SUPREME COURT OF FLORIDA

GERALD SILVA, etc.,

Petitioner,

v. Case No. 77,980

SOUTHWEST FLORIDA BLOOD BANK, INC.,

Respondent. /

JOHN SMITH, et ux., etc.,

Petitioner,

v. Case No. 78,012

SOUTHWEST FLORIDA BLOOD BANK, INC.,

Respondent. /

ON CERTIFIED CONFLICT FROM THE SECOND DISTRICT COURT OF APPEAL

BRIEF OF AMICUS CURIAE AMERICAN RED CROSS AND AMERICAN ASSOCIATION OF BLOOD BANKS IN SUPPORT OF RESPONDENT SOUTHWEST FLORIDA BLOOD BANK, INC.

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STATEMENT OF THE CASE

This Court faces an issue of great significance to the provision of medical services in the State of Florida: whether the professional activities of that part of the medical profession which collects, tests and processes human blood, intended for use in lifegiving transfusions in hospitals throughout this state, constitute medical care and treatment governed by the Florida medical malpractice statute of limitations.

The Second District Court of Appeal below, in Silva v. Southwest Florida Blood Bank, Inc., 578 So.2d 503 (Fla. 2d DCA 1991), and Smith v. Southwest Florida Blood Bank, Inc., 578 So.2d 501 (Fla. 2d DCA 1991), held that Respondent Southwest Florida Blood Bank, Inc. ("Southwest") was a "health care provider" properly subject to the Florida medical malpractice statute of limitations, Fla.Stat. §95.11(4)(b). The Court of Appeal also correctly held that blood banks provide medical diagnosis, treatment or care, within the meaning of the medical malpractice statute of limitations, both to recipients of blood transfusions and to the donors of the blood and blood products transfused. In so doing, the Court of Appeal properly declined to follow the contrary ruling. Durden v. American Hosp. Supply Corp., 375 So.2d 1096 (Fla. 3d DCA 1979), cert. denied, 386 So.2d 633 (Fla. 1980).

Amicus, the American Red Cross and the American Association of Blood Banks,[1] which together account for nearly all of the whole blood and blood products collected from volunteers for use in transfusion in the Untied States, have a profound interest in ensuring that the principles governing negligence actions against them are appropriate. In this case, the Court of Appeal rightly concluded that, like the physicians and hospitals that prescribe blood components and utilize its services, Southwest should be subject to a medical malpractice statute of limitations. Amicus adopt Respondent Southwest's Statement of Facts.

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[1] Amicus American Red Cross is a charitable, not-for-profit organization chartered by Congress. The Red Cross blood services program was originally established to ensure an adequate supply of blood for soldiers wounded during World War II. Today, the Red Cross collects, processes, and distributes approximately one half of the nation's blood supply from millions of volunteer donors, through more than 50 blood services regions. Amicus American Association of Blood Banks ("AABB") is a not-for-profit professional association of thousands of physicians, scientists, and blood services providers from various institutions engaged in blood services and transfusion medicine around the country, including free-standing blood centers, hospital blood banks, and transfusion centers. Several thousand institutional members of the AABB and independent community blood centers, such as Southwest, are responsible for collecting the remainder of the blood supply.

ISSUE PRESENTED

Whether the Second District Court of Appeal properly concluded that donors are recipients of blood components from blood banks "are rendered medical treatment, diagnosis, or care by those health care provider blood banks," and thus are subject to Florida's medical malpractice statute of limitations, Fla.Stat. §95.11(4)(b).

SUMMARY OF THE ARGUMENT

Blood services providers are health care providers within the ambit of the two-year Florida medical malpractice statute of limitations. First, in establishing statutory standards of recovery in medical malpractice cases and enacting the blood shield statute, the Florida Legislature has determined that blood services providers are health care providers subject to a medical professional standard of care and the corresponding medical malpractice two-year statute of limitations. Further, blood services providers, such as Southwest, are an integral, essential part of the nation's medical care system. The services they provide are performed by highly skilled and specialized medical professionals, including physicians, nurses and allied health care professionals. These professionals are engaged in the practice of medicine, and provide important medical services both to the volunteer donors who are the mainstay of the nation's blood supply and to recipients of blood components whose care and attention are its object.

Moreover, the national consensus of courts is that blood services providers are medical professionals subject to the stringent professional negligence standard of care in actions such as this and that their activities are to be judged in light of the medical knowledge and expertise of similarly situated professionals. As a result, courts, like the Court of Appeal below, have held that blood services providers such as Southwest are properly subject to medical malpractice statute of limitations.

ARGUMENT

I. BLOOD BANKS ARE HEALTH CARE PROVIDERS UNDER FLORIDA STATUTES WHOSE SERVICES FORM AN INTEGRAL PART OF MEDICAL TREATMENT AND CARE AND ARE THEREFORE SUBJECT TO FLORIDA'S MEDICAL MALPRACTICE LIMITATIONS PERIOD.

The blood services system is an essential part of the nation's health care system. There can be no dispute that blood is essential for public health: blood is a lifesaving, life-sustaining substance without any substitutes. Approximately 3.5 million people are transfused each year with blood collected from volunteer donors, usually in the form of components such as packed red cells, plasma, or platelets. Blood is a living human tissue that by law cannot be administered without a physician's prescription. 21 U.S.C. § 353; 21 C.F.R. § 606.121(c)(8)(i); see also Doe v. American Red Cross Blood Servs., 125 F.R.D. 637, 645 (D.S.C. 1989).

The Florida Medical Malpractice Statute of Limitations, Fla. Stat. §95.11(4)(b), provides that an action for medical malpractice must be brought within two years:

> 95.11 Limitations other than for the recovery of real property
>
> Actions other than for the recovery of real property shall be commenced as follows:
>
> * * *
>
> (4) Within two years. --
>
> * * *
>
> (b) An action for medical malpractice shall be commenced within 2 years from the time the incident giving rise to the action occurred or

> within 2 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 a claim . . . 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 limitation of actions within this subsection shall be limited to the health care provider and persons in privity with the provider of health care.

This two year statute of limitations thus by its terms applies to "actions for medical malpractice" against "health care providers." Section 95.11(4)(b) does not define "health care providers." Nonetheless, the Florida Legislature, in enacting statutory standards of recovery for medical malpractice actions and the "blood shield statute" barring strict liability and breach of warranty claims, has explicitly determined that volunteer whole blood collectors are "health care providers" engaged in the practice of medicine. Moreover, the activities of blood services providers such as Southwest -- particularly the activities challenged by Petitioners[2] -- are quintessentially medical

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[2] An examination of Petitioners' claims against Southwest demonstrates that they are challenging Southwest's exercise of professional medical judgment and expertise in conducting its blood collection activities. The Smith Petitioners allege, for example, that Southwest breached its duty of care toward them, by "failing to take reasonable measures to screen out high risk blood donors," by "failing to take reasonable measures to screen out blood and blood products obtained from high risk donors," and by "failing to take reasonable measures to test the blood and blood products for AIDS and associated conditions and factors." Smith Petitioner's Br. at 2. As shown below, the screening or testing of donated blood for transfusion into human beings requires medical knowledge and training and is performed by health care professionals such as medical technicians and medical technologists under the supervision of licensed physicians.

professional activities subject to a professional standard of care.

A. The Florida Legislature Has Expressly Determined that Blood Banks Are Health Care Providers Subject to Professional Medical Malpractice Standards of Care

In enacting Fla.Stat. §766.102, which provides the standards for recovery in all medical malpractice actions, the Florida Legislature expressly determined that blood services providers are health care providers subject to a medical professional standard of care. This legislative declaration is conclusive evidence that the Florida Legislature regards blood collectors as health care providers. This Court must give effect to this legislative determination and therefore must apply the medical malpractice statute of limitations to Southwest.[3]

Section 766.102(1) provides:

> In any action of 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 health care providers as defined in s.768.50(2)(b), the claimant shall have the

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[3] See Villery v. Florida Parole and Probation Comm'n., 396 So.2d 1107, 1111 (1980) ("Where possible, [a court] must give effect to all statutory provisions and construe related statutory provisions in harmony with one another."); State v. Gale Distrib., Inc., 349 So.2d 150, 153 (Fla. 1977) ("[I]t is a cardinal rule of statutory construction that the entire statute under consideration must be considered in determining legislative intent and effect must be given to every part of the section and . . . statute as a whole. From a view of whole law . . . the Court will determine legislative intent."); Terrinoni v. Westward Ho!, 418 So.2d 1143, 1146 (Fla. 1st DCA 1982) ("Statutory language is not to be assumed superfluous; a statute must be construed so as to give meaning to all words and phrases contained within the statute.").

> 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.

Fla.Stat. §766.102(1).

Section 768.50(2)(b), in turn, specifically defines "health care provider" to include "clinical laboratories registered under chapter 483" and "blood banks."[4] Petitioners do not dispute that this statutory medical malpractice standard of care applies to blood banks such as Southwest. It would be anomalous to conclude that the Florida Legislature intended a different, non-medical malpractice statute of limitations while at the same time clearly applying the medical malpractice standard of care to blood banks.[5] Accordingly, the Florida Legislature's determination that

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[4] Florida also regulates blood banks as clinical laboratories because they perform examinations on specimens "taken from the humban body to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the assessment of a medical condition." Fla.Stat. §483.041(1). Although the Florida Legislature later repealed Fla.Stat. §768.50(2)(b), the definition of "health care provider" of that provision remains effective as part of Section 766.102(1). As explained in the preface to the Florida Statutes, 1989, which discusses the proper construction of statutory cross-references, "Legislative enactments frequently incorporate portions of the Florida Statutes by reference . . .. [A]s a general rule, a cross-reference to a specific statute incorporates . . . the language of the referenced statute as it existed at that time, unaffected by any subsequent . . . repeal of the incorporated statute." Fla.Stat. §2.04 (Historical and Statutory Notes) (West Supp. 1991) (citations omitted)(emphasis added). Certainly, no basis exists for finding that the present situation warrants an exception to this general rule.

[5] Petitioners similarly do not dispute that the two-year limitation period in Section 95.11(4)(b) applies to the activities of hospitals, including hospital blood banks that screen blood and blood components for the treatment of human beings. Silva Br. at 21. It would defy both justice and reason to conclude that a free-

blood banks are health care providers subject to the statutory medical malpractice standards of liability compels the conclusion that the corresponding medical malpractice statute of limitations applies.

B. The Florida Legislature Has Declared That Blood Banks Are Health Care Providers Engaged In The Practice of Medicine

In concluding that the Florida medical malpractice statute of limitations applies to these cases, the Second District Court of Appeal properly relied on Florida's blood shield statute, reasoning that "[t]he legislature specifically included the procurement of blood in the services it declared to be medical services that are an intricate part of the practice of medicine." Silva v. Southwest Florida Blood Bank, Inc., 578 So.2d at 506, Florida, like most other states, has long recognized that blood services providers perform indispensable, inherently medical services. In 1969, in enacting its "blood shield statute," Fla. Stat. §672.316(5), the Florida Legislature expressly declared that:

> [T]he procurement, processing, storage, distribution, or use of whole blood, plasma, blood

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standing non-profit blood bank like Southwest should be treated for liability purposes differently than a hospital blood bank providing the identical medical services. See, e. g., Kozup v. Georgetown Univ., 663 F.Supp. 1048, 1059 (D.D.C. 1987) (finding "no principled basis" to distinguish community blood banks from hospital blood banks), aff'd in relevant part, 851 F.2d 437 (D.C. Cir. 1988); Balkowitsch v. Minneapolis War Mem. Blood Bank, Inc., 132 N.W. 2d 805, 810 (Minn. 1965) ("[W]e cannot concede that defendant [blood bank], which is a nonprofit corporation, should be treated differently than a hospital [for liability purposes].").

> products and blood derivatives, for the purpose of injecting or transfusing . . . any of them [] into the human body provides the general public with a desirable and necessary medical service[.]
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> * * *
>
> [T]he rendering of this service is an intricate part of the practice of medicine . . . .

Ch. 69-157, Laws of Florida (Preamble to the Florida Blood Shield Statute) (emphasis added).[6]

These characterizations are strong evidence that the Florida Legislature judges blood service providers to be medical professionals. Moreover, the very purpose of the Florida blood shield statute, like other similar statutes, is "bringing the provision of such services necessary for medical treatment into the same category as the provision of other medical services." Zichichi v. Middlesex Mem. Hosp., 528 A.2d 805, 810 (Conn. 1987) (interpreting Connecticut blood shield statute).

Other courts have similarly relied on analogous blood shield statutes in concluding that blood collectors are health care professionals. Thus, in Bradway v. American Nat'l Red Cross, No. 1:89-CV-1073 MHS (N.D. Ga. July 8, 1991) (Appended as Attachment A), appeal pending, the court held, based upon the Georgia blood

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[6] Florida's blood shield statute parallels statutes or common law holdings in all 49 other states and the District of Columbia and expressly characterizes blood collection as a "medical service" that is an "intricate part of the practice of medicine." The Legislature has similarly declared it to be the "policy of the state to encourage the maintenance of an adequate supply of voluntarily donated blood of the highest quality accessible to all in need of blood." Fla.Stat. §381.601(4) (Florida Blood Transfusion Act).

shield statute, that blood banks are health care providers subject to medical malpractice standards and to the medical malpractice statute of limitations, observing that "if the collection, processing, and supply of human blood are medical or health-care services, then the entity that provides these services is a health-care provider." Id., slip op. at 4 (Attachment A hereto).

Similarly, in Doe v. American Red Cross Blood Servs., 377 S.E. 2d 323, 326 (S.C. 1989), the court dealt with a blood shield statute that contained language virtually identical to that in Section 672.316(5) about "medical services." In giving effect to the legislature's determination that blood collection constitutes a medical service, the South Carolina Supreme Court unanimously reasoned that application of the professional standard was an inexorable consequence of that statute:

> [The blood shield statute] reflected a legislative intent to . . . characterize the transfusion of blood as a medical service. Since the transfusion of blood is characterized as a skilled medical service, then we hold that the Red Cross, as a blood collector and processor, should be treated as a professional. Thus, in order to maintain her action for negligence, Doe must prove that the Red Cross failed to conform to the generally recognized and accepted practices in its profession.

Id. at 326 (ellipsis in original) (citation omitted).

As these courts have done, this Court must give effect to every word of the blood shield statute, as long-settled Florida rules of statutory construction require. See, supra n.3. Florida's blood shield statute, in proclaiming that blood

collectors provide medical services and that these services are an "intricate part of the practice of medicine," is strong evidence that the Legislature regards blood banks as health care providers. This Court must therefore defer to that legislative determination and apply the medical malpractice statute of limitations in actions against them.

C. The Activities of Professional Blood Services Providers Constitute Medical Diagnosis, Care and Treatment

The activities of blood services providers, including the actions of Southwest which are at issue here, clearly constitute medical diagnosis, treatment and care for the benefit of human beings. The overriding goal of blood services providers is to supply an essential substance required for the care and treatment of human beings. Blood and its components are living tissue, available from no other source, which are drawn from one human being in a medical procedure, performed by a licensed medical professional, and transplanted into another human being, for the sole purpose of medical treatment and care.

Every step of the blood services process, by federal law and professional blood banking standards, is conducted by or under the supervision of a physician. See, e.g., 21 C.F.R. §§640.3, 640.4. Licensed health care professionals, usually registered nurses or other specially trained health professionals, take detailed health histories from donors, then subject them to limited physical examinations, including examination of the donor's temperature, pulse, blood pressure, and hemoglobin count and examination of the

donor's arms for evidence of intravenous drug use or infectious skin diseases. See, e.g., 21 C.F.R. §640.3. Blood is drawn only by venipuncturists or nurses in a medical procedure called a phlebotomy, performed under the supervision of a physician. 21 C.F.R. §640.4. Each blood donation undergoes extensive and complex diagnostic testing, both for blood type and atypical antibodies and for infectious diseases including, among others, hepatitis, syphilis, and, since 1985, the Human Immunodeficiency Virus ("HIV"). See, 21 C.F.R. §§610.40, 610.45, 640.5; Fla. Stat. §381.6105(1).[7] Similarly, the health history screening, limited physical examination, serologic testing, and processing performed by blood services providers are intimately tied to the diagnosis, prevention, care, and treatment of the disease or medical condition of the transfusion recipient. See, 21 C.F.R. §640.3. Donated blood must be specially processed and stored to retain its lifegiving, lifesaving properties.

The hospitals and transfusion recipients that ultimately receive blood components therefore rely on the medical skill and expertise of blood services providers in collecting, testing, and processing blood. Before it can be transfused into a patient, blood must be carefully matched for compatibility in the same way

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[7] Fla. Stat. §381.6105(1) provides, in relevant part, that "Every donation of blood . . . shall be tested prior to transfusion or other use for human immunodeficiency virus infection and other communicable diseases . . . ." Moreover, under Fla. Stat. §381.6105(5) & (7) blood banks must not only inform blood donors of positive HIV test results, but also counsel them on the meaning of the test results, means of prevention of spread of HIV and the availability of further medical care.

that other human organs that are transplanted must be matched to prevent rejection of the organ or other serious reactions in the recipient. Blood is transplanted into the recipient by a second medical procedure, the transfusion, also performed by health care professionals (usually nurses) acting at the direction and under the supervision of a physician who has determined the transfusion to be medically necessary.

For these and other reasons, as explained above, among others, the collection, processing, storage, and distribution of blood for the health care of human beings was properly declared by the Florida Legislature to be a medical service. See, Ch. 69-157, Laws of Florida; Fla. Stat. §672.316(5). Holding that blood collectors are health care providers thus not only comports with this Legislative finding but also with reality.

D. Blood Service Providers Operate Under Codes of Ethics and High Professional Standards Developed By Professional Consensus

As with other health care professionals, the standards of practice in blood services is set by a consensus of professionals. And, blood service providers are subject to strict licensing requirements, inspection, and accreditation by both governmental and private professional organizations.

The standards and codes of professional ethics that govern each step of the blood services process have been developed through a consensus of medical and health care professionals in

blood services, exercising their professional judgment based on their medical and scientific education, training, and experience. Such standards, which are now codified both in federal regulations and independently promulgated standards, have evolved since World War II, when blood collection first began in earnest in the United States.

The standards of care for blood banking can be derived from three interconnected sources: FDA regulations; the AABB's Standards for Blood Banks and Transfusion Services; and the practices of thousands of independent and hospital-based blood services facilities, which together define acceptable blood banking procedures to minimize risks of infectious diseases.[8]

Detailed federal standards govern donor medical screening, blood collection, laboratory testing, warning labels, storage, and processing of blood and blood components.[9] In order "to assure the production of blood and blood components of uniform high quality throughout the nation," FDA has developed and implemented a "comprehensive industry-wide regulatory program." 30 Fed.Reg. 18,614, 18,615 (May 28, 1974). Whole blood service facilities are licensed, inspected, and regulated by the FDA's Office of Blood

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[8] Blood services health professionals are subject not only to AABB and other blood services standards, but also to the codes of ethics of their underlying professions. Physicians and nurses, for example, are bound not only by the Hippocratic Oath and the Nurses' Oath, but also by codes of ethics promulgated by the American Medical Association and the American Nurses' Association.

[9] See generally, 21 C.F.R. Parts 606, 610, 640.

and Blood Products, whose director must approve the internal procedures of all blood service providers. 21 C.F.R. §640.3(a)(1).

Blood services establishments are also subject to peer-developed standards of care. Peer review and the development of standards of practice based upon peer consensus are key components of the practice of blood services professionals. In particular, the AABB acts as a vehicle for developing, changing, and rapidly disseminating the collective wisdom of the relevant professionals. Trained AABB volunteer professionals inspect both member and non-member blood centers, and the AABB issues accreditations to qualified institutions.

AABB members are subject to a strict Code of Ethics. AABB also promulgates the internationally recognized Standards for Blood Banks and Transfusion Services ("AABB Standards"). Recognizing the authoritativeness of the AABB Standards, both the National Blood Policy and the Code of Federal Regulations defer to them. 39 Fed.Reg. 32,702, 32,706 (Sept. 10, 1974); 21 C.F.R. §606.100(d)(1). The AABB Standards are developed and changed as often as every year through a consensus based process.[10] The AABB Standards are precisely the compilation of collective wisdom based on peer consensus and professional judgment that embodies the

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[10] See "How the AABB Standards are Created," AABB News Briefs (May 1991) (Appended hereto as Attachment B).

essence of professionalism.[11]

E. Challenges to Blood Services Providers' Medical Judgments Must be Judged By The Standards Applicable To The Licensed Professionals Making Such Judgments

As with any institution, blood services providers act through individuals. Nearly all of those individuals are trained health care professionals.

The health care professionals who conduct and supervise blood services -- primarily physicians, registered nurses, and laboratory technologists -- are all highly trained. Federal regulations require that all blood services personnel undergo adequate "educational background, training and experience, including professional training" in order to possess the requisite skills. 21 C.F.R. §606.20(b). In particular, the American Board of Medical Specialties has placed blood banking within the purview of the American Board of Pathology, which, in turn, has made blood services one of the eight board certified subspecialties that it recognizes. Accordingly, the American Board of Pathology certifies specialists in blood banking/transfusion medicine. Such certification requires a minimum of two additional years of full-

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[11] Many other medical professionals operate under similar written professional codes. See, e.g., American Board of Pathology, Information 1991; American College of Surgeons, Statement of Principles; American College of Obstetricians and Gynecologists, Standards of Obstetric-Gynecologic Services; American Nurses' Association, Standards of Nursing Practice; American Nurses' Association, Code for Nurses with Interpretive Statements; Joint Commission on Accreditation of Hospitals, Accreditation Manual for Hospitals.

time medical training beyond medical school internship, and residency. As the Second District Court below held "[p]articularly revealing of the medical nature of blood bank services is the fact that blood bank personnel must have scientific or technical backgrounds and must maintain a current knowledge of their areas of expertise." Silva v. Southwest Florida Blood Bank, 578 S.2d. at 506.

Just as the professional standard would apply to each of these professionals had Petitioners sued them individually, so too it applies to the organizations for who they acted. As the court held in Kaiser v. Memorial Blood Center:

> [I]t is clear that any alleged negligent acts or omissions on the part of the defendants occurred through its doctors or nurses who were responsible for setting the blood banks' policies and carrying out its activities . . .. Because the negligence complained of consists of the actions or inactions of health care professionals, Red Cross . . . may take advantage of the [medical malpractice] statute of limitation defense which is available to those individuals.

721 F.Supp. at 1076.

F. Direct Patient Contact Is Not Required for the Activities of Health Care Professionals to Constitute Rendition of Medical Care, Diagnosis and Treatment

In an unconvincing attempt to distinguish Southwest from the other health care providers covered by Section 95.11(4)(b), Petitioners argue that Southwest cannot assert the two year limitations period for medical malpractice actions because its health care professionals do not have a direct, face-to-face relationship with the recipients of their blood and blood products. Smith Br. at 23; Silva Br. at 15. This argument ignores the fact that the central goal of any blood bank's services is to provide blood and blood components for the medical care and treatment of patients.

For example, in addition to screening voluntarily donated blood, blood banks match units of blood and blood components to the specific traits and characteristics of the patient who will receive the blood, in order to protect the health and promote the treatment of that patient. Similarly, many blood bank physicians advise other physicians regarding indications for transfusions and for particular patients. Cf. Kaiser v. Memorial Blood Center of Minneapolis, Inc., 721 F.Supp. 1073, 1076 (D. Minn. 1989), certified to Minn. Sup. Ct., 938 F.2d 90 (8th Cir. April 10, 1991).

That a blood bank's professionals seldom come face to face with the recipients of its blood or blood components has no bearing on the application of the two year limitations period

contained in Section 95.11(4)(b). Many other health care providers explicitly included in the limitations provisions of section 95.11(4)(b) have no more face to face or direct contact with patients who whom they provide care than does Southwest. For example, a pathologist may have no direct patient contact whatsoever, yet clearly is within the scope of the statute. See, e.g., Wilhelm v. Traynor, 434 So.2d 1011, 1012-13 (Fla. 5th DCA 1983) (malpractice suit against pathologist who failed to diagnose cancer, in tissue samples from a patient he had never met, was barred by Section 95.11(4)(b)).[12] Likewise, other specialists consulted by a primary physician engage in no direct therapeutic relationship with the patient, yet they are clearly covered by Section 95.11(4)(b).[13]

Moreover, as recognized by the Second District Court of Appeal, Petitioners' contention that the blood bank professionals' lack of face-to-face contact in the care of blood recipients precludes application of §95.11(4)(b) is belied by their allegations that Southwest breached a duty towards them:

> However, we note that Silva's allegation of negligence implies that Southwest owed a duty toward Mrs. Silva that it breached. That implication reveals that a relationship existed between Southwest and Mrs. Silva

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[12] Cf. Hickman v. Employers' Fire Ins. Co., 311 So.2d 778, 779 (Fla. 4th DCA 1975) (medical malpractice suit against a laboratory pathologist).

[13] See, e.g., Nardone v. Reynolds, 333 So.2d 25, 30-31 (Fla. 1976) (predecessor statute of limitations barred medical malpractice action against consulting radiologist).

> despite the lack of direct contact between the two.

Silva v. Southwest Florida Blood Bank, Inc., 578 So.2d 503, 505 (Fla. 2d DCA 1991); accord Kaiser v. Memorial Blood Center, 721 F.Supp. at 1075 n.3. That duty, under Florida law as elsewhere,[14] is judged by a professional standard of care -- "that level of care, skill and treatment . . . recognized as acceptable and appropriate by reasonably prudent similar health care providers."[15] Thus, Petitioners' own allegations demonstrate that they are challenging Respondent Southwest's exercise of medical professional judgment.

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[14] See, e.g., Doe v. American Red Cross Blood Servs., 377 S.E.2d 323, 326 (S.C. 1989); Kozup v. Georgetown Univ., 663 F.Supp. 1048, 1055 (D.D.C. 1987), aff'd in relevant part, 851 F.2d 437 (D.C. Cir. 1988); Tufaro v. Methodist Hospital, Inc., 368 So.2d 1219, 1221 (La.Ct.App. 1979).

[15] See Fla.Stat. §766.102(1).

II. ALTHOUGH DURDEN WRONGLY HELD THAT BLOOD DONORS ARE NOT THE RECIPIENTS OF MEDICAL CARE AND TREATMENT, IT DOES NOT COMPEL THE CONCLUSION THAT BLOOD BANKS ARE NOT HEALTH CARE PROVIDERS.

In Durden v. American Hosp. Supply Corp., 375 So.2d 1096 (Fla. 3d DCA 1979), cert. denied, 386 So.2d 633 (Fla. 1980), the Third District Court of Appeal, while properly recognizing that blood banks are "health care providers,"[16] id. at 1099, nonetheless held that the blood bank there had provided no medical services to a paid blood donor who was infected by a dirty needle used to perform a phlebotomy, and hence was not covered by Section 95.11(4)(b). Id. The Court of Appeal properly refused to follow Durden in the present cases and correctly held that the two-year statute of limitations of Section 95.11(4)(b) requires dismissal of Petitioners' actions. Believing that this holding was in conflict with Durden, the Second District Court of Appeal certified its decisions for this Court's review.

To the extent that Durden is in conflict with the decisions below, this Court should decline to follow it. Durden wrongly held that because the plasma collector involved in that case had not provided medical care or treatment to Mr. Durden. Rather, contrary

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[16] Although Petitioners dispute the propriety of the Second District Court of Appeal's ruling that Southwest is a health care provider, that question is not even properly before this Court. No conflict exists between Durden and the present cases on the question of whether a blood bank such as Southwest is a "health care provider" -- all three cases properly accept that it is. Compare Durden, 375 So.2d at 1099 with Smith, 578 So.2d at 503, and Silva, 578 So.2d at 506. Thus, the fact that blood banks are health care providers subject to a medical professional standard of care is not before the Court; the only question before the Court is the applicable statute of limitations.

to the Third District Court's apparent conclusion, plasma donors undergo physical examination, health history screening and a medical procedure, using a needle and syringe to extract plasma from blood while returning red blood cells and other blood components back to the body. Plasma, like whole blood, underoges similar serologic testing. See generally 21 C.F.R. Subpart G (FDA regulations for plasma collectors); see also Fla. Stat. §381.6105(1). Indisputably, such activities constitute medical diagnosis, treatment and care. See, e.g., Mirsa, Inc. v. State Medical Board, 329 N.E.2d 106, 108-09 (Ohio 1975) (describing plasma collection procedures and concluding that they constitute the practice of medicine).

In any event, amicus respectfully submit that even if Durden was not incorrectly decided, it does not control here. Durden involved a negligence claim by a donor, not transfusion recipients who, without question received blood produced as part of essential medical treatment and care. As shown above, the questions of testing and screening donated blood are questions that go directly to patient care and treatment. Every step of the process by which Respondent Soutwest collected, processed, tested and provided the blood components Petitioners required during their medical treatment involved the exercise of medical judgment, expertise and procedures.

III. THE CONSENSUS OF COURTS IS THAT BLOOD SERVICES PROFESSIONALS PROVIDE A MEDICAL SERVICE

The majority of courts nationwide apply a professional or medical malpractice standard of care to volunteer whole blood services providers in cases involving transfusion-associated AIDS. Florida's statute mandating application of a professional standard of care to cases involving the professional activities of blood banks comports with these judicial decisions. Application of a medical malpractice standard of care to blood bank professionals, as other courts have recognized, compels application of a medical malpractice statute of limitations.

Court after court[17] holds blood services providers to a

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[17] See, e.g., Valdiviez v. United States, 884 F.2d 196, 199 (5th Cir. 1989) (screening procedures recommended by the Centers for Disease Control established applicable standard); Kozup v. Georgetown Univ., 663 F.Supp. 1048, 1055 (D.D.C. 1987), aff'd in relevant part, 851 F.2d 437 (D.C. Cir. 1988) (applicable standard of care established by the conduct of the medical community with respect to precautions against transfusion associated AIDS); Shelby v. St. Luke's Episcopal Hosp., No. H-86-3780 (S.D. Tex., March 17, 1988) (1988 W.L. 28996) (Attachment C hereto) (blood bank held to standard of care required for "professional medical services"); Doe v. American Red Cross Blood Servs., 377 S.E.2d 323, 326 (S.C. 1989) (collection and processing of blood for transfusion is a medical service, and a professional standard of care applies to that service); Anonymous Blood Recipient v. William Beaumont Hosp., No. 89-363705-NH, slip op. at 8 (Mich. Cir. Ct. Feb. 7, 1991) (Attachment D hereto) (professional negligence standard applies to blood collectors); Larison v. American Red Cross, No. 86 CV 1543, slip op. at 2 (Wisc. Cir. Ct. July 28, 1988) (Attachment E hereto) (degree of care exercised by other health care professionals in the same or similar circumstances"). See also Sawyer v. Methodist Hosp., 522 F.2d 1102, 1105 (6th Cir. 1975) (accordance with AABB standards); Tufaro v. Methodist Hosp., 368 So.2d 1219, 1221 (La. Ct.App. 1979) (satisfaction of AABB standards); Moore v. Underwood Mem. Hosp., 371 A.2d 105, 107 (N.J. 1977) (compliance with standards within the profession); Hines v. St. Joseph's Hosp., 527 P.2d 1075 (Ct. App.), cert. denied, 529 P.2d 1232 (N.M. 1974) (footnote continued on next page)

professional, medical malpractice standard of care. By the same standard, a medical malpractice statute of limitations should also govern cases involving blood services providers.

These cases compel the conclusion that the applicable statute of limitations for a negligence action is the medical malpractice statute of limitations. See, Kaiser v. Memorial Blood Center, 721 F.Supp. 1073, 1076 (D. Minn. 1989), certified to Minn. Sup. Ct., 938 F.2d 90 (8th Cir. April 10, 1991); Bradway v. American Nat'l Red Cross, No. 1:89-CV-1073-MHS, slip op. at 5 (N.D.Ga. July 8, 1991) appeal pending (Attachment A hereto).

Kaiser involved allegations of negligence strikingly similar to those in the present case. Given the nature of its employees, and the types of services it offered, the Kaiser court concluded that the American Red Cross was a health care professional for purposes of the medical malpractice statute of limitations, which it applied to the case. Id. at 1076.

Bradway arose under the Georgia statute of repose, which provided that no "action for medical malpractice" could be brought more than five years after the date of the allegedly negligent act. Id., slip op. at 2. The court determined, based in part on a blood shield statute worded simiarly to Florida's, that the activities of the American Red Cross are "medical or health-care services." Bradway, slip op. at 3 (Attachment A hereto.) The court concluded

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(footnote continued from preceding page)
(standard measured by what "blood bankers of ordinary care, skill and diligence" would do in the circumstances); Hutchins v. Blood Servs. of Montana, 506 P.2d 449, 452 (Mont. 1973) (same).

that:

> Although the [question] whether an action against a blood bank for the negligent collection and supply of human blood is an action for medical malpractice [] has not been resolved by [the Georgia courts], it is nevertheless clear from the Court's review of Georgia's statutory definition of an action for medical malpractice and treatment of blood banks generally that such an action is an action for medical malpractice.

Id., slip op. at 5 (citation omitted).

The Florida Legislature's statutory declaration of blood banks as health care providers and as institutions to which a professional medical malpractice standard of care applies conclusively demonstrates that blood banks are health care providers engaged in the rendition of medical diagnosis, treatment and care. Therefore, actions against blood bank professionals must be brought within the statutory limitations period for medical malpractice.

CONCLUSION

For the foregoing reasons, amicus respectfully urge the Court to rule that blood services providers such as Southwest are health care providers who render medical diagnosis, treatment and care, and are therefore subject to the Florida two-year medical malpractice statute of limitations.

Respectfully submitted,

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