

DOCKET NO. 33211

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

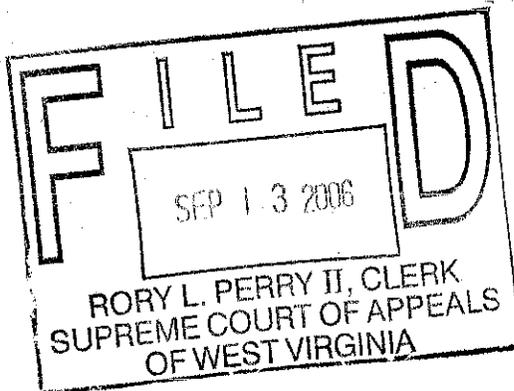
JOHNSON & JOHNSON CORPORATION, a foreign corporation; and JANSSEN PHARMACEUTICA, INC., a foreign corporation and a wholly-owned subsidiary of Johnson & Johnson, Inc.;

Petitioner/Defendant-Below

vs.

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

Respondents.



**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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Comes now the Petitioner/Defendant-Below, Johnson & Johnson and Janssen Pharmaceutica Inc. (hereinafter alternatively referred to as "the Petitioner" or "Janssen"), by and through its respective counsel, and respectfully petitions this Honorable Court for a writ of prohibition. In support of this Petition, Janssen states as follows:

I. PARTIES

Janssen is a corporation doing business in West Virginia, involved in the manufacture, marketing, sales and/or distribution of a prescription medication approved by the Food and Drug Administration known as Propulsid®. This drug was used for the symptomatic treatment of nocturnal heartburn in adults due to gastroesophageal reflux disease ("GERD"). On May 19, 1999, decedent Nancy J. Gellner visited her primary care physician, defendant Dr. Daniel W. Wilson, complaining

of symptoms of "mild reflux." Despite numerous strong, indeed, black box, warnings indicating that Propulsid® was contraindicated, Dr. Wilson prescribed Propulsid® at a dose twice the recommended level according to the label and provided Mrs. Gellner samples of the medication. As set forth in detail below, Dr. Wilson defended his prescribing decision: "[I]t's my job to evaluate her medications, the patient, the whole situation." [Transcript of October 14, 2003 Deposition of Dr. Wilson ("Wilson Dep.") at 297:16 to 18]. Mrs. Gellner died three days later, allegedly from the precise conditions disclosed in the warnings.

The Respondent, The Honorable Mark A. Karl, is a judge of the Circuit Court of Marshall County. It is from a ruling in this capacity, refusing to recognize the application of the learned intermediary doctrine to prescription drug cases as a matter of law that Petitioner's challenge arises.

The Respondent, Gregory Gellner is the son of the decedent and the authorized representative of her estate. He is the Plaintiff in the case below.

The Respondent, Daniel W. Wilson, M.D., was the decedent's family physician. He prescribed Propulsid® to the decedent on May 19, 1999 and is a co-defendant in the case below.

II. ISSUE PRESENTED

Whether the June 13, 2006, ruling of Judge Mark A. Karl rejecting the application of the learned intermediary doctrine to prescription drug cases was arbitrary and capricious or resulted from a clear misapplication of applicable law?

III. RELIEF REQUESTED

WHEREFORE, because the Respondent's June 13, 2006, ruling was arbitrary, capricious and constitutes clear legal error and because there is no other adequate remedy at law, Janssen seeks a writ of prohibition:

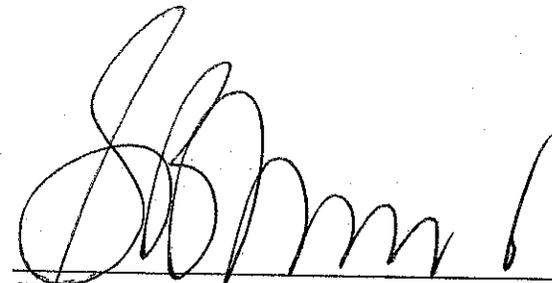
- A. Vacating the June 13, 2006, ruling of Judge Karl;
- B. Confirming West Virginia's adoption of the learned intermediary doctrine in prescription drug cases;
- C. Granting Janssen any and all additional relief deemed just and proper, including, but not limited to, all additional measures necessary to assure that Janssen is adequately protected at the trial of this case in the Court below.

In closing, Janssen requests oral argument on this Petition pursuant to Rule 12 of the West Virginia Rules of Appellate Procedure. Janssen also respectfully directs the Court's attention to the Memorandum of Law in support of its Petition. Finally, should this Court issue a "rule to show cause," a list of those persons to be served has been submitted with this Petition as required by Rule 14(a) of the Rules of Appellate Procedure.

**JOHNSON & JOHNSON and
JANSSEN PHARMACEUTICA INC.,**

Defendants,

By Counsel:



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Respondents.

CERTIFICATE OF SERVICE

I, Stephen B. Farmer, do hereby certify that I have served the foregoing "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" upon all known counsel of record by depositing a true and accurate copy of this pleading in the United States Mail, postage prepaid, as indicated below, this 13th day of September, 2006, addressed as follows:

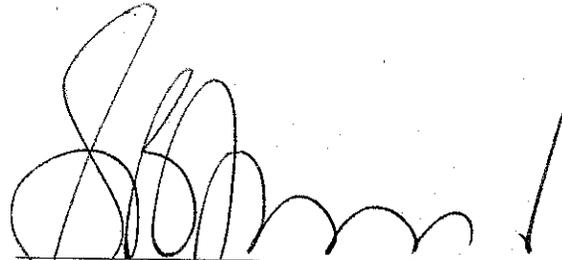
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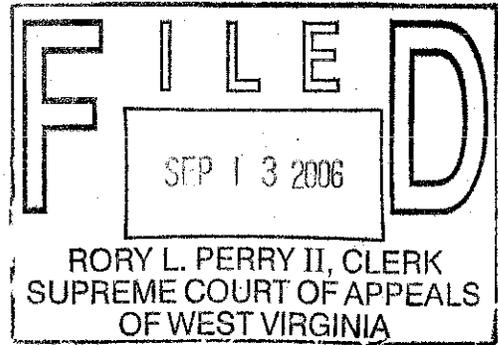
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**MEMORANDUM OF LAW AND CITATION OF RELEVANT AUTHORITIES
IN SUPPORT OF PETITION OF JOHNSON & JOHNSON CORPORATION
AND JANSSEN PHARMACEUTICA INC. FOR RELIEF BY WRIT OF
PROHIBITION FROM A JUNE 13, 2006, RULING OF THE
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Respectfully Submitted

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JUDGE OF THE CIRCUIT COURT OF MARSHALL COUNTY**

**TO THE HONORABLE JUSTICES OF THE SUPREME COURT OF APPEALS OF
WEST VIRGINIA:**

Comes now petitioner Johnson & Johnson and Janssen Pharmaceutica Inc. (hereinafter collectively "Janssen"), by and through its counsel, and petitions this court pursuant to Article VIII, § 3 of the Constitution of West Virginia and West Virginia Code §§ 51-1-3 and 53-1-1 to issue a writ of prohibition against the Marshall County Circuit Court, The Honorable Mark A. Karl presiding, vacating the Court's June 13, 2006, ruling refusing to apply the learned intermediary doctrine to a prescription drug and medical malpractice case pending against Janssen and Daniel W. Wilson, M.D. in the Marshall County Circuit Court.

I. SUMMARY OF ARGUMENT

This Court may issue a writ of prohibition¹ to correct “substantial, clear-cut, legal errors where there is the high probability that the trial will be completely reversed if the error is not corrected in advance.” *Hinkle v. Black*, 164 W. Va. 112, 121, 262 S.E.2d 744, 749-50 (1979). In this prescription medicine case, the Marshall County Circuit Court’s refusal to apply the learned intermediary doctrine constitutes a “substantial, clear-cut, legal error”. Likewise, since the learned intermediary doctrine defines the scope of the manufacturer’s duty, the error must be corrected in advance of the trial.

Pursuant to the learned intermediary doctrine, the manufacturer of a prescribed medicine “fulfills its duty to warn by advising” the prescribing professional “of the dangers of the product.” *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334, 337 (N.D.W. Va. 1995) (citations omitted). Because certain medicines “are only available to the public by prescription,” the doctrine means that once the manufacturer warns the prescribing doctor, it “has no duty to warn the patient.” *Id.* The doctrine is based on the principle that determining “whether certain medications . . . should be utilized in any given case requires an individualized medical judgment which can be made only by the patient’s physician with knowledge of the patient’s characteristics.” *Id. at* 338. Instead of being warned directly from the manufacturer of the prescribed medicine, the patient can rely “on the judgment of an independent physician, who has an obligation to keep informed with respect to medical products.” *Id.*

The learned intermediary doctrine is “nearly universal”. Courts *in all 48 other states* which have considered whether to apply the doctrine have accepted it. Likewise, every

¹ Under W.Va. Code § 53-1-1, the “writ of prohibition shall lie as a matter of right in all cases of usurpation and abuse of power, when the inferior court has not jurisdiction of the subject matter in controversy, or, having such jurisdiction, exceeds its legitimate powers.” Petitioner seeks a writ of prohibition based only on the inferior court exceeding its legitimate powers.

federal court in West Virginia considering the issue has predicted that this state would apply the doctrine. *Id.* The Marshall County Circuit Court's refusal to apply the learned intermediary doctrine breaks rank with the "nearly universal" authority. For these reasons, that decision constitutes clear-cut legal error warranting an immediate writ of prohibition.

II. STATEMENT OF THE CASE

Propulsid[®] (the brand name for cisapride) is a prescription medication approved by the Food and Drug Administration ("FDA") for the symptomatic treatment of nocturnal heartburn in adults due to gastroesophageal reflux disease (GERD). On May 19, 1999, decedent Nancy J. Gellner visited Dr. Wilson, her primary care physician, complaining of symptoms of "mild reflux." The package insert described the patients to whom the medicine should not be prescribed because of their underlying medical condition and/or use of other prescription medications. Despite these strong, indeed, black box, warnings that Propulsid[®] was contraindicated, Dr. Wilson not only prescribed Propulsid[®] at twice the starting dose recommended on the label but also provided Mrs. Gellner samples of the medication. As set forth in detail below, Dr. Wilson defended his prescribing decision: "[I]t's my job to evaluate her medications, the patient, the whole situation." [Transcript of October 14, 2003 Deposition of Dr. Wilson ("Wilson Dep.") at 297:16 to 18]. Mrs. Gellner died three days later, allegedly from the precise conditions disclosed in the warnings.

Mrs. Gellner's estate sued Dr. Wilson for medical malpractice and Janssen, the manufacturer of Propulsid[®], on products liability theories. On August 26, 2004, Janssen filed a motion for summary judgment based on the fact that Janssen had honored its duty to warn Dr. Wilson pursuant to the learned intermediary doctrine. This motion was denied on March 28, 2005, based on the Court's determination that there were still pending disputed

questions of fact, although no order was ever entered. The Court's position on the general application of the learned intermediary doctrine to the case, however, remained unresolved.

This is a pivotal point, because the presentation of proofs and jury instructions at trial hinge on whether West Virginia recognizes the learned intermediary doctrine in prescription drug cases. For this reason, Janssen moved *in limine* to exclude evidence or argument by Plaintiff concerning a duty by Janssen to warn Mrs. Gellner personally. In the absence of a decision by this Court formally adopting the learned intermediary doctrine, however, the trial court declined to apply the doctrine. Conclusions of Law, ¶4. Given the implications of this decision, Janssen seeks a writ of prohibition to resolve this issue.

Propulsid® and the QT Interval

Propulsid® was contraindicated for Mrs. Gellner because, among other things, her electrocardiogram ("EKG" or "ECG") demonstrated prolonged QT intervals, and Propulsid® has the potential to cause potentially fatal adverse events in patients with prolonged QT intervals. The QT interval is the phase of a heartbeat, as measured on an EKG, during which the heart resets or repolarizes in preparation for the next beat. *See In re Propulsid Products Liability Litigation*, 261 F. Supp. 2d 603, 608 (E.D. La. 2003). If the QT interval is prolonged, it is taking the heart longer than normal to prepare for the next beat. In rare circumstances, a patient with QT prolongation may be at risk of developing a type of irregular heartbeat, or arrhythmia, called "torsades de pointes." *Id.* When and if this rare event occurs, the patient may pass out. In the rarest of cases, the patient may die. *Id.* at 607.

Some people are born with congenital Long QT Syndrome, and may experience QT prolongation and the risk of torsades de pointes from an early age. Prolongation of the QT interval may also result from certain cardiac conditions or the use of QT-prolonging

medications. In fact, over seventy commonly used medications are associated with QT prolongation, ranging from cardiac medications (used intentionally to prolong the QT interval) to antibiotics like erythromycin to antifungal medications.

Propulsid®'s FDA-Approved Warnings

When Propulsid® was first approved by the FDA, its propensity to prolong the QT interval was not known. Subsequently, ongoing studies revealed a rare association between Propulsid® and QT prolongation, usually in patients taking other QT-prolonging medications or with underlying medical conditions predisposing them to QT prolongation. Janssen, in conjunction with the FDA, revised and strengthened its warnings and sent "Dear Doctor" letters to advise healthcare providers of the risk of QT prolongation.

The label in use during the time period at issue in this case was implemented in June 1998, nearly a year before Propulsid® was prescribed to the decedent. It contained strongly-worded warnings about the risk of death and the seriousness of potential adverse cardiac events. [See PPI, Part Number 7502614]. The label specifically warned against administration of Propulsid® in patients with a history of QT prolongation and conditions predisposing them to QT prolongation or arrhythmias.² [See PPI, Part Number 7502614]. Specifically, an expanded black box warning at the top of the label highlighted the risks, potential adverse events and contraindications:

² Janssen also warned against use by patients taking any of several types of medications, including cytochrome P-450 inhibitors and medications known to prolong QT intervals on their own (like Nancy Gellner), by patients with chronic obstructive pulmonary disease (COPD) (like Nancy Gellner) and apnea (like Nancy Gellner), and by patients taking diuretics (like Nancy Gellner). [See PPI, Part Number 7502614, implemented in June 1998].

Warning: Serious cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation, torsades de pointes, and QT prolongation have been reported in patients taking PROPULSID®. Many of these patients also took drugs expected to increase cisapride blood levels by inhibiting the cytochrome P450 3A4 enzymes that metabolize cisapride. These drugs include clarithromycin, erythromycin, troleandomycin, nefazodone, fluconazole, itraconazole, ketoconazole, indinavir and ritonavir. Some of these events have been fatal. PROPULSID® is contraindicated in patients taking any of these drugs (See CONTRAINDICATIONS, WARNINGS, PRECAUTIONS and DRUG INTERACTIONS)

QT prolongation, torsades de pointes (sometimes with syncope), cardiac arrest and sudden death have been reported in patients taking PROPULSID® without the above-mentioned contraindicated drugs. Most patients had disorders that may have predisposed them to arrhythmias with cisapride. PROPULSID® is contraindicated for those patients with: history of prolonged electrocardiographic QT intervals; renal failure; history of ventricular arrhythmias, ischemic heart disease, and congestive heart failure; uncorrected electrolyte disorders (hypokalemia, hypomagnesemia); respiratory failure; and concomitant medications known to prolong the QT interval and increase the risk of arrhythmia, such as certain antiarrhythmics, including those of Class 1A (such as quinidine and procainamide) and Class III (such as sotalol); tricyclic antidepressants (such as amitriptyline); certain tetracyclic antidepressants (such as maprotiline); certain antipsychotic medications (such as certain phenothiazines and sertindole); astemizole, bepridil, sparfloxacin and terodiline **(The preceding lists of drugs are not comprehensive.)**

Recommended doses of PROPULSID® should not be exceeded.

Id. (emphasis in original). In other portions of the FDA-approved labeling, Janssen advised physicians that because of the risk of arrhythmia, Propulsid® should be administered only after lifestyle modifications and other therapies failed. *Id.* Under "Contraindications," Janssen reiterated, "Propulsid® is also contraindicated for patients with: history of prolonged electrocardiographic QT intervals, ..." *Id.* The section on "Warnings" provided, in part, "ECG should be considered prior to initiation of cisapride. Cisapride should not be used in patients with a prolonged QT interval at baseline, those with a history of torsades de pointes, or those with long QT syndrome." *Id.* Under "Precautions," Janssen warned, "Potential benefits should be weighed against risks prior to administration of cisapride to patients who have or

may develop prolongation of cardiac conduction intervals, particularly QT." *Id.*

The changes contained in the June 1998 package insert, including the black box warning, were highlighted verbatim in a "Dear Doctor" letter issued on June 26, 1998. [See "Dear Doctor" letter ("DDL") dated June 26, 1998]. They were also included in the Physicians' Desk Reference ("PDR"), which is published annually and supplemented twice yearly as new information becomes available.

Propulsid®'s FDA-Approved Patient Medication Guide

In October 1998, Janssen introduced a Patient Medication Guide. The guide was not an advertisement nor was it promotional in nature. It was reviewed and approved by the FDA as part of the medication's labeling for distribution by physicians to patients after the physicians had weighed the risks and benefits and prescribed the medication to a patient. The first factual statement made about Propulsid® in the Patient Medication Guide is a warning that "PROPULSID® may cause serious irregular heartbeats that may be fatal." *Id.* The Patient Medication Guide also recommended lifestyle changes and the use of acid-reducing agents before Propulsid® use, and included a section on "who should not take Propulsid®," which cautioned that:

- PROPULSID® should not be used in patients with certain medical conditions. In particular, tell your doctor if you have any type of heart condition or kidney or lung disease before taking PROPULSID®. Be sure your doctor knows about your personal and family medical history.
- Tell your doctor about other drugs you are taking, especially diuretics and heart medications. **While taking PROPULSID® do not start a new medicine without first consulting your doctor or pharmacist.**
- If you have not tried other medications to relieve your nighttime heartburn, tell your doctor before using PROPULSID®.

Id. (emphasis in original). The Patient Medication Guide and the package insert were provided to

physicians in a "Dear Healthcare Professional" letter dated November 1998, in which Janssen recommended that physicians include the Guide with every prescription. [See "Dear Healthcare Professional" letter dated November 1998].

Because Mrs. Gellner was a longtime patient of Dr. Wilson he knew she had a heart condition, that she was taking diuretics and other medications, and that she had not tried other medications recently to relieve her nighttime heartburn.

Nancy J. Gellner's Medical History

Mrs. Gellner had a long history of cardiac risk factors, including obesity, hypertension, high cholesterol, hyperlipidemia, cardiomegaly, hypertensive heart disease, valvular heart disease, possible coronary artery disease, dysrhythmia, iron deficiency, anemia and chronic left bundle branch block as well as a family history of heart disease, hypertension and stroke. From 1988 through 1998, Mrs. Gellner was under the care of Dr. Shafqat P. Farooqi, a cardiologist.

Significantly, Mrs. Gellner's EKGs, performed from 1988 forward, repeatedly revealed QT prolongation (i.e., QTc intervals longer than 470 milliseconds). Computer calculations on the EKGs contained in Dr. Farooqi's office chart revealed QTc intervals of 491 ms on February 3, 1988; 500 ms on January 11, 1990; 485 ms on March 8, 1995; 483 ms on March 10, 1995; 494 ms on April 10, 1995; and 512 ms on July 14, 1996. [NJG:PLF:00339, 00111, 00634-635, 636-637, 572-574, 507]. Although the EKGs performed in Dr. Wilson's office between March 1995 and April 1999, do not include computer calculations of QTc intervals, they too demonstrated QT prolongation, [see NJG:DWW:00134, 133, 130, 127, 128, 129], and Dr. Wilson himself acknowledges he could have measured them himself. [Wilson Dep. at 265:24 to 266:19]. Plaintiff's cardiology expert, Dr. Richard P. Friedlander, opines that Mrs. Gellner had a history of QT prolongation and testified that EKGs as late as March 1999 revealed prolonged

QT intervals. [See Transcript of November 22, 2004 Deposition of Dr. Friedlander ("Dr. Friedlander Dep") at 12:5 to 13:13, 42:3 to 25]. Dr. Friedlander's calculations took into account Mrs. Gellner's other cardiac conditions. *Id.* at 53:15 to 54:11.³

On May 17, 1999, an upper gastrointestinal series revealed minimal esophageal reflux, but was otherwise normal. [NJG:PLF:00375]. Notwithstanding Mrs. Gellner's history⁴ of QT prolongation and a diagnosis of only "mild reflux," on May 19, 1999, Dr. Wilson prescribed Propulsid[®] and gave her samples of the medication specifically referencing the Patient Medication Guide. [NJG:PLF:00944; NJG:DWW:00061]. Dr. Wilson did not exhaust other therapies, recommend lifestyle changes or perform an EKG, as recommended in the FDA-approved package insert. Nor, despite of his belief that Ms. Gellner was at an increased risk for a fatal cardiac arrhythmia based on her existing condition, did he contact Dr. Farooqi, the cardiologist with whom Mrs. Gellner treated for over a decade, to discuss her condition, her medications, and the prescription of a contraindicated medication. [Wilson Dep. at 108:23 to 109:14, 267:5 to 268:13].

On May 22, 1999 at 4:30 p.m., Nancy Gellner collapsed at home after helping her companion install an outdoor playground set. She was transported to the hospital, but resuscitative efforts failed. [NJG:PLF:00950-961]. The final diagnosis on the death certificate was sudden death due to suspected cardiac dysrhythmia, with chronic lymphocytic

³ Manual calculations of Mrs. Gellner's QT intervals were also performed by Eric N. Prystowsky, M.D., the defense expert in cardiology and electrophysiology. [See Supplemental Expert Witness Disclosure of Johnson & Johnson and Janssen Pharmaceutica Inc., dated May 27, 2005, Exhibit A]. His evaluation of Mrs. Gellner's EKGs reveal the following:

4/5/99	None	500 ms	NJG:DWW:00129
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⁴ In addition, the records evidence a history of dysrhythmias, multiple cardiac abnormalities, COPD and sleep apnea as well as concurrent use of Albuterol (a QT-prolonging medication), Demadex (a diuretic) and Isoptin (a cytochrome P-450 inhibitor), all contraindicated with Propulsid[®].

leukemia, pending asthma and COPD as other significant conditions contributing to death. [NJG:DWW:00001].

By May 19, 1999, when he prescribed Propulsid[®] for Mrs. Gellner, Dr. Wilson had received numerous warnings that Propulsid[®] was contraindicated in patients like her. This information was communicated to Dr. Wilson by Janssen in the manner expected by Physicians and required by law.

1. Janssen's Dear Doctor Letters

Janssen provided Dr. Wilson with the June 26, 1998 "Dear Doctor" letter with the revised package insert, the November 1998 "Dear Healthcare Professional" letter with the Patient Medication Guide, and all other prior and subsequent "Dear Doctor" letters. Without disputing that the letters were sent by Janssen, Dr. Wilson cannot say whether he received them, [Wilson Dep. at 212:19 to 213:3, 214:8 to 17, 219:15-221:22, 258:20 to 260:8], since by his own admission he is "too busy" to read the mail he receives from drug manufacturers, and accordingly, pursuant to his practice, the "majority [of their mail] gets pitched," or thrown in the garbage. [Wilson Dep. at 181:3 to 182:5, 209:5 to 212:18, 216:18 to 24, 217:14 to 219:2, 221:13 to 22, 226:21 to 227:18, 247:3 to 11].

2. Janssen's Sales Representatives

Dr. Wilson also received numerous copies of the warnings from Janssen's sales representatives David Miller and Arti Malhotra-Arthur. From May 18, 1998 to May 11, 1999, the representatives left 28 sleeves of samples, each accompanied by a package insert, and on each occasion, a physician was required to sign for them. [JPI:DET:00092-99; *see* Transcript of August 9, 2005 Deposition of David M. Miller ("Miller Dep.") at 165:22 to 23; *see*

Transcript of March 15, 2005 Deposition of Malhotra-Arthur ("Malhotra Dep.") at 63:19 to 23]. On November 9 and 17, 1998 and December 7, 1998, the sales representatives provided Dr. Wilson with copies of the "PMG" [Patient Medication Guide] as well. [JPI:DET:00095, 96]. In addition to the package inserts and Patient Medication Guides repeatedly provided with samples, Mr. Miller and Ms. Malhotra left copies of "Dear Doctor" letters with package inserts at Dr. Wilson's office. [Malhotra Dep. at 38:24 to 39:2; Miller Dep. at 198:12 to 22; JPI:DET:00093]. Dr. Wilson acknowledges that they provided up-to-date package inserts when they left samples; indeed, he believes they are mandated to do so. [Wilson Dep. at 253:6 to 15].

3. The Physicians' Desk Reference

Dr. Wilson receives and maintains complimentary copies of the current PDRs, [Wilson Dep. at 19:7 to 15, 180:8 to 23, 254:13 to 255:12, 256:3 to 15], distributed to physicians in November and December of the year prior to their date. Accordingly, the 1999 PDR, which included the June 1998 package insert, was sent to physicians, like Dr. Wilson, in November or December 1998, six to seven months before he prescribed Propulsid[®] to Mrs. Gellner.⁵

Dr. Wilson's Failure to Read Propulsid[®]'s FDA-Approved Warnings

Despite acknowledging that he had available both the PDR and the package inserts provided by Janssen's sales representatives when he prescribed Propulsid[®] to Mrs. Gellner, [Wilson Dep. at 256:3 to 257: 1], Dr. Wilson stated:

Q. Does that mean in – in – in looking back that in May of 1999 – I'm sorry – yeah, May of 1999, when you prescribed Propulsid to Ms. Gellner, you most likely did not consult the contemporary PDR or the contemporary package insert before prescribing it?

A. I most likely did not look at that.

⁵ The two supplements to the earlier 1998 edition were distributed in June 1998 and August or September 1998.

[Wilson Dep. at 257:23 to 258:4 (emphasis added)]. In fact, Dr. Wilson does not recall ever reading the package insert or PDR entry prior to the start of this litigation:

Q. Do you ever remember reviewing a package insert associated with Propulsid?

A. **I'm sure I've looked at it, especially after this case was started.**

Q. I mean — I mean being prior to 19-- prior to May of 1999.

A. **Again, I have no specific recollection of that.**

Q. Do you ever remember consulting the PDR for any reason relating to Propulsid prior to 1999?

A. **I do not have a direct recollection of that.**

[Wilson Dep. at 281:16 to 282:1 (emphasis added)].

Plaintiff's Expert Witnesses

Dr. Richard P. Friedlander (cardiology) and Dr. Arthur H. Herold (family practice), experts retained by *plaintiff*, opined that Janssen's warnings adequately explained that Propulsid[®] was contraindicated for Mrs. Gellner; that Dr. Wilson should not have prescribed Propulsid[®] to Mrs. Gellner; and that Mrs. Gellner died from sudden death due to a lethal ventricular arrhythmia, specifically warned about in Propulsid[®]'s prescribing literature. In his report, Dr. Friedlander notes that Nancy Gellner had a history of QT prolongation.⁶ [May 28, 2001 Report of Dr. Friedlander ("Friedlander Report") at 1]. He observes:

This drug [Propulsid[®]] is know [sic] to increase the QTc interval and predispose individuals to Torsades de Pointes, a very unusual form of ventricular tachycardia. By May 1999, the potential dangers of this medication were well known. Specifically in June 1998, Janssen Pharmaceutica, the manufacturer of Propulsid [sic] announced changes in drug labeling which state that the drug is *contraindicated* in patients with QTc prolongation.

⁶ In his report, Dr. Friedlander opined that EKGs as late as 1996 demonstrated QTc prolongation, [Friedlander Report at 1], however, at deposition, after reviewing additional documents, he testified that EKGs as late as 1999 showed QTc prolongation. [Friedlander Dep. at 12:5 to 13:13].

In summary I am of the opinion that the most likely cause of Ms. Gellner's sudden demise was Torsades de Pointes caused by the administration of Propulsid by Doctor Daniel Wilson on May 19, 1999.

Id. at 1-2 (emphasis in original). During his deposition, Dr. Friedlander unequivocally stated that Propulsid[®] was contraindicated for Mrs. Gellner because of her history of QT prolongation. [Friedlander Dep. at 57:15 to 20]. Indeed, Dr. Friedlander testified, "Any physician worth his salt shouldn't violate a contraindication, a black box contraindication stated in an insert." *Id.* at 65:24 to 66:2. In addition, Dr. Friedlander stated that Mrs. Gellner's history and Emergency Room records were consistent with his conclusion that she died from sudden acute QT prolongation or a lethal arrhythmia – ventricular tachycardia and fibrillation – induced by Propulsid[®]. *Id.* at 40:20 to 41:22, 27:8 to 12, 47:18 to 48:10.

In his report, Dr. Herold concludes that Propulsid[®] was not indicated for Mrs. Gellner due to her diagnosis of mild reflux and that it was contraindicated for various reasons. [February 12, 2004 Report of Dr. Herold at 2]. In addition to Mrs. Gellner's use of contraindicated medications and her underlying medical conditions, at deposition, Dr. Herold testified that Propulsid[®] was contraindicated because of her history of QT prolongation. [Transcript of March 15, 2004 Deposition of Dr. Herold ("Herold Dep.") at 9:15 to 20, 41:14 to 23].

Dr. Wilson's Role as the Learned Intermediary

In prescribing Propulsid[®], Dr. Wilson exercised his discretion and expertise as a physician. Indeed, throughout his deposition he defended this professional prerogative:

Q. A patient who suffers from sleep apnea, COPD, asthma, hypertension, was morbidly obese, had left – this is hypothetical, left ventricular hypertrophy, mitral valve regurg, aortic regurg, left bundle branch block, should that person – is that person in 1999, in May of 1999 a candidate to – to receive a prescription for Propulsid?

....

THE WITNESS: That patient, again, I think you would have to look at their clinical situation. Again, reflux is a significant contributor to asthma, to COPD, to several – several other medical problems and our patient's evaluated and, again, if the clinical benefit risk ratio is felt to be reasonable, then yes, it still could be used.

* * * * *

Q. Do you agree with me that it was your job on May the 19th, 1999, to understand all of Ms. Gellner's physical ailments and conditions before prescribing her Propulsid?

A. **It is my job to know my patient, to make the best medical choices and decisions for her that I can at the time.**

Q. Was it your job to understand and be familiar with all of her physical conditions that day before prescribing her Propulsid?

....

THE WITNESS: Again, it's my job to try to understand my patient, what's gone on before, now and put all of that into prospective and to make a clinical decision on what's best for her.

* * * * *

Q. It is your job and nobody else's that day to understand whether adding Propulsid to the other 12 drugs that she was already taking would be dangerous for Ms. Gellner; right?

....

THE WITNESS: Again, it's my job to evaluate her medications, the patient, the whole situation. That is my job as a physician.

[Wilson Dep. at 288:17 to 289:9, 290:19 to 291:10, 297:10 to 19]. There is no doubt that the learned intermediary doctrine was intended to apply to cases such as this one.

III. ARGUMENT AND CITATION OF AUTHORITY

A. This Court Has Jurisdiction To Review The Order Of The Marshall County Circuit Court Through A Writ of Prohibition.

Pursuant to Rule 14(a) of the West Virginia Rules of Appellate Procedure, this Court has original jurisdiction over petitions for writs of prohibition. This Court may issue writs of prohibition not only to restrain inferior courts from acting beyond the scope of their jurisdiction but also to correct “substantial, clear-cut legal errors where there is the high probability that the trial will be completely reversed if the error is not corrected in advance.” *Hinkle*, 164 W. Va. at 121, 262 S.E.2d at 749-50 . For those cases, “not involving an absence of jurisdiction, but . . . where it is claimed that the lower tribunal exceeds its legitimate powers,” courts examine five factors:

- (1) [W]hether the party seeking the writ has no other adequate means, such as direct appeal, to obtain the desired relief;
- (2) [W]hether the petitioner will be damaged or prejudiced in a way that is not correctable on appeal;
- (3) [W]hether the lower tribunal's order is clearly erroneous as a matter of law;
- (4) [W]hether the lower tribunal's order is an oft-repeated error or manifests persistent disregard for procedural or substantive law; and,
- (5) [W]hether the lower tribunal's order raises new and important problems or issues of law of first impression.

Syl. Pt. 4, *State ex rel. Hoover v. Berger*, 199 W. Va. 12, 483 S.E.2d 12 (1996). “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.” *State ex rel. Jeanne U. v. Canady*, 210 W. Va. 88, 94, 554 S.E.2d 121, 127 (2001).

Writs may be issued to correct a “novel and clear-cut” legal issue. *See e.g. Glover v.*

Narick, 184 W. Va. 381, 392, 400 S.E.2d 816, 827 (1990) (writ issued against enforcement of the lower court's order requiring joinder of infant to civil action brought by his mother insofar as joinder would contravene Rule 19(a) of the West Virginia Rules of Civil Procedure). According to well-settled case law, "extraordinary remedies may be used to control the actions of lower courts when a review of those actions by writ of error [appeal] would *prove costly, time consuming and inappropriate to the task at hand.*" *State ex rel. Bd. of Educ. v. Spillers*, 164 W. Va. 453, 456, 259 S.E.2d 417, 419 (1979) (emphasis added)(citations omitted). In *Spillers*, this Court further explained:

The Rules of Civil Procedure's mandate to secure a just and speedy determination of all matters by facilitating a presentation on the merits further recommends such a course. An unduly restrictive and highly technical interpretation of the rules of pleading defeats the various and laudable purposes of the Rules of Civil Procedure. Absent any showing of prejudice to the adverse parties, the relator should not be compelled to proceed through a lengthy and expensive trial to seek a remedy by writ of error.

Id. See also *State ex rel. Crafton v. Burnside*, 207 W. Va. 74, 78, 528 S.E.2d 768, 772 (2000) (appellate court can review the circuit court's decision not to amend the case management order bifurcating the trial); *State ex rel. Tinsman v. Hott*, 188 W. Va. 349, 355, 424 S.E.2d 584, 590 (1992) (holding "because there is no post-trial remedy, such as appeal, that would serve 'the overall economy of effort and money among litigants, lawyers and courts', the proper remedy is a writ of prohibition."); *Gebr. Eickhoff Maschinefabrik v. Starcher*, 178 W. Va. 618, 632, 328 S.E.2d 492, 506 (1985) (court empowered to review propriety of circuit court's pre-trial orders).

Janssen respectfully submits that when the circumstances before the Court are measured against the standards detailed above, there is no question that a writ should issue. In failing to apply the learned intermediary doctrine to define the duty of a manufacturer to warn in cases

involving prescription medications, the Marshall County Circuit Court committed clear legal error for which no other adequate remedy exists. Further, the issue is one of first impression before this Court which has a far-reaching scope in an important area of law.

B. This Court Should Confirm That West Virginia Applies The Learned Intermediary Doctrine in Prescription Drug Cases to Define a Manufacturer's Duty to Warn.

Resolving whether West Virginia applies the learned intermediary doctrine requires determining the existence of a legal duty compelling manufacturers to warn patients about the potential risks unavoidably associated with prescription medications. This is not a question of fact. "[C]ourts bear the sole responsibility for deciding whether a legal duty is owed in a given case." *Strahin v. Cleavenger*, 216 W. Va. 175, 183, 603 S.E.2d 197, 205 (2004). "The determination of whether a defendant in a particular case owes a duty to the plaintiff is not a factual question for the jury; rather the determination of whether a plaintiff is owed a duty of care by a defendant must be rendered by the court as a matter of law." Syl. Pt. 5, *Aikens v. Debow*, 208 W. Va. 486, 541 S.E.2d 576 (2000). The Marshall County Circuit Court's failure to recognize this basic principle is clear error and, in the context of the learned intermediary doctrine, clear error on an issue of first impression to this Court.

As articulated in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, §6(d)(1) (1998), a drug manufacturer's duty is to provide adequate warnings to "prescribing and other healthcare providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings." Section 6(d)(2) recognizes a direct duty to warn the patient "when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."⁷ This

⁷ This Court has recognized the utility of the RESTATEMENT (THIRD) OF TORTS in other contexts. *Strahin*, 216 W. Va. at 188, 603 S.E.2d at 210.

doctrine has long ago been embraced by the common law. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806-12 (E.D. Tex. 2002) (concluding that 49 states, the District of Columbia and Puerto Rico recognize this common law doctrine, which has yet to be the subject of any state or federal decision in Vermont).⁸

For almost 20 years, federal courts applying West Virginia law have assumed that West Virginia recognizes the learned intermediary doctrine. *See, e.g., Rohrbough v. Wyeth Labs., Inc.*, 719 F. Supp. 470, 478 (N.D.W. Va. 1989) *aff'd* 916 F.2d 970 (4th Cir. 1990); *Pumphrey*, 906 F. Supp. at 338. As recently as last year, the Southern District of West Virginia expressed its belief that the learned intermediary doctrine was an element of West Virginia law, recognizing the doctrine arises from “the primary role of the patient’s physician in diagnosing a particular condition or ailment and prescribing a course of treatment and from the reluctance to place a duty on a manufacturer that may interfere with the physician-patient relationship.” *Ashworth v. Albers Med., Inc.*, 395 F. Supp. 2d 395, 407 (S.D.W. Va. 2005). In its decision below, the Marshall County Circuit Court ignored without comment this substantial body of decisional law by jurists intimately familiar with West Virginia law, and instead read this Court’s decision in *Ilosky v. Michelin Tire Corp.*, 172 W. Va. 435, 307 S.E.2d 603 (1983), as mandating that both scope of duty and breach be resolved as questions of fact.

Ilosky, however, never had cause to address whether the learned intermediary doctrine applies, as the case did not involve prescription medications. *Ilosky* concerned the adequacy of a jury charge in a case in which a tire manufacturer attempted to prove, as a matter of fact under the so called “sophisticated users’ doctrine,” that warnings provided to a garage satisfied the manufacturer’s admitted duty to warn end-users. Here, however, what is at issue is the existence

⁸ The District Court in *Norplant* was convinced, based on federal district court decisions, that West Virginia, along with courts in all other states that had considered the question, had recognized the doctrine.

of a duty to warn patients directly when the patients can receive the medication only through a prescribing physician. Such a physician is required to possess and apply the education, training and expertise necessary to make an independent professional assessment of information bearing on the potential risks and benefits of a particular medication to a particular individual. It is this unique context, absent in a case such as *Hosky* concerning general consumer goods, which gives rise to the learned intermediary doctrine defining the duty of a manufacturer of prescription medications to be that of providing an adequate warning to the treating physician, not the patient.

The common law has long recognized that the different nature of prescription medications gives rise to a different legal duty to warn. In *Vitanza v. Upjohn Co.*, 778 A.2d 829, (Conn. 2001), for example, the plaintiffs advanced the same reasoning relied on by the Marshall County Circuit Court of equating the learned intermediary doctrine and the sophisticated user doctrine and treating both as questions of fact for the jury. In rejecting this argument, the Supreme Court of Connecticut noted that the factual nature of the sophisticated user doctrine stemmed from the fact that it was applicable to manufacturers of a wide variety of products. In contrast, where patients can only get prescription drugs through physicians, “there is not the same concern that the sellers and manufacturers will simultaneously rely on one another to provide warnings with the result that none is issued to the ultimate product user, because prescription drugs may be obtained legally only through a prescribing physician who is in the best position to convey adequate warnings based on the highly personal doctor-patient relationship.” *Id.* at 846. It is because of these special circumstances, unique to prescription medications and absent from cases such as *Hosky* involving general consumer goods, that the learned intermediary doctrine is a rule of law to be applied by the court.

The trial court's belief in the existence of questions of fact for the jury was also based on its misperception of the "Patient Medication Guide" as something analogous to direct to consumer advertising giving rise to a voluntarily-assumed duty to warn patients directly.⁹ (Conclusions of Law, ¶6). Such materials, however, do not negate the learned intermediary doctrine. In *Thom v. Bristol-Meyers Squibb Co.*, 353 F.3d 848 (10th Cir. 2003), for example, the plaintiff argued that a manufacturer's provision of a Patient Information Sheet to a patient through a physician was a gratuitous undertaking subjecting the manufacturer to liability. *Id.* at 852. The Tenth Circuit found this argument to be without merit, noting that "the 'voluntary duty' doctrine is exactly what the learned intermediary doctrine seeks to avoid." *Id.* Therefore, even if the manufacturer of a prescription medicine, "provides pamphlets for distribution to the ultimate drug user, '[t]he patient is expected to place primary reliance on the physician's judgment, and to follow his advice and instructions as to the use of the drug.'" *Id.* (citations omitted).¹⁰

The finding that the Patient Medication Guide was "delivered directly to consumers through pharmacists and doctors," (Findings of Fact, 16) cannot stand either. The materials were not "delivered directly" to Ms. Gellner or any other consumer. Instead, the materials

⁹ In 1999, the Supreme Court of New Jersey, while re-affirming New Jersey's adherence to the learned intermediary doctrine, created a limited exception for drugs subject to extensive direct-to-consumer advertising. *Perez v. Wyeth Lab.*, 734 A.2d 1245 (N.J. 1999). *Perez* has no applicability to this case. The *Perez* court itself, and subsequent New Jersey decisions, have restricted the scope of this exception to advertising that did not comply with applicable FDA regulations. See also *Banner v. Hoffman-La Roche, Inc.*, 891 A.2d 1229 (N.J. App. Div. 2006) ("placement of informational brochures in a physician's office cannot fairly be equated with a course of mass advertising or be deemed direct to consumer advertising so as to remove the predicates of the learned intermediary doctrine."). Moreover, no other court has ever adopted this exception, and several have noted, in the words of the Eastern District of Texas, that *Perez* "is in direct conflict with the law of every other jurisdiction in the United States." *In re Norplant*, 215 F. Supp. 2d at 812. See also *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004) (declining to apply *Perez* to claims not governed by New Jersey law and concluding that with respect to claims under New Jersey law "even applying *Perez* gets the Plaintiffs nowhere.") *aff'd* 2006 U.S. App. LEXIS 11680 (6th Cir. May 11, 2006).

¹⁰ As one court concluded in rejecting a similar voluntary duty argument premised on patient materials, "[p]atient brochures provided by the manufacturer to physicians for distribution to the consumer may aid the physician in communicating with his patient but do not establish the undertaking by the drug manufacturer of a voluntary duty to

were provided to health care professionals for use in fulfilling their own patient counseling duties. Accordingly, the Patient Medication Guide was only available to plaintiff through her physician who prescribed the medication for her. Where a traditional doctor-patient relationship exists, as it does here, no exception to the learned intermediary doctrine should be created.

Vitanza, 778 A.2d at 847.

warn the patient directly.” *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1033 (D.N.J. 1988).

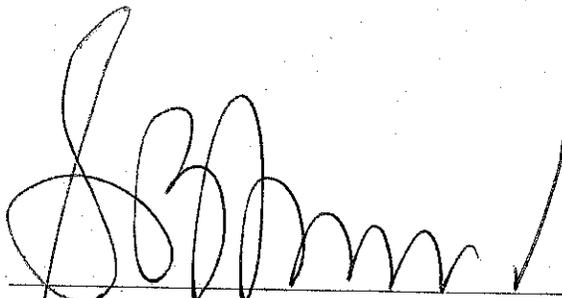
IV. CONCLUSION

WHEREFORE, for the reasons set forth herein, Janssen respectfully requests that this Court issue an immediate writ of prohibition vacating the June 13, 2006 ruling of the Marshall County Circuit Court and confirming that West Virginia does follow the learned intermediary doctrine to define a manufacturer's duty to warn in prescription drug cases.

**JOHNSON & JOHNSON and
JANSSEN PHARMACEUTICA INC.,**

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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

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

vs.

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

Respondents.

CERTIFICATE OF SERVICE

I, Stephen B. Farmer, do hereby certify that I have served the foregoing "MEMORANDUM OF LAW AND CITATION OF RELEVANT AUTHORITIES IN SUPPORT OF 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" upon all known counsel of record by depositing a true and accurate copy of this pleading in the United States Mail, postage prepaid, as indicated below, this 13th day of September, 2006, addressed as follows:

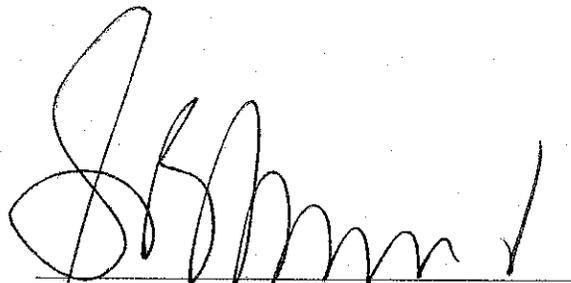
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