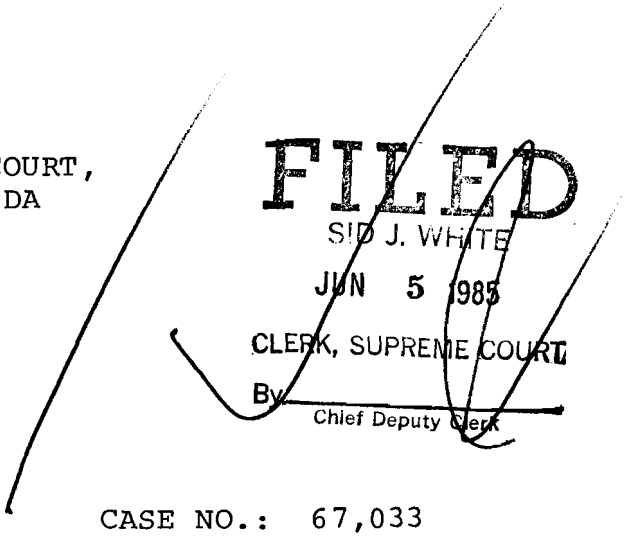
IN THE SUPREME COURT,
STATE OF FLORIDA



MADHU PARIKH, M.D.,

Petitioner,

-vs-

CASE NO.: 67,033

ROSANN CUNNINGHAM and
RONALD CUNNINGHAM, her
husband,

Respondent.
_____/

APPEAL FROM THE FIFTH DISTRICT COURT OF APPEAL,
STATE OF FLORIDA

INITIAL BRIEF OF PETITIONER

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PRELIMINARY STATEMENT

The Petitioner was the Defendant below and will be referred to variously as the Defendant, Dr. Parikh, Petitioner and Appellee.

The Respondent was the Plaintiff below and will be referred to variously as the Plaintiff, Mrs. Cunningham, Respondent and Appellant.

In order to facilitate this Court's review, selected individual documents are attached to the brief and referred to as (Appendix___).

Reference to that portion of the record on appeal from the trial transcripts will use the page numbers of the Court Reporter and will be noted by (T-). The entire trial transcript consists of seven volumes. Volumes One through Five are numbered in chronological order from pages 1 through 746. Volumes Six and Seven are renumbered. Volume Six begins with pages 1 through 174. Volume Seven begins with pages 175 and ends at page 291. The two depositions of Dr. John Bostwick were read during trial, but by stipulation of the parties, the Court Reporter was instructed to not include his testimony in the trial transcript. Petitioner has filed a Motion with the Court to supplement the record on appeal to include those two depositions. Reference to Dr. Bostwick's testimony read during the trial is contained in Volume Six of the record, and will be referenced accordingly along with the page number of the transcript of the deposition.

Footnotes in this brief are set forth on a separate page following the Appendix.

STATEMENT OF THE CASE

This was an action for medical negligence by Mrs. Cunningham against Dr. Parikh. The allegations were lack of informed consent regarding surgical procedures in April of 1980, December of 1980, and medical negligence involving the December 1980 surgery.

The trial lasted eight (8) days. A Special Verdict form was submitted to the jury, allowing the trier of fact to decide if Dr. Parikh negligently failed to obtain the informed consent of Mrs. Cunningham to the April and December 1980 surgeries, and if Dr. Parikh negligently performed the December 1980 surgery. The jury resolved all issues in favor of Dr. Parikh.

A Motion for New Trial was made based upon an objection to the giving of any instruction to the jury regarding the issue of informed consent on the ground that the Florida Medical Consent Law was unconstitutional.

The Motion for New Trial was denied, and an appeal was taken to the Fifth District Court of Appeal on the issue of the constitutionality of the Florida Medical Consent Law.

The Fifth District Court of Appeal held the Florida Medical Consent Law unconstitutional, and remanded the cause for a new trial.

The Defendant filed a Motion for Re-Hearing and Clarification indicating that the Florida Medical Consent Law is subject to a broader interpretation than the District Court applied.

The Fifth District Court of Appeal denied the Defendant's Motion for Re-Hearing and Clarification, and this appeal ensued.

STATEMENT OF THE FACTS

This case involved a medical operation or procedure known as a subcutaneous mastectomy. This operation was developed by plastic surgeons in the 1960's. The purpose of the operation is to provide a prophylactic way of hopefully avoiding the development of breast cancer in those women who are at a high risk to develop breast cancer. (V Six, T-7,T-8)[1] The operation involves the surgical removal of all breast tissue beneath the skin and down to the chest wall muscle, leaving intact the outer skin and the nipple areola complex. (T-55, 391-400) The tissue is replaced either at the time of the original surgery or after a short delay, with a gel-filled implant. (T-582) The implant is placed either in the original breast pocket or beneath the pectoralis muscle. (T-582) Mrs. Cunningham's expert, Dr. Pennisi, testified that subcutaneous mastectomy is the most effective prophylactic procedure available that is acceptable to women who have a high risk of developing breast cancer. (V Six, T-60)[1] In order to do a proper subcutaneous mastectomy, the surgeon has to come extremely close to the nipple areola complex, which may compromise or interfere with the blood supply and, if that does happen, there is a chance that the nipple areola complex may not survive. (V Six, T-170, 171)[1]

Before Mrs. Cunningham met Dr. Parikh, she had had numerous operations including a tonsillectomy, appendectomy, hysterectomy, and a gallbladder operation, as well as numerous surgeries on her foot. In addition, Mrs. Cunningham had had five previous breast

biopsies (T-525). From working in a hospital and from her other previous surgeries, she was familiar with consent forms. (T-392) She was cognizant of the fact that if, for any reason, she decided not to undergo a particular surgery, she could say no or not sign a consent form. (T-392 and 393) She had a breast biopsy by Dr. McSwain, a general surgeon, in February of 1980. Before the operation, she signed a consent form and understood from what Dr. McSwain told her that the general nature of the surgery was that he would do a radical mastectomy to remove her entire breast if either of the breast masses were cancerous. (T-391) She testified that Dr. McSwain probably did tell her about the risk of his surgery, but she could not recall what he said about the risks. (T-391) After the biopsy was done by Dr. McSwain, Mrs. Cunningham developed a condition known as subareola abscesses. (V six, T-138-139;[1] Page 4, Dr. Bostwick's first deposition) A subareola abscess is a separate and different condition than fibrocystic breast disease. (T-732) Mrs. Cunningham had chronic draining with the abscess. (T-397) She consulted Dr. McSwain about the abscess problem and he offered her the option of surgically removing the abscess from her breast, but told her that another abscess could subsequently reoccur in her breast. (T-395, 398) The problem continued and Mrs. Cunningham sought a second opinion from her family physician, Dr. Powell. (T-397) After an attempt to treat the problem with antibiotics, Dr. Powell hospitalized Mrs. Cunningham in April of 1980. Mrs. Cunningham had had pain in her breast off and on for years, but, by the time she was hospitalized in April of 1980, the pain had developed into a constant type of pain. (T-404) She did not respond to conservative therapy insofar

as the abscess was concerned. (V Seven, T-257)[1]

She was admitted to Ormond Hospital on April 18, 1980. Dr. Powell asked Dr. Smith, a general surgeon, to examine Mrs. Cunningham's breast. He found she had developed new lumps in her breast since her biopsies with Dr. McSwain. Dr. Smith operated on Mrs. Cunningham to biopsy the new lumps that had developed. (T-401, 402) The pathology report done on the biopsy indicated that Mrs. Cunningham had the kind of fibrocystic breast disease process that would place her in a category of high risk for developing breast cancer. (V Six, T-62;[1] T-728, and T-525) The type of breast disease that she had also made it difficult for her or her physician to clinically examine her breast for cancer. (T-526, 540) The scarring on her breast from the multiple biopsies also added to the difficulty in conducting an adequate clinical examination. (T-541, 168) Mrs. Cunningham was concerned that she might develop breast cancer. (V Six, T-138, 139)[1]; (Page 24, Dr. Bostwick's first deposition)

Dr. Smith discussed with Mrs. Cunningham the possibility of consulting a plastic surgeon about a subcutaneous mastectomy. She generally understood from what Dr. Smith told her that the nature of the operation would be to take the breast tissue out from underneath the skin and then later replace it with implants. (T-345, 346) Dr. Smith called Dr. Parikh and asked him to see Mrs. Cunningham as a consultant about the possibility of a subcutaneous mastectomy. Dr. Smith told Dr. Parikh that Mrs. Cunningham had multiple problems with her breasts. He told Dr. Parikh about Dr. McSwain's recent biopsy and his own recent biopsy. Dr. Smith also

told Dr. Parikh about the subareola abscess problem and asked Dr. Parikh to examine Mrs. Cunningham. (T-453) Dr. Parikh discussed Mrs. Cunningham with her family physician, Dr. Powell. He also reviewed Mrs. Cunningham's chart before talking to her. (T-455)

On Dr. Parikh's first visit, Mrs. Cunningham recalled that they both recognized each other from previous meetings at the hospital where she worked. (T-348) Mrs. Cunningham told Dr. Parikh that she was concerned about the problems she was having with her breasts, including the multiple biopsies, the abscesses, and that she was worried about the possibility of developing breast cancer. (T-472) Dr. Parikh talked with her about the whole subcutaneous mastectomy procedure, the prognosis, the complications and stressed to her that this was not a cosmetic operation. Mrs. Cunningham seemed to understand Dr. Parikh very well. (T-479, 488-494)

From discussing the case with her general surgeon and family physician, from reviewing her chart, and from talking with Mrs. Cunningham, Dr. Parikh found that she had a history of the following:

1. Multiple reoccurring lumps in her breasts;
2. Multiple surgical biopsies in her breasts;
3. A fear of cancer;
4. A death in her family from cancer;
5. Fibrocystic disease of a sclerosing adenosis type in her breast which is a pre-malignant condition;
6. Large nodular breasts which were difficult for the patient and her doctors to clinically examine;
7. Chronic draining abscesses or boils in her breasts that caused her embarrassment with her husband and at her work; and,

8. Chronic intermittent pain in her breasts that had developed into constant and extensive pain. (T-524-527)

Mrs. Cunningham testified that she knew about this type of operation before she first met Dr. Parikh. (T-399) Dr. Parikh, among other things, explained to Mrs. Cunningham the general nature of the procedure, the medically acceptable alternative to the procedure, and the risks inherent in the procedure. (T-468-472; 479-494) Mrs. Cunningham testified that she understood from the information provided to her that the purpose of the subcutaneous mastectomy would be to try to get rid of the problems she was having, such as the reoccurring lumps in her breasts, the constant pain, the abscesses and drainage, and that hopefully, the operation would be a prevention of breast cancer. (T-404) Mrs. Cunningham had become concerned about breast cancer when she had her original breast biopsy approximately fifteen years earlier. (T-384) She was also concerned and scared of breast cancer at the time she went to see Dr. McSwain a few months earlier. (T-389) She was further concerned when Dr. Smith found two new lumps and did his biopsy. (T-402) Mr. Cunningham testified it was his understanding that his wife's main reason for deciding to undergo the subcutaneous mastectomy was because of her concern about the possibility of developing breast cancer in the future. (V Six, T-142)[1]

Mrs. Cunningham knew from talking to her other previous physicians that one alternative to having a subcutaneous mastectomy was to try to live with her problems. (T-405) She also knew that another alternative was to have a limited operation to just remove the abscess, which had been explained to her by Dr. McSwain. (T-398) Dr. Parikh also explained the alternatives to her. (T-579, 580)

Mrs. Cunningham testified that she was clear-headed when she was talking to Dr. Parikh before her decision to undergo the subcutaneous mastectomy. She remembered that when she was talking to Dr. Parikh, she was able to clearly converse with him, understand what he was telling her, and ask him questions. (T-410, 411) With regard to risks or complications, she specifically recalled that Dr. Parikh told her before the surgery that she would not be able to have a lot of projection after the operation. She also specifically remembered that he told her that there was a risk of losing sensation in her breast. She did not deny that Dr. Parikh told her about other possible risks other than those two, but testified that it was certainly possible that he could have told her about other risks and she simply did not remember them. (T-410)

Mrs. Cunningham testified that although she was the type of person who would rather not hear about the risks and complications of an operation, she understood that there were chances that a risk or complication could occur from the surgery. She weighed the good and the bad possibilities involved with the operation in making her decision to undergo this surgery. (T-406-408) She further testified that before she signed the consent form for the subcutaneous mastectomy, the consent form was explained to her and she was asked if she had any questions about it. She testified that she did not have any questions about the consent form, that she understood it, and signed it. (T-411, 412) Appendix 1

Dr. Parikh told Mrs. Cunningham to think about her decision and that he would come back to see her and talk to her a few days later. When he went back to see her a couple of days later, he again

went over the important points for consideration with her, and she again affirmed to him that it was her decision to have the surgery. (T-550) Dr. Parikh also wanted to talk with her husband about the operation and did discuss it with him after seeing Mrs. Cunningham for the second time. (T-616-618)

After the subcutaneous mastectomy operation and before the second surgery to place the implants, Mrs. Cunningham testified that she had no regrets about her decision to have the subcutaneous mastectomy. Her only concern was her flat appearance at that time. (T-415-418) After her third and final surgery with Dr. Parikh in December of 1980, she testified that her only complaint was that she did not have as much projection as she would have liked. Otherwise, she had no regrets about her decision to undergo the subcutaneous mastectomy. (T-425) She testified that before she had the subcutaneous mastectomy, it was her understanding from talking with Dr. Parikh, that in her clothes, she would have a reasonably normal appearance even though she might have to add something to her bra to give her more projection. Dr. Parikh had explained to her that she would not have a lot of projection after the subcutaneous mastectomy. (T417, 410)

In December of 1980, Dr. Parikh performed a third surgery on Mrs. Cunningham to try to improve the symmetry of her breasts, as well as the location of the nipple areola complex. Mrs. Cunningham testified that Dr. Parikh did explain to her before she consented to the third surgery that there was a chance that the nipple areola complex might be lost because of circulation problems if she had the surgery. (T-418) Mrs. Cunningham decided to have the third surgery and signed

the consent forms. (Appendix 2 and 3) Unfortunately, as a result of circulation problems following the December surgery, Mrs. Cunningham did lose her nipple areola complex.

Subsequently, in March of 1981, Mrs. Cunningham saw Dr. Bostwick at the Emory University Clinic. At that time, her primary concern was to determine if she could have a little larger breast implants to increase her projection. (V Six, T-138, 139)[1]; (Page 5, Dr. Bostwick's first deposition) Dr. Bostwick did operate on Mrs. Cunningham and placed larger implants in her breasts.

Mrs. Cunningham's expert, Dr. Pennisi, examined Mrs. Cunningham's breasts before the trial. He testified that her breasts were soft, had not developed the complication of capsulitis or hardness, and, were satisfactory from a projection standpoint. (V Six, T-42, 37)[1]

Dr. Parikh's expert, Dr. McCarty, testified that the subcutaneous mastectomy in April of 1980 was the procedure of choice for Mrs. Cunningham because of the breast problems that she had. Without the operation, she could have expected to continue to have repetitive breast biopsies. (V Six, T-167)[1] She would have continued to experience the subareola abscess problem without the surgery. (V Six, T-165)[1] Dr. McCarty agreed that the operation was not done for cosmetic purposes, and that cosmetics is the last consideration. (V Six, T-169)[1] In comparing her final result with other patients who have undergone this procedure, Dr. McCarty testified that from a cosmetic standpoint, considering the type of breasts that she had to begin with and the extent of her problems, Mrs. Cunningham ended up with a good result. (V Six, T-171)[1] She was a high risk patient for the development of breast cancer. (V Six, T-172, 173)[1] He testified that the operation reduced her chances of developing breast cancer by ninety (90%) percent or better. (V Seven, T-263, 264)[1]

Mrs. Cunningham's expert, Dr. Pennisi, testified that in his opinion Dr. Parikh should not have performed the type of operation that he used in the third surgery done in December of 1980. He testified that in his judgment a different type of operation would have been preferable. (V Six, T-33, 34, and 35)[1]

Dr. Pennisi also testified that in his opinion Mrs. Cunningham was probably a candidate for a subcutaneous mastectomy. (V Six, T-70, 73)[1] He further testified that he had no criticism of the manner in which Dr. Parikh performed the subcutaneous mastectomy; that Dr. Parikh performed it in a good manner; and that Dr. Parikh performed it in the same way that he would have performed the operation. (V Six, T-42)[1]

Dr. Parikh's expert, Dr. Bostwick, testified that in his opinion Dr. Parikh did not deviate from an acceptable standard of care in his treatment of Mrs. Cunningham. (V Six, T-138, 139;[1] Page 14, 15 Dr. Bostwick's first deposition)

QUESTION PRESENTED

IS THE FLORIDA MEDICAL CONSENT LAW §768.46 CONSTITUTIONAL?

SUMMARY OF ARGUMENT

In 1975, the Florida Legislature, along with approximately twenty-seven (27) other state legislatures, perceived a problem in medical malpractice lawsuits and the rising cost of liability insurance. Part of the Florida legislature's attempt to address the problem was to enact a medical consent law, Florida Statutes §768.46. This statute sets forth a criteria or standard that a physician must follow in obtaining a patient's informed consent to a medical treatment. If the physician can prove compliance with the statute, the physician is immune from liability in that a consent so obtained is presumed to be valid and can only be rebutted by a showing of fraud in the obtaining of the patient's signature on a consent form. The statutory criteria as to the type and sufficiency of the information that the physician must provide to the patient is basically a codification of the criteria required under common law, as was recognized by the Fifth District Court of Appeal in the Ritz case.

The constitutionality of the Florida Medical Consent Law is clothed with a strong presumption of validity. Since there is no fundamental right or suspect classification involved in this statute, it needs only to pass a rational basis test. The State of Florida, like so many other states which have passed similar legislation, has a legitimate interest in setting standards for obtaining valid medical informed consent, as well as an interest in the availability of less costly health care to the citizens of the state. Medical consent statutes passed by the states of North Carolina and Tennessee, which provide lesser standards than does the Florida statute, have survived

similar constitutional attacks in the Appellate Courts.

The Fifth District Court of Appeal applied a strained and unfair interpretation to Florida Statute §768.46 in declaring it unconstitutional. That Court interpreted the statute to only apply to written consents. Further, that Court interpreted the presumption of validity to apply regardless of the evidence concerning the sufficiency of the information given to the patient by the physician. The trial court, another Florida District Court of Appeal, and a Federal Court have placed a broader, fairer, more common sense interpretation to this statute. These courts have interpreted the statute to apply not only to written forms of "consent", but also to verbal "consents" which are subsequently evidenced in writing. This interpretation more fairly tracks the actual language of the statute and further recognizes that most "consents" occur verbally between the patient and the physician after the physician has discussed the pros and cons of a medical procedure with the patient. In the usual circumstance, the "consent" is evidenced by a written consent form which refers to the type of procedure involved and the type of information provided to the patient through discussions with the physician. The trial court and the two other appellate courts have also interpreted the statute to not only require that the "consent" must be evidenced in writing, and signed by a patient who is mentally and physically competent to give consent, but also that the "consent" must meet the requirements of subsection (3) of the statute. This subsection provides that the physician must give sufficient information to the patient so that a reasonable individual would have a general understanding of (a) the procedure, (b) the

medically acceptable alternative procedure, and (c) the substantial risks inherent in the proposed treatment or procedure. Unlike the Fifth District Court of Appeal, these other courts have recognized that the presumption of validity would only arise, under this statute, when all of the criteria set forth in the statute have been complied with, including the subsection which sets forth the sufficiency and type of information that the physician must provide to the patient in order to obtain a valid informed consent. In this case, the trial court recognized that there was arguably some dispute in the evidence as to what information Dr. Parikh had provided to Mrs. Cunningham, as well as the sufficiency of that information. For this reason, the trial court submitted the issue of informed consent to the jury to determine whether the criteria set forth by the statute was met by Dr. Parikh. The jury determined from the evidence that Dr. Parikh did satisfy the statutory criteria in obtaining Mrs. Cunningham's consent.

The interpretation of this statute as applied by the trial court and the other two appellate courts is certainly a fair and reasonable interpretation. An appellate court is bound to adopt such an interpretation. Although the Fifth District Court of Appeal failed to apply this reasonable interpretation, Petitioner would urge this Court to do so and to uphold the constitutionality of the Florida Medical Consent Law. The burden of determining the need, wisdom and appropriateness of a statute rests with the legislature, and courts should not sit in judgment over such legislation unless it involves a fundamental right or suspect classification.

ARGUMENT

The constitutionality of the Florida Medical Consent Law, Fla. Stat. 1975, §768.132, renumbered as §768.46 in Fla. Stat. 1976, Supp., is clothed with a strong presumption of validity that attaches to any legislative enactment. State v. Bales, 343 So. 2d 9 (Fla. 1977) This presumption is based upon the idea that the legislature does not pass unconstitutional statutes. As there is no fundamental right or suspect classification involved in §768.46, Florida Statutes, the statute needs only to pass a rational basis test, Pinillos v. Cedars of Lebanon Hospital Corp., 403 So. 2d 365 (Fla. 1981); that is, that the legislative enactment is rationally related to legitimate state interests. Therefore, the Florida Medical Consent Law, supra, does not violate the Due Process and Equal Protection clauses of the Florida and United States Constitution. Art. I, §2, Fla. Const., U.S.C.A. Const. Amend. 14.

This Court has recently followed the United States Supreme Court's mandate in City of New Orleans v. Dukes, 427 U.S. 297, 303 (1976), that "the judiciary may not sit as a superlegislature to judge the wisdom or desirability of legislative policy determinations made in areas that neither effect fundamental rights nor proceed along suspect lines". Florida Patient's Compensation Fund, et al. v. Susan Ann Von Stetina, ___ So. 2d ___ (Fla. 1985). Questions as to need, wisdom and appropriateness of a statute are therefore left to the legislature, and courts should not sit in judgment when the legislation does not involve a fundamental right or suspect classification. Bales, supra.

Since statutes are "clothed with a presumption of constitutionality", if the resulting law is proper and unambiguous, then courts need look no further than the statute itself. Department of Legal Affairs v. Sanford Orlando Kennell Club, 434 So. 2d 879 (Fla. 1983).

When there is a reasonable interpretation that may be placed on a statute that would render it valid, an appellate court is bound to adopt such an interpretation. Perry v. City of Ft. Lauderdale, 387 So. 2d 518 (Fla. 4th DCA 1980); Miami Dolphins v. Metropolitan Dade County, 394 So. 2d 981 (Fla. 1981); Department of Insurance v. Southeast Volusia Hospital District, 438 So. 2d 815 (Fla. 1983). The unreasonable consequences that result from finding a statute unconstitutional should be avoided. Wukulla County v. Davis, 395 So. 2d 540 (Fla. 1981). Therefore, if courts are faced with a statute that can be interpreted in two differing ways, one of which would render the statute unconstitutional and the other which would render the statute constitutional, courts have a duty to resolve all doubts in favor of the statute's constitutionality. Florida State Board of Architecture v. Wasserman, 377 So. 2d 653 (Fla. 1979). Miami Dolphins v. Metropolital Dade County, supra, and Falco v. State, 407 So. 2d 203 (Fla. 1981).

Since the statute is not unconstitutional simply because it is subject to differing interpretations, Department of Insurance v. Southeast Volusia Hospital District, supra, the Petitioner would urge this Court to uphold the constitutionality of the Florida Medical Consent Law, supra, and reinstate the trial court's decision in the Petitioner's favor.

In the Preamble to "The Medical Malpractice Reform Act of 1975",

Fla. Laws 1975, Ch. 75-9, the Legislature specifically recognized that the medical malpractice "problem had reached a crisis proportion in Florida", and included section 11, dealing with the issue of informed consent.

The legislative intent surrounding the passage of the Act, supra, has been repeatedly reviewed, most recently with regard to the Florida Patient's Compensation Fund, Sections 768.54(2)(b); 768.54(3)(e)3; and, 768.51, Florida Statutes (1981), Von Stetina, supra, Pinillos, supra. In its preamble to the 1976 amendment to these statutory sections, the Legislature demonstrated its intent to alleviate the "compelling social problem" of the medical malpractice crisis. This Court, in Von Stetina, supra, held that the increasing cost of medical malpractice insurance was imposing a threat to the continued availability and adequacy of health care services, and upheld the constitutionality of the statutory sections in question.

In Ritz v. Florida Patients Compensation Fund, 436 So. 2d 987 (Fla. 5th DCA 1983), the Fifth District examined the issue of informed consent. The majority opinion in Ritz, supra, took note of the informed consent statute and stated at page 992, that the statute is basically a mere codification of the Florida case law which governed informed consent before the statute was passed. The statute requires the physician to provide basically the same information to the patient as did common law. Basically, both require sufficient information be given to the patient so that the patient can make a valid informed consent.

The case of Straughn v. Land Management, Inc., 326 So. 2d 421 (Fla. 1976), provides a test for determining the constitutionality of a statutory presumption as follows:

> "The test for the constitutionality of statutory presumptions is two-fold. First, there must be a rational connection between the fact proved and the ultimate fact presumed. Tot v. United States, 319 U.S. 463, 466, 63 S. Ct. 1241, 87 L. Ed. 1519 (1943); United States v. Gainey, 380 U.S. 63, 66, 85 S. Ct. 754, 13 L.Ed. 2d 658 (1965). Second, there must be a right to rebut in a fair manner. Goldstein v. Maloney, 62 Fla. 198, 57 So. 342 (1911); Black v. State, 77 Fla. 289, 81 So. 411 (1919)."

The first part of the test is that there must be a rational connection between the fact or facts proven and the ultimate fact presumed. Under the statute, the physician must prove the following facts before the presumption would arise:

(1) That the action of the physician in obtaining the consent was in accordance with an accepted standard of medical practice.

(2) That the information provided was sufficient so that a reasonable person, under the circumstances, would have general understanding of:

(a) The procedure;

(b) The medically acceptable alternative procedures; and,

(c) The substantial risk inherent in the proposed procedure.

(3) The "consent" must be evidenced in writing; and,

(4) The "consent" writing is signed by a patient who is mentally and physically competent to give consent under all of the surrounding circumstances.

If the patient offers any evidence which would rebut any of the above elements, the issue would be submitted to the trier of fact.

No presumption would arise unless they found in the physician's favor concerning each of the above elements. Then, and only then, would the presumption arise.

Once it is established that each of the required statutory elements were present, there would be a rational connection between those facts proven and the ultimate fact of a valid consent. At that point, the second part of the test is whether there is then a right to rebut the presumption in a fair manner. Once all of the above elements are established, the only question left would be whether there was fraud in the way that the patient's signature was obtained. The statute does not place any restrictions on how the patient could offer any such evidence, if it existed. Again, considering that all of the above elements must be established before the presumption would arise, the method of rebutting the presumption would seem adequate and fair.

The Petitioner would urge the Court to respect the legislative response to the need for the Florida Medical Consent Law, supra, and the judicial decisions that have followed, and resolve all doubts in favor of the constitutionality of the statute.

The District Court did not address the particular wording of the jury charge based upon the Florida Medical Consent Law as given by the trial court. Any objection to the particular wording used by the trial judge was waived by the Respondents since they did not object to the wording of the court's jury charge in this regard at trial. (T-278, 279). Respondent only objected to the giving of any instruction based upon the Florida Medical Consent Law on the basis that the statute was unconstitutional, per se. Respondents conceded this point on page two of their Reply Brief in the District Court wherein they stated that "the only real issue is whether the statute is unconstitutional" (Appendix 4). Therefore, the only issue presented to this Court is whether or not the Florida Medical Consent Law as embodied in Florida Statute §768.46 is constitutional.

The Fifth District Court of Appeal interpreted the statute in question in a narrow or limited fashion. Under its interpretation, the only type of "consent" to which the statute would apply would be a "consent" which is in written form. On page three of its opinion, the Court stated "subsection (4)(a), requires the consent to be in writing." Another possible and reasonable interpretation would be that this statute would apply to any form of consent, whether verbal or written. This interpretation is reasonable in that the statute refers to "a consent". If the legislature had intended the interpretation used by the Fifth District Court of Appeal, they presumably would have said "a written consent". Obviously, there is a difference between "a written consent" and a "consent" which is evidenced in writing. This broader

interpretation would certainly seem to be a reasonable one, since it would recognize that in most circumstances, a "consent" is given by a patient to a physician after the physician and the patient have had verbal discussions about a proposed treatment. The "consent" and the verbal discussions between the physician and the patient can be, and often are, evidenced in writing by a general consent form which is then signed by the patient. The consent form could repeat the discussions between the physician and the patient, or it could merely reflect or evidence that these discussions were held and that the patient did verbally "consent" to the treatment. It would be rare for patients to sign a general consent form before discussing a proposed treatment or operation with their physician. Further, it would be peculiar for a physician to ask a patient to sign a general consent form before the patient indicates to the physician that the decision has been made to undergo a particular operation. Occasionally, there are circumstances where the information provided to the patient by the physician is conveyed to the patient purely in the form of a writing. One example of this type of circumstance is found in the case of Gassman v. United States, 589 F. Supp. 1534 (M.D. Fla. 1984). The government, in providing swine 'flu injections, did not have a physician verbally give information to a patient, and acknowledged that the only information it provided was in the form of a written consent form.

In interpreting this statute to apply to consents which are given verbally by a patient to the physician, as well as to written consents, it is clear that the statute would require that the physician establish certain elements before the conclusive presumption of a

valid consent would arise, so that no recovery would be allowed against the physician based upon the lack of an informed consent. Those elements are as follows:

1. The action of the physician in obtaining the consent of the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training in the same or similar medical community. [§768.46(3)(a)1]

2. A reasonable individual, from the information provided by the physician under the circumstances, would have a general understanding of (a) the procedure, (b) the medically acceptable alternative procedures, (c) and the substantial risks inherent in the proposed procedure. [§768.46(3)(a)2]

3. The "consent" must be evidenced in writing. [§768.46(4)(a)]

4. The "consent" must meet the requirement that sufficient information was provided by the physician to the patient so that a reasonable individual would have a general understanding of the procedure, the medically acceptable alternative procedures, and the substantial risks inherent in the proposed procedure. [§768.46(4)(a) and (3)(a)2]

5. The "consent" which is evidenced in writing and is signed by a patient who was, under all the surrounding circumstances, mentally and physically competent to give consent. [§768.46(4)(a) and (b)]

Under this statute, the physician would not be entitled to a presumption that "the consent" was validly given by the patient unless the evidence presented by the physician established all of the above elements. If there was no dispute in the evidence as to each of the elements, the physician would be entitled, under the statute, to

have a conclusive presumption that the patient's "consent" to a particular procedure was a valid consent and, therefore, there could be no recovery allowed against the physician. If there was a dispute by the patient to one or more of the above elements, an issue of fact would be created which would have to be resolved by the trier of fact. Only when the trier of fact resolved any disputed issue of fact as to any or all of the elements in favor of the physician, would the physician be entitled to a presumption that the patient's "consent" to the particular procedure was a valid one. If a dispute in the evidence as to any of the above elements was resolved in favor of the patient, the physician would not be entitled to a presumption that the "consent" was valid.

If a dispute in the evidence as to the above-mentioned elements was resolved by the trier of fact in favor of the physician, the statute provides a further safeguard in that the patient could nevertheless rebut this presumption if there was evidence of a fraudulent misrepresentation of a material fact in obtaining the signature.

This common sense interpretation recognizes that Florida Statute §768.46(4)(a), not only requires the "consent" to be evidenced in writing, but also requires the "consent" to meet the requirements of subsection (3), which includes subparagraph (3)(a)2. Subparagraph 2 requires the physician to provide sufficient information to the patient (before the patient "consents" to a proposed procedure) so that the patient would have, under the circumstances, a general understanding of (a) the procedure, (b) the medically acceptable alternative procedures, and (c) the substantial risks and hazards

inherent in the proposed procedure. Clearly, this statute requires the physician to not only present evidence, but to establish the sufficiency of the information that he gave to the patient before the patient "consented" to a particular procedure. If there is a dispute in the evidence as to the sufficiency of the information provided by the physician, obviously the question of fact would have to be determined by the trier of fact before they could determine whether or not the "consent" is not only evidenced in writing, but also meets the requirements of subsection (3), including the requirements of subsection (3)(a)2.

This broader and more common sense interpretation was the one applied by the trial court in this case. The trial court recognized that there was arguably some dispute in the evidence as to whether all of the elements, required by the statute in order for the presumption to arise, were met by Dr. Parikh. Using this interpretation the trial court not only allowed testimony by Dr. Parikh as to what information he provided to the patient, but also testimony from Mrs. Cunningham as to what she recalled as to what information Dr. Parikh provided to her before she "consented" to have the proposed operation. Thereafter, there was testimony allowed that Mrs. Cunningham signed a written consent form, evidencing her verbal "consent" to the procedure. Further, since there was arguably some dispute in the evidence as to whether or not sufficient information was provided to Mrs. Cunningham by Dr. Parikh to satisfy the elements required in the statute, the trial court submitted that issue to the jury for its resolution. The jury, by its verdict, found from the evidence that each and every one of the elements

required by the statute was met by Dr. Parikh. The trier of fact, therefore, answered the interrogatory verdict that there was not a failure of informed consent on the part of Dr. Parikh.

The interpretation of the Florida Medical Consent Law by the trial court in this case was also the interpretation of the Third District Court of Appeal in the case of Dandashi v. Fine, 397 So.2d 442 (Fla. 3d DCA 1981). In that case, the court interpreted the statute to require that the "consent" meet the requirements of subsection 3 of the statute, which obviously would include subpart (3)(a)2. In applying this interpretation, the court specifically noted that the conclusive presumption of the statute is conditioned on the "consent" meeting the requirement that the physician provide to the patient sufficient information to make an informed decision as required by the statute. (Emphasis supplied.) The Dandashi court, in determining whether the requirements were met in obtaining the "consent", considered the Plaintiff's testimony as to what he told the doctor, as well as the Plaintiff's understanding of the consent document which evidenced the patient's "consent". The court stated that in determining whether the presumption should apply under the statute, the trier of fact was obligated to consider all of the circumstances including the following:

(1) the medical procedure proposed;

(2) the risk inherent in the procedure; and,

(3) in that light, the adequacy and reliability of the means chosen to communicate that information to the patient considering any known language difficulty.

The interpretation of this statute by the Third District

Court of Appeal was that where there was dispute in the evidence, the trier of fact would have to determine and resolve, under the evidence, whether or not all of the elements required by the statute were met before the presumption would arise. This same interpretation was used in the case of Gassman v. United States, supra, where it was held that before the statutory presumption (which would create immunity from liability) would apply, the statute required certain threshold standards to be met or determined by the trier of fact. (Emphasis supplied.) One of the threshold standards that must be established, under the statute, before the presumption would apply, is subparagraph (3)(a)2, which specifically calls for a determination as to whether the patient was given sufficient information to make an informed decision. The Gassman case involved treatment in the form of a swine 'flu injection provided by the government to patients as a prophylaxis for an illness known as swine 'flu. Because of the number of potential patients involved, the government conceded that there was no verbal communication of information to the patient as would normally be the case in a one-on-one, physician to patient relationship. The only information provided to the patient was provided in a written form. Under those circumstances, the court, as the trier of fact, reviewed the sufficiency of the information provided in the written form to determine whether it contained sufficient information to comply with subparagraph 2 of subsection (3) of this statute. The court found that the information provided was not sufficient to comply with that subparagraph and therefore found that the threshold standards or elements of the statute were not met. Thus, the court

determined that the presumption of a valid "consent" by the patient did not arise under the statute. Both the court in Dandashi, supra, and the court in Gassman, supra, interpreted this statute to require that all of the conditions or threshold standards which are required in the statute must be established before the presumption arises. (Emphasis supplied.)

The interpretation of the Gassman and Dandashi courts should be contrasted with that of the Fifth District Court of Appeal, which interpreted the statute so that the presumption would apply "regardless of the sufficiency of the information given" to Mrs. Cunningham by Dr. Parikh. Under the broader interpretation suggested, the trier of fact would have to consider the sufficiency of the information given by a physician to a patient in order to determine whether or not the elements required by the statute were met. One of the requirements of the statute would be that sufficient information was given so that a patient could give an informed "consent" to a proposed operation. It is a strained interpretation of this statute to say that the legislature intended for a physician to have a presumption of validity to a "consent" given by a patient, if the evidence was that the physician failed to provide the patient with proper advice to adequately inform the patient before the patient gave their "consent" to a proposed procedure. Yet this is precisely the interpretation of the Fifth District Court of Appeal. Their interpretation would be appropriate if the Florida Statute were similar to the Louisiana Statute. (Appendix 5). The Louisiana Statute only addresses "consents" which are in writing.

If the trial court had interpreted this statute as did the

Fifth District Court of Appeal, there would have been no need to submit to the jury the issue as to whether or not the presumption would arise. There was certainly no dispute in the evidence that Mrs. Cunningham signed a written document evidencing her consent and that she was mentally and physically competent to give consent. Therefore, there would have been no need and, in fact, it would not have been proper to submit this issue to the jury. Under the interpretation used by the trial court and by the courts in Dandashi and Gassman, however, there would be a requirement to submit this issue to the jury, because there was some dispute in the evidence as to the sufficiency of the information provided by the physician to the patient, as is required by the statute. This broader and more common sense interpretation also recognizes that the common practice of a patient giving a "consent" to a medical procedure involves circumstances where the physician provides information to the patient through discussions, and questions and answers concerning generally the nature of the procedure, the medically acceptable alternatives, and the risk inherent in the procedure. In most circumstances, as in this case, the physician further discusses with the patient, the patient's prognosis along with the fact that no guarantees of result can be given by the physician. It is only after these verbal discussions between the physician and patient that the patient usually indicates to the physician in a verbal form that the patient has decided to undergo an operation. If the patient's decision, verbally expressed, is to undergo the operation, the patient has verbally "consented" to undergo the procedure and then, after receiving the information and making that decision, the patient usually signs a written form which evidences the "consent"

which has already occurred and been expressed to the physician.

Certainly this broader interpretation as used by the trial court and other appellate courts considering Florida law, is a reasonable and possible interpretation of this statute.

Florida has not been the only state to recognize the problems in medical malpractice suits and the rising cost of liability insurance. Like Florida, some twenty-seven other states have passed statutes attempting to deal with the problem. Comment, Informed Consent in Maine: Woolley v. Henderson and the Informed Consent Statute, 33-34 Me. L. Rev. 311, 321 (1982). (Appendix 6). Most of these states have, as a part of their legislation included a section dealing with medical consent law. The basic purpose of most of these statutes dealing with consent law is to express some criteria by which a physician can protect himself from lawsuits based upon allegations of a lack of informed consent on the part of the patient.

For example, in 1975 the legislature of North Carolina passed an informed consent statute, §90-21.13, which is very similar to the statute passed by Florida. (Appendix 7). There are two basic differences to the North Carolina statute when compared to the Florida statute. First, with regard to the sufficiency of information that the physician must give to the patient, North Carolina only requires two of the three elements required by the Florida statute. Under the North Carolina statute, the physician must give the patient information that would give a reasonable patient a general understanding of (a) the procedure and, (b) the most frequent risks and hazards inherent in the proposed procedure. Unlike the Florida statute, the North Carolina statute does not require the physician

to tell the patient about any medically acceptable alternative procedures. The second difference is that once all criteria set out by the statute have been established, there is a "presumption" of valid consent rather than a "conclusive" presumption. The statute does provide, however, that the presumption may only be rebutted by proof that such consent was obtained by fraud, deception or misrepresentation of a material fact. The effect, therefore, of their presumption, once all the criteria or standards of the statute have been met, is the same as the Florida statute insofar as how the presumption may be rebutted. The only other difference in their statute is that they include the requirement that no action may be maintained against a health care provider upon any guarantee as to the result of any medical procedure, unless the guarantee or some note or memorandum thereof, shall be in writing, and signed by the health care provider. The Florida legislature chose to place the guarantee cause of action under the Statute of Frauds, §725.01, Fla. Stat. (1975), rather than putting it as a part of the medical consent statute.

The constitutionality of the North Carolina statute was considered by the North Carolina Court of Appeal in the case of Dixon v. Peters, 306 S.E.2d 477 (N.C. App. 1983). In that case, the claimant Dixon made three separate constitutional attacks on the North Carolina Informed Consent Statute. He argued that the statute was unconstitutional (a) as a legislative infringement on the judicial power as given to the courts by the North Carolina Constitution; (b) that it denied a plaintiff the state constitutional right that "courts shall be open" as well as the due process requirement of both the North Carolina and United States Constitution; and, (c)

because the statute violated the equal protection clauses of both the North Carolina and United States Constitution.

The North Carolina Court of Appeal considered these arguments and rejected them. In upholding the constitutionality of the North Carolina informed consent statute, the Court of Appeal used the rational relationship test and found that the statute was a rationally related means of accomplishing a desired result. The Court found that the state had a legitimate interest in enacting the medical consent statute because of the medical malpractice crisis of the 1970's. In this regard, the Court stated that "the state does have a legitimate interest in setting the standards by which a jury can determine whether malpractice has occurred.". The Court further stated, "the state most assuredly has an interest in the availability of less costly health care to all its citizens". The court held that the statute did not deny recovery to victims of medical negligence, and that since there was a rational basis for the passage of the statute, it did not violate the equal protection clauses.

As further example, the legislature in the state of Tennessee passed an informed consent statute, §29-26-118, also in 1975. (Appendix 8). The Tennessee statute addresses the problem differently than does the Florida statute, but basically with a similar result and intent. The Tennessee statute provides what the patient must prove in order to recover for an alleged failure of informed consent. Obviously, this approach is different than the Florida statute, which provides what the physician must prove to prevail in an alleged failure of informed consent type of case. The Tennessee statute provides that the plaintiff must prove that the health care

provider did not supply appropriate information to the patient in obtaining his informed consent to the procedure in question. The statute then goes on to define "appropriate" information as that information that would generally be provided by other professionals in the profession and in the specialty of the defendant in his and similar communities. Again, this statute provides a lesser standard in the burden it places upon health care providers than does the Florida statute. The Tennessee statute does not specify the type of information or the elements that the health care provider must provide to the patient to properly secure the patient's valid consent to a medical procedure. The constitutionality of the Tennessee statute was considered in the case of Rush v. Miller, 648 F.2d 1075 (6th Cir. 1981). In that case, the United States Court of Appeals, Sixth Circuit, upheld the constitutionality of the Tennessee informed consent statute.

North Carolina and Tennessee are but two examples of other states that have also recognized a medical malpractice problem and have passed legislation to address that problem. The portion of these two states' statutes dealing with informed consent require less of the health care provider than does the Florida Medical Consent statute, but have survived constitutional attack.

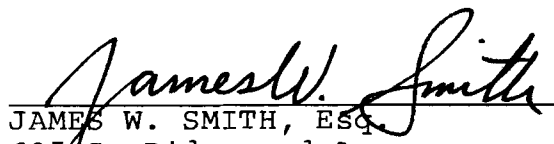
CONCLUSION

Florida Statute §768.46 was a legitimate response by the legislature to a perceived problem of rising costs of medical liability insurance. In establishing a criteria that physicians must follow in obtaining an informed consent to treatment, the statute codifies the same basic requirements that existed under common law. Even when compliance with the statute has been established so that a presumption of validity would arise, there is still a fair way to rebut the presumption if the consent was obtained by a fraudulent misrepresentation.

Petitioner would respectfully request the Court to quash the decision of the Florida Fifth District Court of Appeal, and to declare Florida Statute §768.46 constitutional.

Respectfully submitted,

SMITH, SCHODER, ROUSE & WILL, P.A.



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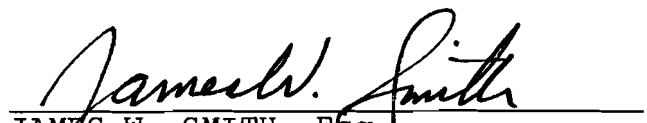
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true copy hereof has been furnished by mail to: Nolan Carter, Esq., P. O. Box 2229, Orlando, FL 32802; and Frederick B. Karl, Esq., 1501 E. Park Avenue, Tallahassee, FL 32301, by U. S. Mail, this 3rd day of June, 1985.

SMITH, SCHODER, ROUSE & WILL, P.A.



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