SUPREME COURT OF APPEALS OF WEST VIRGINIA

J.C., a Minor by and Through His Mother and Next Friend, Michelle C., and I.H., a Minor by and Through Her Mother and Next Friend, Angela H. v. Pfizer, Inc., Roerig, a Division of Pfizer, Inc., and Greenstone, LLC f/k/a Greenstone, Ltd.

814 S.E.2d 234 (W. Va. 2018) · No. 17-0282 · Decided May 15, 2018

SUMMARY

The Supreme Court of Appeals of West Virginia affirmed summary judgment for Pfizer in claims alleging that Zoloft caused birth defects and that Pfizer failed to provide an adequate warning. The court held that, under the circumstances, expert testimony was required to establish the adequacy of the drug's warning because the issues involved complex scientific, medical, and regulatory matters beyond the common knowledge of jurors. The plaintiffs' withdrawal of their labeling expert left them unable to prove an essential element of their claims.

CASE DETAILS

COURT	Supreme Court of Appeals of West Virginia
WRITING FOR THE COURT	Justice Loughry; Justice Workman; Justice Davis; Justice Walker; Judge Wilkes, sitting by special assignment
JURISDICTION	West Virginia
DECIDED	May 15, 2018
DOCKET	17-0282
DISPOSITION	affirmed
PROCEDURAL POSTURE	The plaintiffs appealed the Mass Litigation Panel's grant of summary judgment to Pfizer in their products-liability and negligence action alleging that Zoloft's pregnancy warnings were inadequate.
STANDARD OF REVIEW	Summary judgment is reviewed de novo.
PRECEDENTIAL VALUE	published precedential opinion
PARTIES	J.C., a minor by and through his mother and next friend, Michelle C., I.H., a minor by and through her mother and next friend, Angela H. v. Pfizer, Inc., Roerig, a division of Pfizer, Inc., Greenstone, LLC f/k/a Greenstone, Ltd.

TOPICS

products liability | expert testimony | summary judgment | standard of review | civil procedure

PRACTICE AREAS

products liability | torts | civil procedure | evidence | health law

QUESTIONS PRESENTED

1. Whether expert testimony was required to establish that Pfizer's 2003 Zoloft label inadequately warned of risks associated with use during pregnancy.
2. Whether the plaintiffs could satisfy their evidentiary burden through company documents, product labels, and testimony from Pfizer witnesses rather than through their own labeling expert.
3. Whether summary judgment was proper when the plaintiffs lacked expert testimony on the adequacy of the warning.

HOLDINGS

1. In a failure-to-adequately-warn claim involving complex medical, scientific, epidemiological, and regulatory issues concerning a prescription-drug label, expert testimony is required when the issues are beyond the common knowledge and experience of the average juror. Whether expert testimony is necessary is determined case by case, not under a categorical rule that applies to every products-liability claim.
2. Compliance with applicable regulations is competent evidence of due care, although FDA approval of the Zoloft label does not itself resolve liability.
3. The plaintiffs could not meet their evidentiary burden on the adequacy of the Zoloft label through attorney interpretation of company documents, animal studies, epidemiological materials, adverse-event reports, Core Data Sheets, FDA regulations, or testimony from Pfizer witnesses lacking the necessary labeling opinions.
4. Summary judgment for Pfizer was proper because the plaintiffs lacked expert testimony necessary to prove that Pfizer's warning was inadequate.

KEY QUOTATIONS

> *"The determination of whether expert testimony is necessary to sustain the burden of proof in complex cases involving matters of science, medicine, engineering, technology and the like is made on a case-by-case basis. When the issues involved are beyond the common knowledge and experience of the average juror, expert testimony shall be required."* (syllabus pt. 7)

> *"Our consideration of the complex issues in the case at bar concerning what should and should not be included in a drug label demonstrates that this is a case where expert testimony is necessary."*

FACTUAL BACKGROUND

The plaintiffs alleged that birth defects suffered by their minor children were proximately caused by their mothers' use of sertraline hydrochloride, marketed as Zoloft, during pregnancy. They claimed Pfizer failed to adequately warn of the risk of birth defects, although the 2003 label contained an FDA-approved Category C pregnancy warning and advised patients to notify their physicians if they became or intended to become pregnant. The FDA had repeatedly approved the Zoloft label, and the record included complex animal studies, epidemiological evidence, adverse-event reports, Core Data Sheets, and regulatory materials concerning the medication's risks.

PROCEDURAL HISTORY

The plaintiffs alleged that their mothers' ingestion of Zoloft during pregnancy proximately caused birth defects and that Pfizer failed to provide adequate warnings. The Mass Litigation Panel excluded the plaintiffs' designated labeling expert because he could not be deposed, permitted a replacement designation, and then granted summary judgment after the plaintiffs withdrew their replacement labeling expert. The Supreme Court of Appeals of West Virginia affirmed.

DISPOSITION

affirmed

CASES CITED

- Painter v. Peavy, 192 W. Va. 189, 451 S.E.2d 755 (1994)
- Ilosky v. Michelin Tire Corp., 172 W. Va. 435, 307 S.E.2d 603 (1983)
- Miller v. Warren, 182 W. Va. 560, 390 S.E.2d 207 (1990)
- Roberts v. Gale, 149 W. Va. 166, 139 S.E.2d 272 (1964)
- Totten v. Adongay, 175 W. Va. 634, 337 S.E.2d 2 (1985)
- Morningstar v. Black & Decker Manufacturing Co., 162 W. Va. 857, 253 S.E.2d 666 (1979)
- Honaker v. Mahon, 210 W. Va. 53, 552 S.E.2d 788 (2001)
- State ex rel. Johnson & Johnson Corp. v. Karl, 220 W. Va. 463, 647 S.E.2d 899 (2007)
- Watson v. Inco Alloys International, Inc., 209 W. Va. 234, 545 S.E.2d 294 (2001)
- Campbell v. Boston Scientific Corp., 882 F.3d 70 (4th Cir. 2018)
- Berg v. Johnson & Johnson Consumer Companies, Inc., 983 F. Supp. 2d 1151 (D.S.D. 2013)
- Cross v. Trapp, 170 W. Va. 459, 294 S.E.2d 446 (1982)
- Williams v. Precision Coil, Inc., 194 W. Va. 52, 459 S.E.2d 329 (1995)
- Farley v. Meadows, 185 W. Va. 48, 404 S.E.2d 537 (1991)
- Moats v. Preston County Commission, 206 W. Va. 8, 521 S.E.2d 180 (1999)
- Adkins v. Slater, 171 W. Va. 203, 298 S.E.2d 236 (1982)
- Muzichuck v. Forest Laboratories, Inc., No. 1:07CV16, 2015 WL 235226 (N.D. W. Va. Jan. 16, 2015)
- Dion v. Graduate Hospital of University of Pennsylvania, 520 A.2d 876 (Pa. Super. Ct. 1987)
- Wyeth Laboratories, Inc. v. Fortenberry, 530 So. 2d 688 (Miss. 1988)

- State ex rel. J.C. v. Mazzone, 235 W. Va. 151, 772 S.E.2d 336 (2015)
- State ex rel. J.C. v. Mazzone, 233 W. Va. 457, 759 S.E.2d 200 (2014)
- M.M. v. Pfizer, Inc., 239 W. Va. 876, 806 S.E.2d 800 (2017)
- In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation, MDL No. 2342, 26 F. Supp. 3d 449 (E.D. Pa. 2014)

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