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CLERK OF THE WYANDOTTE COUNTY DISTRICT COURT
CASE NUMBER: 2017-CV-000634

IN THE DISTRICT COURT OF WYANDOTTE COUNTY, KANSAS

WENDY ANN NOON BERNER,

Plaintiff,

v.

THE UNIVERSITY OF KANSAS HOSPITAL AUTHORITY
Serve:
Mr. Bob Page
President and Chief Executive Officer and/or Managing Agent
The University of Kansas Hospital
3901 Rainbow Blvd.
Kansas City, KS 66160

and,

UNIVERSITY OF KANSAS MEDICAL CENTER
Serve:
Dr. Robert D. Simari, M.D.
Interim Executive Vice Chancellor and/or Managing Agent
University of Kansas Medical Center
2032 Murphy Administration Building
Mail Stop 2015
3901 Rainbow Boulevard
Kansas City, KS 66160

and,

THE UNIVERSITY OF KANSAS PHYSICIANS
Serve:
Registered Agent:
REGISTERED AGENT KANSAS, LTD.
10851 Mastin Boulevard, Suite 1000
Overland Park, Kansas 66210

and,

Case No. _____

Division No. _____

Pursuant to K.S.A. Chapter 60

MEENAKSHI SINGH, M.D.)
Serve:)
Residential Service:)
2245 W. 118th Terrace)
Leawood, KS 66211)
)
and,)
)
TIMOTHY M. SCHMITT, M.D.)
Serve:)
Residential Service:)
3012 W. 91st Street)
Leawood, KS 66206)
)
Defendants.)

PETITION FOR DAMAGES

COMES NOW Plaintiff Wendy Ann Noon Berner, by and through her undersigned counsel, and for her Petition for Damages against The University of Kansas Hospital Authority, University of Kansas Medical Center, The University of Kansas Physicians, Meenakshi Singh, M.D., and Timothy M. Schmitt, M.D., states, alleges, and avers as follows:

INTRODUCTION

In 2015, the KU Defendants (as defined below) elevated a new pathologist to their Chair of the Pathology Department with privileges in Cytopathology even though she lacked board certification in Cytopathology, and even though it violated Defendants' own requirements to grant her privileges in Cytopathology. After the new Chair began reviewing Cytopathology cases without meeting Defendants' internal requirements, the pathologist misdiagnosed Plaintiff with a form of invasive cancer that is 94% lethal within 5 years of diagnosis. This misdiagnosis unnecessarily caused Plaintiff to undergo a major Whipple surgery involving lifelong complications and consequences including, without limitation, the removal of multiple body

parts, the removal of a significant portion of an essential organ, and the permanent need for future medication and treatment.

After the unnecessary surgery, and after pre and post-surgery samples were re-examined, the misdiagnosis became obvious, and the Chair admitted her mistake to the surgeon. Despite the above, none of the Defendants—in fact, nobody—ever told Plaintiff about the misdiagnosis, the fact that she never had a cancerous tumor in her pancreas, or the fact that she underwent an unnecessary surgery. Defendants instead took multiple steps to conceal the misdiagnosis and the unnecessary surgery. After Plaintiff was discharged, the Chair (pathologist) added a mysterious "addendum" to Plaintiff's original medical record in an effort to conceal the misdiagnosis. She did not stop there. She also lobbied for revisions to KU's Quality Improvement documents in order to eliminate references to her "major misinterpretations" and the unnecessary surgery. Further, she instructed others to alter meeting minutes in order to eliminate references to the misdiagnosis and the need for a "root cause analysis."

The Chair did not act alone. The surgeon also participated in the cover-up when he made a deceptive statement to Plaintiff about being cancer-free post-surgery. Plaintiff understandably interpreted the surgeon's statement to mean that the surgeon successfully removed the cancerous, neuroendocrine tumor previously identified by the department Chair. After making that statement, the surgeon furthered the false narrative by personally telling Plaintiff that she had a history of a pancreatic neuroendocrine tumor, and continually referenced the cancer misdiagnosis as if it was an accurate evaluation in Plaintiff's medical records. The pathologist and the surgeon never reported the problems to KU Hospital's Chief Medical Officer, Risk Management Committee, or Risk Manager.

A principled pathologist in KU's Pathology Department—Lowell L. Tilzer, M.D.—discovered the misdiagnosis and took a stand consistent with his Hippocratic Oath. Dr. Tilzer demanded a "root cause analysis," changes to Plaintiff's medical records to ensure accuracy, and notification to Plaintiff. Physicians in the Pathology Department at KU began referring to Plaintiff's case as "pathology-gate." When Defendants ignored Dr. Tilzer's requests, Dr. Tilzer reported his concerns to multiple outside agencies. Every step of the way, the KU Defendants elevated their own financial and publicity interests over the interests of patient safety and well-being. KU Hospital's President Bob Page asked Dr. Tilzer to resign, accused him of lying to outside agencies, and referred to his reports as "pitiful" and "despicable." Of course, Mr. Page never acknowledged the irrefutable misdiagnosis and Plaintiff's unnecessary surgery.

When Dr. Tilzer eventually filed a "whistleblower" Petition, Mr. Page sent an email to all KU medical staff, and perpetuated the concealment of the irrefutable misdiagnosis and Plaintiff's unnecessary surgery. The surgeon also contacted Plaintiff and asked her to sign an affidavit affirming, among other things, that "[t]he treatment [she] received from [the surgeon] and from all of the University of Kansas Hospital nurses, doctors, and employees was **wonderful**." (emphasis added). Importantly, at this point, the surgeon also continued the concealment of the irrefutable misdiagnosis and Plaintiff's unnecessary surgery.

Given the suspicious nature of the surgeon's request for Plaintiff to sign an affidavit, Plaintiff did some investigating of her own, found the news article related to Dr. Tilzer's "whistleblower" Petition, and learned for the **very first time** that she was misdiagnosed with cancer, that her medical records were incorrect, that she never had a pancreatic neuroendocrine tumor, and that she underwent an unnecessary surgery bringing about lifelong complications and consequences. This case is filed to pursue the rights of the anonymous patient referenced in Dr.

Tilzer's "whistleblower" Petition; Wendy Ann Noon Berner is the person who had to read a news article in order to discover the grave medical mistakes that will affect her for the rest of her life.

JURISDICTION AND VENUE

1. Plaintiff resides in Johnson County, Kansas.

2. Defendant University of Kansas Hospital Authority (hereinafter "KU Hospital") is a Kansas administrative agency organized pursuant to K.S.A. § 76-3301 *et seq*. with a mailing address at University of Kansas Hospital Authority, 3901 Rainbow Boulevard Kansas City, KS 66160-7220. KU Hospital provided healthcare services to Plaintiff.

3. Defendant KU Hospital can be served with process on the individual referenced in the caption above at the address referenced above and/or to a different managing agent at the same address.

4. University of Kansas Medical Center (hereinafter "KUMC") is a Kansas administrative agency, as defined by K.S.A. § 77-602(k) and K.S.A. § 77-502(a), with a mailing a mailing address at University of Kansas, School of Medicine, Mail Stop 2015, 3901 Rainbow Blvd., Kansas City, Kansas 66160. KUMC provided healthcare services to Plaintiff.

5. Defendant KUMC can be served with process on the individual referenced in the caption above at the address referenced above and/or to a different managing agent at the same address.

6. Defendant The University of Kansas Physicians (hereinafter "UKP," and collectively with KU Hospital and KUMC, the "KU Defendants") is a Kansas non-profit corporation organized and existing under the laws of the State of Kansas, with its principal place

of business located in Wyandotte County, Kansas. UKP provided healthcare services to Plaintiff.

7. According to its 2015 Amended and Restated Articles of Incorporation, UKP was formed "to provide an integrated faculty group practice for the delivery of high quality, cost-effective, patient care and for the furtherance of medical education and research … [by] [e]stablishing, maintaining and supporting the creation of a more clinically integrated enterprise whereby [UKP], [UKP's] physicians, and [KU Hospital] join together, with the support of [KUMC], to create the University of Kansas Health System (the "System") in order to advance fulfillment of their shared health care, research, and education and training missions[.]"

8. Defendant UKP's Registered Agent, Registered Agent Kansas, Ltd., can be served with process at the address set forth in the caption above.

9. Defendant Meenakshi Singh, M.D. ("DR. SINGH"), is, and was at all times relevant to this cause of action, a duly licensed physician representing and holding herself out to the public as such, and, in particular, to Plaintiff.

10. At all times material hereto, DR. SINGH was an employee and/or agent of the KU Defendants whose conduct was authorized or ratified by the KU Defendants, and DR. SINGH acted in that capacity while providing care and treatment to Plaintiff.

11. Defendant DR. SINGH maintains the residential address set forth in the caption above.

12. Defendant Timothy M. Schmitt, M.D. ("DR. SCHMITT"), is, and was at all times relevant to this cause of action, a duly licensed physician representing and holding himself out to the public as such, and, in particular, to Plaintiff.

13. At all times material hereto, DR. SCHMITT was an employee and/or agent of the KU Defendants whose conduct was authorized or ratified by the KU Defendants, and DR. SCHMITT acted in that capacity while providing care and treatment to Plaintiff.

14. Defendant DR. SCHMITT maintains the residential address set forth in the caption above.

15. The injuries, acts, and damages complained of herein arose in Wyandotte County, Kansas, making this Court the proper venue for this cause of action.

KU ERRONEOUSLY APPROVED CYTOPATHOLOGY PRIVILEGES FOR ITS PATHOLOGY DEPARTMENT CHAIRMAN

16. Cytopathology generally involves the diagnosis of human disease by means of the study of cells obtained from body secretions and fluids, by scraping, washing, or sponging the surface of a lesion, or by the aspiration of a tumor mass or body organ with fine needle.

17. According to an Incident Investigation Report prepared by the Kansas City Regional Office of Centers for Medicare and Medicaid Services ("2016 CMS Report"), which is attached hereto as Exhibit A and incorporated by reference, DR. SINGH filed an application with KUMC/KU Hospital in March 2015 requesting privileges in Clinical Pathology, Anatomic Pathology, and **Cytopathology**.

18. DR. SINGH is referenced in the attached report as "Pathologist Staff K," and DR. SCHMITT is referenced as "Surgeon Staff F."

19. At the time of her application, DR. SINGH was not board certified in Cytopathology, and upon information and belief, DR. SINGH has never been board certified in Cytopathology.

20. At the time of her application, according to the 2016 CMS report, KUMC/KU Hospital's internal qualifications for Cytopathology privileges included an American Board of

Pathology ("ABP") certification (or eligibility for added certification) "in cytopathology within 6 months of start date."

21. Board certification in Cytopathology required a 1-year fellowship in addition to successful completion of the exam, and DR. SINGH never completed the required fellowship.

22. Thus, at the time of her application, there was no possibility of DR. SINGH obtaining the necessary board certification (or eligibility for certification) within 6 months of her start date.

23. Despite the above, KUMC/KU Hospital's Clinical Service Chief recommended Cytopathology privileges for DR. SINGH in March 2015, and her Cytopathology privileges were subsequently approved by the Credentials Committee Chair, the Executive Committee of the Medical Staff Chair, and the Board of Directors Representative between May and June 2015.

24. The Clinical Service Chief also signed a separate form answering "Yes" to the question of whether "[t]here [was] adequate documentation in the practitioner's credentials file [to meet] all department/service criteria/standards for [the] privileges requested."

25. Between March and June 2016, and despite her lack of board certification in Cytopathology, DR. SINGH was promoted to **Chair** of the Pathology Department with privileges in Clinical Pathology, Anatomic Pathology, and Cytopathology by the Chief of Clinical Services, the Credentials Committee Chair, the Executive Committee of the Medical Staff Chair, and the Board of Directors Representative.

26. After receiving her Cytopathology privileges, and as the newly appointed Chair of the Pathology Department, DR. SINGH began reviewing Cytopathology cases for the KU Defendants without meeting KUMC/KU Hospital's internal requirements.

THE MISDIAGNOSIS BY THE NON-BOARD CERTIFIED CHAIR OF THE DEPARTMENT

27. In August 2015, after experiencing abdominal pain, Plaintiff underwent fine needle biopsies of her pancreas.

28. In August 2015, DR. SINGH reviewed 3 fine needle aspirate ("FNA") tissue samples from Plaintiff's pancreas.

29. DR. SINGH misdiagnosed one or more of the FNA samples as cancerous, including her primary misdiagnosis of pancreatic neuroendocrine tumor.

30. The Quality Assurance Program at KUMC/KU Hospital requires a concurrent review and signature from a second, qualified pathologist whenever there is a finding of new cancer.

31. Upon information and belief, DR. SINGH falsely represented in Plaintiff's medical records that: "Pursuant to the Quality Assurance Program at KU Med Center this case has been concurrently reviewed by the following pathologist: Maura O'Neill, M.D. who agrees with the above diagnosis."

32. According to the 2016 CMS Report, DR. SINGH admitted that 1 of the FNA samples: 15-1317 (diagnosis: rare atypical cells) was never shown to Maura O'Neill, M.D., and that DR. SINGH "assumed" O'Neil was shown the other 2 FNA samples by someone else.

33. According to the 2016 CMS Report, however, O'Neill never received 2 of the FNA samples, including the FNA sample supporting DR. SINGH's primary diagnosis: 15-1316 (diagnosis: pancreatic neuroendocrine tumor) and 15-1317 (diagnosis: rare atypical cells).

34. With respect to the remaining FNA sample: 15-1315 (pancreatic neuroendocrine neoplasm), intradepartmental reports (pink slips) were never produced reflecting Maura O'Neill, M.D.'s concurrent review, signature, or agreement on the diagnosis associated with that sample.

PLAINTIFF RECEIVES A MEDICAL PROGNOSIS THAT IS 94% LETHAL WITHIN 5 YEARS OF DIAGNOSIS

35. Based on DR. SINGH's misdiagnosis, Plaintiff was informed she had a type of cancer that is 94% lethal within 5 years of diagnosis.

36. According to WebMD, "[a]mong common cancers, pancreatic cancer has one of the poorest prognoses. Because pancreatic cancer often grows and spreads long before it causes any symptoms, only about 6% of patients are still alive five years after diagnosis." Exhibit B (WebMD article).

37. Plaintiff was informed by DR. SCHMITT that surgery was necessary for her survival.

38. In particular, DR. SCHMITT explained to Plaintiff (with great urgency) that she had neuroendocrine tumors, that neuroendocrine tumors are cancerous, that they can spread and multiply, and that "they need to come out."

39. He drew for Plaintiff a picture of the Whipple surgery that he recommended.

40. Aside from drawing a picture, however, DR. SCHMITT failed to explain the inherent risks and hazards of the Whipple procedure, the major consequences and life changes following the operation, or the possible results to be anticipated. In particular, DR. SCHMITT never explained that:

a. The proposed surgery would likely (or even possibly) involve lifelong medical complications;

b. Plaintiff could lose some or all of the essential functions of her pancreas (or the nature of those essential functions);

c. Plaintiff could sustain a temporary or permanent loss of digestive functions and enzyme production;

d. Plaintiff could lose her ability to produce insulin and develop diabetes; or,

e. Plaintiff could be required to take extremely costly medications for the rest of her life in order to address one or more of the above issues, or other complications associated with the surgery.

41. DR. SCHMITT minimalized the inherent risks and consequences of the Whipple procedure by informing Plaintiff that he performed the same surgery on a different female similar in age to Plaintiff, and that she was currently doing "great."

42. DR. SCHMITT performed upon Plaintiff a modified Whipple procedure and open cholecystectomy on September 1, 2015.

43. The modified Whipple procedure is a major surgical operation involving the removal of the head of the pancreas, the duodenum, the proximal jejunum, gallbladder, and part of the stomach.

44. DR. SCHMITT also removed Plaintiff's appendix, a portion of her small intestine, and her bile duct.

45. According to WebMD, the Whipple procedure continues to be one of the most demanding and risky operations for surgeons and patients alike.

46. The Whipple procedure is reserved for patients with the bleakest of medical prognoses, and it involves serious lifelong complications for many patients.

DISCOVERY OF THE MISDIAGNOSIS AND CONCEALMENT FROM PLAINTIFF

47. After Plaintiff's surgery on 9/1/15, tissue samples from Plaintiff's pancreas were examined by other members of the KUMC/KU Hospital Department of Pathology.

48. The post-surgery examination of the Plaintiff's tissue samples (which was conducted by a board certified pathologist) established that Plaintiff's pancreas was essentially normal and was not cancerous.

49. The 9/4/15 surgical pathology report concluded: "[n]egative for tumor in the entirely submitted specimen."

50. After the post-surgery examination determined that Plaintiff's pancreas was not cancerous, the pre-surgery tissue sample was re-examined by the same board certified pathologist.

51. The post-surgery re-examination of the pre-surgery tissue sample established that the pre-surgery sample was not cancerous, and that DR. SINGH misdiagnosed the pre-surgery tissue sample.

52. The removed portion of Plaintiff's pancreas was normal.

53. The entire Whipple procedure on 9/1/15 was unnecessary.

54. DR. SINGH examined Plaintiff's tissue samples after she was informed of her misdiagnosis, and upon information and belief, did not consult with any board certified cytopathologists.

55. According to the 2016 CMS Report, after DR. SINGH became aware of her misdiagnosis, she told DR. SCHMITT "the results of the FNA that she had read and diagnosed as neuroendocrine tumor of the pancreas was inaccurate."

56. According to DR. SCHMITT, this was the first time in 12 years a pathologist ever called him to address a similar situation.

57. According to a subsequent whistleblower complaint filed by Lowell L. Tilzer, M.D. ("DR. TILZER"), which is attached hereto as Exhibit C and incorporated by reference,[1] DR. SINGH did not recognize the difference between acinar cells and islet cells, and covered up her misdiagnosis by placing an addendum to her original report stating the original cancer diagnosis and the normal removed organ matched, thereby concealing her original misdiagnosis and perpetuating Plaintiff's mistaken belief that Plaintiff's removed organ was cancerous.

58. DR. SINGH never added her "addendum" to Plaintiff's original medical record until 9/18/15, or 9 days after Plaintiff's hospitalization concluded on 9/9/15.

59. During the remainder of her eight-day hospital recovery, neither DR. SINGH nor DR. SCHMITT informed Plaintiff about the 9/4/15 results of her post-surgery biopsies.

60. Between the time of her surgery and her discharge on 9/9/15, DR. SCHMITT never returned to visit with Plaintiff for any reason.

61. Despite Defendants' knowledge of the misdiagnosis, Plaintiff was discharged on 9/9/15 with a diagnosis of "primary pancreatic neuroendocrine tumor."

62. Neither DR. SINGH nor DR. SCHMITT ever informed Plaintiff—at any time—that:

a. She was misdiagnosed as having cancer when she did not;

b. She never had a pancreatic neuroendocrine tumor or a form of cancer that is 94% lethal within 5 years of diagnosis; or,

c. She underwent an unnecessary surgery involving lifelong complications.

[1] The attachments to DR. TILZER's original "whistleblower" Petition are omitted.

DR. SCHMITT AND DR. SINGH TOOK ADDITIONAL STEPS TO CONCEAL THE ABOVE

63. Following Plaintiff's discharge, DR. SINGH and DR. SCHMITT took additional steps to actively conceal DR. SINGH's misdiagnosis.

64. For example, according to DR. TILZER's "whistleblower" Petition, DR. SINGH—who was the Chair of the Pathology Department—did not report her misdiagnosis to KU Hospital's Chief Medical Officer, Risk Management Committee, or Risk Manager.

65. Upon information and belief, DR. SCHMITT also failed to report the critical misdiagnosis.

66. During a follow-up appointment on 9/17/15, DR. SCHMITT stated to Plaintiff, "good news, no cancer." Understandably, Plaintiff interpreted DR. SCHMITT's statement to mean that DR. SCHMITT successfully removed the cancerous portion of her pancreas containing the neuroendocrine tumor previously identified by DR. SINGH.

67. Whether or not Plaintiff's initial interpretation of DR. SCHMITT's statement on 9/17/15 was accurate, DR. SCHMITT's subsequent, false statements reinforced Plaintiff's beliefs, and concealed Defendants' mistakes.

DR. SCHMITT PERPETUATED THE FALSE NARRATIVE THAT PLAINTIFF HAD A HISTORY OF PANCREATIC NEUROENDOCRINE TUMOR AND CANCER

68. When Plaintiff was re-hospitalized at KUMC/KU Hospital between 9/27/15 and 9/30/15 with complications from her 9/1/15 surgery, an ER doctor said to her, "Oh, I heard about you, you had an extended Whipple procedure and had your appendix out."

69. Plaintiff was shocked to learn that DR. SCHMITT removed her appendix because DR. SCHMITT never described that part of the procedure.

70. On 10/8/15, when Plaintiff confronted DR. SCHMITT about her appendix during a follow-up appointment, DR. SCHMITT said, **"Oh, I must have forgotten to tell you, I had to take that out because they form the same kind of tumors that your pancreas had."**

71. Importantly, even though DR. SCHMITT was fully aware of Plaintiff's misdiagnosis, and the fact that she never had cancer or a pancreatic neuroendocrine tumor, DR. SCHMITT perpetuated the false narrative that Plaintiff had a history of pancreatic neuroendocrine tumor and cancer.

72. Again, the 9/4/15 surgical pathology report concluded: "[n]egative for tumor in the entirely submitted specimen."

73. DR. SCHMITT also concealed Plaintiff's misdiagnosis by continually referencing the misdiagnosis as if it was an accurate diagnosis in the records.

74. For example, when Plaintiff returned **seven months later** on 4/5/16 for an incisional hernia repair—another complication from her 9/1/15 surgery—DR. SCHMITT's operative note described Plaintiff as a "45F with a history of neuroendocrine tumor of the pancreas."

75. This was not a clerical or charting error; it was a continuation of the efforts to cover-up the misdiagnosis and the unnecessary surgery.

DR. SINGH'S EFFORTS TO INTERFERE WITH THE QUALITY IMPROVEMENT PROCESS

76. Upon information and belief, in early 2016, KUMC/KU Hospital reviewed the three fine needle aspirations during its Quality Improvement process. In doing so, KUMC/KU HOSPITAL classified them as "major misinterpretations," and determined that the misinterpretations led to an unneeded, major surgery.

77. In response, and with motivating self-interest, DR. SINGH lobbied the supervisor of Cytopathology to edit the Quality Improvement document to minimize or eliminate references to the "major misinterpretations," and to minimize or eliminate the fact that an unneeded, major surgery occurred.

78. As an unqualified Chair of the department, DR. SINGH also instructed others to alter meeting minutes referencing her misdiagnosis, and the necessity of conducting a "root cause analysis."

79. A "root cause analysis" investigates the underlying cause of a mistake so that preventive measures can be adopted to avoid the same mistake in the future. A "root cause analysis" is the standard tool for health care agencies to understand and prevent mistakes such as what occurred to Plaintiff.

THE KU DEFENDANTS ALSO REFUSED TO ACT ON THE MISDIAGNOSIS AND CONDUCT A "ROOT CAUSE ANALYSIS"

80. In September 2015, DR. TILZER informed the KU Hospital's Chief Medical Officer and the Risk Management Officer that a "root cause analysis" must be conducted regarding the misdiagnosis.

81. The Chief Medical Officer stated that DR. SINGH's original diagnosis was correct because two other pathologists signed the report. As discussed above, however, the two other pathologists did not agree with the original diagnosis, and the Chair simply wrote their names in the electronic medical record.

82. The Chief Medical Officer refused DR. TILZER's requests to talk to any other pathologist. The Chief Medical Officer's failure to interview other pathologists perpetuated the cover up of the misdiagnosis by the Hospital.

83. Despite DR. TILZER's request, and in violation of KU Hospital's policies, Defendants never conducted a "root cause analysis."

84. According to his "whistleblower" Petition, DR. TILZER also advocated that the medical records be corrected and that Plaintiff be informed of the misdiagnosis.

85. DR. TILZER's concerns regarding DR. SINGH's competence were reinforced by limitations imposed by the Division Director of Cytopathology preventing DR. SINGH from performing cytopathology reviews.

86. DR. TILZER's concerns regarding KU Hospital's ability and desire to manage the Department of Pathology were reinforced when DR. SINGH unilaterally decided that she would perform cytopathology reviews despite the limitation imposed by the Division Director of Cytopathology.

87. DR. TILZER's concerns regarding DR. SINGH's competence and KU Hospital's ability and desire to manage the Department of Pathology were further reinforced when continuing mistakes by DR. SINGH and actual or potential patient harm was brought to DR. TILZER's attention.

88. Upon information and belief, KUMC/KU Hospital have also been presented with several letters and evaluations from residents and physicians citing complaints or criticisms about the job performance, competence, and/or professional demeanor exhibited by DR. SINGH.

89. The physicians in the Department of Pathology and Laboratory Medicine also sent KUMC/KU Hospital a letter (or similar resolution) discussing their lack of confidence in the skill, job performance, competence, and/or professional demeanor exhibited by DR. SINGH.

SIGNIFICANCE OF THE FAILURE TO INFORM THE PATIENT

90. The form of cancer that was erroneously diagnosed within Plaintiff is commonly known to be potentially lethal, and Plaintiff lived with unwarranted fear throughout the period of time the KU Defendants concealed her misdiagnosis.

91. The failure to inform the patient created a conflict of interest between KU Hospital, the physicians, and Plaintiff. Unless and until the Plaintiff was actually informed of the misdiagnosis and cover up, Plaintiff remained unaware of the conflict.

92. The failure to inform the patient and the conflict of interest are contrary to American Medical Association Ethics Opinion 10.01(1) and (3).

DR. TILZER'S REPORT TO THE JOINT COMMISSION

93. After DR. SINGH requested the alteration of medical records, and after KU Hospital failed to conduct a "root cause analysis," DR. TILZER concluded that an external review was necessary according to his "whistleblower" Petition.

94. On 4/1/16, DR. TILZER submitted a report to the Joint Commission regarding the misdiagnosis and KU Defendants' concealment and failure to correct medical records.

95. DR. TILZER's report to the Joint Commission was assigned Incident #72413QOS- 12536ZZC.

96. On 4/1/16, The Joint Commission sent DR. TILZER an email asking whether the Joint Commission could provide DR. TILZER's name to KU Hospital, and DR. TILZER agreed.

97. DR. TILZER's report to the Joint Commission:

a. Identified KUMC and KU Hospital;

b. Explained the misdiagnosis;

c. Identified the Chair of the Department of Pathology;

d. Recited the sequence of events and concealment;

e. Recited the failure to correct the patient's medical records; and,

f. Explained that the patient had not been informed of the misdiagnosis.

KU DEFENDANTS' REACTION TO DR. TILZER'S REPORT TO THE JOINT COMMISSION

98. On 5/5/16, DR. TILZER met with the KU Hospital's Risk Management Officer and Chief Medical Officer regarding DR. TILZER's report to the Joint Commission and DR. TILZER's criticisms of KUMC's and KU Hospital's actions and concealment.

99. On 5/6/16, DR. TILZER met with the Director of Risk Management and discussed the need to conduct a proper "root cause analysis" by interviewing the five board certified cytopathologists and the Head of Surgical Pathology.

100. The Director of Risk Management informed DR. TILZER that she would do so, but to the best of DR. TILZER's knowledge, the Director of Risk Management did not interview the five Board Certified Cytopathologists and the Head of Surgical Pathology.

101. The Director of Risk Management also told DR. TILZER that she would meet with the Cytopathology supervisor who had been told to modify the Quality Improvement document, and that she would meet with the secretary who was instructed to modify the Minutes of the Quality Improvement committee meeting where this problem was discussed. To the best of DR. TILZER's knowledge, she did not interview either the Cytopathology supervisor or the secretary.

102. On 5/31/16, KU Hospital President Bob Page asked DR. TILZER to meet, and DR. TILZER met with Page in Page's office.

103. During DR. TILZER's May 31 meeting, KU Hospital's President Bob Page reprimanded DR. TILZER and attempted to intimidate DR. TILZER by:

a. Asking DR. TILZER if DR. TILZER wanted to resign (to which DR. TILZER stated that he would not resign);

b. Berating DR. TILZER for contacting the Joint Commission;

c. Accusing DR. TILZER of lying to the Joint Commission (to which DR. TILZER responded that his statements to the Joint Commission were truthful);

d. Saying that he (Page) was irritated that DR. TILZER had contacted the Joint Commission;

e. Asking why DR. TILZER had "done this alone" (to which DR. TILZER responded that others in the department were too scared to act); and,

f. Describing DR. TILZER's report to the Joint Commission as "pitiful" and "despicable" behavior.

104. DR. TILZER justifiably perceived Page's May 31 reprimand and attempted intimidation as a serious threat to DR. TILZER's employment and as an attempt to prevent DR. TILZER from any further reporting to the Joint Commission.

105. On 6/4/16, KUMC inquired whether DR. TILZER wanted to take a sabbatical.

106. On 7/1/16, DR. TILZER filed his "whistleblower" Petition asserting much of the above.

107. At that time, Plaintiff still had no idea that a misdiagnosis occurred, that her medical records were incorrect, that she never had a form of cancer that is 94% lethal within 5 years of diagnosis, or that she underwent an unnecessary surgery involving, among other things, the removal of a significant portion of her essential body organ.

KU DEFENDANTS AGAIN DENY THE EXISTENCE OF THE MISDIAGNOSIS AND THE COVER-UP

108. The same day DR. TILZER filed his "whistleblower" Petition, KU Hospital President Bob Page sent an email to all KU medical staff, and perpetuated the KU Defendants' efforts to conceal the misdiagnosis and cover-up from Plaintiff.

109. Page wrote:

> **The hospital received word today (Friday, July 1st) that pathologist Dr. Lowell Tilzer had filed a "Whistleblower" lawsuit against us. The suit alleges a misdiagnosis was made on a cancer patient by a physician, leading to unnecessary surgery. The suit further alleges the hospital ignored Dr. Tilzer's calls for a review of the case and never informed the patient of the misdiagnosis.**
>
> **In short, this is simply not true.**

110. Page's statements were patently false.

DEFENDANTS TAKE ADDITIONAL STEPS TO INSULATE THEMSELVES FROM LIABILITY INSTEAD OF PROTECTING THEIR PATIENT

111. On or about 7/6/16, the Kansas City Regional Office of Centers for Medicare and Medicaid Services ("CMS") began investigating DR. TILZER's allegations.

112. When the CMS investigation began, Plaintiff's medical records were still incorrect, and contained multiple references to her incorrect diagnosis.

113. On 7/26/16, in an effort to further conceal previous wrongdoing, DR. SCHMITT contacted Plaintiff during the CMS investigation, and requested that Plaintiff execute the affidavit attached hereto as Exhibit D.

114. Among other things, DR. SCHMITT and/or his attorney carefully massaged the language in the affidavit to insulate Defendants from liability.

115. The affidavit also:

a. Asked Plaintiff to lie about the timing of when DR. SCHMITT deceptively said to Plaintiff, "good news, no cancer," without fully informing her that a misdiagnosis occurred, that she never had a cancerous pancreatic neuroendocrine tumor, and that she underwent an unnecessary surgery involving lifelong complications;

b. Falsely stated that he told Plaintiff her neuroendocrine tumor diagnosis was "preliminary" in nature, and that it demonstrated only that Plaintiff "might" have "potential pancreatic cancer," rather than acknowledging that he explained to Plaintiff (with great urgency) that she had neuroendocrine tumors, that neuroendocrine tumors are cancerous, that they can spread and multiply, and that "they need to come out," in addition to drawing Plaintiff a picture of a Whipple surgery; and,

c. Failed to mention DR. SCHMITT's additional efforts to conceal the above problems from Plaintiff, including: (1) DR. SCHMITT's 10/8/15 statement to Plaintiff doubling down on the false narrative that she had a history of pancreatic neuroendocrine tumor despite the 9/4/15 surgical pathology report concluding: "[n]egative for tumor in the entirely submitted specimen,"[2] and (2) DR. SCHMITT's continuing references to the misdiagnosis as an accurate diagnosis in the records, including his continuing description of Plaintiff as a "45F with a history of neuroendocrine tumor of the pancreas."

[2] "Oh, I must have forgotten to tell you, I had to take [your appendix] out because they form the same kind of tumors that your pancreas had."

116. DR. SCHMITT also asked Plaintiff to affirm that "[t]he treatment [she] received from Dr. Schmitt and from all of the University of Kansas Hospital nurses, doctors, and employees was **wonderful**." (emphasis added).

117. Given the suspicious nature of DR. SCHMITT's request for Plaintiff to sign an affidavit, Plaintiff did some investigating of her own after the 7/26/16 call, found a news article related to DR. TILZER's "whistleblower" Petition, and learned for the very first time that she was misdiagnosed with cancer, that her medical records were incorrect, that she never had a cancerous pancreatic neuroendocrine tumor, and that she underwent an unnecessary surgery involving lifelong complications.

118. Shortly after receiving DR. SCHMITT's call, Plaintiff requested her own medical records, and her records still contained multiple references to the incorrect misdiagnosis, and her positive history for a pancreatic neuroendocrine tumor.

119. When CMS questioned DR. SCHMITT about his failure to correct Plaintiff's medical records, DR. SCHMITT attempted to blame others, and downplayed the manner in which he perpetuated a false narrative about Plaintiff's medical history.

120. DR. SCHMITT said, "[o]nce the information is placed in the electronic medical record it is hard to get it out of there, that's a job for IT (information technologies)."

121. DR. SCHMITT also said that the medical record "is not very important" and indicated they do not base their diagnosis on past History and Physicals.

122. In its investigation of DR. SCHMITT and KU Hospital, CMS found that "the hospital's medical staff failed to ensure the quality of care provided to [Plaintiff] in that the surgeon and other hospital staff failed to inform the patient during her hospitalization that she did not have cancer and that her appendix had been removed during surgery; failed to update

[Plaintiff's] medical record to remove the diagnosis of cancer, and failed to completely and thoroughly investigate the incident."

123. CMS also found that the governing body of the hospital "failed to ensure the hospital promoted and protected the rights of [Plaintiff] by failing to keep her fully informed of her diagnosis, a misread lab, and her surgical procedure."

124. CMS also found that the governing body of the hospital "failed to ensure that the Medical Staff Committee appointed a qualified Pathologist to a position by not ensuring that she met the special qualifications listed on the application for privileges," **and that the hospital's "deficient practices placed all patients receiving services at [the] hospital at risk for receiving care that does not meet acceptable quality and standards."**

125. Plaintiff's records were later altered without Plaintiff's knowledge to remove references to her positive history for a pancreatic neuroendocrine tumor.

DEFENDANTS SEND OUT THE PATHOLOGY SLIDES FOR AN ADDITIONAL OPINION

126. After multiple agencies were notified about the matters raised by DR. TILZER, the KU Defendants sent Plaintiff's original FNA slides to Dr. Lester Layfield ("DR. LAYFIELD"), a board certified cytopathologist in Columbia, Missouri.

127. DR. LAYFIELD determined—consistent with others at KUMC/KU Hospital—that Plaintiff never had cancer, and that Plaintiff was misdiagnosed by DR. SINGH in August 2015.

128. Based on DR. LAYFIELD's additional determination, KUMC/KU Hospital was forced to issue corrected medical records with a corrected medical diagnosis consistent with DR. LAYFIELD's opinion.

129. Plaintiff was emailed a link to her updated records without any additional explanation.

130. As of August 2016, DR. SINGH's Physician Profile with KU Hospital still stated that DR. SINGH's "specialties include … Cytopathology."

131. In her KUMC "Welcome from Our Chair" webpage, DR. SINGH also stated:

> "I am pleased to greet you as the new Chair in the University of Kansas Medical Center's Department of Pathology and Laboratory Medicine! … Pathology affects nearly every patient who walks through the hospital's doors as well as the treatment choices their physicians make for them. … Our clinical faculty provide expertise in anatomic and clinical laboratory diagnostic services on eight campuses throughout the Greater Kansas City Metropolitan Area. Anatomic subspecialists have been recognized by their local peers as 'top doctors' in their respective fields of work and study. … All our clinical faculty are board-certified…."

132. Plaintiff continues to suffer on a daily basis with pain, discomfort, distress, and a host of other medical complications related to her unnecessary Whipple procedure, and recently underwent an additional hernia repair at St. Joseph Health Center.

133. As a direct and proximate result of Defendants' negligent and wrongful acts and/or omissions discussed above, and as further discussed in the counts that follow, Plaintiff sustained significant, permanent, and debilitating injuries throughout her body, and other serious, painful, and disabling injuries to the bones, muscle, nerves, cartilage, tendons, and blood vessels thereof.

134. As a direct and proximate result of Defendants' negligent and wrongful acts and/or omissions discussed above, and as further discussed in the counts that follow, Plaintiff sustained ongoing and continuous pain and suffering as a result of the injuries mentioned above, medical expenses, both past and future, economic losses, lost earnings, attorneys fees, and non-economic losses including pain, suffering, scarring, distress, mental anguish, and humiliation.

Said injuries also impacted, and will continue to impact, Plaintiff's ability to perform basic daily tasks, and her quality of life, for the remainder of her life.

135. Plaintiff also reserves the right to amend this petition pursuant to K.S.A. § 60-3703 in order to assert a claim for punitive damages based on the matters alleged herein, and any additional information learned throughout discovery.

COUNT I – NEGLIGENCE

136. Plaintiff realleges and incorporates by reference, as if fully set forth herein, all allegations set forth in the preceding paragraphs.

MEENAKSHI SINGH, M.D.

137. Defendant DR. SINGH had a duty to possess and use that degree of skill and learning ordinarily used in the same or similar circumstances by members of her profession in the treatment of Plaintiff, and to provide proper treatment to Plaintiff. Defendant breached her duty, and was thereby negligent and careless, in one or more of the following respects:

a. By carelessly and negligently misdiagnosing Plaintiff with cancer;
b. By carelessly and negligently failing to adhere to KUMC/KU Hospital's Quality Assurance Program mandating a concurrent review and signature from a second, qualified pathologist whenever there is a finding of new cancer;
c. By carelessly and negligently reviewing Cytopathology cases in contravention of KUMC/KU Hospital's credentialing requirements;
d. By carelessly and negligently failing to correct and remedy her earlier negligent acts and omissions; and,
e. In other respects that may become known through further investigation and discovery.

TIMOTHY M. SCHMITT, M.D.

138. Defendant DR. SCHMITT had a duty to possess and use that degree of skill and learning ordinarily used in the same or similar circumstances by members of his profession in the treatment of Plaintiff, and to provide proper treatment to Plaintiff. Defendant's duty included the obligation to provide sufficient information to Plaintiff to permit Plaintiff to make intelligent, informed decisions about her medical treatment, including the obligation to inform Plaintiff of the nature of the patient's illness, of the significant risks and consequences inherent to the proposed treatment or procedure, and of reasonable, medically acceptable alternatives to the proposed treatment, including the option to forego treatment altogether. Defendant breached his duty, and was thereby negligent and careless, in one or more of the following respects:

a. By carelessly and negligently failing to inform Plaintiff that her neuroendocrine tumor diagnosis was merely "preliminary" in nature, and that it demonstrated only that Plaintiff "might" have "potential pancreatic cancer," rather than explaining to Plaintiff (with great urgency) that she had neuroendocrine tumors, that neuroendocrine tumors are cancerous, that they can spread and multiply, and that "they need to come out," in addition to drawing Plaintiff a picture of a Whipple surgery;

b. By carelessly and negligently failing to explain the inherent risks and hazards of the Whipple procedure, the major risks involved, or the possible results to be anticipated. In particular, by failing to explain that:

    1. The proposed surgery would likely (or even possibly) involve lifelong medical complications;

2. Plaintiff could lose some or all of the essential functions of her pancreas (or the nature of those essential functions);
3. Plaintiff could sustain a temporary or permanent loss of digestive functions and enzyme production;
4. Plaintiff could lose her ability to produce insulin and develop diabetes; or,
5. Plaintiff could be required to take extremely costly medications for the rest of her life in order to address one or more of the above issues, or other complications associated with the surgery.

c. By carelessly and negligently failing to provide Plaintiff with sufficient information to intelligently consider the option to forego surgery and/or seek a second opinion; and,

d. In other respects that may become known through further investigation and discovery.

THE UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, UNIVERSITY OF KANSAS MEDICAL CENTER, THE UNIVERSITY OF KANSAS PHYSICIANS

139. KU Defendants, at all times material herein, acting by and through their nurses, physicians, agents and/or employees, had a duty to possess and use that degree of skill and learning ordinarily used in the same or similar circumstances by members of their profession in the treatment of Plaintiff, and to provide proper treatment to Plaintiff. Defendants breached their duty, and were thereby negligent and careless, in one or more of the following respects:

a. By carelessly and negligently misdiagnosing Plaintiff with cancer;

b. By carelessly and negligently failing to inform Plaintiff that her neuroendocrine tumor diagnosis was merely "preliminary" in nature, and that it demonstrated only that Plaintiff "might" have "potential pancreatic cancer," rather than explaining to

Plaintiff (with great urgency) that she had neuroendocrine tumors, that neuroendocrine tumors are cancerous, that they can spread and multiply, and that "they need to come out," in addition to drawing Plaintiff a picture of a Whipple surgery;

c. By carelessly and negligently failing to explain the inherent risks and hazards of the Whipple procedure, the major risks involved, or the possible results to be anticipated. In particular, by failing to explain that:

    1. The proposed surgery would likely (or even possibly) involve lifelong medical complications;
    2. Plaintiff could lose some or all of the essential functions of her pancreas (or the nature of those essential functions);
    3. Plaintiff could sustain a temporary or permanent loss of digestive functions and enzyme production;
    4. Plaintiff could lose her ability to produce insulin and develop diabetes; or,
    5. Plaintiff could be required to take extremely costly medications for the rest of her life in order to address one or more of the above issues, or other complications associated with the surgery.

d. By carelessly and negligently failing to provide Plaintiff with sufficient information to intelligently consider the option to forego surgery and/or seek a second opinion;

e. By carelessly and negligently allowing physicians to falsely represent compliance with KUMC/KU Hospital's Quality Assurance Program mandating a concurrent

review and signature from a second, qualified pathologist whenever there is a finding of new cancer;

f. By carelessly and negligently granting Cytopathology privileges to DR. SINGH and/or permitting DR. SINGH to review Cytopathology cases; and,

g. In other respects that may become known through further investigation and discovery.

THE UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, UNIVERSITY OF KANSAS MEDICAL CENTER, THE UNIVERSITY OF KANSAS PHYSICIANS

140. Additionally, employees of KU Defendants who were not required to obtain insurance under the Health Care Provider Insurance Availability Act at K.S.A. § 40-3401, *et seq*. ("HCPIAA") owed Plaintiff a separate duty of reasonable care in their direct treatment of Plaintiff that was separate and distinct from services provided by DR. SINGH or DR. SCHMITT. Defendants breached their duty of reasonable care, and were thereby negligent and careless, in one or more of the following respects:

a. By carelessly and negligently allowing physicians to falsely represent compliance with KUMC/KU Hospital's Quality Assurance Program mandating a concurrent review and signature from a second, qualified pathologist whenever there is a finding of new cancer;

b. By carelessly and negligently granting Cytopathology privileges to DR. SINGH and/or permitting DR. SINGH to review Cytopathology cases; and,

c. In other respects that may become known through further investigation and discovery.

141. As a direct and proximate result of the negligence specified above, Plaintiff sustained the injuries and damages alleged in the preceding paragraphs.

WHEREFORE, for this Count I, Plaintiff prays for judgment against Defendants, and each of them, for damages in such an amount as shall be fair and reasonable in excess of $75,000.00 for all injuries and damages, together with costs herein incurred and expended, plus pre-judgment interest and post-judgment interest at the rate permitted by law, and such other and further relief the Court deems just and proper.

COUNT II – FRAUD THOUGH SILENCE

142. Plaintiff realleges and incorporates by reference, as if fully set forth herein, all allegations set forth in the preceding paragraphs.

143. Beginning as early as 9/4/15, the Defendants had knowledge of the following material facts which Plaintiff did not have and which the Plaintiff could not have discovered by the exercise of reasonable diligence:

a. Plaintiff was misdiagnosed with cancer;

b. Plaintiff never had a pancreatic neuroendocrine tumor or a form of cancer that is 94% lethal within 5 years of diagnosis; and/or,

c. Plaintiff underwent an unnecessary surgery involving lifelong complications.

144. The Defendants were under an obligation to communicate the material facts to the Plaintiff.

145. The Defendants intentionally failed to communicate to Plaintiff the material facts.

146. The Plaintiff justifiably relied upon the Defendants to communicate the material facts to the Plaintiff.

147. As a direct and proximate result of Defendants' failure to communicate the above, Plaintiff lived with unwarranted fear related to her medical history that was positive for cancer, and Plaintiff sustained additional pain, suffering, distress, and mental anguish.

WHEREFORE, for this Count II, Plaintiff prays for judgment against Defendants, and each of them, for damages in such an amount as shall be fair and reasonable in excess of $75,000.00 for all injuries and damages, together with costs herein incurred and expended, plus pre-judgment interest and post-judgment interest at the rate permitted by law, and such other and further relief the Court deems just and proper.

COUNT III – FRAUD

148. Plaintiff realleges and incorporates by reference, as if fully set forth herein, all allegations set forth in the preceding paragraphs.

149. On 10/8/15, when Plaintiff confronted DR. SCHMITT about her appendix during a follow-up appointment, DR. SCHMITT said, **"Oh, I must have forgotten to tell you, I had to take that out because they form the same kind of tumors that your pancreas had."**

150. In other words, even though DR. SCHMITT was well aware of her original misdiagnosis, and the fact that she never had cancer or a pancreatic neuroendocrine tumor, DR. SCHMITT perpetuated the false narrative that Plaintiff had a history of pancreatic neuroendocrine tumor and cancer.

151. Again, the 9/4/15 surgical pathology report concluded: "[n]egative for tumor in the entirely submitted specimen."

152. DR. SCHMITT also concealed Plaintiff's misdiagnosis by continually referencing the misdiagnosis as if it was an accurate diagnosis in the records.

153. For example, when Plaintiff returned on 4/5/16 for an incisional hernia repair—another complication from her 9/1/15 surgery—DR. SCHMITT's operative note described Plaintiff as a "45F with a history of neuroendocrine tumor of the pancreas."

154. Based on the above, DR. SCHMITT made false or untrue representations as a statement of existing and material fact.

155. The representations were known to be false or untrue by DR. SCHMITT, or were recklessly made without knowledge concerning them.

156. The representations were intentionally made for the purpose of concealing the facts that:

a. Plaintiff was misdiagnosed with cancer;

b. Plaintiff never had a pancreatic neuroendocrine tumor or a form of cancer that is 94% lethal within 5 years of diagnosis; and/or,

c. Plaintiff underwent an unnecessary surgery involving lifelong complications.

157. Plaintiff reasonably relied and acted upon the representations made.

158. As a direct and proximate result of relying on DR. SCHMITT's representations, Plaintiff lived with unwarranted fear related to her medical history that remained positive for cancer, and Plaintiff sustained additional pain, suffering, distress, and mental anguish.

WHEREFORE, for this Count III, Plaintiff prays for judgment against DR. SCHMITT, KU Defendants, and each of them, for damages in such an amount as shall be fair and reasonable in excess of $75,000.00 for all injuries and damages, together with costs herein incurred and expended, plus pre-judgment interest and post-judgment interest at the rate permitted by law, and such other and further relief the Court deems just and proper.

COUNT IV – OUTRAGE

159. Plaintiff realleges and incorporates by reference, as if fully set forth herein, all allegations set forth in the preceding paragraphs.

160. Based on the allegations discussed in the preceding paragraphs, Defendants acted intentionally, or in reckless disregard of the Plaintiff.

161. Taken as a whole, the Defendants' conduct was extreme and outrageous.

162. The Defendants' conduct caused the Plaintiff mental distress, and Plaintiff's mental distress was extreme and severe.

163. As a direct and proximate result of Defendants' extreme and outrageous conduct, Plaintiff was forced to learn the following information about her own body through an article in the Kansas City Business Journal:

a. Plaintiff was misdiagnosed with cancer;

b. Plaintiff never had a pancreatic neuroendocrine tumor or a form of cancer that is 94% lethal within 5 years of diagnosis; and,

c. Plaintiff underwent an unnecessary surgery involving lifelong complications.

164. As a direct and proximate result of Defendants' extreme and outrageous conduct, Plaintiff lived with unwarranted fear related to her medical history that was positive for cancer, and Plaintiff sustained additional pain, suffering, distress, and mental anguish.

WHEREFORE, for this Count IV, Plaintiff prays for judgment against Defendants, and each of them, for damages in such an amount as shall be fair and reasonable in excess of $75,000.00 for all injuries and damages, together with costs herein incurred and expended, plus pre-judgment interest and post-judgment interest at the rate permitted by law, and such other and further relief the Court deems just and proper.

COUNT V – CIVIL CONSPIRACY

165. Plaintiff realleges and incorporates by reference, as if fully set forth herein, all allegations set forth in the preceding paragraphs.

166. Based on the allegations discussed in the preceding paragraphs, two or more of the Defendants (also acting through their respective employees) took steps to fraudulently conceal from Plaintiff the misdiagnosis and her unnecessary surgery.

167. Upon information and belief, two or more of the Defendants (also acting through their respective employees) reached a meeting of the minds in the above-stated object or course of action.

168. Without limitation, the following information was fraudulently concealed from Plaintiff:

a. Plaintiff was misdiagnosed with cancer;

b. Plaintiff never had a pancreatic neuroendocrine tumor or a form of cancer that is 94% lethal within 5 years of diagnosis; and/or,

c. Plaintiff underwent an unnecessary surgery involving lifelong complications.

169. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff lived with unwarranted fear related to her medical history that was positive for cancer, and Plaintiff sustained additional pain, suffering, distress, and mental anguish.

WHEREFORE, for this Count V, Plaintiff prays for judgment against Defendants, and each of them, for damages in such an amount as shall be fair and reasonable in excess of $75,000.00 for all injuries and damages, together with costs herein incurred and expended, plus pre-judgment interest and post-judgment interest at the rate permitted by law, and such other and further relief the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues.

BEAVER LAW FIRM, LLC

/s/ Chad C. Beaver

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1600 Genessee Street, Suite 920
Kansas City, Missouri 64102
ATTORNEY FOR PLAINTIFF

Printed: 12/07/2016 2:07:33PM
Due Date: 08/19/2016
Priority: Non-IJ High

Intake ID: KS00102745
Facility ID: H105002 / HOSP-ACU
Provider Number: 170040
State Region: KDH

ACTS Complaint/Incident Investigation Report

PROVIDER INFORMATION

Name: UNIVERSITY OF KANSAS HOSPITAL
Address: 3901 RAINBOW BLVD
City/State/Zip/County: KANSAS CITY, KS, 66103, WYANDOTTE
Telephone: (913) 588-7332

License #: H105002
Type: HOSP-A
Medicaid #:
Administrator: ROBERT PAGE, ADM

INTAKE INFORMATION

Taken by - Staff: (b)(6)(b)(7)(c)
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
SA Contact: (b)(6)(b)(7)(c)
RO Contact:
Responsible Team: HOSP LICENSE FOR OCTOBER
Source: CMS

Received Start: 07/05/2016 At 13:26
Received End: 07/05/2016 At 13:26
Received by: Media
State Complaint ID:
CIS Number:

COMPLAINANTS

Name	Address	Phone	EMail
CMS KCRO (Primary)	601 E. 12TH ST ROOM (b)(6)(b)(7)(c)	W: (816) 426-2011	
Link ID: (b)(6)(b)(7)(c)	KANSAS CITY, MO 64106		

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged: Time: Shift:

Standard Notes: 7-5-16 The Kansas City Star newspaper reported on 7/2/16 that the chair of this hospitals pathology department mistakenly diagnosed a patient with cancer and covered up the mistake for months after the patient had an essential organ removed that was determined, on examination, to be noncancerous. According to the newspaper article the chair of the pathology department ((b)(6)(b)(7)(c)) added reports to the patient's files to conceal the mistake and instructed others to alter medical records about the misdiagnosis. The physician at the University bringing these allegations to light is (b)(6)(b)(7)(c) a pathologist at the hospital. Please attached newspaper article for details.

Extended RO Notes: The KCRO will authorize an investigation of Surgical Services, Laboratory and Medical Records (b)(6)(b)(7)(c) 8/2/16 - will expand the survey to include the CoP of Patient Rights and Medical Staff.

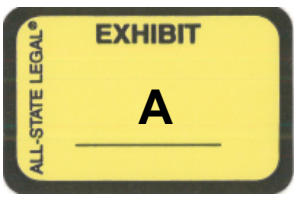
Extended CO Notes:

ALLEGATIONS

Category: Other
Subcategory:
Seriousness:

Findings: Substantiated:Federal deficiencies related to alleg are cited

Deficiencies Cited:
Fed-A-0043-GOVERNING BODY (482.12)
Fed-A-0049-MEDICAL STAFF - ACCOUNTABILITY (482.12(a)(5))
Fed-A-0115-PATIENT RIGHTS (482.13)
Fed-A-0131-PATIENT RIGHTS: INFORMED CONSENT (482.13(b)(2))
Fed-A-0147-PATIENT RIGHTS: CONFIDENTIALITY OF RECORDS (482.13(d)(1))
Fed-A-0338-MEDICAL STAFF (482.22)
Fed-A-0341-MEDICAL STAFF CREDENTIALING (482.22(a)(2))
Fed-A-0441-PROTECTING PATIENT RECORDS (482.24(b)(3))



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Deficiencies Cited: Fed-A-0450-MEDICAL RECORD SERVICES (482.24(c)(1))

Fed-A-0468-CONTENT OF RECORD: DISCHARGE SUMMARY (482.24(c)(4)(vii))

Fed-A-0469-CONTENT OF RECORD: FINAL DIAGNOSIS (482.24(c)(4)(viii))

Fed-A-0749-INFECTION CONTROL PROGRAM (482.42(a)(1))

Fed-A-0951-OPERATING ROOM POLICIES (482.51(b))

Details:

Findings Text: Based on medical record review, document review, patient and staff interview, the hospital's governing body failed to be responsible for the conduct of the hospital in that they failed to ensure the hospital adequately responded to and thoroughly investigated a misread lab sample and ensured the patient involved was fully informed of the misdiagnosis (Refer to A-0049). The governing body also failed to ensure the hospital promoted and protected the rights of a patient by failing to keep her fully informed of her diagnosis, a misread lab, and her surgical procedure (Refer to A-0115 and A-0131). Finally, the governing body failed to ensure that the Medical Staff Committee appointed a qualified Pathologist to a position by not ensuring that she met the special qualifications listed on the application for privileges (Refer to A-0338 and A-0341).

These deficient practices placed all patients receiving services at this hospital at risk for receiving care that does not meet acceptable quality and standards.

Based on record review, document review, patient and staff interview, the hospital's medical staff failed to ensure the quality of care provided to one of eleven patients sampled (Patient #1) in that the surgeon and other hospital staff failed to inform the patient of a misread lab specimen that revealed she did not ever have cancer; failed to inform the patient during her hospitalization that she did not have cancer and that her appendix had been removed during surgery; failed to update patient #1's medical record to remove the diagnosis of cancer, and failed to completely and thoroughly investigate the incident.

Findings Include:

Interview on 7/26/16 between 4:15 PM and 5:30 PM with the (b)(6)(b)(7)(c) revealed, the (b)(6)(b)(7)(c) Staff P and I were aware of patient #1's final diagnosis not being the same as the FNA (fine needle aspiration-a thin needle is inserted into an area of abnormal-appearing tissue or body fluid. As with other types of biopsies, the sample collected during fine needle aspiration can help make a diagnosis or rule out conditions such as cancer) before patient #1 left the hospital. Staff P and I did the initial investigation. The investigation showed a female patient that was profoundly symptomatic and had many studies of her pancreas (CT (computerized tomography) and MRI (magnetic resonance imaging) completed. There were concerns about the patient having acute/chronic pancreatitis (inflammation of the pancreas which can cause abdominal pain, nausea, vomiting, fatigue, and headache).

An endoscope (an instrument used to examine the interior of a hollow organ or cavity) was used to get FNA samples of the pancreas which were reviewed by 2 clinical pathologists (Pathologist Staff G and Pathologist Staff K) and they both agreed on the diagnosis (neuroendocrine tumor of the pancreas-cancerous).

The surgeon determined to take her to surgery based on the findings of the endoscopic procedure, the lab samples, and other radiological exams.

Surgeon Staff F told me he informed the patient about the gland being diseased and not cancerous. The patient was aware of the diagnosis (that she does not have cancer).

Follow up from previous interview on 8/4/2016 at 9:20 AM with the (b)(6)(b)(7)(c) : I did not speak directly to the patient. I was told by Surgeon Staff F that he informed the patient that the FNA results showed that she had cancer, but after the pancreas was tested the results were that there was no cancer. I don't know if anyone sat down and said in exact terms "the initial test was inaccurate" but she knew the FNA results and the final results. (b)(6)(b)(7)(c) Staff P did not speak to the patient to my knowledge. (b)(6)(b)(7)(c) Staff P is no longer employed

ACTS Complaint/Incident Investigation Report

by the facility and unable to be contacted.

Patient # 1 interviewed on 8/8/16 at 12:00 PM indicated that she was not told that she didn't have cancer while she was in the hospital. Surgeon Staff F did tell her on 9/17/2016 at my follow up appointment "good news, no cancer. It was pancreatitis". I know that date because it was the date that I was told I didn't have cancer. That was the first time I had heard about pancreatitis. At none of my follow up visits, no one ever said there might have been a misread, misdiagnosis, or an error in the lab tests.

- Pathology report signed on 8/6/2015 by Pathologist Staff G and reviewed on 7/25/2016 at 4:35 PM revealed:

Cytology # 15-1315
Pancreatic neuroendocrine neoplasm (primary cancer of the pancreas)
Pathologist Staff K agrees with the above diagnosis is documented in the comments section of the document.

Cytology # 15-1316
Pathology report signed on 8/6/2015 by Pathologist Staff G and reviewed on 7/25/2016 at 4:45 PM revealed:
A diagnosis of Pancreatic neuroendocrine tumor
Pathologist Staff K agrees with the above diagnosis is documented in the comments section of the document.

Cytology # 15-1317
Pathology report signed on 8/6/2015 by Pathologist Staff G and reviewed on 7/25/2016 at 4:45 PM revealed:
Diagnosis is Rare atypical cells (not always an indication of cancer, can be a result of inflammation or infection) present.

- Documentation above indicated Pathologist Staff K agreed with the findings in 2 of the 3 Cytology reports (15-1315 and 15-1316). Intradepartmental documents (pink slips) failed to include Pathologist Staff K's signature on one of the two pink slips (15-1315). A concurrent review and signature is required when there is a finding of a new cancer. Only one pink slip (15-1316) was provided by the hospital for review; the other pink slip (15-1315) could not be located.

Pathologist Staff K interviewed on 7/28/16 at 2:00 PM stated, "I did not receive the other two samples (15-1316 and 15-1317) nor was I aware of them. Documentation stating otherwise would be incorrect.

Pathologist Staff G interviewed on 7/27/16 at 9:00 AM, FNA's take some samples out of this entire organ, the journals very well document that there are margins of errors in this type of test. When you have a large organ and you are taking some cells there is a larger possibility of potential error. At least one of the samples were not shown to Pathologist Staff K- the one marked atypical it wouldn't have been required. However, the Fellow (Physician Staff Q) initiates the form (the pink slip), they are supposed to ensure at least two people are on it, the original pathologist, fellow, and the pathologist making the second opinion. I assumed the fellow showed both to Pathologist Staff K. In pathology all around the country they (the pink slips) are not integrated into the medical record, we put it into the report its self in the comments section. Physician Staff Q, Fellow is no longer employed at this hospital and was unable to be contacted.

- Addenda to Patient #1's medical record recorded on 9/18/15 by pathologist Staff G regarding 15-1315 and 15-1316 read: This addendum is done for reporting Cytology-Surgical Pathology correlation. The surgical specimen (S15-22266) was reported as chronic and multifocal pancreatitis. The pancreatitis show reduced acinar cell component (acinar cells produce and transport enzymes that are passed into the duodenum (first part of the small intestine) where they assist in the digestion of food) and prominent nests of neuroendocrine cells (cells that release message molecules (hormones) to the blood)--islet cells (cluster of cells that produce the hormone insulin)(all normal pancreatic cells). The FNA cytology correlates with the surgical specimen (thus indicating a discrepancy with the original FNA diagnosis). Surgeon Staff F was notified of this on 9/4/15 and 9/8/15.

Patient #1's pathology report dated 9/4/2016 revealed the post-surgical pathology results for her pancreas were "Negative for tumor in the entirely submitted pancreatic specimen". The surgical specimens indicated no cancer present in the pancreas. So then, the original FNA specimens 15-1315 and 15-1316 did not show that the patient had a pancreatic neuroendocrine tumor (cancer).

- Even though (b)(6)(b)(7)(c) and the (b)(6)(b)(7)(c) investigated the incident regarding the discrepancy between the FNA specimens and the surgical specimens, they failed to speak to the patient herself (even though they were aware of the issue prior to her discharge) and they failed to investigate potential issues in laboratory proceedings (Pathologist K's claim that she did not perform a concurrent review on specimen 15-1315 and did not sign the pink slip (which cannot be located now).

- Even though Surgeon Staff F was aware that patient #1 did not every have cancer, patient #1's medical record

reviewed on 7/25/2016 at 1:00 PM revealed a discharge diagnosis of a primary pancreatic neuroendocrine tumor (a type of cancer in the pancreas). The medical record lacked evidence Surgeon Staff F corrected the discharge diagnosis and removed the inaccurate diagnosis of a pancreatic neuroendocrine tumor from the patient's record.

Surgeon Staff F interviewed on 7/27/2016 at 12:15 PM stated, "Once the information is placed in the electronic medical record it is hard to get it out of there, that's a job for IT (information technologies)". Staff F stated the medical record "is not very important" and indicated they do not base their diagnosis on past History and Physicals.

- Patient #1 further revealed during the interview on August 8, 2016 that during an emergency room visit in 2016 when I went in for blood work the doctor came in and said "Oh, I heard about you, you had an extended Whipple procedure (a major surgical operation involving the removal of the head of the pancreas, the duodenum, including the duodenal papilla (opening of the pancreatic duct into the duodenum) or ampulla of Vater (formed by the union of the pancreatic duct and the common bile duct), the proximal jejunum (part of the small intestine between the duodenum and ileum), gallbladder (the small sac-shaped organ beneath the liver, in which bile is stored after secretion by the liver and before release into the intestine), and often the distal stomach) and had your appendix taken out". I said wow that's funny I didn't know (that she had her appendix removed). When I was at my follow up appointment with Surgeon Staff F I asked him about it and he said "Oh, I must have forgotten to tell you, I had to take that out because they form the same kind of tumors that your pancreas had". At that point I didn't know what was taken out, I was quite shocked about that.

- I (Patient #1) knew nothing about the test (FNA) being inaccurate until I got a call out of the blue from Surgeon Staff F (Tuesday August 2, 2016) asking me to sign an affidavit and telling me about the test and a disagreement. I told him to send it over and I read it. I had questions about it because he wanted me to say that I was told in the hospital that I didn't have cancer and that it was pancreatitis.

- The medical record lacked documentation that Surgeon Staff F notified patient #1 of the discrepancy between the FNA sample and the final surgical specimen pathology prior to her discharge. The medical record lacked documentation that Surgeon Staff F notified the patient during her hospitalization that she did not have cancer or that her appendix was removed during the surgery.

Based on document review, medical record review, patient and staff interview, the Hospital failed to provide adequate information about a patient's health status and diagnosis to allow her to make informed decisions about her plan of care during her hospitalization (refer to A-0131).

This deficient practice placed all patients at risk for not having adequate information to make informed decisions about their healthcare.

Based on document review, medical record review, patient and staff interview, the Hospital failed to provide

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adequate information about a patient's health status and diagnosis to allow her to make informed decisions about her plan of care during her hospitalization (refer to A-0131).

This deficient practice placed all patients at risk for not having adequate information to make informed decisions about their healthcare.

Based on record review, document review, patient and staff interview, the hospital failed to promote one of eleven patients sampled (Patient #1) right to make informed decisions regarding her care in that they did not keep her informed of her health status by: failing to disclose a discrepancy between the initial FNA (fine needle aspiration-a thin needle is inserted into an area of abnormal-appearing tissue or body fluid. As with other types of biopsies, the sample collected during fine needle aspiration can help make a diagnosis or rule out conditions such as cancer) diagnosing the patient with a neuroendocrine tumor (cancer) of the pancreas and the final surgical pathology revealing no signs of tumor (cancer); by Surgeon Staff F not informing the patient that she was cancer-free during her hospitalization; and by Surgeon Staff F failing to inform the patient that he removed her appendix during the same surgery.

These deficient practices have the potential for all patient receiving services at the hospital to not be fully informed off their health status and to not be able to participate fully in the planning of their care.

Findings include:

Patient #1 interviewed by telephone on Monday August 8, 2016 revealed in part: I was referred to KU Medical Center in August for an upper GI (ERCP)--endoscopic retrograde cholangiopancreatography a specialized technique used to study the bile ducts, pancreatic duct and gallbladder. Ducts are drainage routes; the drainage channels from the liver are called bile or biliary ducts. The pancreatic duct is the drainage channel from the pancreas) to look at the pancreas. At that time they found 3 lesions on the pancreas. They told me I needed to have those removed. From there, I was referred to Surgeon Staff F and I saw him on August 20, 2015. He drew a picture of the Whipple surgery (a major surgical operation involving the removal of the head of the pancreas, the duodenum, including the duodenal papilla (opening of the pancreatic duct into the duodenum) or ampulla of Vater (formed by the union of the pancreatic duct and the common bile duct), the proximal jejunum (part of the small intestine between the duodenum and ileum), gallbladder (the small sac-shaped organ beneath the liver, in which bile is stored after secretion by the liver and before release into the intestine), and often the distal stomach) that I was going to have and where the tumors were. Then they were going to take out a portion of the stomach, the duodenum and part of the pancreas to remove those tumors and the gallbladder to prevent gallstones in the future. The surgery was scheduled for August 31, 2016 and Surgeon Staff F ordered an MRI (Magnetic Resonance Imaging-noninvasive medical test that physicians use to diagnose and treat medical conditions. MRI uses a powerful magnetic field, radio frequency pulses and a computer to produce detailed pictures of organs, soft tissues, bone and virtually all other internal body structures) on August 27, 2015 and I had surgery on September 1, 2015. I remained in the hospital until September 9, 2015.

I (Patient #1) had a follow up visit on September 17, 2015 and that's when Surgeon Staff F told me "good news, no cancer", it was pancreatitis. "You remember that date". No one ever said there might have been a misread, misdiagnosis, or an error at any of my follow up visits.

- Patient #1's medical record reviewed on 7/25/16 at 1:00 PM read in part: Discharge Summaries by APRN (Advanced Practice Registered Nurse),FNP-C (Certified Family Nurse Practitioner) Staff O dictated on 09/09/15 at 8:14 AM:

9/1/15: Exploratory laparotomy (surgical operation where the abdomen is opened and the abdominal organs examined for injury or disease), intraoperative ultrasound (a procedure that uses ultrasound (high-energy sound waves that are bounced off internal tissues and organs) during surgery. Sonograms (pictures made by ultrasound) of the inside of the body are viewed on a computer to help a surgeon find tumors or other problems

during the operation, body pancreatectomy (surgical removal of the body of the pancreas) and pancreaticoduodenectomy (Whipple procedure), open cholecystectomy (removal of the gallbladder), appendectomy (removal of the appendix), reconstruction with pancreaticojejunostomy (the duct and the pancreas are connected to a loop of small intestine), hepaticojejunostomy (connection of the hepatic duct to the jejunem), and gastrojejunostomy (connection of the stomach to the jejunum), omental flap creation, omentopexy and plasty (part of the lining of the abdominal cavity is used to cover or fill a defect, augment arterial or portal venous circulation, absorb effusions (collections of fluids), or increase lymphatic drainage).

Surgical Pathology 9/1/15:
Hilar lymph node #1: There is no evidence of tumor (0/1).
Appendix: Negative for tumor in the entirely submitted specimen.
Pancreas: Localized chronic pancreatitis. Negative for tumor in the entirely submitted specimen.
Lymph nodes: Negative for tumor (0/3).
Hilar lymph node #2: There is no evidence of tumor (0/1).
Gallbladder: No diagnostic abnormalities.
Whipple contents: Pancreas: Multiple foci of chronic pancreatitis. Negative for tumor in the entirely submitted pancreatic.

- Page 1003 of patient #1's medical record contained documentation by Pathologist Staff G written on 9/18/16 that read in part: This addendum is done for reporting Cytology-Surgical Pathology correlation. The surgical specimen was reported as chronic and multifocal pancreatitis (inflammation of the pancreas which can cause abdominal pain, nausea, vomiting, fatigue, and headache). The pancreatitis showed reduced acinar cell component (acinar cells produce and transport enzymes that are passed into the duodenum where they assist in the digestion of food) and prominent nests of neuroendocrine cells (cells that release message molecules (hormones) to the blood)-islet cells (cluster of cells that produce the hormone insulin)-all normal pancreatic cells. The FNA cytology correlates with the surgical specimen (thus indicating a discrepancy with the original FNA diagnosis). Surgeon Staff F was notified of this on 9/4/15 and 9/8/15.

Interview with Surgeon Staff F on 7/29/16 at 12:45 PM, Afterwards she (Pathologist Staff G) came to me and told me the results of the FNA that she had read and diagnosed as a neuroendocrine tumor of the pancreas was inaccurate. First time in 12 years, a pathologist has ever called me. It was within 7-10 days after the surgery. The patient may have been discharged by then. We already knew the final pathology before the call from Pathologist Staff G. The final pathology came back before the patient discharged that showed she did not have cancer; she was told "no cancer" was found in the pancreas. I told her she did not have cancer. I don't know exactly what was said, it was about a year ago.

Patient #1 further revealed during the interview on August 8, 2016 that during an emergency room visit in July 2016 when I went in for blood work the doctor came in and said "Oh, I heard about you, you had an extended Whipple procedure and had your appendix taken out". I said wow that's funny I didn't know. When I was at my follow up appointment with Surgeon Staff F I asked him about it and he said "Oh, I must have forgotten to tell you, I had to take that out because they form the same kind of tumors that your pancreas had". At that point I didn't know what was taken out, I was quite shocked about that.

I (Patient #1) knew nothing about the test (FNA) being inaccurate until I got a call out of the blue from Surgeon Staff F (Tuesday August 2, 2016) asking me to sign an affidavit and telling me about the test and a disagreement. I told him to send it over and I read it. I had questions about it because he wanted me to say that I was told in the hospital that I didn't have cancer and that it was pancreatitis. I didn't say anything to him, but I knew the date that I was told I didn't have cancer. "You remember that date" and so that was 9/17/2015. There was also a statement that in the MRI there were 2 small lesions in the pancreas that was consistent with the endoscopic ultrasound but in that test there were 3 lesions, so that just made me curious because it just didn't seem right.

The medical record lacked documentation that Surgeon Staff F notified patient #1 of the misinterpreted FNA sample even though Pathologist Staff G notified him prior to Patient #1's discharge. The medical record lacked documentation that Surgeon Staff F notified the patient during her hospitalization that she was cancer-free or that he had removed her appendix during the surgery. The medical record continued to indicate that Patient #1 had a primary neuroendocrine tumor to the date of this review 7/25/16 even though the patient did not ever have cancer.

- Patient admission packet reviewed on 8/3/16 in section titled "Patient Rights and Responsibilities" read in part: To receive complete and current information about your diagnosis, treatment and prognosis in terms you can understand.

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The Hospital reported a census of 605 inpatients. Based on observation, medical record review, and staff interview the Hospital failed to protect and secure confidential patient information in one of eleven laboratories (cytopathology lab) located on the main hospital campus. The failure of the Hospital to protect patient information has the potential to expose medical and personal information to unauthorized individuals.

Findings Include:

- Tour of the Hospital on 8/2/2016 at 3:45 PM in the cytopathology lab revealed current documentation called "Intra-departmental consultation form" also known as a "pink slip" , used for internal quality assurance purposes containing patient identification information that are stored in a binder on the top shelf of an open bookshelf. Additional documentation used for internal quality assurance purposes containing patients' identifying information were observed bound together lying on an open work surface in the cytotechnologist area. Neither room is locked during Hospital business hours. Both rooms can be unoccupied at any given time.

Physician Staff G, Physician Staff H, Physician Staff I, and Cytotechnologist Staff J interviewed on 7/27/2016 revealed a document called "Intra-departmental consultation form" used internally for quality assurance purposes is assigned to cytopathology specimens in the cytology lab and accompanies the specimen through the review process by cytopathology. The hospital staff agreed this document contains patients' identifying information. The completed document is kept in a binder on an open shelf in the cytology lab and is accessible for review at any time by any staff working in the lab.

Policy titled "Rules and Regulations of the Medical Staff " reviewed on 8/2/2016 at 4:45 PM revealed "...All Medical Records, the information contained therein, and any other patient-specific information shall be treated in accordance with all applicable legal and ethical rules related to the confidentiality of patient medical information and shall be released only in accordance with the Hospital's Policies and Procedures governing medical records ..."

Policy titled "Confidentiality, Security, and Integrity of Data" reviewed on 8/3/2016 at 10:00 AM revealed "...Access to individual health information will be granted at the minimum necessary level to insure confidentiality without compromising patient care delivery ...Every user of the Hospital systems must sign the Confidentiality Agreement/Signature Attestation ...Breach of confidentiality, unauthorized disclosure, or breach of Hospital policy regarding system use will result in disciplinary action ..."

Based on staff interview, document, and policy review the Hospital failed to ensure the physician appointed as Pathology Chairman met the special qualifications required for Privileges in Cytopathology (diagnosis of human disease by means of the study of cells obtained from body secretions and fluids, by scraping, washing, or sponging the surface of a lesion, or by the aspiration of a tumor mass or body organ with a fine needle including interpretation of Papanicolaou smears of cells from the female reproductive system) by failing to ensure she had completed an accredited residency in anatomic pathology or anatomic/clinical pathology and American Board of

Pathology Boards added certification or met eligibility for added certification in Cytopathology within 6 months of start date (refer to A-0341).

This deficient practice had the potential to allow members of the medical staff the opportunity to provide services they are not qualified for with the potential to cause harm to all patients treated within the hospital.

Based on record review, staff interview, and policy review the Hospital failed to ensure each applicant's suitability for their approved clinical privileges by failing to ensure special qualifications were met for the privileges requested on their application form for 1 of 16 credentialing files reviewed (Pathologist Staff G).

This deficient practice had the potential to allow members of the medical staff the opportunity to provide services they are unqualified for with the potential to cause harm to all patients treated within the hospital.

Findings Include:

- Pathologist Staff G's application for privileges dated 3-24-15 reviewed on 7/28/2016 at 2:30 PM revealed a request for Clinical Pathology Core Privileges, Anatomic Pathology Core Privileges, and Cytopathology (diagnosis of human disease by means of the study of cells obtained from body secretions and fluids, by scraping, washing, or sponging the surface of a lesion, or by the aspiration of a tumor mass or body organ with a fine needle including interpretation of Papanicolaou smears of cells from the female reproductive system). The special qualifications for Cytopathology included "...Criteria: in addition to completion of an accredited residency in anatomic pathology or anatomic/clinical pathology and ABP boards added certification or eligibility for added certification in cytopathology within 6 months of start date ...". Staff G's application revealed they were not board certified in cytopathology.

- A form titled "Criteria-Based Core Privileges: Pathology" completed by Pathologist Staff G on 3/24/16 requested Clinical Pathology Core Privileges and Anatomic Pathology Core Privileges. In addition, Staff G applied for the Special Non-Core Privilege of Cytopathology. Section titled "Recommendation of Clinical Service Chief" signed and dated on 3/31/16 lacked a recommendation of the privileges requested in that there was no indication of what privileges if any he recommended. The form show that the privileges were approved by the Credentials Committee Chair on 5/11/2015, Executive Committee of the Medical Staff Chair on 5/28/2015, and The Board of Directors Representative on 6/9/2015 even though the applicant was not board certified in Cytopathology.

- A form titled "Recommendation and Actions on Appointment and Delineation of Clinical Privileges Initial Appointment/Additional Privilege Request" revealed the Signature of the Clinical Services Chief dated 5/6/15 with the answer "Yes" to the question "There is adequate documentation in the practitioner's credentials file that the practitioner meets all department/service criteria/standards for privileges requested."... D) Privileges: I (Clinical Service Chief) have reviewed the requested clinical privileges and supporting documentation and make the following recommendations(s): Recommend all requested privileges. The Clinical Service Chief recommended all requested privileges for Pathologist Staff G even though their was no documentation in her application showing she met the special qualifications/criteria for clinical privileges in Cytopathology.

- Pathologist Staff G was Recommended for Medical Staff Status as Pathology Chairman with privileges in Anatomic pathology, Clinical pathology, and Cytopathology by the Chief of Clinical Services on 3/31/2015 (5/6/15), Credentials Committee Chair on 5/11/2015, Executive Committee of the Medical Staff Chair on 5/28/2015, and The Board of Directors Representative on 6/9/2015 even though the applicant was not board certified in Cytopathology.

Pathologist Staff N interviewed on 7/28/2016 at 12:00 PM indicated there had been a change in the criteria required to be granted privileges in cytopathology to allow Pathologist Staff G to be able to "sign out" (diagnose) cytopathology cases. The change occurred after Staff G was appointed and granted privileges. Staff N revealed Staff G developed the new criteria herself and presented it at the Credentials Committee meeting on 7/13/2015. The revision was discussed and approved in the Executive Committee of the Medical Staff Meeting on 7/23/2015. The new application form listed the Special Qualifications for Cytopathology to include "...in lieu of added certification in cytopathology, experience as a practicing cytopathologist for at least 10 years in an academic medical center in the US, along with participation in cytopathology specific continuing medical education and teaching cytopathology in an academic medical center ...". Staff N revealed they had previously applied for privileges in Cytopathology and had similar experience as Staff G but were denied because they were not board certified in Cytopathology.

Pathologist Staff L in an email received on 8/2/2016 at 4:13 PM revealed Pathologist Staff G had signed out (diagnosed) 13 cytopathology cases between July 21, 2015 and July 23, 2015 before the criteria change went into effect. Staff L indicated they had two previous hires with similar background that did not have board certification in Cytopathology and they were not allowed to become privileged in Cytopathology. Staff L reported Staff G indicated s/he could modify the criteria to reflect that a person did not have to have the board certification if they had so many years of experience.

Pathologist Staff L interviewed on 8/4/2016 at 12:00 PM confirmed that Pathologist Staff G would not be eligible for board certification in cytopathology at this point. Staff L indicated there is a 4-year residency program for pathology, a 1-year fellowship in Cytopathology and then an exam must be successfully completed. Pathologist Staff G never did a Cytopathology fellowship and that is required for current certification, so again she would not be eligible for the board certification within six months as specified by their privileges application.

- Credentialing Procedures of the Medical Staff reviewed on 8/3/2016 directed "...In connection with all applications affecting Medical Staff membership or clinical privileges, the applicant shall have the burden of producing information for an adequate evaluation of the applicant's qualifications and suitability for the clinical privileges and Medical Staff category requested, resolving any reasonable doubts about such matters, updating any information used during the application process in a timely fashion, and satisfying reasonable requests for additional information about the applicants suitability for the clinical privileges and Medical Staff category requested. The applicant's failure to sustain this burden shall be grounds for denial of the application ..."

The Hospital reported a census of 605 inpatients. Based on observation, medical record review, and staff interview the Hospital failed to protect and secure confidential patient information in one of 11 laboratories located on the main hospital campus (cytopathology lab). The failure of the Hospital to protect patient information has the potential to expose medical and personal information to unauthorized individuals.

Findings Include:

- Tour of the Hospital on 8/2/2016 at 3:45 PM in the cytopathology lab revealed current documentation called "Intra-departmental consultation form", used for internal quality assurance purposes containing patient identification information that are stored in a binder on the top shelf of an open bookshelf. Additional documentation used for internal quality assurance purposes containing patient identifying information were observed bound together lying on an open work surface in the cytotechnologist area. Neither room is locked during Hospital business hours. Bot

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SURVEY INFORMATION

Event ID	Start Date	Exit Date	Team Members	Staff ID
4I8D11	07/25/16	08/04/16		

(b)(6)(b)(7)(c)

Intakes Investigated: KS00102745(Received: 07/05/2016)

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SUMMARY OF CITATIONS:

Event ID	Exit Date	Tag
4I8D11	08/04/2016	

Federal - Link to This Intake

A0469-CONTENT OF RECORD: FINAL DIAGNOSIS
A0043-GOVERNING BODY
A0441-PROTECTING PATIENT RECORDS
A0049-MEDICAL STAFF - ACCOUNTABILITY
A0951-OPERATING ROOM POLICIES
A0115-PATIENT RIGHTS
A0450-MEDICAL RECORD SERVICES
A0131-PATIENT RIGHTS: INFORMED CONSENT
A0749-INFECTION CONTROL PROGRAM
A0147-PATIENT RIGHTS: CONFIDENTIALITY OF RECORDS
A0468-CONTENT OF RECORD: DISCHARGE SUMMARY
A0338-MEDICAL STAFF
A0341-MEDICAL STAFF CREDENTIALING

Federal - Not Related to any Intakes

A0000-INITIAL COMMENTS

4I8D12	10/27/2016	

Federal - Link to This Intake

A0043-GOVERNING BODY
A0049-MEDICAL STAFF - ACCOUNTABILITY
A0115-PATIENT RIGHTS
A0131-PATIENT RIGHTS: INFORMED CONSENT
A0147-PATIENT RIGHTS: CONFIDENTIALITY OF RECORDS
A0338-MEDICAL STAFF
A0341-MEDICAL STAFF CREDENTIALING
A0441-PROTECTING PATIENT RECORDS
A0450-MEDICAL RECORD SERVICES
A0468-CONTENT OF RECORD: DISCHARGE SUMMARY
A0469-CONTENT OF RECORD: FINAL DIAGNOSIS
A0749-INFECTION CONTROL PROGRAM
A0951-OPERATING ROOM POLICIES

Federal - Not Related to any Intakes

A0000-INITIAL COMMENTS

EMTALA INFORMATION - No Data

DEEMED/RO APPROVAL INFORMATION - No Data

RO Approval Date: 07/05/2016

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ACTIVITIES

Type	Assigned	Due	Completed	Responsible Staff Member
Schedule Onsite Visit	07/25/2016	07/25/2016	08/04/2016	

(b)(6)(b)(7)(c)

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INVESTIGATIVE NOTES

ENTRANCE:

An unannounced visit for a complaint investigation regarding the Infection Control Condition of Participation was made on 7/25/2016 at 11:00 AM at University of Kansas Hospital at 3901 Rainbow Boulevard in Kansas City, KS. (b)(6)(b)(7)(c)

(b)(6)(b)(7)(c) was present at entrance. The purpose of the visit was explained. A brief explanation of the visit process and our efforts to maintain a dialog through-out the revisit process took place during entrance.

EXIT:

The exit conference was conducted on 8/4/2016 at 1:00pm. Those present were (b)(6)(b)(7)(c)

(b)(6)(b)(7)(c) Communication with the hospital staff was maintained and opportunities were given to provide information. A Voluntary Survey Comment sheet was presented at that time.

E-MAIL ADDRESS:

(b)(6)(b)(7)(c)

SUMMARY OF FINDINGS:

Review of 13 sampled medical records revealed appropriate nursing care.

The complaint was substantiated for Patient Rights with citations written at A-0146, Medical Staff with a citation written at A-0341, and Medical Records with citations written at A-0441, A-0450, A-0468, and A-0469, and Surgical Services with a citation written at A-0951. An unrelated deficiency was written for Infection Control at A-0749.

- (b)(6)(b)(7)(c) KU Hospital veteran, claims the head of his department misdiagnosed a patient with cancer and then covered up the mistake. (b)(6)(b)(7)(c) reported the hospital refused to rectify the error and retaliated against him after he called the matter to the attention of the Joint Commission, which accredits and certifies hospitals. "The form of cancer that was erroneously diagnosed within the patient is commonly known as potentially lethal; and the patient who was misdiagnosed has lived with this unwarranted fear, "
According to KCUR, the lawsuit does not name the pathology department's chair, but (b)(6)(b)(7)(c) told the radio station in an interview that the current chair, (b)(6)(b)(7)(c) made the misdiagnosis and then covered it up.
(http://www.bizjournals.com/kansascity/news/2016/07/05/ku-hospital-misdiagnosis-coverup-lawsuit.html)

- Wendy Ann Noon-Berner, patient named in the complaint, was admitted to the hospital on 9/1/2015 for an extended whipple (pancreaticoduodenectomy(a surgical procedure to remove the pancreas)) related to the patients previous diagnosis of a neuroendocrine tumor of the pancreas. The medical record revealed the patient signed informed consent documents. The patient received nursing care as ordered, monitoring of pain and medications as ordered, vital sign monitoring, and education including discharge instructions. Occupational and Physical Therapy evaluations conducted and discontinued appropriately. Nutritional assessment complete and patient advanced from a Clear diet to a Regular diet and educated to increase protein intake and eat 4-6 small meals per day prior to discharge.

The History and Physical documented by (b)(6)(b)(7)(c) , the physician preforming the surgical procedure, stated, " After the mass in the pancreas was found, she was then scheduled for endoscopic ultrasound, which identified 2 additional masses. These were biopsied and were found to be neuroendocrine in nature " .

8/6/2015 (b)(6)(b)(7)(c) documented receiving information from (b)(6)(b)(7)(c) indicating the patient ' s FNA (Fine Needle Aspiration) (a procedure where a thin needle is inserted into an area of abnormal-appearing tissue or body fluid and a sample removed for testing) of the lesion within the pancreas is positive for neuroendocrine tumor and (b)(6)(b)(7)(c) conveyed the results to the patient along with a referral to (b)(6)(b)(7)(c)

Pathology report signed on 8/6/2015 by (b)(6)(b)(7)(c) and reviewed on 7/25/2016 at 4:35 PM revealed:
Cytology # 15-1315
Pancreatic neuroendocrin neoplasm
(b)(6)(b)(7)(c) agrees with the above diagnosis is documented in the comments section of the document.
Cytology # 15-1316
Pathology report signed on 8/6/2015 by (b)(6)(b)(7)(c) and reviewed on 7/25/2016 at 4:45 PM revealed:
a diagnosis of Pancreatic neuroendcrine tumor
(b)(6)(b)(7)(c) agrees with the above diagnosis is documented in the comments section of the document.

Cytology # 15-1317
Pathology report signed on 8/6/2015 by (b)(6)(b)(7)(c) and reviewed on 7/25/2016 at 4:45 PM revealed:
diagnosis is Rare atypical cells present.
Documentation indicates (b)(6)(b)(7)(c) agreed with the findings in 2 of the 3 Cytology reports (# ' s 15-1315 and 15-1316), but fails to contain (b)(6)(b)(7)(c) signature on one of the two intradepartmental (pink slip) documents required when there is a finding of a new cancer. Only one pink slip was provided by the facility a second one could not be located.

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Abdominal MRI report dated 8/27/2015 reviewed on 7/25/2016 at 8:45 PM revealed the clinical indication for the MRI test was conducted because the patient was (b)(6)(b)(7)(c) year-old female with a neuroendocrine tumor of the pancreas and malignant carcinoid tumor of other sites. The clinical impression signed by (b)(6)(b)(7)(c) MD on 8/27/2015 indicated there were "TWO SMALL PANCREATIC BODY LESIONS WHICH WOULD BE CONSISTENT WITH KNOWN PANCREATIC NEUROENDOCRINE TUMORS. "

The medical record revealed the Post-Surgical Pathology report as follows:

Surgical Pathology 9/1/15: Hilar lymph node #1: There is no evidence of tumor (0/1).
Appendix: Negative for tumor in the entirely submitted specimen.
Pancreas: Localized chronic pancreatitis. Negative for tumor in the entirely submitted specimen.
Lymph nodes: Negative for tumor (0/3).
Hilar lymph node #2: There is no evidence of tumor (0/1).
Gallbladder: No diagnostic abnormalities.
Whipple contents: Pancreas: Multiple foci of chronic pancreatitis. Negative for tumor in the entirely submitted pancreatic

Pathology Consultation report placed in the patients ' medical record revealed:
After Visit Summary provided to the patient at discharge indicated the patients diagnosis was a primary pancreatic neuroendocrine tumor. The patient was given a copy prior to discharge on 9/9/2015.

The following addendum was placed on the cytology report.
Procedures/Addenda
Addend um Date Ordered: 9/18/2015 Status: Signed Out
Date Complete: 9/18/2015
By: (b)(6)(b)(7)(c)
Date Reported: 9/18/2015
Addendum Diagnosis
See comment.
Addendum Comment
This addendum is done for reporting Cytology-Surgical Pathology
correlation. The surgical specimen (S15-22266) was reported as chronic and multifocal pancreatitis. The pancreatitis shows reduced acinar cell component and prominent nests of neuroendocrine cells-islet cells. The FNA cytology correlates with the surgical specimen. (b)(6)(b)(7)(c) was notified of this on 9/4/15 and 9/8/15.
(b)(6)(b)(7)(c)

The patient presented to the emergency room on 9/27/2015. The medical record's History and Physical revealed the patient had an " h/o (history of) pancreatic neuroendocrine tumor s/p Whipple procedure on 9/1/15 " and she presented to the ED with fever, nausea, and vomiting. (b)(6)(b)(7)(c) documented the final diagnosis as " H/O malignant neuroendocrine tumor (Primary) and Sepsis, due to unspecified organism.

After Visit Summary provided to the patient at discharge indicated the patients diagnosis was a primary pancreatic neuroendocrine tumor. The patient was given a copy prior to discharge on 9/30/2015.
Discharge Signs and symptoms documented on 9/30/2016 revealed a diagnosis of a history malignant neuroendocrine tumor [V10.91 (ICD-9-CM)] in the patient's medical record.
4/5/2016 the patient was admitted for a ventral hernia (located in the abdomen and occurs when an organ pushes through the muscle or tissue that holds it in place). The medical record revealed the patient's medical history includes "a history of neuroendocrine tumor of the pancreas".

The medical record consistently revealed documentation as current as of 4/5/2016 indicating the patient had a diagnosis that included a history of a neuroendocrine tumor.

- Cytopathology Internal-Quality Assurance Report also known as " pink slips " reviewed on 7/26/2016 at 3:30 PM revealed specimen # 15-1316 containing an initial diagnosis of malignancies (illegible documentation with a line through) and a diagnosis signed by (b)(6)(b)(7)(c) on 8/5/2015 indicating a diagnosis of Pancreatic Neuroendocrine Tumor.

- Laboratory Quality Management Committee Meeting Minutes dated 1/22/2016 revealed item #4 for discussion was a " correlation of FNA Cytology Cases with Histological Follow-up: The committee discussed the correlation " and was listed under the " Thresholds Met " section.

- Laboratory Quality Management Committee Meeting Minutes dated 2/18/2016 revealed there was a follow up discussion related to the Committees 1/22/2016 meeting indicating there was Discordance by (b)(6)(b)(7)(c) opting the processes related to 2nd opinion, notification, reporting and evaluation have been appropriately followed.

Timeline of Events provided by (b)(6)(b)(7)(c)
08/04/2015 Patient underwent a fine needle aspirate of the pancreas body lesion
08/06/2015 FNA results read as neuroendocrine tumor by two pathologists
09/01/2015 Patient underwent a Whipple and Subtotal Pancreatectomy
09/04/2015 Final surgical pathology results indicate a neuroendocrine tumor was not found
09/04/2015 Surgeon notified of diagnostic discordance
09/08/2015 Conversation between surgeon and reading FNA pathologist. Surgeon informed reading pathologist that he still planned to remove the pancreas

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due to the patient's clinical condition
09/08/2015 Patient notified that final surgical pathology results showed no cancer
09/11/2015 Request from (b)(6)(b)(7)(c) to conduct an investigation re: "a pathology report that was misread and resulted in the removal of a pancreas resulting in the patient needing to be on insulin forever."
Note: The entire pancreas was not removed. The patient is not insulin dependent.
4/8/2016 Complaint received from Joint Commission Investigation re: pathology discrepancy and a patient believing she had cancer.
07/07/2016 Complaint received from College of American Pathologists re: pathologists' competency and quality management practices in pathology
7/25/2016 KDHE arrival on behalf of CMS for complaint re: newspaper article. Survey under laboratory services, surgical services, and medical record conditions of participation

Patient Interview:
Three attempts were made to contact the patient to gain additional information. After the first phone call to the patient was made she indicated she needed to speak to her lawyer before speaking to anyone about her care at the hospital. The patient stated she would call back. The patient did not call so two additional attempts were made with no answer and no return phone call as of 8/4/2016 at 12:30 PM.

Wendy Noon- Berner Interviewed 8/8/2016 at 12:00 PM via phone with Lawyer on the line.
Heath history started back in February 2015 I was experiencing some light chest pains so I went to see my doctor and was able to see the treating nurse in the office. They did an echocardiogram at the office and ordered some blood work and referred me to a cardiologist. The electrocardiogram was normal. I the saw a the cardiologist at Shawnee Mission Medical Center and had a calcium cardiac score (a non-invasive CT scan of the heart. It will calculate your risk of developing Coronary Artery Disease (CAD) by measuring the amount of calcified plaque in the coronary arteries.) everything on that was fine. I then thought the pain might be my breast so I had a mammogram done at Shawnee Mission Medical Center and that was fine. In June 2015 I still wasn ' t feeling well I was having abdominal pain so I saw my doctor, she then told me to let her know if the pain continued, which it did. I had a abdominal ultrasound which showed I had a 1.7cm mass on the pancreas and a CT results showed that I had a 2cm lesion at Shawnee Mission Medical Center. I was then referred to a gastrointestinal specialist in July to have my gallbladder check, it was good, normal. On July 21st I had an upper endoscopy that looked at a polyp that they retrieved which ended up being normal. I had ulcers and there was no signs of bleeding, in my duodenum there was nothing seen. I was referred to KU Medical Center in August for an upper GI to look at the pancreas. At that time they found 3 lesions on the pancreas. They told me I needed to have those removed and have surgery. From then I was referred to (b)(6)(b)(7)(c) and I seen him on August 20th 2015. He drew a picture out of the Whipple surgery I was going to have and where the tumors were. Then they were going to take out 6 " of where the tumors were a portion of the stomach, the duodenum, part of the pancreas to remove those tumors and the gallbladder to prevent gallstones in the future. I had blood work done then also. The surgery was scheduled for August 31st and (b)(6)(b)(7)(c) ordered an MRI on August 27th 2015 and my scheduled surgery was cancelled due to the doctor having an emergency. It was then rescheduled for September 1st 2015 and I was in the hospital until September 9th 2015. I had a follow up visit on September 17th 2015 and that ' s when he told me " good news, no cancer " . I then was very sick I was having trouble with vomiting, trouble with my bowels, and had a temperature. (b)(6)(b)(7)(c) office told me to go to the emergency room. I had an infection and was in the hospital from September 27th- 30th 2015. I was still having trouble with my bowels after discharge and had a follow up appointment with (b)(6)(b)(7)(c) on October 8th 2015 and he said I could start seeing my regular doctor. I did call him on November 13th because my bowels were greyish yellow and had a foul smell. I was having trouble with my food and they put me on Creaon (an enzyme) and since then I have had blood work and have seen my family doctor. In March of 2016 I went in to see my family doctor because I was having some abdominal pain. I was told I has a hernia and was referred to (b)(6)(b)(7)(c) On March 31st 2016 I went to see (b)(6)(b)(7)(c) he told me I had an incisional hernia and that it would continue to get bigger unless I had surgery. Surgery was scheduled for April 6th 2016 it was an outpatient surgery. I did see (b)(6)(b)(7)(c) for follow up and I had a weakness and a deep achiness in my bones so he had me take a bone density test which showed mild osteopenia and he referred me to an endocrinologist. I have a consult in October, but was able to get an appoint for 8/11/2016 and not at KU Medical Center.

No one had ever explained that any of the tests that I had done were less than accurate. I was never told what the rate was of diagnosis that might result as malignant but might not be malignant.

- During that emergency visit in July when I went in for blood work the doctor came in and said " oh I heard about you, you had an extended Whipple procedure and had your appendix taken out " I said wow that ' s funny I didn ' t know and he said " yeah you did " . When I was at my follow up appointment with (b)(6)(b)(7)(c) I asked him about it and he said " oh, I must have forgotten to tell you, I had to take that out because they form the same tumors that your pancreas had " I said well did you take my spleen and he said " no " . At that point I didn ' t know what was taken I was quite shocked about that.

At none of my follow up visits, no one ever said there might have been a misread, misdiagnosis, or an error. They did say on 9/17/2016 (b)(6)(b)(7)(c) walked in and said " good news, no cancer. It was pancreatitis " . That was the only thing and the first I had heard about pancreatitis with me. Nothing was ever said about the test or a misdiagnosis. It was almost a casual remark.

I spoke with someone at one of my clinic visits in April. She came in while I was in my follow up visit and (b)(6)(b)(7)(c) talked to me about my knee. I thought she was in there to see how I was doing. And my sister told me no that ' s not why she is here. My sister said she is here to ask how your visit was. So my sister explained about my hernia outpatient surgery. My sister told her about the nurses and how they were trying to send me home too fast. The nurse said it was time for me to go. I was out of it so she spoke with my sister. I also was asking about what happened to my knee, there was a big bruise on it and it hurt. (b)(6)(b)(7)(c) (b)(6)(b)(7)(c) said that the nurses weren ' t part of his team and I never heard back from his office about what happened. I don ' t recall telling that woman that " they thought I had cancer, but I don ' t " .

I knew nothing about the test being inacurrate until I got a call out of the blue from (b)(6)(b)(7)(c) asking me to sign an affidavit and telling me about the test and a disagreement. I told him to send it over and I read it. I had questions about it because he wanted me to say that I was told in the hospital that I didn ' t have cancer and that it was pancreatitis. I didn ' t say anything to him, but I knew the date that I was told I didn ' t have cancer and that it was pancreatitis. " you remember that date " and so that was 9/17/2015 there was also a statement that in the MRI there were 2 small lesions in the pancreas that was consistent with the endoscopic ultrasound but in that test there 3 lesions so that just made me curious because it just didn ' t seem right to me. The affidavit didn ' t even have who wrote it, I didn ' t even know it was (b)(6)(b)(7)(c) wrote this up or a lawyer.

Wendy and her lawyer agreed to share a copy of the affidavit sent to her by KU Medical Center.

My current condition is that I still have problems with my bowels. I eat and the within 15-20 minutes I have to go to the bathroom multiple times a day. The endocrinologist that I am scheduled to see asked me if I was on Creaon during a phone conversation and explained to me about it. I didn ' t know any of the

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information about the medication that he gave me. I didn ' t know I could take more than one pill per meal. He told me that I could take as many as I needed to get my bowels back to normal like they were before the surgery (b)(6)(b)(7)(c) never explained in any of the appointments. I asked him about the medication because of my bowel problems and I said " so I just take these, one per meal or one every time I eat " and he said yes. I wish there had been more information. It was over a year after the surgery that I finally found out how Creaon works and it wasn ' t from (b)(6)(b)(7)(c) I didn ' t even know that there was a possibility that I would have to be on a pancreatic enzyme prior to the surgery.

I don ' t think that I was fully informed after surgery or during my follow up visits about important information.

On the discharge paper work it says on the nutrition section that there are no dietary restrictions and to continue with a healthy diet. I was given a brochure for Whipple procedures at some point but I don ' t remember when and there are things in here like potential diabetes that was never discussed with me prior to surgery. I wish I would have had more information than I did.

STAFF INTERVIEWEES:

(b)(6)(b)(7)(c)

INTERVIEWS:

- (b)(6)(b)(7)(c) RM interviewed on 7/25/2016 at 11:30 AM revealed the patient involved in the incident reported in the newspaper is Wendy Ann Noon-Berner and an electronic copy of the medical record was provided for review.

- (b)(6)(b)(7)(c), RM interviewed on 7/25/2016 at 4:02 PM indicated a peer review for (b)(6)(b)(7)(c) has been sent out to the QIO and is currently not complete and therefor unavailable for review during this survey. (b)(6)(b)(7)(c) also revealed the patient ' s medical record had not been updated to reveal the patient did not have a diagnosis or history of a neuroendocrine tumor. (b)(6)(b)(7)(c) reported there is supposed to be a disclosure statement located in the medical record however this statement was not observed in the copy of the patient ' s medical record provided by the hospital. (b)(6)(b)(7)(c) revealed the incident was reviewed by the Pathology Departments Quality Program and the results did not support reporting the incident to the Kansas Department of Health and Environment ' s (b)(6)(b)(7)(c) revealed (b)(6)(b)(7)(c) was the (b)(6)(b)(7)(c) at the time of the incident and is unable to share details of the investigation that are protected within the Risk Program.

- (b)(6)(b)(7)(c) RM interviewed on 7/26/2016 at 9:40 AM indicated the pathology report # ' s 15-1315 and 15-1316 stating that (b)(6)(b)(7)(c) agreed with (b)(6)(b)(7)(c) findings is a dictation only and does not contain (b)(6)(b)(7)(c) signature. (b)(6)(b)(7)(c) revealed there is a pink slip of paper given to the pathologist verifying the findings of another pathologist. After they review the sample, they sign the pink paper for each sample received and reviewed. (b)(6)(b)(7)(c) revealed there was a conversation between (b)(6)(b)(7)(c) and the patient and notes taken by (b)(6)(b)(7)(c) will be provided.

(b)(6)(b)(7)(c) complainant, interviewed on 7/26/2016 between 10:00 AM-11:05AM

(b)(6)(b)(7)(c) Pathology Department (complainant)

The cytopathologist (unnamed) told me that they were concerned there was a misdiagnosis that was read by the chairwoman. ((b)(6)(b)(7)(c) (b)(6)(b)(7)(c) stated fear and intimidation was felt by her so she came to me.

The (b)(6)(b)(7)(c) likes her. (b)(6)(b)(7)(c) one of the faculty was told by the dean that if anyone opposes the chair they will be fired. These are staff in the beginning of their careers and they are afraid of what the hospital/university can do to them.

There was an FNA read by the chair. (b)(6)(b)(7)(c) all 3 sample sets were called enp (tumor) a surgical procedure was performed and they did a resection. The surgical pathologist did not find a tumor, there were 3 trays and up to 60 slides, it was essentially normal pancreas.

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All 5 people reread the sample and said there was no cancer. The pathologist that reviewed it agreed with (b)(6)(b)(7)(c) indicated that (b)(6)(b)(7)(c) never had seen the final pathology report.

(b)(6)(b)(7)(c) claims it was the chair who added their names to (the pathology report) it was not the fellow or the verifying pathologist.

(b)(6)(b)(7)(c) was not boarded in cytopathology. She changed the rules so that she would not have to be boarded to sign out cases in cytology. (Opinion: she wanted to do this because pap smears are easy to read)

(b)(6)(b)(7)(c) would sign out something and ask another pathologists their opinion and then she would change it (what she had written) and then still get it wrong.

(b)(6)(b)(7)(c) is no longer able to sign out cases with residents. There is a file, I think the dean has it (the DIO (b)(6)(b)(7)(c) also has a copy of the file and they indicated that they feel she should not be signing out cases with residents.)---- This documentation was not provided by (b)(6)(b)(7)(c)

I went to the hospital in September and talked to the CMO and told him we have a problem with a patient that was diagnosed with cancer of the pancreas, it was removed.

The fellow would not argue with (b)(6)(b)(7)(c) due to intimidation. Therefore, I told both (b)(6)(b)(7)(c) and (b)(6)(b)(7)(c) that there is a major problem and they said there is not a problem, I told them there was a toxic environment and they refused to investigate. They said she (the patient) feels good and everything is fine. They stated the diagnosis is correct. They refused to talk to any of the other cytopathologists. Nothing could be done. We told the chief of staff, the dean, senior vp, vice chancellor- none would not return emails or calls.

In the Quality meeting it came up there were 3 FNA's that were incorrect after the surgical specimen was sample. We discussed doing a root cause analysis. All notes were removed from the quality meeting minutes. The secretary at the time, (b)(6)(b)(7)(c) was told to redact everything at the order of the person that was being accused of wrong doing (b)(6)(b)(7)(c) She asked the cytopathology supervisor to remove them (the notes and determination that it was a major discrepancy) and make it minor discrepancy, but she refused.

At another meeting, she (b)(6)(b)(7)(c) said it was determined by the hospital to be a nonissue and she decided not to investigate herself. I reported to the Joint Commission as a sentinel event. They will not investigate a specific event.

It was officially reviewed by the Cytology department and was identified as a misdiagnosis- she (b)(6)(b)(7)(c) admitted it was a misdiagnosis 8 months later and still does not change the diagnosis in the computer and had not informed the physician.

(b)(6)(b)(7)(c) said that she (the patient) has been told that she does not have cancer.

The surgeon is excellent but he still took out a perfectly normal pancreas.

The surgeon said it was hard and needed to come out, but did it really need to come out?

(b)(6)(b)(7)(c) was in the meeting with Joint Commission and allowed to grill me. His argument that I was on the credentialing of (b)(6)(b)(7)(c) but historically they (providers applying for privileges) prove themselves once they are here not before they start.

(b)(6)(b)(7)(c) reported that (b)(6)(b)(7)(c) was never interviewed (sec. told to delete QAPI notes)-(Surveyor note: this person is no longer employed by the hospital and contact information is not available)

(b)(6)(b)(7)(c) indicated that (b)(6)(b)(7)(c) talked to (b)(6)(b)(7)(c)) and was told that he was hearing all of the problems within the pathology department and said that I even considered reigning if they would remove (b)(6)(b)(7)(c) but since they didn ' t do it, I wouldn ' t leave. Then they started telling me that he wanted me to resign telling me I was disruptive. I got a lawyer and asked him what I should do and I was told to take out a whistleblower lawsuit.

I was told that they (the fellows and other cytologists) went to the dean and they were told to sign a letter said that they had no confidence in (b)(6)(b)(7)(c) but when they asked if there would be any retribution the dean told them he couldn ' t guarantee that and there might be.

(b)(6)(b)(7)(c) told me about the case originally. (b)(6)(b)(7)(c) they came to me because they were scared. They asked me if I could get this to the right people. We met with Norman before it escalated. He said there was a 90% chance that she going to go. They told him of the bullying and he said he would look into it. When they found out that this case involved this wonderful surgeon they decided to cover it up.

In (b)(6)(b)(7)(c) opinion, (b)(6)(b)(7)(c) wasn ' t to blame.

The faculty and the staff are so afraid of her (b)(6)(b)(7)(c) that they don ' t investigate complaints.

We (the pathologists) were a tight group.

(b)(6)(b)(7)(c) did an addendum instead of an amendment to say that the final diagnosis and the initial diagnosis matched. She has never amended it. I am only aware of what is in the patients chart by what the cytopathologists and (b)(6)(b)(7)(c) have told me. They have given me this information they have access to the pathology computer without accessing the main hospital computer.

I do not know any information that is in the patient ' s record. I do not even know the patients name or outcome. All information I have is second hand information. We call it Pathologygate! there is no secret of what is going on.

There is another case where a clinician came to me and said " I have one case that doesn ' t make sense. The cells are called rare atypical cells " the clinician said, " This patient thinks he has cancer. " I checked into it and had (b)(6)(b)(7)(c) look at it and the sample was normal. I gave her (b)(6)(b)(7)(c) the name of

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this other patient. I was directly involved because I looked up the results for the clinician (the patients name was not provided by (b)(6)(b)(7)(c) I also sign out samples as a clinical pathologist. I was the medical director and the chair at one time and so many people have always come to me.

(b)(6)(b)(7)(c) Pathologist named in the complaint 9:00 AM interview:

This case came up about 2 weeks after I started signing out cytology cases.

After Showing (b)(6)(b)(7)(c) the pink slip she indicated the other handwriting on the top section is (b)(6)(b)(7)(c) (I can ' t remember her last name) she was a fellow. The other handwriting at the top corner says neuroendocrine neoplasm and is my handwriting-this is the form for assentation. I am unable to answer if it is the labs regular practice to have a separate form for each sample provided or just one.
Since this was detected, the Friday before last Labor Day 9/4/2015, (I think) I was notified by a pathologist that told me, I looked at the FNA and we see pancreatitis and not neuroendocrine tumor. At that point, I realized there was a misinterpretation and I immediately notified the surgeon (b)(6)(b)(7)(c) He was out of town and told him there was discordance between the surgical findings and the FNA.

I also found him Monday morning and I spoke with him. I volunteered to speak with the patient. He told me that would not be necessary. (b)(6)(b)(7)(c) said I was doing the surgery, I physically examined the organ and I feared there was worse condition and irrespective of your diagnosis, I would have continued with the surgery.

I told him I would be happy to present this case (to any forum he choose), because we have to learn from our mistakes.

My understanding was that (b)(6)(b)(7)(c) would speak with the patient.

Quality meeting in February. The FNA discordance review had occurred in January and I was not in attendance. I found it important to mention to the group that we followed all the processes that should have happened. There is a large group of individuals that make up the lab in these meetings. I communicated what I thought was important and what did/didn ' t happen in the lab.
The quality review to the best of my knowledge does not identify the patients name in that setting.

I do not know how any individual would be able to gain patient information. I have been in medicine for (b)(6)(b)(7)(c) and I don ' t know how this has happened.

It depends on the scenario if there would be a second opinion. If a new diagnosis of cancer was being made you would want a second opinion. Something that doesn ' t make sense you would show someone else, we do show cases to each other. The form that comes to us there is a history and we print out the prior pathology reports and we have access to the patients record also.

(b)(6)(b)(7)(c) field is different from mine and we do not work together, he was the previous chair before me. My interactions with him would be as the chair and as the clinical service chief.
It was clear that it was misinterpretation right away, the surgical pathologist, the chief of cytopathology was notified, the (b)(6)(b)(7)(c) was notified- she conducted a review and it was a cognitive error. There was no doubt at all to what happened, it was clear what happened and I take full responsibility. I went through every step that a pathologist should have.

The fellow, who had already taken and passed her boards, said it was a carcinoma, I did not call it a carcinoma, I called it a neuroendocrine tumor.

The surgical resection is the gold standard test. The final diagnosis was pancreatitis.

FNA's take some samples out of this entire organ, the journals very well document that there are margins of errors in this type of test. When you have a large organ and you are taking some cells there is a larger possibility of potential error. At least one of the samples were not shown to (b)(6)(b)(7)(c) the one marked atypical it wouldn ' t have been required. However, the fellow initiates the form they are supposed to ensure at least two people are on it, the original pathologist, fellow, and the pathologist making the second opinion. I assumed the fellow showed both to (b)(6)(b)(7)(c) In pathology all around the country they (the pink slips) are not integrated into the medical record, we put it into the report its self in the comments section.

We follow the hospital regulations and the CAP regulations do not say that they need to be in the medical record. That may be more confusing to the clinicians by adding more paperwork.

- Arda Peterson interview:

Directory of Lab and Pathology. role responsibi

CONTACTS - No Data

AGENCY REFERRAL - No Data

LINKED COMPLAINTS - No Data

DEATH ASSOCIATED WITH THE USE OF RESTRAINTS/SECLUSION - No Data

Reason for Restraint:
Cause of Death:

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NOTICES

PROPOSED ACTIONS

Proposed Action	Proposed Date	Imposed Date	Type
Plan of Correction	09/09/2016		Federal

Closed: 11/14/2016 **Reason:** Paperwork Complete

END OF COMPLAINT INVESTIGATION INFORMATION

WebMD

Whipple Procedure

Among common cancers, pancreatic cancer has one of the poorest prognoses. Because pancreatic cancer often grows and spreads long before it causes any symptoms, only about 6% of patients are still alive five years after diagnosis.

For some pancreatic patients, however, a complex surgery known as the Whipple procedure may extend life and could be a potential cure. Those who undergo a successful Whipple procedure may have a five-year survival rate of up to 25%.

The classic Whipple procedure is named after Allen Whipple, MD, a Columbia University surgeon who was the first American to perform the operation in 1935. Also known as pancreaticoduodenectomy, the Whipple procedure involves removal of the "head" (wide part) of the pancreas next to the first part of the small intestine (duodenum). It also involves removal of the duodenum, a portion of the common bile duct, gallbladder, and sometimes part of the stomach. Afterward, surgeons reconnect the remaining intestine, bile duct, and pancreas .

Who Is a Candidate for the Whipple Procedure?

Only about 20% of pancreatic cancer patients are eligible for the Whipple procedure and other surgeries. These are usually patients whose tumors are confined to the head of the pancreas and haven't spread into any nearby major blood vessels, the liver, lungs, or abdominal cavity. Intensive testing is usually necessary to identify possible candidates for the Whipple procedure.

Some patients may be eligible for a minimally invasive (laparoscopic) Whipple procedure, which is performed through several small incisions instead of a single large incision. Compared to the classic procedure, the laparoscopic procedure may result in less blood loss, a shorter hospital stay, a quicker recovery, and fewer complications.

The Whipple procedure isn't an option for the 40% of newly diagnosed patients whose tumors have spread (metastasized) beyond the pancreas. Only rarely is it an option for the 40% of patients with locally advanced disease that has spread to adjacent areas such as the superior mesenteric vein and artery, or for those whose tumors have spread to the body or tail of the pancreas.

Who Should Perform the Whipple Procedure?

The Whipple procedure can take several hours to perform and requires great surgical skill and experience. The area around the pancreas is complex and surgeons o encounter patients who have a variation in the arrangement of blood vessels ar

Sources
SOURCES:
American Cancer Society: "Pancreatic Cancer Surgery."
Mayoclinic.org: "Pancreatic Cancer Treatment."
Pancreatica.org: "What Is the Surgical Treatment of Pancreatic Cancer?"
Beth Israel Deaconess Medical Center: "The Whipple Procedure."
Pri-med Patient Education Center: "The Whipple Procedure."
University of Southern California Department of Surgery - Center for Pancreatic and Biliary Diseases.
Hirshberg Foundation for Pancreatic Cancer Research.

After the Whipple procedure was introduced, many surgeons were reluctant to perform it because it had a high death rate. As recently as the 1970s, up to 25% of patients either died during the surgery or shortly thereafter.

Since then, improvements in diagnosis, staging, surgical techniques, anesthesia, and postoperative care have reduced the short-term death rate to less than 4% in patients whose operation is performed at cancer centers by experienced surgeons. At some major centers, the reported death rate is less than 1%. But the rate may still be above 15% in patients who are treated at small hospitals or by less experienced surgeons.

Because the Whipple procedure continues to be one of the most demanding and risky operations for surgeons and patients, the American Cancer Society says it's best to have the procedure done at a hospital that performs at least 15 to 20 pancreas surgeries per year. The organization also recommends choosing a surgeon who does many such operations.

What Are Complications of the Whipple Procedure?

Immediately after the Whipple procedure, serious complications can affect many patients. One of the most common of these include the development of false channels (fistulas) and leakage from the site of the bowel reconnection. Other possible surgical complications include:

- Infections
- Bleeding
- Trouble with the stomach emptying itself after meals

After surgery, patients are usually hospitalized for a week before returning home. Because recovery can be slow and painful, they usually need to take prescription or over-the-counter pain medications.

At first, patients can eat only small amounts of easily digestible food. They may need to take pancreatic enzymes -- either short-term or long-term -- to assist with digestion. Diarrhea is a common problem during the two or three months it usually takes for the rearranged digestive tract to fully recover.

Other possible complications include:

- Weight loss. Most patients can expect to lose weight after the surgery.
- Diabetes.This condition can develop if too many insulin-producing cells are removed from the pancreas. However, patients who have normal blood sugar before surgery are unlikely to develop diabetes , and those who recently developed diabetes before surgery are even likely to improve.

WebMD Medical Reference | Reviewed by William Blahd, MD on December 06, 2016

Sources
SOURCES:
American Cancer Society: "Pancreatic Cancer Surgery."
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Beth Israel Deaconess Medical Center: "The Whipple Procedure."
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Prognosis After the Whipple Procedure

Overall, the five-year survival rate after a Whipple procedure is about 20 to 25%. Even if the procedure successfully removes the visible tumor, it's possible that some cancer cells have already spread elsewhere in the body, where they can form new tumors and eventually cause death.

The five-year survival rate is higher in node-negative patients (their cancer has not spread to nearby lymph nodes) than for node-positive patients.

Regardless of node status, most patients receive chemotherapy, radiation, or both after surgery. However, cancer specialists have differing opinions on the best combination and the best drugs to use.

It's not yet known if therapy works better before or after surgery. But some research suggests that therapy could allow a few patients who are initially thought to be ineligible for surgery to eventually undergo the Whipple procedure. Studies are ongoing.

WebMD Medical Reference | Reviewed by William Blahd, MD on December 06, 2016

Sources
SOURCES:
American Cancer Society: "Pancreatic Cancer Surgery."
Mayoclinic.org: "Pancreatic Cancer Treatment."
Pancreatica.org: "What Is the Surgical Treatment of Pancreatic Cancer?"
Beth Israel Deaconess Medical Center: "The Whipple Procedure."
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2016 Jul 01 AM 7:47
CLERK OF THE WYANDOTTE COUNTY DISTRICT COURT
CASE NUMBER: 2016-CV-000510

IN THE DISTRICT COURT OF WYANDOTTE COUNTY, KANSAS
CIVIL COURT DIVISION

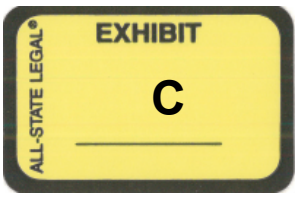
LOWELL L. TILZER M.D.,	)	
	)	
Petitioner,	)	
	)	**Case No.**
v.	)	
	)	**K.S.A. Ch 60**
UNIVERSITY OF KANSAS	)	
HOSPITAL AUTHORITY	)	
A Kansas Administrative Agency,	)	
	)	
Serve:	)	
Bob Page, Pres. and Chief Exec. Officer	)	
The University of Kansas Hospital	)	
3901 Rainbow Blvd.	)	
Kansas City, KS 66160	)	
	)	
Respondent.	)	

PETITION FOR JUDICAL REVIEW PURSUANT TO K.S.A. §§ 77-613, 77-614
AND
KANSAS WHISTLEBLOWER ACT K.S.A. § 75-2973

COMES NOW Lowell Tilzer M.D., by and through his attorneys and pursuant to K.S.A. §§ 75-2973, 77-613 and 77-614 alleges the following claim against the University of Kansas Hospital Authority as set forth below.

INTRODUCTION

Lowell L. Tilzer M.D. is a physician licensed in the State of Kansas. Tilzer is Board Certified by the American Board of Pathology in the field of Anatomic and Clinical Pathology. Tilzer is employed by University of Kansas Physicians and the University of Kansas Hospital Authority (hereinafter "KU Hospital"). Tilzer is employed in the Department Of Pathology which is jointly managed and operated by Kansas University Medical Center and KU Hospital. Tilzer evaluates human blood, body fluids and tissue samples for patients of Hospital and determines whether the patients suffer from cancer or other illnesses.



In 2015 Tilzer learned that the Chair of KUMC's/KU Hospital's Department Of Pathology misdiagnosed a patient's tissue sample by concluding that the patient had cancer. As a result of the misdiagnosis, the patient was erroneously informed that the patient had cancer, and the patient's essential body organ (or a substantial portion of the essential body organ) was removed at Hospital. The patient was not told of the misdiagnosis, and was not informed that the essential body organ was not cancerous. For months KUMC/Hospital withheld the correct diagnosis from the patient, and to the best of Tilzer's knowledge and belief the patient is still unaware that the patient did not have cancer.

When Tilzer learned of the misdiagnosis and the Respondents' failure to inform the patient, Tilzer complained to administrative authorities at KUMC and KU Hospital, and urged the physicians and administrators to rectify the errors by correcting the patient's medical errors and informing the patient. KUMC's and KU Hospital's administrators resisted Tilzer's efforts to thoroughly investigate the matter and conduct a review known as a "Root Cause Analysis"; and KUMC and KU Hospital and did not take corrective action. After KUMC and KU Hospital failed to investigate and take corrective action, Tilzer submitted a report to the Joint Commission, an outside auditing agency. As a result of Tilzer's submission of the report and his persistent requests that the records be corrected and the patient informed, Tilzer has been retaliated against and his job has been threatened in violation of K.S.A. § 75-2973.

In order to avoid disclosure of facts that might be confidential under the Health Information Portability and Accountability Act ("HIPAA") or other statutes, information regarding the patient's age, sex, race, date of surgery, and the bodily organ that was unnecessarily removed, have been omitted from this Petition.

PARTIES

1. Lowell L. Tilzer M.D. is a medical doctor and an individual residing in Johnson County, Kansas.

2. Non-party University of Kansas Medical Center ("KUMC") is a Kansas administrative agency, as defined by K.S.A. § 77-602(k) and K.S.A. § 77-502(a), with a mailing a mailing address at University of Kansas, School of Medicine, Mail Stop 2015, 3901 Rainbow Blvd., Kansas City, Kansas 66160.

3. Respondent University of Kansas Hospital Authority (hereinafter "KU Hospital") is a Kansas administrative agency organized pursuant to K.S.A. § 76-3301 *et seq*. with a mailing address at University of Kansas Hospital Authority, 3901 Rainbow Boulevard Kansas City, KS 66160-7220.

THE MISDIAGNOSIS BY THE CHAIR OF THE DEPARTMENT OF PATHOLOGY

4. The Chair of the KUMC/KU Hospital Department of Pathology is not board certified in cytopathology.

5. In 2015 the Department Chair of the KUMC/KU Hospital Department of Pathology reviewed a tissue sample from the essential body organ of a patient.

6. The KUMC/KU Hospital Chair of the Department of Pathology misdiagnosed the patient's tissue sample as cancerous.

7. As a result of the misdiagnosis by the Department Chair, the patient's essential body organ was surgically removed.

8. After the patient's essential body organ was removed, tissue samples from the patient's essential body organ were examined by other members of the KUMC/KU Hospital

Department of Pathology. The post-surgery examination of the patient's essential body organ established that the patient's essential body organ was essentially normal and was not cancerous.

9. After the post-surgery examination determined that the patient's essential body organ was not cancerous, the pre-surgery tissue sample was re-examined.

10. The post-surgery re-examination of the pre-surgery tissue sample established that the pre-surgery sample was not cancerous, and that the pre-surgery tissue sample had been misdiagnosed by the Chair of the KUMC/KU Hospital Department of Pathology. The removed essential body organ, in fact, was normal, and should not have been removed.

11. The Chair of the KUMC/KU Hospital Department of Pathology examined the patient's tissue samples after she was informed of her misdiagnosis. The Department Chair did not recognize the difference between acinar cell and islet cells, and covered up her misdiagnosis by placing an addendum to her original report stating the original cancer diagnosis and the normal removed organ matched, thereby concealing her original misdiagnosis and perpetuating the patient's mistaken belief that the patient's removed organ was cancerous.

CONCEALMENT OF MISDIAGNOSIS FROM PATIENT

12. The Chair of the Pathology Department did not report her misdiagnosis to KU Hospital's Chief Medical Officer, Risk Management Committee or Risk Manager.

13. In September of 2015 Tilzer informed the KU Hospital's Chief Medical Officer and the Risk Management Officer that a "Root Cause Analysis" must be conducted regarding the misdiagnosis. A Root Cause Analysis investigates the underlying cause of the mistake so that preventive measures can be adopted to avoid the same mistake in the future. A Root Cause Analysis is the standard tool for health care agencies to understand and prevent mistakes such as the erroneous removal of the patient's essential body organ that occurred at KU Hospital.

14. The Chief Medical Officer stated that the Chair's original diagnosis was correct because two other pathologists signed the report; but the two other pathologists did not agree with the original diagnosis, and the Chair simply wrote their names in the electronic medical record.

15. The Chief Medical Officer refused Tilzer's requests to talk to any other pathologist. The Chief Medical Officer's failure to interview other pathologists perpetuated the cover up of the misdiagnosis by the Hospital.

16. Despite Tilzer's request, and in violation of KU Hospital's policies, a Root Cause Analysis was not conducted.

17. In early 2016 the Chair of the Pathology Department instructed others to alter medical records regarding the Chair's misdiagnosis, and to remove from records the any reference that a Root Cause Analysis was necessary.

18. The patient was not informed of the misdiagnosis as of February 2016, and to the best of Tilzer's knowledge the patient still has not been informed that the patient did not have cancer, and that it was unnecessary to remove the patient's essential body organ.

19. Tilzer advocated that the medical records be corrected and that the patient be informed of the misdiagnosis.

20. Tilzer's concerns regarding the competence of the Chair of the Department of Pathology were reinforced by limitations imposed by the Division Director of Cytopathology preventing the Chair from performing cytopathology reviews.

21. Tilzer's concerns regarding KU Hospital's ability and desire to manage the Department of Pathology were reinforced when the Chair of the Department of Pathology

unilaterally decided that she would perform cytopathology reviews despite the limitation imposed by the Division Director of Cytopathology.

22. Tilzer's concerns regarding the competence of the Chair of the Department of Pathology and KU Hospital's ability and desire to manage the Department of Pathology were further reinforced when continuing mistakes by the Chair and actual or potential patient harm were brought to Tilzer's attention.

SIGNIFICANCE OF THE FAILURE TO INFORM THE PATIENT

23. The form of cancer that was erroneously diagnosed within the patient is commonly known to be potentially lethal; and the patient who was misdiagnosed has lived with this unwarranted fear for as long as KUMC/KU Hospital have concealed the misdiagnosis.

24. The failure to inform the patient has created a conflict of interest between KU Hospital, the physicians and the patient – but unless and until the patient is informed of the misdiagnosis and cover up the patient is not aware of the conflict.

25. The failure to inform the patient and the conflict or interest are contrary to American Medical Association Ethics Opinion 10.01(1) and (3). A copy of AMA Opinion 10.01 is attached as Exhibit 1.

TILZER'S REPORT TO THE JOINT COMMISSION

26. After the Chair requested that medical records be altered, and after KU Hospital failed to conduct a root cause analysis, Tilzer concluded that an external review was necessary.

27. The Joint Commission is an independent, not-for-profit organization that was formerly known as the "Joint Commission On Accreditation Of Healthcare Organizations". The Joint Commission evaluates and accredits hospitals and other health care organizations and programs in the United States.

28. On April 1, 2016, Tilzer submitted a report to the Joint Commission regarding the misdiagnosis and KUMC's/KU Hospital's concealment and failure to correct medical records.

29. Tilzer's report to the Joint Commission was assigned Incident #72413QOS-12536ZZC.

30. On April 1, 2016, The Joint Commission sent Tilzer the email that is attached as Exhibit 2 asking whether the Joint Commission could provide Tilzer's name to KU Hospital regarding the report to the Joint Commission.

31. Tilzer informed the Joint Commission that the Joint Commission could provide his name to KU Hospital.

32. Tilzer's report to the Joint Commission:

a. identified KUMC and KU Hospital,

b. explained the misdiagnosis,

c. identified the Chair of the Department of Pathology,

d. recited the sequence of events and concealment,

e. recited the failure to correct the patient's medical records, and

f. explained that the patient had not been informed of the misdiagnosis.

RESPONDENTS' REACTION TO TILZER'S REPORT TO THE JOINT COMMISSION

33. On May 5, 2016, Tilzer met with the KU Hospital's Risk Management Officer and Chief Medical Officer regarding Tilzer's report to the Joint Commission and Tilzer's criticisms of KUMC's and KU Hospital's actions and concealment.

34. On May 6, Tilzer met with the Director of Risk Management and discussed the need to conduct a proper Root Cause Analysis by interviewing the five Board Certified Cytopathologists and the Head of Surgical Pathology. The Director of Risk Management

informed Tilzer that she would do so; but to the best of Tilzer's knowledge the Director of Risk Management still has not interviewed the five Board Certified Cytopathologists and the Head of Surgical Pathology.

35. The Director of Risk Management also told Tilzer that she would meet with the Cytopathology supervisor who had been told to modify the Quality Improvement document, and that she would meet with the secretary that was instructed to modify the Minutes of the Quality Improvement committee meeting where this problem was discussed. To the best of Tilzer's knowledge she still has not interviewed either the Cytopahtology supervisor or the secretary.

36. On May 31, 2016, KU Hospital President Bob Page asked Tilzer to meet; and Tilzer met with Page in Page's office.

37. During Tilzer's May 31 meeting, KU Hospital's President Bob Page reprimanded Tilzer and attempted to intimidate Tilzer by:

a. Asking Tilzer if Tilzer wanted to resign (to which Tilzer stated that he would not resign),

b. Berating Tilzer for contacting the Joint Commission,

c. Accusing Tilzer of lying to the Joint Commission (to which Tilzer responded that his statements to the Joint Commission were truthful),

d. Saying that he (Page) was irritated that Tilzer had contacted the Joint Commission,

e. Asking why Tilzer had "done this alone" (to which Tilzer responded that others in the department were too scared to act), and

f. describing Tilzer's report to the Joint Commission as "pitiful" and "despicable" behavior.

38. Tilzer justifiably perceives Page's May 31 reprimand and attempted intimidation as a serious threat to Tilzer's employment and as an attempt to prevent Tilzer from further reporting to the Joint Commission.

39. On June 4, 2016, KUMC inquired whether Tilzer wanted to take a sabbatical.

40. Because KU Hospital President Bob Page did not provide Tilzer with written documentation of the May 31 reprimand, and because there is not a typical administrative record for the events surrounding Page's reprimand of Tilzer and the events leading to the reprimand and attempted intimidation, the administrative record for review should be supplemented through pre-trial discovery as contemplated by K.S.A. § 77-619(a).

THE JOINT COMMISSION, K.S.A. § 65-429, K.A.R. § 28-34-2 AND K.S.A. § 75-2973

41. The Joint Commission is recognized by the State Of Kansas as the outside agency that audits and certifies hospital compliance with medical standards.

42. The Joint Commission conducts audits of KU Hospital and certifies KU Hospital compliance with medical standards.

43. The Joint Commission performs its audits and certifications under the provisions of state law, including K.S.A. § 65-429 and Kansas Administrative Regulation § 28-34-2.

44. K.S.A. § 65-429 states:

> **§ 65-429. Issuance and renewal of licenses; funding the cost of administration of the medical care facilities licensure and risk management program; display of license**
> Upon receipt of an application for license, the licensing agency shall issue with the approval of the state fire marshal a license provided the applicant and the physical facilities of the medical care facility meet the requirements established under this act. A license, unless suspended or revoked, shall be renewable annually without charge upon the filing by the licensee, and approval by the licensing agency, of an annual report upon such uniform dates and containing such information in such form as the licensing agency prescribes by rules and regulations. A medical care facility which has been licensed by the licensing agency and which has received certification for participation in federal

reimbursement programs and which has been accredited by the joint commission on accreditation of health care organizations or the American osteopathic association may be granted a license renewal based on such certification and accreditation. The cost of administration of the medical care facilities licensure and risk management program provisions of this act pursuant to K.S.A. 65-433 and 65-4921*et seq*., and amendments thereto, shall be funded by an annual assessment from the health care stabilization fund, which assessment shall not exceed $200,000 in any one fiscal year. The licensing agency shall make an annual report to the health care stabilization fund regarding the use of these funds. Each license shall be issued only for the premises and persons or governmental units named in the application and shall not be transferable or assignable except with the written approval of the licensing agency. A separate license is not required for two separate establishments which are located in the same or contiguous counties, which provide the services required by K.S.A. 65-431 and amendments thereto and which are organized under a single owner or governing board with a single designated administrator and medical staff. Licenses shall be posted in a conspicuous place on the licensed premises. (Emphasis added.)

45. Kansas Administrative Regulation § 28-34-2 of the Department Of Health And Environment states in part:

§ 28-34-2. Licensing procedure
Each applicant for an initial license to operate a hospital shall file an application on forms provided by the licensing agency at least 90 days prior to admission of patients. A license previously issued shall be renewed after the licensee has filed an annual report and the licensing agency has approved the same. The licensing agency shall approve the renewal after it has documented that the applicant is in substantial compliance with these regulations. Each application for license renewal shall be filed with the licensing agency at least 90 days before the expiration date of the current license, and the annual report shall be filed no later than 60 days after the beginning of each calendar year. The annual report may include information relating to:
***
(e) If during the term of its current license a facility is surveyed by the joint commission on accreditation of health care organizations (JCAHO) or the American osteopathic association (AOA), the facility shall submit the survey report to the licensing agency toward satisfying the survey requirements for licensure. After reviewing the survey report, the licensing agency may notify the facility that a licensing survey will be conducted. (Emphasis added.)

46. The Joint Commission is an "Auditing Agency" as defined by K.S.A. § 75-2973(b)(1) because the Joint Commission is an "authority performing auditing or other oversight activities under authority of any provision of law authorizing such activities".

47. KUMC and KU Hospital are "State Agencies" as defined by and K.S.A. § 75-2973(b)(3) and K.S.A. § 46-1112.

48. KU Hospital President Bob Page's statements to Tilzer in their face-to-face meeting on May 31, 2016 threatened Tilzer's employment and constitute a "reprimand" and "warning of possible dismissal" under K.S.A. § 75-2973(b)(2).

49. Tilzer is an unclassified employee of two state agencies, KUMC and KU Hospital, and is entitled to file this Petition For Judicial Review pursuant to K.S.A. § 75-2973(h) within 90 days of after the disciplinary act.

50. This Petition for Judicial Review is filed within 90 days after the May 31, 2016 reprimand and attempted intimidation by KU Hospital President Bob Page.

51. Tilzer is entitled to protection from retaliation, protection from dismissal, an award of his legal fees pursuant to K.S.A. § 75-2973(h), and such other relief as the Court deems just and proper.

WHEREFORE, Lowell L. Tilzer M.D. prays that this Court enter judgment:

a. Allowing Tilzer to conduct discovery pursuant to K.S.A. § 77-619(a);

b. Preventing and enjoining the University of Kansas Hospital Authority and its agents including President Bob Page from retaliating against Tilzer for his opposition to the concealment and his report to an auditing agency;

c. Preventing and enjoining the University of Kansas Hospital Authority and its agents including President Bob Page and attempting to intimidate Tilzer and others from reporting to auditing agencies;

b. Preventing and enjoining the University of Kansas Hospital Authority and its agents including President Bob Page from terminating Tilzer's employment;

c. Awarding Tilzer's legal fees and costs;

d. Awarding such other relief as the Court deems just and proper.

Respectfully submitted,

COLANTUONO BJERG GUINN, LLC

By: /s/ Joseph R. Colantuono
Joseph R. Colantuono (KS # 13440)
Isaac Keppler (KS # 25843)
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Timothy Schmitt 7/26/16 Docum Actions

[redacted]

Wendy,

Thank you for talking to me this am. Here is the affidavit. Read it. If you are ok with it we can have Liz (cc'd) meet you someplace to sign it, have you come into the office to sign it, or if you want sign it and have it notarized and send it back in.

Let me know what you prefer.

Thank you

Tim

Timothy M Schmitt MD FACS

Director

University of Kansas Hospital

Center for Transplantation

AFFIDAVIT

STATE OF KANSAS)
)
COUNTY OF JOHNSON)

Date: _____

My name is Wendy Ann Noon Berner, my date of birth is November 19, 1970, and I currently reside at _____.

In August of last year I was told by my treating physicians at The University of Kansas Hospital that a fine needle aspirate biopsy of my pancreas indicated that I might have cancer of the pancreas. As a result of that preliminary diagnosis, I was then referred to and met with Timothy Schmitt, M.D., an operating surgeon. Dr. Schmitt ordered a MRI which showed that there were two small lesions in my pancreas consistent with the endoscopic ultrasound. Dr. Schmitt explained to me that I could watchfully wait and see if these lesions continued to grow or proceed to surgery. After consulting with Dr. Schmitt and carefully considering my options, I decided to have the surgery performed so that the potential pancreatic cancer would be removed from my body.

On September 1 of last year, Dr. Schmitt performed the operation to remove the lesions and a portion of my pancreas. Several days later, while still a patient at The University of Kansas Hospital, I received the news from Dr. Schmitt that the final pathology report of the surgery showed that I did not have pancreatic cancer, but actually had pancreatitis.

I was greatly relieved to learn that I did not have pancreatic cancer.

The treatment I received from Dr. Schmitt and from all of The University of Kansas Hospital nurses, doctors, and employees was wonderful. I feel great and have not had a reoccurrence of my pancreatitis symptoms since the surgery was performed almost 11 months ago.

The above recollection of my medical treatment is true to the best of my knowledge and belief.

_____
Wendy Ann Noon Berner

Date: _____

Subscribed and sworn to before me this ____ day of _____, 2016.

Notary Public in and for said
county and state:

_____
Notary Public

My Commission Expires: _____