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Before The
State Of Wisconsin
MEDICAL EXAMINING BOARD

In the Matter of the Disciplinary Proceedings
Against **ROBERT A. CAVANAUGH, M.D.,**
Respondent

FINAL DECISION AND ORDER

Order No. 0003603

Division of Legal Services and Compliance Case No. 12 MED 351

The State of Wisconsin, Medical Examining Board, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, make the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Medical Examining Board.

The rights of a party aggrieved by this Decision to petition the department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated at Madison, Wisconsin on the 17th day of December, 2014.

Member
Medical Examining Board

Before The
State Of Wisconsin
DIVISION OF HEARINGS AND APPEALS

0003603

In the Matter of the Disciplinary Proceedings
Against **ROBERT A. CAVANAUGH, M.D.,**
Respondent

DHA Case No. SPS-14-0002
DLSC Case No. 12 MED 351

PROPOSED DECISION AND ORDER

The parties to this proceeding for purposes of Wis. Stat §§ 227.47(1) and 227.53 are:

Respondent Robert A. Cavanaugh, M.D., by:

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PROCEDURAL HISTORY

On January 16, 2014, the Department of Safety and Professional Services, Division of Legal Services and Compliance (Division), served a Complaint on Respondent Robert A. Cavanaugh, M.D. The Complaint alleged that in September of 2012, Dr. Cavanaugh engaged in unprofessional conduct pursuant to Wis. Admin. Code § Med 10.02(2)(h), when he failed to consider that his patient, "Patient A," had cancer and failed to have a gynecologic oncologist present or on call for Patient A's surgery for suspected gynecologic cancer. The Complaint was subsequently amended following the hearing to conform to the evidence, withdrawing the allegation that Dr. Cavanaugh failed to consider that Patient A had cancer.

Following Dr. Cavanaugh's filing of an Answer to the Complaint, on February 20, 2014, a prehearing conference was held by telephone, at which the parties agreed to a hearing date of August 26-27, 2014. The ALJ issued a Notice of Hearing and Scheduling Order on February 20, 2014. A hearing was held in Madison, Wisconsin, on August 26-27, 2014, at which Patient A and Drs. Dobie Giles and Carol Ritter testified for the Division and Drs. Cavanaugh, Brent DuBeshter, Stewart Gifford, and Brian Bear testified for Dr. Cavanaugh. A hearing transcript was filed on September 8, 2014.

FINDINGS OF FACT

Treatment of Patient A

1. In August of 2012, Patient A, who was 58 years old, began feeling pain and something hard in her abdomen. She called her sister, Dr. Carol Ritter, who is a gynecologist in Baltimore, Maryland, and informed Dr. Ritter of her symptoms. Dr. Ritter informed Patient A that she would probably need to have a hysterectomy[1] but that it could be something more serious and that she should see a doctor as soon as she returned home to Green Bay, Wisconsin from being out of town. (Hrg. Tr., pp. 22-23, 119-120)

2. When Patient A returned home, she contacted her family physician, who examined her. She underwent an x-ray and ultrasound at Bellin Hospital in Green Bay. On September 11, her family physician called her with the results indicating that she had a 5.5 inch pelvic mass, and referred her to Dr. Cavanaugh. Patient A again contacted her sister, informing her of the results, and her sister ordered a CA 125 to assist Dr. Cavanaugh. (Hrg. Tr., pp. 26, 122, 203, 214)

3. In September of 2012, Dr. Cavanaugh had been practicing as an obstetrician and gynecologist for 29 years. He has never before been the subject of a disciplinary action. (Hrg. Tr., p. 192)

4. Dr. Cavanaugh completed his residency in obstetrics and gynecology in 1983 and has been practicing medicine continuously in Wisconsin since then. In 1985, he obtained board certification in obstetrics and gynecology and has maintained certification since then. He is a fellow with The American Congress of Obstetrics and Gynecologist, a fellow with The American Board of Obstetrics and Gynecology, and a fellow of the American Society of Reproductive Medicine. (Resp. Ex. 104; Hrg. Tr., pp. 191-192, 206)

5. During the course of his career, Dr. Cavanaugh had been doing the full range of procedures in obstetrics and gynecology, including contraceptive procedures, reversals of sterilizations, hysterectomies, removal of ovaries and ovarian cysts, and surgeries for endometriosis[2] and fibroids. During the course of his career, he has delivered over 5,000 babies and has performed 700-800 hysterectomies. He is certified in robotic surgery. (Hrg. Tr., pp. 123, 192-193, 205)

6. During the course of his career, Dr. Cavanaugh saw patients with pelvic masses similar to Patient A's approximately three to eight times per month. (Hrg. Tr. pp. 193, 205)

[1] A hysterectomy is removal of the uterus. (Hrg. Tr., p. 205)

[2] The endometrium is the lining of the uterus. (Hrg. Tr., p. 200)

7. Dr. Cavanaugh uses a variety of methods to determine whether a mass is benign or cancerous, including taking a history and doing a physical examination of the patient, using a transvaginal ultrasound, and utilizing the CA 125. Dr. Cavanaugh testified that the older a patient is, the more concern there is that the mass is malignant. (Hrg. Tr., pp. 194-195)

8. Patient A's appointment was scheduled with Dr. Cavanaugh for September 14, 2012. By the time of the appointment, Dr. Cavanaugh had the results of the CA 125, which was elevated at 1,500. A normal CA 125 result is 35 or under. (Hrg. Tr., pp. 215, 248)

9. Reasons for an elevated CA 125 can be uterine fibroids, pelvic inflammatory disease, endometriosis, ovulation, liver disease, heart disease, diverticular disease and a host of other conditions. Because there are so many conditions that can cause an elevated CA 125, the only FDA-approved use of it is to monitor patients with an established ovarian cancer. (Hrg. Tr., pp. 62, 216, 265-68; DuBeshter Tr., pp. 30-31)

10. Although the CA 125 is not a specific diagnostic indicator for cancer, Dr. Cavanaugh uses it to triage, especially where there is an ovarian cyst. (Id.)

11. The ultrasound report states that the mass is "in the right adnexa abutting the uterus," that "a distinct plane cannot be distinguished between the mass and the uterus," that the mass "could be uterine or ovarian in origin" and that there is "moderate free fluid in the pelvis." Such fluid could be ascites.[3] (Div. Ex. 100, p. 37; Hrg. Tr., p. 240)

12. Moments before seeing Patient A on September 14, 2012, Dr. Cavanaugh spoke to a radiologist about the ulstrasound report. The radiologist was looking at the ultrasound imaging when talking to Dr. Cavanaugh and informed Dr. Cavanaugh that he believed the mass was a pedunculated uterine fibroid, that he could see the blood supply going from the uterus to the fibroid, and that he observed central degeneration in the fibroid. Dr. Cavanaugh took handwritten notes while speaking to the radiologist which he dictated immediately after seeing Patient A. Consistent with the ultrasound report, Dr. Cavanaugh's notes for September 14 state that the ultrasound report showed a 14 cm. heterogeneous mass adjacent to the uterus and that there was no visible plane between the uterus and the mass. His notes further state, "The radiologist was consulted. He felt that this most likely represented a pedunculated uterine fibroid with central degeneration within the fibroid. A vascular stalk was identified arising from the uterus and entering the fibroid. The patient is aware that this possibly could arise from the ovary." (Resp. Ex. 100, p. 19; Div. Ex. 1, p. 37; Hrg. Tr., pp. 241, 239, 245-247)

13. A fibroid is a muscle enlargement within the wall of the uterus. Fibroids are benign 99.7 percent of the time. According to at least one estimate, 50 percent of women will get fibroids, although some estimates are higher, and most of the time women will not know the fibroids are there. A pedunculated fibroid is a fibroid which projects out of the top of the uterus on a stalk. Degeneration within the fibroid means that vascular or blood vessel supply to the fibroid becomes disrupted, which can result in degeneration or death of the fibroid. (Hrg. Tr., pp. 202-204, 213, 266)

14. There is nothing in the ultrasound report regarding a pedunculated fibroid. (Div. Ex. 1, p. 37; Hrg. Tr., p. 239)

[3] Ascites is free fluid in the pelvis.

15. Dr. Cavanaugh agreed that in a postmenopausal woman with a pelvic mass and an elevated CA 125, the mass is presumed to be cancer unless otherwise demonstrated. (Hrg. Tr., pp. 238-239)

16. Patient A's September 14 appointment with Dr. Cavanaugh lasted approximately one hour. Dr. Cavanaugh performed an examination and informed Patient A that he had reviewed the test from the ultrasound, had talked to a radiologist and agreed with the radiologist that it was likely a degenerating pedunculated uterine fibroid, a phrase which he wrote down for Patient A and explained to her, using pictures to help explain. (Hrg. Tr., pp. 28, 30, 36, 214-215, 217)

17. Dr. Cavanaugh reviewed with Patient A a number of different procedural options: an open abdominal procedure; laparoscopy, which is removing tissue through small incisions while a camera attached to a scope is inserted; robotic surgery, which is a type of laparoscopic procedure using robotic instruments and a 3D camera rather than more traditional instruments; myomectomy, which is taking out the fibroid; a hysterectomy; an oophorectomy, which is removal of one or both ovaries; or a combination of these procedures. (Hrg. Tr., pp. 205, 217-221)

18. Dr. Cavanaugh's diagnosis and treatment decisions were not based solely on the conversation with the radiologist but also on his physical examination, the fact that the uterus and cervix moved together with the mass, that it felt like a fibroid, and the onset of symptoms, which were not inconsistent with the degeneration of a fibroid. (Hrg. Tr., p. 223)

19. Patient A chose the laparoscopic procedure and preferred a hysterectomy over a myomectomy, and preferred to have both ovaries removed rather than one. (Hrg. Tr., p. 221)

20. Dr. Cavanaugh ordered another CA 125, which was again elevated. (Hrg. Tr., p. 32)

21. Dr. Cavanaugh explained to Patient A that he would plan on doing a laparoscopic procedure, using robotics, to remove the uterus, tubes and ovaries, as he believed it was a fibroid. However, he explained that although he believed the mass was a benign fibroid, if he went in and discovered it was not a fibroid or if other complications occurred, he may have to convert it to an open procedure.[4] If it turned out to be cancer, he intended to have the gynecologic oncologist, Dr. Erik Jenison, available. Dr. Cavanaugh informed Patient A that Bellin was trying to recruit a gynecologic oncologist to be on staff. Patient A knew that an oncologist is a specialist who cares for people with cancer. (Hrg. Tr., pp. 37-38)

22. Patient A told Dr. Cavanaugh that she was in excruciating pain and wanted to have the surgery and get the mass out as soon as possible. Because of the pain, Patient A could not even stand up straight. The September 14 appointment was on a Friday, and when Dr. Cavanaugh informed her that he performs the procedures on Monday, she expressed interest in having the procedure done the following Monday, three days after the appointment. However, Dr. Cavanaugh informed her that the next Monday was booked and that it would have to be the following Monday, September 24, 2012. (Hrg. Tr. pp. 32, 41, 222-23)

23. When discussing the recovery period following laparoscopic surgery, Patient A asked Dr. Cavanaugh if she would be able to go to her son's college tours in Minneapolis the

[4] Patient A did not recall Dr. Cavanaugh discussing the possibility that the procedure might not be laparoscopic. (Hrg., pp. 31, 40)

weekend following the surgery, and also asked if she could fly to New York for a Broadway audition, which was scheduled for 10 days after the September 24 surgery. Dr. Cavanaugh told Patient A that riding in a car to Minneapolis would be fine but that the audition would not be an option. When she got home the day of the September 14 appointment, cancelled the audition in New York and rescheduled it for Chicago at a later time. (Hrg. Tr., pp. 30-31, 222)

24. Patient A asked Dr. Cavanaugh to call her sister, Dr. Ritter, which Dr. Cavanaugh did during Patient A's September 14 appointment. Dr. Cavanaugh told Dr. Ritter that Patient A had a pedunculated degenerating fibroid and that he was going to remove it with laparoscopic robotic surgery, a procedure which Dr. Ritter also performs. He also told Dr. Ritter that a gynecologic oncologist would be standing by during the surgery. Dr. Ritter asked if he was going to do a CT scan and he stated that he did not plan on it because Patient A was very symptomatic and it would not add much additional information. (Hrg. Tr., pp. 41-42, 124-26, 225-227)

25. The "gold standard" for evaluating a pelvic mass such as Patient A's is the transvaginal ultrasound, which Patient A underwent. According to a 2007 Practice Bulletin issued by The American College of Obstetricians and Gynecologists, "No alternative imaging modality has demonstrated sufficient superiority to transvaginal ultrasound to justify its routine use." (Div. Ex. 5, p. 3; Hrg. Tr., pp. 91, 226)

27. Prior to September of 2012, Bellin did not have any gynecologic oncologists on staff. In September of 2012, there was one full-time gynecologic oncologist working in Green Bay, Dr. Jonathan Tammela, who was employed by Prevea, a health care system which competes with Bellin for physicians and patients.[5] (Hrg. Tr., pp. 207-208; Gifford Tr., p. 9)

28. In September of 2012, Bellin was in the process of hiring a gynecologic oncologist, Dr. Jenison. Dr. Cavanaugh had received an email just prior to Patient A's September 14 appointment, stating that Dr. Jenison would be starting at Bellin the following week. (Hrg. Tr., p. 224)

29. Prior to September of 2012, when Dr. Cavanaugh's primary diagnosis was cancer in a postmenopausal patient with a pelvic mass, acute pain and an elevated CA 125, he would have sent her to Dr. Tammela. He had done so many times. In Patient A's case, Dr. Cavanaugh's primary diagnosis was not cancer. (Hrg. Tr., p. 211)

30. Dr. Cavanaugh had also had patients with pelvic masses which he thought were benign fibroids but turned out to be cancerous. During at least one procedure when he tried to contact Dr. Tammela intra-operatively to have him assist, Dr. Tammela was unable to attend the surgery for an hour and half or two hours. The patient was on the table, under anesthesia, without anything being done during that time. Prolonged anesthesia has its own inherent risks. Also, the longer a surgery takes, the more likelihood there is of developing complications such as blood clots or infections. (Hrg. Tr., p. 212)

31. Approximately one week prior to the scheduled surgery, Dr. Cavanaugh was informed that Dr. Jenison was not available for surgery because he had some additional

[5] In September of 2012, there were four hospitals in Green Bay and three health care systems: Prevea, Aurora and Bellin. (Hrg. Tr., pp. 207)

paperwork to do to get his Wisconsin license. Dr. Cavanaugh then called Dr. Stewart Gifford, a general surgeon for Bellin, and made sure he was available for the surgery. (Hrg. Tr., p. 225)

32. Prior to September of 2012, Dr. Cavanaugh had called Dr. Gifford approximately eight to ten times to assist in procedures where cancer was involved. Dr. Cavanaugh was very comfortable with Dr. Gifford's ability and skills. He had never had a patient where Dr. Gifford did the staging, and the patient, following surgery, required the removal of additional tissues or samples, nor was a patient required to be restaged because Dr. Gifford missed something. (Hrg. Tr., pp. 209-210)

33. Staging means to examine the areas where the suspected cancer is located and to remove tissues and samples for testing to determine the extent of the disease and the cancer's primary site and stage. (Hrg. Tr., pp. 197-198, 201)

34. Dr. Gifford has been a general surgeon for 32 years and is board certified as such. (Hrg. Tr., pp. 4-5)

35. Prior to September 2012, Dr. Gifford had been assisting five other gynecologists with dozens of stagings at Bellin for five to ten years. Two other general surgeons who worked at Bellin assisted in these staging procedures. (Hrg. Tr., pp. 87-88; Gifford Tr., pp. 12-13)

36. Patient A and Dr. Cavanaugh met again for an appointment on September 20, 2012, which lasted approximately 45 minutes to an hour. At the September 20 appointment, they reviewed what they had previously discussed and Dr. Cavanaugh explained to Patient A what to expect when she went into the hospital. He explained the procedures that he anticipated as well as a possible open procedure and what a staging procedure entailed. Post-surgical recovery was discussed. (Hrg. Tr., pp. 32, 42-43, 227-228)

37. Dr. Cavanaugh also informed Patient A that the gynecologic oncologist would not be available but that a general surgeon, Dr. Stewart Gifford, would be available if they needed him.[6] (Hrg. Tr., pp. 227-228)

38. Patient A was still experiencing significant pain and expressed a desire to have the mass removed. Patient A did not ask Dr. Cavanaugh to call her sister. (Hrg. Tr., p. 229)

39. On September 20, 2012, Patient A signed the following informed consent forms: one for an oophorectomy, one for a hysterectomy, and one for a laparoscopy. (Hrg. Tr., p. 221; Resp. Exs. 107, 108, and 109, p. 1)

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[6] I find Dr. Cavanaugh's testimony that he informed Patient A that he would have a general surgeon rather than a gynecologic oncologist available for the surgery more persuasive than Patient A's testimony that he did not inform her of this. Patient A testified that she did not recall what was discussed during the second appointment because she "felt safe and comfortable" and "relieved." She testified that the first time she met with Dr. Cavanaugh, she was very concerned about what was happening to her and listened to everything, but during the second appointment, she thought she was in "good hands." She could not remember all of the tests Dr. Cavanaugh ordered during the second visit. Despite testifying that she could not remember what was discussed during the appointment, when asked if Dr. Cavanaugh made any statement about the team of doctors that would be attending during the procedure, she stated, "No. He did not. He – at that time in that second visit, there was no talk of the doctors that would be attending him, not at all. He did not – no. No talk." She further stated that at the second visit, he never told her that the oncologist would not be there. (Hrg. Tr., pp. 33-34, 43) In view of Patient A's admission that she could not remember the appointment, I credit Dr. Cavanaugh's testimony on this point rather than Patient A's.

40. On September 24, 2012, the date of the surgery, Patient A signed another informed consent form for surgery, namely, a "laporoscopic-assisted vaginal hysterectomy" and "bilateral salpingo oophorectomy," with "robotic assist." (Ex. 109, p. 2).

41. Prior to the commencement of any procedures on September 24, 2012, Patient A was given a general anesthesia. Following anesthesia, Dr. Cavanaugh began surgery by making an incision near Patient A's belly button and inserted the scope and camera through the incision. When he saw that there was an enlargement of the ovary and that it was not all just one big fibroid, he chose to find out if she had cancer or not. It was not clear to him looking through the scope that it was. He converted the procedure to an open incision. He took some pelvic washings,[7] reached down and delivered the mass, which involved the ovary and fallopian tubes, to the surface of the abdomen, packed in sponges and sent the mass to pathology to do a frozen section. He removed the entire mass so as to avoid spillage of the contents, including possible cancerous cells, into the pelvis. (Div. Ex. 1, p. 9; Hrg. Tr., pp. 34-35, 220, 232-233)

42. While in the operating room, he received a call from pathology indicating Patient A had ovarian cancer. At that point, Dr. Cavanaugh contacted Dr. Gifford to help with staging. He did not suspend the operation, close up the patient and refer her elsewhere because he believed that would cause an undue risk, including re-doing the incision and again undergoing anesthesia. Dr. Gifford came in and completed staging. (Hrg. Tr., pp. 234-235)

43. When called into surgery by Dr. Cavanaugh, Dr. Gifford surveyed the abdomen and pelvis visually and by palpation to ascertain the extent of the disease. Dr. Cavanaugh had already removed the uterus, fallopian tubes and ovaries and had taken washings. Dr. Gifford removed the omentum[8] and sent it to pathology, conducted lymph node dissection, removed the lymph node-bearing tissue from the common internal and external iliac arteries and veins, and removed lymph node-bearing tissue between the right and left ureter which covered the vena cava and aorta, and sent that to pathology as a separate specimen. No complications occurred during the staging procedure. (Div. Ex. 1, p. 8; Gifford Tr., pp. 15-17)

44. A total of nine lymph nodes were removed, four of which were periaortic, and all of which were negative for cancer. Pelvic node dissection was also performed. (Resp. Ex. 102, p. 12; Hrg. Tr., p. 277)

45. Dr. Gifford stated that he did not remove or sample the obturator nodes because it was unnecessary given the presumptive diagnosis of ovarian cancer. He stated that if the diagnosis had been endometrial cancer, the recommendation is to take more extensive lymph nodes, including the obturator nodes. (Gifford Tr., pp. 17, 23-24)

46. The final diagnosis for Patient A was advanced endometrial cancer which had spread to the right ovary and tube, a stage 3A cancer with Grade 1 or 2 cell types. Stage 4 is the worst stage and Grade 3 is the most aggressive cell type. (Resp. Ex. 102, p. 3; Hrg. Tr., pp. 51, 276-277, 283, 345-36; DuBeshter Tr., pp. 23-24; Gifford Tr., p. 10)

47. While in the pre-operation room, Patient A had asked Dr. Cavanaugh to call her sister (Dr. Ritter) after the procedure, which Dr. Cavanaugh did. Dr. Cavanaugh informed Dr.

[7] A washing is flushing the area with saline and taking that area as a sample, and sending it to a pathologist to examine the individual cells that come out of the fluid. (Hrg. Tr., p. 198)

[8] An omentum was described by Dr. Gifford as a fatty apron that hangs from the stomach and the colon covering the abdominal contents. (Gifford Tr., p. 11)

Ritter that the surgery had been done by him and a general surgeon rather than a gynecologic surgeon. Dr. Ritter filed a complaint against Dr. Cavanaugh and Bellin with the Wisconsin Medical Examining Board. (Hrg. Tr., pp. 135-136, 145, 155, 244)

48. Following the September 24, 2012 operation, Patient A saw an oncologist, Dr. Peter Johnson, at Aurora Bay Care Medical Center in Green Bay for treatment, beginning on October 3 or 4, 2012. Patient A received radiation and chemotherapy for her cancer, which was completed in March of 2013. Since that time, Patient A must return every three months for a physical examination and a repeat CA 125. She has had no further treatment with respect to her cancer and has been told she is cancer free. (Resp. Ex. 102, p. 15; Hrg. Tr., pp. 49, 51, 236-37, 275-276)

49. Dr. Johnson saw Patient A from 2012-2014, and during that time no other surgeries were performed on Patient A. At no point during this time were more tissues, lymph nodes, or washings removed from Patient A. Second opinions were obtained from Dr. Stephen Rose at UW Hospital in Madison and from Johns Hopkins, both of which agreed in relevant respects with the Bellin pathologist's ultimate conclusion that Patient A had stage 3A endometrial cancer which had spread to the ovary. No further surgery was conducted following the second opinions of Dr. Rose and Johns Hopkins. There is no indication in Dr. Johnson's records that he was considering surgery but did not do so because of some post-operative condition in Patient A. (Resp. Ex. 102, pp. 14-15; Hrg. Tr., pp. 49-50, 88-89, 281-285)

50. One of Dr. Johnson's reports states: "If the CT scan shows any enlarged lymph nodes, we could consider surgery to remove these nodes." A CT scan was conducted on October 30, 2012, approximately six weeks after surgery. The CT scan was negative for enlarged lymph nodes or any other masses or fluid collections, which means it was within normal limits. (Resp. Ex. 102, p. 5; Ex. 117; Hrg. Tr., pp. 278, 280-281)

Expert Testimony

Dr. Dobie Giles

51. Dr. Dobie Giles is a gynecologist who specializes in female pelvic medicine and reconstructive surgery. He graduated from medical school in 2001. Following medical school, he completed a four-year residency in obstetrics and gynecology residency, and then a three-year fellowship in female pelvic medicine and reconstructive surgery at Mayo Clinic in Arizona, which he completed in 2008. As part of that fellowship, Dr. Giles handled benign gynecology but also some gynecologic oncology, although he is not a gynecologic oncologist. His last regular exposure to patients with cancer was during the fellowship at Mayo Clinic, approximately five years prior to the hearing. (Hrg. Tr., pp. 51, 54, 74-75; Div. Ex. 3)

52. Dr. Giles is the chief female pelvic medicine reconstructive surgeon at the University of Wisconsin-Madison, and at the time of hearing was scheduled to be the division director of gynecology and gynecologic subspecialties at the UW-Madison. He had been at the UW-Madison for approximately one year. (Hrg. Tr., pp. 54-55)

53. At the UW-Madison, there are three divisions in gynecology: benign gynecology, gynecologic oncology and infertility. Dr. Giles is in the benign gynecology division, treating women who do not have cancer. If a patient has cancer or a suspicion of cancer, she is sent to a different division. (Hrg. Tr., pp. 73-74)

54. Prior to taking employment with the UW-Madison, Dr. Giles was employed at the Reproductive Specialty Center in Milwaukee for five years, from 2008-2013. While in that position, no patient with known cancer was referred to him for direct care, although he did cover for the gynecologic oncologists when they were out of town. When covering for the gynecologic oncologist, Dr. Giles addressed patients' medical and surgical problems, but did not perform staging or undertake procedures to treat their cancer. (Hrg. Tr., pp. 74-75)

55. Dr. Giles' opinions were based on his education, training and experience and held to a reasonable degree of medical certainty. Dr. Giles' opinion was that it was below the minimum standard of competence to fail to have a gynecologic oncologist present for the surgery or on call for possible intervention. (Hrg. Tr., pp. 58, 66, 117)

56. Dr. Giles' opinion was that once Dr. Cavanaugh found out that a gynecologic oncologist was not available, it was below minimum standard of care for him not to refer Patient A to a place where there was such a specialist and that by not doing so, Patient A was at an "increased risk" of needing future surgery for staging. Dr. Giles stated that if staging is incorrect or incomplete, the patient is placed at an "increased risk" of having her life span unnecessarily reduced. (Hrg. Tr., pp. 66-68)

57. Dr. Giles further opined that neither a delay in referring Patient A elsewhere nor the fact that Bellin's gynecologists had for years routinely used a general surgeon to stage gynecologic cancers, is an acceptable reason to proceed to surgery without a gynecologic oncologist. (Hrg. Tr., p. 69)

58. Dr. Giles also stated that in situations like Patient A's, where cancer is not suspected and the surgery begins laparoscopically but cancer is discovered during surgery, a gynecologic oncologist should have been contacted. If the gynecologic oncologist is not available, the patient should be closed up and the patient should be sent to a gynecologic oncologist for proper staging. (Hrg. Tr., pp. 114- 115)

59. When asked if, preoperatively, cancer should have been the diagnosis of any minimally competent gynecologist, Giles equivocated but ultimately testified that the first diagnosis should have been an adnexal mass concerning for ovarian cancer, and the second diagnosis a fibroid, and that the next step should have been the involvement of a gynecologic oncologist. The reason cancer should have been the first diagnosis according to Dr. Giles is because Patient A was a postmenopausal woman with a pelvis mass with an elevated CA 125. (Hrg. Tr., pp. 63-64, 58-60)

60. Dr. Giles testified regarding publications by the American College of Obstetricians and Gynecologists (ACOG), a nationwide obstetrician and gynecologist (Ob/Gyn) organization that provides education and information regarding women's health care. ACOG issues practice bulletins and committee opinions on a wide variety of topics for Ob/Gyns throughout the country. (Hrg. Tr., pp. 55-70, 206; Div. Exs. 4-6)

61. The ACOG Practice Bulletins explicitly state on their front page, "[This] information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedures. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice." Likewise, on the top of the Committee Opinion testified to by Dr. Giles, it explicitly states: "This document reflects emerging clinical and scientific advances as of the date issued and is subject to change.

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed." (Div. Ex. 4, p. 1; Div. Ex. 5, p. 1; Div. Ex. 6, p. 1)

62. Despite these disclaimers, Dr. Giles believes that these ACOG publications are interpreted as the standard of care, although his testimony was somewhat equivocal on that point. When asked during direct testimony if, as a practical matter, these publications become the standard of care, he responded, "I would say for the most part they do. This is open to some interpretation. They give recommendations based on evidence." When asked if, as a practical matter, Ob/Gyns follow the recommendations of the ACOG's publications, he stated, "Yes. I would say they do." During cross-examination, when he was asked if it was his opinion that the bulletins were the standard of care, he said, "It is." (Hrg. Tr., pp. 55-56, 96)

63. Dr. Giles stated that his opinions in this case depended somewhat on his interpretation of the ACOG standards and what they mean, and that other reasonable gynecologists could disagree with him. (Hrg. Tr., p. 92)

64. ACOG Practice Bulletin Number 65, issued in 2005 and reaffirmed in 2013, is a practice bulletin entitled, "Management of Endometrial Cancer." Under the heading, "Clinical Considerations and Recommendations," and the subheading, "Which patients may benefit from referral to gynecologic oncologist?," it states: "Physicians with advanced training and expertise in the treatment of women with endometrial cancer, such as gynecologic oncologists, understand the nuances of uterine cancer management . . . .When it is practical and feasible, preoperative consultation with a physician with advanced training and demonstrated competency such as a gynecologic oncologist may be recommended." (Div. Ex. 4, p. 8-9; Hrg. Tr. p. 57)

65. Dr. Giles believed it was practical and feasible for Patient A to be referred to a gynecologic oncologist. Even though Patient A was in severe pain and Bellin did not have a gynecologic oncologist on staff, he believed it was nonetheless practical and feasible to refer her to a gynecologic oncologist and that every minimally competent Ob/Gyn should have done so. (Hrg. Tr., pp. 58-60)

66. ACOG Practice Bulletin Number 83, dated 2007 and reaffirmed in 2011, is entitled, "Management of Adnexal Masses" and contains the same disclaimer language as the Bulletin on endometrial cancer. (Div. Ex. 5, Hrg. Tr., p. 60)

67. "Adnexal" refers to the fallopian tubes and ovaries. Ultimately, Patient A's mass was determined to be an adnexal mass. However, at the time Dr. Cavanaugh first made the decision to have Dr. Gifford rather than a gynecologic oncologist available, he did not believe it was an adnexal mass. Although the ultrasound report states that the mass could be uterine or ovarian in origin, the radiologist Dr. Cavanaugh spoke with told Dr. Cavanaugh that he believed it was a uterine fibroid. Dr. Cavanaugh testified that at the time he first saw Patient A, he believed the mass to be a pelvic mass, not an adnexal mass, and that it was not until he inserted the scope on the day of surgery and saw that the ovary was involved, that he believed it was an adnexal mass. (Div. Ex. 1, p. 37; Hrg. Tr., pp. 61, 103, 201, 239, 243-244)

68. In this bulletin on adnexal masses, under the heading, "Clinical Considerations and Recommendations" and the subheading, "When is a CA 125 test warranted?," it states:

> Whereas CA 125 level measurement is less valuable in premenopausal than postmenopausal women in predicting cancer risk, extreme values can be helpful. For example, although premenopausal women with masses and either normal or

> mildly elevated CA 125 usually have benign diagnoses, a markedly elevated CA 125 level raises a much greater concern for malignancy, even though women with benign conditions such as endometriosis can have CA 125 level elevations of 1,000 units/mL or greater.

(Div. Ex. 5, p. 5; Hrg. Tr., p. 62)

69. The bulletin's clinical considerations and recommendations further state:

> The low sensitivity occurs because the CA 125 level is elevated on only one half of early stage epithelial ovarian cancers . . . . The low specificity occurs because the CA 125 level frequently is elevated in many commonly encountered clinical conditions, including uterine leiomyomata (fibroid), endometriosis, acute or chronic pelvic inflammatory disease, ascites of any etiology, and even inflammatory conditions such as systemic lupus erythematosus and inflammatory bowel disease. Because most of these clinical conditions occur in premenopausal women and because most epithelial ovarian cancers occur in postmenopausal women, the sensitivity and specificity of an elevated CA 125 level in concert with a pelvic mass is highest after menopause.

(Div. Ex. 5, p. 5; Hrg. Tr., pp. 97-98)

70. The bulletin lists factors indicating that a referral is warranted. For postmenopausal women, one of the indicators is ascites. The ultrasound showed that Patient A had a moderate amount of free fluid in the pelvis, which Dr. Giles stated is not typically associated with fibroids. Another indicator, however, is a nodular or fixed pelvic mass. According to Dr. Cavanaugh, Patient A's mass was not fixed, but moved. (Div. Ex. 5, p. 7; Hrg. Tr., p. 65)

71. The bulletin's clinical considerations and recommendations further state:

> It has been well-established that women with ovarian cancer whose care is managed by a physician who has advanced training and expertise in the treatment of women with gynecologic cancer, such as a gynecologic oncologist, have improved overall survival rates as compared with those treated without such collaboration. Improved survival rates reflect [] proper staging. . . .

That conclusion is repeated under a section entitled, "Summary of Recommendations and Conclusions." However, the bulletin also states that this is a "Level C" recommendation. Level A recommendations are based on good and consistent scientific evidence. Level B recommendations are based on limited or inconsistent scientific evidence. Level C recommendations are based primarily on consensus and expert opinion. There is a movement in the medical profession in the last 10-15 years toward evidence-based decision making (Level A) and away from anecdotal experience from individual physicians (Level C). Level A is the best quality and Level C is the weakest. (Div. Ex. 4, p. 13; Div. Ex. 5, pp. 6, 9, 14; Hrg. Tr., pp. 98-101)

72. Dr. Giles testified that in 2012, the recommendations in this bulletin on adnexal masses were universally accepted in the practice of gynecology. (Hrg. Tr., p. 60)

73. Dr. Giles also testified regarding ACOG Committee Opinion Number 477, dated March 2011, which is entitled, "The Role of the Obstetrician-Gynecologist in the Early

Detection of Epithelial Ovarian Cancer." This Committee Opinion states, "When a patient with a suspicious or persistent complex adnexal mass requires surgical evaluation, a physician trained to appropriately stage and debulk[9] ovarian cancer, such as a gynecologic oncologist, should perform the operation." (Div. Ex. 6, pp. 1, 3-4; Hrg. Tr., pp. 65-66)

74. The Committee Opinion further states:

> When physical examination and imaging techniques have detected the presence of a pelvic mass that is suspicious for a malignant ovarian neoplasm,[10] the presence of at least one of the following indicators warrants consideration of referral to or consultation with a physician trained to appropriately stage and debulk ovarian cancers such as a gynecologic oncologist: Postmenopausal woman: elevated CA 125 level, ascites, a nodular or fixed pelvic mass or evidence of abdominal or distant metastasis.

(Div. Ex. 6, p. 3, Hrg. Tr., pp. 112-113).

75. Dr. Giles testified that he believes that a gynecologic oncologist would have removed the obturator nodes during staging when the test results showed ovarian cancer. (Hrg. Tr., pp. 93-94, 107-108)

76. Dr. Giles conceded that if the radiologist who spoke with Dr. Cavanaugh were correct that Patient A had a pedunculated fibroid mass, it would not have been necessary to make arrangements to have any kind of gynecologic oncologist present. He further agreed that it would be a waste of time and resources to have a gynecologic oncologist present under such circumstances. (Hrg. Tr., p. 85)

77. Dr. Giles agreed that a CA 125 can be elevated for a wide variety of reasons, including fibroids, endometriosis, pelvic inflammatory disease (PID) and cancer. However, in a postmenopausal woman, there is a "higher likelihood of malignancy." He stated it is uncommon for postmenopausal women to have endometriosis that is active because usually it is an estrogen-sensitive disease and nothing in the history of Patient A would have suggested PID. (Hrg. Tr., pp. 62-63)

Dr. Brent DuBeshter[11]

78. Dr. Brent DuBeshter is a gynecologic oncologist. He is the director of gynecologic oncology at the University of Rochester Medical Center in New York and has been in this position since 1989. His group of three physicians handles all of the gynecologic oncology patients in the Rochester region.

79. Dr. DuBeshter completed medical school in 1978, whereupon he underwent an obstetrics and gynecology residency for four years at Brigham and Women's Hospital, a Harvard hospital in Boston. He then practiced for two years as a generalist, and then went back to

[9] Debulking means removing the tumor. (Gifford Tr., p. 10)

[10] "Neoplasm" means "new growth," and can be malignant or benign. (Hrg. Tr., p. 211)

[11] Dr. Brent Dubeshter's hearing testimony was taken through his August 19, 2012 deposition, played by videotape at hearing and included as a transcript in the record. His testimony is referred to in this decision as "DuBeshter Tr." Dr. Gifford's hearing testimony was also taken through deposition testimony, which is contained in a transcript and not played by video at hearing, and is referred to as "Gifford Tr."

Brigham and Women's Hospital for two years, where he completed a fellowship to obtain certification in gynecologic oncology. He is board certified in obstetrics and gynecology as well as in gynecologic oncology. While in practice for two years following the fellowship, he was on the clinical faculty at Harvard Medical School. (Resp. Ex. 106; DuBeshter Tr., p. 3)

80. Dr. DuBeshter has staged thousands of patients like Patient A, postmenopausal women with pelvic masses. In his current practice, he stages such patients virtually every week. (DuBeshter Tr., pp. 12-13)

81. His duties as director of gynecologic oncology at the University of Rochester Medical Center include seeing patients in clinic approximately three times per week and doing surgeries four to five times per week, most commonly, cancer surgeries involving patients with endometrial cancer having a hysterectomy. (Resp. Ex. 106; DuBeshter Tr., pp. 11-12)

82. Over the course of his 30-year career, Dr. DuBeshter has performed 7,000 – 8,000 hysterectomies. (DuBeshter Tr., p. 12)

83. Since 2007, Dr. DuBeshter has also been a professor of obstetrics and gynecology at the University of Rochester School of Medicine teaching medical students and residents in obstetrics and gynecology. (Resp. Ex. 106; DuBeshter Tr., pp. 3-4, 8)

84. Dr. DuBeshter is a member of the American Society for Colposcopy and Cervical Pathology, the International Gynecologic Cancer Society and the Society of Gynecologic Oncologists. He is also a reviewer for a number of peer-reviewed medical journals, reviewing articles on topics such as gynecologic oncology, obstetrics and gynecology, cancer detection and prevention, and cancer cytopathology to determine whether the articles are worthy of publication. He has also assisted in drafting a handbook on principles of surgery, as well as a textbook chapter entitled, "Primary Care for Women, Gynecologic Cancers" in 2003. (Resp. Ex. 106; DuBeshter Tr., pp. 9-12)

85. Dr. DuBeshter reviewed documents pertaining to this matter, including Patient A's medical records, operation notes, and second-opinion pathology reports, and the depositions of Patient A and Drs. Cavanaugh, Gifford, Ritter, and Giles. (DuBeshter Tr., pp. 15-16)

86. Dr. DuBeshter's opinions were based on a reasonable degree of medical probability. His opinion was that Dr. Cavanaugh not only met all applicable standards of treating someone with Patient A's problem but actually exceeded them. He stated that Dr. Cavanaugh's medical care was "totally appropriate surgical management that [Patient A] would have received in any number of centers across the country." His opinion was that Dr. Cavanaugh's treatment of Patient A did not pose an unacceptable risk of harm to her or to the public's health, welfare or safety. (*Id.*, p. 16-17)

87. In explaining the basis for his opinions, he noted the following.

- Dr. Cavanaugh had a patient with a pelvic mass, who had had an ultrasound and presented with abdominal pain, and he recommended surgery. He recognized that although both he and the radiologist believed that it was likely to be fibroids, which is the most common reason that women undergo hysterectomies in this country, he took into account that it could be a malignancy, and made arrangements to have a gynecologic oncologist available for the surgery. When he found out that the gynecologic oncologist was not going to be available, he defaulted to what had been

the standard management scheme in his hospital, which was to have a general surgeon available if something had to be performed that was beyond the scope of the gynecologist's practice. Dr. Cavanaugh did not put himself in a position where he could not do what was right for the patient, and was prepared to do what was needed. (DuBeshter Tr., pp. 17-21)

- Drs. Cavanaugh and Gifford performed the proper procedures for the condition Patient A ended up having and for what she was thought to have had at the time of the surgery. Dr. DuBeshter, as a board certified gynecologic oncologist, would have done exactly the same procedures under the circumstances. (*Id.*, p. 16-19)

- Probably the majority of hospitals in the country do not have gynecologic oncologists on staff and there are many instances, even in his own area of the country, where a general surgeon will stage the cancer in a situation like Patient A's. (*Id.*, p. 19)

- The staging for Patient A was correct. Patient A had the appropriate lymph node sampling and removal of tissue done. The surgery was as comprehensive as it should have been, all of the appropriate biopsies and exploration that should have been done for Patient A were done, and he would have done the same biopsies and washings had he been standing next to Dr. Cavanaugh. (*Id.*, pp. 20-21)

- Minimal levels of competency did not require the removal or sampling of obturator nodes because Drs. Cavanaugh and Gifford already did lymph node dissections in the pelvis and already knew that they had a tumor involving the ovary, and such a procedure would have had no bearing on Patient A's prognosis or treatment. (*Id.*, pp. 29-30)

88. Dr. DuBeshter further opined that after Dr. Cavanaugh inserted the camera and discovered ovarian involvement and after receiving the results of the frozen sections which indicated ovarian cancer, it was appropriate, did not violate the minimum levels of competency, and was "the totally right thing to do" for Dr. Cavanaugh and Dr. Gifford to proceed with the staging and complete the operation. (*Id.*, pp 32-33)

89. This opinion was based on the fact that Drs. Gifford and Cavanaugh were prepared to do the right surgery for Patient A. He stated that if they were not prepared to do an appropriate surgery for Patient A, then it would have been better to stop the surgery and have someone who was prepared to do the right surgery for her. However, when there is confidence that the physicians present are going to do the right thing by the patient and have been doing that for a number of years, the patient should not be subjected to the delay of having to go see another specialist and having another surgery booked. Drs. Cavanaugh and Gifford did the right thing for Patient A and avoided her getting another anesthetic and suffer a delay in treatment of the cancer. Dr. DuBeshter also believes Patient A would have had exactly the same surgery had a gynecologic oncologist performed it. (*Id.*, pp. 33-34, 41)

90. Dr. DuBeshter disagreed with Dr. Giles that the staging performed by Dr. Gifford was not as thorough or as comprehensive as it should have been. First, Dr. DuBeshter questioned whether Dr. Giles was in a position to make that type of judgment. Second, there is tremendous variation and no consensus, even within gynecologic oncology circles, about how much should be done in different circumstances. Third, for what Patient A had (endometrial

cancer) and what Drs. Cavanaugh and Gifford thought she had (ovarian cancer), full, extensive pelvic and aortic lymphadenectomies are not done. Rather, samplings are done. Therefore, whether to remove or leave alone a particular node is not that important. Staging for ovarian and advanced endometrial cancers are very similar, and involve taking a portion of the omentum out, doing some selective lymph node removals in the pelvic and aortic regions, obtaining fluid from the abdomen, and sending that for cytologic[12] analysis, all of which was done with Patient A. Dr. DuBeshter believed that subsequent records support his position, as no one recommended that she get another operation or remove any other lymph nodes. (Resp. Ex. 102, p. 12; Div. Ex. 1, p. 8; Dubeshter Tr., pp. 27-30; Hrg. Tr., p. 277; Gifford Tr., pp. 15-17)

91. Dr. DuBeshter agreed that gynecologic oncologists have more specific training in staging gynecologic cancers than do general surgeons. Dr. DuBeshter stated it was his preference to have a gynecologic oncologist available, but that it is not always possible or necessary. He also agreed with literature stating that patients staged by general surgeons have worse outcomes statistically than those staged by gynecologic oncologists. However, he stated that the reason for that is that not all general surgeons and not all gynecologists working with general surgeons know the right things to do, which is why there is a movement to have gynecologic oncologists available. But in situations like this, where Dr. Cavanaugh found out a week before surgery that the gynecologic oncologist was not available, there had been a long-standing practice of using a general surgeon, and the general surgeon and Dr. Cavanaugh did the right procedures, he did not believe a gynecologic oncologist was necessary. (*Id.*, pp. 20, 38-40)

92. Dr. DuBeshter stated that because the only FDA-approved use of a CA 125 is to monitor patients with an established ovarian cancer, he uses the CA 125 only to monitor an established diagnosis of ovarian cancer and does not use it to decide whether to perform surgery on a woman suspected of having cancer, although he acknowledged that some doctors do. (*Id.*, pp. 31-32)

93. Dr. DuBeshter stated that the ACOG practice bulletins and committee opinions do not define the standard of care for Ob/Gyns, but instead are issued as guidelines. He stated that the guidelines are not necessarily opinions that everyone holds, but may serve a useful purpose to help people try to manage patients. He stated that to say they represent the standard of care is a "vast overstatement," as indicated by their disclaimers. (*Id.*, p. 37)

Dr. Brian Bear

94. Dr. Bear received his medical degree in 1984 and is board certified in obstetrics and gynecology through the American Board of Obstetrics and Gynecology. Following medical school, he was resident in obstetrics and gynecology for four years at St. Joseph's in Milwaukee, Wisconsin. Since 1989 he has been in private practice. He is currently teaching anatomy and lecturing in obstetrics and gynecology at the Medical College of Wisconsin and is also teaching as a clinical professor in anatomy at Marquette University. He retired from active practice as an Ob/Gyn in June of 2014 due to problems with his hands. (Resp. Ex. 105; Hrg. Tr., 253, 257, 259)

95. In the course of his career, Dr. Bear has evaluated on a weekly basis both post and premenopausal women who had acute onset of pain with pelvic masses. (Hrg. Tr., p. 259)

[12] Cytology refers to the pathologist examining cells. (DuBeshter Tr., p. 25)

96. Dr. Bear has delivered over 10,000 babies and until recent retirement, also had a very busy gynecologic practice with in-office and hospital procedures in the hospital every week, ranging from minor procedures like hysteroscopy and D&Cs to major procedures such as hysterectomies, pelvic reconstructions and, over the last three years, robotic surgery. (Hrg. Tr. pp. 256-57; 105)

97. Dr. Bear was voted by Milwaukee Magazine "Top Docs" in 1996, 2000, 2004, 2008 and 2012, voted "Top Docs in America" in 1999, voted "Milwaukee Super Docs" in 2011, and voted Milwaukee Magazine Top Doctor in 2013. (Resp. Ex. 105; Hrg. Tr., p. 258)

98. Dr. Bear reviewed depositions of Patient A, Dr. Ritter, Dr. Cavanaugh, Dr. Gifford and Dr. DuBeshter and his own deposition. He also reviewed Dr. Cavanaugh's clinic notes and the records from Bellin concerning the procedure and staging for Patient A's surgery, and Dr. Johnson's records from Aurora, and the second-opinion pathology results from the University of Wisconsin Hospital and from Johns Hopkins Medical Center. (Hrg. Tr., p. 262)

99. The opinions he expressed were held to a reasonable degree of probability. He believed that Dr. Cavanaugh met a high level of competence in the practice of gynecology and did not see anything in Dr. Cavanaugh's care and treatment of Patient A that failed to meet the minimal competence in the field of gynecology. He also did not believe that there was any act or omission in Dr. Cavanaugh's treatment of Patient A that posed an unacceptable risk of harm to Patient A or to the public's health, welfare or safety. (Hrg. Tr., pp. 262-264)

100. In summarizing the basis for his opinion, Dr. Bear stated the following. Dr. Cavanaugh did a thorough re-evaluation through ultrasound and strongly believed that the patient had an enlarged uterine fibroid. A uterine fibroid is usually mobile and Dr. Cavanaugh was able to move it around. Dr. Cavanaugh discussed the options at length with Patient A and clearly documented the conversations. He scheduled the surgery appropriately and planned to have the right people there in the event he ran into something unforeseen. He knew exactly what to do when he saw what he was dealing with in the operating room and had the appropriate people come in, who did the appropriate procedure. Patient A was in the hospital for a normal time period and had a great outcome. (Hrg. Tr., pp. 264-266, 273)

101. The larger hospitals where Dr. Bear has worked, St. Joseph's in Milwaukee and West Allis Memorial, have had gynecologic oncologists on staff since Dr. Bear started practicing, but those physicians go to various hospitals in the surrounding communities and are therefore not in the hospital 24 hours a day. He stated that there are not enough gynecologic oncologists to go around and that there are definitely areas in Wisconsin which did not have them available 24/7. (Hrg. Tr., p. 269)

102. Dr. Bear agreed that for surgeries involving conditions similar to Patient A's, gynecologic oncologists have better outcomes than general surgeons. (Hrg. Tr., p. 290)

103. Dr. Bear was aware that Dr. Cavanaugh had made arrangements to have Dr. Jenison available but that Dr. Jenison's recruitment got held up. He was also aware that prior to September 2012, if a gynecologist was performing a procedure on a pelvic mass which turned out to be cancerous, the gynecologist would call in a general surgeon to do the staging. He stated that this procedure was "absolutely" appropriate and did not violate the minimum standards of competency if the general surgeons are capable of doing the procedures. He stated that he has used general surgeons in Milwaukee for these types of procedures when gynecologic oncologists

were not available, even when there are gynecologic oncologists on staff. He also stated it met the minimal level of competency not to remove obturator nodes. (Hrg. Tr., pp. 269-272)

104. Dr. Bear has been a member of ACOG since he was a first-year resident. When asked if ACOG practice bulletins set the standard of care for gynecologists, he stated, "No, absolutely not." He stated that they are merely guidelines. (Hrg. Tr., pp. 272-273)

105. Dr. Bear responded to a statement from Dr. Ritter that it was possible no further surgeries were conducted on Patient A because Patient A had a post-operative ileus, which is the intestines shutting down. He stated that even if Patient A had an ileus, an ileus usually resolves within a few weeks and would not have prevented Dr. Johnson from doing an additional procedure, if he suspected additional cancer was present. (Hrg. Tr., pp. 285-287)

106. Dr. Bear stated that cancer would be on a differential list when a gynecologist sees a postmenopausal woman with a pelvic mass and an elevated CA 125. However, he said where it would be on the differential list would depend on what the radiologic findings are, as well as on how mobile the mass is. (Hrg. Tr., pp. 288-289)

Dr. Ritter

107. Dr. Ritter has been a physician for 30 years, is a gynecologist in Baltimore, Maryland, where she is the director of minimally invasive surgery at a community hospital. Dr. Ritter routinely treats patients with symptoms similar to Patient A's. (Hrg. Tr., pp. 119-120, 138)

108. Dr. Ritter testified that, in her professional opinion,[13] the minimum standards of competence required that a gynecologic oncologist be on call in circumstances such as those presented to Dr. Cavanaugh at his first appointment with Patient A. Her opinion was based on her belief that gynecologists follow the ACOG guidelines and these guidelines state there are better outcomes when gynecologic oncologists are involved. She also stated that while a gynecologist can do the hysterectomy and remove the ovaries and fallopian tubes, the lymph node dissection is what requires a gynecologic oncologist's expertise to obtain. (Hr. Tr., pp. 126-27, 134, 139)

109. Based on her experience, she did not believe that Patient A's situation was so urgent that she could not have been referred to Madison, Marshfield or Milwaukee. (Hrg. Tr., p. 135)

110. Dr. Ritter suggested that the chemotherapy and radiation Patient A received could have eliminated any cancer that remained in Patient A after the surgery. She also suggested that one possibility that no further procedures were conducted on Patient A was that she had post-operative conditions which prevented such procedures, such as an ileus, anemia, a hernia and pain. (Hrg. Tr., pp. 142-143, 149-150)

Dr. Gifford

111. When asked if it would have been statistically preferable in terms of outcome to have a gynecologic oncologist rather than a general surgeon stage Patient A's procedure, Dr. Gifford stated that he disagreed. The rationale for his opinion was that based on statistics he has reviewed, there are differences between gynecologic oncologists, differences between general

[13]Unlike Drs. Giles, DuBeshter and Bear; Drs. Ritter, Gifford and Cavanaugh did not state their opinions regarding the standard of care to a reasonable degree of medical certainty or probability.

surgeons, and differences between gynecologic oncologists and surgeons and that the question is whether the proper procedures were done. (Gifford Tr., p. 22)

Dr. Cavanaugh

112. Dr. Cavanaugh believed that he complied with minimum standards of competency as a gynecologist and did not subject Patient A or the public to any unacceptable risk of harm. (Hrg. Tr., p. 237)

DISCUSSION

Burden of Proof

The burden of proof in disciplinary proceedings is on the Division to show by a preponderance of the evidence that the events constituting the alleged violations occurred. Wis. Stat. § 440.20(3); *see also* Wis. Admin. Code § HA 1.17(2). To prove by a preponderance of the evidence means that it is "more likely than not" that the examined action occurred. *See State v. Rodriguez*, 2007 WI App. 252, ¶ 18, 306 Wis. 2d. 129, 743 N.W.2d 460, citing *United States v. Saulter*, 60 F.3d 270, 280 (7th Cir. 1995).

Allegation of unprofessional conduct

Wisconsin Admin. Code § Med 10.02(2)(h)[14] defines unprofessional conduct to include "[A]ny practice or conduct which tends to constitute a danger to the health, welfare, or safety of patient or public." In interpreting this language, the Wisconsin Supreme Court has stated that "unprofessional conduct" is conduct which does not meet the level of minimal competence using accepted medical standards and which poses an unacceptable risk to the health, welfare or safety of the patients. *Gilbert v. Medical Examining Board*, 119 Wis. 2d 168, 196, 349 N.W.2d 68 (1984).

The Division's position is that it was unprofessional conduct for Dr. Cavanaugh to fail to have a gynecologic oncologist present or at least on call for the September 24, 2012 surgery for suspected gynecologic cancer in Patient A. The Division has not met its burden of establishing by a preponderance of the evidence that the minimal standards of competency required Dr. Cavanaugh to arrange for the presence of a gynecologic oncologist for Patient A's surgery or that failing to make such arrangements created an unacceptable risk to the health, welfare or safety of Patient A or the public.

Dr. Cavanaugh's conduct met levels of minimal competence for gynecologists.

Dr. Cavanaugh's conduct prior to surgery

The undisputed evidence is that Dr. Cavanaugh's primary diagnosis prior to commencement of surgery was a benign uterine fibroid. This determination was based primarily on his conversation with the radiologist who reviewed the report. There is no dispute that the radiologist, while reviewing the ultrasound results, informed Dr. Cavanaugh that he believed Patient A had a pedunculated uterine fibroid, with central degeneration within the fibroid. Dr.

[14]All references to provisions in Chapter Med 10 of the Wisconsin Administrative Code are to the provisions in effect at the time of the alleged conduct in 2012.

Cavanaugh conveyed this information to Patient A and his contemporaneous notes reflect the conversation with the radiologist. There is no dispute that over 99 percent of uterine fibroids are benign. There is also no dispute that an ultrasound is the "gold standard" for evaluating a pelvic mass such as that found in Patient A. Dr. Cavanaugh's observation during his physical examination that the mass was not fixed, but mobile, also supported the conclusion that the mass was benign.

That Patient A was postmenopausal with a highly elevated CA 125 did not require that Dr. Cavanaugh's primary diagnosis be cancer. An elevated CA 125 is not a specific diagnostic indicator for cancer. The only FDA-approved use of the CA 125 is to monitor a patient with known ovarian cancer. Even if an elevated CA 125 is more indicative of cancer in a postmenopausal woman, such elevation can occur for a host of reasons, including fibroids. Thus, the elevated CA 125 was not inconsistent with the conclusions of the radiologist and Dr. Cavanaugh that Patient A had a benign mass.

The radiologist report likewise did not require that Dr. Cavanaugh's primary diagnosis be cancer. Although the report stated that a clear plane between the uterus and the mass could not be distinguished, that the mass could be uterine or ovarian in origin, and that there was moderate free fluid in the pelvis, the record does not establish that these factors were obvious, or even particularly strong, indicators of cancer. Dr. Cavanaugh believed the report was sufficiently ambiguous that he contacted a radiologist for further interpretation. He then made his diagnosis based on all of the information, including the interpretation of a radiologist, who is presumably more fluent in interpreting ultrasound results than a gynecologist.

Despite Dr. Cavanaugh's belief and the radiologist's interpretation that the mass was a fibroid, and despite the overwhelming statistics that fibroids are benign, Dr. Cavanaugh nevertheless made arrangements to have a gynecologic oncologist available. He believed that Dr. Jenison, who Bellin was in the process of recruiting, would be available. He only found out a week before the scheduled surgery that Dr. Jenison was not available. Patient A was in "excruciating" pain and had expressed a strong desire to have the painful mass removed as soon as possible. Believing that the mass was most likely benign, and aware of Patient's A's pain level and her wishes, he then did what was the protocol in Bellin when cancer was not strongly suspected, he contacted one of Bellin's general surgeons, Dr. Gifford, and made sure Dr. Gifford was available.

Dr. Gifford had conducted staging procedures numerous times, was someone with whom Dr. Cavanaugh had performed prior surgeries and whose expertise Dr. Cavanaugh trusted. Dr. Cavanaugh's trust in Dr. Gifford was warranted, as the overwhelming evidence in this case indicates that Dr. Gifford did everything he should have done for Patient A, even according to a highly experienced and qualified gynecologic oncologist, who said he would have done exactly what Dr. Gifford did, had he been standing next to Dr. Cavanaugh. Indeed, following the surgery by Drs. Cavanaugh and Gifford, no additional surgeries were performed on Patient A, no additional tissues or nodes or samples taken from her, and no further washings were conducted, even after obtaining second pathology opinions from Johns Hopkins and UW-Madison Hospital. Patient A is currently cancer free.

Dr. Giles' opinion was that once Dr. Cavanaugh discovered that Dr. Jenison was not available, it fell below the minimal standards of competency to proceed with a general surgeon rather than having a gynecologic oncologist present or on call. Dr. Ritter agreed with Dr. Giles. As a preliminary matter, I note that Patient A signed an informed consent form for the surgery,

even after Dr. Cavanaugh informed her that the gynecologic oncologist was not available and that he would have a general surgeon available should he require the general surgeon's assistance.

However, even without the informed consent, the Division has failed to meet its burden. First, and foremost, the opinion testimony of Dr. Giles (and that of Dr. Ritter, to the extent it was offered as expert testimony) is outweighed by that of Drs. DuBeshter and Bear, both of whom stated opinions to the contrary. Not only was their reasoning more persuasive than that of either Dr. Giles or Dr. Ritter, but their relevant experience was far more extensive than that of Dr. Giles. Dr. Giles specializes in pelvic reconstruction, does not currently see patients suspected of cancer and has had comparatively little experience with patients with Patient A's condition. Unlike Drs. Giles and Ritter, Dr. DuBeshter actually is a gynecologic oncologist and has staged thousands of patients with conditions like Patient A's. The professional opinions of Drs. DuBeshter and Bear were supported by the opinions of Drs. Gifford and Cavanaugh, both of whom also have more experience than Dr. Giles in treating patients such as Patient A.

Also, Dr. Giles' opinion presumes that Dr. Cavanaugh's primary diagnosis of a benign tumor was unreasonable. However, the evidence simply does not show that it fell below levels of minimal competency for Dr. Cavanaugh to have a benign fibroid as his primary diagnosis prior to surgery. Dr. Giles himself conceded that if the radiologist who spoke with Dr. Cavanaugh were correct that it was a pedunculated fibroid mass, it would not have been necessary to make arrangements to have any kind of gynecologic oncologist present. He further agreed that it would be a waste of time and resources to have a gynecologic oncologist present under such circumstances. There was insufficient evidence showing that the standard of care required Dr. Cavanaugh to reject the conclusion of the radiologist. Thus, to the extent the Division's allegation of unprofessional conduct rests on the assumption that the primary diagnosis should have been cancer, the Division's claim fails. Because Dr. Cavanaugh's belief that the mass was benign did not fall below the level of minimal competence, it likewise did not fall below those standards to proceed to surgery with the availability of Dr. Gifford rather than a gynecologic oncologist.

Even if cancer should have been the primary diagnosis, the Division has not met its burden of establishing that the level of minimal competency required the participation of a gynecologic oncologist in staging under the circumstances here. The convincing testimony of Drs. DuBeshter and Bear was that, even if preferable, it was not required.

In addition, both the opinions of Dr. Giles and Dr. Ritter appear to have been based primarily on the ACOG publications, which, as indicated by the publications themselves, and as testified to by Drs. DuBeshter and Bear, do not represent the standard of care but are guidelines only. The bulletins explicitly state: "These *guidelines* should not be construed as dictating an exclusive course of treatment or procedures. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice." (Emphasis added) The opinion likewise states: "This information should not be construed as dictating an exclusive course of treatment or procedure to be followed."

Even without these disclaimers, however, the language relied upon by the Division simply does not establish that levels of minimal competency required Dr. Cavanaugh to have a gynecologic oncologist available for Patient A's surgery.

ACOG Practice Bulletin Number 65 is entitled, "Management of Endometrial Cancer." Here, cancer was not the primary diagnosis prior to surgery, and Dr. Cavanaugh did not know it was any type of gynecologic cancer until he had received the results of the frozen sections. The language relied on does not say that wherever there is any suspicion of gynecologic cancer, the standard of care requires that a gynecologic oncologist be involved in staging. The guidelines at issue appear to presume the presence of, or at least a strong suspicion of, endometrial cancer. That was not the situation here prior to surgery. Moreover, the heading of the language relied on shows that a standard of care is not being discussed as it states only: "Which patients *may* benefit from referral to gynecologic oncologist?"

Finally, even if cancer is presumed, the language relied upon contains so many contingencies that it barely constitutes even a recommendation, much less a standard of care. The language states: *"When it is practical and feasible, preoperative consultation* with a physician with advanced training and demonstrated competency *such as a gynecologic oncologist may be recommended."* First, involvement of such a specialist must be "practical and feasible." The record does not establish by a preponderance of the evidence that a week prior to the scheduled surgery, it was "practical" or "feasible" to get a gynecologic oncologist on board for surgery, particularly given that: (1) Dr. Cavanaugh reasonably did not believe this to be cancer; (2) Patient A was in extreme pain and had informed Dr. Cavanaugh that she wanted the surgery as soon as possible (and there is no indication in the record how long it would have taken to get a gynecologic oncologist on board for surgery); and (3) Bellin did not have a gynecologic oncologist on staff and Dr. Cavanaugh's prior experience with attempting to get assistance from one did not always go smoothly (in fact, on at least one occasion, he had to wait hours in the surgery room with the patient opened up and under anesthesia).

Second, the language recommends only "preoperative consultation," not staging, by such a specialist. Third, the recommendation not only includes a gynecologic oncologist, but also a "physician with advanced training and demonstrated competency," which it appears describes Dr. Gifford. Fourth, consultation with such a specialist is not required but only "may be recommended."

The Practice Bulletin on adnexal masses also fails to establish the standard of care advanced by the Division. As stated, it explicitly states that it does not establish the standard of care. Also, following Dr. Cavanaugh's conversation with the radiologist, it was not clear prior to surgery that Patient A had an adnexal mass. Rather, Dr. Cavanaugh believed it to be a uterine mass. More importantly, none of the language in the bulletin relied upon by the Division establishes by a preponderance of the evidence that Dr. Cavanaugh's conduct of proceeding to surgery with Dr. Gifford rather than a gynecologic oncologist fell below the level of minimal competency. The Division relied on this bulletin to show that, despite Dr. Cavanaugh's conversation with the radiologist, his primary diagnosis should have been cancer based on a pelvic mass in a postmenopausal woman with a highly elevated CA 125. As a result, the Division argues, minimal standards of competency required Dr. Cavanaugh to have a gynecologic oncologist available for staging.

The Division relies in part on the bulletin's language stating that extreme values of a CA 125 "can be helpful" in predicting cancer risk for postmenopausal women, and that for both postmenopausal and premenopausal women, "a markedly elevated CA 125 level raises a much greater concern for malignancy, even though women with benign conditions such as endometriosis can have CA 125 level elevations of 1,000 units/mL or greater." Dr. Cavanaugh's testimony indicates that he was well-aware that the risk for malignancy is higher in

postmenopausal women. Moreover, neither this language nor any other language from the ACOG publications addresses the situation here, where despite the elevated CA 125, a radiologist interpreting the ultrasound informed Dr. Cavanaugh that he believed the mass was a uterine fibroid, more than 99 percent of which are benign, and a physical examination revealed that the mass was mobile, also indicating a benign mass. In addition, the language also undermines the Division's position in that it shows that highly elevated CA 125 levels may occur even with benign conditions.

Also, the bulletin contains other language that cuts against the Division's position. For example, it states that the CA 125 has a low sensitivity because the CA 125 level is frequently elevated in many commonly encountered clinical conditions. In fact, the bulletin states that "the CA 125 level is elevated on only one half of early stage epithelial ovarian cancers."

The fact that the bulletin goes on to state that the sensitivity and specificity is "highest" after menopause does not mean that Dr. Cavanaugh violated the levels of minimal competence by not having a primary diagnosis of cancer prior to surgery or by failing to have a gynecologic oncologist available for surgery. This is especially true where Patient A had undergone an ultrasound, which is the "gold standard" for evaluating a pelvic mass, and Dr. Cavanaugh had received a radiologist's interpretation of the ultrasound indicating that the mass was a pedunculated uterine fibroid.

Other language from this bulletin is neutral at best in terms of which position -- the Division's or Respondent's -- it supports. For example, the bulletin lists factors indicating that a referral to a specialist is warranted. For postmenopausal women, one of the indicators is ascites, which is free fluid in the pelvis. Patient A had a moderate amount of free fluid in the pelvis, which Dr. Giles stated is not typically associated with fibroids. Another indicator for referral, however, is a nodular or fixed pelvic mass. According to Dr. Cavanaugh, Patient A's mass was not fixed, but moved.

The Division also relied on language from this bulletin for the proposition that women referred to a gynecologic oncologist have better outcomes than those who are not. As a preliminary matter, the recommendation is a "Level C" recommendation, the weakest in quality. In addition, as with the other bulletin, the recommendation is not exclusively for a "gynecologic oncologist," but also includes "a physician who has advanced training and expertise in the treatment of women with gynecologic cancer," which Dr. Gifford had. Most significantly, however, "better outcomes" is not the applicable standard in this disciplinary proceeding. Rather, the Division has the burden of establishing by a preponderance of the evidence that failure to have a gynecologic oncologist to stage Patient A's surgery, under the circumstances as they existed, fell below levels of minimal competency and created an unacceptable risk to Patient A or the public's health, safety or welfare. Failing to get the best or a better outcome does not equate to a failure to meet levels of minimal competency or to an unacceptable risk.

The Division's reliance on the ACOG Committee Opinion is equally unavailing. This Opinion states: "When a patient with a suspicious or persistent complex adnexal mass required surgical evaluation, a physician trained to appropriately stage and debulk ovarian cancer, such as a gynecologic oncologist, should perform the operation." As previously noted, following his conversation with the radiologist, Dr. Cavanaugh reasonably believed that the mass was not cancerous. Moreover, even if ACOG publications represented the standard of care, again, the recommendation is not exclusively for a gynecologic oncologist, but also includes a "physician trained to appropriately stage and debulk ovarian cancer." The evidence shows that Dr. Gifford

was such a physician, especially the testimony of Dr. DuBeshter, a gynecologic oncologist who stated that he would have performed the same procedures as Dr. Gifford and that, under the circumstances here, it was not below levels of minimal competency for Dr. Cavanaugh to arrange to have Dr. Gifford to assist him rather than a gynecologic oncologist.

The Opinion further states:

> When physical examination and imaging techniques have detected the presence of a pelvic mass that is suspicious for a malignant ovarian neoplasm, the presence of at least one of the following indicators warrants consideration of referral to or consultation with a physician trained to appropriately stage and debulk ovarian cancers such as a gynecologic oncologist: Postmenopausal woman: elevated CA 125 level, ascites, a nodular or fixed pelvic mass or evidence of abdominal or distant metastasis.

Again, this language does not establish that a gynecologic oncologist was required. First, the physical examination and imaging techniques did not make Dr. Cavanaugh's primary diagnosis cancer, but rather, a benign fibroid. Second, even with the suspicion of cancer, the opinion does not state that a gynecologic oncologist is required for staging, only that referral "or consultation" "warrants consideration." Finally, the recommendation is not exclusively for a gynecologic oncologist but also includes "a physician trained to appropriately stage and debulk ovarian cancers." The record does not show that Drs. Cavanaugh and Gifford did not appropriately stage and debulk the cancer once it was detected.

In sum, the facts of record do not show that the Division met its burden of establishing that, prior to surgery, Dr. Cavanaugh failed to meet levels of minimal competence by having Dr. Gifford, rather than a gynecologic oncologist, on call for the staging and surgery of Patient A.

Dr. Cavanaugh's conduct during the surgery

Even if it was not unprofessional conduct for Dr. Cavanaugh to begin the surgery without ensuring the availability of a gynecologic oncologist, the Division states that it was unprofessional conduct for Dr. Cavanaugh to continue the surgery with a general surgeon rather than a gynecologic oncologist after Dr. Cavanaugh inserted the scope with the camera and observed involvement of the ovary. The Division notes that, at that point, there was only a small incision made, and Dr. Giles stated that, at that point, Dr. Cavanaugh should have sewn up Patient A and referred her to a gynecologic oncologist. It is undisputed, however, that at the point he put the scope in, it was ambiguous as to whether cancer was present. It was for this reason that Dr. Cavanaugh sent tissues and washings to pathology for cancer testing.

Also, I find credible and convincing the testimony of Drs. DeBeshter and Bear that staging with a competent general surgeon was completely appropriate here. Their opinions that Dr. Cavanaugh's conduct was appropriate applied to all aspects of his treatment of Patient A. Dr. DuBeshter also credibly testified that it is probably the majority of hospitals in the country which do not have gynecologic oncologists on staff, and that there are many instances, even in his own area of the country, where a general surgeon will stage the cancer in a situation like Patient A's. Similarly, Dr. Bear credibly testified that he has used general surgeons in Milwaukee for these types of procedures when gynecologic oncologists were not available, even when there are gynecologic oncologists on staff.

In addition, Dr. DuBeshter credibly testified that even after seeing the results of the frozen sections indicating ovarian cancer, it was appropriate for Dr. Cavanaugh to proceed with surgery with Dr. Gifford completing the staging. Dr. DuBeshter stated that these doctors were prepared to do the right surgery for Patient A and had been doing similar procedures for years, and that he would not subject the patient to the unknown delay and further anesthesia involved in having her see another specialist and have another surgery. He also believed the same procedures would have been done had there been a gynecologic oncologist to do it. The evidence overwhelmingly showed that these two doctors did the right procedures with respect to Patient A, and that no further procedures were required or indicated.

Finally, for many of the same reasons discussed above, the ACOG publications likewise do not show that, at any point during surgery, levels of minimal competency required Dr. Cavanaugh to enlist a gynecologic oncologist for staging.

Based on the foregoing, the Division has failed to meet its burden that Dr. Cavanaugh's conduct, either prior to or during surgery, did not conform to levels of minimal competency for gynecologists.

Dr. Cavanaugh's conduct did not create an unacceptable risk to the health, welfare or safety of Patient A or the public.

Dr. Giles testified that, by not having a gynecologic oncologist available for surgery, Patient A was at an "increased risk" of needing future surgery for staging and that, if staging is incorrect or incomplete, a patient is placed at an "increased risk" of having her life span unnecessarily reduced. The Division also produced evidence that, statistically, there are "better outcomes" when gynecologic oncologists are involved in staging than without them. However, neither "increased risk" nor "better outcomes" is the standard for these proceedings. Rather, the Division was required to show an "unacceptable risk." The Division failed to specifically elicit such testimony, nor does the testimony establish that the risks were unacceptable under the circumstances here.

Dr. DuBeshter credibly testified that Dr. Cavanaugh's conduct with respect to Patient A's care was "totally appropriate surgical management that [Patient A] would have received in any number of centers across the country." When asked if Dr. Cavanaugh's treatment of Patient A posed an unacceptable risk of harm to her or to the public's health, welfare or safety, he credibly responded, "Absolutely not." Dr. Bear also credibly testified that there was no act or omission in Dr. Cavanaugh's treatment of Patient A that posed an unacceptable risk of harm to the health, welfare or safety of Patient A or the public.

The Division stated in its closing argument that an "unreasonable" risk is simply one that is "unnecessary." No authority was offered in support of that interpretation, and after researching the subject, I have not found such authority. If anything, the primary case on the standard of care, *Gilbert*, undermines this position. *See Gilbert*, 119 Wis. 2d at 200 ("That more aggressive measures to restore blood circulation and blood pressure were 'probably more appropriate' do not indicate that Gilbert's treatment constituted incompetence or presented unacceptable risks to [the patient's] health.")

For these reasons and for many of the reasons explained in discussing minimal competency, above, the Division has not met its burden of establishing that Dr. Cavanaugh's conduct created an unacceptable risk to the health, welfare or safety of Patient A or the public.

As a result, the Division has not established that Dr. Cavanaugh engaged in unprofessional conduct with respect to his treatment of Patient A.

CONCLUSIONS OF LAW

The Division has not met its burden of establishing by a preponderance of the evidence that Dr. Cavanaugh failed to meet levels of minimal competency in gynecology or that he posed an unacceptable risk to the health, welfare or safety of Patient A or the public by failing to have a gynecologic oncologist available for Patient A's staging and instead having Dr. Gifford, a general surgeon, assist with Patient A's staging.

ORDER

For the reasons set forth above, IT IS ORDERED:

The Division's complaint against Dr. Cavanaugh is dismissed, effective the date the final decision in this matter is signed by the Board.

Dated at Madison, Wisconsin on October 13, 2014.

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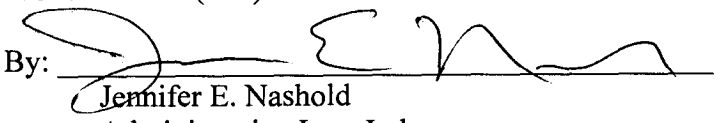
By: 

Jennifer E. Nashold
Administrative Law Judge