



THE FLORIDA SENATE
SPECIAL MASTER ON CLAIM BILLS

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DATE	COMM	ACTION
1/22/18	SM	Unfavorable
	JU	
	AHS	
	AP	

January 22, 2018

The Honorable Joe Negrón
President, The Florida Senate
Suite 409, The Capitol
Tallahassee, Florida 32399-1100

Re: **SB 42** – Senator Jose Rodriguez
HB 6505 – Representative Jenne
Relief of Vonshelle Brothers, Individually, and as the Natural Parent and
Guardian of Iyonna Hughey

SPECIAL MASTER'S FINAL REPORT

THIS IS A SETTLED EXCESS JUDGMENT CLAIM FOR \$1 MILLION. THE CLAIM SEEKS COMPENSATION FROM THE GENERAL REVENUE FUND FOR THE ALLEGED MEDICAL MALPRACTICE COMMITTED BY THE BREVARD COUNTY HEALTH DEPARTMENT DURING THE PRENATAL CARE OF VONSHELLE BROTHERS AND THE RESULTING DAMAGES TO HER DAUGHTER, IYONNA HUGHEY.

CASE SUMMARY:

Iyonna Hughey is a 7-year-old child who developed meningoencephalitis¹ soon after birth. The disease was both an infection of the meninges, the tissue covering the brain, and an infection of the brain tissue itself. The disease was caused by herpes simplex virus type 2. As a result, Iyonna is severely brain damaged and has profound developmental delays.

Vonshelle Brothers, the Claimant, is Iyonna's mother. Vonshelle alleges that the infection and resulting damage were caused by the failure of the Brevard County Health

¹ Iyonna's condition is referred to throughout the depositions as being meningoencephalitis, herpetic encephalopathy, and alternatively, herpetic encephalitis.

Department to sufficiently test her, the mother, for herpes. Adequate testing, the Claimant argued, would have led to Vonshelle's treatment with an anti-viral drug that would have prevented her from passing the virus to Lyonna. However, the evidence submitted through deposition testimony and medical records demonstrated that Vonshelle Brothers did not have the herpes simplex virus type 2. As a result, Lyonna must have contracted the herpes virus by contact with another person who had the infection. Because the Department did not cause the injuries to Lyonna, I recommend this claim unfavorably.

BACKGROUND INFORMATION: As a foundational matter, it is helpful to understand how Lyonna may have contracted the herpes virus. The herpes simplex viruses exist in two forms: herpes simplex virus type 1, which is oral herpes and abbreviated as HSV-1, and herpes simplex virus type 2, which is genital herpes and abbreviated as HSV-2.

HSV-1 generally causes sores near the mouth and lips, which are referred to as cold sores or fever blisters. HSV-1 is usually transmitted by oral-to-oral contact through oral secretions or sores on the skin and can be spread through sharing eating utensils and toothbrushes or kissing. With HSV-2, sores generally occur around the genitals or rectum. Genital herpes may be caused by HSV-1 or HSV-2, but most cases are caused by HSV-2 and are spread during sexual contact with someone who has a genital herpes type 2 infection. HSV-2 is highly contagious.

Many people infected with genital herpes do not display symptoms or have mild symptoms that are not noticed. When symptoms are noticed, they present as blisters, open ulcers, scabs, fever, muscle aches, or swollen lymph nodes. Both HSV-1 and HSV-2 remain in a person's body for life, even when no signs of infection are present. While it is rare, HSV-2 may be transmitted from a mother to her baby during

the delivery process.² The incubation period for HSV-1 or HSV-2 ranges anywhere from 2 to 12 days.³

FINDINGS OF FACT:

Initial Pre-Natal Visit

On March 16, 2010, Vonshelle Brothers visited the Brevard County Health Department to determine if she was pregnant.

Regina Pappagallo, a registered nurse, performed the initial intake interview and obtained a Patient History from Vonshelle.

To complete the Prenatal History form, Nurse Pappagallo asked Vonshelle two pages of extensive questions about her previous pregnancies, medical history, genetic screening, and infection history. The nurse recorded Vonshelle's response to each question. Under the "infection history" portion of the screening, Vonshelle responded "no" when asked if she or her partner had a history of genital herpes.⁴

Elena Cruz-Hunter, a certified nurse mid-wife and advanced registered nurse practitioner, then reviewed the patient history taken by Nurse Pappagallo, performed a vaginal exam, and conducted a Pap test to screen for the presence of pre-cancerous cells on the cervix.⁵

In conducting the initial physical examination, Ms. Cruz-Hunter was required to examine and note whether 17 specific areas of Vonshelle's body were normal or abnormal. The notations from the physical exam recorded no lesions, discharge, or inflammation in the areas of the vulva, vagina,

² WebMD, *Herpes Simplex: Herpes Type 1 and 2*, <http://www.webmd.com/genital-herpes/pain-management-herpes#1>; Center for Disease Control and Prevention, *2015 Sexually Transmitted Diseases Treatment Guidelines, Genital HSV Infections*, available at <https://www.cdc.gov/std/tg2015/herpes.htm>; World Health Organization, *Herpes simplex virus*, available at <http://www.who.int/mediacentre/factsheets/fs400/en/>; Mayo Clinic, *Genital herpes*, available at <http://www.mayoclinic.org/diseases-conditions/genital-herpes/basics/complications/con-20020893>; Johns Hopkins Medicine, *Herpes Meningoencephalitis*, available at http://www.hopkinsmedicine.org/healthlibrary/conditions/adult/nervous_system_disorders/herpes_meningoencephalitis_134,27/.

³ The American College of Obstetricians and Gynecologists, ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists, *Management of Herpes in Pregnancy*, Number 82, June 2007.

⁴ The Prenatal History indicates that Vonshelle acknowledged smoking 4 cigarettes per day for about 2 years and noted "daily" drug use/abuse for about 3 years, and drinking socially for about 1 year, but stated that she did not participate with tobacco, drugs, or alcohol when pregnant.

⁵ The Pap test, or Pap smear, is a screening, not a diagnostic test, in which cells are scraped from the cervix and sent to a lab for testing to determine if abnormal cells are present that could lead to cancer. Deposition testimony from medical professionals in the case and The American College of Obstetricians and Gynecologists, *Frequently Asked Questions*, available at <http://www.acog.org/Patients/FAQs/Cervical-Cancer-Screening#cervical>.

or cervix. She checked that each of the specific areas was normal. In her deposition, Ms. Cruz-Hunter testified that she did not see any indication of any lesions or any signs or symptoms that suggested the presence of the herpes simplex virus. The urine test performed on Vonshelle that day was negative and showed that her urine was “perfectly normal.” She noted that Vonshelle’s uterus size indicated that she was 8-10 weeks pregnant. The Pap test used to screen for precancers was sent to Quest Diagnostics for interpretation.

Pap Test Results from Quest Diagnostics

On March 22, 2010, Quest Diagnostics reported that the patient was 9 weeks pregnant⁶ and that the Pap test culture was satisfactory for evaluation. In the category titled “Interpretation/Result” the report stated:

“Negative for intraepithelial lesion or malignancy.
Cellular changes consistent with Herpes simplex virus
Shift in vaginal flora suggestive of bacterial vaginosis.”

Under the comment section, the following cryptic and ambiguous phrase was noted: “Queued for Alerts call.” No deposition testimony of any Quest pathologist was submitted to clarify what Quest meant by this ambiguous notation or if Quest made a call to the Brevard County Health Department alerting them to this observation. Accordingly, it is unclear if this phrase meant that Quest was indicating that someone in its office would call the clinician to alert them to this additional observation, given that someone at Quest was commenting on an issue outside the scope of the initial test for precancer or pre-malignancy.

Brevard County Health Department’s Lab Slip Tracking Policy

The Claimant attached, as an exhibit to Nurse Regina Pappagallo’s deposition, the cover page for the Brevard County Health Department Tracking Policy, dated 07-10-06, which did not contain the terms of the policy. The Claimant also attached the Brevard County Health Department Tracking [Policy for] Lab Slips and Missed Appointments, dated 7/15/10,⁷ which contained the policy’s contents. This

⁶ This was Vonshelle’s third pregnancy, which would be followed by two additional pregnancies. None of the other four pregnancies involved herpes simplex virus issues or injuries.

⁷ The date of “7/15/10” is almost 4 months after Vonshelle visited the Brevard County Health Department. It is unclear if this policy was also in place when she visited the Department for her initial pregnancy exam.

policy explains what the staff members are to do when they receive the result of lab tests, like the results of Vonshelle's Pap test.

The policy for reviewing lab slips was a two-step process, and how the second step was to be completed depended on whether the lab test results were positive or negative. The first step in the policy required that a nurse review and initial the incoming lab slip. The second step required the medical staff to file the slip in the client's medical record if the results were negative, or pull the slip and give it to a nurse/clinician for additional orders if the results were positive. Under the policy, all abnormal slips needed to be signed by a clinician. The nurse would then determine how the client was to be contacted about the positive results—whether by the health support technician or nurse and whether by a letter or phone call. Someone was then required to make three documented attempts to reach the client. The Sr. CHN Supervisor⁸ or designee was to determine if there were a need to send a certified letter. The policy also established the procedure for notating when a client failed to make an appointment.

The Quest Diagnostic lab report for Vonshelle was initialed by Nurse Pappagallo in the upper right hand corner, as required. A checkmark was placed at the end of the phrase “Negative for intraepithelial lesion of malignancy” indicating that the diagnosis was reviewed. Accordingly, the Pap test lab slip was negative for a malignancy, so it was placed in Vonshelle's medical records, in compliance with the policy. The purpose of the test was to determine the existence of precancerous cells, not herpes or another sexually transmitted disease. Among Vonshelle's additional medical records, labeled “Laboratory Results” and the category of Pap Test, it is recorded “3/16/10” and the word “normal” is circled. If the results had been abnormal, or positive for a malignancy, the records should have been pulled by the medical records staff and given to the nurse/clinician for possible orders and the nurse would have determined the type of contact with the patient that was appropriate.

What is confusing in this case but important to the issue of liability is the meaning of the unusual and added verbiage stating, “Cellular changes consistent with Herpes simplex

⁸ It is unclear what this designation means.

virus.” This is apparently an unusual notation to be placed on a Pap test result. According to the deposition testimony of Nurse Pappagallo, she had never seen this writing on another Pap smear; it was the first time she had ever seen this notation. Dr. Mark Sargent, the Brevard County Health Department physician who was Vonshelle’s obstetrician, testified that he had “never even heard of this result on a pap smear . . . it’s not even supposed to be on a pap smear and I’ve never seen it on a pap smear.” He said that he did not know if the nurse was confused by the remark, because it was so unusual, but if he had seen the notation he would have certainly pursued it.

Additionally, there is no evidence in the record to demonstrate that Quest Diagnostic contacted the Clinic as suggested by the phrase “Queued for Alerts call.” Further, Quest’s lab results did not state whether herpes simplex virus type 1 or type 2 might be indicated.

No additional tests were performed by the Brevard County Health Department during the pregnancy to determine whether Vonshelle was infected with the herpes virus. Additionally, there is no documentation in the medical records that Vonshelle complained to the medical staff or requested prescriptions to alleviate the common symptoms of the herpes simplex virus.

The Pregnancy

According to the medical records, the pregnancy was not without complications and Vonshelle did not consistently comply with medical advice. Vonshelle had low amniotic fluid, which can be dangerous for the baby. She was admitted to the hospital for a 3-day stay in September to monitor pre-term contractions and preterm labor at 31 weeks. She was advised to stay 3 days and increase her fluids. Vonshelle left the hospital 1 day early, against the doctor’s recommendation. She was given multiple sonograms throughout the pregnancy to monitor the level of amniotic fluid.

Because she had given birth prematurely in two earlier pregnancies, Vonshelle was given a prescription of progesterone to help reduce the risk of early labor.⁹ The

⁹ In his deposition, Dr. Mark Sargent testified that he gave the nurse a progesterone prescription for Vonshelle on August 12, but Vonshelle later denied ever having it. He wrote another prescription for progesterone on August 26, and handed the prescription to Vonshelle. Dr. Sargent had someone call Vonshelle on August 30 to follow up

medical notes indicate that she smoked cigarettes and declined Quitline¹⁰ at her initial visit and stated that she could quit smoking on her own.¹¹

Delivery

On October 14, 2010, an ultrasound and non-stress test were performed on Vonshelle. Because of the stress test results and decreased fetal movement, she was admitted to the labor and delivery unit at Wuesthoff Memorial Hospital in Melbourne and labor was induced. Vonshelle gave birth by vaginal delivery to Lyonna Hughey that night at 36 weeks and 4 days gestation.

On October 16, 2010, Vonshelle and Lyonna were discharged 2 days later, both in good condition. In her deposition testimony, Vonshelle stated that at the time of Lyonna's delivery she did not have any lesions or sores on her vagina or elsewhere on her body. This was confirmed by Dr. Mark Sargent, the delivering doctor, who stated that Vonshelle never indicated any lesions either pre-pregnancy, early pregnancy, or during the labor and delivery process. He noted that other than the "spurious finding on the pap smear, there is no indication that she ever had herpes."

Vonshelle returned with Lyonna to her home where her two older daughters were living and another woman, Cynthia Retland. It is unclear if Cynthia Retland's sons were also living in the home at that time.

Emergency Room Visit

On October 31, 2010, at about 11:00 p.m., Vonshelle took Lyonna to the emergency room at Wuesthoff because Lyonna had a fever, was lethargic and pale, was not eating, and was sleeping a lot. She stated in her deposition that the fever may have been present for a couple of days. Vonshelle stated that

to make certain that the prescription was filled, but Vonshelle said she was unable to fill the prescription. Vonshelle did not show for her next appointment, and it is unclear when she actually began taking the progesterone.

¹⁰ Quitline is a tobacco cessation service that supplies nicotine replacement therapy at no cost to the participants. http://c.ymcdn.com/sites/www.naquitline.org/resource/resmgr/ppp/fl_bureau_of_tobacco_prevent.pdf.

¹¹ Smoking during pregnancy can cause problems with the placenta and reduce a baby's food and oxygen. Smoking is known to increase the risk that a baby will be born prematurely or have a low birth weight. This increases the likelihood that the baby will be sick and require a longer hospitalization. See Centers for Disease Control and Prevention, Reproductive Health, *Tobacco Use and Pregnancy*, available at <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/tobaccousepregnancy/index.htm>.

her mother kept saying that night that something was not right with Lyonna, and she was pale.

Vonshelle's deposition states that she signed in and spoke with a nurse in the front area of the waiting room. She estimates that she was in the waiting room for a total of about 30 minutes during which she spoke with a nurse for about 10 minutes. Vonshelle said that the nurse told her that the way Lyonna was behaving was "what newborns do, they sleep." Vonshelle stated that the nurse told her to take a cold rag and rub it over Lyonna's body and see if that would wake her. Vonshelle stated that the nurse told her to go home and come back in the morning if something was not right. Vonshelle left the emergency room and did not wait for her name to be called to see medical personnel. She stated that she thought, "maybe we are just overreacting. So, we left."

Vonshelle stated that she did not tell the nurse that Lyonna was lethargic or had a fever. Vonshelle added that she really thought nothing was wrong. She took Lyonna home, and both slept through the night from about midnight until 7:00 a.m.

Wuesthoff Memorial Hospital

On November 1, the next morning, when Vonshelle woke, she noticed that Lyonna was not responsive, her eyes were rolling back in her head, her lips were dark, she would not eat, and her breathing was shallow. Vonshelle called her mother who came and drove them to the Wuesthoff Hospital. She did not call 911.

Transfer to Arnold Palmer Hospital

The staff at Wuesthoff performed a lumbar puncture on Lyonna and drew spinal fluid. She was transferred to Arnold Palmer Hospital for Children in Orlando for further evaluation and care. The lumbar puncture was repeated and the results came back positive for herpes simplex virus type 2. Lyonna was diagnosed with herpes meningoencephalitis, meaning that her brain tissue was infected. She remained at Arnold Palmer for 36 days, from November 1, 2010 until her discharge on December 6, 2010. While at the hospital, Lyonna was treated intravenously with acyclovir for 21 days, to stop the viral growth, followed by oral acyclovir for suppressive therapy. She was fed through a gastric tube and was on a ventilator.

lyonna's Injuries and Disabilities

The viral infection caused severe brain damage and neurological disabilities that impair Lyonna's ability to develop and function as a normal child. This was caused by the herpes simplex virus type 2. At the time of the special master hearing Lyonna spoke only about 20 words, could feed herself, but could not walk independently or bathe herself, and wore diapers each day. She was in kindergarten in a special needs program at Palm Bay Elementary. Lyonna rode a special needs school bus to and from school each day. She had a walker and wheelchair at school for mobility. She enjoyed playing games on a tablet, coloring, and watching television. The professionals who have observed Lyonna believe that she is going to need continuous care throughout her lifetime and will never be able to live or function independently due to the brain damage she received from the herpes meningoencephalitis.

Subsequent Herpes Tests

Vonshelle returned to the Brevard County Health Department for a subsequent pregnancy test in 2014, almost 4 years after Lyonna's birth. She did not alert the Health Department that she might be carrying the herpes virus, which allegedly caused the severe brain damage to Lyonna. If Vonshelle believed she had herpes, one would have expected her to disclose this information to the Department in order to protect her next child from the virus and the potential for brain damage. However, the Department recognized Vonshelle's name because of the ongoing litigation and tested her for herpes to determine if an anti-viral medication needed to be prescribed to prevent the fetus from getting the disease.

Blood was drawn from Vonshelle on August 1, 2014, for two separate HerpeSelect tests¹² and sent to different labs. The first blood sample was collected on August 1, 2014, and tested by Health Management System. The second blood sample was collected a few minutes later and tested by Quest Diagnostics. Both tests were negative for HSV-1 and HSV-2.¹³

¹² According to a website, the HerpeSelect test "is the most commonly used HSV antibody test in the U.S." The test can detect antibodies and differentiate between HSV-1 and HSV-2. It generally takes about 3-6 weeks for someone to develop a detectable amount of antibodies to the herpes simplex virus. Most everyone will have detectable antibodies 16 weeks after exposure. <http://www.healthassist.net/medical/herpes-test.shtml>

¹³ There is a third DOH hsv test result in the records, apart from the two tests discussed above, which shows that more blood was drawn from Vonshelle on August 4, 2014, and also sent to Quest Diagnostics. This was also

On November 20, 2014, Vonshelle's attorneys initiated a third, and different type, of herpes test on Vonshelle. Blood was collected in Florida for an HSV Western Blot test¹⁴ and sent overnight to the University of Washington Medical Center in Washington state. That test found that Vonshelle had been exposed to HSV-1, but was "indeterminate" for antibodies to HSV-2. No additional Western Blot tests were performed to clarify the results. The Claimant's attorneys did not reveal this test to the Brevard County Health Department during discovery claiming it was protected under the Claimant's work product privilege. Because the attorneys for the Department were unaware of the test's existence, they did not question any experts on the Western Blot's credibility or reliability.

Not one of the three blood tests performed on Vonshelle has demonstrated that she was exposed to herpes simplex virus, type 2.

LITIGATION HISTORY:

Litigation

Vonshelle Brothers filed a medical malpractice suit, individually and on behalf of her daughter, Iyonna Hughey, a minor, against the Brevard County Health Department on October 9, 2012. The suit was filed in the Circuit Court of the Eighteenth Judicial Circuit in and for Brevard County. The Brevard County Health Department is a division of the Florida Department of Health, an agency of the State of Florida. An extensive period of discovery ensued, and depositions were taken in 2014, 2015, and 2016.

Mediation

The parties attempted to mediate the case on February 10, 2015, but were not able to reach a settlement.

Settlement

The trial was scheduled to begin April 25, 2016. Approximately 1 week before the trial, the parties reached their first of two settlement agreements. The Department of

initiated by DOH. The results were again negative for HSV type-1 and HSV type-2. The expert witness depositions seem to only discuss two tests initiated by the Department of Health, so the presence of this third hsv test, although present in the submitted records, does not appear to be mentioned in the depositions. Because the Department of Health did not present a case at the claim bill hearing, this third DOH test, nor any of their theories, were argued at the hearing.

¹⁴ In the last paragraph of the HSV Western Blot test results two sentences are printed: "This test was developed and its performance characteristics determined by UW Medicine, Department of Laboratory Medicine. *It has not been cleared or approved by the U.S. Food and Drug Administration.*" (Emphasis added.)

Health agreed to pay the statutory cap of \$200,000, and the Claimant would pursue a claim bill for the excess amount of \$3 million. However, the Department maintained the right to contest the claim bill during the legislative process.

The Department then paid the \$200,000, the maximum amount that may be paid without legislative authority which was disbursed as follows:

\$101,841.41	Litigation Expenses Paid to Plaintiff's Law Firm
\$7,560.58	Payment of Medical Liens
\$50,000.00	Purchase of Annuity for Lyonna Hughey ¹⁵
<u>\$40,698.01</u>	Disbursement to Vonshelle Brothers
\$200,000.00	

As of the date of the special master hearing, the Claimant's law firm had not received any fees for its legal work, only reimbursements for costs. An additional \$71.19 is due the firm for interest accrued.

The Claimant's attorneys later offered to reduce the claim to \$1 million if the Department would not contest the claim bill. The Department accepted this offer and has agreed to maintain a neutral position on the claim bill, but it has not admitted liability.

Claim Bill Hearing

On February 24, 2017, a lengthy, almost day-long hearing was held before the House and Senate special masters. Ronald Gilbert and Jonathan Gilbert appeared with their clients, Vonshelle Brothers and Lyonna Hughey. Patrick Reynolds, Chief Legal Counsel for the Department, Michael J. Williams, Assistant General Counsel, and Maria Stahl, Health Officer for Brevard County, appeared for the Department of Health. Because the Department agreed that it would not oppose the claim bill, it did not present any theories, arguments, or evidence on the Department's behalf. However, the Department did provide documentation in response to specific requests by the special masters. The Department did not admit fault in this claim.

¹⁵ The annuity will begin making payments to Lyonna Hughey when she is 18 years old. As the annuity is structured, Lyonna will receive annual income of \$2,500 per year for 5 years when she turns 18, \$3,500 per year for 5 years when she turns 23, \$4,500 per year for 5 years when she turns 28, \$5,500 per year for 5 years when she turns 33, and lump sum annual disbursements of \$6,500 payable at ages 38, 39, and 40, then \$3,825.85 when she is 41, for a total lifetime yield of \$103,325.85.

CLAIMANT'S POSITION:

Vonshelle Brothers' position is that the Brevard County Health Department was negligent and did not meet the standard of care when reviewing her Pap test. Her argument then follows that, if the lab slip had been properly reviewed, additional testing would have revealed that Vonshelle carried the herpes virus. A proper course of treatment could have then prevented Lyonna from contracting the herpes virus, suffering herpetic encephalitis, and sustaining substantial brain damage.

RESPONDENT'S POSITION:

While the Respondent did not present a case at the special master hearing, a review of the depositions taken over the course of discovery in this case reveals what its arguments might have been. Based upon the depositions of expert witnesses, the Department was likely preparing to argue that Vonshelle did not have the herpes virus and therefore, could not have transmitted the virus to Lyonna during the pregnancy or delivery.

An alternative theory might have been that Vonshelle contributed to Lyonna's damage by transmitting the herpes virus to her. Additionally, it might have been argued, that Vonshelle did not seek timely medical attention when severe symptoms were apparent on the night that she left the emergency room without seeing a doctor, thereby delaying treatment for Lyonna by 7 or 8 hours. Prompt treatment for Lyonna might have prevented or mitigated her brain damage.

A case might also have been built on missed opportunities by Vonshelle. She missed many obstetrical appointments and apparently did not fill an initial progesterone prescription to prevent early labor, which required that a second prescription be written for her, thus causing the medicine to be taken later. Lyonna missed many appointments for speech therapy, physical therapy, occupational therapy, and Vonshelle chose not to acquire a wheelchair that was prescribed for Lyonna because she did not want people to see Lyonna in a wheelchair. It was questioned whether she made a diligent effort to enroll Lyonna in school as early as she could have.

CONCLUSIONS OF LAW:

The Brevard County Health Department, a department of the Florida Department of Health, is an agency of the State of Florida. Under the legal doctrine of *respondeat superior*, the Department is liable for its employees' wrongful acts, or medical negligence, committed within the scope of their employment.

When a plaintiff seeks to recover damages for a personal injury and alleges that the injury resulted from the negligence of a health care provider, the plaintiff bears the legal burden of proving, by the greater weight of the evidence, that the alleged actions of the health care provider were a breach of the prevailing professional standard of care for that health care provider. The prevailing professional standard of care is defined in statute as “that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.”¹⁶ The standard of care is established at trial by providing expert testimony from professionals in that field.

To establish liability in a medical malpractice action, the plaintiff must prove:

- (1) A duty of care owed by the healthcare provider to the injured party;
- (2) A breach of that duty;
- (3) Causation--that the breach of the duty caused the plaintiff's injury;¹⁷ and
- (4) Damages.

In this case, the Department's liability turns on whether the Department breached a duty and whether it caused Lyonna's damages. To express these legal principles in the factual context of this case, the issues are whether the Department should have tested Vonshelle Brothers for the herpes simplex virus, and whether that testing would have led to treatment that could have prevented Lyonna Hughey from acquiring meningoencephalitis, which caused her brain damage.

These elements as outlined below are based upon depositions, testimony, and other information provided before and during the special master hearing. Medical malpractice cases generally “involve a battle of expert witnesses.”¹⁸ This claim is no exception. The parties deposed medical experts in several cities in Florida, Atlanta, New York City, and Michigan to support their cases.

¹⁶ Section 766.102(1), F.S.

¹⁷ *Saunders v. Dickens*, 151 So. 3d 434, 441 (Fla. 2014).

¹⁸ *Id.*

Duty

As discussed above, a health care facility and its employees have a duty to provide a professional standard of care to its patients that is recognized as acceptable and appropriate by reasonably prudent similar health care providers.¹⁹ The issue of whether the Brevard County Health Department owed a duty to Vonshelle Brothers is not contested in this case. The duty was owed.

Breach of Duty

If this case had proceeded to trial, it would likely have been disputed whether the duty of care owed to Vonshelle Brothers and Lyonna Hughey was breached. Three areas of a potential breach were identified:

(1) Whether the Department breached the standard of care when it received and filed the Pap test lab results in Vonshelle's medical records and did not have a clinician review the results or pursue additional testing to determine if she carried the herpes virus.

(2) Whether the Health Department breached its duty by not starting Vonshelle on a regimen of anti-viral medicines that would have suppressed the alleged HSV in her body, thereby preventing her from passing the disease to Lyonna during the birth process.

(3) Whether an anti-viral medicine should have been given to Vonshelle and when it should have been given because of her history of delivering two earlier babies before full-term gestation at 40 weeks.²⁰

Based upon the deposition testimony of medical experts, each side would have had arguments to support its case before a jury.

The Claimant's Arguments

The Claimant provided experts who testified in depositions that the Brevard County Health Department breached the duty of care owed to Vonshelle.

¹⁹ Section 766.102(1), F.S.

²⁰ Authoritative medical literature and expert witness medical testimony suggest waiting until the 36th week of pregnancy to begin an anti-viral medicine for the mother.

Dr. Berto Lopez

Dr. Berto Lopez, a medical doctor practicing in obstetrics and gynecology, testified as a standard of care expert. He stated that he personally reads the results of all Pap smears that he orders and that Dr. Mark Sargent, Vonshelle's obstetrician at the Brevard County Health Department, should have read the results himself rather than allowing a subordinate on staff to read the results. In his opinion, this was a breach of the standard of care. Regarding the issues of initiating an anti-viral medicine and when the anti-viral should be initiated, he stated that he generally starts women on an anti-viral drug early in the pregnancy. To prevent the passage of the disease to the baby at birth, he does not wait until 36 weeks to begin suppression therapy.

Nurse Sharon Hall

Sharon Hall²¹ testified in her deposition about the nursing standard of care at the Brevard County Health Department. Nurse Hall is an obstetrical nurse who formerly practiced in high-risk labor and delivery. She stated that it was a deviation from the standard of care when the Department nurse did not report to Dr. Sargent the changes that were observed in the Pap smear report.

The Respondent's Arguments

Perhaps the Respondent's theory would have been that the added phrase "Cellular changes consistent with Herpes simplex virus" was so out of place on a Pap test report that it did not actually alert the nurse to notify a clinician. Because the test was negative for precancers, she technically complied with the policy for handling negative lab slips.

Dr. Mark Sargent

Dr. Mark Sargent, Vonshelle's treating obstetrician, stated in his deposition that he felt the findings should have been reported to him, but that he had "never even heard of this result on a Pap smear. It's not even – it's not even supposed to be on a pap smear and I've never seen it on a pap smear....I would have expected, had I seen it, I would have certainly pursued it." Dr. Sargent said that he would have expected the nurse to bring this report to someone's attention.

²¹ Sharon Hall is an obstetrical nurse with approximately 30 years of experience. She has a bachelor's degree in nursing and a master's degree and is also certified in inpatient obstetric care and electronic fetal monitoring.

Dr. David Colombo

Dr. David Colombo was also deposed as a defense expert witness for the Department. He is a practicing physician in obstetrics and gynecology and maternal fetal medicine.²² He stated in his deposition that he believed that Dr. Sargent deviated from the standard of care by not personally reviewing the Pap test results. However, as will be discussed later, he did not believe that this deviation caused any damage.

Conclusion

Accordingly, I find that the Brevard County Health Department deviated from the acceptable standard of care owed to Vonshelle Brothers by not having a clinician review the results of the Pap test that was ordered by a nurse midwife.²³

Causation

If this case had proceeded to trial, it would likely have been disputed whether the damage to Lyonna was actually caused by the negligence of the employees of the Brevard County Health Department. The Claimant argues that the failure of the Brevard County Health Department to discover whether Vonshelle had herpes, and its subsequent failure to provide her with anti-viral medication that would have prevented her from passing the herpes virus to Lyonna at birth, is the cause of Lyonna's injuries. It is undisputed that Lyonna contracted HSV-2, which caused her brain damage. Whether she contracted the disease from her mother at birth is not so clear.

The Claimant's Arguments

Dr. Berto Lopez

Dr. Berto Lopez, an expert witness for the claimant, testified that, upon receiving and reviewing Vonshelle's Pap smear lab slip, he would have given her extra tests to determine whether she had herpes. He would have given her anti-viral medication early in the pregnancy and would not have waited until she was 36 weeks pregnant. He believed that there was

²² Dr. Colombo is a former clinical assistant professor of maternal fetal medicine at the Ohio State University hospitals and associate professor of obstetrics and gynecology and maternal fetal medicine at Michigan State University.

²³ The Brevard County Health Department instituted a new policy for reviewing lab slips, on or around August, 2015, according to an affidavit submitted by Maria Stahl, the Administrator for the Brevard County Health Department. The ordering clinician must review and acknowledge the laboratory results, in addition to the review performed by the assigned nursing staff. The laboratory review process is reviewed at all new employee orientations for the Brevard County Health Department.

no harm in giving the anti-viral medication to Vonshelle early, but that there could be tremendous harm to the baby if the medication were not given.

Dr. Fred Gonzalez

Dr. Fred Gonzalez, a board certified perinatologist²⁴ or maternal fetal medicine specialist, practicing in New York City, was another expert witness for the claimant. He also testified that when he has a pregnant patient with a recurrent herpes infection and she has not had an outbreak in the last year, he puts her on an anti-viral drug for suppression therapy at 36 weeks. He then lets the pediatrician or neonatologist know that the mother has a history of herpes. According to Dr. Gonzalez, the mother's primary outbreak is the most dangerous to the baby. When asked if he recommended beginning anti-viral therapy earlier than 36 weeks for someone with previous pre-term births at 35 or 36 weeks, he said he did not. If a mother has herpes symptoms or a lesion at the time of delivery, the treatment is to do a Caesarean section.

Dr. Catherine Lamprecht

Dr. Catherine Lamprecht, a pediatric infectious disease specialist for the claimant, treated Lyonna at Arnold Palmer Hospital for Children. She testified that she could say with medical certainty that Lyonna was exposed to hsv and suffered meningoencephalitis as a result. Dr. Lamprecht was asked in her deposition if she was an expert in the prenatal care of a mother with herpes who was about to give birth. She stated that she did not consider herself an expert in that area. Dr. Lamprecht said that she could not give a medical expert opinion as to whether Vonshelle had herpes.

Respondent's Arguments

Dr. Mark Sargent

Diagnosing Herpes In Pregnant Women

Dr. Mark Sargent, Vonshelle's treating obstetrician, testified in his deposition that he had dealt with approximately 10,000 patients in his obstetrical career of which "a couple hundred" were pregnant women having confirmed cases of herpes simplex virus.

²⁴ Perinatology is a subspecialty within the field of obstetrics and gynecology. It focuses on high-risk, complicated pregnancies. Perinatology is also referred to as maternal-fetal medicine. <http://www.perinatologist.net/>

When asked how he confirms that a pregnant woman has herpes, Dr. Sargent responded that, if the woman has been diagnosed with herpes or told of it and treated for it, that is the first way. If the patient tells him that she has a lesion in the vaginal area or vulva, he cultures the lesion, sends it to a lab, and if it comes back positive, that is definitive. A third way, which is less definitive, is a blood test to determine the presence of herpes antibodies, because it means that a patient has been exposed to herpes.

Sores or Boils

Later in the deposition, Dr. Sargent discussed Vonshelle's claim that she had boils. Vonshelle stated that she had a sore under her arm and in the area of the crease in her leg near the vaginal area during the pregnancy. She described the sores to be boils about the size of a penny. When asked if this could be characteristic of a herpes lesion, Dr. Sargent said "No" and that boils are not cratered lesions characteristic of herpes. Moreover, Dr. Sargent testified that there was nothing in the medical records that indicated that Vonshelle had any boils during her pregnancy. He said that he would have examined those areas and the information would have been in Vonshelle's medical records if he had been notified, but there was nothing in her records about boils.

Standard of Care and Suppression Therapy

When asked what Dr. Sargent would have done if the Quest Pap test lab report had been brought to his attention, he replied that he would have gotten a second opinion about starting an anti-viral medicine on a baby in the first trimester. He does not order acyclovir, an anti-viral prescription that suppresses herpes, in the first trimester, but waits until the last trimester, at approximately 34 or 36 weeks, if the mother has a history of herpes. He stated that it is too late to treat a mother with acyclovir during the birthing process because it would not be helpful to her, the mother. Additionally, a Caesarean section was never recommended for Vonshelle because they were not aware that she had herpes.

Dr. Sargent testified that treating the mother at 34 to 36 weeks with acyclovir does not protect the baby and because Vonshelle delivered Lyonna at 36 weeks, the medicine would not have been in Vonshelle's system long enough to help the baby. He stated that the medical recommendation is that the

drug needs to be administered for 4 to 6 weeks before it is helpful.

When asked if Lyonna likely contracted herpes during the birthing process, Dr. Sargent responded, "No." He said that he really did not know when the transmission of the disease likely occurred, and commented that the case was very odd.²⁵

Dr. Keith Van Dyke

Herpes Testing

Dr. Keith Van Dyke was also deposed as a defense expert witness. At the time of his deposition, he was a practicing gynecologist who had worked in high risk obstetrics. He stated that he had never had a patient who tested positive for hsv on a Pap test.

Whether Vonshelle Had the Herpes Simplex Virus

Dr. Van Dyke stated that Vonshelle "has never had herpes based on her lab test from 2014." He noted that Vonshelle took a blood serum test and the results test were negative.

Dr. Van Dyke was asked to comment on conclusions made by Dr. Lamprecht, the infectious disease specialist practicing at Arnold Palmer Hospital for Children. Dr. Lamprecht concluded that Lyonna contracted hsv during the vaginal birth. Dr. Van Dyke stated that Dr. Lamprecht was wrong to conclude that Lyonna was exposed to hsv during the vaginal delivery. He based this on the fact that Vonshelle tested negative for herpes.

When asked if false-negatives could occur, he responded that it is possible if the herpes test is performed on someone soon after the virus is transmitted to them. This is because the particular anti-body had not been around long enough in the body to register. However, Dr. Van Dyke said that he was not aware of any false negative tests in the literature he reviewed. When asked if Vonshelle could have had a false negative for the hsv test, Dr. Van Dyke stated, "I would think not."

Lyonna's Acquisition of Herpes

When asked his opinion of how Lyonna acquired the herpes simplex virus, Dr. Van Dyke stated, "I can only suppose that

²⁵ At the time of Dr. Sargent's deposition on March 13, 2014, Vonshelle had not been tested for herpes. The multiple HerpeSelect tests were not taken until almost 5 months later, in August 2014. It was then that people became aware that she did not have the herpes type 2 virus.

the baby acquired it after delivery.” The follow up question was asked if there were any possibility that the baby would have acquired the virus before labor and delivery and he responded, “No.”

Herpes Incubation Period

During Dr. Van Dyke's deposition, the issue was raised about the length of an incubation period for the herpes simplex virus. Dr. Van Dyke stated that generally, the incubation period before lesions appear is 2 to 12 days or so after exposure.

Validity of HSV Test

Dr. Van Dyke placed more validity on the negative hsv test than on the Pap test report which stated “cellular change consistent with herpes simplex virus.” He explained his reasoning as being that the blood serology test, or the test that was performed on Vonshelle in 2014 after lyonna's birth in 2010, is an antibody test, and if someone has been exposed to the herpes virus, the person will remain positive for antibodies for his or her lifetime. He said that this holds true if it was a blood sample test, regardless of the location of where the blood was drawn or the amount of blood that was drawn.

Dr. Van Dyke stated that, in his opinion, other than when the test was performed during the early stage of an initial or primary herpes outbreak, a negative result would be 100 percent confirmation that the patient had never had herpes.

Suppression Therapy

Dr. Van Dyke relies on the American Congress of Obstetrics and Gynecology's publication, the Herpes Management in Pregnancy document, published in 2007 and reaffirmed in 2014. It states that suppression therapy for herpes should begin at 36 weeks. He found the bulletin to be authoritative and follows its guidelines for suppression therapy.

Dr. Van Dyke was asked about suppression therapy for hsv and using a daily therapy drug such as acyclovir or Valtrex to prevent recurrences of herpes outbreaks, and whether that would affect the results of an antibody hsv test. He stated suppression therapy would not affect those test results because “antibodies” are for life and that “They don't go away.”

When asked if he would have begun a regimen of suppression therapy based upon the Pap test results, he responded that it would not have been appropriate to initiate suppression therapy without a diagnosis of hsv with a serum blood test. He stated, once again, that Vonshelle did not have a diagnosis of herpes simplex, and in his opinion, because Vonshelle never had herpes, it would not matter. He noted that it is not good practice to give medicine for no reason. Dr. Van Dyke expounded that suppression therapy is a treatment for a known disease. He stated that suppression will decrease outbreaks, but some of his patients on daily suppression still get outbreaks of herpes. Unless it is a primary outbreak during pregnancy, suppression is used for recurrences at 36 weeks and up.

Standard of Care

When asked whether the handling of Vonshelle's Pap test met the standard of care, Dr. Van Dyke responded that he did not think there was a standard of care on this particular Pap test because it was so unusual. He said, "It's got to be rare because I've never seen one. I wouldn't know that there would be a standard." He noted that the Pap test result did not say "diagnostic of" herpes, and suggested that there are other possibilities that might not always be true, such as other infections. He concluded that the Pap test results did not need to be communicated to Vonshelle because the results were negative for what it was tested for, cervical disease, dysplasia, and malignancy.

Dr. Van Dyke also stated that the pathologist's notation about cellular changes did not make any distinction between herpes-1 and herpes-2. He stated, once again, that note on the Pap smear lab slip is odd and extremely rare and he could not say what the standard of care would be for it.

He further stated that a Pap test is not diagnostic of herpes.

Transmission from Mother to Baby

When asked his theories of how a baby could acquire HSV-2 after birth, Dr. Van Dyke said that if someone had lesions in his or her mouth, he or she could shed the virus through saliva. If someone has active herpes or lesions on their genitals and they touch themselves and then touch the baby, that is a possible way to transmit the virus as well. "So, kissing, touching."

In summary, when Dr. Van Dyke was asked if it was his opinion that the baby absolutely did not acquire hsv from the mother during vaginal birth but rather was exposed to the herpes simplex virus after birth by someone other than the mother, he replied, "Correct."

Dr. David Columbo

Dr. David Columbo was also deposed as a defense expert witness. He is board certified in obstetrics and gynecology and maternal fetal medicine.²⁶ He regularly addresses the prevention of neonatal herpes in his maternal fetal medicine practice.

Impact of Previous Pre-term Births on this Pregnancy

When asked if Vonshelle's two earlier pre-term births were important to the issues in this case, Dr. Columbo stated, "No." He said that he would not have done anything differently than what Dr. Sargent did in treating Vonshelle in 2010.

He agreed with the American Congress of Obstetrics and Gynecology's guidelines for maternal fetal medicine. Those guidelines recommend beginning an anti-viral medicine at 36 weeks, and he found those guidelines to be reliable and well thought out. This opinion is in direct conflict with the testimony offered by the Claimant's medical expert, Dr. Berto Lopez.

Whether Vonshelle had the Herpes Simplex Virus

Dr. Colombo commented on the testimony of Dr. Lamprecht, the pediatric infectious disease specialist. He stated that her testimony was actually very good but her conclusion was wrong when she was asked about the pathology results showing cellular changes consistent with herpes. He also said that Dr. Lamprecht was wrong to conclude that Vonshelle had hsv during her pregnancy. When asked to elaborate, he said that Vonshelle Brothers did not have hsv during her pregnancy. He based that opinion upon the 2014 test results of the antibody screen for HSV-1 and HSV-2, after the 2010 pregnancy. Those test results show that it was impossible for her to have had hsv during her pregnancy.

²⁶ Dr. Colombo served as a clinical assistant professor of maternal fetal medicine at the Ohio State University hospital system and at the time of the deposition was an associate professor at Michigan State University in obstetrics and gynecology and maternal fetal medicine.

Dr. Colombo expounded on the pathology notation about changes consistent with herpes. He said that the pathologist saw a multinucleated giant cell with inclusions in the nucleus that were not specific for herpes. At that point, he felt that it was the obstetrician's job to do an antibody screen to see if Vonshelle actually had herpes or if it were due to another cause. The fact that the obstetrician did not follow up then was not an issue because the fact that the tests were negative years later meant that the results would have been negative at the time that the Pap smear was done in 2010.

He felt that the pathologist was correct to say that he saw those type of cells, but those types of cells could also be human papilloma virus, chronic inflammation, or a lot of things that can give that appearance. He felt that the pathologist was unable to distinguish between herpes simplex virus and other viruses or infections at that point. Dr. Colombo felt that the pathologist made an incorrect assumption that the cells were herpes simplex virus.

The Method of Transmission to Lyonna

Dr. Colombo believed that Dr. Lamprecht actually gave the method of Lyonna's transmission in her deposition when she related the story of someone with a cold sore kissing a baby. He concluded that what happened to Lyonna was either "in the nursery or a family member, somebody with herpes contacted this child shortly after delivery and transmitted the herpes virus then." He stated, "But the mom didn't have it. So it had to be that other two percent where somebody else gave it to the kid shortly after delivery."

Standard of Care

Dr. Colombo felt that Dr. Sargent deviated from the standard of care by failing to review the lab report. However, because the mistake did not result in any damage, the mistake is less relevant. He found no causal connection between the deviation in the standard of care and the resulting damages.

Suppression Therapy

If he had received a positive antibody screen on Vonshelle, he would have offered acyclovir at 36 weeks. He would not have started it any sooner even though she had two pregnancies that delivered at 32 and 36 weeks.

Dr. Colombo stated that, if a mother has antibodies and a recurrent infection, the risk of transmitting herpes to the baby is about 1 in 4,000. Some people have a reaction or side effects to acyclovir or Valtrex which could be catastrophic, even fatal. He did not think that giving the medicines in a timely manner would prevent herpetic meningoencephalitis, but would decrease the risk of herpetic meningoencephalitis.

Dr. Colombo said that the HSV-2 antibody test used in 2014 for determining whether Vonshelle had herpes is a very good test.

Source of Transmission of HSV to Lyonna

Dr. Colombo testified that the virus likely came from a well-meaning relative who was excited for the baby, who came in with a cold sore and kissed the child. He noted that it could have been a nurse or tech in the newborn nursery who picked the child up without gloves and had a herpes lesion on her or his hand. He said that this method is consistent with the incubation period because it happened shortly after delivery.

Dr. Colombo expressed once again that Lyonna's exposure to the virus was not during labor and delivery and he based that upon the fact that Vonshelle tested negative for herpes in a subsequent pregnancy. He also noted that if Vonshelle were exposed to herpes, she would have antibodies in her blood for life. He stated that because she twice tested negative for herpes means that she was never exposed to the virus

Incubation Period

Dr. Colombo testified that herpes incubation periods generally occur with a general range of time. The shortest incubation period he has seen was 7 days and the longest was 21 days.

Conclusion

In light of the negative HerpeSelect tests²⁷ and expert witness testimony, as well as the Western Blot test, I find that Vonshelle did not have HSV-2 while pregnant with Lyonna. She was, therefore, incapable of transmitting the virus to Lyonna during the birth process and causing her neurological

²⁷ According to a website, the HerpeSelect test "is the most commonly used HSV antibody test in the U.S." The test can detect antibodies and differentiate between HSV-1 and HSV-2. It generally takes about 3-6 weeks for someone to develop a detectable amount of antibodies to the herpes simplex virus. Most everyone will have detectable antibodies 16 weeks after exposure. <http://www.healthassist.net/medical/herpes-test.shtml>

damage. Lyonna's infection must have originated from coming into contact with another person who had the infection.

Damages

The parties agreed to settle this claim for:

- (1) The \$200,000 statutory cap, which was previously paid to the Claimant and her attorneys; and
- (2) The right to pursue a claim bill for no more than \$1 million that would not be contested by the Department of Health.

As discussed on page 11, the attorneys have been reimbursed \$101,841.41 for their costs, but have not received any compensation for their legal services. Vonshelle has received \$40,698.01. An annuity costing \$50,000 has been purchased for Lyonna.

Vonshelle has incurred no out-of-pocket medical expenses because she and Lyonna are covered by Medicaid. According to Vonshelle's deposition testimony in 2014, she received \$720 per month in Social Security disability payments for Lyonna.

FINAL CONCLUSION IN LIGHT OF THE EVIDENCE:

I do not find that the Claimant has proven, by the greater weight of the evidence, that the Brevard County Health Department is responsible for Lyonna's neurological injuries.

The Department's breach of the standard of care when Dr. Sargent did not review the entire results of Vonshelle's Pap test did not cause Lyonna's injuries. Vonshelle has never tested positive for HSV-2, in separate tests submitted to the special masters, and therefore, she did not have the virus and was not capable of passing the virus to Lyonna. Any further testing by the Department for hsv after the lab slip noted the cellular changes consistent with the herpes virus would not have yielded a positive test result. Therefore, the Department is not liable for any damages.

ATTORNEY FEES:

Section 768.28, F.S, limits the claimant's attorney fees to 25 percent of the claimant's total recovery by way of any judgment or settlement obtained pursuant to s. 768.28, F.S. The claimant's attorney has agreed to limit attorney fees to 15 percent of the claim bill award.

RECOMMENDATIONS:

Based upon the foregoing, the undersigned recommends that Senate Bill 42 be reported UNFAVORABLY.

Respectfully submitted,

Eva M. Davis
Senate Special Master

cc: Secretary of the Senate