

IN THE SUPREME COURT OF FLORIDA

KAYNAN FITCHNER, as Personal
Representative of the Estate
of Chase Fitchner,

Petitioner/Plaintiff,

vs.

LIFESOUTH COMMUNITY BLOOD
CENTERS, INC.,

Respondent/Defendant.

Case No. SC08-174

First DCA Case No. 1D06-4475

8th Cir. Case No. 01-04-CA-1574

**ANSWER BRIEF OF RESPONDENT,
LIFESOUTH COMMUNITY BLOOD CENTERS, INC.**

On Review from the District Court of Appeal,
First District, State of Florida

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PRELIMINARY STATEMENT

Respondent, LifeSouth Community Blood Centers, Inc., is referred to as either "LifeSouth" or "Defendant." Petitioner Kaynan Fitchner, as Personal Representative of the Estate of Chase Fitchner, the Plaintiff below, is referred to as "Plaintiff." The Fitchners are individually referred to by their given names.

The trial court record is contained in 75 volumes¹ and one supplemental volume, and is referred to as "Rx y-z," where "x" is the volume and "y-z" are the record page number(s). For ease of reference, the volume numbers are presented in arabic numerals rather than roman numerals.

The trial and hearing transcripts are referred to as "Tx y-z." The trial exhibits are identified as Pl.Ex.# for Plaintiff's exhibits or Def.Ex.# for Defendant's exhibits.

The identity of the anonymous blood donor whose donation is the subject of this lawsuit remains confidential, pursuant to an order of the trial court. R1 38-39; R2 362-63. Accordingly, he is referred to throughout the briefs as "Donor."

All emphasis contained in quotations from the record or from case law has been added unless otherwise indicated.

¹ Note: there are two different volumes in the record index that are designated as Volume 2--R2 201-393 and R2 394-593.

STATEMENT OF THE CASE AND FACTS

Plaintiff's statement of the case and facts omits material facts that are critical to the consideration of the certified question before this Court--whether Florida's statutory presuit notice requirements "apply to a blood bank that is supplying blood to a patient"? Accordingly, LifeSouth submits the following additions and corrections to Plaintiff's statement.

A. Background

In August 2002, Chase Fitchner was admitted into Shands Hospital to receive a bone marrow transplant as a curative treatment for Faconi's anemia. T53 5. During the six-week period after his transplant, Chase received 57 transfusions of blood and blood components. T62 1269. Chase was released from Shands on October 7, 2002, but readmitted the next day with a fever. T58 789-90. Shands determined that Chase had been infected with West Nile Virus. T58 783; T59 964, 985.

Shands reported Chase's West Nile Virus diagnosis to the federal Center for Disease Control ("CDC"). T62 1262; see also Def.Ex.9, Tab 1. The CDC asked LifeSouth to participate in a voluntary "look-back" study, in an effort to determine the source of the West Nile Virus infection. T62 1272.

Shands provided LifeSouth with the 57 different serial numbers on the blood units that were transfused into Chase, so LifeSouth could identify the 57 volunteers who donated that

blood. T62 1269-70. At the CDC's request, LifeSouth attempted to contact all 57 donors, but only 12 donors agreed to participate in the CDC study. T62 1272-77; 1283. Donor was one of the 12 who agreed to participate in the study. T62 1283-84.

As a result of this CDC look-back study, it was determined that the blood donation given by Donor in September 2002 was the likely source of Chase's infection with West Nile Virus. T53 5; see also T57 695.

B. The Blood Collection And Screening Processes That Are Performed By All Blood Banks

Blood banks are heavily regulated by the U.S. Food and Drug Administration ("FDA"), and accredited by agencies such as the America Association of Blood Banks ("AABB"). T62 1237. For each donor who volunteers to give blood, a blood bank prepares a Single Donation Record ("SDR"), an FDA-approved form used by all blood bank interviewers to record a potential donor's medical history and vital signs. T63 1351; T55 409; see also Def.Ex.6 and 8. The SDR contains about 48 carefully crafted and highly personal questions about the donor's health, lifestyle, and habits. See, e.g., Def.Ex.8; see also T55 408. These questions are intended, in part, to identify certain high-risk blood donors who may statistically be more likely to be infected with a particular blood-borne disease. T57 690; T57 673-90.

The FDA guidelines provide that every step of the blood collection process, including the blood donor interview, must be conducted or supervised by a qualified physician. 21 C.F.R. §§ 640.3, 640.4. The pre-donation interviewer establishes that the donor is in good health on the day of the donation, reviews the donor's medical history, confirms the donor's temperature, blood pressure, and hemoglobin level, and checks for respiratory diseases and signs or symptoms of drug use. T62 1241-42.

After blood is taken from a donor, the blood is brought to one of the blood bank's component laboratories and split into its components--red cells, platelets and plasma. T62 1237. The donor's blood samples are scientifically tested in LifeSouth's laboratories for the presence of various known diseases (such as AIDS, HIV, and hepatitis). Id.; T65 1669. The blood components are then sent to local hospitals to be transfused into the patients who need this blood. T62 1237.

C. LifeSouth's Process Of Collecting And Screening This Donor's Blood

Between 1998 and 2002, Donor volunteered to give blood ten times. T58 715-17; T56 516; T58 715. He successfully donated blood nine times, but was turned away once when he had an elevated temperature. T58 715-16. His September 18, 2002 donation was his last blood donation. T56 528-29. Each of the ten times Donor tried to donate blood, he was asked a series of

questions from the SDR questionnaire by a LifeSouth donor services specialist who was being supervised by a medical doctor. T56 516-29.

Donor testified that he understood the questions he was being asked by LifeSouth's donor services specialists. T56 520-29, 537, 545. All of the LifeSouth donor services specialists who remembered this Donor testified that they could understand him. See T63 1413-14 (Regina Hart, four donations); T65 1783-85 (Wendy Joy Hill, 4 donations); T65 1806-08 (Charles Cohen, 5 donations); T1825-29 (Nicole Santerfeit, 3 donations); T65 1725-28 (Kim Otte, interviewed Donor for the CDC study).

D. Before Plaintiff Files Her Lawsuit, She Sends LifeSouth An Extensive Presuit Document Demand

On March 2, 2004, Plaintiff's attorneys sent LifeSouth an extensive presuit document demand, together with a HIPPA-compliant authorization for release of information, signed by Kaynan Fitchner.² See Notice of Correction, Dec. 7, 2007, filed in the District Court. Plaintiff indicated that she had previously obtained Chase's blood transfusion records from Shands and provided copies to LifeSouth. Id. These documents identified by number each of the donors who provided the blood units that were utilized for Chase's blood transfusions. Id.

² This letter was filed by LifeSouth in the District Court in connection with arguments raised by Plaintiff in her Motion for Certification and Clarification, and was relied on by Plaintiff in her initial brief to this Court. See IB at 5 n.5.

Plaintiff's attorneys represented to LifeSouth that they had been retained to represent the Fitchners "with regard to injuries their minor son, Chase Fitchner, sustained when he contracted West Nile encephalitis through blood products supplied to Shands by LifeSouth Community Blood Centers." Id. Plaintiff requested that LifeSouth supply them with certain documents so that they could "properly investigate this claim." Id. Among the documents Plaintiff requested from LifeSouth are:

1. Copies of all oral and written policies and procedures regarding screening of blood donors that LifeSouth had in effect in August, September and October of 2002.
2. A copy of all documentation supplied by LifeSouth to the CDC as a part of its investigation in or about October of 2002, following notification that tainted blood was supplied by LifeSouth to Shands.
3. A copy of any and all documentation regarding the donor who was found to have tested positive for the West Nile virus as a result of the CDC investigation in October of 2002, of tainted blood supplied by LifeSouth to Shands.

Id.

Plaintiff states in her brief, without providing any record citation, that LifeSouth opposed her efforts to obtain information about Donor's blood donation before this lawsuit was filed. See IB at 5. There is nothing in this record, however, that suggests LifeSouth did not promptly provide Plaintiff with all of the documents she requested in her March 2, 2004 letter.

E. Plaintiff Sues LifeSouth Without First Serving LifeSouth With A Presuit Notice

Plaintiff elected not to send a presuit notice before she sued LifeSouth and, instead, on April 23, 2004, filed a lawsuit claiming LifeSouth negligently provided her son with blood infected with West Nile Virus. R1 1-4. Plaintiff alleged that LifeSouth "negligently designed and/or failed to implement reasonable screening procedures which would have prevented the dissemination . . . of blood contaminated with West Nile Virus." R1 2. Plaintiff further alleged that LifeSouth "negligently failed to adopt or implement reasonable screening procedures for the particular donor from whom the tainted blood was collected." R1 3. After Chase died, Plaintiff amended her complaint to assert a wrongful death claim. R2 218-24.

F. LifeSouth Moves To Dismiss Plaintiff's Lawsuit Because She Failed To Comply With Florida's Presuit Notice Requirements

LifeSouth filed a Motion to Dismiss, asserting that Plaintiff did not comply with the presuit requirements of section 766.106, Florida Statutes (2003), that apply to claims for medical negligence against healthcare providers. R1 14-19; see also R1 9-13. Plaintiff agreed that LifeSouth was a healthcare provider, but opposed LifeSouth's motion to dismiss by asserting that "the requirements of Chapter 766 are not applicable to this action." R1 42.

In opposing LifeSouth's motion to dismiss, Plaintiff did not suggest she was unable to provide a presuit notice or expert affidavit to support her claim, nor did she ever raise any constitutional challenge to section 766.106(2), Florida Statutes (2003), based on a denial of access to courts. See R1 42-46. When Plaintiff filed her memo of law opposing LifeSouth's motion to dismiss (in June 2004), she was well within the time to serve a notice of intent under section 766.106(2). See R1 42-47.

The trial court ruled that LifeSouth was a healthcare provider as defined in sections 766.202(4) and 766.102(1). R1 62. However, the trial court further ruled that this lawsuit was not controlled by Chapter 766 because "the acts for which the Plaintiff complains are not medical malpractice pursuant to the provisions of that chapter." Id. Thereafter, each time LifeSouth sought to enforce any of its rights under Chapter 766, Plaintiff argued, and the trial court agreed, that the pre-trial ruling on LifeSouth's motion to dismiss--i.e., that Chapter 766 did not apply to Plaintiff's claims--was "law of the case." See, e.g., T74 2507 at 69-70, 78-80; T60 1044-45.

G. LifeSouth Moves For Summary Judgment Asserting Plaintiff Could Not Establish Causation

LifeSouth moved for summary judgment, asserting that Plaintiff could not establish the requisite causal link between any alleged negligence in LifeSouth's blood screening process

and Chase's death from West Nile Virus. R2 515-50. According to Dr. Sandler, Plaintiff's own medical expert, at the time when Chase received blood infected with West Nile Virus, "[t]here was neither a requirement or an FDA licensed test available for routine use in blood centers in the United States to test for West Nile Virus." R33 4761 (Dr. Sandler's 11/15/2005 Depo at p.50); see also R2 518, 526 (LifeSouth's MSJ).

In addition, according to Dr. Sandler, there was no information that a blood bank could obtain from a potential blood donor that might lead a blood bank to believe the donor may be a carrier of West Nile Virus except: a) if the donor has a fever; or b) if the donor responds "no" to the question "Are you feeling well today"? See R33 4773 (Dr. Sandler 11/15/2005 Depo at p.100); see also R2 521. There was no dispute that, when Donor gave blood on September 18, 2002, he did not have any symptoms of West Nile Virus, did not have a fever, and felt fine. R33 4773; R2 517, 519, 521-22; see also T56 530.

LifeSouth asserted that the basis for Plaintiff's causation theory--that Donor could not sufficiently understand the questions on the SDR because his primary language was Spanish--was legally insufficient to establish a fact issue regarding causation. R2 538-39. The undisputed evidence was that, even if Donor spoke perfect English or if, (as Plaintiff suggested) LifeSouth had provided Spanish-language SDR forms and a Spanish

interpreter, there was no way LifeSouth could have determined that Donor's blood was infected with West Nile Virus. See R2 528-29, 531-36. For that reason, Plaintiff failed, as a matter of law, to establish causation. See R2 526, 538-43, 548-49.

In opposing LifeSouth's summary judgment motion, Plaintiff argued that "the record contains disputed issues of fact regarding proximate causation," citing McCain v. Florida Power & Light Co., 593 So. 2d 500 (Fla. 1992), for the proposition that "proximate causation must be resolved by the trier of fact." R7 1262 at 28; 18-27; T74 at 47-48. The trial court denied LifeSouth's summary judgment motion on causation. R13 2359-61.

H. LifeSouth's Pretrial Compliance Statement

Plaintiff asserts that LifeSouth "stipulated" that the only issue in this case was whether LifeSouth established "clear enough communication" with the Donor. See IB at 6, 7. However, in the pretrial compliance statement, LifeSouth expressly incorporated its pending summary judgment motions as issues still to be resolved, including its argument that Plaintiff could not establish causation because West Nile Virus was not detectable in blood. See R12 2285, R13 2357-58. Before and after trial, LifeSouth consistently asserted that clear communication (for example, through the use of a Spanish interpreter), would not have prevented the transmission of West Nile Virus to this blood recipient. See R4 795 at 24-30.

I. Rulings Made At Trial That Were Challenged On Appeal But Not Reached By The First District

Over LifeSouth's objections, the trial court permitted Plaintiff to present the non-medical expert testimony of a linguistics expert to support Plaintiff's medical negligence claims. R13 2402-03; T57 557. On the other hand, the trial court would not permit LifeSouth to present any testimony at all regarding the West Nile Virus. See T57 655-56. LifeSouth's experts were thus precluded from telling the jury that there was no pre-donation interview question or test that could detect West Nile Virus in blood. T57 655-56, 691-99; T58 705-06. As such, LifeSouth asserted it was precluded from presenting the evidence necessary to establish the lack of any causal link between LifeSouth's alleged negligence in its screening procedures and Chase's infection with West Nile Virus. See T57 655-56.

At the close of Plaintiff's case (T60 1021), and again at the close of all evidence (T66 1896), LifeSouth moved for a directed verdict on: 1) Plaintiff's failure to establish a breach of the standard of care applicable to blood banks, and 2) the failure to establish that any actions by LifeSouth were the proximate cause of Plaintiff's death by West Nile Virus. The trial court denied LifeSouth's motions. T60 1032; T67 1958.

J. The Verdict, Final Judgment, And Appeal

The jury returned a verdict finding LifeSouth was negligent in its blood screening procedures and that the negligence was a legal cause of Chase's death. R13 2426-27. The court entered a final judgment for Plaintiff in the amount of \$8,029,425, which included \$8 million for non-economic damages. R13 2428-29.

LifeSouth filed post-trial motions for renewed directed verdict, R13 2441-56, for new trial, R13 2457-71, and to enter judgment in accordance with Florida's statutory cap on non-economic damages in medical negligence cases against healthcare providers. R13 2433-40. The statutory limit on non-economic damages against a non-practitioner for a medical negligence claim is \$1.5 million. See § 766.118(4), Fla. Stat. (2003).

The court denied LifeSouth's post-trial motions and refused to enforce the statutory damages limit. R16 2886-89. LifeSouth appealed the final judgment to the First District, raising several issues, including:

- a) the failure to require Plaintiff to comply with the presuit notice requirements of section 766.106;
- b) the failure to limit expert testimony on the standard of care for blood banks to experts who are licensed healthcare providers, under section 766.102;
- c) the failure to enforce the medical negligence non-economic damages cap as set forth in section 766.118;

- d) Plaintiff's failure to establish the requisite causal link between Lifesouth's blood screening processes and Chase's death from exposure to West Nile Virus; and
- e) error in excluding all testimony by Lifesouth's experts regarding West Nile Virus.

On appeal the First District reversed on the first issue, holding that "the trial court erred in failing to grant Appellant's motion to dismiss for failure of the appellee to comply with the presuit notice requirements contained in section 766.106(2), Florida Statutes." LifeSouth Cmty. Blood Ctrs., Inc. v. Fitchner, 970 So. 2d 379, 382 (Fla. 1st DCA 2007).

The appellate court provided a detailed analysis explaining why, in light of Florida's sweeping medical malpractice reform legislation that was enacted in 2003, the medical services that a blood bank provides in screening blood for a patient is "intimately tied to the care and treatment provided to the blood recipient." Id. Based on that analysis, the court held that LifeSouth was entitled to receive a presuit notice before Plaintiff could sue LifeSouth for negligently screening the blood that was transfused into Chase Fitchner. Id. at 384.

In light of that holding, the court did not reach any of the other issues raised by LifeSouth on appeal. Id. at 380.

SUMMARY OF THE ARGUMENT

The First District correctly concluded that the trial court erred in failing to afford LifeSouth the statutory protections available to all healthcare providers in medical negligence cases like Plaintiff's lawsuit. In 2003, the legislature clearly and unambiguously amended Florida's medical malpractice statutes to define blood banks as healthcare providers. That amendment abrogated the then-existing case law, and provided that blood banks were entitled to the same protections against lawsuits enjoyed by other healthcare providers--including compliance with Florida's presuit notice requirements, set forth in section 766.106(2), Florida Statutes.

Plaintiff asserts that Florida's presuit notice is only required to be given in lawsuits against healthcare providers for negligently providing "diagnosis, treatment, or care." But section 766.106 does not say that. Presuit notice is required for any claim against a healthcare provider "arising out of the rendering of, or failure to render, medical care or services."

As the First District correctly analyzed and explained, "the screening of blood to be provided to a patient is part of the medical services to that patient." Florida and federal law mandate that blood be collected under the supervision of a medical doctor, and every step of the blood collection process requires that medical professionals exercise medical judgment.

The First District explained why this appeal was not controlled by the Silva or Damiano decisions. First, the holding in Silva was limited to whether blood banks were subject to the two-year statute of limitations for medical malpractice suits. Second, both Silva and Damiano were decided before the Legislature made crucial changes to Chapter 766, in particular, broadening its application to blood banks.

It would make no sense at all for the legislature to designate blood banks as health care providers, but then provide that collecting, screening, and supplying blood to patients--the essential and fundamental service that blood banks provide--is not "health care." Such an interpretation would impermissibly render this significant statutory change to be meaningless.

Finally, requiring Plaintiff to comply with Florida's presuit notice requirement does not deny her access to courts. Before filing a lawsuit against LifeSouth, Plaintiff was entitled by statute to request copies of all documents pertaining to the blood donation that was infected with West Nile Virus, which is precisely what she did. Plaintiff never suggested that she was unable to comply with Florida's statutory presuit investigation process, nor did she ever assert the denial of access to courts as grounds for excusing her failure to comply with Florida's mandatory presuit notice requirements.

ARGUMENT

I. UNDER SECTION 766.106(2), FLORIDA STATUTES (2003), A BLOOD BANK IS A HEALTHCARE PROVIDER THAT IS ENTITLED TO RECEIVE PRESUIT NOTICE BEFORE IT CAN BE SUED FOR NEGLIGENTLY SCREENING BLOOD THAT IS TRANSFUSED INTO A PATIENT

A. Standard of Review

LifeSouth agrees that the standard of review on issues involving the interpretation of statutes is de novo. See B.Y. v. Dep't of Children & Families, 887 So. 2d 1253, 1255 (Fla. 2004) (citing State v. Burris, 875 So. 2d 408, 410 (Fla. 2004)).

B. Florida's 2003 Amendments To Chapter 766 Unambiguously Provide That Blood Banks Are Entitled To Presuit Notice For Any Lawsuit Asserting A Claim For Medical Negligence

Plaintiff sued LifeSouth, a healthcare provider, for negligently collecting and screening blood that was infused into Chase Fitchner's body. As the First District correctly concluded, that claim arises out of the performance of a medical service, and as such is governed by Florida's medical negligence statutes, Chapter 766.

Plaintiff expressly concedes that LifeSouth is a healthcare provider. See IB at 15. Plaintiff argues, however, that the First District misconstrued section 766.106(2) as applying to this case because LifeSouth supposedly did not provide "care" or "treatment" to Chase Fitchner. That is simply wrong.

When a court construes a statute, it looks first to the statute's plain meaning. See State v. J.M., 824 So. 2d 105, 110

(Fla. 2002). Here, the plain language used in section 766.106(2), entitled "Notice before filing action for medical negligence," does not limit its presuit notice requirement to healthcare providers who provide "care" or "treatment" to a patient; indeed, those words appear nowhere in that statute.

Instead, presuit notice must be given to any "healthcare provider" who is sued for negligence "arising out of" the rendering of "medical care or services." §766.106(1)(a), Fla. Stat. Because Plaintiff failed to provide such a notice in this case, her complaint was properly dismissed. See Goldfarb v. Urciuoli, 858 So. 2d 397, 399 (Fla. 1st DCA 2003) (stating "if the required presuit notice is not given to a health care provider, the complaint is properly dismissed").

1. The Screening And Testing Of Blood Is A Medical Service That Is Provided By Blood Banks To Blood Recipients

Plaintiff's claim that her son was infected by blood supplied by LifeSouth unquestionably "arises out of" the provision of "medical services" rendered by a healthcare provider blood bank to a blood recipient. A blood bank-- indisputably a healthcare provider--is performing a medical service when it collects, tests, and screens human blood that is to be injected into another human body. That collection, testing and screening process is a service that is necessarily

being provided to the blood recipient. It is not a service to the hospital, the doctor, the blood donor, or to anyone else.

Screening, testing, and providing human blood to recipients in hospitals who need that blood is the primary and essential service that a blood bank provides, and is the very reason that blood banks exist. See Preamble, Laws of Fla., Ch. 69-157 (reciting findings by the Legislature that the procurement of blood "provides the general public with a desirable and necessary medical service," and that "the rendering of this service is an intricate part of the practice of medicine.").

Plaintiff argues that, although the 2003 amendments to chapter 766, Florida Statutes, were intended to provide some level of protection from medical negligence claims to blood banks, these changes only apply to claims by a donor arising from the collection, screening, and testing of the blood, but not to claims by the patient who receives this blood. The First District correctly rejected that argument, observing that any suggestion that the 2003 amendments would only apply to the blood bank-donor relationship is in conflict with the Legislature's amended definition of "health care provider":

The greatest liability exposure of blood banks is not in the relatively simple process of taking blood, but in the donor screening process, where critical decisions are made about providing blood to sick patients. . . .

[B]y including blood banks in the definition of "health care provider," the Legislature implied a relationship between blood banks and persons needing or receiving health care. **A donor is not seeking health care but only donating blood; the party receiving the blood is the one seeking health care.**

Id. at 383 (emphasis added).

The First District's conclusion that blood banks are providing a medical service to the patients who receive the blood is consistent with, and gives effect to, the stated purpose of Chapter 2003-416--to address the malpractice crisis being faced by all healthcare providers by making quality health care available to citizens of the State of Florida. See Ch. 2003-416, §1, Laws of Fla. The greatest liability exposure of blood banks is not in the relatively simple process of taking blood, but in the donor screening process, where critical medical decisions are made about obtaining and testing blood to provide to sick patients. The narrow scope proposed by Plaintiff is inconsistent with the stated legislative purpose of the 2003 amendments to Chapter 766.

In her brief, Plaintiff repeatedly refers to blood as a "product." See IB at 10, 13, 16, 25. She is wrong. Under Florida law, there can be no dispute on this point--blood is not a product, it is a service. See §672.316(5), Fla. Stat. (2003).

Plaintiff also suggests that there is no privity between the blood bank and the blood recipient. See IB at 29-30. Once

again, she is wrong. Each blood recipient knows the precise origin of each blood unit--it originates from a specific volunteer donor, is extracted, labeled, screened, and tested by the blood bank, and then injected into the blood recipient. It is precisely this contiguous, identifiable chain of services that begins with the blood donor and ends with the blood recipient that is the source of the blood banks' duty to the blood recipient. If, as Plaintiff suggests, this process is not a service from the blood bank to the blood recipient, then the blood bank would owe no duty to the blood recipient.

2. The Screening And Testing Of Blood Requires The Application Of Medical Skill And Knowledge

Plaintiff acknowledges that, to determine whether a claim arises from the provision of a medical service, one must determine whether the services hinge on the application of "medical skill or knowledge." Lakeland Reg'l Med. Ctr., Inc. v. Allen, 944 So. 2d 541, 543 (Fla. 2d DCA 2006); see also S. Baptist Hosp. of Fla., Inc. v. Ashe, 948 So. 2d 889 (Fla. 1st DCA 2007) (holding that a lawsuit against a hospital was not subject to presuit notice requirements if the suit did not challenge a medical decision that required professional skill or judgment). That is exactly the case here.

Each step of the blood collection process--gathering and evaluating information about a donor's medical history and

health conditions, as well as the collecting, processing, testing, storing, and distributing blood and blood components for transfusion into a human body--requires "medical skill and knowledge" on the part of the blood bank. Blood donations are highly regulated by both state and federal law. LifeSouth is a federally and state licensed blood bank and, as such, it is obligated to follow the national standards set by the American Association of Blood Banks and the regulations of the FDA. See 21 C.F.R. § 606.100 (defining the minimum operating requirements for processing blood and blood components for transfusion).

Federal regulations expressly require that a medical doctor must be in charge of the blood collection process. See 21 C.F.R. § 640.3(a),(b). Florida law specifically requires that a medical doctor conduct or supervise all blood donor interviews. See §381.06014, Fla. Stat. Consistent with these regulatory requirements of physician oversight, Plaintiff relied at trial upon a medical doctor to establish the professional standard of care for LifeSouth's blood donor interviews.

When the Legislature changed the medical negligence standard of care in section 766.102 to encompass blood banks, it was aware of prior Florida appellate court rulings, and necessarily intended that the presuit notice requirements in section 766.106 would apply to medical negligence claims against blood banks. For example, in Weinstock v. Groth, 629 So. 2d

835, 838 (Fla. 1993), this Court held that "the proper test for determining whether a defendant is entitled to notice under section 766.106(2) is whether the defendant is directly or vicariously liable under the medical negligence standard of care set forth in section 766.102(1)." The Legislature is presumed to know the construction of that statute. See Fla. Dept. of Rev. v. City of Gainesville, 918 So. 2d 250, 264 (Fla. 2005) (holding that the Legislature "is presumed to have adopted prior judicial constructions of a law unless a contrary intention is expressed.").

LifeSouth obviously does not suggest that all claims against healthcare providers are medical negligence claims. For example, in Tenet St. Mary's, Inc. v. Serratore, 869 So. 2d 729 (Fla. 4th DCA 2004), the court held that Chapter 766 did not apply to a lawsuit brought by a patient for injuries sustained when a medical center employee kicked her in the foot while attempting to kick the footrest of a chair. That claim did not arise from the receipt of medical care or services, and "[t]here is clearly no professional standard of care involved in attempting to kick a footrest of the reclining chair." See also Quintanilla v. Coral Gables Hosp., Inc., 941 So. 2d 468, 469 (Fla. 3d DCA 2006) (holding that injuries caused by scalding hot tea spilled by nurse onto patient constituted a negligence claim, not a claim for medical malpractice).

But Plaintiff's claim against LifeSouth is nothing like the kicked footrest in Tenet St. Mary's or the spilled tea in Quintanilla. The screening of donated blood products based on a volunteer donor's medical history, health condition, and potential exposure to viruses or diseases, necessarily involves "medical skill or knowledge," and a professional standard of care, which Plaintiff sought to establish at trial by the expert testimony of a medical doctor.

The mere fact that blood donor screeners are not themselves doctors--but rather are required to operate under a licensed doctor's direct supervision--does not change the fact that LifeSouth, as a healthcare provider, is entitled to the protections of Chapter 766 with respect to its essential services. See, e.g., Goldman v. Halifax Medical Center, Inc., 662 So. 2d 367 (Fla. 5th DCA 1995) (holding defendant entitled to the protections of Chapter 766 when their non-health care employees commit acts or omissions); see also Puentes v. Tenet Hialeah Healthsystem, 843 So. 2d 356 (Fla. 3d DCA 2003) (holding that a patient's negligence claim against a hospital, arising out of hospital dieticians and kitchen employees to provide patient with hypoallergenic diet as ordered by physician, was a medical malpractice action that required presuit notice).

For these reasons, the First District correctly concluded that a blood bank's screening and testing of blood and its

components, which are then provided to a specific, identifiable blood recipient patient, "is part of the medical services to that patient." LifeSouth Cmty. Blood Ctrs., 970 So. 2d at 383. As such, LifeSouth was entitled to all of the protections set forth in Chapter 766, including: a) the right to require a presuit notice before being sued for medical negligence, b) the right to demand arbitration with limitations on damages; c) the right to enforce the statutory damages limitations applicable to such claims, and d) the right to require that standard of care experts must be similarly qualified healthcare providers.

C. The First District Correctly Articulated Why Neither Silva Nor Damiano Controlled The Outcome Of This Case

Plaintiff erroneously rests her entire argument on two cases that were decided before the 2003 Medical Malpractice reforms became the law in Florida. The First District correctly explained why this appeal was not controlled by either Silva v. Southwest Florida Blood Bank, Inc., 601 So. 2d 1184 (Fla. 1992), or Community Blood Centers of South Florida, Inc. v. Damiano, 697 So. 2d 948 (Fla. 4th DCA 1997). First, the Silva holding was limited to whether blood banks were subject to the two-year statute of limitations for medical malpractice suits in 1991. Second, after Silva and Damiano were decided, the legislature "made crucial changes to the medical malpractice statute, in particular, broadening its application to blood banks."

LifeSouth Cmty. Blood Ctrs., 970 So. 2d at 381-82 (citing Ch.2003-416, Laws of Fla.).

In order to understand why the 2003 amendments to section 766.106(2), Florida Statutes, "broadened its application to blood banks," it is helpful to review and understand the development over the past four decades of the Florida law that controls negligence claims against blood banks.

1. The Development Of Florida Law Concerning Negligence Lawsuits Against Blood Banks

In the 1960s, Florida courts held that blood banks did not provide a service; rather, they were selling a product. See, e.g., Community Blood Bank v. Russell, 196 So. 2d 115 (Fla. 1967). In response, the legislature changed the law, amending section 672.316, to expressly provide that the processing of blood donations is "the rendering of a service." § 672.316(5), Fla. Stat. (1969).

Thereafter, this Court determined that claims against blood banks were not subject to the two-year statute of limitations for medical malpractice lawsuits. See Silva v. Southwest Fla. Blood Bank, Inc., 601 So. 2d 1184, 1186 (Fla. 1992). Under subsection 95.11(4)(b), the action must have arisen out of "medical . . . diagnosis, treatment, or care," rendered by a "provider of health care." Based on the allegations in the

Silva complaint and the law in effect at the time, this Court concluded that neither prong was met.

First, this Court held that the blood bank did not provide "diagnosis, treatment, or care," to Mrs. Silva. Id. at 1188-89. Second, this Court could find no indication that the legislature intended for blood banks to be considered "providers of health care" for purposes of the medical malpractice statute of limitations. Id. at 1189. The Court held that:

[i]n the absence of clear legislative intent to the contrary, we are not at liberty to construe that term [providers of health care] so as to deprive plaintiffs of their causes of action.

Id. (citation omitted).

But Silva was interpreting a different statute than the one at issue here, with materially different language. Section 95.11 (b)(4), Florida Statutes (1989) (the statute this Court interpreted in Silva) contains an express definition of the term "action for medical malpractice"--an action that arises from the "diagnosis, treatment, or care by any provider of health care." In stark contrast, the statute interpreted by the First District here--section 766.106, Florida Statutes (2003)--has an entirely different and much broader definition of the same term: "[c]laim for medical negligence" or "claim for medical malpractice," which, in this different context, applies to all claims "arising out of the rendering of . . . medical care or services."

Shortly after the Silva decision, the Fourth District addressed the question of whether a blood bank is a "health care provider" for purposes of requiring plaintiffs to comply with medical malpractice presuit notice and screening requirements in effect at that time. See Cmty. Blood Ctrs. of S. Fla., Inc. v. Damiano, 697 So. 2d 948 (Fla. 4th DCA 1997). Relying on Silva, the Fourth District held that "[w]ithout a clear expression of legislative intent to the contrary," blood banks were not covered by the presuit requirements of section 766.106, in actions for supplying contaminated blood. Id. at 952.

2. The Post-Silva Change To Florida Law Concerning Blood Banks

In 2003, the Florida Legislature provided a clear expression of its intent on this issue. Florida was in the midst of a medical malpractice insurance crisis that affected all of its citizens. The Legislature made extensive findings that the crisis could only be eliminated with dramatic statutory changes. See Ch. 2003-416, §1, Laws of Fla. With the full knowledge of the statutory interpretations in Silva and Damiano, the Legislature expressed its clear intent to override those decisions, substantially rewriting chapter 766, in particular, broadening its application to blood banks.

To begin with, the Legislature expressly provided that blood banks are healthcare providers. Id.; §766.202(4), Fla.

Stat. (2003). The Legislature also amended section 766.102, to incorporate the "health care provider" definition from section 766.202(4) (which now included "blood banks"). It defined "medical negligence" as a claim against a healthcare provider "arising out of the rendering, or failure to render, medical care or services." §766.102, Fla. Stat. (2003).

It bears emphasis that the language employed by the Legislature in these amended statutes was drawn directly from the Silva decision, where this Court recognized and articulated the conceptual distinction between claims for "diagnosis, treatment, or care" and claims for "medical services":

. . . even if the legislature was making a broad policy statement that blood banks provide a "medical service," the plain wording of section 95.11(4)(b) indicates that the legislature intended for the shorter limitations period to apply only to **a narrow class of medical services**. The statute of limitations does not speak to **all medical services**, but only to **"diagnosis, treatment, or care"** by a health care provider. **Had the legislature intended a broader coverage, it would have used the "medical services" language from the chapter 69-157 preamble.**

Silva, 601 So. 2d at 1188. In the preamble of chapter 69-157, Laws of Fla., the Legislature characterized "the process of collecting and processing human blood for transfusion purposes" as "a desirable and necessary medical service."

Hence, the 2003 Legislature adopted for Chapter 766 the term "medical services," described by this Court in Silva as a broader category of claims than claims that are based on "diagnosis, treatment, or care." See Silva, 601 So. 2d at 1188. The Legislature amended sections 766.106, 766.1115, 766.112, 766.113, 766.201, 766.203, 766.2021, and 768.21, Florida Statutes (2003), which previously referred to "medical malpractice" claims, to now refer to the broader term: claims for "medical negligence."

The Legislature also enacted two additional statutes in 2003 that pertained exclusively to blood banks. First, the Legislature enacted §381.06014(2), Fla. Stat. (2003), a new law requiring that all "blood establishments" in Florida must comply with 21 C.F.R. § 600-640 (2003), the federal regulations governing blood banks. See Ch. 2003-38, Laws of Fla. Under those regulations, every step of the blood collection process--including all blood donor interviews--must be conducted or supervised by a qualified physician. 21 C.F.R. §§ 640.3, 640.4.

Second, the Legislature amended section 672.316(5), Florida Statutes (2003), to eliminate the then-existing statutory exception by which blood might be considered a "product," subject to implied warranties under the Uniform Commercial Code ("UCC"). When section 672.316(5) was originally enacted in

1969, it included a statutory exception by which human blood could be found to be subject to implied warranties:

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 for any purpose whatsoever is declared to be the rendering of a service by any person participating therein and does not constitute a sale, whether or not any consideration is given therefor; and the implied warranties of merchantability and fitness for a particular purpose are not applicable **as to a defect that cannot be detected or removed by a reasonable use of scientific procedures or techniques.**

§672.316(5), Fla. Stat. (1969). Hence, under the statute in effect when Silva and Damiano were decided, implied warranties applied to blood that contained a defect that could be detected or removed by "scientific procedures or techniques." Id.

In 2003, however, the bolded part of section 672.316(5) (above) was deleted. Hence, the process of collecting and processing human blood for transfusion was now considered, without exception, to be a medical service and not a product subject to implied warranties. See Ch. 2003-74, Laws of Fla.

Notably, even under the old statute, blood contaminated with West Nile Virus would not have been subject to implied warranties because, as all the experts in this case agreed, West Nile Virus could not be detected in blood by any known scientific procedure or technique. Exactly the opposite was

true in Silva, where the blood bank in that case was alleged to have represented that "its blood supply was safe and free from HIV **because of the testing procedures used.**" Silva, 601 So. 2d 1186. Hence, under the 1969 UCC version of section 672.316(5), which was in force when Silva was decided, blood contaminated with HIV was subject to implied warranties of merchantability and fitness for a particular purpose. That is yet another reason why Silva does not control in this case.

Finally, in 2003, the legislature enacted several new statutes that expanded protections to all healthcare providers; for example, section 766.118, Florida Statutes (2003), which imposed a limit on non-economic damages in all judgments arising from medical negligence claims against healthcare providers.

When read together, the sweeping changes that were made to Chapter 766 in 2003 are clear and unambiguous. By including blood banks in the definition of "health care provider," the legislature expressly declared that blood banks provide health care services. It would make no sense for the legislature to designate "blood banks" as "health care providers," but then provide that the screening and collection of that blood--the essential and fundamental service that blood banks provide--is not a medical service. That would impermissibly render this explicit change in the statute meaningless. See Heart of Adoptions, Inc. v. J.A., 963 So. 2d 189, 198-99 (Fla. 2007)

(holding that "the Legislature does not intend to enact useless provisions, and courts should avoid readings that would render part of a statute meaningless.").

D. Plaintiff's Suggestion That Enforcing Florida's Presuit Notice Requirement Denies Her Access To Courts Is Without Merit

Plaintiff claims that the First District's decision enforcing Florida's presuit notice requirements denies her access to courts. She is wrong for several reasons.

1. Plaintiff's Belated Claim That She Could Not Provide An Affidavit From A Medical Expert To Support Her Presuit Notice Is Not Supported By This Record

Plaintiff complains that she could not have complied with the presuit requirements of chapter 766. There is nothing in this record to support that claim. As her own presuit document demand to LifeSouth demonstrates, Plaintiff was able to request copies of all documents pertaining to Chase's infected blood transfusion from both Shands and LifeSouth, which is precisely what she did. Under §766.204(2), Fla. Stat. (2003), if Plaintiff did not promptly receive the documents she requested from LifeSouth, she was not required to provide an affidavit from a medical expert with any presuit notice to LifeSouth.

When the Legislature changed chapter 766 in 2003 to define blood banks as health care providers, it imposed on all blood banks new obligations with which all healthcare providers--

including blood banks--must comply. Under section 766.204(1), healthcare providers must make available to any claimant "copies of any medical record relevant to any litigation of a medical negligence claim." If a healthcare provider fails to provide the requested information to a claimant within 10 business days, the healthcare provider waives the requirement for written medical corroboration. See §766.204(2), Fla. Stat. (2003).

Hence, when the Legislature designated that blood banks are healthcare providers, it automatically granted a new statutory right to all blood recipients, including this Plaintiff--the right to obtain relevant documents from a blood bank before filing a medical negligence lawsuit. Moreover, if LifeSouth had failed to comply with that request (and there is no evidence here that LifeSouth failed to comply with any document request), it would have waived the right to require an accompanying presuit affidavit with the notice of intent. See section 766.204(2). This new right guarantees access to courts for all individuals who may have a potential medical negligence claim against a blood bank.

Plaintiff suggests that "[b]ecause neither Petitioner nor her minor son had any relationship with the blood bank or the infected donor, she had no legal right, prior to filing suit, to confidential information in the possession of LifeSouth

regarding the individual donor at issue." IB at 30-31. That argument is without merit.

Plaintiff, like every recipient who obtains blood from a blood bank, knew from the hospital's records the precise source of each unit of donated blood that was transfused. Under chapter 766, blood recipients are entitled to obtain from blood banks the details of the blood testing and screening processes for the specific blood units they received, including the blood donation documents--except for the identity of the donor. See §381.0043, Fla. Stat. (2005)(a blood bank "may not be compelled to disclose the identity or any identifying characteristics of a person who donates blood").

Had Plaintiff established below that LifeSouth failed to provide her with information in its possession that was essential to her case, then, by law, Plaintiff would not have needed to obtain an expert before filing a lawsuit. Under the statutory framework, LifeSouth would have been deemed to have waived that requirement. Indeed, LifeSouth might also have exposed itself to serious sanctions, including the potential striking of LifeSouth's defenses, if it failed to provide any documents to Plaintiff that it was obligated to provide. See §§ 766.106(7), 766.205(3), 766.206(3), Fla. Stat. (2003).

But Plaintiff never asserted that LifeSouth failed to comply with its presuit document production obligations and

thereby waived its right to require a presuit notice with an expert affidavit. She argued only that the statute did not apply to her claim in the first instance.

Simply put, there is no record basis on which this Court should speculate that requiring Plaintiff to file a presuit notice unconstitutionally denied her access to courts. Plaintiff can hardly argue, after the fact, that she had no ability to comply with Florida's statutory presuit investigation process when she never asserted that claim below. This is particularly so here, where LifeSouth's timely invocation of its statutory presuit rights occurred at a point in time when Plaintiff still could have complied with those rights.

Had Plaintiff sent LifeSouth a presuit notice, LifeSouth would have been afforded an opportunity to avoid litigation entirely, and could have elected to resolve Plaintiff's medical negligence claim through binding arbitration under section 766.207. Under that statute, LifeSouth's potential liability for non-economic damages would have been limited to \$250,000. Plaintiff's conscious and strategic election not to comply with the mandatory presuit notice process deprived LifeSouth of that opportunity.

2. Plaintiff Could Have Served LifeSouth With A Presuit Notice Without Attaching An Expert Affidavit; Because She Did Not Do That, Her Access To Courts Argument Is Waived

Under the statutory presuit scheme, Plaintiff could have served a presuit notice on LifeSouth without including an affidavit from a healthcare provider if LifeSouth failed to provide documents to her, as she now asserts in advancing her access to courts argument. Section 766.204(2), Florida Statutes, provides that the failure of a healthcare provider to provide copies of medical records at a reasonable charge to a plaintiff who requests such records "shall constitute evidence of failure of that party to comply with good faith discovery requirements and shall waive the requirement of written medical corroboration by the requesting party." (emphasis added).

Notably, however, even when a defendant healthcare provider fails to comply with the good faith discovery requirements of Chapter 766, the plaintiff still has an obligation to serve a presuit notice. See Otto v. Rodriguez, 710 So. 2d 1 (Fla. 4th DCA 1998) (failure to provide full and complete medical records to plaintiff in malpractice action, which prevented plaintiff from obtaining medical affidavit as required by statute, did not constitute waiver of required notice of intent to file suit); Wilkinson v. Golden, 630 So. 2d 1238 (Fla. 2d DCA 1994) (failure

by a healthcare provider to comply with presuit requirements only waives the right to receive medical corroboration).

The reason for that requirement is simple. The purpose behind the notice of intent to file suit is "to give the defendant notice of the incident in order to allow investigation of the matter and promote presuit settlement of the claim." Kukral v. Mekras, 679 So. 2d 278, 282 (Fla. 1996). In contrast, the purpose of the corroborating medical opinion is to substantiate the legitimacy of the claim and prevent the filing of baseless litigation. Id.

In this case, Plaintiff never suggested that Florida's presuit notice requirements were unconstitutional as applied to her because it was impossible for her to comply with those requirements. LifeSouth raised its objection that Plaintiff failed to comply with Florida's presuit notice in May 2004, well within the time when Plaintiff could have complied with the presuit notice requirements.

Instead, Plaintiff made a strategic decision not to comply with the presuit requirements, and elected to stand on her argument that her lawsuit against LifeSouth was not controlled by chapter 766. By doing so, Plaintiff sought to deprive LifeSouth of all of the statutory protections afforded to healthcare providers under Chapter 766--presuit notice

requirements, limitations on experts, special arbitration provisions, and limits on non-economic damages.

In light of her strategic decision to only raise her statutory argument, Plaintiff waived her new access to courts argument. Plaintiff cannot now be heard to claim that she could not comply with her presuit obligations. The fact is, she served LifeSouth with a presuit demand for documents. If LifeSouth's response to that request was inadequate (although the record suggests no such thing), Plaintiff had a remedy, and she still could have complied with her statutory obligations.

In all events, because Plaintiff raised her access to courts argument for the first time in her Motion for Rehearing to the First District, this issue is not preserved for appellate review. See Fla. Dept. of Fin. Servs. v. Freeman, 921 So. 2d 598, 602 (Fla. 2006) (holding an "as applied" constitutional challenge cannot be raised for the first time on appeal); Thompson v. Napotnik, 923 So. 2d 537, 540 (Fla. 5th DCA 2006) (same); Bush v. Holmes, 886 So. 2d 340, 365 (Fla. 1st DCA 2004)(the constitutionality of the application of a statute "must be raised first at the trial level").

E. LifeSouth Is Entitled To Relief Based On The Other Issues It Raised On Appeal Which The First District Never Reached

For the reasons set forth above, this Court should answer the certified question "yes," and confirm that, under section

766.106(2), blood banks, as healthcare providers, are entitled to presuit notice for any medical negligence claims arising from the supplying of blood to a patient. However, even if this Court disagrees that LifeSouth was entitled to presuit notice under the facts of this case, LifeSouth would still be entitled to relief based on the other issues raised in its appeal.

First, even if the presuit notice requirement in section 766.106 did not apply in this case, the non-economic damages cap in section 766.118--which applies in all medical negligence cases against healthcare providers--still should be enforced. LifeSouth is a health care provider. The Legislature enacted section 766.118 to ease that insurance crisis for health care providers like LifeSouth. Blood banks, like all other health care providers, were devastated by the same medical malpractice insurance crisis that hit all health care providers. Under the plain language of section 766.118, the non-economic damages limitation should apply in this medical negligence case against a healthcare provider.

Second, section 766.102(5) unambiguously provides that the plaintiff must prove that a health care provider breached "the prevailing professional standard of care for that health care provider." A witness may not give expert testimony on the professional standard of care unless that person is a licensed health care provider and meets certain additional criteria.

Plaintiff should not have been permitted to prove her negligence claim through testimony by a linguistics expert who did not meet those statutory requirements.

Third, Plaintiff failed to establish the requisite causal link between the alleged inadequate screening of the donor and Chase's infection with West Nile Virus. At the time of this blood donation, there was no test to detect West Nile Virus via any blood screening process. Had LifeSouth provided Donor with Spanish forms or a Spanish interpreter (as Plaintiff suggested should have been done), there was no evidence that LifeSouth could have known that this donor's blood was infected with West Nile Virus. See, e.g., Kipp v. United States, 88 F.3d 681, 684 (8th Cir. 1996). For that reason, any negligence in obtaining answers to donor screening questions cannot, as a matter of law, be the proximate cause of a death by West Nile Virus.

Finally, if the issue of proximate cause implicated a fact issue for the jury, then LifeSouth should have been allowed to present all of its evidence on lack of causation. LifeSouth's experts should have been allowed to explain to the jury that West Nile Virus was undetectable in blood and that a donor would not exhibit any symptoms at the time he actually was infectious. These facts were highly relevant to LifeSouth's defense that there was no causal chain from LifeSouth's alleged negligence to Chase's injury from the infected blood.

CONCLUSION

For the reasons asserted above, this Court should answer the certified question "yes." If for any reason this Court should disagree and determine that LifeSouth was not entitled to presuit notice in this case, then the case must be remanded to the First District for consideration of all of the other issues that LifeSouth raised on appeal but which the court did not reach in its review.

Respectfully submitted,

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CERTIFICATE OF TYPE SIZE AND STYLE

I HEREBY FURTHER CERTIFY that the type size and style used throughout this brief is 12-point Courier New double-spaced, and that this brief fully complies with the requirements of Florida Rule of Appellate Procedure 9.210(a)(2).

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