[Cite as *Balow v. Univ. of Cincinnati*, 2009-Ohio-5448.]

Court of Claims of Ohio
The Ohio Judicial Center
65 South Front Street, Third Floor
Columbus, OH 43215
614.387.9800 or 1.800.824.8263
www.cco.state.oh.us

RAY BALOW, Admr., etc.

Plaintiff

v.

THE UNIVERSITY OF CINCINNATI

Defendant
Case No. 2005-07810

Judge Joseph T. Clark

DECISION

{¶ 1} Plaintiff Ray Balow, Administrator of the Estate of his daughter, Alexandria Hall, brings this action alleging wrongful death. The issues of liability and damages were bifurcated and the case proceeded to trial on the issue of liability.

{¶ 2} At approximately 12:00 a.m. on September 8, 2004,[1] Hall was bitten by a venomous South American Urutu pit viper[2] that she kept in her home as a pet. Hall drove herself to Mercy Hospital in Mt. Airy and was initially treated there; however, medical personnel quickly transferred her to the emergency room (ER) at defendant's University Hospital (UH), a level one trauma center. Curtis Snook, M.D., was the attending physician on duty in the emergency room.

{¶ 3} Dr. Snook, who is also a toxicologist, began antivenin[3] protocol with

[1]All dates in this decision refer to the year 2004.

[2]"Bothrops" is a genus of venomous pit viper. "Bothrops alternatus" is the species name; "Urutu" is the common name.

[3]The terms "antivenin" and "antivenom" were used interchangeably at trial and both are defined as an antitoxin for venom.

"CroFab," a serum that is produced from the blood of sheep which have been injected with the venom of four species of snake native to North America.[4] Hall was initially administered four vials of CroFab at approximately 5:50 a.m. on September 8 and was subsequently given an additional two vials at approximately 7:30 a.m. Based upon laboratory testing of Hall's blood, she was diagnosed with a coagulopathy: a decrease in the ability of her blood to clot.

{¶ 4} Hall was later transferred from the ER and admitted to UH under the care of attending physician Mark Schroer, M.D. Hall was given fresh frozen plasma (FFP) at 3:45 p.m. and additional doses of CroFab at both 4:30 and 10:30 p.m., respectively. On September 9, Hall was given an additional dose of CroFab at 11:30 a.m.

{¶ 5} At 6:10 a.m. on September 10, Hall's lab values had returned to levels consistent with her admission to the ER. According to Dr. Schroer, he was especially concerned regarding the extremely low level of fibrinogen[5] present in Hall's blood. However, despite her poor lab values, Hall did not appear to be bleeding anywhere. Hall was given additional units of FFP at approximately 9:47 a.m. Because of the unique nature of Hall's ongoing coagulopathy, Dr. Schroer consulted with Herbert Flessa, M.D., a hematologist/oncologist. At 7:07 p.m. on September 10, Dr. Schroer ordered eight units of cryoprecipitate to try to increase Hall's fibrinogen level.[6]

{¶ 6} On September 11, at approximately 12:45 a.m., Hall complained of a severe headache and was sent for a CT scan. The scan revealed that she had suffered an intracranial bleed. Hall was transferred to the critical care unit and was intubated at approximately 4:00 a.m.; however, she lost consciousness and showed limited neurological response. Hall continued to receive FFP until her death at approximately 10:30 a.m.

{¶ 7} Plaintiff alleges that defendant's employees failed to meet the standard of care in their treatment of Hall. Specifically, plaintiff contends that if Dr. Schroer had administered additional doses of CroFab on September 10, Hall likely would have survived. Defendant denies liability and asserts that given the limited availability of data

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[4]The four species are: Western Diamondback Rattlesnake, Eastern Diamondback Rattlesnake, Mojave Rattlesnake, and Water Moccasin (Cottonmouth).

[5]Fibrinogen is a fibrous protein found in blood that helps the blood to clot.

regarding the treatment of Bothrops envenomation, the decision to treat Hall with a combination of CroFab and blood products was appropriate. In addition, defendant also contends that Hall was comparatively negligent for keeping a venomous snake in her home.

Law

{¶ 8} "In order to establish medical malpractice, it must be shown by a preponderance of the evidence that the injury complained of was caused by the doing of some particular thing or things that a physician or surgeon of ordinary skill, care and diligence would not have done under like or similar conditions or circumstances, or by the failure or omission to do some particular thing or things that such a physician or surgeon would have done under like or similar conditions and circumstances, and that the injury complained of was the direct result of such doing or failing to do some one or more of such particular things." *Bruni v. Tatsumi* (1976), 46 Ohio St.2d 127, 131, paragraph 1 of the syllabus.

Dr. Snook

{¶ 9} Dr. Snook testified that he was board-certified as a medical toxicologist and that he initially examined Hall when she presented to the ER.[7] Dr. Snook testified that Hall's lab values showed that she had a coagulopathy. He explained that a normal INR[8] range was from .9 to 1.1, and that when Hall's lab values were first taken, her INR was greater than 22.5. Dr. Snook further explained that a normal PT range is from 12.3 to 15.0 seconds, and that Hall's was greater than 150.0. Dr. Snook stated that in an "ideal world," he would have chosen an antivenin that was derived from the venom of an Urutu pit viper. However, when he called the Cincinnati Zoo because UH carried the zoo's antivenin stock, he was informed that the zoo did not house any Urutus. Dr. Snook also testified that a drug company, Wyeth, had made an antivenin at one time

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[6]Both cryoprecipitate and FFP are concentrated sources of substances found in blood that assist the blood to clot.

[7]Dr. Snook testified that on September 8, he worked until 7 p.m. and then went out of town for a meeting.

[8]International normalization ratio (INR) and protime (PT) are measurements of coagulability. Partial thromboplastin time (PTT) signifies the number of seconds it takes for blood to clot.

that was made from Bothrops venom, but that it was not available at the time of Hall's admission. Because CroFab was available, it was chosen for Hall's treatment. Dr. Snook explained that he followed the dosage guidelines contained on the package insert for CroFab.

{¶ 10} Dr. Snook stated that in addition to Hall's lab values, he also considered the clinical signs of a coagulopathy, which include bleeding at the gums, bleeding at the site of an IV line, and blood in the urine or stool, to be important in evaluating the course of treatment. After reviewing all of Hall's medical records, Dr. Snook testified that Hall never showed any clinical signs of bleeding.

Dr. Schroer

{¶ 11} Dr. Schroer testified that he was both a member of the faculty at University of Cincinnati and the attending physician in charge of Hall's care. Dr. Schroer stated that when he first examined Hall, he was informed that she had sustained a bite from a venomous snake. He noted that her PT, PTT, INR and fibrinogen levels were all abnormal and that she was suffering from a coagulopathy. The medical records show that when he first saw her, her PT was greater than 150, her PTT was greater than 200, her INR was greater than 22.5, and her fibrinogen was less than 60.[9] According to Dr. Schroer, on September 8, the plan was to support Hall's major organ systems, and that the expected course of care may have required a ventilator and repeated doses of antivenin. Dr. Schroer stated that his primary source for deciding on the dosage schedule of antivenin was an article he found in the New England Journal of Medicine.[10] Dr. Schroer followed the recommended dosing schedule and administered 2 vials of CroFab at 4:30 and 10:30 p.m., respectively, on September 8, and again at 11:30 a.m. on September 9.

{¶ 12} Dr. Schroer testified that on September 10, at 6:10 a.m, Hall's lab values had returned to the same abnormal levels that she had when she presented to the ER. Dr. Schroer testified that he was unsure why Hall, who had been administered 12 vials

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[9]According to the medical records, the normal ranges are the following: PT is 12.3 to 15.0; PTT is 25.7 to 35.7; INR is 0.9 to 1.1; and fibrinogen is 210 to 248.

[10]Gold, et al, Bites of Venomous Snakes (Aug. 1, 2002), N Engl J Med Vol. 347, No. 5, pps. 347-356. (Plaintiff's Exhibit 10.)

of CroFab and multiple units of FFP, continued to show such poor lab values but showed no clinical signs of such coagulopathy. Dr. Schroer testified that on September 10, he considered giving Hall additional CroFab, but that he was trying to figure out "what was really helping her." Dr. Schroer ordered a mixing study to determine whether there was some sort of inhibitor present in Hall's blood. Dr. Schroer testified that he was trying to determine whether the lab values were accurately reflecting Hall's condition.

{¶ 13} Dr. Schroer consulted Dr. Herbert Flessa, a hematologist, who recommended checking Hall's fibrinogen levels twice per day. Acting on Dr. Flessa's advice, at 7:10 p.m., Dr. Schroer ordered eight units of cryoprecipitate, which he described as "super-concentrated FFP," to be administered to Hall in the hope that it would increase her fibrinogen levels, which had remained too low to quantify since her arrival at the hospital. Dr. Schroer testified that he ordered Hall's lab values to be checked the following morning, and that if her levels had not improved, he would have considered additional CroFab at that time.

Dr. Flessa

{¶ 14} Herbert Flessa, M.D., testified that he was an emeritus professor of internal medicine, hematology and oncology at defendant's college of medicine. Dr. Flessa stated that he examined Hall on September 10 as a hematology consult because her fibrinogen level was so low. Dr. Flessa stated that in assessing her coagulation deficit, he suggested that Hall be given cryoprecipitate in order to raise the level of fibrinogen in her blood. Dr. Flessa testified that 8 units of cryoprecipitate is equivalent to the entire amount of fibrinogen present in an a normal adult.

Dr. Bush

{¶ 15} Plaintiff's first expert witness was Sean Bush, M.D. Since 1995, Dr. Bush has held a faculty appointment at Loma Linda University School of Medicine in California and has been an attending ER physician in the department of emergency medicine. Dr. Bush is board-certified in emergency medicine, has published numerous articles on snake bites, and was featured in a television series called "Venom ER." Dr.

Bush estimated that he has treated hundreds of snake bite victims, including himself. Dr. Bush testified that he has never treated a patient with an Urutu envenomation, but that he had been involved in the treatment of patients who had been bitten by Bothrops species in both South and Central America.

{¶ 16} Dr. Bush stated that Hall's medical records show that she suffered some local effects where she was bitten and that she had a coagulopathy which he described as a thinning of the blood. Dr. Bush explained that Hall's fibrinogen level was unmeasurable during her entire stay at UH, inasmuch as it was always less than 60. Dr. Bush also testified that Hall's protime measurements were "all over the map," but that there were also times, particularly after Hall was treated with FFP and CroFab that her protime would improve to near normal levels.

{¶ 17} Dr. Bush testified that the standard of care in treating snake bites is to give antivenin. According to Dr. Bush, the ideal treatment would be an antivenin made from a Bothrops or similar South American pit viper; however, as it was undisputed that the hospital did not have such a substance available, CroFab was chosen as the next best treatment. Dr. Bush opined that it was within the standard of care to give CroFab to Hall.

{¶ 18} Dr. Bush testified that antivenin binds to venom in the bloodstream and renders the venom inactive until it can be eliminated from the body. Dr. Bush criticized the fact that more CroFab was not administered to Hall when she "got worse." Dr. Bush likened the administration of blood products to treating the effect of an envenomation rather than its cause, a course of action that he described as "more or less futile."

{¶ 19} According to Dr. Bush, "recurrence phenomenon" occurs when the effects of envenomation return shortly after the antivenin wears off. Dr. Bush testified that CroFab has a shorter half-life relative to other antivenins, therefore it is eliminated from the body faster than the venom is. Dr. Bush further stated that when the effects of the venom return, it is recommended that additional CroFab be administered, as indicated.

{¶ 20} Dr. Bush identified an article upon which he based his testimony regarding the appropriate standard of care.[11] According to the Boyer article, an INR of greater

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[11]Boyer, et al., Recurrence Phenomena After Immunoglobulin Therapy for Snake Envenomations: Part 2. Guidelines for Clinical Management With Crotaline Fab Antivenom, (February 2001), Annals of Emergency Medicine, pps. 196-201 (Boyer article). (Plaintiff's Exhibit 6.)

than 3, a platelet count of less than 25 or a fibrinogen level of less than 60 indicates the necessity of treatment with additional antivenin.

{¶ 21} According to her medical records, Hall's final dose of CroFab was given at 11:30 a.m. on September 9. At 7:58 that evening, Hall's PT was 38.9 and her INR was 3.9. Dr. Bush testified that at that time, Hall should have been given at least an additional two vials of CroFab.

{¶ 22} According to Dr. Bush, defendant's treatment of Hall continued to fall below the standard of care on September 10. After the lab values taken at 6:10 a.m. returned to the same abnormal levels that Hall had upon admission, Dr. Schroer administered several units of FFP. Hall showed significant improvement in the lab values that were taken after the FFP was administered. However, Dr. Bush testified that Dr. Schroer ignored two facts. First, that after the administration of blood products, a patient will almost always show a transient improvement in lab values simply because the product begins to circulate throughout the bloodstream. The venom, however, will consume the additional clotting factors unless additional antivenin is given. Second, Dr. Bush reiterated that regardless of the improvement from the FFP, an INR of 3.5, per the Boyer article, warrants additional doses of CroFab. According to Dr. Bush, Dr. Schroer's decision to not administer additional doses of CroFab on September 10 fell below the standard of care.

{¶ 23} Dr. Bush testified that Dr. Schroer failed to recognize the concept of recurrence phenomenon, and that he neglected to consult other references, besides the New England Journal of Medicine, that discuss how to treat recurrence phenomenon. Dr. Bush opined that Dr. Schroer failed to meet the standard of care when he did not recognize recurrence phenomenon and failed to give Hall additional antivenin. Dr. Bush further opined that if Dr. Schroer had given Hall additional CroFab on the morning of September 10, she would not have had a spontaneous intracranial bleed, and that she would have survived the envenomation.

{¶ 24} On cross-examination, Dr. Bush acknowledged that he was not aware of any peer-reviewed medical literature that has analyzed the effects of CroFab on an envenomation by an Urutu pit viper. In addition, he acknowledged that Hall's first clinical sign of bleeding was when she complained of a headache on the morning of

September 11. Dr. Bush also acknowledged that Hall's platelet count was in the normal range throughout her hospitalization until the intracranial bleed was discovered.

Dr. Muncie

{¶ 25} Plaintiff's other expert witness, Herbert Lee Muncie, Jr., M.D., is board-certified in family medicine. Dr. Muncie testified that he had no specialized training in treating snake bites, and that he had never treated a patient for a snake bite. However, Dr. Muncie opined that the standard of care dictated that Dr. Schroer call Poison Control and be in constant contact with a toxicologist during the treatment of a snake bite. Dr. Muncie also testified that based upon the medical records, the effects of CroFab had worn off on September 10 and the standard of care required the administration of additional CroFab at that time.

{¶ 26} Dr. Muncie relied on the same article in the New England Journal of Medicine that Dr. Schroer had consulted to support his opinions. According to Muncie, the article included a suggested treatment schedule that called for an initial dose of four to six vials of CroFab. Then, if "initial control," defined as "a reversal or marked attenuation of the effects of the venom," were achieved, a dose of two vials of CroFab every six hours for the next 18 hours was recommended. If however, initial control were not achieved, another four to six vials should have been given. According to Dr. Muncie, Dr. Schroer deviated from this dosing schedule when he failed to administer any subsequent vials of CroFab on the morning of September 10. In his opinion, another four to six units of CroFab was warranted at that time. Dr. Muncie opined that more likely than not, if Hall had received additional CroFab on the morning of September 10, she would not have had an intracranial bleed. Dr. Muncie further opined that Hall's intracranial bleed was the result of a recurrence which could have been prevented if Schroer had given her additional doses of CroFab.

{¶ 27} On cross-examination, Dr. Muncie was unable to definitively state whether Dr. Schroer had achieved "initial control" in treating Hall with CroFab. In addition, Dr. Muncie stated that he was not aware of any studies where CroFab was used to treat envenomation from a Bothrops species of snake.

Dr. Curry

{¶ 28} Defendant's expert witness, Steven Curry, M.D., who is board-certified in medical toxicology and emergency medicine, is the Director of the Department of Medical Toxicology at Banner Good Samaritan Hospital and a professor of clinical medicine at the University of Arizona College of Medicine. Dr. Curry related that snake bites are relatively common in Arizona and that he sees approximately 250 to 270 snake bite patients per year. Dr. Curry testified that he had treated over 1,000 snake bites during his career but that he had never treated a Bothrops envenomation. In addition, Dr. Curry testified that he was involved in the initial development of CroFab including some of the clinical trials.

{¶ 29} Dr. Curry testified that a universal antivenin does not exist, and that there are over 100 antivenins that are available commercially. Much of Dr. Curry's testimony focused on whether CroFab was an effective treatment for a Bothrops envenomation. Dr. Curry testified that there are no published studies to determine whether CroFab is effective in treating envenomation by an Urutu. Dr. Curry further stated that CroFab is not effective against all venomous snakes found in North America. Dr. Curry emphasized that an effective antivenin must come from a snake with a similar venom. Dr. Curry stated that after a literature search, he found one paper that was authored in South America regarding the symptoms of an Urutu envenomation.

{¶ 30} Dr. Curry testified that the characteristics of venom of different species of snakes vary widely. In North American pit viper envenomations, symptoms include swelling and destruction of tissue, changes in the number of platelets, and at times excessive clotting of the blood while a Bothrops envenomation is more likely to damage the walls of the blood vessels themselves. Thus, when treating an envenomation patient, Dr. Curry stated that he consults a publication known as an "Anti-Venom Index" which identifies venomous animals and suitable substances with which to treat their respective envenomations. Dr. Curry testified that CroFab is not listed as a treatment for Bothrops envenomation. Finally, Dr. Curry testified that it was impossible in Hall's case to determine whether the CroFab, the blood products, or a combination of both caused her lab values to improve.

{¶ 31} Dr. Curry opined to a reasonable degree of medical probability that the

cause of Hall's death was a hemorrhage of the cerebellum; that she suffered a spontaneous hemorrhage in the early morning hours of September 11; and that the bleeding in her brain was caused by envenomation by an Urutu pit viper. Dr. Curry testified that with a Bothrops envenomation, it would be more likely that the blood vessels themselves would become damaged, and that damage along with the coagulopathy, would cause internal bleeding.

{¶ 32} Dr. Curry opined that Dr. Schroer did not deviate from the standard of care by failing to give Hall additional CroFab on September 10. Dr. Curry explained that CroFab is not claimed to be effective with a Bothrops envenomation and that no scientific data exist to prove that CroFab is effective with a Bothrops envenomation. Dr. Curry further opined that based upon Hall's medical records, it is impossible to determine whether the CroFab, the blood products, or a combination of both resulted in any benefit to Hall. Furthermore, Dr. Curry opined that Dr. Schroer met the standard of care in treating Hall's coagulopathy because he consulted a hematologist.

{¶ 33} Dr. Curry further opined that it cannot be known whether Hall would have survived if she had been given additional CroFab on September 10 because there is no scientific information to show that CroFab is effective in the treatment of an Urutu bite, and that the medical records do not show whether the CroFab that she was given was effective. In addition, Dr. Curry stated that the brain bleed may have occurred even if the coagulopathy were corrected because of the type of damage that Bothrops venom can inflict on blood vessels.

Conclusion

{¶ 34} Upon review of all the evidence, the court finds that plaintiff has failed to prove that defendant's treatment of Hall fell below the standard of care. The court finds that the testimony of both Drs. Bush and Curry was compelling.[12] However, given the fact that CroFab was not derived from the venom of a Bothrops species of snake, along with Dr. Curry's testimony regarding the wide variations in the characteristics of different snake venoms, the court finds that plaintiff has not proven that Dr. Schroer's failure to administer additional CroFab on September 10 was the proximate cause of Hall's brain

[12]The court notes that the testimony of Dr. Muncie was not particularly persuasive.

hemorrhage. All of the medical experts agreed that no studies regarding the effect of CroFab against a Bothrops envenomation have been reported in medical literature.

{¶ 35} Although it was undisputed that CroFab was the only antivenin available, the medical records are inconclusive as to whether the administration of CroFab, blood products, or a combination of both treatments resulted in any benefit to Hall. The court cannot conclude that additional CroFab on September 10 would have prevented Hall's brain hemorrhage.

{¶ 36} For the foregoing reasons, the court finds that plaintiff has failed to prove any of his claims by a preponderance of the evidence and, accordingly, judgment shall be rendered in favor of defendant. In light of this decision, any discussion of comparative negligence is rendered moot.

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Defendant
Case No. 2005-07810

Judge Joseph T. Clark

JUDGMENT ENTRY

This case was tried to the court on the issue of liability. The court has considered the evidence and, for the reasons set forth in the decision filed concurrently

herewith, judgment is rendered in favor of defendant. Court costs are assessed against plaintiff. The clerk shall serve upon all parties notice of this judgment and its date of entry upon the journal.

_____
JOSEPH T. CLARK
Judge

cc:

Daniel R. Forsythe
Karl W. Schedler
Assistant Attorneys General
150 East Gay Street, 18th Floor
Columbus, Ohio 43215-3130

John D. Holschuh Jr.
Sarah Tankersley
600 Vine Street, Suite 2700
Cincinnati, Ohio 45202

HTS/CJT/cmd
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