UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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FINDINGS OF FACT AND RULINGS OF LAW

February 4, 2015

DEIN, U.S.M.J.

I. INTRODUCTION

This malpractice action, brought under the Federal Tort Claims Act, arises out of the medical treatment the plaintiff received at the Department of Veterans Affairs Medical Center in Jamaica Plain, Massachusetts, on July 13, 2007. Specifically, the plaintiff challenges the manner in which an esophagogastroendoscopy ("EGD" or "endoscopy") was performed, and the sufficiency of the information he was provided prior to consenting to the procedure. A jury-waived trial was held before this court on October 6, 7 and 8, 2014. The court heard testimony from the plaintiff, Enoch Woodhouse II; his wife Stella Sealy Woodhouse; his treating physician at Massachusetts General Hospital, Christopher R. Morse, MD, Internal Medicine, Gastroenterology; and three treating physicians from the VA Medical Center in Jamaica Plain: Sharmeel Wasan, MD, Fellow in Gastroenterology; Satish Singh, MD, Staff Gastroenterologist; and Marcos

C. Pedrosa, MD, Chief of Endoscopy. The plaintiff's primary care physician, Carl Dettman, MD, testified by deposition. The parties submitted proposed findings of fact and rulings of law on December 17 and 22, 2014. The court has been provided with transcripts of the trial proceedings. After careful consideration of the transcripts, exhibits, and the parties' submissions, this court makes the following findings of fact and rulings of law. Judgment shall enter in favor of the defendant for the reasons detailed herein.

II. FINDINGS OF FACT¹

- 1. The plaintiff, Enoch Woodhouse, was born in 1927 in Boston, Massachusetts. He enlisted in the army at age 17 during World War II, and was a member of the Tuskegee Airmen, a group with which he is still involved. After being discharged from the army, Mr. Woodhouse attended Yale on the GI Bill, and graduated in the class of 1952. He attended Boston University and Yale law schools, and received his JD degree. (I:76-78).
- 2. After law school, the plaintiff was appointed as a United States Diplomatic Courier with the State Department, and later served as a JAG officer for the Air Force before starting his own law practice in Boston. (I:77-79). There is no question that Mr.

¹ Exhibit 1 contains the medical records from the VA Medical Center. Exhibit 2 contains the medical records from Massachusetts General Hospital ("MGH"). Exhibit A is the transcript of the deposition of Dr. Carl E. Dettman, which was admitted by agreement in lieu of live testimony. There are three days of trial transcripts cited by day and page number.

Woodhouse has served his country honorably and proudly and, as his counsel argued, that he had earned the right to quality healthcare services. (See III:91).

- 3. Mr. Woodhouse developed dysphagia, <u>i.e.</u>, difficulty in swallowing. On March 18, 2002, he was seen as an outpatient at the VA Medical Center in Jamaica Plain, where he complained that he had been having difficulty swallowing pills and solid food for the past two years. (Ex. 1 at 327; I:81-82). At that time, he had no complaints about weight loss. (Ex. 1 at 327).
- 4. On April 3, 2002, he underwent a barium swallow and upper GI exam at the VA Medical Center. The test showed a "small Zenker's diverticulum, and no relaxation phase of the cricopharayngeal [muscle] and [a] small hiatal hernia, no other mechanical abnormalities." (Ex. 1 at 322).
- 5. A Zenker's diverticulum is an outpouching, or defect, of the posterior wall of the esophagus. It forms posterior to and above the cricopharyngeus muscle (the "CP muscle") when a hypertonic, or tense, CP muscle partially obstructs the flow of food down the esophagus during swallowing. When the food hits the obstruction, it finds a point of weakness above that obstruction and creates a pouch, which is the Zenker's diverticulum. (I:24-25). As in the case of Mr. Woodhouse, a Zenker's diverticulum in and of itself can be asymptomatic. It may become problematic, however, if it causes regurgitation or aspiration, or if it causes halitosis. (I:25; II:103-04).
- 6. In 2002, Mr. Woodhouse and his doctor agreed to a conservative course of treatment for his swallowing difficulties. Mr. Woodhouse was to manage his condition

by breaking up his pills, chewing his food well, drinking a lot of fluid while eating, and monitoring his progression. (Ex. 1 at 322).

- 7. Mr. Woodhouse continued to have difficulty swallowing. In 2004, he was seen by his primary care doctor at the VA Medical Center, Dr. Carl Dettman. (Ex. 1 at 297). In March 2004, he reported to Dr. Dettman that he was "concerned" because "others have commented on his [weight] loss" and attributed his weight loss to difficulty chewing due to new false upper teeth. (Ex. 1 at 307). His records showed a slow weight loss over the last 1½ years "most likely due to dentition." (Id.). By October 2004, his weight had declined from 138 in March to 131¾ pounds. (Ex. 1 at 297, 307). His weight remained stable through about June 2007. (See Ex. 1 at 278).
- 8. On May 17, 2007, Mr. Woodhouse was seen by Dr. Dettman complaining that over the "last couple of months" he had had difficulty swallowing solids, which were getting stuck in his throat, and in swallowing pills. (Ex. 1 at 278-79). His weight was recorded at 134 pounds. (Ex. 1 at 279). While the plaintiff attributed his difficulty to his Zenker's diverticulum, the doctor questioned whether this was the cause. (Ex. 1 at 279).
- 9. Dr. Dettman ordered another barium swallow and upper GI, which was performed on June 4, 2007. (Ex. 1 at 278). The exams disclosed no changes since 2002. There was still a small Zenker's and non-relaxation of the CP muscle. (Ex. 1 at 278). Dr. Dettman wrote that he "doubt[ed] Zenker's is cause of swallowing problems," but since the patient was "very symptomatic" and Mrs. Woodhouse, a nutritionist, was "very concerned about weight loss, and malnutrition relating to swallowing difficulty," he

ordered further review by a gastroenterologist. (Ex. 1 at 278). Dr. Dettman discussed the test results with Mr. and Mrs. Woodhouse on June 5, 2007. (Ex. 1 at 278).

10. I find that while the medical records do not support a finding of significant weight loss from 2004 through 2007, Mr. and Mrs. Woodhouse consistently reported in 2007 that Mr. Woodhouse was losing a lot of weight, and that they were concerned that he would become malnourished. The doctors at the VA Medical Center took the Woodhouses' concerns seriously.

The Recommended Procedure

- 11. On June 26, 2007, Mr. Woodhouse had a gastroenterology consult with Dr. Raj Goyal at the VA Medical Center. (Ex. 1 at 274). Dr. Goyal is a pre-eminent expert in his field of the esophagus and esophageal diseases. (II:65-66). The plaintiff has raised no objection to the care provided by Dr. Goyal.
- 12. Mr. Woodhouse complained to Dr. Goyal that he had been suffering from dysphagia for many years, which he described as being localized to the throat and limited mostly to solids. (Ex. 1 at 274). According to Mr. Woodhouse (although not supported by the medical records), he had lost over 15 pounds over 5 years due to poor food intake. (Ex. 1 at 274). Dr. Goyal noted that there had been a "recent barium swallow for worsened symptoms (but no further weight loss)" which revealed no change there was still a small Zenker's and non-relaxation of the CP muscle. (Ex. 1 at 274). Dr. Goyal recommended an upper endoscopy ("EGD") with empiric dilation of the upper esopha-

geal sphincter. (Ex. 1 at 276). According to Dr. Goyal's notes "[t]he assessment and plan were discussed with the patient who appears to understand." (Ex. 1 at 276).

- 13. An upper endoscopy (EGD) is performed using a scope that is passed down the esophagus into the stomach and into the first portion of the duodenum, or the area of the bowel after the stomach, in order to look for any abnormalities. (I:27).
- 14. The EGD is done to assist in identifying the cause of dysphagia. In the case of a patient such as Mr. Woodhouse, <u>i.e.</u>, an older patient who was complaining of a worsening condition and weight loss, I find that it is common and within the standard of care to use the EGD to rule out cancer. (II:52, 68-69, 118). While cancer may be identified through a barium swallow, an endoscopy may help to reveal lesions that are not evident in a barium swallow. (I:65).²
- 15. An EGD may also result in a limited dilation of the sphincter simply due to the passage of a scope through the constricted area. (III:54-55). This might result in some relief to the patient, although it would be very temporary. (III:12).
- 16. A dilation is a procedure using a balloon or series of dilators (long tubes of varying increasing sizes) that are passed down the esophagus over the obstruction in order to stretch out a stricture that is causing the narrowing of the esophagus. (I:27-28, 70). Generally, a scope is passed through the narrowed area to assess it, and a guide wire is

² Stable weight would mitigate against a finding of cancer. (<u>See III:71</u>). In light of Mr. and Mrs. Woodhouse's reports of significant weight loss, however, I find that the VA doctors acted appropriately in seeking to rule out cancer.

then left behind. The scope is taken out and then, using the guide wire, either a series of dilators that are tapered and rigid, or a balloon that will have a central channel that could be threaded over the wire, is inserted to stretch out the area. (II:71). The guide wire helps insure that the dilators are placed down the esophagus and not diverted into the diverticulum, so it is not prudent to dilate a patient with a Zenker's diverticulum without some sort of guidance or tract. (II:71). However, the existence of a Zenker's diverticulum does not render an endoscopy inappropriate treatment. (See I:65-66).

- 17. With an "empiric dilation," a dilation is performed to treat whatever is causing the symptoms, without knowing what in actuality is causing the symptoms. (II:69-70).
- 18. The dilation is intended to provide temporary relief by stretching the non-relaxing CP muscle. (I:28-29). At some point following a dilation, the muscle will recontract back. (I:28). There is a study, however, albeit involving only a limited number of patients, that shows "that endoscopic dilation can be an effective treatment for patients with oropharyngeal dysphagia because of a CP bar" and that the temporary relief provided can last as long as a period of years, even if the patient has a Zenker's diverticulum. (I:70-72, III:33-34, 42-43).
- 19. As a general statement, a dilation will not treat a Zenker's diverticulum, and the pouch will still exist. (I:28-29; II:121; III:67).
- 20. The plaintiff's expert, Dr. Morse, initially questioned the decision to attempt to perform the endoscopy and dilation on a patient with a known Zenker's

diverticulum and negative barium swallow on the basis that the risk of cancer was low. Instead, he testified that Mr. Woodhouse should have been sent to surgery initially, with an endoscopy performed in connection with the surgery. (See II:34-35, 59). However, Dr. Morse subsequently testified that the EGD and dilation may have been an appropriate initial course of treatment. (I:65-66 ("I don't know that the initial decision was incorrect or correct. That's a physician's judgment call.")). The plaintiff has made it clear that he is not challenging the initial decision to perform the endoscopy and dilation. (I:66; III:91-92). Rather, the issue is whether, as detailed below, the VA doctors should have continued attempts to insert the scope after having difficulty with the procedure. (I:66).

21. To the extent that it is an open issue, I find that it was within the acceptable standard of care for the VA doctors to have attempted to perform an endoscopy and dilation without first proceeding to surgery. As an initial matter, Mr. Woodhouse's Zenker's diverticulum was both small and asymptomatic, so there is evidence that there was no need to treat it surgically in 2007. (II:104; III:43). Moreover, an endoscopy is a much less invasive procedure, and does not require general anesthesia so it has less potential dangers for the patient. (II:120; III:33-34, 43-44). It is recommended by doctors that you start with the least invasive and less risky procedures before moving on to more invasive procedures. (II:120; III:16-17, 43-44). The results of the endoscopy, along with other tests such as a functional test, would provide information to determine if surgery was warranted. (II:46).

The Procedure at the VA Medical Center

- 22. As detailed above, Dr. Goyal recommended that Mr. Woodhouse undergo an upper endoscopy with an empiric dilation of the upper esophageal sphincter. (Ex. 1 at 276). Mr. Woodhouse underwent the procedure at the VA Medical Center in Jamaica Plain on July 13, 2007. (Ex. 1 at 272-73). He was 80 years old at the time.
- 23. Approximately 15 minutes before the start of the procedure, Mr. Woodhouse met with Dr. Sharmeel Wasan. (II:15, 17). Dr. Wasan had completed a three year Residency in internal medicine, worked as a hospitalist at Brigham and Women's Hospital for a year, and was starting as a Gastroenterology Fellow, a three year program. (II:23-25). She had just started at the VA Medical Center on July 1, 2007. (II:25-26). She had been taught how to obtain an informed consent. (II:27-28).
- 24. Dr. Wasan had no independent memory of obtaining consent from Mr. Woodhouse. I find, however, that Dr. Wasan followed her usual procedure in the case of Mr. Woodhouse. I also find that since Dr. Wasan was new to the VA, it is likely that she would have been even more careful to follow appropriate procedure, especially since, as was standard procedure, she was being overseen by the attending physician, Dr Singh. (See II:17-18).
- 25. It was Dr. Wasan's practice to explain the scheduled procedure, but not the alternatives to the procedure. (II:18). While the plaintiff argues that Dr. Wasan should have explained the alternative of surgery to Mr. Woodhouse, I find that the plaintiff has not established that it was Dr. Wasan's role to explain alternative procedures, especially since she was not responsible for determining the appropriate course of treatment.

Rather, the record establishes that Dr. Dettman discussed the test results with Mr. and Mrs. Woodhouse on June 5, 2007. (Ex. 1 at 278). Mr. Woodhouse 's condition was then assessed by Dr. Goyal, who determined the appropriate course of treatment. (Ex. 1 at 276). Moreover, according to Dr. Goyal's notes, he reviewed his "assessment and plan" with Mr. Woodhouse who understood them. (See Ex. 1 at 276). The plaintiff has not challenged Dr. Goyal's treatment of him. I find that the plaintiff has failed to establish that Dr. Wasan was responsible for advising him of alternative treatment options and/or that Dr. Goyal did not fully explain the available treatment options.

26. In connection with obtaining consent for the endoscopy and dilation procedure, it was Dr. Wasan's practice to explain that there were risks, including, without limitation, "risks of bleeding, infection and even a small tear or a perforation that can require an emergency surgery. These risks are very rare but they do exist." (II:29). In addition, it was Dr. Wasan's practice to tell a patient with a medical history of a Zenker's diverticulum that "because you have Zenker's diverticulum, there is a slightly increased risk of having a tear that can cause a surgery." (II:29-30). Dr. Wasan's practice would have been to have the patient sign a consent form. (II:30). The form Mr. Woodhouse signed expressly provided: "[p]otential complications include perforation (a hole in the esophagus, stomach or small intestine[)], bleeding requiring transfusion, infection, drug reaction, the need for surgery, or death." (Ex. 1 at 36).

- 27. I find, therefore, that Mr. Woodhouse was informed, both orally and in writing, that there was a risk of perforation during the EGD and that his Zenker's diverticulum increased the risks. (II:29; Ex. 1 at 36).
- 28. The risk of perforation during a routine upper endoscopy is less than one percent, although as the condition becomes more and more advanced, the risk becomes higher. (III:13). The risk of perforation for a patient with Zenker's diverticulum is somewhere between three and five percent. (II:37).
- 29. Mr. Woodhouse testified that if he been advised that there was a risk of bleeding requiring a transfusion, or a possibility of a drug reaction, a possible need for surgery, or that the procedure could result in death, he "never" would have agreed to the procedure. (I:86). I find, however, that Mr. Woodhouse was appropriately advised and that he did consent to the procedure freely and voluntarily. In fact, as detailed below, he subsequently agreed to a much more invasive, surgical procedure, which was performed by Dr. Morse with similar warnings.
- 30. Dr. Satish Singh was assigned to perform the EGD on Mr. Woodhouse. (II:64-65). Dr. Singh graduated from Boston University medical school in 1987. He completed a three year residency at University of Rochester, Strong Memorial Hospital. He did a GI Fellowship at Yale University, Yale New Haven Hospital, and he is board certified in gastroenterology. (II:57-58). Prior to the day in question, Dr. Singh had performed hundreds of EGDs. (II:59-60).

- 31. Dr. Singh reviewed portions of Mr. Woodhouse's medical records prior to the procedure, including Dr. Goyal's notes. (II:42-43). He was aware that Mr. Woodhouse had a Zenker's diverticulum. (II:46). As ordered by Dr. Goyal, Dr. Singh planned on doing an upper endoscopy and, if appropriate, an esophageal dilation. (II:43). The endoscopy would determine whether the dilation, which as detailed above included the passing of a wire into the stomach, could be performed, and whether there were other causes of the dysphagia. (II:44-45). The fact that Mr. Woodhouse had a Zenker's diverticulum put Dr. Singh "at high alert" and he knew that he should be "very careful" when introducing the scope. (II:46).
- 32. Mr. Woodhouse was consciously sedated, which meant that he could still interact with the doctor. (II:133). Under conscious sedation, the patient responds to both verbal stimuli and to touch. (III:10).
- 33. Dr. Singh first attempted to pass the 180 adult endoscope. (II:46). Normally, a physician puts the endoscope down the patient's throat right on the sphincter and asks the patient to swallow. With gentle pressure the endoscope can then be advanced into the esophagus. (II:134). This is a standard procedure which plaintiff's expert agrees has a very small risk of perforation. (I:44). Dr. Singh attempted this procedure three to five times, but was unsuccessful. (II:47). I find that Dr. Singh did not push the scope into the esophagus because of his concerns about the Zenker's diverticulum. (II:78-79). I also find that Dr. Singh did not push the scope into the Zenker's. If he had done so, it would have been obvious from the pictures being generated by the scope. (II:75-76).

- 34. Dr. Singh felt that there was something that he couldn't explain, so he then called Dr. Marcos Pedrosa for assistance. (II:46-47). Dr. Pedrosa was the Chief of Endoscopy at the VA Medical Center and had performed approximately 8,000 or more upper endoscopic procedures as of that time. (II:129-130). Dr. Pedrosa was board certified in internal medicine and gastroenterology and had advanced training in endoscopy. (II:127).
- 35. Dr. Singh advised Dr. Pedrosa that Mr. Woodhouse had progressive dysphagia and a history of a Zenker's diverticulum, and that Dr. Singh had been unable to pass the scope. (II:48).
- 36. Like Dr. Singh, Dr. Pedrosa first tried a standard endoscope. Again, however, Mr. Woodhouse's sphincter did not relax and he was unable to swallow and pass the scope into the esophagus. (II:134). Dr. Pedrosa then tried to pass a thinner, nasogastric (nasal) endoscope through Mr. Woodhouse's mouth, but again this did not work. (II:134-35). Finally, Dr. Pedrosa passed the thinner, nasogastric endoscope through Mr. Woodhouse's nose. (II:79-80, 135). That procedure went smoothly. Thus, Dr. Pedrosa inserted a J-wire down in the stomach as a guide wire. (II:135). The nasal scope was withdrawn. Using the J-wire as a guide, Dr. Pedrosa passed a Q 180 scope orally into position, allowing the doctors to examine the esophagus, stomach and duodenum. (II:81, 135-36). No significant abnormalities were noted. (Ex. 1 at 2).
- 37. As he was engaged in the procedure, Dr. Pedrosa noted a significant amount of scarring in the sphincter area. (III:5-6). He opined that scarring is usually

caused by a chronic inflammation. (III:6). Dr. Pedrosa testified that the scarring is visible on pictures he had taken during the endoscopy. (III:5; Ex. 1 at 4-5; Ex. 5). However, the defendant's expert, Dr. Cave, did not see scarring on the photographs. (III:77-78). I find that since Dr. Pedrosa was viewing the photographs in real time, and in the context of performing the endoscopy, his testimony concerning the existence of scarring is credible.

- 38. Mr. Woodhouse was originally scheduled for a full dilation, but that was not done because Dr. Pedrosa was concerned about the amount of time that Mr. Woodhouse had already been under sedation. (III:10-11)
- 39. Mr. Woodhouse was monitored post-procedure for approximately an hour. This was the standard amount of time. (II:85). When Mr. Woodhouse awoke from the sedation, he complained of pain and difficulty swallowing. (II:31, 86; Ex. 1 at 40). Mr. Woodhouse testified that there was blood coming out of his mouth. (I:87-88). However, that is not reflected in the medical records and no medical witness testified as to the existence or significance, if any, of any blood. I do note, however, that the informed consent form identifies bleeding as a potential risk. (Ex. 1 at 36).
- 40. Mr. Woodhouse was monitored post-surgery by Dr. Wasan, among others. (II:31-32). He was complaining of dysphagia with sharp pain on swallowing, even his saliva, and he was unable to drink. However, there was no substenal chest pain, no shortness of breath, no abdominal pain, and no nausea or vomiting. He was alert and oriented and speaking in full sentences. His abdomen was soft, non-tender and non-

distended. (Ex. 1 at 273; II:32). Pain and difficulty swallowing could be due to natural swelling caused by the scope passing, and would be temporary once the inflammation and trauma caused by the scope healed itself. (II:91).

41. Drs. Singh and Wasan discussed his situation and decided to have Mr. Woodhouse admitted to the hospital for further observation. (II:32). Mr. Woodhouse was transferred to the inpatient facility at the VA Medical Center in West Roxbury, and was admitted to the surgical intensive care unit for further monitoring. (Ex. 1 at 40, 273; II:87). Dr. Singh's progress notes provided as follows:

Plan:

- -- Admit to medicine service for further monitoring, IV hydration.
- -- Daily trial of sips of fluids to see if pain is secondary to endoscope trauma.

Would not pass an NG tube down blindly for feeding as patient has a zenker's diverticulum.

- -- Please put in a GI consult so that we can follow the patient.
- -- Would check chest/abdominal xray to r/o [rule out] perforation given the complexity of the endoscopy done this morning; though given patient's hemodynamic stability and good 02 s[t]ats on room air this is highly unlikely.

(Ex. 1 at 273). Thus, Mr. Woodhouse's vital signs, including his blood pressure, were fine and he was not having trouble breathing. (II:92).

42. A CT scan and x-rays were taken on July 13, 2007. The scan did not reveal a specific perforation, but there was "a suggestion of a small mural rent within the cervical esophagus[.]" (Ex. 1 at 116). This could not be confirmed due to a lack of contrast in that area. (Id.). While there was a suggestion of a tear within the inner lining of the esophagus, there was no leakage of liquid into the body. (Id.; I:52). The CT scan, as

well as the x-ray, did reveal, however, that there was subcutaneous air in many locations. (Ex. 1 at 116-17).

- 43. Mr. Woodhouse was put on antibiotics and referred to thoracic surgery for a consultation, "although surgical intervention may not be indicated at the present time." (Ex. 1 at 264).
- 44. A barium swallow done on July 14, 2007 confirmed that there was no leakage of liquid out of the esophagus. (II:97; Ex. 1 at 111). Similarly, CT scans without contrast of the abdomen and thorax done on July 14, 2007 continued to show subcutaneous air in many locations with a "suggestion of a tear within the wall of the esophagus" but no leakage of fluid. (Ex. 1 at 101). A number of tests were performed between July 13 and 19, 2007. None of them revealed an actual hole. (I:49; Ex. 1 at 94-132). Throughout his stay at the VA Medical Center, Mr. Woodhouse did not demonstrate any signs of infection or inflammation, such as fever, elevation in the white blood count or abnormalities in other chemistries. In addition, he was able to swallow his secretions, and after the very initial recovery period, repeatedly reported having no pain. (E.g., Ex. 1 at 247, 234-35, 238-41, 255; I:112-14).
- 45. Mr. and Mrs. Woodhouse met with a nutritionist on July 20, 2007 at the VA Medical Center, and it was decided that he would continue on puréed food with supplementation. He was discharged home on July 20, 2007 with a diagnosis of "esophageal perforation." (Ex. 1 at 220). The decision was made to continue

conservative management for a limited perforation, <u>i.e.</u>, not a hole. (II:99). Conservative treatment is basically nonsurgical, observation and antibiotics. (II:100).

- 46. Mr. Woodhouse was seen by Dr. Daniel Cohen, Chief of Thoracic Surgery at the VA Medical Center on July 31, 2007. (Ex. 1 at 216). According to Dr. Cohen's notes, Mr. Woodhouse was "presenting for follow up after esophageal perforation during upper endoscopy for evaluation of upper esophageal stricture/Zenker diverticulum. He was discharged 1 week ago on a full liquid diet which he tolerated well since then. He reports a stable [weight] gain since discharge[.]" (Ex. 1 at 216). They discussed the risks and benefits of a crycomyotomy (surgery) which could be scheduled in approximately a month. (Ex. 1 at 216-17) Mr. Woodhouse had no pain or fever, and no residual subcutaneous air. (Ex. 1 at 217).
- 47. On August 22, 2007, Mr. Woodhouse was contacted by the VA, but declined to go for pre-surgery testing, reporting that he was seeking a second opinion. (Ex. 1 at 213). I find that he refused to undergo surgery at the VA because of his dissatisfaction with his treatment.
- 48. On November 19, 2007, Mr. Woodhouse was seen by Dr. Dettman at the VA Medical Center, his primary care physician. (Ex. 1 at 210). Mr. Woodhouse reported that Dr. Dettman was the only doctor at the VA he was willing to see, and that he had sought other opinions about possible surgery for dysphagia, but had not made a decision. He was continuing to eat puréed foods, and reported a stable to increased weight. His weight was 140 pounds. (Ex. 1 at 210-11).

49. Mr. Woodhouse did not seek further medical treatment for his dysphagia for more than two years. During this period, he continued to eat pureed foods and maintained his weight. (Ex. 2 at 124).

Treatment in 2010

- 50. Mr. Woodhouse was seen by Dr. Christopher Morse at Massachusetts
 General Hospital on January 6, 2010 for a consultation about his Zenker's diverticulum.

 (Ex. 2 at 125). Dr. Morse testified at trial as an expert for the plaintiff. He is board certified in surgery and cardiothoracic surgery. (I:23). Dr. Morse is an assistant professor of surgery at Harvard Medical School and a thoracic surgeon at MGH. He is co-director of the gastroesophageal surgery program. (I:24).
- 51. At the time he first saw Mr. Woodhouse in 2010, Dr. Morse wrote to Dr. Dettman that Mr. Woodhouse's treatment at the VA in 2007 "was complicated by a perforation which was treated conservatively and did resolve." (Ex. 2 at 125). Mr. Woodhouse continued to be unable to tolerate solid food, but his weight was stable. (Ex. 2 at 125). Mr. Woodhouse continued to have "dysphagia with almost everything he eats and does have mild nocturnal regurgitation" but no halitosis. (Id.). A barium swallow revealed a large Zenker's diverticulum (though as noted below surgery did not confirm this condition) with a severe stricture of the esophagus. (Ex. 2 at 123).
- 52. Dr. Morse scheduled an EGD and a surgical repair of the Zenker's diverticulum by way of a cricopharyngeal myotomy. (Ex. 2 at 123). On April 9, 2010, Dr. Morse conducted a flexible upper GI endoscopy, left neck exploration, and

cricopharyngeal myotomy. (Ex. 2 at 140). The consent form given to Mr. Woodhouse by Dr. Morse contained similar language as the consent form used by the VA Medical Center in 2007, although it was even less specific. (I:66-68; Ex.1 at 36; Ex. 2 at 59). Thus, the risks identified in the MGH form included "drug reactions, bleeding, infection, and complications from receiving blood or blood components" as well as "unexpected complications." (Ex. 2 at 59). Mr. Woodhouse was placed under general anesthesia for this procedure. (Ex. 2 at 99).

- 53. Dr. Morse made two attempts to do an EGD with different scopes, but they were blocked by a "quite tortuous bend in the esophagus" which he could not navigate with the scope. (Ex. 2 at 140). As a result, Dr. Morse performed a left neck exploration and a cricopharyngeal myotomy. Dr. Morse found "a very tight narrowing consistent with scarring, inflammation and very hypertonic cricopharyngeal muscle." (Ex. 2 at 140). He did not take any pictures of the scarring. (III:78). Dr. Morse attributes the scarring to the procedure at the VA Medical Center, and opined that there was no other plausible explanation for the source of the scar tissue that he encountered. (I:40).
- 54. Dr Morse did not find a large Zenker's diverticulum, but rather found something "that looked more like redundant esophageal tissue[.]" (Ex. 2 at 117). Although Dr. Morse did not find a Zenker's diverticulum, he believes that it had existed and was not identifiable because the area was scarred and densely inflamed, which was consistent with a perforation. (I:37).

- 55. Mr. Woodhouse remained in the hospital for postoperative care until April 15, 2010, when he was discharged home. (Ex. 2 at 99). As of May 19, 2010, Dr. Morse reported that Mr. Woodhouse was tolerating a soft solid diet with some mild dysphagia. He recommended another upper GI endoscopy and dilation in several months once Mr. Woodhouse healed. (Ex. 2 at 117).
- 56. On June 25, 2010, Mr. Woodhouse was readmitted to MGH for further endoscopy and dilation, which were performed without complication. (Ex. 2 at 130). According to Dr. Morse, this second procedure was necessary because of the amount of scarring he found during the first procedure. (I:41). It was very unusual for a second procedure to be necessary. (I:40-41).
- 57. Mr. Woodhouse remains on a puréed diet after these two procedures, although he can eat a broader range of foods. (I:137, 96-97). Mr. Woodhouse testified that, as of the time of trial, he was still unable to eat solid food. (I:91).

Plaintiffs' Expert Opinions

58. Dr. Morse testified as an expert on behalf of Mr. Woodhouse. As noted above, the plaintiff is not challenging the initial decision to perform the EGD and empiric dilation. However, Dr. Morse opined that once the VA doctors encountered difficulties, there was no medical reason to continue to attempt the endoscopy, and that to do so was outside the standard of care. (I:66). Thus, Dr. Morse opined that he would expect any cancer to have been evident from the barium swallow. Since Mr. Woodhouse's barium swallow was normal, in Dr. Morse's opinion it was below the standard of care to proceed

with the endoscopy once difficulties had been encountered. (I:32-33). Rather, Mr. Woodhouse should have been referred for surgical correction of his Zenker's diverticulum. (I:43-44).

- 59. In Dr. Morse's opinion, there was no benefit to Mr. Woodhouse in performing the endoscopy as it did not treat the Zenker's diverticulum, which had existed at the time of the 2007 procedure, and which needed to be treated through surgery. (I:35).
- 60. Dr. Morse opined that as a result of the procedure at the VA Medical Center, Mr. Woodhouse "had a perforation of his esophagus as evidenced by the air that they saw in his neck and his mediastinum or the upper chest. I believe that despite them not seeing much extravasation or leakage of contrast that there were bacteria and oral saliva that was extravasated through that perforation which caused a significant inflammatory response of his upper neck and around the esophagus and made the subsequent operation that I performed infinitely more difficult than it would have been as a primary procedure." (I:36)
- 61. In Dr. Morse's opinion, if Mr. Woodhouse had had surgery in 2007 instead of the EGD, Dr. Morse would have been able to achieve a much better end result. Due to the perforation and scarring, however, Dr. Morse opined that Mr. Woodhouse's swallowing will never be perfect. (I:41-42).

Defendant's Expert Opinions

62. As detailed above, the VA doctors were of the opinion that Mr.

Woodhouse's Zenker's diverticulum did not warrant surgery in 2007. This opinion was

shared by the defendant's expert, Dr. Cave. (See III:60-61). At that time, the Zenker's was small and asymptomatic. Dr. Cave opined that the Zenker's diverticulum did not cause the difficulty swallowing but, rather, was a result of the difficulty passing food into the esophagus. (See, e.g., III:66-67).

- 63. Defendant's expert witness was Dr. David Cave. Dr. Cave completed his surgical training and obtained a PhD in 1976 from King's College in London, England. He then moved to the United States, did his Residency at the University of Chicago and then a two year Fellowship in gastroenterology at the University of Chicago. He is board certified in internal medicine and gastroenterology. From 1983 until 1992, he was at Boston University, where he was chief of endoscopy. From 1992 until 2005, he was at St. Elizabeth's Medical Center, where he was the chief of the gastroenterology division, which includes endoscopy. In 2005, he moved to the University of Massachusetts, where he was the chief of the GI training program until 18 months ago. He is still at UMass focusing on research. (III:20-25). He has performed many thousands of upper esophagus endoscopies, and many hundreds of dilations of the upper esophagus. (III:26).
- 64. Dr. Cave opined that the decision to perform an EGD on Mr. Woodhouse on July 13, 2007 was entirely appropriate. (III:27). Prior to undertaking a dilation, he testified that it is important to determine that there are no other co-existing problems causing the dysphagia, including cancer. (III:39-40).
- 65. Dr. Cave further opined that the manner in which the EGD was performed was within the standard of care. (III:28).

- 66. It is undisputed that a perforation is a known potential complication of an endoscopy. (III:48). Even Dr. Morse opined that a perforation may occur even without negligence. (I:68-69). Dr. Cave explained that various physical conditions, especially in older patients, can cause a perforation. (III:49-50).
- 67. Dr. Cave opined that nothing that was done during the EGD caused Mr. Woodhouse's condition to worsen. (III:57).
- 68. During the EGD, air was pumped in to distend the pathway to allow the scope to pass and to allow the doctor to see more clearly. (III:8-9). Dr. Cave opined that during this procedure, an extremely small tear in the esophageal wall occurred so that air was trapped in the tissue. The air would be expected to last for several days. (III:52-53). However, the micro perforation would seal itself once the scope was removed. (III:52). This opinion was shared by other defense witnesses. (See II:53-54 (Dr. Singh); II:124-26 (Dr. Pedrosa)).
- 69. In support of his opinion, Dr. Cave pointed to the fact that repeated testing showed some air in the surrounding tissues, but no leakage of any liquid such as barium. (III:52). Any true hole would be seen on an x-ray following a barium swallow. (III:53-54).
- 70. While the witnesses defined the term "perforation" differently, all agreed that no true hole was seen on any of the tests. (See I:49).
- 71. Dr. Cave further opined that the micro perforation would not cause the massive scarring reported by Dr. Morse. (III:62).

- 72. Dr. Cave was of the opinion that the endoscopy did benefit Mr. Woodhouse, and that there was some dilation of the CP muscle which improved the patient's swallowing and delayed the need for surgical intervention. (III:28).
- 73. In support of this opinion, Dr. Cave relied on the fact that Mr. Woodhouse did not seek medical advice for several years, indicating that there was some relief of symptoms. Also, between the time of his procedure on July 13, 2007 and the time he sought medical advice on March 11, 2010, Mr. Woodhouse's weight went from 129 pounds to 141 pounds. (III:56-57).
- 74. Finally, Dr. Cave opined that the informed consent procedure at the VA Medical Center was entirely appropriate. (III:28).

Conclusions of Fact

- 75. I find that it was reasonable for the VA doctors to perform the least invasive procedure first and to try to rule out alternative causes of the dysphagia before considering surgery. Therefore, it was appropriate for the VA doctors to attempt the EGD and empiric dilation in 2007.
- 76. I also find that in 2007, there was no indication that surgery was warranted for the Zenker's diverticulum. It was small and asymptomatic. It was also not the cause of Mr. Woodhouse's swallowing difficulties.
- 77. I find that Mr. Woodhouse was advised of the risks involved in the scheduled procedure at the VA Medical Center. I further find that he gave his consent freely and voluntarily.

- 78. I find that the repeated attempts by Drs. Singh and Pedrosa to pass the scope were not excessive. As evidenced by Dr. Morse, multiple efforts are not unusual. I find that both Drs. Singh and Pedrosa were highly skilled and were very careful not to divert the scope or wire into the Zenker's diverticulum.
- 79. I also find that neither Dr. Singh nor Dr. Pedrosa caused anything more than a micro tear in the tissue and that it did not cause any harm. I find Dr. Cave's explanation of the air escaping and being caught in the tissue to be persuasive.
- 80. I reject Dr. Morse's contention that the scarring he allegedly found was caused by the procedure at the VA Medical Center. There was no leaking of any liquids, as evidenced by the repeated tests Mr. Woodhouse underwent following the procedure. Significantly, Mr. Woodhouse showed no signs of any infection and he was put on antibiotics following the procedure. His pain went away promptly after the procedure. Furthermore, Dr. Morse reported to Dr. Dettman that any perforation had healed by the time he saw Mr. Woodhouse, and Mr. Woodhouse did not complain of pain, fever or the like for years after the procedure. Thus, there is no support for Dr. Morse's hypothesis that, beginning at the time of the 2007 procedure, bacteria and oral saliva "was extravasated through a perforation which caused a significant inflammatory response in his upper neck[.]" (I:36).
- 81. I find that the pain that Mr. Woodhouse suffered following the procedure was a natural consequence of the procedure and was not the result of any negligence.
 - 82. I find that Mr. Woodhouse benefitted from the procedure.

III. RULINGS OF LAW

- 1. The plaintiff has brought this malpractice action against the United States under the Federal Torts Claims Act. Pursuant to the Act, "the law of the place where the act or omission occurred" is controlling. 28 U.S.C. § 1326(b)(1); Zabala Clemente v. United States, 567 F.2d 1140, 1143 (1st Cir. 1977). Therefore, as the parties agree, the law of Massachusetts applies in the instant case.
- 2. To prevail on his claims, the plaintiff must prove every essential element of his claim by a fair preponderance of the evidence. A "proposition is proved by a preponderance of the evidence if it is made to appear more likely or probable in the sense that actual belief in its truth, derived from the evidence, exists in the mind or minds of the tribunal notwithstanding any doubts that may still linger there." <u>Sargent v. Mass.</u>

 <u>Accident Co.</u>, 307 Mass. 246, 250, 29 N.E.2d 825, 827 (1940).
- 3. "In order to prove her medical malpractice claim, the plaintiff must show that (1) a doctor-patient relationship existed; (2) the defendant failed to conform to good medical practice; and (3) the defendant's negligence caused [plaintiff's] injury." <u>Doherty v. Hellman</u>, 406 Mass. 330, 333, 547 N.E.2d 931, 933 (1989)
- 4. In the instant case, there is no dispute that a patient-physician relationship existed between Mr. Woodhouse and Drs. Wasan, Singh and Pedrosa, that the doctors were employees or agents of the VA Medical Center Boston, and that the facilities in which Mr. Woodhouse was treated were owned and operated by the United States

Department of Veteran Affairs. It is also undisputed that the defendant United States is the proper defendant in this action.

Standard of Care

- 5. "To prevail on a claim of medical malpractice, a plaintiff must establish the applicable standard of care and demonstrate both that a defendant physician breached that standard, and that this breach caused the patient's harm." <u>Palandjian v. Foster</u>, 446 Mass. 100, 104, 842 N.E.2d 916, 920 (2006).
- 6. The proper standard of care "is whether the physician, if a general practitioner, has exercised the degree of care and skill of the average qualified practitioner, taking into account the advances in the profession. A specialist should be held to the standard of care and skill of the average member of the profession practicing the specialty, taking into account the advances in the profession." Palandjian, 446 Mass. at 104, 842 N.E.2d at 920 (quoting Brune v. Belinkoff, 354 Mass. 102, 109, 235 N.E.2d 793, 798 (1968) (punctuation omitted)).
- 7. This standard "does not require physicians to provide the best care possible." Palandjian, 446 Mass. at 105, 842 N.E.2d at 921. Moreover, "[b]ecause the standard of care is based on the care that the average qualified physician would provide in similar circumstances, the actions that a particular physician, no matter how skilled, would have taken are not determinative." Id. at 104-105, 842 N.E.2d at 920-21.
 - 8. The plaintiff defines his claim as follows:

According to the preponderance of the evidence, Dr. Singh and Dr. Pedrosa failed to exercise the care and skill of the average qualified gastroenterologist, taking into account the advances in the profession. Although the decision to perform the EGD and attempt a dilation procedure on Mr. Woodhouse may have been reasonable under the circumstances, to make repeated attempts at passing the endoscope after encountering difficulties in an eighty year old patient with two reassuring barium swallows, performed five years apart, whose weight has been stable over the previous three years, with a known Zenker's diverticulum that significantly increased his risk of perforation from less than one percent to between three and five percent, was not, and constituted a breach of the standard of care.

(Docket No. 58 at Plaintiff's Proposed Rulings of Law ¶ 13).

9. I find, however, that the plaintiff has failed to prove that continuing with the endoscopy after having some difficulties breached the acceptable standard of care. There is no evidence in the record as to how many attempts would be too many, and even Dr. Morse attempted the endoscopy more than once before going into surgery. I find that Mr. Woodhouse presented himself in 2007 as a patient for whom a long-standing problem had recently become much worse. Moreover, he advised Dr. Goyal that he had lost a considerable amount of weight over the last several years. Since the medical records would only reflect Mr. Woodhouse's weight at the time of a specific visit, I find that the doctors were justified in accepting the representation of Mr. Woodhouse (and his wife) that they were concerned about his weight loss even if the loss was not reflected in the medical records. Under such circumstances, performing an endoscopy for the purpose of ruling out cancer or other causes for Mr. Woodhouse's dysphagia was appropriate.

10. I also find that performing the EGD in and of itself could, and in fact did, provide some relief to Mr. Woodhouse, so continuing with the procedure while the patient was still able to tolerate it was appropriate. The EGD was clearly a much less invasive procedure than the surgery later performed by Dr. Morse. Moreover, I find that the plaintiff has failed to establish that Dr. Singh's decision to ask for the assistance of Dr. Pedrosa was unreasonable. Dr. Pedrosa was the Chief of Gastroenterology and had performed thousands of endoscopies. The plaintiff has failed to establish that Dr. Pedrosa's use of different methods, in which he had received special training, was in any way inappropriate. Once the nasal scope was used through the patient's nose, the procedure was completed easily. Thus, I find that the plaintiff has failed to prove that the doctors breached the standard of care by continuing with the endoscopy.

Causation

11. The plaintiff has the burden of proving that the actions of the doctors was the proximate cause of his alleged injuries. "The plaintiff [is] not required to show the exact cause of [his] injuries or to exclude all possibility that they resulted without fault on the part of the [the doctors]. It was enough if [he] showed that the harm which befell [him] was more likely due to negligence of the [doctors] than to some other cause for which [the doctors were] not liable." Woronka v. Sewall, 320 Mass. 362, 365, 69 N.E.2d 581, 582-83 (1946). Thus, the plaintiff must establish "that there was greater likelihood or probability that the harm complained of was due to causes for which the [doctors were] responsible than from any other cause[,]" and he is "not required to eliminate

entirely all possibility that the [doctors'] conduct was not a cause." <u>Carey v. Gen. Motors</u> <u>Corp.</u>, 377 Mass. 736, 740, 387 N.E.2d 583, 585 (1979).

- 12. Here the plaintiff contends that "Dr. Singh's and Dr. Pedrosa's breach of the standard of care was the proximate cause of Mr. Woodhouse's injury, a perforation of his esophagus." (Docket No. 58 at Plaintiff's Proposed Rulings of Law ¶ 16).
- 13. I find, however, that the plaintiff has not met his burden of proof that the actions of the doctors caused him injury. As an initial matter, I find that the plaintiff has failed to establish that there was a perforation either of the esophagus or the Zenker's diverticulum which allowed the leakage of bacteria, saliva and other contaminants, and, consequently, inflammation and infection. As detailed above, repetitive testing showed no leakage of fluids, and if the scope had entered the Zenker's it would have been visible on the camera during the procedure. Moreover, Mr. Woodhouse exhibited no signs of infection despite constant monitoring. While the testing did show that air passed out of the esophagus, I find Dr. Cave's explanation to be persuasive. Thus, I find it more likely that the tissue of the esophagus was scraped during the EGD procedure, and because the scope uses air to inflate the tube during the procedure, the air may have been pushed through the tissue through the small tear, which closed itself once the scope was removed.
- 14. I further find that the plaintiff has failed to prove that there was extensive scarring formed as a result of the 2007 procedure. Consequently, the plaintiff has failed to establish that the 2007 procedure caused Dr. Morse's surgery to be made more difficult, or to create the need for a second procedure. Again, the absence of any evidence of

an infection, such as a fever or high white blood count, negates a finding that there was inflammation and infection which led to extensive scarring. Dr. Morse did not take any pictures of scarring. I find credible Dr. Pedrosa's testimony that he encountered scarring during the 2007 procedure.

15. Finally, I note that the plaintiff has not put forth any evidence or hypothesis as to when during the course of the 2007 procedure the alleged harm to Mr. Woodhouse occurred. Since according to the plaintiff it could have happened during the first attempt by Dr. Singh, and the plaintiff has conceded that the decision to make the first attempt was not malpractice, the fact that several attempts were made may be irrelevant. Thus, Mr. Woodhouse has failed to prove by a preponderance of the evidence that the continued efforts to complete the EGD was either malpractice or the cause of his alleged injuries.

Informed Consent

16. "To recover under a theory of informed consent in Massachusetts, a patient must prove that the physician has a duty to disclose certain information and that a breach of that duty caused the patient's injury. To establish a breach of the physician's duty of disclosure, the plaintiff must establish that: (1) a sufficiently close doctor-patient relationship exists; (2) the doctor knows or should know of the information to be disclosed; (3) the information is such that the doctor should reasonably recognize that it is material to the patient's decision; and (4) the doctor fails to disclose this information." Harrison v. United States, 284 F.3d 293, 298 (1st Cir. 2002) (internal citations omitted).

- 17. With respect to the issue of informed consent, "a physician owes to his patient the duty to disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure." Harnish v. Children's Hosp. Med. Ctr., 387 Mass. 152, 155, 439 N.E.2d 240, 243 (1982).
- 18. The extent to which a physician must share information with his or her patient "depends upon what information he should reasonably recognize is material to the plaintiff's decision." Id. at 156, 439 N.E.2d at 243. "Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether to submit or not to submit to surgery or treatment." Id. (quoting Wilkinson v. Vesey, 110 R.I. 606, 627, 295 A.2d 676, 689 (1972)). "Appropriate information may include the nature of the patient's condition, the nature and probability of risks involved, the benefits to be reasonably expected, the inability of the physician to predict results, if that is the situation, the irreversibility of the procedure, if that be the case, the likely result of no treatment, and the available alternatives, including their risks and benefits. The obligation to give adequate information does not require the disclosure of all risks of a proposed therapy, or of information the physician reasonably believes the patient already has, such as the risks, like infection, inherent in any operation." Id. (internal citations omitted).

- 19. In the instant case, Mr. Woodhouse contends that the information with which he was provided was insufficient because Dr. Wasan did not advise him of the alternatives to the scheduled procedure, <u>i.e.</u>, surgery, and because neither Dr. Wasan nor Dr. Singh allegedly advised him of the "significantly increased risk of perforation due to his Zenker's diverticulum." (Docket No. 58 at Plaintiff's Proposed Rulings of Law ¶ 24). Moreover, according to Mr. Woodhouse, he would not have undergone the procedure if he had been made aware of the risks. (<u>Id.</u>)
- 20. I find that the plaintiff has failed to meet his burden that the defendant is liable for malpractice due to a failure to obtain informed consent. Rather, I find that Dr. Dettman and Dr. Goyal reviewed Mr. Woodhouse's test results and treatment options with him, and that he fully understood them. I find that Dr. Wasan was not the appropriate doctor to advise Mr. Woodhouse about treatment options since he was not her patient.
- 21. I find further that Dr. Wasan adequately explained the risks to Mr. Woodhouse, including the fact that there was a risk of perforation, and that the risk was higher because of the existence of his Zenker's diverticulum. Mr. Woodhouse also was given the opportunity to review the consent form and ask any questions that he had. The consent form clearly states that perforation is a risk of the endoscopy. I find that Mr. Woodhouse signed the form freely and did not ask any questions.
- 22. The form used by the VA Medical Center is more detailed than the form used by MGH. Mr. Woodhouse signed the MGH form before undergoing surgery with

Dr. Morse. Therefore, I find that Mr. Woodhouse had sufficient information to give his

informed consent to the 2007 procedure.

23. It is Mr. Woodhouse's theory that the VA doctors committed malpractice

because they made a perforation in his esophagus. I have found that Mr. Woodhouse has

not met his burden of proof on the issue of malpractice. Moreover, it is clear from the

record that perforation was a known risk of the endoscopy, and Mr. Woodhouse was

advised of that risk.

ORDER

For the reasons detailed herein, judgment will be entered in favor of the

Defendant.

SO ORDERED.

/ s / Judith Gail Dein

Judith Gail Dein

United States Magistrate Judge