IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

R. KENNETH WEISS and JANET HURWITZ, his wife, Plaintiffs	: 4:CV-99-974 : (Judge McClure)
V.	:
JOHN GREEN, D.O., Defendant	:

MEMORANDUM

February 7, 2001

BACKGROUND :

On June 11, 1999, plaintiffs R. Kenneth Weiss and Janet Hurwitz, his wife, filed a three-count complaint against defendant John Green, D.O., pursuant to the diversity jurisdiction of this court. 28 U.S.C. § 1332. On August 12, 1997, plaintiff Weiss underwent a hernia repair procedure, known as bilateral laparoscopic inguinal herniorrhaphy, performed by defendant. Plaintiff Weiss claimed that this operation resulted in excruciating groin pain from damage to the ilioinguinal nerve (diagnosed as ilioinguinal genitofemoral neuropraxia), and numerous follow-up surgical procedures in an attempt to relieve his pain. He claimed that he continues to suffer from mental and physical pain and extreme loss of enjoyment of life.

Count I of plaintiffs' complaint, alleging that defendant negligently performed laparoscopic hernia repair surgery on plaintiff Weiss on August 12, 1997, has been withdrawn by plaintiffs.¹ In Count II of the complaint, plaintiffs allege

¹ Unless otherwise specified, "plaintiff" refers to R. Kenneth (continued...)

that defendant did not obtain plaintiff's informed consent to perform the surgery. Specifically, plaintiffs allege that defendant did not advise plaintiff of the alleged risk of permanent intractable pain resulting from ilioinguinal nerve injury. Additionally, at trial, plaintiffs claimed that defendant did not obtain plaintiff's informed consent to perform a right side hernia repair. In Count III, plaintiff Hurwitz asserts a claim for loss of consortium stemming from her husband's purported physical and mental injuries.

On January 3, 2001, the court proceeded with a bench trial as to Counts II and III of plaintiffs' complaint. Both parties waived their right to a trial by jury.

DISCUSSION:

I. DEFENDANT'S MOTION IN LIMINE

On December 28, 2000, defendant filed a motion in limine to preclude plaintiffs from introducing any evidence or testimony that defendant did not obtain plaintiff's informed consent to perform a right side hernia repair (record document no. 33).² Specifically, defendant contends that plaintiffs did not introduce the issue of informed consent with respect to plaintiff's right side hernia repair in their pretrial memorandum and that the issue was also not referenced in plaintiffs' expert

1(...continued)
Weiss.

² At trial, the court allowed evidence and testimony on this issue to be presented and informed counsel that this motion would be addressed at a later time.

reports, thereby causing defendant to be "substantially prejudiced in the preparation and presentation of his defense by plaintiffs' attempted introduction of a new theory of liability at this later date, after completion of discovery, and after completion of the pretrial conference, and in effect, after trial of the case has begun." Brief in Support Defendant's Motion in Limine Regarding Informed Consent to Right Side Surgery, at 2. Plaintiffs, on the other hand, argue that (1) plaintiff's answers to interrogatories, including a response by plaintiff that "there was also nothing said about the right side of my body," indicated that plaintiffs would be pursuing the right side theory, and (2) the only discussion at the pretrial conference was whether the negligence claim in Count I would be pursued in addition to the informed consent claim. Plaintiffs' Response to Defendant's Motion in Limine Regarding Informed Consent to Right Side Surgery, at $\P\P$ 7, 9.

Fed. R. Civ. P. 26(2)(B) requires an expert report to "contain a complete statement of all opinions to be expressed and the basis and reasons therefor" In this case, we agree with defendant that the reports of plaintiffs' medical experts, Guy R. Voeller, M.D. and I. Michael Leitman, M.D., do not reference the issue of informed consent as to plaintiff's right side hernia.³ We also agree that plaintiffs did not disclose in

³ The report of plaintiffs' expert, Dr. Leitman, does disclose in its case summary that a right hernia repair was repaired by (continued...)

their pretrial memorandum any issue as to informed consent to the right side hernia.

In any event, we find that defendant was put on notice that the issue of informed consent as to plaintiff's right side hernia would be pursued at trial based on the general allegation in plaintiffs' complaint (record document no. 1, filed June 11, 1999, at ¶¶ 14-15) regarding defendant's failure to obtain plaintiff's informed consent, plaintiff's answers to defendant's interrogatories mentioned above, and the Informed Consent to Surgery signed by plaintiff which only specifically referenced surgery to plaintiff's left inguinal hernia.

Additionally, the court does not find that defendant is prejudiced by the theory of liability revolving around informed consent to plaintiff's right side hernia because we believe that there was no further preparation that defendant could have engaged in to provide a stronger defense at trial. As discussed below, defendant testified as to what he routinely told, and did not tell, patients prior to laparoscopic hernia repair. Defendant's expert also testified, based on a reasonable degree of medical certainty, as to what he considered to be the material risks of laparoscopic hernia repair. Presumably, these risks are the same for the procedure, regardless of whether the right or left side was being operated on, as the procedure performed by

3(...continued) defendant on August 12, 1997. Defendant's Exhibit 53, at 1. defendant did not vary significantly from one side to the other.

Furthermore, it is important to note that this court does not believe that expert testimony is helpful to the court, as the trier of fact, as to whether the standard of care mandates that the patient be informed of the risks, benefits, and complications of the surgery. <u>Festa v. Greenberg, M.D.</u>, 511 A.2d 1371, 1376 (Pa. Super. 1986) ("It is well-established in Pennsylvania that in informed consent cases, expert testimony is not necessary to establish the medical community's standard of disclosure.") (citing <u>Cooper v. Roberts</u>, 286 A.2d 647, 651 (Pa. Super. 1971)).⁴ Rather, expert testimony is necessary to assist the court in determining what facts a reasonable person would consider "material" in his or her decision to undergo medical treatment. <u>Cosom v. Marcotte, M.D.</u>, 760 A.2d 886, 890 (Pa. Super. 2000) ("Expert testimony is generally required in informed consent cases to establish risks and alternatives presented by proposed surgical procedure.").

In this case, both expert reports address the issue of informed consent and the risk of pain from injury to the ilioinguinal nerve during hernia surgery in terms of the "standard of care," requiring physicians to discuss this risk and

⁴ A federal court sitting with diversity jurisdiction applies the law of the state whose law governs the action, <u>Greater New York Mut. Ins.</u> <u>Co. v. North River Ins. Co.</u>, 85 F.3d 1088, 1091 (3d Cir. 1996), which generally is the law of the forum state. <u>Clark v. Modern Group Ltd.</u>, 9 F.3d 321, 326 (3d Cir. 1993). Here, Pennsylvania law governs.

other complications and alternatives to surgery. Defendant's Exhibits 53, 54. We do not believe that defendant is substantially prejudiced by the court's review of plaintiffs' expert reports which lack specific reference to the issue of informed consent to the right side hernia repair, as we do not find altogether helpful the context in which the reports discuss the issue of informed consent.

Accordingly, we deny defendant's motion in limine, and consider the evidence and testimony presented at trial concerning the issue of informed consent to the right side hernia repair.

II. FINDINGS OF FACT

The court heard five days of testimony. The plaintiff testified, as did his wife, three lay witnesses, and two medical experts on plaintiffs' behalf.⁵ In addition, plaintiffs presented the transcripts of four medical experts, three of whom had physically examined and treated plaintiff after the hernia repair procedure performed by defendant.⁶ Defendant testified on his own behalf and presented the testimony of five medical experts including that of a psychiatrist, psychologist, neurologist, general surgeon and the videotaped deposition of one

⁵ Lawrence Tomack, M.D. provided expert testimony on the issue of causation, and Guy R. Voeller, M.D. provided expert testimony on the risks involved with TEP laparoscopic hernia repair.

⁶ I. Michael Leitman, M.D. provided expert testimony on the informed consent issues; Rene R. Rigal, M.D. and Daniel J. Glunk, M.D. provided expert testimony on causation, and William J. Todhunter, M.D. testified as a fact witness.

medical expert, four of whom had performed independent medical examinations of the plaintiff.⁷

On the basis of all the evidence presented, the court makes the following findings of fact.

A. General

1. Plaintiffs R. Kenneth Weiss and Janet Hurwitz commenced this action on June 11, 1999, and have been at all times pertinent hereto, husband and wife.

2. Plaintiff is the step-father of two children.

3. At all times pertinent hereto, plaintiffs were residents at 161 West Hills Drive, Williamsport, Lycoming County, Pennsylvania 17701.

4. Defendant John Green, D.O. is a general surgeon board certified by the American Board of Osteopathic Surgery.

5. At all pertinent times, defendant maintained a surgical practice in Muncy, Pennsylvania.

6. At the time this action was commenced by plaintiffs, defendant was an adult individual practicing medicine in Ohio.

7. Defendant performed approximately 25-30 laparoscopic hernia repairs prior to the one performed on plaintiff.

8. Plaintiff was born on December 12, 1954, and is a high school graduate.

⁷ Christopher J. Daly, M.D., testified as an expert witness regarding the material risks of laparoscopic hernia repair; Richard P. Bonfiglio, M.D., Milind J. Kothari, D.O., Timothy J. Michals, M.D., and Steven E. Samuel, Ph.D., testified as experts on the causation issue.

9. Plaintiff was graduated from Slippery Rock State College with a B.A. in psychology in 1972.

10. Plaintiff was graduated from Eastern Baptist Theological Seminary School with a Master's in Divinity in 1986.

11. Plaintiff attended most of the classes required in the Ph.D. program in clinical psychology at Penn State University between 1988 and 1990.

12. Plaintiff became a full-time minister sometime in or around 1995.

13. Prior to August 1997, plaintiff led an active social life.

14. Prior to August 1997, plaintiff was an active member in civic organizations and served as President of the Williamsport Kiwanis Club.

15. Prior to August 1997, plaintiff had an active sexual relationship with his wife, Janet Hurwitz.

B. Plaintiff's Pre-Operative Consultation with Defendant

16. In early 1997, plaintiff was referred by his primary physician, James Baldys, M.D., to defendant for a surgical consultation regarding possible hernia repair surgery.

17. On May 21, 1997, plaintiff first saw defendant regarding possible hernia repair surgery.

18. Defendant physically examined plaintiff on May 21, 1997.

19. On May 21, 1997, after examining plaintiff, defendant diagnosed plaintiff with a left side inguinal hernia and a

possible, but questionable, right side hernia, which he charted in his exam notes.

20. At the May 21, 1997 examination, defendant discussed with plaintiff the treatment options available, including surgery by open incision or by laparoscopic procedure, and the risks associated with not treating inguinal hernias.

21. The laparoscopic hernia repair surgery defendant discussed with plaintiff was a totally extra-peritoneal technique (TEP), also known as totally pre-peritoneal technique.⁸

22. The laparoscopic hernia repair is performed through three or four half-inch incisions in the patient's abdomen. The laparoscope, inserted through a small navel incision, consists of a tiny fiberoptic telescope and also carries light into the abdominal cavity. The surgical space is inflated through the use of a balloon-like instrument so that the surgeon can see clearly into both sides of the groin.

23. Defendant does not have a specific recall of the conversation with plaintiff regarding the surgical options and the risks and benefits of each.

24. Defendant's routine discussion with his patients regarding hernia surgery included an explanation that a laparoscopic hernia repair procedure generally has a shorter recovery time than a repair by open incision.

⁸ Throughout this memorandum, the term "laparoscopic" refers to the TEP laparoscopic hernia repair unless otherwise specified.

25. Defendant's routine discussion with his patients regarding laparoscopic hernia surgery included showing the patient the prosthetic mesh and surgical tacking instruments to be used in the surgery. The prosthetic mesh is secured internally with surgical tacks.

26. Defendant routinely discussed with his hernia surgery patients the potential complications with hernia surgery, by laparoscopic and by open incision. These complications included, in part, the possibility of hernia recurrence, bleeding and infection.

27. Defendant routinely told his hernia surgery patients about the additional possibility of short-term nerve injury which could result in numbness or temporary pain.

28. Defendant did not routinely discuss with his hernia surgery patients a risk of permanent, intractable and disabling pain resulting from ilioinguinal nerve injury.

29. Because of the shorter recovery period experienced by most laparoscopic hernia surgery patients, defendant routinely recommended laparoscopic hernia repair over repair by open incision, unless there was something atypical or unusual regarding a particular patient's presentation.

30. There was nothing unusual or atypical regarding plaintiff's clinical presentation on May 21, 1997.

31. Defendant's routine discussion regarding hernia surgery, including laparoscopic repair, did occur with plaintiff.

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32. During the May 21, 1997 examination, defendant explained to plaintiff how the laparoscopic procedure is performed, including the placement of prosthetic mesh and surgical tacks.

33. During the May 21, 1997 examination, defendant explained to plaintiff that one advantage of the laparoscopic procedure was that defendant would be able to see both the left and right side of plaintiff's groin.

34. During the May 21, 1997 examination, defendant explained to plaintiff how the open incision technique is performed.

35. In addition to defendant's routine discussion regarding hernia repair surgery, defendant gave to plaintiff a brochure that briefly explained some of the benefits of laparoscopic repair including a smaller incision and shorter recovery time than that of open hernia repair. The brochure also mentioned the risk of hernia recurrence.

36. Defendant also gave to plaintiff a videotape which explained laparoscopic hernia repair and mentioned a decreased likelihood of nerve injury with the laparoscopic procedure.

37. On May 21, 1997, while at defendant's office, plaintiff was presented with, and signed a document entitled, "Informed Consent to Surgery."

38. The "Informed Consent to Surgery" document signed by plaintiff on May 21, 1997 referenced the repair of a left inguinal hernia with mesh and did not specifically reference a right side hernia repair or bilateral hernia repair.

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39. In a letter to Dr. Baldys dated June 2, 1997, defendant summarized his findings pertaining to his initial consultation with plaintiff. In this summary, defendant stated: "Examination reveals a large left inguinal hernia with bulging down through the external ring suggestive of possible indirect hernia. There is no evidence of hernia on the right."

C. Laparoscopic Hernia Repair Performed by Defendant

40. On or about August 5, 1997, plaintiff asked defendant to schedule his laparoscopic hernia repair. The surgery was then scheduled for August 12, 1997.

41. On August 12, 1997, plaintiff signed an Informed Consent to Anesthesia form.

42. On August 12, 1997, defendant performed on plaintiff a left laparoscopic hernia repair at Muncy Valley Hospital. Defendant, while performing the repair of the left inguinal hernia identified a right inguinal hernia. Both sides were repaired with placement of prosthetic mesh. The procedure performed on plaintiff was not considered an emergency procedure by defendant.

43. Because the August 12, 1997 laparoscopic surgery spanned over three hours in the afternoon, plaintiff remained in the hospital overnight and was discharged around noon on August 13, 1997.

44. On August 12, 1997, following the plaintiff's bilateral laparoscopic hernia repair performed by defendant, defendant told plaintiff he had performed laparoscopic hernia repair surgery on both his left and right side and showed him photographs to that effect. Plaintiff did not object to the bilateral procedure at that time.

D. Post-Operative Events

45. On August 15, 1997, plaintiff's wife, plaintiff Janet Hurwitz, called the office of defendant to advise that plaintiff claimed to be experiencing gas pain and cramps which started at 4:00 a.m. on August 15, 1997. Plaintiff also had nausea and emesis, and had not had a bowel movement since the surgery of August 12, 1997. Defendant modified plaintiff's medication prescription and recommended a liquid diet and an increase in physical activity. Plaintiff verbalized an understanding of the instructions of defendant and advised that the gas pain was improving. These complaints had nothing to do with the complaints which are the subject matter of his lawsuit.

46. On August 16, 1997, defendant saw plaintiff for reported blisters on the trocar incision sites.⁹ Defendant noted the blisters to be friction blisters secondary to the adhesive bandages. These complaints had nothing to do with the complaints which are the subject matter of his lawsuit. Plaintiff made no other complaints on August 16, 1997.

47. On August 22, 1997, plaintiff attended the first regularly scheduled post-operative visit with defendant. At that

^{9 &}quot;Trocar" was defined at trial as an instrument placed in the incision through which the laparoscope and other instruments were guided in order to perform the laparoscopic hernia repair.

time, plaintiff noted no problems, and stated to defendant's nurse, Margaret Hulien, R.N., that "everything [was] working well."

48. At the office visit on August 22, 1997, it was noted that the friction blisters and the trocar site incisions were healing.

49. At some point during the second post-operative week, after the August 22, 1997 office visit, while visiting with June and Norman Morris at the hospital, plaintiff suddenly began to experience right groin pain for the first time.

50. Plaintiff was reaching for Mr. Morris's hand to offer a prayer, when he doubled up in apparent pain. Plaintiff offered a prayer, and then left under his own power, and without assistance from anyone.

51. Plaintiff claims to have felt no discomfort in the region of his right groin prior to the event with June and Norman Morris. The onset of the alleged right groin pain was sudden, and came without warning.

52. Plaintiff visited Norman Morris in the hospital subsequent to the time when he first began to experience right groin pain. Plaintiff had no other such episodes of alleged sudden pain during the subsequent visits.

53. On August 27, 1997, plaintiff attended a second postoperative office visit with defendant. At that time, plaintiff first reported to defendant that he claimed to experience pain after sitting for five hours, and also complained of severe sharp pain on occasion in his right groin.

54. On August 27, 1997, defendant concluded and charted in his record that plaintiff was reporting symptoms out of proportion to his clinical examination.

55. On August 30, 1997, plaintiff went to Divine Providence Hospital emergency room in Williamsport, Pennsylvania with complaints of right groin pain.

56. On August 30, 1997, the emergency room physician diagnosed possible neural inflammation and discharged plaintiff with anti-inflammatory medication (Relafen) samples to take twice daily.

57. On September 2, 1997, plaintiff reported to defendant that the right groin pain was improving.

58. On September 2, 1997, defendant noted that plaintiff reported pain when sitting for an extended period.

59. On October 6, 1997, plaintiff stated to defendant that he had pain in his right groin with sitting only.

60. On October 6, 1997, plaintiff advised defendant that he was back to routine activities.

61. On October 24, 1997, defendant performed a pain block injection in the area of the right pubic tuberacle, the area of plaintiff's claimed pain.

62. On November 4, 1997, plaintiff reported to defendant that he experienced no appreciable relief from the pain block injection administered on October 24, 1997. 63. On November 11, 1997, defendant attempted a second pain block injection in the region of plaintiff's complaints, with no appreciable relief noted by plaintiff.

64. In December, 1997 defendant asked for a consultation from pain management physician, Dr. Rene Rigal, of Williamsport, Pennsylvania.

65. Rene Rigal, M.D. is a pain management specialist employed by Susquehanna Health System.

66. Dr. Rigal treated plaintiff for the presence of pain in the right inguinal area into the right testicle.

67. On December 11, 1997, Dr. Rigal's first physical examination of plaintiff was performed and revealed that plaintiff claimed to have pinpoint tenderness, over the pubic ramus near the symphysis pubis with exquisite pain at that site.

68. As of December 11, 1997, plaintiff was taking the prescription pain medication, Percocet, at night.

69. On December 11, 1997, Dr. Rene Rigal placed plaintiff on additional prescription medications, including 300 mgs of Neurontin (anti-convulsant) three times daily, and Elavil (antidepressant).

70. On December 11, 1997, Dr. Rigal ordered a bone scan to determine if there was inflammation of the lining of the bone in the area of plaintiff's complaints. The bone scan performed pursuant to Dr. Rigal's orders did not show evidence of injury or inflammation over the pubic bone and pubic ramus, which was the area of plaintiff's pain complaints. 71. Dr. Rigal referred plaintiff back to defendant for surgical exploration of the pain site but, instead, plaintiff sought a second surgical opinion from Dr. William Todhunter.

72. Plaintiff first saw Dr. Todhunter on September 11, 1997, at which time Dr. Todhunter performed a physical examination of the plaintiff.

73. Upon examining plaintiff on September 11, 1997, Dr. Todhunter noted a solid repair of the hernia by defendant. There was no evidence of mass or recurrence of the hernia.

74. Dr. Todhunter initially thought plaintiff may have an inflammatory process causing the pain. He prescribed an antiinflammatory medication which did not resolve plaintiff's subjective pain complaints.

75. On January 12, 1998, Dr. Todhunter performed an abdominal surgical exploration via open incision, in an attempt to identify the anatomical source of plaintiff's complaints.

76. During the January 12, 1998 exploratory surgery, Dr. Todhunter removed some of the mesh and approximately two or three of the titanium tacking screws placed by defendant on plaintiff's right side.

77. Dr. Todhunter saw and identified plaintiff's ilioinguinal nerve during the surgery of January 12, 1998 and found nothing out-of-the-ordinary.

78. During the January 12, 1998 surgery, Dr. Todhunter found no obvious signs of nerve entrapment, which he charted in his record. 79. During the January 12, 1998 surgery, Dr. Todhunter found that the mesh placed by defendant was well incorporated with no evidence of infection.

80. During the surgery of January 12, 1998, Dr. Todhunter found that defendant's repair of the hernia appeared to be very strong, and there was no indication of recurrence.

81. During the January 12, 1998 surgery, Dr. Todhunter found no abnormalities in the area of defendant's laparoscopic hernia repair.

82. During the January 12, 1998 surgery, Dr. Todhunter observed that defendant's laparoscopic surgery was a totally preperitoneal (TEP) laparoscopic hernia repair.

83. After removing some of the mesh placed by defendant, Dr. Todhunter placed new prosthetic mesh in the right ilioinguinal region, which he secured with sutures.

84. Prior to January 12, 1998, Dr. Todhunter had never performed a surgical exploration for purposes of repairing a previous laparoscopic hernia repair.

85. On January 26, 1998, plaintiff reported to Dr. Todhunter that he had no testicular pain, and that his symptoms were now quite different from those which had prompted the re-exploration by Dr. Todhunter.

86. On February 16, 1998, plaintiff reported to Dr. Todhunter that he was experiencing pain in his right inguinal area. 87. Dr. Baldys, plaintiff's family physician, referred plaintiff to Dr. Rigal again on April 6, 1998 and April 20, 1998 for another series of ilioinguinal and genitofemoral nerve block injections.

88. On April 20, 1998, Dr. Rigal's therapeutic plan included another nerve block.

89. In addition to nerve block injections, Dr. Rigal also placed plaintiff on non-steroidal anti-inflammatory medications, including Relafen and Tegretol.

90. Although the plaintiff initially described some pain relief from the April 6 and April 20, 1998 nerve block injections by Dr. Rigal, plaintiff reported to Dr. Rigal that the injections did not provide him with significant pain relief.

91. On May 4, 1998, Dr. Rigal found and charted in his record that the plaintiff had not responded to the pain block injections of April 6, 1998 and April 20, 1998 and, therefore, Dr. Rigal decided not to proceed with additional pain block injections.

92. Dr. Rigal noted on May 4, 1998, that plaintiff was going to be treated at Johns Hopkins Medical Center, Baltimore, Maryland for a second opinion.

93. On May 22, 1998, plaintiff sought treatment with Dr. Sunil Panchal at the Pain Management Clinic at Johns Hopkins Medical Center.

94. When plaintiff began his treatment at Johns Hopkins on May 22, 1998, Dr. Panchal charted in the record that the plaintiff had tried various prescription medications, including Neurontin, Elavil, Ibuprofen, Relafen, Tegretol and Percocet, all of which had provided no noticeable pain relief.

95. On June 17, 1998, Dr. Panchal performed an ilioinguinal nerve block injection at Johns Hopkins Medical Center. Plaintiff reported no change in the intensity or quality of the pain after the nerve block injection.

96. On June 17, 1998, after performing the ilioinguinal nerve block injection, the Johns Hopkins physicians assessed that plaintiff's pain component was not coming from the ilioinguinal or genitofemoral nerve distribution.

97. On July 14, 1998, plaintiff underwent a bilateral hypogastric plexus nerve block under fluoroscopic guidance at Johns Hopkins.

98. Plaintiff reported no pain relief from the bilateral hypogastric plexus nerve block injections of July 14, 1998.

99. Plaintiff reported minor temporary reduction in pain from a right inguinal scar neuroma injection also performed on July 14, 1998.

100. During the course of plaintiff's treatment at Johns Hopkins, plaintiff's doctors increased his prescribed doses of Neurontin from 300 mg daily to 3600 mg daily, and increased the Elavil prescription from 10 mgs daily to 150 mgs daily.

101. On September 3, 1998, plaintiff returned to Johns Hopkins for another series of right inguinal scar neuroma injections. 102. The plaintiff reported no pain relief after the September 3, 1998 right inguinal scar neuroma injections.

103. After the September 3, 1998 right inguinal scar injections failed to provide plaintiff with relief, Dr. Panchal stopped the nerve block injection treatment and discussed with plaintiff the treatment option of pursuing chronic opiate therapy.

104. Throughout the period that plaintiff sought treatment from defendant, Dr. Todhunter, Dr. Rigal, and Dr. Panchal, plaintiff also continued to see Dr. Baldys.

105. On September 4, 1998, plaintiff wrote to Dr. Baldys to advise that the attempted nerve block injections at Johns Hopkins had failed, and that there had been no change in his pain levels from that treatment.

106. On September 4, 1998, Dr. Baldys started plaintiff on MS Contin 15 mgs, twice daily. MS Contin is a long-acting morphine sulphate.

107. On September 14, 1998, plaintiff reported to Dr. Baldys that 15 mgs of MS Contin three times daily had not helped his pain.

108. On September 14, 1998, Dr. Baldys increased plaintiff's MS Contin prescription to 30 mgs in the morning, 15 mgs at noon, and 30 mgs in the evening.

109. On October 27, 1998, plaintiff reported to Dr. Baldys that he continued to have a great deal of pain.

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110. On October 27, 1998, Dr. Baldys increased the MS Contin prescription to 45 mgs three times per day.

111. Plaintiff continued to complain of unrelieved groin pain, and on December 1, 1998, Dr. Baldys again increased the three times daily dosage of MS Contin by increasing the nighttime dosage to 60 mgs.

112. On December 11, 1998, plaintiff saw a Harrisburg, Pennsylvania neurosurgeon, Barry B. Moore, M.D., for evaluation of right groin pain.

113. On December 16, 1998, Dr. Moore performed a right side ilioinguinal nerve block injection on plaintiff.

114. On January 21, 1999, plaintiff reported to Dr. Moore that he obtained no pain relief from the ilioinguinal nerve block injection of December 16, 1998.

115. On January 21, 1999, Dr. Moore performed a second ilioinguinal nerve block injection.

116. Several days after the January 21, 1999 ilioinguinal nerve block injection by Dr. Moore, plaintiff reported to Dr. Moore that he had absolutely no relief from any of the pain.

117. In January, 1999, plaintiff wrote to Dr. Baldys and requested another increase in the MS Contin dosage to 60 mgs in the morning, 45 mgs in the afternoon, and 60 mgs in the evening.

118. On February 18, 1999 Dr. Baldys increased plaintiff's MS Contin dosage to 60 mgs three times per day.

119. On March 4, 1999, Dr. Baldys, with input from Dr. Panchal of Johns Hopkins, modified the narcotic pain medication therapy to include Fentanyl 25 mgs per day, with 15 mgs of MS Contin three times per day.

120. On March 4, 1999, plaintiff advised Dr. Baldys that plaintiff had seen Dr. Lawrence Tomack for a left foot problem, and that Dr. Tomack prescribed Relafen, a pain medication, in addition to the pain medications prescribed by Dr. Baldys.

121. Dr. Tomack had treated plaintiff sporadically for back pain, heel pain and elbow pain. In or about September, 1997, Dr. Tomack saw plaintiff in connection with his complaints of pain resulting from defendant's hernia repair procedure, but provided no follow-up treatment aside from his writing of ongoing pain medication prescriptions.

122. On March 5, 1999, Dr. Baldys received a fax transmission from the Penn State Geisinger Health System Pain Medicine Clinic which indicated that the plaintiff had contacted the pain clinic for purposes of treatment there.

123. On March 10, 1999, Dr. Tomack reported to Dr. Baldys that plaintiff was apparently having withdrawal symptoms from changing pain medication. At that time, Dr. Baldys recommended that Dr. Tomack take over prescription of plaintiff's pain medications.

124. On March 10, 1999, Dr. Baldys charted in his record that, "clearly the patient has decided to discuss further treatment with other physicians with regards to his pain medications, and I do not feel that we should continue to prescribe medication in this scenario." 125. On March 11, 1999, plaintiff wrote to Dr. Baldys and indicated that he was no longer taking the Fentanyl, and intended to wean himself from the MS Contin.

126. Also on March 11, 1999, plaintiff advised Dr. Baldys that he was never pain-free, despite the high levels of narcotic pain medication.

127. On March 18, 1999 and March 22, 1999, plaintiff wrote to Dr. Baldys requesting enough MS Contin to get him through the period of time needed to wean himself off of the narcotic pain medication.

128. In early 1999, Dr. Baldys referred plaintiff to TerriL. Calvert, M.D., for a psychiatric consultation.

129. On March 18, 1999, plaintiff attended a psychiatric evaluation with Dr. Calvert, psychiatrist.

130. On March 18, 1999, Dr. Calvert diagnosed that plaintiff suffered from a depressive disorder.

131. On March 18, 1999, Dr. Calvert prescribed the antidepressant medication, Wellbutrin for plaintiff.

132. On March 18, 1999, plaintiff reported to Dr. Calvert that he was presently taking 210 mgs per day of MS Contin.

133. Plaintiff sought surgical intervention from Steven Weiss, M.D. and Barry Moore, M.D.

134. Dr. Moore pre-operatively diagnosed plaintiff with ilioinguinal nerve pain.

135. On April 12, 1999, Dr. Moore performed an exploratory surgical procedure on plaintiff at Polyclinic Hospital in

Harrisburg, Pennsylvania in an attempt to identify the anatomical source of plaintiff's pain complaints. Dr. Moore performed a surgical exploration of plaintiff's right ilioinguinal nerve region via open incision. During the exploratory surgery, Dr. Moore explored the areas of defendant's and Dr. Todhunter's surgeries.

136. Pre-operatively, Dr. Moore intended to locate the right ilioinguinal nerve, and cut it.

137. Dr. Moore reportedly removed all previously placed surgical tacks.

138. The removal of a surgical screw found near the exit point of plaintiff's ilioinguinal nerve did not result in any pain relief for plaintiff.

139. Dr. Moore did not observe the main branch of the right ilioinguinal nerve during the April 12, 1999 exploratory surgery, but did observe several distal branches of the nerve near the external ring.

140. On April 16, 1999, plaintiff saw Dr. Baldys for a postsurgical wound check. At that time, plaintiff stated to Dr. Baldys that he felt that, other than the incisional pain, his pain was much relieved.

141. Soon after the April 12, 1999 surgery by Dr. Moore, plaintiff continued to report pain in his right ilioinguinal area.

142. On April 26, 1999, plaintiff wrote to Dr. Baldys to request additional MS Contin medication, and indicated that he

was taking 30 mgs in the morning, 15 mgs at noon, and 30 mgs in the evening in an effort to wean himself from that medication.

143. On May 14, 1999, plaintiff wrote to Dr. Baldys to request additional MS Contin medication.

144. On June 8, 1999, plaintiff wrote to Dr. Baldys to request additional MS Contin medication and indicated that he was taking 15 mgs four times per day.

145. On June 16, 1999, Dr. Moore reported that the plaintiff had obtained "absolutely no relief from our exploration of his groin area"

146. On June 16, 1999, Dr. Moore recommended the trial of an epidural stimulator, because all treatment attempted by Dr. Moore, including two series of pain block injections and surgery, had failed to provide pain relief.

147. Plaintiff saw Dr. Calvert for psychiatric evaluation on March 18, 1999; April 5, 1999; August 27, 1999; and, October 22, 1999.

148. On August 27, 1999, plaintiff reported to Dr. Calvert that Dr. Moore found that the nerve believed to be responsible had been severed, and that plaintiff was suffering from "phantom pain."

149. On September 24, 1999, Dr. Calvert added to plaintiff's prescribed medications the anti-depressant drug, Zoloft, in combination with Wellbutrin.

150. Dr. Calvert discontinued Wellbutrin in December, 1999, but continued to prescribe Zoloft. 151. Plaintiff terminated his physician-patient relationship with Dr. Baldys in September, 1999.

152. In September, 1999, plaintiff transferred his primary medical care to Dr. Daniel Glunk, a board certified internist.

153. On October 19, 1999, plaintiff's wife, Janet Hurwitz, faxed Dr. Glunk a request for additional pain medications for plaintiff.

154. On or about October 28, 1999, Dr. Glunk increased plaintiff's dosage of MS Contin to 75 mgs three times daily.

155. On November 1, 1999 plaintiff reported to Dr. Glunk that his pain was somewhat improved and requested an increase in his MS Contin pain medication.

156. Also on November 1, 1999, plaintiff asked Dr. Glunk to begin prescribing Ritalin in addition to increasing the dosage of MS Contin.

157. On November 1, 1999, Dr. Glunk began to prescribe Ritalin in combination with MS Contin.

158. On November 10, 1999, Dr. Glunk increased plaintiff's dosage of MS Contin to 90 mgs three times daily.

159. On November 30, 1999, Dr. Glunk increased plaintiff's dosage of Neurontin to 300 mgs, three times daily.

160. Plaintiff received follow-up treatment at the Geisinger Medical Center under the direction of Kalyan Krishnan, M.D.

161. On December 6, 1999, plaintiff first saw Dr. Krishnan, a pain management physician at Geisinger Medical Center, Danville, Pennsylvania for evaluation of his complaints. 162. As of December 6, 1999, plaintiff's medications included MS Contin 270 mgs/daily, Neurontin 900 mgs/daily, Elavil 100 mgs/daily, and Percocet as need (about 2 tabs/daily).

163. On December 6, 1999, Dr. Krishnan recommended increasing the dosage of Neurontin to 3600 mgs daily.

164. On January 26, 2000, Dr. Krishnan increased the dosage of Neurontin to 3600 mgs/daily, and also increased the MS Contin dosage to 120 mgs three times daily. Dr. Krishnan also maintained plaintiff on Ritalin, twice daily.

165. On February 17, 2000, Dr. Krishnan surgically positioned a spinal cord stimulator in the epidural space under fluoroscopic guidance on the right side of T10-11.

166. On February 24, 2000, plaintiff reported to Dr. Krishnan that he received no help from the electric stimulator placed on February 17, 2000, and told Dr. Krishnan that he continued to have pain.

167. On May 19, 2000, Dr. Krishnan increased the dosage of MS Contin to 420 mgs per day.

168. On June 6, 2000, plaintiff was admitted to Geisinger Medical Center for the surgical placement of an epidural dilaudid pump for trial.

169. An epidural dilaudid pump was placed by Dr. Krishnan on June 7, 2000.

170. On the third day after placement of the epidural narcotic pump, Geisinger physicians determined that the epidural pump trial had failed.

171. The epidural dilaudid pain pump trial of June 7, 2000 failed to provide plaintiff with pain relief, and was deemed a failed trial by Dr. Krishnan.

172. Dr. Krishnan stated to plaintiff that the pain plaintiff claims to experience may be "centralized in the [plaintiff's] brain."

173. On July 6, 2000, plaintiff first saw Charles E. Argoff, M.D., neurologist, at the Pain Management Center at Syosset, New York, for evaluation of his pain.

174. On July 6, 2000, plaintiff reported to Dr. Argoff that physical therapy, spinal stimulator trials, epidural steroid injections, nerve block injections, and a dilaudid epidural pump trial all failed to provide pain relief.

175. As of July 6, 2000, plaintiff's medications included MS Contin 420 mgs/daily, Ritalin 30 mgs/daily, Neurontin 2400 mgs/daily, Percocet as needed for breakthrough pain, Roxanol 20 mgs as needed for breakthrough pain, and Zoloft 50 mgs/daily.

176. On July 6, 2000, Dr. Argoff's impression was that plaintiff's signs and symptoms were compatible with a neuropathic and myofacial pain syndrome, and considered the possibility that plaintiff's pain may have a spinal etiology related to spinal degenerative disease.

177. Also on July 6, 2000, plaintiff saw Jeffrey M. Epstein, M.D., neurosurgeon, in Babylon, New York, for evaluation of his pain. 178. On July 7, 2000, Dr. Epstein performed multi-level

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dorsal root ganglion stimulation with radio frequency lesioning of the nerve roots at the levels of L1-L2 and L2-L3.

179. On July 17, 2000, plaintiff reported to Dr. Epstein that he obtained only very mild relief from the July 7, 2000 radio frequency lesioning procedure.

180. On July 27, 2000, plaintiff saw Dr. Argoff for followup assessment.

181. On July 27, 2000, Dr. Argoff increased the MS Contin dosage to 150 mgs every eight hours.

182. On July 28, 2000, Dr. Epstein performed L1-L2 radio frequency denervation of the L2 nerve root.

183. On August 28, 2000, plaintiff reported to Dr. Epstein that he had received substantial pain relief from the radio frequency denervation procedure.

184. On September 21, 2000, plaintiff was reassessed by Dr. Argoff.

185. On September 21, 2000, plaintiff advised Dr. Argoff that the pain management physicians at the Geisinger Clinic treated plaintiff inappropriately when plaintiff returned for a follow-up because the physicians were supposedly unhappy with plaintiff pursuing treatment in New York.

186. On November 16, 2000, plaintiff reported to Dr. Epstein that the radio frequency lesioning offered significant pain relief to left lower back and radicular symptoms. However, plaintiff complained of a constant sharp burning sensation in the right groin region. 187. On November 16, 2000, Dr. Epstein advised plaintiff that he did not think that additional radio frequency lesioning was indicated, owing to the fact that plaintiff had not had any pain relief which was apparently achieved when first attempted in July, 2000.

188. On November 16, 2000, plaintiff also was assessed by Dr. Argoff.

189. On November 16, 2000, Dr. Argoff changed plaintiff's MS Contin medication regimen to a different analgesic regime in the form of a Duragesic patch.

190. Plaintiff continues to suffer burning pain in his lower groin and right testicle. Plaintiff's complained of pain worsens with sitting.¹⁰

E. Psychological Evaluation of Plaintiff

191. Plaintiff has a history of psychological treatment prior to August 12, 1997.

192. Plaintiff was treated for depression when he attended college, and received anti-depressant medication at that time.

193. Timothy J. Michals, M.D., a board certified psychiatrist, performed an independent psychiatric examination of plaintiff on March 21, 2000.

194. Steven Samuel, Ph.D. is a licensed psychologist who performed an independent psychological evaluation of plaintiff on

10 Plaintiff remained standing for the duration of trial.

March 21, 2000 in conjunction with Dr. Michals's psychiatric evaluation of plaintiff.

195. Dr. Michals diagnosed plaintiff with underlying personality traits of a hysterical and dependent nature that add to the maintenance of his ongoing symptoms.

196. Dr. Michals found that plaintiff is not disabled on a psychiatric basis and does not require psychiatric treatment.

197. Dr. Michals also concluded that the pre-existing personality traits of plaintiff could explain, in part, plaintiff's perception of ongoing pain despite the absence of a physiological cause or origin of said perceived pain.

198. Dr. Samuel did not diagnose plaintiff with any mental disorder, but did diagnose plaintiff with long-standing hysterical and dependent personality traits.

199. Dr. Samuel's impression was that plaintiff's personality traits pre-existed the August 12, 1997 surgery performed by defendant, and that his psychological profile is consistent with medical complaints appearing and becoming exacerbated during stressful times and "may not be traceable to actual organic changes."

III. INFORMED CONSENT

Plaintiffs' informed consent claims are twofold. First, plaintiffs submit that plaintiff did not give his informed consent to the surgery because defendant failed to advise him of the possibility of permanent, disabling and intractable pain as a result of injury to the ilioinguinal nerve. Second, after denying defendant's motion in limine detailed above, we consider the claim that defendant did not have plaintiff's informed consent to perform a right side laparoscopic hernia repair. We address each claim, in turn, below.

In Pennsylvania, a physician performing a non-emergency surgical procedure is required to obtain the informed consent of a patient prior to surgery where the patient is mentally and physically able to discuss his or her medical condition. <u>Southard v. Temple Univ. Hosp.</u>, 731 A.2d 603, 610 (Pa. Super. 1999).

Previously, in <u>MacDonald v. United States</u>, 767 F.Supp. 1295, 1310 (M.D.Pa. 1991), this court addressed the issue of informed consent, relying, in great part, on the well-settled doctrine of the "prudent patient" standard set forth by <u>Cooper v. Roberts</u>, 286 A.2d 647, 650-51 (Pa. Super. 1971). Under this standard, in order for a patient's consent to be informed, the physician must inform a patient of the `"material facts, risks, complications and alternatives to surgery, which a reasonable [person] in the patient's position would have considered significant in deciding whether to have the operation." <u>Cosom v. Marcotte, M.D.</u>, 760 A.2d 886, 889 (Pa. Super. 2000) (quoting Southard, 731 A.2d at 610). Thus, the focus is not on what a reasonable physician would have done in a situation but is, rather, on whether the physician disclosed information considered by a reasonable person as material to his or her decision to undergo the surgery. Cooper, 286 A.2d at 650-51. It is for the court, being the

finder of fact in this case, to assess the "materiality" of the information provided to the patient. <u>Cosom</u>, 760 A.2d at 890.

"Lack of informed consent is the legal equivalent to no consent; thus, the physician or surgeon who operates without his patient's informed consent is liable for damages which occur, notwithstanding the care exercised." <u>Gouse v. Cassel, M.D.</u>, 615 A.2d 331, 334 (Pa. 1992).

A. Information Regarding Possible Long-Term Pain From Injury to the Ilioinguinal Nerve During Laparoscopic Hernia Repair

As stated above, plaintiffs' position at trial was that defendant failed to obtain plaintiff's informed consent for the laparoscopic hernia repair because defendant did not disclose to him the risk of disabling long-term pain from injury to the ilioinguinal nerve during surgery.¹¹ It is for this court to determine whether plaintiffs have proven, by a preponderance of

¹¹ Plaintiffs, in their post-trial memorandum, contend that defendant's failures to obtain informed consent include: (1) performing a right side hernia repair, (2) failing to inform plaintiff of the possibility of nerve injury as a result of laparoscopic hernia repair, and (3) failing to inform plaintiff of the possibility of long-term pain as a result of the surgical Plaintiffs' Memorandum Regarding Trial Testimony and procedure. Law on Informed Consent, at 1 (record doc. no. 56, filed January 22, 2001). Plaintiffs did not, prior to this memorandum, identify the possibility of long-term pain and ilioinguinal nerve injury as two distinct theories of informed consent. Consequently, we agree with defendant that the primary pretrial and trial issue on informed consent focused on "[w]hether a material risk of TEP laparoscopic surgery is an alleged risk of permanent, disabling and intractable pain as a result of injury to the ilioinguinal nerve." Defendant's Post-Trial Reply Memorandum, at 1-2 (record document no. 58, filed January 29, 2001)(citing plaintiffs' pretrial memorandum). Therefore, we consider aforementioned prongs (2) and (3) as one theory of informed consent and, based on our above ruling on defendant's motion in limine, prong (1) as another.

the evidence, that defendant failed to disclose to plaintiff all the risks material to his decision to undergo the procedure. For the reasons that follow, we do not believe that plaintiffs have met their burden.

Although defendant testified at trial that he could not recall with specificity his conversation with plaintiff prior to his surgery, he did testify as to what his routine pre-surgery discussion with hernia repair plaintiffs entails. Specifically, he routinely tells his patients about the TEP laparoscopic hernia repair procedure and the differences between the TEP procedure and hernia repair done via open incision. Defendant also routinely discusses the risks of laparoscopic hernia repair, including recurrence, bleeding, infection, and the possibility of temporary pain and numbness from nerve injury. Further, defendant routinely provides to patients a video entitled "A Kinder Cut," Defendants Exhibit 67, which discusses some of the benefits of laparoscopic hernia repair, including the decreased likelihood of nerve injury. It is undisputed that defendant does not routinely tell patients about long-term pain as a result of ilioinguinal nerve injury. The court found the defendant credible and, therefore, finds that defendant's routine discussion occurred with plaintiff.

In assessing the materiality of long-term pain resulting from ilioinguinal nerve injury during laparoscopic hernia repair, the court considers not only the testimony of defendant, but also the testimony of other medical experts at trial, as well as the transcript of Dr. Leitman's deposition submitted on plaintiffs' behalf.

Plaintiffs produced the testimony of two board certified medical experts on the issue of informed consent, Dr. Voeller and Dr. Leitman.

Dr. Voeller was involved in the initial development of the TEP laparoscopic procedure, and has performed approximately three thousand TEP laparoscopic hernia repairs. Dr. Voeller testified on direct examination that the risks associated with laparoscopic hernia repair depend on the experience of the surgeon and generally include those risks associated with hernia repair by open incision. He further testified that in the hands of an experienced physician it is very uncommon for the ilioinguinal nerve to be damaged during laparoscopic hernia repair. He opined that the experience of the physician is based, in part, on the knowledge of the surgeon and the number of procedures he or she has performed, with most surgeons feeling confident after 20-30 repairs.¹² On cross examination, he testified that a small minority of patients, approximately 2 to 8 percent, depending on the surgical literature reviewed, may experience long-term pain after laparoscopic hernia repair surgery. Upon further questioning by defense counsel, he testified that the pain he was referring to may not necessarily be from impact with a nerve but,

¹² Defendant testified that he had performed approximately 25-30 laparoscopic hernia repairs prior to plaintiff's procedure. See Findings of Fact, \P 7.

rather, includes the "universe" of potential complications which can occur during a laparoscopic procedure creating long-term pain. In a 1995 article authored by Dr. Voeller, he reported on 300 patients that had undergone the TEP procedure with the use of a distention balloon.¹³ In those 300 cases, there were no reports of recurrence and no reports of neuropathy. Additionally, the percentage of patients in that study that developed short-term pain was zero.¹⁴

Dr. Leitman testified during his deposition that he routinely informs patients of the risk of injury to the ilioinguinal nerve prior to laparoscopic hernia repair surgery. Plaintiff's Exhibit 28, at 14. He further testified that ilioinguinal nerve damage is a risk of laparoscopic hernia repair with an incident rate of approximately 2 percent. <u>Id.</u> at 11. Dr. Leitman based his opinion on various studies, a majority of which grouped together all laparoscopic hernia repair patients and compared that group with those patients that underwent open repair surgery. <u>Id.</u> at 27-30. Specifically, the studies did not distinguish between the TEP procedure and the transabdominal extraperitoneal approach (TAP), a procedure that takes place within the peritoneum and approaches the hernia through a

14 Dr. Voeller could not testify as to long-term pain because he had only followed the subjects over the short-term.

¹³ Voeller GR, Mangiante EC. Totally preperitoneal laparoscopic inguinal herniorrhaphy using balloon distention. Scandinavian Journal of Gastroenterology 1995; 30 Supp 208; 67-73. Plaintiffs' Exhibit 30, at 8.

different anatomical path than the TEP procedure performed on plaintiff.¹⁵ Indeed, on cross examination, Dr. Leitman admitted that, of the four medical studies he relied upon to form his opinion, two of the studies did not distinguish between the TAP and TEP procedures, one addressed the TAP procedure only, and the study that did specifically refer to the TEP procedure only reported incidences of short-term nerve complications. <u>Id.</u> Additionally, Dr. Leitman estimated that approximately .5 percent of patients that end up with injury to the ilioinguinal nerve during laparoscopic hernia repair develop intractable, permanent pain. <u>Id.</u> at 39.

Defendant presented the expert testimony of Christopher J. Daly, M.D. Dr. Daly testified that he performs approximately one-hundred hernia repairs per year, both open and laparoscopic, and has done so over the course of twenty years in private

15 The following exchange took place between Mr. Bahl, counsel for defendant, and Dr. Leitman:

Mr. Bahl: If one looks at statistics dealing with a complication rate of open hernia repairs versus laparoscopic hernia repairs, that really doesn't mean anything unless you look at whether those laparoscopic repairs are done by the TAP or TEP method, correct?

Dr. Leitman: Not necessarily. There are some complications that are much more likely to occur from the TAP repair than from the TEP repair because of the exposure of the intraabdominal organs to the mesh or to the surgery.

But there are complications that occur in the TEP repair that occur much less frequently with an open traditional hernia repair because of the nature of the way the repair is done. Plaintiffs' Exhibit 28, at 23, lines 9-25. practice.¹⁶ During his testimony, he stated that the ilioinguinal nerve is sometimes severed during hernia repair via open incision, but that during TEP laparoscopic hernia repair, the ilioinguinal nerve cannot be injured, as the surgical site is physically separated from the nerve by one and a half layers of thick muscle tissue.¹⁷ Further, he testified that it is his practice to see patients approximately one week to ten days after hernia repair surgery, and again one year later to check if the repair has held up. He has never observed anyone with debilitating pain, such as the plaintiff's, after laparoscopic hernia repair. He also told the court that he routinely discusses with hernia repair patients the possibility of bleeding, infection, development of fluid collection, difficulty passing urine and recurrence. He does not inform patients about the risk of injury to the ilioinguinal or genitofemoral nerves

¹⁶ Dr. Daly acknowledged that at the time of trial, it had been "at least one year" since he had performed a laparoscopic hernia repair, testifying that hospitals generally discourage the procedure due to the exorbitant costs involved.

¹⁷ The court was presented with an inconsistency between Dr. Daly's aforementioned testimony at trial and his expert report, Defendant's Exhibit 59, at 2, where he states: "[the ilioinguinal nerve] is routinely manipulated and not infrequently divided during the course of a hernia repair, whether this repair is done endoscopically or through a more conventional open incision." Defendant's testimony on direct examination, however, corroborated that of Dr. Daly's trial testimony in that the ilioinguinal nerve is positioned well below the muscle. Specifically, defendant stated that the ilioinguinal nerve is approximately 2 layers of muscle below the placement of mesh and that no surgical tacks are placed down in that area.

because the risk is not anticipated whether the repair is done from an open incision or laparoscopic technique.

Defendant, Dr. Daly and Dr. Leitman, in their experience, have never before seen a patient experience the type of pain plaintiff complains of after undergoing a laparoscopic hernia repair. Dr. Leitman testified that he had observed ilioinguinal nerve pain in his patients following surgery; however, the pain had never "lasted for more than a few months," and he never had a patient with "persistent pain such as the pain that [plaintiff] has to date." Plaintiffs' Exhibit 28, at 14-15. Indeed, as stated above, Dr. Leitman testified that, in his opinion, the risk of intractable permanent pain from laparoscopic hernia repair has an incident rate of .5 percent. Additionally, although Dr. Leitman did see "a couple of" patients experience persistent numbness, he opined that such numbness was "on the basis of nerve injury that can occur on re-operation." Id. at 15.

In addition, Dr. Voeller explained that in experienced hands the risk of injury to the ilioinguinal nerve during the procedure is "very uncommon." At the time defendant performed the procedure on plaintiff, he had performed 25-30 laparoscopic hernia repairs. This factor, according to Dr. Voeller, is one that would be considered in finding defendant "experienced."

In this case, defendant disclosed all material risks of the procedure to plaintiff, including the risk of bleeding, infection, recurrence and, notably, the possibility of short-term

pain or numbness from nerve injury. Further, the aforementioned video provided to plaintiff by defendant mentioned a decreased likelihood of nerve injury with the laparoscopic method as compared to the method performed by open incision.¹⁸ Also significant is the Informed Consent to Surgery form signed by plaintiff on May 21, 1997, the date of his initial consultation with defendant. This form provides, in relevant part, the following:

1. I, <u>Ken Weiss</u>, authorize the performance of the following operation/procedure/therapy <u>repair of left</u> <u>inguinal hernia with mesh - laparoscopic method</u> performed by Doctor <u>Green</u> and such other alternate or assistants as he/she may choose;¹⁹

2. Prior to my consent, the physician or his alternate (a physician) has explained to me in detail the nature and purpose of the operation/procedure/therapy, the possible alternative methods of treatment or diagnosis, the risks involved with each method, the possible consequences, and the possibility of complications;

* * *

5. I acknowledge that no guarantee or assurance has been given by anyone as to the results that may be obtained;

* * *

9. I have had the opportunity to ask additional questions of the physician or his/her alternate (a

19 The underlined portions represent blanks filled in by defendant.

¹⁸ Plaintiff testified at trial that he did not remember receiving the video [or brochure] from defendant. However, he could not testify with certainty that he did not receive the informational materials. We find credible defendant's testimony that it was his routine practice to provide such materials to his patients and find that he in fact did so with plaintiff.

physician) about the authorized operation/procedure/therapy.

10. I declare that I have read and fully understand the above consent. All blanks or statements requiring insertion or completion were filled in and inapplicable paragraphs, if any, were stricken before I signed.

Defendant's Exhibit 4, at 7.

Therefore, based on the foregoing, the plaintiffs have failed to show by a preponderance of the evidence that the risk of long-term pain from injury to the ilioinguinal nerve during laparoscopic hernia repair is a risk considered by a reasonable person as material to his or her decision to undergo the procedure. Accordingly, we hold that defendant obtained plaintiff's informed consent to perform the laparoscopic hernia repair.

B. Right Side Hernia Repair

Plaintiffs also contend that defendant did not obtain plaintiff's informed consent to operate on his right side hernia, alleging that he "would not have consented to a bilateral procedure due to his desire to perform a memorial service several days after the operation." Plaintiffs' Memorandum Regarding Trial Testimony and Law on Informed Consent, at 4. In forming their argument, plaintiffs rely on paragraph 4 of the Informed Consent form signed by plaintiff which provides:

> 4. In the course of the operation/procedure/therapy any unforeseen complications and/or conditions should arise, I consent to the performance of additional procedures, not contemplated, which in the opinion of the physician or his/her alternate (a physician) are deemed appropriate.

Defendant's Exhibit 4, at 7. Plaintiffs submit that plaintiff signed the aforementioned Informed Consent form for the left side inguinal hernia and other conditions that were unforeseen, and that defendant knew of, and should have obtained his consent to repair, plaintiff's right side hernia prior to the surgery. In support of their argument that the right side procedure was foreseen, plaintiffs reference defendant's medical chart which includes defendant's diagnosis of plaintiff's condition during his initial exam on May 21, 1997. Defendant's Exhibit 4, at 4. Defendant diagnosed plaintiff with a positive left inguinal hernia. <u>Id.</u> He also recorded no obvious right side hernia, but noted that upon performing a "fingertip" test, he did feel a slight bulge. <u>Id.</u>

Based on defendant's May 21, 1997 examination notes, it is plausible that defendant perceived the possibility, albeit remote, of an abnormality on plaintiff's right side. The court, however, finds that the right side hernia repaired by defendant was predominantly unanticipated and unforeseen. In support of this finding is a letter dated June 2, 1997 to Dr. James Baldys where defendant states: "Examination reveals a large left inguinal hernia with bulging down through the external ring suggestive of possible indirect hernia. There is no evidence of hernia on the right." Defendant's Exhibit 4, at 9. Furthermore, the court finds that plaintiff's right side hernia repair was not contemplated until defendant was performing laparoscopic hernia repair for plaintiff's left side and, at that time, observed a right side hernia in need of repair. Defendant explained to plaintiff that one of the benefits of the laparoscopic procedure was that he would be able to view both the left and right side of plaintiff's groin. Additionally, prior to surgery, defendant told plaintiff he would take a "look around" for additional hernias. Plaintiffs' Memorandum Regarding Trial Testimony and Law on Informed Consent, Exhibit A.

"Where ... consent is given for a particular surgical procedure and an unanticipated condition is found during surgery, absent an emergency situation, the physician must have the express or implied consent of the patient to extend the surgery." <u>Millard v. Nagle</u>, 587 A.2d 10, 14 (Pa. Super. 1991). <u>See also</u> <u>Gray v. Grunnagle</u>, 223 A.2d 663 (Pa. 1966) (holding that in extension of surgery case issue of whether the plaintiff had consented was an issue for the jury).²⁰

In this case, we believe that plaintiff, by signing the above mentioned Informed Consent to Surgery form, gave defendant his express consent to repair his right side hernia which was unforeseen prior to surgery. Furthermore, the court finds the extension of the hernia repair procedure to plaintiff's right

²⁰ Plaintiffs quote <u>Gouse</u>, 615 A.2d at 334: "'where a physician or surgeon can ascertain in advance of an operation alternative situations and no emergency exists, a patient should be informed of the alternative possibilities and given a chance to decide before the doctor proceeds with the operation.'" (further citation omitted). The court believes that "alternative situations" in <u>Gouse</u> referred to alternatives to surgery and, therefore, is not directly applicable to the instant case where there was no alternative to surgery available to repair plaintiff's hernia.

side was deemed appropriate by defendant. As indicated by his testimony, a TEP laparoscopic hernia repair can be performed only once due to the formation of scar tissue which develop upon closing the abdominal space after the procedure. In the event of a hernia recurrence, repair must be completed via open incision or, as Dr. Daly testified, through TAP laparoscopic repair, both of which require opening and operating within the peritoneum. Ιn order to prevent plaintiff having to undergo a subsequent, more invasive procedure, the court finds that defendant rightfully found it appropriate to repair plaintiff's right side hernia while plaintiff was already undergoing the laparoscopic repair on his left side. Furthermore, we find incredulous plaintiff's argument that he would not have consented to a bilateral procedure because he was to perform a memorial service a few days after the surgery, as no evidence was presented to establish that the recovery time or the risk involved was any different than that of surgery to repair the left side hernia alone.

As the laparoscopic procedure performed on plaintiff's left side did not vary significantly from that of the right side, neither did the material risks involved. Accordingly, based on our finding that defendant disclosed all material risks of the procedure to plaintiff and plaintiff gave his express consent to the unforeseen right side repair, the court finds that defendant obtained plaintiff's informed consent to operate on plaintiff's left and right side hernias.

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IV. CAUSATION

Even if there was enough evidence to substantiate a finding of a lack of informed consent, there is, nonetheless, insufficient evidence to establish, by a preponderance of the evidence, that plaintiff's complaints of pain from the alleged injury to his ilioinguinal nerve were caused by the laparoscopic hernia repair surgery performed by defendant.

"As liability is based on the absence of informed consent, the court in determining damages must first determine what injuries 'resulted from the invasion.'" <u>MacDonald v. United</u> <u>States</u>, 767 F.Supp. 1295, 1313 (M.D.Pa. 1991)(citing <u>Cooper v.</u> <u>Roberts</u>, 286 A.2d 647, 649 (Pa. Super. 1971)).

In <u>MacDonald</u>, this court previously addressed a claim of lack of informed consent. 767 F.Supp. at 1309. Contrary to this case, however, we found that the defendant in <u>MacDonald</u> did not obtain plaintiff's informed consent to arterial bypass surgery and, therefore, was liable to plaintiff for any damages resulting from the course of treatment performed by defendant. <u>Id.</u> at 1313. There, where the plaintiff suffered "swelling, pitting edema and severe dermatitis in his left leg" immediately after surgery and prior to discharge from the hospital, we held that plaintiff proved by a preponderance of evidence that his injury -- specifically, continuing pain in his lower left extremity -was caused by the surgery "even though [t]he precise physiological basis for the causal link [had] not been established." Id.

In the instant case, plaintiff's surgery was on August 12, 1997. He next saw defendant on August 16, 1997 for the treatment of friction blisters caused by adhesive bandages on the trocar incision sites. Plaintiff made no other reports of pain at that time. On August 22, 1997, plaintiff attended his first regularly scheduled post-operative visit with the defendant. At that time, he noted no problems, and stated to defendant's nurse that "everything was working well." It was at some point after the August 22, 1997 office visit, that plaintiff experienced a sudden onset of right groin pain for the first time. Specifically, sometime after August 22, 1997, plaintiff was visiting Norman Morris in the hospital and when he reached for Mr. Morris's hand to offer a prayer, he doubled up in pain. Subsequently, on August 27, 1997, plaintiff saw defendant for his second postoperative visit at which time defendant noted in his exam chart that plaintiff was exhibiting pain "out of proportion to [his] clinical presentation." Defendant's Exhibit 4, at 21. Thus, unlike <u>MacDonald</u>, there was a period of approximately two weeks between the surgery and plaintiff's onset of abnormal postoperative pain, precluding a finding of any direct causal link between the two.²¹

²¹ Defendant testified at trial that incisional pain, blistering around the trocar incisions, and general discomfort are (continued...)

Similar to MacDonald, we find that, based on the evidence presented at trial, there is no physiologic explanation for plaintiff's complaints of pain. Indeed, all of the experts presented, including plaintiff's treating physicians, confirmed that plaintiff has no objective basis for his pain.²² Plaintiffs' expert, Dr. Rigal, did, however, diagnose plaintiff with "neurapraxia of the ilioinguinal nerve," i.e. injury to the nerve, and performed an ilioinguinal nerve block. Plaintiff's Exhibit 26, at 13. This nerve block provided plaintiff with transient relief, id. at 15-17, and, according to Dr. Rigal, was presumptive evidence that "pain was arising from the ilioinguinal area." Id. at 16. Dr. Rigal also opined that a finding of a surgical screw at the exit point of the ilioinguinal nerve would explain the nature of plaintiff's pain and why he did not respond to the nerve blocks over the long-term. Id. at 21. On cross examination, however, Dr. Rigal conceded that the alleged lack of pain relief from the various ilioinguinal nerve blocks performed

21(...continued)
considered to be "normal post-operative pain."

22 Plaintiff's expert and treating physician, Dr. Tomack testified that he had diagnosed plaintiff with ilioinguinal nerve injury as a result of the laparoscopic hernia surgery. However, the court declines to credit his testimony, based, in part, on his personal relationship with plaintiff. Dr. Tomack's testimony disclosed that his wife and plaintiff Hurwitz are close personal friends, he and plaintiff had played golf on several occasions (including once after plaintiff's hernia repair), and that the four of them had gone out to dinner and to the Community Arts Theater together. Furthermore, his credentials indicate that his education and experience are not on par with that of defendant's experts. could be due to the fact that there was no physiological injury to the nerve itself. Id. at 32-33.

Plaintiffs contend that Dr. Moore's removal of a surgical tack near the exit point of the ilioinquinal nerve during his April 12, 1999 exploratory surgery on plaintiff establishes that the ilioinguinal nerve was impinged, and thus injured, during defendant's hernia repair surgery on August 12, 1997. This contention was contradicted by the evidence presented at trial. As mentioned above, defendant testified that he does not place surgical tacks along the ilioinguinal nerve during laparoscopic hernia repair because the surgical site is separated from the nerve by approximately two layers of muscle tissue. Additionally, Dr. Daly testified that if the nerve had been impinged by defendant, plaintiff would have experienced some relief in his pain after the tacks were removed by Dr. Todhunter and Dr. Moore.²³ Dr. Todhunter testified that during his exploratory surgery on January 12, 1998 he had observed the ilioinguinal nerve of plaintiff distally to the site of defendant's surgery and he found the nerve to be intact, with no signs of injury, inflammation or infection. Dr. Moore's surgical findings revealed that he did observe distal branches of the ilioinguinal nerve, although he did not observe the main trunk of

²³ Dr. Leitman testified that literature suggests that once the tacks and mesh are removed, the pain goes away. Plaintiff's Exhibit 28, at 38. However, he opined the pain may still persist after the removal of tacks where the nerve is entrapped by scar tissue and becomes inflamed. <u>Id.</u> at 41-42.

the nerve. Dr. Kothari, a board certified neurologist, testified that had nerve injury occurred during defendant's surgery, the nerve would atrophy and wither distally to the point of injury, concluding that the distal branches of the nerve observed by Dr. Moore could not exist and be viable unless the ilioinguinal nerve was intact proximately.²⁴ Dr. Kothari opined that plaintiff did not suffer any nerve injury during the hernia repair procedure performed by defendant.

Over the course of approximately three years following plaintiff's surgery by defendant, plaintiff has been taking numerous prescription medications including, in part, Percocet, Neurontin, MS Contin, Elavil, and Ritalin. He received nerve blocks from defendant, Dr. Rigal, Dr. Moore and pain management experts at Johns Hopkins Medical Center, and had a spinal cord stimulator and an epidural dilaudid pump surgically placed by Dr. Krishnan. Additionally, Dr. Epstein performed a root ganglion stimulation with radio frequency lesioning of the nerve roots at the levels of L1-L2 and L2-L3. None of the aforementioned procedures and prescriptions has provided plaintiff with any significant or long-lasting pain relief. He also obtained no relief from the two exploratory surgeries performed by Dr. Todhunter and Dr. Moore.

²⁴ Although Dr. Daly testified that there could be a nerve impingement proximately with no evidence of nerve damage distally, it is for the court to determine the weight of the evidence.

Defendant's expert, Dr. Bonfiglio, a highly respected and qualified physician practicing physical medicine and rehabilitation, testified that he found "it very unusual" that plaintiff had not obtained relief from the nerve blocks, and that, in his opinion, there is no "good physiologic basis for [plaintiff's] pain report." Defendant's Exhibit 69.1, at 21-22. In his report, Dr. Bonfiglio states: "[Plaintiff's] description of the pain (especially considering the constellation of its burning quality, its unresponsive [sic] to the numerous treatments attempted, and its marked exacerbation with sitting) is not consistent with any recognized pathology. Considering the location of the pain and the presumed inciting nerve tissues, sitting should not increase the discomfort." Defendant's Exhibit 61. It was also Dr. Bonfiglio's opinion that, while plaintiff generally believes in and perceives his pain, there is a "significant psychological component to that," as plaintiff does not present a "classic ilioinguinal nerve injury." Defendant's Exhibit 69.1, at 44, 51. Furthermore, Dr. Bonfiglio testified that, in twenty years of practice, he had never "prescribed narcotics for non-cancer patients at this level." Id. at 58-59.

Additionally, testimony of Dr. Michals, a psychiatrist, and Dr. Samuel, a psychologist, both of whom independently examined plaintiff, revealed that plaintiff has a pre-existing psychological make-up that may help to explain his subjective complaints of pain. Specifically, Dr. Michals opined based on a reasonable degree of psychiatric certainty that plaintiff has hysterical dependent personality traits, which he developed prior to the hernia repair surgery. These personality traits, according to Dr. Michals, include a "preoccupation with physical complaints." Dr. Michals believed that the pre-existing personality traits of plaintiff could explain, in part, plaintiff's perception of ongoing pain despite the absence of a physiological cause or origin of said perceived pain.

Dr. Samuel concurred with Dr. Michals that plaintiff has underlying hysterical and dependent personality traits. When asked by the court to define "hysterical personality trait," Dr. Samuel explained that it represents patients that are "over dramatic," "over reactive," and "seen as directing attention away from others towards oneself."

Based on the foregoing, the court finds that plaintiff has not established by a preponderance of the evidence that the surgery was a substantial factor in bringing about plaintiff's complaints of pain.

V. CONCLUSIONS OF LAW

_____1. Plaintiff gave his informed consent to the TEP laparoscopic hernia repair performed by defendant for plaintiff's left and right sides.

2. Plaintiff's long-term disabling pain was not caused by the surgery.

3. Because plaintiff Hurwitz's loss of consortium claim is wholly dependent on the success of her husband's claim, Hurwitz cannot recover for loss of consortium. 4. Defendant is not liable to plaintiffs for damages.

_____An order consistent with this memorandum will issue.

James F. McClure, Jr. United States District Judge

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

R. KENNETH WEISS and JANET HURWITZ, his wife, Plaintiffs	: 4:CV-99-974 : (Judge McClure)
V.	
JOHN GREEN, D.O., Defendant	:

ORDER

February 7, 2001

On the basis of the findings of fact and conclusions of law, and supporting reasons, set forth in the accompanying memorandum,

IT IS ORDERED THAT:

 The clerk is directed to enter judgment on the Complaint (record document no. 1, filed June 11, 1999) in favor of defendant and against both plaintiffs.

2. The clerk is directed to close the case file.

James F. McClure, Jr. United States District Judge

FILED: 02/07/01