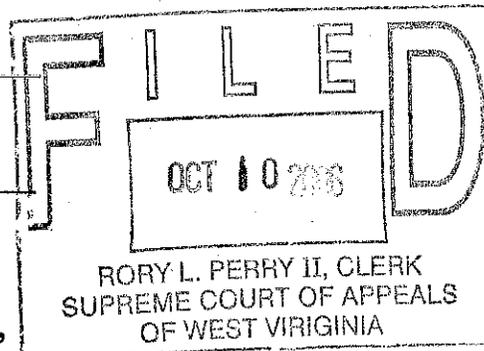


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No. 062498

IN THE SUPREME COURT OF APPEALS
OF THE STATE OF WEST VIRGINIA

CHARLESTON



JOHNSON & JOHNSON CORPORATION, a foreign corporation; and **JANSSEN PHARMACEUTICA, INC.**, a foreign corporation and a wholly-owned subsidiary of **Johnson & Johnson, Inc.**;

Petitioner/Defendant-Below,

v.

THE HONORABLE MARK A. KARL;
DANIEL W. WILSON, M.D.; and
ESTATE OF NANCY J. GELLNER,
By **Gregory A. Gellner, Executor,**

Respondents.

**RESPONSE OF THE ESTATE OF NANCY J. GELLNER
TO THE PETITION OF JOHNSON & JOHNSON CORPORATION
AND JANSSEN PHARMACEUTICA, INC. FOR RELIEF
BY WRIT OF PROHIBITION FROM A JUNE 13, 2006
RULING OF THE HONORABLE MARK A. KARL, IN HIS CAPACITY
AS A JUDGE OF THE CIRCUIT COURT OF MARSHALL COUNTY**

Respectfully submitted:

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Respondents.

Comes now the Respondent, The Estate of Nancy J. Gellner, by and through its counsel and respectfully requests that this Honorable Court deny the Petition for Relief by Writ of Prohibition filed by the petitioners, Johnson & Johnson Corporation and Janssen Pharmaceutica, Inc. In support of this Response, The Estate of Nancy J. Gellner, states as follows:

I. FACTS

On or about May 17, 2001, the Respondent filed this wrongful death action in the Circuit Court of Marshall County, West Virginia alleging, among other things, that the

Petitioners/Defendants below Johnson & Johnson Corporation and Janssen Pharmaceutica, Inc., are strictly liable to the respondents/plaintiffs below for the manufacture, sale and distribution of Propulsid which caused the death of Nancy Gellner.

The respondent, Johnson & Johnson Corporation sold consumer products, prescription drugs and non-prescription medications, including Propulsid, while the respondent, Janssen Pharmaceutica, Inc., was in the business of formulating, manufacturing, packaging, labeling, marketing, advertising, distributing and selling prescription drugs, including Propulsid. Janssen is a wholly-owned subsidiary of Johnson & Johnson Corporation.

The respondent has alleged that Propulsid was sold and/or distributed throughout the United States, including Marshall County, West Virginia, from the time of its FDA approval in approximately 1993 through its withdrawal from the market announced on or about March 23, 2000. In 1998, Propulsid was the 72nd leading prescription drug sold in the United States. In 1999, approximately six million Propulsid prescriptions were filled in this country, and about 30 million have been filled since its approval. Propulsid was withdrawn from the market after having caused hundreds of deaths and countless injuries. After FDA scrutiny that was delayed by the actions of Johnson & Johnson and Janssen, these companies finally succumbed and withdrew the deadly heartburn medicine from the market. Propulsid was a \$500,000,000.00 per year U. S. seller. It is asserted that profits were purposely placed above human life in the decisions to delay the withdrawal of the product from the market.

On May 19, 1999, the respondent's decedent, Nancy J. Gellner, was given samples of Propulsid for day time heartburn by her physician, the respondent and defendant below, Daniel J. Wilson, M.D. Nancy J. Gellner had a history of heart conditions and was taking

several other other medications at the time she was given Propulsid. She took two 20 mg doses of Propulsid on May 19, May 20 and May 21, 1999, and one 20 mg dose on May 22, 1999. On May 22, 1999, Nancy J. Gellner had a sudden cardiac arrhythmia and died. This event was classic as to the publicized problems caused by Propulsid. (See report of Joel Morganroth, M.D. cardiologist dated December 18, 2002 attached as **Exhibit A**).

The respondent alleges that Propulsid contains chemical compounds which when taken by people can have devastating health consequences, including cardiac arrhythmias, which can lead directly or indirectly to death or to a shortened life expectancy, as well as other adverse effects. Additionally, it has been alleged that Propulsid as manufactured, labeled and ultimately delivered to and taken by Nancy J. Gellner is not reasonably safe and thus is a defective product. Moreover, Propulsid was and is defective in that it was not properly conceived, designed, formulated, tested, researched, studied, packaged, distributed and sold and, particularly, in that it was not accompanied by effective and proper warnings and instructions.

Further as part of the complaint, the respondent has alleged that the petitioners/defendants below published, disseminated and circulated misleading information, orally and in print, including labeling, advertising and promotional materials which induced West Virginia residents, including Nancy J. Gellner, to use Propulsid, and which induced West Virginia doctors to prescribe Propulsid and distribute samples of it.

On August 24, 2004, the petitioners filed a motion for summary judgment in the lower court alleging that they met their duty to warn under the learned intermediary doctrine. On or about March 28, 2005, the Honorable Mark A. Karl, Judge for the Circuit Court of Marshall County, denied said motion for summary judgment because genuine issues of fact clearly exist.

The petitioners do not seek prohibition of this ruling. On or about August 26, 2004, the petitioners also filed a *motion in limine* seeking to exclude from trial any evidence suggesting that the petitioners had a duty to warn Nancy J. Gellner of the dangers of Propulsid. The lower court refused to grant said motion, by Order of June 13, 2006, recognizing that the learned intermediary doctrine does not exist in West Virginia. (**Exhibit B** attached). It is with respect to this order that the petitioners now seek to prohibit. The petitioners have conceded at the Trial Court level and in their petition that Judge Karl was correct in finding that the doctrine has not been embraced in West Virginia. However, the petitioners are now attempting the improper procedural avenue of a writ to seek "new law."

II. ARGUMENT

A. The Petitioners Cannot Show That A Writ of Prohibition is the Proper Remedy Under These Circumstances

The petitioners have sought an extraordinary remedy from this Court pursuant to Rule 14(a) of the West Virginia Rules of Appellate Procedure. Specifically, the petitioners seek a writ of prohibition with respect to Judge Karl's denial of their Motion In Limine seeking the application of the learned intermediary doctrine, which has not been adopted in the State of West Virginia.

It is undisputed that a writ of prohibition "lies only to restrain inferior courts from proceeding in causes over which they have no jurisdiction or, in which, having jurisdiction, they are exceeding their legitimate powers and may not be used as a substitute for writ of error, appeal or certiorari." *Crawford v. Taylor*, 138 W.Va. 207, 75 S.E.2d 370 (1953), *syllabus point 1*.

In the instant matter, there has been no allegation that Judge Karl lacks

jurisdiction over the cause at issue. Therefore, "where prohibition is sought to restrain a trial court from the abuse of its legitimate powers, rather than to challenge its jurisdiction, the appellate court will review each case on its own particular facts to determine whether a remedy by appeal is both available and adequate, and only if the appellate court determines that the abuse of powers is so flagrant and violative of petitioner's rights as to make a remedy by appeal inadequate, will a writ of prohibition issue." *Woodall v. Laurita*, 156 W.Va. 707, 195 S.E.2d 717 (1973), syllabus point 2. It is the respondent's contention that the petitioner cannot, under any circumstances, show that Judge Karl abused his discretion, let alone do it in such a way as to be "flagrant and violative" of petitioner's rights. Further, based upon the following, it is clear that the petitioner would have an adequate remedy by appeal, if necessary, thus preventing a writ from issuing.

In *State, ex rel Blackhawk Enterprises, Inc. v. Bloom*, 633 S.E.2d 278 (W.Va. 2006), the West Virginia Supreme Court of Appeals reiterated its long held standards for granting a writ of prohibition and stated that:

In determining whether to entertain and issue the writ of prohibition for cases not involving an absence of jurisdiction but only where it is claimed that the lower tribunal exceeded its legitimate powers, this Court will examine five factors: (1) whether the party seeking the writ has no other adequate means, such as direct appeal, to obtain the desired relief; (2) whether the petitioner will be damaged or prejudiced in a way that is not correctable on appeal; (3) whether the lower tribunal's order is clearly erroneous as a matter of law; (4) whether the lower tribunal's order is an oft repeated error or manifests persistent disregard for either procedural or substantive law; and (5) whether the lower tribunal's order raises new and important problems or issues of law of first impression. These factors are general guidelines that serve as a useful starting point for determining whether a discretionary

writ of prohibition should issue. Although all five factors need not be satisfied, it is clear that the third factor, the existence of clear error as a matter of law, should be given substantial weight.

Id., 633 S.E.2d at 279 (citing, syllabus point 4, State, ex rel Hoover v. Berger, 199 W.Va. 12, 483 S.E.2d 12 (1996)).

In applying the above five factors to the *case sub judice*, it is clear that the petitioners cannot prevail in having their writ issued. First, the petitioners do have other adequate means by which to obtain their desired relief through a direct appeal, post-verdict, if appropriate. The respondent has alleged not only that the petitioners failed to warn the decedent of the dangers of Propulsid, he has also alleged that product medication was defective and not fit for its intended use. Basically, the Johnson & Johnson and Janssen parties sold a heartburn medicine that caused people to die. The risk-benefit of such product obviously did not warrant that it ever be sold. Additionally, the complaint alleges breaches of both expressed and implied warranties as well as negligence and fraud. As for the defense of learned intermediary, this is one part of the defense for failure to warn and not an all encompassing aspect of the case to be tried and defended. The petitioners have admitted that Judge Karl denied their motion for summary judgment based upon the fact that there were material issues of fact in dispute. The trial will flush out these facts and a jury will decide whether or not the petitioners are liable under any or all of the above theories. Certainly, the petitioners will have an adequate remedy at law by virtue of their appeal rights attendant to any verdict against them. And, at that point, it will be clear whether or not the issue of learned intermediary was even a factor in the jury's verdict. It appears that they are attempting to "pre-try" this issue absent resolution by the jury.

In analyzing the second factor set forth in *Hoover*, the petitioners likewise fail in that they cannot show that they will be damaged or prejudiced and to such an extent that is not correctable on appeal. As previously stated, the case to be tried deals with multiple theories against the petitioners. They have not shown that the issue related to the learned intermediary defense will cause them to expend money or time to such an expense that it cannot be remedied by an appeal. Further, should the jury determine that the petitioners failed to warn the decedent of the dangers of Propulsid, and the learned intermediary doctrine was not allowed, the petitioners can simply appeal the issue.

As for the third factor, Judge Karl's order cannot be held to be clearly erroneous as a matter of law in that the petitioners themselves admit that West Virginia has not adopted the learned intermediary doctrine. It is unfathomable to the respondent as to how the lower court can be found to have been wrong in its ruling denying petitioner's Motion In Limine as to their duty to warn the end user, when that motion was based upon a mere assertion that the West Virginia Supreme Court of Appeals may someday, at some point in time, adopt the learned intermediary doctrine. Clearly, Judge Karl adhered to the current common law in this state in denying the motion and rightfully so. And, in that same vein, the petitioners cannot prove, under factor four, that the ruling was an "oft repeated error or manifests persistent disregard for either procedural or substantive law." In fact, the petitioners have failed to cite to any previous rulings by the lower court that are akin to the one at issue.

Finally, the petitioners will attempt to have their writ issued, perhaps, under factor five alone. This, too, will fail. When determining whether the lower tribunal's order raises new and important problems or issues of law of first impression, it is clear that the order itself is

nothing new but rather only determines that there are issues of fact to be decided and that existing law allows the full development of the claims and defenses. In fact, on page 4 of the Order in question, the Court states under paragraph 5 that "existing West Virginia law permits the full development of the claims and defenses as to the adequacy and method of communicating warnings without adopting the Learned Intermediary Doctrine." (*See attached hereto as Exhibit B*). In other words, the court will allow the petitioners to claim that the physician received adequate warnings that he, in turn, should have passed along to the consumer. The lower court is not limiting, in any way, the petitioners' ability to defend itself by offering evidence that the "intermediary" was warned and should have then warned the consumer.

Also, pursuant to *Hinkle v. Black*, 164 W.Va. 112, 262 S.E.2d 744 (1979), this Honorable Court has held that:

In determining whether to grant a rule to show cause in prohibition when a court is not acting in excess of its jurisdiction, this Court will look to the adequacy of other available remedies such as appeal and to the over-all economy of effort and money among litigants, lawyers and courts; however, this Court will use prohibition in this discretionary way to correct only substantial, clear-cut, legal errors plainly in contravention of a clear statutory, constitutional, or common law mandate which may be resolved independently of any disputed facts and only in cases where there is a high probability that the trial will be completely reversed if the error is not corrected in advance.

Id., at syllabus point 1.

Once again, it is the respondent's position that there are no "substantial, clear-cut, legal errors plainly in contravention of a clear statutory, constitutional, or common law mandate" with respect to Judge Karl's order. In fact, just the opposite is true. The learned intermediary doctrine is not a clearly statutory, constitutional or common law mandate - - - it is no mandate at

all. It does not exist under West Virginia law. Judge Karl could not have made a substantial, clear-cut, legal error when there is no law by which he was compelled to adhere.

Based upon the above analysis, it is the respondent's position that a writ of prohibition is not the proper remedy for the petitioners. Should a trial prove that the petitioners breached their duties to the respondent's decedent, then the petitioners can appeal the verdict.

B. West Virginia Does Not Recognize the Learned Intermediary Doctrine Nor Should It

West Virginia has not adopted the doctrine of learned intermediary in products liability cases involving drug manufacturers. It is the respondent's contention that because the fault of parties (manufacturer and doctor) is compared, one with the other, this doctrine is unnecessary in West Virginia.

The petitioner argues that a manufacturer's duty to warn of possible side effects is satisfied if adequate warning is given to a patient's health care provider. This doctrine is an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer. Restatement (3d) of Torts, §6(d).

Despite the fact that several other states have adopted the learned intermediary doctrine, the medical-legal jurisprudence underlying this doctrine is based upon images of health care that no longer exist. Originating in 1948 with the case of Markus v. Specific Pharmaceuticals, 77 N.Y.S.2d 508 (N.Y.Sup.Ct. 1948), the phrase itself was coined in 1966 in the case of Sterling Drug, Inc. v. Cornish, 370 S.E.2d 82 (Cir. 1966). During this time period, there is no question that medical advice was received from a person's physician. Today, medical

services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy departments of supermarkets and often paid for by third-party providers. And, it should be noted that the development of direct-to-consumer advertising has indelibly changed the realities of the physician-patient relationship. It is common occurrence for those watching television to be faced with a barrage of pharmaceutical products which suggest that the ultimate consumer ask their physician to prescribe a particular drug instead of having the physician merely prescribing the medication. There is no doubt that manufacturers believe that they have effective means to communicate directly with consumers. As of 2000, consumer marketing had made the pharmaceutical industry the 13th largest advertiser in the U.S. *Mitchell S. Berger, The Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion, 55 Food & Drug Journal 525 (2000).*

Because pharmaceutical manufacturers are now directly marketing and, as a consequence, benefitting by increased sales, they must also assume an increased share of the risks and duties attendant to selling their products. This Court should not recognize the learned intermediary doctrine because the changed realities of the health care system as set forth above have undermined the rationales upon which that doctrine is based.

The petitioners rely upon *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983), to support their argument that West Virginia should adopt the learned intermediary doctrine. However, in that case, the West Virginia Supreme Court of Appeals held that “the determination of whether a defendant’s efforts to warn of a product’s danger are adequate is a jury question.”

In *Ilosky*, the plaintiff brought a products liability action against a tire manufacturer for its failure to give an adequate warning of an alleged defect to the ultimate consumer. *Id.*, 307 S.E.2d at 610-611. The plaintiff claimed that the Michelin tire she purchased became unreasonably dangerous when used in combination with certain types of other tires and, further, claimed that the manufacturer had a duty to warn her of the hazards associated with such mixed tire use. *Id.*, 307 S.E.2d at 610. This court pointed out that the plaintiff had purchased her tires from a retailer and that the manufacturer might satisfy its duty to warn by providing the retailer with the warning.

Certain jury instructions were the subject of appeal in *Ilosky*. They included one which instructed the jury that the defendant had a duty to adequately warn users of the risks associated with all foreseeable uses. Another one instructed the jury that if it concluded that ultimately users would not be warned by providing warnings to "middlemen" or could not receive an adequate warning by other means, then Michelin had a duty to affix a warning on the tires themselves. Finally, the jury was instructed that the seller of a product has a duty to affix a warning of the dangers or potential dangers of using the product to the product itself where the danger is such that it is unreasonable to entrust conveyance of the warning to ultimate users by middlemen or where it is reasonably foreseeable that ultimate users will not receive adequate warnings not affixed to the product itself.

The *Ilosky* court approved these instructions, and further found that if the jury reached the conclusion that other means would not adequately warn persons such as the plaintiff of the dangers of mixing tire types, then the manufacturer had a duty to adequately warn the plaintiff by affixing a warning to the product itself. This case demonstrates that the West

Virginia Supreme Court of Appeals has recognized that at times a warning to an intermediary may be sufficient, but it equally demonstrates that the Supreme Court has refused to give blanket immunity to a manufacturer who provides warnings only to a middleman of the dangerous circumstances surrounding a product. Therefore, it stands to reason that the learned intermediary doctrine has not been approved in West Virginia and that the Supreme Court in *Ilosky* set forth an adequate standard for the duty to warn when there is an intermediary or middleman. As stated by Judge Karl, current law adequately allows the development of the defenses asserted. Since the comparative fault of the manufacturer and Dr. Wilson will be assessed by the jury, the adequacy of the warnings and method of communicating those warnings are all factors in assessing the issues of comparative fault.

C. Even If the Court Adopts the Learned Intermediary Doctrine, an Exception to that Doctrine Should Exist When Pharmaceutical Manufacturers Engage in Direct-to-Consumer Advertising

Although the *Restatement (3d) of Torts, supra*, sets forth the learned intermediary doctrine, it also has noted that “developing case law” may create exceptions to this doctrine so that, under certain circumstances, the manufacturer of a prescription drug has a duty to warn potential consumers directly rather than simply warning doctors. See *Restatement (3d) of Torts, §6, comment e (1997)*.

At least one court has noted an exception to the learned intermediary doctrine when the drug manufacturer engages in direct-to-consumer advertising. In *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N. J. 1999), the court held that when mass marketing of

prescription drugs seeks to influence a patient's choice of drug, a pharmaceutical manufacturer who makes direct claims to consumers as to the efficacy of its product should not be unqualifiedly relieved of a duty to provide the proper warning of the dangers or side effects of the product.

This exception is a valid one in that consumer-direct advertising belies each of the premises upon which the learned intermediary doctrine rests. First, the fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the physician, not the patient, who decides whether a drug or device should be used.

Second, it is illogical to believe that requiring manufacturers to provide direct warnings to a consumer will undermine the patient-physician relationship, when, by its very nature, consumer-directed advertising interferes with that relationship by encouraging consumers to request prescriptions for advertised drugs by name.

Finally, consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers. Because the FDA requires that ads for prescription drugs and devices carry warnings, the consumer may reasonably presume that the advertiser guarantees the adequacy of its warnings. Thus, the common law duty to warn the ultimate consumer should apply.

With respect to the present case, it is clear that the circumstances supporting an exception to the learned intermediary doctrine when pharmaceutical manufacturers directly advertise to consumers exist. The evidence at trial will show that in the late 1990s, Janssen engaged in an aggressive marketing campaign for its drug Propulsid which was, at least in part,

directed at consumers. Evidence at trial will also show that at some point in the 1990s, Propulsid was the sixth most advertised prescription drug. Having undertaken this aggressive direct-to-consumer advertising campaign, the defendants should be subject to the exception of the learned intermediary doctrine if such doctrine exists in West Virginia placing a duty on them to warn ultimate consumers of the risks of Propulsid.. In addition, the petitioner's own trial exhibits reflect that Janssen affirmatively undertook to have "patient medication guides" delivered directly to consumers through pharmacists and doctors. (See petitioners proposed trial exhibit 2.K. attached hereto as **Exhibit C**).

D. Should the Court Find That the Learned Intermediary Doctrine Applies to This Case and That No Exception to the Doctrine Exists for Direct-to-Consumer Advertising, Defendants' Warnings to Physicians Were Inadequate to Trigger the Doctrine's Protections

Even if the Court finds that the learned intermediary doctrine exists in West Virginia, but without exception for direct-to-consumer advertising, the petitioners' warnings to physicians were inadequate to trigger the doctrine's protections. Under the learned intermediary rule where a prescription drug manufacturer's duty to warn runs only to the learned intermediary, such as a physician, that warning must still be adequate. In the present case, the respondent will offer evidence that the petitioners' warnings to physicians were inadequate, insufficient and/or misleading.

Specifically, at trial it is anticipated that respondent's expert, Joel Morganroth, M.D., a cardiologist will testify that petitioners' communications, literature and promotional materials were insufficient, inadequate and/or misleading in regard to the associated risks and

benefits of Propulsid. In fact, Janssen purposely overstated the effectiveness and downplayed the danger. See Morganroth report of April 29, 2004 attached hereto as **Exhibit D**. Likewise, Dr. Wilson's expert, Bruce Stambler, M.D. finds the warnings wholly inadequate. For example, see transcript of Stambler pages 202 to 207 attached as **Exhibit E**. In addition, respondent will offer evidence that the petitioners provided scripted messages to their sales force to use as a sales pitch telling physicians that recent FDA demands requiring defendants to add black box warnings to the Propulsid literature, new drug interaction warnings, new dear doctor letters and labeling changes were all common events for the most widely prescribed drugs so that the physicians would continue to prescribe Propulsid as before and not be worried about the drug's safety. In essence, they purposely undertook to negate the warnings in favor of profits.

Further, the respondent will also offer evidence to show that the petitioners encouraged physicians and others to assist the petitioners via free dinners, merchandise and other items of value, as well as advertising in medical professional journals and promoting the use of Propulsid. Again, an important part of petitioners' promotional effort was to minimize the importance and significance of the changes in prescribing information made by the petitioners leaving an impression with the physicians that they could reasonably continue to prescribe Propulsid based on the original prescribing information. Remarkably, even after the warnings were increased, Propulsid sales continued to climb due to the successful efforts of the salesmen in overriding the warnings' effectiveness.

In conclusion, even should the learned intermediary doctrine exist in West Virginia, the petitioners cannot claim its protection because the respondent will offer evidence

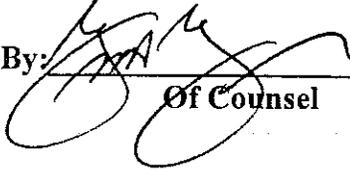
showing that the petitioners' warnings to physicians were insufficient, inadequate and/or misleading.

III. CONCLUSION

Johnson & Johnson's and Janssen's Petition for Writ of Prohibition should be REFUSED because the petitioners have not shown that a Rule to Show Cause should be issued. Upon reviewing the particular facts of this case, it is clear that there are other remedies on appeal both available and adequate, and that the lower court did not abuse its powers, let alone do so flagrantly and violative of petitioner's rights as to make a remedy by appeal inadequate. As such, the Petition for Writ of Prohibition should be REFUSED, as the Circuit Court's ruling is plainly right.

Respectfully submitted,

THE ESTATE OF NANCY J.
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Respondents.

CERTIFICATE OF SERVICE

Service of the foregoing **RESPONSE OF THE ESTATE OF NANCY J. GELLNER
TO THE PETITION OF JOHNSON & JOHNSON CORPORATION AND JANSSEN
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13, 2006 RULING OF THE HONORABLE MARK A. KARL, IN HIS CAPACITY AS A
JUDGE OF THE CIRCUIT COURT OF MARSHALL COUNTY** was had upon the
defendants by depositing a true copy thereof in the United States Mail, postage prepaid, this 9th
day of October, 2006, addressed to counsel for the defendants and a courtesy copy to the
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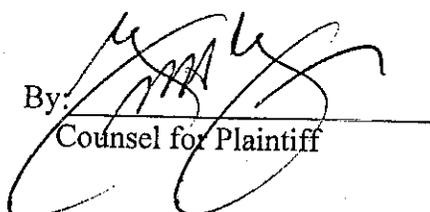
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