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IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE

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RICHARD R. ROOKER, CLERK

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WAYNE A. REED, individually and as husband and next of kin of decedent, DIANA E. REED,	**Case No.** _____ **Jury Demand**
Plaintiff,	
v.	
SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC, HOWELL ALLEN CLINIC a Professional Corporation, SAINT THOMAS NETWORK, SAINT THOMAS HEALTH, and ST. THOMAS HOSPITAL	
Defendants.	

13C-417

COMPLAINT

Plaintiff, WAYNE A. REED, individually as husband and as next of kin of his deceased wife, DIANA E. REED, respectfully states as follows for his causes of action against the Defendants:

INTRODUCTION AND SUMMARY OF CLAIMS

1. This case arises from the wrongful conduct of corporate defendants who sold dangerous products to innocent patients. Those companies recklessly disregarded patient safety by purchasing and selling injectable steroids that they knew or should have known were dangerous. The Defendants acted in concert to operate a for-profit pain clinic known as Saint Thomas Outpatient Neurosurgical Center. That pain clinic disregarded alarming and important information when it selected New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") as its supplier of injectable steroids. Long before the present fungal meningitis outbreak, the medical and regulatory communities published substantial information about the dangers of pharmacy compounding in general and NECC in particular. In

spite of that information, the pain clinic chose to purchase and sell injectable steroids made by NECC, a company that is now bankrupt. The pain clinic chose NECC as its supplier of injectable steroids for reasons that have nothing to do with patient safety. Tennessee Law requires the pain clinic and its corporate operators to stand behind the products that it sold and injected into the bodies of innocent patients. Therefore, Wayne Reed respectfully asserts strict product liability claims, and claims for negligence and recklessness, arising from the wrongful, needless and preventable death of his wife, Diana Reed.

PARTIES

2. Plaintiff Wayne Reed is a resident of Brentwood, Davidson County, Tennessee. He is the widower of Diana Reed, deceased. Diana Reed died on October 3, 2012 of fungal meningitis.

3. Wayne Reed suffers from Amyotrophic lateral sclerosis, also known as Lou Gehrig's disease. Wayne Reed is wheelchair bound, and he requires substantial care and assistance.

4. Prior to her death, Wayne Reed's wife, Diana Reed, was Wayne Reed's primary caregiver. Wayne Reed depended on his wife to help him with daily activities including showering, getting dressed, and communicating with others. Wayne and Diana Reed were married for 37 years before Diana's death. She was 56 years old when she died.

5. The Defendant Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Neurosurgical") is a Tennessee for profit limited liability company.

6. Saint Thomas Neurosurgical's principal place of business is located on the 9th floor of the Medical Plaza East office building on the St. Thomas Hospital campus at 4230 Harding Pike in Nashville, Davidson County, Tennessee 37205.

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7. Saint Thomas Neurosurgical's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

8. The Defendant Howell Allen Clinic a Professional Corporation, ("Howell Allen Clinic") is a Tennessee professional corporation with its principal place of business in Nashville, Davidson County, Tennessee. Howell Allen Clinic's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

9. At the time of the events described herein, the Defendant Howell Allen Clinic employed Saint Thomas Neurosurgical's Medical Director, John Culclasure, M.D., as well as its Facility Director, Debra Schamberg, R.N.

10. The Defendant Saint Thomas Network is a Tennessee non-profit corporation with its principal place of business located on the St. Thomas Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas Network's registered agent for service of process is E. Berry Holt, III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205.

11. Defendant Saint Thomas Network was formerly known as Saint Thomas Health Services.

12. Saint Thomas Network is a successor of Saint Thomas Health Services.

13. Saint Thomas Network, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

14. Saint Thomas Network, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.

15. The Defendant Saint Thomas Health is a Tennessee non-profit corporation with its principal place of business in Nashville, Davidson County, Tennessee. Saint Thomas

Health's registered agent for service of process is E. Berry Holt, III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205.

16. Defendant Saint Thomas Health was formerly known as Saint Thomas Health Services.

17. Saint Thomas Health is a successor of Saint Thomas Health Services.

18. Saint Thomas Health, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

19. Saint Thomas Health, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.

20. Defendants Saint Thomas Network and Saint Thomas Health are hereinafter referred to collectively as "Saint Thomas."

21. At the time of the events described herein, the Defendants Saint Thomas and Howell Allen Clinic acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.

22. The Defendant St. Thomas Hospital is a Tennessee non-profit corporation with its principal place of business located on the St. Thomas Hospital Campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. St. Thomas Hospital's agent for service of process is E. Berry Holt, III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205.

JURISDICTION AND VENUE

23. This Court has jurisdiction over this proceeding pursuant to Tenn. Code Ann. § 16-10-101 and Tenn. Code Ann. § 29-14-102. Venue is proper pursuant to Tenn. Code Ann. § 20-4-101(a).

FACTS

24. Plaintiff's deceased wife, Diana Reed, received three cervical epidural steroid injections during August and September 2012 at Saint Thomas Neurosurgical. Dr. John Culclasure, medical director of Saint Thomas Neurosurgical, administered those cervical epidural steroid injections.

25. The steroid injected into Mrs. Reed's cervical spine was methylprednisolone acetate ("MPA") manufactured by NECC.

NECC History

26. NECC began operations in June 1998. The first government enforcement action against NECC began in April 1999, just 10 months after it obtained its license. The Massachusetts Board of Registration in Pharmacy (the "MA Board") filed a complaint asserting that NECC was including blank prescriptions in its solicitations to doctors, in violation of state law.

27. In 2002, a doctor reported to the United States Food and Drug Administration ("FDA") that as many as five patients became ill following epidural injections that contained NECC medications.

28. In July 2002, a patient in New York contracted bacterial meningitis and later died after being injected with contaminated MPA compounded by NECC. In 2004, the patient's family sued the NECC and the medical providers who performed the injection.

29. In August 2002, additional adverse events were reported to the FDA concerning patients who contracted meningitis. The suspected source of the infections was epidural injections that contained methylprednisolone acetate compounded by NECC. The FDA investigated NECC following those adverse events and found that five of 16 vials were

contaminated with bacteria. The investigators concluded "sample results revealed that the firm has sterility and potency issues with injectable steroid suspensions (betamethasone repository USP and methylprednisolone acetate USP)."

30. In December 2006, the FDA issued a Warning Letter to NECC. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years. The FDA posted that letter under the heading "Significant Compliance Actions."

31. In 2011, the Colorado Board of Pharmacy issued a Cease and Desist letter to NECC as a result of distribution of non-patient specific compounded drugs to hospitals in Denver. The Colorado Board of Pharmacy provided a copy of that Cease and Desist letter to the MA Board.

32. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC. To date, more than 690 people have been sickened by MPA compounded by NECC and more than 40 people have died.

Dangers of Compounded Drugs

33. The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak.

34. Compounding pharmacies are not subject to the same FDA regulations as drug manufacturers and compounded drugs are not FDA approved. As a result, compounded medications are more likely to be contaminated with dangerous pathogens.

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35. Trade groups and public health officials have been warning of the special risks posed by compounded drugs for more than a decade. For example, in 2002, the United States Centers for Disease Control and Prevention ("CDC") published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination."

36. In October 2003, the United States Senate held a hearing regarding regulatory issues in the compounding industry. Experts testified at length regarding the dangers of compounded drugs during that hearing.

37. On March 24, 2005, *USA Today* published a front page article with the following headline: "**Safety concerns grow over pharmacy-mixed drugs**". That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

38. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the US during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

39. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded

products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

40. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

41. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
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> . . .
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> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

42. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

Safe Purchasing Practices Recommended

43. The American Society of Health System Pharmacists ("ASHP") also played an active role in warning the pharmacy and medical communities of the risks of using compounded drugs. In 2010 they published the "ASHP Guidelines on Outsourcing Sterile Compounding Services." They also developed a "Contractor Assessment Tool" for healthcare organizations to use in conjunction with their guidelines. That document was developed for health systems to use when deciding whether to purchase compounded medications.

44. The ASHP guidelines state that healthcare providers should perform certain due diligence before purchasing drugs from compounders. For example, health systems should: (1) have an employee or agent visit the compounding pharmacy; (2) determine whether the compounding pharmacy has had product liability lawsuits filed against it; (3) determine whether the compounding pharmacy has ever recalled any of its compounded preparations; (4) review regulatory surveys conducted of the compounding pharmacy's site, including copies of significant regulatory actions; and (5) determine whether the compounding pharmacy maintains adequate liability insurance.

45. In December 2011, the International Academy of Compounding Pharmacists published the "Compounding Pharmacy Assessment Questionnaire." That document is an assessment tool designed to help healthcare providers evaluate whether particular compounding pharmacies are safe and reliable.

Injections Given to Diana Reed

46. Prior to her death, Mrs. Reed was active and in good health. In 2010, she began experiencing chronic neck pain. That pain likely resulted from injury that Mrs. Reed suffered while lifting her husband, Wayne, from his wheelchair. She initially tried physical therapy and trigger point injections, which did not alleviate her symptoms. A series of MRIs indicated multi-level facet disease without significant cord or root compression.

47. In August 2012, Mrs. Reed's primary care physician referred her to Dr. Gregory Lanford in the Howell Allen Clinic. Dr. Lanford assessed Mrs. Reed and referred her to Saint Thomas Neurosurgical for a series of three fluoroscopy guided cervical epidural steroid injections ("ESIs").

48. Dr. Lanford, through the Howell Allen Clinic, maintains a financial interest in Saint Thomas Neurosurgical.

49. Mrs. Reed received the first ESI on August 21, 2012. During that procedure, the anesthesiologist, Dr. John Culclasure, injected 80mg of methylprednisolone acetate ("MPA") into Mrs. Reed's neck at C7/T1 using a translaminar approach. That injection came from a lot of MPA that was subsequently recalled by NECC.

50. Mrs. Reed received a second ESI on September 4, 2012 at Saint Thomas Neurosurgical. Dr. Culclasure administered a 120mg dose of MPA for that injection. That injection came from a lot of MPA that was subsequently recalled by NECC.

51. Approximately one week after the second injection, Mrs. Reed began experiencing increased pain and bilateral numbness in her hands. She returned to Dr. Lanford on September 13, 2012. Dr. Lanford examined Mrs. Reed and determined that she did not have any new spinal cord compression. He decided not to re-image her and recommended that she go forward with the third cervical epidural injection.

52. Mrs. Reed received the third and final ESI on September 18, 2012. Dr. Culclasure again administered a 120mg dose of MPA. That injection came from a lot of MPA that was subsequently recalled by NECC.

53. At the time that he administered epidural steroid injections to Diana Reed, Dr. John Culclasure was a member or employee of the Howell Allen Clinic, and he was the Medical Director of Saint Thomas Neurosurgical.

54. At the time that he administered epidural steroid injections to Diana Reed, Dr. John Culclasure was acting within the course and scope of his employment or agency for Saint Thomas Neurosurgical.

55. At the time that he administered epidural steroid injections to Diana Reed, Dr. John Culclasure was acting within the course and scope of his employment or agency for Howell Allen Clinic.

56. One or more of the three epidural steroid injections administered to Mrs. Reed contained MPA from lots that NECC subsequently recalled.

57. Diana Reed played no role in selecting the supplier of the steroids that she received. She relied upon her healthcare providers to make those decisions.

58. No one ever advised Mrs. Reed that the steroid injected into her cervical spine was obtained from a compounding pharmacy and was not FDA approved.

59. Before Mrs. Reed received the epidural steroid injections, none of her healthcare providers, including Saint Thomas Neurosurgical, Saint Thomas Network, Saint Thomas Health, St. Thomas Hospital, and Howell Allen Clinic, nor any of their agents, managers or employees, conducted adequate due diligence regarding whether NECC was a safe and reliable source for sterile compounding. Specifically, none of Mrs. Reed's healthcare providers followed the recommendations of the American Society of Health System Pharmacists regarding the outsourcing of sterile compounding.

60. Mrs. Reed's healthcare providers did not visit NECC's compounding facilities. They did not determine whether NECC had ever recalled any of its compounded products. They did not check with the FDA or the MA Board regarding NECC's regulatory history, and they failed to determine whether NECC had a history of being sued by victims injured by its products.

61. Compounding pharmacies such as NECC are not permitted to manufacture and sell compounded medications in bulk. Such compounding pharmacies are only allowed to fill

individual prescriptions for individual patients written by appropriately licensed healthcare providers.

62. Saint Thomas Neurosurgical, acting through and on behalf of Saint Thomas and Howell Allen Clinic, failed to use patient specific individual prescriptions when buying purportedly sterile injectable steroids from NECC in bulk.

63. According to information compiled by the FDA, Saint Thomas Neurosurgical purchased 2,500 vials of MPA from NECC during a three month period.

64. After purchasing MPA in bulk from NECC, Saint Thomas Neurosurgical, acting through and on behalf of Saint Thomas and Howell Allen Clinic, stored the injectable steroid for longer than its acceptable shelf life. Numerous patients received injections of the preservative free medication after the material sat on the shelf for more than 60 days.

65. None of Mrs. Reed's healthcare providers warned her of the extraordinary risks associated with receiving cervical spinal injections of compounded medicines manufactured in bulk by an out-of-state compounding pharmacy not regulated by the FDA.

Fungal Meningitis

66. On September 18, 2012 (the same day as Mrs. Reed's third injection), a Vanderbilt clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of epidural steroid injections at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health, contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

67. Dr. Kainer told St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received epidural steroid injections at Saint Thomas Neurosurgical. She

requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

68. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

69. Also on September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.

70. On September 20, 2012, no one attempted to contact Diana Reed to inquire about troubling symptoms or to request that she come in for evaluation.

71. On September 21, 2012, another patient with meningitis and stroke reported to St. Thomas Hospital. That patient also had a history of ESI at Saint Thomas Neurosurgical.

72. Also on September 21, 2012, no one attempted to contact Diana Reed to inquire about troubling symptoms or to request that she come in for evaluation.

73. On September 22, 2012, no one attempted to contact Diana Reed to inquire about troubling symptoms or to request that she come in for evaluation.

74. On September 23, 2012 (three days after Saint Thomas Neurosurgical closed), Mrs. Reed went to the St. Thomas Hospital Emergency Room reporting symptoms consistent with meningitis. She arrived at the ER at approximately 2:30 a.m. She underwent lumbar

puncture in the ER and was admitted for treatment of meningitis. Mrs. Reed was started on oral anti-fungal medications.

75. The physician or physicians who ordered oral anti-fungal therapy for Mrs. Reed on September 23, 2012 were acting as agents of St. Thomas Hospital, Saint Thomas Network, and/or Saint Thomas Health, and they were acting within the scope of that agency.

76. From September 23 to September 26, 2012, Mrs. Reed did not receive intra-venous anti-fungal drug therapy.

77. Mrs. Reed's condition rapidly deteriorated. By September 26, she was having trouble focusing and began slurring her words. On September 27, she became non-responsive. Imaging studies revealed infarction of the entire cerebellum and brainstem. Mrs. Reed passed away on October 3, 2012 at St. Thomas Hospital.

78. St. Thomas Hospital conducted an autopsy of Mrs. Reed's remains.

79. Autopsy results showed fungal hyphae around the injection site and extensive necrosis of the entire brain stem and upper spinal cord. Examination of the brain and upper spinal cord revealed necrotic debris containing septated fungal hyphae and extensive necrosis in the cerebellar hemispheres.

80. The autopsy revealed that Mrs. Reed's upper spinal cord and brain were infested with *Exserohilum rostratum.*

81. *Exserohilum rostratum* is the same type of fungus as was found by government investigators in unopened vials of MPA seized from NECC.

82. Mrs. Reed's Death Certificate lists the immediate cause of her death as being "Fungal meningitis."

PRODUCT LIABILITY CLAIMS AGAINST SAINT THOMAS NEUROSURGICAL

83. The MPA injected into Mrs. Reed's cervical spine on August 21, 2012, September 4, 2012 and September 18, 2012 was manufactured by NECC.

84. On December 21, 2012, NECC filed a voluntary petition under Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the district of Massachusetts (Eastern Division) No. 12-19882-HJB.

85. Pursuant to 11 U.S.C. § 362(a) all actions against NECC are stayed.

86. The Plaintiff Wayne Reed is prohibited from issuing or employing process against NECC by virtue of the automatic stay provisions of 11 U.S.C. § 362(a)(1).

87. Saint Thomas Neurosurgical procured the MPA injected into Diana Reed's cervical spine from NECC.

88. NECC's product was defective and unreasonably dangerous when it left NECC's control, and it was in substantially the same condition at the time that Saint Thomas Neurosurgical injected it into Diana Reed's cervical spine on August 21, 2012, September 4, 2012 and September 18, 2012.

89. Saint Thomas Neurosurgical charged Diana Reed money for the epidural steroid injections that she received.

90. Saint Thomas Neurosurgical acted as a seller or distributor of MPA manufactured by NECC when it administered epidural steroid injections to patients, including Diana Reed, for profit.

91. Tenn. Code Ann. § 29-28-106(4) authorizes the Plaintiff Wayne Reed to prosecute product liability claims against Saint Thomas Neurosurgical as the seller of the MPA

injected into Diana Reed's cervical spine because the manufacturer of the product, NECC, cannot be served with process in this state.

92. The MPA that Saint Thomas Neurosurgical injected into Diana Reed's cervical spine was unreasonably dangerous and defective at the time it left the control of Saint Thomas Neurosurgical because it was contaminated with lethal pathogens, specifically *Exserohilum rostratum*.

93. Saint Thomas Neurosurgical is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Diana Reed's cervical spine.

94. Saint Thomas Neurosurgical's decision to select NECC as its supplier of purportedly sterile injectable steroids was negligent.

95. Saint Thomas Neurosurgical knew or should have known that NECC was not a safe and reputable supplier of injectable steroids.

96. Saint Thomas Neurosurgical, acting through and on behalf of Saint Thomas and Howell Allen Clinic, failed to use patient specific individual prescriptions when buying purportedly sterile injectables from NECC in bulk.

97. The person or persons who decided to procure MPA from NECC and then sell that product to patients, including Diana Reed, were employees or agents of Saint Thomas Neurosurgical, and they were acting within the course and scope of their employment or agency. Accordingly, Saint Thomas Neurosurgical is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

98. Investigations conducted by the CDC and by the FDA determined that the contaminated MPA manufactured by NECC caused a wide-spread fungal meningitis outbreak.

99. As a direct result of receiving the contaminated product manufactured by NECC, more than 690 people have been sickened and more than 40 people have died. One of those deaths was Diana Reed.

100. The CDC determined that three lots of 80mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

101. NECC recalled all three of those lots of contaminated MPA. Ultimately, NECC recalled every product that it compounded due to concerns regarding wide spread contamination.

102. The MPA injected into Diana Reed's cervical spine came from one or more of the three lots initially recalled.

103. On October 2, 2012, FDA investigators began inspections of NECC.

104. Upon inspecting NECC's facility, the FDA observed that 83 vials of MPA, out of a bin containing 321 vials, contained greenish-black foreign matter.

105. The FDA conducted further laboratory analysis of 50 vials of MPA seized from NECC and found microbial growth in all 50 vials tested.

106. The MPA sold and distributed by Saint Thomas Neurosurgical was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Saint Thomas Neurosurgical breached its warranties, both express and implied, as stated in Tenn. Code Ann. §47-2-313, §47-2-314 and §47-2-315, including its warranty of fitness for a particular purpose.

107. As a direct and proximate result of the contaminated epidural steroid injections administered by Saint Thomas Neurosurgical, Diana Reed became very ill, suffered horribly, and died at St. Thomas Hospital on October 3, 2012.

108. Saint Thomas Neurosurgical's conduct was reckless. Saint Thomas Neurosurgical was aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Accordingly, Saint Thomas Neurosurgical should be compelled to pay punitive damages in order to punish its wrongful conduct and deter similar wrongful conduct in the future.

OTHER CLAIMS AGAINST SAINT THOMAS NEUROSURGICAL

109. All the above paragraphs are incorporated herein by reference.

110. Defendant Saint Thomas Neurosurgical, acting though its managers, agents and employees, was negligent in its care and treatment of Diana Reed. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and drug procurement practices in this or similar communities and was a proximate cause of Mrs. Reed's injuries and death. Specifically, Saint Thomas Neurosurgical was negligent and rendered substandard care in the following respects:

a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

b. failed to visit NECC's facilities before procuring spinal injection medicines from that company as recommended by the American Society of Health System Pharmacists;

c. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;

d. failed to investigate NECC's regulatory history with the FDA and/or the MA Board before procuring spinal injection medicines from that company;

e. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;

f. failed to keep abreast of the dangers of sterile compounding;

g. purchased compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions;

h. injected preservative free steroids into Diana Reed's cervical spine after allowing those medications to sit on the shelf beyond their acceptable use date and longer than was safe;

i. failed to adequately supervise and train the agents and employees who ordered MPA from NECC;

j. failed to implement policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

k. procured compounded injectable steroids from NECC without input from a licensed pharmacist or a hospital pharmacy department;

l. purchased MPA from NECC because it was less expensive than safer alternatives;

m. injected steroids into Diana Reed's cervical spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens; and

n. failed to notify Diana Reed that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt and life-saving treatment of her fungal infection.

111. As a direct and proximate result of the negligent acts and omissions described above, Mrs. Reed suffered injuries and death that would not have otherwise occurred.

112. The person or persons who decided to procure MPA from NECC and who injected that steroid into Diana Reed's cervical spine were employees or agents of Saint Thomas Neurosurgical, and they were acting within the course and scope of their employment or agency.

Accordingly, Saint Thomas Neurosurgical is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

113. In addition to being negligent, the conduct of Saint Thomas Neurosurgical was reckless. Saint Thomas Neurosurgical was aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Accordingly, Saint Thomas Neurosurgical should be compelled to pay punitive damages in order to punish its wrongful conduct and deter similar wrongful conduct in the future.

CLAIMS AGAINST SAINT THOMAS[1]

114. All the above paragraphs are incorporated herein by reference.

115. Saint Thomas[1] and Howell Allen Clinic acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.

116. Saint Thomas and Howell Allen Clinic were negligent in the manner in which they operated Saint Thomas Neurosurgical.

117. Saint Thomas, acting though its agents and employees, was negligent in its care and treatment of Diana Reed. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and health system drug procurement practices in this or similar communities and was a proximate cause of Mrs. Reed's injuries and death.

118. Saint Thomas was negligent in the following respects:

a. permitted or authorized its agent Saint Thomas Neurosurgical to procure injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether

[1] As noted in paragraph 20 above, Defendants Saint Thomas Network and Saint Thomas Health are collectively referred to as "Saint Thomas".

NECC was a reputable and safe supplier of sterile injectable compounds;

b. failed to implement or enforce policies and procedures that required Saint Thomas Neurosurgical to comply with the recommendations of the American Society of Health System Pharmacists regarding the outsourcing of sterile compounding;

c. failed to visit NECC's facilities before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

d. failed to determine whether NECC had a history of recalling compounded medications before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from that company;

e. failed to investigate NECC's regulatory history with the FDA and/or the MA Board before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

f. failed to determine whether NECC had a history of product liability suits against it before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

g. failed to keep abreast of the dangers of sterile compounding;

h. failed to manage Saint Thomas Neurosurgical with reasonable and due care, including a complete failure to manage its drug procurement practices reasonably;

i. failed to supervise Saint Thomas Neurosurgical adequately;

j. failed to exercise due and reasonable care in conducting Saint Thomas Neurosurgical's financial and contracting operations;

k. allowed its agent Saint Thomas Neurosurgical to purchase compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions;

l. allowed its agent Saint Thomas Neurosurgical to procure compounded injectable steroids from NECC without input from a licensed pharmacist or a hospital pharmacy department;

m. failed to implement or enforce policies and procedures that would prevent Saint Thomas Neurosurgical from injecting preservative free steroids into Diana Reed's cervical spine after allowing those

medications to sit on the shelf beyond their acceptable use date and longer than was safe;

n. failed to adequately supervise and train the agents and employees who ordered MPA from NECC;

o. failed to implement or enforce policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

p. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives;

q. entered into a business relationship with Howell Allen Clinic that created perverse incentives and threatened patient safety;

r. failed to notify Diana Reed that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt and life-saving treatment of her fungal infection; and

s. failed to treat Diana Reed with intra-venous anti-fungal therapy of sufficient dose to control her fungal infection when she was admitted to the St. Thomas Hospital Emergency Room on September 23, 2012.

119. As a direct and proximate result of the negligent acts and omissions described above, Mrs. Reed suffered injuries and death that would not have otherwise occurred.

120. The person or persons who decided to procure MPA from NECC were employees or agents of Saint Thomas, and they were acting within the course and scope of their employment or agency. Accordingly, Saint Thomas is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

121. In addition to being negligent, the conduct of Saint Thomas was reckless. Saint Thomas was aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Accordingly, Saint Thomas should be

compelled to pay punitive damages in order to punish such wrongful conduct and deter similar wrongful conduct in the future.

122. Saint Thomas Neurosurgical is the actual, ostensible, and apparent agent of Saint Thomas. Therefore, in addition to Saint Thomas being directly liable for its own conduct, it is also liable for the conduct of its agent, Saint Thomas Neurosurgical, under the doctrine of *respondeat superior* and under basic principles of agency.

123. Saint Thomas Neurosurgical is the agent of Saint Thomas because Saint Thomas Neurosurgical shares Saint Thomas' name, is located on Saint Thomas' campus, and is operated in part by Saint Thomas. Saint Thomas handles Saint Thomas Neurosurgical's contracting and finances. Moreover, once the fungal meningitis outbreak occurred, Saint Thomas Neurosurgical instructed many patients (other than Diana Reed) to report to the St. Thomas Hospital Emergency Room for evaluation and treatment.

124. Saint Thomas failed to maintain an arms-length relationship with Saint Thomas Neurosurgical. Saint Thomas and Saint Thomas Neurosurgical share a common name and common business location. The entity known as Saint Thomas Neurosurgical was used as a subterfuge in order to engage in the illegal conduct of purchasing 2,500 vials of adulterated MPA from NECC in contravention of important patient safety laws requiring specific prescriptions for individual patients. In addition, Saint Thomas Neurosurgical is grossly under-capitalized and unable to meet its obligations to injured tort victims, and it is being used as a business conduit designed to enrich Saint Thomas while shifting the risk of devastating loss to innocent patients. Accordingly, to the extent that the fiction of a corporate veil exists at all around Saint Thomas Neurosurgical, justice and equity require that said veil be pierced, and Saint Thomas should be held liable for the obligations of Saint Thomas Neurosurgical.

CLAIMS AGAINST ST. THOMAS HOSPITAL

125. All the above paragraphs are incorporated herein by reference.

126. St. Thomas Hospital, acting though its agents and employees, was negligent in its care and treatment of Diana Reed. Such care and treatment fell below the recognized standard of acceptable professional practice for the treatment of infectious diseases and health system drug procurement practices in this or similar communities and was a proximate cause of Mrs. Reed's injuries and death. Specifically, St. Thomas Hospital was negligent in the following respects:

a. permitted or authorized it agent Saint Thomas Neurosurgical to procure injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

b. failed to implement policies and procedures following the recommendations of the American Society of Health System Pharmacists regarding the outsourcing of sterile compounding;

c. failed to visit NECC's facilities before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

d. failed to determine whether NECC had a history of recalling compounded medications before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from that company;

e. failed to investigate NECC's regulatory history with the FDA and/or the MA Board before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

f. failed to determine whether NECC had a history of product liability suits against it before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

g. failed to notify Diana Reed that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt and life-saving treatment of her fungal infection;

h. failed to take adequate measures to make sure that victims of the contaminated steroid injections received prompt and aggressive anti-fungal therapy; and

i. failed to treat Diana Reed with intra-venous anti-fungal therapy of sufficient dose to control her fungal infection when she was admitted to the St. Thomas Hospital Emergency Room on September 23, 2012.

127. As a direct and proximate result of the negligent acts and omissions described above, Mrs. Reed suffered injuries and death that would not have otherwise occurred.

128. In addition to being negligent, the conduct of St. Thomas Hospital was reckless. St. Thomas Hospital was aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Accordingly, St. Thomas Hospital should be compelled to pay punitive damages in order to punish such wrongful conduct and deter similar wrongful conduct in the future.

129. Saint Thomas Neurosurgical is the actual, ostensible, and apparent agent of St. Thomas Hospital. Therefore, in addition to St. Thomas Hospital being directly liable for its own conduct, it is also liable for the conduct of its agent, Saint Thomas Neurosurgical, under the doctrine of *respondeat superior* and basic principles of agency. Saint Thomas Neurosurgical is the agent of St. Thomas Hospital because Saint Thomas Neurosurgical shares a common name with St. Thomas Hospital and is located on the hospital's campus. In addition, once the fungal meningitis outbreak occurred, Saint Thomas Neurosurgical instructed many patients (other than Diana Reed) to report to the St. Thomas Hospital Emergency Room for evaluation and treatment.

CLAIMS AGAINST HOWELL ALLEN CLINIC

130. All the above paragraphs are incorporated herein by reference.

131. Howell Allen Clinic and Saint Thomas acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.

132. Howell Allen Clinic and Saint Thomas were negligent in the manner in which they operated Saint Thomas Neurosurgical.

133. Howell Allen Clinic, acting though its agents and employees, was negligent in its care and treatment of Diana Reed. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and health system drug procurement practices in this or similar communities and was a proximate cause of Mrs. Reed's injuries and death.

134. Howell Allen Clinic was negligent in the following respects:

a. referred Mrs. Reed to Saint Thomas Neurosurgical (an entity that it owns, manages, and derives profits from) without taking reasonable measures to ensure that the medicines injected into Mrs. Reed's cervical spine were safe and free from lethal pathogens;

b. operated Saint Thomas Neurosurgical in a manner which facilitated the procurement of injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

c. failed to implement or enforce policies and procedures that required Saint Thomas Neurosurgical to comply with the recommendations of the American Society of Health System Pharmacists regarding the outsourcing of sterile compounding;

d. failed to visit NECC's facilities before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

e. failed to determine whether NECC had a history of recalling compounded medications before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from that company;

f. failed to investigate NECC's regulatory history with the FDA and/or the MA Board before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

g. failed to determine whether NECC had a history of product liability suits before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;

h. failed to keep abreast of the dangers of sterile compounding while operating Saint Thomas Neurosurgical;

i. failed to operate Saint Thomas Neurosurgical with reasonable and due care, including a complete failure to supervise its drug procurement practices reasonably;

j. failed to supervise Saint Thomas Neurosurgical adequately;

k. allowed Saint Thomas Neurosurgical to procure compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions;

l. allowed Saint Thomas Neurosurgical to procure compounded injectable steroids from NECC without input from a licensed pharmacist or a hospital pharmacy department;

m. failed to implement or enforce policies and procedures that would prevent Saint Thomas Neurosurgical from injecting preservative free steroids into Diana Reed's cervical spine after allowing those medications to sit on the shelf beyond their acceptable use date and longer than was safe;

n. failed to adequately supervise and train the agents and employees who ordered MPA from NECC;

o. failed to implement or enforce policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

p. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives;

q. facilitated or permitted the injection of steroids into Diana Reed's cervical spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;

r. entered into a business relationship with Saint Thomas that created perverse incentives and threatened patient safety; and

s. failed to notify Diana Reed that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt and life-saving treatment of her fungal infection.

135. As a direct and proximate result of the negligent acts and omissions described above, Mrs. Reed suffered injuries and death that would not have otherwise occurred.

136. The person or persons who decided to procure MPA from NECC and who injected that steroid into Diana Reed's cervical spine were employees or agents of Howell Allen Clinic, and they were acting within the course and scope of their employment or agency. Accordingly, Howell Allen Clinic is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

137. In addition to being negligent, the conduct of Howell Allen Clinic was reckless. Howell Allen Clinic was aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Accordingly, Howell Allen Clinic should be compelled to pay punitive damages in order to punish such wrongful conduct and deter similar wrongful conduct in the future.

138. Howell Allen Clinic represented to patients that Saint Thomas Neurosurgical is part of Howell Allen Clinic. Both Howell Allen Clinic and Saint Thomas Neurosurgical billed for and were paid for the epidural steroid injections administered to Diana Reed. Therefore, Saint Thomas Neurosurgical was the actual or apparent agent of Howell Allen Clinic. Howell Allen Clinic is liable for the conduct of Saint Thomas Neurosurgical under the doctrine of *respondeat superior* and basic principles of agency. In addition, Saint Thomas Neurosurgical should be deemed an alter ego of Howell Allen Clinic.

139. Howell Allen Clinic operated Saint Thomas Neurosurgical and failed to maintain an arms-length relationship with that entity. Through its operation of Saint Thomas Neurosurgical, Howell Allen Clinic dominated and controlled Saint Thomas Neurosurgical, while employing its Medical Director and its Facility Director, such that Saint Thomas Neurosurgical functioned as an instrumentality of Howell Allen Clinic. Saint Thomas Neurosurgical is grossly under-capitalized and unable to meet its obligations to injured tort victims, and it is being used as a business conduit designed to enrich Howell Allen Clinic while shifting the risk of devastating loss to innocent patients.

140. The entity known as Saint Thomas Neurosurgical was used as a subterfuge in order to engage in the illegal conduct of purchasing 2,500 vials of adulterated MPA from NECC in contravention of important patient safety laws requiring specific prescriptions for individual patients. Therefore, to the extent that the fiction of a corporate veil exists at all around Saint Thomas Neurosurgical, justice and equity require that said veil be pierced, and Howell Allen Clinic should be held liable for the obligations of Saint Thomas Neurosurgical.

DAMAGES

141. All the above paragraphs are incorporated herein by reference.

142. As a direct and proximate result of the Defendants' wrongful conduct as described above, Diana Reed endured horrible pain, enormous suffering and ultimately died. She was 56 years old at the time of her death. Before her death, she knew that something was terribly wrong, and she experienced enormous anguish. Her husband Wayne Reed watched his wife suffer and die.

143. Wayne and Diana Reed were married for 37 years. Wayne Reed experienced and continues to experience tremendous grief, mental anguish and emotional loss. As a result of his

wife's injury and death, Wayne Reed lost his wife's valuable and irreplaceable care, companionship, love, affection, society, partnership, solace, comfort, services and consortium.

144. Before her death, Diana Reed was Wayne Reed's primary caregiver. She provided substantial daily nursing care, services and aid to him, and she assisted him with the activities of daily living. She enabled him to practice accounting by being his voice and his physical aid. Wayne Reed is entitled to recover the economic value of all of those important services.

145. Wayne Reed is entitled to recover for Diana Reed's pre-death pain and suffering, her medical expenses as well as the pecuniary value of Diana Reed's life. Wayne Reed is entitled to recover for the loss of a loving companion and for all of the daily care and services that Diana Reed provided to him. Wayne Reed hereby claims all damages and losses occasioned by Diana Reed's wrongful death.

146. Wayne Reed is entitled to recover compensatory damages in the amount of $12,500,000 including: non-economic damages of $7,500,000 and economic damages of $5,000,000.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

147. All the above paragraphs are incorporated herein by reference.

148. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Wayne Reed's non-economic damages are purportedly capped at $750,000, and his ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.