IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PATRICK GAITENS and YVONNE GAITENS,

Plaintiffs,

v.

THE UNITED STATES OF AMERICA,

Defendant.

No. 18-cv-1011-RGA

MEMORANDUM OPINION

Francis J. Murphy, Kelly M. Huff, MURPHY & LANDON, Wilmington, DE.

Attorneys for Plaintiffs.

David C. Weiss, UNITED STATES ATTORNEY, Dylan J. Steinberg, Carly A. Hudson, ASSISTANT UNITED STATES ATTORNEYS, Wilmington, DE.

Attorneys for Defendant.

August 26, 2019

ANDREWS, U.S. DISTRICT JUDGE:

On July 9, 2018, Patrick and Yvonne Gaitens filed suit against the United States of America for damages under the Federal Tort Claims Act. 28 U.S.C. § 1346(b)(1). Plaintiffs allege medical negligence in the treatment of Mr. Gaitens by Defendant's employees at the Wilmington Veterans Administration Medical Center ("WVA") in Wilmington, Delaware. (D.I. 1). I held a bench trial from June 10 to 12, 2019. (D.I. 81-83).

Based on the following findings of fact and conclusions of law, Fed. R. Civ. P. 52(a)(1), I find that Plaintiffs have not proven medical negligence.

I. BACKGROUND

Mr. Gaitens is a pillar of his community. He is a Vietnam War veteran and a hero to his grandchildren. He and his wife Yvonne have been married for 48 years. Mr. Gaitens was first diagnosed with lung cancer in 2011. He had surgery to remove a portion of his lung and, aside from shortness of breath, made a full recovery. Mr. and Mrs. Gaitens were well on their way to a long and active retirement when they learned that Mr. Gaitens' cancer had returned. In late 2016, Mr. Gaitens was diagnosed with terminal stage four lung cancer. There is no question that Mr. Gaitens' illness is a tragedy. It has brought tremendous suffering on him and his family. It is not, however, a tragedy for which Defendant is liable.

Mr. Gaitens first began treatment at the WVA in November 2014. He was scheduled to have regular CT scans after his surgery in 2011. The scans from 2011 to 2013 were done at Cooper University Hospital, where the surgery had been performed. (D.I. 81 at 4:13-17). He had his first CT scan at WVA in November 2014, which was read by Dr. Priya Prabhakar. JTX-2. He had a second CT scan in November 2015, which was read by Dr. Gerald Lee. JTX-10. Neither Dr. Prabhakar nor Dr. Lee found reoccurrence of Mr. Gaitens' cancer. It was not until

Mr. Gaitens' third CT scan in November 2016 that the reviewing radiologist noted suspicious morphology and ordered a follow-up PET scan. JTX-8. The PET scan showed that Mr. Gaitens' cancer had not only returned but was stage four. JTX-12; (D.I. 81 at 174:4-21).

II. LEGAL STANDARD

The Federal Tort Claims Act makes the United States liable for the negligent or wrongful acts of its employees "under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b)(1). To assess a claim under the Act, courts should apply "the whole law of the State where the act or omission occurred," including that state's choice-of-law rules. *Richards v. United States*, 369 U.S. 1, 11-14 (1962).

The parties agree that Delaware law controls for liability. (D.I. 79 at 3 & n.3; D.I. 80 at 5 (Plaintiffs wrongly asserting that Defendant seeks to apply California law to liability)).[1] Under Delaware law, "a party alleging medical malpractice must produce expert medical testimony that specifies (1) the applicable standard of care, (2) the alleged deviation from that standard, and (3) the causal link between the deviation and the alleged injury." *Green v. Weiner*, 766 A.2d 492, 494-95 (Del. 2001) (citing 18 Del. C. § 6853). Plaintiffs must show negligence by a preponderance of the evidence. *Culver v. Bennett*, 588 A.2d 1094, 1096-97 (Del. 1991).

III. ANALYSIS

Plaintiffs have two claims for negligence. First, Plaintiffs argue that Dr. Prabhakar breached the standard of care in reviewing Mr. Gaitens' 2014 CT scan. (D.I. 78 at 13-15). Second, Plaintiffs argue that Dr. Lee breached the standard of care in reviewing Mr. Gaitens' 2015 CT scan. (*Id.* at 16-17). Under both claims, Plaintiffs argue that the breach caused a delay

[1] The parties disagree over the law that should apply to damages. (D.I. 79 at 2-3 & n.3). As I find for Defendant on liability, I do not need to resolve the dispute over damages.

in Mr. Gaitens' diagnosis, which has dramatically decreased his life expectancy. Plaintiffs' theory is that Mr. Gaitens' cancer remained stage one through the date of the 2015 CT scan, meaning that it could have been treated with surgical resection. Plaintiffs assert that, with surgery, Mr. Gaitens would have had a five-year survival rate of 90% in 2014 and 73% in 2015. (D.I. 78 at 8-11, 16, 17-20). Instead, he has a five-year survival rate of 10% from his date of diagnosis of stage four cancer in 2016. (*Id.* at 12).

For the following reasons, I find that Dr. Lee alone breached the standard of care. However, I also find that Plaintiffs failed to show a causal link between Dr. Lee's breach and Mr. Gaitens' harm. Therefore, Plaintiffs cannot recover for negligence.

A. The Standard of Care

Neither party articulated an objective standard of care. Plaintiffs argue, based on the testimony from their experts Drs. Rigney and Kramer, that the standard of care requires a radiologist to review all the images on a CT scan[2] and "report all significant findings." (D.I. 78 at 13). Plaintiffs do not define "significant findings." Dr. Kramer stated that to "miss something that's clinically significant" is a breach of the standard of care. However, he went on to note that some findings are "too subtle to say that everyone would have seen it" and clarified that the standard is based on "a typical radiologist . . . with normal knowledge, skill, and ability." (D.I. 81 at 136:6-17). Dr. Rigney testified that radiology is a "subjective practice" (*id.* at 59:21-23), but that "20 out of 20" radiologists should correctly report "positive findings such as pneumonia[and] cancer" (*id.* at 60:3-10).

Defendant does not articulate a standard at all but relies on the testimony from its expert, Dr. Itri. Dr. Itri reviewed and reported on the 2014 and 2015 CT scans as if he were the treating

[2] There is no evidence that Drs. Prabhakar or Lee failed to review all the images in the 2014 or 2015 scans.

radiologist. He then provided testimony on breach using his reports as a "barometer" for the standard of care. (D.I. 79 at 4).

Based on the present record, I find that the standard of care requires acting with the skill and diligence of an ordinary radiologist. In view of the testimony from Drs. Kramer and Itri, I reject as unconvincing Dr. Rigney's opinion that a radiologist must correctly report *all* pneumonia and cancer irrespective of the particular details of a scan. Both parties provided expert testimony on how an ordinary radiologist would have read the scans at issue. I use that testimony to guide my analysis of whether Drs. Prabhakar or Lee breached the standard of care.

B. Breach of the Standard of Care

1. 2014 CT Scan—Dr. Prabhakar

Dr. Prabhakar reviewed Mr. Gaitens' November 2014 CT scan. She noted that no prior scans were available for comparison. JTX-2 at US-314. She identified scarring on both lung apices and a 7-millimeter nodule on the right upper lobe. *Id.* at US-315. Upon follow-up, the 7-millimeter nodule was determined to be benign. (D.I. 81 at 22:5-22, 66:22-67:2, 122:20-123:1, 222:5-12).

There appear to be three distinct issues related to Dr. Prabhakar's review of the 2014 CT scan. First, did Dr. Prabhakar breach the standard of care by failing to compare the 2014 CT scan to the prior Cooper University Hospital scans during her review? Second, did Dr. Prabhakar breach the standard of care by failing to identify an 8-millimeter nodule in the left lung apex during her review? Third, did Dr. Prabhakar breach the standard of care by failing to order additional follow-up on the left lung apex after her review? I address each issue separately.

a. Failure to Compare the 2014 CT Scan to Prior Scans During Review

I addressed this issue at the close of trial. As Dr. Prabhakar noted in her report, the prior scans were not available for comparison when she reviewed the 2014 CT scan. JTX-2 at US-314. Therefore, I found that she did not breach the standard of care by failing to compare the 2014 CT scan with the prior scans during her review. (D.I. 83 at 38:6-24).

b. Failure to Identify an 8-millimeter Left Apical Nodule During Review

Drs. Rigney and Kramer identified an 8-millimeter nodule in the left lung apex of the 2014 CT scan. (D.I. 81 at 37:18-19, 39:3-4, 77:14-15, 83:12-13). Drs. Prabhakar and Itri did not identify that nodule but noted that there was scarring in the same lung region. JTX-2 at US-315 (identifying biapical scarring); DX-16 (same). Plaintiffs argue that Dr. Prabhakar breached the standard of care by failing to identify the 8-millimeter nodule. (D.I. 78 at 1, 13-16).

Although Drs. Rigney and Kramer identified the 8-millimeter nodule in the 2014 CT scan, both had to rely on a prior 2013 CT scan to determine that it was a significant finding. Dr. Rigney admitted that, without the comparison, the finding would have been "equivocal." (D.I. 81 at 41:11-16). Dr. Kramer testified that the finding alone "doesn't mean much." (*Id.* at 78:11-20). He opined that, without the comparison, a radiologist would not have been able to distinguish the nodule from scarring. (*Id.* at 92:6-21). The determining factor was whether there was a change between the 2013 and 2014 CT scans. (*Id.* at 92:19-93:1("[I]t doesn't matter how big something is if it didn't change.")).

Like Dr. Prabhakar, Dr. Itri did not have the 2013 CT scan for comparison. DX-16. Also like Dr. Prabhakar, Dr. Itri identified biapical scarring. *Id.* He explained that he determined the left apical structure was scarring based on its linear morphology. (D.I. 82 at 416:9-417:18).

That is consistent with the Fleischner guidelines,[3] which state that such linear structures are "likely scarring or characteristic of scarring." (*Id.* at 418:13-17). He noted that the 2014 CT scan could be misleading because the left apical structure would appear either linear or nodular depending on the plane of the CT image. (*Id.* at 417:10-418:12). Dr. Rigney agreed that the structure appeared linear in at least one plane. (D.I. 81 at 44:3-5 (describing the structure as "a thin linear finding" in the coronal plane of the 2014 CT scan)).

It is undisputed that the 2014 CT scan showed some structure in the left lung apex. Drs. Rigney and Kramer identified an 8-millimeter nodule while Drs. Prabhakar and Itri identified scarring. Plaintiffs argue that the nodule and scarring are different structures. (D.I. 78 at 13 n.2). I think the more likely explanation is that the doctors characterized the same structure in different ways. (*See* D.I. 81 at 120:25-121:5; D.I. 79 at 7 n.7).

I do not think Plaintiffs have shown that Dr. Prabhakar breached the standard of care by failing to identify an 8-millimeter left apical nodule in the 2014 CT scan. Both Drs. Rigney and Kramer admitted that a radiologist would not have been able to identify the left apical structure as a significant finding without comparison to the 2013 CT scan. Dr. Kramer also testified that, without the 2013 CT scan, a radiologist could not have differentiated between what he identified as a nodule and scarring. Indeed, in the left lung apex where Drs. Rigney and Kramer identified the nodule, Dr. Prabhakar noted scarring. Dr. Itri, reviewing the 2014 CT scan alone, also identified left apical scarring. Therefore, it seems that Dr. Prabhakar identified the same structure as Drs. Rigney and Kramer but determined that it was scarring rather than a nodule. I do not think that determination was a breach of the standard of care given that Dr. Prabhakar did not have the 2013 CT scan available for comparison.

[3] The Fleischner guidelines are professional guidelines that were followed at the WVA in 2014. (D.I. 81 at 218:21-22). Both parties' experts incorporated the Fleischner guidelines in their analyses.

c. Failure to Order Additional Follow-up After Review

Plaintiff argues that, since the prior scans were unavailable, Dr. Prabhakar breached the standard of care by failing to order a 3-month follow-up after her review of the 2014 CT scan. (D.I. 78 at 15).[4]

It is undisputed that scarring is not diagnostically significant and does not warrant a follow-up. (D.I. 81 at 47:15-21 (Dr. Rigney), 129:25-130:3 (Dr. Kramer); D.I. 82 at 398:9-16 (Dr. Itri)). However, I do not think that means a structure identified as scarring never requires a follow-up. It seems that when a structure is sufficiently ambiguous, the standard of care requires some follow-up to reach a more certain conclusion. (*See* D.I. 81 at 41:11-16). Whether a structure is sufficiently ambiguous is determined from the perspective of a radiologist acting with ordinary skill and diligence. *See supra* Section III.A.

The parties' presented conflicting testimony on how an ordinary radiologist would view the left apical structure. Dr. Rigney opined that, given Mr. Gaitens' history of lung cancer, he would consider the left apical structure to be an "equivocal" finding, which should be followed up with a 3-month CT. (D.I. 81 at 41:11-16). As discussed, Dr. Itri concluded that the structure was scarring due to its linear morphology, consistent with the Fleischner guidelines. (*E.g.*, D.I. 82 at 416:22-417:1). He noted that it looked "linear" on the axial plane, and "very linear" on the coronal plane, and that he did not think "it was a nodule or had a nodule component." (*Id.* at 417:15-18). Dr. Rigney agreed that the structure appeared linear in the coronal plane. (D.I. 81 at 44:3-5).

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[4] It should be noted that Dr. Prabhakar did order a follow-up on what she identified as a 7-millimeter nodule in the right lung. JTX-2 at US-315. As a result, WVA staff requested Mr. Gaitens' prior scans, found that the right lung nodule had been stable for several years, and correctly determined that it was benign. (D.I. 81 at 22:5-22). Plaintiffs argue that Dr. Prabhakar should have ordered an additional follow-up relating to the structure in the left lung apex.

Mr. Gaitens was also in a category of patients likely to present apical scarring. Dr. Kramer agreed that benign structures "presumably due to scarring are extremely common in the apical areas of older patients." (D.I. 81 at 130:4-7). In addition, Mr. Gaitens had been a pack-a-day smoker for 35 years before quitting in 2006. (*Id.* at 217:5-8; D.I. 82 at 295:22-296:7). Dr. Itri explained that "typically all smokers have apical scarring." (D.I. 82 at 419:25-420:1).

I do not think Plaintiffs have shown that Dr. Prabhakar breached the standard of care by failing to order additional follow-up on the left apical structure. I credit Dr. Itri's testimony that a linear morphology is indicative of scarring. Based on his findings that the left apical structure appeared linear, and Dr. Rigney's agreement that it appeared linear in at least one plane, it seems likely that the structure was linear. Further, although Mr. Gaitens had a history of lung cancer, he was also in a category of patients almost assured to have apical scarring. Thus, I find that an ordinary radiologist could have identified the left apical structure as scarring and would not have considered that finding so ambiguous as to require a follow-up.

Therefore, I find that Dr. Prabhakar did not breach the standard of care in relation to her review of the 2014 CT scan.

2. 2015 CT Scan—Dr. Lee

Dr. Lee reviewed the November 2015 CT scan with the November 2014 CT scan as a comparison. He reported that Mr. Gaitens was stable with no evidence of reoccurrence of cancer. JTX-10.

Both Drs. Rigney and Kramer testified that the left apical nodule they identified in the 2014 CT scan was significantly larger in the 2015 CT scan. (D.I. 81 at 43:18-44:3, 87:24-88:1). Dr. Rigney also noted that the nodule had developed "spicules or spokes," which was a sign of malignancy. (*Id.* at 43:18-21). That finding is supported by a WVA report from December

2016, which described the same nodule as "spiculated." JTX-12 at US-1069. In addition, both experts identified two small nodules, one in each lung, that were not present in the 2014 CT scan. (D.I. 81 at 44:23-45:6, 97:20-23).

Dr. Itri again identified the left apical structure as scarring. (D.I. 82 at 423:5-18). He compared the 2014 and 2015 CT scans but found that, [g]iven the errors between different CTs," the change was too small to be considered significant. (*Id.* at 423:21-24, 426:8-11). Dr. Itri admitted, "Spiculation with a lung lesion is typically associated with cancer because of its growth pattern," but added that it can also be the result of scarring. (*Id.* at 420:18-24).

It is undisputed that the left apical structure grew significantly between the 2014 and 2015 CT scans. Dr. Itri measured the structure at 6 millimeters in 2014 and 12 millimeters in 2015. (*Id.* at 423:25-424:2, 424:7-11). Dr. Kramer measured the structure at 8 millimeters in 2014 and 16 millimeters in 2015. (D.I. 81 at 87:24-88:1). The December 2016 WVA report described the structure as having been 15 millimeters in 2015. JTX-12 at US-1069 (noting the nodule was "previously 15 x 9 mm on 11/5/2015").

I find that Dr. Lee breached the standard of care by failing to identify the left apical structure in the 2015 CT scan. Unlike Dr. Prabhakar, Dr. Lee had a prior scan for comparison. Therefore, he should have noted the changes in size and shape between the 2014 and 2015 scans. The structure grew from about 6-8 millimeters in 2014 to about 12-16 millimeters in 2015. There was also evidence of spiculation, which the parties' experts agree is typically a sign of lung cancer. Therefore, I do not credit Dr. Itri's testimony that the changes between the 2014 and 2015 scans were too small to be significant. I believe an ordinary radiologist would view that level of growth, in addition to the spiculation, as evidence of cancer warranting a follow-up.

Therefore, Dr. Lee breached the standard of care by concluding that Dr. Gaitens was stable with no signs of reoccurrence.

C. Causal Link to the Alleged Harm

Plaintiffs argue that Mr. Gaitens had stage one cancer at the time of the November 2015 CT scan and that the cancer could have been surgically removed, resulting in a five-year survival rate of about 73%. (D.I. 78 at 10-11, 17-20). In contrast, Mr. Gaitens' current diagnosis is stage four cancer with a five-year survival rate of 10%. (D.I. 82 at 255:6-8, 256:3-20 (five years from the date of diagnosis in November 2016)). Unlike stage one, stage four cancer cannot be treated with surgery. (*Id.* at 255:9-14).

Defendant argues that Plaintiffs have failed to show that the cancer was stage one or that it could have been surgically removed. (D.I. 79 at 11-17). Cancer staging is based on three factors—tumor (T), nodes (N), and metastases (M). T is based on the size of the tumor, N is based on whether there is lymph node involvement, and M is based on whether the tumor is metastatic, meaning it has spread to another organ or region of the body. (D.I. 82 at 246:13-247:2, 345:14-346:4). Stage one indicates a tumor less than 3 centimeters (T-1), with no lymph node involvement (N-0), and no metastases (M-0). (*Id.*; *id.* at 248:13-14). Mr. Gaitens' tumor was no more than 16 millimeters in 2015. Therefore, to succeed on liability, Plaintiffs must show that as of the 2015 CT scan, Mr. Gaitens' cancer had no lymph node involvement and had not spread from his left to right lung. If Mr. Gaitens' cancer was present in both lungs, it was stage four. (*Id.* at 346:16-21; *see also id.* at 251:15-25 (Plaintiffs' expert Dr. Hirschman concluding no metastatic stage four cancer based on no evidence of cancer in the right lung)).

It is undisputed that the 2015 CT scan shows a nodule in the right lung. Dr. Hirschman testified, however, that the 2016 PET scan shows that the right lung nodule was not cancer. (*Id.*

at 251:21-25, 252:10-23). A PET scan will show the standardized uptake value ("SUV") of a nodule, which indicates the metabolic activity level of that nodule as compared to the surrounding normal tissues. A higher SUV is more indicative of cancer. (*Id.* at 244:1-4, 347:7-9). The right lung nodule had an SUV of 1.3 in the 2016 PET scan. JTX-12 at US-1069 (identified as a "6 x 6 mm nodule in the right upper lobe"). Dr. Hirschman concluded that a SUV of 1.3 "is not something that anyone would worry about for invasive cancer." (D.I. 82 at 252:20-23).

In contrast, Defendant's expert Dr. Kratze testified, "In the lung, due to the fact that a nodule is surrounded by air, really, any activity is worrisome." (*Id.* at 347:9-11). He further noted that the nodule grew between the 2015 CT scan and the 2016 PET scan, which was suggestive of cancer. (*Id.* at 347:11-19); JTX 12 at US-1069 (the 2016 PET report describing the nodule as "6 x 6 mm . . . versus previously 5 x 4 mm on 11/5/2015").

It is undisputed that PET scans are only reliable for structures of a certain size. The right lung nodule was 6 millimeters. (D.I. 82 at 261:10-11). Both of Plaintiffs' radiology experts indicated that 8 millimeters is the cut-off for PET scan sensitivity. (D.I. 81 at 42:1-8 (Dr. Rigney noting that 8 millimeters "is borderline for level of detectability on a PET scan," while "10 milimeters is an acceptable size for a finding [] to be effective"), 83:15-16 (Dr. Kramer stating that there is "some sensitivity for PET" at 8 millimeters); *see also id.* at 220:8-10 (Mr. Horstmyer, Mr. Gaitens' treating nurse practitioner, stating in deposition, "The earliest the PET can detect the malignant tumor is eight millimeters")). Dr. Hirschman also admitted that PET scans are less reliable with smaller lesions. (D.I. 82 at 261:12-17).

I do not think Plaintiffs have shown that Mr. Gaitens had stage one cancer as of the 2015 CT scan. Plaintiffs rely solely on Dr. Hirschman's testimony that a SUV of 1.3 is too low to

indicate cancer. However, testimony from Plaintiffs' other experts shows that the right nodule, being only 6 millimeters, was below the size cut-off for reliable PET sensitivity. On the other hand, it is clear that the right nodule was growing. JTX-12 at US-1069. Therefore, I cannot conclude that it is more likely than not that Mr. Gaitens' cancer was isolated in his left lung—*i.e.*, that it had not metastasized. Without that finding, I cannot conclude that Mr. Gaitens had stage one cancer.

Plaintiffs' theory of causation also depends on finding that Mr. Gaitens' cancer could have been treated with surgical resection had Dr. Lee diagnosed it in the 2015 CT scan. Even assuming that Mr. Gaitens had stage one cancer in 2015, Plaintiffs have failed to show that surgery would have been a viable option.

Mr. Gaitens had his left upper lobe surgically removed in 2011 when he was first diagnosed with lung cancer. (D.I. 81 at 216:20-21). When Mr. Gaitens began treatment at the WVA in November 2014, he was already experiencing shortness of breath that interfered with his everyday activities. JTX-1 at US-1241 ("he says he is significantly [short of breath] after a city block, can't mow lawn and can't take out garbage [without] getting [short of breath]"). Dr. Hirschman testified that there is a limit to how much lung tissue can be surgically removed while still maintaining lung function. Therefore, "[b]efore any surgery on the lung, you do a lab or testing of the lung function to make sure you don't remove too much lung and kill the patient." (D.I. 82 at 270:7-13). Although no such studies were done on Mr. Gaitens, Dr. Hirschman opined that Mr. Gaitens could have survived additional resection of his lungs to remove the nodules in the 2015 CT scan. (*Id.* at 270:14-271:8). But he admitted that, not having reviewed Mr. Gaitens' imaging studies and not being a lung surgeon, he did not actually know how much of Mr. Gaitens' lung would need to be removed for such resections. (*Id.* at 271:9-272:9).

Plaintiffs rely entirely on Dr. Hirschman's testimony. (D.I. 80 at 9). In view of Dr. Hirschman's lack of information and surgical training, I find his testimony not supported by sufficient relevant expertise and do not accept it. Given that Mr. Gaitens was already suffering from reduced lung function, it is unclear whether he could have survived further loss of lung tissue. At minimum, I expect Mr. Gaitens would have needed an analysis of his lung function and the portions of lung to be removed to determine whether surgery was a viable treatment option. It is Plaintiffs' burden to show that Mr. Gaitens could have been treated with surgery had Dr. Lee diagnosed him in 2015. Having presented no evidence besides Dr. Hirschman's unconvincing testimony, Plaintiffs have failed to meet their burden.

Based on the evidence at trial, I cannot find that Mr. Gaitens had stage one cancer treatable with surgery as of the 2015 CT scan. Therefore, Plaintiffs have failed to establish the requisite causal link between Dr. Lee's breach and Mr. Gaitens' injury.

IV. CONCLUSION

For the foregoing reasons, I find that Plaintiffs have not met their burden on negligence. Therefore, Defendant is not liable for any damages. I will enter a separate final judgment consistent with this memorandum opinion.