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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.

ANSWER BRIEF OF BOYD B. FARNES

ON DISCRETIONARY REVIEW
FROM THE THIRD DISTRICT COURT OF APPEAL

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FARNES' RESPONSE TO CONNAUGHT'S INTRODUCTION

This action arose because CONNAUGHT's influenza vaccine caused FARNES to contract Guillain Barre' Syndrome ("GBS") and to suffer horrific, continuing and permanent injuries to his body and his mind. FARNES had already once suffered from GBS as a youth but had recuperated. CONNAUGHT, prior to 1985, had expressly warned physicians not to prescribe the vaccine to patients with a history of GBS. CONNAUGHT chose to remove the express GBS warning from its package insert in 1985 and replace it with language that, according to FARNES' medical expert and substantial other evidence, was "misleading and grossly inadequate" because it gave the physician a false sense of assurance that the vaccine would no longer cause GBS.

The trial judge rejected the unobjected to testimony of FARNES' medical expert on the warning issue and re-engineered the evidence before finding its manifest weight to be contrary to the jury's verdict. Contrary to CONNAUGHT's contentions, the district courts did not re-weigh the evidence and it did not opine that trial courts cannot consider witness credibility when deciding motions for new trial. Instead, it reviewed the evidence as a whole and determined that reasonable men could not agree with the propriety of the trial court's conclusion that the jury's decision on the warning issue was contrary to the manifest weight of the evidence.

STATEMENT OF THE CASE

At issue in this case is CONNAUGHT's duty to adequately warn the learned intermediary of the risk that its influenza vaccine might cause GBS. Contrary to CONNAUGHT's representation at page 2 of its Initial Brief, the evidence on this point consisted of far more than "a single expert witness" presented by each party. The evidence, most of which is ignored by CONNAUGHT, will be discussed at length under FARNES' Statement of the Facts.[1]

The Order Granting New Trial and the Petitioners' Initial Brief, clearly reveal that a new trial was granted only because the trial court was of the independent belief that the jury should not have accepted the opinions of FARNES' expert medical witness on the warning issue. (R.999-1006; Petitioners' Brief, p.2). No issue exists at this juncture as to whether CONNAUGHT's vaccine caused FARNES' recurrence of GBS; or as to FARNES' pre-trial medical expenses which were stipulated to exceed One Million Three Hundred Thousand and 00/100 Dollars ($1,300,000.00); or as to FARNES' future medicals and other economic damages which exceed Twenty-Five

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[1] Citations to the record are indicated as "R.___." The Plaintiff's trial exhibits are indicated as "Pl.Ex.____." The transcript of the trial proceedings of October 20, 1994 have been numbered as pages R.1363 through 1436111 and appear in the Appendix to the Initial Brief before the District Court of Appeal, and has been included in the Record on Appeal as an Appendix by the Clerk of the District Court.

Million and 00/100 Dollars ($25,000,000.00) before reduction to present value.[2] (R.694-95, 1262, 1531, 1545).

Although CONNAUGHT alludes throughout its Brief to the actions of the responsible heath care professionals, it never asked that any individual or entity be included on the verdict form for apportionment of damages purposes except for FARNES. Also, the jury instructions and verdict form requested by CONNAUGHT were provided and used, including all provisions relating to the warning issue. (R.1597-1610).

CONNAUGHT admits in its Statement of the Case that the district court modified its initial decision, *Farnes* **v.** *E.R. Squibb and* Sons, *Inc.*, 21 Fla. L. Weekly D.2 and D.392 (Fla. 3rd DCA, Dec. 20, **1995** and Feb. 14, 1996) (R.1777-79), yet fails to remind this Court that it relied in substantial part on language resulting from a scrivener's error in the original, now vacated, opinion in its jurisdictional arguments. This omission is material because, now

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[2] Unrefuted evidence of the injuries to FARNES' health, the extensive medical care provided, the severe complications of the treatment required to save FARNES' life, needed future medical care, and the cost of past and future care and damages was provided by the following witnesses. Andrew Taylor, M.D., Internist and Endocrinologist, (R.894-929); Timothy G. Murray, M.D., Ophthalmological Surgeon, (R.930-72); Jay Michael Weinstein, Ph.D., Psychologist, (R.973-98); Robert Shebert, M.D., Neurologist, (R.848-93); Cheryl Meyers, Physical Therapist, (R.1365-70); Michael Morganstern, Vocational Rehabilitation Expert, (R.1371-91); Jeffery Lee Hortstmyer, M.D., Neurologist, (R.1439-66); Robert Casola, M.D., Orthopaedic Surgeon, (R-1486-1507); Frederick Raffa, Ph.D., Economist, (R.1509-44).

on the merits, CONNAUGHT's assault on the district court's opinion is founded on the flawed premise that this Court should infer non-existent language into the district court's opinion that would, according to CONNAUGHT, be contrary to the mandate in Smith v. Brown regarding consideration of witness credibility.[3]

STATEMENT OF THE FACTS

CONNAUGHT's 'Statement of the Facts" is primarily a recitation of the trial court's independent recollections of the evidence along with inferences, that CONNAUGHT, would like to see drawn. CONNAUGHT ignores the significant, material and voluminous evidence presented to the jury and upon which its determination of the warning issue was based. Accordingly, FARNES is compelled to include a far more extensive Statement of the Facts than would ordinarily be the case in an Answer Brief presented to this Court.

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[3] Indeed, the Petitioners appear to have retreated from their primary jurisdictional argument that express and direct conflict appears from the original, now vacated, opinion which contained a scrivener's error as to the standard of review. Clearly, under the applicable constitutional mandate, conflict must be both express and direct and not inferred. *The Department of Health v. National Adoption* Counseling, **498 So.** 2d **888** (Fla. **1986**); *Kennedy v.* Kennedy, **641 So.** 2d **408** (Fla. **1994**). FARNES will not re-argue the matters addressed in his Brief on Jurisdiction but would ask that they be considered if this Court elects to revisit the issue of conflict jurisdiction.

I. FARNES' INOCULATION WITH THE FLU VACCINE AND THE EXTREMELY GRAVE NATURE OF THE GBS RISK.

The jury heard extensive evidence from which it could determine how the lack of warning about GBS impacted upon FARNES' receipt of CONNAUGHT's vaccine and from which it could determine the severe gravity of the risk posed by GBS to those who contract it from influenza vaccine.

FARNES was employed as a site technician at the Guidance Clinic of the Florida Keys ("the Guidance Clinic") on October 17, 1989 when he was administered an influenza virus vaccine by Cynthia Fox, a registered nurse, who was working under the clinical supervision of Paul Jahnig, M.D. (R.1209-1221, 14363, 1436J.) FARNES permitted himself to be inoculated after being advised by the medical personnel that he should not receive the vaccine if:

1. He was allergic to eggs;
2. He had a respiratory tract infection; or
3. He had previously reacted adversely to a flu shot.

(R.1436H-J)

The warnings discussed with FARNES were contained in the vaccine's product insert prepared by the manufacturer, CONNAUGHT (Pl.Ex.3).

FARNES was never informed that the vaccine could cause the recipient to contract Guillain-Barre' Syndrome ("GBS"), a rare, but a severely crippling and sometimes fatal, neurological disorder. (R.1220-23) GBS involves a reaction by the body's immune system, in some people prone to the illness, where the myelin sheaths surrounding the nerves are mistaken for a foreign protein and attacked by the immune system. (R.855-62, 1291-92) FARNES had suffered from GBS as a child and was confined to a wheelchair throughout his teen years. (R.1205, 1267-68) By October

1989, FARNES had fully recovered from his earlier GBS except: for some minor effects. (R.1206-07). Tragically, FARNES had no idea that CONNAUGHT's influenza vaccine would place him at risk of re-contracting the terrible illness. (R.1218-1223).

FARNES was not informed that CONNAUGHT's influenza vaccine could cause him to again contract GBS because the responsible corporate officials at CONNAUGHT had decided to remove an earlier express warning directed at people with a history of GBS and, instead, include language that would assure physicians that influenza vaccines would not cause the disease. (Pl.Ex. 3; R.1202, 1436PP-QQ).

FARNES, as a person susceptible to GBS, would pay a heavy price for the "misleading and grossly inadequate" language contained in the CONNAUGHT package insert (R.1309). Ten (10) days after receiving the injection, FARNES began to experience numbness in his lower extremities which signified the onset of GBS and the beginning of a nightmarish battle with the disease that would ravage FARNES' mind and body and end, more than three (3) years later, in a tenuous truce held in place only by continuous application of high technology medical care. (R.1223-63)

The horrific destruction wrought upon FARNES vividly highlights the grave risk about which the Petitioners were obligated to adequately warn prescribing physicians. FARNES' battle with GBS was fought for One Thousand Eighty-Five (1,085) days as an in-patient at Jackson Memorial Hospital and later at a county operated nursing home (R.1232) and has included periods of partial paralysis and total quadriplegia. (R.1233-34, 1256) FARNES has been forced to undergo massive doses of steroidal drugs to combat the illness, and the turn of the battle has changed from time

to time as FARNES would gain ground on his GBS and then again lapse into complete paralysis. (R.1223-63).[4]

After spending his 33rd, 34th and 35th birthdays in the hospital, FARNES was discharged on December 17, 5992 and transferred to a county operated nursing home. (R.1249) He is now totally disabled but able to reside at home if he receives the home health therapies and other medical care necessary to stave off a relapse of his GBS which is now chronic and may never be totally in remission. (R.1254-59) FARNES begins to experience the numbness and tingling which marks the onset of another bout with paralysis on a monthly basis that is reversed only through intravenous infusions of a highly expensive drug, known as immunoglobulin. (R1250, 1257) Without this ongoing treatment, FARNES' GBS will progress again to paralysis and may result in death. (R.1256-57, 1336, 1461) FARNES is expected to need the therapy for the rest of this life. (R.1461)

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[4] The battle raging in FARNES' body nearly ended in death on several occasions,. He suffered from pulmonary emboli twice when his physicians thought he would die. (R.1236-40, 1459-60) Then, the blood thinning agents required to treat the emboli nearly caused him to bleed to death from a simple tooth extraction. (R.1240-42) FARNES' body swelled to over 400 pounds (R.1235-36) and his flesh was so devastated that a nurse, attempting to turn him, inadvertently pushed her hand through his skin. (R.1249) Calcium depletion arising from the drugs needed to save FARNES' life has caused his bones to deteriorate, (R.1243-44) his teeth to fall out, (R.1240) his vertebrae to break, (R.1243) and this hips to develop avascular necrosis which will necessitate total hip replacements. (R.1250) Not even FARNES' eye sight could be saved from the effects of the disease and requisite life saving treatment. FARNES now suffers from posterior cataracts which cloud his vision and blind him in bright sun light. (R.1247) FARNES will require surgery to partially restore his vision in both eyes. (R.1279).

FARNES' chief treating neurologist, Robert Shebert, M.D., a professor of neurology at the University of Miami School of Medicine, and FARNES' expert medical witness, Peter Lichtenfeld, M.D., both concluded that FARNES' current GBS was caused by the influenza vaccine injection on October 17, 1989. (R.868-70, 1335-36). Even the defense expert, W.C. Wiederholt, M.D., conceded that the onset of FARNES' GBS ten (10) days after injection, was in the window most likely consistent with causation in the opinion of Dr. Wiederholt, as well as "everyone else" based on the 1976 epidemiological study.[5] (R.1585-86)

II. THE EVIDENCE OF RECORD RELATING TO THE INADEQUACY OF THE WARNING.

A. The Evidence about CONNAUGHT's Package Insert.

CONNAUGHT admits in its Brief, that its package insert included the following language:

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[5] Dr. Wiederholt has testified, in the past, that the 1976 vaccine caused some specific patients to contract GBS. (R.1569-73) Dr. Wiederholt, who never examined FARNES, continued to stand by his opinion at trial, however, that vaccines manufactured after 1976 from different virus strains have not been associated with an increased risk of GBS. (R.1568-73) Dr. Wiederholt is also of the opinion that physicians need not warn patients of the risk of contracting GBS before prescribing a flu shot. (R.1580) Dr. Wiederholt was unaware that the 1989 vaccine was manufactured in the same way as the 1976 vaccine and contains foreign proteins such as myelin (R.1587). The fact that CONNAUGHT's influenza vaccine caused FARNES' GBS was established at trial and is not at issue in the new trial granted solely as to the warning issue.

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

CONNAUGHT's Brief also admits that the following sentence was included in CONNAUGHT'S 1989 package insert immediately after the above language:

> "However, this association has been questioned by other physicians." (Pl.Ex.3; **R.1308-1311).**

CONNAUGHT fails to apprise the court, however, that while CONNAUGHT called into question the results of the 1976 study, its competitors were careful to include language to alert the physician that the risk of GBS still exists. The package inserts provided by the other three (3) manufacturers of influenza vaccine in 1989/1990 were admitted into evidence as Plaintiff's Exhibits 12, 13 and 14. (R.1392) CONNAUGHT stipulated to their authenticity and that they are the inserts actually provided with the vaccines of the other manufacturers. **(R.1035,** 1037) Each **of** the other manufacturers included language that insures that the physician would not be mislead to believe that the studies of data for years after 1976 meant that no GBS risk exists. Two (2) of them, Parke Davis and Weyeth, went so far as to describe the later studies as merely not demonstrating a "significant excess risk." The material difference between the language used by CONNAUGHT and the other manufacturers

is best demonstrated by comparing the language used immediately after describing the 1976 and later studies:

CONNAUGHT: "However, this association has been questioned by other physicians." (Pl.Ex.3)

WYETH: "Nevertheless, candidates for influenza virus vaccines should be made aware of the benefits and possible risks, including GBS, of administration. (Pl.Ex.13)

PARKE- DAVIS: Nonetheless, persons who receive influenza vaccine should be made aware of this [GBS] possible risk." **(Pl.Ex.14)**

LEDERLE: "Nevertheless, candidates for influenza virus vaccine should be made aware of the benefits and possible risks of administration, including GBS." (Pl.Ex.12)

Only Dr. Samuelson, CONNAUGHT's medical director and the person responsible for the language in its influenza vaccine insert (R.1404, **1436PP,** 1631), refused to believe the results of the 1976 study. (R.1436EE)

The Order Granting New Trial failed to acknowledge that CONNAUGHT never offered into evidence the relevant excerpts from the CDC's *Morbidity* ***and*** *Mortality Weekly Reporter* ("MMWR") which allegedly contained certain suggested language nor did CONNAUGHT present evidence that its package insert included <u>all</u> of the information allegedly recommended by the CDC. Instead, CONNAUGHT's medical advisor, Dr. Samuelson, testified that the language **used** by his company, like other influenza manufacturers, "are almost word

for word coming out of the MMWR for all of them, except for maybe one or two sentences." (R.1436TT) Dr. Samuelson further testified that he would be surprised if CONNAUGHT's warning language about GBS differed from that used by the other manufacturers. (R.1436TT) Yet, the evidence presented to the jury clearly established that CONNAUGHT's language about GBS significantly and materially differed from that of the other manufacturers in a way that caused CONNAUGHT's warning to mislead the physician about the risk of contracting GBS. (Pl.Ex.12, 13 and 14; R.1392).[6]

Dr. Samuelson, the person responsible at CONNAUGHT for the language in the package insert, even differed with the opinion of the defense expert at trial, Dr. Wiederholt, that influenza virus vaccines had been proven to cause Guillain Barre' Syndrome in some recipients. (R.1404, 1436EE, 1436PP, 1631) In fact, Dr. Samuelson testified that his company continues to receive adverse reaction reports each year of patients developing GBS after receiving CONNAUGHT's influenza virus vaccine and added "some of them are so

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[6] CONNAUGHT represents that the wording, in its insert, as it relates to GBS "was taken directly from the Public Health Services Immunization Practices Advisory Newsletter, which the insert specifically referenced." (Petitioners' Brief, p.5). As stated above, the actual evidence of record shows that CONNAUGHT chose to use language different from its competitors, failed to offer the alleged recommended language into evidence, and, at no time, offered evidence that any public agency advised or recommended that it downplay the 1976 epidemiological study or otherwise fail to clearly inform the physician that a risk of contracting GBS from influenza vaccine exists.

off the wall I just laugh at them" (R.1436CC) and he has never seen a report that he feels is not "off the wall." (R.1436DD). CONNAUGHT chose not to disclose these adverse reaction reports in its package insert. (Pl.Ex.3).

The evidence at trial was also undisputed that reliance upon alleged government recommended language to be included in package inserts does not equate with adequacy. Dr. Lichtenfeld, the Plaintiff's expert, testified that reliance upon such recommended language should not cause a warning to be adequate. (R.1328) Dr. Ralph Vosdingh, CONNAUGHT's Director of Regulatory Affairs, testified that drug manufacturers must warn about medical risks whether or not the requisite language is suggested by the CDC; and that they should warn about possible adverse reactions that are temporally associated even if the causal association has not been proven to the manufacturer's satisfaction when the drug is sold. (R.1421-22) CONNAUGHT's Vice President for Operations, Gary Ebert, Ph.D, conceded that his company "absolutely" does not leave it up to the Food and Drug Administration to comply with its warning responsibilities (R.1639) and further testified that his company must follow FDA regulations prohibiting misleading language in package inserts and that language is:

> "Misleading if it fails to reveal facts that are material in light of other representations made or suggested by statement, word, design, device, advice or any combination thereof." (R.1636) (Referring to 21 C.F.R. §1.21)

The Petitioners also failed to admit into evidence the medical literature articles referred to in their package insert which they now cite in their Brief. (Petitioners' Brief, p.5). No expert testified at trial that the information from the articles referred to in the package insert adequately warned the physician of the risk of contracting GBS. The only expert witness to testify about this point was FARNES' expert, Dr. Lichtenfeld, who testified that the insert references those studies which question the 1976 association, but 'doesn't reference any of the multitude of medical literature that identifies and proves the association. It doesn't reference those at all." (R.1310-11) Moreover, CONNAUGHT never offered one word of testimony, expert or otherwise, to the effect that the referenced articles contained information which adequately evaluated the risk of contracting Guillain-Barre' Syndrome from the influenza vaccine.

B. Expert Testimony at Trial.

A review of the trial court's order in this case as well as CONNAUGHT's Statement of the Facts, would lead one to conclude that CONNAUGHT's expert, Dr. Wiederholt, testified emphatically that the package insert adequately warned the physician of the GBS risk while FARNES' expert, Dr. Lichtenfeld, possessed marginal credentials and expressed no more than a personal preference based upon 'junk science." A review of the evidence of record presents

quite a different picture and reveals facts that clearly and unequivocally support the jury's determination.

1. Dr. Wiederholt:

The trial court's order erroneously credits Dr. Wiederholt with the following expert medical testimony:

> "Dr. Wiederholt testified that the package insert adequately warned the physician of the GBS risk potentially associated with influenza vaccine because it accurately reported the state of medical knowledge both in 1989, and to this day." (R.1005)

The record, however, reveals that Dr. Wiederholt merely said the following with respect to CONNAUGHT's package insert:

> "Question: Doctor, have you reviewed the CONNAUGHT package insert in this case?
>
> Answer: Yes, I have.
>
> Question: Do you have an opinion whether that insert provides adequate state of the art medical information to the health care providers?
>
> Answer: I think it does."

(R.1573)

Dr. Wiederholt never testified that "the package insert adequately warned the physician of the GBS risk potentially associated with influenza vaccine . . . " (R.1005) which was the precise issue about which the trial court found the jury's determination to be contrary to the manifest weight of the evidence. Moreover, Dr. Wiederholt offered absolutely no testimony

regarding MMWR, FDA or CDC recommended package insert language and at no time implied that CONNAUGHT had properly utilized such language or that such language equates to adequacy. Dr. Wiederholt never testified that he has reviewed package inserts in the past or that he has at any time helped prepare one. In short, Dr. Wiederholt's testimony did not even relate to the specific question of whether or not CONNAUGHT's package insert adequately warned the physician about the risk of contracting Guillain Barre' Syndrome.

2. Dr Lichtenfeld.

The trial court's order finds Dr. Lichtenfeld to be no more than ". . . a neurologist in private practice on suburban Long Island, New York." (R.1003) The undisputed evidence of record, however, clearly demonstrates that Peter Lichtenfeld, M.D., is a Board Certified Neurologist (R.1285), a diplomat of the National Board of Medical Examiners, a fellow of the American academy of Neurology, the current and past holder of several teaching positions in the field of neurology[7] and has prepared and had published, in professional journals, articles on subjects including Guillain Barre' Syndrome. (R.1286-88) Dr. Lichtenfeld's interest in Guillain Barre' Syndrome goes far beyond his personal experience as a victim of the disease which was emphasized by CONNAUGHT and the trial court. Dr. Lichtenfeld specializes in the treatment of GBS and receives referrals of patients and requests for

[7] Dr. Lichtenfeld teaches or has taught medicine at the following institutions: Mount Sinai School of Medicine, New York; Brown University College of Medicine; State University of New York; Albert Einstein College of Medicine; and Cornell Medical College at Cornell University.

consultations from physicians from "all other the country and many parts of the world." **(R.1288-89)** Dr. Lichtenfeld has provided direct care, **as** either the primary or consulting physician in approximately three hundred **(300) GBS** cases, constantly sees new GBS cases and has followed old GBS cases for years. **(R.1291)** Dr. Lichtenfeld **has** also developed specialized expertise over the years in the association between GBS and vaccines, including flu vaccines. **(R.1291-98)** He has personally researched the world's literature on this subject and is familiar with the pertinent epidemiological studies in the area. **(R.1288, 1295-1304, 1324-26, 1391)** Dr. Lichtenfeld himself participated in CDC sponsored studies concerning the association between GBS and flu vaccines, **(R.1293-96)** and, contrary **to** the finding in the Order, has studied the warnings contained in the package inserts of manufacturers of flu vaccines over the years, including the warning at issue in the present case. **(R.1295-99)**

The Order Granting New Trial also inaccurately states that Dr. Lichtenfeld 'has testified repeatedly on behalf of plaintiffs in GBS cases involving influenza and other vaccines." **(R.1004)** The record establishes that Dr. Lichtenfeld said "Yes" when asked on direct and cross-examination if he has "been involved in testifying as an expert witness in **cases** involving GBS and vaccines before?" **(R.1291, 1343)** Dr. Lichtenfeld then discussed one of those cases. **(R.1344)** No evidence of record indicates that Dr. Lichtenfeld "testifies routinely on behalf of Plaintiffs in GBS cases . . ." as was determined by the trial court.

Dr. Lichtenfeld was expressly presented as an expert in neurology, Guillain Barre' Syndrome, the association between GBS and vaccines and the warnings included in product inserts. **(R.1296)** After availing himself of

the opportunity to voir dire Dr. Lichtenfeld on his expert qualifications, counsel for the defense replied as follows to FARNES' counsel's presentation of Dr. Lichtenfeld to the Court as an expert in each of these areas:

> MR. MURRAY: I think that is an outmoded practice, Judge. We don't do that anymore. The Court doesn't place some stamp of approval on him. If I don't object, he can testify. (R.1299)
>
> THE COURT: Okay. **(R.1299)**

Dr. Lichtenfeld's expert medical testimony, including his opinions regarding the adequacy of CONNAUGHT's package insert language about GBS, was admitted largely without objection **and** CONNAUGHT at no time attempted to exclude any of Dr. Lichtenfeld's opinions on any basis whatsoever. The Order Granting New Trial substantially mischaracterizes Dr. Lichtenfeld's expert opinions regarding the CONNAUGHT's package insert. For example, the Order provides, in part, as follows:

> "Dr. Lichtenfeld testified CONNAUGHT should have warned more emphatically that a causal connection existed between flu vaccine (and in his opinion all vaccines) and GBS. In particular Dr. Lichtenfeld testified the warning should have stressed that FARNES should not have received the shot because of his past history of GBS. Dr. Lichtenfeld **gave** no particular basis apart from personal preference, for his opinion that the warnings should have been stronger. See, Daubert v. ***Merrill Dow*** Pharmaceuticals, **1135 S.** Ct. **2786** (1993) (condemning "junk science.") He agreed, in essence, that no epidemiological study has shown a statistically significant association between influenza vaccine **and** GBS since 1976."

(R.1004)[8]

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[8] The trial court's reference to the United States Supreme Court decision in the *Daubert* case is unreasonable since it does not state the law in Florida, *Flanigan* v. State, 625 ***So.*** **2d 827** (Fla. 1993), and no objections were made with respect to the

All experts agreed that the studies of the 1976 data established epidemiologically the causal association between influenza vaccines and Guillain Barre' Syndrome. Contrary to the assertions made by the Petitioners, even Dr. Wiederholt admitted that he has testified to this association on many occasions in the past. (R.1577-78). No such epidemiological study has been fully completed using data subsequent to 1976, however, a significant risk of contracting GBS from influenza vaccine continues to exist. (R.1324-26)[9]

The New Trial Order concludes that Dr. Lichtenfeld merely believed the warnings should have been stronger solely on the basis

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scientific basis for Dr. Lichtenfeld's opinions on the warning issue. See Fla. R. Evid. 705; 590.705, Fla. Stat. (1993).

[9] Dr. Lichtenfeld testified that the causal association between flu vaccine and GBS was accepted and documented in the medical literature long before and since 1976. (R.1300-03) The unusually large (45 million) number of people vaccinated in a short time (ten weeks) in 1976 provided a data base from which the association could be confirmed. (R.1300, 1302) A CDC study of 1978-79 data, in which Dr. Lichtenfeld participated, was inconclusive due to under reporting, (R.1324-26) but showed some increase in the incidence of GBS. (R.1325-26) Dr. Lichtenfeld's opinion about the causal association between flu vaccine and GBS, which has long been medically recognized, was corroborated by: (1) the study of the 1976 data; (2) reports of GBS following vaccination within the time window consistent with causation that are continuously made (R.1300-03); (3) the fact that the influenza vaccine continues to be manufactured exactly as it was in 1976, the only difference, according to the undisputed evidence, is the strain of the virus which changes every year (R.1393, 1436, 1573); and (4) the fact that the foreign proteins, such a myelin, which are contained in the manufacturing process, are still present in flu vaccines (R.1633) and it is the immune system's reaction to such proteins, in some people, that results in GBS. (R.1300-03)

of his personal preference. (R.1005). The record, however, clearly establishes that Dr. Dr. Lichtenfeld's opinion was that the warning was grossly misleading and inadequate because it falsely assured the physician that the risk of contracting GBS from influenza vaccine no longer existed in 1989. (R.1308-1338) Dr. Lichtenfeld testified at length about GBS, the causal association between GBS and flu vaccines (R.1288-1350), the fact that CONNAUGHT's vaccine caused FARNES' recurrence of GBS (R.1335-36) and about the inadequacy of CONNAUGHT's warning. (R.1307-36) As to the package insert language itself, Dr. Lichtenfeld testified, in part, as follows:

Q. Do you have an opinion within a reasonable degree of medical probability, whether this statement under the adverse reaction portion of the product insert: Unlike the 1976 swine influenza vaccine, subsequent vaccines prepared from other virus strains have not been associated with increase frequency of Guillain Barre' Syndrome.

Do you have an opinion whether or not that statement is adequate to properly convey to a doctor the risks associated between flu vaccine and GBS?

A. I do.

Q. What is your opinion?

A. That it is misleading and grossly inadequate.

Q. In what way?

A. It gives a false sense of assurance. There is no hesitancy on the part of this company in this product

insert to describe isolated reports of other things that happened.

For example, under warnings it states --

MR. MURRAY: I object. He has gotten off to some narrative that has nothing to do with the last question which simply is this an adequate warning and why not.

THE COURT: Objection overruled.

THE WITNESS: Under warnings it says isolated reports of an effect of flu vaccines, and it lists several medications have not been confirmed. It states that in the package insert. In other words, it raises a warning in the doctor's or in the nurse's mind that if *you* are taking some of those medications that there have been reports of an interaction with the flu vaccine. Those are isolated reports and that is appropriate.

Why is the fact that isolated reports, many of them, of people developing GBS after flu vaccine are not spoken of in the same way. That should be warned against. This statement that 1976 happened and then left just like that is inappropriate. The fact is that **1976** happened and nobody did any basic research to see --

MR. MURRAY: Objection, this is a rambling narrative and it has no end in sight.

MR. SINCLAIR: We'll get into that.

BY MR. SINCLAIR:

Q. What does this tell *you* as a doctor looking at the insert? Would this tell you there is an association or would this tell you there is no association?

A. If you knew nothing else other than what you read here, you would think that there is no association. That something happened in **1976**, but for **some** reason it doesn't happen anymore.

(R.1308-10)

* * *

Q. Does this statement in yellow here that I have highlighted out of the product insert accurately in your professional opinion, does it accurately reflect the medical opinions in this field?

A. No, it doesn't even reflect the subsequent studies that were done.

Q. Doctor, what about the next statement that follows this in the product insert that I have not highlighted but says after that: However, this association has been questioned by other physicians. What does that indicate to you?

A. That indicates that even the 1976 association has been questioned by some physicians. And then it references those. But it doesn't reference any of the multitude of medical literature that identifies and proves the association. It doesn't reference those at all.

(R.1310-11)

Q. Is there any warning contained in this entire product insert that you reviewed, Doctor, that conveys a warning concerning the risks associated between -- or concerning the association between Guillain-Barre' Syndrome and this vaccine?

A. Just the opposite. It implies here -- No, it doesn't even leave it neutral, it implies that there is no association.

(R.1311)

Dr. Lichtenfeld also testified, without objection that neither the average doctor, practitioner nor nurse was aware of the causal relationship between flu vaccines and GBS in October 1989. (R.1337-38)

Dr. Lichtenfeld also testified about the adverse reaction information available to CONNAUGHT to confirm the continuing risk of contracting GBS from influenza vaccines manufactured up to 1989.[10] (R.1314) Although Dr. Lichtenfeld was permitted to testify about the importance of the adverse reaction data (R.1323-1327, 1313-14), the trial judge sustained one of CONNAUGHT's objections in this area to this and made the following finding:

> THE COURT: He [Lichtenfeld] knows all about these adverse reactions form other sources. All he is telling the jury is that the language ain't worth a darn. What else do you want? Do you want to pollute it some more or make it more comfortable for the defendant, more than it should be?

(R.1319-20)

The above discourse demonstrates that Dr. Lichtenfeld, without any objection to his qualifications as a medical expert, established a sound factual basis for the jury's determination that the warning was inadequate. Lest there be any doubt about this, the trial judge then commented:

> THE COURT: That happens. An expert, like he is, he said that is not a good enough warning. I don't know how you beat a dead horse? (R.1321)

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[10] This is the information that CONNAUGHT's medical adviser, Dr. Samuelson, testified that his company receives in the form of adverse reaction reports each year of patients developing GBS after receiving CONNAUGHT's influenza vaccine and about which he testified "but some of them are so off the wall I just laugh at them." (R.1436CC)

The Order Granting New Trial, as well as CONNAUGHT'S Brief, also mischaracterizes the evidence of Dr. Lichtenfeld's opinion regarding the New England Journal of Medicine article and the publication of Guillain Barre' Society International.

The Order provides in part, as follows:

> "Furthermore Dr. Lichtenfeld conceded that both that New England Journal of Medicine and the Guillain-Barre' Society International, on whose medical advisory board he sits, recommended that persons with a past history of GBS receive influenza vaccine. He simply disagreed with these recommendations of established medicine."

(R.1004)

The referenced articles do not even deal with the question of whether persons with a history of GBS should be warned about the risk of re-contracting the disease from influenza vaccine. The articles were not offered into evidence and no evidence was presented that the articles stated an applicable standard of care or practice that would indicate that their authors spoke for the majority of experts in the field or that their views constituted "recommendations of established medicine."

Dr. Lichtenfeld was never even asked about the New England Journal of Medicine article and no evidence was presented that "the New England Journal of Medicine . . . recommended that persons with a past history of GBS receive influenza vaccine." Moreover, The author of the publication from the Guillain Barre' Society, with whom Dr. Lichtenfeld disagreed, was not even a neurologist and

failed to consult with any member of the Society's Medical Advisory Board. (R.1349-50)

The Order's conclusion that Dr. Lichtenfeld disagrees with recommendations of established medicine, therefore, is based upon the trial court's independent determination that Dr. Wiederholt's opinion, on the question of vaccinating patients with a history of GBS, is shared by established medicine and differs materially from Dr. Lichtenfeld's. A further review of the evidence reveals that Dr. Lichtenfeld's disagreement with Dr. Wiederholt on this point, if any, was strictly limited to his medical opinion about weighing the relative risks of vaccination, and is totally mischaracterized by the order. Dr. Lichtenfeld's own testimony best demonstrates this point:

> Q. (By MR. MURRAY) Doctor, is it fair to say that you would have said that a former GBS patient simply shouldn't get flu vaccine or any vaccine?
>
> A. No. What I told patients and have been telling them always and still do, is that if it is not a life threatening situation avoid any injection of anything that might contain a foreign protein or vaccinations or immunizations like that. If it is not essentially for your health, don't take a chance.

(R.1347-48)

The Order Granting New Trial and CONNAUGHT's Initial Brief thus relies heavily on allegedly conflicting evidence as to whether and when persons with a past history of GBS should receive influenza vaccine. Neither the record, the Order Granting New

Trial nor CONNAUGHT's Brief, however, contains any evidentiary basis supporting the failure to warn the physician of the risk of GBS in the first place so that an independent medical judgment call can be made in consultation with a patient who has already once suffered the horrors of GBS.

SUMMARY OF THE ARGUMENT

The trial court's determination that the jury's decision on the warning issue is contrary to the manifest weight of the evidence is simply unsupported by the evidence of record in this case. *Wackenhut Corp. v. Canty*, 359 So. 2d 430, 434 (Fla. 1978); *Laskey v. Smith*, 239 So. 2d 13, 14 (Fla. 1970). The trial court engaged in an impermissible re-weighing of the evidence, drew inferences unsupported by the record, viewed the evidence in the light most favorable to CONNAUGHT, and ignored the manifest weight of the evidence which preponderated in favor of the jury's determination. The trial court then improperly took on the role of a seventh juror and vetoed the reasoned conclusions that the jury reached after several days of trial and deliberation. *Wackenhut Corp. V. Canty*, 359 So. 2d at 435.

The district court's opinion is in compliance with this Court's prior decisional authorities. *Upjohn Co. v. MacMurdo*, 562 So. 2d 680 (Fla. 1990) (the adequacy or inadequacy of a drug package insert to warn the physician of a risk is ordinarily a question for expert medical opinion testimony.); *Smith v. Brown*,

525 So. 2d 868 (Fla. 1988) (it is a jury function to evaluate the credibility of any given witness); *Easkold v. Rhodes*, 614 So. 2d 495 (Fla. 1993) (it is the jury's province to determine the credibility and weight of expert witness testimony); *Wackenhut Corp. V. Canty*, 359 So. 2d 430 (Fla. 1978) (the reasons for granting a new trial must be set forth in the order so that appellate courts can "fulfill their duty of review"); and *Baptist Memorial Hospital, Inc. v. Bell*, 384 So. 2d 145 (Fla. 1980) (the appellate court may reverse a new trial order only if reasonable men cannot differ as to the propriety of the action taken by the trial court.)

CONNAUGHT's contention that the district court's opinion is in conflict with this Court's decision in *Smith v. Brown* finds no support in the record or in the district court's opinion itself. The instant case presents a proper application of the appellate review function as determined by this Court in cases such as *Smith v. Brown*, and CONNAUGHT merely seeks a second appeal.

CONNAUGHT's additional untimely contention that the trial court erred in failing to direct a verdict in this cause, entirely ignores the requirement that a drug warning be clear, accurate and unambiguous before it can be deemed adequate as a matter of law. *MacMurdo*, supra and *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989). A verdict may not be directed where any evidence of record exists to support the jury's determination. *Cadore v. Karp*,

91 So. 2d 806 (Fla. 1957); *Parsons v. Reyes*, 238 So. 2d 561 (Fla. 1970); and *Dania Jai-Alai Palace, Inc. v. Sykes*, 450 So. 2d 1114 (Fla. 1984).

The undisputed evidence of record reveals that Nurse Fox, acting under Dr. Jahnig's supervision, carefully read the package insert and assured that the patient was made aware of all risks that were warned about in it. A warning about the risk of GBS was not provided to FARNES because CONNAUGHT failed to adequately warn the learned intermediary about the risk. Accordingly, CONNAUGHT is not entitled to the special protections afforded drug manufacturers who adequately warn of risks. *Felix v. Hoffman-LaRoche, Inc.*, 540 So.2d 102 (Fla. 1989)

ARGUMENT

I. THE DISTRICT COURT OF APPEAL PROPERLY CONDUCTED A THOROUGH REVIEW OF THE RECORD IN THIS CASE AND CONCLUDED THAT REASONABLE MEN COULD NOT FIND THE JURY'S DECISION, THAT THE DRUG WARNING WAS INADEQUATE, TO BE CONTRARY TO THE MANIFEST WEIGHT OF THE EVIDENCE.

FARNES has no quarrel with CONNAUGHT's presentation of this Court's longstanding and well reasoned decisional authorities which permit appellate courts to reverse orders granting new trials on "manifest weight of the evidence" grounds, only where reasonable men cannot differ as to the propriety of the trial court's action. *Cloud v. Fallis*, 110 So. 2d 669 (Fla. 1959); *Baptist Memorial Hospital, Inc. v. Bell*, 384 So. 2d 145 (Fla. 1980); *Ford Motor Co. v. Kikis*, 401 So. 2d 1341 (Fla. 1981); *Smith v. Brown*, 525 So. 2d

868 (Fla. 1988). Central to the instant appeal, is the fact that the district court expressly applied this very standard in the opinion presented for review:

> "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."

Farnes v. E.R. Squibb and Sons, Inc., 21 Fla. L. Weekly D392 (Fla. 3d DCA February 14, 1996). (R.1779).

A. CONNAUGHT should not be given a second bite at the appellate apple after the district court thoroughly reviewed the record and applied the proper standard of appellate review.

It is well settled that the trial court's ". . . superior vantage point does not give a trial judge unbridled discretion to order a new trial . . ." and that ". . . the reasons which produce the new trial must be set forth in the order." *Wackenhut Corp. V. Canty*, 359 So. 2d at 434, citing to, *Stewart Bonded Warehouse, Inc. v. Bevis*, 294 So. 2d 315, 317 (Fla. 1974). The reasons stated in the new trial order must support the conclusion ". . . that the verdict is against the manifest weight of the evidence . . ." *Id* at 435. This Court, in *Laskey v. Smith*, 239 So. 2d 13, 15 (Fla. 1970) emphasized the correct standard which it again quoted in *Wackenhut Corp. v. Canty*, 359 So. 2d at 435:

> "In other words, the trial judge does not sit as a seventh juror with veto power. Its setting aside a verdict that must be supported by the record, as in *Cloud*

v. Fallis, (Fla. 1959) 110 So. 2d 669, or by findings reasonably amenable to judicial review."

The present case clearly demonstrates that the issue of the appellate review standard for new trial orders has long been established by this Court and the district court of appeal merely performed its duty to apply that standard in light of its thorough review of the record. *Wackenhut Corp. v. Canty*, 359 So. 2d 430, 434, 435 (Fla. 1978). CONNAUGHT, however, contends that this Court should accept the Order Granting New Trial on its face and not look behind it, as the district court did, to determine if its conclusions are supported by the evidence of record. CONNAUGHT, in effect, would have this Court ignore both the express application of the correct standard of review by the district court in its opinion and this Court's own decisional authorities which require that the appellate court examine the record to determine if reasonable men could agree with the trial court's conclusions as to the manifest weight of the evidence are supported. *Smith v. Brown*, 525 So. 2d at 870.

B. The district court's opinion does not infringe upon the trial court's duty to consider the credibility of witnesses in ascertaining the manifest weight of the evidence.

CONNAUGHT would have this Court infer into the opinion of the district court non-existent language that would preclude trial judges from considering witness credibility in new trial orders.

Contrary to the inferences drawn by CONNAUGHT, the district court's opinion says the following:

> "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." (R.1779)

FARNES is unable to comprehend anything in this statement that could conflict with the longstanding, fundamental and precious right to trial by jury. *Easkold v. Rhodes*, 614 So. 2d at 497, (jury free to "accept or reject testimony of medical expert just as it may accept or reject that of any other expert").

The district court in this case also said:

> "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." (R.1779)

Again, FARNES fails to see how this fundamental and well settled aspect of the right to trial by jury is in opposition to this Court's prior decisional authorities. *Smith v. Brown*, 525 So. 2d at 870, citing *Laskey v. Smith*, 239 So. 2d 13 (Fla. 1970) (Clearly, it is a jury function to evaluate the credibility of any given witness.); (the trial judge should refrain from acting as an additional juror).

CONNAUGHT seems to contend at Page 15 of its Brief that the jury's role in resolving conflicting testimony should and can be usurped by the trial judge in any situation unless "equally

credible witnesses provide conflicting testimony." By logical extension, CONNAUGHT appears to espouse that this Court's decision in *Smith v. Brown*, 525 So. 2d at 870, means that once the trial judge makes an independent decision that one witness is more credible than another, he or she is then free to overrule a jury's determination and order a new trial. Indeed, CONNAUGHT goes so far as to contend that because the trial judge found the defense expert to be more credible than FARNES' on the warning issue, he should have directed a verdict.

FARNES fully understands and accepts the important role of the trial judge in protecting the integrity of our system of justice by overruling jury decisions that are contrary to the manifest weight of the evidence. The new role advanced by CONNAUGHT, however, would severely curtail and materially redefine the role of the jury, in that it would require trial judges to engineer the manifest weight of the evidence by rejecting expert witness testimony, that the jury finds to be credible, merely because the trial judge would make a different and independent credibility determination.

This Court was careful in *Smith v. Brown* to remind us that while trial judges consider witness credibility along with all the other evidence, it is the jury's role to evaluate the credibility of any given witness. 525 So. 2d at 870. A review of the facts of

Smith v. Brown highlights the district court's adherence to its requirements in the present case.

In *Smith* it was readily apparent that the claimant had not been truthful with the jury or with her physicians and that the claimant's lack of candor infected the expert medical testimony given on her behalf at trial. (See the dissenting opinion in *Smith v. Brown*, 511 So. 2d 659 (Fla. 4th DCA)). The jury rendered a zero dollar verdict which the trial court determined to be contrary to the manifest weight of the evidence. In short, even if the claimant did lie, the manifest weight of the evidence still established some injury to require some damages award, albeit less than would be the case had the claimant's testimony been credible. The district court of appeal affirmed the new trial order but certified a question which this Court construed to be directed at uncertainty "with respect to whether a trial judge can order a new trial when the credibility of witnesses is at issue." 525 So. 2d at 870.

This Court affirmed the district court's decision in *Smith*, and thus the trial judge's, notwithstanding the fact that the credibility of the plaintiff was substantially attacked, because this Court was:

> "unable to say, after viewing the evidence as a whole, that reasonable men could not have concluded that the verdict for petitioners was against the manifest weight of the evidence."

525 So. 2d at 870.

A careful reading of *Smith* thus reveals that the trial judge, the district court and this Court each accepted the jury's determination that the claimant had not been truthful. The circumstances in *Smith* were directly opposite of those presented by the instant case where the jury clearly found credible FARNES' expert's opinion that the warning was inadequate, yet the trial court vetoed they jury's evaluation.[11]

In short, the trial judge below re-weighed the witness' credibility rather than give weight to the jury's evaluation of the "credibility of any given witness." *Smith v. Brown*. The district court, however, properly considered the evidence as a whole, including witness credibility, in deciding what reasonable men could see as the manifest weight of the evidence. The district court's opinion in this case is clearly consistent with *Smith v. Brown*.

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[11] CONNAUGHT admits in its Brief that the trial court below simply re-weighed the expert witness testimony:

> "It was the experts' credibility that the trial court weighed and discussed in its new trial order." (Petitioners' Brief at 16).

C. Assuming arguendo, that *Smith v. Brown* should be read to give trial judges veto power to re-weigh witness credibility evaluations, there is no record support for a new trial in this case.

It is important to note that the trial court vetoed the jury's evaluation of Dr. Lichtenfeld's credibility only as to the question of the inadequacy of CONNAUGHT's package insert to warn about Guillain Barre' Syndrome. The jury's decision as to the other areas of Dr. Lichtenfeld's testimony remain intact. In this regard it must be remembered that the adequacy or inadequacy of a package insert to warn the learned intermediary of a drug's risks is a question for expert medical opinion testimony. *Upjohn v. MacMurdo*, 562 So. 2d at 683.

The trial judge seemed to find most fault with Dr. Lichtenfeld's opinions as to the weight the physician should give to the risk of GBS once he or she is adequately warned of its existence. It is CONNAUGHT's failure to adequately warn the physician of the GBS risk that is the crux of this case, not what physicians would do with the risk information once they receive it.

The question, therefore, is whether, from the physician's perspective, CONNAUGHT's language adequately warned the learned intermediary of the GBS risk. *Upjohn v. MacMurdo*, 562 So. 2d at 683. Again, only Dr. Lichtenfeld spoke directly to this issue and unequivocally testified that CONNAUGHT's language is "misleading and grossly inadequate" and gives the physician a false sense of

assurance that in 1989 there was no reason to be concerned about patients getting Guillain Barre' Syndrome from influenza vaccines. (R.1309-1312). An examination of the other evidence of record reveals the following corroboration of Dr. Lichtenfeld's opinion:

1. The defense expert never said that the package insert adequately warned the physician of the GBS risk. Obviously, if Dr. Wiederholt truly believed that it was an adequate warning as to GBS specifically, he would have specifically said so.

2. Dr. Wiederholt never testified that the average physician would not be falsely assured by CONNAUGHT's GBS' language. If he disagreed with Dr. Lichtenfeld on this point, he would have said so.

3. Dr. Ebert, CONNAUGHT's Vice President for Operations, and Dr. Vosdingh, its Director of Regulatory Affairs, both testified that CONNAUGHT must warn of risks associated with their vaccines even if CONNAUGHT is not convinced as to actual causation and regardless of government recommended or approved language. (R.1414-22; 1636-39) Dr. Ebert further confirmed that it was CONNAUGHT's duty to include any language necessary to insure that the package insert would not mislead the physicians. (R.1636).

4. The unrebutted testimony of CONNAUGHT's officials, as well as CONNAUGHT's answers to interrogatories, confirm that CONNAUGHT's 1989 influenza vaccine was made exactly as its 1976

vaccine, except for the virus stain, and contains foreign proteins as did the 1976 vaccine. (R.1394, 1436GG, 1632-35)

5. Dr. Wiederholt was unaware that CONNAUGHT has not changed its vaccine manufacturing process since 1976 or that the 1989 vaccine contained foreign proteins. (R.1587)

6. All other manufacturers were careful to clearly explain that a possible GBS risk still existed, in spite of the lack of a completed epidemiological study using post 1976 data. (Pl.Ex.12, 13 and 14). CONNAUGHT chose, instead, to include language which called into question even the study of the 1976 data, which all experts accept as establishing a causal link. (R.1560-70, 1586).

7. Dr. Samuelson, CONNAUGHT's medical official responsible for the package insert language, testified that he would be surprised if CONNAUGHT's language about GBS was different from its competitors, yet the undisputed evidence proved that CONNAUGHT's language about GBS was materially different. (R.1436TT).

8. Dr. Samuelson admitted that CONNAUGHT continues to receive adverse reaction reports of GBS following administration of its flu vaccine and that, rather than inform physicians of this fact in the package insert, he just laughs at some of them. (R.14364-DD)

9. Dr. Samuelson elected to exclude language used up to 1985, even by CONNAUGHT, that specifically warned physicians about

the risk posed to patients with a history of Guillain Barre' Syndrome. (R.1436PP-QQ)

10. Dr. Samuelson disagreed with all experts in the field that the 1976 study proved a causal association between flu vaccines and Guillain Barre' Syndrome. (R.1436PP-QQ).

FARNES respectfully submits that there is no way that any reasonable person could possibly conclude that the manifest weight of the evidence established that CONNAUGHT provided an adequate warning about GBS. The trial court's expressed reasons for ordering a new trial reveal mistaken recollections of the evidence and resultant erroneous inferences. The abuse of discretion in the new trial order could not be more clear and the district court was correct in reversing it based upon its thorough review of the record.

D. The District Court of Appeal properly conducted a close examination of the record in this case yet CONNAUGHT asks that this Court rely solely upon the trial court's mistaken recollections of the evidence rather than the record itself.

CONNAUGHT calls for a new standard of review of new trial orders where appellate courts are bound by a trial judge's recollection of the evidence rather than the record of that evidence itself. A search for record support for the trial court's findings relied upon by CONNAUGHT in its Brief merely serves to reaffirm why appellate review is such a fundamental part of our system of due process of law, including cases involving new trial

orders. *Laskey v. Smith*, 239 So. 2d at 13; and *Wackenhut Corp. v. Canty*, 359 So. 2d at 436.

CONNAUGHT continuously makes representations about the testimony of Dr. Lichtenfeld which, although perhaps consistent with the trial court's erroneous recollection of the testimony, are not consistent with what the record shows was actually said. Significant parts of Dr. Lichtenfeld's testimony are quoted verbatim at pages 15 through 24 of this Brief. CONNAUGHT, however, cites the trial court's order (R.1003-1006) in support of its contentions as to the evidentiary basis for the trial court's conclusions. FARNES respectfully requests that this Court consider the actual evidence of record, as the district court properly did. Just a few examples of CONNAUGHT's erroneous recitations of the evidence are as follows:

Subparagraph (1) states that "he [Dr. Lichtenfeld] admitted CONNAUGHT's warning was not in violation of community standards." Dr. Lichtenfeld never said such a thing.

Subparagraph (2) refers to the lack of a completed study after 1976 but omits Dr. Lichtenfeld's testimony about partial studies and the fact that no expert has concluded, based upon any study, that no risk of contracting GBS from influenza vaccine existed in 1989.

Subparagraph (3) represents that Dr. Lichtenfeld admitted that he had never reviewed other package inserts. What Dr. Lichtenfeld actually testified to was a follows:

> "I never said that. I said in preparation for this case I looked at the package insert for the product that Mr. FARNES received. I have looked at many other package inserts over the years."

(R.1297)[12]

Throughout page 17 of its Brief, CONNAUGHT continues to rely upon mischaracterizations of Dr. Lichtenfeld's expert opinion testimony. These conclusions, although not supported by record evidence, do nothing to negate the fact that a possible risk of influenza vaccine causing Guillain Barre' Syndrome existed in 1989 or that CONNAUGHT's insert falsely assured the physician that no such risk existed. CONNAUGHT goes so far as to add to the mischaracterization by representing that Dr. Lichtenfeld "was unable to cite any reports or articles on which he claimed to have relied." CONNAUGHT cites to Page 1302 through 1303 of the record. A review of the actual record reveals that Dr. Lichtenfeld was

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[12] CONNAUGHT's reference to the trial court's finding that Dr. Lichtenfeld has not prepared a package insert in the same subparagraph further demonstrates the trial court's failure to follow this Court's mandates. In *Upjohn v. MacMurdo*, the Court rejected a pharmacologist's testimony as not probative of what the language means to a physician, even though he had worked for three pharmaceutical companies writing package inserts. 562 So. 2d at 683, 684.

never asked to cite any reports or articles but instead described the recent studies.[13] Dr. Lichtenfeld testified that his opinion, in part, was based upon his review of "all the world's [medical] literature." (R.1303).

In the second paragraph on Page 17 of their Brief, CONNAUGHT refers to Dr. Lichtenfeld's testimony regarding the Morbidity and Mortality Weekly Reporter and reports published by the Advisory Committee On Immunization Practices (ACIP) and represent that the record establishes the following:

> "He would not say that reliance on those guidelines violated the standard of care in the industry; he said only that it should."

CONNAUGHT grossly misstates the record on this point. Dr. Lichtenfeld testified that he did not believe that reliance upon government recommended language should equate with adequacy (R.1328) On the other hand, CONNAUGHT's corporate officials, Dr. Vosdingh and Dr. Ebert, both testified that reliance upon such government recommended language does not equate with adequacy and CONNAUGHT never put into evidence the recommended language it contends it followed. (R.1414-22, 1636-39).

In the last paragraph on Page 17 of their Brief, CONNAUGHT again misquotes Dr. Lichtenfeld's testimony when it states that he

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[13] CONNAUGHT's representation that Dr. Lichtenfeld was unable to cite articles is particularly unreasonable in view of the fact that, at trial, CONNAUGHT did not cross-examine Dr. Lichtenfeld about articles. Rule 706, Florida Rules of Evidence.

opined "that prior GBS sufferers should never be vaccinated." As noted above, Dr. Lichtenfeld's testimony reveals that he merely testified that prior GBS sufferers should avoid anything containing a foreign protein, such as vaccines, unless absolutely essential for their health. (R.1347-48).

Again in the last paragraph on page 17 of its Brief, CONNAUGHT represents that Dr. Lichtenfeld's opinion about the inadequacy of CONNAUGHT's insert regarding GBS "is not consistent with medical literature or experience." Absolutely no evidence was offered or introduced at trial which reflects that CONNAUGHT's package insert, with respect to GBS, is "consistent with medical literature or experience" to the extent that it fails to warn of the GBS risk.

Contrary to CONNAUGHT's representations in the last sentence of page 17 and at subparagraph 3 at page 18 of their Brief, Dr. Wiederholt never expressly said that CONNAUGHT's package insert adequately warned of GBS and CONNAUGHT's contention that the trial court could properly give Dr. Wiederholt's opinion in this regard more weight than Dr. Lichtenfeld's is unreasonable.

FARNES respectfully submits that CONNAUGHT's desparate attempt to draw favorable inferences, no matter how inconsistent with the record, is necessary only because the manifest weight of the evidence clearly preponderates in favor of the jury's determination.

E. The district courts of appeal are able to properly apply the standard of review of new trial orders mandated by this Court and CONNAUGHT's plea for uniformity is illusory.

At pages 21 through 23 of its Brief, CONNAUGHT cites a multitude of appellate decisions involving appeals of new trial orders and appears to conclude that those opinions correctly apply the law only when the trial court is affirmed and are less than faithful to the mandates of this Court any time a decision is made to reverse. FARNES respectfully submits that this Court has clearly annunciated the reasonable man standard of review applicable in new trial cases. See e.g., *Cloud v. Fallis*; *Laskey v. Smith*; *Hedge v. Jacksonville Terminal Co.*, 234 So. 2d 645 (Fla. 1970); *Stewart Bonded Warehouse, Inc. v. Bevis*, 294 So. 2d 315 (Fla. 1974); *Wackenhut Corp. v. Canty*; *Ford Motor Co. v. Kikis*; *Smith v. Brown*. Further clarification of the standard is simply not necessary to enable the district courts of appeal to fulfill their duty of appellate review.

Even CONNAUGHT has difficulty articulating precisely what it is that it contends is unclear about this Court's prior decisions or what it is that CONNAUGHT contends the district courts of appeal are confused about. CONNAUGHT's reference to *Crown Cork & Seal Co., Inc. v. Vroom*, 480 So. 2d 108 (Fla. 2d DCA 1985) demonstrates the illusory nature of CONNAUGHT's argument. CONNAUGHT criticizes the *Crown Cork & Seal* court because it found that "reasonable men could not differ that the verdict was not against the manifest weight of the evidence" rather than stating that it applied the reasonable man standard to "the propriety of the trial court's action" as was done in *McNair v. Davis*, 518 So. 2d 416, 417 (Fla. 2nd DCA 1988). CONNAUGHT raises what is, at most, a distinction without

a difference. Indeed, this Court has expressed the correct application of the standard of review by using both kinds of descriptions. First, in *Ford Motor Co. v. Kikis*, 401 So. 2d at 1342, this Court held:

> "If reasonable men could differ as to the propriety of the action taken by the trial court, then there is no abuse of discretion."

Later, in *Smith v. Brown*, the case that CONNAUGHT contends the district court failed to follow below, this Court articulated the standard of review using substantially the same words that appear in *Crown, Cork & Seal* and which are now criticized by CONNAUGHT:

> " . . . we are unable to say, after reviewing the evidence as a whole, that reasonable men could not have concluded that the verdict for petitioners was against the manifest weight of the evidence." 525 So. 2d at 879.

The district court of appeal in the instant case adhered to the standard as articulated by this Court in *Smith v. Brown* and held:

> "A trial court may not properly grant a new trial when reasonable persons cannot differ that the verdict was not against the manifest weight of the evidence." (R.1779)

The "varied results" complained of by CONNAUGHT (Petitioners' Briefs, p.23) stem from the simple reality that, sometimes in cases such as the instant one, trial courts commit prejudicial error by ordering a new trial when reasonable men could not find the jury's determination to be contrary to the manifest weight of the evidence.[14]

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[14] CONNAUGHT's contentions are also inherently incongruent. *Becker v. Williams*, 652 So. 2d 1182, 1184-85 (Fla. 4th DCA 1995), is cited by CONNAUGHT, apparently as an example of the failure of some appellate panels to properly adhere to CONNAUGHT's

A review of the appellate decisions cited by CONNAUGHT clearly establishes that the district courts of appeal, including the Third District Court of Appeal in the instant case, are conscious of and adherent to the appropriate standard of review as repeatedly articulated by this Court.

F. The instant case does not support adoption of a special rule requiring district courts to write special opinions in new trial cases.

CONNAUGHT contends that this Court should, for new trial cases only, place special limitations and restrictions on the role of district courts mandated by the 1980 amendments to the Florida Constitution. Nothing in the present case calls for such a radical departure from this Court's continued adherence to both the letter and spirit of the constitutional provisions placing final review authority of such cases in the district courts of appeal. FARNES respectfully submits that there is no constitutionally or practically sound basis for mandating an elevated degree of

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interpretation of this Court's decisions in that:

> "the court reversed an order granting new trial where the trial judge chose to believe the plaintiff's over the defendant's expert. . ." (Petitioners' Brief, p. 22)

CONNAUGHT felt differently about the *Becker* decision when it filed its Brief on Jurisdiction in the instant case because *Becker v. Williams* is cited, at page 4, footnote 2, as one of the decisions allegedly in conflict with the instant case.

specificity for opinions in new trial appeals to enable the losing party the opportunity for a second appeal in this Court.

CONNAUGHT concedes as much at page 23 of its Brief where it notes that the 1980 Amendments to Article V, §3(b(3) of the Florida Constitution:

> "ceded complete authority to the district courts to decide not only **whether** they would choose to write, but **what** they would chose to write."

(Emphasis supplied by CONNAUGHT.)

CONNAUGHT thus asks that this Court impose controls over the drafting of district court opinions that are inconsistent with the trust and confidence in those same courts that was demonstrated by the citizenry through the 1980 Amendments. CONNAUGHT's argument further highlights its inability to demonstrate express and direct conflict between the district court's opinion in the present case and the prior decisions of this Court or the other district courts of appeal. See eg., *Jerry's Inc. v. Marriott Corporation*, 401 So. 2d 1335 (Fla. 1981) (Justice England concurring).

G. CONNAUGHT has failed to demonstrate error in the opinion of the district court.

The district court correctly applied the required standard of review below and properly reversed because the trial court vetoed the jury's acceptance of unobjected to expert witness opinion testimony and ordered a new trial and the record demonstrates that reasonable men could not find the verdict to be contrary to the manifest weight of the evidence. FARNES respectfully submits that CONNAUGHT has had its day in court and the jury has made its decision. Nothing in this case justifies requiring

FARNES to once again prove his case to yet another jury before he can be compensated for the catastrophic injuries he has suffered.

II. THE DISTRICT COURT WAS CORRECT IN AFFIRMING THE TRIAL COURT'S DENIAL OF A DIRECTED VERDICT BECAUSE THE RECORD CANNOT POSSIBLY SUPPORT JUDGMENT FOR CONNAUGHT AS A MATTER OF LAW.

CONNAUGHT contends that it is entitled to a directed verdict because it purportedly

> " . . . 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. Hoffman-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989), and *MacMurdo*, 562 So. 2d at 680. (R.1641)"

(Petitioners Brief, p.25)

A review of the record as cited by CONNAUGHT, however, reveals that CONNAUGHT merely moved for a directed verdict, in general, and never stated that its warning was adequate as a matter of law. (R.1641). Notwithstanding its failure to preserve the issue, the trial court entertained CONNAUGHT's arguments on its Motion for Judgment in Accordance with its Motion for Directed Verdict and again denied the motion. (R.999-1006). FARNES respectfully submits that, even assuming arguendo CONNAUGHT had preserved the issue, it is not entitled to the benefit of the protections afforded pharmaceutical manufacturers who adequately warn the learned intermediary of their product's potential risks.

CONNAUGHT now contends that its package insert was "accurate, clear and unambiguous" as a matter of law. The record, however, demonstrates that CONNAUGHT's language about GBS was not accurate and it certainly was not clear or unambiguous. The trial court and the district court were correct in concluding that the issue of the adequacy or inadequacy of

warning about GBS was a jury question to be answered on the basis of medical expert opinion testimony. *Upjohn v. MacMurdo*, 562 So.2d at 683.

In *MacMurdo*, no medical expert testified that the warning was inadequate and even the prescribing physician admitted that, had he read the insert, " . . . he might have concluded the drug was causing [the Plaintiff's] problem." 560, So. 2d at 683. On the other hand, the defense presented a medical expert who testified that "the insert was adequate to warn physicians of all adverse bleeding reactions from use of the drug." 516 So. 2d at 683, footnote 2. Clearly, the facts in the instant case are materially different than those in *MacMurdo* and necessitate an opposite result.

CONNAUGHT, after choosing to include language directed at assuring the learned intermediary that no GBS risk exists, while its competitors chose the opposite path, now asks this Court to exercise further discretionary jurisdiction and craft a special form of legal protection for it. CONNAUGHT relies on its characterization of the testimony of Dr. Jahnig's assistant, Nurse Fox, who it concedes carefully read the entire product insert. Nurse Fox testified that she informed FARNES of all risks that had been warned of in the product insert (R.1436K, 1436M) and CONNAUGHT's language about GBS did not warn that a risk of GBS existed. (R.1436L,M). Nurse Fox also testified that she would have been warned of the possibility of GBS had CONNAUGHT included the language such as it had removed in the 1985 insert regarding persons with a past history of GBS. (R.1436M). Moreover, CONNAUGHT presented no evidence which would indicate that Dr. Jahnig, who supervised Nurse Fox with respect to the

Guidance Clinic's influenza immunization program, was adequately warned by CONNAUGHT's package insert.

Notwithstanding Nurse Fox's actual testimony, CONNAUGHT contends that, since GBS is a neurological disease, its reference to delaying vaccinations of patients with active neurological disorders makes its warning adequate. It then asks that this Court find, as a matter of law, "that the learned intermediary fully understood the information in the package insert and knew the relevance of that information to GBS." (Petitioners' Brief, p.25). The record clearly demonstrates that FARNES was not suffering from "an active neurological disorder" when he was vaccinated. (R.1206-07; 1335). Moreover, the average nurse, practitioner and physician was unaware of the risk of GBS being caused by influenza vaccines in October 1989. (R.1337-8). Finally, no medical expert testified that CONNAUGHT's language about "active neurological disorders" somehow overcame its otherwise misleading references to the GBS risk. Instead, the testimony of CONNAUGHT's own medical advisor, Dr. Samuelson, clearly shows that the language about "active neurological disorders" was not a warning about a GBS risk at all. (R.1436HH-1436JJ).[15]

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[15] When asked about the active neurological disorder language, as it relates to "the risk of exacerbating or contracting a disease," Dr. Samuelson testified as follows:

> "No, no. It doesn't do that, but it makes the patient suffer for unnecessary reasons. They have enough problems." (R.1436JJ)

Notwithstanding the absence of support for its position in the record, CONNAUGHT once again asks that this Court assume that its " . . . insert actually tracked the language and recommendations of the ACIP, an expert panel commissioned by the CDC for that purpose." (Petitioners' Brief, p.28). As noted above, however, CONNAUGHT never placed the purported ACIP language into evidence and its competitors, who it also claimed followed ACIP recommendations, used materially different language and expressly warned of the GBS risk. Even if CONNAUGHT had used the ACIP language, all witnesses, including CONNAUGHT's own officials testified that such language does not equate to adequacy. (R.1414-22; 1636-39).

The record in this case bulges with evidence supporting the jury's determination that CONNAUGHT failed to adequately warn the learned intermediary about the GBS risk and that CONNAUGHT's failure to warn caused or contributed to FARNES' injuries. It is well settled that a verdict may not be directed where any evidence of record supports the jury's determination. *Cadore v. Karp0*, 91 So. 2d 806 (Fla. 1957); *Parsons v. Reyes*, 238 So. 2d 561 (Fla. 1970); *Dania Jai-Alai Palace, Inc. v. Sykes*, 450 So. 2d 114 (Fla. 1981). This Court clearly stated the applicable standard in *Parsons v. Reyes*:

> "It does not lie withing the province of the court to weigh evidence or determine issues of credibility and, where there is the possibility of different conclusions or inferences from the evidence, the court should submit the issue to the jury." 238 So. 2d at 563.

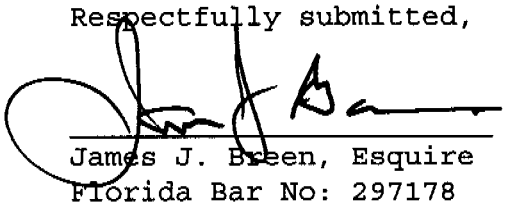
FARNES clearly met his burden and was entitled to have a jury determine the facts in this case, including the adequacy or inadequacy of CONNAUGHT's package insert to warn of GBS. CONNAUGHT, on the other

hand, has failed to demonstrate that no evidence supports the jury's determination that it failed to adequately warn of the GBS risk.

CONCLUSION

The district court properly applied this Court's decisional authorities and correctly concluded that reasonable persons could not find the jury's decision on the warning issue to be contrary to the manifest weight of the evidence. FARNES is thus entitled to reinstatement of the jury's verdict and the final judgment in this cause. No reason exists for this Court to exercise its discretionary jurisdiction to disturb the opinion and mandate of the district court below. FARNES respectfully requests that this Court either set aside its prior Order Accepting Jurisdiction or, in the alternative, affirm the decision of the district court for the reasons aforesaid.

Respectfully submitted,



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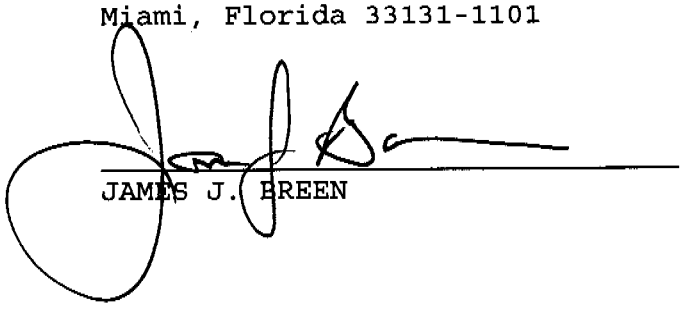

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