Supreme Court of Florida

E.R. SQUIBB AND SONS, INC., et al.,
Petitioners.

vs.

BOYD B. FARNES,
Respondent.

No. **87,632**

[June 19, 1997]

SHAW, J.

We have for review Farnes v. E.R. Squibb & Sons, Inc., ***667*** **So.** 2d 1004 (Fla. 3d **DCA** 1996), which conflicts with Smith v. Brown, 525 **So.** 2d ***868*** (Fla. **1988).** We have jurisdiction. ***Art.*** V, § 3(b)(3), Fla. Const. We quash Farnes,

Boyd Farnes worked at a drug rehabilitation clinic in the Florida Keys, and because his work entailed an increased risk of viral infection, the clinic offered, and he accepted, a **flu** shot. He was inoculated by nurse Cynthia Fox (by designation of Dr. Paul Jahnig) in October **1989,** and subsequently developed **a** recurrence of Guillain-Barré Syndrome **(GBS),** a rare neurological disorder. He sued Connaught Laboratories, Inc., E.R. Squibb & Sons, Inc., and Henry Schein, Inc., the manufacturer and distributors of the vaccine (referred to collectively as "Connaught"), alleging that the package insert was inadequate to warn of the risk of GBS.

The jury returned a verdict for Farnes for $13,500,000, but the trial judge ordered a new trial, finding that the verdict was against the manifest weight of the evidence. The district court reversed, reasoning thusly:

> **A** trial court may not properly grant a motion for a new trial where reasonable persons cannot differ that the verdict was not against the manifest weight of the evidence. Where, as in the instant case, each party had an expert witness testify at trial regarding causation, it is for the jury to resolve and weigh the conflicting testimony. Trial court judges do not have the discretion to substitute their judgment for that of the jury in regard to the conflicting testimony of **expert** medical witnesses.

Farnes, **667** So. 2d at 1005 (citations omitted).

Farnes claims that the trial court impermissibly reweighed the evidence, and that the district court applied the proper standard for abuse of discretion. We disagree.

This Court addressed a similar scenario in Smith v. Brown, 525 **So.** 2d ***868*** (Fla. 1988), wherein we described the circumstances under which a trial court "can and should" grant a new trial:

> Clearly, it is a jury function to evaluate the credibility of any given witness. Moreover, the trial judge should refrain from acting as an additional juror. Nevertheless, the trial judge can and should grant

> a new trial if the manifest weight of the evidence is contrary to the verdict. In making this decision, the trial judge must necessarily consider the credibility of the witnesses along with the weight of all of the other evidence. The trial judge should only intervene when the manifest weight of the evidence dictates such action. However, when a new trial is ordered, the abuse of discretion test becomes applicable on appellate review. The mere showing that there was evidence in the record to support the *jury* verdict does not demonstrate an abuse of discretion.

Id. at 870 (emphasis added and omitted)(citations omitted).

Due to procedural concerns and the trial court's favored vantage point, this "abuse of discretion" standard is highly deferential:

> In reviewing [an order for a new trial], the appellate court should apply the reasonableness test to determine whether the trial judge abused his [or her] discretion. If reasonable [persons] could differ as to the propriety of the action taken by the trial court, then the action is not unreasonable and there can be no finding of an abuse of discretion.

Id. at **869-70** (emphasis added)(quoting Baotist Memorial Hospital. Inc. v. Bell, **384** So. 2d 145, 146 (Fla. 1980)).

Applying this standard to the present case, **we** note that the package insert contained information about health-related risks and included the following statements:

> CONTRAINDICATIONS
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> . . . .
>
> Immunization should be delayed in a patient with an active neurologic disorder, but should be considered when the disease process has been stabilized.
>
> . . . .
>
> PRECAUTIONS
> GENERAL
>
> . . . .
>
> Prior to an injection of any vaccine, all known precautions should be taken to prevent side reactions. This includes a review of the patient's history with respect to possible sensitivity to the vaccine or similar vaccine.
>
> . . . .
>
> ADVERSE REACTIONS
>
> Unlike the 1976 swine influenza vaccine, subsequent vaccines prepared from other virus strains have not been associated with an increased frequency of Guillain-Barré syndrome. However, this association has been questioned by other physicians.

Connaught argues that its package insert warnings could not have been the proximate cause of Farnes's condition in light of nurse Fox's testimony which demonstrated that she understood the warnings, knew the associated **risks,** but failed to conduct **an** adequate inquiry into Farnes's medical history. In its order granting Connaught's motion for a new trial, the court focused on the language of the insert and the other evidence, but first explained that Connaught's duty was to warn the physician, not Farnes:

> Prescription or ethical drugs

(which includes influenza vaccine) can be administered only under the direction of a physician, and Florida law requires that the manufacturer provide an adequate warning only to the physician, or "learned intermediary." Whether the physician in fact reads the warning, or passes its contents along to the recipient of the drug is irrelevant. See, e.g., **Felix** v. Hoffmann-LaRoche, **540** So. 2d [102] (Fla. **1989);** Buckner v. Allergan Pharmaceuticals. Inc., 400 ***So.*** 2d 820 (Fla. 5th **DCA** 1981). Pharmaceutical manufacturers discharge their duty to warn the learned intermediary by way of a package insert which accompanies each vial of vaccine.

Fairly read, the Connaught insert advises that in 1976, influenza vaccine was associated with an increased risk of recipients contracting GBS, but that such a connection has not been demonstrated in subsequent years. This was an accurate statement of fact. Plaintiff offered no evidence the statement was untrue or inaccurate. Moreover, the insert followed the recommendation of the Advisory Committee on Immunization Practices, an expert panel commissioned by the CDC. The FDA approved the labeling prior to the release of the vaccine. The package insert, as its name implies, goes in the **box** with each 10-dose vial of vaccine. It necessarily does not expand at length on any particular point, relying on citations to reference materials and on the education and training of the "learned intermediary" to explore questions raised by reviewing the insert.

> Farnes contends Connaught should have been more emphatic in stating that a connection between influenza vaccine and **GBS** existed and could have tailored the warning to fit better his particular situation. . . . Florida law does not impose liability on the manufacturer of a properly made, medically necessary vaccine based on such a subjective standard,

Our review of the record shows that although there was **an** evidentiary basis for the jury verdict, there also was extensive evidentiary support for the trial court's ruling. In fact, the key piece of information, i.e., that **flu** vaccines used since 1976 had not been associated with an increased risk of **GBS,** was uncontroverted. Further, as the trial court pointed out in its order, Farnes's expert, Dr. Lichtenfeld, had himself suffered from **GBS** and could give no particular basis, other than personal preference, for his opinion that the insert was inadequate. Connaught's expert, Dr. Weiderholt, on the other hand, presented convincing testimony that the insert accurately reflected the state of medical knowledge in **1989.**

Based on the foregoing, "we are unable to say, after viewing the evidence as a whole, that reasonable [persons] could not have concluded that the verdict . . . was against the manifest weight of the evidence." See Smith, 525 **So.** 2d at **870.** In short, reasonable persons could agree with the trial court.

We quash Farnes and remand for

proceedings consistent with this opinion.'

It **is** so ordered.

KOGAN, C.J., and OVERTON, **GRIMES,** HARDING and ANSTEAD, JJ,, concur.
WELLS, J., dissents with an opinion.

NOT FINAL UNTIL TIME EXPIRES TO FILE REHEARING MOTION **AND,** IF FILED, DETERMINED.

WELLS, J., dissenting.

I dissent because the Third District's revised opinion does not conflict with Smith v. Brawn, ***525*** **So.** 2d **868** (Fla. 1988). I **also** dissent **because** the majority's decision **makes** the judge a super-juror in violation of the respondent's guaranteed right to a trial by jury.

Application for Review of the Decision of the District Court of **Appeal** - Direct Conflict of Decisions

Third District - Case No. **95-274**

(Monroe County)

Arthur J. England, Jr. and Alison Marie Igoe of Greenberg, Traurig, Hoffman, Lipoff, Rosen & Quentel, **P.A.,** Miami, Florida,

for Petitioners

Charles H. Sinclair of Thornton, Mastrucci & Sinclair, Coral Gables, Florida,

for Respondent

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[1]We decline to **address** Connaught's claim that its **package** insert was adequate as a matter **of** law.