IN THE SUPREME COURT
STATE OF FLORIDA

CASE NO. 87,632

E.R. SQUIBB & SONS, INC.,
CONNAUGHT LABORATORIES, INC. and HENRY SCHEIN, INC.,

Petitioners,

v.

BOYD B. FARNES,

Respondent.

INITIAL BRIEF OF E.R. SQUIBB & SONS, INC., CONNAUGHT LABORATORIES, INC. and HENRY SCHEIN, INC.

ON DISCRETIONARY REVIEW
FROM THE THIRD DISTRICT COURT OF APPEAL

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INTRODUCTION

After receiving a flu vaccination prescribed by a physician at the medical clinic where he worked, Boyd Farnes began to experience a recurrence of symptoms associated with Guillain-Barré Syndrome (GBS), a rare neurological disorder. He sued the manufacturer and distributors of the vaccine, alleging that the package insert that accompanied each vial of the vaccine was inadequate to inform him specifically, or through a learned intermediary, about a possible connection between the influenza vaccine and GBS.

A jury determined that the package insert was inadequate and the proximate cause of Farnes' illness. The trial judge vacated the jury award and ordered a new trial on the ground that the verdict was against the manifest weight of the evidence. The court's detailed order evaluated the credibility of both parties' expert witnesses along with all of the evidence. It applied the principles for evaluating pharmaceutical inserts in *Upjohn Co. v. MacMurdo*, 562 So. 2d 680 (Fla. 1990), to conclude that the package insert was accurate, clear and unambiguous. The court denied the defendants' motion for a directed verdict, however.

On appeal, the Third District re-weighed the evidence, reversed the new trial order, and reinstated the verdict on a finding that the trial judge had abused his discretion. In stark contrast to *Smith v. Brown*, 525 So. 2d 868, 870 (Fla. 1988), which held that trial judges "must necessarily consider the credibility of the witnesses," in this case the district court faulted the trial judge for weighing the credibility of the expert witnesses in reaching his decision. The Court granted review of the district court's decision on the petitioners' suggestion that it was in conflict with *Smith v. Brown* as regards the standard by which district courts review orders granting a new trial.

At issue on the merits is whether, as a matter of law under *MacMurdo* and *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989), the manufacturer and the distributors of a vaccine can be held liable for adverse reactions when the physician is advised by the package insert about the benefits and risks of vaccination, is provided with accurate information on the state of medical knowledge as to a possible connection between the vaccine and this rare

disorder, is alerted as to circumstances under which informed consent should be obtained from a patient, and is expressly alerted to give special consideration to those with either an active or stabilized neurological disorder, such as GBS. In this case, the "learned intermediary" was a nurse, acting under the direction of the physician/medical director at Farnes' clinic, who acknowledged that she read and understood the package insert, knew that GBS is a neurological disorder, but nonetheless failed to inquire of Farnes as to his medical history or to delay administering the vaccine until she consulted with a physician.

STATEMENT OF THE CASE

Farnes sued Connaught Laboratories, Inc., E.R. Squibb & Sons, Inc. and Henry Schein, Inc. (collectively called "Connaught" for convenience), alleging that the failure of its 1989-90 package insert to warn of a possible connection between the vaccine and GBS was the proximate cause of a recurrence of his disorder. (R. 4-30; 264-305). Farnes maintained that the information it did provide was not emphatic enough. *Id.*

Each party presented a single expert witness to opine on the adequacy of the package insert. (R. 1284-1350; 1547-97). The jury returned a verdict awarding Farnes $13,500,000, but finding Farnes 10% comparatively negligent. (R. 694-95).

Connaught requested a directed verdict based on *MacMurdo* and, in the alternative, a new trial. (R. 697-704). The court denied a directed verdict, but granted a new trial in an eight-page order that articulated its reasoning with particularity — addressing the language and adequacy of the package insert, the recommendations of established medicine, and the weight to be given the credibility of the expert witness's testimony. (R. 999-1006).

Farnes appealed the grant of a new trial to the Third District, and Connaught cross-appealed the court's denial of a directed verdict. (R. 1007-16). The district court reversed grant of a new trial and remanded with instructions to reinstate the jury verdict, later issuing a post-decision clarification that modified its decision. *Farnes v. E.R. Squibb and Sons, Inc.*, 21 Fla. L. Weekly D2 and D392 (Fla. 3d DCA Dec. 20, 1995 and Feb. 14, 1996). (R. 1777-

79). Connaught sought review on the basis of decisional conflict, which the Court granted. On Connaught's motion, the Court extended the time for service of its initial brief to August 5.

STATEMENT OF THE FACTS[1]

Connaught Laboratories is one of a number of manufacturers licensed by the FDA to produce an influenza vaccine. Each year, the Federal Center for Disease Control (CDC) chooses a particular strain of virus that is circulating worldwide and is likely to circulate in the United States the following winter. (R. 1436FF-HH). Each manufacturer receives an inactive viral strain from which it produces the vaccine. (R. 1436FF-HH; 1436Y).

Connaught manufacturers its vaccine in chicken egg embryos and then tests it on animals for general safety. (R. 1436CCC-EEE; 1427). The resulting product is reviewed by the FDA under established criteria and quality control standards. (R. 1402).

The vaccine is not sold or made available to the general public. Connaught sells it directly to physicians, the so-called "learned intermediaries," who administer it. (R. 1402). Accompanying each vial of the 1989-90 vaccine was a package insert that described the vaccine and informed the physician about a number of matters, including health-related risks. (R. 1402). The language in all package inserts is reviewed and approved by the FDA. (R. 1420-21). Physicians are responsible for informing each patient about the risks and benefits of receiving the vaccine, and for obtaining the patient's informed consent. (R. 1402).

I. Connaught's package insert.

Connaught's package insert contained the following sections: (1) Description; (2) Clinical Pharmacology; (3) Indications and Usage; (4) Warnings; (5) Precautions; (6) Adverse Reactions; (7) Dosage and Administration; and (8) References. (Pl. Ex. 3 at 1-4).

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[1] Citations to the record are indicated as "R. __". The plaintiff's trial exhibits are indicated as "Pl. Ex. __".

The Clinical Pharmacology section classified and discussed the different types of viruses and noted that, because new variations of influenza appear every year, the CDC uses characteristics of current strains to select those to be included in the next year's vaccine. This section was based primarily on the "Recommendations of the Public Health Service Immunization Practices Advisory Committee," whose report, "Prevention and Control of Influenza; Part I, Vaccines," is published in the *Morbidity and Mortality Weekly Reporter*, volume 38 at 297-311 (1989). (Pl. Ex. 3 at 1). This section also described the considerable risks of influenza. *Id.*

The Indications and Usage section described certain groups that should consider vaccination. The insert recommended vaccination for health care providers, including those in out-patient settings, since they have extensive contact with high-risk individuals to whom it might be passed and from whom influenza might be contracted. The general target groups included "any person who wishes to reduce his/her chances of acquiring influenza infection." (Pl. Ex. 3 at 2).

The Contraindications section also explained that the influenza virus is propagated in eggs, and beyond warning physicians that it should not be administered to anyone with a history of an allergy to eggs or egg products, it noted:

> Immunization should be delayed in a patient with an active neurological disorder, but should be considered when the disease process has been stabilized.

(Pl. Ex. 3 at 3). The Precaution section noted:

> 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.*

Id. (emphasis supplied).

The Adverse Reaction section discussed several possible systemic and allergic reactions based on probable hypersensitivity to any of the vaccine's components. The section language pertinent to this lawsuit stated:

> Unlike the 1976 swine flu influenza vaccine, subsequent vaccines prepared from other virus strains have not been associated with an increased frequency of Guillain-Barré Syndrome.

Id. This statement was documented with three footnotes that referenced primary literature on the subject, two of which relate specifically to GBS,[2] and with endnote references to 23 separate works that also include references related specifically to a possible connection between flu vaccine and GBS. Immediately following these references, the insert states that the connection "has been questioned by other physicians," followed by two referenced articles specifically dealing with GBS.[3]

The wording of the package insert as it relates to GBS was taken directly from the Public Health Services Immunization Practices Advisory Committee Newsletter, which the insert specifically referenced. (Pl. Ex. 3 at 4, n.1; R. 1406).

II. Farnes' inoculation with the flu vaccine.

Farnes understood the risks of contracting influenza, and chose to receive the vaccine because he was working in a health care facility where he faced a risk of exposure. (R. 1216-17). Dr. Paul Jahnig, the medical director of the clinic where Farnes was employed and was vaccinated, delegated the task of vaccinating its employees to the nursing staff. (R. 1436E). Dr. Jahnig did not testify.

Cynthia Fox, the acting head nurse, vaccinated Farnes. Because she had never previously given any type of vaccine, she read the entire package insert before proceeding. (R. 1436G). Fox recalled that the insert warned against administering the vaccine to anyone

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[2] Recommendation of the Public Health Service Immunization Practices Advisory Committee (ACIPT). Prevention and Control of Influenza: Part I, Vaccines. MMWR 38:298-311, 1989; Schonberger, L.B., et al.: Guillain-Barré syndrome following vaccination in the National Influenza Immunization Program, U.S., 1976-77. AM J EPID 110: 105-123, 1979; and Schonberger, L.B., et al.: Guillain-Barré Syndrome: its epidemiology in associations with influenza vaccination. Ann. Neurol. 9 (Suppl.): 31-38, 1981.

[3] Baghi, E., et al.: Guillain-Barré Syndrome Clinicoepidemiologic features and effect of influenza vaccine. Arch. Neurol., Vol. 42, 1053-1057, 1985; and Kurland, L.T., et al.: Swine influenza vaccine and Guillain-Barré syndrome. Epidemic or artifact? Arch Neurol. Vol. 42, 1089-1090, 1985.

with an allergy to eggs, suffering from a respiratory infection, or with a prior negative reaction to a flu shot. (R. 1436H). As a result of these warnings, she said she would have asked any patient about these particular subjects. *Id.*

She also read the insert's information about neurological disorders and understood that vaccination of a patient with an active neurological disease should be delayed. She also understood that she should refer anyone with a history of a previous but stabilized neurological disorder to a physician before administering the vaccine. (R. 1436P). She knows that GBS is a neurological disease. *Id.* She testified that, if she had been aware that Farnes had a prior neurological condition, she would not have given the injection without consulting the physician who prescribed the vaccine, but she could not remember whether she ever asked Farnes if he currently or previously suffered from any neurological disorder. *Id.* She did *not* refer him to Dr. Jahnig, and did *not* consult his medical history. (R. 1436K-L).

III. Expert testimony.

Farnes relied on Dr. Peter Lichtenfeld as an expert to opine on the adequacy of the insert's warning. Dr. Lichtenfeld is a neurologist in private practice who has a personal history of GBS. (R. 1285).

Dr. Lichtenfeld authored a single article related to GBS that appeared in 1971 in a peer-reviewed professional journal titled "Automatic Dysfunction and Guillain-Barré Syndrome." The article discussed cardiac and blood pressure problems associated with GBS, but did not discuss the possibility of a causal connection between flu vaccine and GBS. (R. 1287-89; 1345).

Dr. Lichtenfeld served on the Medical Advisory Board for the International Guillain-Barré Syndrome Foundation, an organization that promotes research, meetings, communications and support among doctors and professionals who deal with GBS patients and their families. (R. 1290). The Foundation provides information on a regular basis through

newsletters, meetings, and lectures by Medical Advisory Board members like himself. *Id.* In a 1990 newsletter the Foundation wrote:

> The safety of flu vaccine for the current or former Guillain-Barré patient is unclear. However, *the risk of the vaccine triggering the symptoms is much lower than the risks associated with influenza. Indeed, flu vaccines used since 1976 have not been associated with an increased risk of contracting GBS.*

(R. 1348-50) (emphasis added).

Dr. Lichtenfeld disagreed with the Foundation's statement. He had argued his position at a post-publication Foundation meeting, but he agreed that the Foundation's newsletter was still being distributed to members of the Foundation at the time of trial. (R. 1350).

Dr. Lichtenfeld did not discuss the risks of influenza, or weigh the risks associated with contracting that illness against the risk of the vaccine triggering GBS. Dr. Lichtenfeld believed that, all factors being equal, persons who have had a history of GBS should not receive a flu vaccination. (R. 1332). His opinion was based in part on his belief that all vaccines are capable of causing GBS. (R. 1344, 1348). He acknowledged, however, that a causal relationship will never be proven statistically because the number of reported incidents is small. (R. 1302). He was unable to identify how a particular vaccine causes GBS, but testified only: "It is something in the vaccine that doesn't mix with the recipient that causes it. That something has not been identified." (R. 1348).

Dr. Lichtenfeld had never worked for a pharmaceutical company, had never worked for the FDA, had never worked for the CDC (although he participated as one neurologist of many in a CDC study), had never written a package insert, had never reviewed a package insert for government approval, and had never been involved in the manufacture of vaccines. (R. 1346-47). In preparation for his testimony, Dr. Lichtenfeld reviewed only Connaught's insert for the 1989-90 vaccine and no others. (R. 1297-98).[4]

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[4] Over the years, he had accumulated various package inserts, but he did not review them before his testimony in this case. (R. 1299-1300).

Dr. Lichtenfeld does not buy flu vaccines, does not administer them (R. 1298), and, therefore, has never had the occasion to question the adequacy of a package insert as a treating physician. Nonetheless, he opined that the Adverse Reaction section of Connaught's package insert failed to reflect adequately the medical opinions in the field. (R. 1308-09). He spoke in general about medical literature that supported his viewpoint, but did not identify any particular journal, article, or test. (R. 1303). He was unaware that the statement — "Unlike the 1976 swine flu influenza vaccine, subsequent vaccines prepared from other virus strains have not been associated with an increased frequency of Guillain-Barré Syndrome"— originated with the CDC, or that the CDC had reviewed it. (R. 1346-47). He was also unaware that the *Morbidity and Mortality Weekly Reporter* used this language when it published the recommendations from the Advisory Committee on Immunization Practices (ACIP), and he admitted that he had never read nor ever seen that publication. *Id.* He did not say that reliance on ACIP wording in preparing a package insert falls outside the medical community's standard of care, only that in his opinion it should. (R. 1328).

Dr. W.C. Wiederholt, Connaught's expert witness on the adequacy of the package insert, is a board-certified neurologist. He was trained, writes and publishes in the field of epidemiology, which is the study and prevention of disease in populations. (R. 1550-55). He has written approximately 100 or more articles in his field, five to ten of which directly addressed Guillain-Barré Syndrome. (R. 1561). He is the former Chairman of the Department of Neuro-Sciences at the University of California, San Diego, where he is currently a professor of neuro-sciences. (R. 1559).

Dr. Wiederholt first studied the possibility of a connection between flu vaccine and GBS in the early 1960s. The study analyzed 198 cases in a search for common events preceding the onset of GBS symptoms. (R. 1561-62). He and others determined that GBS is often preceded by an upper respiratory infection, a viral infection with diarrhea and vomiting, surgery, trauma, and vaccinations. They concluded, however, that the temporal relationship between a preceding event and GBS did not necessarily prove that the two events were

related. (R. 1563-65). Depending on the particular study, approximately 25 to 40 percent of patients diagnosed with GBS had no precipitating events. (R. 1563). He testified that, although a "temporal relationship" may be established, if its distribution in a large number of situations is random, it does not prove a statistically valid relationship. (R. 1554-55).

Dr. Wiederholt testified that, during the 1976 swine flu period, there were 1,098 reported cases of GBS. (R. 1569). Of these, approximately 200 had received a flu vaccine, although this association had never been reported. (R. 1569-70). The swine flu vaccine was well known. It had been used in the armed forces for a number of years without side effects or a noticeable increase in the rate of GBS. It had also been used in Holland with no reported increase in the incidence of GBS. (R. 1569-72). The CDC terminated the swine flu vaccine program and launched a study in 1978-79, using a third of all practicing neurologists in the United States, including Dr. Lichtenfeld, to report incidents of vaccine related cases of GBS. (R. 1570-71). After collecting the data, the CDC concluded that subsequent immunization was not associated with an increased risk of GBS. (R. 1571).

Dr. Wiederholt and Dr. Kurland from the Mayo Clinic analyzed the results of the CDC's study of the relationship between 1976 swine flu vaccination and GBS to determine the validity of its findings. (R. 1568-69). They published their results in a peer-reviewed publication identified in the Connaught package insert. (R. 1568-69). Dr. Wiederholt testified that the increase in the incidence of GBS associated with the 1976 flu vaccine was related to the viral agent itself and that there exists no evidence of an increase of a risk of GBS from vaccines prior to or after 1976. (R. 1572-73).

Dr. Wiederholt reviewed the Connaught insert and opined that it adequately informed the reader of the state-of-the-art medical data. He also opined that a person with a history of GBS should receive a flu shot if he otherwise needs it; his opinion is consistent with the recommendation of the International Guillain-Barré Syndrome Foundation. He also expressed the view that Farnes' flu shot did not cause his symptoms, and that his condition was not GBS

but a disease with no identified cause known as Chronic Inflammatory Demyelinating Polyneuropathy. (R. 1573-75).

SUMMARY OF ARGUMENT

The standard for review of an order granting a new trial was developed by this Court over more than 100 years, and refined in *Smith v. Brown*. The Court held that if reasonable men can differ about **the propriety of the trial court's action** in granting a new trial, then the trial court did not abuse its discretion. 525 So. 2d at 869-70. The Court also held that the trial court, when considering a new trial motion, "must necessarily" consider the credibility of the witnesses with all the evidence. *Id.* at 870. Nevertheless, the district court ruled that the trial judge, who followed that directive, erred because trial 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*, 21 Fla. L. Weekly at D2.

The Third District did not follow the *Smith* standard. Rather, it rejected the trial court's obligation to weigh the credibility of the witnesses along with all of the evidence, re-weighed the evidence itself and, on its independent evaluation of that evidence, declared that the trial judge had abused his discretion. Had the Third District properly applied *Smith v. Brown*, it would have eschewed a re-weighing of the evidence, would have accepted as necessary the trial court's evaluation of the credibility of expert witnesses along with the other evidence, and would have asked only whether reasonable men could differ as to the propriety of the action taken by the trial court. Had the district court performed that role on review of the new trial order, it would have affirmed the trial court's action. The court's disregard of the *Smith* standard, coupled with the need to bring the Third District into harmony with the other district courts, is the first issue addressed in this brief.

The trial court found this case indistinguishable from *MacMurdo*, in which the Court said that, when a pharmaceutical package insert is accurate, clear, and unambiguous, its adequacy is a question of law. 562 So. 2d at 681-82. Nonetheless, the trial court declined to

direct a verdict for Connaught. Connaught cross-appealed. The district court did not address the *MacMurdo* standard, but, by reinstating the jury verdict, effectively affirmed the trial court's decision. Connaught brings that issue before the Court under the principle that it will consider the merits of the entire case once it is accepted for conflict review. *See Jacobson v. State*, 476 So. 2d 1282, 1285 (Fla. 1985); *Bankers Multiple Line Ins. Co. v. Farish,* 464 So. 2d 530, 531 (Fla. 1985); and *Bould v. Touchette*, 349 So. 2d 1181, 1183 (Fla. 1977).

Connaught's 1989-90 package insert was accurate and, under *MacMurdo*, was adequate as a matter of law to advise physicians about the possibility of a connection between flu vaccine and GBS. The trial court should have directed a verdict in favor of Connaught. An additional reason for granting a directed verdict, under *Felix*, is that the undisputed facts establish that Connaught's package insert was not the proximate cause of Farnes' illness.

ARGUMENT

I. An appellate court may not overrule a trial judge's discretion to grant a new trial because the verdict is against the manifest weight of the evidence when the trial court has weighed all of the evidence and has expressed its reasoning in a written order, *unless* the appellate court concludes that reasonable men cannot differ about the propriety of the trial court's action.

The guiding principle for appellate review of orders granting a new trial is neither obscure nor equivocal. It has been developed and refined by the Court over many years. That history is the foundation for this appeal.

A. Trial judges in Florida have a responsibility to override jury verdicts that are the product of passion, prejudice and mistake, or otherwise, including witness incredibility, are against the manifest weight of the evidence.

The role of a Florida trial judge in ruling on post-verdict requests for a new trial originated in *Schultz v. Pacific Insurance Co.*, 14 Fla. 73 (1872). Even at that early stage, the Court recognized the need for trial judges to review juries' decisions in order to protect fact-finding, including the evaluation of witness credibility, from manifest injustice.

> While it is true that [comparing and weighing the testimony of witnesses] is the proper function and province of the jury, it is at the same time true that in cases where there is conflict in the testimony, it is within the province and power of the court to set aside a verdict which does not reach a substantially just conclusion in cases where the conflicts are of such character and the circumstances of such nature as to give just grounds for the belief that the jury acted through prejudice, passion, mistake or any other cause which should not properly control them. This power exists in the court. *In exercising it the court does not encroach upon the province of the jury, for the reason that is does not conclusively settle facts in the form of a verdict, but only gives another jury the opportunity of so doing, and of correcting what appears to be a mistake.*
>
> . . . The rule which should govern a court in the exercise of this power should be a fair view of . . . the character of the conflicting testimony . . . . This is the rule which should govern the judge of the court presiding at the trial, who has the same opportunity as the jury to observe what occurs in the trial.

Id. at 93-94 (emphasis added).

Several years later, the Court re-emphasized the responsibility of trial judges to assure just results through jury verdict review. *See Turner v. Frey*, 81 So. 2d 721 (Fla. 1955). The Court reaffirmed the trial court's duty to order a new trial when "the trial court is of the opinion that the verdict does not accord with the manifest weight of the evidence," even though there was in the case evidence "upon which the jury could find the verdict which they did." *Id.* at 722 (quoting from *Talley v. McCain*, 128 Fla. 418, 174 So. 841 (1937)).

B. The Florida standard of appellate review for orders granting a new trial has evolved over more than 100 years, culminating with the 1988 formulation expressed in *Smith v. Brown*.

Although the role of trial judges remained stable over decades of jurisprudence, there eventually developed divergent views as to the role of appellate judges in reviewing new trial orders. The Court addressed the appellate standard not for the first time, but in response to a need for further explication, in *Cloud v. Fallis*, 110 So. 2d 669 (Fla. 1959). The Court set out to reconcile two inconsistent lines of authority, one that had developed a "broad discretion" rule, and the other that had developed a less deferential "substantial competent evidence" rule. *Id.* at 671. The Court found the former standard the proper one, "placing in trial courts broad discretion of such firmness that it would not be disturbed except on clear showing of

abuse." *Id.* at 672. The Court then "restate[d] the law on the subject," beginning with the observation that the trial judge,

> who because of his contact with the trial and his observation of the behavior of those upon whose testimony the finding of fact must be based is better positioned than any other one person fully to comprehend the processes by which the ultimate decision of the triers of fact, the jurors, is reached.

Id. at 673. The Court re-emphasized the trial judge's "duty" to grant a new trial when the verdict is against the manifest weight of the evidence. *Id.*

Over time, the *Cloud* standard proved to run against the grain of appellate judges, and their role commanded the Court's attention again in *Wackenhut Corp. v. Canty*, 359 So. 2d 430 (Fla. 1978). In *Wackenhut*, the Third District applied the "substantial competence evidence" rule to reverse a new trial order — a choice that the Court found conflicted with its decision in *Cloud*. The Court's decision in *Wackenhut* reiterated two items of importance. First, it revitalized the requirement expressed in *Stewart Bonded Warehouse, Inc. v. Bevis*, 294 So. 2d 315 (Fla. 1974), that new trial orders, rather than leaving the district court "to grasp at straws when it reviewed the order," must set forth "reasons capable of demonstration in the record" in order to "facilitate intelligent appellate review." *Id.* at 434.[5] Concomitantly, it refined the *Cloud* standard according to *Hodge v. Jacksonville Terminal Co.*, 234 So. 2d 645 (Fla.), *cert. denied*, 400 U.S. 904 (1970), ruling that a new trial order is insufficient if it does no more than merely recite that a verdict is contrary to the evidence. *Wackenhut*, 359 So. 2d at 434.

> Orders granting motions for new trials should articulate reasons for so doing so that appellate courts may be able to fulfill their duty of review by determining whether judicial discretion has been abused.

Id. at 435.

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[5] The Court noted also that the orders should, where appropriate, set forth reasons demonstrating any basis which is "beyond" the record, such as those which might have aroused the passion and prejudice of the jury. 359 So. 2d at 434.

The battle for uniformity of review was not over, however. It re-surfaced two years later when the Court reviewed a decision of the First District reversing a trial court's order for new trial that contained a detailed recitation of its reasons. In *Baptist Memorial Hospital, Inc. v. Bell,* 384 So. 2d 145 (Fla. 1980), the Court found that the trial court had "properly applied the dictates" of *Wackenhut,* and reversed the district court. Commenting from a prior decision that "[m]ere disagreement from an appellate perspective is insufficient as a matter of law to overturn a trial court on the need for a new trial,"[6] the Court restated the rule to be applied by the district court:

> If reasonable men 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 146. This formulation was reiterated in *Ford Motor Co. v. Kikis*, 401 So. 2d 1341, 1342 (Fla. 1981), in which the Court noted that it had "stated and restated the appropriate standard for district courts."

Eight years found the district courts still unsettled. In *Smith v. Brown*, the Court was asked in a certified question whether the reasonable man standard of *Baptist Memorial* applied to the "determination" of the trial court in ordering a new trial, or rather to the trial court's "perception of the evidence." Based on discussion in the dissent in the district court,[7] the Court re-framed the issue to consider "whether a trial judge can order a new trial when the credibility of witnesses is at issue." 525 So. 2d at 869. The Court answered that question in the affirmative stating that, although a jury first evaluates a witness's credibility, the trial judge "can and should" grant a new trial if the manifest weight of the evidence is contrary to the verdict and, in making that decision

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[6] This dogma was restated and applied in *Castlewood Int'l Corp. v. LaFleur*, 322 So. 2d 520, 522 (Fla. 1975).

[7] The Court noted that "the majority opinion below contains neither facts nor analysis." The dissent, however, had specifically addressed credibility determinations of expert witnesses, and expressed the view that they are out of the reach of trial court judges. 525 So. 2d at 870.

the trial judge *must necessarily consider the credibility of the witnesses* along with the weight of all of the other evidence.

Id. at 870 (emphasis added).[8]

C. To evaluate a new trial request properly under *Smith v. Brown*, the trial court must consider, along with all of the other evidence, the credibility of witnesses, including expert witnesses.

A trial judge is obliged to grant a new trial when a jury verdict is against the manifest weight of the evidence. See, *e.g.*, *Cloud v. Fallis*, 110 So. 2d 669. In order to determine whether the jury verdict is against the manifest weight of the evidence, the trial judge, who has necessarily heard and observed all the witnesses and viewed the evidence, must consider *all* of the evidence. Since a witness's credibility determines what weight is given to his testimony, this process "necessarily" includes weighing the credibility of the witnesses. *Smith v. Brown*, 525 So. 2d at 870; *Ford v. Robinson*, 403 So. 2d 1379 (Fla. 4th DCA 1981).

A trial court's duty to weigh the credibility of witnesses is not confined to lay witnesses, but requires the court to weigh the credibility of expert witnesses. *Smith v. Brown*, 525 So. 2d 869. In cases that question the adequacy of a manufacturer's information about a vaccine's inherent risks, the adequacy must be proved by expert testimony. *See MacMurdo*, 562 So. 2d at 683.

When equally credible witnesses provide conflicting testimony, the conflict is a jury question that the trial court may not disturb. *Jones v. Stevenson*, 598 So. 2d 219 (Fla. 5th DCA 1992). If one or more witnesses are found **not** to be credible, however, and the effect of discounting that testimony is to tip the manifest weight of the evidence on the decisive issue in the trial against the jury verdict, the court can and must set aside the jury's verdict and grant a new trial. That was the situation here.

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[8] The Court went on to sustain the new trial order that had been entered although "the credibility of the respondent was substantially attacked," inasmuch as the Court was "unable to say, after viewing the evidence as a whole, that reasonable men could not have concluded that the verdict" was against the manifest weight. 525 So. 2d at 869.

D. The trial judge properly performed his responsibility under *Smith v. Brown*, such that reasonable men cannot uniformly conclude that the action taken by the trial judge was improper.

In this case, Farnes relied on the opinion of Dr. Lichtenfeld, while Connaught relied on Dr. Wiederholt. It was these experts' credibility that the trial court weighed and discussed in its new trial order. The trial court found Dr. Lichtenfeld's testimony to be incredible for the following reasons, expressly detailed in its order:

1. Dr. Lichtenfeld, who himself had contracted GBS from unknown sources, offered no more than a personal preference for his view that Connaught should have warned "more emphatically" about a causal connection between this vaccine, indeed all vaccines, and GBS. (R. 1003-04). He admitted Connaught's warning was not in violation of community standards. *Id.*

2. Dr. Lichtenfeld acknowledged no epidemiological study had shown a statistically significant link between flu vaccine and GBS dating from 1976, as Connaught's insert noted. (R. 1004).

3. Dr. Lichtenfeld conceded that he had not reviewed the package inserts used for other vaccines, and that he had never himself prepared a package insert. (R. 1004).

4. Dr. Lichtenfeld admitted that the newsletter published by the International Guillain-Barré Syndrome Foundation, on the board of which he served, recommended that persons with a history of GBS *should receive* a flu vaccine, but that he simply disagreed with that recommendation. (R. 1004).

5. Dr. Lichtenfeld acknowledged that he had not published anything on the subject of GBS since 1971 — before the FDA's study and resulting change in position on variant virus strains — and that his earlier article addressed how GBS affects the heart and lungs but did not discuss a possible connection between flu vaccine and GBS. (R. 1004).

Dr. Lichtenfeld expressed his strong personal belief in a causal connection between influenza vaccine and GBS, but he was forced to admit that "this is something that will never be proven with the numbers," and he was unable to cite any reports or articles on which he claimed to have relied. (R. 1302-03). He held the view that incidents of GBS temporally linked with the influenza vaccine are "grossly underreported," and he suggested that "if you study a large group of patients with GBS and you question them, what went on in your life the weeks before the neurological symptoms began, there will always be a certain percentage that would report having received the vaccination." (R. 1303, 1330). The comprehensive study conducted by the CDC in which he participated, however, did not bear out his theory.[9] (R. 1326).

Dr. Lichtenfeld was unfamiliar with the *Morbidity and Mortality Weekly Reporter*, a publication that reports the guidelines for immunization practice developed by the Advisory Committee on Immunization Practice (ACIP) and on which Connaught relied. He would not say that reliance on those guidelines violated the standard of care in the industry; he said only that it *should*. He holds the view that manufacturers have access to other information which they should use to prepare package inserts for flu vaccine, including adverse reaction reports (R. 1328), but this belief inherently contradicts his testimony that adverse reactions are generally unknown because they are grossly underreported.

Dr. Lichtenfeld's opinion, that Connaught's package insert was inadequate and that prior GBS sufferers such as Farnes should never be vaccinated, is not consistent with medical literature or experience. In weighing his opinion, the trial court gave it significantly less weight than Dr. Wiederholt's, if any.

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[9] While he maintained that he was the only doctor who reported any cases in his community (R. 1325), the record showed that he reported 52½ times as many cases as *any* of the 231 other doctors who participated in the study. (R. 1342).

Dr. Wiederholt opined that Connaught's insert was factually accurate, and supported by the test results and by published medical journals. (R. 1573). In considering his credibility, the court noted:

1. that Dr. Wiederholt authored written numerous articles about the relationship between influenza vaccine and GBS;

2. that he had co-authored one of the articles cited in the Connaught package insert (R. 1004-05); and

3. that he opined that Connaught's 1989-90 package insert **did** adequately warn physicians — the learned intermediaries — of a possible connection between the vaccine and a recurrence of GBS, because it accurately reported the state of medical knowledge in 1989. (R. 1005).

The trial court's meticulous adherence to the requirements of *Wackenhut* and *Smith v. Brown* is evident from his order. The order indisputably articulated the basis for its conclusion in a manner sufficient to allow appropriate appellate review, as *Wackenhut* requires. The trial judge clearly recognized the importance of observing the demeanor of the witnesses and considering their qualifications, and so noted in his order. This trial judge did precisely what the Court has instructed him to do.

If the district court judges had followed the Court's directives for appellate review, they would have asked themselves, as reasonable men, whether they could really differ with the trial court's reasoned analysis that the *manifest* weight of the evidence did not favor an award for Farnes, disregarding for that purpose how *they* personally might have weighed the credibility of the two experts. Under that circumstance, if they were to say: "we can indeed differ among ourselves about the propriety of this action," they would have affirmed the trial

court's order. The analysis leading to that conclusion might have emerged from a hypothetical conference colloquy following oral argument along these lines:

> PRESIDING JUDGE: All right, the issue before us in this case is whether we, as reasonable men, can differ with Judge Lester's determination that the manifest weight of the evidence does not support the jury's verdict for Mr. Farnes against Connaught, Squibb and Schein. How shall we begin?
>
> SECOND PANELIST: Well, this case is assigned to me, and as I understand it the liability of Connaught and the others exists, if at all, based on the package insert that accompanied each vial of Fluzone given to the Guidance Clinic of the Middle Keys for administration to its patients, one of whom was Mr. Farnes. Under the test established in *MacMurdo* and in *Felix*, there should be no liability if Connaught accurately conveyed information regarding the risk of GBS, if any, in language that was clear and unambiguous. Preliminarily, I'm satisfied that Judge Lester applied the right legal standard for entering an order that grants a new trial: he evaluated all of the evidence regarding the adequacy of the package insert under the *MacMurdo* test, including the credibility of the only two witnesses who provided evidence on that issue, for its manifest weight.
>
> THIRD PANELIST: And I agree that he met the preliminary requirement for our review of his order: he wrote down his reasons for ordering a new trial with sufficient detail for our review. That leaves us with only one question, then, doesn't it? Whether any one of us could differ with Judge Lester that the opinion of Dr. Lichtenfeld — that the package insert provided inadequate information about the linkage between a flu vaccine and GBS — was not competent or credible when weighed against Dr. Wiederholt's opinion that the insert accurately reflected the history and the state of medical knowledge concerning that linkage.
>
> SECOND PANELIST: That's how I see it. Our role is a narrow one. We know that, if the two experts are equally credible, then Judge Lester was wrong to override the jury's verdict. It seems to me that leaves us with a limited number of questions to ask ourselves. First, are we in agreement that they were both qualified to express their opinions, based on training, experience and familiarity with the subject? Second, since the adequacy of the package insert as it relates to GBS could only be evaluated by experts in the field, are we in agreement that both had sound scientific foundations for their opinions? I have a view on both questions, but I'd like to hear yours first.
>
> PRESIDING JUDGE: I don't mind starting, since I had a chance to read the testimony of both of them before the argument. They were both neurologists, they were both well-trained medically, and they were both somewhat familiar with the possible effects of flu vaccines on GBS. Dr. Lichtenfeld had suffered from GBS, although not from having received a flu or other type of vaccine, and he had direct experience with private patients and had participated in the big CDC study on this very subject. Dr. Wiederholt was active in research and he participated in analyzing data from studies about the possible connection between flu vaccines and GBS.

THIRD PANELIST: But the level of their expertise was quite different. Judge Lester couldn't discount entirely that Dr. Lichtenfeld had developed a bias against the use of *any* vaccine by a person who had suffered from GBS. Perhaps that's understandable since the causes of GBS are apparently unknown — the testimony is that this disorder/disease is idiopathic — but nonetheless his view is based largely on a strong personal but scientifically unproved bias. Nor could Judge Lester discount that Dr. Lichtenfeld had last written on the subject 5 years before the 1976 study that changed the CDC's entire approach to viral strains for flu vaccines, and that he had not even read the latest literature on the subject. And all of this was in comparison to Dr. Wiederholt, who was conversant with the research, the studies, the findings of those studies, and the most current literature.

PRESIDING JUDGE: But I can't help asking myself whether the difference in their expertise wasn't a matter that we let juries decide? And isn't the difference in their experience or familiarity with the literature a matter that goes to the weight to be given to their respective opinions by the jurors, and not by the trial judge? Which suggests to me that Judge Lester should not have substituted his judgment for the jury's — or as the decisions say: "act as the seventh juror."

SECOND PANELIST: I hear you, but as best I can make out from a long line of decisions from the Supreme Court, that is not the issue we should be addressing. That line of inquiry was certainly what *Judge Lester* was required to pursue, to assure himself he was not simply substituting his judgment for that of the jurors. But it is not *our* job to pursue that line of inquiry again, because Judge Lester necessarily knew things we can never know. He saw the two experts, and he heard the inflections in their voices, the intonations in their answers, the pauses, the stridency and the querulous nature of their answers to questions. He saw their body language. He can, and was entitled to consider their credibility in light of things we are simply unable to discern from the cold record on appeal. That's why *our* role is different from his, and why we cannot pursue the same questions or analysis that he did.

Our job is to don our "reasonable man" hats, and in that role to take a look at what Judge Lester said in ordering a new trial. We have to ask ourselves only if, based on his reasoned analysis, we can differ with him that the *manifest* weight of the evidence — which *includes* the discernible, transcribed differences in the testimony of both experts but is by no means limited to what we can read on those printed pages — favored Connaught and not Mr. Farnes. Put another way, we have to ask, being reasonable in our approach, whether Judge Lester could have fairly concluded that Dr. Wiederholt was in the far better position than Dr. Lichtenfeld to provide expertise on the nexus between flu vaccines and GBS, and based on that expertise to say whether Connaught's package insert was accurate in terms of the scientific literature, and adequate to inform physicians on that subject — persons presumed to be familiar with the technical terms on the package insert, and concerned enough for their patients to ask the right questions of them or withhold inoculation until they could themselves read the literature identified on the insert.

E. The *Smith v. Brown* formulation has not been applied by the district courts of appeal in a uniform manner.

In recent years, each of the district courts has expressed itself on the standard for reviewing orders granting new trials. A cursory review of the rationale for those decisions illustrates the diversity of the application of the standard.

The First District has strictly followed the dictate of *Ford Motor Co. v. Kikis*. *See, e.g.*, *Crosby v. Fleming & Sons, Inc.*, 447 So. 2d 347 (Fla. 1st DCA 1984) (finding no abuse of discretion in an order that contained the trial court's reasons justifying a new trial).

The Second District, in *Crown Cork & Seal Co., Inc. v. Vroom*, 480 So. 2d 108 (Fla. 2d DCA 1985), was verbally faithful to the Court's standards as expressed in *Kikis* (reverse "only for an abuse of the broad discretion vested in trial courts"), in *Baptist Memorial* (trial court must give express reasons), and in *Wackenhut* (a mere recitation of "contrary to the evidence" is insufficient).[10] The *Crown Cork* court found the trial judge had abused its discretion, not by reason of the action he had taken, but "because reasonable men could not differ that the verdict was not against the manifest weight of the evidence." 480 So. 2d at 110. The court followed the correct standard, though, in reversing new trial orders in *McNair v. Davis*, 518 So. 2d 416, 417 (Fla. 2d DCA 1988) (no abuse if reasonable men could differ as to the propriety of the trial court's action). In *Fitzgerald v. Molle-Teeters*, 520 So. 2d 645, 648 (Fla. 2d DCA 1988), and in *Case v. Bentley*, 527 So. 2d 939, 940 (Fla. 2d DCA), *review denied*, 534 So. 2d 398 (Fla. 1988), the court could discern no difference between an appellate court's evaluation of the jurors as reasonable men and an appellate evaluation of the trial court's action. The court reversed without explanation in *Hawk v. Seaboard System R.R., Inc.*, 547 So. 2d 669 (Fla. 2d DCA), *review dismissed*, 549 So. 2d 1014 (Fla. 1989), and in *Phar-Mor of Florida, Inc. v. Steuernagel*, 550 So. 2d 548 (Fla. 2d DCA 1989), and affirmed without opinion in *DeLucia v. Egan*, 540 So. 2d 937 (Fla. 2d DCA 1989).

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[10] 480 So. 2d at 110.

The Third District frequently reverses new trial orders. It affirmed on negligence and causation with respect to orthopedic injuries, but reversed on the causal relationship of a heart attack in *North Dade Golf, Inc. v. Clarke*, 439 So. 2d 296 (Fla. 3d DCA 1983), *review denied*, 449 So. 2d 264 (Fla. 1984). The court reversed new trial orders in *Tuttle v. Miami Dolphins, Ltd.*, 551 So. 2d 477 (Fla. 3d DCA 1988), *review denied*, 563 So. 2d 635 (Fla. 1990), in *Oakes v. Pittsburgh Corning Corp.*, 546 So. 2d 427 (Fla. 3d DCA 1989), in *Rety v. Green*, 546 So. 2d 410 (Fla. 3d DCA), *review denied*, 553 So. 2d 1166 (Fla. 1989), and in *Atkins v. Hansel*, 668 So. 2d 663 (Fla. 3d DCA), *review dismissed*, 675 So. 2d 120 (Fla. 1996). A new trial order was affirmed, without explanation and over the dissent of the chief judge, in *Montgomery Ward & Co. v. Pope*, 532 So. 2d 722 (Fla. 3d DCA 1988).

In the Fourth and Fifth Districts, similar patterns emerge. In *Becker v. Williams*, 652 So. 2d 1182, 1184-85 (Fla. 4th DCA 1995), the court reversed an order granting a new trial where the trial judge chose to believe the plaintiff's expert over the defendant's expert, while in *Ford v. Robinson*, 403 So. 2d 1379, 1383 (Fla. 4th DCA 1981), the court affirmed "because the trial judge is on the spot and has some ability to measure not only the tangible evidence but also the intangible, such as the credibility of witnesses, [and] his decision is given great deference." In *Cardinal v. Wendy's of South Florida*, 529 So. 2d 335 (Fla. 4th DCA 1988), *review denied*, 541 So. 2d 1172 (Fla. 1989), the court simply affirmed a new trial order on the basis of *Smith v. Brown*.

The Fifth District has generally adhered to *Kikis* and *Cloud v. Fallis*. *See, e.g.*, *Phillips Buick-Pontiac-GMC, Inc. v. Dallon*, 602 So. 2d 594, 596 (Fla. 5th DCA), *review denied*, 613 So. 2d 2 (Fla. 1992); *Papcun v. Piggy Bag Discount Souvenirs, Food & Gas Corp.*, 472 So. 2d 880 (Fla. 5th DCA 1985). In *Jones v. Stevenson*, 598 So. 2d 219 (Fla. 5th DCA 1992), however, the court reversed a new trial order on the basis that the witnesses for both sides were equally credible and the trial court improperly re-weighed the evidence.

These varied results stem in part from an inability or failure of the district courts to confine themselves to a proper, limited analysis of new trial orders.

F. Continued adherence and consistent application of the *Smith v. Brown* formulation by the district courts requires the Court to adopt a new approach to appellate review of new trial orders.

In 1980, Article V of the Florida Constitution was amended to give the Court more control of its docket and more time to exercise its role to set policy. Concomitantly, district courts' decisions were given a higher degree of finality and greater shelter from review. The district courts had always exercised their decisional authority without being required to write opinions. The 1980 amendments, however, ceded complete authority to the district courts to decide not only **whether** they would choose to write, but **what** they would choose to write.[11]

While the constitution was being amended, the district courts continued to grow. This combination of events lessened the Court's ability to exercise supervisory control necessary to maintain uniform application of policies developed through guideline pronouncements. The policy guideline that operates in this case — interaction between trial judges and the appellate courts on new trial motion orders — has historically been among the most troublesome and recurring, as evidenced by the Court's return to the issue on numerous occasions.

Simply restating the standard, as the Court has done over the course of 100 years, is no longer adequate to assure uniformity. While no radical departure from established principles is required, Connaught respectfully suggests that a new approach is needed, and that there already exists an appropriate mechanism for that purpose.

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[11] The discretionary review authority of the Supreme Court was amended in 1980 to foreclose review of district court decisions that had did not present manifest decisional disharmony. To be eligible for review, district court decisions had to articulate a legal principle expressly, and conflict had to be direct. See Art. V, section 3(b)(3). The Court made clear its adherence to the new constitutional requirements in a series of post-1980 decisions. *See, e.g., Dodi Publishing Co. v. Editorial America, S.A.*, 385 So. 2d 1369 (Fla. 1980); *Robles Del Mar, Inc. v. Town of Indian River Shores*, 385 So. 2d 1371 (Fla. 1980).

Just as the Court has required circuit court judges to articulate their reasons for granting a new trial in order to assure adequate appellate review,[12] the Court can require district court judges who reverse a trial court's exercise of its authority by granting a new trial to articulate *their* reasons for concluding that reasonable men *cannot* differ that the trial court abused its discretion. In so doing the Court can, and Connaught respectfully suggests should, require the district court to explain with particularity the foundation for its action.[13]

In creating an articulation requirement for the district courts, the Court should make clear that merely repeating the standard for review is **not** sufficient. Rather, the Court should require the district courts to articulate it reasons with the same degree of detail and specificity that now assures appellate review of new trial orders — keeping in mind that to reverse such an order requires that reasonable men cannot differ about the impropriety of the trial court's action. That is, there must be a clear view, by *reasonable* persons, that the trial court had no basis to conclude that the weight of the evidence manifestly did not support the jury's verdict. An articulation mechanism will permit the parties in the first instance, and subsequently the Court itself, to monitor the district courts' application of its standard of review for consistency, without creating an undue or unwarranted burden on district court judges.

G. Conclusion as to why the trial court's new trial order was proper.

For the reasons expressed, the trial court's order granting a new trial should have been affirmed by the Third District. The order expressly set forth why the respective expert witnesses were and were not credible, with the relevance of the subject of their testimony tied to the legal standard for evaluating drug product package inserts. Without question, it cannot be said that the trial court's on-site oversight was so deficient or mistaken that reasonable men

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12 *Wackenhut v. Canty*, 359 So. 2d 430.

13 Some of the district court decisions in this area do contain analyses of the reasons for appellate disagreement with the trial judge. Any dissent from the reversal of a new trial order would, obviously, by itself, establish the error of the majority's decision.

could *only* find that ordering a new trial was an improper conclusion to be drawn from the evidence as a whole.

II. Connaught's 1989-90 package insert adequately informed the physicians, to whom the vaccine is provided, of a possible connection between the vaccine and the onset of neurological disorders, including the rare Guillain-Barré Syndrome, when it identified the state of medical knowledge in accurate and unambiguous language.

Connaught moved for a directed verdict at the close of the evidence, asserting that the adequacy of its package insert was a question of law under *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989), and *MacMurdo*, 562 So. 2d at 680. (R. 1641). After the verdict, Connaught moved for judgment in accordance with its motion for directed verdict. (R. 697-704). The trial court denied the motion. (R. 999-1006). Connaught cross-appealed the issue, and the district court affirmed without discussion of that point. (R. 1777-79). That issue is properly before the Court for plenary review. *Bankers Multiple Line Ins. Co. v. Farish*, 464 So. 2d 530, 531 (Fla. 1985) ("Once we take jurisdiction because of conflict on one issue, we may decide all issues."); *Bould v. Touchette*, 349 So. 2d 1181 (Fla. 1977) (If conflict appears and this Court acquires jurisdiction, we then proceed to consider the entire cause on the merits."); *see also Jacobson v. State,* 476 So. 2d 1282, 1285 (Fla. 1985) (Court decided to "dispose of case on a ground other than the conflict ground.").

The trial court found that Connaught's insert was accurate and clear. (R. 1005). The court also found that Farnes offered no evidence that the insert was untrue or inaccurate. *Id.* It was undisputed that the learned intermediary fully understood the information in the package insert and knew the relevance of that information to GBS. On these facts, and under the principles of *MacMurdo* and *Felix*, the court should have concluded that the adequacy of the package insert was a question of law to be decided by the court, and based on that determination directed a verdict in favor of Connaught on two grounds. First, the court should have held that the package insert was fully adequate to inform physicians of a possible link

between the vaccine and GBS. Second, the court should have held that the package insert could not have been the proximate cause of Farnes' injuries in any event.

A. The adequacy of warning regarding the administration of a flu vaccine to a former GBS sufferer was an issue without sufficient evidence to submit to a jury.

A manufacturer's sole duty is to inform the physician of risks associated with its vaccines. The physician acts as a "learned intermediary" between the manufacturer and the ultimate consumer. *Felix*, 540 So. 2d at 104. The learned intermediary considers the patient's needs, and weighs the potential benefits of the product against the risks of harm to the patient, whenever deciding whether to recommend the treatment. *Id.* The critical issue in these situations is whether the manufacturer of a drug has furnished adequate information in the text of its package insert so that the physician's decision can be an informed one. 540 So. 2d at 103. If the language of a package is accurate, clear and unambiguous, the manufacturer cannot be liable. 540 So. 2d at 105. *See also MacMurdo*, 562 So. 2d 680.

Juries can have a role in evaluating accuracy, clarity and ambiguity, of course. But some circumstances present no possible factual dispute on that issue.

> While in many instances the adequacy of warnings concerning drugs is a question of fact, we hold that it can become a question of law where the warning is accurate, clear, and unambiguous . . . . In the instant case, the district court of appeal . . . held that 'it is inconceivable that reasonable persons could disagree as to the adequacy of the warnings in conveying *to physicians* that the prescription drug . . . should not have been prescribed . . . .' We agree.

Felix, 540 So. 2d at 105 (emphasis added). The Court has recognized that, while certain technical language that appears in an insert might not be familiar to a patient or layman, it can be adequate as a matter of law because it is intended to be read by persons familiar with medical vocabulary, and experienced in the treatment of and risks to the human condition. *Id.*

Under the insert section titled Contraindications, Connaught's package insert told physicians not to administer the vaccine to patients with an active neurological disorder, but to

"consider" inoculation of a patient with a neurological disorder that had stabilized. The insert then specifically advised, in no uncertain terms, what steps should be taken before considering the injection of **any** vaccine:

> 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.*

(Pl. Ex. 3 at 3) (emphasis added).There is nothing ambiguous or unclear about a directive that a patient's history should be taken before inoculation for the flu, and nothing ambiguous or unclear **to a physician** about the term "neurological disorder."[14]

Nor was there anything misleading or unclear about the fact that there had been a concern in medical circles about a link between GBS and flu vaccines. The term "Guillain-Barré Syndrome" appears repeatedly in the medical literature listed on the package insert.[15] Physicians are fully familiar with that insert terminology, and Dr. Lichtenfeld did not suggest otherwise.

Given that the insert directs physicians to obtain a medical history from a patient being considered for vaccination, and given that the insert specifically highlighted neurological disorders in general and GBS specifically, no reasonable person could say that the insert was inadequate as a "heads up" warning **to physicians**. Learned intermediaries were unquestionably put on unambiguous notice of the questions that they should be asking when considering inoculation for influenza in 1989. Dr. Lichtenfeld at no time said that medical histories were not a specially-noted, essential prerequisite to inoculation.

As regards its accuracy, Connaught's package insert contained state-of-the-art medical knowledge about a possible connection between the 1989-90 strain of influenza vaccine and GBS. It highlighted the reported connection in 1976, but accurately noted that no increase had been observed since. The insert actually tracked the language and recommendation of the

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[14] Nurse Fox stated she knew what the term meant.

[15] Nurse Fox know, as well, that GBS is a neurological disorder.

ACIP, an expert panel commissioned by the CDC for that purpose. Indeed, it did not even go so far as the newsletter of Dr. Lichtenfeld's organization, the International Guillain-Barré Syndrome Foundation, which affirmatively advised that "the risk of the vaccine triggering the symptoms [of GBS] is much lower than the risks associated with influenza." Dr. Lichtenfeld himself acknowledged that he knew of no way to prove statistically a connection between the flu vaccine and GBS, based on his belief that physicians typically do not report adverse reactions. The trial court properly discounted Dr. Lichtenfeld's personal preference for more emphatic language regarding a neurological disorder from which he personally had suffered, and found the insert was accurate if "fairly read." (R. 1005).

Mass inoculation to control the further spread of epidemics is essential to the welfare of the nation. The policy of the law ensures that pharmaceutical manufacturers are not held liable when a treatment, which is otherwise beneficial, is linked to an occurrence of a rare disorder or disease. This is particularly necessary, if epidemics are to be controlled, when causation between onset of a rare disorder and the product is not proven. The RESTATEMENT OF TORTS as adopted in Florida, *see, e.g., Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728 (Fla. 2d DCA 1991); *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So. 2d 820 (Fla. 5th DCA 1981); *E.R. Squibb & Sons, Inc. v. Jordan*, 254 So. 2d 17 (Fla. 1st DCA 1971), addresses the distribution of products, including vaccines like the influenza vaccine, that have unavoidable side effects:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many

> of which for this very reason cannot be legally sold except to physicians, or under the prescription of a physician.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1959).

The risks associated with influenza make the vaccine precisely the type of product that should be made readily available to the public. Its possible connection to the onset of GBS was discussed in its package insert. The insert did not emphatically warn to Dr. Lichtenfeld's satisfaction that the vaccine could cause GBS, but even he conceded that GBS is a rare disorder and its statistical connection to the vaccine may never be proven. Tellingly, he did acknowledge the risks posed by *influenza*, and he acknowledged that the increased incidence of GBS in 1976 was the direct result of a mass vaccination needed to combat that serious epidemic. "When you do have those numbers, then what is a rare occurrence becomes obvious." (R. 1302).

The ultimate legal question in pharmaceutical warning disputes is whether the insert was adequate to inform a physician "of the possibility that [the treatment] might be causing the condition." *MacMurdo*, 562 So. 2d at 683. Connaught's package insert specifically and affirmatively advised the physician to delay vaccination of an individual with an active neurological disorder. It further advised that, while vaccination may be *considered* when the disorder has stabilized, specific inquiry is required and a patient with a history of a neurological disorder should be referred to a physician before receiving an injection. Nurse Fox understood those directions. Thus, no reasonable person could hold Connaught liable for an insert that adequately informed even a medically-trained person like Nurse Fox. The "expert" opinion of Dr. Lichtenfeld that a more forceful warning was needed is contradicted by the fact evidence. Just as in *MacMurdo*, the evidence was insufficient to present a jury question. 562 So. 2d at 683.

B. Based on the record evidence, Connaught's package insert was not the proximate cause of Farnes' injuries.

Farnes asserted that Connaught's allegedly inadequate insert was the proximate cause of his illness. (R. 267). He argued that Connaught had a duty to warn him, directly and through a learned intermediary, of the possible connection between the vaccine and GBS. (R. 267). Connaught's duty was to the physician, though, not to Farnes.

> Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus *if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume the physician will exercise the informed judgment there gained in conjunction with his own independent learning*, in the best interest of the patient.

Buckner, 400 So. 2d at 823 (emphasis added) (quoting *Terhune v. A.H. Robbins Co.*, 577 P.2d 975, 978 (Wash. 1978)). Thus, where the record evidence establishes that the prescribing physician understood the warnings in the package insert and had knowledge of the associated risks, the Court has held that the adequacy or inadequacy of a warning cannot be the proximate cause of the injuries claimed.

> The [district] court reached the conclusion [that there was no proximate cause] because the prescribing physician testified that he fully understood the warnings and also had prior knowledge of the [harmful] propensity of [the product]. Therefore, we agree that any inadequacy in the [product] warning could not have been the proximate cause of the [harm] in this case.

Felix, 540 So. 2d at 105.

The learned intermediary in this case was Nurse Fox, by designation of Dr. Jahnig. Her testimony established a break in proximate cause which made irrelevant the adequacy or inadequacy of Connaught's package insert. Nurse Fox had never given a vaccine prior to injecting Farnes. She testified that, for that very reason, she read the entire package insert.

She further testified that she understood from the insert that while an individual with an active neurological disorder should not receive the vaccine, inoculation could indeed be considered for an individual with a history of a neurological disorder, after physician approval. She was aware that GBS is a neurological disorder, and she understood the importance of reviewing a patient's history. She said she could not remember whether she asked Farnes if he had any history of a neurological disorder, but remembered that she did not consult his medical file or refer him to Dr. Jahnig.[16] "Since physicians do not have an absolute duty to inform patients of all possible side effects in every instance, failure to do so in a particular instance should not give rise to a duty in the manufacturer." *Buckner*, 400 So. 2d at 824.

In light of Nurse Fox's testimony and the absence of anything to the contrary concerning the knowledge and understanding of the vaccine-administering "learned intermediary," Dr. Lichtenfeld's opinion as an "expert" that the language in the insert referring to GBS was misleading as to the connection between the vaccine and the symptoms of GBS was irrelevant. His bottom line opinion was that, "all factors being equal," he would not give a flu vaccine to a former GBS sufferer. (R. 1332). This qualification on his opinion provides the key to a directed verdict for Connaught, for here all factors were *not* equal.

Farnes was employed in a medical clinic where exposure to influenza was potentially hazardous both to patients of the clinic (if he were a carrier) and to himself (from patients suffering from the flu). This setting was one specifically mentioned in the package insert as being appropriate for getting a flu inoculation. Farnes, a health care provider himself, requested the flu shot to protect *himself* against exposure to persons suffering from influenza. (R. 1216-17). Nurse Fox knew from the insert of the risks that influenza poses to health care workers and their patients. Nurse Fox knew that, for Farnes and the other clinic employees, all factors were anything *but* equal. Under these circumstances, the trial court should have

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[16] Farnes testified that she did not ask him about his history of GBS and he did not offer the information. (R. 1275). He did say, however, that if he had been asked if he had GBS he would have answered "yes." (R. 1221).

held that Connaught's package insert was not the proximate cause of Farnes' illness, and that Connaught was entitled to a directed verdict.

CONCLUSION

Connaught, Squibb, and Schein request that the Court find that the district court's decision failed to apply the *Smith*, *Felix*, and *MacMurdo* decisions to hold, on this record:

1. that the trial court properly weighed the credibility of the parties' expert witnesses with all of the evidence;

2. that the trial court did not abuse its discretion in setting aside the jury verdict as being against the manifest weight of the evidence;

3. that the district court's decision, directing the trial court to reinstate the jury verdict, be vacated;

4. that the package insert supplied to physicians with Connaught's flu vaccine was adequate to inform them of the possible connection between the vaccine and a recurrence of GBS, as a matter of law, and in any event the vaccine was not the proximate cause of Farnes' illness; and

5. that the trial court be directed to enter judgment for Connaught, Squibb, and Schein.

To avoid future disharmony in the law, the Court should also require the district courts, when reversing a trial court's order granting a new trial, to articulate with specificity their reasons for doing so.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing brief on the merits was mailed on August 5, 1996 to:

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