 1, Ex. C. ADC chose at that time to disclose redacted materials responsive to Plaintiff's AFOIA, including the package inserts and labels for its existing supply of execution drugs. *Id.* ADC's new-found interpretation of the AMEA is not intended to protect some legitimate seller or supplier of these drugs; it appears to be an attempt by the State to shield a person or entity that is selling these drugs to ADC, purportedly in direct violation of their contracts with the manufacturers and expressly against each manufacturer's publically-stated wishes. *See* Complaint, Ex. 1, Ex. B ("ADC has determined that it would be impossible to disclose the inserts and labels that are potentially responsive to your request while simultaneously maintaining as confidential the identity of the suppliers and sellers of those drugs"). Thus, ADC's stated reason for not disclosing the requested records is not intended to protect the identity of the *manufacturer* of the ADC's execution drugs,

which is the only entity the package inserts and labels could potentially identify, and is at odds with ADC's past policy and the plain meaning and spirt of both the AFOIA and the AMEA.

IV. CONCLUSION

For the reasons set forth herein and in the Complaint, Plaintiff respectfully requests that the Court enter judgment on his Petition and issue an order compelling the ADC to comply with its obligations under the Arkansas Freedom of Information Act.

Respectfully submitted,

WILLIAMS & ANDERSON PLC
111 Center Street, Suite 2200
Little Rock, Arkansas 72201
Telephone: 501-372-0800
Facsimile: 501-372-6453

/s/ Alec Gaines
Philip E. Kaplan (AR68026)
pkaplan@williamsanderson.com
Heather G. Zachary (AR2004216)
hzachary@williamsanderson.com
Alec Gaines (AR2012277)
againes@williamsanderson.com

Attorneys for Steven Shults

CERTIFICATE OF SERVICE

On this 18th day of September, 2017, I sent a copy of this pleading by electronic mail only to the following:

Jennifer Merritt
Senior Assistant Attorney General
Office of Arkansas Attorney General Leslie Rutledge
jennifer.merritt@arkansasag.gov

/s/ Alec Gaines
Alec Gaines

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SEVENTEENTH DIVISION

STEVEN SHULTS PLAINTIFF

v. No. 60CV-17-4931

ARKANSAS DEPARTMENT OF CORRECTION
and WENDY KELLEY, in her official capacity DEFENDANTS

DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT OR, IN THE ALTERNATIVE, TO STAY PROCEEDINGS PENDING A RELATED APPEAL

Defendants Arkansas Department of Correction and Wendy Kelley, in her official capacity as Director of the ADC (collectively, "ADC" or "the State") move to dismiss the Complaint under Ark. R. Civ. P. 12(b)(1), 12(b)(6), and 12(b)(8) or, alternatively, for a stay of proceedings pending the final resolution of a related case, *Ark. Dep't of Correction v. Shults*, Ark. Sup. Ct. No. CV-17-544 ("*Shults I*"), and, in support, state:

1. This case involves the proper scope and application of confidentiality provisions in the Arkansas Method of Execution Act, Ark. Code Ann. § 5-4-617 ("MEA"), that require the ADC to maintain the confidentiality of lethal drug sellers and suppliers.

2. Plaintiff Steven Shults is an Arkansas citizen and attorney with no apparent connection to death-penalty litigation or death-row inmates. He is not a prisoner facing a scheduled execution, nor does he represent a prisoner facing a scheduled execution. Shults brings this action under the Arkansas Freedom of

Information Act, Ark. Code Ann. § 25-19-101 *et seq.* ("FOIA"), seeking records that are specifically exempted from public disclosure by the MEA.

3. Beginning in late 2016, Shults has made frequent FOIA requests to the ADC seeking records relating to executions and execution drugs. *See* Compl. Ex. 1 ¶¶ 2 & 8, & Ex. 1(C). Earlier this year, ADC declined to produce lethal drug labels and package inserts to Shults on the basis that they are exempt from disclosure under the MEA. Shults sued in Pulaski County Circuit Court, Fifth Division. *See* Complaint in *Steven Shults v. Ark. Dep't of Corr. et al.*, Circuit Court of Pulaski County, Arkansas, No. 60CV-17-1419, which is attached and incorporated as Exhibit 1; *see also* Affidavit of ADC Deputy Director Rory Griffin in No. 60CV-17-1419, which is attached and incorporated as Exhibit 2 (explaining rationale for ADC's decision).

4. Judge Griffen ruled in Shults's favor and ordered the ADC to immediately produce full and complete copies of lethal-drug labels and package inserts. *See* Mem. Order Granting Pl.'s Compl. for Relief for Violation of AFOIA (Mar. 31, 2017), which is attached and incorporated as Exhibit 3.

5. ADC filed an emergency motion for an immediate stay of Judge Griffen's order with the Arkansas Supreme Court, which was granted. *See* Formal Order in *Ark. Dep't of Corr. et al. v. Steven Shults*, Ark. Sup. Ct. No. CV-17-267 (Apr. 4, 2017), which is attached an incorporated as Exhibit 4.

6. ADC also immediately filed a notice of appeal of Judge Griffen's disclosure order. The appeal in *Shults I*, Ark. Sup. Ct. No. CV-17-544, is pending.

7. Shults submitted the FOIA request at issue here on August 21, 2017, during the pendency of the appeal in *Shults I.* Shults again requested lethal drug labels and package inserts. (Compl. Ex. 1(A)).

8. ADC provided Shults with responsive records on August 24, 2017, revealing that the Department had recently acquired 40 vials of midazolam, which is one of the drugs listed in its execution protocol. (Compl. ¶ 7). As it had done this past spring, ADC informed Shults that it was in possession of pharmaceutical package inserts and labels for those bulk-manufactured, FDA-approved drugs that were potentially responsive to his request. (Compl. Ex. 1(B) at 1). But ADC explained that those records were exempt from FOIA disclosure under the MEA because, under that provision, ADC is required to "keep confidential all information that may identify or lead to the identification of . . . the entities . . . who . . . test, sell, or supply the drug or drugs . . . for the execution process." *Id.* (quoting Ark. Code Ann. § 5-4-617(i)(2)(B)). ADC explained that its disclosure of lethal-drug labels and package inserts in the past led to the identification of the drugs' suppliers and sellers in violation of the MEA, and that it could no longer produce such records in response to FOIA requests. *Id.* at 1-2. Although the ADC did not provide the requested records, it did provide Shults with websites where packing inserts, labels, and other publicly-available lethal-drug information can be found. *Id.* at 2.

9. Shults filed this second lawsuit on September 7, 2017, alleging that the ADC violated the FOIA and the MEA by failing to provide him with copies of the

package inserts and labels for the newly-acquired midazolam. The matter is set for hearing on Tuesday, September 19, 2017.

10. The Complaint fails as a matter of law and should be dismissed for two reasons.

11. First, Shults fails to state a cognizable claim of a constitutional or statutory violation and, therefore, the suit is barred by sovereign immunity. Even assuming that all of the factual allegations in the Complaint are true, Shults has not stated a viable claim because the records he seeks are confidential under the MEA, and the ADC is absolutely prohibited from disclosing them in response to a FOIA request. Lethal-drug labels and package inserts readily identify the manufacturers of the drugs, who are sellers and suppliers protected by the plain language of the confidentiality provisions of the MEA. Interpreting the confidentiality provisions of the MEA to include manufacturers, moreover, comports with both legislative intent and public policy. The Court should dismiss under Ark. R. Civ. P. 12(b)(1) and 12(b)(6).

12. Second, the pendency of the appeal in *Shults I*, which is between the same parties and involves the same factual and legal issues, requires dismissal under Ark. R. Civ. P. 12(b)(8). The outcome of that appeal will bind the parties and this Court under the doctrines of *res judicata*, collateral estoppel, and *stare decisis*.

13. Both of these reasons warrant dismissal of the instant Complaint with prejudice.

14. In the alternative, this Court should stay all proceedings until final resolution of the appeal in *Shults I.*

15. A brief in support is being filed with this motion and is incorporated by reference.

WHEREFORE, the Arkansas Department of Correction and Wendy Kelley, in her official capacity as Director of the Arkansas Department of Correction, pray that the Court grant their motion to dismiss, dismiss this case with prejudice, and enter judgment accordingly or, in the alternative, stay all proceedings pending final resolution of *Shults I.*

Respectfully submitted,

LESLIE RUTLEDGE
Attorney General

By: */s/ Jennifer L. Merritt*
JENNIFER L. MERRITT (2002148)
Senior Assistant Attorney General
KA TINA R. HODGE (2003100)
Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Tel: (501) 682-1319
Fax: (501) 682-2591
Jennifer.Merritt@ArkansasAG.gov
KaTina.Hodge@ArkansasAG.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I, Jennifer L. Merritt, do hereby certify that on this 18th day of September, 2017, I electronically filed the foregoing with the Clerk of Court using the eFlex electronic filing system, which shall send notification of the filing to any participants. I also certify that I sent a copy of the forgoing via electronic mail to the following:

Alec Gaines, Esq.
againes@williamsanderson.com

Heather G. Zachary, Esq.
hzachary@williamsanderson.com

/s/ Jennifer L. Merritt
Jennifer L. Merritt

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
CIVIL DIVISION

STEVEN SHULTS — PLAINTIFF

v. CASE NO: _____

ARKANSAS DEPARTMENT OF CORRECTIONS;
WENDY KELLEY, in her Official Capacity — DEFENDANTS

COMPLAINT

Steven Shults, for his Complaint against the Arkansas Department of Corrections ("ADC") and Wendy Kelley, in her official capacity as director of the ADC, states:

1. This case is an appeal from denial of rights guaranteed under the Arkansas Freedom of Information Act ("AFOIA"), and it is brought pursuant to Ark. Code Ann. § 25-19-107(a).

PARTIES, JURISDICTION, AND VENUE

2. Plaintiff Steven Shults is a resident of the State of Arkansas, and brings this action in his capacity as a citizen entitled to request and receive certain public records under the AFOIA. Ark. Code Ann. § 25-19-101, et seq.

3. Defendant Arkansas Department of Correction ("ADC") is a "department, agency, or institution of the" State of Arkansas and is subject to the AFOIA's requirements of providing access to certain public records upon request.

4. Defendant Wendy Kelley is the director of the ADC and she is being sued in her official capacity because she has administrative control over certain records that form the basis for this lawsuit, making her the "custodian" of those records within the meaning of the AFOIA. Ark. Code Ann. § 25-19-103(1)(A).

5. Jurisdiction and venue are proper in this Court, as ADC is "a department, agency, or institution of the" State of Arkansas. *See* Ark. Code Ann. § 25-19-107(a).

STATEMENT OF FACTS

6. On February 9, 2017, Plaintiff submitted a Freedom of Information Act Request to the ADC via e-mail. Attached as Exhibit 1 to the Complaint is the Affidavit of Steven Shults. Exhibit A to Exhibit 1 is the February 9, 2017, AFOIA request. In his Request, Plaintiff sought, in part, information relating to the ADC's supply of drugs intended for use in lethal injection executions. *Id.*

7. ADC acknowledged receipt of the Request on February 16, 2017, and stated it was in the process of identifying records it was able to disclose. Ex. 1, Ex. B. After a series of e-mails, ADC claimed there were no new responsive records following an earlier request by Plaintiff. *Id.*

8. In the same correspondence, ADC acknowledged the possibility that responsive records might be produced in anticipation of upcoming executions, and requested that Plaintiff resubmit identical FOIA requests weekly to obtain any newly-created records. *Id.*

9. Plaintiff complied, and resubmitted his February 9, 2017 request on Tuesday, March 7th. Ex. 1, Ex. C.

10. In response to this request, ADC provided records on March 10, 2017, revealing that it had acquired 100 vials of potassium chloride, a drug listed in its execution protocol. Ex. 1, Ex. D.

11. ADC refused to disclose the package inserts or labels for the newly-acquired supplies of potassium chloride as required by the AFOIA and Arkansas Method of Execution Act ("AMEA") because it took the position it is "prohibited from disclosing the pharmaceutical

package inserts and labels" because the labels could be used to identify the sellers or suppliers of the drugs to ADC. *Id.*

12. ADC's interpretation renders portions of the AMEA, Ark. Code Ann. § 5-4-617(j)(1) in particular, meaningless.

COUNT 1: VIOLATION OF THE AFOIA

13. ADC has violated Plaintiff's rights under the AFOIA and AMEA by failing to provide records of lethal injection drug product labels and package inserts, documents that are "public records" under the Arkansas FOIA and *specifically* subject to disclosure under the AMEA. Ark. Code Ann. §§ 25-19-105; 5-4-617.

14. In the context of these records, the AMEA *specifically* requires ADC to disclose the very materials requested by Plaintiff in this action: the "[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 . . . ." Ark. Code Ann. § 5-4-617(j)(1).

15. ADC's stated reason for refusing to produce the requested records is contrary to the plain meaning of the AMEA and constitutes a violation of the AFOIA. Furthermore, ADC's actions are contrary to established ADC policies and procedures regarding disclosure of package inserts and labels. *See* Ex. 1, Ex. E.

16. ADC does not have substantial justification to refuse to disclose the requested records to the Plaintiff.

REQUEST FOR RELIEF

17. Plaintiff requests and is entitled to a hearing on this matter within seven (7) days of the date of this application. *See* Ark. Code Ann. § 25-19-107(b). Given the execution of

prisoners has been scheduled for next month, Plaintiff respectfully requests the Court expedite this matter.

18. Plaintiff, through undersigned counsel, reserves the right to seek reasonable attorney's fees and costs from the Arkansas Claims Commission upon successful completion of this matter. See Ark. Code Ann. § 25-19-107(e)(2)(B).

WHEREFORE, the Plaintiff, Steven Shults, prays that this Court will hold a hearing and enter an Order finding Defendant violated the AFOIA through improper interpretation of Ark. Code Ann. § 5-4-617(j)(1), that Defendant was not substantially justified in its refusal to provide the records as requested, and that Plaintiff is entitled to unredacted copies of product labels and inserts and all such additional relief as is necessary and proper.

WILLIAMS & ANDERSON PLC
111 Center Street, Suite 2200
Little Rock, Arkansas 72201
Telephone: 501-372-0800
Facsimile: 501-372-6453

/s/ Alec Gaines
Philip E. Kaplan (AR68026)
pkaplan@williamsanderson.com
Heather G. Zachary (AR2004216)
hzachary@williamsanderson.com
Alec Gaines (AR2012277)
againes@williamsanderson.com

Attorneys for Steven Shults

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
5TH DIVISION

STEVEN SHULTS **PLAINTIFF**

VS. **Case No. 60CV-17-1419**

ARKANSAS DEPARTMENT OF CORRECTION; and
WENDY KELLEY, in her official capacity **DEFENDANTS**

Affidavit of Rory Griffin

1. I, Rory Griffin, have personal knowledge regarding the facts stated herein and I am competent to testify.

2. I am employed with the Arkansas Department of Correction (ADC) as Deputy Director, Health and Correctional Programs. I have held this position continuously since January 1, 2014, and I held this position at all times relevant to this affidavit.

3. The ADC is required by the Arkansas Method-of-Execution-Act (MEA), Ark. Code Ann. § 5-4-617, to "keep confidential all information that may identify or lead to the identification of . . . the entities . . . who . . . test, sell, or supply the drug or drugs . . . for the execution process." Ark. Code Ann. § 5-4-617(i)(2)(B). While the MEA generally requires the ADC to disclose "[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," ADC may only do so where "the information that

[redacted]

40

may be used to identify the . . . seller, or supplier is redacted and maintained as confidential." Ark. Code Ann. § 5-4-617(j)(1).

4. The ADC attempts to comply with both the disclosure and confidentiality provisions of the MEA in response to requests under the Arkansas Freedom of Information Act (FOIA), Ark. Code Ann. § 25-19-101 et seq., for inspection and/or copying of pharmaceutical package inserts and labels of drugs used for the execution process. In the past, the ADC provided copies of labels and inserts that redacted logos, addresses, and other information that the ADC believed could be used to identify suppliers and sellers. An example of that past practice is shown in Exhibit E to Mr. Shults' affidavit filed with the Complaint in this case. As explained in the ADC's March 10, 2017 letter to Mr. Shults (Exhibit D to his affidavit), some recipients of the redacted labels and inserts provided by the ADC in the past were able to compare the redacted labels and inserts to publicly-available information and readily determine the identity of the drugs' suppliers and/or sellers. Accordingly, the ADC's past disclosure failed to comply with the confidentiality provisions of the MEA.

5. As stated correctly in Mr. Shults' affidavit (¶ 9), the ADC has recently acquired a supply of potassium chloride, a drug listed in the ADC's execution protocol. In response to Mr. Shults' FOIA request for copies of the package insert and label for that potassium chloride, I carefully studied the package insert and label for that potassium chloride in the ADC's possession and I attempted to redact a copy of the package insert and label in a way that is consistent with the

41

ADC's Exhibit 1

confidentiality and disclosure provisions of the MEA (as the ADC has done in the past). After my careful study of the package insert and label, and my attempts at redaction, I ultimately concluded that it is not possible for the ADC to redact the package insert and label in any fashion—short of complete and wholesale redaction—that would not allow a person in possession of redacted copies of the package insert and label to determine the identity of the drug's supplier and/or seller based on a comparison with publicly-available information about package inserts and labels for sellers and/or suppliers of injectable potassium chloride. The only way for the ADC to comply with the confidentiality provision of the MEA is for the ADC to decline disclosure of a redacted copy of the package insert and label for its recently-acquired potassium chloride—because any disclosure without complete and wholesale redaction would lead to the identification of the seller and/or supplier based on the unique format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance of the package insert and label. Accordingly, the ADC declined to provide redacted copies of the package insert and label for the recently-acquired potassium chloride in response to Mr. Shults' FOIA request.

6. In addition to my study and attempt to redact the package insert and label in the ADC's possession, I obtained copies of the publicly-available package inserts and labels for six sellers and suppliers of injectable potassium chloride from the website www.druginserts.com, which was noted in the ADC's March 10, 2017 letter to Mr. Shults. These are the only sellers and suppliers of injectable potassium chloride I am aware of. Because the actual (physical) package inserts

ADC's Exhibit 1 42

and labels of drugs often contain unique variations in size, shape, color, and appearance, I thought it might be possible to locate the publicly-available package insert and label for the potassium chloride in the ADC's possession, and redact that in a way that was consistent with the confidentiality and disclosure provisions of the MEA. Unfortunately, this effort also proved to be unsuccessful. Even with the elimination of some unique variation in size, shape, color and appearance by using the package insert and label available on www.druginserts.com for the potassium chloride in the ADC's possession instead of the actual physical package insert and label in the ADC's possession, the package insert and label still contained unique format, style, diction, font, organization, grammar, and spelling that would enable a person in possession of a redacted printout of the package insert and label from www.druginserts.com to compare that to inserts and labels for sellers and suppliers of injectable potassium chloride available on www.druginserts.com, and determine the seller and/or supplier of the potassium chloride in the ADC's possession through that comparison.

7. For the convenience of the Court, attached to this affidavit as Exhibits A, B, C, D, E, and F are printouts from www.druginserts.com of the package inserts and labels for injectable potassium chloride from six different sellers and suppliers. With these exhibits, the Court can conduct the same analysis that I conducted, to confirm my conclusion that anything short of complete and wholesale redaction will not comply with the confidentiality provisions of the MEA.

8. I declare under penalty of perjury that the above information is true and correct to the best of my knowledge.

Rory Griffin

STATE OF ARKANSAS)
)
COUNTY OF Jefferson)

Subscribed to and sworn before me this 29 day of March, 2017.

Notary Public

My Commission Expires: 11-25-2019

KAREN BOTTOMS
Notary Public-Arkansas
Desha County
My Commission Expires 11-25-2019
Commission # 12699142

Potassium Chloride: Package Insert and Label Information

By APP Pharmaceuticals, LLC | Last revised: 19 August 2011

POTASSIUM CHLORIDE- potassium chloride injection, solution, concentrate
APP Pharmaceuticals, LLC

Concentrate Must Be Diluted Before Use

FOR INTRAVENOUS INFUSION ONLY

MUST BE DILUTED PRIOR TO INJECTION

DESCRIPTION

Potassium Chloride for Injection Concentrate, USP is a sterile, nonpyrogenic concentrated solution of Potassium Chloride, USP in Water for Injection to be administered by intravenous infusion only after dilution in a larger volume of fluid.

Each mL of Potassium Chloride for Injection Concentrate contains 2 mEq of K^+ and Cl^- equivalent to 149 mg of potassium chloride and has an osmolarity of 4000 mOsmol/L (calc). A more concentrated Potassium Chloride for Injection Concentrate is also available. Each mL of this injection contains 3 mEq of K^+ and Cl^- equivalent to 224 mg of potassium chloride and has an osmolarity of 6000 mOsmol/L(calc).

pH (4.0-8.0) may have been adjusted with hydrochloric acid and if necessary, potassium hydroxide.

Some packages are intended for multiple dose use and contain preservatives (0.05% methylparaben and 0.005% propylparaben). A summary of the available products is presented in the **HOW SUPPLIED**section.

Potassium Chloride for Injection Concentrate (appropriately diluted) is a parenteral fluid and electrolyte replenisher.

CLINICAL PHARMACOLOGY

Potassium is the chief cation of body cells (160 mEq/L of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well, so that during fasting, or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

INDICATIONS AND USAGE

Potassium Chloride for Injection Concentrate, USP is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

CONTRAINDICATIONS

Potassium Chloride for Injection Concentrate is contraindicated in diseases where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

Rory Griffin Affidavit Exhibit A

Add. 38

WARNINGS

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

PRECAUTIONS

General

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Pregnancy

Teratogenic Effects: Pregnancy Category C — Animal reproduction studies have not been conducted with potassium chloride. It is also not known whether potassium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium chloride should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, hypervolemia, and hyperkalemia.

Too rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Rory Griffin Affidavit Exhibit A

Add. 39

OVERDOSAGE

In the event of fluid overload during parenteral therapy, reevaluate the patient's condition, and institute appropriate corrective treatment.

In the event of overdosage with potassiumcontaining solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection, USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL/hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION

Potassium Chloride for Injection Concentrate must be diluted before administration. Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

The dose and rate of administration are dependent upon the specific condition of each patient.

If the serum potassium level is greater than 2.5 mEq/L, potassium can be given at a rate not to exceed 10 mEq/hour and in a concentration of up to 40 mEq/L. The 24 hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2 mEq/L and electrocardiographic changes and/or muscle paralysis), potassium chloride may be infused very cautiously at a rate of up to 40 mEq/hour. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in a 24 hour period. In critical conditions, potassium chloride may be administered in saline (unless contraindicated) rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Prior to entering a vial, cleanse the rubber closure with a suitable antiseptic agent.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

HOW SUPPLIED

The following are packaged in plastic vials.

Product No.	NDC No.	Total Potassium Ion	Potassium Chloride per mL	Volume
96505	63323-965-05	10 mEq (0.39 g)	149 mg	5 mL in a 10 mL vial
96510	63323-965-10	20 mEq (0.78 g)	149 mg	10 mL in a 10 mL vial
96515	63323-965-15	30 mEq (1.17 g)	149 mg	15 mL in a 20 mL vial
96520	63323-965-20	40 mEq (1.56 g)	149 mg	20 mL in a

				20 mL vial

These are Single Dose Vials, no preservative added, packaged 25 vials per tray. Unused portion of vial should be discarded.

Product No.	NDC No.	Total Potassium Ion	Potassium Chloride per mL	Volume
96730	63323-967-30	60 mEq (2.35 g)	149 mg	30 mL in a 30 mL vial

This is a Multiple Dose Vial, preserved with 0.05% methylparaben and 0.005% propylparaben, packaged 25 vials per tray.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Use only if solution is clear, seal intact and undamaged.

Vial stoppers do not contain natural rubber latex.

APP
APP Pharmaceuticals, LLC
Schaumburg, IL 60173

45767F

Revised: April 2008

PACKAGE LABEL — PRINCIPAL DISPLAY — Potassium Chloride 5 mL Single Dose Vial Label
NDC 63323-965-05

96505

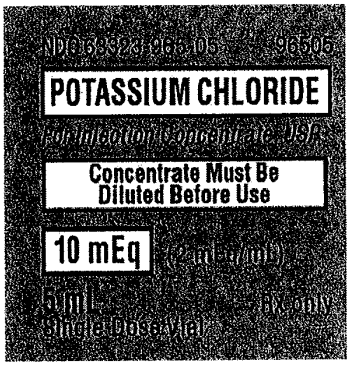
POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE, USP

Concentrate Must Be Diluted Before Use

10 mEq (2 mEq/mL)

5 mL Single Dose Vial

Rx only



PACKAGE LABEL — PRINCIPAL DISPLAY — Potassium Chloride 30 mL Multiple Dose Vial Label

48

Rory Griffin Affidavit Exhibit A

NDC 63323-967-30

96730

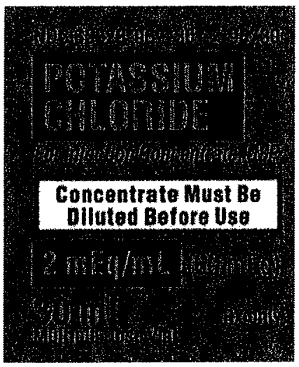
POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE, USP

Concentrate Must Be Diluted Before Use

2 mEq/mL (60 mEq)

30 mL Multiple Dose Vial

Rx only



(click image for full-size original)

POTASSIUM CHLORIDE

potassium chloride injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63323-965
Route of Administration	INTRAVENOUS	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (POTASSIUM CATION)	POTASSIUM CATION	2 meq in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
HYDROCHLORIC ACID	
POTASSIUM HYDROXIDE	

Packaging

#	Item Code	Package Description	Multilevel Packaging
1	NDC:63323-965-05	25 VIAL, SINGLE-DOSE (25 VIAL) in 1 TRAY	contains a VIAL, SINGLE-DOSE
1		5 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (63323-965-05)
2	NDC:63323-965-10	25 VIAL, SINGLE-DOSE (25 VIAL) in 1 TRAY	contains a VIAL, SINGLE-DOSE
2		10 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (63323-965-10)
3	NDC:63323-965-15	25 VIAL, SINGLE-DOSE (25 VIAL) in 1 TRAY	contains a VIAL, SINGLE-DOSE
3		15 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (63323-965-15)
4	NDC:63323-965-20	25 VIAL, SINGLE-DOSE (25 VIAL) in 1 TRAY	contains a VIAL, SINGLE-DOSE
4		20 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (63323-965-20)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088901	09/27/1999	

Rory Griffin Affidavit Exhibit A 49

POTASSIUM CHLORIDE

potassium chloride injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63323-967
Route of Administration	INTRAVENOUS	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (POTASSIUM CATION)	POTASSIUM CATION	2 meq in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN	
PROPYLPARABEN	
HYDROCHLORIC ACID	
POTASSIUM HYDROXIDE	

Packaging

#	Item Code	Package Description	Multilevel Packaging
1	NDC:63323-967-30	25 VIAL, MULTI-DOSE (25 VIAL) in 1 TRAY	contains a VIAL, MULTI-DOSE
1		30 mL in 1 VIAL, MULTI-DOSE	This package is contained within the TRAY (63323-967-30)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088908	09/05/2000	

Labeler — APP Pharmaceuticals, LLC (608775388)

Establishment

Name	Address	ID/FEI	Operations
APP Pharmaceuticals, LLC		840771732	MANUFACTURE

Revised: 08/2011

APP Pharmaceuticals, LLC

Potassium Chloride: Package Insert and Label Information (Page 2 of)

By Atlantic Biologicals Corps | Last revised: 1 December 2016

POTASSIUM CHLORIDE- potassium chloride solution
Atlantic Biologicals Corps

1 INDICATIONS AND USAGE

Potassium Chloride is indicated for the treatment and prophylaxis of hypokalemia in patients for whom dietary management with potassium-rich foods or diuretic dose reduction are insufficient.

2 DOSAGE AND ADMINISTRATION

2.1 Administration and Monitoring

Monitoring

Monitor serum potassium and adjust dosages accordingly. For treatment of hypokalemia, monitor potassium levels daily or more often depending on the severity of hypokalemia until they return to normal. Monitor potassium levels monthly to biannually for maintenance or prophylaxis.

The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance, volume status, electrolytes, including magnesium, sodium, chloride, phosphate, and calcium, electrocardiograms and the clinical status of the patient. Correct volume status, acid-base balance and electrolyte deficits as appropriate.

Administration

Dilute the potassium chloride solution with at least 4 ounces of cold water [see Warnings and Precautions (5.1)].

Take with meals or immediately after eating.

If serum potassium concentration is <2.5 mEq/L, use intravenous potassium instead of oral supplementation.

2.2 Adult Dosing

Treatment of hypokalemia

Daily dose range from 40 to 100 mEq. Give in 2 to 5 divided doses: limit doses to 40 mEq per dose. The total daily dose should not exceed 200 mEq in a 24 hour period.

Maintenance or Prophylaxis

Typical dose is 20 mEq per day. Individualize dose based upon serum potassium levels.

Studies support the use of potassium replacement in digitalis toxicity. When alkalosis is present, normokalemia and hyperkalemia may obscure a total potassium deficit. The advisability of use of potassium replacement in the setting of hyperkalemia is uncertain.

2.3 Pediatric Dosing

Treatment of hypokalemia

Rory Griffin Affidavit Exhibit B

Pediatric patients aged birth to 16 years old: The initial dose is 2 to 4 mEq/kg/day in divided doses; do not exceed as a single dose 1 mEq/kg or 40 mEq, whichever is lower; maximum daily doses should not exceed 100 mEq. If deficits are severe or ongoing losses are great, consider intravenous therapy.

Maintenance or Prophylaxis

Pediatric patients aged birth to 16 years old: Typical dose is 1 mEq/kg/day. Do not exceed 3 mEq/kg/day.

3 DOSAGE FORMS AND STRENGTHS

Oral Solution 10%: 1.3 mEq potassium per mL.

Oral Solution 20%: 2.6 mEq potassium per mL.

4 CONTRAINDICATIONS

Potassium chloride is contraindicated in patients on potassium sparing diuretics

5 WARNINGS AND PRECAUTIONS

5.1 Gastrointestinal Irritation

May cause gastrointestinal irritation if administered undiluted. Increased dilution of the solution and taking with meals may reduce gastrointestinal irritation [see Dosage and Administration (2.1)].

6 ADVERSE REACTIONS

The most common adverse reactions to oral potassium salts are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea.

7 DRUG INTERACTIONS

7.1 Potassium-Sparing Diuretics

Use with potassium-sparing diuretic can produce severe hyperkalemia. Avoid concomitant use.

7.2 Angiotensin-Converting Enzyme Inhibitors

Use with angiotensin converting enzyme (ACE) inhibitors produces potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiving ACE inhibitors only with close monitoring.

7.3 Angiotensin Receptor Blockers

Use with angiotensin receptor blockers (ARBs) produces potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiving ARBs only with close monitoring.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with potassium chloride. It is unlikely that potassium supplementation that does not lead to hyperkalemia would have an adverse effect on the fetus or would affect reproductive capacity.

8.3 Nursing Mothers

The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

8.4 Pediatric Use

The safety and effectiveness of potassium chloride have been demonstrated in children with diarrhea and malnutrition from birth to18 years.

8.5 Geriatric Use

Clinical studies of Potassium Chloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 OVERDOSAGE

10.1 Symptoms

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly potentially fatal hyperkalemia can result.

Hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5–8.0 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9–12 mEq/L).

10.2 Treatment

Treatment measures for hyperkalemia include the following:

1. Monitor closely for arrhythmias and electrolyte changes.
2. Eliminate foods and medications containing potassium and of any agents with potassium-sparing properties such as potassium-sparing diuretics, ARBS, ACE inhibitors, NSAIDS, certain nutritional supplements and many others.
3. Administer intravenous calcium gluconate if the patient is at no risk or low risk of developing digitalis toxicity.
4. Administer intravenously 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1000 mL.
5. Correct acidosis, if present, with intravenous sodium bicarbonate.
6. Use exchange resins, hemodialysis, or peritoneal dialysis.

In patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

11 DESCRIPTION

Potassium Chloride is a white crystalline or colorless solid. It is soluble in water and slightly soluble in alcohol. Chemically, Potassium Chloride is K-Cl with a molecular mass of 74.55.

Oral Solution: 10%: Each 15 mL of solution contains 1.5 g of potassium chloride, USP and the following inactive ingredients: citric acid anhydrous, FD&C Yellow #6, glycerin, methylparaben, natural/artificial orange flavor, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, sucralose.

Oral Solution 20%: Each 15 mL of solution contains 3.0 g of potassium chloride, USP and the following inactive ingredients: citric acid anhydrous, FD&C Yellow #6, glycerin, methylparaben, natural/artificial orange flavor, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, sucralose.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The potassium ion (K+) is the principal intracellular cation of most body tissues. Potassium ions participate in a number of essential physiological processes including the maintenance of intracellular tonicity; the transmission of nerve impulses; the contraction of cardiac, skeletal, and smooth muscle; and the maintenance of normal renal function.

The intracellular concentration of potassium is approximately 150 to 160 mEq per liter. The normal adult plasma concentration is 3.5 to 5 mEq per liter. An active ion transport system maintains this gradient across the plasma membrane.

Rory Griffin Affidavit Exhibit B

Potassium is a normal dietary constituent, and under steady-state conditions the amount of potassium absorbed from the gastrointestinal tract is equal to the amount excreted in the urine. The usual dietary intake of potassium is 50 to 100 mEq per day.

12.3 Pharmacokinetics

Based on published literature, the rate of absorption and urinary excretion of potassium from KCl oral solution were higher during the first few hours after dosing relative to modified release KCl products. The bioavailability of potassium, as measured by the cumulative urinary excretion of K+ over a 24 hour post dose period, is similar for KCl solution and modified release products.

16 HOW SUPPLIED/STORAGE AND HANDLING

Product: 17856-1542

NDC: 17856-1542-1 15 mL in a CUP

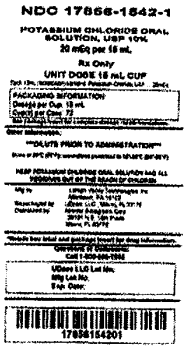
NDC: 17856-1542-3 30 mL in a CUP

Rx only

Manufactured by:
Lehigh Valley Technologies, Inc.
Allentown, PA 18102

Distributed by:
Qualitest Pharmaceuticals
Huntsville, AL 35811

POTASSIUM CHLORIDE SOLUTION



(click image for full-size original)

POTASSIUM CHLORIDE potassium chloride solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17856-1542(NDC:0603-1542)
Route of Administration	ORAL	**DEA Schedule**	
Active Ingredient/Active Moiety			
Ingredient Name		**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (POTASSIUM CATION and Chloride Ion)		POTASSIUM CHLORIDE	20 meq in 15 mL
Inactive Ingredients			
Ingredient Name		**Strength**	
Anhydrous Citric Acid			
FD&C Yellow No. 6			
Glycerin			
Methylparaben			

Propylene Glycol	
Propylparaben	
Sodium Citrate	
Sucralose	
Water	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#Item Code	Package Description	Multilevel Packaging
1 NDC:17856-1542-1	15 mL in 1 CUP	None
2 NDC:17856-1542-3	30 mL in 1 CUP	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA206814	05/04/2015	

Labeler — Atlantic Biologicals Corps (047437707)

Establishment

Name	Address	ID/FEI	Operations
Atlantic Biologicals Corps		047437707	RELABEL (17856-1542), REPACK (17856-1542)

Revised: 12/2016 Atlantic Biologicals Corps

POTASSIUM CHLORIDE: Package Insert and Label Information

By B. Braun Medical Inc. | Last revised: 8 April 2014

POTASSIUM CHLORIDE- potassium chloride injection, solution, concentrate
B. Braun Medical Inc.

PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION

FOR INTRAVENOUS INFUSION ONLY MUST BE DILUTED PRIOR TO INJECTION

DESCRIPTION

A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture service and are restricted to the preparation of admixtures for intravenous infusion.

Potassium Chloride for Injection Concentrate USP is a sterile, nonpyrogenic, concentrated solution of Potassium Chloride USP in Water for Injection USP to be administered by intravenous infusion only after dilution in a larger volume of fluid. No bacteriostatic or antimicrobial agent has been added.

Each 100 mL of Potassium Chloride contains:

Potassium Chloride USP 14.9 g; Water for Injection USP qs

pH: 5.4 (4.0–8.0); Calculated Osmolarity: 4000 mOsmol/liter

Concentration of Electrolytes (mEq/mL): Potassium 2; Chloride 2

The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Potassium Chloride USP	KCl	74.55

Potassium chloride injection (approximately diluted) is a parenteral fluid and electrolyte replenisher.

CLINICAL PHARMACOLOGY

Potassium is the chief cation of body cells (160 mEq/liter of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. Chloride, the major extracellular anion, closely follows the metabolism of sodium and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting, or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

INDICATIONS AND USAGE

Potassium Chloride for Injection Concentrate USP is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

This is a concentrated solution which is intended for use in a pharmacy admixture service and is restricted to the preparation of admixtures for intravenous infusion.

CONTRAINDICATIONS

Potassium Chloride for Injection Concentrate USP is contraindicated in diseases where high potassium levels may be encountered, in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present, or where additives of potassium and chloride could be clinically detrimental.

WARNINGS

Strongly Hypertonic Solution. Must be properly diluted and thoroughly mixed before injection.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 μ g/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

This concentrated solution of potassium chloride is for use in intravenous admixtures only and must not be used undiluted for direct patient injection. Direct patient injection of potassium chloride at this concentration may be instantaneously fatal.

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.

In patients with diminished renal function, administration of solutions containing potassium ions may result in potassium retention.

PRECAUTIONS

General

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing potassium in a greater concentration than 40 mEq/liter may result in significant irritation to peripheral or central veins.

For peripheral administration of solutions containing potassium, slowly infuse the solution through a small bore needle, placed well within the lumen of a large vein. Carefully avoid infiltration.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

Use only if solution is clear and vacuum is present. Discard the container no later than 4 hours after initial closure puncture.

Pregnancy

(I) Teratogenic effects. Pregnancy Category C

Animal reproduction studies have not been conducted with potassium chloride injection. It is also not known whether potassium chloride injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium chloride injection should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Reactions which may occur because of the potassium-containing solutions or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection or extravasation, hypervolemia, and hyperkalemia.

To rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

Potassium-containing solutions are intrinsically irritating to tissues. Therefore, extreme care should be taken to avoid perivascular infiltration. Local tissue necrosis and subsequent sloughing may result if extravasation occurs. Chemical phlebitis and venospasm have also been reported.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of fluid overload during parenteral therapy, reevaluate the patient's condition and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION

Not for direct patient injection. Potassium Chloride for Injection Concentrate USP, Pharmacy Bulk Package is for preparation of intravenous admixtures only and must be diluted before administration. Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

Dosage and rate of administration are to be directed by the physician and are dependent upon the specific conditions of each patient (*e.g.*, age, weight, clinical condition of the patient and laboratory determinations). Frequent laboratory determinations and clinical evaluation are essential to monitor changes in electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

If the serum potassium level is greater than 2.5 mEq/liter, potassium can be given at a rate not to exceed 10 mEq/hour and in a concentration of up to 40 mEq/liter. The 24 hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2.0 mEq/liter and electrocardiographic changes and/or muscle paralysis), potassium chloride may be infused very cautiously at a rate of up to 40 mEq/hour. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in a 24 hour period. In critical conditions, potassium chloride may be administered in saline (unless contraindicated) rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Directions for Use of Pharmacy Bulk Package in B. Braun Glass Containers with Solid Stoppers

Warning: Not for direct infusion. For preparation of admixtures for intravenous infusion.

The pharmacy bulk package is for use in a Pharmacy Admixture Service only. Use of this product is restricted to a suitable work area, such as a laminar flow hood (or an equivalent clean air compounding area).

Additives should not be made to Pharmacy Bulk Packages.

Designed for use with a vented sterile dispensing set.

Before use, perform the following checks:

1. Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date. Verify that closure is black and is printed with the words "MUST BE DILUTED".
2. Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter; check the bottle for cracks or other damage. In checking for cracks, do not be confused by normal surface marks and seams on bottom and sides of bottle. These are not flaws. Look for bright reflections that have depth and penetrate into the wall of the bottle. Reject any such bottle.
3. To remove the outer closure, lift the tear tab and pull up, over, and down until it is below the stopper (See Figure 1). Use a circular pulling motion on the tab until it breaks away.

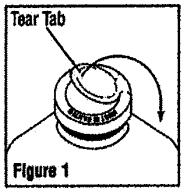


Figure 1

4. Grasp and remove the metal disk, exercising caution not to touch the exposed sterile stopper surface.
5. Check for vacuum at first puncture of the stopper. Insert the spike fully into the target area of the rubber stopper (See Figure 2 and promptly invert the bottle. Verify vacuum by observing rising air bubbles. Do not use the bottle if vacuum is not present. Refer to

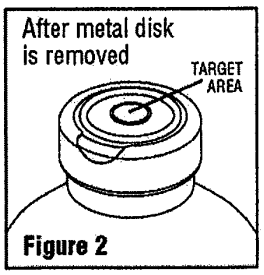


Figure 2

Directions for Use of set to be used.

6. If set insertion is not performed immediately following removal of protective metal disk, swab stopper with a suitable disinfectant.

The container closure may be penetrated only one time, utilizing a suitable sterile dispensing set which allows measured dispensing of the contents.

Transfer individual dose(s) to appropriate intravenous infusion solutions. Use of a syringe with needle is not recommended. Multiple entries increase the potential of the microbial and particulate contamination.

The withdrawal of container contents should be accomplished without delay using aseptic technique. Discard container no later than 4 hours after initial closure puncture.

The bottle may be stored under laminar flow hood at room temperature (25°C) after the closure has been entered. Date and time of container entry should be noted in the area designated on the container label.

HOW SUPPLIED

Potassium Chloride for Injection Concentrate USP (2 mEq K^+ /mL) is supplied sterile and nonpyrogenic in 250 mL glass containers with solid stoppers, Pharmacy Bulk Packages, packaged 12 per case.

NDC	REF	Size
Potassium Chloride for Injection Concentrate USP		
0264-1940-20	S9402-11	250 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat (40°C/104°F). Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Rx only

Revised: November 2013

B. Braun Medical Inc.
Irvine, CA 92614-5895 USA
1-800-227-2862
www.bbraun.com
Made in USA

Y36-002-852 LD-426-2

PRINCIPAL DISPLAY PANEL — 250 mL Container Label

250 mL

NDC 0264-1940-20
S9402-11

Potassium Chloride for
Injection Concentrate USP
(2 mEq K^+ /mL)

PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION

Each 100 mL contains:
Potassium Chloride USP 14.9 g
Water for Injection USP qs
pH: 5.4 (4.0-8.0)
Calc. Osmolarity: 4000 mOsmol/liter

Electrolytes mEq/mL: Potassium 2; Chloride 2

Contains no more than 25 μ g/L of aluminum.

B. Braun Medical Inc.
Irvine, CA USA 92614-5895

Opened:
Date
Time

Sterile, nonpyrogenic. Pharmacy Bulk Package.

No antimicrobial or bacteriostatic agent has been added.

Recommended Storage: Room temperature (25°C).
Avoid excessive heat (40°C/104°F). Protect from freezing.
See Package Insert.

Usual Dosage and Directions for Use:
See Package Insert.

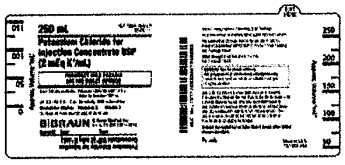
WARNING: Not for direct infusion.
For preparation of intravenous admixtures only.
Concentrated solution: dilute in suitable fluid prior to administration.

Use only if solution is clear and vacuum is present.
A single entry through the vial closure should be made with a sterile dispensing set. Transfer individual doses to appropriate intravenous infusion solutions without delay.
Use of a syringe with needle is not recommended. The above process should be carried out under a laminar flow hood using aseptic technique.

Discard the container no later than 4 hours after initial closure puncture.

Rx Only

Made in USAY37-002-288



(click image for full-size original)

POTASSIUM CHLORIDE potassium chloride injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-1940
Route of Administration	PARENTERAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (POTASSIUM CATION and CHLORIDE ION)	POTASSIUM CHLORIDE	14.9 g in 100 mL

Inactive Ingredients

Rory Griffin Affidavit Exhibit C 61

Ingredient Name	Strength
WATER	

Packaging

#Item Code	Package Description	Multilevel Packaging
1 NDC:0264-1940-20	12 CONTAINER (12 CONTAINER) in 1 CASE	contains a CONTAINER
1	250 mL in 1 CONTAINER	This package is contained within the CASE (0264-1940-20)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085870	03/21/1978	

Labeler — B. Braun Medical Inc. (002397347)

Revised: 04/2014

B. Braun Medical Inc.

Potassium Chloride: Package Insert and Label Information

By Baxter Healthcare Corporation | Last revised: 20 March 2007

POTASSIUM CHLORIDE- potassium chloride injection
Baxter Healthcare Corporation

Pharmacy Bulk Package Not for Direct Infusion

For intravenous use only. Must be diluted prior to injection.

DESCRIPTION

Potassium Chloride for Injection Concentrate, USP is a sterile, nonpyrogenic, hypertonic, concentrated solution of Potassium Chloride, USP in Water for Injection, USP to be administered by intravenous infusion only after dilution in a larger volume of fluid.

Each mL of Potassium Chloride for Injection Concentrate, USP contains 2 mEq (150 mg) of Potassium Chloride, USP. Osmolarity: 4024 mOsmol/L (calc). pH: 6.0 (4.0 to 8.0). It does not contain an antimicrobial agent.

Potassium Chloride for Injection Concentrate, USP (appropriately diluted) is a parenteral fluid and electrolyte replenisher.

A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture service and are restricted to the preparation of admixtures for intravenous infusion.

CLINICAL PHARMACOLOGY

Potassium is the chief cation of body cells (160 mEq/liter of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base of the body are reflected by changes in the chloride concentration.

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting, or in patients on a potassium free diet, potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

INDICATIONS AND USAGE

Potassium Chloride for Injection Concentrate, USP is indicated in the treatment of potassium deficiency states when oral replacement therapy is not feasible.

CONTRAINDICATIONS

Potassium Chloride for Injection Concentrate, USP is contraindicated in disease where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

WARNINGS

This injection is for preparation of intravenous admixtures only, not for direct infusion.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.

Rory Griffin Affidavit Exhibit D

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

GENERAL

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Drug product contains no more than 25 µg/L of aluminum.

Usage in Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with potassium chloride. It is also not known whether potassium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium chloride should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, hypervolemia, and hyperkalemia.

Too rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of fluid overload during parenteral therapy, reevaluate the patient's condition, and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection, USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION

Potassium Chloride for Injection Concentrate, USP must be diluted before administration. Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

The dose and rate of administration are dependent upon the specific condition of each patient.

If the serum potassium level is greater than 2.5 mEq/liter, potassium can be given at a rate not to exceed 10 mEq/hour in a concentration of up to 40 mEq/liter. The 24 hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2.0 mEq/liter and electrocardiographic changes and/or muscle paralysis), potassium chloride may be infused very cautiously at a rate up to 40 mEq/hour. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in a 24 hour period. In critical conditions, potassium chloride may be administered in saline (unless contraindicated), rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Directions for Use of the Pharmacy Bulk Package container

For preparation of intravenous admixtures only, not for direct infusion.

Do not use unless vacuum is present and solution is clear. Unit must be used with a vented set or a nonvented set with a vented spike adapter.

1. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).
2. Remove outer seal and metal disc; prepare stopper with a suitable antiseptic solution.
3. Insert vented connector of transfer set and suspend unit. Refer to directions accompanying set.
4. Sequentially dispense aliquots of Potassium Chloride for Injection Concentrate, USP into appropriate intravenous infusion solutions using a dispensing set. Note: The closure shall be penetrated only one time with a suitable sterile dispensing set which allows measured dispensing of the contents. Once container closure has been penetrated withdrawal of contents should be completed without delay. Use of a syringe with needle is not recommended. Multiple entries will also increase the potential of microbial and particulate contamination.
5. Dispense contents within 4 hours after initial entry.
6. After initial entry, it is recommended the product be stored at room temperature.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions, where possible.

HOW SUPPLIED

Potassium Chloride for Injection Concentrate, USP (2 mEq/mL) is supplied in a glass Pharmacy Bulk Package container as follows:

1D4192 250 mL NDC 0338-0318-02

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

Baxter Healthcare Corporation

Clintec Nutrition Division

Deerfield, IL 60015 USA

POTASSIUM CHLORIDE

potassium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0318
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Potassium Chloride (Potassium Chloride)	Potassium Chloride	150 g in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
Water	

Packaging		
#Item Code	**Package Description**	**Multilevel Packaging**
1 NDC:0338-0318-02	250 mL (250 MILLILITER) in 1 BOTTLE	None

Labeler — Baxter Healthcare Corporation

Revised: 03/2007

Baxter Healthcare Corporation

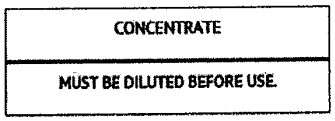
Potassium Chloride: Package Insert and Label Information

By General Injectables and Vaccines, Inc. | Last revised: 9 February 2017

POTASSIUM CHLORIDE- potassium chloride injection, solution, concentrate
General Injectables and Vaccines, Inc.

Potassium Chloride
for Injection
Concentrate, USP

for Injection
Concentrate, USP



(click image for full-size original)

FOR INTRAVENOUS INFUSION ONLY;

MUST BE DILUTED PRIOR TO INJECTION.

Ampuls

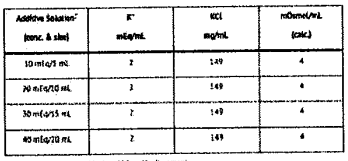
Fliptop Vials

Pintop Vials

Pressurized Pintop Vials

DESCRIPTION

Potassium Chloride for Injection Concentrate, USP, is a sterile, nonpyrogenic, concentrated solution of potassium chloride, USP in water for injection administered by intravenous infusion only after dilution in a larger volume of fluid. They are provided in the following variety of concentrations and sizes comprising a choice of single-dose containers, all designed to provide the commonly prescribed amounts of potassium chloride for single-dose infusion after dilution in suitable large volume parenterals.



Additive Solution* (conc. & size)	K^+ mEq/mL	KCl mg/mL	mOsmol/mL (calc.)
10 mEq/5 mL	2	149	4
30 mEq/20 mL	3	149	6
30 mEq/15 mL	2	149	4
40 mEq/20 mL	2	149	4

* May contain hydrochloric acid for pH adjustment

(click image for full-size original)

The solutions contain no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and each is intended only for single-dose injection (after dilution). When smaller doses are required, discard the unused portion. The pH is 4.6 (4.0 to 8.0).

Potassium Chloride for Injection Concentrate, USP (appropriately diluted) is a parenteral fluid and electrolyte replenisher.

Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

Rory Griffin Affidavit Exhibit E

Add. 60

The semi-rigid material used for the plastic vials is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene.

The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

CLINICAL PHARMACOLOGY

Potassium is the chief cation of body cells (160 mEq/liter of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and, to a small extent, in perspiration. The patients on a potassium-free diet, potassium loss from the body continues, resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

INDICATIONS AND USAGE

Potassium Chloride for Injection Concentrate, USP is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

CONTRAINDICATIONS

Potassium Chloride for Injection Concentrate, USP is contraindicated in diseases where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

WARNINGS

To avoid potassium intoxication, do not infudse solutions rapidly. In patients with severe renal insufficiency, administration of potsddium chloride may cause potassium intoxication and life threatening hyperkalemia.

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing confested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

General

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Pregnancy

Teratogenic Effects: Pregnancy category C. Animal reproduction studies have not been conducted with potassium chloride. It is also not known whether potassium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium chloride should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of adminstration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, hypervolemia, and hyperkalemia.

Too rapid infusion of hypertonic solutions may cause local pain and rarely, vein irritiation. Rate of adminstration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If an adverse reaction does not occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of fluid overload during parenteral therapy, re-evaluate the patient's condition, and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately, and institute corrective therapy to reduce serum potassium levels.

1. Dextrose Injection USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, at a rate of 300 to 500 mL per hour.

2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.

3. Hemodialysis and pritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION

Potassium Chloride for Injection Concentrate, USP must be diluted before administration. Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

The dose and rate of administration are dependent upon the specific condition of each patient.

If the serum potassium level is greater than 2.5 mEq/liter, potassium can be given at a rate not to exceed 10 mEq/hour in a concentration of up to 40 mEq/liter. The 24-hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2.0 mEq/liter with electrocardiographic changes and/or muscle paralysis) potassium chloride may be infused very cautiously at a rate of up to 40 mEq/liter. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in saline (unless contraindicated), rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Rory Griffin Affidavit Exhibit E

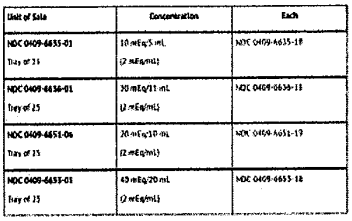
Prior to entering vial, remove the metal seal and clease the rubber closure with a suitable antiseptic agent.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

TO PREVENT NEEDLE-STICK INJURIES, NEEDLES SHOLD NOT BE RECAPPED, PURPOSELY BENT, OR BROKEN BY HAND.

HOW SUPPLIED

Potassium Chloride for Injection Concentrate, USP, is supplied in single-dose containters as follows:



Unit of Sale	Concentration	Each
NDC 0409-6635-01 Tray of 25	10 mEq/5 mL (2 mEq/mL)	NDC 0409-6635-19
NDC 0409-6636-01 Tray of 25	20 mEq/10 mL (2 mEq/mL)	NDC 0409-6636-19
NDC 0409-6651-06 Tray of 25	20 mEq/10 mL (2 mEq/mL)	NDC 0409-6651-19
NDC 0409-6653-01 Tray of 25	40 mEq/20 mL (2 mEq/mL)	NDC 0409-6653-18

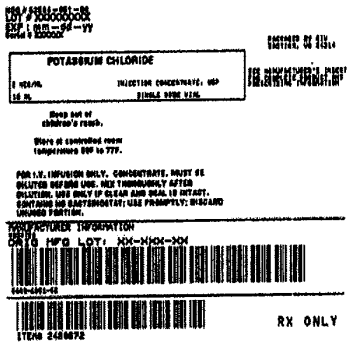
(click image for full-size original)

Store at controlled room temperature 15° to 30°C (68° to 77°F) [See USP.]

Revised: 9/2014

HOSPIRA, INC., LAKE FOREST, IL 60045 USA

SAMPLE PACKAGE LABEL



(click image for full-size original)

POTASSIUM CHLORIDE
potassium chloride injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52584-651(NDC:0409-6651)
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (POTASSIUM CATION)	POTASSIUM CHLORIDE	149 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER	
HYDROCHLORIC ACID	

Packaging		
#Item Code	**Package Description**	**Multilevel Packaging**
1 NDC:52584-651-06	1 VIAL, SINGLE-DOSE in 1 BAG	contains a VIAL, SINGLE-DOSE

4	1 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the BAG (52584-651-06)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080205	11/16/2015	

Labeler — General Injectables and Vaccines, Inc. (108250663)

Revised: 02/2017

General Injectables and Vaccines, Inc.

POTASSIUM CHLORIDE: Package Insert and Label Information

By Hospira, Inc. | Last revised: 17 February 2015

POTASSIUM CHLORIDE- potassium chloride injection, solution, concentrate
Hospira, Inc.

for Injection
Concentrate , USP

CONCENTRATE
MUST BE DILUTED BEFORE USE.

FOR INTRAVENOUS INFUSION ONLY;
MUST BE DILUTED PRIOR TO INJECTION .
Fliptop Vials

DESCRIPTION

Potassium Chloride for Injection Concentrate, USP, is a sterile, nonpyrogenic, concentrated solution of potassium chloride, USP in water for injection administered by intravenous infusion only after dilution in a larger volume of fluid. They are provided in the following variety of concentrations and sizes comprising a choice of single-dose containers, all designed to provide the commonly prescribed amounts of potassium chloride for single-dose infusion after dilution in suitable large volume parenterals.

Additive Solution * (conc. & size)	K^+ mEq/mL	KCl mg/mL	mOsmol/mL (calc.)
10 mEq/5 mL	2	149	4
20 mEq/10 mL	2	149	4
30 mEq/15 mL	2	149	4
40 mEq/20 mL	2	149	4

* May contain hydrochloric acid for pH adjustment.

The solutions contain no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and each is intended only for single-dose injection (after dilution). When smaller doses are required, discard the unused portion. The pH is 4.6 (4.0 to 8.0).

Potassium Chloride for Injection Concentrate, USP (appropriately diluted) is a parenteral fluid and electrolyte replenisher.

Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

The semi-rigid material used for the plastic vials is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

CLINICAL PHARMACOLOGY

Rory Griffin Affidavit Exhibit F

Potassium is the chief cation of body cells (160 mEq/liter of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and, to a small extent, in perspiration. The kidney does not conserve potassium well so that during fasting, or in patients on a potassium-free diet, potassium loss from the body continues, resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

INDICATIONS AND USAGE

Potassium Chloride for Injection Concentrate, USP is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

CONTRAINDICATIONS

Potassium Chloride for Injection Concentrate, USP is contraindicated in diseases where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

WARNINGS

To avoid potassium intoxication, do not infuse solutions rapidly. In patients with severe renal insufficiency, administration of potassium chloride may cause potassium intoxication and life threatening hyperkalemia.

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

General

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Pregnancy

Teratogenic Effects: Pregnancy category C. Animal reproduction studies have not been conducted with potassium chloride. It is also not known whether potassium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium chloride should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, hypervolemia, and hyperkalemia.

Too rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of fluid overload during parenteral therapy, re-evaluate the patient's condition, and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately, and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, at a rate of 300 to 500 mL per hour.

2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.

3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION

Potassium Chloride for Injection Concentrate, USP must be diluted before administration. Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

The dose and rate of administration are dependent upon the specific condition of each patient.

If the serum potassium level is greater than 2.5 mEq/liter, potassium can be given at a rate not to exceed 10 mEq/hour in a concentration of up to 40 mEq/liter. The 24-hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2.0 mEq/liter with electrocardiographic changes and/or muscle paralysis) potassium chloride may be infused very cautiously at a rate of up to 40 mEq/hour. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in a 24 hour period. In critical conditions, potassium chloride may be administered in saline (unless contraindicated), rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Prior to entering vial, remove the metal seal and cleanse the rubber closure with a suitable antiseptic agent.

Rory Griffin Affidavit Exhibit F

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

TO PREVENT NEEDLE-STICK INJURIES, NEEDLES SHOULD NOT BE RECAPPED, PURPOSELY BENT, OR BROKEN BY HAND.

HOW SUPPLIED

Potassium Chloride for Injection Concentrate, USP, is supplied in single-dose containers as follows:

Unit of Sale	Concentration	Each
NDC 0409-6635-01 Tray of 25	10 mEq/5 mL (2 mEq/mL)	NDC 0409-6635-18
NDC 0409-6636-01 Tray of 25	30 mEq/15 mL (2 mEq/mL)	NDC 0409-6636-18
NDC 0409-6651-06 Tray of 25	20 mEq/10 mL (2 mEq/mL)	NDC 0409-6651-19
NDC 0409-6653-05 Tray of 25	40 mEq/20 mL (2 mEq/mL)	NDC 0409-6653-18

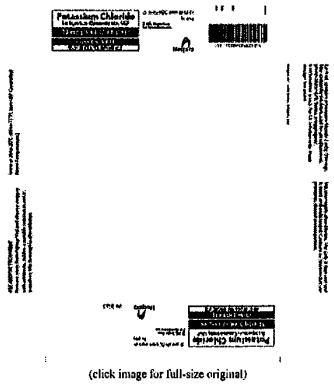
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Revised: 9/2014

EN-3583

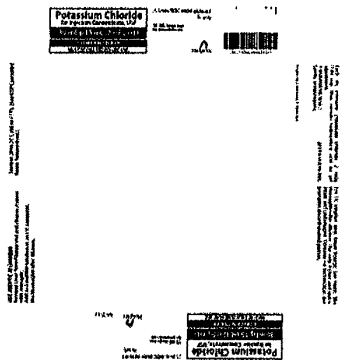
Hospira, Inc., Lake Forest, IL 60045 USA Hospira

IM-3543



(click image for full-size original)

IM-3544

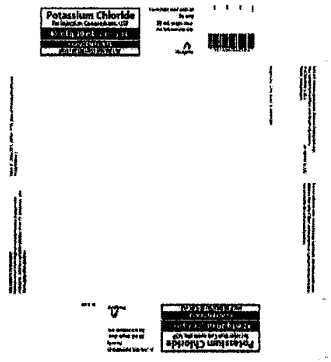


(click image for full-size original)

IM-3545

(click image for full-size original)

IM-3546



(click image for full-size original)

POTASSIUM CHLORIDE potassium chloride injection, solution, concentrate			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-6635
Route of Administration	INTRAVENOUS	**DEA Schedule**	
Active Ingredient/Active Moiety			
Ingredient Name		**Basis of Strength**	**Strength**
POTASSIUM CHLORIDE (POTASSIUM CATION and CHLORIDE ION)		POTASSIUM CHLORIDE	149 mg in 1 mL
Inactive Ingredients			
Ingredient Name			**Strength**
WATER			

HYDROCHLORIC ACID	

Packaging

#Item Code	Package Description	Multilevel Packaging
1 NDC:0409-6635-01	25 VIAL, SINGLE-DOSE in 1 TRAY	contains a VIAL, SINGLE-DOSE (0409-6635-18)
1 NDC:0409-6635-18	5 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (0409-6635-01)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080205	03/16/1972	

POTASSIUM CHLORIDE

potassium chloride injection, solution, concentrate

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-6651
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (POTASSIUM CATION and CHLORIDE ION)	POTASSIUM CHLORIDE	149 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER	
HYDROCHLORIC ACID	

Packaging

#Item Code	Package Description	Multilevel Packaging
1 NDC:0409-6651-06	25 VIAL, SINGLE-DOSE in 1 TRAY	contains a VIAL, SINGLE-DOSE (0409-6651-19)
1 NDC:0409-6651-19	10 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (0409-6651-06)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080205	03/16/1972	

POTASSIUM CHLORIDE

potassium chloride injection, solution, concentrate

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-6653
Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (POTASSIUM CATION and CHLORIDE ION)	POTASSIUM CHLORIDE	149 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER	
HYDROCHLORIC ACID	

Packaging

#Item Code	Package Description	Multilevel Packaging
1 NDC:0409-6653-05	25 VIAL, SINGLE-DOSE in 1 TRAY	contains a VIAL, SINGLE-DOSE (0409-6653-18)
1 NDC:0409-6653-18	20 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (0409-6653-05)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080205	03/16/1972	

POTASSIUM CHLORIDE

potassium chloride injection, solution, concentrate

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-6636

Route of Administration	INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CHLORIDE (POTASSIUM CATION and CHLORIDE ION)	POTASSIUM CHLORIDE	149 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER	
HYDROCHLORIC ACID	

Packaging

#Item Code	Package Description	Multilevel Packaging
1 NDC:0409-6636-01	25 VIAL, SINGLE-DOSE in 1 TRAY	contains a VIAL, SINGLE-DOSE (0409-6636-18)
1 NDC:0409-6636-18	15 mL in 1 VIAL, SINGLE-DOSE	This package is contained within the TRAY (0409-6636-01)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080205	03/16/1972	

Labeler — Hospira, Inc. (141588017)

Revised: 02/2015

Hospira, Inc.

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
FIFTH DIVISION

STEVEN SHULTS — PLAINTIFF

v. — CASE NO. 60CV-17-1419

ARKANSAS DEPARTMENT OF CORRECTIONS;
WENDY KELLEY, in her Official Capacity as Director — DEFENDANTS

MEMORANDUM ORDER GRANTING PLAINTIFF'S COMPLAINT FOR RELIEF FOR VIOLATION OF ARKANSAS FREEDOM OF INFORMATION ACT

Introduction

The Court held an expedited hearing on March 30, 2017, pursuant to the Arkansas Freedom of Information Act (hereafter "AFOIA") on the March 23, 2017 complaint filed by Steven Shults, in his capacity as a citizen, who seeks information from Defendants relating to the identity of the manufacturer of the supply of drugs in Defendants' possession intended for use in lethal injection executions. The parties agree to the following relevant facts:

1. Plaintiff is an appropriate person entitled to bring this action pursuant to AFOIA, Ark. Code Ann. § 25-19-101 et seq.

2. Defendant Arkansas Department of Correction (hereafter "ADC") is a state agency subject to AFOIA.

3. Defendant Wendy Kelley (hereafter "Kelley" or "Director Kelley") is a custodian of the ADC's records under AFOIA.

4. Jurisdiction and venue are proper.

5. On February 9, 2017, Plaintiff submitted an AFOIA Request to ADC via e-mail identified as Exhibit 1 to the Complaint and Exhibit A thereto, in which Plaintiff sought information relating to the ADC's supply of drugs intended for use in lethal injection executions pursuant to the Arkansas Method-of-Execution Act (MEA), Ark. Code Ann. § 5-4-617.

6. ADC acknowledged receipt of Plaintiff's AFOIA request on February 16, 2017, and stated that it was in the process of identifying records it was able to disclose. ADC eventually informed Plaintiff that there were no new responsive records following an earlier request Plaintiff had submitted.

79

7. Plaintiff resubmitted his AFOIA request on Tuesday, March 7, 2017. On March 10, 2017, ADC responded to that request and provided records which revealed that it had acquired 100 vials of potassium chloride, a drug listed in Defendants method-of-execution (MOE) protocol.

8. Defendants have refused to disclose the package inserts or labels for the potassium chloride.

Defendants contend that they properly declined to disclose the package inserts or labels for the potassium chloride and cite Ark. Code Ann. § 5-4-617(i)(2)(B) and the Arkansas Supreme Court decision in *Kelley v. Johnson*, 2016 Ark. 268, 496 S.W.3d 356 (2016), *certiorari denied,* No. 16-6496, 2017 WL 670646 (U.S. Feb. 21, 2017) as authority for its position. In their brief for the instant matter, Defendants cited this Court's March 28, 2017 Memorandum Order that granted their motion to dismiss the second amended complaint filed on behalf of eight death row inmates who are scheduled for execution in coming weeks which stated that "[t]he Arkansas Supreme Court decided that Defendants may conceal the identity of the supplier(s) and manufacturer(s) of the lethal injection drugs." *Memorandum Order Granting Defendants' Motion to Dismiss Second Amended Complaint for Declaratory and Injunctive Relief*, at 7, No. 60CV-15-2921 (March 28, 2017). However, during argument at the March 30 hearing in the instant matter, the Court and counsel for Defendants agreed that the Arkansas Supreme Court did not mention manufacturers of lethal injection drugs in *Kelley v. Johnson.* Counsel for both sides agree that the question of whether the MEA prohibits the ADC from disclosing any information that may identify the manufacturers of lethal injection drugs made by FDA-approved manufacturers presents a question of first impression in Arkansas.

Plaintiff, citing Ark. Code Ann. § 5-4-617(j)(1), argues that the MEA explicitly requires ADC to disclose "[p]ackage inserts and labels, if the drug or drugs [used for lethal injections in the MOE protocol] ... have been made by a manufacturer approved by the United States Food

and Drug Administration ("FDA")... ." Defendants acknowledge their obligation to disclose those documents pursuant to AFOIA and the MEA, but contend that disclosure is only permissible in such instances where "the information that may be used to identify the ... seller, or supplier is redacted and maintained as confidential." Relying on the sworn affidavit of ADC Deputy Director Rory Griffin, Defendants contend that any disclosure of the package inserts and labels for the potassium chloride in their possession would lead to identification of the seller and/or supplier of that lethal injection drug due to "the unique format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance of the package insert and label in the ADC's possession." *Defendants' FOIA Hearing Brief,* p. 4.

Analysis

After reviewing the pertinent provisions of the MEA and AFOIA, considering the briefs and exhibits submitted by the parties in support of the complaint and answer herein, and considering the arguments presented by counsel during the March 30, 2017 AFOIA hearing, the Court holds that the MEA does not make the identity of manufacturers of FDA-approved drugs used in the lethal injection MOE confidential. The Court further holds that the package insert and labels of lethal injection drugs manufactured by FDA-approved manufacturers do not 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) a compounder, testing laboratory, seller, or supplier of the lethal injection drugs. Rather, the Court holds that Ark. Code Ann. § 5-4-617(i) mandates that "the Department [ADC] 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: ... package inserts and labels if the drugs ... have been made by a manufacturer approved by the United States Food and Drug Administration." [Emphasis added].

Ark. Code Ann. § 5-4-617 states, in pertinent part, as follows:

> (i)(1) The procedures under (g)(1) of this section [which pertain to the logistical procedures necessary to carry out the sentence of death], the implementation of the procedures 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 [ADC] 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) [which identifies the drugs that may be used for a lethal-injection protocol], 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 ... have been made by a manufacturer

approved by the United States Food and Drug Administration.

Defendants admit that the potassium chloride in their possession for use in lethal injections pursuant to the MEA is made by a manufacturer approved by the United States Food and Drug Administration and that subsection (j)(1) of Ark. Code Ann. § 5-4-617 renders the package inserts and labels for that potassium chloride subject to disclosure pursuant to AFOIA, "so long as the information that may be used to identify the ... seller, or supplier is redacted and maintained as confidential." However, Defendants contend (1) that "seller" and "supplier" in the statute means "manufacturer," (2) that the package inserts and labels identify the proximate "seller" and "supplier" of lethal injection drugs, and (3) that the ADC is unable to redact the requested package insert and labels for the 100 vials of potassium chloride in its possession for use in lethal injections in such a way that will prevent the recipients, of even redacted documents, from identifying the sellers and/or suppliers of the potassium chloride.

Arkansas Courts have established certain rules that govern statutory construction, the first of which is to give effect to the intent of the General Assembly. *Hartford Fire Ins. Co. v. Sauer*, 358 Ark. 89, 94, 186 S.W.3d 229, 233 (2004) (citing *Bond v. Lavaca Sch. Dist.*, 347 Ark. 300, 64 S.W.3d 249 (2001); *Ozark Gas Pipeline v. Arkansas Pub. Serv. Comm'n*, 342 Ark. 591, 29 S.W.3d 730 (2000)). The Court must construe the statute just as it reads, giving the words their ordinary and usually accepted meaning in common language. *Hartford Fire Ins. Co. v. Sauer*, 358 Ark. 89, 94, 186 S.W.3d 229, 233 (2004) (citing *Stephens v. Arkansas Sch. for the Blind*, 341 Ark. 939, 20 S.W.3d 397 (2000)). The Court must not leave any word void, superfluous, or insignificant; and meaning and effect must be given to every word in the statute if possible. *Id.*

Defendants' contention that "seller" and "supplier" in the MEA means "manufacturer" violates longstanding principles of statutory construction. When the MEA was enacted, the

Arkansas General Assembly did not include "manufacturer" among the entities shielded from being identified. In addition to the explicit mention of manufacturers at subsection (j)(1), at subsection (d)(1) the MEA provides that the drug or drugs used in the lethal injection protocol shall be "made by a manufacturer approved by the United States Food and Drug Administration ..."[1]

The General Assembly could have easily included "manufacturer" among the entities whose identity is confidential for purposes of the MEA had it desired to do so. This should not be treated by courts as an oversight, but a matter of legislative intent that the identity of a manufacturer of FDA-approved lethal injection drugs is not confidential. As such, there is no legal basis for courts to issue protective orders before the ADC discloses the package inserts and labels of lethal injection drugs made by a manufacturer approved by the United States Food and Drug Administration.

Moreover, the plain language of the MEA mandates, at subsection (j)(1), that the ADC "shall make available to the public ... package inserts and labels if the [lethal injection protocol] drug or drugs ... have been made by a manufacturer approved by the United States Food and Drug Administration.

Clearly, the Arkansas General Assembly understood the difference between a "manufacturer," a "seller," and a "supplier" when it enacted the MEA. Words used in legislation are accorded their ordinary meaning unless specifically defined otherwise. According to the Oxford American Dictionary, "manufacture" means "to make or produce (goods) on a large scale by machinery." "Seller" is defined as "a person who sells something." "Supplier" is a derivative

[1] Alternatively, the lethal injection drugs used prescribed by the AMEA may be "obtained from a compounding pharmacy that has been accredited by a national organization that accredits compounding pharmacies." *See* Ark. Code Ann. § 5-4-617(d)(3).

of "supply" which means "to give or provide with (something needed or useful), to make available for use." Those words have distinct meanings in ordinary usage.

They also have distinctly different connotations for purposes of construing the MEA, as a "manufacturer" approved by the United States Food and Drug Administration that makes drugs used in the MEA lethal injection protocol is distinct from anyone who "sells" lethal injection drugs to Defendants. Indeed, in their pleadings throughout the course of litigation challenging the constitutionality of the MEA, Defendants have consistently asserted that protecting the identity of the "sellers" and "suppliers" of lethal injection drugs is important because "manufacturers" of pharmaceutical products have prohibited their products from being sold to corrections departments for use in lethal injection executions. Thus, Defendants' arguments that "sellers" and "suppliers" mean "manufacturers" contradict arguments they asserted in *Kelley v. Johnson.*

However, Defendants argue that despite the explicit requirement of subsection (j)(1), they cannot produce the package inserts and labels for lethal injection drugs made by a manufacturer approved by the United States Food and Drug Administration because "the ADC is unable to redact anything short of the entire package insert and label without identifying or leading to the identification of the drug's seller and/or supplier in direct violation of the MEA." In their brief, Defendants assert that "the last two times partially redacted package inserts and labels were disclosed, they in fact led to the identification of the seller and/or supplier." *Defendants' FOIA Hearing Brief*, p. 1. Defendants claim that "[t]he label on the ADC's potassium chloride is, of course, an actual label – unique in size, shape, coloring, font, and general appearance. And the actual package insert is unique in size, shape, coloring, font, and general appearance." *Defendants' FOIA Hearing Brief, p. 5.*

Defendants' argument in this regard is, to put it plainly, mistaken. Package inserts and labels for pharmaceutical products are not provided by sellers or suppliers, but by the manufacturers of those products. Package inserts and labels are provided by manufacturers because manufacturers, rather than the sellers and suppliers of pharmaceutical products, are obligated by law to disclose information regarding the active ingredients, dosage, use indications, contraindications, and adverse reactions of those products. This information is not produced by drug sellers or suppliers, but by drug manufacturers, who are obligated by governmental regulations to make it available to the public when the pharmaceutical product is manufactured. *See*, https://www.fda.gov/Drugs/InformationOnDrugs/ucm079450.htm.

Defendants' reliance on 21 C.F.R. § 210.3 is equally misplaced. Part 210 of Title 21 in the Code of Federal Regulations is titled "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs." Subsection (b) of the regulation contains the following definitions:

> (2) Batch means a specific quantity of a drug or material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture. ...
>
> (10) Lot means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specified identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.
>
> (11) Lot number, control number, or batch number means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and

> distribution of a batch or lot of drug product or other material can be determined.
>
> (12) Manufacture, processing, packing, or holding of a drug product includes packaging and labeling operations, testing, and quality control of drug products.
> ...
>
> (15) Quality control unit means any person or organizational element designated by the firm to be responsible for the duties relating to quality control.

The terms "batch number," "lot number," and "control number" are not terms used to identify entities that sell or supply FDA-approved drugs. Those terms are used by the pharmaceutical industry and governmental regulators of that industry to enable manufacturers and regulators to identify crucial quality control features related to the manufacture of pharmaceutical drugs and ensure that a drug product is of uniform character and quality and identify when it was manufactured.

In the event of a product recall or allegation of harm associated with use, drug manufacturers and governmental regulators identify drugs suspected of being defective by tracking their batch, lot, and control numbers. That information identifies when the product was manufactured, during what production cycle, and the limits on applicable standards for determining product quality and efficacy. None of this information is generated by, let alone identifies, who will sell the drug, let alone who will supply the drug for ultimate sale to an end user. Defendants' contention that they cannot disclose the package inserts and labels for the potassium chloride in their possession for use in lethal injections because doing so will, or may, identify the sellers and/or suppliers of that drug is, to be blunt, incorrect.

The only way the ADC can know whether it has obtained potassium chloride by a manufacturer approved by the FDA is by inspecting the package insert and product label. Because the MEA obligates the ADC to use drugs "made made by a manufacturer approved by the United States Food and Drug Administration," the General Assembly expressly mandated that package inserts and product labels be disclosed. Stated differently, package inserts and product labels for such drugs are not shielded from AFOIA disclosure requirements by any provision of the MEA. Disclosure of package inserts and product labels goes to the very purpose of the AFOIA, to ensure that the public may know whether Defendants are using drugs made by FDA-approved manufacturers. The public, including Plaintiff herein, has no other way to verify whether Defendants are complying with that requirement.

Conclusion

It follows, therefore, that Plaintiff is entitled to receive the package inserts and product labels for the supply of potassium chloride Defendants possess for use in the lethal injection protocol mandated by the MEA. The ADC violated the AFOIA by its refusal to produce those documents. That refusal was not justified by the language of the MEA in any respect. Defendants are hereby ordered to produce the requested information to Plaintiff without further delay.

ORDERED this 31st day of March, 2017.

CIRCUIT JUDGE

FORMAL ORDER

STATE OF ARKANSAS,)
) SCT.
SUPREME COURT)

BE IT REMEMBERED, THAT A SESSION OF THE SUPREME COURT BEGUN AND HELD IN THE CITY OF LITTLE ROCK, ON APRIL 4, 2017, AMONGST OTHERS WERE THE FOLLOWING PROCEEDINGS, TO-WIT:

SUPREME COURT CASE NO. CV-17-267

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

V. APPEAL FROM PULASKI COUNTY CIRCUIT COURT, FIFTH DIVISION – 60CV-17-1419

STEVEN SHULTS RESPONDENT

PETITIONERS' EMERGENCY MOTION FOR IMMEDIATE STAY IS GRANTED. WOMACK, J., ADDITIONALLY WOULD ORDER THE RETURN OF THE PREVIOUSLY PROVIDED INFORMATION AND ISSUE A PROTECTIVE ORDER PROHIBITING THE JUDGE OR THE PARTIES FROM RELEASING ANY OF THE PREVIOUSLY PROVIDED INFORMATION TO ANY THIRD PERSON.

IN TESTIMONY, THAT THE ABOVE IS A TRUE COPY OF THE ORDER OF SAID SUPREME COURT, RENDERED IN THE CASE HEREIN STATED, I, STACEY PECTOL, CLERK OF SAID SUPREME COURT, HEREUNTO SET MY HAND AND AFFIX THE SEAL OF SAID SUPREME COURT, AT MY OFFICE IN THE CITY OF LITTLE ROCK, THIS 4TH DAY OF APRIL, 2017.

Stacey Pectol
CLERK

BY: _____
DEPUTY CLERK

ORIGINAL TO CLERK

89

CC: COLIN R. JORGENSEN, SENIOR ASSISTANT ATTORNEY GENERAL
PHILIP KAPLAN, HEATHER ZACHARY, AND ALEC GAINES
HONORABLE WENDELL GRIFFEN, CIRCUIT JUDGE

[redacted]

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SEVENTEENTH DIVISION

STEVEN SHULTS — PLAINTIFF

v. — No. 60CV-17-4931

ARKANSAS DEPARTMENT OF CORRECTION
and WENDY KELLEY, in her official capacity — DEFENDANTS

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT OR, IN THE ALTERNATIVE, TO STAY PROCEEDINGS PENDING A RELATED APPEAL

Defendants Arkansas Department of Correction and Wendy Kelley, in her official capacity as Director of the ADC (collectively, "ADC" or "the State") submit this brief in support of their motion to dismiss. This Complaint fails as a matter of law for two reasons. First, Plaintiff fails to state a cognizable claim of a constitutional or statutory violation and, therefore, the suit is barred by sovereign immunity. Even assuming that all of the factual allegations in the Complaint are true, Plaintiff has not stated a viable claim because the records he seeks are confidential under the Arkansas Method of Execution Act, and the ADC is absolutely prohibited from disclosing them in response to a Freedom of Information Act request. Second, the Court should dismiss based on the pendency of another action between the same parties and involving the same factual and legal issues, which is currently on appeal to the Arkansas Supreme Court. The outcome of that appeal will bind the parties and this Court under the doctrines of *res judicata*, collateral estoppel, and *stare decisis*. For both of these reasons, the Court should dismiss the Complaint with prejudice pursuant to Rules 12(b)(1), 12(b)(6), and

12(b)(8) of the Arkansas Rules of Civil Procedure. In the alternative, the Court should stay this case pending the final resolution of the related appeal.

FACTUAL BACKGROUND

This case involves the proper scope and application of confidentiality provisions in the Arkansas Method of Execution Act, Ark. Code Ann. § 5-4-617 ("MEA"), that require the Arkansas Department of Correction ("ADC") to maintain the confidentiality of lethal drug sellers and suppliers.

The FOIA request. Plaintiff Steven Shults is an Arkansas citizen and attorney with no apparent connection to death-penalty litigation or death-row inmates. He is not a prisoner facing a scheduled execution, nor does he represent a prisoner facing a scheduled execution. On August 21, 2017, Shults submitted a FOIA request to the ADC seeking, among other things, records related to the Department's lethal-drug supply. (Compl. Ex. 1(A)). Shults specifically requested documents or records in any form (including labels on drug bottles, packaging, or inserts) containing the following information about all drugs intended for use in judicial executions: drug name, manufacturer/compounder, concentration, expiration date(s), and lot numbers. *Id.*

ADC's response. ADC provided Shults with responsive records on August 24, 2017, revealing that the Department had recently acquired 40 vials of midazolam, which is one of the drugs listed in its execution protocol. (Compl. ¶ 7). ADC informed Shults that it was in possession of pharmaceutical package inserts and labels for those bulk-manufactured, FDA-approved drugs that were potentially

responsive to his request. (Compl. Ex. 1(B) at 1). But ADC explained that those records were exempt from FOIA disclosure under the MEA because, under that provision, ADC is required to "keep confidential all information that may identify or lead to the identification of . . . the entities . . . who . . . test, sell, or supply the drug or drugs . . . for the execution process." *Id.* (quoting Ark. Code Ann. § 5-4-617(i)(2)(B)). ADC acknowledged that, while the MEA generally requires disclosure of "[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," ADC may only disclose such documents where "the information that ***may be used*** to identify the . . . seller, or supplier is redacted and maintained as confidential." *Id.* (quoting Ark. Code Ann. § 5-4-617(j)(1)) (emphasis added). ADC explained that the Arkansas Supreme Court had recently sustained the constitutionality of the MEA in *Kelley v. Johnson*, 2016 Ark. 268, 496 S.W.3d 346, and that ADC was required to fully comply with the confidentiality provisions of the law. *Id.*

ADC explained to Shults that, consistent with the MEA's broad prohibition on the disclosure of all information that may identify or lead to the identification of entities that sell or supply drugs for the execution process and the requirement that any package inserts and labels be redacted to maintain that confidentiality, ADC had determined that it was prohibited from disclosing the drug package inserts and labels that potentially would be responsive to his request. *Id.* ADC explained that, based on its previous experience disclosing inserts and labels, along with a detailed comparison of such documents used by different drug manufacturers, production of

those records would identify or lead to the identification of the suppliers and sellers of those drugs. *Id.*

ADC noted that it had previously disclosed drug labels and package inserts but redacted manufacturer logos, addresses, and other information which the ADC believed could be used to identify sellers or suppliers. *Id.* at 2. But, despite those efforts, news outlets were able to compare the redacted inserts and labels with publicly-available (unredacted) information and readily discern the identity of the drugs' suppliers and sellers. *Id.* (identifying three examples of news reports publishing the names of the manufacturers of the drugs in ADC's possession after production of redacted package inserts and labels). Such identification despite ADC's efforts at redaction was "unsurprising" "[g]iven variations in format, style, diction, font, organization, grammar, and spelling between the labels and inserts used by various manufacturers[.]" *Id.* "As a result, it is not possible to redact the labels or package inserts in a manner that would—as required by the Method of Execution Act—maintain confidentiality." *Id.*

In order to provide Shults with as much information as possible, ADC confirmed that its recent purchase was of bulk-manufactured, FDA-approved midazolam with an expiration date of January 2019. *Id.* at 1. ADC also provided URL addresses for a number of websites where Shults could find package inserts, labels, and other information for *all* FDA-approved drugs, including midazolam. *Id.* at 2.

The current lawsuit. Shults filed suit on September 7, 2017, alleging that the ADC violated the FOIA and the Method of Execution Act by failing to provide him with copies of the package inserts and labels for the newly-acquired midazolam. Compl.¶ 10. Shults requested that this Court hold a prompt hearing and enter an order finding that ADC violated the FOIA through improper interpretation of Ark. Code Ann. § 5-4-617(j)(1), that ADC was not substantially justified in its refusal to provide the records as requested, and that Plaintiff is entitled to unredacted copies of lethal drug labels and package inserts. Compl. at 3, Wherefore Cl. The matter has been set for hearing on September 19, 2017.

The pending Fifth Division lawsuit. The same factual and legal issues that are presented in this case are also the subject of another FOIA lawsuit that Shults filed in March 2017 in Pulaski County Circuit Court No. 60CV-17-1419 ("*Shults I*").[1] *See* Compl. in No. 60CV-17-1419, which is attached to ADC's Motion to Dismiss as Exhibit 1. In *Shults I*, Shults complained about the ADC's failure to disclose package inserts and labels for potassium chloride, which is a different drug in its lethal-injection protocol. *Id.* ADC submitted unrebutted evidence that the documents requested by Shults would identify lethal-drug sellers or suppliers in violation of the MEA. *See* Affidavit of Deputy Director Rory Griffin in *Shults I*, which is attached to ADC's motion as Exhibit 2. Judge Wendell L. Griffen held a

[1] This Court may take judicial notice of documents in the public record and consider them in ruling on the State's motion to dismiss. *See, e.g., Papasan v. Allain*, 478 U.S. 265, 269 n.1 (1986); *Levy v. Ohl*, 477 F.3d 988, 991 (8th Cir. 2007) (citing *Stahl v. U.S. Dep't of Agriculture*, 327 F.3d 697, 700 (8th Cir. 2003)). In Arkansas, as in other states, court records are public records. *See Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597-98 (1978).

hearing and ultimately held that the ADC's failure to disclose those package inserts and labels violated the FOIA. *See* Mem. Order Granting Pl.'s Compl. for Relief in *Shults I,* which is attached to ADC's Motion as Exhibit 3. The State immediately filed a notice of appeal of that order and obtained an emergency stay from the Arkansas Supreme Court in *Arkansas Department of Correction et al. v. Steven Shults,* Supreme Court Case No. CV-17-267. A copy of the Supreme Court's Formal Order immediately staying Judge Griffen's disclosure order is attached to ADC's motion as Exhibit 4. The appeal on the merits is currently pending before the Supreme Court in Case No. CV-17-544. The State's abstract, brief, and addendum in that appeal are due later this week, on September 21, 2017.

ARGUMENT

Arkansas has a clear fact-pleading requirement. Any valid claim for relief must contain "a statement in ordinary and concise language of facts showing that the court has jurisdiction . . . and that the pleader is entitled to relief . . . ." Ark. R. Civ. P. 8(a)(1). A plaintiff must do more than allege that his FOIA rights were violated, because that is a legal conclusion, not facts. *See Brown v. Ark. Dep't of Corr.*, 339 Ark. 458, 461, 6 S.W.3d 102, 104 (1999). Similarly, allegations that characterize events through conclusions or labels, rather than describing the actual events, do not meet the plaintiff's burden of stating facts. *Simons v. Marshall,* 369 Ark. 447, 154-55, 255 S.W.3d 838, 843-44 (2007). To survive a motion to dismiss, a complaint must allege facts which, if proven, would establish "every *fact and element* essential to the cause of action[.]" *Kohlenberger, Inc. v. Tyson's Foods, Inc.,*

256 Ark. 584, 590, 510 S.W.2d 555, 560 (1974) (emphasis added). Plaintiff's Complaint here fails to meet these pleading standards, and the Court should dismiss.

I. THE COURT LACKS JURISDICTION OVER THIS CASE UNDER THE DOCTRINE OF SOVEREIGN IMMUNITY.

The Court should dismiss Plaintiff's Complaint for failure to state facts overcoming the Defendants' sovereign immunity from suit. "[S]overeign immunity is jurisdictional immunity from suit, and jurisdiction must be determined entirely from the pleadings." *Ark. Tech Univ. v. Link*, 341 Ark. 495, 501, 341 Ark. 495, 812 (2000). This immunity arises from Article 5, § 20 of the Arkansas Constitution, which makes clear that "[t]he State of Arkansas shall never be made defendant in any of her courts." The Supreme Court of Arkansas has repeatedly held that sovereign immunity bars suit against not only the State itself, but also suits against state agencies and employees sued in their official capacities. *Bd. of Trs. of Univ. of Ark. v. Burcham*, 2014 Ark. 61, at 3; *Ark. Dep't of Community Corr. v. City of Pine Bluff*, 2013 Ark. 36, at 3, 425 S.W.3d 731, 733. If a judgment for the Plaintiff will operate to control the action of the State or subject it to liability, then the suit is barred by the doctrine of sovereign immunity unless one of a few narrow exceptions applies. *Ark. Dep't of Community Corr.*, 2013 Ark. 36, at 4, 425 S.W.3d at 734. In his Complaint, Plaintiff has requested injunctive relief and a judgment that would operate to control the actions of the State and subject it to potential liability for costs and attorneys' fees, so his lawsuit is barred unless one of those narrow exceptions applies.

None does. The illegal-acts exception is the only one that could possibly apply here under the facts alleged in the Plaintiff's Complaint. *See id.* To survive a motion to dismiss under the illegal-acts exception, the Plaintiff must state facts showing a plausible claim that the Defendants acted illegally or unconstitutionally. *See id.* at 3-4, 425 S.W.3d at 733-34; *Link*, 341 Ark. at 501, 504, 507, 17 S.W.3d at 813-14, 817. The Plaintiff fails to do so in his Complaint because he does not state a valid FOIA claim. Therefore, the Court should dismiss the Complaint, and thus the entire lawsuit, for lack of jurisdiction pursuant to the doctrine of sovereign immunity. *Ark. Lottery Comm'n v. Alpha Mktg.*, 2013 Ark. 232, at 7-15, 428 S.W.3d 415, 420-24 (2013).

A. The Complaint is barred by sovereign immunity because the lethal-drug information requested by Shults is confidential and not subject to disclosure under the FOIA.

On the undisputed facts, disclosure of lethal-drug package inserts and labels would identify or lead to the identification of sellers or suppliers of those drugs in violation of the Method of Execution Act, Ark. Code Ann. § 5-4-617(i)(2)(B). Manufacturers are "sellers" or "suppliers" in the chain of distribution and therefore fall within the MEA's confidentiality provisions under their plain terms. Interpreting the confidentiality provisions of the MEA to include manufacturers, moreover, comports with both legislative intent and public policy. Given the specific confidentiality afforded this information under the MEA, it is not subject to disclosure under the FOIA as a matter of law. Because Shults has failed to state a

cognizable claim, his suit is barred by sovereign immunity, and the Court should dismiss the case with prejudice.

1. The Method of Execution Act expressly requires the ADC to maintain the confidentiality of lethal drug sellers and suppliers.

The basic rule of statutory construction is to "give effect to the intent of the legislature." *Hammerhead Contracting & Dev't, LLC v. Ladd*, 2016 Ark. 162, at 7, 489 S.W.3d 654, 659. "The first rule of statutory construction is to construe a statute just as it reads, giving the words their ordinary and usually accepted meaning." *Id.* As discussed below, the plain language of the MEA requires the ADC to maintain the confidentiality of lethal drug sellers and suppliers.

The Arkansas General Assembly amended the Method of Execution Act in 2015, in part, "to address the problem of drug shortages." Ark. Act 1096 of 2015, § 1(a). In addition to adopting a new drug protocol, Act 1096 included new nondisclosure provisions providing that "[t]he department shall keep confidential all information that may identify or lead to the identification of . . . [t]he entities and persons who compound, test, sell, or supply the drug or drugs . . . for the execution process." Ark. Code Ann. § 5-4-617(i)(2)(B). The act permits the ADC to disclose package inserts and labels for bulk-manufactured, FDA-approved drugs upon request, ***but only if*** "information that may be used to identify" a "seller" or "supplier" "is redacted and maintained as confidential." Ark. Code Ann. § 5-4-617(j)(1). Thus, when construing the statute just as it reads, it clearly affords confidentiality to any seller or supplier of lethal-injection drugs.

2. Manufacturers "sell" and "supply" lethal drugs in the distribution chain.

As discussed above, the confidentiality provisions in the MEA are broadly worded to apply to any seller or supplier of lethal drugs. *See* Ark. Code Ann. § 5-4-617(i)(2)(B) & (j)(1). The MEA does not define the terms "seller" or "supplier," so this Court affords those words their ordinary and usually-accepted meaning. *Hammerhead Contracting*, 2016 Ark. 162, at 7, 489 S.W.3d at 659. According to Black's Law Dictionary, a "seller" is "[o]ne who sells anything" and a "supplier" is a "party supplying services or goods." *See* http://thelawdictionary.org/seller/ and http://thelawdictionary.org/supplier/ (last visited Sept. 18, 2017). And the Arkansas Supreme Court has recognized for well over a century that manufacturers "sell" or "supply" their products in the stream of commerce. *See, e.g., Mosley Mach. Co. v. Gray Supply Co.*, 310 Ark. 214, 833 S.W.2d 772 (1992) (discussing implied duties and warranties running from "the manufacturer-seller in a sales contract" to the purchaser); *Crow v. Fones Bros. Hardware Co.*, 176 Ark. 933, 4 S.W.2d 904 (1928) (using terms "manufacturer," "seller," and "supplier" interchangeably); *Jeffries v. State*, 52 Ark. 420, 12 S.W. 1015 (1890) (holding that, "as in all commercial transactions, [a] manufacturer may sell by his agents").

Under the plain meaning of the MEA, a drug manufacturer is a seller or supplier in the lethal-drug distribution chain. Public records available here in Arkansas—filed by some of the manufacturers of Arkansas's lethal drugs, no less—demonstrate that lethal-drug manufacturers "sell" or "supply" them to distributors and place the drugs into the stream of commerce. *See infra* Part I.A.4. As a result,

this Court should conclude as a matter of law that drug manufacturers are sellers and/or suppliers within the scope of the MEA's confidentiality provisions.

3. The State's interpretation of the statute gives full effect to all of its provisions and is consistent with legislative intent.

In construing any statute, this Court places it beside other relevant provisions and "ascribe[s] meaning and effect to be derived from the whole." *State v. Colvin*, 2013 Ark. 203, at 7, 427 S.W.3d 635, 640. "Statutes relating to the same subject must be construed together and in harmony, if possible." *Id.* The stated purpose of Act 1096 was to help remedy the problem of lethal-drug shortages. Act 1096 of 2015, § 1(b). To that end, the legislature afforded complete confidentiality to drug sellers and suppliers as well as entities and persons who compound and test drugs (along with others involved in the execution process). Ark. Code Ann. § 5-4-617(i)(2) & (j)(1). While the MEA does contemplate disclosure of redacted package inserts and labels for drugs made by FDA-approved manufacturers (which includes the midazolam at issue here), that disclosure provision mandates that the ADC "redact[] and maintain[] as confidential" all "information that may be used to identify" any "seller" or "supplier." Ark. Code Ann. § 5-4-617(j)(1).

As established by the affidavit of ADC Deputy Director Rory Griffin in *Shults I*, the *only* way to reconcile the MEA's mandatory confidentiality and disclosure provisions under the undisputed facts of this case is for the ADC to decline disclosure altogether of package inserts and labels for its recently-acquired midazolam. *See* Griffin Aff., Mot. to Dismiss Ex. 2. Based on recent experience, ADC knows that any disclosure short of complete and wholesale redaction would

lead to the identification of the seller or supplier of the ADC's midazolam based on the unique format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance of drug package inserts and labels in the ADC's possession. *See id.* This Court can and should take judicial notice of the fact that news reporters published the names of lethal-drug manufacturers—including the manufacturer of ADC's previous supply of midazolam—despite the ADC's redaction of all of the obvious identifying information on the package inserts and labels (such as manufacturer name, logo, address, and the like). *See* Compl. Ex. 1(B) at 2; Griffin Aff., Mot. to Dismiss Ex. 2, at 2. That prior experience demonstrates that it is simply not possible for the ADC to redact the requested package insert and label of the midazolam in a way that would protect the confidentiality of the seller or supplier of the drug as required by the MEA. The ADC's interpretation is the only possible way to reconcile the various MEA provisions on the undisputed facts of this case.

4. As a matter of public policy, lethal-drug confidentiality provisions should apply to all sellers and suppliers in the chain, including the original manufacturers.

Public policy is best served by an interpretation of the MEA's confidentiality provisions that includes manufacturers. In sustaining the constitutionality of the MEA's confidentiality provisions in *Kelley v. Johnson*, the Court observed that the General Assembly has declared, as a matter of public policy, that capital murder may be punishable by death. 2016 Ark. 268, at 26, 496 S.W.3d 346, 363 (2016), *cert. denied sub nom. Johnson v. Kelley*, 137 S. Ct. 1067 (2017). The Court also

recognized that the State "has a legitimate interest in carrying out a sentence of death in a timely manner," and the General Assembly adopted the confidentiality provisions of the MEA "[i]n aid of that process." *Id.* (quoting *Baze v. Rees*, 553 U.S. 35, 61 (2008)). This Court should similarly interpret the MEA's confidentiality provisions in this case with that public policy in mind.

The *Kelley v. Johnson* Court specifically noted the "undisputed affidavits" offered by the ADC in that case that "demonstrate[d] ADC's own obstacles to acquiring the drugs and the unwillingness of suppliers to sell the drugs to a department of correction." *Id.*, 2016 Ark. at 25, 496 S.W.3d at 362. It was an undisputed fact in *Kelley* that the ADC's supplier of the drugs it had at that time "agreed to provide them only on the condition of anonymity, and that supplier is no longer inclined to sell the drugs to ADC." *Id.* The undisputed evidence in that case also established "that manufacturers prohibit distributors from selling the drugs to departments of correction." *Id.* This Court observed that, "[g]iven the practical realities of the situation," public disclosure of the identity of suppliers of drugs for lethal injections would frustrate the State's ability to carry out lawful sentences. *Id.* at 25-26, 496 S.W.3d at 362-63. The Court noted further that "[t]he General Assembly has determined that there is a need for confidentiality" and "[t]he question whether the enactment is wise or expedient is a matter exclusively for the General Assembly to decide." *Id.* at 26, 496 S.W.3d at 363.

In a subsequent challenge to the MEA brought by the same prisoners in *Kelley* in a federal-court case styled *Jason McGehee, et al. v. Asa Hutchinson, et al.*,

U.S. District Court for the Eastern District of Arkansas No. 4:17-cv-00179-KGB, two lethal-drug manufacturers sought leave to file an *amicus* brief in support of the prisoners' case. *See* Mtn. for Leave by Fresenius Kabi USA, LLC, and West-Ward Pharmaceuticals Corp. (Apr. 13, 2017) in Case No. 4:17-cv-00179-KGB (DE 42). In their supporting brief, the manufacturers objected to the State of Arkansas's use of their drugs in lethal injections "despite the Manufacturers' implementation of distribution protocols to prevent this[.]" *Id.*, DE 43 at 2.

Fresenius Kabi, which manufactures most of the potassium chloride in the United States, averred that "[i]f the State of Arkansas has obtained Fresenius Kabi-manufactured potassium chloride to use in capital punishment—as appears to be the case—it would have been contrary to and in violation of the company's contractual supply-chain controls." *Id.* at 4. Fresenius Kabi specifically referenced (and attached as an exhibit to its federal-court filing) a redacted label and package insert previously produced by the ADC in response to FOIA requests to show that the ADC's potassium chloride "originated from Fresenius Kabi[.]" *Id.*

Similarly, West-Ward explained that it appeared to be the manufacturer of the State's midazolam based on another redacted label and package insert previously disclosed by the ADC. *Id.* at 5. Like Fresenius Kabi, West-Ward detailed the various efforts it has undertaken to keep its drugs out of the hands of departments of correction for use in capital punishment, including the implementation of "distribution controls to ensure that the drugs are not used in connection with lethal-injection protocols, including instructing that such medicines

be sold only to pre-authorized customers who agree not to sell them to departments of correction, other entities that intend to use them for lethal injection, secondary distributors, or retail pharmacies." Doc. 43 at 5. West-Ward complained that the ADC's acquisition of its midazolam for use in capital punishment violated those "contractual controls." *Id.* at 5-6. These public records demonstrate why the broadest possible construction of the MEA's confidentiality provisions is required to protect the ADC's lethal-drug supply.

An interpretation of the MEA's confidentiality provisions in a way that includes drug manufacturers would further the express purpose of the MEA—to help the ADC acquire the drugs that are necessary for it to perform its legal duty and carry out lawful sentences. Absent such an interpretation, drug manufacturers will continue to be publicly identified in published news reports and will continue to interject themselves into litigation in an effort to halt the State's use of their drugs for capital punishment. In addition, public pressure from anti-death-penalty advocates likely would lead manufacturers to implement even more distribution controls that would, as a practical matter, make it impossible for the State to acquire the drugs in its lethal-injection protocol. *See Glossip v. Gross*, 135 S. Ct. 2726, 2733 (2016) (discussing the "practical obstacle" to lethal injection that emerged when "anti-death-penalty advocates pressured pharmaceutical companies to refuse to supply the drugs used to carry out death sentences"). This Court should not sanction such a result, which would obliterate the stated purpose for the MEA's confidentiality provisions.

5. The confidentiality provision in the Method of Execution Act trumps the FOIA.

The intent of the General Assembly in adopting broad confidentiality provisions in Act 1096 of 2015 would be thwarted if the ADC is forced to disclose package inserts and labels that identify lethal-drug sellers and suppliers in response to FOIA requests. Both the MEA and the FOIA govern disclosure of public records in response to citizen requests, so they are in *pari materia* and must be construed harmoniously, if capable of reconciliation. *Bd. of Trustees for the City of Little Rock Police Dep't Pension & Relief Fund v. Stodola*, 328 Ark. 194, 200, 942 S.W.2d 255, 258 (1997).

The MEA is a specific statute that concerns the disclosure of lethal-drug package inserts and labels in response to citizen requests. Ark. Code Ann. § 5-4-617(j)(1). The FOIA relates to disclosure of public records generally. *See* Ark. Code Ann. § 25-19-101 *et seq.* "A general statute must yield when there is a specific statute involving the particular subject matter." *Stodola*, 328 Ark. at 201, 942 S.W.2d at 258. In addition, the fact that Act 1096's confidentiality and disclosure provisions were enacted in 2015, long after the FOIA, is a factor to which our Supreme Court has given credence in statutory interpretations. *Id.* (citing *Donoho v. Donoho*, 318 Ark. at 639, 887 S.W.2d at 291; *Moore v. McCuen*, 317 Ark. 105, 876 S.W.2d 237 (1994); *Uilkie v. State*, 309 Ark. 48, 827 S.W.2d 131 (1992)).

Under these principles of statutory construction, this Court should hold that the lethal-drug package inserts and labels requested by Shults are not subject to disclosure under the FOIA. While both the MEA and the FOIA deal with disclosure

of public records, when the records requested relate to lethal-injection drugs (or other information covered by the MEA), § 5-4-617(j)(1) controls. *See id.* The clear intent behind § 5-4-617, as expressed by the General Assembly's legislative findings in Section 1 of Act 1096 of 2015, is to address the problem of lethal-drug shortages by affording confidentiality to all participants in the process, including drug sellers and suppliers. Act 1096 is the more specific, and the more recent, statute governing disclosure of records regarding lethal-injection drugs. It therefore controls under longstanding Arkansas Supreme Court precedent.

6. Even if the identity of lethal-drug manufacturers is not confidential under the Method of Execution Act, the ADC still must redact certain information from drug labels to protect the confidentiality of other sellers and suppliers in the chain of distribution.

In the alternative, even if this Court concludes that the Complaint states a cognizable FOIA claim (which it does not), the Court should nevertheless dismiss that portion of Shults's claim seeking wholesale unredacted disclosure of lethal-drug labels. As a matter of law, those labels contain unique identifying information such as lot and batch numbers that could lead to the identification of downstream sellers and suppliers—including the entity or person that sold or supplied the drugs to the ADC—in violation of the MEA. *See* 21 C.F.R. § 210.3(b)(11) (defining "lot number, control number, or batch number" as "any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and *distribution* of a batch or lot of drug product or other material can be determined") (emphasis added). The MEA

expressly requires the ADC to maintain confidentiality of "all information that *may* identify or lead to the identification of" sellers and suppliers of lethal drugs. Ark. Code Ann. § 5-4-617(i)(2)(B) (emphasis added). Lot numbers, batch numbers, and the like clearly fall within the scope of that protection, even if the Court determines that manufacturers do not.

For all of the foregoing reasons, the Court should conclude that the Complaint fails to state a cognizable FOIA claim and is therefore barred by sovereign immunity.

II. THE PENDING FIFTH DIVISION CASE BARS THIS SUIT UNDER ARK. R. CIV. P. 12(b)(8).

Rule 12(b)(8) of the Arkansas Rules of Civil Procedure requires dismissal of a complaint when there is another action pending between the same parties that involves the same issues. Ark. R. Civ. P. 12(b)(8). Under that rule, when a suit is brought while another suit is pending between the same parties concerning the same subject matter, the trial court where the second suit is brought has no choice but to dismiss the second suit. *Brandon v. Ark. W. Gas Co.*, 76 Ark. App. 201, 212, 61 S.W.3d 193, 201 (2001) (citing *Mark Twain Life Ins. Corp. v. Cory*, 283 Ark. 55, 670 S.W.2d 809 (1984)). Here, court records show that this case and *Shults I* involve the same parties and subject matter. In both cases, Shults requested disclosure of lethal-drug records under the FOIA, and the ADC declined to produce the records on the basis that they are confidential under the MEA because they revealed the identity of a "seller" or "supplier" of lethal drugs. Both cases involve the issue of whether a drug manufacturer is a "seller" or "supplier" that must be

afforded confidentiality under the MEA. *Compare* Complaint here *with Shults I* Compl., Mot. to Dismiss Ex. 1. Thus, the Court should dismiss this case under Rule 12(b)(8).

Dismissal makes practical sense as well because the outcome of *Shults I* will bar relitigation of Shults's lethal-drug FOIA claim under the doctrines of *res judicata* and collateral estoppel. *Res judicata* puts an end to litigation by preventing a party who had one fair trial on a claim or cause of action from relitigating the matter a second time. *Powell v. Lane*, 375 Ark. 178, 185, 289 S.W.3d 440, 444 (2008); *Jayel Corp. v. Cochran*, 366 Ark. 175, 178, 234 S.W.3d 278, 281 (2006). Similarly, collateral estoppel bars relitigation of factual or legal issues that were determined in a prior court action. *Bradley Ventures, Inc. v. Farm Bureau Mut. Ins. Co.*, 371 Ark. 229, 264 S.W.3d 485 (2007). The Arkansas Supreme Court will decide whether lethal-drug labels and package inserts are subject to disclosure under the FOIA in *Shults I*. Regardless of the outcome of that appeal, the parties here will be bound by that decision under the doctrines of *res judicata* and collateral estoppel. That decision will also conclusively bind this Court under the doctrine of *stare decisis*.

III. IN THE ALTERNATIVE, THE COURT SHOULD STAY THESE PROCEEDINGS PENDING THE FINAL RESOLUTION OF *SHULTS I*.

In the alternative, this Court should stay all proceedings until final resolution of the appeal in *Shults I*. As discussed above, that appeal involves the same factual and legal issues presented here, and its resolution will control the outcome of this case. In addition, and any disclosure order in this case would

effectively void the emergency stay granted by the Supreme Court in connection with *Shults I*. *See* Mot. to Dismiss Ex. 4. A stay of circuit court proceedings is warranted under these circumstances. *See Unborn Child Amendment Comm. v. Ward*, 318 Ark. 165, 883 S.W.2d 817 (1994) (granting a stay of state-court proceedings pending resolution of a related federal appeal when the State could not comply with the terms of one injunction without violating the terms of another).

Issuing a stay of circuit court proceedings when related matters are being addressed in a separate proceeding is not uncommon under Arkansas law. For example, Ark. Code Ann. § 16-108-202 permits a stay of circuit court proceedings when the issues are subject to arbitration. *Oakwood Homes Corp. v. Woodall*, 348 Ark. 575, 74 S.W.3d 626 (2002). Likewise, the federal courts in our circuit have issued and affirmed stays pending resolution of related court proceedings. *See, e.g., Manley, Inc. v. Keystone Food Prods., Inc.*, 859 F.2d 80 (8th Cir. 1988) (affirming stay of federal-court proceedings pending outcome of related state-court proceedings); *DeBoom* v. *Raining Rose, Inc.*, 456 F.Supp.2d 1077 (N.D. Iowa 2006) (staying federal action pending final resolution of related state-court appeals).

Importantly, a stay in this matter is consistent with the stay already in effect in the *Shults I* appeal.[2] *See* Mtn. to Dismiss Ex. 4. Had the Supreme Court not issued a stay in *Shults I*, then the ADC would have been deprived of appellate

[2] Rule 8 of the Arkansas Rules of Appellate Procedure—Civil grants the Arkansas Supreme Court the discretion to stay a lower-court judgment pending appeal. *Smith v. Denton*, 313 Ark. 463, 855 S.W.2d 322 (1993).

review. The same is true if the ADC is not granted a stay in the instant matter.[3] Forcing the ADC to disclose confidential and protected drug information in this case (*Shults II*) would effectively deprive the ADC of appellate review in both cases. Equally compelling is Justice Womack's opinion in granting the stay in connection with *Shults I* that would have ordered Shults to return information that ADC had provided under threat of contempt proceedings by Judge Griffen. Justice Womack would have also issued a protective order prohibiting Judge Griffen or the parties from releasing any of the previously-provided information to any third person. *See id.*

Further, the four factors that guide our appellate courts in deciding whether to grant a motion for stay pending appeal support a stay here: (1) the appellant's likelihood of success on the merits; (2) the likelihood of irreparable harm to the appellant absent a stay; (3) whether the grant of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Smith v. Pavan,* 2015 Ark. 474, at 3. First, the ADC has a strong likelihood of success on the merits in *Shults I,* considering the plain and unambiguous language of the MEA, legislative intent, and public policy issues supporting confidentiality for all sellers and suppliers of lethal drugs, including manufacturers. That favorable ruling will control the outcome of this case. Second, absent a stay, the ADC could

[3] Admittedly, Rule 8 of the Rules of Appellate Procedure does not specifically apply to this matter in that the stay sought here is not pending a direct appeal. Nevertheless, the spirit of Rule 8 applies and mitigates in favor of a stay. Consideration of a request for a stay includes preservation of the status quo ante, if possible, and the prejudicial effect of the passage of time necessary to consider the appeal. *Id.*

be irreparably harmed, deprived of appellate review in two cases, and its ability to carry out lawful executions detrimentally frustrated if this Court were to grant the relief requested by Shults. On the other hand, Shults will not be harmed by a stay of this matter. He has no constitutional right to access lethal-drug information. *See Kelley*, 2016 Ark. 268, 496 S.W.3d 346. Finally, the public interest lies in granting a stay to preserve the status quo pending the Supreme Court's resolution of the significant issues of first impression presented in *Shults I.*

All of these reasons support a stay in the event the Court denies the State's motion to dismiss.

CONCLUSION

As shown, the Court should dismiss Shults's Complaint for two independently-dispositive reasons. First, Shults has failed to state a valid FOIA claim, barring his Complaint under the doctrine of sovereign immunity. Second, another action is pending between Shults and the ADC that involves the same factual and legal issues presented here. For both of these reasons, this Court should dismiss the Complaint with prejudice pursuant to Rules 12(b)(1), 12(b)(6), and 12(b)(8) of the Arkansas Rules of Civil Procedure. In the alternative, the Court should stay all proceedings pending final resolution of *Shults I.*

Respectfully submitted,

LESLIE RUTLEDGE
Attorney General

By: */s/ Jennifer L. Merritt*
JENNIFER L. MERRITT (2002148)
Senior Assistant Attorney General
KA TINA R. HODGE (2003100)
Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Tel: (501) 682-1319
Fax: (501) 682-2591
Jennifer.Merritt@ArkansasAG.gov
KaTina.Hodge@ArkansasAG.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I, Jennifer L. Merritt, do hereby certify that on this 18th day of September, 2017, I electronically filed the foregoing with the Clerk of Court using the eFlex electronic filing system, which shall send notification of the filing to any participants. I also certify that I sent a copy of the forgoing via electronic mail to the following:

Alec Gaines, Esq.
againes@williamsanderson.com

Heather G. Zachary, Esq.
hzachary@williamsanderson.com

/s/ Jennifer L. Merritt
Jennifer L. Merritt

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SEVENTEENTH DIVISION

STEVEN SHULTS **PLAINTIFF**

VS. **Case No. 60CV-17-4931**

ARKANSAS DEPARTMENT OF CORRECTION; and
WENDY KELLEY, in her official capacity **DEFENDANTS**

AFFIDAVIT OF RORY GRIFFIN

1. I, Rory Griffin, have personal knowledge regarding the facts stated herein and I am competent to testify.

2. I am employed with the Arkansas Department of Correction ("ADC") as Deputy Director, Health and Correctional Programs. I have held this position continuously since January 1, 2014, and I held this position at all times relevant to this affidavit. I am a Licensed Practical Nurse ("LPN"), I have a Bachelor of Science in Organizational Management, a Master's of Health Administration, and I have worked within the ADC systems since 1992 as a nurse, Health Services Administrator, Administrator of Medical and Dental Services, and Deputy Director, Part of my responsibilities as Deputy Director include assisting the Director in obtaining drugs for the ADC to use in judicial executions. Given my education, professional background, and personal experience, I am very familiar with issues relating to drug packaging and labels.

3. The ADC is required by the Arkansas Method of Execution Act, Ark. Code Ann. § 5-4-617 ("MEA"), to "keep confidential all information that may identify or lead to the identification of . . . the entities . . . who . . . test, sell, or supply the drug or drugs . . . for the execution process." Ark. Code Ann. § 5-4-617(i)(2)(B). While the MEA generally requires the ADC to disclose "[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," ADC may only do so where "the information that may be used to identify the . . . seller, or supplier is redacted and maintained as confidential." Ark. Code Ann. § 5-4-617(j)(1).

4. The ADC attempts to comply with both the disclosure and confidentiality provisions of the MEA in response to requests under the Arkansas Freedom of Information Act, Ark. Code Ann. § 25-19-101 *et seq.* ("FOIA"), for inspection and/or copying of pharmaceutical package inserts and labels of drugs used for the execution process.

5. In the past, the ADC provided copies of lethal-drug labels and package inserts that redacted logos, addresses, lot/batch numbers, and other information that the ADC believed could be used to identify suppliers and sellers. An example of that past practice is shown in Exhibit C to Mr. Shults's affidavit filed with the Complaint in this case. ADC believed at that time that redacted disclosure of drug package inserts and labels would protect the identity of sellers and suppliers of the drugs.

6. As explained in the ADC's August 24, 2017, e-mail to Mr. Shults (Exhibit B to his affidavit), some recipients of the redacted labels and inserts provided by the ADC in 2016, including news reporters, were able to compare the redacted labels and inserts to publicly-available information and readily determine the identity of the drugs' suppliers and/or sellers. This is because each manufacturer's labels and package inserts are unique in many material respects, including format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance. Accordingly, the ADC's past disclosure of redacted labels and inserts failed to comply with the confidentiality provisions of the MEA.

7. In March of 2017, Mr. Shults submitted a FOIA request for copies of the package insert and label for another lethal-injection drug, potassium chloride. At that time, I carefully studied the package insert and label for the potassium chloride and attempted to redact them in a way that was consistent with the confidentiality and disclosure provisions of the MEA. After my careful study of the package insert and label, and my attempts at redaction, I ultimately concluded that it was not possible for the ADC to redact the package insert and label in any fashion—short of complete and wholesale redaction—that would not allow a person in possession of redacted copies of the package insert and label to determine the identity of the drug's supplier and/or seller based on a comparison with publicly-available information about package inserts and labels for sellers and/or suppliers of injectable potassium chloride. As such, ADC declined to produce potassium

chloride labels and package inserts in response to Mr. Shults's request. He filed a lawsuit against the ADC under the FOIA, which remains pending at this time.

8. As stated correctly in Mr. Shults's affidavit (¶ 6), the ADC has recently acquired a supply of midazolam, a drug listed in the ADC's execution protocol. Mr. Shults submitted a FOIA request for the package insert and label for the recently-acquired midazolam on August 21, 2017 (¶¶ 2 & 4).

9. Given the unique character of drug labels and package inserts, the only way for the ADC to comply with the confidentiality provision of the MEA was for the ADC to decline disclosure of those records. Any disclosure without complete and wholesale redaction would lead to the identification of the seller and/or supplier of the ADC's midazolam based on the unique format, style, diction, font, organization, grammar, spelling, size, shape, coloring, and appearance of the package insert and label. Accordingly, the ADC declined to provide copies of the package insert and label for the recently-acquired midazolam in response to Mr. Shults's most recent FOIA request.

10. Drug labels not only reveal the identity of the manufacturer, which is the initial "seller" or "supplier" of the drug into the stream of commerce. Drug labels also contain unique identifying information in the form of lot and/or batch numbers that may be used to trace the drug through the distribution chain, all the way from the manufacturer through its supply chain and to the end user, which in this case is the ADC. Accordingly, the MEA absolutely prohibits the ADC from disclosing lot and/or batch numbers in response to FOIA requests.

11. I declare under penalty of perjury that the above information is true and correct to the best of my knowledge.

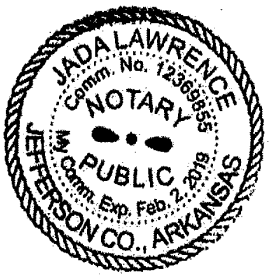
Rory Griffin

STATE OF ARKANSAS)
)
COUNTY OF Jefferson)

Subscribed to and sworn before me this 15th day of September, 2017.

Notary Public

My Commission Expires:



IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SEVENTEENTH DIVISION

STEVEN SHULTS — PLAINTIFF

v. CASE NO: 60CV-17-4931

ARKANSAS DEPARTMENT OF CORRECTION;
WENDY KELLEY, in her Official Capacity — DEFENDANTS

PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, TO STAY PROCEEDINGS PENDING A RELATED APPEAL

Plaintiff, Steven Shults, for his response to Defendants' Motion to Dismiss or, in the Alternative, to Stay Proceedings Pending a Related Appeal, states:

I. Sovereign immunity is not applicable to this case.

The doctrine of sovereign immunity is not applicable to this Arkansas Freedom of Information Act ("AFOIA") appeal. The Defendants try to work around this by arguing the underlying merits of the AFOIA appeal operate as a bar to the claim itself. Defendants' Motion, pp. 7-18. This is not a proper application of Ark. R. Civ. P. 8 and 12.

The Arkansas Supreme Court has recognized three ways in which a claim of sovereign immunity may be surmounted: (1) where the State is the moving party seeking specific relief; (2) where an act of the legislature has created a specific waiver of sovereign immunity; and (3) where the state agency is acting illegally or if a state agency officer refuses to do a purely ministerial action required by statute. *Arkansas Dept. of Correction v. City of Pine Bluff*, 2013 Ark. 36, at *5, 425 S.W.3d 731, 734. A statutory waiver can be express or implied. *Id.* at *5-*6, 425 S.W.3d at 734-35 (*citing* Ark. Code Ann. § 26-18-507(e)(2)(A) which expressly provides

taxpayer may sue State for improperly collected sales tax). Similar to Ark. Code Ann. § 26-18-507(e)(2)(A), the AFOIA is an express waiver of sovereign immunity.

The Policy Statement of the AFOIA states:

> It is vital in a democratic society that public business be performed in an open and public manner so that the electors shall be advised of the performance of public officials and of the decisions that are reached in public activity and in making public policy. Toward this end, this chapter is adopted, making it possible for them or their representatives to learn and to report fully the activities of their public officials.

Ark. Code Ann. § 25-19-102. As an enforcement mechanism, the AFOIA provides:

> Any citizen denied the rights granted to him or her by this chapter **may appeal immediately from the denial to the Pulaski County Circuit Court or to the circuit court of the residence of the aggrieved party, if the State of Arkansas or a department, agency, or institution of the state is involved,** or to any of the circuit courts of the appropriate judicial districts when an agency of a county, municipality, township, or school district, or a private organization supported by or expending public funds, is involved.

Ark. Code Ann. § 25-19-107(a) (emphasis added). Thus, the AFOIA specifically provides that the State may be sued for alleged violations of the AFOIA. Without the ability to sue the State or its agencies to enforce the AFOIA's provisions, the AFOIA would be worthless. The motion to dismiss on sovereign immunity grounds should be denied.

A. The drug package inserts and labels are subject to disclosure under the AFOIA.

ADC argues that manufacturers are "sellers" or "suppliers" subject to the protections of the Arkansas Method of Execution Act ("AMEA"), Ark. Code Ann. § 5-4-617(i)(2)(B). ADC's interpretation of the AMEA is inherently flawed for those reasons stated in Plaintiff's Trial Brief.[1] Additionally, consideration of Defendants' arguments on the merits of the AFOIA appeal is improper in relation to its sovereign immunity argument, as outlined *supra*.

[1] Plaintiff filed a separate trial brief today that refutes Defendants' arguments in sections A1-A6 of the Motion to Dismiss.

II. The Fifth Division Case (now Seventeenth Division) does not bar this suit pursuant to Ark. R. Civ. P. 12(b)(8).

Rule 12(b)(8) does not require a dismissal of this action. Rule 12(b)(8) is "a matter of venue" and only prohibits "*identical* actions from proceeding between identical parties in two courts of this state. *National Bank of Commerce v. Dow Chemical Co.*, 327 Ark. 504, 506, 938 S.W.2d 847, 949 (1997) (emphasis added). "If the objects of two suits are different, they may progress at the same time, although the thing about or in reference to which they are brought is the same in each case." *Wilson v. Sanders*, 217 Ark 326, 328, 230 S.W.2d 19, 21 (1950).

This lawsuit is not *identical* to Case No. 60CV-17-1419 ("Shults I"). That lawsuit concerned ADC's failure to disclose package inserts and labels for its supply of potassium chloride. The instant lawsuit concerns ADC's failure to disclose package inserts and labels for its newly-purchased supply of midazolam. Thus, the suit is not *identical* and should not be barred under Ark. R. Civ. P. 12(b)(8).

III. There is no basis for a stay.

This case should not be stayed pending the final resolution of Shults I. In Shults I, ADC partially complied with Judge Griffen's order by providing Plaintiff unredacted copies of the package insert and a redacted copy of the label. *See* Exhibit 1, Emergency Motion for Immediate Stay, ¶ 8. The only stay that went into effect concerned ADC's failure to disclose unredacted copies of the label for its stock of potassium chloride. *See* Motion to Dismiss, Ex. 4. Thus, a decision by this Court that orders ADC to produce unredacted copies of the package inserts and a redacted copy of the labels for its midazolam supply would not offend the stay in Shults I.

As ADC notes, Ark. R. App. P. 8 is not applicable to ADC's motion for stay. Even if it were, the factors cited by the ADC favor Mr. Shults. Mr. Shults believes there is a high likelihood of his success on ADC's appeal of Shults I. There is no irreparable harm to the ADC

absent a stay because the ADC will continue its executions regardless of the outcome of this case. Despite using its expiring supply of midazolam as a reason to schedule a record eight executions in eleven days in April of this year, ADC miraculously found a supplier to sell it 40 more vials for $250.00 ***cash***. *See* Exhibit 2, ADC Records for August 4, 2017, Midazolam Purchase. It seems evident the ADC is overplaying the difficulty involved in obtaining its supply of execution drugs. On the other hand, Mr. Shults will be irreparably harmed if a stay is granted because it is very unlikely that the Shults I case will be completed by the next execution date (November 9, 2017), which would deprive him his right under the AMEA to ensure ADC's compliance. Finally, the public interest weighs strongly in Mr. Shults favor. The AFOIA demands production of the documents sought by Mr. Shults to ensure public business is conducted in an open and public manner. If a stay is granted, the public will be denied the opportunity to ensure ADC's supply of midazolam is compliant with the protocols of the AMEA. These reasons support a denial of the ADC's stay request.

WHEREFORE, for the reasons cited herein, ADC's motion should be denied in full.

Respectfully submitted,

WILLIAMS & ANDERSON PLC
111 Center Street, Suite 2200
Little Rock, Arkansas 72201
Telephone: 501-372-0800
Facsimile: 501-372-6453

/s/ Alec Gaines
Philip E. Kaplan (AR68026)
pkaplan@williamsanderson.com
Heather G. Zachary (AR2004216)
hzachary@williamsanderson.com
Alec Gaines (AR2012277)
againes@williamsanderson.com

Attorneys for Steven Shults

CERTIFICATE OF SERVICE

On this 18th day of September, 2017, I sent a copy of this pleading by electronic mail only to the following:

Jennifer Merritt
Senior Assistant Attorney General
Office of Arkansas Attorney General Leslie Rutledge
jennifer.merritt@arkansasag.gov

Monty V. Baugh
Deputy Attorney General
Office of Arkansas Attorney General Leslie Rutledge
monty.baugh@arkansasag.gov

/s/ Alec Gaines
Alec Gaines

IN THE ARKANSAS SUPREME COURT

WENDY KELLEY, in her official capacity as Director of the Arkansas Department of Correction, and the ARKANSAS DEPARTMENT OF CORRECTION — APPELLANTS

v. No. CV 17-267

STEVEN SHULTS — APPELLEE

EMERGENCY MOTION FOR IMMEDIATE STAY

Wendy Kelley, in her official capacity as Director of the Arkansas Department of Correction, and the ADC (collectively, "ADC") file this emergency motion for an immediate stay of the circuit court's order and a stay of all circuit-court proceedings pending appeal, and in support, state:

1. Circuit Judge Wendell Griffen has ordered ADC to disclose records that may identify or lead to the identification of the seller and/or supplier of a lethal-injection drug acquired by ADC in violation of the Arkansas Method-of-Execution-Act (MEA), Ark. Code Ann. § 5-4-617.

2. ADC seeks an emergency stay of Judge Griffen's March 31, 2017 *Memorandum Order Granting Plaintiff's Complaint for Relief for Violation of Arkansas Freedom of Information Act.* Judge Griffen has now ordered ADC to appear at 9:00 a.m. April 5 (tomorrow) for a contempt hearing. To avoid a contempt finding, ADC therefore also seeks a stay of all circuit-court proceedings.

If the Court cannot decide this emergency stay motion by the end of business today, ADC respectfully requests that the Court enter a temporary stay as described above until the Court can reach a decision on this stay motion.

3. The lawsuit giving rise to this appeal involves a request for disclosure of records made under the Arkansas Freedom of Information Act (FOIA), Ark. Code Ann. § 25-19-101 et seq. The Plaintiff-Appellee, Steven Shults, is an Arkansas citizen and attorney. He is not a prisoner facing a scheduled execution, nor does he represent a prisoner facing a scheduled execution.

4. ADC recently acquired a supply of bulk-manufactured and FDA-approved injectable potassium chloride for use in executions under the MEA. Dating back to 2016, Plaintiff-Appellee Shults made numerous FOIA requests in which he requested, among other things, copies of any pharmaceutical package inserts and labels for bulk-manufactured and FDA-approved drugs in ADC's possession. On March 10, 2017, ADC wrote a three-page letter to Mr. Shults in response to his then-latest FOIA request, in which ADC acknowledged that it was in possession of package inserts and labels that are potentially responsive to Mr. Shults' FOIA request, but declined to disclose copies of the inserts and labels because ADC determined that the inserts and labels are exempt from disclosure under the MEA because the information contained in the insert and label might lead to the identification of ADC's seller and/or supplier.

5. Plaintiff-Appellee Shults filed a lawsuit under the FOIA on March 23, 2017. On March 29, ADC filed an Answer to the Complaint. ADC submitted an Affidavit of ADC Deputy Director Rory Griffin in which Deputy Director Griffin explained ADC's effort to comply with Shults' FOIA request and ADC's reasoning for concluding that the package inserts and labels could not be disclosed consistent with ADC's confidentiality obligations under the MEA—not even with redactions. And ADC submitted a FOIA Hearing Brief in which ADC outlined its legal argument to support ADC's position. Plaintiff-Appellee Shults submitted a trial brief outlining his position that ADC should not be permitted to redact information that might lead to the discovery of a drug *manufacturer*, as opposed to information that might lead to the discovery of a drug *supplier* or *seller*. Based on the arguments presented by Plaintiff-Appellee Shults' counsel in his trial brief and at the hearing, *infra*, Plaintiff-Appellee Shults concedes that ADC is required to redact information that might lead to the discovery of ADC's supplier and/or seller, as opposed to information that would lead to the discovery of the manufacturer of the potassium chloride.

6. The circuit court held a hearing on March 30, 2017. Counsel for the parties presented argument about the confidentiality provisions of the MEA and whether ADC is required to disclose the drug inserts and labels at all, and if so, whether ADC should redact certain information prior to disclosure. Counsel for

ADC argued that even if information that might lead to the discovery of a drug *manufacturer* is not exempt under the MEA (though ADC contends that it is), at a minimum Judge Griffen must allow ADC to redact any batch numbers, lot numbers, or control numbers appearing on the drug label because those numbers might lead to the identification of ADC's seller and/or supplier. Counsel for the ADC cited 21 CFR 210.3(b)(11), which states: "Lot number, control number, or batch number means any distinctive combination of letters, numbers, or symbols, or any combination of them, **from which the complete history of the** manufacture, processing, packing, holding, and ***distribution*** **of a batch or lot of drug product or other material can be determined.**" *Id.* (Emphases added). Counsel for ADC argued that ADC must be permitted to redact these numbers from any drug label prior to disclosure even if ADC is required to otherwise disclose the package inserts and labels—because the lot/control/batch numbers could lead to the identification of ADC's seller and/or supplier. *See infra* at ¶ 13.

7. After the close of business on March 30, Judge Griffen ordered ADC to "immediately" disclose *unredacted* copies of the package insert and label for the recently-acquired potassium chloride. Judge Griffen expressly and repeatedly explained that ADC was not permitted to redact *any* information from the package insert and label—not even any lot/batch/control numbers appearing on the drug

label. And Judge Griffen told counsel for ADC that ADC had 30 minutes after the conclusion of the hearing to fully comply with his order.

8. Faced with the dilemma of producing confidential information or violating Judge Griffen's order, ADC decided to provide an unredacted copy of the package insert for the potassium chloride, and a *redacted* copy of the label for the potassium chloride. ADC redacted lot/batch/control numbers from the label. ADC disclosed everything else, thereby plainly identifying the manufacturer of the potassium chloride contrary to ADC's position that the manufacturer is confidential under the MEA. But ADC did not disclose the lot/batch/control numbers on the label because that information could lead to the identification of the supplier and/or seller of the potassium chloride in violation of the MEA.

9. ADC filed a notice of appeal in the evening after the conclusion of the March 30 hearing, and on the morning of March 31, ADC lodged a partial record and filed a motion for immediate stay with this Court in Case No. CV-17-261. The Court ordered Plaintiff-Appellee Shults to respond to the motion by 12:00 noon on March 31, and he did. On the afternoon of Friday, March 31, Judge Griffen entered his *Memorandum Order Granting Plaintiff's Complaint for Relief for Violation of Arkansas Freedom of Information* Act—memorializing the ruling he made from the bench after the close of business on the previous day. At 4:24 p.m. on Monday, April 3, the Court entered a formal order in Case No. CV-17-261

dismissing ADC's appeal without prejudice for lack of a written order in the record. Counsel for ADC filed an amended notice of appeal in the court below on April 3 (after the close of business), and obtained and lodged a new partial record with the Clerk on the morning of April 4, 2017, including *inter alia* the complaint, answer, Judge Griffen's written orders, both notices of appeal filed by ADC, and a motion for contempt that has now been filed by Plaintiff-Appellee Shults. As stated in ADC's amended notice of appeal, ADC will ultimately obtain a full record of all proceedings below, including a transcript of the March 30 hearing, for the full appeal in this case. Just this morning, Judge Griffen issued an order compelling ADC to either comply with his March 31 order by 9:30 a.m. today or appear for a contempt hearing at 9:00 a.m. tomorrow, April 5, 2017. This order is included in the partial record.

10. Judge Griffen's March 31 order clearly violates Act 1096 of 2015, codified at Ark. Code Ann. § 5-4-617 (the MEA). The MEA's confidentiality provisions were upheld by this Court in *Kelley v. Johnson*, 2016 Ark. 268, 496 S.W.3d 346 (2016). The General Assembly adopted the confidentiality provisions in the MEA to address the highly-publicized "problem of drug shortages" preventing the ADC from accessing drugs for use in lethal-injection executions. Act 1096, §1(b). It is important to the State and its citizens that this Court decide this question of significant public policy import.

11. The MEA requires ADC to "keep confidential all information that may identify or lead to the identification of . . . the entities . . . who . . . test, sell, or supply the drug or drugs . . . for the execution process." Ark. Code Ann. § 5-4-617(i)(2)(B). While the MEA generally requires ADC to disclose "[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," the ADC may only do so where "the information that ***may be used*** to identify the . . . seller, or supplier is redacted and maintained as confidential." Ark. Code Ann. § 5-4-617(j)(1) (emphasis added). This is reinforced by other portions of the statute, which require the ADC to maintain the confidentiality of "all information that may identify or lead to the identification of" the seller or supplier. Ark. Code Ann. § 5-4-617(i)(2)(B).

12. While the parties disagree about whether the MEA renders confidential information that identifies or may lead to the identification of a drug *manufacturer*, it cannot be honestly disputed that ***at the very least***, § 5-4-617(j)(1) requires redaction of any information on a label or package insert that ***could potentially*** lead to the identification of the ***seller*** or ***supplier*** of the drug.

13. The label that Judge Griffen ordered ADC to disclose *without redaction* contains information that could lead to the identification of the seller or supplier. As explained in 21 CFR 210.3(b)(11), *supra* ¶ 6, the lot number, control

number, and batch number are used to provide a complete history of a drug's distribution. It is very likely that manufacturers and/or their wholesalers could use these numbers to identify the seller or supplier that provided the potassium chloride to ADC. Given that the MEA prevents disclosure of information that ***may*** lead to identification of sellers and suppliers, these indicia should plainly be redacted as confidential under the MEA prior to any disclosure of a drug label.

14. Judge Griffen's March 31 order ignores the plain language of 21 CFR 210.3(b)(11) and ignores the plain language of the MEA that protects the confidentiality of information that may lead to the identification of the seller or supplier of a lethal-injection drug. By forcing disclosure of an ***unredacted*** copy of the drug label at issue, Judge Griffen's order violates the confidentiality provisions of the MEA.

15. ADC requires immediate relief so as not to be in held contempt of Judge Griffen's erroneous order. Indeed, following the Court's dismissal of the ADC's first appeal (Case No. CV-17-261), Plaintiff-Appellee Shults promptly filed a motion for contempt in which he requests that Judge Griffen "find the Defendants in contempt of [Judge Griffen's] March 30, 2017, oral Order, and [Judge Griffen's] March 31, 2017, written Order."

16. Rule 8 of the Arkansas Rules of Appellate Procedure—Civil grants this Court the discretion to stay a lower-court judgment pending appeal. *See Smith*

v. Pavan, 2015 Ark. 474, at 3 (per curiam) (citing *Smith v. Denton*, 313 Ark. 463, 855 S.W.2d 322 (1993)). ADC meets the standard for a stay articulated in *Smith v. Pavan*. This Court's consideration of a request for a stay includes preservation of the status quo ante, if possible, and the prejudicial effect of the passage of time necessary to consider the appeal. *Id.* The Court is also guided by four factors in deciding whether to grant a motion for an emergency stay: (1) the appellant's likelihood of success on the merits; (2) the likelihood of irreparable harm to the appellant absent a stay; (3) whether the grant of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Id.* (Citing *Hilton v. Braunskill*, 481 U.S. 770 (1987)).

17. Beyond being likely to succeed in an appeal of Judge Griffen's order because the order requires disclosure of information that may lead to the identification of ADC's seller and/or supplier, ADC stands to be irreparably harmed without a stay because of the negative and irreversible consequences of revealing the seller and/or supplier of the potassium chloride if ADC is forced to follow Judge Griffen's erroneous order, and the potential for contempt given ADC's choice to redact portions of the label prior to disclosure. The balance of equities is in ADC's favor. As this Court recognized in *Johnson*, there is a strong public interest in and reason for the confidentiality provisions of the MEA; it is the only way sellers and suppliers are even potentially willing to provide ADC drugs

necessary to carry out lawful death sentences. On the other hand, the FOIA requestor in this case is not one of the condemned prisoners nor does he represent one of them. The requestor may have an interest in the information as a citizen, but there is no serious argument that there is any significant harm to him from a stay while the Court decides this appeal.

18. Unless this Court enters a stay immediately, the circuit court's order will effectively deprive ADC of appellate review. Stated differently, if ADC fully complies with Judge Griffen's order as he has ordered ADC to do "without further delay," the order will effectively give the FOIA requestor an unreviewable victory that will completely undermine and obviate the confidentiality provisions in the MEA. No further disclosure should be required until the issue is finally resolved on the merits by this Court.

19. Based on the foregoing, ADC requests an emergency stay of Judge Griffen's March 31 order, as well as a stay of all proceedings in the circuit court pending the final disposition of this appeal. If the Court cannot decide this emergency stay motion by the end of business today, ADC respectfully requests that the Court enter a temporary stay as described above until the Court can reach a decision on this stay motion.

WHEREFORE, the Appellants pray that their Emergency Motion for Immediate Stay is granted, and for all other just and appropriate relief.

Respectfully submitted,

Leslie Rutledge
Arkansas Attorney General

By: /s/ Colin R. Jorgensen
Ark. Bar No. 2004078
Senior Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Tel: (501) 682-3997
Fax: (501) 682-2591
colin.jorgensen@arkansasag.gov

Attorneys for Appellants

CERTIFICATE OF SERVICE

I, Colin R. Jorgensen, do hereby certify that on this 4th day of April, 2017, I filed the foregoing document with the Clerk of the Supreme Court and I served a copy via e-mail upon the following:

Phillip Kaplan
pkaplan@williamsanderson.com

Heather Zachary
hzachary@williamsanderson.com

Alec Gaines
againes@williamsanserson.com

/s/ Colin R. Jorgensen

From: Solomon Graves <Solomon.Graves@arkansas.gov>
Sent: Friday, August 25, 2017 10:02 AM
To: Robin Brady
Cc: Steve Shults; Jim Depriest
Subject: Re: FOIA Request
Attachments: Drug Supply as of 080417.pdf; ATT00001.htm; WK TR-2.pdf; ATT00002.htm

My apologies. See attached.

134

PATIENT Stock

DRUG/STR Vecuronium Bromide 20mg/20mL Vials

DIRECTIONS _____

DOCTOR _____ DOSAGE ROUTE _____

PHARMACY

RX# _____ RX DATE _____

RX# _____ RX DATE _____

RX# _____ RX DATE _____

TRANSFERRED FROM EXCEL CSV

DATE	TIME	QTY ON HAND	AMOUNT USED	RCD FROM PHARM	TOTAL REM	NURSES SIGNATURE
7-12-10	1100	0	0	100	100	
7-19-10	0939	100	1		99	
7-26-10	1135	99		1	100	
8-2-10	1500	5	5		95	
8-9-10	1500	95	5		90	
8-16-10	1500	90	5		85	
8-23-10	1500	85	5		80	
8-30-10	1500	80	5		75	

[redacted]

TRANSFERRED TO EXCEL CSV

DISPOSITION OF UNUSED DRUG

DATE DISCONTINUED _____ METHOD OF DISPOSITION _____ RECUIRED DISCREPANCY

13

14

PATIENT [redacted]
DRUG/STR Potassium Chloride 40 mEq/packet
DIRECTIONS [redacted]
DOCTOR _____ DOSAGE ROUTE _____

PHARMACY _____
RX# _____ RX DATE _____
RX# _____ RX DATE _____
RX# _____ RX DATE _____

TRANSFERRED FROM PAGE _____ SIGNATURE _____

DATE	TIME	QTY ON HAND	AMOUNT USED	RCD FROM PHARM	TOTAL REM	NURSES SIGNATURE	DATE	TIME	QTY ON HAND	AMOUNT USED	RCD FROM PHARM	TOTAL REM	NURSES SIGNATURE
3/9/13	1430	0		100	100								
4/20/13	1120	94	6		94								
4/20/13	1406	88	6		88								
4/20/13	1405	82	6		82								
4/20/13	1405	76	6		76								
4/20/13	1405	70	6		70								

TRANSFERRED TO PAGE _____ SIGNATURE _____

DISPOSITION OF UNUSED DRUG

DATE DISCONTINUED _____ METHOD OF DISPOSITION _____ REQUIRED DISCREPANCY REPORT ON FILE

DATE REMOVED _____ DATE OF DISPOSITION _____ DATE _____

QUAN REMOVED _____ DISPOSITION BY _____ DATE _____

VERIFICATION OF DISPOSITION BY _____

PATIENT [redacted]
DRUG/STR [redacted]
DIRECTIONS [redacted]
DOCTOR [redacted] DOSAGE ROUTE [redacted]

PHARMACY [redacted]
RX# [redacted] RX DATE [redacted]
RX# [redacted] RX DATE [redacted]
RX# [redacted] RX DATE [redacted]

TRANSFERRED FROM PAGE [redacted] QTY [redacted] SIGNATURE [redacted]

DATE	TIME	QTY ON HAND	AMOUNT USED	RCD FROM PHARM	TOTAL REM	NURSE'S SIGNATURE	DATE	TIME	QTY ON HAND	AMOUNT USED	RCD FROM PHARM	TOTAL REM	NURSE'S SIGNATURE
8/4/17	1740	—	—	40	40	[redacted]							

TRANSFERRED TO PAGE [redacted] QTY [redacted] SIGNATURE [redacted]

DISPOSITION OF UNUSED DRUG

DATE DISCONTINUED [redacted]	METHOD OF DISPOSITION [redacted]	REQUIRED DISCREPANCY REPORT ON FILE:
DATE REMOVED [redacted]	DATE OF DISPOSITION [redacted]	DATE [redacted]
QUANTITY REMOVED [redacted]	DISPOSTION BY [redacted]	DATE [redacted]
REMOVED BY [redacted]	VERIFICATION OF DISPOSITION BY [redacted]	

DEPARTMENT OF CORRECTION
MISCELLANEOUS EXPENSE REIMBURSEMENT FORM, TR-2

RECEIVED
AUG 11 2017
ACCOUNTING OPER.

Unit/Division: Central Office/Director's Office
Name of Payee: Wendy Kelley
Place of Residence: Pine Bluff, AR 71603
Address: [redacted]

Date 2017	DESCRIPTION OF EXPENSE - GIVE COMPLETE INFORMATION	AMOUNT
7-Aug	Purchased Midazolam 50mg/10ml vials	$250.00
	See attached receipts	
	[redacted]	
	TOTAL OF MISCELLANEOUS EXPENSES CLAIMED	$ 250.00

I hereby certify that the expenses itemized above are true and correct and were incurred in the performance of official duties.

APPROVED BY:

TRAVEL ADMINISTRATOR OR SUPERVISOR

Wendy Kelley

SIGNATURE OF PAYEE

Retailer [redacted]

Name [redacted] Address

[redacted] DEA registration number

Exp 3/30/14

Description	Quantity	Unit	Price
Midazolam 50mg/10ml inj	40	Vials	$250.00

Purchaser

Arkansas Dept of Correction

Name Address

[redacted] DEA registration number

6814 Princeton Pike, Pine Bluff, AR 71602

Method of Transfer (picked up by the customer, etc.) Picked up

Date of Transaction 8/4/12

Paid in cash PD

[redacted] PD

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SEVENTEENTH DIVISION

STEVEN SHULTS — PLAINTIFF

v. CASE NO: 60CV-17-4931

ARKANSAS DEPARTMENT OF CORRECTION;
WENDY KELLEY, in her Official Capacity — DEFENDANTS

ORDER

The Court held an expedited hearing on September 19, 2017, pursuant to the Arkansas Freedom of Information Act (hereafter "AFOIA") on the September 7, 2017, complaint filed by Steven Shults, in his capacity as a citizen, who seeks information from Defendants relating to the package inserts and labels of the supply of midazolam in Defendants' possession intended for use in lethal injection executions. The parties agree to the following relevant facts:

1) Plaintiff is an appropriate person entitled to bring this action pursuant to AFOIA, Ark. Code Ann. § 25-19-101 et seq.

2) Defendant Arkansas Department of Correction (hereafter "ADC") is a state agency subject to AFOIA.

3) Defendant Wendy Kelly (hereafter "Kelly") is a custodian of the ADC's records under AFOIA.

4) Jurisdiction and venue are proper.

5) On August 21, 2017, Plaintiff submitted a Freedom of Information Act Request to the ADC via e-mail. Complaint, Ex. 1, Ex. A. In his Request, Plaintiff sought, in part, information relating to the ADC's supply of drugs intended for use in lethal injection executions. *Id.*

6) On August 24, 2017, ADC provided a response to the August 21, 2017 AFOIA request. ADC provided records revealing that Director Wendy Kelley acquired 40 vials of midazolam, a drug listed in its execution protocol, on August 4, 2017. Complaint, Ex. 1, Ex. B.

7) ADC did not disclose the package inserts or labels for the newly-acquired supplies of midazolam because it took the position it is "prohibited from disclosing the pharmaceutical package inserts and labels" because the labels could be used to identify the sellers or

suppliers of the drugs to ADC in violation of the Arkansas Method of Execution Act's ("AMEA") (Ark. Code Ann. § 5-4-617) confidentiality provisions.

Having considered the briefing, arguments made by counsel at the September 19, 2017, hearing, and the evidence before it, the Court holds the AMEA 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.

Defendants' contention that "seller" or "supplier" in the AMEA means "manufacturer" violates longstanding principles of statutory construction. The Arkansas General Assembly did not include "manufacturer" among the entities shielded from being identified, despite explicit mention of "manufacturers" in other subsections, including (d)(1) and (j)(1). The General Assembly could have easily included "manufacturer" among the entities whose identity is confidential for purposes of the AMEA had it desired to do so. The General Assembly understood the difference between a "manufacturer," a "seller," and a "supplier" when it enacted the AMEA. Each of these words have distinct meanings in ordinary usage. This was not an oversight by the General Assembly, and the Court refuses to read the word "manufacturer" into (i)(2)(B).

Moreover, the plain language of the AMEA mandates in section (j)(1) 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 [lethal injection protocol] drug or drugs . . . have been made by a manufacturer approved by the [FDA]." (emphasis added). Under ADC's interpretation of the AMEA, this subsection of the Code would be given no effect.

The AMEA permits the ADC to use drugs "made by a manufacturer approved by the [FDA]." The General Assembly expressly mandated that package inserts and product labels for FDA-approved drugs be disclosed upon request so long as information that may be used to identify the seller or supplier is redacted and maintained as confidential. Package inserts and labels are not shielded from disclosure by any provision of the AMEA. Indeed, disclosure of package inserts and labels goes to the very purpose of the AFOIA and AMEA, to ensure that the public may know whether ADC is using execution drugs made by FDA-approved manufacturers. The public, including Plaintiff herein, has no other way to verify whether ADC is complying with that requirement.

WHEREFORE, the Court holds as follows:

1) Defendants do not have sovereign immunity from Plaintiff's lawsuit;
2) Plaintiff's Complaint sets forth a proper claim for relief sufficient to survive Ark. R. Civ. P. 8, 12(b)(1), and 12(b)(6) scrutiny;
3) Plaintiff's Complaint is not barred by Case No. 60CV-17-1419 pursuant to Ark. R. Civ. P. 12(b)(8);
4) Defendants' request for a stay of this proceeding pending the Supreme Court's final determination of the merits of Case No. CV-17-544 is denied;
5) Plaintiff is entitled to receive unredacted copies of the package inserts and labels for Defendants' supply of midazolam;
6) The Defendants violated the AFOIA in failing to produce unredacted copies of the package inserts and labels upon request;
7) The Defendants' position was not substantially justified;
8) The Defendants are hereby Ordered to produce unredacted copies of the package inserts and labels for Defendants' supply of midazolam by 5:00 p.m. on September 28, 2017.

ORDERED, this 22nd day of September, 2017.

Honorable Mackie Pierce
Circuit Judge

Prepared by:

/s/ Alec Gaines
Alec Gaines, Ark. Bar No. 2012277
Williams & Anderson PLC
111 Center Street, Suite 2200
Little Rock, AR 72201

Attorney for Plaintiff

Approved as to Form by:

/s/ Jennifer L. Merritt
Jennifer L. Merritt
Senior Assistant Attorney General
Office of Arkansas Attorney General Leslie Rutledge
323 Center Street, Suite 200
Little Rock, AR 72201

Attorney for Defendants

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SEVENTEENTH DIVISION

STEVEN SHULTS — PLAINTIFF

v. — No. 60CV-17-4931

ARKANSAS DEPARTMENT OF CORRECTION
and WENDY KELLEY, in her official capacity — DEFENDANTS

NOTICE OF APPEAL

The Arkansas Department of Correction and Wendy Kelley, in her official capacity as Director of the Arkansas Department of Correction hereby give notice of their appeal to the Arkansas Supreme Court.

1. **Appealing Parties.** The parties taking this appeal are the Arkansas Department of Correction and Wendy Kelley, in her official capacity as Director of the Arkansas Department of Correction.

2. **Order Being Appealed.** Defendants appeal from the Circuit Court's September 22, 2017, order denying Defendants' motion to dismiss and compelling complete and unredacted disclosure of package inserts and labels for midazolam, a drug Defendants recently acquired for use in lethal-injection executions, by 5:00 p.m. on September 28, 2017.

3. **Designation of Record.** Defendants designate the entire record in this matter as the record on appeal—including all of the pleadings, exhibits, briefs, and the transcript of the hearing held in this case on September 19, 2017.

4. **Certificate of Transcript.** The Defendants have ordered the transcript of the hearing in this matter, which was held on September 19, 2017, and

have also made financial arrangements required by the court reporter under Ark. Code Ann. § 16-13-510(c).

5. **Jurisdiction of the Arkansas Supreme Court.** Defendants take this appeal to the Arkansas Supreme Court, which has appellate jurisdiction in this important matter concerning the death penalty and construction of the Arkansas Method-of-Execution-Act, Ark. Code Ann. § 5-4-617, and the Arkansas Freedom of Information Act, Ark. Code Ann. § 25-19-101 et seq. *See* Ark. R. App. P.—Civil 2(a)(2) ("An appeal may be taken from a circuit court to the Arkansas Supreme Court from . . . [a]n order which in effect determines the action and prevents a judgment from which an appeal might be taken, or discontinues the action"); Ark. Sup. Ct. R. 1-2(b) (providing that the Supreme Court has jurisdiction to hear issues of first impression, issues of substantial public interest, significant issues needing clarification or development of the law, and appeals involving substantial questions of law concerning the validity, construction, or interpretation of an act of the General Assembly).

6. **Abandonment of Claims.** Defendants have not asserted any claims against a party in this matter, so Rule 3(e)(vi) of the Rules of Appellate Procedure—Civil does not apply to them. Moreover, an appealing party is not required to make this statement with regard to the interlocutory order at issue in this appeal. Ark. R. App. P.—Civil 3(e)(vi).

Respectfully submitted,

LESLIE RUTLEDGE
Attorney General

By: */s/ Jennifer L. Merritt*
MONTY V. BAUGH (2008138)
Deputy Attorney General
JENNIFER L. MERRITT (2002148)
Senior Assistant Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201
Tel: (501) 682-1319
Fax: (501) 682-2591
Monty.Baugh@ArkansasAG.gov
Jennifer.Merritt@ArkansasAG.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I, Jennifer L. Merritt, do hereby certify that on this 18th day of September, 2017, I electronically filed the foregoing with the Clerk of Court using the eFlex electronic filing system, which shall send notification of the filing to any participants. I also certify that I sent a copy of the forgoing via U.S. Mail, Return Receipt Requested, to the following:

Alec Gaines, Esq.
Williams & Anderson PLC
111 Center Street, Suite 2200
Little Rock, Arkansas 72201

/s/ Jennifer L. Merritt
Jennifer L. Merritt