# IN THE SUPREME COURT OF FLORIDA

GERALD	SILVA,	ETC.

Petitioner,

vs.

Case No. 77,980

SOUTHWEST FLORIDA BLOOD BANK, INC.,

Respondent.

JOHN SMITH, ET UX., ETC.,

Petitioner,

vs.

Case No. 78,012

SOUTHWEST FLORIDA BLOOD BANK, INC.,

Respondent.

ON CONSOLIDATED PETITIONS TO REVIEW CERTIFIED CONFLICT FROM THE SECOND DISTRICT COURT OF APPEAL OF FLORIDA

ANSWER BRIEF OF RESPONDENT, SOUTHWEST FLORIDA BLOOD BANK, INC.

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#### INTRODUCTION

This Answer Brief of Respondent is respectfully submitted by Southwest Florida Blood Bank, Inc. ("Southwest") in these consolidated actions to review Silva v. Southwest Florida Blood Bank, Inc., 578 So.2d 503 (Fla. 2nd DCA 1991) and Smith v. Southwest Florida Blood Bank, Inc., 578 So.2d 501 (Fla. 2nd DCA 1991).

The separate records will be identified as (<u>Smith R. \_\_\_</u>) and (<u>Silva R. \_\_\_</u>). The Petitioners will be referred to as "Smith" and "Silva," where appropriate.

## STATEMENT OF THE CASE AND FACTS

# A. The Silva Action.

With the exception of some editorialization, the Statement of the Case and Facts set forth in Silva's Initial Brief is generally acceptable.

Regardless of whether asserted under its express warranty, implied warranty or negligence counts, the Second Amended Complaint (Silva R. 88-92) contained the following pertinent allegations:

4. ANNE MARIE N. SILVA'S doctors relayed the assurances of the BLOOD BANK that cryo precipitate manufactured from the BLOOD BANK'S blood supply would be safe and free from the HIV virus because of testing proceduresutilized by the BLOOD BANK. (Silva R. 88).

\* \* \*

12. The BLOOD BANK was negligent in not adequately testing or monitoring the cryo precipitate given to ANN MARIE N. SILVA and in failing to adequately warn ANNE MARIE N. SILVA of the risks of using cryo precipitate furnished by the BLOOD BANK.

15. The BLOOD BANK and literature published and distributed by it expressly warranted that its blood and blood by-products such as cryo precipitate were safe and would not be sold for use by patients such as ANNE MARIE N. SILVA if they tested positive for the HIV virus.

16. ANN MARIE N. SILVA relied upon the BLOOD BANK'S warranty, which was conveyed by the BLOOD BANK to various members of the medical community, in turn to be communicated by the physician to his patient. The failure of the BLOOD BANK to fulfill its express warranty, conveyed to the doctor as a learned intermediary, proximately damaged ANNE MARIE N. SILVA in that she contracted as AIDS-related disease as a result.

\* \* \*

18. The scientific techniques which existed by the summer of 1985 for testing blood were such that the BLOOD BANK should have been able to detect the presence of HIV virus in blood and blood products. (Silva R. 89-90).

In <u>Silva</u>, the Trial Court found that Southwest was a health care provider entitled to the benefits of the medical malpractice statute of limitations, §95.11(4)(b), Florida Statutes. (<u>Silva</u> R. 99-101). The Second District Court of Appeal affirmed. <u>Silva v.</u> Southwest, <u>supra</u>.

## B. The Smith Action.

Smith's Initial Brief on the merits is accurate with respect to its Statement of the Case. The pertinent allegations of Smith's Complaint (Smith R. 1) essentially paralleled those of Silva.

As Smith's Initial Brief notes, and as in  $\underline{Silva}$ , Southwest's Motion to Dismiss in the Circuit Court raised numerous alternative grounds not reached by the Circuit Court. (Smith R. 8-12).

Southwest's primary assertion was that it was a health care provider to Smith for purposes of §95.11(4)(b). Its secondary assertion was that if it was not strictly a health care provider, it was in privity with South Florida Baptist Hospital, which was unquestionably a health care provider.

The Trial Court found that Southwest came within the "privity" provision of \$95.11(4)(b). (Smith R. 37, 39-40).

# C. The Second District's Decisions In Smith and Silva.

The decisions in <u>Smith v. Southwest</u> and <u>Silva v. Southwest</u> are interconnected. The Second District ruled that Southwest was a health care provider for purposes of the medical malpractice statute of limitations. Thus, it did not need to address the privity argument which the Trial Court in Smith had relied upon.

In certifying alleged conflict with <u>Durden v. American</u>
<u>Hospital Supply Corp</u>, 375 So.2d 1096 (Fla. 3rd DCA 1979) cert.
denied 386 So.2d 633 (Fla. 1980), the Second District apparently
perceived that there was no distinction between extraction of blood
from a donor in the <u>Durden</u> situation, and the providing of blood
components for transfusion and use in the treatment of a patient as
in the Smith and Silva circumstances. Silva v. Southwest, at 506.

This Court has reserved determination on the sole jurisdictional issue of whether there is, in fact, conflict between the decisions sought to be reviewed and <u>Durden</u>.

# STATEMENT OF THE ISSUES ON APPEAL

The initial issue concerns this Court's jurisdiction:

DOES THIS COURT HAVE JURISDICTION BASED UPON THE SECOND DISTRICT'S PERCEPTION OF A CONFLICT BETWEEN THE DECISIONS SOUGHT TO BE REVIEWED AND DURDEN V. AMERICAN HOSPITAL SUPPLY CORP., 375 So.2d 1096 (FLA. 3rd DCA 1979), CERT. DENIED 386 So.2d 633 (Fla. 1980)?

If this Court finds that there is direct and express conflict between the decisions sought to be reviewed and <u>Durden</u>, the issues on the merits may be stated as:

II.

IN PROCURING, PROCESSING AND SUPPLYING BLOOD FOR TRANSFUSION, IS SOUTHWEST A HEALTH CARE PROVIDER FOR THE PURPOSES OF THE MEDICAL MALPRACTICE STATUTE OF LIMITATIONS?

III.

ALTERNATIVELY, IN PROCURING, PROCESSING AND SUPPLYING BLOOD FOR TRANSFUSION, IS SOUTHWEST IN PRIVITY WITH A HEALTH CARE PROVIDER FOR PURPOSES OF APPLICATION OF FLORIDA'S MEDICAL MALPRACTICE STATUTE OF LIMITATIONS?

Additionally, Silva, Amici Doe and the Academy of Florida Trial Lawyers have attempted to interject the statute of repose provision of §95.11(4)(b), Florida Statutes, and constitutional arguments which were not raised or determined below. The dispositive issue is:

IV.

WHETHER THE STATUTE OF REPOSE PROVISION IN THE MEDICAL MALPRACTICE STATUTE OF LIMITATIONS, PREVIOUSLY HELD CONSTITUTIONAL, IS IMPLICATED IN THESE CASES?

### SUMMARY OF ARGUMENT

Ι

There is a distinct factual difference between the decisions sought to be reviewed and <u>Durden v. American Hospital Supply Corp.</u>, 375 So.2d 1096 (Fla. 3rd DCA 1979) cert. denied 386 So.2d 633 (Fla. 1980). Southwest, as a community blood bank procuring and providing blood and blood components for the specific purpose of transfusion, has been Legislatively mandated to be providing a medical service to the patient which is both necessary and an integral part of the practice of medicine. Preamble, Ch. 67-69 157, Laws of Fla. This policy is reflected in Florida's statutory and regulatory provisions.

<u>Durden</u>, on the other hand, involved hepatitis contracted by a paid donor at blood plasma center from a dirty needle. That injury did not involve the rendering of medical care to the donor, a fact recognized in Durden. Thus, no conflict exists.

II

Florida's legislative and regulatory provisions, including a clear statement of legislative public policy that blood banks supplying blood for transfusion render not only necessary medical services, but are involved in the practice of medicine and not simply a sale of a commodity, makes it evident that Southwest is a health care provider for purposes of the medical malpractice statute of limitations.

The term " any provider of health care" as utilized in \$95.11(4)(b), Florida Statutes must be read in pari materia with

Florida's policy statement and statutory provisions relating to blood banks supplying blood for patient transfusion. In doing so, as did the Second District in the decision sought to be reviewed, the actual real world of the practice of medicine cannot be ignored.

It cannot be denied that the processing and providing of blood by a blood bank for purposes of a transfusion, which blood subsequently causes injury to the <u>recipient</u>, gives rise to a " . . . claim . . . for damages because of . . . injury . . . arising out of any medical . . . diagnosis treatment or care by any provider of health care.". §95.11(4)(b), <u>Fla. Stat.</u>

III

If Southwest is not a direct health care provider it is certainly within the scope of the privity provision of §95.11 (4) (b) Florida Statutes. There is a contract privity and an identity of interest between the blood bank and the hospital/doctor with respect to the patient and the mutual goal to effectuate treatment and cure.

IV.

Neither <u>Smith</u> nor <u>Silva</u> involve the medical malpractice statute of repose. In each of these cases, the presence of HIV anti-bodies in the blood stream was detected well before the two year statute of limitations ran. The statute of repose is constitutional in any event.

#### ARGUMENT

Ι

THERE IS NO CONFLICT BETWEEN THE DECISIONS SOUGHT TO BE REVIEWED AND DURDEN V. AMERICAN HOSPITAL SUPPLY CORP., 375 So. 2d 633 (Fla. 3rd DCA 1979, cert. denied, 386 So.2d 633 (Fla. 1980), WHICH IS THE ONLY DECISION CERTIFIED AND PROPERLY BEFORE THE COURT FOR CONFLICT CONSIDERATION.

This Court's jurisdiction rests solely on the Second District's certification of conflict with <u>Durden v. American</u>

<u>Hospital Supply Corp.</u>, 386 So.2d 633 (Fla. 1980). Art. V,

§3(b)(3), Fla. Const. (1980); Fla. R. App. P. 9.030(a)(2)(a)(vi).

The <u>Silva</u> Initial Brief attempts to make a perfunctory argument regarding alleged conflict with <u>Brown v. St. George Island, Ltd.</u>, 561 So.2d 253 (Fla. 1990) and <u>Baskerville-Donovan Engineers</u>, Inc. v. <u>Pensacola Executive House Condominium Association</u>, Inc., 16 F.L.W. S440 (Fla. June 13, 1991). (<u>Silva Initial Brief</u>, p. 38). Silva did not invoke this Court's jurisdiction under Article V, § (b) (3), Florida Constitution (1980), as implemented by Florida Rule of Appellate Procedure 9.030 (a)(2)()A)(iv): i.e., non-certified conflict.

It is respectfully submitted that such a separate and distinct invocation of this Court's jurisdiction is required, as is inherently recognized in Fla. R. App. P., 9.120 (d). Neither Art. V, \$3 (b)(3), nor Fla. R. App. P., 9.030 (a)(2) grant jurisdiction in this Court to review decisions on its own motion. As such, only the asserted conflict with Durden need be discussed. Nevertheless, Silva's assertion of conflict with Brown and Baskerville is inherently fallacious under the standards which govern this Court's conflict jurisdiction. Silva v. Southwest does not enunciate a rule of law which expressly and directly conflicts with Brown or Baskerville, nor does it involve the same controlling facts as Brown or Baskerville. (Infra, pp. 20-27).

Under the constitutional prerequisite of express and direct conflict, one of two situations must clearly appear: (1) an announced rule of law which conflicts with other appellate or Supreme Court expressions of law; or (2) an established rule of law is applied to produce a different result in a case which involves the same controlling facts as the prior case. E.g., Nielsen v. City of Sarasota, 117 So.2d 731, 732 (Fla. 1960); Ansin v. Thurston, 101 So.2d 808 (Fla. 1958). Essentially, jurisdiction exists only if the essential effect would be that the case sought to be reviewed overrules the case cited for conflict. Ansin, supra, at 811. The Second District's perception of a conflict between the cases sought to be reviewed and Durden is thus clearly misplaced.

The Second District is correct in holding that the preamble to Chapter 69-157, Laws of Florida and the Legislature's treatment of blood banks mandates that a community blood bank such as Southwest be declared and held to be within the term "any provider of health care," when providing blood for transfusion to a patient, as that term is used in \$95.11(4)(b), Florida Statutes. However, it failed to recognize the primary factual distinction between the cases sought to be reviewed and Durden.

<u>Durden</u> involved a <u>paid donor's</u> action against a commercial blood donor center after <u>he</u> contracted hepatitis. The Third District refused to apply the medical malpractice statute of limitations to that situation. While correctly acknowledging that

a blood center is a "health care provider" for some distinct factual circumstances, <u>Durden</u> recognized that in <u>taking</u> the blood from the <u>seller/donor</u> in that case, and injuring the <u>seller/donor</u>, the plasma center was not rendering care or treatment to a <u>patient</u> or even providing a medical service to the <u>"donor"</u>. Thus, the donor does not have a medical malpractice cause of action.

Certainly, the paid donor's injury did not arise out of any medical diagnosis, treatment or care by any provider of health care, or anyone in privity with a provider of health care, as contemplated by \$95.11 (4)(b), Florida Statutes:

An action for medical malpractice shall be commenced within two years from the time the incident giving rise to the action occurred or within two years from the time the incident is discovered or should have been discovered with the exercise of due diligence;

\* \* \*

An "action for medical malpractice" is defined as claim in tort or in contract for damages because of the death, injury, or monetary loss, to any person arising out of any medical, dental, or surgical diagnosis, treatment or care by any provider of health care. The limitations of actions within this subsection shall be limited to the health care provider and persons in privity with the provider of health care. (Emphasis added).

This fact was recognized in <u>Durden</u>'s holding that the plasma center was not rendering care or treatment to the donor:

Construing Section 95.11(4)(b) in its plain and ordinary sense, it is apparent that more

<sup>&</sup>lt;sup>2</sup> Southwest never claimed that <u>Durden</u> was wrongly decided. Of course, this Court would be free to determine that <u>Durden</u> was wrongly decided if properly presented with the issue. However, such a determination is not necessary in this case.

than just the fact that a party defendant is a health care provider is required to bring a cause of action within this two-year statute In addition, the claim for of limitations. damages must arise as a result of medical, dental or surgical diagnosis, treatment or care on the part of the health care provider. See Jackson v. Biscayne Medical Center, Inc., 347 So.2d 721, 722 (Fla. 3d DCA 1977). Durden sold his blood to American. There was no diagnosis, surgical medical, dental or treatment or care rendered by American to The relationship contemplated by the subject statute of limitation is in the nature (dentist)-patient or hospitaldoctor in contrast to the vendor-vendee patient (Emphasis relationship in the case at bar. added).

[375 So.2d at 1099].

In this respect, the <u>Durden</u> Court did not have to address the following provisions of the preamble of Ch. 69-157, Laws of Florida, or other statutory and regulatory provisions as addressed by the Second District, <u>Silva v. Southwest</u>, at 505-506, in order to determine whether the specific activities and relationship in that case met the otherwise <u>undefined term</u> " . . . <u>any provider of health care</u>" as envisioned by §95.11 (4) (b). Of course, <u>Durden does not even evidence that Court's awareness of these provisions</u>.

As the Second District's opinion in <u>Silva v. Southwest</u> at 505 cogently notes, the Legislature's public policy statement embodied in the enacting provisions of Chapter 69-157, amending §672.316, Florida Statutes (1967) and creating the "blood shield statute," authoritatively established that, <u>as to the patient recipient</u>, the activities leading to the <u>transfusion</u> of blood are not merely the sale of a product, but constitute the rendition of a necessary medical service which is "... an intricate part of the practice

of medicine. . . ". This policy statement predated the enactment of the two-year medical malpractice statute of limitations: 3

WHEREAS, the procurement, processing, storage, distribution, or use of whole blood, plasma, blood products, and blood derivatives, for the purpose of injecting or transfusing the same or any of them, into the human body provides the general public with a desirable and necessary medical service, and

\* \* \*

WHEREAS, the rendering of this service is an intricate part of the practice of medicine, and

\* \* \*

WHEREAS, the continuance of the operation of community and private blood banks provides the citizens of Florida with a service which might otherwise have to be provided by the State of Florida, and

WHEREAS, the public policy declared by this enactment is a Legislative prerogative, NOW, THEREFORE, . . . (Emphasis added).

Indeed, the difference is recognized in the statutory provisions relating to blood transfusions<sup>4</sup> which Petitioners seek to ignore. For example, the definitions of "donations" and "transfusions" contained in §381.601 (b) and (k) of the "Florida Blood Transfusion Act," predate the transfusion in these cases and provide:

Florida did not separately define medical malpractice until 1975, and there was no distinction whatsoever between medical malpractice and any other negligence prior to 1974. Ch. 75-9, §7, Laws of Fla. §95.11 (4) (a), Fla. Stat. (supp. 1974); amended, §95.11 (4)(b), Fla. Stat. (1975), effective May 20, 1975.

<sup>&</sup>lt;sup>4</sup> <u>Also</u>, the definition of a clinical laboratory, which a blood bank is, in §483.041(1), <u>Fla. Stat.</u>, (1989). Quoted <u>infra</u>, p. 32.

"Donations" means any transaction involving the person from whom blood is withdrawn, whether he presents himself for the withdrawal of blood on his own initiative or on the initiative of another person, in which he receives no consideration other than credit through blood assurance programs or other intangible benefits.

\* \* \*

"Transfusion" means the use of blood in which the blood is administered to a human being <u>for treatment of sickness or injury</u>. (Emphasis added).

§381.601(2)(h) defines a "paid donor" to mean " . . . a person who donates blood and who seeks payment in return. . .".

The medical procedures directly related to the entire process of transfusion for the benefit of the recipient patient is the bright line difference between the <u>Durden</u> situation and the present situation. The Legislature has patently recognized that the activities as related to the transfusion of the patient, which would include breaches of duty in procuring the blood such as a failure to screen the donor, is medical care and treatment of human beings. §381.601 (2) (a), Florida Statutes further strengthens this definition by excluding from the term "blood" "... blood derivatives manufactured or processed for industrial use."

The Second District's decision in <u>Silva v. Southwest</u> simply lost sight of this essential dividing line in its reading and analysis of <u>Durden</u> and the word "procurement" in the preamble. It failed to recognize that the present cases involve medical procedures directed to <u>transfusion services to the patient</u> as an integral part of the practice of medicine. <u>E.g., Silva v.</u>

Southwest, at 506.

There is no "direct or express" conflict between the decisions sought to be reviewed and <u>Durden</u>. The decisions sought to be reviewed represent decisions of the first impression by the Second District Court of Appeal. Accordingly, this Court should dismiss this action for lack of jurisdiction.

II.

SOUTHWEST, IN ITS ACTIVITIES AS A PROVIDER OF BLOOD FOR TRANSFUSION, IS A HEALTH CARE PROVIDER FOR THE PURPOSE OF THE MEDICAL MALPRACTICE STATUTE OF LIMITATIONS.

The fact that Petitioners attempted to bring a non-medical malpractice action against Southwest and could not sue the doctor or hospital because of \$95.11(4)(b), is not determinative of whether Southwest in procuring, testing (including the screening of donors and the testing of the blood itself) and processing blood for the purpose of transfusion to the recipient, is rendering "... any medical . . . diagnosis, treatment or care by any provider of health care," for the purposes of \$95.11(4)(b).

Ignoring the preamble, quoted <u>supra</u>, p. 11, Petitioners attempt to argue that the blood shield statute, §672.316(5), Florida Statutes, (1967) created only a "legal fiction," as it were, by "simply" eliminating actions for strict liability or pure breach of warranty. However, the preamble is a controlling statement of public policy which is wholly within the Legislature's domain. Van Bibber v. Hartford Accident & Indemnity Insurance Co., 439 So.2d 880, 883 (Fla. 1983); American Liberty Insurance Company v. West and Conyers Architects and Engineers, 491 So.2d 573, 575

(Fla. 2nd DCA 1986).

As they did below, Petitioners attempted to gain some comfort from the fact that the blood shield statute preserves limited contract actions. This fact does not affect the application of \$95.11(4)(b) any more than do the allegations of inadequate screening of donors or the testing and monitoring of the cryoprecipitate, or the failure to warn of the risks of cryoprecipitate, as alleged in the Petitioners' Complaints.

\$95.11(4)(b) applies to any suit, whether in tort or contract.

C.f., Shiels v. Jack Eckert Corporation, 560 So.2d 361 (Fla. 2nd DCA 1990). Insofar as \$95.11(4)(b) is concerned, the Legislature could have prohibited all actions sounding in contract or warranty, preserving only negligence actions based on the same standard of care. The purpose of the statute parallels the express recognition of the fact that, insofar as the entire transfusion process as it relates to the patient recipient is concerned, blood banks are an integral part of the practice of medicine. The blood shield statute provides a limited contractual cause of action for any malpractice based upon the prevailing, available and current scientific knowledge and procedure. If this standard is breached, a cause of action exists. However, the cause of action must be brought within two years.

In fact, the elimination of such "product" actions as strict liability was intended to bring blood banks in line with hospitals under the common law's recognition that in administering transfusions, hospitals are rendering medical care and treatment,

and were not involved in the sale of a product. Howell v. Spokane

<u>& Inland Empire Blood Bank</u>, 114 Wash. 2d 42, 785 P.2d 815, 820-822

(Wash. 1990); see also, McKee v. Cutter Laboratories, Inc., 866

F.2d 219 (6th Cir. 1989).

It is evident that the Petitioner's attempt to circumvent and ignore the preamble of Chapter 69-157 rests on an attempted isolation of the term "medical service." As previously noted in Argument I, with reference to the policy statement's term "procurement" of blood products, the policy statement must be read as a whole:

distribution or use of whole blood, plasma, blood products and blood derivatives, for the purpose of injection or transfusing the same or any of them, into the human body provides the general public with a desirable and necessary medical service, . . . the rendering of this service is an integral part of the practice of medicine. . ".

As the Petitioners recognize, (<u>see</u>, Silva Initial Brief, p. 13), the term "<u>any</u> provider of health care" was specifically left undefined by the Legislature in the subsequently enacted \$95.11(4)(b). This omission was not an oversight. It is evident that the Legislature intended that the term be given a flexible construction which takes into consideration the existing as well as subsequently developed practices, relationships or procedures in the medical sciences and community. In reading the Florida statutory provisions as a whole, as the Second District did, <u>in pari materia</u> with the policy statement in Chapter 69-157, no conclusion can be reached other than that a blood bank supplying

blood for transfusion to a patient comes within of §95.11(4)(b).

The medical malpractice statute of limitations applies to any injury "arising out of any . . . diagnosis, treatment or care . . ". In the Second District, Petitioners offered no argument which could logically rebut the fact that wherever used, whether in contracts or statutes, the term "arising out of" simply requires a causal connection. C.f., Fidelity and Casualty Company of New York v. Moore, 143 Fla. 103, 196 So. 495 (1940) (involving the statutory requirement that injury "arise out of and in the course of employment" within the "workers compensation act); Watson v. Watson, 326 So.2d 48, 49 (Fla. 2nd DCA 1976) (the term "arising out of" as to automobile insurance policy and claims "arising out of the ownership, maintenance or use of a motor vehicle.")

Furthermore, the statute operates upon any loss, "... arising out of <u>any</u>... medical... diagnosis, treatment or care by <u>any</u> provider of health care." Petitioners cannot deny that the term "any" must be given its natural meaning. The use of the term "any" is a further indication that in enacting §95.11(4)(b), the Legislature was not tying itself to narrow identifications of "health care providers" used in other limited contexts.

In essence, it did not want to fashion a word of art "straight jacket" for itself, the courts, or the medical community. Essentially, the Petitioners totally miss the essence of the public policy stated in Chapter 67-159, as further reflected in Florida's statutory and regulatory provisions addressed by the Second District in Silva v. Southwest, and in Florida Association of Blood

Banks, et al. v. Department of Health and Rehabilitative Services, et al., 9 FALR 367 (DOAH 1986), upon which Silva quite inappropriately attempts to rely.

Petitioner's arguments are premised on the assumption that blood and blood components for transfusion are products similar to a manufactured drug or medical equipment rather than an integral part of the practice of medicine and the diagnosis and treatment of illnesses. Petitioners fail to address the essential difference between blood or blood components in this context and manufactured products such as drugs and medical supplies. Medical science and the Legislature recognize the inherent distinction.

Especially in enacting Chapter 69-157's policy statement, Florida's Legislature did not blindly create only a "legal fiction" that blood is not a product. <u>See also</u>, §381.601(4), <u>Fla</u>. <u>Stat</u>. Quoted <u>infra</u>, p. 48.

A manufacturer of a product develops it, markets it and bears the responsibility if it is not free from defects because it controls all aspects of the manufacturing process. On the other hand, a unit of blood is not a "product" of the blood bank. A unit of blood is a voluntary donation of human tissue. A blood bank does not manufacture that unit of human tissue. Rather, it screens the health of the donor for possible health risks in determining whether or not to accept the unit of blood, and performs a number of specific medical procedures ranging from hematocrits and hemoglobins to very sophisticated tests for hepatitis, HIV antibodies and other evidence of infectious disease. These

procedures are inherently medical in nature in an attempt to determine whether the unit is safe for transfusion as is reasonably medically possible. The final medical diagnosis provided by the blood bank is to test the unit of blood to see whether it is compatible with that of the recipient (the cross-match).

All of these activities are medical services which are provided for the ultimate benefit of the recipient of the transfusion. In testing and processing blood it is not "manufactured" in any way. If any concerns are raised about the unit of blood, then the unit is discarded and is not available for transfusion.

Procedures performed by the blood bank must employ the latest developments in medical technology, and they are inherently reflective of the exercise of medical judgment. Unlike the manufacturer of a drug or other medical supply, a blood bank must be managed and supervised by a licensed physician with expertise in hematology or pathology and must employ qualified medical, chemical and biological techniques. §10 D-41.079, F.A.C. By definition, the tests performed are "examinations . . . [of] materials or specimens taken from the human body to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the assessment of a medical condition." §483.041(1), Florida Statutes. This is fundamentally different from manufacturing a product. The medical procedures and laboratory services provided by a blood bank with respect to the unit of blood which is to be transfused are no different in character than

pathology or x-ray services performed for a physician, testing of human tissue for infectious disease, testing for compatibility of organ and tissue transplants, or many other medical procedures which can now, and <u>must be</u> performed to assist in the <u>diagnosis</u>, prevention or treatment of a disease or the assessment of a medical condition.

Certainly, Petitioners do not question the fact that the diagnosis of HIV which prompted their suits was due to the performance of laboratory procedures to detect the presence of HIV antibodies. Yet, under the arguments which they now advance, the identical testing of the blood for the presence of HIV antibodies is a function different than the medical diagnosis, care and treatment of the condition. Obviously, any such conclusion is illogical and contradicts common sense. Medical laboratory and other procedures performed by blood banks in screening, processing and cross-matching a unit of blood for transfusion must be considered in the same light. When the functions that a blood bank performs are viewed in the light of common sense, legislative policy and enactments, the only conclusion which can be reached is that they are performed for the sole purpose of providing for and are inherent in the medical care and treatment of the transfusion recipient.

Technology has not yet developed blood in the form of a synthetic product. Until it does, medical science is left with only the option of obtaining blood from volunteer donors and testing the tissue as carefully as possible to make it safe for the

recipient. Medical science has been able to make the transfer of blood from one human to another far more safe than the transfer of organs and limbs at this point in time. Unfortunately, however, it is not free from risk.

The Petitioners attempt to present the Second District's opinion in Silva v. Southwest as merely a determination that the Legislature had in mind a particular "definition" of "any provider of health care" as contained in various identifications of "health care providers" utilized by the Legislature in other statutes. This is but another instance of the attempt to avoid the Legislature's stated policy with respect to the role of blood banks in the transfusion process which pre-existed any such definitions.

Again, the fallacy in Petitioners' arguments lies in the fact that the Legislature intentionally chose not to define the term "any provider of health care" for limitations purposes so as not to form a "straight jacket" which would be inoperable in the "real world" of medical science and practice.

In this respect, as Petitioners' must admit, the Legislature was presumed to know of its previous unambiguous policy statement with respect to the blood bank's role in the patient transfusion process when it enacted \$95.11(4)(b). E.g., Oldham v. Rooks, 361 So.2d 140, 143 (Fla. 1978). Accordingly, Silva's reliance upon Brown v. St. George Island, supra and Baskerville, supra, and its statutory construction argument as a whole, is severely misplaced. Thus, the Second District held in Silva v. Southwest, at 505 n. 1, the fact that Chapter 75-9, \$7, Laws of Florida, originally

enacting \$95.11(4)(b), was already in effect when \$768.50(2)(b) was enacted by Chapter 77-64 \$7, Laws of Florida, is not fatal to the continued effectiveness of \$768.50(2)(b).

\$768.45, Florida Statutes (1987), which was contained in Part Two in the Chapter on Negligence, and relates to "medical malpractice and related matters, "is now \$766.102, Florida Statutes (1989) which also is contained in the present chapter on "medical malpractice and related matters." That statute provides the standard of care in all medical malpractice cases: 5

766.102 Medical negligence; standards of recovery.-

(1) In any action for recovery of damages based on the death or personal injury of any person in which it is alleged that such death or injury resulted from the negligence of a care provider as defined s.768.50(2)(b), the claimant shall have the burden of proving by the greater weight of evidence that the alleged actions of the health care provider represented a breach of the prevailing professional standard of care for that health care provider. The prevailing professional standard of care for a given health care provider shall be that level of care, skill and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by health reasonably prudent similar providers.

\$768.50(2)(b), referenced in that statute was repealed by Chapter 86-160, \$68, Laws of Florida. However, as noted by Revision Note 1, \$766.102, Florida Statutes (1989), and as stated in the preamble to the Florida Statutes, 1989, vol. 4, p. viii,

<sup>&</sup>lt;sup>5</sup> Indeed, this standard parallels the standard of care of the Blood Shield Statute itself.

that cross reference was not affected by the repeal. <u>E.g.</u>, <u>Hecht v. Shaw</u>, 112 Fla. 262, 151 So. 333 (Fla. 1933). <u>See also</u>, 49 Fla. Jur.2d, Statutes, §19,21; <u>State v. M</u>, 388 So.2d 1227 (Fla. 1990). Here, the language of the adopting statute in no way indicates that repeal of the adopted provision of §768.50(2)(b) would operate to repeal that provision as adopted.

The adopted provision, §768.50(2)(b), Florida Statutes (1977), provides:

(b) "Health care provider" means hospitals physicians 395, chapter licensed under 458: osteopaths licensed under chapter 459, podiatrists licensed under chapter licensed under chapter 461: dentists licensed under chapter 466: chiropractors licensed under chapter 460: naturopaths licensed under chapter 462: nurses licensed under chapter clinical laboratories registered under chapter 483: physicians' assistants certified under chapter 458: physical therapists and maintenance organizations physical certificated under part II of Chapter 641: ambulatory surgical centers as defined in paragraph (c): blood banks; plasma centers, clinics, and renal dialysis industrial associations, professional facilities; or partnerships, corporations, joint ventures, or other associations for professional activity by health care providers. (Emphasis added).

Blood Banks continue to be regulated as clinical laboratories and health care facilities. §483.041, Fla. Stat. (1989); §\$10D-93.062, 10D-41.066(1) F.A.C. The Legislature's policy statement embodied in Chapter 69-157, Laws of Florida, supra, must be read in conjunction with the identification of blood banks and clinical laboratories in the general standard of care relating to any and all medical malpractice.

The point to be made is that when the Legislature enacted

\$768.50(2)(b), Florida Statutes (1985), it was aware not only of its previous policy statement in Chapter 67-159, but that it intentionally chose not to define "any provider of health care" in \$95.11(4)(b). This fact operates as the unravelling point of Silva's reliance misplaced upon Brown and Baskerville. Indeed, the Second District's observation in Silva v. Southwest at 505, n. 1, had reference to the continued effectiveness of \$768.50(2)(b) (now \$766.102) which defines the standard of care in all medical negligence actions and the statute is clearly applicable to "any provider of health care" in the medical malpractice statute of limitations.

Certainly, nothing in <u>Baskerville</u> or <u>Brown</u> serves to refute or conflict with the Second District's decision in <u>Silva v. Southwest.</u>

More fundamentally, both <u>Baskerville</u> and <u>Brown</u> present factual circumstances and legislative histories and purposes far different from the present situation. <u>Supra</u>, p. 7, n.1. <u>Brown</u> involved this Court's determination of the <u>absence</u> of any inter-relationship of the disqualification provisions of \$\$38.02 and 38.10, Florida Statutes. Because those statutes were not interrelated and were clearly intended to address <u>distinctly</u> different circumstances, this Court correctly held that the Legislature could not have intended that \$38.10 referred to the later enacted \$38.02. A different situation exists in this case. The statutory enactments must be read <u>in pari materia</u> with knowledge of the Legislature's decision not to define "any provider of health care." The general standard of care applicable to all health care providers, including

blood banks and clinical laboratories, has a direct relation to \$95.11(4)(b). In including blood banks and clinical laboratories in what is now \$766.102, the Legislature was not writing on a clean slate. It had previously enacted the blood shield statute, which provided the same professional standard of care specifically as to blood banks as envisioned in \$766.102(2), and had enunciated its policies regarding the essential medical role of blood banks in the transfusion process.

In <u>Baskerville</u>, at S441, this Court correctly observed that the Legislature's use of the word "privity" in the statute of limitations regarding "professional negligence" other than medical malpractice was without the benefit of later developed third party beneficiary doctrines which served to "expand liability where a duty of care exists between a third party and a professional, . . . despite the lack of direct contractual privity." This correct statement of the law has absolutely no bearing upon the fact that the Legislature, in this instance, chose not to define "any provider of health care" so that later developments <u>could be</u> appropriately addressed and included, notwithstanding the fact that it had <u>already</u> proclaimed blood banks to be an intricate part of the practice of medicine and decreed and that blood banks and clinical laboratories were health care providers subject to the same standard of care as doctors and hospitals, etc.

Silva's argument that the fact that the Legislature felt the need in 1977 Legislation to define "health care provider" specifically, and in different ways (for different purposes)," . .

rhetoric. Similarly, its argument that the fact that the Legislature has never amended \$95.11(4)(b) "... to specifically redefine providers of health care to include blood banks" (emphasis added) turns a blind eye to the effect of the Legislature's never having defined "any providers of health care" in \$95.11(b)(4). Thus, under the curious rationale employed by Silva and the Academy there is no definition which could be applied.

In a moment of extreme candor, the Court in Mozer v. Semenza, 177 So.2d 880, 883 (Fla. 3rd DCA 1965), with respect to proximate cause, stated:

It is notorious that proximate cause in most cases is what the courts will it to be and that it is at best a theory under which the courts justify liability or shield from liability those that the courts find should not reasonably and logically be responsible for a given result.

The rationale of this statement applies to the present issue in light of the fact that the Legislature intentionally did not define "any providers of health care," and has <u>retained</u> reference to \$768.50(2)(b).

on any specific statute, but the necessity to read its policy statements and statutory enactments <u>in pari materia</u>, which is not controlled by any date of enactment. In the absence of direct, positive inconsistency courts must construe statutes <u>in pari materia</u>, reserving to each their "evident intent" where they relate to the same subject matter or have the same purpose. The essential

guidepost is the purpose to be accomplished regardless of whether the statutes make any reference to each other. Mann v. Goodyear Tire & Rubber Company, 300 So.2d 666, 668 (Fla. 1974); Miami Dolphins, Ltd. v. Metropolitan Dade County, 394 So.2d 981, 988 (Fla. 1981). Certainly, the Legislature was aware that it chose not to define "any provider of health care" in \$95.11(4)(b) when it included blood banks and clinical laboratories in the standard of care applicable to the practice of medicine. This inclusion was entirely consistent with and mandated by its prior policy statement in the preamble to Chapter 69-157 which, in turn, predated \$95.11(4)(b).

Neither can Silva take comfort in the fact that there are other statutes which have definitions of "health care providers" in The omission from mentioned. which blood banks are not §766.101(1)(b), Florida Statutes is completely logical because the definition is strictly limited to medical review committees. That \$766.101(1)(b) was not intended to be "all inclusive" with respect to "health care providers" is evident from the limitation contained in §766.101(1)(a)(e), Florida Statutes. However, as will be more fully evident, infra, pp. 28-32, in discussing the Florida Association case, a blood bank operating a "transfusion service" within a hospital would be subject to this statute as part of the In the same light, §766.105(1)(b) is specifically hospital. limited to Florida's Patient's Compensation Fund, which was intended to be limited in scope and to incorporate only those entities composed of its member health care providers.

On the other hand, §766.102 is broad in scope and, as applied to Southwest as a blood bank and clinical laboratory, reflects the mandate of Chapter 69-157. It applies the identical standard of care to a blood bank that must be applied to a doctor, or to a hospital, nurse or hospital laboratory. Again, read in conjunction with the policy established in Chapter 69-157, and applying the standards of statutory construction recognized by this Court in Baskerville, the Legislature's intent is manifest.

Petitioners eventually are caught in the web of their own arguments. Silva refers to Chapter 72-62, \$1, Laws of Florida, and Chapter 73-50, Laws of Florida, both of which relate to medical review committees and which were revised to the present \$766.101, Florida Statutes. Ch. 77-461, §1, Laws of Fla. (Silva, Initial Brief, p. 14). In correctly noting that blood banks and clinical laboratories were not included in the narrow context of that statute, Silva fails to account for the fact that pharmacists licensed under Chapter 465 are included. Under the semantical statutory construction rationale advanced by Petitioners, that inclusion of pharmacists must mean that they are included in the term "any health provider" utilized by the Legislature This is contrary to Silva's attempt to rely upon §95.11(4)(b). Shiels, supra. (Discussed, further, infra p. 35, n. 10).

It is of interest that hospitals <u>per se</u> were not added by the Legislature to the definition of "health care providers" contained in §768.40(1)(b), Florida Statutes, until 1985. Ch. 85-175, §8, Laws of Florida; relating to medical review committees. This

corrected an obvious oversight. It further emphasizes the pitfalls of attempting to straight jacket the Legislature, by myopic reference to "health care providers" identified in other contexts, to the exclusion of the recognition of the actual functioning of the medical community as a whole.

When the provisions of the medical malpractice statute of limitations are considered in pari materia with all related Legislative enactments it is readily apparent that Silva's attempt to narrow its Second Amended Complaint to a claim of failure to properly screen donors is totally unavailing, as its out of context presentation of Florida Association of Blood Banks v. Department of Health and Rehabilitative Services, supra. While that decision involved whether a blood bank which operated multiple "transfusion services" was required to pay separate license fees for each, the case is instructive in describing and recognizing the medical nature of all functions performed by a blood bank with respect to transfusion to a patient.

Florida Association noted that the services provided by a "transfusion service" in a hospital were clinical laboratory procedures and thus inherently no different than hematocrits, hemoglobins and other processing and screening procedures performed by an outside blood bank. 9 FALR at ¶¶ 12, 14, 16, and 18. Thus, Florida Association does not, as Silva contends, separate the functions of a blood bank between "medically related" services and "products." Rather, all are medical, clinical laboratory procedures employed to provide for the care and treatment of the

transfusion recipient. The assertion that the only medical "activity" related to Mrs. Silva's transfusion was a "cross matching" is absolutely absurd. (Silva Initial Brief, pp. 22-23).

The belated attempt to limit Southwest's medical "activity" to "cross matching" as opposed to the entire process involved, and as specifically related to Mrs. Silva's injury, contradicts the allegations of the Second Amended Complaint. (Quoted, supra, pp. Those allegations include a failure to properly test the 1-2).cryoprecipitate which forms the basis of the alleged breaches, as well as the alleged failure to warn of the possibility of contamination of cryoprecipitate. If Silva's argument were accepted in the context of the real world of medicine, it could only logically be concluded that a physician who fails to diagnose or adequately warn a patient of medical risks (i.e. a violation of the requirement of obtaining informed consent) could be sued under the four year tort limitation statute because the failure predated an operation or an administration of medication, etc.

Florida Association sets forth the undisputed basic facts surrounding the medical practices and activities engaged in by blood banks in providing and processing blood for transfusion, whether it be within a hospital or from its outside facility. Contrary to Silva's considerable misrepresentation of Florida Association, there are not " . . . three types of services a blood bank performs on blood before selling it: collection, processing

<sup>&</sup>lt;sup>6</sup> The Petitioners' rhetorical propensity to ignore Florida's statutes and regulations continues. Under §381.601(2)(g) and (i) the fees of a blood bank and "related blood transfusion charges"

and transfusion services." As noted in <u>Florida Association</u>, "transfusion services" is a term of art utilized within the medical community and recognized by the Department of Health and Rehabilitative Services to denote facilities operated <u>within a hospital</u>. As even a cursory reading of that opinion reveals, the entire process from the time of collection (including donor screening) to the ultimate point of delivery <u>for transfusion</u> is, wherever performed, as the Legislature has recognized, "... an intricate part of the <u>practice of medicine</u>, ... ". While the issue of where a particular element of the entire process is performed by a blood bank for purposes of payment of licensing fees was critical in <u>Florida Association</u>, it has absolutely no bearing upon the fact that, as stated in 9 FALR at ¶ 5:

"Blood banking" is an activity which 5. involves administrative and medical functions making available for transfusion to patients human blood and blood components. The operational procedures of a blood bank typically involve recruiting activities to attract volunteer donors. These donors are evaluated screened, questioned, and suitability. If suitable, a blood donation is obtained. Screening voluntarily collection procedures involve performance of a hematocrit, hemoglobin and blood typing These procedures are clinical laboratory procedures subject to regulation under Chapter 483,

are not "payment". \$381.601(5) mandates reciprocal exchange of blood between blood banks, hospitals, clinics, nursing homes, and other users of blood and blood products in further recognition of the necessary "medical service" involved as well as the fact that it is "an intricate part of the practice of medicine". Smith's propensity to refer to a voluntary blood bank's activity as the purchase of blood is intentionally misleading. Southwest obtains its blood from voluntary donors. Under the Petitioners' analysis only charitable doctors and hospitals who did not charge for their services would be entitled to a two year statute of limitations.

Florida Statutes. They provide information about the health of the prospective donor and the suitability of blood for ultimate transfusion. Blood is typically collected at either the principal blood bank facility or at remote collection stations sometimes referred to as branch offices or mobile donor units. Blood is infrequently collected at facilities known as transfusion services.

It is the entire process of preparation which resulted in the blood transfused in these cases. Although, with respect to blood banks, this function is normally performed outside of the hospital, it can equally be and at times is accomplished within the "transfusion service" facility at a hospital. 9 FALR at ¶ 14.8

#### As stated at 9 FALR at 18:

The Department justifies its distinction between those activities which are referred to as a "transfusion service" and those activities which are not and require licensure and payment of a separate fee, by claiming that certain activities performed by "transfusion services" are not "clinical However, even this laboratory" procedures. explanation is contradicted by the evidence. uncontradicted testimony is The collection of blood involves performance of procedures known as hematocrit, hemoglobin and

The particular blood component transfused in these cases was cryoprecipitate. See, Gray, Attorneys' Text Book of Medicine, Vol. 4 C, ¶ 304.51(2) (3d Ed.). Cryoprecipitate results in enhanced antihemophilicglobulin (known as Factor 8).

The hospital and non-hospital blood bank facilities use the identical medical procedures and are governed by the identical federal and State professional codes and regulations and provide identical services, often for the very same recipients. Does it make any sense, from a limitations or other standpoint, to have a different result based largely on the fact that small hospitals cannot support in-house "transfusion services?" As a matter of judicial policy applied to health care in general, or regarding transfusions in particular, there is no rational difference. See Kozup v. Georgetown University, 663 F.Supp. 1048, 1059-1060 (D.C. 1987), rev'd in part, aff'd in part 851 F.2d 439 (D.C. Cir. 1988).

blood typing. These procedures are acknowledged to be clinical laboratory procedures. Hence, under the Department's own analysis, a "transfusion service" performing collection of blood would be a clinical laboratory and thus fail the Departments rule definition.

Of course, the definition of "clinical laboratory" in \$483.041(1) precludes any claim that blood banks provide only a "product" or a mere "medical service" which, Petitioners' wrongly argue, does not encompass ". . . medical diagnosis, treatment or care . . . " as envisioned by \$95.11(4)(b):

A laboratory where examinations are performed on materials specimens taken from the human body to provide information or materials for use in the diagnosis, prevention or treatment of a disease or the assessment of a medical condition.

The statutory definition has been further refined in §10D-41.066(1), F.A.C.:

Clinical Laboratory -- Laboratories operated by <u>hospitals</u>, <u>blood banks</u> . . . where a microbiological histocompatibility testing or other examination of materials from the human body are performed. (Emphasis added).

When specifically involved in testing for the HIV antibody, under  $\P10D-93.062(6)$ , (12) and (13), blood banks are regulated both as "health care facilities" and as a "health care provider".

In arguing that a blood bank is not providing " . . . a

Immunohematology is an aspect or branch of hematology, involving the study of blood cell antigens which elicit immune responses and antibodies which are proteins which attack antigens. Gray, supra, Vol. 4C, ¶304.20. Histocompatibility is the degree of immunologic similarity or identity of tissue sufficient to permit transfusion or transplanting. Skin, Stedman's Medical Dictionary, p. 580 (3d Ed.).

desirable and necessary medical service . . . the rendering of which is an integral part of the practice of medicine," Smith attempts to rely on Quintana v. United Blood Services, 811 P.2d 424 (Col. App. 1991), cert. granted \_\_\_\_ P.2d \_\_\_, June 3, 1991, and Silva attempts to rely upon Miles Laboratory, Inc. v. Doe, 315 Md. 704, 556 A.2d 1107, 1125 (1989). Quintana was not a statute of limitations case and involved Colorado's significantly different blood shield statute. Nevertheless, as the Court in Quintana was forced to acknowledge, its decision was decidedly against the weight of authority of 49 other jurisdictions (see, Kozup, supra) and \$766.102(1), Florida Statutes, which have held that a blood bank involved in transfusion to a patient is entitled to be judged under the same standard of care as doctors, hospitals and other "health care providers." E.g., Kaiser v. Memorial Blood Center of Minneapolis, 721 F.Supp. 1073 (D.C. Minn 1989); Coe v. Superior Court, 220 Cal. App. 3d, 48, 269 Cal. Rptr. 368 (Cal. 1st DCA 1990), rev. denied \_\_\_ P.2d \_\_\_ (Cal. 1990); Bradway v. The American National Red Cross, F.Supp. , Case No. 1:89-CV-1073-MHS (N.D. Ga., July 8, 1991); Doe v. American Red Cross Blood Services, S.C. Region, 125 F.R.D. 637 (D.C. S.C. 1989); McKee v. Miles Laboratory, Inc., 675 F.Supp. 1060 (E.D. Ky. 1987), affirmed McKee v. Cutter, 866 F.2d 219 (6th Cir. 1984); Howell v. Spokane & Inland Empire Blood Bank, supra.

In any event, Quintana and Miles are totally at odds with Florida's stated policy, statutes and regulations when it comes to recognizing that in the context of transfusions blood banks are

involved in the practice of medicine. Miles involved Maryland's Health Care Malpractice Claims Act which, unlike \$95.11(4)(b), contained a very limited definition of "heath care provider." Nevertheless, the Supreme Court of Maryland's one paragraph conclusion is unsupported by any logical discussion, reflecting the fact that it is against the weight of authority and notwithstanding the fact that it is totally irrelevant to Florida's policy and statutory provisions.

Bradway, supra, recognized that a blood bank was entitled to the protection of Georgia's medical malpractice statute of repose, \$9-3-70, Official Code of Georgia (1982), as involving "... any claim for damages resulting from death of or injury to any person arising out of ... health, medical, dental or surgical service, diagnosis, prescription, treatment or care rendered by personnel authorized by law to perform such service ... or care or service rendered by any public or private hospital, nursing home, clinic, hospital authority, facility or institution ...". Its analysis parallels the analysis of the Second District in Silva with respect to Georgia's statutory framework, including its blood shield statute, \$51-1-28, Official Code Georgia (1982), and Georgia's inclusion of blood banks within the term "clinical laboratory" under \$31-22-1(2), Official Code Georgia (1982):

A "clinical laboratory" is defined as a facility where "examination[s are performed on] materials derived from the human body for the diagnosis of, recommendation of treatment of, or for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

[Slip opinion at 3-4.]

In <u>Kaiser</u> there was a tubal ligation involving units of blood and the development of HIV. The Plaintiff sued Red Cross and Memorial Blood Center. Because of the lack of any comprehensive legislative guide to the definition of "health care professional" in Minnesota, the <u>Kaiser</u> Court ultimately rested its decision directly on the fact that the institutions were acting through licensed physicians and "health care professionals" as defined and regulated in Minnesota, and application of the rule that a valid statute of limitations defense by employee is also a defense to a <u>respondent superior</u> claim. 721 F. Supp. at 1076. 10

Florida's statutory scheme is a model of clarity with respect to "definitions" and recognition of "health care providers" in comparison to Minnesota's. With respect to Silva's reliance upon Miles (Silva, Initial Brief, p. 17) in an attempt to draw a distinction between outside blood banks and hospitals, when performing the same medical procedures, the Minnesota Court, in the course of its opinion, 761 F.Supp. at 1075, stated:

The identical conclusion was reached by the Court in Shiels, supra, upon which Silva attempts to rely, with respect to pharmacists under \$95.11(4)(a) upon whose negligence an action against the pharmacy is based. The medical malpractice statute was not raised in Shiels; only the "professional malpractice" provision, which also is two years. Regardless of pharmacists could or should be brought under the Regardless of whether malpractice statute of limitations, in "whole" or in "part" depending on the function at issue, unlike blood banks, neither pharmacies or pharmacists have been legislatively defined as health They are only so defined in care providers in §766.102(1). \$766.101(1)(b), a much narrower statute. More importantly, pharmacists have never been legislatively proclaimed to be an intricate part of the more commonly understood "practice medicine" as are blood banks with respect to transfusions.

Plaintiffs have argued that a blood bank is not an individual, that it is not listed as an institution covered by the statute, and that it is illogical to consider blood banks health care professionals because they provide no direct care to a recipient. 3 Defendants contend that Red Cross and Memorial are obviously health care professionals and that it would be inequitable to treat independent blood banks differently from a blood bank affiliated with the hospital or to give a blood bank less of a "health care status" than given a veterinarian. (Emphasis added).

## In Footnote 3, the Court stated:

3. This last contention is belied by the fact that plaintiffs premise their entire allegations on the fact that blood banks have a duty to the possible recipients of the blood or blood products. The allegation of duty points to the fact that blood banks do have a relationship with the recipients of their products, even without direct contact between the blood bank and the eventual recipient.

## [721 F.Supp. at 1075-1076]

Although Respondents complain of the Second District's citation to <u>Kaiser</u>. That complaint is again based upon their attempt to ignore existing policy of the Legislature, as further reflected in other statutory and regulatory provisions, and the real world inter-relationship of medical disciplines.

Similarly, in <u>Coe</u>, <u>supra</u>, the California Court of Appeals held that Erwin, a blood bank, was a "health care provider" within the context of California's Medical Injury Compensation Reform Act. As with <u>Kaiser</u>, <u>supra</u>, the rationale of <u>Coe</u>, read in light of Florida statutory's scheme and expressions of public policy, inescapably dictates that blood banks in Florida also be determined to be "any provider of health care."

One of the observations made in <u>Coe</u>, 69 Cal. Rptr. at 371 n. 3, is particularly instructive with respect to the fact that Florida's medical malpractice statute of limitations does not directly define any health care provider, and Petitioner's attempt to argue that somehow a logical distinction could be made between a blood bank operating within a hospital and outside a hospital, although performing the same medical function. As observed by the Court in <u>Coe</u>, <u>supra</u>, which statement also serves to answer Silva's reliance upon <u>Miles</u>:

3. Irwin refers us to the example of the Home Dialysis Agency as a newly evolved provider regulated for the first time in 1989. (Health & Saf. Code, §1794.01 et seq.) There would be no logical basis for distinguishing between those who provide dialysis in a hospital or clinic setting and those who provide the same in the patient's home; the health care provided is the same.

Indeed, it would be totally illogical to base a tort system upon any such distinction, especially where, as recognized in Florida Association, Coe, and Kozup, the benefit to the patient is the same whether or not the blood bank staffs a "transfusion service" in conjunction with the hospital or conducts the same medical procedures outside of the four walls of the hospital.

In attempting to rely upon Lewis v. Associated Medical Institutions, Inc., 345 So.2d 852 (Fla. 3rd DCA 1977), cert. denied 353 So.2d 676 (Fla. 1977), and <u>Dubin v. Dow Corning Corporation</u>, 478 So.2d 71, 73 (Fla. 2nd DCA 1985), <u>Silva</u> makes the ambiguous rhetorical statement that "... if blood banks want to accept the benefit of the shield statute for liability purposes, they must

accept its necessary implications for limitations purposes." (Silva, Initial Brief, p. 25). It is Petitioners who seek to avoid not just the "necessary implications" but the reality of medical practice, an unambiguous statement of public policy, as well as the fact that \$95.11(4)(b), Florida Statutes applies to any action, whether in tort or contract. <u>Dubin</u>, which involved a defective roof on a building, has nothing to do with the present case or statute. Both cases discuss when a statute of limitation attaches and runs, which is not an issue here.

In any event, in <u>Lewis</u>, the applicable statute was the four year "catch all" provisions of §95.11(4), <u>Fla. Stat.</u> (1973). <u>Lewis</u> at 853-854. Again, Florida had not separately defined medical malpractice until 1975. <u>Supra</u>, p. 11 n. 3. The Complaints on their face show the statute has run. Both Smith and Silva were aware of the "incident" the injury and the connection to Southwest and Complaints were not filed until more than two years from the time the incident was discovered and damages accrued. <u>Barron v. Shapiro</u>, 565 So.2d 1319 (Fla. 1990).

It defies rationalization that blood banks, specifically recognized as providing a "necessary medical service" as "an integral part of the practice of medicine" with respect to the relationship to the patient, and entitled to the professional standard of care applicable to doctors, nurses, anesthesiologists, radiologists, hospital employed laboratory personnel, etc., are not to be afforded the same period of limitations for actions against them when the identical medical procedure is involved. Although

solely involving the standard of care, and not specifically the statute of limitations which was not at issue, the rationale underlying the following statement from <u>Kozup v. Georgetown</u> <u>University</u>, 663 F.Supp. at 1057, is fully applicable to such a conclusion: 11

It is difficult to conceive of a negligence system which would permit some members of a professional community-those "on the cutting edge," as plaintiffs put it, Deposition of E. Allen Griggs at 62, to be held to a unique standard above that of other members of the same community.

It is respectfully submitted that the question of whether a blood bank in collecting, screening and processing blood and blood products for direct transfusion to a patient is a "health care provider" for purposes of \$95.11(4)(b) is not to be reduced to myopic arguments concerning how "health care providers" are identified or not in clearly limited contexts, or whether the blood bank has a direct "hands on" relationship with the patient. Rather, this Court must decide whether or not the supplying of blood in this context is an intricate part of the practice of medicine as recognized by our Legislature long before "medical malpractice" became a distinct action for limitations purposes.

It is respectfully submitted that under Silva's interpretation of legislative intent it would be very difficult to include a radiologist, pathologist or diagnostician who never sees the

Ultimately, the Court in <u>Kozup</u> rejected the plaintiffs' claim that the supply of blood for transfusion was a sale of goods as opposed to a medical service under the District of Columbia Consumer Protection Act. 633 F.Supp. at 1060.

patient within the term "health care provider." Such specialists, who have contact only with the treating physician or hospital and who interpret films and data for the benefit and furtherance of the treatment of the patient, would be considered only selling a "service" under the rationale advanced by Petitioners.

Petitioners' attempt to equate Southwest with a maintenance service taking care of floors in a hospital which negligently allows a plaintiff to slip, or food poisoning, is absolutely For the purposes of §95.11(4)(b) and an "action for medical malpractice," and especially the arising out of language, the action brought against Southwest by Silva is certainly closer to medical malpractice than situations in numerous Florida cases which have been recognized as medical malpractice. E.g., Neilinger v. Baptist Hospital of Miami, Inc., 460 So.2d 564 (Fla. 3rd DCA 1984), where the Court distinguished its prior decision in Durden, supra, and held that a patient slipping on a pool of ambiotic fluid while she was descending from the examination table had stated an action for medical malpractice. See also, Mount Sinai Hospital of Greater Miami, Inc. v. Wolfson, 327 So.2d 883 (Fla. 3rd DCA 1976) (adequacy of the warning system whereby a patient in distress could summon nurses and attendants and effectiveness of bed rails); Zobac v. Southwestern Hospital District of Palm Beach County, 382 So.2d 829 (Fla. 4th DCA 1980).

II.

ALTERNATIVELY, SOUTHWEST IS IN PRIVITY WITH THE HOSPITAL.

Petitioners curiously offer no response to the fact that the

Legislature's inclusion of the "privity" provision in the statute further evidences its intent for a construction which takes into account not semantical niceties, but the practicalities of the "real world" of the medical system and community. The inclusion of the privity provision further demonstrates the Legislature's concern that the statute adequately meet and apply to often rapidly changing conditions unforeseen by society in general, the medical profession and, in particular, the Legislature itself.

Certainly, the observations of the Court in Coe, quoted <u>supra</u>, p. 37 and <u>Kaiser</u>, <u>supra</u>, p. 31, n. 8 and quoted <u>supra</u>, pp. 35-36, 39, have even greater force and significance under Florida's privity provision <u>if</u> the absence of "direct contact" with the patient is to be the deciding factor in whether or not Southwest is a provider of health care.

At least Silva does not attempt to rely upon Gonzalez v. Jacksonville General Hospital, Inc., 365 So.2d 800 (Fla. 1st DCA 1978), quashed on other grounds Homemakers, Inc. v. Gonzalez, 400 So.2d 965, 968 (Fla. 1981), which is advanced by Smith. Gonzalez was implicitly overruled in Thaddiken v. Florida Patient's Compensation Fund, 478 So.2d 1058 (Fla. 1985). While, as noted in Burr v. Florida Patient's Compensation Fund, 447 So.2d 349, 351 (Fla. 2nd DCA 1984), this Court expressly refrained from reaching the privity issue when it quashed the District Court's opinion in Gonzalez, the clear wording of the statute is contrary to any suggestion that the term "privity" applies to the patient rather than the relationship between health care providers for the direct

use and benefit of the patient. Within the context of the providing of blood products for transfusion, as stated by the Court in <u>Burr</u>, <u>supra</u> at 351, \$95.11(4)(b) must be applied " . . . when anyone connected with the incident against whom the claimant alleges damages is in a privity relationship with the health care provider."

In this respect, Smith's reliance upon <u>Baskerville</u> is indeed curious. It is obvious that with respect to the intricate involvement of blood banks in the medical practice of transfusion there is an element of privity with the patient as well as the hospital and/or doctor. There is definitely direct contract privity between the blood bank and hospitals and doctors in these cases.

The fact that §95.11(4)(b), Florida Statutes (1987) does not provide a strict definition of "privity" is itself instructive. As with the term "any provider of health care," the Legislature did not want to "box itself in." Again, it was mindful of the need to adequately meet and address changes, unseen or unknown conditions, and circumstances in the "real world" of medicine. The analysis set forth in Arguments I and II compels, at least, the conclusion that Southwest is in privity with the hospital and doctor when it supplies blood for transfusions.

Silva implied below that only the Florida Patient's Compensation Fund or similar entities can meet the definition of privity. The retreat from that position was mandated by the fact that at the time the Legislature first included the "privity"

language there was no separate <u>medical</u> malpractice statute of limitation, and the fund was not in existence. <u>E.g.</u>, <u>Florida Patient's Compensation Fund v. Von Stetina</u>, 474 So.2d 783, 787 (Fla. 1985); §95.11(4)(a), <u>Fla. Stat.</u> (supp. 1974), amended §95.11(4)(b), <u>Fla. Stat.</u> (1975), effective May 20, 1975. Thus, any attempt to analogize the Fund to the exact type or character of privity which the Legislature intended is without merit as a matter of strict statutory construction or otherwise.

Similarly, Silva's new argument that the Legislature merely intended to encompass some type of successor relationship, such as a physician's estate or a successor hospital corporation, is absurd. Had this been the sole intent of the Legislature it would have said so.

Contrary to Petitioners' assertion, the statement by this Court in Taddiken at 1062, aptly and completely describes the concept of privity which exists between a blood bank processing and supplying a doctor or hospital with blood for transfusion to the The Petitioners simply fail to heed this Court's admonition that any definition must be flexible because there " . . . can be no definition of privity that can be applied in all cases. . . " This admonition parallels the Legislature's obvious concern that the statute be applicable to the "real world" without the need to revisit it every year, or with every evolution in the health care system. There is a clear derivative interest, or "mutuality of interest," between the doctor and administering the blood, and the blood bank in procuring,

processing and supplying the blood for transfusion to the patient. Furthermore, it is evident from <u>Taddiken</u> and the Second District's decision in <u>Burr</u>, that the term privity as used in §95.11(4)(b) is to be given a realistic reading with due recognition of the necessities and actual practice of medicine.

Certainly, there is also a ". . . mutual or successive relationship to the same right of property . . ." (the blood to be transfused). There is also " . . . identification of interest of one person with another as to represent the same legal right . . . ," in that the hospital or a doctor, and the patient as Silva has alleged (Silva, R. 88, 44), depends on the blood bank's performance of its duties to insure the patient's safety and recovery. See, Florida Association, supra; Kaiser, 721 F.Supp at 1075, n. 3, quoted, supra, pp. 35-36; Howell, supra.

As previously noted, the Petitioners present strained, illogical analogies in an attempt to characterize the medical procedures engaged in by blood banks in the transfusion process as no different than those provided by food or linen services in a hospital. These strawman arguments are nonsensical. A food provider or linen supplier may be in privity with the hospital through a service contract. However, neither provides medical services of any type, much less the performance of medical procedures. A blood bank, x-ray laboratory, clinical laboratory and other such entities provide both medical services and perform medical procedures and diagnosis, which are part of the diagnosis, health care and treatment of a patient. Therefore, they are at

least in privity with a "direct" health care provider.

As <u>Florida Association</u> points out, the medical procedures are the same whether performed outside a hospital or directly within a hospital, whether performed by the hospital or a doctor individually, or by a blood bank.

III.

THE STATUTE OF REPOSE IS NOT IMPLICATED IN THESE CASES, AND IS CONSTITUTIONAL.

Over objection by Southwest, this Court has at least initially allowed Petitioner Silva, and Amici, Doe and the Academy, the opportunity to raise the "issue" of the statute of repose. As footnote 4 at pages 7-8 of Silva's Initial Brief confesses, this is not an issue in these cases.

Neither of these cases present the specter of the statute of repose barring a cause of action before it ever accrues so as to formulate even a possible basis for the invocation of Article I, §21, Florida Constitution. In each of these cases, the presence of HIV anti-bodies in the blood stream was detected well before the two year statute of limitations ran. This, in and of itself, constitutes notice and "an injury." Barron v. Shapiro, supra; Jackson v. Georgopolous, 552 So.2d 215 (Fla. 2nd DCA 1980). Although, in a limited number of cases it may be some time before the syndrome known as AIDS develops, it is the HIV virus which is the cause. All damages, past, present or future, including those associated with the ultimate development any syndrome of AIDS or the aids related complex, immediately become recoverable. This was essentially recognized by Silva when his Complaint was filed, and admitted by Silva in his final response to Southwest's Motion to Strike previously filed in these cases. <sup>12</sup> In short, this Court does not exist to give advisory opinions on cases which are not before it, notwithstanding the fact that this Court has now settled the issue that the statute of repose provisions are constitutional. That is now a Legislative rather than a judicial issue.

In <u>Carr v. Broward County</u>, 541 So.2d 92 (Fla. 1989), approving <u>Carr v. Broward County</u>, 505 So.2d 568 (Fla. 4th DCA 1987), this Court reiterated the specific findings in the preamble to Chapter 75-9, Laws of Florida, 541 So.2d at 94, which referenced the cost of purchasing medical professional liability for doctors and <u>other health care providers</u>. The rationale underlying the ongoing attempt at medical care cost containment applies equally to the cost of units of blood as it does to the costs of a doctor's or hospital's attendance.

This Court's decision in <u>Carr</u>, especially with respect to its disapproval of <u>Phelan v. Hanft</u>, 471 So.2d 648 (Fla. 3rd DCA 1985), appeal dismissed 488 So.2d 531 (Fla. 1986), clearly recognized that the statute of repose began to run from the incident of malpractice regardless of its discoverability. This essential fact was recognized and reiterated in <u>University</u> of Miami v. Bogorff, 16

The implication by Amici and Silva that a claimant would await, or that any responsible attorney would allow his client to await the actual onset of one of the many complications which, singularly or together, make up the syndrome known as AIDS is not only specious, it would be malpractice. See Barron v. Shapiro, at 1320-1321 which reaffirmed Nardone v. Reynolds, 333 So.2d 25 (Fla. 1976) and City of Miami v. Brooks, 70 So.2d 306 (Fla. 1954), with respect to the fact that the statute begins to run upon any injury, even though all damages may not have yet "accrued."

F.L.W. S149 (Fla. January 18, 1991) with respect to the seven year repose period applicable even to cases of <u>fraud or concealment</u>.

<u>Bogorff</u>, at S150-S151. That essential fact was unanimously reaffirmed by this Court in <u>Public Health Trust of Dade County</u>,

<u>Florida v. Menendez</u>, 16 F.L.W. S496 (Fla. August 15, 1991):

Thus, under this statute a two-year limitation begins on the date of actual or constructive discovery; but there is also a "repose" period that bars any and all claims brought more than four years after the actual incident, even for acts of negligence that could not have been reasonably discovered within this period of time. (Emphasis added; footnote deleted).

Assuming, for the sake of argument since there is no record, Amici Doe did not and could not "discover" that his wife contracted HIV until after the four years had run, his circumstances are no different from that of any other litigant faced by the statute of repose and which the Legislature undoubtedly recognized in weighing the competing social interests.

Certainly, there is absolutely no evidence that the Legislature intended that the statute of repose be governed by the nature of any particular type of disease, or any particular type of alleged "malpractice." 13

The Legislature has validly balanced medical costs and the tort system through the Medical Malpractice Reform Act of 1975 and

In Nameth v. Harriman, 16 F.L.W. D2118 (Fla. 2nd DCA, August 7, 1991), issued without benefit of the unmistakable, clear language of this Court's opinion in Menendez, the Second District certified the issue of whether the statute of repose operates even if the injury resulting from the malpractice would not manifest itself within the four year period. Thus, should this Court wish once again to revisit the repose provision of the statute, it will have a proper case in which to address that issue.

its various subsequent amendments. Additionally, it has specifically enacted §381.601 (4), Florida Statutes, which in turn compliments the preamble of Chapter 69-157 and the Reform Act:

It is the policy of the state to encourage the adequate supply maintenance of an voluntarily donated blood of the highest quality accessible to all in need of blood. The state seeks with this policy to assure for its residents and visitors a system of blood supply, transfer, and replacement that can supply all of the requirements for blood without unduly burdening persons who, due to age, illness or other circumstances, are for blood unable to replace or arrange replacement.

It cannot be denied that with respect to many medical procedures, indeed "blood is life" and that this essential medical necessity is affected just as much as doctor's and hospital's fees by the cost of insurance and litigation. AIDS is a modern health tragedy, both with respect to its impact on individuals and the medical community. However, the specter of the statute repose cutting off "unaccrued actions" has been greatly diminished with the rapid increase in medical knowledge since 1983, which has also resulted in greater public awareness and knowledge. Until 1984, AIDS was not generally understood by the medical community to be transmitted by blood transfusions. Kozup, 1052. discovered and understood, a test to expose infection and reveal the presence of HIV was in use by the spring of 1985. proven to be very reliable with a detection prevalence exceeding 99 Kozup; Kirkendall v. Harbor Insurance Co, 698 F. Supp. The vast majority of the medical 768, 779 (W.D. Ark. 1988). community considers six months to be the outside limit between infection and detectibility of HIV (seroconversion). <u>E.g.</u>, Menitove, <u>Current Risk of Transfusion-Associated Human Immuno Deficiency Virus Infection</u>, Arch. Pathol. Lab. Med., Vol. 114, pp. 330, 332 (March 1990).

## CONCLUSION

This Court is without conflict jurisdiction and the petitions for review should be dismissed. In any event, Southwest is a "provider of health care" for purposes of the medical malpractice statute of limitations, or at least falls within the privity provision of that statute when providing blood for transfusion to a patient.

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing has been furnished by U. S. Mail to the following persons on this 3rd day of September, 1991: Raymond T. Elligett, Jr., Esquire, Schropp, Buell & Elligett, P. A., NCNB Plaza, Suite 2600, 400 N. Ashley Drive, Tampa, Florida 33602, Attorneys for Gerald Silva; F. Ronald Fraley, Esquire, Fraley & Fraley, 501 E. Kennedy Blvd., Suite 1002, Tampa, Florida 33602, Attorneys for Gerald Silva, Robert A. Foster, Jr., Esquire, Robert A. Foster, Jr., P. A., Landmark Building, Suite 1207, 412 E. Madison Street, Tampa, Florida 33602, Attorneys for Gerald Silva; Kelley B. Gelb, Esquire, Krupnick, Campbell, Malone & Roselli, P. A., 700 Southeast Third Avenue, Suite 100, Fort Lauderdale, Florida 33316, Attorneys for Academy of Florida Trial Lawyers; Andre Perron, Esquire, Blalock, Landers, Walters & Vogler, P. A., 802 11th Street, West, Bradenton, Florida 34205, Attorneys for Academy of Florida Trial Lawyers; Kennedy Legler, III, Esquire, Legler & Flynn, 2027 Manatee Avenue, West, Bradenton, Florida 34205, Attorneys for Amicus John Doe; Thomas J. Guilday, Esquire, Huey, Guilday, Kuersteiner & Tucker, P. A., 106 E. College Avenue, Suite 900, P. O. Box 1794, Tallahassee, Florida 32301, Elizabeth Russo, Esquire, Anderson, Moss, Parks & Russo, P. A., Suite 2500, New World Tower, 100 N. Biscayne Boulevard, Miami, Florida 33132, Attorneys for Petitioners in Smith; Judith S. Kavanaugh, Esquire, Peeples, Earl & Blank, 1800 Second St., Suite 888, Sarasota, Florida 34236, Attorneys for Petitioners in Smith; Jeanette M. Andrews, Fuller, Johnson & Farrell, P. A., 111 North

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