THE STATE OF SOUTH CAROLINA
IN THE SUPREME COURT

APPEAL FROM YORK COUNTY
COURT OF COMMON PLEAS
THE HONORABLE R. SCOTT SPROUSE
CIRCUIT COURT JUDGE

RECEIVED
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S.C. SUPREME COURT

APPELLATE CASE NO. 2019-000838
CIVIL ACTION NO. 2015-CP-46-00882

Opinion No. 2019-UP-067 (S.C. Ct. App. Feb. 13, 2019)

Lorrie Dibernardo, individually and as the Personal Representative of the Estate of Anthony Dibernardo, deceased,

PETITIONER,

versus

Carolina Cardiology Associates, PA and Naresh Mori, MD,

RESPONDENTS,

RETURN TO PETITION FOR WRIT OF CERTIORARI

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The Trial Court correctly refused to give Petitioner's requested jury charge which would have invited the jury to find negligence by the physician based solely upon the occurrence of an adverse result during a medical procedure because such a charge is contrary to a plaintiff's burden of proof in a medical malpractice action and because furthermore, the evidence at trial, in which it was repeatedly shown that the procedure performed on Petitioner's decedent carried with it a number of known potential complications, did not support Petitioner's requested jury charge.

COUNTERSTATEMENT OF THE CASE

Petitioner Lorrie Dibernardo brought this medical malpractice action on March 23, 2015 individually and as the personal representative of the estate of Anthony Dibernardo against Respondents Carolina Cardiology Associates, PA ("Carolina Cardiology") and Naresh Mori, MD ("Dr. Mori") alleging that Mr. Dibernardo suffered a fatal injury during a pericardiocentesis, a procedure whereby a build-up of fluid around the heart is drained and removed through an inserted tube or catheter. [App. 65-82.] Respondents answered on April 29, 2015, denying the material allegations of the lawsuit and further asserting that any injuries were due to Mr. Dibernardo's underlying medical condition and complications arising therefrom. [App. 83-85.]

The case proceeded to trial before The Honorable R. Scott Sprouse and a jury on September 12, 2016 where for approximately three days the jury heard and considered the evidence. [App. 87-583.] On September 15, 2016, the jury returned a verdict in favor of Respondents, finding Dr. Mori did not violate generally accepted standards of medical care in his treatment of Mr. Dibernardo. [App. 33-35; 581-582.]

Petitioner appealed the verdict to the Court of Appeals on or about September 26, 2016 where she contended the Trial Court erred by declining to give the following jury charge:

> When a thing which causes injury is shown to be under the management of the defendant, and the accident is such as in the ordinary course of things does not happen if those who have management use proper care, it affords a reasonable

evidence, in the absence of explanation by the defendant, that the accident arose from a want of care.

[App. 640-661.]

On February 13, 2019, the Court of Appeals affirmed the jury's verdict in favor of Respondents. In rejecting Petitioner's requested jury charge, the Court of Appeals recognized that plaintiffs in a medical malpractice action are required to present evidence that the defendant departed from the recognized and generally accepted standards, practices, and procedures that a competent practitioner in the defendant's field of medicine would exercise under the same or similar circumstances. The Court of Appeals further cited the longstanding principles that "[a] doctor is not an insurer of health and negligence may not be inferred" and that factfinders are "not permitted to speculate that misfortune was the result of negligence in the absence of any evidence as to how the physicians deviated from the standard of care." [App.1-2.]

Petitioner filed a Petition for Rehearing with the Court of Appeals on March 13, 2019 which was denied April 24, 2019. [App. 3-14.] Petitioner has now filed this Petition for Writ of Certiorari with this Court seeking review of the Court of Appeals' decision.

COUNTERSTATEMENT OF FACTS

Mr. Dibernardo was a patient of Carolina Cardiology from approximately 2005 until his passing in 2013 and was primarily seen by Dr. Jay K. Shah, a cardiologist with Carolina Cardiology. [App. 161, l. 1 – 162, l. 9.] He was born with Noonan's syndrome, a genetic disorder which caused him to have a larger than normal heart, as well as other physical abnormalities. As a result, Mr. Dibernardo had a longstanding history of heart problems, including congestive heart failure. The left and right atria of his heart had dilated massively and already failed as a consequence of his genetic condition, and a pathologic over-thickening of his heart muscle led to

progressive heart failure for which he dealt with for many years. Over the years, he also developed significant edema, or swelling of the lower extremities. His heart had failed to such an extent that the fluid had built up in both the legs and the abdomen. Finally, Mr. Dibernardo had a condition known as atrial fibrillation for which he was on a blood thinner. Because of his numerous heart conditions, it became increasingly hard for him to breathe and his lifestyle was severely limited. [App. 144, ll. 13-25; 163, ll. 2-8; 164, ll. 10-19; 292, l. 19 – 293, l. 21; 396, l. 24 – 398, l. 17; 399, ll. 1-15; 461, l. 18 – 462, l. 7; 585; 587-589.]

Dr. Shah eventually diagnosed Mr. Dibernardo with a large pericardial effusion. [App. 206, ll. 21-22; 586.] A pericardial effusion occurs when there is a build-up of fluid in the sac surrounding the heart. [App. 163, ll. 9-15; 206, ll. 10-14; 399, ll. 12-15.] Mr. Dibernardo had a massive pericardial effusion which was causing high pressures within his heart chambers and in turn increasing the size of the heart preventing it from functioning normally which resulted in the shortness of breath experienced by Mr. Dibernardo. [App. 202, ll. 7-12; 294, ll. 10-17.]

Mr. Dibernardo's symptoms markedly worsened in the months preceding July 2013. [App. 176, ll. 23-25; 462, ll. 8-14.] On June 14, 2013, Dr. Shah saw Mr. Dibernardo and noted that Mr. Dibernardo complained of increasing difficulty breathing, ankle swelling, and the inability to walk in his house without labored breathing. [App. 176, ll. 9-22.]

Dr. Shah again saw Mr. Dibernardo on July 19, 2013 where he informed Dr. Shah that he could no longer walk in his house without losing the ability to breathe. [App. 175, ll. 10-12.] Dr. James Story, a cardiologist admitted at trial as an expert in the field of cardiology and invasive cardiology, opined that Mr. Dibernardo was suffering from class four heart failure – meaning the heart is failing to do its job as a pump such that a patient has signs and/or symptoms of heart failure

at rest and has difficulty conducting minimal activities - and "was a very sick man." [App. 394, ll. 2-10; 395, ll. 17-19; 398, ll. 7-16; 399, ll. 10-20; 419, ll. 2-10; 462, ll. 18-23.] Dr. Michael Foster, an interventional cardiologist also admitted at trial as an expert in the field of cardiology and invasive cardiology, concurred that Mr. Dibernardo was having class four congestive heart failure when he was seen on July 19, 2013. [App. 458, l. 22-459, l. 4; 460, ll. 22-24; 462, ll. 8-25.] The five-year survival rate for heart failure is only twenty percent. [App. 399, ll. 21-22.]

Dr. Shah convinced Mr. Dibernardo to be seen in the hospital to try to alleviate the large amount of fluid around his heart which was contributing to his decline and he agreed. [App. 175, ll. 8-15; 462, ll. 8-14.] He was admitted to Piedmont Medical Center by Dr. Shah on July 19, 2013. [App. 292, ll. 5-8; 585-586; 587-589.]

Dr. Shah believed Mr. Dibernardo needed a surgical evaluation for his worsening of fluid around the heart. Mr. Dibernardo had a difficult effusion and for that reason he was referred to surgery. For a complicated pericardial effusion, surgery is the preferred option for treating the effusion. Mr. Dibernardo, however, refused to undergo any surgical procedure to open the pericardium to drain the fluid. [App. 174, l. 23 – 175, l. 4; 277, ll. 7-9; 293, l. 22 – 294, l. 5; 351, ll. 11-15; 354, ll. 21-23; 400, ll. 9-18; 464, ll. 4-17.]

In the hospital, after declining direct surgical intervention, Mr. Dibernardo met with Dr. Mori, an interventional cardiologist with Carolina Cardiology. [App. 290, ll. 2-16; 292, ll. 3-18.] Because Mr. Dibernardo had declined surgery, Dr. Mori felt it was reasonable to offer to perform a procedure called a pericardiocentesis to remove the fluid. [App. 294, ll. 6-13.]

A pericardiocentesis is a procedure whereby fluid is drained and removed from the space around the heart usually through a tube or catheter. [App. 202, ll. 4-25.] If surgery is

eliminated as an option, a pericardiocentesis is the next best alternative to provide relief for a patient suffering from a pericardial effusion. All experts at trial, including Petitioner's expert, agreed it was appropriate for Dr. Mori to recommend Mr. Dibernardo undergo a pericardiocentesis to remove the fluid from around his heart in light of his refusal to undergo surgery. [App. 246, ll. 22-25; 253, ll. 6-10; 400, ll. 1-18; 464, ll. 4-20.]

Dr. Mori believed that Mr. Dibernardo's presenting symptoms – the shortness of breath and swelling of the legs and abdomen – were symptoms of heart failure and would become progressively worse without this treatment. [App. 325, ll. 8-20.] Petitioner's expert agreed that if left untreated, Mr. Dibernardo's heart condition would have continued on a downhill progression. [App. 254, ll. 9-14.]

As with all cardiac procedures, there are risks associated with even a properly performed pericardiocentesis. Because a pericardiocentesis involves the insertion of a needle and catheter or other tube into the space surrounding the heart containing the fluid, there is a risk of striking veins, vessels, or the heart muscle itself. Therefore, the most common and prominent complication from a pericardiocentesis is bleeding from injury to the heart or one of the vessels close to the heart. Other complications include arrhythmia and risk of infection. [App. 164, l. 22-165, l. 7; 175, ll. 16-23; 294, l. 18 – 295, l. 5; 400, l. 19-401, l. 16; 464, l. 21 – 465, l. 15.] Compounding the risk of complications arising from the procedure was Mr. Dibernardo's multiple underlying medical issues and physical conditions, including a deformed chest cavity. [App. 175, l. 25; 293, ll. 17-21; 297, ll. 20-23; 549, ll. 15-16.]

Mr. Dibernardo was advised of the risks of a pericardiocentesis and informed of the complications that could occur during the procedure, including bleeding. [App. 175, ll. 16-23;

295, ll. 6-11.] He understood all risks and complications of the procedure, continued to decline surgery, and opted to undergo a pericardiocentesis to try to improve his symptoms. He signed an informed consent indicating that he understood the procedure's risks. [App. 295, l. 12 – 296, l. 7.]

Mr. Dibernardo was on blood thinner and when he was admitted to the hospital on July 19, 2013, his blood was very thin. The procedure was delayed until July 22, 2013 to eliminate the blood thinner from his system so the blood could clot normally. [App. 176, ll. 1-7; 466, l. 5-21.]

At trial, Dr. Mori described the pericardiocentesis performed on Mr. Dibernardo on the morning of July 22, 2013. Dr. Mori's description of the procedure illustrated the numerous risks and complications he encountered due to not only the normal risks of a pericardiocentesis, but from Mr. Dibernardo's underlying medical conditions and physical anatomy.

The procedure began with the placement of a local anesthetic and a small incision in the chest area, and the subsequent insertion of a hollow needle with a syringe attached into the pericardial space through what is called the subxiphoid process, meaning the needle is inserted under the sternum, or breast bone, toward the heart at a 45-degree angle. [App. 297, ll. 1-5; 299, ll. 19-23; 402, l. 20 – 403, l. 3; 467, ll. 3-21.] The subxiphoid approach is the safest and most commonly used approach. [App. 245, ll. 18-20; 350, ll. 9-10; 351, ll. 20-22; 352, ll. 20-22.] A syringe is attached to the needle, aspirating as the needle is inserted so the physician will know when he has reached the pericardial space because fluid will be withdrawn. [App. 467, ll. 19-21.]

Dr. Mori explained that while an injury to the heart or a vessel should not occur, there is nevertheless always a risk of injury and bleeding because the physician is entering the space with a sharp object. Because the physician is inserting a sharp needle into the space surrounding the heart, there is a risk of injury by entering the blood vessels, either a vein or artery, or even the heart

muscle itself. In Mr. Dibernardo's case, the risk was magnified because of his enlarged heart. The enlarged heart was very close to the space in which the needle had to be inserted, significantly increasing the risk of injury and bleeding because of the limited space for the needle insertion without touching the heart. [App. 297, ll. 1-19; 299, ll. 19-23; 307, ll. 5-8.]

In addition, Mr. Dibernardo had a deformity in the chest area called ectis exoskeleton in which the chest bone is not flat but rather caved in. This chest deformity made it more difficult for Dr. Mori to access the area with the needle. [App. 293, ll. 17-21; 297, ll. 20-23; 549, ll. 15-16.]

Furthering complicating a pericardiocentesis procedure is that the needle is to be inserted into the space surrounding the heart – a fibrous membrane – in which fluid has accumulated. The fluid, however, is not evenly distributed around the heart. The width of fluid is different from one area to the next. If the fluid was evenly distributed, insertion of the needle without injury would be more possible because the physician would be aware of the exact space for needle insertion available before hitting the heart muscle or a vessel. But because the fluid is not distributed evenly, it is much more difficult for the physician to determine the amount of space available for the insertion. Particularly, in Mr. Dibernardo's case, there was not as much fluid around the right ventricle of his heart and most of the fluid was located behind the left ventricle. Therefore, there was not much fluid for access around the right ventricle where the needle was to be inserted which increased the risk of injury by hitting a vessel or the heart muscle itself. Dr. Mori discussed this complication with Mr. Dibernardo prior to the procedure. [App. 298, ll. 1-19; 306, l. 13 – 307, l. 5; 307, l. 16 – 308, l. 8; 309, ll. 9-11; 348, ll. 20-25.]

Finally, the heart is not static. Dr. Mori explained it moves around in the pericardial fluid. Therefore, the heart is not a fixed target. There is a risk of injury from the insertion of the needle

because the needle could stick the moving heart. Dr. Mori described this as a known complication from the procedure. [App. 307, ll. 9-15; 348, l. 20 – 349, l. 4; 401, l. 17 – 402, l. 1.]

In summary, the pericardiocentesis on Mr. Dibernardo began with Dr. Mori's insertion of the needle at about a 45 degree angle into the pericardial space under an echo (ultrasound) and fluoroscopy (similar to an x-ray movie) and under telemetry monitoring called electrocardiographic ("ECG") guidance[1]. These aids were to assist Dr. Mori in determining whether the needle was being inserted properly without injuring the heart or any vessel. [App. 298, l. 22 – 299, l. 2; 300, ll. 4-6; 344, ll. 2-5; 345, ll. 1-18; 347, ll. 2-15.]

At some point the procedure and insertion of the needle does become blind as the needle is entering the pericardial space. The physician is unable to see where the needle is going even with the use of x-ray technology because the x-ray is a two-dimensional imaging technique yet the heart is three-dimensional. As such, the x-ray imaging will at a point become of no value in providing guidance. [App. 299, ll. 3-5; 468, ll. 6-10.] As noted above, the blind approach, coupled with the size and swinging motion of the heart, as well as the lower amount of fluid around the right ventricle where the needle is inserted, all leads to a risk of bleeding. [App. 308, ll. 17-25.]

Dr. Mori inserted the needle using the xipoid approach as described above. Because of Mr. Dibernardo's difficult anatomy, it took Dr. Mori more than one attempt to insert the needle. [App. 314, ll. 2-6.] Once the physician feels fluid coming back, it is confirmed that the needle has

[1]While the Petitioner asserts Dr. Mori used EKG, or an alligator clip guidance, Dr. Mori used telemetry electrocariographic guidance. [App. 344, ll. 4-5; 345, ll. 12-18; 347, ll. 2-15.] There was no evidence at trial that Dr. Mori's use of telemetry electrocariographic guidance violated any standard of care. This is one reason why an alarm would not sound if Dr. Mori had hit the heart because of his use of different monitoring. [App. 209, ll. 1-6.] In addition, no alarm would sound if a vessel not near the heart was hit by the needle, which could have occurred in this case to cause Mr. Dibernardo's bleeding. [App. 209, ll. 1-6; 211, ll. 10-13; 447, l. 16 – 448, l. 8 (explaining only arteries or veins hit near the heart would signal an alarm).] Further, under ECG guidance, the physician instead monitors for premature beats that might signify that the physician is in contact with the ventricle. [App. 345, ll. 1-8.]

entered the pericardial space. [App. 299, ll. 6-11; 300, ll. 5-10; 468, ll. 11-15.] A flexible guide wire is passed through the center of the needle. This is a thin wire which serves as a guide for the catheter intended to be placed in the pericardium. A pigtail catheter, which is a relatively small catheter with a little loop on the end and a series of very small, tiny holes, is then inserted. The catheter is designed to allow fluid to filter into the catheter and be aspirated out through that catheter. Once it is determined on the fluoroscopy that the catheter is in place, the guide wire is removed. [App. 300, ll. 16-25; 468, l. 16 – 469, l. 6.]

Dr. Mori was able to confirm proper placement of the pigtail catheter around 10:40 a.m. [App. 301, ll. 3-18; 302, ll. 12-17; 309, ll. 12-17.] He began drawing the fluid from Mr. Dibernardo's pericardial space but what started out as pinkish fluid became "frank bloody." It took a few minutes for the color to change from pink to bloody. The fluid coming out became increasingly bloody, and Dr. Mori began having difficulty getting any fluid out at all. [App. 302, ll. 18-23; 314, l. 7 – 315, l. 2; 340, l. 4 – 341, l. 6; 404, ll. 2-9; 469, ll. 11-25.] The bleeding was concerning to Dr. Mori, and he believed if Mr. Dibernardo kept bleeding, he would develop a fatal condition known as cardiac tamponade. With cardiac tamponade, blood will eventually fill the pericardial space, the heart chambers become compressed, blood pressure drops, and the patient ultimately suffers cardiac arrest. [App. 302, l. 5 – 303, l. 21; 304, l. 8 – 305, l. 10; 315, ll. 14-18.]

Dr. Mori testified, and Respondents' experts concurred, that the echocardiogram showed the first signs of a blood clot around 10:53 a.m. which confirmed the existence of bleeding. [App. 309, l. 24 – 310, l. 17; 315, ll. 9-11; 335, ll. 4-9; 416, l. 24 – 417, l. 8; 457, ll. 11-17; 478, ll. 17-25.] The timing of the blood clot indicated that the bleeding occurred as a result of a needle injury, of

which, as Dr. Mori explained, was a known risk of the procedure compounded by the size of Mr. Dibernardo's heart, his chest anatomy, and heart's movement. [App. 310, ll. 5-23; 376, ll. 5-12.]

Dr. Mori initially removed the pigtail catheter to flush it out to try to remove any clot or debris out of the little holes and then reinserted it. [App. 404, ll. 14-17; 470, ll. 1-11.] Due to the hemorrhagic conversion from a pinkish fluid to bloody fluid and Dr. Mori's concerns about the bleeding and the overall condition of Mr. Dibernardo, Dr. Mori made a medical judgment to remove the catheter and change to a sheath. [App. 305, ll. 11-15; 335 ll. 4-9.]

The sheath is made of soft plastic with a single large hole at the end larger than the holes on the pigtail catheter. [App. 404, ll. 18-24; 470, ll. 13-15, ll. 23-25.] The sheath was inserted around 10:59 a.m. It was only inserted after Dr. Mori observed bleeding which occurred as a result of the needle injury. He recognized the needle injury early in the procedure and stated he had a definite change in color of the fluid from initial pink to frank blood towards the end. [App. 310, ll. 18-23.]

Dr. Mori chose to insert the sheath to try to save Mr. Dibernardo's life. [App. 310, l. 24 – 311, l. 1.] Dr. Mori was not getting enough fluid though the catheter which he suspected had clogged. The deliberate medical decision to change to the sheath was to treat the bleeding. [App. 311, ll. 3-8; 367, l. 17 – 368, l. 14.] Dr. Mori chose a larger and longer sheath over a smaller sheath because of the size of Mr. Dibernardo's heart. [App. 312, ll. 19-25.] Dr. Mori inserted enough guide wire to properly exchange the catheter for a sheath. [App. 312, l. 19 – 313, l. 10.]

Due to the presence of bleeding and Mr. Dibernardo's risk of developing cardiac tamponade and ultimately cardiac arrest, Dr. Mori testified it would not have been appropriate to have simply left in the original pigtail catheter for fluid to drain and to have sent Mr. Dibernardo to the intensive care unit. [App. 315, l. 3 – 316, l. 1.] Respondents' cardiology experts agreed

that leaving the original pigtail catheter in, attaching it to a drain, and sending the patient to the recovery room would not have been appropriate. [App. 418, ll. 10-22; 483. ll. 2-9.]

Because of the degree of bleeding, Dr. Mori was worried about injury to the heart and immediately called for the surgeon to find the source of the bleeding and take further measures to treat the source. [App. 316, ll. 2-10.] The surgeon was not available right away, and therefore, Dr. Mori began the process of an autotransfusion whereby blood from the source of the bleeding, here the pericardium, is withdrawn and given back to the patient through a sheath placed in the femoral vein – the vein in the leg. These efforts were undertaken to halt the drop in blood pressure. The autotransfusion was successful in stabilizing Mr. Dibernardo until the surgeon was available, and his blood pressure improved. He was alert and talking following the autotransfusion and never lost consciousness or became unresponsive. [App. 250, ll. 13-23; 316, l. 11 – 317, l. 8; 318, l. 18 – 319, l. 5; 405, ll. 5-12; 471, ll. 8-25.]

After Mr. Dibernardo was stabilized, the surgeon was able to see him and agreed Mr. Dibernardo needed surgery because of the significant bleeding. [App. 319, ll. 6-9.] During the surgery, the surgeon removed a large blood clot and found an abrasion across the right ventricle possibly from the sheath. The surgeon found no significant ongoing bleeding from this abrasion and placed a piece of SurgiSeal, a type of gel, on the abrasion "just in case." No stitches were required to repair the heart. [App. 321, l. 3 – 323, l. 2; 348, ll. 5-7; 408, ll. 2-22; 609.]

The sheath did not penetrate the heart. The surgeon found no hole in the heart. There was no damage to the heart requiring stitches. While the sheath came into contact with the right ventricle of the heart, such contact was a known potential risk of using the sheath but the use of the sheath was necessary to control the bleeding. [App. 320, l. 7 – 321, l. 2; 408, ll. 2-25; 409, ll. 1-4.]

Dr. Mori testified that the sheath's contact with the heart wall was not sufficient to account for all the blood he had to pull out of Mr. Dibernardo. The significant bleeding and the blood clot were present before the sheath placement occurred. Respondents' cardiology expert, Dr. Story, opined that the needle possibly struck a small artery or vessel, some which can be half a millimeter in diameter that the surgeon would not have seen. [App. 323, l. 7 – 324, l. 3; 343, ll. 18-22; 409, ll. 5-8; 418, ll. 2-9; 447, l. 16 – 448, l. 8; 452, l. 16 – 453, l. 1; 457, ll. 11-17.]

Dr. Story agreed that the injury to the heart was caused by the initial needle insertion based on the amount of bleeding and the timing of the blood clot and that Dr. Mori appropriately managed the bleeding complication that occurred during the procedure. [App. 418, ll. 2-5; 441, ll. 6-16.] He concurred that the sheath's contact with the heart wall could not have produced all the bleeding Dr. Mori encountered, further indicating that the bleeding was due to an injury caused by the initial needle insertion. [App. 409, ll. 1-8; 441, ll. 6-16.] By exchanging the catheter for a sheath, Dr. Mori managed a known complication – injury to the heart or vessel by the initial needle insertion – in accordance with the generally accepted standards of care.

Mr. Dibernardo survived the heart surgery and was placed on a ventilator. [App. 324, ll. 4-11.] Due to the surgery and his underlying medical conditions, Mr. Dibernardo was not successful in coming off the ventilator, and Mr. Dibernardo's family, specifically his wife, elected to terminate the ventilation. [App. 284, ll. 9-12; 326, ll. 13-17.] He died on July 24, 2013. [App. 636.] Following his death, Petitioner brought this medical malpractice action alleging that Respondents failed to perform an appropriate pericardiocentesis. [App. 65-82.]

At trial, Dr. Mori explained that even if the physician does everything properly during a pericardiocentesis and all precautions are taken, complications can still occur as did in Mr.

Dibernardo's case. [App. 348, ll. 12-18; 349, ll. 1-4, 10-20] He further testified that a pericardiocentesis is never 100 percent fool proof and that even if the procedure is performed with all appropriate steps taken, an injury can still occur. [App. 377, ll. 7-17; 380, ll. 1-4.] The fact that an injury occurs is not indicative of a physician's departure from the standard of care and even if the standard of care is met, a patient can still have a complication. [App. 380, ll. 5-15.]

Cardiology experts at trial, Dr. Story and Dr. Foster, concurred that Dr. Mori complied with the generally accepted standards of medical care in performing the pericardiocentesis and conducted the procedure appropriately. [App. 396, ll. 4-23; 403, ll. 17-19; 454, ll. 13-22; 484, ll. 9-17.] Dr. Story confirmed that a pericardiocentesis is a difficult procedure given the insertion of a needle in a tight space with a beating, moving heart. [App. 401, l. 10 – 402, l. 1.] He explained that even if safeguards are used, injuries can still occur and the fact that an injury or bleeding occurs during the procedure does not mean that the physician has done anything wrong. [App. 402, ll. 2-15; 446, ll. 23-24; 450, l. 23 – 451, l. 4; 452, ll. 12-15.] In a procedure involving the placement of a sharp needle near a beating heart, even if a physician performs all appropriate steps, an injury can occur and is not, alone, evidence of malpractice. [App. 454, ll. 4-12.] According to Dr. Story, complications can arise even if all standard procedures are followed for either the initial needle insertion or the insertion of the sheath. [App. 408, ll. 2-10; 450, l. 23 – 451, l. 4.]

Dr. Foster likewise agreed that complications can occur even when a physician properly performs a pericardiocentesis and that evidence of bleeding during the procedure is not by itself evidence that the physician committed malpractice. A physician can perform the procedure with the highest standard of care and still have a bleeding complication. [App. 464, l. 21 – 465, l. 25.]

Dr. Foster agreed with Dr. Story that complications can occur even if all proper techniques are followed for either the initial needle insertion or sheath insertion. [App. 498, ll. 5-14.]

In Dr. Foster's opinion, the bleeding that occurred during the procedure occurred because of the needle stick. The needle insertion is the most common reason why bleeding occurs during a pericardiocentesis, and the needle is the only sharp instrument utilized during the procedure. [App. 472, l. 23 – 473, l. 5.] Because the needle insertion is essentially a "blind stick," there are all sorts of bodily structures that can get in the way and can be injured, including organs grossly enlarged because of a patient's condition. [App. 473, ll. 6-13.] Dr. Foster also testified that it was not surprising that Dr. Mori did not initially draw back blood after the needle insertion because fluid will clear out of the needle first before blood is drawn back. [App. 473, l. 21 – 474, l. 2.]

While Petitioner argued at trial that Mr. Dibernardo's blood pressure did not drop until after the sheath was inserted, which she believed showed that the injury was caused by the sheath and not the needle, Dr. Foster explained that even for grave injuries, blood pressure does not begin to drop until usually thirty minutes after the injury. [App. 475, l. 8 – 477, l. 6.]

Dr. Foster also confirmed that the blood clot was visible on the echocardiogram prior to the insertion of the sheath and had to have occurred prior to the sheath's insertion. Given the blood that Dr. Mori was drawing out, the presence of the blood clot, and the timing of the blood pressure drop, Dr. Foster opined that the injury to Mr. Dibernardo occurred prior to the insertion of the sheath.[2] [App. 478, ll. 9-25; 500, l. 5 – 501, l. 7.]

[2]There was some dispute at trial about the timing of the blood clot and whether timing on the images from the cath lab were off. Petitioner tried to argue at trial the clot appeared after the sheath was inserted but Dr. Foster confirmed at trial that it would have been impossible for a blood clot to form only a minute and a half after the sheath was inserted even if Petitioner's timing was assumed. [App. 500, l. 5 – 501, l. 7.]

Petitioner's expert, Dr. Schob, agreed that performing a pericardiocentesis on a patient has a number of risks associated with it, including bleeding. [App. 245, l. 21 – 246, l. 2.] He further agreed that bleeding can occur even when the procedure is performed within the standard of care. [App. 246, ll. 3-6.] Dr. Schob acknowledged that the occurrence of a bleeding complication does not by itself mean that the physician committed malpractice. [App. 246, ll. 7-10; 257, ll. 4-10.] He conceded that the riskiest time of a pericardiocentesis is during the insertion of the needle. [App. 210, ll. 20-23.] He further agreed that the needle was the sharpest instrument utilized during Mr. Dibernardo's pericardiocentesis – sharper than the sheath or catheter. [App. 249, ll. 3-16.]

Respondents argued to the jury that a known, potential complication occurred during the pericardiocentesis performed on Mr. Dibernardo, a patient who had a massive heart and a large effusion along with a difficult anatomy, which Dr. Mori managed appropriately by exchanging the catheter for a sheath and by conducting an autotransfusion to stabilize Mr. Dibernardo.

At the close of the evidence, the Trial Court instructed the jury on the applicable law, including that to recover in a medical malpractice action, the plaintiff must prove the standard of care owed by the defendant to the patient and must prove the defendant negligently departed from that standard of care. [App. 561, l. 12 – 562, l. 14.] The Trial Court also correctly charged the jury that a "doctor is not an insurer of a cure or even of a positive result; therefore, the mere fact that a treatment does not benefit the patient or that it even harms the patient does not in and of itself mean that the defendant was negligent. A bad result, injury, death or failure to cure is not by itself enough to show that the defendant was negligent." [App. 562, ll. 15-22.] Finally, the Trial Court instructed the jury on the use of circumstantial evidence. [App. 558, l. 9 – 559, l. 2.]

After considering the evidence, the jury returned a defense verdict, finding Dr. Mori did

not violate the standard of care in treating Mr. Dibernardo. [App. 33-35.] At trial and on appeal, Petitioner contended that the Trial Court erred by declining to give the following jury charge:

> When a thing which causes injury is shown to be under the management of the defendant, and the accident is such as in the ordinary course of things does not happen if those who have management use proper care, it affords a reasonable evidence, in the absence of explanation by the defendant, that the accident arose from a want of care.

[App. 577, l. 8 – 578, l. 11; 639.]

The Trial Court rejected Petitioner's requested charge, ruling that such a charge "establishes a different standard, a different burden of proof that is not in accordance with our medical malpractice burden of proof that the plaintiff has." [App. 578, ll. 5-11.] On appeal and after consideration of the briefs filed by the parties, the Court of Appeals affirmed. [App. 1-2.]

ARGUMENT

The Trial Court correctly refused to give Petitioner's requested jury charge which would have invited the jury to find negligence by the physician based solely upon the occurrence of an adverse result during a medical procedure because such a charge is contrary to a plaintiff's burden of proof in a medical malpractice action and because furthermore, the evidence at trial, in which it was repeatedly shown that the procedure performed on Petitioner's decedent carried with it a number of known potential complications, did not support Petitioner's requested charge.

Seeking review of the Court of Appeals' affirmance of the Trial Court's refusal to give the control of the instrumentality charge, Petitioner challenges the Court of Appeals' reliance upon well-established principles of law that a plaintiff must present evidence of a defendant's breach of the generally accepted standards, practices, and procedures in a medical malpractice action and that an unfortunate result alone cannot establish a failure to meet the standard of care.

As an initial matter, Petitioner bases her Petition upon the spurious claim that the evidence at trial was undisputed that if the pericardiocentesis was performed correctly, the injury would not have occurred. In making this false claim, Petitioner ignores the copious amount of evidence that known complications occur even when the procedure is properly performed. As Petitioner has done throughout this appeal, she erringly takes the testimony of Dr. Mori and Respondents' expert out of context. While Dr. Mori testified that the goal of a pericardiocentesis is that injury should not occur if the procedure is done properly, this testimony should be construed against the backdrop of Dr. Mori's repeated explanation of the known complications which can occur during a properly performed pericardiocentesis. [App. 347, l. 16 – 349, l. 20; 374, l. 15 – 378, l. 22.] Dr. Story explained that while the intent of a proper pericardiocentesis is not to cause an injury to the patient, including the patient's heart, complications and injuries can occur even with the best standard of care and techniques used. [App. 445, l. 4 – 446, l. 24.]

Petitioner also contends that the trial testimony showed there was no explanation for Mr. Dibernardo's injury but for an improper control of the procedure. Once again, in making such an outlandish allegation, Petitioner neglects to account for all of the evidence regarding the known complications of the procedure. This includes evidence that the most common and prominent complication from a pericardiocentesis is bleeding, particularly because a pericardiocentesis involves the insertion of a needle and catheter or other tube into the space surrounding the heart which contains a risk of striking veins, vessels, or the heart muscle itself. See supra, pp. 5-8, 13-15.

Petitioner's expert agreed that a pericardiocentesis involves a number of risks and complications and that an occurrence of an injury during the procedure, whether from the use of needles or equipment such as a sheath, is not indicative of a physician's negligence or malpractice:

Q: Performing a pericardiocentesis on a patient has a number of risks associated it with it; is that true?

A: That's true.

Q: And bleeding is one of those risks; is that true?

A: Yes.

Q: And bleeding can occur even when the procedure is performed within the standard of care, can it not?

A: Yes, sir.

Q: And the fact that bleeding – a bleeding complication occurred by itself doesn't mean the physician did something wrong, does it?

A: In general, no.

. . .

Q: Needle injuries, equipment injuries, any kind of an injury will cause bleeding with this procedure; is that true?

A: In general, yes,

Q: And just because there's bleeding that doesn't mean somebody's committed a malpractice?

A: In general, that's correct.

[App. 245, l. 21 – 246, l. 10; 257, ll. 4-10.]

Petitioner further discounts that Mr. Dibernardo's physical condition also raised the risk of complications during a properly performed pericardiocentesis. Mr. Dibernardo's massively enlarged, moving, and beating heart increased the difficulty of inserting a needle into a tight space with little room available for the insertion of the needle. The fluid into which the needle was to be inserted was not evenly distributed and most of the fluid was located behind the left ventricle, not around the right ventricle near where the needle was to be inserted. The narrow amount of fluid

located at the needle insertion site left little room for the needle insertion with no risk of injury. Mr. Dibernardo's abnormal anatomy and deformity in his chest area causing it to cave in also made access to his heart area difficult. See supra, pp. 6-8.

Relying upon her distorted view of the evidence, Petitioner argues that her requested jury instruction should have been charged. The requested charge, however, does not accurately state the law and the burden of proof for a medical malpractice case in South Carolina which requires a plaintiff to present evidence that the defendant departed from the recognized and generally accepted standard, practices, and procedures in the defendant's field of medicine. Hoard ex rel. Hoard v. Roper Hosp., Inc., 387 S.C. 539, 546, 694 S.E.2d 1, 4-5 (2010). The requested charge is irreconcilable with the burden of proof in a medical malpractice case because it eliminates the plaintiff's burden to prove a defendant's departure from the applicable standard of care and instead would permit an inference, based upon the occurrence of an injury or adverse result during a medical procedure, that the defendant must have failed to properly adhere to the standard of care. Rather than having to present evidence and prove the standard of care and departure therefrom, the requested charge would permit a plaintiff to elude those requirements when a plaintiff could not prove them with properly admitted direct or circumstantial evidence.

Petitioner argues that the Court of Appeals has confused the doctrines of *res ipsa loquitur* and circumstantial evidence. While Petitioner's argument is somewhat difficult to discern and contradictory (in that she claims to not be relying on the fact of injury to prove negligence but then argues that negligence should be inferred when an injury occurs during a medical procedure), Petitioner seems to argue that she is not seeking to prove negligence by the fact of injury alone and

rather only wants a charge that permits an inference of negligence based upon the admitted circumstantial evidence. The Trial Court gave such a charge to the jury:

> Circumstantial evidence is proof of a chain of facts and circumstances indicating the existence of a fact. It is evidence which immediately establishes collateral facts from which the main fact may be inferred. Circumstantial evidence is based on inference and not on personal knowledge or observation. It is proof that does not actually establish the fact in question but that asserts or describes something else from which you may either reasonably infer the truth about the fact or at least reasonably infer an increase in the probability that the fact is true.
>
> For circumstantial evidence to be sufficient to warrant the finding of a fact the circumstances must lead to that fact with reasonable certainty. The facts and circumstances should be considered in light of ordinary experience and common sense.
>
> . . .
>
> The law makes absolutely no distinction between the weight or value to be given to either direct or circumstantial evidence, nor is a greater degree of certainty required of circumstantial evidence than of direct evidence.

[App. 558, ll. 9-25; 559, ll. 3-7.] Petitioner's purported concerns about the use of circumstantial evidence are therefore unfounded.

Petitioner further challenges the Court of Appeals' reliance on Fletcher v. Med. Univ. of South Carolina, 390 S.C. 458, 702 S.E.2d 372 (Ct. App. 2010) and attempts to create a conflict in the law where none exists. In Fletcher, the patient filed suit against a hospital for medical malpractice after the patient suffered complications following subclavian bypass surgery. Id. at 461-62, 702 S.E.2d at 373-74. The plaintiff's expert, while testifying that he believed the physicians deviated from the standard of care, also conceded that he did not find any evidence in the medical records which indicated the physicians used any improper techniques during the operation. The plaintiff's expert further acknowledged that complications could occur during the procedure in the absence of any surgical negligence. Because the plaintiff presented no evidence

of negligence in the performance of the procedure, the trial court directed a verdict in favor of the hospital on the medical malpractice claim. Id. at 462-63, 702 S.E.2d at 374.

In affirming the directed verdict on appeal, the Court of Appeals observed that the patient was in essence asking the Court "to conclude that the occurrence of a complication [was] itself evidence of negligence." Id. at 463-65, 702 S.E.2d at 374-75. Noting South Carolina's rejection of *res ipsa loquitur*, the Court of Appeals held it was "not permitted to speculate that misfortune was the result of negligence in the absence of any evidence as to how the physicians deviated from the standard of care." Id. at 464, 702 S.E.2d at 374.

In stressing the requirement that a plaintiff cannot rely on the fact of injury to establish a physician's negligence or departure from the standard of care in a medical malpractice case, the Fletcher court relied upon Bowie v. Hearn, 292 S.C. 223, 355 S.E.2d 550 (Ct. App. 1987) (Bowie I) which also addressed this very principle. In Bowie I, the plaintiff sued the physician who delivered him via cesarean section because he was cut on the cheek during the procedure, resulting in a scar. Id. at 224–25, 355 S.E.2d at 551. The plaintiff's expert testified the standard of care required the physician not to cut the baby. Id. at 226, 355 S.E.2d at 552. In analyzing the sufficiency of this testimony, the court referenced another oft-cited medical malpractice case:

> Under the plaintiff's reasoning in this case [Bowie I] the doctors in [Cox v. Lund, 286 S.C. 410, 334 S.E.2d 116 (1985)[3]] could simply have testified that normally colons are not perforated during colonoscopies, the standard of care, therefore, is a doctor should not perforate the colon, and to do so violates the standard of care. Such reasoning would, in effect, make a doctor an insurer of perfect result in every

[3]In Cox, the patient died because his colon was perforated during a colonoscopy, performed by the defendant-doctor. The decedent's administratrix, who brought the action, produced expert testimony detailing the appropriate measures in preparing the colon for the procedure and in conducting the procedure. The expert witnesses also detailed exactly how the defendant-doctor deviated from the standard of care; namely in not properly preparing the colon and in persisting with the procedure when he knew or should have known to stop.

surgical procedure. *A doctor is not an insurer of health and negligence may not be inferred.*

Bowie I, 292 S.C. at 227, 355 S.E.2d at 552 (emphasis added).

Bowie I was reversed by this Court in Bowie v. Hearn, 294 S.C. 344, 364 S.E.2d 469 (1988) (Bowie II) on the particular facts presented in that case, namely that the plaintiff had in fact presented evidence at trial that the physician deviated from the standard of care for a caesarean procedure by making three or four swipes with a scalpel in order to incise the uterine wall. This Court in Bowie II made no commentary on the legal analysis of the Court of Appeals in Bowie I and only reversed the case on the basis of the particular facts presented by the plaintiff relating to the standard of care. In relying upon Bowie I for its reasoning in Fletcher, the Court of Appeals specifically recognized the reversal of Bowie I but noted that the reasoning employed by the court in Bowie I remained instructive. Fletcher, 390 S.C. at 464, 702 S.E.2d at 374. This Court denied certiorari of Fletcher on May 25, 2012. Fletcher remains good law.

There is no conflict between Bowie II and Fletcher. Fletcher is based upon the well-established burden of proof in medical malpractice cases that a plaintiff must present evidence of the standard of care and a departure from that standard of care by the defendant and that where a plaintiff does not do so, the plaintiff cannot rely upon the injury or adverse result as proof of any negligence. This Court in Bowie II merely found that in that case, the plaintiff had presented such evidence sufficient to go before a jury.

Petitioner further contends that Fletcher somehow limits the use of inferences of negligence from circumstantial evidence in medical malpractice cases. Fletcher does no such thing. Inferences as to whether injuries are due to the negligence of a defendant can still be made from properly admitted evidence on the issue of standard of care and breaches of that standard of

care. What cannot be done is reliance upon the fact of injury occurring during a medical procedure to prove that a defendant did in fact depart from the standard of care. This is what Petitioner seeks to do with her requested jury charge, and it is contrary to the well-established principles set forth in the arena of medical malpractice law.

Even if the requested jury charge could ever be appropriate in a medical malpractice action, the charge would not have been proper in this case because it was repeatedly shown at trial that the procedure performed on Mr. Dibernardo carried with it a number of known potential complications. The requested charge required Petitioner to show (1) that the thing which caused injury was shown to be under the management of the defendant; (2) the accident was such as in the ordinary course of things does not happen if proper care is used; and (3) there was no other explanation by defendant of how the injury could have occurred. A failure of Petitioner to meet even one of these elements defeats the charge.

Dr. Mori and all experts, including Petitioner's expert, agreed there are numerous known complications of a properly performed pericardiocentesis. Petitioner cannot show that the injury here was one that would not have occurred in the ordinary course if proper care was used. Further, the requested charge would only be applicable if the defendant could not explain why the injury occurred. Dr. Mori and Respondents' experts explained how the injury could have occurred even with proper care. They discussed the known complications of the procedure and how Mr. Dibernardo's physical condition increased the risk of injury. Finally, the requested jury charge requires "the thing" which causes injury to be under the management of the defendant. In any procedure involving a patient such as Mr. Dibernardo, who has numerous pre-existing conditions

complicating a physician's performance of the procedure, a physician does not have full control and management over the patient's physical anatomy which contributes to the injury.

The requested charge would have permitted a jury to find negligence based upon solely the occurrence of injury during the medical procedure. The requested charge not only would have invoked the inapplicable doctrine of *res ipsa loquitur* into a medical malpractice action and relieved the plaintiff from its burden of proof, but was also not supported by the evidence presented at trial. Bleeding was a known complication of a pericardiocentesis and the risks from the procedure were heightened by Mr. Dibernardo's difficult anatomy, massively enlarged heart, and large pericardial effusion with uneven fluid distribution. While any injury to a patient during a medical procedure is unfortunate and undesired, the fact of an injury does not indicate malpractice. The Trial Court properly rejected the requested jury charge on the control of the instrumentality.

CONCLUSION

For the reasons set forth herein, Respondents respectfully request this Court to deny the Petition for Writ of Certiorari filed by Petitioner.

Respectfully submitted,

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July 10, 2019.

CERTIFICATE OF SERVICE

I, the undersigned, attorney for Respondents, Carolina Cardiology Associates, PA and Naresh Mori, MD, do hereby certify that I have this date served a copy of the foregoing Return to Petition for Writ of Certiorari, dated July 10, 2019, by causing the same to be deposited in a United States Postal Service mailbox, postage prepaid, addressed to counsel of record as indicated below:

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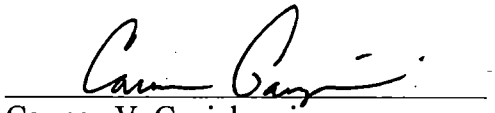

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