IN THE SUPREME COURT OF FLORIDA
TALLAHASSEE, FLORIDA

KAYNAN FITCHNER, as Personal Representative of the ESTATE of CHASE FITCHNER, deceased,

Petitioner/Plaintiff,

vs.

CASE NO. SC08-174
Lower Tribunal Nos. 1D06-4475
1D06-4597

LIFESOUTH COMMUNITY BLOOD CENTERS, INC., a Florida corporation,

Respondent/Defendant.

AMICUS CURIAE BRIEF OF AMERICA'S BLOOD CENTERS, AMERICAN ASSOCIATION OF BLOOD BANKS, AND AMERICAN RED CROSS IN SUPPORT OF RESPONDENT

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TABLE OF CONTENTS

Page

IDENTITY OF *AMICI CURIAE* AND STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 4

ARGUMENT 5

I. INTRODUCTION. 5

II. BLOOD BANKING IS A CRITICAL LINK IN THE AMERICAN HEALTHCARE SYSTEM. 5

III. BY EXPRESSLY ADDING "BLOOD BANKS" TO THE COVERAGE OF FLORIDA'S MEDICAL LIABILITY LAW, THE LEGISLATURE INTENDED TO INCLUDE THE SCREENING OF BLOOD AND BLOOD DONORS. 9

IV. DECISIONS FROM OTHER JURISDICTIONS ALSO SUPPORT THE CONCLUSION THAT BLOOD BANKS PROVIDE MEDICAL SERVICES WHEN SCREENING DONORS AND THEIR BLOOD. 12

CONCLUSION 15

TABLE OF AUTHORITIES

Page

CASES

Bradway v. American National Red Cross, 426 S.E.2d 849 (Ga. 1993) ... 15

Coe v. Superior Court, 220 Cal.App.3d 48, 269 Cal.Rptr. 368 (1990) ... 14

Delcambre v. Blood Systems, Inc., 893 So.2d 23 (La. 2005) ... 15

Doe v. American National Red Cross, 500 N.W.2d 264 (Wis. 1993) ... 14

Doe v. American National Red Cross, 798 F.Supp. 301 (E.D.N.C. 1992) ... 14

Estate of Doe v. Vanderbilt University, Inc., 824 F.Supp. 746 (M.D. Tenn. 1993) ... 13, 15

LifeSouth Community Blood Centers, Inc. v. Fitchner, 970 So.2d 379 (Fla. 1st DCA 2007). ... 11

Miles Labs., Inc. v. Doe, 556 A.2d 1107 (Md. 1989) ... 14

Rasmussen v. South Florida Blood Service, Inc., 500 So.2d 533 (Fla. 1987) ... 2

Smith v. Paslode Corp., 7 F.3d 116 (8th Cir. 1993), *on remand*, *Smith v. American Red Cross*, 886 F.Supp. 1494 (E.D. Mo. 1995) ... 14

Wilson v. American Red Cross, 600 So.2d 216 (Ala. 1992) ... 14

STATUTES AND OTHER AUTHORITIES

§ 766.106, Fla. Stat. (2003). 10, 12

§ 766.202, Fla. Stat. (2003). 10

21 C.F.R. § 640.3(a). 6

21 C.F.R. § 640.4.. 6

L.E. Boulware, *et al*., "The Contribution of Sociodemographic, Medical, and Attitudinal Factors to Blood Donation Among the General Public," 42 Transfusion 669 (2002).. 8

Standards for Blood Banks and Transfusion Services, 25th ed. at 1.1.1 (AABB Press 2008). 7

IDENTITY OF *AMICI CURIAE* AND STATEMENT OF INTEREST

America's Blood Centers, the American Red Cross, and the American Association of Blood Banks have joined together to submit this brief in support of Respondent, LifeSouth Community Blood Centers, Inc. Together, these three organizations represent over 400 FDA-licensed and registered blood establishments and account for virtually all of the nation's volunteer donor blood supply. Our members share in the mission of helping to improve patient and donor care and safety.

America's Blood Centers (www.americasblood.org) is a non-profit corporation headquartered in Washington, DC. It is the voice of 76 non-profit community-based blood centers located in the U.S. and Canada. ABC member centers receive over 10 million volunteer blood donations per year. Those donations are transfused into over 2.5 million patients annually. ABC's members account for approximately half the U.S. blood supply and all of the Canadian blood supply. Respondent LifeSouth Community Blood Centers is a member of ABC.

ABC was organized for the purpose, among other things, of providing scientific and technical assistance to its members, sharing of best practices,

networking, serving as a collective voice in communicating with administrative and legislative bodies on regulatory and public policy issues affecting blood, and developing tools such as donor awareness programs to help enhance and preserve North America's blood supply.

As part of its public policy mission, ABC has appeared in the past as *amicus curiae* in other proceedings affecting blood centers, including a previous case before this Court. *Rasmussen v. South Florida Blood Service, Inc.*, 500 So.2d 533 (Fla. 1987).[1]

The American Association of Blood Banks (doing business as AABB) is a not-for-profit international association representing individuals and institutions involved in activities related to transfusion and cellular therapies, including transplantation medicine. AABB member facilities are responsible for collecting virtually all of the nation's blood supply and transfusing more than 80 percent of all blood and blood components used in the United States.

Since its inception in 1947, AABB has continued to support the highest standards of medical, technical and administrative performance;

[1] ABC was known at that time as the Council of Community Blood Centers.

scientific investigation; and clinical application through standards-setting, accreditation, education, advocacy and other activities. The association also is dedicated to increasing public awareness of the importance of voluntary blood donation.

Nearly 2,000 institutions, including community and hospital blood banks, hospital transfusion services and laboratories, and about 8,000 individuals, including physicians, nurses and other health care providers, scientists, administrators, medical technologists, blood donor recruiters, and public relations practitioners, are members of AABB.

The American Red Cross is a non-profit, charitable corporation, chartered by the United States Congress, which operates a nationwide blood system. Each year, the American Red Cross's 36 blood services regions collect approximately 6.5 million units of blood from approximately 4.5 million volunteer blood donors. From these donations, the Red Cross distributes approximately 9.5 million blood products each year to patients at thousands of hospitals and transfusion centers across the country.

SUMMARY OF ARGUMENT

Blood banks are a critical link in the nation's healthcare system. Transfusions – the "gift of life" – are an essential service, which save millions of lives annually. Nonprofit charitable blood centers fulfill almost all of these transfusion needs. The blood center is responsible for arranging the volunteer donation, collecting the blood, and screening both the donor and the blood itself, under the direction of one or more physicians. The blood center then makes the blood components available to hospitals or other health care facilities for transfusion.

In 2003, the Florida legislature enacted amendments to Florida's medical malpractice/medical negligence law to expressly include blood centers as "health care providers." Contrary to the plaintiff's suggestion, those amendments were not intended to be merely cosmetic, e.g., covering blood centers to the extent they provided typing and matching services that are generally provided by the hospital anyway.

Rather, with their focus on whether the blood center is rendering a "medical service," and their shift from "medical malpractice" to the more inclusive term "medical negligence," the 2003 amendments make clear that blood centers are covered for the vital medical service of screening blood

donors and blood donations for potential infectious diseases and other threats. When performing this medical service, the blood center's activities fall squarely within the medical negligence statute. For these reasons, the First District Court of Appeal's decision was correct and should be affirmed.

ARGUMENT

I. INTRODUCTION.

Plaintiff asserts that when the Florida legislature decided to expressly include blood banks in 2003 in its medical liability laws, it did not intend to include them when they are engaged in the critical tasks of screening blood donors, blood and blood derivatives for infectious disease. This proposition is inconsistent with the legislative history of the 2003 amendments, contrary to public policy, and simply does not make sense. The only logical interpretation of the 2003 amendments – and the one consistent with precedents in other jurisdictions – is that the Florida legislature intended to bring these screening activities within the scope of Florida's medical liability laws.

II. BLOOD BANKING IS A CRITICAL LINK IN THE AMERICAN HEALTHCARE SYSTEM.

Every year, approximately 20 million units of blood are donated by generous Americans. In an effort to avoid the transmission of blood-borne

illnesses and injuries, both the donors and their donations undergo a rigorous screening process under the supervision of physicians and other health care professionals. The donor provides a medical history and undergoes a physical examination. The donation is then subjected to testing for numerous infectious diseases (e.g., HIV, hepatitis B and C).

This screening process is required, by federal law and prevailing industry standards, to be conducted under the supervision of a licensed physician. Federal law provides that the suitability of the donor "shall be determined by a qualified physician or by persons under his supervision and trained in determining suitability." 21 C.F.R. § 640.3(a). Further, the federal regulations require that "[b]lood shall be drawn from the donor by a qualified physician or under his supervision by [trained] assistants." 21 C.F.R. § 640.4. The industry standard, developed by AABB and required of all of its nearly 2,000 institutional members, requires that blood banks have a medical director who is a licensed physician and "who shall have responsibility and authority for all medical and technical policies, processes and procedures – including those . . . that pertain to the care and safety of donors and/or transfusion recipients." *Standards for Blood Banks and Transfusion Services, 25th ed*. at 1.1.1 (AABB Press 2008).

In the United States, the entities collecting and testing these blood components are almost all nonprofit, charitable blood centers – either members of ABC or divisions of the American Red Cross. These centers are not in the business of making money and charge service fees that are only intended to cover their costs of operation. In the United States, voluntary blood donations save approximately five million lives a year. About one in seven hospitalized patients will need a blood transfusion. These transfusions support, among other things, treatments for cancer, major trauma, transplants, sickle cell anemia, and other surgeries. Even at the present time, blood centers (including centers in Florida) occasionally encounter shortages and have to call on other blood centers to provide necessary inventory, especially during disasters such as hurricanes. Moreover, the blood supply needs to be constantly replenished. For example, red cells have a shelf life of only 42 days and platelets only five days.

However, despite publicly and privately funded efforts to increase recruitment of blood donors, donation rates in the population have been regularly declining in recent years. *See* L.E. Boulware, *et al.*, "The Contribution of Sociodemographic, Medical, and Attitudinal Factors to Blood Donation Among the General Public," 42 Transfusion 669 (2002). At

the same time, the demand for blood has increased as our population ages and more aggressive, blood-intensive medical therapies are used to cure disease and prolong life.

Experts and relevant government agencies have stated that the blood supply is safer now than it has ever been before. *See* http://www.fda.gov/cber/faq/bldfaq.htm ("the blood supply is safer from infectious diseases than it has been at any other time"). Indeed, the events that gave rise to this case would not have happened today. When Chase Fitchner suffered his tragic death, urgent efforts were already underway to develop a diagnostic blood test for the West Nile Virus. Due to these efforts, a WNV test was implemented nationwide on an experimental IND basis beginning in June 2003, approximately eight months after Chase Fitchner was infected.[2]

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[2] Because it is undisputed that no test available to blood centers at the time would have detected the donor's exposure to the WNV, and it is further undisputed that this donor would have been allowed to donate (because his answers to the relevant questions would have been the same) regardless of whether a Spanish interpreter had been provided, *amici* believe that the plaintiff's case is missing a basic element of proximate cause. However, this amicus brief is confined to the question of the interpretation of the 2003 amendments.

Nevertheless, the nation's blood system remains dependent upon charitably-motivated donors and charitable blood centers. Some blood centers have annual *revenues* as low as $2 million. Many blood centers are effectively self-insured through a cooperative. For some blood centers, an adverse judgment in a single transfusion case could easily exceed the available insurance coverage and put the blood center out of business.

III. BY EXPRESSLY ADDING "BLOOD BANKS" TO THE COVERAGE OF FLORIDA'S MEDICAL LIABILITY LAW, THE LEGISLATURE INTENDED TO INCLUDE THE SCREENING OF BLOOD AND BLOOD DONORS.

Against this backdrop, in 2003, the Florida legislature expanded the list of "health care providers" covered by its medical liability law and specifically included "blood banks." § 766.202(4), Fla. Stat. (2003). The legislature at the same time also revised the presuit notice provisions of chapter 766 so they applied to any claim for "medical negligence," as well as claims for "medical malpractice." § 766.106(1), Fla. Stat. (2003).

Thus, Florida's medical liability law now requires certain presuit notice procedures to be followed in either a "medical negligence" case or a "medical malpractice" case, defined as a case arising out of the rendering of "medical services." § 766.106(1), Fla. Stat. (2003). Hence, the only

question presented in this appeal is whether LifeSouth – having been deemed a *health care provider* by the legislature in this context – would be considered to have provided a *medical service*. Since, among other things, federal regulations and industry standards require the suitability of donors and their blood to be determined by or under the supervision of a licensed physician, the answer to this question is self-evident.

The Florida legislature, in characterizing blood banks as "health care providers" for medical liability law purposes, intended to broaden the scope of the medical activity to be covered by the law. It follows, then, that by broadening the scope of chapter 766, the legislature intended to include all medical services carried out by blood banks. As reasoned by the appellate court, "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. Thus, the narrow scope proposed by [plaintiff] appears to be inconsistent with the stated legislative purpose." *LifeSouth Community Blood Centers, Inc. v. Fitchner*, 970 So.2d 379, 383 (Fla. 1st DCA 2007).

The plaintiff's own expert (a physician practicing in the field of transfusion medicine) made clear in his testimony that screening of donors and donations is a specialized medical activity:

> Transfusion medicine is a medical specialty that on the one side deals with blood transfusions in hospitals. It deals with patients in the hospital side, and *transfusion medicine deals with the qualification and collection of blood in blood centers*, so we deal with healthy people in the community on the blood center side and we deal with sick people in the hospital on the hospital side. (T55 354) (emphasis added).
>
> Q. And, Doctor, does your training of these doctors to run blood banks include all of the levels of safety in the blood donation process?
> A. Yes.
> Q. Does it include recruitment?
> A. Yes.
> Q. Does it include donor interviews?
> A. Yes.
> Q. Does it include postdonation screening?
> A. Yes.
> Q. Does it include the written forms that are given to donors?
> A. Yes.
> Q. Does it include quality control issues?
> A. Yes.
> Q. Does it also include blood testing?
> A. Yes. (T55 359).

Plaintiff's expert went on to testify that the "primary mission" of a blood bank is "to collect safe blood." (T55 387).

Plaintiff does not directly dispute any of this in her brief. Instead, plaintiff seeks to add a coverage requirement that the statute does not contain. Section 766.106 does not require the defendant to have provided treatment or care directly to the plaintiff. Rather, all it requires is that the defendant provided a "medical service" and that the claim arose out of that service. The physician-supervised screening of donors and donations performed by blood centers, which as described by plaintiff's own expert is indisputably their most important medical activity, falls within the term "medical service" as used in § 766.106.

IV. DECISIONS FROM OTHER JURISDICTIONS ALSO SUPPORT THE CONCLUSION THAT BLOOD BANKS PROVIDE MEDICAL SERVICES WHEN SCREENING DONORS AND THEIR BLOOD.

The issue that arose in this case has also surfaced in other jurisdictions. When a state's legislature has made an *express* decision to characterize blood banks as health care providers, courts have regularly found blood/donor screening lawsuits against those blood banks to be covered by the state's applicable medical liability law. As one court has reasoned, "It would be incongruous to hold the [blood center] to be a health care provider and not hold that its principal function was the provision of

medical care." *Estate of Doe v. Vanderbilt University, Inc*., 824 F.Supp. 746, 749 (M.D. Tenn. 1993). In *Estate of Doe*, the question before the court was whether a blood center was entitled to the three-year medical malpractice statute of repose. Noting that the same Tennessee Act imposed administrative fees on different categories of "health care providers" – and expressly included blood centers on such a list of "health care providers" – the court found that the three-year statute applied.

Some courts have had to decide whether blood centers are subject to certain laws where the legislation refers to health care providers but does not mention blood centers, as was originally the case in Florida. In the following cases, despite legislative silence, each of the courts found the blood center in question to be covered by the state's medical liability law for its blood safety assurance activities: *Wilson v. American Red Cross*, 600 So.2d 216 (Ala. 1992) (a blood center is a health care provider for purposes of the Alabama Medical Liability Act); *Coe v. Superior Court*, 220 Cal.App.3d 48, 269 Cal.Rptr. 368 (1990) (blood centers are health care providers under California's MICRA); *Smith v. Paslode Corp*., 7 F.3d 116 (8th Cir. 1993), *on remand*, *Smith v. American Red Cross*, 886 F.Supp. 1494

(E.D. Mo. 1995) (a blood center is a health care provider that provides health care services for purposes of Missouri's medical malpractice law).[3]

This is not, however, a legislative silence case and thus is far easier to decide. As noted earlier, whenever a state's legislature has expressly classified blood banks as health care providers, courts have regularly concluded that blood and donor screening activities are covered by the state's medical liability law. In addition to the aforementioned decision in *Estate of Doe*, in *Bradway v. American National Red Cross*, 426 S.E.2d 849 (Ga. 1993), the Georgia Supreme Court confronted the question whether a blood center in a donor/blood screening case could rely upon Georgia's statutes of limitations and repose for medical malpractice cases. The court reasoned that it could, because, among other things, blood centers were included in a statutory list of health care facilities. *Id*. at 851 n.1 (noting that

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[3] *But see, Miles Labs., Inc. v. Doe*, 556 A.2d 1107 (Md. 1989) (a blood center is not a health care provider under Maryland medical malpractice law); *Doe v. American National Red Cross*, 798 F.Supp. 301 (E.D.N.C. 1992) (blood centers are not health care providers under North Carolina medical malpractice law); *Doe v. American National Red Cross*, 500 N.W.2d 264 (Wis. 1993) (blood centers are not health care providers under the Wisconsin medical malpractice law).

under Georgia law blood banks are deemed "clinical laboratories," and clinical laboratories are deemed health care facilities).

The Louisiana Supreme Court's recent decision in *Delcambre v. Blood Systems, Inc.*, 893 So.2d 23 (La. 2005), proves the same point. In that case, the court noted that the Louisiana legislature had clearly added "blood banks" to the statute in order to bar claims by patients alleging negligent screening, such as the present case. *Id*. at 30-31. Although *amici* respectfully disagree with the court's further holding that claims by injured blood *donors* were not covered by the Louisiana statute, there was no doubt that blood and donor screening activities were so covered.

In other words, case law from other jurisdictions supports the conclusion that when a state explicitly includes blood centers in the state's medical liability reform law, the legislative purpose is to include their donor/blood screening activities.

CONCLUSION

In 2003, the Florida legislature corrected a potential unfairness. In the situation where a transfusion-related illness or injury is suspected, the hospital, the attending physician(s), their clinic(s), and the blood center are often all regarded as potential defendants. By including blood centers within

the medical liability law, the legislature assured that all defendants would be treated equally. Not only the hospital, the clinics, and the physicians would receive the protections of the legislation, but also the blood center – a nonprofit charity. It would be incongruous if a plaintiff could proceed directly into litigation with a nonprofit blood center while being forced to go through various presuit procedures before bringing suit against any of the other defendants. For these reasons, and those stated in the briefs of LifeSouth and the Florida Association of Blood Banks, ABC, AABB and the American Red Cross respectfully urge this Court to affirm the decision of the First District Court of Appeal.

Respectfully submitted,

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