


State Medical Board of Ohio
30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

(614) 466-3934
med.ohio.gov

November 14, 2007

Joseph Thayer Caligaris, M.D.
12304 Cooperwood Lane
Cincinnati, OH 45242

Dear Doctor Caligaris:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of R. Gregory Porter, Esq., Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on November 14, 2007, including motions approving and confirming the Report and Recommendation as the Findings and Order of the State Medical Board of Ohio.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Such an appeal must be taken to the Franklin County Court of Common Pleas.

Such an appeal setting forth the Order appealed from and the grounds of the appeal must be commenced by the filing of an original Notice of Appeal with the State Medical Board of Ohio and a copy of the Notice of Appeal with the Franklin County Court of Common Pleas. Any such appeal must be filed within fifteen (15) days after the mailing of this notice and in accordance with the requirements of Section 119.12, Ohio Revised Code.

THE STATE MEDICAL BOARD OF OHIO



Lance A. Talmage, M.D.
Secretary

LAT:jam
Enclosures

CERTIFIED MAIL NO. 91 7108 2133 3931 8317 8455
RETURN RECEIPT REQUESTED

Cc: Eric J. Plinke, Esq.
CERTIFIED MAIL NO. 91 7108 2133 3931 8317 8462
RETURN RECEIPT REQUESTED

Mailed 11-16-07

CERTIFICATION

I hereby certify that the attached copy of the Entry of Order of the State Medical Board of Ohio; Report and Recommendation of R. Gregory Porter, State Medical Board Attorney Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on November 14, 2007, including motions approving and confirming the Findings of Fact, Conclusions and Proposed Order of the Hearing Examiner as the Findings and Order of the State Medical Board of Ohio; constitute a true and complete copy of the Findings and Order of the State Medical Board in the matter of Joseph Thayer Caligaris, M.D., as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.



Lance A. Talmage, M.D.
Secretary

(SEAL)

November 14, 2007

Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF

*

*

JOSEPH THAYER CALIGARIS, M.D.

*

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on November 14, 2007.

Upon the Report and Recommendation of R. Gregory Porter, State Medical Board Attorney Hearing Examiner, designated in this Matter pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated herein, and upon the approval and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

It is hereby ORDERED that:

- A. No further action shall be taken in the matter of Joseph Thayer Caligaris, M.D.
- B. Dr. Caligaris is released from the terms and conditions set forth in his December 20, 2002, Consent Agreement.

This Order shall become effective immediately upon the mailing of notification of approval by the Board.

(SEAL)



Lance A. Talmage, M.D.

Secretary

November 14, 2007

Date

**REPORT AND RECOMMENDATION
IN THE MATTER OF JOSEPH THAYER CALIGARIS, M.D.**

The Matter of Joseph Thayer Caligaris, M.D., was heard by R. Gregory Porter, Hearing Examiner for the State Medical Board of Ohio, on March 2, 16, and April 13, 2007.

INTRODUCTION

I. Basis for Hearing

In a December 14, 2006, letter to Joseph Thayer Caligaris, M.D., the State Medical Board of Ohio [Board] informed Dr. Caligaris that, pursuant to the terms of the Consent Agreement that the Board and Dr. Caligaris had entered into effective December 20, 2002 [2002 Consent Agreement], the Board had scheduled a hearing to address a matter arising under that Consent Agreement.

In its letter, the Board noted that Dr. Caligaris had agreed in the 2002 Consent Agreement to participate in an evaluation to be conducted by the Center for Personalized Education for Physicians [CPEP]. In addition, the Board stated that Dr. Caligaris had further agreed that, if CPEP were to recommend education, preceptorship, mentorship, or practice limitations, he would enter into a subsequent consent agreement that would include "terms, conditions, and limitations as determined by the Board based upon the recommendations of CPEP." The 2002 Consent Agreement further stated: "If the Board and Dr. Caligaris are not able to agree on the terms of a written consent agreement, then Dr. Caligaris further agrees to abide by any terms, conditions, and limitations imposed by Board Order after a hearing conducted pursuant to Chapter 119. of the Ohio Revised Code."

The Board further stated that a CPEP assessment had taken place in February 2003 and that the Board had received CPEP's assessment report and education plan for Dr. Caligaris in February 2004. In addition, the Board stated that, despite ongoing negotiations, the Board and Dr. Caligaris had been unable to reach agreement concerning the terms, conditions, and limitations, if any, for Dr. Caligaris' subsequent consent agreement.

Accordingly, the Board advised Dr. Caligaris that, pursuant to the 2002 Consent Agreement, the Board had scheduled the matter for a hearing under Chapter 119 to determine what terms, conditions, and limitations, if any, that should be imposed by Board Order. The Board's letter included the date and time of the hearing. (State's Exhibit 1A)

II. Appearances

- A. On behalf of the State of Ohio: Marc Dann, Attorney General, by Barbara J. Pfeiffer, Assistant Attorney General.
- B. On behalf of the Respondent: Eric J. Plinke, Esq.

EVIDENCE EXAMINED

I. Testimony Heard

- A. Presented by the State
- Martha Illige, M.D.
- B. Presented by the Respondent
1. A. Dennis Miller, Esq.
 2. Bruce H. Allen, M.D.
 3. Joseph T. Caligaris, M.D.
 4. Reed A. Shank III, M.D.

II. Exhibits Examined

- A. Presented by the State

State's Exhibits 1A through 1K: Procedural exhibits.

State's Exhibit 2: Certified copy of a December 20, 2002, consent agreement between Dr. Caligaris and the Board [2002 Consent Agreement].

State's Exhibit 3 through 6: Certified copies of the following documents as maintained by CPEP:

- Final CPEP Assessment Report for Dr. Caligaris signed February 19, 2004, with attachments;
- January 30, 2004, letter to Board staff from Kristin Y. Hasley, CPEP Education Consultant;
- May 31, 2006, letter to Eric J. Plinke, Esq., from Elizabeth J. Korinek, Executive Director of CPEP; and
- An unsigned document entitled "Revised 11/14/3 Education Plan for Joseph T. Caligaris, M.D."

State's Exhibit 7: State's Closing Argument. [Note: This exhibit was marked and admitted by the Hearing Examiner post-hearing.]

B. Presented by the Respondent

Respondent's Exhibit A: Information from the Ohio eLicense Center concerning Dr. Caligaris; copy of the December 2002, Consent Agreement; and copy of the Board's July 10, 2002, notice of opportunity for hearing sent to Dr. Caligaris.

Respondent's Exhibit B: Copy of May 14, 2003, letter to CPEP from A. Dennis Miller, Esq., on behalf of Dr. Caligaris.

Respondent's Exhibit C: Copy of February 19, 2004, CPEP Assessment Report for Dr. Caligaris, with attachments. (Duplicate of State's Exhibit 3)

Respondent's Exhibit D: Copy of Dr. Caligaris' May 14, 2003, response to the initial CPEP Assessment Report.

Respondent's Exhibit E: Copy of June 16, 2003, letter to Dr. Caligaris from Megan Barnhurst, Education Program Coordinator for CPEP, and attached Education Plan.

Respondent's Exhibit F: Copy of June 24, 2003, letter to CPEP from Mr. Miller, and attached release.

Respondent's Exhibit F-1: Copy of Joint Education Plan Proposal and attached front page of journal article.

Respondent's Exhibits G through J: Copies of correspondence between Dr. Caligaris and CPEP.

Respondent's Exhibit K: Copy of March 15, 2004, letter to Board staff from J. Stephen Teetor, Esq.

Respondent's Exhibit L: Copy of March 15, 2004, letter to Dr. Caligaris from CPEP.

Respondent's Exhibit M: Copy of March 16, 2004, letter to Board staff from CPEP.

Respondent's Exhibits N through P: Not presented.

Respondent's Exhibits Q through U: Copies of bulletins from the American College of Obstetricians and Gynecologists [ACOG].

Respondent's Exhibit V: Excerpt from Dickey, *Managing Contraceptive Pill Patients* (7th ed.).

Respondent's Exhibit W: Excerpt from Speroff and Darney, *A Clinical Guide for Contraception* (3d ed.).

Respondent's Exhibit X: Berghella A.; Baxter J.; Pereira L.: "Cerclage: Should We Be Doing Them?" *Contemporary OB/GYN* (December 1, 2005).

Respondent's Exhibits Y through DD: Correspondence and documentation related to Dr. Caligaris' resignation of his Massachusetts certificate.

Respondent's Exhibit EE through II: Copies of correspondence between Dr. Caligaris and third-party payors.

Respondent's Exhibit JJ: Copy of letter of support for Dr. Caligaris from Eric F. Stamler, M.D.

Respondent's Exhibit KK: Respondent's Closing Argument. [Note: This exhibit was marked and admitted by the Hearing Examiner post-hearing.]

C. Admitted by the Hearing Examiner Post-Hearing

Board Exhibit A: Copy of April 2, 2007, Entry scheduling an additional day of hearing for April 13, 2007.

PROCEDURAL MATTERS

At the conclusion of the hearing, the hearing record in this matter was held open to give the parties an opportunity to submit written closing arguments. (Hearing Transcript Volume III at 28-29) The hearing record closed on May 11, 2007, the date that the Respondent's closing argument was filed.

SUMMARY OF THE EVIDENCE

All exhibits and transcripts of testimony, even if not specifically mentioned, were thoroughly reviewed and considered by the Hearing Examiner prior to preparing this Report and Recommendation.

Background Information

1. Dr. Caligaris testified that he had obtained his medical degree in 1983 from Boston University. From 1983 through 1987, Dr. Caligaris participated in an OB/GYN residency at the University of Cincinnati. In 1987, following completion of his residency, he went into practice with another physician in Cincinnati, Ohio, for one year. Subsequently, he returned to his hometown of Milford, Massachusetts, where he practiced as a solo practitioner for two years. In 1990, he returned to Cincinnati. Dr. Caligaris noted that his wife is a native of Cincinnati and "she didn't like the east coast very much. So we moved

back to Cincinnati where her family was.” Dr. Caligaris testified that he has been engaged in the solo practice of OB/GYN in Cincinnati since that time. (Hearing Transcript Volume II [Tr. Vol. II] at 87-89)

Dr. Caligaris testified that he was board-certified in 1990, and that he has continuously renewed his board certification. (Tr. Vol. II at 90-91)

Dr. Caligaris testified that he practices at three hospitals. His primary hospital is Christ Hospital, and he also practices at Bethesda North Hospital and Good Samaritan Hospital. (Tr. Vol. II at 91)

Dr. Caligaris testified that, since the time that he finished his residency program, he has been involved in teaching residents. Dr. Caligaris further testified that he teaches residents from both residency programs in Cincinnati—the Alliance program at Christ Hospital, which is affiliated with the University of Cincinnati, and the TriHealth program at Bethesda and Good Samaritan hospitals, which is a private residency program. (Tr. Vol. II at 91-93)

December 20, 2002, Consent Agreement between Dr. Caligaris and the Board

2. Effective December 20, 2002, Dr. Caligaris entered into a Consent Agreement with the Board [2002 Consent Agreement] “in lieu of further formal proceedings or determinations at this time based upon the allegations set forth in the Notice of Opportunity for Hearing issued on July 10, 2002 * * *.” The 2002 Consent Agreement included no finding that Dr. Caligaris had violated any provision of the Medical Practices Act of Ohio. Rather, it stated: “Dr. Caligaris acknowledges that the Notice of Opportunity for Hearing issued by the Board on July 10, 2002, includes concerns about patient care where improvement over past practices is appropriate, and enters into this Agreement to address those concerns.” (State’s Exhibit [St. Ex.] 2 at 1)

The 2002 Consent Agreement set forth several Agreed Conditions, including the following:

- a. Section A stated that, within 90 days of the effective date of the 2002 Consent Agreement, Dr. Caligaris was to submit documentation to the Board verifying that he had participated in the Colorado Physicians Effectiveness Program, which is now known as the Center for Personalized Education for Physicians [CPEP]. Among other things, this condition stated:

Dr. Caligaris shall ensure that all reports generated in connection with his involvement in the CPEP program, including, but not limited to, the written Assessment Report and any Education Plan, be provided to the Board within 10 days of the date of issuance. Dr. Caligaris shall work with CPEP to ensure that the written Assessment Report includes, but is not limited to, the following:

- A detailed plan of recommended practice limitations, if any;

- Any recommended education;
- Any recommended mentorship or preceptorship; and
- Any reports upon which the recommendation is based, including reports of physical examinations and psychological or other testing.

(St. Ex. 2 at 2-3)

b. Section B required, in part, as follows:

Dr. Caligaris agrees that if CPEP recommends education, preceptorship, mentorship, or practice limitations, he shall cooperate with CPEP to establish the Education Plan within 90 days. Dr. Caligaris shall enter into a subsequent written consent agreement which shall include any terms, conditions, and limitations as determined by the Board based upon the recommendations of CPEP. If the Board and Dr. Caligaris are unable to agree on the terms of a written consent agreement, then Dr. Caligaris further agrees to abide by any terms, conditions, and limitations imposed by Board Order after a hearing conducted pursuant to Chapter 119 of the Ohio Revised Code.

(St. Ex. 2 at 3)

c. Section C provided for the contingency that, “[i]f CPEP determines that Dr. Caligaris currently possesses appropriate skills and educational remediation is not required,” then Dr. Caligaris would agree to certain probationary terms and conditions as specified therein for a period of at least three years. Among the probationary terms and conditions, Dr. Caligaris would be required:

- To submit quarterly declarations of compliance with the terms of probation and appear before the Board or its representative on a semiannual basis;
- Obtain approval from the Board of a monitoring physician who “shall monitor Dr. Caligaris, review Dr. Caligaris’ patient charts, and provide supervision of Dr. Caligaris’ medical practice”; and
- Provide to the Board patient records for the Board’s review if requested to do so.

(St. Ex. 2 at 3-4)

d. Sections D and E required that, within 30 days of the effective date of the 2002 Consent Agreement, Dr. Caligaris shall provide copies of that agreement to employers and hospitals where he holds privileges, and to the licensing authorities of other jurisdictions where he holds a professional license or where he applies for a professional license. (St. Ex. 2 at 5)

3. Dr. Caligaris testified that it had been his understanding that the 2002 Consent Agreement required him to be evaluated by CPEP and, following that evaluation and depending on the results of the evaluation, he would “then go back to the Medical Board and another Consent Agreement or decision would be made concerning what the next step of action would be.” (Tr. Vol. II at 94-95)

The CPEP Assessment Process in General

4. Martha Illige, M.D., testified on behalf of the State. Dr. Illige testified that she had obtained her medical degree in 1977 from the University of California at San Diego, and in 1980 completed a residency in family medicine at the University of Colorado. Dr. Illige further testified that she was board-certified in family medicine in 1980. (Hearing Transcript Volume I [Tr. Vol. I] at 15-16)

Dr. Illige testified that she has practiced family medicine since finishing her residency. In addition, Dr. Illige has been a clinical instructor at the University of Colorado Department of Family Medicine for fifteen years. Finally, since 1994, Dr. Illige has worked for CPEP as a consultant, senior consultant, associate medical director, and medical director. (Tr. Vol. I at 16-17)

5. Dr. Illige testified that CPEP is a nonprofit organization founded in 1990 for the purpose of providing personalized assessments and education for physicians. Dr. Illige further testified that, since its inception, CPEP has assessed approximately 700 physicians. (Tr. Vol. I at 17-18)
6. Dr. Illige’s testimony indicates that she has worked for CPEP since 1994, and that she had served as Medical Director of CPEP from 1988 through May 2005. Accordingly, Dr. Illige had been the Medical Director at the time of Dr. Caligaris’ assessment. Dr. Illige testified that she now serves as a Senior Consultant. (Tr. Vol. I at 18-19)
7. Dr. Illige testified that a CPEP assessment consists of a two- or three-day, on-site assessment. It includes two or three structured oral interviews who are board-certified physicians who practice in the participant’s specialty.¹ Dr. Illige further testified that each of the two consultants who had been involved in Dr. Caligaris’ assessment had been board certified. (Tr. Vol. I at 19-23)
8. Dr. Illige testified that an Associate Medical Director coordinates and oversees a participant’s assessment and authors the assessment report. Dr. Illige’s testimony indicates that the Associate Medical Director assigned to a case may not practice in the same specialty area as the participant. Dr. Illige could not recall who had served as Associate Medical Director in Dr. Caligaris’ case. (Tr. Vol. I at 18, 31-32)

¹ These physicians are hereinafter referred to as “consultants.”

9. Dr. Illige testified that a draft assessment report is completed and sent to a participant usually within three to six weeks following the assessment. The participant is then given ten days to provide a written participant response. Dr. Illige testified that, if the participant submits a response, “we try to look at [it] to make sure that we correct any factual errors” prior to issuing a final assessment report. Dr. Illige testified that the participant’s response is reviewed by the Associate Medical Director who had authored the assessment report. (Tr. Vol. I at 24, 26-27, 36)

Dr. Illige testified that CPEP corrects only factual errors. She stated that the final assessment report is not modified to reflect what it considers to be contrasting opinions rather than factual errors. Instead, the participant’s response is appended to the final report so that recipients of the report can read it. (Tr. Vol. I at 27, 37-38)

Dr. Illige testified that she does not know whether the policy described in the preceding paragraph had been explained to Dr. Caligaris. (Tr. Vol. I at 27)

10. Dr. Illige testified that, during the process of performing an assessment, CPEP accumulates a large amount of “source material” that includes the reports dictated by the consultants who conduct the clinical interviews. Dr. Illige further testified that such source material is shredded by CPEP after an assessment report has been completed. Dr. Illige explained that an assessment report is deemed complete upon either CPEP’s receipt of the participant’s written response or upon the expiration of the ten-day period for submitting a participant response. (Tr. Vol. I at 25-26, 33-34, 45)

Prior to Dr. Caligaris’ CPEP Assessment

11. Dr. Caligaris testified that, in January 2003, a CPEP representative contacted him concerning information that he needed to provide to CPEP prior to the assessment. Among other things, Dr. Caligaris testified that he had been asked to forward to CPEP copies of sixteen of his patient charts with all patient identifying information redacted. Eight of the patient charts were to relate to obstetrical issues and the remaining eight patient charts were to relate to gynecological issues. Dr. Caligaris further testified that CPEP wanted patient charts that dealt with specific issues and/or procedures. Moreover, the issues and/or procedures were to have occurred within one or two years of the CPEP assessment, and were to be received by CPEP no later than one month prior to the assessment. Finally, Dr. Caligaris testified that, although he had had a very short time frame to respond, CPEP had received his patient charts in a timely manner. (Tr. Vol. II at 95-100)

Dr. Caligaris’ February 18 and 19, 2003, Assessment

12. Dr. Caligaris flew to Colorado for a two-day CPEP assessment on February 18 and 19, 2003. (Tr. Vol. I at 61)

According to the final CPEP Assessment Report for Dr. Caligaris that was issued in February 2004, Dr. Caligaris' CPEP assessment had included the following elements:

- Two interviews of Dr. Caligaris by OB/GYN consultants;
- Review of Dr. Caligaris' patient charts;
- Two written examinations: a Multiple-Choice Question Knowledge Test addressing OB/GYN topics, and a Fetal Monitor Strip Interpretation Test wherein Dr. Caligaris provided his interpretation and course of action for 15 fetal monitor strips;
- A Physician/Patient Communication Evaluation using interviews of three simulated patients. Dr. Caligaris composed a progress note for each patient interview;
- A review of Dr. Caligaris' Patient Care Documentation using the medical charts that Dr. Caligaris had provided to CPEP, and using the progress notes from the simulated patient interviews; and
- A cognitive function screen and a review of the recent physical examination of Dr. Caligaris.

(Respondent's Exhibit [Resp. Ex.] C)

13. Dr. Caligaris testified that, when he had first presented to CPEP to begin the assessment, CPEP had assigned to his case an individual whom Dr. Caligaris referred to as a case manager. However, Dr. Caligaris testified that, on the second day of his assessment, the assigned case manager did not appear. Dr. Caligaris testified that "they scrambled for about an hour-and-a-half to find somebody to take over that role." Dr. Caligaris testified that the second case manager had been a family practitioner. Dr. Caligaris added that the second case manager had sat in during the clinical interviews and taken notes. (Tr. Vol. II at 107-108)

Dr. Caligaris testified that, at the conclusion of the interviews, he had asked the case manager if he could review her notes to make sure that they were factually correct, but that she had refused. Dr. Caligaris further testified:

[T]he reason I asked that question was because throughout the whole process with the assessors [consultants], this family practitioner repeatedly had to stop us to spell words, to ask me to explain what we were talking about, and in terms she would understand.

So throughout the whole process, I am trying to discuss it in terms that I would expect my assessor to know, which is in our field. And here is the person over here taking notes, who isn't in my field, who doesn't even understand some of the terms and how to spell them.

And it became very discouraging after a while because it broke up—a lot of times broke up my train of thought, would break up the assessor's train of thought because we'd have to go back and backtrack because she didn't get it down or she wanted to make sure she got it right.

(Tr. Vol. II at 109-110)

CPEP's May 2003 Initial Assessment Report

14. In May 2003, Dr. Caligaris received CPEP's initial Assessment Report. Dr. Caligaris was given ten days in which to sign and return the report, and prepare and return a written Participant Response to the report if he chose to do so. On May 14, 2003, Dr. Caligaris signed the initial Assessment Report and his Participant Response. (Resp. Exs. B and D; Resp. Ex. J at 4; Tr. Vol. I at 26-27, 60)

In his Participant Response, Dr. Caligaris included a number of disagreements that he had had with the Assessment Report. Pertinent details of the Assessment Report and Dr. Caligaris' response will be addressed later in this Report and Recommendation. (Resp. Ex. D)

15. Dr. Caligaris testified concerning his understanding of the initial CPEP Assessment Report:

They made a specific point to say it would be a preliminary assessment, I would have time to rebut any type of discrepancies I felt were in the assessment * * *. They would go back and look at any discrepancies I had versus what their assessors or anybody else had, and then I would be given an official report.

(Tr. Vol. II at 103-104)

16. A. Dennis Miller, Esq., testified that he is an attorney and that he had assisted Dr. Caligaris in Dr. Caligaris' interactions with CPEP. (Tr. Vol. I at 57-59)

Mr. Miller testified that the Assessment Report and Dr. Caligaris' May 14, 2003, Participant Response had been signed by Dr. Caligaris and Mr. Miller sent them to CPEP within the required ten-day period. (Tr. Vol. I at 78)

17. Mr. Miller testified that the initial Assessment Report stated that Dr. Caligaris had failed to cooperate by not forwarding to CPEP a recent physical examination. Mr. Miller testified that this was not true. Mr. Miller further testified that the physical examination had in fact been previously sent to CPEP via facsimile, and that Mr. Miller again sent the physical examination and the earlier fax cover sheet to CPEP along with Dr. Caligaris' signed Assessment Report, Participant Response, and a May 14, 2003, cover letter. (Tr. Vol. I at 60-61)

18. In his May 14, 2003, cover letter to CPEP, Mr. Miller had written, among other things:

It is my understanding that CPEP will develop a proposed educational plan. The order from the Medical Board requires that the Medical Board and Dr. Caligaris agree on the plan of action and that a Supplemental Order will be issued by the Board. I do not believe that any action can be taken by the physician without the Board's consent.

(Resp. Ex. B)

CPEP's June 2003 Initial Education Plan

19. By letter dated June 16, 2003, CPEP provided its initial Education Plan to Dr. Caligaris and advised him that he was to sign the plan, date it, and return the original to CPEP within ten days. CPEP further advised Dr. Caligaris that he would later receive an Education Plan notebook that would include materials that he needed to initiate the plan. Finally, CPEP advised Dr. Caligaris that he was required to submit the curriculum vitae of a proposed preceptor with thirty days of signing the Education Plan. (Resp. Ex. E)

Dr. Caligaris testified that he had been upset when he received the Education Plan because he had understood that the plan was to be developed jointly by CPEP and him. Moreover, Dr. Caligaris understood that, prior to developing the Education Plan, he was to have received the final Assessment Report that addressed the issues raised in his Participant Response. However, Dr. Caligaris testified that, at the time he had received the Education Plan, he had not yet received a final Assessment Report or any contact from CPEP concerning the issues he had raised in his Participant Response. (Tr. Vol. II at 103-104, 116)

20. The initial CPEP Education Plan included three primary objectives, two of which were broken down into secondary objectives, as follows:

OBJECTIVE I: *To improve medical knowledge in the following content areas:*

- 1) *Hormone therapy, including the appropriate use of oral contraceptive pills, Depo-Provera, and hormone replacement therapy;*
- 2) *Evaluation and treatment of pelvic pain and pelvic inflammatory disease;*
- 3) *Current antibiotic selection;*
- 4) *Risk stratification in treatment of thromboembolic disease in surgical and obstetric patients;*
- 5) *Pathophysiology, diagnosis and treatment of polycystic ovarian syndrome;*
- 6) *Treatment strategies for abnormal Pap smears;*
- 7) *Accurate knowledge of amniocentesis procedure; and*
- 8) *Indications and timing for cerclage placement.*

* * *

OBJECTIVE II: *To improve clinical decision-making in the following areas:*

- 1) *Consistent application of knowledge to patient care management;*
- 2) *Appropriate correlation between the evaluative process and the differential diagnosis;*
- 3) *Prudent use of consultants on a consistent basis; and*
- 4) *Establishment of boundaries related to patient volume that optimizes comprehensive and thoughtful care.*

* * *

OBJECTIVE III: *To improve legibility and demonstrate consistent documentation skills, with attention to inclusion of pertinent laboratory results in patient charts.*

(Resp. Ex. E) (Emphasis in original) The initial Education Plan also included performance objectives and evaluation methods to be employed. (Resp. Ex. E)

The initial Education Plan indicated that, for the duration of plan, reports of progress as specified in the plan would be sent to CPEP staff for review. (Resp. Ex. E)

21. Mr. Miller responded to CPEP by letter dated June 24, 2003. In that letter, among other things, Mr. Miller stated that CPEP's Education Plan was "totally unacceptable to Dr. Caligaris." He further stated that CPEP had represented to Dr. Caligaris that there would be a joint decision concerning the education program. (Resp. Ex. F)

Dr. Caligaris' Response to the Recommendations in the CPEP Initial Education Plan

22. Mr. Miller testified that, after Dr. Caligaris had received the initial Education Plan, he had recommended to Dr. Caligaris that he begin acting upon the recommendations. Mr. Miller testified that Dr. Caligaris obtained a preceptor, Michael S. Baggish, M.D. Mr. Miller further testified that Dr. Caligaris selected and participated in educational programs related to the objectives identified by CPEP. Moreover, Mr. Miller testified that, since Dr. Caligaris is an assistant clinical professor at the University of Cincinnati College of Medicine and teaches residents at Christ Hospital, Dr. Caligaris also participated in grand rounds. (Tr. Vol. I at 69-70)

Mr. Miller further testified that one of the educational programs was offered by Wayne State University in Detroit, Michigan. The University has sent articles to Dr. Caligaris; Dr. Caligaris has reviewed the articles, completed exams, and returned the completed exams to that university. Mr. Miller further testified that Dr. Caligaris has attended annual meeting(s) of ACOG, which have included one week of educational programs. Moreover, Mr. Miller testified that, in addition to the foregoing, Dr. Caligaris has continued to take his required 40 hours of CME. Finally, Mr. Miller testified that Dr. Caligaris has sent quarterly reports to the Board advising what he has been doing. (Tr. Vol. I at 71-73, 76)

23. Mr. Miller testified that, beginning in June or July 2003, Dr. Caligaris had sent his OB/GYN operative reports to Dr. Baggish for review. Mr. Miller further testified that Dr. Baggish sent reports to the Board. (Tr. Vol. I at 70-71)

Mr. Miller testified that Dr. Baggish had continued as Dr. Caligaris' preceptor for a while, but resigned in November or December 2003. Mr. Miller explained that Dr. Baggish resigned because his offices are at Good Samaritan Hospital and that Dr. Caligaris does the majority of his practice at Christ Hospital. Mr. Miller testified: "[T]o be respectful, that is like water and oil. The two are very competitive." (Tr. Vol. I at 85-86)

Dr. Caligaris' Proposed Alternative Education Plan

24. Mr. Miller testified that he had contacted CPEP on multiple occasions after Dr. Caligaris received the initial CPEP Education Plan. Mr. Miller testified that he had never spoken to the same person twice, nor did he ever get to speak with Dr. Watlington, the physician who had authored Dr. Caligaris' Education Plan. (Tr. Vol. I at 73-74)

Mr. Miller further testified that, in November 2003, he had sent to CPEP Dr. Caligaris' proposed alternative education plan. (Resp. Ex. F1; Tr. Vol. I at 72-73, 76)

25. Dr. Caligaris' Joint Education Plan Proposal included the same primary and secondary objectives as CPEP's plan, except that Dr. Caligaris' plan did not include Objective II number 4, "Establishment of boundaries related to patient volume that optimizes comprehensive and thoughtful care." However, there were differences in the performance objectives and evaluation methods to be employed. Most significantly, Dr. Caligaris' plan would utilize the Board, rather than CPEP, as a monitor. (Resp. Ex. F1)
26. By letter dated November 21, 2003, Kristin Y. Hasley, Director for Education Services for CPEP, responded to Dr. Caligaris' proposed alternative education plan. Ms. Hasley indicated that she had reviewed Dr. Caligaris' alternative plan with Dr. Watlington, and that they had incorporated some of the revisions suggested. However, Ms. Hasley further stated that much of Dr. Caligaris' proposal had "altered CPEP's monitoring processes, which cannot be accommodated." (Resp. Ex. G)

A comparison of CPEP's initial Education Plan with its "Revised 11/14/3 Education Plan" does not reveal any significant difference between them. The revised plan eliminated a requirement under Objective I that Dr. Caligaris review two journal articles each week and provide reports. Further, under Objective II, the revised plan reduced from 16 to 12 the number of Dr. Caligaris' charts to be reviewed monthly by his preceptor. (St. Ex. 6; Resp. Ex. E)

27. Mr. Miller testified that, although CPEP had been willing to accept some of Dr. Caligaris' proposals:

[CPEP] would not accept the proposals that we directly communicate with the Board and do our own assessment.

They wanted—It was a money issue. They wanted \$500 a month for us to send reports to them, who could turn around—same thing Dr. Caligaris was doing to the Board—turn around and send it to them. They wanted \$7,500 from him and they wanted him to come back out to be reassessed and I couldn't get a timeline from them, initially, on the assessment part. * * * They wanted their money and that is all they wanted and they wanted Dr. Caligaris to continue to send them all the documents.

(Tr. Vol. I at 75-76)

CPEP's February 2004 Final Assessment Report

28. Dr. Caligaris testified that, in or before February 2004, he had received from CPEP what he had believed to be a second copy of the Assessment Report he had signed in May 2003, and a cover letter asking for his signature. Dr. Caligaris had been concerned about signing the new document because he did not trust CPEP at that time. He testified that he had not understood why CPEP had sent the Assessment Report to him again. Dr. Caligaris further testified that, accordingly, he forwarded the CPEP report to Mr. Miller asking if he needed to sign it again. Dr. Caligaris testified that Mr. Miller told him that he had already signed the document. Accordingly, Dr. Caligaris testified that he never signed the second Assessment Report. (Tr. Vol. II at 222-223)
29. After Dr. Caligaris had received the second Assessment Report and the request for Dr. Caligaris' signature, CPEP had forwarded to Dr. Caligaris the final CPEP Assessment Report. The cover letter stated that a copy of the final report had been forwarded to the Board per Dr. Caligaris' request. (Resp. Ex. I; Tr. Vol. I at 78)

The February 2004 Assessment Report had been signed by Debbie Waugh, Assistant Director for Assessment Services for CPEP, and by Dr. Illige, on February 18 and 19, 2004, respectively. However, the space for Dr. Caligaris' signature contained the following statement: "PHYSICIAN DID NOT RESPOND TO OUR REQUEST FOR A SIGNATURE." (St. Ex. 3 at 20) (Emphasis in original)

30. By letter dated February 27, 2004, Mr. Miller responded. Mr. Miller stated that "Dr. Caligaris has never requested that the CPEP Assessment Report be sent to the State of Ohio Medical Board. This matter was provided to the Medical Board last year when the study was completed." Further, with reference to the statement that Dr. Caligaris had failed to respond to a request for signature, Mr. Miller stated that that was false and libelous. Moreover, Mr. Miller stated, "You have damaged Dr. Caligaris' reputation, filed a false report with a

State agency and have demonstrated to us a continuing concern that we have with your organization.” Finally, Mr. Miller attached a copy of the signature page from the initial Assessment Report, which indicates that the initial report had been signed by Dr. Caligaris on May 14, 2003, and by Dr. Illige and Ms. Waugh on May 16, 2003. (Resp. Ex. J)

Mr. Miller testified that he believes that the final Assessment Report had implied dishonesty on Dr. Caligaris’ part, although Dr. Caligaris “had always communicated a willingness to work with” CPEP. (Tr. Vol. I at 79-80)

31. By letter dated March 15, 2004, Elizabeth J. Korinek, Executive Director of CPEP apologized to Dr. Caligaris “for any errors or misunderstandings attributed to CPEP.” Ms. Korinek further stated, “I have reviewed CPEP’s handling of your situation and realize we made some significant errors.” Moreover, Ms. Korinek stated, in part:

Additionally, CPEP did not articulate the need for re-signing the report. CPEP should have informed you of the necessity to revise the Report, which required your signature in February. CPEP regrets any implication that you were not compliant with CPEP’s report signature policy.

(Resp. Ex. L)

32. By letter dated March 16, 2004, Ms. Waugh advised Board enforcement staff:

It has come to CPEP’s attention that we made errors in our recent handling of Dr. Caligaris’ final Assessment Report. Specifically, CPEP did not provide Dr. Caligaris with sufficient information regarding the reason he was being asked to sign the Assessment Report.

Please note that Dr. Caligaris did cooperate with CPEP’s initial request for signature following the completion of his Report in 2003.

(Resp. Ex. M)

33. Mr. Miller testified that, following CPEP’s apology letter to Dr. Caligaris and follow-up letter to the Board, he has had no further interaction with CPEP. (Tr. Vol. I at 84)

Stipulation of the Parties

34. At hearing, the parties agreed to the following stipulation:

It is stipulated by and between counsel for the State Medical Board of Ohio, hereafter Board, and counsel for Joseph Caligaris, M.D., having called upon to testify, Karen Mortland would testify under oath as follows: She is an enforcement attorney for the Board and has been so employed since December 31, 2001. As part of her duties she coordinates the investigation of

licensees and applicants under the jurisdiction of the Board and assembles evidence necessary to prove potential violations of the Medical Practices Act of Ohio.

Pursuant to the terms of the 2002 Consent Agreement entered into by and between the Board and Dr. Caligaris (marked as State's Exhibit 2) she worked with Dr. Caligaris' attorneys in formulating a subsequent agreement which would include terms, conditions and limitations as determined by the Board based upon the recommendation of CPEP. Her efforts included gathering information related to the CPEP assessment, drafting and revising proposed subsequent consent agreements, reviewing such subsequent consent agreements with the Board's Secretary and Supervising Member and obtaining their input and authorization to extend offers to Dr. Caligaris, negotiating such subsequent consent agreements with Dr. Caligaris' attorneys and exploring alternative actions to a subsequent consent agreement. In particular, from on or about March 29, 2005, through in or about November 2006, she engaged in such negotiations through the offering of consent agreements to Dr. Caligaris and the review of counter proposals from Dr. Caligaris to the Board. However, no agreement could be reached between the parties.

Accordingly, the Board and Dr. Caligaris have been unable to agree on the terms of a written consent agreement in accordance with the terms of Item B of the Agreed Conditions of the 2002 Consent Agreement.

(Tr. Vol. I at 47-49)

Evidence Concerning CPEP's Assessment Report of Dr. Caligaris

35. The majority of the CPEP Assessment Report reflected positively upon Dr. Caligaris, finding many aspects of Dr. Caligaris' care to be appropriate. However, CPEP criticized Dr. Caligaris with regard to several issues. In his Participant Response, Dr. Caligaris addressed all or nearly all of those issues, which he divided into twelve numbered comments. Further, at hearing, Dr. Caligaris' testimony, along with the testimony of Bruce H. Allen, M.D., addressed CPEP's criticism. (Resp. Exs. C and D; Tr. Vol. II)

Dr. Allen - Introduction

36. Bruce H. Allen, M.D., testified on behalf of Dr. Caligaris. Dr. Allen testified that he practices OB/GYN in Cincinnati, and that he has practiced for about 30 years. Dr. Allen testified, "[I am] an assistant voluntary professor at the University of Cincinnati, Department of Obstetrics and Gynecology. I'm also an assistant voluntary professor at the Department of Family Practice. I'm their gynecological consultant." (Tr. Vol. II at 8, 12-13)

Dr. Allen further testified that he has known Dr. Caligaris since Dr. Caligaris was a resident. Moreover, Dr. Allen testified that he had been on the teaching staff where

Dr. Caligaris had performed his residency. In addition, Dr. Allen testified that he and Dr. Caligaris both practice at Christ Hospital and that Dr. Allen has also observed Dr. Caligaris operate at Bethesda North Hospital. (Tr. Vol. II at 8-9)

37. Dr. Allen testified that he and Dr. Caligaris are part of a group of physicians in solo practice who share call with one another. Dr. Allen testified that “sharing call” means that, for example, if Dr. Caligaris is out of town, Dr. Allen will cover Dr. Caligaris’ patients, and vice versa. Through that experience, Dr. Allen testified, he has become familiar with the care that Dr. Caligaris provides to Dr. Allen’s own patients. Moreover, Dr. Allen testified that, in his professional opinion: “Dr. Caligaris provides excellent care. I have never had a problem with any of my patients that Dr. Caligaris has ever seen. I haven’t had any complaints.” Dr. Allen further testified that he has observed Dr. Caligaris in the operating room and that “[t]here’s never been a problem.” (Tr. Vol. II at 9-11)
38. Dr. Allen testified that he did not review any of Dr. Caligaris’ patient charts that had been evaluated by the CPEP consultants. (Tr. Vol. II at 63)

Issues related to Comment 1

39. Comment 1 of Dr. Caligaris’ Participant Response addressed CPEP’s statement that Dr. Caligaris had failed to provide a recent physical examination. CPEP corrected that information in its February 2004 report. (Resp. Exs. C and D; Tr. Vol. I at 106; Tr. Vol. II at 193-194)

Issues related to Comment 2

40. Under the heading Clinical Interview #1, the CPEP report states, in part:

The consultant commented on two high-risk obstetric cases, involving chronic hypertension and fetal trisomy 18. The documentation suggested timely and appropriate evaluation of the patients, with modifications to match their high risk needs. In the patient with chronic hypertension, visit frequency was increased to two times a week with a record of blood pressures and fetal evaluation. However, the consultant noted inadequate follow-up of some laboratory results. In one patient, a Group B Streptococcus (GBS) culture was positive. Dr. Caligaris initialed the lab slip but did not add it to the problem list. Upon admission for delivery, the nursing assessment identified the patient as GBS negative. The consultant opined that this oversight could have adversely affected this patient’s care. Overall, the consultant thought that Dr. Caligaris rendered appropriate obstetric care with prudent use of consultants for high-risk conditions such as genetic abnormalities and hypertension based on review of these cases.

(Resp. Ex. C at 7)

41. In Comment 2 of his response, Dr. Caligaris stated as follows:

[T]he consultant commented on the [GBS] culture not being added to the prenatal record problem list. He commented that I had seen the result and initialed the report. Unfortunately it was not added to the problem list which is an oversight by my office. Regardless, it would have had no bearing on my patient's care. The reason for this is that we send our prenatal records to the hospital at 28 weeks gestation. The [GBS] culture is not done until 35-37 weeks and sent separately by fax to the hospital so it can be added to the prenatal record. This is a very inefficient system with a large margin for error. In order to compensate for this error, I also carry a copy of each patient's [GBS] culture result with me until they deliver. This is so I can consult it if the faxed copy is misplaced. In this situation, if the nurse on admission of my patient did not find a copy of the result, they many times enter a negative finding. I always locate the copy of the [GBS] culture and if it is not with the prenatal record, I will find my copy in my briefcase. This is the best system I could come up with because the lab will not send the results directly to labor and delivery. I was never asked to explain this clinical situation by my consultant who may have had a different opinion.

(Resp. Ex. D at 1)

42. Dr. Caligaris testified that the issue of GBS cultures was never addressed during the interviews. Dr. Caligaris further testified: "[W]hen I looked at the report, that came out of the blue. I was like, that's an easy one to answer, why didn't they ask me about it?" (Tr. Vol. II at 125-126)
43. Dr. Caligaris testified that, by 2006, one laboratory had become predominant in Cincinnati and had taken over much of the lab work in the area. Dr. Caligaris further testified that that has largely alleviated the problem he described in his Participant Response. (Tr. Vol. II at 128-129)
44. Dr. Allen confirmed that the problem described by Dr. Caligaris with regard to GBS cultures is "a huge institutional problem." Dr. Allen testified that a patient's file is sent to the hospital early in case the patient should go into delivery early. However, after the GBS culture is obtained later in the course of the pregnancy, the results of that culture often do not make it to the patient's chart at the hospital. Dr. Allen testified that Dr. Caligaris is "probably doing more than most of us are doing" by carrying his patients' GBS results with him. (Tr. Vol. II at 17-20)

Additionally, Dr. Allen testified that the GBS test is not essential because if the mother's GBS status is unknown, she is treated with antibiotics. Likewise, if the infant to be delivered is premature or otherwise at high risk, the mother is treated with antibiotics regardless of the results of a GBS test. (Tr. Vol. II at 81)

Issues related to Comment 3

45. The CPEP Assessment Report states, in part, under the heading Clinical Interview #1:

The consultant thought that Dr. Caligaris demonstrated superficial understanding of the advantages and disadvantages of low molecular weight heparin and unfractionated heparin. Dr. Caligaris incorrectly stated that low molecular weight heparin has a short half-life that would enable patients to receive an epidural within 12 hours of the last dose. The consultant pointed out that current protocols include switching patients from low molecular weight heparin to unfractionated heparin at term so that they are candidates for epidural anesthesia.

(Resp. Ex. C at 8)

46. In his response, Dr. Caligaris stated:

[T]he consultant commented that I incorrectly stated that low molecular weight (LMW) heparin has a short half-life and would enable patients to receive an epidural within 12 hours of the last dose. He felt the patients needed to be switched to unfractionated heparin at term so they could get an epidural. This is definitely a valid plan of management but if you read the ACOG Practice Bulletin Number 19 issued August of 2000, entitled Thromboembolism in Pregnancy,² it states that patients on low dose LMW heparin could have an epidural [needle] placement by 10-12 hours after the last dose was given. You do not necessarily have to change to unfractionated heparin during labor unless anticoagulation is deemed necessary throughout the labor. This is not very common. Therefore I feel I was correct on this issue.

(Resp. Ex. D at 1-2)

47. Dr. Caligaris testified that the consultant had indicated that a physician would have to wait until 24 hours after the last dose of LMW heparin to place an epidural needle. However, the ACOG bulletin he referred to in his comment stated that an epidural needle may be placed 10 to 12 hours following an injection of LMW heparin in a patient receiving a single dose of LMW heparin per day. (Resp. Ex. Q; Tr. Vol. II at 131-135)

Dr. Caligaris further testified that the consultant had wanted him to say that he would move all his patients to unfractionated heparin at 36 weeks gestation. However, Dr. Caligaris testified that can be cumbersome and painful for the patient because lab work needs to be done every one to two days. Dr. Caligaris further testified that, with LMW heparin, the patient is given one injection per day and no laboratory work is necessary. (Tr. Vol. II at 133)

² Resp. Ex. Q.

48. Dr. Allen testified that heparin is an anticoagulant medication, and the risk of placing an epidural following a dose of heparin is that “you could nick a blood vessel and now you have bleeding in the back that is uncontrollable.” Dr. Allen further testified that, previously, heparin had been given by injection every eight hours; however, LMW heparin only needs to be given once per day. Dr. Allen stated that a problem arises when a patient comes in for early delivery and she has not yet been switched over to the older, shorter-acting form of heparin. However, Dr. Allen noted that ACOG stated in its bulletin that it is safe to place an epidural 12 hours after the last dose of LMW heparin with only minimal risk of bleeding. Finally, Dr. Allen testified that he agrees with ACOG and Dr. Caligaris concerning LMW heparin therapy. (Tr. Vol. II at 23-25)

Issues related to Comment 4

49. The CPEP Assessment Report states in part, under the heading Clinical Interview #1:

The consultant was concerned that Dr. Caligaris performed his own amniocentesis but demonstrated only a superficial knowledge of the procedures. Dr. Caligaris reported that he performed three to four amniocenteses per month and that many of his patients were over the age of 35. When the consultant asked Dr. Caligaris what type of needle he used, he said either a 26 or 28 gauge needle or whatever needle came in the kit. The consultant commented that most amniocentesis kits have a 20-gauge needle and that the smallest needle used would be a 22 gauge. A 26 or 28 gauge needle would be inappropriate because they are too thin and flimsy, especially when they are several centimeters long.

(St. Ex. C at 8)

50. In response, Dr. Caligaris stated:

[T]he consultant felt I had only superficial knowledge of amniocentesis because I was incorrect on the gauge of spinal needle used to do the procedure. At my hospital we use standard amniocentesis trays which have been changed numerous times over the last 13 years. These kits have all the necessary items needed to do the procedure and have been selected by our perinatologist. I do not think I have looked at the needle gauge in over 10 years. I assumed my perinatologist chose the correct kit. Regardless, I recently reviewed our kits and currently we are using 24 gauge spinal needles. I suppose we were both incorrect. I do not think this reflects on my ability to do the procedure or my selection of the patients who need the procedure.

(Resp. Ex. D at 2)

51. Dr. Allen testified that he regards CPEP’s criticism concerning the size of needle used for amniocentesis as “a relatively curious comment.” Dr. Allen testified that he has performed

amniocentesis for 30 years. He further testified that he had probably used 20 or 22 gauge needles early on, but that for the previous 15 years he has never looked at the size of the needle. Moreover, Dr. Allen testified that he has performed amniocentesis at Christ Hospital, Good Samaritan Hospital, and at Bethesda Hospital, and that all of those hospitals currently purchase kits for amniocentesis that include the needle that they want the physician to use. Furthermore, Dr. Allen testified, "We really have no choice on what needle that we're going to be given." Finally, Dr. Allen testified that the size of the needle has nothing to do with technique. (Tr. Vol. II at 25-28)

52. Dr. Caligaris' testimony on the issue of the needles used for amniocentesis echoed that of his written response and the testimony of Dr. Allen. (Tr. Vol. II at 135-138)

Issues related to Comment 5

53. The CPEP Assessment Report states, in part, under the heading Clinical Interview #1:

A final hypothetical case [addressed by the first consultant] covered cerclage issues. Dr. Caligaris knew the surgical controversies but seemed unfamiliar with all but the obvious indications for cerclage. The consultant described a patient with suspected passive dilation of the cervix at 28 weeks. Dr. Caligaris stated that he would consider a cerclage in the situation for a patient up to 32 weeks gestation. The consultant noted that, although some perinatologists took this approach, indications for cerclage are limited after 24-26 weeks. Dr. Caligaris did not suggest consultation. His described surgical technique was valid and contemporary, but the consultant disagreed with his stated patient selection.

(Resp. Ex. C at 8)

54. In response, Dr. Caligaris stated:

[T]he consultant thought I was unfamiliar with all but the obvious indications for cerclage. I do not understand what this means. Cervical incompetence is fairly obvious by history, ultrasound findings and/or clinical exam. The perinatologists in my community are very aggressive in treating this condition and advocate cerclage up to 32 weeks gestation. This was noted by the consultant as an approach by some perinatologists. I feel this reflects a difference in clinical practice between different areas of the country. Furthermore, the studies that reflect the consultant's opinion are primarily retrospective. Therefore this topic remains very controversial and many different opinions pervade the literature.

(Resp. Ex. D at 2)

55. Dr. Caligaris testified that the consultant had believed that after 24 to 26 weeks, there is no advantage to placing the cerclage. However, Dr. Caligaris testified that, in his community, there are “perinatologists that put them in up to 35 weeks.” Moreover, Dr. Caligaris testified that the standard for performing cerclage depends on how aggressive the perinatologists are in the community, because perinatologists set the standard for the care of high-risk obstetric patients. (Tr. Vol. II at 138-141)

Dr. Caligaris further testified that the consultant had believed “that any baby over 28 weeks was okay to deliver.” Finally, Dr. Caligaris testified:

I think that if you are able to maintain and keep a baby in to 32 weeks, they do a heck of a lot better. The parents do a lot better. [The babies] have less risk of intracerebral bleeds. They have less risk of blindness.

(Tr. Vol. II at 138-139)

56. In support for his position, Dr. Caligaris presented an article published in “Contemporary OB/GYN” in December 2005 concerning cerclage. (Resp. Ex. X)
57. Dr. Allen testified that he disagrees with the CPEP consultant’s opinion concerning cerclage. Dr. Allen further testified that cerclage is often performed after 24 to 26 weeks at Christ Hospital under appropriate circumstances. Dr. Allen testified that the decision to perform cerclage depends on the condition of the patient, the level of the nursery, the area were one practices, and how aggressive the physician wishes to be. Moreover, Dr. Allen testified that he believes that CPEP’s blanket statement appeared to be “cookbook medicine[.]” (Tr. Vol. II at 28-29)

Issues related to Comment 6

58. The CPEP Assessment Report states, in part, under the heading Clinical Interview #2, concerning abnormal Pap smears:

[I]f pathology showed a moderate dysplasia but not high-risk HPV [human papilloma virus] types, Dr. Caligaris recommended a repeat Pap in three months, since a large percentage of these lesions regress. If the changes persisted, Dr. Caligaris stated that he would perform a LEEP [loop electrosurgical excision procedure]. The consultant disagreed with his approach, because all patients with moderate dysplasia should undergo a LEEP regardless of HPV status. * * *

(Resp. Ex. C at 12)

59. In response, Dr. Caligaris stated:

[T]he consultant stated I would watch a patient with moderate dysplasia but low risk HPV types. This is incorrect. At the time of our discussion we were talking about mild dysplasia, not moderate dysplasia. I always perform a LEEP procedure when a patient has moderate dysplasia regardless of the HPV type. This reflects a misunderstanding by myself or the consultant during our discussion.

(Resp. Ex. D at 2)

60. Dr. Caligaris testified he believes that the case manager had become confused and had misunderstood the discussion concerning the levels of treatment for abnormal Pap smears and mild and moderate dysplasia. Dr. Caligaris further testified:

[The case manager] really got tied up in the difference of dysplasia mild and moderate, with and without HPV and all the letters of LEEP and cone biopsies and this and that and she really got all mixed up.

And I'm convinced, because I have never not treated moderate dysplasia in my whole career as Dr. Allen has mentioned, we were talking about mild for a long period of time where we would conservatively follow mild dysplasia. And I'm sure there was a mix-up at that point because she was not very adept at understanding these terms.

(Tr. Vol. II at 165-166)

61. Dr. Allen stated that dysplasia is a pre-cancerous condition that is graded on a scale ranging from mild to moderate to severe to superficial cancer to cancer. Dr. Allen testified that he cannot believe that any practicing gynecologist would state that he would simply watch moderate dysplasia. Dr. Allen further testified that it "is so, so wrong that it defies logic." Moreover, Dr. Allen believes that it is so basic that CPEP's statement had to have resulted from a communication problem. (Tr. Vol. II at 29-32)

Issues related to Comment 7- Part 1

62. The CPEP Assessment Report states, in part, under the heading Clinical Interview #2:

The consultant noted that [a] patient had suffered a deep venous thrombosis (DVT) at 22 weeks gestation. Dr. Caligaris saw her multiple times for this, yet did not clearly document it on her OB flow sheet or in the problem list at the top of the ACOG prenatal record. He treated her appropriately and referred her to a hematologist and perinatologist. The patient's labor was complicated by failure to progress and she had a C-section. She used Depo-Provera for contraception after delivery. The consultant commented

that the literature indicates that Depo-Provera can increase the risk of thrombosis. The consultant cautioned that such a patient needed clear informed consent with specific reference to blood clots, but he found no documentation in this patient's chart.

(Resp. Ex. C at 13)

63. In response, Dr. Caligaris stated:

[T]he consultant discussed my use of Depo-Provera in a patient who had a DVT in pregnancy. He felt the patient needed informed consent on this issue. After reviewing my notes, I found that on two separate office visits I discussed Depo-Provera with my patient prior to the institution of this therapy. On 3/19/01 and 4/26/01 it states I discussed Depo-Provera. This discussion would have involved the unclear incidence of thrombosis with the use of this medication. This was a decision based on my patient's need and desire for hormonal therapy. Since oral contraceptives were far more risky, we chose Depo-Provera instead. Her hematology workup was negative. She was eager to use this modality.

(Resp. Ex. D at 2) In addition, Dr. Caligaris referenced literature in support of his position.
(Resp. Ex. D at 2; Resp. Ex. W)

64. Dr. Caligaris testified that the issue of his patient who received Depo-Provera for contraception post-delivery had not been addressed during the interview. (Tr. Vol. II at 171-172)
65. With regard to the use of Depo-Provera in a patient with history of DVT, Dr. Caligaris referred to an excerpt from A Clinical Guide for Contraception: Third Edition, by Leon Speroff, M.D., and Philip D. Darney, M.D.:

The freedom from the side effects of estrogen allows Depo-Provera to be considered for patients with congenital heart disease, sickle cell anemia, patients with a previous history of thromboembolism, and women over age 35 who smoke or have other risk factors. The absolute safety in regard to thrombosis has not been proven and never will be in a controlled study. However, an increased risk of thrombosis has not been observed in epidemiologic evaluation of Depo-Provera users. A World Health Organization case-control study could find no evidence for increased risks of stroke, myocardial infarction, or venous thromboembolism.

(Resp. Ex. W at 202; Tr. Vol. II at 172-173)

66. Dr. Allen noted that Depo-Provera is a medication that can be used to prevent pregnancy. Dr. Allen testified that there is controversy concerning whether Depo-Provera can cause thrombosis. However, Dr. Allen testified that, in that regard, Depo-Provera is safer than

birth control pills. He further stated that Depo-Provera can be reasonable choice in a patient with a history of thrombosis if the risks are discussed with the patient. (Tr. Vol. II at 32-33)

Dr. Allen further testified that Dr. Leon Speroff “is one of the leading people in our field. He would be considered one of the most authoritative voices.” Moreover, Dr. Allen testified that Dr. Caligaris had accurately characterized Dr. Speroff’s statement on the safety of Depo-Provera with regard to thrombosis. (Tr. Vol. II at 33)

Issues related to Comment 7- Part 2

67. With regard to the same patient, the CPEP Assessment Report states:

The patient took Depo-Provera for several months. Six months after her last Depo-Provera shot, she returned to [Dr. Caligaris’] office for Clomid therapy to attempt pregnancy one more time. The consultant thought that the patient should have been counseled about how Depo-Provera might reduce her ability to conceive immediately after discontinuing it. The consultant commented that for a patient interested in a short interval between pregnancies, Depo-Provera is not a good choice.

(Resp. Ex. C at 13)

68. In Comment 7 of his written response, Dr. Caligaris stated:

Although it is true that Depo-Provera can reduce a patient’s ability to conceive, this patient had a long history of irregular cycles. I discussed with my patient the fact that she needed clomid to conceive with her first pregnancy. Therefore I simply reinstated this therapy which was quickly successful. If we waited for her ability to conceive to return after Depo-Provera, it would have just delayed the inevitable use of Clomid for this patient. My patient was made very aware of these facts, although I admit I didn’t document every single issue.

(Resp. Ex. D at 2)

Issues related to Comment 8

69. The CPEP Assessment Report states, in part, under the heading Clinical Interview #2:

Dr. Caligaris outlined his approach to hormone replacement therapy (HRT) in a hypothetical patient who had undergone a total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH/BSO) for diffuse endometriosis. The consultant stated that this patient had residual disease. Dr. Caligaris would recommend no hormone therapy for three months, then offer low dose estrogen and progesterone. The consultant pointed out that patients without a

uterus or ovaries need only estrogen replacement. The consultant agreed that waiting a short time before instituting therapy with estrogen was reasonable treatment for patients with endometriosis.

(Resp. Ex. C at 11)

70. In response, Dr. Caligaris stated:

[T]he consultant felt that after hysterectomy a patient with diffuse endometriosis only needs estrogen replacement. This issue is still very unclear. If you read the ACOG Technical Bulletin (#184)³ and the ACOG Practice Bulletin (#11)⁴ which deal with endometriosis treatment, you will find that experts feel the institution of a combination estrogen and progesterone therapy in patients with hysterectomies may afford several advantages. It may decrease the incidence of malignant transformation in residual implants and cause decidualization in residual implants with eventual atrophy. In the hypothetical patient which was discussed with my consultant there was diffuse disease which would have not been totally removed at surgery. It therefore is not unheard of to institute therapy following surgery after a short interval and to add a progestational agent.

(Resp. Ex. D at 3)

71. Dr. Caligaris testified that he had discussed this issue extensively with the consultant, and they disagreed on whether to give progesterone. (Tr. Vol. II at 150-153)

At hearing, Dr. Caligaris presented the two articles that he had referenced in his written response. Dr. Caligaris testified that ACOG Technical Bulletin #184 states that it is prudent to give progesterone to a patient with residual endometriosis “to try to prevent progression in the disease process * * *.” (Resp. Ex. R at 406; Tr. Vol. II at 154-155) Moreover, Dr. Caligaris testified that ACOG Practice Bulletin #11 states: “There is also a concern about the possibility of estrogen induced malignant transformation in residual endometriosis implants * * *, which has led some to recommend the routine addition of a progestin to the estrogen therapy, although there are no outcomes-based evidence to support this recommendation.” (Resp. Ex. S at 967; Tr. Vol. II at 156-157)

72. Dr. Caligaris agreed with the bulletin’s statement that “there are no outcomes-based evidence to support” the addition of progesterone to estrogen therapy for a patient with residual endometriosis. However, Dr. Caligaris testified that there are a lot of things that physicians do that are not supported by outcomes-based evidence. (Resp. Ex. S at 967; Tr. Vol. II at 227)

³ Resp. Ex. R.

⁴ Resp. Ex. S.

73. Dr. Allen testified that he agrees with Dr. Caligaris' statements in Comment 8. In a patient who has had her ovaries removed, estrogen therapy is instituted to prevent the sudden onset of menopause and its attendant symptoms. Dr. Allen further stated that progesterone protects the lining of the womb. In an ordinary case, once the uterus has been removed, there is no need to institute progesterone therapy because there is no womb to protect. However, Dr. Allen testified that an exception exists when a patient has residual endometriosis. (Tr. Vol. II at 33-36)

Dr. Allen testified that endometriosis is a condition in which the lining of the womb spreads outside of the uterus. Dr. Allen further testified that the result can be "little implants of endometriosis throughout the pelvis." When that occurs, is not always possible for the physician to surgically remove all of the implants, and some are left behind. Dr. Allen testified that the implants that are left behind are referred to as residual disease. (Tr. Vol. II at 60-61)

Dr. Allen testified that endometriosis is estrogen dependent. (Tr. Vol. II at 36) Furthermore, Dr. Allen testified:

[W]hen you [institute estrogen therapy], there is a chance that you're going to reactivate some of the [endometriosis] that you've left behind. So there is a school of thought that says, in this one particular instance, it might be helpful to give some progesterone to try to help counteract the reactivation of the endometriosis, yet still make the woman comfortable.

So the [CPEP] consultant is right in a sense that, under most circumstances, you really don't have to give progesterone because it's not necessary without a uterus. * * * [T]he one exception is with endometriosis, that it's permissible and there is a strong school of thought that says that is very beneficial.

(Tr. Vol. II at 35)

Issues related to Comment 9

74. The CPEP Assessment Report states, in part, under the heading Clinical Interview #2:

The consultant reviewed an additional patient chart from Dr. Caligaris' practice that was discussed during the interview. The patient had vulvovaginal itching. Dr. Caligaris did not do a wet prep, pH, potassium hydroxide (KOH), or cultures. Dr. Caligaris documented a discussion about hygiene issues and recommended sitz baths. He offered no diagnosis. The consultant questioned the efficacy of the sitz baths for this symptom. This patient desired pregnancy but had irregular menstrual cycles. After she tried to get pregnant for three months, Dr. Caligaris started her on Clomid therapy. The consultant pointed out that Dr. Caligaris should first verify a normal sperm count by semen analysis; however, it was difficult to tell from the chart

whether this test had been ordered. The patient became pregnant and Dr. Caligaris saw her frequently. The reasons for this were unclear. Dr. Caligaris offered HIV testing but the patient declined. He did a GBS culture at six weeks. The consultant pointed out the GBS screening is usually done between 35 and 37 weeks.

(Resp. Ex. C at 13)

75. In response, Dr. Caligaris stated:

[T]he consultant discussed the evaluation of my patient who had vulvovaginal itching. After review of this chart, the patient had no evidence of vulvovaginal changes and I felt she had an allergic reaction or activity related irritation. I did not find any evidence of vulvovaginitis and recommended more hygiene related treatments. These measures worked. I would have reevaluated the situation if the patient's symptoms changed or worsened. In my notes, I gave the patient indicators to watch for (10/25/99).

The consultant also commented on my use of clomid in this patient after 3 months of trying to conceive. In fact, clomid wasn't started until 7 months after her initial visit which was 10 months after trying to conceive. A semen analysis was not done because she conceived after only two months on clomid despite a long history of very dysfunctional menses. I feel I was successful with this therapy.

(Resp. Ex. D at 3)

76. Dr. Caligaris testified that the issue of vulvovaginal itching had not been discussed during the interview. Dr. Caligaris testified that the issue of Clomid had been discussed. (Tr. Vol. II at 168)

Dr. Caligaris testified with regard to vulvovaginal itching that, upon his examination of the patient, he found that she did not have a vaginal infection. However, Dr. Caligaris testified: "She had a vulvitis, I think, presumably from detergent changes and things like that. So I didn't do a culture on her because I didn't feel it was necessary. He criticized me for not doing a culture when there was nothing to culture." Dr. Caligaris added that the patient got better following his recommended treatment. (Tr. Vol. II at 144-145)

With regard to Clomid therapy, Dr. Caligaris testified that the consultant had criticized him for failing to obtain a sperm count. Dr. Caligaris testified that he was perplexed by that criticism. Dr. Caligaris further testified that he had obtained progesterone levels over a three-month period, which the consultant never mentioned. In addition, Dr. Caligaris testified that he had known that the patient had been having anovulatory cycles. Moreover, Dr. Caligaris testified that he had known that the patient had previously had a child with the

same partner. Finally, Dr. Caligaris testified that she had conceived within two months of the initiation of Clomid therapy. (Tr. Vol. II at 145-147)

77. Dr. Caligaris testified that the GBS culture issue had not been discussed during the interview with regard to this patient. Dr. Caligaris testified that he had obtained a GBS culture at six weeks on this patient because, as had been documented in his chart, she had had a history of GBS in her first pregnancy. Dr. Caligaris testified that he had obtained the early culture because he had wanted to find out if GBS was still present. Dr. Caligaris acknowledged that that information had not changed what he had done with the patient, other than watch “for asymptomatic urinary tract infections.” Dr. Caligaris further testified that he had still obtained a culture at 36 weeks. Finally, Dr. Caligaris testified that, even if the GBS culture is negative, he treats the patient with antibiotics if, as in this case, the patient had a history of previous infection. (Resp. Ex. C at 13; Tr. Vol. II at 168-170)
78. Dr. Allen testified that, with regard to the patient’s vulvovaginal itching, “you really have to see a patient to know if [you] should do cultures or what’s going on.” Dr. Allen further testified that any number of things could have caused an allergic response. Moreover, Dr. Allen testified: “So my understanding of his description was he treated her appropriately and she got better. So I wouldn’t necessarily start—the minute someone came in and running all kinds of cultures and looking for something which she doesn’t have.” (Tr. Vol. II at 36-37)

With regard to Clomid therapy, Dr. Allen testified that he, too, would have used Clomid on the patient and would not have obtained a semen analysis. Dr. Allen noted that the patient had been having irregular, dysfunctional periods. From this, one could assume the patient was not ovulating. Dr. Allen stated that Clomid is an inexpensive and easy way to correct that. (Tr. Vol. II at 37)

With regard to semen analysis, Dr. Allen testified that, if the patient had been unable to conceive while having regular periods and no other symptoms, and perhaps a child from a previous relationship, a semen analysis would be appropriate. However, in this patient’s case, she had presented “with probably the most common infertility problem,” and semen analysis would not have been an appropriate first step. (Tr. Vol. II at 37-38)

Issues related to Comment 10

79. The CPEP Assessment Report states, in part, under the heading Clinical Interview #2:

The consultant queried Dr. Caligaris for his recommended management of a 220 pound, 39 year old female who desired pregnancy. She had sporadic but prolonged periods and had had no menses for three to four months. Dr. Caligaris would appropriately assess her smoking and medical history. He would request a pregnancy test, thyroid function tests, prolactin level, possibly a follicle stimulating hormone (FSH) level, and a vaginal probe pelvic ultrasound. An endometrial biopsy would help to assess the status of the

uterine lining and the presence of dyssynchronous endometrium. Dr. Caligaris failed to address this patient's excessive weight. The consultant asked him what findings would be consistent with polycystic ovarian syndrome (PCOS) and Dr. Caligaris listed hirsutism, elevated levels of dihydroxy epiandrosterone sulfate (DHEA-S), and ovarian enlargement on ultrasound. The consultant pointed out that, according to [ACOG], a diagnosis of PCOS cannot be made by ultrasound. Dr. Caligaris was aware of this.

The consultant asked about insulin resistance in patients with PCOS. Dr. Caligaris explained how to diagnose glucose intolerance/diabetes, but did not mention fasting insulin levels for PCOS diagnosis. The consultant thought that Dr. Caligaris should have immediately recognized PCOS in this patient. In addition to the laboratory evaluation suggested by Dr. Caligaris, the consultant would add luteinizing hormone (LH) and a free testosterone level. Such patients should be monitored for elevated glucose and cholesterol levels.

(Resp. Ex. C at 11)

80. In response, Dr. Caligaris stated:

[T]he consultant felt I should have immediately recognized PCOS in the presented hypothetical patient. I do not understand how that would be the case if I am only presented a scenario of a 220 pound, 39 year old who desires to conceive and has irregular cycles. In this age group, I am evaluating for many issues, i.e., early menopause, pregnancy, thyroid disease and ovarian pathology to name a few. PCOS is not my primary diagnosis in this age group. I also don't feel this patient can be classified as having excessive weight if she only weighs 220. When we discussed PCOS, I was able to elaborate on each component of this disease process, i.e., hirsutism, glucose intolerance, anovulation and infertility. I was criticized for not suggesting a fasting insulin level. This test is helpful but if you read ACOG Practice Bulletin (#41)⁵ it is an optional test to be considered. Therefore it would be drawn after a definite diagnosis had been made, not at the initial evaluation.

(Resp. Ex. D at 3)

81. Dr. Allen testified that PCOS is a group of conditions where a woman does not ovulate and "has some other metabolic problems that have a fairly common, typical way they present." Dr. Allen further testified that he agrees with Dr. Caligaris' position in Comment 10. Moreover, Dr. Allen testified that he believes that "the consultant seemed to have a tendency to run every test known to mankind on [a] patient when the patient walked in, which would be tremendously expensive and would give you vast amounts of useless information." Dr. Allen stated that it is better to work up a patient in a systematic way,

⁵ Resp. Ex. T.

where the results of one test can lead to another test, and so forth. Further, Dr. Allen testified that the practice bulletin referenced by Dr. Caligaris states that, statistically, a fasting insulin level has not proven to be of much value under the hypothetical patient's presenting circumstances. (Tr. Vol. II at 40-42)

82. With regard to Dr. Caligaris' comment that 220 pounds is not "excessive" weight, Dr. Allen testified that "excessive" is difficult to define because it is a qualitative term. Dr. Allen further testified that 220 pounds would certainly be overweight. Moreover, Dr. Allen testified that, although excessive weight is a factor in diagnosing PCOS, it is only one of many factors. (Tr. Vol. II at 56-57)
83. Dr. Caligaris testified that he had wanted to ensure that the hypothetical patient was not pregnant and was not going through menopause, and he had wanted to check her FSH, prolactin, and thyroid levels. Dr. Caligaris further testified that these are the basic things that need to be checked before moving on to other possibilities. With regard to obtaining a fasting insulin level, Dr. Caligaris testified that he would not obtain that at the first visit. He stated that obtaining a fasting insulin level becomes important in managing a patient's glucose intolerance after the patient has been diagnosed as having PCOS. However, Dr. Caligaris testified that insulin levels are not the first thing he would check when presented with a patient who is not having periods but wants to conceive. Finally, Dr. Caligaris presented a copy of ACOG Practice Bulletin #41 as support for his position. (Resp. Ex. T; Tr. Vol. II at 160-164)

Issues related to Comment 11

84. The CPEP Assessment Report states, in part, under the heading Clinical Interview #2:

The consultant inquired about a patient of Dr. Caligaris' who had prolonged pelvic pain. At her first visit, Dr. Caligaris ordered a pregnancy test (negative), a complete blood count (CBC), which showed a normal white blood [cell] count (WBC), and a pelvic ultrasound, which was normal. Dr. Caligaris explained that since the patient did not have purulent drainage from the cervix, he opted not to obtain cultures. The patient returned one week later with worsening symptoms and Dr. Caligaris recommended diagnostic laparoscopy. The consultant asked Dr. Caligaris for his preoperative diagnosis. Dr. Caligaris listed pelvic inflammatory disease (PID) and endometriosis as potential etiologies. Dr. Caligaris also stated that an erythrocyte sedimentation rate (ESR) and CA 125, which can be elevated in moderate endometriosis, might also be helpful.

The consultant thought that Dr. Caligaris' initial evaluation of a pregnancy test, CBC, and ultrasound was reasonable. However, the consultant commented that Dr. Caligaris should have obtained cervical cultures because PID was considered a possible diagnosis. The consultant pointed out that cultures for gonorrhea and Chlamydia should always be obtained in suspected

PID with or without mucopurulent discharge. A WBC and an ESR can be helpful, but a CA 125, a nonspecific finding, would not be useful and could be falsely positive.

Dr. Caligaris perform diagnostic laparoscopy on this patient and found tubo-ovarian abscesses and bilateral hydrosalpinx with massive adhesions. He suggested chlamydia as the presumptive cause, despite the fact that cultures were negative. The patient was placed on triple antibiotic therapy (ampicillin, clindamycin, and gentamicin) in the hospital and discharged on Flagyl and doxycycline. The consultant asked Dr. Caligaris how he would determine the duration of antibiotic therapy. Dr. Caligaris stated that he used the patient's pain as his guide. The consultant offered that a WBC, ESR, or C-reactive protein might be helpful markers in determining the endpoint of treatment. In addition, the consultant commented that Dr. Caligaris' antibiotic choices were outdated. A better regimen would include a third-generation cephalosporin and doxycycline or azithromycin. The consultant also noted that despite five subsequent visits for recurrent pelvic pain after the surgery, Dr. Caligaris did not repeat cervical cultures, although he did so he eventually.

(Resp. Ex. C at 10)

85. In response, Dr. Caligaris stated:

[T]he consultant reviewed our discussion of my patient who had PID and adhesions. The consultant felt I [should] have done vaginal cultures because PID was considered. Unfortunately, there were no clinical signs of PID, especially no discharge. Cultures had already been done 3 months earlier, which were negative. Her CBC at that time was normal. Although subclinical PID is always part of my differential diagnosis of lower abdominal pain in this patient, it was down on my list. It wasn't until the laparoscopic evaluation revealed the significance of her problem. Once the surgery had been done, her history and clinical findings suggested a subclinical infection which usually is a result of chlamydia. Despite negative intraoperative cultures she still needed antibiotic therapy and chlamydial coverage.

The consultant also felt I used antibiotic choices which were outdated. The antibiotics I used are still options per ACOG Technical Bulletin (#237),⁶ especially in the year 2000. The triple antibiotics used covered a broad spectrum of organisms and my patient responded well to them. Since her intraabdominal cultures were negative, I felt I had to cover for chlamydial and anaerobic organisms as an outpatient. The antibiotics I used are still in wide use today.

⁶ Resp. Ex. U.

The consultant also felt I should have used some type of laboratory marker to determine duration of therapy (i.e., CBC, ESR, etc.). In this situation, my patient never had an elevated marker, so I was left with clinical symptoms as my best indicator of improvement.

Finally, the consultant felt she had recurrent pain after surgery and cultures were not immediately done. In fact, my patient was hospitalized in mid-December, 2000, and was seen [again] at the end of December. She was still on her initial antibiotics. I documented no pain at that time. She was again seen in mid-January, 2001. At that time she had no pain and felt better. Of course no cultures were done. She was seen again in March, 2001, and had no signs or symptoms of recurrent disease. I believed repeat cultures were not necessary at that time. She again was seen in December, 2001, with again no findings of pain. Finally, in March, 2002 (15 months after her hospitalization) she presented with the beginnings of recurrent pelvic/abdominal pain. With these new symptoms cultures were done at this visit. This is the first visit where pain was found either clinically or by history. I feel my use of cultures in this situation was appropriate. She had no pain until 15 months after the initial hospitalization.

(Resp. Ex. D at 4)

86. Dr. Caligaris testified:

[T]his disagreement mostly was over, one, what antibiotics to use; two, whether we should follow-up her post surgery and post treatment with sedimentation rates, C-reactive protein, white blood cell counts, those type of issues. He seemed to be wanting me to culture her every single time that she came into the office. And I didn't agree with that because there was nothing to culture.

(Tr. Vol. II at 176)

87. With regard to the consultant's criticism that Dr. Caligaris should have obtained a test for Chlamydia in a patient who suffered from pelvic pain, Dr. Caligaris testified:

[T]he problem in this patient was that we had no diagnosis until we laparoscoped her. He jumped to the conclusion that because we found something at laparoscopy, that we should have known it beforehand. And when she was in my office, she wasn't in there for pelvic infection. She was in there for pelvic pain. There was no discharge. We had done a culture on the previous visit, which was negative. She had a white blood cell count, which was normal.

* * * [M]y evaluation was* * * for pelvic pain. Now, there are many causes of pelvic pain, pelvic inflammatory disease being one. So we never made a diagnosis until we laparoscoped her in the hospital and found that she had extensive pelvic inflammatory disease and admitted her immediately from the operating room.

(Tr. Vol. II at 178-179)

88. With regard to his choice of antibiotics, Dr. Caligaris testified that he has “a big disagreement” with the consultant. Dr. Caligaris testified that this particular patient “had bilateral tubo-ovarian complexes, which [are] basically abscesses.” Dr. Caligaris further testified that it had therefore been necessary to treat her for anaerobic organisms. Moreover, Dr. Caligaris testified that the antibiotics suggested by the consultant “do not cover anaerobic organisms. Now, Flagyl, which is what I put this patient on, covers for this type of organism.” (Tr. Vol. II at 179-180)

Dr. Caligaris referenced ACOG Educational Bulletin #237 as support for his position concerning antibiotics. Dr. Caligaris testified that the bulletin recommends broad spectrum antibiotic coverage for sepsis. Dr. Caligaris further testified: “[O]nce I knew that that patient has bilateral tubal ovarian abscesses, that is sepsis to some extent. And that patient needed broad-spectrum antibiotics, which is consistent with what I treated [her] with because of the issue of an anaerobic organism.” (Resp. Ex. U at 289; Tr. Vol. II at 202-203)

89. Dr. Caligaris testified that ESR is a sedimentation rate, and is a “very nonspecific test” for inflammation. He further testified that it is “elevated in rheumatologic conditions such as lupus” but can also be elevated in someone who has an infection. (Tr. Vol. II at 177)

Dr. Caligaris testified that CA 125 is a screening test for cancer, “usually ovarian cancer.” Dr. Caligaris further testified that the test is “not very specific.” Moreover, Dr. Caligaris testified that the consultant had criticized him for using a CA 125 test in a patient who the consultant described as having a pelvic mass. Dr. Caligaris testified that he had told the consultant “it can be elevated in nonmalignant conditions, but if we end up finding a malignancy or something, at least we have a baseline. So it’s an easy test to do and that is why we do it in a person with a pelvic mass.” (Tr. Vol. II at 177-178)

90. Dr. Caligaris testified that he disagrees with the consultant’s comment that Dr. Caligaris had seen the patient for recurring pelvic pain for five subsequent visits without doing a repeat cervical culture. Dr. Caligaris testified that the five visits “were not for pelvic pain. They were follow-up visits where she had no pain. It wasn’t until she had pain several months later. And at that point, he even admits I did a culture at that point. But prior to that, she was doing fine.” (Tr. Vol. II at 180-181)
91. Dr. Allen testified that he agrees with Dr. Caligaris’ responses concerning the diagnosis of PID. Dr. Allen further testified that Dr. Caligaris had diagnosed PID laparoscopically,

which Dr. Allen characterized as a definitive method of diagnosing that condition.
(Tr. Vol. II at 42)

Moreover, Dr. Allen testified that Dr. Caligaris had used “standard triple therapy, which has been done for years and covers absolutely everything. I’ve seen infectious disease consultants with this type of patient use the same type of antibiotics.” Moreover, Dr. Allen testified that newer antibiotics are not always the best choice when the minimal increase in efficacy is compared to the extra cost. (Tr. Vol. II at 42-44)

Issues related to Comment 12

92. The CPEP Assessment Report states in part, under the heading Clinical Interview #2:

The patient was on the oral contraceptive pills (OCPs) and was experiencing vaginal spotting. Dr. Caligaris excluded pregnancy as a cause and correctly changed the OCP. The consultant asked if there would be less spotting with triphasic versus monophasic contraceptives. Dr. Caligaris responded that it depended on the type of pill. He stated that LoOvral, a monophasic pill, caused infrequent spotting and Nordette, also a monophasic pill, had a greater incidence of spotting. He listed Tri-Cyclen as causing a low incidence of spotting. The consultant commented that Dr. Caligaris’ knowledge about how to adjust OCPs to eradicate breakthrough bleeding was unacceptable. The timing of the breakthrough bleeding (early, mid, or late in the cycle) should determine the type of pill change. The consultant also noted that Dr. Caligaris’ information about the amount of breakthrough bleeding occurring with LoOvral, Nordette and Ortho Tri-Cyclen was not supported in the medical literature. Dr. Caligaris was aware that OCPs can exacerbate depression.

Dr. Caligaris explained that he might choose a lower dose estrogen pill for patients who are over 35 and do not smoke. The consultant thought that this was reasonable. However, Dr. Caligaris stated that he would also use a lower dose estrogen pill for those having side effects of acne and moodiness and teenagers who might be noncompliant. The consultant thought that a low dose estrogen pill in these two patient populations was not appropriate. His management of the patient experiencing migraines on OCPs would likely involve changing to a lower dose pill, but this might vary depending upon the timing of the migraines within the menstrual cycle. Dr. Caligaris was not familiar with the new oral contraceptive available that includes only two days of inert ingredients. This would prevent a withdrawal type migraine headache. Although Dr. Caligaris appreciated the relationship between the part of the cycle in which headaches are experienced and hormone doses, the consultant stated that Dr. Caligaris’ knowledge of OCP management in this context was limited.

(Resp. Ex. C at 9)

93. In response, Dr. Caligaris stated:

[T]he consultant felt my knowledge of OCP adjustment to breakthrough bleeding was unacceptable. I remember discussing with the consultant that it depended on the cycle timing and type of pill being used to determine the changes to be made. If you consider the information from Dickey's book on Contraceptive Management,⁷ statistically LoOvral has less of an incidence of breakthrough bleeding than Nordette (almost half as great). In fact, if you remove early withdrawal bleeding for [Ortho Tri-Cyclen] (seen in first 3 months) the incidence of [breakthrough bleeding] is similar to monophasic pills.

The consultant also felt a low dose estrogen pill in the teenage population with acne, moodiness and possible noncompliance was not appropriate. According to Dickey, compliance is difficult to combat but with acne and moodiness you want to decrease the estrogen/progesterone dose if possible to minimize these side effects. I feel the consultant misunderstood when I stated I would use a low dose pill. I meant not only low dose estrogen but also low dose progesterone with a lower androgenic potential.

Finally, the consultant discussed a patient with migraines on OCPs. We discussed continuous therapy to minimize the withdrawal period. In fact, both Dickey and Speroff advocate lowering the estrogen level in these types of patients. Essentially using a lower dose pill as I stated. I feel strongly that we miscommunicated on the subject on several levels.

(Resp. Ex. D at 4-5)

94. Dr. Allen testified that he supports Dr. Caligaris' position concerning LoOvral and breakthrough bleeding. Dr. Allen further testified that, although LoOvral is an older medication, it continues as the standard to which new medications are compared with regard to breakthrough bleeding. (Tr. Vol. II at 44-45)

In addition, Dr. Allen testified that LoOvral has a lower incidence of breakthrough bleeding than Nordette. Dr. Allen further testified: "Common sense would tell you that because it's almost twice the hormones. The reason they came out with Nordette as opposed to LoOvral is because they've tried to drop the total hormone content to theoretically make the pill safer. But in doing that, you start picking up breakthrough bleeding." Dr. Allen further testified that both Nordette and LoOvral provide the same protection rate, but the breakthrough bleeding rate is lower for LoOvral because of its higher hormone content. (Tr. Vol. II at 45-46)

⁷ Resp. Ex. V.

95. With regard to the issue of breakthrough bleeding, Dr. Caligaris testified that his information had been based upon the recommendations of Richard P. Dickey, M.D., in his book entitled *Managing Contraceptive Pill Patients*. Dr. Caligaris questioned the consultant's statement that Dr. Caligaris' information concerning breakthrough bleeding with LoOvral, Nordette, and Ortho Tri-Cyclen was not supported by literature. Dr. Caligaris testified that Dr. Dickey's book contains a table that gives specific breakthrough bleeding rates on different medications. Dr. Caligaris pointed out that, in Table 5 of that book, LoOvral has the best breakthrough bleeding profile of all the medications at 9.6 percent. Nordette is higher at 14 percent. (Resp. Ex. V at 134-135; Tr. Vol. II at 182-187)

Dr. Caligaris further testified that the consultant had criticized him because he would lower the estrogen level of OCPs in a teenage patient with moodiness and acne. However, Dr. Caligaris testified that, in another part of the report, the consultant stated that Dr. Caligaris had understood that OCPs could cause depression. Dr. Caligaris further testified that "moodiness and depression kind of go hand in hand." Accordingly, Dr. Caligaris stated that, if the patient is a teenager who is moody or depressed, it is best to decrease the estrogen level of the OCP she is taking. (Tr. Vol. II at 187-188)

In addition, Dr. Caligaris testified that the consultant believed that a physician should not prescribe OCPs to a noncompliant teenage patient. Dr. Caligaris testified that he does not "necessarily agree with that until she's shown to be noncompliant." Dr. Caligaris further testified that he would give the patient a chance "and try to educate her to understand what she is supposed to do to prevent pregnancy. Many of these girls just don't understand because there is no one there to explain it to them." However, Dr. Caligaris testified that the consultant had believed "that any noncompliant patient shouldn't be treated with birth control pills * * *." (Tr. Vol. II at 188)

Additional CPEP Criticisms Not Addressed by Dr. Caligaris in His Participant Response, but Addressed at Hearing

96. The consultant who performed the second interview noted that he had asked Dr. Caligaris to describe his approach to prevent thromboemboli in surgical patients. The Assessment Report states: "Dr. Caligaris correctly listed those patients with V Leiden deficiency and a history of previous deep venous thrombosis as being at increased risk. However, he did not mention other important patient-specific factors such as age and obesity or procedure-specific factors such as prolonged operating time." (Resp. Ex. C at 11)
97. Dr. Caligaris testified that he and the consultant had discussed what they "would use as prophylaxis in surgical situations." Dr. Caligaris further testified: "He then asked me what type of patients would you think would be at high risk. So I listed those two patients. And that's where the conversation ended." (Tr. Vol. II at 157-158)
98. The Assessment Report states, in part, with regard to clinical interview #2: "Dr. Caligaris correctly identified several side effects of Depo Provera, including a possible delay of the

return of normal menses. He did not mention increased risk of blood clots.” (Resp. Ex. C at 12)

99. Dr. Caligaris testified that he finds that statement to be perplexing because the issue of Depo Provera and thrombosis had been addressed elsewhere in the Assessment Report. He attributed that criticism to poor note-taking or lack of understanding on the part of the case manager who sat in on the interviews and took notes. (Tr. Vol. II at 167)

Written Examinations

100. With regard to the Multiple Choice Question Knowledge Test, the CPEP Assessment Report states that Dr. Caligaris had adequate knowledge in gynecology and obstetrics, although the report stated that Dr. Caligaris “missed questions in the area of coagulation.” (Resp. Ex. C at 14)
101. The CPEP report indicates that Dr. Caligaris performed well on the Fetal Monitor Strip Interpretation test. (Resp. Ex. C at 14)

Physician/Patient Communication Evaluation

102. With regard to the simulated patient interviews, the Assessment Report included a number of positive comments concerning Dr. Caligaris’ communication skills, but noted that Dr. Caligaris needed to give the patients more time to speak before interrupting. (Resp. Ex. C at 14-15)
103. Dr. Caligaris testified:

I had 20 minutes and I was trying to get as much information in the 20 minutes as I could. Some of these patients were tending to ramble, kind of playing their role a little bit. I needed to direct them, as you do sometimes with patients, onto what was more pertinent to what I needed to know.

(Tr. Vol. II at 189-190)

Patient Care Documentation

104. With regard to Dr. Caligaris’ patient charts, the CPEP report stated:

The consultants commented that Dr. Caligaris’ handwriting was barely legible. His notes contained a paucity of clinical information. His progress note sheets were antiquated, but the consultant noted that Dr. Caligaris used the ACOG standard prenatal record. In one case, a positive GBS culture was not entered on the problem list section in the prenatal record. Therefore, she was incorrectly thought to be GBS negative on presentation

to the labor and delivery ward. A dictated operative report contained in the records was well done.

(Resp. Ex. C at 15)

105. Dr. Caligaris testified that neither consultant had discussed with him the legibility of his patient records. (Tr. Vol. II at 212, 229-230)

Dr. Caligaris testified that he believes the legibility of his patient records “is as good as anybody else’s out there.” Dr. Caligaris acknowledged that he uses some abbreviations and shorthand as do other physicians in his own and other specialties. Dr. Caligaris also testified that he does not “necessarily write down every negative finding like some people say you should.” Dr. Caligaris testified that, nevertheless, another physician could follow his charts, understand his train of thought, and comprehend his treatment plan and the outcome. (Tr. Vol. II at 196, 212)

With regard to his documentation of the simulated patient visits, Dr. Caligaris testified that they would have been more legible had he been able to dictate the notes. He further testified that he was given 10 minutes with each patient to write the history, what he would have found on the physical examination, and his assessment and findings. Dr. Caligaris testified that, given the circumstances, he had written the notes as fast as he could. (Tr. Vol. II at 192-193)

106. Dr. Caligaris further noted that the GBS culture issue quoted above is the same issue addressed earlier. (Tr. Vol. II at 190)

107. Dr. Allen testified that he has seen Dr. Caligaris’ medical documentation on occasions when he has covered for Dr. Caligaris and one of Dr. Caligaris’ patients goes into labor. Dr. Allen testified that he has never had any difficulty with Dr. Caligaris’ record-keeping or with the legibility of his records. (Tr. Vol. II at 15-16)

Additional Information

Testimony of Dr. Caligaris

108. Dr. Caligaris testified that he had found CPEP’s methods to be questionable. Dr. Caligaris further testified that, CPEP had sought to be the entity that managed his re-education; therefore, it had had an interest in finding problem areas that needed re-education. Dr. Caligaris stated that he would have felt better being assessed by a program that would not profit from his re-education. (Tr. Vol. II at 122-123)

In addition, Dr. Caligaris testified that the CPEP consultants had had certain questions that they expected to be answered in a particular way. Dr. Caligaris testified, “I have a hard time with that because medical practice is not always black and white.” He further testified that there are regional differences, personal differences based on one’s experience level, and just “general disagreements” on how aggressive a physician wants to be in his or her treatment

of a patient. Moreover, Dr. Caligaris testified, “[F]rom my viewpoint, to be black and white in an assessment of medical treatment, I think, is very unfair.” (Tr. Vol. II at 122-124)

Further, Dr. Caligaris testified that he does not believe that the final Assessment Report adequately described the interviews because it had been written by a third person. Dr. Caligaris further testified:

Now, whether it was written by the family practitioner who was in the room or not, I don’t know. But the point is that they used words like * * * ‘opine.’ I can tell you right now [the consultants] didn’t opine to me. So they were opining to somebody. Now, whether they were opining to each other or * * * to the person writing the assessment, I don’t know.

But I feel that in the assessment there [are] a lot of discrepancies, a lot of things taken out of context. Some of the assessment was done on patients they never even asked me about. * * *

(Tr. Vol. II at 124-126)

109. Dr. Caligaris testified that he does not believe that he is technically under probation to the Board at the present time. However, Dr. Caligaris testified that third parties have treated him as though he is under probation. Dr. Caligaris further testified that several third-party payors dropped him as a provider within three to six months of signing the 2002 Consent Agreement. Another wanted him to be recredentialed. Moreover, Dr. Caligaris testified that, following his retirement of his Massachusetts certificate, Aetna had evidently assumed that he was retiring from practice altogether and sent letters to that effect to his patients who were Aetna policyholders. Dr. Caligaris testified that he had lost a substantial number of patients before that mistake was corrected. Finally, Dr. Caligaris explained that the Massachusetts medical board brought an action against his inactive license to practice in that state, and that he had retired his Massachusetts license to settle the matter. (Resp. Exs. Y through II; Tr. Vol. II at 197-199)

Testimony of Reed A. Shank III, M.D.

110. Reed A. Shank II, M.D., testified on behalf of Dr. Caligaris. Dr. Shank is a urologic surgeon who practices with a large urology group in Cincinnati, and is the Director of the Department of Urology at Christ Hospital. Dr. Shank testified that he practices primarily at Christ Hospital, but also holds privileges at Deaconess Hospital, University Hospital, and Bethesda North Hospital. (Hearing Transcript Volume III [Tr. Vol. III] at 6-7, 9)

Dr. Shank testified that he had obtained his medical degree in 1984 from the University of Cincinnati College of Medicine. He further testified that, from 1984 through 1990, he participated in a residency in urology at that same institution. Moreover, Dr. Shank testified that he is board-certified in urology. Furthermore, Dr. Shank testified that he is an

Assistant Professor of Urologic Surgery at the University of Cincinnati College of Medicine, and actively participates in resident training. (Tr. Vol. III at 8-10)

Dr. Shank noted that, prior to attending medical school, he had practiced as a physician assistant in a urology practice beginning in 1975. (Tr. Vol. III at 8)

111. Dr. Shank testified that he has known Dr. Caligaris for approximately 20 years, since Dr. Shank was in medical school and Dr. Caligaris was a resident. (Tr. Vol. III at 10-11)

Dr. Shank testified that, since entering practice, “I have worked with Dr. Caligaris frequently, both surgically as well [as] receiving referrals from him and sending referrals to him for various combined procedures that we’ve done” in cases where both urology and OB/GYN expertise is required. Dr. Shank further testified that he has collaborated with Dr. Caligaris on nonsurgical patients as well, including patients with complex pelvic pain disorders, recurring infections, and “stones that are managed urologically.” Moreover, Dr. Shank testified that a lot of their shared patients require medical management rather than surgery. (Tr. Vol. III at 11-12)

Dr. Shank testified that Dr. Caligaris consults with him in cases in which Dr. Caligaris suspects a urologic problem may exist. Dr. Shank further testified: “In general, I found Dr. Caligaris to be heads above a lot of other OB/GYNs that work in the area because he does keep an eye open for some of the more unusual things that we tend to deal with.” Dr. Shank gave examples of interstitial cystitis⁸ and pelvic pain syndromes. Moreover, Dr. Shank testified that Dr. Caligaris “asks the right questions ahead of time to know if there’s something going on urologically with the patient instead of the patient being treated, for example, for recurrent urinary tract infections when they really don’t have infections.” Finally, Dr. Shank testified that he has never found deficits in Dr. Caligaris’ clinical knowledge or skills. (Tr. Vol. III at 12-15)

112. Dr. Shank testified that he works with Dr. Caligaris in surgery approximately every month to two months. Dr. Shank testified that sometimes they work in tandem, and other times they work as co-surgeons. Dr. Shank further testified that Dr. Caligaris “does a good job from a surgical perspective” and does not exhibit any deficits. (Tr. Vol. III at 15-17)

In addition, Dr. Shank testified that there have been occasions when Dr. Caligaris has requested a urologic consult or assistance in the middle of an OB/GYN surgical procedure. Dr. Shank stated:

Since there’s a relatively high incidence of urologic injuries that occur during the course of gynecologic surgery, the key is to recognize it early on and ask for help to correct the problem.

⁸ Dr. Shank noted that interstitial cystitis is not an unusual condition, but it is an underdiagnosed condition and that, “if you don’t look for it, you don’t find it.” Moreover, Dr. Shank testified that many patients with interstitial cystitis either go untreated or improperly treated. (Tr. Vol. III at 26)

And Dr. Caligaris—Even if there is a hint of suspicion that there may be a problem, he’s very likely to call early on to get us involved in case there is a problem or to clear it if there is no problem at all.

(Tr. Vol. III at 17) Furthermore, Dr. Shank testified that requesting urologic consults intraoperatively during gynecologic surgery is good practice and is “[a]bsolutely not” unique to Dr. Caligaris. (Tr. Vol. III at 27-28)

113. Dr. Shank testified that he has no hesitation referring his patients to Dr. Caligaris and, “as a matter of fact, I would not hesitate to send a family member to see Dr. Caligaris.” (Tr. Vol. III at 18)
114. Dr. Shank testified that he has had an opportunity to review Dr. Caligaris’ patient charts on occasions when they have a patient in common. Dr. Shank further testified that he has not had any difficulty reading Dr. Caligaris’ handwriting. (Tr. Vol. III at 23-24)
115. Dr. Shank testified that he socializes with Dr. Caligaris on occasion, about once a year, and that he considers Dr. Caligaris to be a good friend. (Tr. Vol. III at 26-27)

Dr. Stamler’s Letter of Support

116. Eric F. Stamler, M.D., wrote a letter in support of Dr. Caligaris dated March 10, 2006. In his letter, Dr. Stamler stated that he has known Dr. Caligaris since Dr. Stamler was an OB/GYN intern and Dr. Caligaris was his chief resident. Dr. Stamler further stated that he has since had an opportunity to work with and observe Dr. Caligaris, both during Dr. Stamler’s residency and as a colleague in the OB/GYN department at Christ Hospital. Dr. Stamler stated that Dr. Caligaris had been an outstanding teacher and that he is an outstanding physician who is respected by hospital staff and other physicians. Finally, Dr. Stamler wrote that he would be comfortable if his family members were treated by Dr. Caligaris. (Resp. Ex. JJ)

FINDINGS OF FACT

1. Effective December 20, 2002, Joseph Thayer Caligaris, M.D., entered into a Consent Agreement with the Board [2002 Consent Agreement] “in lieu of further formal proceedings or determinations at this time based upon the allegations set forth in the Notice of Opportunity for Hearing issued on July 10, 2002, * * *.” The 2002 Consent Agreement included no finding that Dr. Caligaris had violated any provision of the Medical Practices Act of Ohio.

Pursuant to the 2002 Consent Agreement, Dr. Caligaris agreed to certain terms, conditions, and limitations, including that he would participate in the Colorado Physicians Effectiveness Program, which is now known as the Center for Personalized Education for Physicians

[CPEP]. Among the terms, conditions, and limitations set forth in the 2002 Consent Agreement was the following:

Dr. Caligaris agrees that if CPEP recommends education, preceptorship, mentorship, or practice limitations, he shall cooperate with CPEP to establish the Education Plan within 90 days. Dr. Caligaris shall enter into a subsequent written consent agreement which shall include any terms, conditions, and limitations as determined by the Board based upon the recommendations of CPEP. If the Board and Dr. Caligaris are unable to agree on the terms of a written consent agreement, then Dr. Caligaris further agrees to abide by any terms, conditions, and limitations imposed by Board Order after a hearing conducted pursuant to Chapter 119 of the Ohio Revised Code.

Dr. Caligaris submitted to a CPEP assessment from February 18 through February 19, 2003. In or about February 2004, the Board received from CPEP a final Assessment Report for Dr. Caligaris. The Board also received CPEP's revised November 14, 2003, Education Plan for Dr. Caligaris. In the final Assessment Report, CPEP recommended that Dr. Caligaris undertake education to address areas of demonstrated need and that he participate in a preceptorship.

2. Despite ongoing negotiations, Dr. Caligaris and the Board have been unable to agree upon terms, conditions, or limitations for a subsequent written consent agreement. Therefore, in accordance with the 2002 Consent Agreement, a hearing conducted pursuant to Chapter 119 of the Ohio Revised Code was held to determine the terms, conditions, and limitations, if any, that should be imposed upon Dr. Caligaris by Board Order. The following Findings of Fact reflect the outcome of that hearing.
3. With regard to the issues identified by CPEP as being problem areas for Dr. Caligaris, the evidence is sufficient to support the following findings:
 - a. With regard to CPEP's criticism concerning documentation of a positive Group B Streptococcus culture, Dr. Caligaris presented persuasive evidence concerning the reason for that problem and how he had worked satisfactorily around it. Accordingly, this issue need not be addressed further.
 - b. With regard to the issue of unfractionated heparin versus low molecular weight [LMW] heparin late in pregnancy, Dr. Caligaris provided evidence that it is acceptable to place an epidural needle after 10 to 12 hours following the last dose of low dose, once daily LMW heparin. That evidence substantially supports Dr. Caligaris' position on that issue. Moreover, Dr. Caligaris provided reasons why a physician may want to continue a patient on LMW heparin rather than switch her to unfractionated heparin. Accordingly, this issue need not be addressed further.

- c. The comment in the CPEP report that Dr. Caligaris “demonstrated only a superficial knowledge of [amniocentesis] procedures” is on its face troubling. However, the only example provided by CPEP was that Dr. Caligaris could not identify the needle gauge he uses to perform a procedure.

The evidence demonstrates that, in three major hospitals in the Cincinnati area, the hospitals provide amniocentesis kits selected by the hospitals’ perinatologists that include the needle to be used. Both Dr. Caligaris and Dr. Allen testified that they do not look at the gauge of the needle that is provided because it is not necessary to do so. This evidence is persuasive, and this issue need not be addressed further.

- d. With regard to the issue of placement of a cerclage later than 26 weeks into pregnancy, Dr. Caligaris provided persuasive evidence that, in his geographic area, it is not uncommon for that to happen. Dr. Caligaris further provided acceptable reasons why a physician would want to place a cerclage late in pregnancy under appropriate circumstances. Accordingly, this issue need not be addressed further.
- e. Dr. Caligaris provided convincing evidence that, although he would follow mild dysplasia conservatively, he has always treated moderate dysplasia.
- f. With regard to CPEP’s criticism that Dr. Caligaris had treated a patient for deep venous thrombosis [DVT] at 22 weeks gestation without clearly documenting it on the OB flow sheet or in the problem sheet in the ACOG prenatal record, Dr. Caligaris did not respond directly.

With regard to the same patient, who received Depo-Provera as a contraceptive following delivery, the CPEP consultant stated that he could not find documentation of informed consent concerning Depo-Provera and blood clots in Dr. Caligaris’ patient chart. However, Dr. Caligaris testified that, first, this issue had not been discussed with him during the interviews. Second, he testified that he had documented two occasions during which he had discussed Depo Provera with the patient prior to the institution of that therapy. Finally, Dr. Caligaris testified that an authoritative source in the medical literature questions whether Depo-Provera actually causes an increased risk of thrombosis. Accordingly, based on the evidence in the record, this issue need not be addressed further.

Lastly, with regard to the same patient, the CPEP consultant criticized Dr. Caligaris for not having counseled the patient that Depo-Provera might reduce her ability to conceive immediately after discontinuing it. The consultant further noted that the patient had required Clomid to conceive. Dr. Caligaris responded that he had made the patient aware of those facts, although he admitted that he “didn’t document every single issue.” Dr. Caligaris further stated that the patient had a history of irregular menstrual cycles and had required Clomid for her first pregnancy. Therefore, six months after discontinuing Depo-Provera, he placed her on Clomid “which was quickly successful.” Accordingly, based on the evidence in the record, this issue need not be addressed further.

- g. With regard to CPEP's criticism concerning a course of treatment for a hypothetical patient with residual endometriosis following a total hysterectomy and bilateral salpingo-oophorectomy, Dr. Caligaris provided overwhelming evidence in favor of his position versus that of CPEP. Accordingly, this issue need not be addressed further.
- h. With regard to the patient with vulvovaginal itching, Dr. Caligaris provided persuasive evidence in support of his position that that a "wet prep, pH, potassium hydroxide" and cultures were not necessary in this patient's case. This issue need not be addressed further.

With regard to the same patient, CPEP criticized Dr. Caligaris for placing the patient on Clomid to treat her for conception difficulties without first verifying a normal sperm count by semen analysis. Dr. Caligaris provided persuasive evidence in support of his position that a semen analysis was not first necessary. Accordingly, he prevails on this issue.

Moreover, with regard to the same patient, CPEP criticized Dr. Caligaris for obtaining a GBS culture at six weeks. Dr. Caligaris provided testimony that the patient had a history of GBS during her first pregnancy, and that he had wanted to know if she still had it. He acknowledged that it would not have changed his course of treating the patient other than to watch for asymptomatic urinary tract infections. He further testified that he obtained another GBS culture at 36 weeks, and treated her with antibiotics because of her history. Although the evidence presented by Dr. Caligaris concerning this issue is not persuasive—he testified that the six-week GBS result would not change his treatment of the patient—the issue is so minor that, unless GBS cultures are very expensive or risky to the patient, it is not worthy of further action or concern.

- i. CPEP criticized Dr. Caligaris for failing to immediately recognize polycystic ovarian syndrome [PCOS] in a hypothetical patient described to Dr. Caligaris as being 39 years old, weighing 220 pounds, having sporadic but prolonged periods, and no menses for three or four months. Dr. Caligaris presented persuasive evidence concerning why he would not immediately suspect PCOS in a patient as described by the CPEP consultant.

Moreover, CPEP criticized Dr. Caligaris for not mentioning a fasting insulin level to diagnose PCOS. Dr. Caligaris presented persuasive evidence that a fasting insulin level is important in managing, but not diagnosing, PCOS.

Accordingly, the issues described above need not be addressed further.

- j. With regard to the patient who Dr. Caligaris had treated for pelvic inflammatory disease, he provided persuasive evidence concerning his reasons for not obtaining cervical cultures.

Further, with regard to CPEP's criticism that he had improperly obtained a CA 125 test on the patient, Dr. Caligaris testified that the consultant had asked him whether he would obtain that test if the patient had a pelvic mass. Dr. Caligaris' testimony that the CA 125 would provided a baseline should malignancy be found is persuasive.

Moreover, with regard to the issue of antibiotic selection, the evidence favors Dr. Caligaris.

Furthermore, with regard to CPEP's criticism that Dr. Caligaris had seen the patient five times post-surgery for recurring pelvic pain without obtaining a cervical culture. Dr. Caligaris provided testimony that the patient had, in fact, not been seen for pain until the fifth visit following surgery about 15 months post-surgery, at which time he had obtained a culture. Dr. Caligaris' testimony is found to be persuasive.

Accordingly, each of the issues described above requires no further consideration.

- k. With regard to the effect of oral contraceptive pills on breakthrough bleeding, and their use with certain patients, the evidence favors Dr. Caligaris' positions.
- l. With regard to Dr. Caligaris' list of patients who would be at increased risk of thromboemboli during surgery, Dr. Caligaris' provided credible testimony that he had not believed that the list was to be exhaustive. The fact that Dr. Caligaris omitted other factors does not warrant remediation. Accordingly, this issue need not be addressed further.
- m. Dr. Caligaris' rationale for managing the simulated patient interviews was persuasive.
- n. The CPEP final Assessment Report indicates that there were problems with Dr. Caligaris' patient documentation with regard to legibility and completeness. In his Participant Response, he acknowledged that he had failed to document some items in his patient charts. However, it must be noted that CPEP's criticism had been based, at least in part, on the issue of the positive GBS culture, which Dr. Caligaris amply refuted.

With regard to CPEP's claim of poor legibility of Dr. Caligaris' notes of the simulated patient interviews, Dr. Caligaris' explanation was persuasive. Dr. Caligaris presented the testimony of Dr. Allen and Dr. Shank, both of whom testified that they have found Dr. Caligaris' patient records to be legible. Moreover, Dr. Allen testified that he has not had difficulty with Dr. Caligaris' record-keeping.

- 4. Based upon Findings of Fact 3, above, the final CPEP Assessment Report does not justify future remediation via an education plan or preceptorship, as recommended by CPEP. It is further found that neither the initial CPEP Education Plan nor the Revised 11/14/3 Education Plan is warranted.

5. Although Dr. Caligaris had agreed in the 2002 Consent Agreement to submit to terms, conditions, and limitations to be established by a future consent agreement or Board Order, the 2002 Consent Agreement had not been based upon a finding of violation of the Ohio Medical Practices Act. Accordingly, this is a non-disciplinary matter.

CONCLUSIONS OF LAW

The Chapter 119 hearing as described in Findings of Fact 2, above, has been completed. The Board may now issue an Order setting forth the terms, conditions, and limitations, if any, that it determines should be imposed upon Joseph Thayer Caligaris, M.D.

* * * * *

It is clear from the evidence that the assessment process anticipated in Dr. Caligaris' 2002 Consent Agreement did not occur. The core of the 2002 Consent Agreement was an assessment by CPEP of Dr. Caligaris' medical knowledge and skills. Dr. Caligaris would then enter into a second consent agreement with the Board that would include terms and conditions as determined by the Board to be necessary based upon CPEP's recommendations. Unfortunately, much of Dr. Caligaris' interaction with CPEP consisted of a series of miscommunications and/or misunderstandings.

Following his assessment, Dr. Caligaris received an assessment report that included clinical judgments and opinions with which he disagreed, and the evidence indicates that his opinions are meritorious. However, his opinions were not considered by CPEP in the development of the education plan that he received from CPEP shortly thereafter. Moreover, he was not involved in the development of that education plan as he had believed he would be. Furthermore, Dr. Caligaris had not expected that CPEP would manage his education plan, but had instead believed that the Board would oversee his education and monitoring under the terms of the future consent agreement.

With regard to Dr. Caligaris' medical knowledge, the evidence presented in this matter is largely favorable to Dr. Caligaris. With regard to some issues addressed in the assessment report, such as the hypothetical patient with residual endometriosis, the evidence indicates that Dr. Caligaris' treatment approach is at the very least valid, and is probably preferable to the treatment approach recommended by CPEP. With regard to other issues, Dr. Caligaris either provided a reasonable explanation, such as the institutional problem that had caused the GBS culture issue, or cited to medical literature that supported his position, such as his positions regarding the LMW heparin issue and oral contraceptive pills. Overall, when the assessment report is considered along with the evidence presented by Dr. Caligaris, there does not appear to be substantial evidence that Dr. Caligaris is in need of further education or monitoring. Nevertheless, the evidence indicates that Dr. Caligaris had taken it upon himself to address many of the objectives of the CPEP Education Plan rather than wait for the plan to take effect, an event that never occurred.

In the 2002 Consent Agreement, Dr. Caligaris agreed to a three-year period of probation in the event that CPEP found that remediation was not required. However, for the reasons discussed

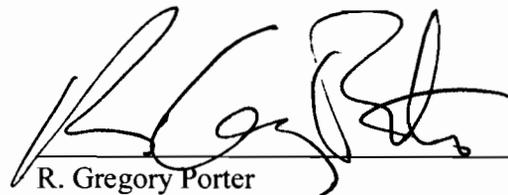
above, such measures are unnecessary. Accordingly, the Proposed Order takes no further action against Dr. Caligaris, and releases him from the terms of his 2002 Consent Agreement.

PROPOSED ORDER

It is hereby ORDERED that:

- A. No further action shall be taken in the matter of Joseph Thayer Caligaris, M.D.
- B. Dr. Caligaris is released from the terms and conditions set forth in his December 20, 2002, Consent Agreement.

This Order shall become effective immediately upon the mailing of notification of approval by the Board.



R. Gregory Porter
Hearing Examiner



State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

(614) 466-3934
med.ohio.gov

EXCERPT FROM THE DRAFT MINUTES OF NOVEMBER 14, 2007

REPORTS AND RECOMMENDATIONS

Dr. Kumar announced that the Board would now consider the Reports and Recommendations appearing on its agenda. He asked whether each member of the Board had received, read, and considered the hearing records, the proposed findings of fact, conclusions of law, and orders, and any objections filed in the matters of: Savitri Bhama, M.D.; Joseph Thayer Caligaris, M.D.; Gregory Lee Ebner, D.O.; and Joseph William Fischkelta, P.A. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Egner	- aye
	Dr. Varyani	- aye
	Dr. Madia	- aye
	Mr. Browning	- aye
	Dr. Robbins	- aye
	Dr. Steinbergh	- aye
	Dr. Kumar	- aye

Dr. Kumar asked whether each member of the Board understands that the disciplinary guidelines do not limit any sanction to be imposed, and that the range of sanctions available in each matter runs from dismissal to permanent revocation. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Egner	- aye
	Dr. Varyani	- aye
	Dr. Madia	- aye
	Mr. Browning	- aye
	Dr. Robbins	- aye
	Dr. Steinbergh	- aye
	Dr. Kumar	- aye

Dr. Kumar noted that, in accordance with the provision in Section 4731.22(F)(2), Revised Code, specifying that no member of the Board who supervises the investigation of a case shall participate in further adjudication of the case, the Secretary and Supervising Member must abstain from further participation in the adjudication of these matters. In the matters before the Board today, Dr. Talmage served as Secretary and Mr. Albert served as Supervising Member.

The original Reports and Recommendations shall be maintained in the exhibits section of this Journal.

.....

JOSEPH THAYER CALIGARIS, M.D.

.....

MR. BROWNING MOVED TO APPROVE AND CONFIRM MR. PORTER'S FINDINGS OF FACT, CONCLUSIONS OF LAW, AND PROPOSED ORDER IN THE MATTER OF JOSEPH THAYER CALIGARIS, M.D. DR. STEINBERGH SECONDED THE MOTION.

.....

A vote was taken on Mr. Browning's motion to approve and confirm:

ROLL CALL:	Mr. Albert	- abstain
	Dr. Egner	- aye
	Dr. Varyani	- aye
	Dr. Madia	- aye
	Mr. Browning	- aye
	Dr. Robbins	- aye
	Dr. Steinbergh	- aye
	Dr. Kumar	- aye

The motion carried.



State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3934 • Website: www.med.ohio.gov

December 14, 2006

Joseph Thayer Caligaris, M.D.
12304 Cooperwood Lane
Cincinnati, Ohio 45242

Dear Doctor Caligaris:

In accordance with Chapter 119., Ohio Revised Code, and the terms of the Consent Agreement Between Joseph T. Caligaris, M.D., and The State Medical Board of Ohio, effective on or about December 20, 2002 [December 2002 Consent Agreement], you are hereby notified that the State Medical Board of Ohio [Board] intends to determine whether or not to impose terms, conditions, and/or limitations upon your certificate to practice medicine and surgery, including, but not limited to, those set forth in Section 4731.22(B), Ohio Revised Code. A copy of the December 2002 Consent Agreement is attached hereto and incorporated herein.

The basis for the Board's proposed action is more fully set forth as follows:

- (1) On or about July 10, 2002, the Board issued a Notice of Opportunity for Hearing [July 2002 Notice] to you, alleging that you violated Section 4731.22(B)(2), Ohio Revised Code, as in effect prior to March 9, 1999, and Section 4731.22(B)(6), Ohio Revised Code. A copy of the July 2002 Notice is attached hereto and incorporated herein.

In lieu of further formal proceedings or determinations based upon the allegations set forth in the July 2002 Notice, you entered into the December 2002 Consent Agreement.

Pursuant to the December 2002 Consent Agreement, you agreed to certain terms, conditions and limitations, including that you would participate in the Colorado Physicians Effectiveness Program [CPEP]. In the December 2002 Consent Agreement, you further agreed to the following:

Dr. Caligaris agrees that if CPEP recommends education, preceptorship, mentorship, or practice limitations, he shall cooperate with CPEP to establish the Educational Plan within 90 days. Dr. Caligaris shall enter into a subsequent written consent agreement which shall include any terms, conditions, and limitations as determined by the Board based upon the recommendations of CPEP. If the Board and Dr. Caligaris are

Mailed 12-14-06

unable to agree on the terms of a written consent agreement, then Dr. Caligaris further agrees to abide by any terms, conditions, and limitations imposed by Board Order after a hearing conducted pursuant to Chapter 119. of the Ohio Revised Code.

From on or about February 18, 2003, through on or about February 19, 2003, CPEP performed an assessment of you. In or about February 2004, the Board received from CPEP an Assessment Report for Joseph T. Caligaris, M.D., and a CPEP Education Plan for Joseph T. Caligaris, dated November 14, 2003. In the Assessment Report, CPEP recommended that you undertake education to address areas of demonstrated need and that you participate in a preceptorship.

- (2) Despite ongoing negotiations, you and the Board have not been able to agree upon terms, conditions, or limitations for a subsequent written consent agreement. Therefore, in accordance with the December 2002 Consent Agreement, a hearing conducted pursuant to Chapter 119. of the Ohio Revised Code is required in order to determine the terms, conditions, and limitations, if any, that should be imposed upon you by Board Order.

Pursuant to Chapter 119., Ohio Revised Code, **you are hereby advised that a hearing is scheduled in this matter** at the offices of the State Medical Board of Ohio, 77 South High Street, 17th Floor, Columbus, Ohio, **on Thursday, February 8, 2007, at 9:30 a.m.**, before R. Gregory Porter, Hearing Examiner.

You are further advised that you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

You are further advised that, whether or not you or your representative attend such hearing, the State Medical Board, through its counsel, will present evidence and/or examine witnesses in support of its position, arguments, or contentions in this matter.

You are further advised that in the event that you or your representative do not attend such hearing, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to impose terms, conditions, and/or limitations upon your certificate to practice medicine and surgery, including, but not limited to, those set forth in Section 4731.22(B), Ohio Revised Code.

Copies of the applicable sections are enclosed for your information.

Very truly yours,



Lance A. Talmage, M.D.
Secretary

LAT/KHM/flb
Enclosures

CERTIFIED MAIL # 7004 2510 0006 9802 9742
RETURN RECEIPT REQUESTED

cc: Eric Plinke, Esq.
Porter, Wright, Morris and Arthur, LLP
41 South High Street
Columbus, Ohio 43215-6194

CERTIFIED MAIL # 7004 2510 0006 9802 9094
RETURN RECEIPT REQUESTED

cc: R. Gregory Porter, Hearing Examiner
State Medical Board of Ohio

**CONSENT AGREEMENT
BETWEEN
JOSEPH T. CALIGARIS, M.D.
AND
THE STATE MEDICAL BOARD OF OHIO**

This Consent Agreement is entered into by and between Joseph T. Caligaris, M.D., ["Dr. Caligaris"] and the State Medical Board of Ohio ["Board"], a state agency charged with enforcing Ohio Revised Code ["R.C."] Chapter 4731.

Dr. Caligaris enters into this Consent Agreement being fully informed of his rights under R.C. Chapter 119, including the right to representation by counsel and the right to a formal adjudicative hearing on the issues considered herein.

BASIS FOR ACTION

This Consent Agreement is entered into on the basis of the following stipulations and understandings:

- A. The Board is empowered by R.C. 4731.22(B), to limit, revoke, suspend a certificate, refuse to register or reinstate an applicant, or reprimand or place on probation the holder of a certificate for any of the enumerated violations.
- B. The Board and Dr. Caligaris enter into this Consent Agreement in lieu of further formal proceedings or determinations at this time based upon the allegations set forth in the Notice of Opportunity for Hearing issued on July 10, 2002, attached hereto as Exhibit A and incorporated herein by this reference. The Board expressly reserves the right to institute additional formal proceedings based upon any other violations of R.C. Chapter 4731, whether occurring before or after the effective date of this Consent Agreement. Dr. Caligaris acknowledges that the Notice of Opportunity for Hearing issued by the Board on July 10, 2002 includes concerns about patient care where improvement over past practices is appropriate, and enters into this Agreement to address those concerns.
- C. Dr. Caligaris is currently licensed to practice medicine and surgery in the State of Ohio, License #35-050658.
- D. Dr. Caligaris also holds a license to practice medicine and surgery in Massachusetts. That license is currently inactive.

JOSEPH T. CALIGARIS, M.D.
Consent Agreement
Page 2

AGREED CONDITIONS

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any further formal proceedings at this time, Dr. Caligaris knowingly and voluntarily agrees with the Board to the following TERMS, CONDITIONS and LIMITATIONS:

Participation in the Colorado Physicians Effectiveness Program

- A. Within 90 days from the effective date of this Consent Agreement, Dr. Caligaris shall submit documentation acceptable to the Board verifying his participation in the Colorado Physicians Effectiveness Program (hereinafter "CPEP") program. Participation in all phases of the CPEP program will be at Dr. Caligaris' own expense and shall be subject to the following conditions:
1. Prior to undertaking participation in the CPEP program, Dr. Caligaris shall furnish CPEP with copies of the Board's Notice of Opportunity for Hearing, a copy of the Board's expert report, and any other documentation that the Board has advised Dr. Caligaris that it deems appropriate or helpful to that assessment. Should Dr. Caligaris desire additional information be sent to CPEP, such information shall be sent to the Board for its review. If the Board deems such information appropriate or helpful, it shall be submitted to CPEP, with copies retained by the Board.
 2. Prior to the initial assessment phase of the CPEP program, Dr. Caligaris shall submit to the Board two copies of all patient records, as identified by the Board, for assessment by CPEP. The Board shall send one copy of these records to CPEP. The expense of providing these copies to both the CPEP program and the Board will be borne by Dr. Caligaris. Dr. Caligaris and the Board shall ensure that CPEP maintains patient confidentiality in accordance with R.C. 4731.22(F)(5).
 3. Dr. Caligaris agrees to undergo any physical examinations and psychological or other testing if requested by CPEP. Dr. Caligaris shall undergo any such examination or testing requested by CPEP within 60 days of that request, by a physician approved by the Secretary and Supervising Member of the Board. Dr. Caligaris shall submit the report of examination or testing to CPEP and the Board. Such reports, if any, shall be considered medical records for purposes of R.C. 149.43.
 4. Dr. Caligaris shall ensure that all reports generated in connection with his involvement in the CPEP program, including, but not limited to, the written Assessment Report and any Education Plan, be provided to the Board within ten

JOSEPH T. CALIGARIS, M.D.

Consent Agreement

Page 3

days of the date of issuance. Dr. Caligaris shall work with CPEP to ensure that the written Assessment Report includes, but is not limited to, the following:

- a. A detailed plan of recommended practice limitations, if any;
- b. Any recommended education;
- c. Any recommended mentorship or preceptorship;
- d. Any reports upon which the recommendation is based, including reports of physical examinations and psychological or other testing.

Subsequent Consent Agreement

- B. Dr. Caligaris agrees that if CPEP recommends education, preceptorship, mentorship, or practice limitations, he shall cooperate with CPEP to establish the Educational Plan within 90 days. Dr. Caligaris shall enter into a subsequent written consent agreement which shall include any terms, conditions, and limitations as determined by the Board based upon the recommendations of CPEP. If the Board and Dr. Caligaris are unable to agree on the terms of a written consent agreement, then Dr. Caligaris further agrees to abide by any terms, conditions, and limitations imposed by Board Order after a hearing conducted pursuant to Chapter 119. of the Ohio Revised Code.

Further, if an administrative hearing is necessitated, the Board reserves the right to proceed on the July 10, 2002 Notice of Opportunity for Hearing and may, at its discretion, use the findings and recommendations of the CPEP program in connection with said hearing, and/or as evidence in the hearing, as may Dr. Caligaris.

Probationary Terms

- C. If CPEP determines that Dr. Caligaris currently possesses appropriate skills and that educational remediation is not required, Dr. Caligaris agrees to the following PROBATIONARY TERMS AND CONDITIONS for a period of at least three years:
1. Dr. Caligaris shall submit quarterly declarations under penalty of Board disciplinary action or criminal prosecution, stating whether there has been compliance with all the conditions of this Consent Agreement. The first quarterly declaration must be received in the Board's offices on the first day of the third month following the month in which these probationary terms are effective. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.

JOSEPH T. CALIGARIS, M.D.

Consent Agreement

Page 4

2. Dr. Caligaris shall appear in person for an interview before the full Board or its designated representative during the third month following the effective date of these probationary terms. Subsequent personal appearances must occur semi-annually thereafter, and/or as otherwise requested by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.
3. Dr. Caligaris, within thirty days of receipt of the assessment from CPEP, shall submit for the Board's prior approval, the name and curriculum vitae of a monitoring physician. In approving an individual to serve in this capacity, the Board will give preference to a physician who practices in the same locale as Dr. Caligaris and who is engaged in the same or similar practice specialty;

The monitoring physician shall monitor Dr. Caligaris, review Dr. Caligaris' patient charts and provide supervision of Dr. Caligaris' medical practice. The chart review may be done on a random basis, with the frequency and number of charts reviewed to be determined by the Board.

Further, the monitoring physician shall provide the Board with reports on the monitoring of Dr. Caligaris, on the review of Dr. Caligaris' patient charts, and on the supervision of Dr. Caligaris' medical practice. Dr. Caligaris shall ensure that the reports are submitted to the Board on a quarterly basis and are received in the Board's offices no later than the due date for Dr. Caligaris' quarterly declarations.

In the event that the designated monitoring physician becomes unable or unwilling to serve in this capacity, Dr. Caligaris must immediately notify the Board in writing. In addition, Dr. Caligaris shall make arrangements acceptable to the Board for another monitoring physician within 30 days after the previously designated monitoring physician becomes unable or unwilling to serve, unless otherwise determined by the Board. Furthermore, Dr. Caligaris shall ensure that the previously designated monitoring physician also notifies the Board directly of the inability to continue to serve and the reasons therefore.

4. Dr. Caligaris agrees, upon request by the Board, to provide patient records for the Board's review.
5. In the event that Dr. Caligaris should leave Ohio for three continuous months, or reside or practice outside the State, Dr. Caligaris must notify the Board in writing of the dates of departure and return. Periods of time spent outside Ohio will not apply to the reduction of this period under this Consent Agreement, unless otherwise determined by motion of the Board in instances where the

JOSEPH T. CALIGARIS, M.D.

Consent Agreement

Page 5

Board can be assured that probationary monitoring is otherwise being performed.

6. In the event Dr. Caligaris is found by the Secretary of the Board to have failed to comply with any provision of this Consent Agreement, and is so notified of that deficiency in writing, such period(s) of noncompliance will not apply to the reduction of the probationary period under this Consent Agreement.

REQUIRED REPORTING BY LICENSEE

- D. Within thirty days of the effective date of this Consent Agreement, Dr. Caligaris shall provide a copy of this Consent Agreement to all employers or entities with which he is under contract to provide health care services or is receiving training, and the Chief of Staff at each hospital where he has privileges or appointments. Further, Dr. Caligaris shall provide a copy of this Consent Agreement to all employers or entities with which he contracts to provide health care services, or applies for or receives training, and the Chief of Staff at each hospital where he applies for or obtains privileges or appointments.
- E. Within thirty days of the effective date of this Consent Agreement, Dr. Caligaris shall provide a copy of this Consent Agreement by certified mail, return receipt requested, to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license. Dr. Caligaris further agrees to provide a copy of this Consent Agreement by certified mail, return receipt requested, at time of application to the proper licensing authority of any state in which he applies for any professional license or for reinstatement of any professional license. Further, Dr. Caligaris shall provide the Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.

The above-described terms, conditions, and limitations may be amended or terminated in writing at any time upon the agreement of both parties.

FAILURE TO COMPLY

If, in the discretion of the Secretary and Supervising Member of the Board, Dr. Caligaris appears to have violated or breached any term or condition of this Consent Agreement, the Board reserves the right to institute formal disciplinary proceedings for any and all possible violations or breaches, including, but not limited to, alleged violations of the laws of Ohio occurring before the effective date of this Consent Agreement.

JOSEPH T. CALIGARIS, M.D.
Consent Agreement
Page 6

ACKNOWLEDGMENTS/LIABILITY RELEASE

Dr. Caligaris acknowledges that he has had an opportunity to ask questions concerning the terms of this Consent Agreement and that all questions asked have been answered in a satisfactory manner.

Any action initiated by the Board based on alleged violations of this Consent Agreement shall comply with the Administrative Procedure Act, R.C. Chapter 119.

Dr. Caligaris hereby releases the Board, its members, employees, agents, officers and representatives jointly and severally from any and all liability arising from the within matter.

This Consent Agreement shall be considered a public record as that term is used in R.C. 149.43, and may be reported to appropriate organizations, data banks, and governmental bodies. Dr. Caligaris agrees to provide his social security number to the Board and hereby authorizes the Board to utilize that number in conjunction with that reporting.

EFFECTIVE DATE

It is expressly understood that this Consent Agreement is subject to ratification by the Board prior to signature by the Secretary and Supervising Member and shall become effective upon the last date of signature below.

Joseph T. Caligaris
JOSEPH T. CALIGARIS, M.D.

Date: 12/15/02

J. Stephen Tector
J. Stephen Tector, Esq.
Douglas Boatwright, Esq.
Attorneys for Dr. Caligaris

Date: 12/17/02

Anand G. Garg, M.D.
Anand G. Garg, M.D.

Secretary
Date: 12/19/02

Raymond J. Albert
Raymond J. Albert
Supervising Member

Date: 12/20/02

*TRD
Phone
authorization*

JOSEPH T. CALIGARIS, M.D.
Consent Agreement
Page 7


Rebecca J. Albers
Assistant Attorney General

Date: 12/18/02



State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3934 • Website: www.state.oh.us/med/

July 10, 2002

Joseph T. Caligaris, M.D.
9403 Kenwood Road
Suite A130
Cincinnati, Ohio 45242

Dear Doctor Caligaris:

In accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the State Medical Board of Ohio intends to determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery, or to reprimand or place you on probation for one or more of the following reasons:

- (1) In the routine course of your obstetrics/gynecology practice, you undertook the treatment of Patients 1-7 (as identified on the attached Patient Key- Key confidential to be withheld from public disclosure).
- (2) In your treatment of Patients 2, 4, 5 and 6, you performed surgical procedures that were inappropriate, excessive and/or not indicated. Examples of such procedures include, but are not limited to, the following:
 - (A) Although Patient 2 was known to form pelvic adhesions, you removed a small hemorrhagic corpus luteum cyst from Patient 2's ovary which resulted in bleeding and subsequent adhesion formation;
 - (B) You performed six operations on Patient 4 over a period of 27 months, although the surgeries were not always indicated and Patient 4 continued to experience pain;
 - (C) You performed six operations on Patient 5 for pain and adhesions over a period of two years although Patient 5 continued to experience problems following the operations and although the organs removed were essentially normal, except for adhesions and a fecalith in the appendix; and
 - (D) You performed eight operations on Patient 6 over a period of three years although Patient 6 continued to suffer from the same symptoms. In addition, you inappropriately removed several corpus luteum cysts from Patient 6.

Mailed 7-11-02

- (3) In your treatment of Patients 2, 3, 5, 6 and 7, you prescribed narcotics and/or psychoactive agents that were excessive and/or inappropriate. You further failed to appropriately address Patient 2's prescription drug abuse. Examples of such prescribing include, but are not limited to, the following:
- (A) You continued to treat Patient 2 with narcotics although your medical records reflect that other providers who examined Patient 2 documented concerns about Patient 2's narcotic use and despite information from Patient 2's insurance administrator indicating that Patient 2 was being prescribed multiple narcotics by different providers;
 - (B) You issued to Patient 3 an excessive number of prescriptions for narcotic analgesics, including Tylenol with Codeine, Percocet and Lorcet Plus, over a period of approximately two years, despite the addictive potential of the medications and often without indications for the narcotic analgesics documented;
 - (C) You inappropriately treated Patient 5 with narcotics and psychoactive agents over a period of approximately three and a half years despite the addictive potential of these medications and although you had information that Patient 5 may have altered a prescription;
 - (D) Over a prolonged period of time, you repeatedly prescribed narcotics to Patient 6 rather than referring Patient 6 to a pain specialist; and
 - (E) You treated Patient 7 with large quantities of narcotics although she was pregnant and although she was later nursing her infant.
- (4) In your treatment of Patients 1, 2, 3, 4, 5 and 6, your charting was inappropriate in that it contained inaccurate information, omissions and/or discrepancies. Examples of such charting include, but are not limited to, the following:
- (A) You failed to document any discussion with Patient 1 regarding a total abdominal hysterectomy prior to the patient undergoing such surgery;
 - (B) Following an appendectomy on Patient 2, you noted in the discharge summary that Patient 2's appendix was adhered into an inflammatory mass despite the fact that the operative note and a prior laparoscopy did not reflect this. In addition, the pathology report indicated that the appendix was normal and did not show a fecalith;
 - (C) You repeatedly described Patient 3's uterus as enlarged although ultrasounds and/or pre-operative examinations indicated that Patient 3's uterus was normal.

Further, you failed to document complete information, i.e. indications and amounts given, when prescribing narcotics to Patient 3;

- (D) Your findings of an eight to ten week size enlarged uterus following a laparoscopy on Patient 4 contradict an ultrasound performed less than a week earlier showing a normal size uterus;
 - (E) In an operative note, you described Patient 5's right tube to be normal, despite the fact that in a prior operative note, you indicated that Patient 5's right tube had been removed. In addition, you stated in a discharge summary that Patient 5 had a D&C and an ovarian cystectomy, despite the fact that she did not have either of these procedures; and
 - (F) In an operative note on Patient 6, you included a finding of an 8 to 10 centimeter ovarian cyst, despite the fact that an ultrasound scan performed two days earlier showed a 3 centimeter cyst and the pathology report noted only a small amount of tissue.
- (5) In your treatment of Patient 7, you inappropriately prescribed oral terbutaline, without prior parenteral treatment; you failed to establish a correct estimated date of conception; and you diagnosed the patient as having gestational diabetes without proper criteria and then failed to follow-up appropriately. In addition, you subjected Patient 7 to four amniocenteses, although three of the amniocenteses were not indicated.
- (6) You inappropriately treated Patient 1's post-operative metritis with oral antibiotics.

Your acts, conduct, and/or omissions as alleged in paragraphs (2) through (6) above, individually and/or collectively, constitute "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.

Further, your acts, conduct, and/or omissions as alleged in paragraph (3) above, individually and/or collectively, constitute "[f]ailure to use reasonable care discrimination in the administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code, as in effect prior to March 9, 1999.

Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty (30) days of the time of mailing of this notice.

You are further advised that, if you timely request a hearing, you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty (30) days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery or to reprimand or place you on probation.

Please note that, whether or not you request a hearing, Section 4731.22(L), Ohio Revised Code, effective March 9, 1999, provides that "[w]hen the board refuses to grant a certificate to an applicant, revokes an individual's certificate to practice, refuses to register an applicant, or refuses to reinstate an individual's certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate."

Copies of the applicable sections are enclosed for your information.

Very truly yours,



Anand G. Garg, M.D.
Secretary

AGG/blt
Enclosures

CERTIFIED MAIL # 7000 0600 0024 5142 0249
RETURN RECEIPT REQUESTED

**CONSENT AGREEMENT
BETWEEN
JOSEPH T. CALIGARIS, M.D.
AND
THE STATE MEDICAL BOARD OF OHIO**

This Consent Agreement is entered into by and between Joseph T. Caligaris, M.D., ["Dr. Caligaris"] and the State Medical Board of Ohio ["Board"], a state agency charged with enforcing Ohio Revised Code ["R.C."] Chapter 4731.

Dr. Caligaris enters into this Consent Agreement being fully informed of his rights under R.C. Chapter 119, including the right to representation by counsel and the right to a formal adjudicative hearing on the issues considered herein.

BASIS FOR ACTION

This Consent Agreement is entered into on the basis of the following stipulations and understandings:

- A. The Board is empowered by R.C. 4731.22(B), to limit, revoke, suspend a certificate, refuse to register or reinstate an applicant, or reprimand or place on probation the holder of a certificate for any of the enumerated violations.
- B. The Board and Dr. Caligaris enter into this Consent Agreement in lieu of further formal proceedings or determinations at this time based upon the allegations set forth in the Notice of Opportunity for Hearing issued on July 10, 2002, attached hereto as Exhibit A and incorporated herein by this reference. The Board expressly reserves the right to institute additional formal proceedings based upon any other violations of R.C. Chapter 4731, whether occurring before or after the effective date of this Consent Agreement. Dr. Caligaris acknowledges that the Notice of Opportunity for Hearing issued by the Board on July 10, 2002 includes concerns about patient care where improvement over past practices is appropriate, and enters into this Agreement to address those concerns.
- C. Dr. Caligaris is currently licensed to practice medicine and surgery in the State of Ohio, License #35-050658.
- D. Dr. Caligaris also holds a license to practice medicine and surgery in Massachusetts. That license is currently inactive.

JOSEPH T. CALIGARIS, M.D.
Consent Agreement
Page 2

AGREED CONDITIONS

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any further formal proceedings at this time, Dr. Caligaris knowingly and voluntarily agrees with the Board to the following TERMS, CONDITIONS and LIMITATIONS:

Participation in the Colorado Physicians Effectiveness Program

- A. Within 90 days from the effective date of this Consent Agreement, Dr. Caligaris shall submit documentation acceptable to the Board verifying his participation in the Colorado Physicians Effectiveness Program (hereinafter "CPEP") program. Participation in all phases of the CPEP program will be at Dr. Caligaris' own expense and shall be subject to the following conditions:
1. Prior to undertaking participation in the CPEP program, Dr. Caligaris shall furnish CPEP with copies of the Board's Notice of Opportunity for Hearing, a copy of the Board's expert report, and any other documentation that the Board has advised Dr. Caligaris that it deems appropriate or helpful to that assessment. Should Dr. Caligaris desire additional information be sent to CPEP, such information shall be sent to the Board for its review. If the Board deems such information appropriate or helpful, it shall be submitted to CPEP, with copies retained by the Board.
 2. Prior to the initial assessment phase of the CPEP program, Dr. Caligaris shall submit to the Board two copies of all patient records, as identified by the Board, for assessment by CPEP. The Board shall send one copy of these records to CPEP. The expense of providing these copies to both the CPEP program and the Board will be borne by Dr. Caligaris. Dr. Caligaris and the Board shall ensure that CPEP maintains patient confidentiality in accordance with R.C. 4731.22(F)(5).
 3. Dr. Caligaris agrees to undergo any physical examinations and psychological or other testing if requested by CPEP. Dr. Caligaris shall undergo any such examination or testing requested by CPEP within 60 days of that request, by a physician approved by the Secretary and Supervising Member of the Board. Dr. Caligaris shall submit the report of examination or testing to CPEP and the Board. Such reports, if any, shall be considered medical records for purposes of R.C. 149.43.
 4. Dr. Caligaris shall ensure that all reports generated in connection with his involvement in the CPEP program, including, but not limited to, the written Assessment Report and any Education Plan, be provided to the Board within ten

JOSEPH T. CALIGARIS, M.D.

Consent Agreement

Page 3

days of the date of issuance. Dr. Caligaris shall work with CPEP to ensure that the written Assessment Report includes, but is not limited to, the following:

- a. A detailed plan of recommended practice limitations, if any;
- b. Any recommended education;
- c. Any recommended mentorship or preceptorship;
- d. Any reports upon which the recommendation is based, including reports of physical examinations and psychological or other testing.

Subsequent Consent Agreement

- B. Dr. Caligaris agrees that if CPEP recommends education, preceptorship, mentorship, or practice limitations, he shall cooperate with CPEP to establish the Educational Plan within 90 days. Dr. Caligaris shall enter into a subsequent written consent agreement which shall include any terms, conditions, and limitations as determined by the Board based upon the recommendations of CPEP. If the Board and Dr. Caligaris are unable to agree on the terms of a written consent agreement, then Dr. Caligaris further agrees to abide by any terms, conditions, and limitations imposed by Board Order after a hearing conducted pursuant to Chapter 119. of the Ohio Revised Code.

Further, if an administrative hearing is necessitated, the Board reserves the right to proceed on the July 10, 2002 Notice of Opportunity for Hearing and may, at its discretion, use the findings and recommendations of the CPEP program in connection with said hearing, and/or as evidence in the hearing, as may Dr. Caligaris.

Probationary Terms

- C. If CPEP determines that Dr. Caligaris currently possesses appropriate skills and that educational remediation is not required, Dr. Caligaris agrees to the following PROBATIONARY TERMS AND CONDITIONS for a period of at least three years:
1. Dr. Caligaris shall submit quarterly declarations under penalty of Board disciplinary action or criminal prosecution, stating whether there has been compliance with all the conditions of this Consent Agreement. The first quarterly declaration must be received in the Board's offices on the first day of the third month following the month in which these probationary terms are effective. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.

JOSEPH T. CALIGARIS, M.D.

Consent Agreement

Page 4

2. Dr. Caligaris shall appear in person for an interview before the full Board or its designated representative during the third month following the effective date of these probationary terms. Subsequent personal appearances must occur semi-annually thereafter, and/or as otherwise requested by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.
3. Dr. Caligaris, within thirty days of receipt of the assessment from CPEP, shall submit for the Board's prior approval, the name and curriculum vitae of a monitoring physician. In approving an individual to serve in this capacity, the Board will give preference to a physician who practices in the same locale as Dr. Caligaris and who is engaged in the same or similar practice specialty;

The monitoring physician shall monitor Dr. Caligaris, review Dr. Caligaris' patient charts and provide supervision of Dr. Caligaris' medical practice. The chart review may be done on a random basis, with the frequency and number of charts reviewed to be determined by the Board.

Further, the monitoring physician shall provide the Board with reports on the monitoring of Dr. Caligaris, on the review of Dr. Caligaris' patient charts, and on the supervision of Dr. Caligaris' medical practice. Dr. Caligaris shall ensure that the reports are submitted to the Board on a quarterly basis and are received in the Board's offices no later than the due date for Dr. Caligaris' quarterly declarations.

In the event that the designated monitoring physician becomes unable or unwilling to serve in this capacity, Dr. Caligaris must immediately notify the Board in writing. In addition, Dr. Caligaris shall make arrangements acceptable to the Board for another monitoring physician within 30 days after the previously designated monitoring physician becomes unable or unwilling to serve, unless otherwise determined by the Board. Furthermore, Dr. Caligaris shall ensure that the previously designated monitoring physician also notifies the Board directly of the inability to continue to serve and the reasons therefore.

4. Dr. Caligaris agrees, upon request by the Board, to provide patient records for the Board's review.
5. In the event that Dr. Caligaris should leave Ohio for three continuous months, or reside or practice outside the State, Dr. Caligaris must notify the Board in writing of the dates of departure and return. Periods of time spent outside Ohio will not apply to the reduction of this period under this Consent Agreement, unless otherwise determined by motion of the Board in instances where the

JOSEPH T. CALIGARIS, M.D.

Consent Agreement

Page 5

Board can be assured that probationary monitoring is otherwise being performed.

6. In the event Dr. Caligaris is found by the Secretary of the Board to have failed to comply with any provision of this Consent Agreement, and is so notified of that deficiency in writing, such period(s) of noncompliance will not apply to the reduction of the probationary period under this Consent Agreement.

REQUIRED REPORTING BY LICENSEE

- D. Within thirty days of the effective date of this Consent Agreement, Dr. Caligaris shall provide a copy of this Consent Agreement to all employers or entities with which he is under contract to provide health care services or is receiving training, and the Chief of Staff at each hospital where he has privileges or appointments. Further, Dr. Caligaris shall provide a copy of this Consent Agreement to all employers or entities with which he contracts to provide health care services, or applies for or receives training, and the Chief of Staff at each hospital where he applies for or obtains privileges or appointments.
- E. Within thirty days of the effective date of this Consent Agreement, Dr. Caligaris shall provide a copy of this Consent Agreement by certified mail, return receipt requested, to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license. Dr. Caligaris further agrees to provide a copy of this Consent Agreement by certified mail, return receipt requested, at time of application to the proper licensing authority of any state in which he applies for any professional license or for reinstatement of any professional license. Further, Dr. Caligaris shall provide the Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.

The above-described terms, conditions, and limitations may be amended or terminated in writing at any time upon the agreement of both parties.

FAILURE TO COMPLY

If, in the discretion of the Secretary and Supervising Member of the Board, Dr. Caligaris appears to have violated or breached any term or condition of this Consent Agreement, the Board reserves the right to institute formal disciplinary proceedings for any and all possible violations or breaches, including, but not limited to, alleged violations of the laws of Ohio occurring before the effective date of this Consent Agreement.

JOSEPH T. CALIGARIS, M.D.
Consent Agreement
Page 6

ACKNOWLEDGMENTS/LIABILITY RELEASE

Dr. Caligaris acknowledges that he has had an opportunity to ask questions concerning the terms of this Consent Agreement and that all questions asked have been answered in a satisfactory manner.

Any action initiated by the Board based on alleged violations of this Consent Agreement shall comply with the Administrative Procedure Act, R.C. Chapter 119.

Dr. Caligaris hereby releases the Board, its members, employees, agents, officers and representatives jointly and severally from any and all liability arising from the within matter.

This Consent Agreement shall be considered a public record as that term is used in R.C. 149.43, and may be reported to appropriate organizations, data banks, and governmental bodies. Dr. Caligaris agrees to provide his social security number to the Board and hereby authorizes the Board to utilize that number in conjunction with that reporting.

EFFECTIVE DATE

It is expressly understood that this Consent Agreement is subject to ratification by the Board prior to signature by the Secretary and Supervising Member and shall become effective upon the last date of signature below.

Joe T. Caligaris
JOSEPH T. CALIGARIS, M.D.

Date: 12/15/02

J. Stephen Tector
J. Stephen Tector, Esq.
Douglas Boatwright, Esq.
Attorneys for Dr. Caligaris

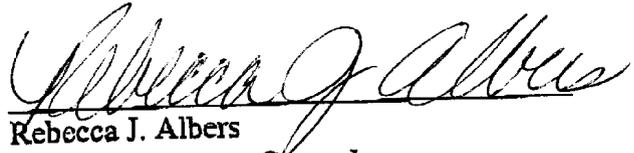
Date: 12/17/02

Anand G. Garg, M.D.
Anand G. Garg, M.D. *TAD*
Secretary *Phone authorization*
Date: 12/19/02

Raymond J. Albert
Raymond J. Albert
Supervising Member

Date: 12/20/02

JOSEPH T. CALIGARIS, M.D.
Consent Agreement
Page 7



Rebecca J. Albers
Assistant Attorney General

Date: 12/18/02



State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3934 • Website: www.state.oh.us/med/

July 10, 2002

Joseph T. Caligaris, M.D.
9403 Kenwood Road
Suite A130
Cincinnati, Ohio 45242

Dear Doctor Caligaris:

In accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the State Medical Board of Ohio intends to determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery, or to reprimand or place you on probation for one or more of the following reasons:

- (1) In the routine course of your obstetrics/gynecology practice, you undertook the treatment of Patients 1-7 (as identified on the attached Patient Key- Key confidential to be withheld from public disclosure).
- (2) In your treatment of Patients 2, 4, 5 and 6, you performed surgical procedures that were inappropriate, excessive and/or not indicated. Examples of such procedures include, but are not limited to, the following:
 - (A) Although Patient 2 was known to form pelvic adhesions, you removed a small hemorrhagic corpus luteum cyst from Patient 2's ovary which resulted in bleeding and subsequent adhesion formation;
 - (B) You performed six operations on Patient 4 over a period of 27 months, although the surgeries were not always indicated and Patient 4 continued to experience pain;
 - (C) You performed six operations on Patient 5 for pain and adhesions over a period of two years although Patient 5 continued to experience problems following the operations and although the organs removed were essentially normal, except for adhesions and a fecalith in the appendix; and
 - (D) You performed eight operations on Patient 6 over a period of three years although Patient 6 continued to suffer from the same symptoms. In addition, you inappropriately removed several corpus luteum cysts from Patient 6.

Mailed 7-11-02

- (3) In your treatment of Patients 2, 3, 5, 6 and 7, you prescribed narcotics and/or psychoactive agents that were excessive and/or inappropriate. You further failed to appropriately address Patient 2's prescription drug abuse. Examples of such prescribing include, but are not limited to, the following:
- (A) You continued to treat Patient 2 with narcotics although your medical records reflect that other providers who examined Patient 2 documented concerns about Patient 2's narcotic use and despite information from Patient 2's insurance administrator indicating that Patient 2 was being prescribed multiple narcotics by different providers;
 - (B) You issued to Patient 3 an excessive number of prescriptions for narcotic analgesics, including Tylenol with Codeine, Percocet and Lorcet Plus, over a period of approximately two years, despite the addictive potential of the medications and often without indications for the narcotic analgesics documented;
 - (C) You inappropriately treated Patient 5 with narcotics and psychoactive agents over a period of approximately three and a half years despite the addictive potential of these medications and although you had information that Patient 5 may have altered a prescription;
 - (D) Over a prolonged period of time, you repeatedly prescribed narcotics to Patient 6 rather than referring Patient 6 to a pain specialist; and
 - (E) You treated Patient 7 with large quantities of narcotics although she was pregnant and although she was later nursing her infant.
- (4) In your treatment of Patients 1, 2, 3, 4, 5 and 6, your charting was inappropriate in that it contained inaccurate information, omissions and/or discrepancies. Examples of such charting include, but are not limited to, the following:
- (A) You failed to document any discussion with Patient 1 regarding a total abdominal hysterectomy prior to the patient undergoing such surgery;
 - (B) Following an appendectomy on Patient 2, you noted in the discharge summary that Patient 2's appendix was adhered into an inflammatory mass despite the fact that the operative note and a prior laparoscopy did not reflect this. In addition, the pathology report indicated that the appendix was normal and did not show a fecalith;
 - (C) You repeatedly described Patient 3's uterus as enlarged although ultrasounds and/or pre-operative examinations indicated that Patient 3's uterus was normal.

Further, you failed to document complete information, i.e. indications and amounts given, when prescribing narcotics to Patient 3;

- (D) Your findings of an eight to ten week size enlarged uterus following a laparoscopy on Patient 4 contradict an ultrasound performed less than a week earlier showing a normal size uterus;
 - (E) In an operative note, you described Patient 5's right tube to be normal, despite the fact that in a prior operative note, you indicated that Patient 5's right tube had been removed. In addition, you stated in a discharge summary that Patient 5 had a D&C and an ovarian cystectomy, despite the fact that she did not have either of these procedures; and
 - (F) In an operative note on Patient 6, you included a finding of an 8 to 10 centimeter ovarian cyst, despite the fact that an ultrasound scan performed two days earlier showed a 3 centimeter cyst and the pathology report noted only a small amount of tissue.
- (5) In your treatment of Patient 7, you inappropriately prescribed oral terbutaline, without prior parenteral treatment; you failed to establish a correct estimated date of conception; and you diagnosed the patient as having gestational diabetes without proper criteria and then failed to follow-up appropriately. In addition, you subjected Patient 7 to four amniocenteses, although three of the amniocenteses were not indicated.
- (6) You inappropriately treated Patient 1's post-operative metritis with oral antibiotics.

Your acts, conduct, and/or omissions as alleged in paragraphs (2) through (6) above, individually and/or collectively, constitute "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.

Further, your acts, conduct, and/or omissions as alleged in paragraph (3) above, individually and/or collectively, constitute "[f]ailure to use reasonable care discrimination in the administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code, as in effect prior to March 9, 1999.

Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty (30) days of the time of mailing of this notice.

You are further advised that, if you timely request a hearing, you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty (30) days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery or to reprimand or place you on probation.

Please note that, whether or not you request a hearing, Section 4731.22(L), Ohio Revised Code, effective March 9, 1999, provides that "[w]hen the board refuses to grant a certificate to an applicant, revokes an individual's certificate to practice, refuses to register an applicant, or refuses to reinstate an individual's certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate."

Copies of the applicable sections are enclosed for your information.

Very truly yours,



Anand G. Garg, M.D.
Secretary

AGG/blt
Enclosures

CERTIFIED MAIL # 7000 0600 0024 5142 0249
RETURN RECEIPT REQUESTED