NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

COLLEEN MARY GROBELNY AND ROBERT GROBELNY	Civil Action No. 05-cv-4645 (PGS)
Plaintiffs,	**OPINION**
v.	
BAXTER HEALTHCARE CORP., ET AL.	
Defendants.	

SHERIDAN, U.S.D.J.

This matter came before the Court on Defendants' motion for reconsideration seeking this Court to reverse its denial of summary judgment on the issue of the adequacy of the warning on the drug insert. The Court denied the motion for reconsideration and converted it into a motion in limite regarding the reliability and qualifications of plaintiff's expert Dr. Wurpel. At the in limite hearing, Dr. Wurpel testified. After assessing the testimony of Dr. Wurpel, reviewing the pertinent case law, and following up with counsel in this matter, the Court finds the Plaintiff's evidence on the sufficiency of the warning to be sufficient to raise a question of fact for the jury to determine. Accordingly, summary judgment in favor of the defendants is denied.

I.

The facts in this case are well known to the parties and have been set forth in this Court's previous opinion on the record denying Defendants' motion for summary judgment. Thus, there is no need to repeat them herein.

Pursuant to N.J. Stat. § 2A:58C-4, "[a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, *or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.*" (Emphasis added).

Defendants argued at the hearing that Plaintiff cannot sustain a failure to warn claim because she had no expert supporting her contention that the warning was inadequate.[1] In other words, Plaintiff's own testimony and/or the certifications of her attorneys are inadequate to establish the "ordinary knowledge common to the prescribing physician" as is necessary in a case such as this. Further, Defendants argue that Plaintiff's proffered expert, Dr. Wurpel, offered no testimony and had no qualifications to testify as to the reliability of the warning as interpreted by a prescribing physician. The Court, recognizing its gate keeping function, tested these theories at a hearing conducted on May 15, 2008. *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

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[1] It should be noted that the cases relied upon by Defendants in their brief on the motion for reconsideration are distinguishable in the sense that they stand for the proposition that expert testimony is required to prove the *causation* element of a failure to warn case. *See e.g., Toms v. J.C. Penny Co.*, No. 05-2582, 2007 WL 2893052 (D.N.J. Sept. 28, 2007); *Curtis v. Besam Group*, No. 05-2807, 2007 WL 3232589 (D.N.J. Oct. 31, 2007).

As a general rule, and contrary to Defendants' argument, expert testimony is not always required in the context of the *adequacy* of a warning. As noted above, most of the case law[2] (and Defendants' briefs) indicate that expert testimony is often required to prove proximate causation. However, case law and treatises indicate that such expert testimony is not *necessary* in proving the adequacy element in a warning case. One treatise writes that "[c]ourts frequently state that the adequacy of the warning is a question for the trier of fact" but that "[e]xpert testimony is admissible to assist the trier of fact in determining whether a warning is adequate" subject to the standards set forth in *Daubert*. 2 Louis R. Frumer & Melvin I. Friedman, Products Liability § 12.03[1][b], at p. 12-49, 12-51 (2008). In *Macri v. Ames McDonough Co.*, 211 N.J. Super. 636, 642 (App. Div. 1986), the New Jersey Superior Court, Appellate Division, held that the trial court's requirement of an expert to prove adequacy of a warning "reflects a basic misconception of the need for expert testimony to support such a claim and therefore requires reversal." *Id.* at 642. The court held that "[e]xpert testimony is only required to support a claim when the subject matter is so esoteric that jurors of common judgment and experience are unable to make a determination without the benefit of the information and opinions possessed by a person with specialized knowledge." *Id.*

In this case, the Court finds that testimony of a physician would be necessary for the trier of fact to understand whether the warning was adequate. *Macri* is factually distinguishable because that case was about the adequacy of a warning on a household hammer, and the court found that "it was within the competence of the jury, unaided by expert testimony, to determine the need for warnings and the adequacy of the warnings placed on the hammer by the manufacturer. A hammer is a commonly used consumer product . . . . Therefore, while expert testimony could have been of

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[2] *Id.*

assistance, it was not a prerequisite for the submission of plaintiff's inadequate warnings claim to the jury." *Macri*, 211 N.J. Super. at 643. Because the product here is a complex pharmaceutical compound – Immune Globulin Intravenous ("IGIV") – with a complicated warning insert, testimony of a physician would be necessary in order to aid the jury in determining whether the warning was adequate.

Although Dr. Wurpel has an advanced degree in pharmacology and toxicology, he has no experience with pharmaceutical labels because, as he admitted, he is neither a practicing physician nor a licensed pharmacist. He is an academian. At the hearing, Dr. Wurpel waffled as to some of the provisions of the pharmaceutical insert, his opinion as to the warning's adequacy, and appeared, at times, to be surprised as to the package insert's contents. Having stated same, the Court finds that Dr. Wurpel is qualified to testify as to the issue of causation (Defendants concede same) that use of IGIV caused thrombotic episodes in the Plaintiff. In addition, Dr. Wurpel, as a toxicologist and pharmacologist, can explain technical aspects of the insert. That is, he may define terms such as IGIV, thrombosis, Polygam S/D, Gammagard S/D, and Idiopathic Thrombocytopenia Purpura ("I.T.P."). Dr. Wurpel cannot testify as to the adequacy of the warning.

However, subsequent to the hearing, counsel for Plaintiff advised the Court that Dr. Fang, Plaintiff's treating physician and the physician who prescribed the IGIV infusion, will testify as to his personal knowledge. Evidently, Dr. Fang will testify as to whether he reviewed the drug insert and whether he realized the risks associated with prescribing the drug to Plaintiff. Dr. Fang will testify as a fact witness, and the Court finds that his testimony will be adequate and sufficient in conjunction with Dr. Wurpel's testimony for the jury to understand "the characteristics of, and the ordinary knowledge common to, the prescribing physician" in accordance with N.J. Stat. § 2A:58C-

4. Thus, because "the subject matter is so esoteric that jurors of common judgment and experience are unable to make a determination without the benefit of the information and opinions possessed by a person with specialized knowledge," the Court finds that the testimony of Drs. Fang and Wurpel together will satisfy the requirement of expert testimony on the issue of the adequacy of the warning. Since expert testimony is generally not mandatory in adequacy of warnings cases, and because the main purpose of providing such testimony is to assist the jury in understanding issues beyond the ken of the average lay person, the testimony of Drs. Fang and Wurpel is sufficient to raise a fact issue as to the adequacy of the warning.

PETER G. SHERIDAN, U.S.D.J.

May 22, 2008