STATE OF FLORIDA DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH,)		
BOARD OF MEDICINE,)		
Petitioner,)		
)		
VS.)	Case No.	02-0340PL
)		
ALEXANDER D. J. BRICKLER, III,)		
M.D.,)		
)		
Respondent.)		
)		

RECOMMENDED ORDER

Notice was provided and on July 17 through 19, 2002, a formal hearing was held in this case. Authority for conducting the hearing is set forth in Sections 120.569 and 120.57(1), Florida Statutes. The hearing location was the Office of the Division of Administrative Hearings, Tallahassee, Florida. The case was held before Charles C. Adams, Administrative Law Judge.

APPEARANCES

For Petitioner: Robert C. Byerts, Esquire

Kim M. Kluck, Esquire Department of Health

4052 Bald Cypress Way, Bin C-65 Tallahassee, Florida 32399-3265

For Respondent: David W. Moye, Esquire

Linda Loomis Shelley, Esquire

Fowler, White, Boggs and Banker, P.A.

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STATEMENT OF THE ISSUE

Should Petitioner discipline Respondent's license to practice medicine?

PRELIMINARY STATEMENT

By an Amended Administrative Complaint in Case No. 1999-56830, before the State of Florida, Department of Health, Respondent is accused of failing to practice medicine with the level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances in the treatment of patient A.G. by performing a LEEP/Conization on patient A.G. in violation of Section 458.331(1)(t), Florida Statutes. Petitioner questions the performance of this procedure on A.G., rather than patient N.C. who was scheduled for the procedure, having failed to identify A.G. before performing the procedure intended for N.C. The Amended Administrative Complaint was filed with the Department of Health on December 18, 2001. Consistent with his opportunities Respondent elected to contest the facts that underlie the Amended Administrative Complaint through a formal hearing. On January 25, 2002, the case was received by the Division of Administrative Hearings. The case was assigned and heard on the dates stated.

CASE HISTORY

Various motions were made seeking official recognition of Sections 458.331, 464.003 and 464.012, Florida Statutes, together with Rule 64B8-8.001, Florida Administrative Code. requests were granted by written order and through rulings announced at the hearing, as transcribed. Official recognition of final orders entered by Petitioner in disciplinary cases were ruled on through a written order or as noted in the hearing record, subject to the opportunity for the parties in the course of proposed recommended orders to argue the issue of the relevance of those decisions to the present case as precedent for imposing discipline. Official recognition was provided in a written order concerning the case of Alexander D.J, Brickler, M.D., Plaintiff vs. Florida Department of Health, Defendant, Case No. 01-CA-2244, in the Circuit Court in and for Leon County, Florida, in relation to an order on a motion to dismiss. in limine concerning conduct of the final hearing were ruled on by written order. Petitioner's motion to offer a further amendment to the Amended Administrative Complaint by relinquishment of jurisdiction to the Board of Medicine for that purpose was denied by written order. A written order was entered ruling on the affirmative defenses raised by Respondent in addressing the Amended Administrative Complaint. Respondent's Motion to strike the use of Drs. Zelnick, Fojo, and Kast as

witnesses was denied by written order. Shortly before hearing,
Respondent moved to dismiss the Amended Administrative Complaint.
That motion was denied as reflected in the hearing transcript.
Petitioner's Motion to Deem Admitted the allegations set forth in paragraphs 2 and 3 to the Amended Administrative Complaint was granted as reflected in the hearing transcript.

At final hearing Joint Exhibits numbered 1 through 4 were received. Petitioner's Exhibits numbered 1 through 3 were received. Video depositions and transcripts of Roberto Fojo, M.D., and Edward Zelnick, M.D., are Petitioner's Exhibits numbered 2 and 3 respectively. Those depositions are received in their entirety. Respondent's Exhibits numbered 1 through 3 were received.

In addition to the testimony of Drs. Fojo and Zelnick,

Petitioner presented Rolando Gomez, patient A.G.; patient A.G.'s

husband T.Q.; Patricia Charbonneau, R.N.; Katherine Turner;

Margaret Canter, Midwife/Family Nurse Practitioner; Jamie Martin,

R.N.; Dale Dunsmore, R.N.; Jean Mauch, C.R.N.A.; Valerie Lazzell,

M.D.; Woodward Burgert, M.D.; and Michelle McCallanahan, M.D.

Respondent testified in his own behalf and presented the testimony of Valerie Lazzell, M.D.; Diane Jordan, Surgical Technician; Jana Bures-Forsthoefel, M.D.; Kenneth McAlpine, M.D.; David O'Bryan, M.D.; and Roberto Morales, M.D.

The five-volume transcript was filed with the Clerk of the Division of Administrative Hearings on September 10, 2002.

Consistent with their opportunities the parties had timely filed proposed recommended orders by September 30, 2002. Those proposed recommended orders have been considered in preparing the Recommended Order.

FINDINGS OF FACT

- 1. At the times relevant to the inquiry Petitioner was the state agency charged with regulating the practice of medicine in Florida, pursuant to Section 20.43, Florida Statutes, and Chapters 456 and 458, Florida Statutes.
- 2. Respondent is and has been at all times material hereto a licensed physician within the state of Florida, having been issued license No. ME0045474, effective December 28, 1984.

 Respondent's last known address is 1401 Centerville Road, Suite 202, Tallahassee, Florida 32308.
- 3. Respondent is board-certified in obstetrics and gynecology. The board certification is by the American Board of Obstetrics and Gynecology. Respondent is a fellow of the American College of Obstetricians and Gynecologists.
- 4. Respondent received his undergraduate degree from Florida State University and his medical degree from Howard University. His training at Howard University included a four-year residency program from 1982 to 1986.

5. Respondent holds staff privileges at Tallahassee Memorial Hospital (TMH) in Tallahassee, Florida.

Patient A.G.

- 6. Patient A.G. began treatment with Respondent in 1998 and continues as Respondent's patient. A.G. is an Hispanic female who is not proficient in English. When seen by Respondent in his office she has been accompanied by an interpreter that would allow Respondent to discuss details of her health care in English for translation into Spanish for the patient's benefit. Respondent's understanding of Spanish is limited to education in high school and a year at the university. He has the ability to describe some matters that are pertinent to gynecologic practice or obstetric practice and in particular as it relates to telling patients, for example "how to push and when not to push." The record does not reveal that Respondent has the ability to discuss A.G.'s overall health care in Spanish, her language.
- 7. A.G.'s husband, T.Q., who accompanied her at relevant times principally spoke Spanish and not English. He is somewhat proficient in English.
- 8. On June 16, 1999, A.G. had an office appointment with Respondent. At that time A.G. had undergone gallbladder surgery but her pelvic pain persisted. In consultation on that day it was decided that A.G. would undergo diagnostic laparoscopy to explore the reason for her chronic pelvic pain. Through the

discussion the patient was told that biopsies of the pelvic anatomy might be performed during the procedure and that any problems that could be addressed through laparoscopy would be addressed as Respondent felt comfortable in carrying out that correction. Otherwise, Respondent said that he would "take pictures" and "get out of the case" with the decision to offer further treatment left for another time.

- 9. Patient A.G. had been referred to Respondent for her persistent pelvic pain following an examination on April 27, 1999, that had been made by Margaret Cantor, a Nurse/Mid-Wife and Registered Nurse. She conducted a pelvic examination of the patient that date. The examination included the use of speculum to examine the cervix and vagina in the interest of looking for abnormalities, lesions, growths, and discolorations. No cervical lesions were found in this examination. A pap smear taken at the time revealed normal results with some inflammation.
- 10. Diagnostic laparoscopy is a surgical procedure involving an incision in the abdominal wall through which a scope is inserted to visualize the abdominal cavity. Typically the workup for performing a diagnostic laparoscopy would include use of ultrasound, pelvic examination, and a pap smear. Possible complications in this procedure include vascular injury, bowel injury, bladder injury, infection, and bleeding. Preliminary to the diagnostic laparoscopy it is the custom and practice in the

medical community to perform a vaginal examination with the use of a speculum.

- 11. On July 1, 1999, patient A.G. was seen by the Respondent in his office for her pre-operative check. On this occasion A.G. was unaccompanied by a translator. Nonetheless, Respondent was able to perform a brief physical and obtain a history with the assistance of A.G.'s husband. Respondent listened to the patient's heart and lungs and performed a bi-manual examination in which one or two fingers were inserted in the vagina and with a hand on the abdomen compression was performed on the pelvic viscera, uterus, tubes, and ovaries and the lower section of the pelvis. Nothing significant was observed in the patient since last seen.
- 12. On July 1, 1999, an employee in Respondent's office witnessed patient A.G. sign a consent form allowing the diagnostic laparoscopy. The consent form makes no reference to the agreement for Respondent to perform a loop electrocautery excision procedure, referred to by abbreviations as a "LEEP" conization biopsy procedure or a LEEP cone. No evidence of such consent is contained in patient A.G.'s medical records maintained at Respondent's office.
- 13. The diagnostic laparoscopy was to be performed at TMH.

 On July 1, 1999, Patricia Charbonneau, a clinical nurse at the hospital, reviewed a consent form with patient A.G. concerning

the diagnostic laparoscopy for the purposes of that facility.

Nurse Charbonneau was aware of the scheduling of the diagnostic laparoscopy by reference to the history and physical prepared by the Respondent. This conference involved the discussion of potential risks and complications of the laparoscopy. No discussion was conducted concerning possible risks and complications of a LEEP conization biopsy.

- and the diagnostic laparoscopy stated "If any unforeseen condition arises and additional surgery is deemed medically necessary during my procedure, I request and authorize my physician to proceed." Nurse Charbonneau was left with the impression that the patient understood the explanation concerning the upcoming procedure and gave her consent. Ms. Charbonneau was assisted in this communication by A.G.'s husband. No discussion was held concerning the performance of a LEEP cone biopsy, in that the permit from Respondent made no mention of that procedure. Ms. Charbonneau took steps for an interpreter to be available the next morning when the surgery was to be performed given the nature of the surgery, the use of anesthesia and the desire to have "everything" reviewed again.
- 15. A LEEP conization is a form of biopsy performed either in an office or hospital setting with anesthesia. The cervix is examined with the assistance of a speculum. Lugol solution is

placed on the cervix to identify any abnormal cells and an excession is made by shaving a small piece of the cervix for examination. The workup for LEEP conization includes a pap smear and a colposcopy. The performance of LEEP conization presents potential risks and complications related to infection, endometrious, bleeding, cervical stenosis, and cervical incompetence.

- 16. On July 2, 1999, patient A.G. came to the TMH outpatient surgery center for her scheduled diagnostic laparoscopy to be performed by Respondent. She was the fourth patient on a schedule of surgeries to be performed by Respondent on that date. Respondent was conversant with the sequence of surgeries to be performed.
- 17. Patient A.G. was placed in a holding area in the outpatient surgery center to prepare her for her surgery and to await transport to the operating room. Sometime before moving the patient to the operating room Respondent saw the patient in the holding area. Respondent addressed patient A.G. by saying hello and asking her how she was doing. This was not a visit intended to educate the patient and was not involved with any other medical purpose. At the time the patient's husband was with her during this brief encounter which was intended to confirm that the patient was there for the surgery as had been previously arranged. Several hours may have passed between the

time Respondent saw patient A.G. in the holding area and when he next encountered the patient in the operating room.

- 18. Respondent also saw patient N.C. in an adjacent cubicle to where patient A.G. was located while the patients were awaiting their surgery. Patient N.C. was the third patient on the schedule, there for the performance of a LEEP conization biopsy.
- 19. Respondent followed his surgical schedule for the first two patients in the intended sequence. Some delay was occasioned by a problem experienced in the surgery performed on the second patient.
- 20. Valerie Anne Lazzell, M.D., is an anesthesiologist licensed to practice in Florida. She is employed by Anesthesiology Associates of Tallahassee, Florida. It was intended that she provide anesthesia during Respondent's performance of the diagnostic laparoscopy for patient A.G. It was anticipated that the patient be subjected to general anesthesia which involves a rapid loss of consciousness and blocks the sensory, mental and motor functions of the patient. A general anesthesia can be provided by using an endotracheal tube, with a mask or with an LMA. This is as distinguished from the use of a neurolept employed in most instances when performing LEEP conization biopsies. In that setting the patient is generally anesic, not really aware, and has analgesia "on board."

The use of a neurolept promotes a pain-free state of immobility and an insensitivity to pain and is usually accomplished by use of IV medications.

- 21. From the record, it appears that Jean Mauch, C.R.N.A., with Anesthesiology Associates was scheduled to provide anesthesia by neurolept for the third patient N.C. who was scheduled for LEEP conization biopsy.
- 22. Patient A.G. at the time in question was 4'9" tall and weighed 103 pounds. Patient N.C., an African-American woman was 5'2" tall and weighed 242 pounds. Their skin tone was similar in color.
- 23. Dr. Lazzell saw patient A.G. before the patient was taken for surgery. In this examination the doctor filled out the patient's airway, listened to her heart and lungs, and considered the patient's ASA classification which was one of good health. Dr. Lazzell considered the plan for anesthesia with an endotracheal tube. She gained the assistance of a Dr. Becker who was fluent in Spanish in explaining the use of anesthesia to the patient. Dr. Lazzell sought Dr. Becker's assistance when the hospital did not make an interpreter available. Dr. Lazzell discussed the possible risks and complications of use of this form of anesthesia and a consent form was signed and dated. While this assessment was being made A.G.'s husband was in attendance. It was Dr. Lazzell's expectation that the patient

- A.G. would next be seen as scheduled when the nurse anesthetist called Dr. Lazzell to the operating room to intubate patient A.G. in association with the provision of anesthesia for the diagnostic laparoscopy.
- 24. Jean Mauch, C.R.N.A., when performing her duties in the operating room setting at TMH outpatient surgery center was expected to induce anesthesia, maintain the anesthesia, monitor vital signs, treat untoward events during surgery and maintain fluids in the patient while under the supervision of the physician, in this instance, Dr. Lazzell.
- 25. Nurse Mauch was principally responsible for providing the anesthesia for the third procedure on patient N.C., the LEEP conization biopsy. This included preparation in the operating room of medications and other related tools and supplies. The third procedure, the LEEP conization biopsy for N.C., was referred to on a typed surgical schedule in the preoperative desk in the outpatient surgery center. Having checked the schedule Nurse Mauch obtained the chart for N.C. and went to the cubical, not of N.C. but A.G. When Nurse Mauch arrived at A.G.'s cubical, Jamie Martin, R.N., the pre-op nurse and Dale Dunsmore, R.N., the circulating nurse, were there. Nurse Dunsmore and Nurse Mauch arrived at the cubicle where patient A.G. was located at about the same time. When arriving at the cubicle for patient A.G.,

getting ready for the surgery to be performed on patient N.C. While in the cubical Nurse Mauch introduced herself to the person she believed to be the patient N.C., at which time Nurse Dunsmore said that the patient only speaks Spanish. Nurse Mauch recalls that a translator was not available for assisting in any communication with patient A.G. Realizing that Nurse Dunsmore was checking the armband for identification, the reference to the fact that the patient only spoke Spanish did not cause Nurse Mauch any concern. Nurse Mauch never heard Nurse Dunsmore orally refer to patient A.G. by name. Nurse Mauch continued with her presentation by commenting that she was the nurse anesthetist who was going to put the patient to sleep. Patient A.G. nodded her head in response to Nurse Mauch's physical gesture that the patient was going to be put to sleep. Beyond that point Nurse Mauch and Nurse Dunsmore took patient A.G. to the operating room ostensibly as the third patient on the schedule for provision of a LEEP conization biopsy wherein Nurse Mauch would provide the necessary anesthesia. The chart for N.C. was brought to the operating room.

- 26. Before the patient was removed from the cubicle Nurse Martin provided pre-op medication to patient A.G., phenergan robinul.
- 27. The fact that Nurse Martin was giving preoperative medication and that Nurse Dunsmore was checking the armband on

what turned out to be patient A.G. led Nurse Mauch to believe that patient A.G. was patient N.C. the third scheduled patient, according to Nurse Mauch.

28. As Nurse Mauch recalls, when the Respondent entered the operating room where the third scheduled procedure was to be performed he checked the chart for patient N.C. Respondent went out and washed his hands, returned and started the procedure. the end of the procedure Nurse Mauch recalls Respondent commenting that the next patient speaks only Spanish, to which Nurse Mauch said, "No, this patient," meaning the patient who had been subjected to the procedure is the one who speaks Spanish. Respondent replied "I must be mixed up." Nurse Mauch recalls Dr. Lazzell arriving at the door of the operating room with patient A.G.'s chart. Dr. Lazzell looked surprised to find the circumstances. Nurse Mauch told Dr. Lazzell that this is the neurolept, the case involving the LEEP conization biopsy. Dr. Lazzell commented that "No it isn't." Nurse Mauch heard Dr. Lazzell ask Respondent, "What procedure did you do?" Respondent replied "LEEP conization." Dr. Lazzell said "No, this was supposed to be the diagnostic laparoscopy." Nurse Mauch observed Respondent leave the room and return. Patient A.G. was re-preped and the diagnostic laparoscopy scheduled to be provided was performed with the patient being intubated by the use of an endotracheal tube.

- 29. Nurse Martin in her capacity as pre-op nurse was responsible for receiving patients and getting the patients ready for administering medications that were prescribed and getting IVs and things started on the patients prior to the patients being sent to the operating room. She recalls performing preoperative duties on the patient A.G. Nurse Martin was familiar with the schedule of patients, the sequence. She understood that patient A.G. was the fourth patient in the schedule and provided the pre-anesthetic to patient A.G. in preparation for the operation. This involved the use of phenergan. Nurse Martin made no mistake in identifying patient A.G. when providing care. Nurse Martin heard Nurse Dunsmore identify patient A.G. in Nurse Martin's presence and agreed with that identification. Nurse Martin had seen the patient A.G. before the occasion at which Nurse Mauch and Nurse Dunsmore were there with the patient in Nurse Martin's presence and the patient A.G. was taken to the operating room. Nurse Martin had reviewed patient A.G.'s chart earlier in caring forward responsibilities for preparing the patient for the operation.
- 30. Nurse Dunsmore identified her duties as circulating nurse at TMH outpatient surgery center as being related to setting up rooms for surgeries, transporting patients from pre-op holding areas, identifying patients, verifying surgeries, verifying allergies, and so forth. Ordinarily Nurse Dunsmore in

performing her duties would read the chart of the patient scheduled for a procedure to make certain that all permits were signed. She would then go to where the patient was being held, introduce herself to the patient and ask for identification, verifying the surgery that is scheduled for the patient, and perform other related assignments. In performing her duties

Nurse Dunsmore would accompany the patient with the anesthesiologist to the operating room. The method of identification in effect at the time in question would be to compare an addressograph card which accompanied the patient's chart with the information on an identification bracelet worn by the patient.

- 31. Nurse Dunsmore verified that the operating room for the third procedure was set up for a LEEP conization biopsy.
- Dunsmore recalls that she went to patient A.G.'s room. However Nurse Dunsmore had handed Nurse Mauch patient N.C.'s chart.

 Nurse Mauch carried the chart to patient A.G.'s cubicle. The two nurses essentially entered the cubicle together. Nurse Martin and patient A.G.'s husband were already there. Nurse Martin left the cubicle shortly thereafter. Nurse Dunsmore introduced herself to the patient and reached for the patient's identification bracelet and read it out loud. The patient smiled and nodded in response. In turn the patient's husband smiled and

nodded in response. Patient A.G. was then taken to the operating room by Nurse Dunsmore and Nurse Mauch. The patient was sedated by Nurse Mauch and positioned for provision of the LEEP conization biopsy.

- 33. Nurse Dunsmore observed the Respondent enter the operating room and look at the chart which was in relation to patient N.C., not patient A.G. Nurse Dunsmore saw Respondent leave the operating room to scrub. Nurse Dunsmore was in attendance when the procedure was performed. Nurse Dunsmore recalls Dr. Lazzell entering the operating room at the end of the procedure with the chart belonging to patient A.G. and the realization by those in attendance that the chart in the operating room was for N.C., whom they understood to be undergoing the procedure when in fact the patient undergoing the procedure was A.G.
- 34. Diane Jordan was a surgical technician assigned to assist in the third procedure, the LEEP conization biopsy. She recalls the patient being put to sleep by Nurse Mauch and the patient being prepared for the procedure. The patient was covered by draping towels across the upper portion of the thighs. A blanket was placed over the patient's torso. The patient was placed in the lithotomy position allowing observation of the patient's buttocks, vulva, vagina and external pelvic organs. The patient had a mask on her face and a surgical hat to cover

her hair. All of these arrangements had been made before
Respondent entered the operating room. Ms. Jordan recalls that
the chart in the room was for N.C., the patient anticipated to
undergo the LEEP conization biopsy. Ms. Jordan did not realize
that the patient in reality was patient A.G. Ms. Jordan recalls
that the Respondent when entering the room asked is this "such
and such" in relation to a LEEP conization biopsy and that Nurse
Dunsmore replied in the affirmative. Ms. Jordan remembers
Respondent looking at the chart for N.C. and signing it.
Ms. Jordan was in attendance while the procedure was performed.
Ms. Jordan heard Respondent mention something about a lesion
before he started. Ms. Jordan provided medication to be injected
during the LEEP conization. Ms. Jordan identified the fact that
a specimen was obtained which was given to her and provided to
the nurse to send to pathology for evaluation.

35. When Respondent entered the room for what he anticipated to be the third procedure what he asked specifically was "Is this Ms. C our case for the LEEP?" referring to the LEEP conization to be performed on patient N.C. That is when Nurse Dunsmore responded in the affirmative. After inquiring about the identification of the patient in association with the nature of the procedure Respondent expected to perform and in receiving an affirmative response, Respondent took no further steps to personally confirm the identity of the patient. Respondent

opened the chart that was patient N.C.'s chart. Respondent took a drawing from his pocket that a Dr. Thompson had made of patient N.C.'s cervix when he had treated the patient. The drawing was in association with a colposcopy. Respondent intended to compare that drawing with what was observed in the patient during the performance of the LEEP conization biopsy in locating the suspected pathology. In proceeding with what he considered to be the third scheduled procedure for N.C., Respondent placed the speculum, applied the tenaculum and observed what looked to be a lesion that roughly approximated what he anticipated it would be based upon the drawing from Dr. Thompson. Respondent applied Lugol's solution and proceeded with the LEEP conization biopsy. Having applied the solution there was an indication of some pathology in roughly the position as the drawing had depicted. Respondent obtained the sample from the cervix. The size of the specimen was less than the diameter of a dime with a depth or thickness of about two dimes.

36. The performance of the LEEP conization biopsy took less than five minutes. As Respondent finished Dr. Lazzell came to the operating room and informed Respondent that this was not the patient the he thought he was treating. Having been told by Dr. Lazzell that there was a misidentification, Respondent for the first time while engaged with the patient in the operating room proceeded to the front of the table and looked at the

patient while the patient was being unmasked. By doing so Respondent discovered that indeed the patient had been misidentified and that he had actually performed surgery on patient A.G., not patient N.C. Respondent left the operating room and informed patient A.G.'s husband of the problem. Respondent returned to the operating room. The patient was provided anesthesia by Dr. Lazzell and the diagnostic laparoscopy that was scheduled was performed.

37. Notwithstanding that it was never intended that Respondent perform a biopsy on patient A.G. from the cervix, Respondent expresses the opinion that if the physician encounters a visible lesion some form of biopsy is in order. Respondent expresses the opinion that in performing procedures such as a diagnostic laparoscopy greater latitude is afforded in terms of what the physician can do when he or she discovers "What's amiss with the patient." This in Respondent's view is because the patient is going into the procedure with the understanding that there may be an unanticipated problem and if the unexpected problem can be addressed, it should be taken care of. Of course this assumes that the biopsy that was performed on patient A.G. was in association with the scheduled diagnostic laparoscopy, when in fact the biopsy was the product of happenstance, in that, Respondent when addressing what he considered to be the condition in the patient N.C., by chance observed a similar condition in

the patient A.G. Respondent concedes that prior to patient A.G.'s arrival at the outpatient surgical center that LEEP conization was not an indicated procedure for that patient. The biopsy that was performed was with the misapprehension as to the patient whose needs were being addressed, not merely an unanticipated circumstance in a patient whose identity was established when Respondent performed the biopsy. This was not an additional surgical procedure that came about in connection with the scheduled diagnostic laparoscopy; it was perceived by Respondent as the intended surgery being performed on a different patient when the case began. As a consequence it is the plannedfor diagnostic laparoscopy which became the additional procedure. Nonetheless, Respondent tries to explain his result by expressing the opinion that other unexpected and unplanned-for procedures may be undertaken in the instance "Within the realm of the comfort level of the physician and the patient ahead of time; where they know each other, other things can be done as well." Respondent believes that the ability to proceed with the biopsy on patient A.G. while thinking that he was responding to the case involving patient N.C. is implicit and is promoted by "A feeling of trust that we had developed at the point in time." This refers to the point in time at which the other surgery, the diagnostic laparoscopy was being discussed with the patient A.G.

Respondent with patient A.G. that led to the biopsy was compatible with condyloma with warty atypia. That is what Respondent observed and collected for evaluation. The laboratory confirmation of the specimen was performed by Dr. Woodard Burgert, a board-certified anatomic and clinical pathologist. In his assessment Dr. Burgert observed that the cone biopsy in question was compatible with condyloma with warty atypia. There was no significant dysplasia.

Expert Opinions

39. Dr. Edward Zelnick is a board-certified obstetrician and gynecologist who practices in Florida. He has hospital privileges at Hollywood Medical Center and Memorial Regional Hospital. He is familiar with the procedures involved in patient A.G.'s care based upon his own experience. He is sufficiently familiar with the facts in this case to render an opinion concerning Respondent's level of care for that patient. In the instance where pathology is found in examining the cervix, Dr. Zelnick believes that action should be taken in addressing that pathology, but only in the instance where the pathology has been discussed with the patient and the appropriate alternative treatment has been discussed. Absent an emergency it is necessary to provide the patient the alternative to surgery and identify the risk of surgery. Absent life-threatening

circumstances, a biopsy such as that performed on patient A.G. should not be performed without the patient's consent, which had not been given. Dr. Zelnick further describes the instance in which a biopsy in a case such as this would be in order, would be in relation to an instance in which it appeared that the circumstance was an immediate threat to the health of the patient that needed to be addressed. None of the exigent circumstances existed in this case. Therefore, Dr. Zelnick expresses the opinion that the performance of the biopsy by Respondent did not meet the expected standard of care.

- 40. Based upon his familiarity with the form of consent in this case which states, "If any unforeseen condition arises and additional surgery is deemed medically necessary during my procedure I request and authorize my physician to proceed,"

 Dr. Zelnick believes that the physician's responsibility there is to respond during the course of the surgery, if medically necessary, to such matters as repairing of a blood vessel that has been cut or damage to an internal organ or bowel. None of those circumstances were associated with the biopsy performed on the patient A.G..
- 41. While Dr. Zelnick delegates patient identification to surgical staff or nursing staff, he believes that the ultimate responsibility for patient identification to make certain that the right operation is performed on the proper patient resides

with the surgeon. To do less is to practice below the standard of care universally accepted and a matter of common sense.

According to Dr. Zelnick, Respondent did not meet that standard when performing the biopsy on patient A.G. who was misidentified. Whatever rules and procedures may be in place setting standards for identification in a hospital, Dr. Zelnick does not believe those standards abrogate the duty of the physician to properly identify the patient. What is expected of a physician is 100 percent certainty as to who the proper patient is and to assure that the proper procedure is carried out on the proper patient. The method of arriving at that determination is not significant, in Dr. Zelnick's view.

42. Dr. Roberto Fojo is a board-certified obstetrician and gynecologist licensed to practice medicine in Florida. He has hospital privileges at Jackson Memorial and North Shore Medical Center in South Florida, and he is affiliated with the University of Miami, Department of Obstetrics and Gynecology, Division of Gynecology. He is familiar with the procedures involved in patient A.G.'s care based upon his own experience. He is sufficiently familiar with the facts in this case to render an opinion concerning Respondent's level of care for that patient. He does not view a diagnostic laparoscopy as being intended to discover and diagnose cervical lesions, where, as here, the lesion is on the surface of the cervix and vagina. A diagnostic

laparoscopy is not intended to promote an examination of the cervix, according to Dr. Fojo.

43. Dr. Fojo is familiar with the consent form executed by patient A.G., the language previously described. He has seen that language before or something similar to it and considers it part of the standard surgical consent in connection with a diagnostic laparoscopy that was intended in this case. consent is designed to allow the surgeon to address matters such as puncture of the bowel or a problem with a major artery or veins or scar tissue or adhesions. This consent would not include addressing lesions on the cervix. A LEEP conization procedure is not an accepted procedure to perform in the patient undergoing diagnostic laparoscopy unless the LEEP conization had already been discussed and there was a problem with the cervix that the patient knew about. There, in Dr. Fojo's perception, the patient would be undergoing what he refers to as dual procedure. Dr. Fojo does not believe that surgery should be performed on a patient absent the patient's consent as being part of the original procedure or in an emergency. The LEEP conization biopsy by Respondent was not related to the consent that had been provided nor pertaining to an emergency. In this sense, Dr. Fojo expresses the opinion that Respondent failed to meet the standard for medical practice when performing the LEEP conization biopsy on Patient A.G.

- 44. Dr. Fojo believes that a surgeon should ascertain without any doubt that the patient in the room is a patient that he or she should be performing surgery on, the appropriate surgical procedure. This need for identification is an independent responsibility of the physician and may not be delegated. It requires 100 percent accuracy, according to Dr. Fojo. Dr. Fojo holds to the opinion that the physician is responsible for the identification regardless of his or her efforts that may have been compromised by others in attempting to properly identify the patient and perform the indicated procedure. He believes this to be common medical practice. Respondent was not within the standard of care in performing the LEEP conization procedure on patient A.G. under Dr. Fojo's assessment.
- 45. Dr. Michelle McCallanahan is a board-certified obstetrician and gynecologist who is licensed in Florida and practices in Jacksonville, Florida. She is familiar with the procedures involved in patient A.G.'s care based upon her own experience. She is sufficiently familiar with the facts in this case to render an opinion concerning Respondent's level of care for that patient. The consent form executed by patient A.G. is not unfamiliar to Dr. McCallanahan. Her perception of this consent language is that it relates to complications that occur during the course of the diagnostic laparoscopy that were not

foreseen and constitute an emergency requiring an immediate procedure to correct the condition. Examples are vascular injuries to vessels, bowel injury, bladder injury, infection and bleeding. By contrast, lesions on the cervix do not constitute an example of an unforeseen circumstance. Dr. McCallanahan expresses the opinion that an appropriate workup for LEEP conization was not done for the patient A.G. Nonetheless, there are some circumstances in which it would not be violative of the standard of care to perform LEEP conization without conducting a workup. That circumstance would be in the instance where the lesion that was observed was highly suggestive of cervical cancer, according to Dr. McCallanahan. The case that Respondent was presented with did not constitute such a condition. Ordinarily, the standard of care contemplates the discussion of possible risks or complications associated with LEEP conization procedures before performing them. According to Dr. McCallanahan it would be appropriate to perform a surgical procedure without discussion of the risks and possible complications in an emergency when the patient was unconscious and could not give consent in advance. Those are not the facts here.

46. While Dr. McCallanahan relies upon the assistance of other persons within the surgical and nursing staff, she expresses the opinion that the ultimate responsibility for patient identification prior to the performance of surgery

resides with the physician. She believes that it is below the standard of care to not correctly identify the patient before the procedure is done and perform an improper procedure or non-consenting procedure on that patient, as was the case here.

- 47. Dr. Jana Bures-Forstheoefel is a board-certified obstetrician and gynecologist who is licensed in Florida. She practices in Tallahassee, Florida, and has privileges at TMH and performs surgeries in the outpatient surgery center. She is familiar with the procedures involved in patient A.G.'s care based upon her own experience. She is sufficiently familiar with the facts in this case to render an opinion concerning Respondent's level of care for that patient. She believes that Respondent met the standard of care for identifying patient A.G. before performing surgery on the patient. The method used by Respondent to identify the patient was common to the practice of other physicians who performed surgeries in that setting, according to Dr. Forstheoefel.
- 48. In the event that Dr. Forstheoefel was performing a diagnostic laparoscopy and observed a cervical lesion she would evaluate the condition to include the performance of a biopsy, the most common method for cervical biopsy being a LEEP conization. Notwithstanding the lack of specific consent by the patient for Respondent to perform the LEEP conization,

- Dr. Forstheoefel holds to the opinion that it was correct to biopsy, given what was observed in the patient.
- 49. The prospect that a physician would be 100 percent accurate in identifying a patient undergoing surgery is not humanly possible and is a standard that should not be imposed upon a physician in Dr. Forstheoefel's opinion. She considers that the matter of proper identification preoperatively is a team effort. One person should not be solely responsible for all things in making certain of the patient's safety and assuring that the right thing is done.
- obstetrician and gynecologist. He is licensed in Florida. At times relevant he performed surgeries at the TMH outpatient surgery center. He is familiar with the procedures involved in patient A.G.'s care based upon his own experience. He is sufficiently familiar with the facts in this case to render an opinion concerning Respondent's level of care for that patient. He believes that Respondent met the standard of care in identifying the patient A.G. before performing the surgery and in performing the LEEP conization on that patient. Although Dr. McAlpine has not experienced a situation in which he observed a reason to do a LEEP conization in a diagnostic laparoscopy case, where consent for LEEP conization had not been given ahead of time, he does not question the decision to address the

condition observed, such as in the case at issue. From his point of view, it was acceptable to do a LEEP conization biopsy to address the lesion. Although no prior indication existed before the lesion was observed during the procedure Dr. McAlpine would not want to ignore the lesion.

- 51. Dr. McAlpine believes that the process that Respondent undertook in identifying the patient A.G. before surgery was consistent with practices in effect at the hospital, this included reliance on staff in the operating room. Dr. McAlpine does not believe that it is necessary for a physician to be 100 percent accurate in the identification as a person ultimately in charge. No matter as to the facts, he sees the issue of the identification being a multi-disciplinary approach among health care providers.
- 52. Dr. David O'Bryan practices obstetrics and gynecology. He is licensed in Florida. At times relevant he performed surgeries at TMH outpatient surgery center. He is familiar with the type procedures involved in patient A.G.'s care based upon his own experience. He is sufficiently familiar with the facts in this case to render an opinion concerning Respondent's level of care for the patient. The method employed by Respondent in identifying the patient was consistent with the practice used in the immediate medical community at the time, according to Dr. O'Bryan.

- appropriate surgery on Patient A.G. For Dr. O'Bryan, what is more important in addressing the patient's needs is the apparent pathology, not the consent that may have been provided by the patient in advance of the procedure. It would be negligent not to address the lesion on the cervix in his view. The pathology present determines the response even without a consent for the procedure. Dr. O'Bryan did not consider that the pathology constituted an issue of life or death. The fact that the LEEP conization biopsy was not planned was less significant than the need to address the pathology. It does not matter if the patient were A.G. or N.C. or some other patient, Dr. O'Bryan believes that it was appropriate to perform the biopsy.
- 54. Dr. O'Bryan believes that the surgeon bears a great deal of responsibility in patient identification, but the ultimate responsibility for identification does not reside with the physician or any other operating room staff member in Dr. O'Bryan's assessment. Dr. O'Bryan does not conceive that there can be any greater comfort in the identification than in the instance where the "operating room crew" tells the physician who it is and the physician has a chart in his hands which indicates that it is the same patient as the operating staff has identified and the pathology that was found is consistent with

what had been anticipated according to the patient chart and the staff identification.

- 55. Nothing in medicine involves the imposition of a 100 percent standard of care to include properly identifying the patient preoperatively, according to Dr. O'Bryan.
- Dr. Roberto Morales is a board-certified obstetrician in gynecology licensed to practice in Florida. At times relevant, he performed surgery at the TMH outpatient surgery center. He is familiar with the type procedures involved in Patient A.G.'s care based upon his own experience. He is sufficiently familiar with the facts in this case to render an opinion concerning Respondent's level of care for the patient. Dr. Morales believes that Respondent met the standard of care for identifying the patient A.G. in that hospital and in other places as well. Dr. Morales believes that the patient was correctly identified by Respondent earlier in the day and that the incorrect patient was brought back to the operating room. those circumstances, Respondent did what was appropriate to identify the patient in the performance of the LEEP conization on patient A.G. and was within the standard of care, according to Dr. Morales.
- 57. Assuming the patient was scheduled for a diagnostic laparoscopy, if during the examination, visualization of the cervix, a lesion was observed, a biopsy would be the typical next

step, according to Dr. Morales. The caveat to his opinion in the ability to perform that biopsy would depend upon the patient that was being taken care of and the sense that the physician had about the patient's expectations of what should be done and not done. It is assumed that Dr. Morales believed that the level of relationship between Respondent and Patient A.G. would allow the performance of the LEEP conization biopsy.

- 58. Dr. Morales believes that the attempt to be 100 percent accurate in the identification of patients preoperatively is an aspirational goal, not a requirement. For him all persons concerned have the responsibility for taking care of the patient.
- 59. Having considered the opinions expressed by the experts, the ultimate facts to be determined must be based upon the realization that Respondent proceeded to perform the LEEP conization biopsy on patient A.G. without advance written consent, that Respondent believed that he was confronting the case of patient N.C., and that the performance of the LEEP conization on Patient A.G. was not in its timing and justification part of the diagnostic laparoscopy scheduled to be performed on Patient A.G. The earlier effort by Respondent to identify his patient in the holding area was sufficient for that stage of the process. Respondent acted in the customary manner in relying upon his knowledge that Patient N.C. was to be the third patient based upon the schedule. It was not unexpected

that Respondent would rely upon the surgical staff in orally confirming the patient identity and the procedure to be performed when entering the operating room for the scheduled third procedure. This identification was further confirmed by the presence of the chart for Patient N.C. Respondent's failure to take further steps to physically identify the patient by looking at her arm bracelet, by looking at her face, or in some other manner recognizing the mistake that had been made by others in readying Patient A.G., and not Patient N.C. for surgery could be forgiven if there were no consequences, but there were. Although Respondent should not be the absolute quarantor in the identification of the patient, what he did in the operating room was not enough, when the result is that Respondent performed the LEEP conization that was not consented to in advance, and performed believing that the patient was N.C., the patient for whom the procedure was intended, and was not in response to an emergency regardless of patient identity. As a result, Respondent failed to meet the standard of care for reasonably prudent similar physicians under acceptable similar conditions and circumstances in his actions. In mitigation, the outcome was not harmful to the patient. Moreover, other health care professionals were in great measure responsible for the failure to properly identify the patient.

CONCLUSIONS OF LAW

- 60. The Division of Administrative Hearings has jurisdiction over the subject matter and the parties to this proceeding in accordance with Sections 120.569 and 120.57(1), Florida Statutes.
- 61. Petitioner is a state agency charged with the regulation of the practice of medicine pursuant to Section 20.43, Florida Statutes, and Chapters 456 and 458, Florida Statutes. Respondent, as a licensed physician, is subject to that regulation.
- 62. In the case, by an Amended Administrative Complaint, it is alleged that Respondent violated Section 458.331(1)(t), Florida Statutes, by failing to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances in his treatment of Patient A.G. by performing a LEEP conization on the patient.
- Administrative Complaint by clear and convincing evidence to show a violation of Section 458.331(1)(t), Florida Statutes.

 Department of Banking and Finance v. Osborne Stern and Company, 670 So. 2d 932 (Fla. 1996) and Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987). That burden of proof is explained in Slomowitz v. Walker, 429 So. 2d 797 (Fla. 4th DCA 1983).

64. In deciding whether there is a violation of Section 458.331(1)(t), Florida Statutes, resort must be made to Section 762.102, Florida Statutes, which states:

The prevailing professional standard of care for a given health care provider shall be that level of care, skill and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by a reasonably prudent similar health care provider.

- 65. Proof of a deviation from the standard of care or compliance with that standard is in association with the opinions of experts in the medical profession. <u>Purvis vs. Department of Professional Regulation</u>, 461 So. 2d 134 (Fla. 1st DCA 1984).
- responsible for mistakes in patient identification. However, errors in identification of the patient A.G., leading to the surgery on Patient A.G. that was intended for Patient N.C., the LEEP conization biopsy, is an instance where Respondent does bear responsibility for his own conduct, even where others have contributed to the confusion. In this case, Respondent did not do enough to fulfill his role in practicing with the level of care, skill, and treatment which is recognized by reasonably prudent similar physicians as being acceptable under similar conditions and circumstances in the attempt to identify the patient in the operating room and avoid the mistake that led to performing a procedure that the patient had not provided consent

for and was not a matter of emergency without regard for patient identity.

- 67. The recommendation for the imposition of a penalty for the violation is made with an understanding of the range of penalties referred to in Rule 64B8-8.001, Florida Administrative Code, to include matters of mitigation which have been discussed.
- 68. Petitioner is entitled to the costs related to investigation and prosecution. Section 456.072(4), Florida Statutes.

RECOMMENDATION

Upon consideration of the facts found and conclusions of law reached, it is

RECOMMENDED:

That a final order be entered finding Respondent in violation of Section 458.331(1)(t), Florida Statutes, and imposing a \$1,000.00 administrative fine and costs of investigation and prosecution.

DONE AND ENTERED this 8th day of November, 2002, in Tallahassee, Leon County, Florida.

CHARLES C. ADAMS
Administrative Law Judge
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Filed with the Clerk of the Division of Administrative Hearings this 8th day of November, 2002.

COPIES FURNISHED:

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this recommended order. Any exceptions to this recommended order should be filed with the agency that will issue the final order in this case.