Brach Eichler L.L.C.
COUNSELLORS AT LAW
101 Eisenhower Parkway • Roseland, New Jersey 07068 • t. 973.228.5700 • f. 973.228.7852
www.bracheichler.com

Eric W. Gross
Direct Dial: 973-364-5228
Direct Fax: 973-618-5588
E-mail: egross@bracheichler.com

October 6, 2010

VIA LAWYERS SERVICE

William V. Roeder
Executive Director
New Jersey State Board of Medical Examiners
P.O. Box 183
140 East Front Street, 2nd Floor
Trenton, New Jersey 08625-0183

Re: I/M/O Steven C. Brigham, M.D.
Our File No.: AME444-260333

Dear Mr. Roeder:

This office represents Respondent, Steven C. Brigham, M.D. in the above stated matter. Enclosed for filing are an original and one copy of the following documents:

1. Notice of Motion to Dismiss Counts I, III, IV, V, and VI of the Verified Complaint;

2. Certification of Eric W. Gross, Esq.; and

3. Brief.

Thank you for your attention to this matter. If you have any questions, please feel free to contact me.

Very truly yours,

Eric W. Gross

EWG/bjm
Enclosures

cc: Jeri L. Warhaftig, D.A.G. (w/encl.)
Steven C. Brigham, M.D. (w/encl.)

BRACH EICHLER L.L.C.
101 Eisenhower Parkway
Roseland, New Jersey 07068-1067
(973) 228-5700
Attorneys for Steven C. Brigham, M.D.

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF

STEVEN C. BRIGHAM, M.D.,

TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

Administrative Action

NOTICE OF MOTION TO DISMISS COUNTS I, III, IV, V AND VI OF THE VERIFIED COMPLAINT

Jerry Warhaftig, D.A.G.
Division of Law
Hughes Justice Complex
25 Market Street
P.O. Box 903
Trenton, New Jersey 08625-0093

PLEASE TAKE NOTICE that Respondent, Steven Brigham, M.D., hereby makes application before the New Jersey State Board of Medical Examiners at 9:00 October 13, 2010 for an Order Dismissing Counts I, III, IV, V and VI of the Amended Verified Complaint filed by the Attorney General of the State of New Jersey seeking the summary suspension of Respondent's license to practice medicine in the State of New Jersey.

PLEASE TAKE FURTHER NOTICE that in support of the within Motion, reliance shall be placed upon the Certification of Eric W. Gross, Esq., and the brief enclosed herewith.

PLEASE TAKE FURTHER NOTICE that a proposed form of Order is supplied herewith.

PLEASE TAKE FURTHER NOTICE that Respondent requests oral argument.

BRACH EICHLER, L.L.C.
Attorneys for Respondent
Steven C. Brigham, M.D.

By: Eric W. Gross
ERIC W. GROSS, ESQ.

DATED: October 6, 2010

BRACH EICHLER L.L.C.
101 Eisenhower Parkway
Roseland, New Jersey 07068-1067
(973) 228-5700
Attorneys for Steven C. Brigham, M.D.

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF

STEVEN C. BRIGHAM, M.D.,

TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

Administrative Action

CERTIFICATION
OF
ERIC W. GROSS, ESQ.

ERIC W. GROSS, ESQ. certifies as follows

1. I am a New Jersey licensed attorney and an associate at the firm of Brach Eichler, L.L.C., counsel for Respondent Steven Brigham, M.D. in the above captioned matter. I make this certification in support of Respondent's Motion to Dismiss Counts I, III, IV, V and VI of the Verified Complaint.

2. Attached hereto as Exhibit 1 is a true and accurate copy of the Verified Complaint filed against Respondent by the Attorney General of the State of New Jersey on November 24, 1993.

3. Attached hereto as Exhibit 2 is a true and accurate copy the August 28, 1996 (nunc pro tunc August 14, 1996) Order of the New Jersey State Board of Medical Examiners in I/M/O Steven Brigham, M.D., BDS 1303-94, 2468-95.

4. Attached hereto as Exhibit 3 is a true and accurate copy of the April 12, 1996 Initial Decision of the Honorable Joseph Fidler, A.L.J. in I/M./O Steven Brigham, M.D., BDS 1303-94 and 2468-95.

5. Attached hereto as Exhibit 4 is a true and accurate copy of the September 10, 2010 Cease and Desist Order of the New Jersey State Board of Medical Examiners.

6. Attached hereto as Exhibit 5 is a true and accurate copy of the August 25, 2010 Cease and Desist Order issued by the Maryland Board of Physicians.

7. Attached hereto as Exhibit 6 is a true and accurate copy of the Notice of Appeal and Request for Hearing filed by Respondent's Maryland attorney, Marc Cohen, Esq.

8. Attached hereto as Exhibit 7 is a true and accurate copy of an excerpt from the transcript of the testimony of Nicholas Kotopoulos, M.D. before the Honorable Joseph F. Fidler, A.L.J. on November 17, 1994.

9. Attached hereto as Exhibit 8 is a true and accurate copy of a printout from the website "Google Maps" which sets forth the driving directions between 1 Alpha Avenue, Voorhees (Echelon), New Jersey 08043 and 126 East High Street, Elkton, Maryland 21921

10. Attached hereto as Exhibit 9 is a true and accurate copy of a printout from the website "Google Maps" which sets forth the driving distance between 1 Alpha Avenue, Voorhees (Echelon), New Jersey 08043 and 6390 Austin Street, #101, Flushing, New York 11375.

11. Attached hereto as Exhibit 10 are a true and accurate copies of the January 26, 1999 letter from Stuart Phillips, Esq. to Judith Gleason, Executive Director of the New Jersey State Board of Medical Examiners and a follow-up letter from Mr. Phillips dated October 21, 1999.

12. Attached hereto as Exhibit 11 is a true and accurate copy of the letter from Judith Gleason, Executive Director of the New Jersey State Board of Medical Examiners to Stuart Phillips, Esq., which was received by Mr. Phillips' office on November 8, 1999.

13. Attached hereto as Exhibit 12 is a true and accurate copy of the December 12, 2007 Society For Family Planning Guideline Number 20073.

14. Attached hereto as Exhibit 13 is a true and accurate copy of the October 5, 2010 expert report of Gary Mucciolo, M.D. and Curriculum Vitae of Dr. Mucciolo.

15. Attached hereto as Exhibit 14 is a true and accurate copy of an excerpt from Black's Law Dictionary, Seventh Edition.

I certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false I am subject to punishment.

By: _____
ERIC W. GROSS, ESQ.

DATED: October 6, 2010

EXHIBIT 1

FRED DEVESA
ACTING ATTORNEY GENERAL OF NEW JERSEY

By: Linda S. Ershow-Levenberg
Deputy Attorney General
Division of Law - 5th Fl.
124 Halsey Street
P.O. Box 45029
Newark, New Jersey 07101
Tel. (201) 648-3696

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF MEDICAL EXAMINERS
DOCKET NO.

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF Steven Chase Brigham, M.D. License No.51068 TO PRACTICE MEDICINE & SURGERY IN THE STATE OF NEW JERSEY	Administrative Action VERIFIED COMPLAINT

Fred DeVesa, Acting Attorney General of New Jersey, by Linda S. Ershow-Levenberg, Deputy Attorney General, with offices located at the Division of Law, Fifth Floor, 124 Halsey Street, Newark, New Jersey 07102, by way of Complaint, says:

COUNT I

1. Complainant Attorney General of New Jersey is charged with enforcing the laws of the State of New Jersey pursuant to N.J.S.A. 52:17A-4 and is empowered to initiate administrative disciplinary proceedings against persons licensed by the Board of Medical Examiners pursuant to N.J.S.A. 45:1-14 et seq.

2. The New Jersey State Board of Medical Examiners is

empowered with the duty and responsibility of regulating the practice of medicine & surgery in the State of New Jersey pursuant to N.J.S.A. 45:9-1 et seq. and N.J.S.A. 45:1-14 et seq.

3. The Board of Medical Examiners is empowered pursuant to N.J.S.A. 45:1-22, upon notice to the licensee, to enter a temporary order suspending or limiting any license issued by the board pending plenary hearing on an administrative complaint provided that the verified application by the Attorney General palpably demonstrates a clear and imminent danger to the public health, safety and welfare.

4. Respondent Steven Chase Brigham is the holder of License No. 51068, with offices at 1 Alpha Avenue, suite 27, Voorhees, NJ, and has been licensed to practice medicine and surgery in the State of New Jersey at all times relevant hereto.

5. Respondent commenced medical practice in New Jersey in or about June, 1992.

6. Respondent does not hold hospital privileges in any hospitals in New Jersey.

7. Respondent appeared with counsel for an investigative inquiry conducted by the Deputy Attorney General on December 21, 1993 and testified under oath.

8. Respondent has had no formal training in obstetrics and gynecology, and is neither Board-eligible nor Board-certified in any specialty.

9. The insertion of laminaria in a patient who is past 14 weeks LMP (i.e., since the first day of the "last menstrual period") constitutes the commencement of an abortion in the

second trimester.

10. The surgical removal of a demised fetus from the uterus of a pregnant patient constitutes the performance of an abortion.

11. On or about July 14, 1992, respondent commenced medical care of J.K. at his office in Voorhees for purposes of terminating a 23 week pregnancy. Utilizing ultrasound, Respondent diagnosed a spontaneous intrauterine fetal demise, and commenced the process of abortion by dilating the cervix by insertion of Laminaria Japonica.

12. Respondent discharged the patient to her home which was 56 miles from his office. He intended to transport her to All Women Medical Pavilion in Queens, New York City on July 16 to complete the abortion utilizing a Dilatation & Extraction procedure.

13. J.K. returned to respondent's office on July 15, at which time respondent removed the laminaria. During this procedure, J.K.'s membranes spontaneously ruptured. Respondent inserted approximately 22 fresh laminaria and one Dilapan, prescribed Anaprox and discharged her to her home, still intending to transport her to All Women Medical Pavilion in Queens, New York City on July 16 to complete the abortion.

14. On the evening of July 15, J.K. developed fever, bleeding and contractions and was hospitalized through the emergency room of Robert Wood Johnson Medical Center in New Brunswick.

15. By inserting laminaria in J.K. under the

circumstances set forth above, respondent violated N.J.A.C. 13:35-4.2, which restricts the performance of second-trimester abortions to licensed ambulatory care facilities and hospitals. and further restricts the performance of abortions past 20 weeks LMP to specified circumstances with the specific approval of the Board.

16. Respondent's management plan for J.K. was a gross deviation from generally accepted standards for a two-day termination of late-stage pregnancy, in that he inserted the laminaria in a patient who had to travel over an hour to and from his office each day and he further intended to transport her an additional two hours to the clinic in New York for the actual completion of the procedure, and he had no admitting privileges or backup arrangements with another physician at any local hospitals so as to ensure prompt continuity of care in the event of an emergency.

17. Respondent's conduct subjected J.K. to enhanced risk of hemmorrhage and all risks which flow from that.

18. By the foregoing, respondent engaged in gross or repeated acts of negligence, malpractice or incompetence as well as professional misconduct, and exhibited poor judgment which calls into question his ability to safely practice medicine in this State.

19. Respondent's conduct as alleged in this Count, when taken in combination with conduct alleged in the other counts of this Complaint, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting

grounds pursuant to N.J.S.A. 45:1-21(d) for the revocation or suspension of his license to practice medicine in this State.

20. All of the foregoing constitutes grounds pursuant to N.J.S.A. 45:9-16 and 45:1-21 (c),(d), (e) and (h) for the revocation or suspension of respondent's license to practice medicine and surgery in this State.

COUNT II

1. Complainant repeats the allegations of Count I as if fully set forth herein.

2. In or about May, 1993, respondent performed an abortion on a patient who was at 23 weeks gestation. Respondent claimed that such a procedure was permissible in an office setting because the fetus was already demised before he began the procedure.

3. Removal of a 23-week demised fetus from a pregnant patient constitutes the performance of an abortion.

4. An abortion may only be performed in a private office setting up to 14 weeks LMP.

5. An abortion may only be performed after 20 weeks LMP with the express permission of the Board of Medical Examiners in accordance with the requirements set forth in N.J.A.C. 13:35-4.2(f) and (g).

6. Respondent by the foregoing violated N.J.A.C. 13:35-4.2.

7. The aforesaid violation constitutes grounds pursuant to N.J.S.A. 45:1-21(h) for the suspension or revocation of

respondent's license to practice medicine and surgery in this State.

COUNT III

1. Complainant repeats the allegations of Counts I and II as if fully set forth herein.

2. On May 8, 1992, respondent commenced an abortion at Flushing Gynecology Center in New York on A.W. who was 24 weeks pregnant. During this procedure, respondent perforated her uterus, did not immediately recognize that the perforation had occurred, and continued to operate outside the uterus, grasping other tissues and organs with his instrument and injuring them.

3. Respondent did not interrupt the procedure until he saw omentum. He contacted an ambulance service and accompanied the patient to the hospital where other physicians rendered emergency care and performed surgery to repair the damage done.

4. A.W.'s injuries were: an 8-10 cm uterine laceration, bilateral pelvic peritoneal lacerations, disruption of the sigmoid mesentery, transmural laceration of the sigmoid colon, fecal contamination of the peritoneal cavity and extensive damage to both ureters.

5. Respondent's conduct jeopardized the health and life of A.W.

6. By failing to quickly recognize that he had perforated the uterus, and by continuing to operate on the patient outside the uterus, and by therefore causing the extensive damage set forth above, respondent engaged in gross and repeated acts of negligence, malpractice, or incompetence.

7. Respondent's conduct with regard to A.W. constitutes grounds pursuant to N.J.S.A. 45:9-16 and 45:1-21(c) and (d) for the revocation or suspension of his license to practice medicine in this State.

8. Respondent's conduct as alleged in this Count, when taken in combination with conduct alleged in the other counts of this Complaint, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds pursuant to N.J.S.A. 45:1-21(d) for the revocation or suspension of his license to practice medicine in this State.

COUNT IV

1. Complainant repeats the allegations of Counts I-III as if fully set forth herein.

2. On or about 8/12/92, respondent performed an abortion at his office in Voorhees, N.J. on patient S.C. The chart reflects that despite the patient's reported date of Last Menstrual Period ("LMP"), the aborted fetus was noted to be of 15-16 week gestation. The fetal foot length is recorded in the chart as 14 mm, which corresponds to 15-16 weeks. Additionally, the sonogram in this chart, which was reviewed by the Board's investigators on 9/15/93, stated 20-22 weeks [gestational age].

3. On 9/29/93, the Board's investigators obtained the original chart from respondent pursuant to a court order. The sonogram was missing from the chart.

4. Respondent failed to accurately assess the status of S.C.'s pregnancy, performed an abortion in his office at a point

later than 14 weeks LMP, and intentionally or negligently altered his medical chart for S.C.

5. By the foregoing, respondent engaged in conduct which violates N.J.A.C. 13:35-4.2 and N.J.A.C. 13:35-6.5, and has engaged in the use of dishonesty, deception, or misrepresentation as well as professional misconduct.

6. All of the foregoing constitutes grounds pursuant to N.J.S.A. 45:9-16 and 45:1-21(b),(e) and (h) for the revocation or suspension of respondent's license to practice medicine in this State.

7. Respondent's conduct as alleged in this Count, when taken in combination with conduct alleged in the other counts of this Complaint, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds pursuant to N.J.S.A. 45:1-21(d) for the revocation or suspension of his license to practice medicine in this State.

COUNT V

1. Complainant repeats the allegations of Counts I - IV as if fully set forth herein.

2. On or about 11/11/92, respondent commenced or completely performed an abortion on B.A. at his Voorhees office.

3. In the chart for B.A. that was reviewed by Division of Consumer Affairs Investigators on September 15, 1993, the two-sided Abortion Procedure Record was completely filled out and was signed by respondent. The final estimated gestation recorded on that form was 23-24 weeks. The sonogram film/report in the chart

also said 23 weeks.

4. On 9/29/93, the Board's investigators obtained the original chart on B.A. from respondent pursuant to a court order. In the chart provided at that time by respondent, the procedure section of the 2-sided Abortion Procedure Record was blank. The chart contained a handwritten "obstetrical sonogram report" which recorded 23 weeks, and a one-page report detailing the insertion of laminaria.

5. The insertion of laminaria in a patient who is at 23 weeks gestation constitutes the commencement of an abortion in a patient in late second trimester.

6. With regard to B.A., respondent performed an abortion in his office at a point later than 14 weeks LMP, and intentionally or negligently altered his medical chart for B.A.

7. By the foregoing, respondent engaged in conduct which violates N.J.A.C. 13:35-4.2 and N.J.A.C. 13:35-6.5, and has engaged in the use of dishonesty, deception, or misrepresentation as well as professional misconduct.

8. All of the foregoing constitutes grounds pursuant to N.J.S.A. 45:9-16 and 45:1-21(b),(e) and (h) for the revocation or suspension of respondent's license to practice medicine in this State.

9. Respondent's conduct as alleged in this Count, when taken in combination with conduct alleged in the other counts of this Complaint, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds pursuant to N.J.S.A. 45:1-21(d) for the revocation or suspension

of his license to practice medicine in this State.

COUNT VI

1. Complainant repeats the allegations of Counts I - V as if fully set forth herein.

2. On or about September 1, 1993, patient F.E. presented at the emergency room of West Jersey Hospital in Voorhees with a chief complaint of fever and right lower quadrant abdominal pain. She was status 5 days post abortion performed at 10-11 weeks. Exploratory abdominal surgery revealed an abcess in the right adnexa caused by the perforation of F. E.'s uterus during the abortion.

3. Despite F.E.'s complaint to respondent during the abortion that she was experiencing sharp lower quadrant pain in her abdomen, respondent failed to recognize that a complication had occurred, to wit, that he had perforated her uterus, and he failed to refer her to the hospital for treatment.

4. Respondent's failure to recognize the above-described complication in this first-trimester abortion case, and his failure to refer the patient for medically necessary emergency followup, constitutes gross negligence, malpractice or incompetence and created a risk to the life and health of F.E.

5. Respondent's conduct as outlined above constitutes grounds pursuant to N.J.S.A. 45:9-16 and 45:1-21 (c) for the suspension or revocation of his license to practice medicine and surgery in this State.

6. Respondent's conduct as alleged in this Count, when

taken in combination with conduct alleged in the other counts of this Complaint, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds pursuant to N.J.S.A. 45:1-21(d) for the revocation or suspension of his license to practice medicine in this State.

COUNT VII

1. Complainant repeats the allegations of Counts I - VI as if fully set forth herein.

2. Respondent stores thousands of charts for his Voorhees, New Jersey medical practice from June 1992 to the present at an office in Spring Valley, New York and in Greenwich, CT, locations which are at least three (3) hours' drive from his Voorhees office. Respondent does not keep a register of which records are at which location.

3. In mid-September, 1993, respondent began removing charts from his office and storing them off-premises promptly after abortion procedures were completed, such that the registered nurse practitioner who performed the 2-week postoperative examinations had to perform those examinations without benefit of any medical records or histories for the patients she was examining.

4. The sonograms in respondent's charts are not identified with the patient's name or the date and in some instances bear little correlation to the other information contained in the patients' charts.

5. By the foregoing, respondent has violated the

intent of the patient records rule, N.J.A.C. 13:35-6.5, impeded the ability of his staff to provide adequate post-surgical follow-up care, and engaged in repeated acts of negligence and in professional misconduct.

6. The aforesaid conduct constitutes grounds pursuant to N.J.S.A. 45:1-21(d), (e) and (h) for the revocation or suspension of respondent's license to practice medicine in this State.

COUNT VIII

1. Complainant repeats the allegations of Counts I-VII as if fully set forth herein.

2. On 9/29/93, respondent was performing abortions on patients at his Voorhees office. Several patients were escorted out of the office a few minutes after their procedures were completed, without having spent any time in respondent's recovery room.

3. Respondent's procedure records for abortion procedures he performs do not reflect intraoperative or postperative monitoring of vital signs.

4. Failure to adequately allow for and failure to monitor a patient's recovery following an abortion constitutes professional misconduct and repeated acts of negligence.

5. The aforesaid conduct therefore constitutes grounds pursuant to N.J.S.A. 45:1-21(d) and (e) for the revocation or suspension of respondent's license to practice medicine in this State.

6. Respondent's conduct as alleged in this Count, when

taken in combination with conduct alleged in the other counts of this Complaint, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds pursuant to N.J.S.A. 45:1-21(d) for the revocation or suspension of his license to practice medicine in this State.

COUNT IX

1. Complainant repeats the allegations of Counts I-VIII as if fully set forth herein.

2. In October, 1993, respondent performed an abortion on a 14 year old patient whose mother accompanied her to the office. Respondent refused to permit the mother to remain in the operating room with her daughter during the procedure because she could not pay his $50 surcharge for the presence of a family member in the operating room.

3. Respondent directed that an excessive amount of sedation be administered to the patient. Respondent further placed a handful of gauze in the child's mouth during this procedure.

4. Nursing staff had difficulty arousing the patient following the procedure, and her heartrate was 110-120 beats per minute by stethoscope and 160 by pulse oximeter, which also showed 85% oxygenation. Respondent removed the pulse oximeter despite these findings and insisted that the patient be walked out of the operating room into recovery.

5. Respondent's conduct as set forth hereinabove constitutes gross or repeated acts of negligence, malpractice or

incompetence as well as professional misconduct.

6. Respondent's conduct as set forth in hereinabove constitutes grounds pursuant to N.J.S.A. 45:1-21 (c), (d) and (e) for suspension or revocation of his license to practice medicine and surgery in this State.

COUNT X

1. Complainant repeats the allegations of Counts I - IX as if fully set forth herein.

2. Respondent published advertising in New Jersey in 1992 and 1993 which advertised "abortions to 24 weeks, safe, gentle, painless," lists a New Jersey telephone number and respondent's Voorhees address, and states at the bottom of the ad "offices in NJ and N.Y. City."

3. Respondent's advertisement is deceptive and misleading because surgical procedures ipso facto involve or result in pain and discomfort to a patient, and because the ads offer services which it is illegal for respondent to perform in his office, to wit, abortions past 14 weeks LMP.

4. For the foregoing reasons, the aforesaid advertising violates N.J.A.C. 13:35-6.10.

5. The foregoing constitutes grounds pursuant to N.J.S.A. 45:1-21 (h) for the revocation or suspension of respondent's license to practice medicine in this State.

COUNT XI

1. Complainant repeats the allegations of Counts I - X

as if fully set forth herein.

2. Respondent attempts to resterilize disposable plastic gloves used in the performance of examinations and surgical procedures by processing them in the steam autoclave used for sterilizing metal instruments.

3. By the foregoing, respondent engages in unsterile practices and engages in professional misconduct.

4. The foregoing constitutes grounds pursuant to N.J.S.A. 45:1-21 (e) for the revocation or suspension of respondent's license to practice medicine in this State.

5. Respondent's conduct as alleged in this Count, when taken in combination with conduct alleged in the other counts of this Complaint, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds pursuant to N.J.S.A. 45:1-21(d) for the revocation or suspension of his license to practice medicine in this State.

COUNT XII

1. Complainant repeats the allegations of Counts I - XI as if fully set forth herein.

2. Respondent's actions as set forth above in Counts I-XI and verified by the Affidavits of Linda S. Ershow-Levenberg, Special Investigators Mary Peterson, Ben Ricciardi, and Deborah Zuccarelli, Ellen Stott, R.N. (Nurse Practitioner/Clinical Nurse Specialist), Lynette Campbell, R.N., the expert's reports of Nicholas Kotopoulos, M.D., and by respondent's advertising, and by the patient records for all patients identified in the

Verified Complaint, palpably demonstrate that his continued practice of medicine and surgery poses a clear and imminent danger to the public health, safety and welfare, thus warranting the immediate Temporary Suspension or Limitation of his medical license pursuant to N.J.S.A. 45:1-22.

WHEREFORE, it is respectfully demanded that the State Board of Medical Examiners:

1. Temporarily suspend or otherwise limit and restrict the license heretofore issued to respondent Steven C. Brigham, M.D. to practice medicine and surgery in the State of New Jersey;
2. Suspend or revoke the license heretofore issued to respondent Steven Brigham, MD to practice medicine and surgery in the State of New Jersey;
3. Issue an Order directing respondent to cease, desist and refrain from the practice of medicine and surgery in the State of New Jersey;
4. Assess such monetary penalties for each separate unlawful act as set forth in Counts I - XI above;
5. Order payment of costs, including investigative costs, fees for expert witness and costs of trial, including transcripts;
6. Issue an Order directing respondent to restore to any party or governmental entity aggrieved by the unlawful acts or practices of respondent, any monies acquired by respondent in the course of

such conduct; and

7. Order such other and further relief as the Board of Medical Examiners shall deem just and appropriate.

FRED DEVESA
ACTING ATTORNEY GENERAL OF
NEW JERSEY

By: Linda S. Ershow-Levenberg
Deputy Attorney General

DATED: November 24, 1993

ATTORNEY GENERAL'S EXHIBITS

Exhibit #1:12/21/93 transcript [to be provided at hearing];

Exhibit #2: patient records of J.K. [to be provided at hearing];

Exhibit #3: Kotopoulos report 1/28/93

Exhibit #4: Affidavit of Ellen Stott, R.N.

Exhibit #5: A.W.'s patient records [to be provided at hearing];

Exhibit #6: Kotopoulos report 10/11/93

Exhibit #7: Respondent's chart on S.C.;

Exhibit #8: Respondent's chart on B.A.;

Exhibit #9: Affidavit "A" of Investigator Mary Peterson

Exhibit #10: F.E.'s medical records [to be provided at hearing];

Exhibit #11: Affidavit "B" of Investigator Mary Peterson

Exhibit #12: Affidavit of Investigator Ben Ricciardi

Exhibit #13: Affidavit of Investigator Deborah ~~Wacker~~ Zuccarelli

Exhibit #14: Affidavit "C" of Investigator Mary Peterson

Exhibit #15: patient records for M.B.

Exhibit #16: patient records for C.E. [to be provided at hearing]

Exhibit #17: patient records for L.R. [to be provided at hearing]

Exhibit #18: patient records for M.A. [to be provided at hearing]

Exhibit #19: Affidavit of Lynette Campbell, R.N.

Exhibit #20: Advertising received by Board of Medical Examiners

Exhibit #21: Affidavit of Charles A. Janousek ref. letter received from Dr. Apetz

Exhibit #22: Affidavit of Dr. Apetz ref. letter he copied to Board of Medical Examiners

Exhibit #23: Affidavit of Dr. Rosen [to be provided at hearing]

EXHIBIT 2

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

CHRISTINE TODD WHITMAN
Governor

PETER VERNIERO
Attorney General
MARK S. HERR
Director

In reply respond to:
140 E Front Street 2nd Fl.
Trenton NJ 08608
(609) 826-7100

September 4, 1996

Beatriz Valera-Schutz
Deputy Attorney General
Division of Law
Post Office Box 45029
Newark, NJ 07101

Jeff Berkowitz, Esq.
c/o Nathan Dembin & Associates
225 Broadway, Suite 1905
New York, NY 10007

RE: Steven Chase Brigham, M.D.

Dear Attorneys:

Enclosed find a certified true copy of the Administrative Action FINAL DECISION AND ORDER filed with the New Jersey Board of Medical Examiners in this matter.

Should you have any questions, please do not hesitate to contact this office.

Very truly yours,

Kevin B. Earle
Executive Director

Carolyn Maschal
Administrative Assistant

Enclosure

FILED

August 28, 1996
NEW JERSEY STATE BOARD
OF MEDICAL EXAMINERS

EFFECTIVE

August 14, 1996
NEW JERSEY STATE BOARD
OF MEDICAL EXAMINERS

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
DOCKET NO. BDS 1303-94 & BDS 2468-95

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF:	:	Administrative Action
STEVEN CHASE BRIGHAM, M.D. LICENSE #51068	:	FINAL DECISION AND ORDER
TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	:	

This matter commenced with the filing of a Verified Complaint and Order to Show Cause by the Attorney General of New Jersey against respondent, Steven Chase Brigham, M.D. on November 24, 1993. The Verified Complaint alleged, among other things, that respondent violated board regulations by performing second trimester abortions at a New Jersey office, that his treatment of four patients who sought abortion services constituted gross malpractice, gross negligence and/or repeated negligence or incompetence in violation of N.J.S.A. 45:1-21, and that he posed a clear and imminent danger to the public health, safety and welfare, thus warranting imposition of an immediate temporary suspension. Respondent's answer to the complaint essentially denied all allegations of negligence and malpractice and asserted that his conduct was consistent with accepted standards of care.

Following a hearing held on an application for temporary suspension in December of 1993, the Board issued an Interim Order

finding that as Dr. Brigham's unrestricted practice palpably demonstrated a clear and imminent danger to the public, his practice must be limited. The restrictions included a bar on his initiation or participation in second trimester abortions, (encompassing but not limited to the insertion of lamanaria in patients for purposes of cervical dilatation preceding evacuation of the uterus); and included his retention of a supervisor to review his patient records and to assure respondent's compliance with New Jersey law and the restrictions imposed.

The Attorney General filed a second Order to Show Cause and Verified Complaint in July 1994 seeking to temporarily suspend the license held by respondent. The complaint alleged that the care rendered to two abortion patients, constituted gross and/or repeated malpractice or incompetence in violation of N.J.S.A. 45:1-21. Again, respondent's answer essentially denied the allegations of the complaint.

Following a hearing on August 1, 1994 a committee of the Board of Medical Examiners denied the application of the Attorney General to temporarily suspend Dr. Brigham's license and declined to find a clear and imminent danger to the public in the continuation of Dr. Brigham's practice under the restrictions previously imposed by the Board. Motions to accept and reject the committee's recommendations failed to attract a quorum of the Board at its meeting of August 19, 1994 and a further request of the Attorney General to have the matter considered at the Board's September meeting was tabled. No further action was taken.

The matter was referred to the Office of Administrative Law and an Initial Decision was rendered on April 12, 1996.[1] The Attorney General requested a 60 day extension of time through June 24, 1996 for the filing of exceptions. The extension was granted without objection of respondent. Simultaneously, the Board granted respondent's request, with the consent of the Attorney General, to his re-entry into the practice of medicine, pending the issuance of a final decision by the Board of Medical Examiners. The reinstatement of respondent's license was subject to the condition that he limit his performance of abortions in the State of New Jersey to first trimester abortions. Following additional extensions of time for the filing of exceptions, this matter was scheduled for final disposition before the Board of Medical Examiners on August 14, 1996.

At the hearing before the Board, the respondent appeared with counsel, Nathan L. Dembin, Esq. Jeri L. Warhaftig, Deputy Attorney General, represented the complainant.

---

[1] In December of 1994, following commencement of the hearing in this matter, a third complaint was filed alleging that respondent's license to practice medicine and surgery was revoked in the State of New York for gross negligence in respondent's care of patient M.B. (whose care was the subject of Count I of the Attorney General's complaint in New Jersey) and gross and repeated acts of medical negligence in his care and treatment of A.W. (Count III of the Attorney General's complaint in New Jersey). Respondent's answer asserted that the New York decision was not final and that the decision was fundamentally flawed. Upon the Attorney General's application to suspend or revoke respondent's license based on the New York action, the Board declined to make any determination, and accepted respondent's offer to cease practicing medicine and surgery in New Jersey until the Board had an opportunity to consider the initial decision of an administrative law judge in this matter.

Based on due consideration of the Administrative Law Judge's decision and the underlying record in this case, and upon the arguments of counsel, the Board adopts as its final decision the findings of fact and conclusions of law of the Administrative Law Judge.[2] Thus the Board upholds the ALJ's findings dismissing all allegations in the complaint except Count X of the Amended Complaint and Count III of the Second Complaint concerning misleading advertisement. The Board notes that in authorizing the initiation of a disciplinary action, the Board determined that sufficient cause existed for a full evidentiary determination in this matter. Similarly, following hearing regarding temporary suspension, the Board determined that sufficient cause existed to restrict respondent's license until conclusion of the plenary proceedings. However, upon review of the record of the plenary hearing in this matter, the Board adopts the decision dismissing the bulk of the allegations.

In considering the penalty to be imposed in this matter, the Board afforded both respondent and complainant the opportunity to present mitigating circumstances or make further argument beyond that contained in their written exceptions. Both counsel declined

---

[2] Thus the Board has denied the State's application to afford collateral estoppel effect to the disciplinary action of a sister state (N.Y.) regarding the same incidents involved in two counts of the complaint. However, the Board reaffirms the continuing applicability of that doctrine and its history of applying it and in taking action based on the suspension or revocation of a license in another state, in virtually all circumstances, and its intent to do so in the future. However, in the unique circumstances of this matter, the Board has chosen to review the entire record of the proceedings below.

the opportunity for further argument. The Board modified the penalty recommended by the ALJ to eliminate the requirement that respondent must obtain prior approval of the Board for all advertisements to prevent those which mislead or have the capacity to mislead. The penalty is modified to provide that respondent shall in the future cease and desist utilizing either the term "safe" or the term "painless" in any advertising, and shall cease and desist from any advertisements which mislead or have the capacity to mislead as prohibited by N.J.A.C. 13:35-6.10(c) and N.J.S.A. 45:1-21(b). The Board believes that the requirement of the ALJ that respondent obtain from the Board pre-approval of all advertisements is unnecessary in the circumstances presented in this case.

THEREFORE, IT IS ON THIS 13th DAY OF August 1996,

NUNC PRO TUNC AUGUST 14, 1996,

ORDERED:

1. Respondent shall cease, desist and refrain from any and all advertising which misleads or has the capacity to mislead, and shall cease, desist and refrain from utilizing the term "safe" or the term "painless" in any advertising.

2. All counts of the complaints filed against respondent with the exception of Count X of the Amended Complaint and Count III of the Second Complaint are dismissed.

3. Respondent's license to practice medicine and surgery in the State of New Jersey is fully reinstated effective August 14, 1996.

STATE BOARD OF MEDICAL EXAMINERS

By: _____
Robert L. Johnson, M.D., F.A.A.P
President

EXHIBIT 3

State of New Jersey

OFFICE OF ADMINISTRATIVE LAW

9 Quakerbridge Plaza
CN 049
Trenton, New Jersey 08625
(609) 588-6584

A copy of the administrative law judge's decision is enclosed.

This decision was mailed to the parties on APR 17 1996.

State of New Jersey
OFFICE OF ADMINISTRATIVE LAW

INITIAL DECISION
OAL DKT. NOS. BDS 1303-94 AND
BDS 2468-95
AGENCY DKT. NOS. ---
(CONSOLIDATED)

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF STEVEN CHASE BRIGHAM, M.D., TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY.

Linda S. Ershow-Levenberg, Deputy Attorney General, on behalf of complainant Attorney General of New Jersey (Deborah T. Poritz, Attorney General of New Jersey, attorney)

Nathan L. Dembin, Esq., member of the New York Bar, admitted *pro hac vice*, on behalf of respondent Steven Chase Brigham, M.D. Attorney of Record: Kenneth S. Javerbaum, Esq. (Javerbaum, Wurgaft & Hicks, attorneys)

Record Closed: September 26, 1995 Decided: April 12, 1996

BEFORE **JOSEPH F. FIDLER**, ALJ

STATEMENT OF THE CASE

This matter arises out of three complaints filed by the Attorney General of New Jersey ("complainant") with the State Board of Medical Examiners ("the Board") seeking sanctions against Steven Chase Brigham, M.D.("respondent"), pursuant to *N.J.S.A.* 45:1-21. At issue in this matter is whether respondent committed the acts and violations alleged in the complaints, and if so, should his license to practice medicine and surgery in the State of New Jersey be suspended

or revoked pursuant to *N.J.S.A.* 45 1-21, and should other penalties and costs be imposed. Also at issue is whether the revocation of respondent's license by the State of New York constitutes a revocation of medical licensure for reasons consistent with *N.J.S.A.* 45 1-21 and therefore constitutes grounds for disciplinary action against his medical license in New Jersey, pursuant to *N.J.S.A.* 45 1-21(g)

PROCEDURAL HISTORY

The first complaint was filed on November 24, 1993, and was subsequently amended ("Amended Complaint"). The respondent's answer to this complaint was filed on December 9, 1993. By Interim Decision and Order dated February 3, 1994, the Board placed certain restrictions on the respondent's practice, directing that he not initiate or participate in second trimester abortions, including the insertion of laminaria in patients for purposes of cervical dilation preceding evacuation of the uterus The Board also ordered the appointment of an acceptable monitor. On February 10, 1994, the matter was transmitted to the Office of Administrative Law for determination as a contested case, pursuant to *N.J.S.A.* 52:14F-1 to -13. The second complaint was filed on July 5, 1994 ("Second Complaint"), and the respondent's answer was filed on July 20, 1994 Following an Order to Show Cause proceeding before the Board on August 1, 1994, the Board declined to place any further restrictions on respondent's practice pending a plenary hearing Consolidation of the second complaint was confirmed at the telephone prehearing conference conducted on August 31, 1994

On December 2, 1994, the complainant filed another complaint with the Board ("Third Complaint"), also seeking sanctions against the respondent, based upon the allegation that the respondent's license to practice medicine in the State of New York had been revoked by the New York State Department of Health Administrative Review Board for Professional Medical Conduct. By Order effective December 14, 1994, the Board accepted respondent's offer to cease practicing in New Jersey and declined to then impose revocation of respondent's license based on New York's action, pending the New Jersey administrative law proceeding. On March 9, 1995, the New Jersey Board also transmitted this complaint to the Office of Administrative Law for determination as a contested case. The complainant moved for consolidation with the earlier

matters and also moved for partial summary decision and other relief The respondent opposed the application and by cross-motion sought an order to dismiss the latest complaint The motion for consolidation was granted on the record on May 26, 1995, pursuant to *N.J.A.C.* 1 1-17 3 However, ruling on the remainder of the motions was deferred until completion of the evidentiary record, based on the Board's ruling of December 14, 1994

Hearing sessions were held at the Office of Administrative Law, in both Newark and Mercerville, New Jersey. There were 29 days of hearing, beginning October 24, 1994 and ending June 30, 1995. At the close of the hearing, counsel for complainant requested permission to submit an opinion letter from Dr. Hollander in rebuttal Permission was granted, and the letter was admitted into evidence as Exhibit P-66. Complainant later objected to respondent's offer of additional opinion letters Exhibits R-67 and R-68, by Drs. Fogel and Burnhill, submitted as "surrebuttal" to the opinion letter of Dr Hollander However, the additional letters were useful and have been admitted into evidence Complainant filed a post-hearing motion to correct the record to accurately and fully state a stipulation which had been read into the record during the hearing The motion is unopposed and is granted

The record also remained open following the hearing to permit submission of post-hearing briefs The last of these was received on September 26, 1995, and the record closed on that date The time limit for filing this Initial Decision was extended by Orders of Extension.

OPINION WITNESSES

Complainant's Experts

Nicholas Kotopolous, M.D. is a Board certified obstetrician/gynecologist and a fellow of the American College of Obstetrics and Gynecology. He has been the Medical Director of Metropolitan Medical Associates in Englewood, New Jersey, since 1980, with an active clinical practice in first and second trimester abortions. He has performed abortions numbering many thousands, including thousands of second trimester procedures over 18 weeks gestation. As a formal instructor for the Englewood Hospital residence program, Kotopolous has trained approximately 120 resident physicians, and he is the primary consultant for cases at the hospital

involving termination of pregnancy The State Board of Medical Examiners has authorized Kotopolous to perform abortions up to 24 weeks LMP, the legal limit in New Jersey Dr Kotopolous testified for the complainant as an expert and, in part, a fact witness, concerning patients J K., A W., Y.B., M.B., and D.V..

It should be noted here that respondent argues that the inevitable possibility of bias of a business competitor so taints and undermines Dr. Kotopolous' objectivity that his testimony can not be given great weight. Further, respondent contends that the Federal Health Care Quality Improvement Act mandates that Dr. Kotopolous' competition with Dr. Brigham disqualify him as a witness in this matter. Complainant contends Dr Kotopolous was no less credible in this matter because some or all of Dr Brigham's patients might go to Dr. Kotopolous' facility if Dr Brigham were not practicing in New Jersey. There is ample evidence in the record to establish that Dr. Kotopolous and Dr Brigham have shared at least a portion of the abortion patient pool, and could fairly be said to be in economic competition. Two patients (T.F and D V) called the State to complain about Dr. Brigham while they were at Dr Kotopolous' facility in Englewood.

David Hollander, M.D., is a Board certified obstetrician/gynecologist and has been engaged in an active clinical practice since 1980. His involvement in ob/gyn related committees includes hospital prenatal quality assurance, and he was Chief of the Division of Maternal-Fetal Medicine at St. Barnabas Medical Center in Livingston, New Jersey, from 1986 to 1991. Dr. Hollander has held teaching appointments including an assistant clinical professorship at the University of Medicine and Dentistry of New Jersey. He has performed second trimester abortions up to 24 weeks, all in a hospital setting, and he has dealt with complications from abortions performed by others up to 24 weeks. Since 1984, Dr. Hollander has performed between 120 and 140 second trimester abortions using the D&E method. He has done his own ultrasounds since 1986. Dr. Hollander testified as an expert witness for the complainant.

Respondent's Experts

Dr. Michael Policar, who is licensed to practice medicine in California, is Board certified in obstetrics and gynecology and has been Fellow of Obstetrics and Gynecology since 1984. He served on the faculty of the University of California, Los Angeles and San Francisco Schools of

Medicine. He is currently an Assistant Clinical Professor of Obstetrics and Gynecology at the University of San Francisco. For twelve years, Dr Policar has taught first and second trimester abortion procedures, primarily to ob/gyn residents He has also lectured extensively on abortion topics to practitioners and at medical schools, as well as periodic meetings of the National Abortion Federation. He has served on the board of advisors of that organization and was an *ex officio* member of its Board of Directors for three years, while he served as the Vice President for Medical Affairs of Planned Parenthood

Dr. Policar is familiar with the National Abortion Federation medical standards of practice and has been involved with formulating their updates and revisions. He has also been national spokesperson for the National Office of Planned Parenthood and as Vice President for Medical Affairs of Planned Parenthood, he was responsible for drafting National Planned Parenthood standards and procedures for performing abortions that apply to all Planned Parenthood affiliates Dr. Policar has co-authored a curriculum on abortion practice for the National Abortion Federation, and he wrote two chapters of Precis of the American College of Obstetrics and Gynecology

Dr Jeffrey Moskowitz is licensed to practice medicine in the State of New York. He is a graduate of Yale University and Toronto Medical School Dr Moskowitz is a Board certified obstetrician/gynecologist, with privileges at Lenox Hill Hospital In February 1991 he became medical director and administrator of Eastern Women's Center, specializing in terminations of pregnancies from 5 weeks to 24 weeks. Dr. Moskowitz believes that Eastern is the largest provider of abortion services in the United States, performing approximately 20 thousand procedures in a year. Among his duties is evaluation of all physicians at Eastern, and he chairs the quality assurance committee. Dr. Moskowitz is familiar with the standards of medical practice.

Dr. Michael Burnhill is licensed to practice medicine in several states, including New Jersey and New York. He is a Board certified obstetrician/gynecologist and is a fellow of the American College of Obstetricians & Gynecologists and the Society of Reproductive Medicine. Dr. Burnhill is a member of the Society of Reproductive Health Professional, the National

Abortion Federation, the American College of OB/GYN and the New York Obstetrical Society (Exhibit R-60)

Dr. Burnhill has long been involved in the provision of abortions. He has been a member of the Association of Planned Parenthood Physicians since 1965, and in 1970 he became the liaison member to the National Committee of Planned Parenthood. In 1972 he became the Director of the Margaret Sanger Center in New York City. Dr. Burnhill was Chair of the standards implementation committee of the National Abortion Federation for four years and he has chaired and participated in postgraduate seminars dealing with quality control, risk management, detection, prevention and treatment of complications. He has served on the faculty of the Downstate Medical Center since 1965, and has been a Clinical Associate Professor at Cornell Medical Center and at the George Washington Medical Center. Dr. Burnhill also was an Associate Professor at Johns Hopkins University and he has served since 1979 as Professor at Robert Wood Johnson Medical Center in New Brunswick, New Jersey.

Dr. Burnhill has served as the Vice President of the National Abortion Federation and has been on that organization's board of advisors for ten years. He has annually presented lectures to the National Abortion Federation and Planned Parenthood for about twenty years. Dr. Burnhill has also lectured extensively elsewhere annually and has published numerous articles in peer review journals on abortion topics. According to Dr. Burnhill, there are two current published standards for abortion procedures: the Manual of the National Abortion Federation and the Standards and Guidelines of the Planned Parenthood Federation.

William Henry Knorr, M.D. is a Board Certified OB/GYN and Fellow of the American College of Obstetrics and Gynecology. He maintains privileges at three hospitals. Dr. Knorr began performing abortions immediately after his residency in 1984, and has personally performed approximately 30,000 abortions over the last ten years. He has performed greater than 1,000 second trimester abortion procedures.

M.A.B., M.D., is presently actively engaged in providing abortions. He obtained his medical education in England, Germany, Canada and the United States. He has attending

privileges at Beth Israel Hospital in New York and St Agnes Hospital in Westchester and is also a clinical instructor at Mt. Sinai. He is a member of the American College of Obstetricians and Gynecologists, to which he has presented papers, and the American Fertility Society Dr. M.A.B. has performed approximately 8,000 termination of pregnancy procedures, and approximately 800 of those have been dilation and evacuation procedures Dr. M.A.B. served as an owner and president of Queens OB-GYN Services

Anthony Mustalish, M D , graduated Phi Beta Kappa from New York University in 1962 and then from New York University School of Medicine. He served in two field hospitals in Vietnam in 1969 and 1970, where more than one-half of his patients were wounded soldiers who had suffered traumatic injuries causing profound blood loss and shock He also received a masters in Public Health from Harvard School of Public Health Dr Mustalish became Board Certified in Preventive Medicine and was appointed Deputy Commissioner of Health in the City of New York, serving until 1977 He is also Board Certified in Emergency Medicine, and is recognized as a Diplomat and specialist in emergency medicine He is also certified in a number of other specialized areas of emergency medicine including advanced trauma life support, advanced cardiac life support, and basic life support

Dr. Mustalish served as the Chief of the Emergency Department at Brookdale Hospital in New York, where he saw approximately 100,000 patients a year. Dr Mustalish has also served as Senior Vice President for Operations and Chief Operating Officer at Lenox Hill Hospital and was Chief of the Emergency Room Department. He established standards of care and practice, developed policies and procedures, and provided quality assurance. As Chief Operating Officer, Dr. Mustalish was responsible for quality assurance throughout the entire hospital. In the 1980's, Dr. Mustalish became the first chairman for the Standards Committee in New York, creating statewide standards for emergency care practice. Dr. Mustalish was also the director of the ambulance service at Lenox Hill Hospital, where he expanded the program and set up the first paramedic program. He was also part of the Medic Advisory Committee for EMS in the City of New York and was on the faculty of the EMS academy, providing training, teaching, certification and re-certification of New York paramedics.

Since 1990, Dr Mustalish has been an assistant professor of Emergency Medicine in Public Health and has been fulfilling dual appointments at the Cornell University Medical College while he serves as an attending physician in the Emergency Department at New York Hospital. He has testified before legislative hearings and council hearing concerning standards for emergency medical services and he has been recognized as an expert in several state courts. Dr. Mustalish has cared for many patients following abortions who have had emergency complications, including bleeding and cervical lacerations.

Narda Johnson has been a diagnostic ultrasound technician or sonographer since 1983. She has been certified as a sonographer since 1984. Ms. Johnson completed a one year course with Ultrasound Diagnostic School, continued her education at New York University and took courses at Yale on High Risk Obstetrics. She has worked at Greenwich Hospital and Wilson Memorial Hospital in North Carolina In private practice, she reviews cases with radiologists. Ms Johnson performs level two ultrasounds and does multiple measurements for gestational age. 90 percent of Ms Johnson's sonographer work involves obstetrics, estimating gestational age.

A.K., D.O., is an obstetrician gynecologist who was approved by the Board to monitor Respondent. He has performed over ten thousand late second trimester termination of pregnancy procedures Linda Ball has been a licensed Registered Nurse since 1968 and is one of the first certified as a Women's Health Care Nurse Practitioner. She received her training at Englewood Hospital School of Nursing and achieved a Masters in community health education. Ms. Ball also participated in the ambassadorship program in women's health in China.

Ms. Ball was Clinic Supervisor of a Planned Parenthood location, and she also served as Associate Executive Director to Planned Parenthood, overseeing the day to day operation of four locations.. She has served as Head Nurse, Nurse Practitioner, and administrator of an abortion facility for approximately eight years. Ms. Ball has participated in approximately 5,000 first trimester procedures and approximately 1,000 second trimester procedures.

Tiberious Dengelegi, M.D., submitted an affidavit on behalf of Dr. Brigham. He has been practicing obstetrics/gynecology for more than 30 years, and he worked with Dr. Brigham. Dr.

Kotopolous testified that he knows Dr Dengelegi and has a high regard for him as a physician Dr. Kotopolous personally observed Dr Dengelegi while he was operating at Eastern Women's Center, and he believes that Dr. Dengelegi is well recognized and experienced in abortions, and is Board certified in Obstetrics/Gynecology

Philip Stubblefield, M.D., submitted an affidavit on behalf of Dr Brigham (Exhibit P-57). He is currently Chairman of the Department of Obstetrics and Gynecology at Boston University Medical School Dr Stubblefield has personally performed, and taught Ob/Gyn residents how to perform, thousands of abortion procedures. He is widely known in the field of abortion and the author of many published articles on that topic. Dr. Stubblefield is also the author of the "Pregnancy Termination" section of the American College of Obstetrics and Gynecology's Precis V

Marvin Fogel, M.D., also submitted an affidavit on behalf of Dr. Brigham. This obstetrics/gynecology practitioner is former Dean of Mount Sinai Medical School, Director of Quality Assurance of Mt Sinai Medical Center, and Professor of Obstetrics and Gynecology. Charles H Debrovner, M.D., also submitted an affidavit on behalf of Dr. Brigham. He has been a Board Certified Ob/Gyn since 1968 and is an attending physician at four major New York metropolitan hospitals He has lectured and authored extensively in the field of obstetrics/gynecology

Anthony M Vintzileos, M.D., submitted an affidavit on respondent's behalf (Exhibit R-40). He is presently Professor of Obstetrics and Gynecology and Director of the Division of Maternal/Fetal Medicine at Robert Wood Johnson Medical School. Dr. Vintzileos is a fellow of the American College of Obstetricians and Gynecologists. He has published scientific papers on the subject of obstetrical ultrasound.

Steven Chase Brigham, M.D., was graduated from MIT in 1978, and from Columbia Medical School in 1986. His training in medical school included clinical emergency room rotation for two months. He then performed a one year internship in internal medicine at Westchester

Medical Center, which included several weeks of emergency room rotation He had part-time positions in emergency rooms and a walk-in clinic

Brigham's experience also includes emergency room service at Keller Hospital at the United States Military Academy for one to three shifts per week and one or two shifts per week at Ellenville Hospital. He also worked some shifts at West Point during the Persian Gulf War. In addition, he had a short period of service at an urgi-center in Fair Lawn, New Jersey. Brigham estimated that he has treated several thousand patients in emergency rooms. After his internship and about two years of practice in New York State, Brigham opened a practice in the State of Pennsylvania He did some house calls and participated in a wellness program for children, and he also performed some abortions, which he found rewarding, primarily because he was helping women

Brigham's post-graduate training in abortion and gynecology was attained primarily through attendance at numerous medical education symposia, through observation of experienced practitioners, and through some programs involving hands-on experience under supervision. He considers the National Abortion Federation to be a vital source of information on abortion techniques He described the Federation as a voluntary association of abortion providers set up to provide high quality medical care through dissemination of information. Brigham had no ob/gyn residency, and he is not Board certified in ob/gyn, but he noted that the same is true for many prominent practitioners in the abortion field. According to Brigham, most ob/gyn residency training does not include training in performing abortions, and it was his opinion that the American College of Ob/Gyn has almost abdicated its role concerning abortion related matters, even though abortions are the most common surgical procedure.

Beginning in 1990 or 1991, Brigham was primarily engaged in the medical practice of performing abortions. In the State of Pennsylvania, he performed abortions at two different office locations and at a clinic in Harrisburg, and he estimated that he performed between two and four thousand abortions. Brigham faced overt hostility in Pennsylvania because of his abortion practice and he eventually decided he could no longer practice there. In April 1992, Brigham closed his practice in Pennsylvania and signed a Consent Agreement to permanently retire his

Pennsylvania license No evidence was presented in this matter to establish any improprieties in Pennsylvania, and no charges were ever filed against Brigham in that state

Dr Brigham estimated that he has performed about fifteen thousand 1st trimester abortions Of these, eight or nine thousand have been performed in New Jersey Without complications, a first trimester abortion takes three or four minutes and involves no cutting of tissue or suturing When there in no use of general anesthesia, intraoperative vital signs would not be monitored, according to Dr Brigham, because the procedure is so brief He noted that anesthesiologists only monitor vital signs every five minutes.

Brigham numbered his second trimester abortions at over one thousand Using what he called the classical D&E procedure, adequate dilatation is first achieved by inserting laminaria, and fetal demise would be induce by an injection of digoxin The fetus is easier to dismember when it is dead Because less force is necessary, there is less risk of harming the patient When dilatation is adequate, the demised fetus is grasped with an instrument, dismembered, and removed from the uterus piece by piece While Brigham prefers to remove the placenta first, that is not always possible He acknowledged that the potential for uterine perforation is greater with a second trimester abortion, and he stated that he knew of no abortion practitioner who has never had a perforation of any kind It was Brigham's testimony that out of all the first and second trimester abortions he has performed, he was aware of significant complications only in the A W and M.B cases.

The Case of J.K. (Amended Complaint, Count I)

Complainant alleges that respondent Brigham's conduct concerning patient J.K constitutes gross or repeated acts of negligence, malpractice or incompetence, as well as professional misconduct, and that he exhibited poor judgment which calls into question his ability to safely practice medicine in this State Complainant further asserts that respondent's conduct therefore constitutes grounds pursuant to *N.J.S.A.* 45:9-16 and 45:1-21(c), (d), (e) and (h) for the revocation or suspension of his license to practice medicine and surgery in this State.

At the completion of the Complainant's case in chief, some of the allegations in this count of the first amended Complaint were dismissed for failure to establish a *prima facie* case. The remaining allegations concerning the time J.K. was in respondent's care are that.

1. By inserting laminaria in J.K., respondent violated *N.J.A.C.* 13:35-4.2, which restricts the performance of second trimester abortions to licensed ambulatory facilities and hospitals, and further restricts the performance of abortions past 20 weeks LMP to specified circumstances with the specific approval of the Board;

2. Respondent's management plan for J.K. was a gross deviation from generally accepted standards for a two day termination of late stage pregnancy, in that he inserted the laminaria in a patient who had to travel over an hour to and from his office each day and he further intended to transport her an additional two hours to the clinic in New York for the actual completion of the procedure.

3. Respondent's conduct subjected J.K. to enhanced risk of hemorrhage and infection and all risks which flow from that.

The findings of fact which follow are derived from the credible evidence in the record. J.K. was 24 weeks pregnant when she sought an abortion at All Women's Medical Pavilion in Queens, New York on July 2, 1992. Ultrasound confirmed fetal heartbeat and a 24 week gestation (Exhibit R-18). She could not afford to have the abortion there. She testified that she did not meet respondent that day and someone just mentioned his name to her as a doctor who might help her with the financial problem of having a 24 week abortion at an affordable cost.

J.K. lived over 50 miles away from respondent's Voorhees office. She called there and was subsequently examined by respondent on July 14, 1992. She was 5'9" tall and weighed 105 pounds. No fetal heartbeat was detected and respondent's conclusion was that there was a fetal demise. J.K. did not want to have to have an induced-labor type abortion. Respondent explained that he would insert laminaria to dilate her cervix for two days and on the third day he would do the abortion at the Queens facility where she would be his private patient and he could charge her

a lower fee He inserted 8 laminaria, four large and four small He prescribed doxycycline, and discharged J K. to return the next day She rode away on the back of a motorcycle

The next day, J.K. came back to respondent's office. Her cervix was already dilated to 2.4 centimeters. Dr. Brigham removed the laminaria and her membranes spontaneously ruptured. At the point, respondent believed that J K was at a higher risk for infection Nevertheless, respondent stayed with his plan He inserted 22 fresh laminaria, still planning to complete the abortion the next day in Queens. It is undisputed that Dr. Brigham did not telephone his local backup physician on the first day or second day, nor did not refer J.K. to a hospital or to a licensed ambulatory care clinic or to any other practitioner on the second day for completion of the abortion at that time He did not suggest to J.K. that they go to Queens that afternoon or evening to complete the abortion

J.K. again went home on a motorcycle. The patient called him at 7:00 p.m. reporting a 102 degree fever and cramps She informed him that she had not taken the antibiotics. Respondent did not contact his local backup physician, and at that time, he did not refer J.K. to her local hospital's emergency room Instead, he called in a prescription to J.K.'s pharmacy and told her to call him again.

At 8:00 p.m. respondent called J.K., who told him that she was feeling better; he told her to call him if things got worse. When she called again at 11:00 reporting a fever of 102 7 degrees, slow bleeding from her vagina and contractions four to five minutes apart, he told her to go to the nearest emergency room. Respondent called that hospital and spoke with the charge nurse and the chief resident. The examining doctors, Dr. Hamley and Dr. Houlihan, were of the view that she had clinical chorioamnitis, an infectious process (P-1A), a clinical assessment with which Dr. Burnhill, who was Chief of the Ob-Gyn Department at Robert Wood Johnson at that time, had no quarrel as an initial, presumptive diagnosis. However, this diagnosis was not born out by pathological confirmation or through positive microbiological identification.

J.K. was admitted to labor and delivery. She received intravenous pain medication and antibiotics. She labored until 5:00 a.m., at which point the dead fetus was delivered and shown to

her by the apparently unsympathetic staff. J.K. testified that she was extremely distressed and angry over the course of events, but she fortunately suffered no additional untoward physical results.

It was the opinion of Dr. Kotopolous that Dr. Brigham should have diagnosed the condition of 24 weeks pregnancy with intrauterine fetal demise, and then referred J.K. to a hospital where the abortion procedure could be performed and attendant risks and complications addressed. Dr. Kotopolous opined that fetal demise can subject a patient to risks of spontaneous disseminated intravascular coagulopathy ("D.I.C."), a clotting disorder. He also was concerned that with a patient such as J.K., a severe infection could develop within 24 hours or less. In Dr. Kotopolous' opinion, these complications could not be handled on an outpatient basis.

Unlike Dr. Kotopolous, the complainant's other expert, Dr. Hollander, did not find fault with respondent's management of J.K. on the first day. Rather, his concern was with the insertion of additional laminaria on the second day, after the patient's membranes had ruptured and she was dilated at 2.4 centimeters. He opined that Dr. Brigham should have promptly referred J.K. to the nearest hospital or other facility or to another physician for completion of the procedure. There was adequate minimal dilatation according to the standards articulated even by some of the respondent's experts. Since complainant himself believed J.K. to be at a higher risk of infection in light of her ruptured membranes, he could have taken her to New York on the second day to complete the procedure. Both Dr. Hollander and Dr. Kotopolous felt that it was a gross deviation from the generally accepted standards of care for Dr. Brigham not to have chosen on of the alternatives available to him and to instead stay with his original plan of treatment.

Dr. Brigham testified that J.K. was extremely thin and gaunt looking, and she seemed anxious and depressed. Based on his pelvic exam, he felt she was at 22 to 24 weeks, and the sonogram revealed, among other things, a femur length equating to 23 weeks, 3 days. After reviewing the mylar sonography images and a real-time sonogram, Dr. Brigham concluded that the fetal demise was no more than four days earlier. He noted that Dr. Hollander had no disagreement with his handling of J.K. on the first visit. It was a recent fetal demise, so clotting factors were not an issue, and although he did not consider it definitive, he actually observed her

blood clotting. Further, it was appropriate to insert laminaria to obtain adequate cervical dilatation. He disagreed with Dr. Kotopolous' opinion that J.K. needed to be transferred to a hospital on the first day. Dr. Brigham suggested to J.K. that she stay in a nearby motel after insertion of the laminaria, but she said she could not afford it. He gave her enough antibiotics to last several days.

Dr. Brigham testified that when J.K. returned the next day, he removed the laminaria. Within seconds, the patient's bulging membranes ruptured. He drained the amniotic fluid that came out of her uterus and cervix, and inserted more laminaria. According to Dr. Brigham, if there was adequate dilatation at that time, he and the patient would have gone to New York and he would have done the abortion, but he did not think she was adequately dilated. He suggested that J.K. go to the hospital because of her fragile mental state and because he was under the impression there was an increased risk of infection from the ruptured membrane. Dr. Brigham testified that he was surprised to learn that Dr. Moskowitz's data indicates there is no increased risk. However, J.K. refused to go to the hospital, telling the doctor that she could not afford it. The abortion procedure was to be done the next morning in New York. When Dr. Brigham saw J.K. getting ready to leave on the back of a motorcycle, he ran out and pleaded with her not to ride it, and he offered her money for the train. J.K. declined, saying she would be all right.

Dr. Brigham noted that it is normal in the abortion provision field that patients come from all over and often travel large distances between home and the doctor's office. He had back up arrangements with two ob/gyns with hospital admitting privileges in the Voorhees area, but he could not possible have back up arrangements at hundreds of hospitals in several states from which his patients came. He knew that J.K. lived within walking distance of Robert Wood Johnson Hospital, and he felt she would not be denied emergency care if she needed it. In addition, he was going to be evacuating her uterus in less than 24 hours, and he had given her antibiotics.

That evening, J.K. called Dr. Brigham and told him she had cramping and fever, and she admitted that she had not taken the antibiotics. He called in a prescription for a stronger antibiotic to her pharmacy, and told her to take it. About an hour later, J.K. called back and told

Dr. Brigham that she had no fever and a little cramping She was taking the new drug However, later that night there was another call J.K. reported that the fever was back, there was slow bleeding, and there were contractions every five minutes. She wanted to know if she could get on the motorcycle and come to Dr. Brigham's office, about 50 miles away He testified that he told her that was not a good idea, and she should go to the hospital, not on the motorcycle but in a car or ambulance He told her he would call there and let them know the information they would need

Dr Brigham called the emergency room and explained the patient history to the doctor in charge The emergency room doctor said he was just going to send J.K. up to labor and delivery Dr Brigham left his name and phone number so he could be contacted. He felt his efforts constituted prompt continuity of care. Around midnight, Dr. Brigham received a call from Dr Handley, a resident in ob/gyn, who wanted to discharge J K. from the emergency room. She said the patient had a normal temperature and was not bleeding, although she was having contractions Dr Handley wanted to know if she could discharge J.K. to Dr. Brigham's care. Dr. Brigham noted in his testimony that J.K.'s situation must not have constituted a medical emergency in Dr Handley's opinion, if she was seeking to discharge the patient. However, Dr. Brigham was felt J.K. should be monitored for awhile, and he offered to come to the hospital to assist. Dr Handley did not want him to do that, because he did not have privileges, and rather than discharging J K to her home, the hospital was to monitor her for a longer period.

It was Dr. Brigham's testimony that he called the hospital about an hour later and Dr Handley told him that J.K. was having contractions every two minutes, and they would keep her She said J.K. was febrile., and she asked for Dr. Brigham's suggestions. He said to draw blood for a culture and remove the laminaria, and he suggested an induction procedure. Dr. Handley agreed. At about 6:30 a.m., Dr. Brigham spoke to a labor and delivery nurse, who said that J.K. had spontaneously delivered the dead fetus around 5:30 that morning. The nurse described the procedures followed and the drugs used.

Dr. Brigham went that afternoon to visit J.K. in the hospital and asked her how she was feeling. She was angry and upset about comments hospital staff had made to her and she wanted

to sign out, but Dr. Brigham advised her not to do that He learned from a nurse that J K had tested positive for cocaine in her urine (Exhibit P-1B), and he spoke to her about that J.K admitted that she had been using cocaine heavily for about six months, but had not revealed it to him because she was afraid he would not help her.

Dr. Brigham testified that it is well documented in medical literature that cocaine can cause intrauterine fetal demise, and can also cause abrupt onset of labor almost immediately after usage. J.K. told him she had ingested cocaine after insertion of the laminaria He noted that cocaine can also cause fever. However, he also noted that the patient had not met the criteria for febrile, as her temperature had been over 104 degrees for only 55 minutes, and was 103 degrees or higher for only two hours In addition, not one of the three blood cultures taken to look for bacteria grew a culture, and her cervical culture was negative. In Dr Brigham's opinion, there was no pathological confirmation of an infection from examination of the placenta, and no scientific validation of the hospital's presumptive diagnosis of an infection

Dr Brigham testified sincerely and credibly that he believes his management of J.K was within the generally accepted standard of care What he did for her was insertion of laminaria, and every physician he knows who does late abortions sends the patient home after insertion of laminaria, to return the next day for completion of the procedure. Dr. Brigham believes that the plan he had for the remainder of J.K.'s care was also within the generally accepted standard of care. He characterized as ridiculous the assertion that insertion of laminaria in J.K. was the performance of an abortion, and he noted that if he had thought insertion of laminaria in J K. violated the regulation, he would not have done it. According to Dr. Brigham, he has been told by some of Dr. Kotopolous' patients that he inserts laminaria when their membranes have ruptured, even when they have to travel. Dr. Brigham felt it was interesting that Dr. Kotopolous did not criticize him for insertion of laminaria when J.K.'s membranes had ruptured, but criticized him for almost everything else he did, while Dr. Hollander was mainly critical of that very action.

Dr. Michael Burnhill testified that D.I.C. is not seen in a recent fetal demise. However, if the demise had occurred a week or more before seeing the patient, he would do a bloodclotting profile. With patient J.K., the fetal demise was quite recent, so no clotting test was needed. Dr.

Burnhill stated that he is unaware of any school of thought or publication which suggests that insertion of laminaria is contraindicated with a fetal demise and ruptured membranes In his opinion, that circumstance presents two choices: either induce labor or increase dilatation until it is adequate to prepare for an evacuation procedure Dr Burnhill reviewed the J.K records and noted that if a patient refused to go to the hospital, he would have to acquiesce. There are risks with inducing labor at the hospital and most women are traumatized psychologically by going into labor with a dead fetus. He concluded that there was no departure by Dr Brigham from the generally accepted standard of care in his management of this patient Dr. Burnhill was a candid and sincere witness.

Dr. A.K., who served as Dr. Brigham's monitor, testified that it is not a medical emergency if membranes rupture during insertion of laminaria He has handled many patients with fetal demise, including ones with ruptured membranes, and it is his opinion that insertion of laminaria is the indicated procedure in such circumstances He considers a recent demise to be within a week to ten days Dr A K sees no increase in the incidence of infection when laminaria are inserted in ruptured membranes, and he noted that laminaria can raise a patient's temperature, unrelated to any infection. When dilatation is adequate, the uterus can be evacuated. Dr. A.K. noted that he has patients who come to his Philadelphia office from as far away as Wilkes Barre, Pennsylvania, and Atlantic City, New Jersey, for laminaria insertion They will then travel home and return later for the evacuation procedure. Dr A K also noted that he does not have hospital admitting privileges in every area where his patients reside, and it is very appropriate in an emergency for a patient to go to an emergency room. That is what emergency rooms are for.

Dr. Jeffrey Moskowitz testified on behalf of respondent that he is familiar with patient J.K.'s records. He said that he has encountered ruptured membranes in second trimester abortion patients. About 40 percent of the patients at Eastern have been second trimester pregnancies, and Moskowitz estimated that about 8 to 10 percent of those have ruptures of membranes after insertion of laminaria. He does not consider that circumstance a medical emergency. Since the patient's objective is termination of the pregnancy, adequate dilatation of the cervix must be achieved. Thus, there may still be a need to insert more laminaria after rupture, and he does not believe this is a departure from generally accepted standards of medical care.

Dr. Moskowitz testified that a patient may be sent home after additional laminaria are inserted, to return when adequate dilatation is achieved. In his opinion, it makes no difference if there has been a fetal demise by the time of the membrane rupture It is not a departure from standards if the patient must travel after insertion In addition, Dr Moskowitz testified that he has found no increased incidence of infection in such cases He also noted that many patients have vaginal bleeding when laminaria are inserted

It was the testimony of Dr. Moskowitz that it was not a departure for respondent to not send J.K. to the hospital at the time of the ruptured membranes He said the records revealed J.K. had bulging membranes when she appeared on the second day, and he testified that he would consider 2.4 cm. dilatation about one-half the dilatation necessary. He also noted that it is accepted practice in the United States for high volume abortion provider physicians to not have ob/gyn training. Not having local hospital admitting privileges is also not a departure, since many hospitals do not allow abortions on the premises It is customary for many patients to travel great distances for abortions, particularly during the second trimester However, he noted that he does have privileges at local hospitals.

Dr. Moskowitz testified that he saw no lapse in respondent's medical judgment or in his medical plan for J.K. He felt respondent acted in a manner consistent with accepted standards of care. Moskowitz noted that Brigham told him that he had back up arrangements with a physician who had hospital privileges, and Moskowitz said it was not necessary for the back up to have skill in doing abortions. Whoever it was would have to be willing to take care of a patient with complications from an abortion. While Moskowitz acknowledged that it may have been an alternative for respondent to have called his back up to examine J.K., there was no need to do that. The ruptured membrane is not considered a medical emergency, nor was it anything which required a second opinion.

DISCUSSION

Complainant contends that respondent had several reasonable medical alternatives available to him which would have been safer for the patient and some of which would have better ensured that the abortion would be completed via D&E. Respondent could have brought the patient to Queens for the D&E on the first day knowing she was carrying a dead fetus. He could have brought the patient to Queens once he saw that the membranes had ruptured, and could have further dilated the patient's cervix using manual dilators to complete the D&E at that time. Alternatively, respondent could have called his backup physician and asked that physician to take the patient on the second day and complete the abortion by the D&E method at a licensed abortion clinic or hospital.

Complainant contends that all of these were reasonable medical alternatives, and there was no necessity to stay with the original three-day plan. A patient's concerns regarding money cannot override the physician's exercise of appropriate judgment in knowing when to make appropriate referral arrangements which would be in the patient's best interest. Complainant argues that respondent's claim that there were no other safe or feasible alternative to what he chose to do in this case must be rejected.

Complainant contends that respondent Brigham deviated from generally accepted standards of care by undertaking the treatment of J.K. in his office. As noted above, it was the opinion of Dr. Kotopolous that Dr. Brigham should have diagnosed the condition of 24 weeks pregnancy with intrauterine fetal demise, and then referred J.K. to a hospital where the procedure could be performed and attendant risks and complications addressed. Dr. Kotopolous opined that the possible complications of D.I.C. and severe infection could not be handled on an outpatient basis.

Significantly, Dr. Hollander was not in complete accord with Dr. Kotopolous. Dr. Hollander did not find fault with respondent's management of J.K. on the first day. Rather, his concern was with the insertion of additional laminaria on the second day, after the patient's

membranes had ruptured and she was dilated at 2-4 centimeters. He opined that Dr. Brigham should have promptly referred J.K. to the nearest hospital or other facility or to another physician for completion of the procedure, or he could have taken her to New York on the second day to complete the procedure himself. As noted above, both Dr. Hollander and Dr. Kotopolous felt that it was a gross deviation from the generally accepted standards of care for Dr. Brigham not to have chosen one of the alternatives available to him and to instead stay with his original plan of treatment. Complainant argues that respondent's care of J.K. placed her at risk of harm and was a gross departure or extremely high deviation from accepted standards of care.

Respondent argues that he exercised reasonable, sound and prudent medical judgment in his management of this patient. He emphasizes that through his care, J.K. did not suffer either any injury, nor any scientifically established increased risk of injury. It was the unrefuted testimony of Dr. Moskowitz that in a study of more than three thousand patients like J.K., insertion of laminaria in a patient with ruptured membranes did not cause any increased risk of complication. Similarly, a recent fetal demise did not increase risk of complication. It is respondent's position that J.K.'s situation was no different than that of a patient who had an induced fetal demise with digoxin in preparation for a late abortion.

Respondent acknowledges that he did not include in his medical note every comment and remark exchanged with the patient. He deliberately did not include details of J.K.'s marital problems or suicidal thoughts, yet J.K. confirmed these matters in her unrefuted and credible testimony. Respondent further contends that it must be remembered that J.K. was a highly non-compliant patient, even by her own admission. She ingested cocaine, which likely induced labor and elevated her temperature. She did not take the antibiotics given to her; she rode a motorcycle against Dr. Brigham's advice, and she flatly refused his advice to go to the hospital. The patient's actions and decisions curtailed the respondent's options. Under the circumstances the patient presented, Dr. Brigham reasonably exercised his medical judgment in the patient's best interest, and within generally accepted standards of care. Because of her refusal, the respondent did not have available the option to send J.K. to the hospital, and to perform the procedure with inadequate or barely adequate dilation would subject her to greater risk. Respondent also argues

that manual dilators would have subjected the patient to risks, while the insertion of laminaria was safer

Respondent also emphasizes that complainant has made no effort to reconcile the completely contradictory opinions of Dr Kotopolous and Dr Hollander as to why respondent was negligent While Dr Hollander found no fault with Dr Brigham's care of J K on the first day, Dr Kotopolous was critical of almost everything he did While Dr Hollander criticized Dr Brigham for inserting laminaria on the second day after rupture of the membranes, Dr Kotopolous mentioned no criticism of that practice The complainant did not attempt to refute the respondent's evidence that Dr Kotopolous himself inserts laminaria in ruptured membranes Thus, what Dr Kotopolous claims to be negligence, Dr Hollander says is not, and what Dr Holander claims is negligence raises no criticism from Dr Kotopolous

Aside from the inherent contradiction in the opinions of the complainant's expert witness, respondent asserts that management of a patient with a late second term intrauterine fetal demise is acceptable as an outpatient D&E procedure As testified to by Dr Burnhill, Dr Moskowitz, Dr K., and Dr Brigham, the National Abortion Federation, the Planned Parenthood Federation of America, and the Precis V all support this approach Dr Hollander did not disagree Patient J K had a very recent fetal demise, so the risk of D I C was minimal, and there was actually no increased risk of infection, according to Dr Burnhill and Dr Moskowitz Dr Moskowitz would have handled patient J K at his state-licensed facility in the same manner Dr Brigham did, and his facility's protocols are reviewed and approved by the State of New York

I agree with the respondent's contentions The complainant has failed to meet her burden of persuasion I **FIND** that respondent's treatment plan for J K was consistent with generally accepted standards of care, and the medical judgment exercised by respondent was sound and reasonable Using his skills, knowledge, and observations, respondent established that J K had a recent fetal demise and clotting was present, eliminating undue concern for D I C and infection Respondent's options were subsequently limited by the patient's circumstances and non-compliant attitude, but he continued to practice good and caring medicine I **FIND** that insertion of laminaria in ruptured membranes was not a departure from generally accepted standards of care,

and that respondent did not subject J K to enhanced risk of hemorrhage and infection. The reliable evidence in the record established that it is customary for patients to return to their homes following insertion of laminaria, while adequate dilation is achieved, and it is not the standard of care that back-up arrangements be available near each patient's home After ingesting cocaine, J.K had a fever for at most three hours Respondent properly recommended at the appropriate times that J K go to the hospital, and eventually she stopped refusing and went Respondent then appropriately followed up on the patient's care at the hospital

Based on the foregoing, I further **FIND** that respondent Brigham's conduct concerning patient J K did not constitute gross or repeated acts of negligence, malpractice or incompetence, nor professional misconduct, and that he did not exhibit poor judgment calling into question his ability to safely practice medicine in this State Thus, I **CONCLUDE** that respondent's conduct did not constitute grounds pursuant to *N.J.S.A.* 45:9-16 and 45 1-21(c), (d), (e) and (h) for the revocation or suspension of his license to practice medicine and surgery in this State

The issue of whether respondent violated the termination of pregnancy regulation, *N.J.A.C.* 13 35-4.2, by inserting laminaria in a patient who was beyond the 14th week LMP will be addressed below

The Case of A.W. (Amended Complaint, Count III)

Complainant alleges that respondent Brigham's conduct concerning patient A.W., constitutes gross and repeated acts of negligence, malpractice, or incompetence. Complainant asserts that this conduct constitutes grounds pursuant to *N.J.S.A.* 45:9-16 and *N.J.S.A.* 45:1-21(c) and (d) for the revocation or suspension of his license to practice medicine in this State. Complainant further alleges that respondent's conduct, when taken in combination with conduct alleged in other counts of the complaint, constitutes repeated acts of negligence, malpractice or incompetence, thereby constituting grounds pursuant to *N.J.S.A.* 45:1-21(d) for the revocation or suspension of his license to practice medicine in this State. The allegations concerning respondent's care of A.W. are that his conduct jeopardized her health and life by failing to quickly recognize that he had perforated her uterus, and by continuing to operate on the patient outside

the uterus, and by therefore causing extensive damage. The injuries alleged are an eight to ten centimeter laceration of the uterus, bilateral pelvic peritoneal lacerations, disruption of the sigmoid mesentery, transmural laceration of the sigmoid colon, fecal contamination of the peritoneal cavity, and extensive damage to the ureters

The findings of fact which follow are derived from the credible evidence in the record A.W sought an abortion because she learned late in her second trimester that she was carrying a fetus with multiple congenital anomalies which rendered it nonviable. She was at 24 weeks when Dr. Brigham examined her He recalled that she had been referred by the Hershey Medical Center and that numerous Pennsylvania doctors had declined to do the procedure. After ascertaining that adequate dilatation was achieved, Dr Brigham commenced the abortion at 11:30 a.m. on May 9, 1992, at Flushing Gynecology Center in Forest Hills, Queens, under general anesthesia and using real time ultrasound. According to Dr. Brigham, the ultrasound gave exquisite lateral views, but its only two dimensional, meaning that the procedure remains blind in the anterior/posterior plane

Dr. Brigham testified that with an abnormal fetus such as this, it was not clear how it would feel when grasped with forceps Similarly, the placenta was abnormal and that would affect the degree of invasion of the uterine wall. He removed a limb of the fetus and the placenta. He now believes that an eight to ten centimeter tear in the uterine wall occurred when he grasped and removed the placenta

Dr. Brigham next attempted to grasp the fetal skull with large McMahon forceps (Exhibit R-10). The McMahon forceps are large enough to reach from one end of the pelvis to the other when open. In doing grasping, Dr. Brigham felt soft tissue. The image on the ultrasound indicated to him that his forceps were around the fetal skull. However, he now knows that his forceps were actually behind the fetal skull and outside the uterus, rather than around the fetal skull.

Dr. Brigham made small exploratory movements of the forceps from side to side and up and down with a rotating motion of his wrist, in an effort to find the fetal skull. When he closed the forceps to grasp the tissue, it felt soft and mushy, but he thought this might be due to the fetal

abnormality of hydrocephaly. However, when he pulled down the tissue which he thought was the fetal skull, he saw that he had grasped omentum and he then knew that his forceps had been outside the uterus.

Dr. Brigham testified that it was hard for him to say how wide he had opened the forceps. He thought about 10 inches, but he could not say for sure. He suggested that 10 inches was the maximum; it may have been less, but he did not think it was more. Dr. Brigham acknowledged that he may have said in his testimony in the State of New York that he opened the forceps no more than 10 to 15 centimeters, which would be four to six inches. He did not believe that he moved the forceps in and out of the uterine perforation more than once.

The structures Dr. Brigham had contacted with the forceps were actually in A.W.'s pelvic area, rather than fetal tissue in her uterus. Upon seeing the omentum, he immediately stopped the procedure and called Dr. Dengelegi to arrange to have A.W. promptly admitted to Elmhurst Hospital. She was given intravenous pitocin in the recovery room to decrease bleeding, and Dr. Brigham then accompanied her to the hospital in the ambulance.

At surgery, the fetus was found to be extruding into the pelvic cavity from a posterior uterine perforation of eight to ten centimeters in length. The fetus was removed and the perforation was repaired. It is more likely than not that the perforation was originally smaller and was extended by uterine contractions pushing the fetus through the perforation. The surgeons repaired the other injuries. The left ureter had been transected, while the right ureter had a small nick which was repaired with a single suture. There were peritoneal lacerations. The surgery chief resident reported a perforation of A.W.'s sigmoid colon through its mesentery, and a section of the mucosa was denuded and devascularized (Exhibit P-5). A section of the colon was removed and sent to pathology, and a temporary colostomy was performed. However, the pathologists did not note any perforation of the sigmoid colon. A.W. did not require a hysterectomy, and she was subsequently discharged to home in good condition.

Dr. Kotopolous offered his opinion on how a physician recognizes that a perforation in the uterus has happened in a 23 week procedure. He stated, "This is where the experience of the

surgeon comes in to realize that a perforation happened, to realize that he started in a certain direction into the uterus and then all of a sudden his instruments are in a different direction, different from the initial direction, and he's working in an area outside the uterus." It was Dr Kotopolous' opinion that Dr Brigham did not immediately recognize that he had perforated the uterus, and the location of the injuries to the patient suggested that Dr. Brigham put his instrument through the perforation more than once or twice It was his view that Dr. Brigham had deviated from the generally accepted standards of care in failing to recognize the uterine perforation. However, he agreed that failing to immediately recognize a perforation is not necessarily negligent, even if it results in injury to the abdominal aorta which causes death.

Dr. Hollander also reviewed the records concerning A.W., and he acknowledged that perforations do happen during abortions He said that just failing to immediately recognize the perforation, without more, would not be negligent. However, in this case, there was more There was movement of the forceps in different directions and the striking of organs in different planes with the forceps. In Dr Hollander's opinion, a surgeon can tell there has been a perforation in several ways: by feeling the instrument go through the uterus, by symptoms like loss of blood or by seeing tissue damage, or by realizing the instrument is going further than the understood size of the uterus. When any of these indicia occur, the physician should stop the procedure It was Dr. Hollander's opinion that respondent did not immediately recognize that he had perforated A.W.'s uterus because his instrument had injured both her left and right sides, outside the uterine perforation. He did not see anatomically how all the injuries could have been caused by just one opening and closing of the instrument, and he considered this to be a deviation from the generally accepted standard of care.

Dr. Policar testified that he reviewed the records concerning A.W., and he concluded that Dr. Brigham did not depart from the standard of care. The placenta was on the posterior wall, which meant that it was likely that the uterine wall was even thinner than it might have been if the placenta were attached elsewhere. Dr. Policar estimated the rate of uterine perforations in late abortions to be two to five per one thousand procedures. At the San Francisco Hospital, almost all of the perforations in late abortions are posterior, and its even more likely when there is a posterior placenta.

According to Dr Policar, the large forceps are inserted closed, and are not removed until a fetal tissue structure is firmly grasped and removed. It is a blind procedure and the physician works by feel. Dr. Policar stated that there is no way of knowing specifically what tissues are being grasped The first indication Dr. Brigham had of the perforation of the uterus was when he saw omentum being extracted. Dr Policar testified that the insertion of the forceps alone could have perforated the uterine wall, and a single opening and turning of the forceps could have caused the injuries to the patient, because of the large span of the forceps (Exhibit R-10)

Dr. Policar further explained that the injuries to A.W. could have occurred with one pass of the forceps through the uterine wall, if the forceps were then moved around within the pelvis. The injured organs were to the left, to the right, and to the back, so there must have been some degree of movement of the forceps after they were passed through the uterine wall. Although Dr. Policar testified that he has never done an abortion procedure where there was a uterine perforation and injury to organs on the left, right, and back, he also said these complications to A.W could have happened in the best of hands. In fact, it would not be a departure from generally accepted standards of care in a late second trimester abortion to have a perforated uterus and injury to the aortic artery which causes the patient to bleed to death. The physician must open and close the large forceps to grasp tissue, so Dr. Brigham's movements of the forceps would be integral to properly performing the procedure, and he did not depart from the generally accepted standards of care. In Dr. Policar's opinion, there was no gross negligence, nor repeated acts of negligence, nor any negligence in Dr. Brigham's handling of this patient.

Dr. Moskowitz testified that he reviewed the patient record concerning A.W., and he found no problems with the medical judgment exercised by respondent. First, perforations of the uterus are a know complication, and he felt there was no departure from generally accepted standards of medical care with the occurrence of the perforation during this abortion. He explained that the uterus has a fixed amount of muscle and the later the pregnancy, the thinner and softer the uterine wall becomes. The wall has less resistance to the pressure of an instrument, which may then pass through the uterine wall.

Dr. Moskowitz testified that it is not a departure from the accepted standard of medical care for a physician to not immediately recognize that there has been a perforation. The physician can not see beyond the end of the cervix and can not see inside the uterus. He must operate by feel. The instruments are quite long and have a fulcrum effect; a small opening of the part of the instrument outside of the uterus creates quite a large opening at the other end. He opined that an 8 to 10 cm. rent in the uterine wall does not indicated a departure, but he agreed that it was in the category of a large perforation In regard to A.W.'s injuries outside the uterus, Dr. Moskowitz did not believe their location indicated the physician lacked skill or ability, nor were they a departure from good and accepted standards of care, because it is a blind procedure and the uterus is very, very soft He acknowledged that if the physician is operating outside the uterus it is inappropriate, since that is not part of the abortion procedure, but he did not feel it was a departure.

Dr Moskowitz agreed that if there has been a perforation and the physician believes he is still operating inside the uterus, but is actually not, movement of the instrument can cause several injuries He noted that in his career at Eastern, and in his review of charts over the last ten years, he has seen circumstances similar to A.W.'s injuries. He said there were injuries to the sigmoid colon and there were injuries to each ureter However, he acknowledged that he had never before seen injury to both ureters and the sigmoid colon in the same patient. He characterized these injuries as a major complication Nevertheless, Moskowitz testified that Dr. Brigham realized there was a complication upon seeing omentum, and Moskowitz did not believe this was a departure Calling for hospital admission and riding there with the patient was also appropriate.

Dr. Michael Burnhill noted that a physician does not need to be an ob/gyn or need to have done an ob/gyn residency to competently perform abortions. Even a Board certified ob/gyn physician must be trained by an abortion practitioner to perform the procedure properly. According to Dr. Burnhill, there are many prominent abortion providers who are not ob/gyns.

In regard to patient A.W., it was Dr. Burnhill's testimony that a perforated uterus does not necessarily indicate malpractice or incompetence because the physician does not know how thick the uterine wall will be, and there may be surgical or congenital reasons for a weakening of

the uterine wall. In addition, the size of the uterine cavity can vary, the patient can move, and the uterus is a muscular organ that relaxes and contracts from moment to moment. The physician can only approximate by feel and experience where his instrument is in the uterus, and he characterized the process as an art form as well as a skill

Dr. Burnhill testified that an 8 to 10 cm. perforation of the uterus would not indicate a departure from the generally accepted standard of care; in late second trimester abortions the instruments are large, so lacerations tend to be larger. The risk of perforation is part of a patient's informed consent Similarly, because the grasping forces tend to be large, injuries following perforation tend to be extensive According to Dr Burnhill, the problem is recognizing when the uterus has been perforated, the wall is so thin that the physician may have no sense of a perforation and will be probing with the instrument for fetal parts. There is a lot of room inside the uterus, so having a lot of room to move the instrument would not be a clue that the instrument is extrauterine. Often, a physician will not be aware that he is working outside of the uterus until he brings down some tissue that discloses it

Dr Burnhill testified in essence that a physician who performs many late second trimester abortions will eventually have a perforation and injuries to the patient. He acknowledged that there is not a strong likelihood of a perforation and that a perforation might be the result of negligence Dr. Burnhill stated that the number one cause of negligent perforations in late second trimester abortions is failure to obtain correct cervical dilatation; fetal parts may cut the uterine artery as they are pulled through the cervix. The second most likely cause of negligent complications is lack of appropriate training. Other causes of negligent injury would be failure to ascertain the gestational age and a physician who in an impaired state. In Dr. Burnhill's opinion, there was no departure from the generally accepted standard of care in Dr. Brigham's treatment of A.W., although there was certainly a terrible result.

DISCUSSION

Complainant argues for rejection of respondent's theory that all of the injuries occurred during one single ten-inch opening and closing of the forceps through the uterine perforation.

First, respondent admitted during cross-examination that there were multiple smaller movements of his forceps as well as the single large opening and closing Second, the injuries were not all on the same plane The uterine perforation was an uncommonly large 10 cm (4 inches) vertical perforation. The injured organs were above, below, to the right and to the left of the location of that perforation Complainant asserts that there had to have been multiple movements of the forceps in different directions within the abdominal cavity and outside of the uterus to cause all of this damage. Complainant argues that while it is likely that there was more than one pass of the forceps through the uterine perforation, even if there was only one large opening and closing motion, there had to have been multiple other movements of the forceps in the pelvis.

Complainant acknowledges that a uterine perforation can occur during an abortion without there necessarily being negligence on the part of the physician However, complainant contends it was respondent's negligent failure to promptly recognize that the perforation occurred which caused the extensive damage to the patient Even using real-time ultrasound, respondent did not realize he was operating outside the uterus when he was making his exploratory movements and small closing maneuvers with his forceps Difficulty may be caused by the fact that the uterus can contract and move A physician performing late second trimester abortions would presumably be aware of this phenomena and could use his hand on the patient's abdomen to aid him in performing the abortion safely

Respondent contends that he handled A.W.'s difficult late second trimester abortion appropriately, skillfully, and competently, with no departures from accepted standards of care. Uterine perforations are known and accepted complications of abortion. With A.W.'s thin uterine wall and fetal anomalies, Dr. Brigham could not immediately determine when the uterus was perforated by the large forceps

Respondent argues that the evidence establishes that simply opening the large forceps outside the uterus could reach the left and right ureter. Once closing could nick one ureter and transect the other, and cause injury to the colon and peritoneum. It is respondent's argument that there is absolutely no indication that he improperly continued to operated outside the uterus, or caused extensive injury inconsistent with one opening and closing of the forceps.

I agree with the respondent's contentions The complainant has failed to meet her burden of persuasion. The credible evidence and the substantial weight of expert opinion support respondent's position If a physician has brought the requisite degree of care and skill to his patient, he is not liable simply because of failure to cure or for bad results that may follow. *Schueler v. Strelinger*, 43 *N.J.* 330, 344 (1964) The experts who offered opinions on respondent's behalf testified persuasively that it is quite possible for the injuries to have been cause by one pass through the uterine perforation, with tilting of the forceps in different angles looking for fetal tissues, just as respondent described This is not a departure from the generally accepted standards of care. I **FIND** that respondent quickly recognized that he had perforated A.W.'s uterus and had injured her and that he did not deviate from generally accepted standards of care when he unintentionally operated on her outside the uterus

Based on the foregoing, I further **FIND** that respondent Brigham's conduct concerning patient A.W did not constitute gross or repeated acts of negligence, malpractice, or incompetence Thus, I **CONCLUDE** that respondent's conduct did not constitute grounds pursuant to *N.J.S.A.* 45:9-16 and *N.J.S.A.* 45:1-21(c) and (d) for the revocation or suspension of his license to practice medicine and surgery in this State

The Case of Y.B. (Amended Complaint, Count IX)

Complainant alleges that respondent Brigham's conduct concerning patient Y.B. constitutes gross or repeated acts of negligence, malpractice, or incompetence, as well as professional misconduct. Complainant asserts that this conduct constitutes grounds pursuant to *N.J.S.A.* 45:1-21(c), (d), and (e) for the suspension or revocation of his license to practice medicine and surgery in this State. The allegations concerning respondent's care of Y.B. are that he administered a normal dose of conscious sedation to her, and then administered another half dose without waiting to see if the first dose had the necessary effect. Complainant alleges that respondent then place a handful of gauze into the patient's mouth, creating a risk of airway obstruction. Complainant further alleges that the respondent's nursing staff had difficulty

arousing the patient following the procedure, had to hold her up to walk to the recovery room, and had difficulty maintaining her in a state of arousal without stimulation from ammonia salts, verbal commands, and physical contact

The findings of fact which follow are derived from the credible evidence in the record. Y.B. was fourteen years old when she came to respondent's office on October 26, 1993, with her mother. She was six weeks pregnant by dates and by pelvic exam (P-33), and she was suffering from vomiting because of her pregnancy. She previously had an abortion at Dr. Kotopolous' facility in Englewood when she was 13. Y.B. was 5 feet tall and weighed just 102 pounds. Once in the examination room, she was crying and visibly scared to be there, even though she had experienced the prior abortion. She was crying during the pelvic exam and also was crying very hard during the process of attaining I.V. access.

Lynette (Campbell) Zielke, R.N., was the registered nurse who was working with respondent and attempted to insert the IV needle into Y.B.'s arm. Ms. Zielke has been a registered nurse for over 11 years, with experience working in several hospitals on respiratory and surgical units. She is presently a community health nurse who assesses and monitors patients who have been discharged from the hospital. Ms. Zielke is certified in advanced cardiac life support, has CPR certification, and is certified in I.V. conscious sedation from a nursing perspective. Her experience includes seven years of work at Cooper Hospital recovering patients from intravenous conscious sedation, specifically including Versed and Fentanyl. She began working at respondent's office in late June 1993, assisting with procedures and examination of patients.

Ms. Zielke testified that she attempted to obtain I.V. access in Y.B.'s right arm but had difficulty because the patient was upset and very tense. Recognizing this problem with the patient, she asked respondent to obtain access, and he did so. Ms. Zielke testified that the patient was still upset. According to Ms. Zielke, Dr. Brigham administered the first dose of medication, and then he turned around and grabbed some gauze. She testified that without saying anything, Brigham put it in the patient's mouth. Ms. Zielke testified that she then whispered to him, "Are you sure you want to do that?" He said that he did; and that he wanted to give her a little extra sedation, too, because she needed it.

It was Ms Zielke's testimony that Dr Brigham then looked at Y B and told her to bite down on the gauze. Then he turned around and took another syringe. Ms. Zielke said that she protested that the patient was only 14 and looked like she weighed 85 pounds. Respondent said she'd be okay, and Ms Zielke further protested that they would not be able to wake her up later. Ms. Zielke said that this protest elicited no response from the respondent. She testified that the respondent later told her that he was concerned that the patients in the waiting room would hear Y.B. crying and would become upset

According to Ms Zielke, while respondent was administering the second dose, Y.B. still had the gauze hanging out of the front of her mouth Ms Zielke asked the patient if she was okay, and the patient shook her head that she was. In Ms Zielke's estimation, there was less than a five second delay between the first dose and the second dose, so that the initial dose was not observed for effect before the second dose was put in

The anesthesia used on Y B was known as "conscious sedation," a combination of Fentanyl or Sublimaze and Versed The syringes were prefilled with these two drugs, although the respondent could change the dose at time of administration. A single syringe contained the standard dose Respondent gave Y B a dose and a half, using a full syringe and then a half of another The record (P-33) reflects that the total quantity of sedation administered was 3 mg. Midazolam (Versed) and 112 5 mcg. of Fentanyl

After administering the second dose, respondent sat down at the foot of the table and started to open his equipment to begin the procedure. At that time, Ms. Zielke took the gauze out of Y.B.'s mouth. She testified that she did this because she did not think it was a safe situation. Ms. Zielke thought it was unsafe because of obstruction of the airway and obstruction of the patient's ability to communicate. In the years she had worked as a nurse, she had not seen other physicians use gauze in this way Ms. Zielke testified that it would surprise her if she heard that other physicians even of good credentials utilized gauze in the way respondent did with Y.B.

Y.B 's oxygen saturations were monitored using a pulse oximeter, and the nurse had to watch for saturation dipping below 90 While respondent was in the room, Y.B 's oxygen saturation level never stayed below 90 The abortion took about four minutes. According to Ms. Zielke, Y B was very lethargic as an effect of the sedation she had been given. Witness B G agreed that by the end of the procedure, Y B was extremely drowsy Ms. Zielke found that as they tried to arouse Y.B. after the abortion, she was groaning and not forming full sentences. She was not sitting up on her own. Her breathing was slow and shallow and she needed stimulation to take a deep breath, which also showed the effect of the sedation They sat her up, but she could not sit on her own and they had to hold her up According to Ms. Zielke, Y.B. needed smelling salts, but when they were taken away, the patient returned to shallow respirations.

Ms Zielke asked someone to bring Dr Brigham back in When he arrived, she told him that the patient's pulse oximetry reading was dropping to 85 and she could not keep it up. She said there were several pulse oximetry readings which were down at 85. Dr. Brigham then removed the pulse oximeter and told the nurse to stand the patient up, but Ms. Zielke told him that Y B could not stand They then took Y B off the table According to Ms. Zielke, she was holding Y B up because she felt the patient would otherwise fall She said that the respondent wanted her to let go of the patient

Ms Zielke set Y B. up in the recovery room, where she was monitored for heart rate, pulse and blood pressure until her vital signs were all stable and she did not need stimulation to take deep breaths. After the patient was stabilized, Ms Zielke spoke at length with respondent about the quality of the care that had been provided for this patient. She let him know that she could not condone how he practiced. According to Ms. Zielke, he asked her not to leave and wanted to know if she would stay if he promised he would never put gauze in anybody's mouth when she was in the room. Zielke testified that she responded she could not work for anybody who thought that was okay to begin with. Respondent indicated he was more experienced and that it was a common practice. She stated that he offered to buy any safety equipment she suggested and he indicated he was concerned about other patients in the waiting area hearing the crying girl. Ms. Zielke said that she did not agree with his choice between hearing a patient cry or

gag. Ms Zielke quit respondent's employ, even though she had two children to support and quitting meant she would lose 20% of her income.

Dr Brigham agreed that Y B was frightened and anxious in general. She previously had a painful experience with an IV insertion and was apprehensive. A second assistant, B G., was brought in to hold the patient's hand and talk to her According to Dr. Brigham, Y B tolerated the pelvic examination pretty well and he was able to apply local anesthesia around the cervix Meanwhile, Ms Zielke was trying to insert the IV needle in the patient's arm vein. This caused Y.B to be even more afraid and to move even more, which made it more difficult to insert the needle At that point, Ms. Zielke asked for Dr. Brigham's help to insert the needle.

Dr Brigham testified that he then got up from where he was and touched the patient's arm and spoke to her, trying to calm her He testified that he told Y.B. he was going to take some four inch by four inch gauze and she should bite on it, and then they would be able to get the IV in for some sedation B G. stroked the patient's hair and reassured her that Dr. Brigham was really good at inserting needles According to Dr Brigham, having patients bite on gauze to distract them from the needle insertion is a technique he had observed and had used with many patients, especially the elderly. He had found it to be very effective and never had a problem with it It was Dr Brigham's opinion that the process of the patient clenching her teeth on the gauze and holding the mouth shut actually prevents obstruction of the airway.

Dr Brigham stated that he took a sterile piece of gauze and folded it up, then inserted it between the patient's upper and lower teeth on the left side of her jaw, with most of the gauze protruding out of her mouth. He believes he told her to grit her teeth, and he said she seemed to be gearing herself up to do as he said and to try to be brave. Ms. Zielke asked Y.B. if she was okay with the gauze in her mouth and she nodded that she was. Dr. Brigham then used a tourniquet on Y.B.'s arm and found the vein. He told her she would feel a little pinch. The needle went right in and he released the fluid. At that point, Ms. Zielke reached over and removed the gauze and Dr. Brigham told her okay, although he had the impression Ms. Zielke had surprised the patient.

According to Dr Brigham, Fentanyl is a narcotic analgesic used to dull the patient's sense of pain, and it has some sedative effect. Versed is a tranquilizer intended for calming anxious patients. It also has the effect of blocking a patient's memory Many patients who have had conscious sedation think they have been asleep during the procedure when they were actually able to have a conversation with the physician Dr. Brigham estimated that he has used these two medications in combination several thousand times without difficulty.

It was Dr Brigham's testimony that the patient's fright and crying caused him to decide to increase the sedation. He stated that he did not want Y.B. to be scared, and he wanted to calm her for a painless and safe procedure He felt that if she were moving around during the abortion, the risk of uterine puncture would be increased. So, it was his medical judgment to increase the sedation. Dr. Brigham testified that he started with a dose of 2 mg. Versed and 75 mcg Fentanyl, and he said that this takes 20 to 40 seconds to reach the brain

Y.B.'s crying stopped and her pulse rate fell appropriately, but Dr. Brigham felt she was still frightened and anxious. It was his testimony that he felt after observing her for a minute or two that she would benefit from an additional 1 mg. of Versed and 37 and one-half mcg of Fentanyl. He explained that the time interval between doses was actually about one minute, after completion of the first dose, which he took about 30 seconds to slowly administer He wrote what he observed in Y.B.'s chart (Exhibit P-33), and he noted that the time shown there for observation is not 3 0 seconds, but looks that way because there was probably a speck on the paper that looks like a decimal point on the copy.

In Dr. Brigham's opinion, he waited and observed sufficiently long after giving the first dose before administering the second dose. He feels that the total amounts administered would have been appropriate even if they were administered all at once, as it was not a large dose and still constituted conscious sedation by far. Dr. Brigham did not understand why Ms. Zielke was concerned about Y.B.'s sedation. After he performed another procedure in another room, which took three or four minutes, Dr. Brigham returned and observed that Y.B. was sitting up and talking, but was still sedated.

In Dr Brigham's opinion, Y B was fine, with a slow steady pulse and no respiratory distress, and she was simply still sedated He took the patient's arm and she then walked under her own power into the recovery room. Y.B. was in no danger, and she thanked the doctor on her way out. Dr. Brigham testified that Y B subsequently returned for another abortion and thanked him again for the prior procedure. He gave her the same dose of medication and she again did fine It was Dr Brigham's sincere opinion that Y.B was well served by him and there was no gross negligence, nor was there any departure from generally accepted standards of medical care Patient Y B testified on his behalf, and explained how the gauze was carefully placed between her teeth, with much of it hanging out of her mouth. She felt Dr. Brigham was kind and respectful toward her.

The material factual dispute apparent from review of Ms. Zielke's and Dr Brigham's testimony is whether the folded gauze remained between Y.B 's clenched teeth after Dr. Brigham began administering the conscious sedation. It is clear that the purpose of the gauze was to calm the patient by distracting her from the process of inserting the IV needle. When that purpose was accomplished, the gauze was no longer needed Thus, it is more likely than not that the gauze did not remain between Y B 's clenched teeth after Dr. Brigham began to administer the conscious sedation.

It was the opinion of Dr. Kotopolous that the insertion of gauze in a patient's mouth who is receiving conscious sedation is not within the generally accepted standard of care. He feels the dosage of sedation itself could suppress respiration, so obstructing the airway can compound the problem. Dr. Kotopolous testified that he is indirectly familiar with the effects of conscious sedation. He has an anesthesiologist administer it to his patients. It was also Dr. Kotopolous' opinion that the usual dose of conscious sedation is two milligrams, given one milligram at a time, every two to three minutes. He testified that Dr. Brigham did not follow this standard.

By affidavit, Dr. Carl Weiner, a New Jersey and New York licensed physician who provides anesthesia services at All Women's Medical Pavilion in Queens, New York, stated that it is not inappropriate to have a patient bite down on rolled up gauze to distract her while an IV needle is being inserted into her arm for administration of conscious sedation (Exhibit R-21. This

affidavit also stated that there is a dose requirement variation from patient to patient, and this is particularly true for a patient who is anxious, frightened, and upset He has personally administered doses of midazolam greater than 3 milligrams with no ill effects toward his patients, and he does not believe such administration would be any departure from accepted standards of care for the administration of conscious sedation.

Dr Philip Stubblefield, who wrote the pregnancy termination chapter of the *Precis V* of the American College of Obstetricians and Gynecologists, stated in an affidavit (Exhibit R-57) that there are many regimens of medications that are perfectly acceptable and commonly utilized for conscious sedation during abortion procedures According to Dr. Stubblefield,

> A regimen of two milligrams of midazolam and seventy-five micrograms of fentanyl, followed by an additional dose of one milligram of midazolam and 37.5 micrograms of fentanyl, which results in a total dose administered of 3 milligrams of midazolam and 112.5 micrograms of fentanyl, could be a perfectly acceptable regimen for conscious sedation for an anxious and frightened patient undergoing an abortion procedure. These dosages would in no way indicate "overdose" of the patient. This regimen would be consistent with acceptable standards of care, and prudent judgment.

Dr Burnhill also had studied Y. B 's records It was his opinion that the dosage for conscious sedation must be individualized to the patient, and that the dosage given Y.B. was no departure from generally accepted standards of care According to Dr. Burnhill, the patient's weight was not strictly relevant; the dose required had more to do with the patient's level of agitation. Dr. Burnhill acknowledged that a physician must wait between doses, but he stated that the drug is fast acting and it would not take long to see if a second dose were necessary. He noted that the patient's oxygen saturation was fine and that the variations were not significant. In his opinion, the use of the gauze was a distractive technique because it utilized teeth clenching, and he did not consider it a departure from generally accepted standards of care.

DISCUSSION

Complainant contends that respondent Brigham should have instructed patient Y.B. to return a few days later for her abortion, when she might have been calmer and would not have

required so much sedation There was no medical or legal necessity to perform the abortion that day. Complainant also contends that respondent did not wait a sufficient amount of time before administering the additional dose of conscious sedation. When administering conscious sedation, it is important to maintain an open airway and monitor the patient's respiratory status Complainant argues that by stuffing gauze in the patient's mouth, the physician has obstructed the airway and compounded the problem that may have been caused by oversedation.

Respondent replies that there is no reason to believe Y B would have been any less upset on another day, and she was also in danger of dehydration from her vomiting due to her pregnancy. It was a reasonable exercise of medical judgment to proceed with the abortion that day, even if it involved slightly more anesthesia. Respondent contends that he carefully placed folded gauze between Y.B 's teeth and had her bite down, as a distractive and calming technique so he could insert the IV needle In no way was the patient's airway obstructed He objects to complainant's characterization of "stuffing gauze in the patient's mouth," as no one has said that is what happened

Respondent further contends that he administered the proper dosage of conscious sedation to patient Y.B., in two stages, and that he waited a sufficient time between them to assess the effects of the first stage. This contention is supported by experts in the field. The sedation worked as it was supposed to, and the abortion was successfully completed. The patient's oxygen saturation fell only momentarily below 90 percent, which was not indicative of any complication. The patient was soon able to walk to the recovery room and was pleased with her treatment, with no ill effects.

I agree with the respondent's contentions. The complainant has failed to meet her burden of persuasion. I **FIND** that Dr. Brigham properly exercised his clinical judgment to give his anxious and frightened patient an appropriate dosage and effective combination of medications, and he did not depart from generally accepted standards of care. That his medical judgment was sound is supported by persuasive expert practitioners. I **FIND** that Dr. Brigham did not stuff gauze in Y.B.'s mouth while she was undergoing conscious sedation; rather, Dr. Brigham had the patient bite down on a piece of folded gauze to distract and calm her while he inserted the IV

needle. I **FIND** that the gauze did not obstruct the patient's airway and it was removed before the conscious sedation was administered. I further **FIND** that patient Y.B appropriately responded to the conscious sedation and experienced no respiratory distress. She was able to walk to the recovery room following the procedure and had a normal recovery from the anesthesia.

Based on the foregoing, I further **FIND** that respondent Brigham's conduct concerning patient Y.B did not constitute gross or repeated acts of negligence, malpractice, or incompetence, nor professional misconduct. Thus, I **CONCLUDE** that respondent's conduct did not constitute grounds pursuant to *N.J.S.A.* 45:1-21(c), (d), and (e) for the suspension or revocation of his license to practice medicine and surgery in this State.

The Case of M.B. (Second Complaint, Count I)

Complainant alleges that respondent Brigham's conduct concerning patient M.B constitutes gross or repeated acts of negligence, malpractice or incompetence as well as professional misconduct, endangerment of M.B.'s life; and medical judgment contrary to the safety and well-being of the public of this State. Complainant further contends that respondent's alleged acts and failures concerning M.B. constitute grounds pursuant to *N.J.S.A.* 45:9-16 and 45:1-21(c), (d), (e) and (h) for the revocation or suspension of his license to practice medicine and surgery in this State.

At the completion of the Complainant's case in chief, some of the allegations in this count of the second Complaint were dismissed for failure to establish a *prima facie* case. The remaining allegations are that, during the time M.B. was in his care, respondent:

1. Failed to assure adequate dilatation prior to commencement of the extraction;
2. Failed to estimate the probable extent of the laceration upon examination an hour after the procedure had been completed;
3. Inappropriately and prematurely ruled out uterine perforation;

4 Inappropriately attempted to repair the cervical laceration by applying silver nitrate;

5. Inappropriately waited approximately three hours after M.B. began hemorrhaging before transferring her to a hospital for immediate medical attention

Based on these allegations, complainant further asserts that respondent grossly mismanaged the care of M.B. by:

1 Undertaking to perform a 26-week abortion in an office setting;

2. Failing to appropriately address the patient's prolonged abnormal bleeding;

3. Failing or refusing to transfer her to a nearby hospital for emergency treatment in a timely manner.

4. Failing to exercise reasonable medical judgment throughout his care of M.B

The findings of fact which follow are derived from the credible evidence in the record. M.B. was a 20 year old mother of one child who had called Dr. Brigham's office in Voorhees, New Jersey, to schedule an abortion Because she the information she provided indicated that she was well beyond 14 weeks LMP, M.B was advised to call respondent's office in Spring Valley, New York, where second trimester abortions were performed. After letting considerable time pass, M.B. made an appointment and she and B.B., who is now her husband, went to respondent's office in Spring Valley, New York, on the afternoon of November 10, 1993. M.B. went through the customary steps of intake which included filling out various forms. She discussed her medical history form during intake counseling with nurse Wendy Jacquet, and her questions were answered. Dan De la Pena, M.D., introduced himself to the couple as a medical assistant. Although he is called "Dr. Dan," it is undisputed that Dr. De la Pena is not a licensed physician in the State of New York. He was a licensed physician in the Philippines, where he had substantial emergency room experience. He is now assistant administrator of an adult home in Rockland County, New York, and is studying for medical licensing in the United States. Dr. De La Pena did M.B.'s blood and urine testing

M.B then had a lengthy counseling session with Wendy Jacquet, and the two to three day procedure was explained in detail M.B was given a fact sheet which listed possible complications, including cervical laceration, uterine perforation, hysterectomy, and death Dr Brigham introduced himself to M.B and he answered her questions about the risk of complications He counseled her and she indicated she still wanted an abortion Then, in the presence of B.B., she was examined by Dr Brigham He found on examination that M.B had "a very long vagina, and her obesity made exam a little difficult The cervix was noted to be "very short-lipped and with a long cervical canal" (emphasis in original) (P-22, page 4, also P-22, page 24). Dr Brigham performed an ultrasound which revealed a single intrauterine pregnancy with a biparietal diameter of 61 millimeters, which corresponds to 26 weeks gestation on a Hobbins scale He told the couple that he could do the abortion for M B , and she continued to want the procedure after she and B.B. conferred.

Using ultrasound guidance, Dr Brigham injected 1 5 milligrams of Digoxin into the amniotic fluid to effect a painless intrauterine fetal demise He then inserted 12 eight millimeter laminaria into the patient's cervix M B was then sent to the recovery room, where she was observed, given antibiotics, and instructed on what to expect that evening and when to return the next day

The next morning, Dr. Brigham examined M.B and noted that the 12 laminaria were in place and were swollen. After removing the laminaria, he was able to pass an 89 French Hern Dilator, so that he knew M.B.'s cervix was dilated at least three centimeters. Dr. Brigham inserted three fingers into her cervix, by which he estimated M.B.'s cervical dilation to be four to five centimeters. With this estimate, he decided to proceed with the abortion. He was assisted throughout by Michelle Smith, and in part by nurse M.F. and nurse Jacquet. An intravenous line was started and M.B. was given a paracervical and intracervical block. Her membranes were ruptured and the amniotic fluid was drained. M.B. was given conscious sedation, so she remained awake throughout the procedure.

Dr. Brigham performed a modified Dilatation and Evacuation procedure in his routine manner, and the procedure appeared to be normal. According to Dr. Brigham's record, the fetus

dismembered easily, but there was some resistance in extracting the fetal skull While performing the abortion, he noted that fetal skull plates were extruding from the side of the decompressed fetal skull This was also normal for a termination in a pregnancy of this duration Dr Brigham did not feel there was anything unusual about the procedure, and M.B was comfortable throughout Dr. Brigham testified credibly that he did a visual vaginal inspection at the end of the abortion procedure He did not observe M.B. to be bleeding Dr Brigham did not use instruments or maneuvers to manipulate the cervix, so an endocervical laceration was not visible to him at that time

In fact, M.B. did have an endocervical laceration, which Dr Brigham would later detect. It is more likely than not that as the fetal bones were being withdrawn through M.B 's cervical canal during the course of the abortion, a sharp bone such as a skull plate lacerated the endocervical canal. It is also more likely than not that the sharp bone severed the uterine artery There can be little doubt that the severed uterine artery must have spasmed quickly, retracted, and thrombosed, limiting the initial blood loss to an insignificant amount Since bleeding is the evidence that an artery has been severed, confirmation of severance of the uterine artery could not come until an operative procedure was undertaken later at the hospital

Following the procedure, M B. seemed to be fine. Shortly after 11 00 a.m., she was able to dress and walk from the procedure room to the recovery room, pushing an I.V pole, accompanied by B.B and Michelle Smith. The events in the recovery room were established by the credible testimony of staff members and were even corroborated by L.P., another patient who was present M.B. sat on a sofa in the recovery room and was attended by Dr. De La Pena. He monitored her vital signs regularly, and they appeared to be within the normal range. She had moderate bleeding, which was not unusual following a 26 week abortion. M.B. stayed awake, and was able to answer Dr. De La Pena's questions. She drank some juice and ate some cookies. She was able to stand and walk unassisted to the bathroom at about 12 o'clock.

At about 12:15 p.m., Dr. De La Pena noticed some blood on the pad on which M.B. was sitting, and he asked a staff member to have Dr. Brigham come to the recovery room. Dr. Brigham arrived and had M.B. stand. When she stood, 100 to 200 cc of blood came out of her

vagina and pooled on the floor, frightening the patient She became very unsteady, but was not disoriented. Drs. Brigham and De La Pena had her sit in a chair with wheels, and they wheeled M B. back into the procedure room at about 12.20 p m

Dr Brigham was alarmed by the blood loss, it was not normal. His first concern was to assess the patient's hemodynamic stability to see if she was stable enough for further evaluation in the office. Upon examination, Dr Brigham found M B.'s vital signs to be within the normal range While the amount of blood loss was not typical, and was clinically significant, Dr Brigham did not consider it to be hemodynamically significant. M.B. was awake and alert, but frightened and confused by the situation She was pale, but not ashen or cyanotic, and she showed no signs of shock Dr Brigham noted blood clots, making disseminated intravascular coagulopathy unlikely While bright red blood would indicate fresh arterial bleeding, M B 's blood was dark red, meaning it had accumulated There was no clinical evidence of hypovolemia. M B. was dripping blood at a steady rate of about 2 cubic centimeters a minute, and was not spurting This was not a dangerous rate of blood loss

Present in the procedure room throughout the rest of the afternoon were nurse Jacquet, Michelle Smith, Elizabeth Navarra, Dr De La Pena, and Dr Brigham Ms. Navarra and Ms Smith were directly assisting Dr. Brigham at the foot of the table Ms Jacquet and Dr. De La Pena were at the head of the table. She was measuring M.B 's vital signs and taking timed notations of events on table paper, while Dr. De La Pena was talking to the patient and comforting her, while monitoring her intravenous fluids.

At 12:30 p.m., Dr. Brigham measured the patient's vital signs in the supine and sitting positions and these measures confirmed that she had not lost a significant blood volume, and she was sufficiently stable to continue evaluation. Her pulse oximeter readings were fine. Respondent decided to continue to examine and observe M.B., and considered that he would transport her to the hospital immediately if her clinical course deteriorated or if her problem required admission (P-22, page 7).

When respondent examined M B at 12:30 p.m., he detected a two to three centimeter endocervical canal laceration (P-22, page 7). His notes state that the laceration extended into the cervical canal; they do not indicate that the laceration extended beyond the canal. Dr. Brigham testified sincerely and credibly that if the laceration had extended beyond the cervical canal, he would have put that information in his notes. While the notes also do not state how he detected the presence of the laceration, it was also Dr. Brigham's sincere and credible testimony that he detected the laceration first by palpation and then by visualization. He stated that he could feel both ends of the laceration. He inserted a speculum in M.B.'s vagina and used Hanson's Maneuver to bring the cervix closer to his hand and eye. He could then see that the laceration was two to three centimeters long. He could see both ends, and the laceration did not extend into the lower uterine segment. Dr. Brigham noted its location as about 10 o'clock in the cervical canal.

The cervical laceration by itself did not indicate that M.B. would require hospitalization. It was a small cut. Dr. Brigham was concerned that there might be internal bleeding that he was not seeing, but all the vital signs still indicated that the patient was not hemodynamically unstable. He wanted to test for and rule in or rule out the possible diagnoses. At about 1 p.m., Dr. Brigham took a curette (Exhibit P-43) and gently scraped along the edges of the uterus. He did this to make sure the uterus was empty of the products of conception and to feel for discontinuity of the surface, indicating a uterine perforation. Dr. Brigham testified credibly that he was careful to not go near the cervical laceration with the curette. He did not find a uterine perforation and felt that it was likely ruled out.

At about 1:10 p.m., Dr. Brigham performed a transabdominal ultrasound to look for internal bleeding, but he detected none using this technique. Next, he applied silver nitrate to cauterize any small blood vessels that were bleeding. This can aid visualization of the operative field. He was not attempting to repair the laceration with silver nitrate. He showed the cervical laceration to Michelle Smith and Elizabeth Navarra. M.B. was still clinically stable, and there was no evidence of internal bleeding. A slight fall in her hematocrit was consistent with the observed blood loss. At that point, Dr. Brigham decided that M.B. was sufficiently stable for him to attempt to suture the cervical laceration. He hoped to be able to suture the apex of the laceration.

M B was awake and alert during the entire suture effort With his assistants pushing on the fundus of the uterus and pulling on the cervical lip, Dr Brigham was able to appose the edges of the laceration and secure it with one suture in the center of the laceration He then abandoned the attempt to place any further sutures It was Dr Brigham's credible testimony that the apex of the laceration had not extended during the suture effort The chart states, "1.50 p.m. Abandoned attempt to suture cervix Difficulty in suturing cervix was threefold 1) Pt has a very long cervical canal which makes it difficulty to reach the cervix, 2) Pt is obese. Due to obesity lateral vaginal walls obscured cx. 2nd speculum used. 3) The patient has a very small external cervix. All of these combined together to make transvaginal repair of Cx difficult." (P-22, pages 10-11)

At 1:58 p.m., Dr Brigham observed that M B was not bleeding from her vagina. There was no indication from her vital signs that she had internal bleeding. Her hematocrit readings were completely consistent with the external bleeding which had been observed. Between 2 00 and 2 30 p.m., Dr Brigham was the most confident that there was no internal bleeding. He and his assistants continued to monitor M B 's vital signs Her blood pressure was steady and consistent with her preoperative readings Her oxygen saturation was fine. Dr. Brigham gave M B. some oxygen, but she did not like it and it was removed.

At 2.30 p.m., M B urinated 200 cc. of clear urine, indicating that she was not hypovolemic. She was not bleeding from her vagina, and she was neither diaphoretic nor cyanotic. There was no reason at that time to transfer M.B. to the hospital. However, she soon thereafter took a turn for the worse. It is more likely than not that around 2:35 p.m., the severed and thrombosed uterine artery began to bleed again, due to disintegration of the blood clot. Dr. Brigham began to observe subtle changes, which were signs that M.B. might be bleeding internally. There was mild tachycardia, which was nonspecific, as it can be caused by a variety of conditions, including anxiety or cramping. Dr. Brigham again gave M.B. a complete examination. It was significant to him that M.B. was passing gas, as this indicated she had peristaltic function. Her blood pressure was at 70/50 and her pulse was at 104.

By 2 40 p m , Dr Brigham noted M B 's blood pressure was at 80/50, her pulse was elevated to 112, and she was pale but not ashen or cyanotic She was woozy although awake and talking. At 2 45 p m , M B 's blood pressure was still at 80 50, but her heart rate had risen to 115 From 2 35 until 2 55 p.m., five sets of vital signs were recorded. Her oxygen saturation was fine, and her blood pressure was fine, too. However, at 2.55 p m., M B sat up and felt dizzy, and blood came out of her vagina. This was evidence of additional bleeding, but she was not in shock Also at 2 55 p m., M B 's hematocrit reading was at 18 percent It had dropped eleven points in 15 minutes This was significant and was the first moment that M B 's internal bleeding was diagnosable Dr Brigham knew then that he could not handle the patient himself in his office and he called for an ambulance Knowing then that M B would need a transfusion and surgery, Dr. Brigham called the Nyack hospital and explained the situation to Dr Rausch, the emergency room physician He also called the office of the surgeon, Dr Jakus, and asked that he be paged at he hospital and given the necessary information. He did not utilize his backup agreements with area physicians, choosing instead to have M.B. admitted through the emergency room.

While waiting for the Emergency Medical Service ("EMS") to arrive, M.B. was not in frank, overt shock She was hemodynamically stable, and continued to be so after the EMS arrived The EMS personnel included Jeff Rabrich and John White. Although they testified in essence that M B was confused, lethargic, pale and agitated, they scored M.B. at 13/15 and later 14/15 on the Glascow Coma Scale. These were essentially normal scores, implying that M.B. was awake and not disoriented. None of the paramedics or emergency medical technicians checked off "shock" on the Prehospital Care Report (Exhibit P-22, pages 41 to 43). The patient's cool and dry skin noted by the paramedics also indicated that she was not in shock. The paramedics were apparently not in a rush. The spent 16 minutes at Dr. Brigham's office without doing anything of therapeutic value, indicating there was a lack of urgency in the situation. The vital signs they recorded were essentially consistent with the vital signs record earlier by Dr. Brigham's staff.

Dr. Brigham went to the hospital with M.B. in the ambulance. She was awake and talking on the trip, and complained about the bumpy ride. She was able to give oral informed consent at the hospital for surgery although she was unable to sign a written consent form. The triage nurse

described her as "AA+O [awake, alert and oriented], skin extremely pale" (P-22, page 38) Her temperature upon arrival in the emergency room was 96 degrees, with a pulse of 113 Her blood pressure, which had been 90/60 before the abortion, was 88/52. Thus, the vital signs taken in the doctor's office, the vital signs taken by the EMS, and the emergency room vital signs, were all consistent with each other, and consistent with a uterine artery that was not actively hemorrhaging.

Dr Brigham explained to the emergency room nurse what had happened and what he had done, and said that he felt M.B needed a blood transfusion and surgery. However, M.B. was not immediately given a transfusion, and blood was not drawn from her for about one-half hour after she arrived The emergency room physician, Dr Rausch, noted that M.B was alert and mentating He went on to examine other patients after he examined M.B., which indicates that she was not in hypovolemic shock At 4:30 p.m., the hospital laboratory called in the results of the hematological blood tests It is more likely than not that the lab results were in error because the blood sample was drawn downstream from the I.V. containing five percent dextrose Lab values included nine percent hematocrit and a serum glucose level of 726. The hospital hematologist later noted that the decreased hematocrit was likely the result of the dilutional effect on the blood sample. Even though the erroneous test result prompted M.B.'s discharge from the emergency room to the operating room at 4.30 p.m., she was noted to be in "good" condition at that time Dr Rausch noted that M.B had a small, supercervical tear, palpable to his vaginal exam

While the preop report indicates M.B.'s color was "ashen (Exhibit P-22, page 48), it is more likely than not that M.B. was not in frank shock when she was brought to the operating room. Prior to surgery, the surgeon took an oral informed consent from M.B., indicating that the surgeon must have felt she was alert, oriented and competent to give consent. She was placed under general anesthesia and examined in the operating room, starting at 4:30 p.m., but it was not until about 5:05 p.m. that the first blood transfusion was given. Also indicating that M.B. was not in hypovolemic shock, the surgeons first attempted to repair the cervical laceration from below. 45 minutes were spent examining, suturing, and monitoring the patient while she was anesthetized, before surgery began.

At 5 15 p m., the surgeons opened M B with a small incision There was no damage to the mesosalpinx noted by the surgeons, and no blood was noted in the abdomen. The uterine artery was found severed and retracted and thrombosed in the retroperitoneal cavity, and that cavity held about 350 c.c.s of blood and clots. A total abdominal hysterectomy was performed, with M.B 's normal ovaries left in place Dr Jakus reported that M B had a one centimeter perforation in the low uterine segment as well as a cervical laceration of four and one-half to five centimeters extending into the lower uterine segment almost at the level of the arrival of the uterine artery from the lateral areas, and he opined that this "was probably the reason for the severance of the uterine artery " However, the surgical pathologist, Dr. Susan Jormack, examined M B 's uterus and she did not confirm the presence of a four to five centimeter laceration extending into the lower uterine segment

Dr David Hollander testified that he has studied M.B.'s medical records. It was his opinion that it was not within the generally accepted standard of care for Dr. Brigham to commence a 26 week abortion in his office setting because the risk to the "mother" and her cervix of infection and perforation of the uterus is greater. If a complication occurs, the physician should have back up mechanisms and personnel in place to handle the increased risk. As a pregnancy increases in duration, the fetus becomes bigger, so greater dilatation of the cervix is required for the evacuation. The fetus' head is bigger, so the skull may need to be fractured and decompressed to remove it. In addition, the uterus is bigger, softer, and easier to tear. In short, the bigger the "baby," the more difficult the procedure, according to Dr. Hollander.

Dr. Hollander opined that the degree of risk was even greater for M.B., because she had a very long vagina; she was obese, so the cervix was harder to see; and her cervix was short lipped so it was harder to grasp. He felt these anatomical features made M.B. a harder patient to deal with if there were complications. According to Dr. Hollander, the physician must decide at the time of the preop consultation how difficult the surgery will be and so choose the appropriated setting. He described M.B. as a patient whose abortion should have been done in an in-patient facility.

It was the testimony of Dr. Hollander that Dr Brigham, upon detecting the cervical laceration following the abortion procedure, should have first found its apex and sutured it to stop the bleeding, before doing anything else. He felt that other procedures, such as curetting the uterus, would by manipulation tend to make the cervical tear dissect upwards further, toward the uterus According to Dr Hollander, this would endanger other organs and make the cervical tear harder to repair Dr Hollander concluded from the medical records that no suture was actually placed, and he opined that Dr Brigham should have transferred the patient to a facility that could accomplish the suture, since he had determined it should be done but could not do it.

Significantly, Dr. Hollander did not interpret Dr. Brigham's description of the laceration of "extending into the cervical canal" to mean that the laceration went beyond the cervical canal He also did not believe that the uterine artery laceration was present at the time the initial abortion procedure terminated It was his opinion that the laceration continued to extend upward on subsequent manipulation. Dr. Hollander also noted that a two centimeter cervical laceration is not unusual on childbirth, and that often a physician would not suture such a laceration and it would heal on its own.

Dr Hollander concluded from the test results of the first blood sample drawn from M.B. at the hospital that she was going into hypovolemic shock. He opined that Dr. Brigham had unduly delayed transporting M.B. to the hospital, and that this delay had an adverse impact. He felt that M.B. developed D.I.C., making surgery more difficult, and that the change in M.B.'s vital signs indicated that the laceration was getting worse. It was Dr. Hollander's opinion that Dr. Brigham's decision to undertake this patient's care and his overall management of the case did not comport with generally accepted standards of care. He considered the deviation from standards to be high, with the strongest deviation being the failure to immediately suture the bleeding cervical laceration.

Dr. Nicholas Kotopolous testified that it is important to achieve adequate dilatation of the cervix for late second trimester abortions because of the large fetal parts coming through the cervix. In his opinion, two days dilatation or more generally should be provided for termination of a 25 or 26 week pregnancy. He stated that one insertion of laminaria and completion of the

abortion procedure the next day is not the standard of care, and he concluded that patient M.B was inadequately dilated In particular, Dr Kotopolous had difficulty believing that Dr Brigham had inserted 12 eight millimeter laminaria at one sitting. In his opinion, Dr Brigham should not have handled M B 's procedure in his office

Dr Kotopolous testified that when Dr Brigham encountered resistance in extracting the fetal skull, he should have realized that the cervix was only partially dilated He noted that here is a great likelihood of injury to the uterine artery from the bony fetal skull coming through an inadequately dilated cervix While a lacerated cervix can be repaired in the office if its extent can be determined, a ruptured uterine artery must be repaired by laparotomy in the hospital. Interestingly, it was Dr Kotopolous' opinion that Dr Brigham saw the cervical laceration at the end of the original procedure and that he deviated from the generally accepted standard of care by sending M.B to the recovery room without making an appropriate diagnosis. According to Dr Kotopolous, at 12 30 p m. when Dr Brigham says the cervical laceration was detected, the indications were that something was very wrong, and Dr. Brigham should have then taken M.B to the hospital rather than monitoring her in his office. In his opinion, the hysterectomy could have been avoided if Dr Brigham had timely transferred M B to the hospital Dr. Kotopolous characterized Dr Brigham's efforts as acts of desperation, and he opined that M.B. was in a life threatening situation by the time she reached the hospital In Dr Kotopolous' opinion, respondent deviated grossly from the accepted standards of care

Dr. Michael Policar testified that neither New York nor California require that late second trimester abortions be performed in hospital settings He said that there is no medical reason requiring that all such procedures be done in hospitals, and while some patients' conditions dictate hospital car, the reality is that most of the procedures are done in an office setting, consistent with good standards of care. Dr. Policar acknowledged that most Planned Parenthood clinics put an upper limit on abortions at 20 weeks, but that relatively conservative limit was due to self-insurance and legal protection concerns, and not because of ethical or medical considerations.

Dr. Policar reviewed the records concerning M.B. and concluded that the office setting was appropriate for her abortion procedure. He noted that the insertion of 12 eight mm. laminaria

was both medically possible and consistent with generally accepted standards of care He has himself inserted this many and more in patients with late second trimester abortions. In addition, insertion of laminaria a day or two in advance of evacuation of the uterus is customary, common, and in accordance with generally accepted standards of care Dr Policar opined that insertion of laminaria does not constitute an abortion; they can be removed and the pregnancy can proceed to term. He feels insertion of laminaria is an abortion procedure, but it is not equivalent to an abortion itself

It was the opinion of Dr Policar that M.B 's cervix was adequately dilated. Because Dr Brigham was able to pass an 89 French Hern dilator, the cervix was dilated at least 3 centimeters Three fingers (Exhibit P-22) generally is 5 cm., which would be more than adequate for commencement of the abortion procedure. According to Dr Policar, using two measures of dilatation showed good judgment and procedure

Dr Policar testified that following the evacuation of the uterus, the physician should visually inspect the cervix for a laceration or bleeding, as Dr Brigham did. Insertion of a finger into the cervix would not normally be done, avoiding more uterine contamination from bacteria In Dr Policar's opinion, M B 's endocervical laceration would not be observable upon visual inspection. Dr Brigham had no reason to expect excessive cervical bleeding or an endocervical laceration, and his actions comported with generally accepted standards of care. M.B was properly monitored following the procedure, in Dr Policar's opinion. When subsequent bleeding was assessed, M.B was returned to the procedure room and an endocervical laceration was then identified. Dr. Policar testified that there is no indication that Dr. Brigham failed to estimate the probable extent of the laceration. Consistent with good practice, Dr. Brigham also went through an extensive list of possible causes of bleeding.

Dr. Policar opined that the greatest proportion of M.B.'s blood loss was from laceration of the uterine artery. He has experience managing uterine artery lacerations occurring as complications in abortions, which he noted is an unusual but well known complication of a well-performed abortion. It occurred once in an abortion performed by Dr. Policar, and the laceration

was caused by a piece of fetal skull His patient was transferred to the emergency room and an abdominal hysterectomy was performed

Dr Policar testified as to every step in the course of Dr Brigham's handling of M B , and he believes Dr Brigham appropriately addressed her bleeding. He properly stabilized the patient and attempted to suture the cervical laceration, consistent with generally accepted standards of care. There was no emergency that required the patient's immediate transfer to the hospital It was Dr. Policar's opinion that every step in the procedure and the pattern of care show that Dr Brigham properly observed and monitored M.B., and exercised reasonable medical judgment. Dr Policar testified persuasively that the appropriate standard of care was provided at every step, and that Dr. Brigham's management of M.B. was also in accord with national standards for these practices In Dr Policar's opinion, there was no gross negligence, nor repeated acts of negligence, nor any negligence in Dr. Brigham's handling of this patient.

Dr A.K , who was appointed to serve as Dr Brigham's monitor, testified that he performs abortions in New York State up to the legal time limit. It is permissible and the accepted practice that such abortions are done there in the doctor's office Some doctors advertise this service Dr A.K testified that he reviewed M B 's chart, and it was opinion that there was nothing about her LMP, vagina size, or cervical size that had any bearing on having the abortion procedure done in the doctor's office. Similarly, M.B.'s height and weight were not factors having a bearing on whether or where the procedure was done. According to Dr. A.K., what really matters is being able to see and grasp the cervix, and being able to insert laminaria. In this case, the critical factor was satisfied because the insertion of twelve laminaria indicates Dr. Brigham was able to see and grasp the cervix.

Dr. A.K. testified that he has performed abortions in the office setting for patients at 26 weeks who were obese and had long vaginas and short cervical lips. This was consistent with the generally accepted standard of care. He determines the adequacy of dilatation by removing laminaria, grasping the cervical lip with forceps, and inserting forceps requiring about 2 centimeters diameter. If necessary, he will insert progressively larger dilators to achieve an opening sufficient for insertion of the forceps. In his opinion, four to five centimeters is more than

enough dilatation, and three fingers of dilatation is closer to six centimeters dilatation. Dr A.K. testified that the size of M.B.'s cervix and vagina did not affect the amount of dilatation required.

Dr. M.A.B. testified that it is not inappropriate to perform a 24 to 26 week abortion in a doctor's office if the doctor has experience. He was familiar with Dr. Brigham's reputation as an abortion provider, and he stated that from all reports he had, Dr. Brigham was technically excellent, with a very low complication rate. In Dr. M.A.B.'s practice, he has had occasion to deal with cervical lacerations. In his opinion, a two centimeter laceration is not large, and the mere occurrence of a cervical laceration does not require transferring a patient to the hospital. In fact, the vast majority of lacerations do not even require suture. With a two to three centimeter cervical laceration, it would be appropriate to observe the patient and monitor vital signs before attempting to suture the laceration. This would not be altered if a patient is obese, with a long vagina and a short cervix.

Dr. Anthony Mustalish reviewed M.B.'s records (Exhibits P-22a to c). He noted that it is not unusual to have a health care worker take notes on table paper or even a bed sheet. The intention is that the recorded data and key events would then be taken so that a narrative and formal record of salient events could be prepared. In his opinion, it is completely proper for a nurse to monitor and record vital signs, and for the physician to rely on the data later to write the definitive note in the report. The physician must wait for the next best opportunity to write the report, which might be the next day, or even within a week. Since Dr. Brigham had accompanied M.B. to the hospital, it was in accord with generally accepted standards of care for him to write his record the next day.

Dr. Mustalish disagreed with the opinion that M.B. should have been immediately transported to the hospital upon discovery of the cervical laceration. In his opinion, to a reasonable degree of medical certainty, the patient record for M.B. reveals that it was not necessary to transport her to the hospital prior to the time Dr. Brigham took that action. The patient's normal and routine parameters used to evaluate her condition had no significant changes until just before 3:00 p.m., so until then, she was stable.

According to Dr. Mustalish, the physician must first assess the size and shape of a cervical laceration and the amount of bleeding, and must monitor the patient's vital signs Dr Mustalish testified that it would be appropriate for a physician to place one stitch in the center of a one or one and one-half inch cervical laceration, if the edges were apposed Since silver nitrate coagulates bleeding, its use may help visualize the laceration and would be consistent with generally accepted standards of care Bleeding of the cervical laceration contributed only a minor blood loss, while a lacerated uterine artery could rapidly result in major blood loss Given M B 's stable vital signs over several hours, Dr. Mustalish concluded that the patient's uterine artery went into spasm and thrombosed, therefore not contributing to significant blood loss Significantly, Dr Mustalish opined that the uterine artery laceration was not a clinically diagnosable situation, it could only be discovered operatively

It was Dr Mustalish's opinion that Dr Brigham's management of M B , including continuous observation, monitoring, control of bleeding, and diagnostic measures, was in accord with generally accepted standards of care Because of his compulsive attention and patience in monitoring M B., Dr. Brigham was able to pick up a subtle clinical change in her condition, and he immediately arranged for her transport to the hospital

Dr Mustalish noted that the EMS paramedics were at Dr Brigham's office for 16 minutes He said this would be considered a long time if M.B. had been in any extremis, and it indicated her condition was not so urgent as to require a "scoop and run" approach He also noted that the paramedics took no significant intervention measures, and did not check off on their form that M.B. was in shock. Her presenting condition indicated that she was not in shock The Glasgow Coma Scale was used to describe M.B.'s level of consciousness, and it indicated she was awake and not disoriented. She was not in shock on the way to the hospital.

It was Dr. Mustalish's opinion that Dr. Brigham acted consistently with generally accepted standards in providing continuity of care. He called ahead to the hospital and provided the information the hospital would need, and he rode to the hospital with the patient. It is normal for hospitals to treat patients of physicians who do not have admitting privileges. This particularly applies to out patient abortion procedures, where patients may travel great distances for the

procedure When M.B arrived at the emergency room, there were emergency concerns, but she was stable That the hospital did not immediately give her universal donor blood and waited about one-half hour to draw her blood indicates that it was a routine handling and that M.B. was not in shock upon arrival It was Dr. Mustalish's opinion that Dr Brigham's records, the EMS records, and the hospital records, all indicate that M.B was a stable patient. He believes that Dr Brigham's exercise of medical care and judgment was good, to a reasonable degree of medical certainty, and consistent with generally accepted standards of care Dr Mustalish was sincere and candid He was an impressive witness

Dr. Brigham testified that upon seeing the cervical laceration, it would not have been appropriate to rush M B to the hospital The rate of blood loss of about two cc per minute was not dangerous The laceration was a small cut which did not extend into the lower uterine segment, contrary to Dr Kotopolous' opinion, and there was no indication from the cervical laceration alone that hospitalization would be required at all Dr. Brigham testified that he totally disagreed with the opinion of Dr Hollander that the first thing he should have done was to suture the laceration It was Dr Brigham's opinion that he first needed to rule out any life threatening causes, and the cervical laceration was low on the list of concerns to check out His biggest concern was internal bleeding He was worried that M.B might be bleeding at some undetectable rate into the abdominal cavity, but all the vital signs indicated there was not hemodynamic instability If he had thought there was a uterine perforation, he would have hospitalized M.B immediately, since he could not repair that in the office

DISCUSSION

Complainant contends that M.B. was a high-risk patient for an abortion in an out-patient setting. The reason she was high risk were that she was undergoing a 26-week abortion and the risks attendant to abortion increase with each passing week; she was obese; and respondent found her to have a very long vagina, long cervical canal an short cervical lip. Complainant argues that given the greater likelihood of encountering problems, which respondent should have anticipated, he should have referred her to have the procedure done at a more appropriate facility. Referral to another practitioner for an abortion by induction was one alternative that would have been

available in this case. Referral of the patient to a practitioner who would perform this procedure in a hospital or clinic facility was another alternative that would have been available and prudent in this case

By the time respondent completed M.B.'s 26-week abortion, her cervix had been lacerated. Complainant argues that this may have been due in part to inadequate dilatation of M.B.'s cervix. Complainant notes that respondent did not begin an attempt to suture the bleeding cervical laceration until 1:20 p.m. He worked on it for one-half hour and then abandoned this attempt, citing the anatomical difficulties he'd found at the initial examination the previous day as the reason. The chart states, "1:50 p.m. Abandoned attempt to suture cervix. Difficulty in suturing cervix was threefold. 1) Pt has a very long cervical canal which makes it difficulty to reach the cervix. 2) Pt is obese. Due to obesity lateral vaginal walls obscured cx. 2nd speculum used. 3) The patient has a very small external cervix. All of these combined together to make transvaginal repair of Cx difficult." (P-22, pages 10-11). Complainant contends that a plain reading of this chart suggests that no stitches were placed and that the foregoing three points were the reasons for abandoning the attempt to suture the bleeding cervical laceration.

Complainant also contends that respondent did not truly estimate the probable extent of the laceration an hour after the procedure had been completed. His note does not state that he ascertained the upper apex of this laceration, whether by palpation or by sight. Knowing where the apex is and thus whether the laceration extends up into the lower uterine segment is quite significant. Complainant asserts that if respondent actually did ascertain the full extent of this laceration, it would have been to his benefit to note this fact in his chart, for it might justify his actions that afternoon.

Complainant contends that promptly suturing that laceration was the indicated procedure assuming respondent could diagnose the full extent of the laceration. Instead, he embarked on other diagnostic examinations such as curetting for retained products, and ultrasound. Complainant argues that an unsutured cervical laceration can extend upwards toward the lower uterine segment similar to a hem ripping, if there are manipulative procedures, such as curetting

when using a weighted speculum. The chart reflects use of a "2nd speculum" during the suturing and respondent described using a "weighted speculum"

Complainant argues that if a patient is bleeding internally, rapid deterioration can set in even in a young healthy patient who has been able to compensate well for blood loss (Exhibit P-66). The physician therefore must take into account the likely lag time which may occur once he calls for emergency help Respondent did not contact any backup physician or send the patient to the hospital at the point when he knew he had not sutured the apex of the cervical laceration Rather, he continued to monitor her in his office, purportedly because her vital signs were stable, the external bleeding had stopped, and he did not see anything wrong with her condition. When there is significant internal bleeding, blood moves from the extremities to the heart and internal organs Complainant contends that the patient's growing pallor could have signaled significant problems, and would have occurred over the course of the afternoon, not just in the least 10 minutes.

The respondent contends that Dr Hollander's testimony is called into question because of bias and lack of scientific understanding of procedures, as well as medical errors. Respondent points out that Dr Hollander's subspecialty is in Perinatology, and his training and allegiance are directed toward delivering 26 week fetuses He has not performed elective abortions past 18 weeks, the vast majority have been for genetic problems with the fetus Dr. Hollander has never actually performed a D&E procedure on any patient as late as either J.K., A.W., or M.B., and he has never performed a second trimester abortion on an outpatient basis. In his entire career, most of the abortions he has done in the hospital were done via the induction method. Dr. Hollander is not a member of the National Abortion Federation, although he has some familiarity with their published Standards of Care.

Respondent contends that Dr Hollander made fundamental errors in anatomy and sonography, such as Dr. Hollander's assertion in his rebuttal letter (Exhibit P-66) that the uterine artery is not in the retroperitoneal cavity, and therefore, one would not see primarily a retroperitoneal bleed. As stated by Dr. Fogel, Dean of Mount Sinai Medical School, in his reply to Dr. Hollander's assertion (Exhibit R-68), "Clearly, the uterine artery and most of the

gynecological organs, their blood and nerve supply are all retroperitoneal Indeed, the surgical findings in this case similarly describe a thrombosed uterine artery in the retroperitoneal space " Dr. Burnhill similarly found fault in Dr Hollander's knowledge of anatomy (Exhibit R-67) He said, "This statement is anatomically wrong. The uterine artery is retroperitoneal Furthermore, the surgeons in this case found M B 's uterine artery in the retroperitoneal cavity Therefore, one would expect to see primarily a retroperitoneal bleed in M.B.'s case In fact, this is what the surgeons saw at Nyack Hospital " Dr Burnhill did not mince words. His rebuttal letter concludes

> Dr Hollander's assumptions and ideas are anatomically and physiologically inaccurate This includes errors as to how arteries can thrombose, and even more surprisingly, mistakes as to the simple anatomy of the main blood supply to the uterus. It is difficult to understand how Dr. Hollander, a board certified and practicing Perinatologist, could not know the anatomy of the uterus and its blood supply Someone who is specifically trained in gynecological surgery, and who has devoted his career to his specialty of preserving and delivering healthy 24 and 26 week fetuses, should be an expert in the anatomy of the uterus Yet his statement contains basic and glaring errors In fact, his statement is so medically inaccurate that it raises the question of whether his rebuttal letter was accidentally imprecise or intentionally misleading Regardless, nothing contained within Dr. Hollander's letter changes my view that Dr Brigham's care and treatment of the J.K. and M.B. cases was well within acceptable standards of care

Respondent contends that it was an appropriate and reasonable exercise of his medical judgment to undertake to perform M.B.'s abortion procedure in his well-equipped New York office, and he points to the substantial expert opinion he presented in support of this position. The credible evidence establishes that he acheived adequate dilatation for performance of the abortion by insertion of 12 laminaria, notwithstanding the opinion of Dr. Kotopolous. Respondent further contends that he properly estimated the probable extent of the laceration, and his credible testimony on this subject was confirmed by the credible testimony of his assistants who observed the laceration. Significantly, while Dr. Kotopolous opined that Dr. Brigham had misdiagnosed the extent of the laceration, the complainant's other expert, Dr. Hollander, did not share that opinion.

Respondent further contends that the evidence does not establish that he inappropriately and prematurely ruled out uterine perforation, as asserted by only Dr Kotopolous He properly checked for uterine perforation and detected none, but there is no evidence to suggest he ruled it out Respondent also contends that the evidence establishes that he did not attempt to repair the cervical laceration by applying silver nitrate Rather, the silver nitrate was used to cauterize small blood vessels in preparation for repairing the laceration, and the experts agree that such use was appropriate

It is respondent's position that he appropriately addressed M.B.'s bleeding, and that he did not fail to timely transfer M.B to the hospital He palpated and observed the extent of the cervical laceration, and then appropriately assessed the patient's stability and ruled out life-threatening diagnoses prior to attempting to suture the laceration. Respondent asserts that Dr. Hollander's opinion that this course constitutes negligence is unreasonable and contrary to the testimony of numerous experts who supported Dr. Brigham's care and treatment of this patient In addition, respondent notes that Dr Hollander and Dr. Kotopolous disagreed about, among other things, whether the laceration should even be sutured in the office at all. Respondent contends that he carefully monitored and observed M.B., and he timely transferred her to the hospital when her clinical picture began to change, as Dr Mustalish emphatically agreed. Thus, respondent contends that he properly exercised reasonable medical judgment throughout his care of this patient.

I agree with the respondent's contentions. The complainant has failed to meet her burden of persuasion. The respondent was a sincere and credible witness on his own behalf, and the expert testimony in support of his competence and adherence to the generally accepted standards of care was impressive and persuasive. I **FIND** that respondent properly undertook performance of M.B.'s 26-week abortion in his office setting, which was appropriately equipped and well-staffed. I **FIND** that respondent properly assured adequate dilatation prior to commencement of the extraction, and he properly ascertained the extent of the cervical laceration upon examination an hour after the procedure had been completed.

I further **FIND** that respondent did not inappropriately and prematurely rule out uterine perforation, and he did not attempt to repair the cervical laceration by applying silver nitrate I **FIND** that respondent appropriately addressed the patient's abnormal bleeding, and that he appropriately transferred her to a nearby hospital for emergency treatment in a timely manner. In summary, I **FIND** that respondent exercised reasonable medical judgment throughout his management of M.B., in accordance with generally accepted standards of care.

Based upon the foregoing, I further **FIND** that respondent Brigham's conduct concerning patient M.B did not constitute gross or repeated acts of negligence, malpractice or incompetence, nor professional misconduct He did not endanger M.B.'s life and he did not exercise medical judgment contrary to the safety and well-being of the public of this State. Thus, I **CONCLUDE** that respondent's conduct concerning M.B did not constitute grounds pursuant to *N.J.S.A.* 45:9-16 and 45:1-21(c), (d), (e) and (h) for the revocation or suspension of his license to practice medicine and surgery in this State

Alleged Record Keeping Violations

Alteration of Records (Amended Complaint, Counts IV [S.C.] and V [B.A.])

Failure to Maintain Accurately Identified Sonograms (Amended Complaint, Count VII)

Failure to Maintain Records of Intraoperative or Postoperative Vital Signs (Amended Complaint, Count VIII)

Complainant alleges at Count IV of the Amended Complaint that respondent failed to accurately assess the status of S.C.'s pregnancy, performed an abortion in his office at a point later than 14 weeks LMP, intentionally or negligently altered his medical chart for S.C. by removing a portion of the chart, or maintained an inaccurate record by placing someone else's sonogram into S.C.'s chart. Based on these allegations, Complainant contends that respondent Brigham was negligent and engaged in conduct which violates *N.J.A.C.* 13:35-4.2 and -6.5. Complainant further contends that this alleged conduct constitutes grounds for the revocation or suspension of respondent's license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-

21(d) and (h), and when taken in combination with conduct alleged in other counts, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds for the revocation or suspension of respondent's license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-21(d).

Complainant alleges at Count V of the Amended Complaint that with regard to patient B.A., respondent performed an abortion in his office at a point later than 14 weeks LMP, and intentionally or negligently altered his medical chart for the patient. Based on these allegations, Complainant contends that respondent Brigham engaged in conduct which violates *N.J.A.C.* 13:35-4.2 and -6.5, and has engaged in the use of dishonesty, deception, or misrepresentation, as well as professional misconduct. Complainant further contends that this alleged conduct constitutes grounds for the revocation or suspension of respondent's license to practice medicine in this State, pursuant to *N.J.S.A.* 45:9-16 and *N.J.S.A.* 45:1-21(b), (e) and (h), and when taken in combination with conduct alleged in other counts, constitutes repeated acts of negligence, malpractice or incompetence, therefore constituting grounds for the revocation or suspension of respondent's license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-21(d).

At the completion of the Complainant's case in chief, some of the allegations in Count VII of the Amended Complaint were dismissed for failure to establish a *prima facie* case. The complainant's remaining allegation in this count is that the sonograms in respondent's charts for dates prior to October 1993 were not identified with the patient's name or the date and in some instances bore little correlation to the other information contained in the patients' charts. Complainant alleges that the respondent has thus engaged in repeated acts of negligence and in professional misconduct, constituting grounds for the revocation or suspension of respondent's license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-21(d), (e), and (h).

Complainant alleges at Count VIII of the Amended Complaint that patient records for abortion procedures performed prior to October 1993 reviewed at respondent's office did not reflect intraoperative or postoperative monitoring of vital signs. Complainant asserts that the failure to record and failure to monitor a patient's recovery following an abortion constitutes professional misconduct and repeated acts of negligence. According to the complainant, this

conduct constitutes negligence and violates *N.J.A.C.* 13:35-6.5, and therefore constitutes grounds for revocation or suspension of respondent's license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-21(d) and (h).

The findings of fact which follow are derived from the credible evidence in the record. On September 15, 1993, Investigators Mary Peterson, Deborah Zuccarelli and John Czuba went to respondent's office, accompanied by Lt. Keith Hummel of the Voorhees Police Department, to impound D.V.'s record and to review other charts. According to Ms. Peterson, before they began reviewing the charts they had a discussion with respondent about whether Medicaid or Medicare records were kept separately. She said that he assured them that all records for each patient were in those file cabinets and that was all the records he had in the office.

Investigator Peterson and Investigator Zuccarelli selected 20 charts at random from respondent's file cabinets and reviewed them. Of the 20, they had concerns about seven. They wrote detailed notes and copied information verbatim from the records. They replaced all of the charts along with about 50 others on top of the cabinets. Later, Investigator Zuccarelli reviewed the final information by checking it against the notes which Investigator Peterson was putting into her report. The two investigators believed that the S.C. and B.A. charts reflected second trimester procedures having been performed. Sonograms were not identified, and there were no records of postoperative monitoring.

Investigator Peterson returned to the Voorhees office with the second impound order (Exhibit P-63) on September 29, 1993. With her were Investigator Zuccarelli and Investigator Ben Ricciardi, as well as Lt. Hummel. Her purpose was to obtain the original seven records that were reviewed on the 15th of September. She gave Elizabeth Navarra a copy of the order and began to look for the records in the same cabinet as before. She could only find L.R.'s chart. Respondent did not know to which other office the other charts had been moved. Eventually, Dr. Brigham located S.C.'s chart within the cabinet and gave it to the investigators. The investigators later drove up to Spring Valley where respondent's staff had moved many charts, and a staff member provided the originals of four other charts. The M.A. chart was later found back in the Voorhees office. The charts at issue are Exhibits P-6, P-7, P-10, P-11, P-12, and P-13.

Investigator Peterson believed there were two material alterations found when she compared these charts with her notes from the 15th of September She believed S.C.'s chart originally had a sonogram reflecting 22-23 weeks; this sonogram had vanished from the chart by the time the investigators returned to impound it 14 days later. She believed B.A.'s chart originally had a fully completed abortion procedure record signed by respondent as part of the chart when it was inspected on September 15, 1993, by September 29, all that was left of this part of the chart was a page-long description of the procedure of insertion of laminaria in the patient.(Exhibit P-21). Five charts which showed completed abortions had no recovery room records.

Dr. Kotopolous testified that it is the generally accepted standard of care in New Jersey to identify sonogram prints with the patient's name and the date. In his opinion, the absence of the patient's name and the date on the sonogram prints for patients M.B. and J.K. (Exhibits P-22A and P-1A) is a deviation from the generally accepted standard of care. It was Dr. Hollander's opinion that sonograms should be identified with a patient identification number or a patient name. Dr. Kotopolous also testified that it is the generally accepted standard of care to monitor vital signs during and after an abortion procedure This is done so that if there is any abnormality, intervention measures can be taken It was also his opinion that it is the generally accepted standard of care to record the findings, for future reference medically and legally.

E.C. is a diagnostic medical sonographer She testified that usually the name of the patient should be shown on the sonogram print However, sometimes it is forgotten. She did not see this to be a problem if there is a report. Dr. Burnhill testified that some of the older machines did not have the capacity to print the name of the patient. Since the sonogram when viewed real time has so much more information than can be represented in a mylar printout, it is not the standard of care to keep the mylar printouts in the record of examination. Rather, the written report is kept, and only the report and live pictures can be relied upon in patient care and diagnosis. This is illustrated by the hospital report for J.K., where no mylar printout was kept, and all that is contained in the record is the sonogram report.

Dr Brigham testified that no ultrasound imaging was done for patient S C., and therefore, no ultrasound report was done. He said that if the State's investigators saw a sonogram printout or report in S C.'s chart, it did not belong there He also noted that there would never be a mylar print without a report, although there might be a report without a mylar print. After S.C.'s procedure on August 12, 1992, Dr Brigham had no dealing with S.C.'s chart until it was handed to the investigators during the second of their two visits in September 1993. He sincerely testified that he neither put anything in the chart nor took anything out during that time, nor did he ask or approve of anyone else doing that

In regard to patient B A., Brigham emphatically and sincerely denied terminating her pregnancy and evacuating her uterus in the Voorhees office. Rather, the abortion procedure was performed in New York, at the All Women's Medical Pavilion. Brigham believed that B.A was the last patient who had her laminaria inserted in New Jersey, and he said that there was no dishonesty or deception in the records; they reflect what happened with the patient. The Voorheess record reflected what occurred there The record forms and notations are those commonly used in this area of practice and they are consistent with good and accepted standards of medical care and record keeping The rest of the abortion procedure record was completed in New York. Brigham absolutely denied any alteration of B.A.'s records between visits by the State's investigators and he insisted that the laminaria insertion notes were in the chart on September 15, 1993 It was also his opinion that even if there were any deviation in record keeping in these cases, it had no effect on the care that the patients received, and therefore there was no negligence.

Kathleen Parisi is a licensed practical nurse who has cared for many ill patients in her career and who has attended numerous seminars and conferences on medical care. She started working at the American Women's Center in Voorhees in June 1992 and is now the office manager. Ms. Parisi identified her handwriting on the recovery room records for patients L.R., C.E., M.B., and S.C. (Exhibits R-2, R-42, R-43, and R-44). It was Ms. Parisi's sincere and credible testimony that she created the documents on the dates shown to record the patients' vital signs on those dates, and she signed them. She testified that she followed the same procedure of monitoring and recording vital signs for all patients in the recovery room.

Ms Parisi testified that she was present at the office on September 15, 1993, when the investigators came. They made no request of her and they refused the offer of a room Instead, they stayed in the main hallway looking at charts, and there was a lot of commotion. Ms. Parisi testified that when the investigators came to the office, the recovery room records were in a cabinet right near the table where they were looking at patient charts. The cabinet had initially been in the recovery room, but was moved next to the table some months earlier. Ms. Parisi was a sincere and credible witness

B.G. is a registered medical assistant and blood lab work technician. She was hired at the Voorhees office in September 1992. It was her credible testimony that patients were monitored in the recovery room and the vital signs were recorded It was B G 's task to photocopy the blank recovery room forms every week, as a new form was needed for each patient. Originally, the filled out and signed recovery room records were kept in a file in the recovery room Later the file cabinet was moved out of the recovery room B G. testified that she was present when the investigators came to the office She felt they were arrogant and rude, and noted that they did not ask for any specific records The recovery room records were at that time in a filing cabinet right next to the desk which the investigators were using B G. was a credible witness.

DISCUSSION

Complainant asserts that the evidence is clear that on September 29, 1993 the investigators served respondent or his staff with a court order for production of complete medical records on certain patients (Exhibit P-63) and that respondent and several staff members were aware of the contents of the Order and were consulting with counsel about it. The evidence is also clear that five of the charts retrieved on September 29, 1993, including four produced from their place of storage in Rockland County, did not have recovery room records (Exhibits P-6, P-10, P-11, P-12 and P-13). Three months later, in response to the charges filed by the Attorney General, respondent's office suddenly produced copies of the purported original recovery room records which were maintained on these five patients. As admitted by Kathy Parisi, that was the first time these records were produced (Exhibits R-2, R-23, R-42, R-43 and R-44) despite the mandate of the court order. The complainant suggests that these five recovery room records be

place side-by-side and examined as to whether they bear the indicia of contemporaneous records In particular, complainant notes the constancy of the handwriting and striking similarity of the actual entries

Respondent asserts that he has committed no act of negligence in regard to these allegations. The evidence as to the records of S.C. and B.A. which the complainant presented was dependent on the memories of the investigators. There is no credible evidence in the record to establish that there actually was an alteration of records, or that any such alteration was intentionally done, or that it was done by respondent. Since S.C.'s own affidavit establishes that she did not have a sonogram, and B.A.'s abortion was clearly not performed in New Jersey, there was never any wrongdoing by respondent and no reason to alter records existed.

Respondent also asserts that he has shown that it is not the standard of care to even print a mylar printout of a sonogram, as it is not used in the diagnosis of the patient. The lack of a patient identifier on a mylar printout has not been shown to have any impact on the quality of care provided, and complainant thus can not establish any negligence. Respondent also asserts that because of the gestational age of D.V.'s fetus, she was not accepted as his patient. Therefore, a sonogram report was not necessary for patient care.

I agree with the respondent. I **FIND** that the respondent did not intentionally or negligently alter his medical chart for S.C. by removing a portion of the chart, or maintain an inaccurate record by placing someone else's sonogram into S.C.'s chart. I **FIND** with regard to patient B.A. that the respondent did not intentionally or negligently alter his medical chart for the patient.

Based upon the foregoing, I further **FIND** that respondent Brigham was not negligent and did not engage in conduct which violates *N.J.A.C.* 13:35-4.2 and -6.5. Thus, I **CONCLUDE** that respondent's conduct did not constitutes grounds for the revocation or suspension of his license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-21(d) and (h).

I **FIND** that some of the sonograms in respondent's charts for dates prior to October 1993 were not identified with the patient's name or the date. However, I further **FIND** that this was not a departure from generally accepted standards of care and that it in no way interfered with the quality of care provided. I further **FIND** that this conduct does not constitute repeated acts of negligence or professional misconduct. Thus, I **CONCLUDE** that respondent's conduct did not constitute grounds for the revocation or suspension of his license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-21(d), (e), and (h).

Based upon the credible evidence in the record, I **FIND** that respondent properly monitored intraoperative and postoperative vital signs. I **FIND** that it was not within the generally accepted standards of care to record intraoperative vital signs for first trimester abortions lasting under five minutes. I **FIND** that respondent's staff properly monitored and recorded patient's postoperative vital signs in the recovery room.

Base upon the foregoing, I further **FIND** that respondent's conduct did not constitute professional misconduct, nor repeated acts of negligence. Thus, I **CONCLUDE** that respondent's conduct did not violate *N.J.A.C.* 13:35-6.5, and did not constitute grounds for revocation or suspension of his license to practice medicine in this State, pursuant to *N.J.S.A.* 45:1-21(d) and (h).

The issue of whether respondent violated the termination of pregnancy regulation, *N.J.A.C.* 13:35-4.2, by inserting laminaria in patients who were beyond the 14th week LMP will be addressed below.

Alleged Failure to Ascertain Length of Pregnancy Within Generally Accepted Margin of Error (Amended Complaint, Count IV [S.C.]) and Second Complaint, Count II [D.V.]

Complainant's allegations at Count IV of the Amended Complaint concerning patient S.C. are described above. At the completion of the complainant's case in chief, some of the allegations of Count II of the Second Complaint were dismissed for failure to establish a *prima*

facie case. The complainant's remaining allegations in this count of the Second Complaint are that on August 19, 1993, respondent was unable to determine the gestational age of patient D.V.'s pregnancy with any specificity, and that he advised D.V. that the gestational age was between 16 and 30 weeks. Complainant alleges that D.V. was between 32 and 35 weeks pregnant when respondent examined her, and that his inability to determine her gestational age within any range of medical certainty constitutes gross incompetence. Thus, complainant alleges that respondent's conduct constitutes grounds pursuant to *N.J.S.A.* 45:1-21(c) for the revocation or suspension of his license to practice medicine or surgery in this State.

The findings of fact which follow are derived from the credible evidence in the record. D.V. was a 20 year old patient who went to respondent's office on August 19, 1993. She has claimed that Dr. Brigham gave her varying estimates of her weeks of gestation, from 16 to 30, and then said he did not know. D.V. has acknowledged that Dr. Brigham advised her in front of his assistant that she was 32 weeks pregnant, but has also claimed that he called her aside into his office and insinuated that he might be able to do something for her if she would go to his Rockland County office. D.V. then went to Metropolitan Medical Associate where Dr. Kotopoulos took a sonogram and told her that she was late in her third trimester, about 35 weeks or 88 mm. BPD. (Exhibit P-25).

Respondent's chart (Exhibit P-24) contained 8 undated, unidentified sonograms of D.V. and no written sonogram report. He was using a 7.5 mgh transvaginal probe because his 3.5 mgh transabdominal probe was broken. The 7.5 mgh transvaginal probe is not the right piece of equipment to use when one needs to obtain an accurate sonogram in the third trimester. Instead, a 3.5 mgh tranabdominal probe is the correct equipment. Use of a 7.5 mgh transabdominal ultrasound results in not being able to obtain a complete BPD because the 7.5 produces lesser penetration and a narrower field of view.

S.C.'s chart (P-6) reflects the following: LMP of 9 weeks, pelvic exam findings of 11 weeks, tissue examination finding of 15-16 weeks. Complainant also asserted that there was an unidentified sonogram originally seen by investigators Peterson and Zuccarelli in S.C.'s chart reflecting 20-22 weeks gestation. If the sonogram did pertain to S.C., it clearly did not

correspond to the other findings for it was well beyond the acceptable margin of error for a second trimester pregnancy in second trimester The 15 to 16 weeks conclusions are also well beyond the margin of error if the patient's report of 9 weeks LMP was correct. Dr Brigham testified that his pelvic examination of S C gave him a gestational age estimate of 11 weeks, and he believes about 13 and one-half weeks was the true gestational age. Thus, he feels his estimate was within the accepted margin of error and within the generally accepted standard of care

Narda Johnson is a diagnostic ultrasound technician She has worked in that field since 1983, and has been a certified sonographer since 1984 An employee of Greenwich Ultrasound, with duties at Greenwich Hospital in Connecticut, Johnson specializes in obstetrical sonography. She normally uses three measurements for determining gestational age of a fetus. She specializes in high risk fetuses, and testified that it can take up to 30 minutes to do an obstetrical scan. Ms. Johnson estimated that she has done close to 80 thousand ultrasounds

Ms. Johnson examined sonograms from Exhibits P-24 and P-25, concerning patient D.V., and acknowledged that a biparietal measurement could not be done with the 7.5 transvaginal probe. She said that she could see the femur bone in the first two sonograms (Exhibit P-24), and she opined that the sonograms were appropriately taken and measured. Ms. Johnson noted that inexperienced people sometimes measure "artifacts" or "noise" shown in the picture In these sonograms, the artifact was not included in the caliper placement, indicating that respondent knew what he was doing. Since he was using a 7 5 mgh transducer, she felt he was doing a very good job, and she considered the gestational age estimate for the second picture to be accurate. On the other hand, the picture of the fetal skull in the third picture was taken at an oblique angle, and it would not provide a correct gestational age, because one can not use a 7.5 probe for the biparietal measurement, and because the correct anatomical plane has not been used.

According to Ms. Johnson, the fifth picture appeared to be the correct anatomical plane. She identified brain tissue, and said that for an accurate measurement of the fetal head, the fetal brain is a landmark to look for. In her opinion, the picture did not show the bladder. She felt picture five indicated how one would try to use a 7.5 probe for a biparietal measurement if forced to do so. In other words, it shows the operator knew what he was doing, trying to use the

equipment as best he could He could approximately identify anatomical structures, and he knew what measurements to try to take to have sufficient information to estimate gestational age She acknowledged that if respondent told the patient that she was at 15 or 16 weeks, or at 25 or 26 weeks, that information would not have been correct However, In her opinion, Brigham correctly used the femur length for his gestational age estimate of 32 weeks. It was enough information to tell the patient she was too far along to have an abortion Ms. Johnson was a sincere, candid and credible witness

Kathleen Parisi recalled patient D V , as she had missed two appointments before coming to the office. Noting that no patients are alone with the doctor, Ms. Parisi stated that she was present the entire time D V was with Dr Brigham on August 19, 1993. He did a pelvic examination and told her that she was further along than she thought. D V made it clear that she wanted to have an abortion Dr Brigham gave her an ultrasound, but he tried to do it using the vaginal probe, because the abdominal probe had been sent out to be fixed. According to Ms Parisi, Dr. Brigham kept looking at the screen as he moved the probe, and he took numerous pictures After a considerable time, he told her that she was 32 weeks pregnant and that he could not do the abortion D V was hysterical at this news and said she would do anything to have an abortion Dr. Brigham told her it was not a financial issue; it was a legal matter D V gave birth about four weeks later, and the hospital estimated her gestational age to be 35 to 36 weeks.

In regard to patient S C., Dr Brigham testified that she had indicated her LMP to be June 13, 1992, which would mean about nine weeks gestation. When he did his pelvic examination of S.C., Dr. Brigham estimated the pregnancy to be at eleven weeks, which he described as within the accepted range of error. It was not a large discrepancy from the patient's information. The respondent testified that no sonogram was necessary, and it was not his practice to do a sonogram under the circumstances. It is his opinion that it is not within the generally accepted standard of care to do an ultrasound for first trimester abortions, when the pelvic examination and the patient's estimate are consistent, and both are within the first trimester. He said that his opinion comports with the standards of the National Abortion Federation. Dr. Brigham testified that neither the Harrisburg nor Flushing centers do sonograms for first trimester abortions, and he is aware of at least two licensed New Jersey facilities where this is also true.

Dr Brigham explained that he was trained to do pelvic examinations by observation, and then he was observed and supervised as he did them. He has similarly trained others, and he estimated that he has done between twenty thousand and thirty thousand pelvic exams Dr Brigham described the method he followed for a pelvic examination He first examines the external genitalia for normalcy, then inserts one and then two lubricated fingers into the vagina He places his left hand on the fundus of the uterus and pushes By doing this, he is seeking a clear understanding of the angle of the cervix and cervical canal, and the size of the uterus. There is an approximate correlation between the size of the uterus and gestational age, with a margin of error of about three weeks

Dr Brigham testified that some patients are more difficult to assess for gestational age because of factors such as obesity, retroverted uterus, tensed abdomen, infection or pelvic tenderness making the exam painful According to Dr Brigham, he has had a number of ways to assess the accuracy of his pelvic exams At Columbia Medical School, he had the feedback of professors who examined the same patients he did Planned Parenthood did not do ultrasounds, so a good pelvic exam was important, and Dr Brigham testified that they felt his estimates were on target. However, the most accurate feedback he has received has been from doing thousands of pelvic exams following sonography, and the estimates of gestational age have correlated very closely. Dr Brigham feels he will be within a week or two of the sonographer's estimate.

Dr. Brigham noted that there has been no other allegation raised concerning the adequacy of his pelvic exams besides that concerning S.C., and she had refuted the Complainant's allegations in her affidavit (Exhibit R-14). She did not receive an ultrasound, and to the best of her knowledge, she was in her first trimester of pregnancy at the time of the abortion. Dr. Brigham also noted that the fetal tissue examiner had recorded 14 millimeters as the fetal foot length (Exhibit P-6). Dr. Brigham testified sincerely that he did not know who wrote on S.C.'s chart an estimated gestational age of 15 to 16 weeks, followed by two question marks, but he interpreted the entry to mean that the tissue examiner on his relatively inexperienced staff was doubly unsure of the estimate. According to Dr. Brigham, the examiner strains the products of conception and then lays out the fetal part for measurement with a ruler. A fetal foot length of 14

millimeters, as was measured by the tissue examiner, corresponds to a gestational age of 13 and one-third weeks LMP according to the tables of the National Abortion Federation (Exhibit R-55) Even assuming the full margin of error of two millimeters, a fetal foot length of 16 millimeters would correspond to only 14 weeks LMP (Exhibit R-55), and would be within the legal limit for the procedure.

In regard to patient D.V., Dr Brigham testified that she had come to his office seeking an abortion and not to get an estimate of her gestational age He noted that she went to Dr Kotopolous' facility in Englewood after leaving his office According to Dr. Brigham, by her reported LMP, she would have been late in her second trimester He did an external exam of her abdomen and a pelvic exam and estimated the gestational age to be 32 weeks from LMP D V was emphatic about wanting an abortion, and he tried to break it to her gently that she was too far along in her pregnancy In accord with the testimony of Ms. Parisi, Dr. Brigham testified that he did the best he could to obtain a satisfactory sonogram measurement using the transvaginal probe Eventually he obtained an accurate measurement of femur length, yielding an estimated gestational age of 32 weeks He told D V this news and that he could not do an abortion. He suggested that she plan for prenatal care. Dr. Brigham's testimony was thorough, sincere, and entirely worthy of belief

DISCUSSION

Complainant argues that the sonograms respondent took of D.V. reflect that respondent lacks knowledge in taking accurate sonogram measurements and in dating a pregnancy. In #1 and #2, the femur lengths are not accurately measured and in #3 the biparietal diameter (BPD) does not reflect necessary landmarks; in #5, a 33 mm. PBD measurement is of the bladder, not the fetal head; in #6 there is no structure which can design the head even though it is denominated a biparietal diameter (BPD); #7 is a BPD but again does not clearly measure the head; and #8 is partly the head and partly the bladder even though it is denominated BPD. The generally accepted margin of error for a patient who is 32 weeks pregnant is plus or minus 17 to 21 days. Six of D.V's eight sonograms were therefore outside the acceptable margin of error.

Complainant contends that for S C , the pelvic exam findings reasonably correlated to the 9 week LMP, but was 5 to 6 weeks inaccurate when compared to the actual gestational age assessed at the end (15-16 weeks) The discrepancy in these findings demonstrates that respondent failed to accurately assess the gestational age of S.C.'s pregnancy and that he was negligent

Respondent contends that he accurately estimated D V 's gestational age, even though he was handicapped by broken equipment. Not only was his estimate within any reasonable range of medical certainty, it was correct. Complainant concedes that respondent told D V. she was at 32 weeks gestation Respondent also asserts that he was within an acceptable range of error in estimating the S C 's gestational age The measured fetal foot length of 14 millimeters corresponds to 13 weeks and three days, so his estimation of gestational age by examination was only off by two weeks.

I agree with the respondent I **FIND** that respondent did not fail to accurately assess the status of S C 's pregnancy and that he was able to determine the gestational age of patient D V 's pregnancy with specificity. I further **FIND** that respondent Brigham's conduct concerning patients S C and D V did not constitute negligence nor gross incompetence. Thus, I **CONCLUDE** that respondent's conduct did not constitute grounds pursuant to *N.J.S.A.* 45:1-21(c) for the revocation or suspension of his license to practice medicine or surgery in this State.

Alleged Commencement or Performance of Abortions at a Point Beyond the 14th Week LMP in Violation of State Regulations

J.K. (Amended Complaint, Count I)

Case in May 1993 (Amended Complaint, Count II)

S.C. (Amended Complaint, Count IV)

B.A. (Amended Complaint, Count V)

The allegations and facts concerning patients J K , S C , and B A are described above and need not be repeated here. As to Count II of the Amended Complaint, the complainant alleged that respondent performed an abortion at the Voorhees office around May 1993 on a patient who was at 23 weeks gestation. The source of this allegation was Ellen Stott, who is a registered nurse practitioner in obstetrics and gynecology and who has been a practicing nursing for ten years As a result of her specialized registration as a nurse practitioner, she can have her own patients and provide a certain specified range of care for them. She was employed by respondent from April 1993 to October 1993, when she quit.

Ms. Stott claimed that about two or three weeks after she started working for respondent, she was informed by Kathy Parisi and B.G. that a 24 to 26 week procedure had been performed in the office, and that staff member B G. had been the only staff member on the premises at the time and had become very upset about it. Ms Stott further claimed that Ms. Parisi had found the products of conception in a medical waste bag When she confronted Dr Brigham about this, she says he did not deny that this event had taken place; rather, he justified the abortion by saying that it was a fetal demise and was a 23 week procedure, not 26 weeks. She said that it was an explanation that she could deal with

Respondent, Ms Parisi, and B.G. each denied that the abortion described by Ms. Stott had taken place. There testimony was candid and sincere, and entirely worthy of credit. It is more likely than not that Ms. Stott, who herself saw none of what she described, was confused by discussion at the office concerning the case of J.K., and that Ms. Stott must have been mistaken. I so **FIND.** Thus, I **CONCLUDE** that Count II of the Amended Complaint must be dismissed.

DISCUSSION

N.J.A.C. 13:35-4.2 sets forth the regulations regarding termination of pregnancy. The rule clearly contemplates that beyond 14 weeks LMP, the uterus cannot be evacuated except in specified facilities by physicians with specified credentials. There is no distinction stated in the rule for cases in which the fetus had demised before the abortion. The rule is silent on insertion of laminaria.

Complainant contends that the insertion of laminaria in a patient who intends to have an abortion, when the laminaria are inserted for the purpose of dilating the cervix preparatory to removal of the fetus and placenta, is the commencement of that abortion procedure Although some patients may have the laminaria removed and go on to successfully deliver a baby, the basic premise is still that insertion of laminaria commits the patient to termination of the pregnancy

Complainant further contends that the insertion of the laminaria was the initial medical procedure towards J.K.'s abortion, since Dr. Brigham was utilizing a passive dilation technique. There was no other purpose for the laminaria insertion in J.K. To the extent that laminaria might be removable from a patient and the process of dilation and abortion interrupted, respondent no doubt knew that he would not be removing the laminaria and thus stopping this process in J.K., who had a fetal demise

Dr Jeffrey Moskowitz testified on behalf of respondent that, in his opinion, insertion of laminaria does not constitute performance of an abortion. Laminaria are intended to dilate the cervix, while he defines an abortion as evacuation of the uterus These procedures have separate billing codes Dr Moskowitz said that in New York, nurse practitioners are allowed to insert laminaria, but they are not allowed to perform abortions He also noted that patients are vigorously counseled (that insertion of laminaria is intended to dilate the cervix so the abortion can be performed), but some patients change their minds and have the laminaria removed The vast majority of these patients go on to deliver a baby at the end of their pregnancy. Unlike the laminaria, the evacuation of the uterus can not be reversed. The essence of Dr. Moskowitz's opinion in this regard was that insertion of laminaria does not evacuate the uterus, so it is not commencement of an abortion. He acknowledged that insertion of laminaria is a step in the process, in the same way that the decision to have an abortion is a step.

Dr. M.A.B. testified that insertion of laminaria does not and could not equal an abortion. The insertion of laminaria involves only the cervix. It is simply a means of softening and dilating the cervix, and it does not cause an abortion. The patient can change her mind, the laminaria can be removed, and the patient can carry to term and deliver.

It was the opinion of respondent Brigham that insertion of laminaria does not constitute performance of an abortion He offered several reasons First, insertion of laminaria does not terminate the pregnancy; it neither kills nor evacuates the fetus It is possible to remove the laminaria and have the patient go on to deliver a healthy baby Second, their are separate codes for insurance coverage for insertion of laminaria and for abortions, and laminaria may be inserted for dilatation purposes unrelated to abortions Finally, in some contexts it is permissible for non-physicians to insert laminaria, but only licensed physicians may perform abortions So, Dr Brigham testified, he had every reason to believe that in New Jersey insertion of laminaria would not be deemed performance of an abortion He felt that he was in compliance with the spirit and the letter of the time limit regulation, and with the standard of practice in this state Nevertheless, he stopped inserting laminaria in New Jersey around December 1992, based upon his understanding that the Board felt he should not

Putting aside the question of laminaria insertion, Dr. Brigham categorically denied ever intentionally performing an abortion in New Jersey beyond the 14 weeks limitation. As noted above, Dr. Brigham testified that his pelvic examination of S.C. gave him a gestational age estimate of 11 weeks, and he believes about 13 and one-half weeks was the true gestational age Thus, he feels his estimate was within the accepted margin of error and within the generally accepted standard of care. He likewise categorically denied the allegation of evacuating a fetal demise at 23 weeks in his New Jersey office Dr Brigham testified that there has never been a fetus of any gestational age placed in his trash. Also as noted above, in regard to patient B.A., Dr. Brigham emphatically and sincerely denied terminating her pregnancy and evacuating her uterus in the Voorhees office. Rather, the abortion procedure was performed in New York, at the All Women's Medical Pavilion.

It is clear that insertion of laminaria does not terminate a pregnancy. It is likewise clear that it is a necessary step in achieving adequate cervical dilatation so that evacuation of the uterus can be accomplished safely. The Board is of course free to interpret the scope of its rule on termination of pregnancy, in accordance with reason, fairness, and adequate notice to those who are regulated. It would be well if the rule specifically addressed the use of laminaria, as I am

convinced that Dr Brigham would not have utilized the procedure in New Jersey for patients beyond the 14th week of pregnancy if the rule expressly defined laminaria insertion as a termination procedure. Dr. Brigham voluntarily stopped inserting laminaria in New Jersey about a year before the Board issued its interim order barring him from such procedures, when he learned of the Board's apparent interpretation

Based upon the foregoing, I **FIND** that respondent did not intentionally nor negligently violate *N.J.A.C.* 13:35-4.2. Thus, I **CONCLUDE** that respondent's conduct does not constitute grounds for the revocation or suspension of his license to practice medicine and surgery in this State

Alleged Misleading Advertising (Amended Complaint, Count X; Second Complaint, Count III)

Complainant alleges at Count X of the Amended Complaint that respondent's published advertising in New Jersey in 1992 and 1993 for his New Jersey and New York offices of safe, gentle, and painless abortions to 24 weeks was deceptive and misleading. Complainant alleges that this violates *N.J.A.C.* 13:35-6.10 and constitutes grounds for the revocation or suspension of Respondent's license to practice medicine in this State pursuant to *N.J.S.A.* 45:1-21(h).

Complainant alleges at Count III of the Second Complaint that respondent's telephone yellow pages advertising as of March or April 1994 of safe, gentle abortions constituted the employment of deception, misrepresentation, false promise or false pretense, in violation of *N.J.S.A.* 45:1-21(b).

Tom Kearney testified that he is a sales representative for New Jersey Yellow Pages advertising, and he handled the accounts for American Women's Center. He dealt with respondent beginning in June 1992, and they met to discuss the Center's account which was billed to a Voorhees phone number. Kearney also met with Kathy Parisi and Liz Navarra who acted on respondent's behalf. In 1992 and 1993, respondent had ads running in almost all of the 38 New

Jersey Yellow Pages Directories It is unrefuted that Dr Brigham has directed that changes be made in his advertisements when he has learned that the Board had concerns about their content. It is also unrefuted that Dr Brigham believed his advertisements, which offered safe, gentle, painless abortions, and later offered safe, gentle abortions, to be truthful.

DISCUSSION

Complainant contends that respondent's advertisements are deceptive and misleading. Some of the respondent's ads offer "safe, gentle, painless" abortions (Exhibits P-14, P-16, P-51, and P-52). On the other hand, the fact sheet provided to patients as part of the informed consent paperwork (see, Exhibit P-22, pages 18 and 19) describes possible complications that would no doubt cause pain, including perforations, lacerations, and suturing. In addition, it is undisputed that insertion of laminaria in second trimester terminations can cause significant cramping. Complainant asserts that these factors are inconsistent with representations of "safe" and "painless."

Respondent asserts that the advertising is true. No patient complained of pain or of being misled. The fact that there is a slight chance of a complication, or that there might be cramps after the procedure, does not render it unsafe or painful. Respondent had a reasonable basis for the clarity and accuracy of the advertisements and he had no intent to mislead or deceive. In addition, respondent asserts that he has acted in good faith in changing his advertisements. He points to his undisputed efforts to receive guidance from the Board, which notified him on three different occasions over the course of two years of three different problems it had with the same advertisement. He has attempted to comply with the Board's wishes.

N.J.A.C. 13:35-6.10 regulates advertising and solicitation practices. The relevant part appears to be

> (c) A Board licensee who engages in the use of advertising which contains any of the following shall be deemed to be engaged in professional misconduct:
>
> 1. Any statement, claim or format including, but not limited to, a graphic representation, which is false, fraudulent, misleading or deceptive.
>
> [*N.J.A.C.* 13:35-6.10(c)1.]

N.J.S.A. 45.1-21(b) prohibits the use of dishonesty, fraud, deception, misrepresentation, false promise or false pretense. The Appellate Division construed and applied *N.J.S.A.* 45 1-21(b), as well as *N.J.S.A.* 45 12-11(h) and (o), in *In re Shack*, 177 *N.J. Super.* 358 (App Div 1981). The latter two sections prohibited false, fraudulent or misleading advertising of the practice of optometry and any conduct which is of a character likely to deceive or defraud the public. The case involved alleged violations of the foregoing statutes by two optometrists who placed a newspaper ad regarding soft contact lenses.

The court determined that valid analogies may be drawn from those cases construing the "deception" portions of the New Jersey Consumer Fraud Act and the Federal Trade Commission Act. *Id.* at 363. The court quoted the Consumer Fraud Act's definition of an unlawful practice as the "use or employment of any deception [or] misrepresentation ... in connection with the sale or advertisement of any merchandise or real estate . . , whether or not any person has in fact been misled, deceived or damaged thereby." *Ibid.* The criterion by which the advertising was judged was "the likelihood of deception or the capacity to deceive." *Ibid.* A prime element of deception was determined to be the capacity to mislead. *Ibid.*

I agree with the complainant's contentions. Without suggesting that a physician need list possible complications or side effects in his or her advertisements, the unstated possibility of those events occurring means that the unqualified declaration of the availability of "safe" and "painless" abortions had the capacity to mislead a prospective patient. I **FIND** that the advertisements of respondent which are the subject of these charges had the capacity to mislead. However, it is apparent that the respondent believes his advertisements have been truthful, and I **FIND** that he had no intent to deceive or mislead. Nevertheless, I **CONCLUDE** that this conduct violates *N.J.A.C.* 13:35-6.10(c)1, and that the respondent is therefore deemed to have engaged in professional misconduct. I further **CONCLUDE** that this conduct violates *N.J.S.A.* 45:1-21(b) because the advertisements had the capacity to mislead.

The respondent's lack of intent to deceive is significant Equally significant are his earnest efforts to comply with the Board's wishes concerning advertising While his violations of the foregoing regulation and statute constitute grounds for revocation or suspension of his license to practice medicine and surgery in New Jersey pursuant to *N.J.S.A.* 45 1-21(b), (e), and (h), his lack of intent and his good faith efforts to comply compel a less harsh result **I CONCLUDE** that the appropriate resolution of these violations is prospective; the respondent shall not place any advertisements which mislead or have the capacity to mislead, as determined by prior approval from the Board

Alleged Failure to Comply with the Board's Monitoring Order in a Timely Manner.

Complainant has charged Dr Brigham with failure to timely comply with the Interim Order of the State Board of Medical Examiners, announced orally on December 23, 1993, and issued in writing on February 7, 1994, which in part required him to secure the services of a supervisor acceptable to the Board who would review his records and file monthly reports Complainant asserts that the alleged failure to timely comply constitutes professional misconduct and is therefore violative of *N.J.S.A.* 45 1-21(e)

The oral order set forth no time frame for compliance It was the unrefuted and credible testimony of Dr Brigham that he asked Deputy Attorney General Nancy Costello-Miller, counsel for the Board on December 22, 1993, what he needed to do about the monitoring and was told that the Board would be getting in touch with him. Dr. Brigham then heard nothing on the subject for about two months, and not knowing what kind of person the Board would consider for a monitor, he admittedly did not contact anyone about assuming that task during that time. During the last week of February 1994, Dr. Brigham met with his counsel to discuss compliance with the Board's written Order. Since the Order did not describe the necessary monitor credentials, Dr. Brigham surmised that the Board's concern was verification that he was not performing second trimester abortions. Thus, he felt someone from his office would be appropriate, but he also compiled a list of possible monitors which included a variety of outside professionals.

Dr Brigham knew that he would be unable to meet and reach agreement with the people on his list in the eight business days remaining before the next meeting of the Board, so his self-imposed deadline for submitting the list was April 13, 1994, the date of the following Board meeting Most of the many people Dr Brigham approached to become his monitor refused, for a variety of reasons Meanwhile, no one from the Board contacted him before he submitted his first list of seven proposed monitors on April 8, 1994 (Exhibit P-34) Dr Brigham asked that the Board give him guidance if the list, which included Dr A.K., was not acceptable The Board met on April 13, 1994, and it requested a copy of Dr. A K 's curriculum vitae By letter dated April 21, 1994 (Exhibit P-54), counsel for complainant sent counsel for Dr. Brigham the monitoring agreement to be immediately signed and delivered upon the Board advising that Dr A.K. was acceptable On April 25, 1994, counsel for Dr Brigham faxed Dr A.K.'s curriculum vitae to counsel for the Board

On May 2, 1994, counsel for complainant sent counsel for Dr Brigham two revised copies of the monitor agreement (Exhibit P-56), with instruction that they be signed and mailed to the Board's Executive Director immediately Counsel for complainant also stated that Dr. A.K. should be instructed to start the monitoring process By letter dated May 10, 1994 (Exhibit P-57), Dr Brigham submitted the monitor's agreement that he and Dr A K had signed Dr. Brigham testified that he then waited to see if the agreement would be ratified by the Board, or disapproved, but he heard nothing. Notwithstanding that he did not hear back from the Board, Dr. Brigham asked Dr A.K. to begin monitoring. Dr A.K. had two problems which prevented him from beginning immediately. One was his concern about liability, and the other was his wife's illness. Dr. K. was able to and did begin monitoring in June 1994, and issued his first monitoring report on July 15, 1994.

Dr. A.K. testified that he agreed to be respondent's monitor without reservation, and his immediate concern was whether the respondent could sue him if he came out with a harsh criticism. He was also concerned about potential liability if the respondent mishandled a patient. According to Dr. A.K., he tried to discuss these issues with the Attorney General's office, but had trouble getting through to the person to whom he needed to talk. It took about five weeks to have the matter worked out in writing, and then he spent about four weeks taking care of his wife

after she had serious surgery As soon as he was able, he commenced monitoring It was the testimony of Dr. A K that he undertook to check respondent's records and monitor his practice as the eyes and ears of the Board

According to Dr A.K., Dr Brigham was very cooperative and provided complete access, and instructed his staff to do the same. Dr A.K found respondent's equipment to be far above average; his sonography equipment was state of the art and he had a trained sonographer Dr K stated in his monitoring report (Exhibit P-36).

> In my review of the above documents [patient medical records], I found no violations of the Board's order To the contrary, at every point Dr Brigham evidenced good faith in complying with the order Also, during my review of the records, I found no evidence of any violations of New Jersey Law, and no substantial deviations from generally accepted medical standards
>
> I would like to point out that my monitoring of Dr. Brigham has gone far beyond the mere "chart review" mandated by the Board in the agreement I signed. With the full and complete cooperation of both Dr Brigham and his staff, I have conducted a complete inspection of both offices, interviewed and questioned the staffs of both offices, reviewed the practice protocols and procedures currently in existence, checked the medical equipment and emergency supplies, reviewed the back-up arrangements, held extensive discussions with Dr Brigham and other physicians working with him; and I have even personally observed Dr. Brigham as he performed an abortion on a patient. All of this was done with the cooperation and even encouragement of Dr Brigham.
>
> Based upon all of this information, as well as the chart reviews, I would like to inform the Board that I believe Dr Brigham's total practice is within generally accepted standards of care. I also believe that he does not pose a danger to the people of the State of New Jersey
>
> In conclusion, I view my role as the "eyes and ears of the Board." In that capacity, I feel the Board needs to have very little concern over Dr. Brigham. Of course, it is inevitable that complications will occur as with any physician, but this physician's complication rates are very low, and his is currently practicing above the standard of care. Even more important, is that his attitude is one of a willingness to cooperated, to obey the Board's orders, and to improve in any way possible as a physician and as a provider

DISCUSSION

Complainant contends that there was an inordinate delay on respondent's part in securing a monitor. No effort was made to secure a monitor in response to the Board's oral order of December 22, 1993, and complainant asserts that respondent should have begun efforts to find a supervisor in anticipation of the anticipated written order. Even though the written order was filed on February 7, 1994, the monitor's first report was not issued until July 15, 1994. Complainant contends that this delay constitutes professional misconduct, in violation of *N.J.S.A.* 45:1-21(e).

Respondent first contends that he was advised of no time frame for securing a monitor, and when he specifically inquired of Deputy Attorney General Nancy Costello-Miller, who was then representing the Board, he was told the Board would be getting in touch with him. Second, respondent contends that after he submitted the monitor agreement he and Dr. A.K. had signed in May 1994, he never heard back from the Board as to whether it had approved or disapproved the agreement. He nevertheless was able to have Dr. A.K. begin the monitoring within a month of submitting the agreement, and the first report was timely issued on July 15, 1994. It is respondent's contention that he proceeded in good faith, without guidance or instruction from the Board, to timely obtain a monitor. He did obtain a monitor and has cooperated fully with the monitoring. Respondent argues that the charge of professional misconduct should be dismissed.

I agree with the respondent that this charge of professional misconduct should be dismissed. Professional misconduct has not been specifically defined in the statutes or regulations governing the medical profession but has been addressed to some extent in the case law. The courts have rejected the argument that unprofessional conduct is punishable only if specifically proscribed by statute or regulation. *In re Polk License Revocation*, 90 *N.J.* 550 (1982); *In re Suspension of Heller*, 73 *N.J.* 292 (1977)[1]

The physician in *Polk* sexually abused an adolescent patient under the guise of treatment which the Court found constituted gross malpractice. *Polk, supra*, 90 *N.J.* at 574. In rejecting

[1] Even though *Heller* dealt with "grossly unprofessional conduct" its analysis is instructive. The Court found that a pharmacist's indiscriminate sale of codeine-based cough syrup, a controlled dangerous substance, constituted "grossly unprofessional conduct."

the physician's claim that the statutory standards were vague, both as written and in their application to his conduct, the Court, revisiting *Heller*, stated that

> [i]t has never been necessary for the Legislature to define with particularity acts which would constitute unprofessional conduct, and since it would be impracticable for the Legislature to catalogue and specify every act or course of conduct that would constitute such offenses as "bad moral character" and "unprofessional and dishonorable conduct," a doctor's license could also be revoked for having committed a nonspecifically enumerated act of unprofessional conduct
>
> [*Ibid.* (citations omitted)]

In other words, even though a statute or regulation may enumerate certain acts and classify same as unprofessional conduct, the Legislature "*did not thereby intend to exclude all other acts or conduct in the practice of the healing arts which by common understanding render the holder of a license unfit to practice*." *Heller, supra*, 73 *N.J.* at 299 (quoting *Kansas State Bd. of Healing Arts v. Foote*, 200 *Kan.* 447, 436 *P.*2d 828 (Sup. Ct. 1968))(emphasis in *Heller*)

For example, *Heller* pointed to a case where a doctor's license was revoked for his having participated in a scheme to sell medical licenses. *Heller, supra*, 73 *N.J.* at 300 (citing *State ex rel. Lentine v. State Bd. of Health*, 334 *Mo.* 220, 65 *S.W.* 2d 943 (Sup. Ct. 1933)). Though not specifically enumerated in the relevant statute, the conduct was deemed unprofessional. *Ibid.* The Court determined that the "need for special identification does not exist in respect to conduct inherently wrong and obviously 'unprofessional'." *Id.* at 306; *see also, In re Suspension of License of Silberman*, 169 *N.J. Super.* 243, 253 (App. Div. 1979) (where court found that evidence established that podiatrist who billed for services which were not performed and performed services which were neither required or requested, engaged in unprofessional conduct).

It appears that a common sense approach should dictate any determination as to what constitutes unprofessional conduct. It is also apparent that the conduct need not be specifically related to medical treatment or diagnosis. Had Dr. Brigham purposefully ignored the Board's order to obtain a monitor, with no intention of complying, I believe such defiance would be

inherently wrong and obviously unprofessional However, that is not what happened Dr. Brigham appropriately inquired as to what was expected of him and was told by counsel for the Board that he would be told He heard nothing until he received the written order He in good faith expended considerable effort finding people willing to serve as an abortion practitioner's monitor Eventually Dr A.K. agreed, and he began monitoring as soon as he was able.

I **FIND** that Dr Brigham intended to proceed expeditiously and in good faith to timely comply with the Interim Order of the State Board of Medical Examiners, announced orally on December 23, 1993, and issued in writing on February 7, 1994, which in part required him to secure the services of a supervisor acceptable to the Board who would review his records and file monthly reports I further **FIND** that Dr. Brigham's conduct concerning compliance with the Interim Order did not constitute professional misconduct. Thus, I **CONCLUDE** that respondent's conduct did not constitute grounds pursuant to *N.J.S.A.* 45 1-21(e) for the suspension or revocation of his license to practice medicine and surgery in this State

Motion to Impose Sanctions Based on the New York Revocation, pursuant to N.J.S.A. 45:1-21(g) (Third Complaint)

As noted above, the complainant filed another complaint with the Board ("Third Complaint") on December 2, 1994, also seeking sanctions against the respondent, based upon the allegation that the respondent's license to practice medicine in the State of New York had been revoked by the New York State Department of Health Administrative Review Board for Professional Medical Conduct. By Order effective December 14, 1994, the Board accepted respondent's offer to cease practicing in New Jersey and declined to then impose revocation of respondent's license based on New York's action, pending the New Jersey administrative law proceeding. On March 9, 1995, the New Jersey Board transmitted this third complaint to the Office of Administrative Law for determination as a contested case. The complainant moved for consolidation with the earlier matters and also moved for partial summary decision and other relief. The respondent opposed the application and by cross-motion sought an order to dismiss the latest complaint. The motion for consolidation was granted on the record on May 26, 1995,

pursuant to *N.J.A.C.* 1:1-17.3. However, ruling on the remainder of the motions was deferred until completion of the evidentiary record, based on the Board's ruling of December 14, 1994.

Complainant asserts that the New York decision and order finding respondent to have engaged in gross and repeated acts of negligence resulting in direct and substantial patient harm should be adopted here as expressly permitted by *N.J.S.A.* 45:1-21(g). Complainant further asserts that the New York decision and order should form the basis for a disciplinary sanction regarding patients M.B. and A.W., since the New York authorities took final action against Dr. Brigham's license there based on his treatment of those two patients.

N.J.S.A. 45:1-21 provides:

> A board . . . may suspend or revoke any . . . license issued by the board upon proof that the . . . holder of such . . . license . . .
>
> * * *
>
> c. Has engaged in gross negligence, gross malpractice or gross incompetence,
>
> d. Has engaged in repeated acts of negligence, malpractice or incompetence;
>
> * * *
>
> g. Has had his authority to engage in the activity regulated by the board revoked or suspended by any other state or authority for reasons consistent with this section;
>
> * * *

It is the complainant's contention that the facts and conclusions set forth in the New York final order amply establish that in his care of patients M.B. and A.W., respondent engaged in gross negligence and negligence on repeated occasions. The revocation in New York is thus for reasons consistent with the grounds for revocation stated in *N.J.S.A.* 45:1-21(c) and (d). Therefore, the Board may take disciplinary action against respondent under *N.J.S.A.* 45:1-21(g), based solely upon the revocation in New York. *Matter of Cole*, 194 *N.J. Super.* 237 (App. Div. 1984).

Respondent objects to application of *N.J.S.A.* 45:1-21(g), or collateral estoppel, and urges that the third complaint be dismissed. He has recited at length the procedural history of the complaints and proceedings against him, and argues that it is clear the Board has elected to

exercise independent judgment in determining the facts for itself, rather than relying on the New York proceeding

In particular, when the question of the New York revocation was directly before the Board on December 14, 1994, the Board declined to make any determination upon the Complainant's application to impose discipline based on the New York action, instead accepting Dr Brigham's offer to cease practicing medicine and surgery in New Jersey until the Board has had the opportunity, after review of the record, to accept, reject, or modify the initial decision of the administrative law judge and issue its own final order in this matter. Respondent notes that the obvious result of the Board's action in December 1994 was a full adjudication in this proceeding of the allegations concerning the two patients who were also the subject of the New York proceeding Having allowed the adjudication on the allegations concerning M.B. and A.W to continue to completion, it would be inequitable and fundamentally unfair for the Board to now foreclose consideration of those proofs and instead sanction respondent based upon New York's determination

I agree with the respondent While the New York revocation is for reasons consistent with *N.J.S.A.* 45:1-21(c) and (d), application of *N.J.S.A.* 45 1-21(g) in this matter would be both unfair and anomalous Unlike *Matter of Cole, supra*, the issues concerning M.B and A.W have been fully litigated here There will be no savings of time or expense available by relying on the New York result More important, however, is the result itself. With regard to the allegations concerning patients M.B. and A.W., the complainant here failed to meet her burden of persuasion. It would be grossly unfair to nevertheless sanction respondent in New Jersey because the New York forum reached a different conclusion. An administrative agency, in determining how best to effectuate public policy, must apply principles of fundamental fairness. *State Dept. of Envir. Protection v. Stavola*, 103 *N.J.* 425, 436 n.2 (1986); *In re Arndt*, 67 *N.J.* 432 (1975). Accordingly, I **CONCLUDE** that the complainant's motion for partial summary decision or collateral estoppel should be denied, and the respondent's cross-motion for dismissal of the third complaint should be granted.

SUMMARY

As fully described above, complainant has sustained her burden of persuasion as to the allegations remaining in Count X of the Amended Complaint and Count III of the Second Complaint, which concern misleading advertising Respondent shall not place any advertisements which mislead or have the capacity to mislead, as determined by prior approval of the Board.

All other allegations of violations of the laws and regulations of New Jersey should be dismissed, for the reasons stated above. In short, the evidence against the respondent is insufficient to stand as a basis to bar Dr Brigham from performing first trimester abortion procedures in New Jersey. Respondent voluntarily ceased practice in New Jersey in December 1994. He should now be permitted to resume practice, in accordance with all applicable laws and regulations

It is so **ORDERED.**

I hereby **FILE** my initial decision with the **BOARD OF MEDICAL EXAMINERS** for consideration

This recommended decision may be adopted, modified or rejected by the **BOARD OF MEDICAL EXAMINERS**, which by law is authorized to make a final decision in this matter. If the Board of Medical Examiners does not adopt, modify or reject this decision within forty-five (45) days and unless such time limit is otherwise extended, this recommended decision shall become a final decision in accordance with *N.J.S.A.* 52:14B-10.

Within thirteen (13) days from the date on which this recommended decision was mailed to the parties, any party may file written exceptions with the **EXECUTIVE DIRECTOR OF THE BOARD OF MEDICAL EXAMINERS, 140 East Front Street, 2nd Floor, Trenton, New Jersey 08608**, marked "Attention Exceptions" A copy of any exceptions must be sent to the judge and to the other parties

April 12, 1996
DATE

Joseph F Fidler
JOSEPH F. FIDLER, ALJ

Receipt Acknowledged.

4-12-96
DATE

Darlene Stein
BOARD OF MEDICAL EXAMINERS

Mailed To Parties

APR 17 1996
DATE

Barbara A Harned
OFFICE OF ADMINISTRATIVE LAW

LIST OF EXHIBITS

For Petitioner

P-1 J.K.'s medical records from the American Women's Center and Robert Wood Johnson Hospital

P-2 Respondent's letter to Peterson regarding J.K.

P-3 Lynette Zielke's Affidavit (pages 1-3, only)

P-4 &

P-5 A.W.'s medical records from Flushing Gynecology Center and Elmhurst Hospital Center

P-6 S.C.'s medical records from American Women's Center

P-7 B.A.'s medical records from the American Women's Center

P-8 T.F.'s medical records from American Women's Center

P-9 T.F.'s medical records from the Metropolitan Medical Associates

P-10 M.B.'s records without intraoperative or postoperative vital signs monitoring

P-11 C.E.'s records without intraoperative or postoperative vital signs monitoring

P-12 L.R.'s records without intraoperative or postoperative vital signs monitoring

P-13 M.A. records without intraoperative or postoperative vital signs monitoring

P-14 Advertising published by respondent in 1992 NJ Bell

P-15 Advertising published by respondent in 1994-1995 Phillipsburg, New Jersey

P-16 Advertising published by respondent in 1994-1995 Easton Pennsylvania

P-17 Advertising published by respondent in 1993-1994 Phillipsburg

P-18 Not in evidence

P-19 June 6, 1994, letter from respondent

P-20 Not in evidence

P-21 Interim Order, New Jersey Board of Medical Examiners

P-22 M.B.'s patient records including American Women's Center (pp. 3-29), Prehospital care reports (pp. 41-43) and Nyack Hospital (pp. 30-39 and 44-173)

P-23 Originals prehospital care report -- Rockland Paramedics -- M.B.

P-24 D.V.'s medical reports for American Women's Center

P-25 D.V.'s medical records for Metropolitan Medical Associates

P-26 D.V.'s medical records Medical Center of Ocean County

P-27 Not in evidence

P-28 Not in evidence

P-29 Not in evidence

P-30 C.V. Dr. Kotopoulos

P-31 Investigative Report page 6, paragraph 1, regarding B.A.

P-32 C.V., Dr. Hollander

P-33 Y.B.'s patient record

P-34 Respondent's April 28, 1994 letter

P-35 Respondent's May 10, 1994 letter with signed monitor's report

P-36 First Monitor's report of July 15, 1994

P-27 to

P-46 Medical instructions for performing abortion

P-47 Laminaria

P-48 Dilapan

P-49 Not in evidence

P-50 Not in evidence

P-51 New Jersey Bell Ad. Suburban Essex Directory of November 1993

P-52 New Jersey Bell Ad, Suburban Essex Directory of October 1993

P-53 Not in evidence

P-54 April 21, 1994 letter from Deputy Attorney General to Dembin

P-55 April 29, 1994 Fax of C.V. to Dr. Jacobs

P-56 May 2, 1994 letter by Deputy Attorney General to Dembin

P-57 Certification from Executive Director regarding monitors agreement with respondent's May 10, 1994 letter

P-58 Not in evidence

P-59 D.V.'s transcript

P-60 Memo to Deputy Attorney General with attached monitor list

P-61 Not in evidence

P-62 Not in evidence

P-63 Order for Access to Premises and for Impoundment of Evidence dated September 24, 1993

P-64 Not in evidence

P-65 Letter to Deputy Attorney General from Laurie Lowstein concerning Medicaid providers

P-66 Dr. Hollander's rebuttal opinion letter dated July 4, 1995

For respondent.

R-1 Not in evidence

R-2 Recovery room records for L.R

R-3 Letter from Kearny dated November 30, 1993

R-4 Affidavit of Kearny dated July 12, 1994

R-5 Yellow Pages ads

R-6 Pratt Dilator

R-7 Dr. Policar's C.V.

R-8 December 1993 affidavit of Dr. Policar

R-9 July 1994 affidavit of Dr. Policar

R-10 Forceps as used for A.W. procedure, McMahon or modified Hern

R-11 Ultrasound sonograms

R-12 Not in evidence

R-13 B.A.'s affidavit, dated December 6, 1993

R-14 S.C.'s affidavit, dated December 2, 1993

R-15 Affidavit of Kenneth Mallory, USAF, concerning S.C.

R-16 Recovery room log (copy) from All Women's, concerning B.A.

R-17 B.A.'s patient record from New York (copy)

R-18 J.K.'s New York records

R-19 N.Y. City Yellow Pages ads for abortions up to 24 weeks

R-20 Dr. Dengelegi letter dated July 4, 1993

R-21 Dr. Weiner's affidavit dated March 3, 1993

R-22 C.V. of Dr. Binder

R-23 M.A.'s recovery room record dated February 18, 1993

R-24 Not in evidence

R-25 Phone message record regarding D V. dated August 20, 1993

R-26 Dr Knorr-Dr. Brigham backup agreement, dated October 22, 1993

R-27 Spring Hill Ambulance Transfer Acceptance agreement dated October 18, 1993

R-28 Dr Rosenzweig backup agreement, dated February 18, 1993

R-29 Larsen/Kennedy Memorial Service agreement (undated)

R-30 Stat Medical Transport Service agreement, dated March 3, 1993

R-31 Iron Mountain letter to Navarrra, dated December 17, 1993

R-32 S.C. letter dated December 7, 1993

R-33 Planned Parenthood letter dated February 4, 1993

R-34 Dr. Daniel Holschauer letter of reference dated July 11, 1993

R-35 Patient affidavits concerning Englewood Clinic competition

R-36 Dr Charles Debrovner's peer review opinion dated July 2, 1993, regarding A.W

R-37 Dr. Debrovner's C.V

R-38 Dr. Thomas D Kerenyi's opinion on A.W dated July 13, 1993

R-39 Not in evidence

R-40 Dr Anthony Vintzileos' opinion regarding D V 's sonogram, dated July 26, 1994

R-41 Dr. Vintzileos's C.V

R-42 C.E.'s recovery room record

R-43 M.B 's recovery room record

R-44 S.C 's recovery room record

R-45 D V. child birth record, Medical Center of Ocean County

R-46 Chart folder for M.B.

R-47 Flexible dilator

R-48 Flexible cannula

R-49 Flexible cannula

R-50 EKG Datascope readout example

R-51 Not in evidence

R-52 Dr. Titkun character reference

R-53 Dr. Campana character reference

R-54 National Abortion Federation continuing education certifications

R-55 Fetal foot length charts

R-56 Monitoring report

R-57 Dr Stubblefield's affidavit

R-58 Letter from Board dated January 12, 1993

R-59 Response letter to Executive Director dated January 13, 1993

R-60 Dr. Burnhill's C V

R-61 Affidavit of Dr Burnhill

R-62 "86" French Hern dilator

R-63 Hern Forceps, as used for M.B procedure

R-64 Not in evidence

R-65 Affidavit of Mary Peterson

R-66 Affidavit of Benedict Riccardi

R-67 Dr Burnhill's surrebuttal letter dated July 12, 1995

R-68 Dr Fogel's surrebuttal letter dated July 31, 1995

WITNESSES

For Petitioner:

Lynette Zielke

Ellen M. Stott

B. B.

M. B.

Mary Peterson

Deborah Zuccarelli

John J. White

Jeffrey Rabrich

T. F.

Nicholas Kotopolous, M.D.

David Hollander, M.D.

Benedict Riccardi

Keith Hummel

EXHIBIT 4

PAULA T. DOW
ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street
P.O. Box 45029
Newark, New Jersey 07101

By: David M. Puteska
Deputy Attorney General
Tel. (973) 648-2972

FILED

September 10, 2010

NEW JERSEY STATE BOARD
OF MEDICAL EXAMINERS

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF

STEVEN C. BRIGHAM, M.D.
LICENSE NO. MA05106800

TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY

Administrative Action

CEASE AND DESIST ORDER

This matter was opened to the State Board of Medical Examiners (the "Board") on September 8, 2010 by the Paula T. Dow, Attorney General of the State of New Jersey upon the filing of an order to show cause, verified complaint and supporting documents. The verified complaint alleges that Steven C. Brigham, M.D. ("Respondent") has engaged in various violations of the statutes governing the lawful practice of medicine in the State of New Jersey, N.J.S.A. 45:9-1, et seq. and/or the related administrative regulations. The return date of the order to show cause, which seeks the temporary suspension of Respondent's license to practice medicine and surgery in New Jersey, is September 15, 2010.

CERTIFIED TRUE COPY

Respondent denies the conduct as alleged in the verified complaint but has requested, without admissions, additional time to prepare his defense, and in exchange has agreed to voluntarily cease and desist from the practice of medicine and surgery in New Jersey until the Attorney General's application is considered by the Board at its regularly scheduled meeting on October 13, 2010 or other date mutually agreed to between the parties or ordered by the Board.

The Board finding the within disposition adequately protective of the public health, safety and welfare, and other good cause having been shown,

IT IS, therefore, on this 10TH day of September, 2010,

ORDERED THAT:

1. Effective on September 16, 2010, Respondent, Steven C. Brigham, M.D., shall cease and desist from the practice of medicine and surgery in the State of New Jersey. This cease and desist order shall continue until the Board's consideration of the Attorney General's temporary suspension application.

2. This Order shall not be construed as an admission of any liability by Respondent and shall not constitute a disciplinary action against Respondent.

3. Effective September 16, 2010, Respondent shall also cease and desist from prescribing and/or dispensing any and all medications until further order of the Board.

4. Respondent shall file his answer to the verified complaint upon the Board, with a copy to the Attorney General, on or before September 23, 2010.

5. If the Attorney General files a brief in support of her application for temporary

suspension Respondent shall have a minium of five (5) business days to file his response.

NEW JERSEY STATE BOARD OF
MEDICAL EXAMINERS

By: _____
Paul T. Jordan, M.D.
President

I have read and understand
the above Order and I agree
to abide by its terms.

_____
Steven C. Brigham, M.D.

Consented to as to form:

Brach Eichler, L.L.C.
Attorney for Dr. Brigham

By: _____
Joseph M. Gorrell, Esq.

EXHIBIT 5

IN THE MATTER OF	*	**BEFORE THE**
STEVEN CHASE BRIGHAM, M.D.	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
Unlicensed	*	**Case Numbers: 2007-0448, 2010-0304.**
	*	**& 2011-0117**

* * * * * * * * * * * * *

CEASE AND DESIST ORDER

Pursuant to the authority granted to the Board under Md. Health Occ. Ann §14-206 (e), the Maryland State Board of Physicians (the "Board") hereby orders Steven Chase Brigham, M.D.,(the "Respondent") (D.O.B.08/29/1956), a physician unlicensed in Maryland to immediately **Cease and Desist** from practicing medicine in Maryland without a license.

Based upon the investigative information received by the Board thus far, the Board has probable cause to believe that the following facts are true:

1. The Respondent is not and has never been licensed to practice medicine in Maryland.
2. The Respondent has performed surgical procedures in Elkton, Maryland on a regular basis, performing two to three procedures on each visit during each of approximately two visits per week for at least several months prior to the date of this Order.
3. On August 13, 2010, the Respondent initiated a procedure, which then had to be completed on an urgent basis. The Respondent then followed the patient in an automobile as the patient, under his instructions, traveled to Elkton, Maryland for the completion of the procedure. In Elkton, Maryland, the patient was admitted, as planned, to a clinic owned by the Respondent for the completion of the procedure. The Respondent directed the surgical procedure that took place at his clinic on that date.
4. As recently as Friday, August 20, 2010, the Respondent arranged for and attempted to assist in surgical procedures at Elkton, Maryland.

5. The Respondent has been observed performing surgical procedures on approximately 50 occasions in Maryland at the Elkton location since January 2010.

The health of Maryland patients is being endangered by the Respondent's unlicensed practice of medicine in this State. The Board's investigation into the matter is ongoing.

CONCLUSIONS OF LAW

The practice of surgery, the assisting in or direction of the practice of surgery by another, and the initiation of a procedure which then must be completed on an urgent basis by medical treatment in this State planned and participated in by the initiator of the procedure, constitutes the practice of medicine in Maryland. The Respondent's apparent practicing of medicine without a license in Maryland to the detriment of Maryland patients justifies and requires the Board to exercise its powers under Md. Health Occ. Code Ann ("H.O.") §14-206 (e) to issue a Cease and Desist Order to the Respondent.

ORDER

Based on the foregoing, it is this 25th day of August, 2010, by a majority of the quorum of the Board:

ORDERED that pursuant to the authority vested by Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann ("H.O.") § 14-206 (e), the Respondent shall **IMMEDIATELY CEASE and DESIST** practicing medicine without a license at American Women's Services located at 3506 N. Calvert Street, Suite 110, Baltimore, MD 21218; 6005 Landover Road, Suite 6, Cheverly, MD 20785; 801 Toll House Avenue, H-6, Frederick, MD 21201; 4700 Berwyn House Road, College Park, MD; 126 East High Street, Elkton, MD 21921; and any other Maryland locations. This prohibition includes but is not limited to performing any surgical procedure in Maryland, initiating procedures that then must be completed on an urgent basis by

medical treatment in Maryland planned and participated in by the initiator of the procedure, and assisting in the provision of any surgical procedure in Maryland by providing direction or assistance during the procedure to any physician performing a procedure in Maryland. And it is further

ORDERED that this is a public document pursuant to Md. State Gov't Code Ann. § 10-611 *et seq.*

25 August 2010
Date

P. T. Elder MD
Paul T. Elder, M.D.
Board Chair

NOTICE

This Order is effective when issued. If the Respondent either challenges this Order or violates it, the matter is adjudicated according to the procedures in the Board's regulations at COMAR 10.32.02.03. See COMAR 10.32.02.09

EXHIBIT 6

STEVEN C. BRIGHAM, M.D.	*	
Respondent	*	
MARYLAND STATE BOARD OF PHYSICIANS	*	
	*	**Case No: 2011-0117**

* *

NOTICE OF APPEAL
REQUEST FOR CASE RESOLUTION CONFERENCE AND HEARING

The Respondent, Steven C. Brigham, M.D., hereby appeals the Cease and Desist Order issued in the above captioned case and for the reasons set forth herein requests that it be rescinded or modified.

Contrary to the factual allegations in the Cease and Desist Order, the Respondent does not independently practice medicine in the State of Maryland. Rather, pursuant to Section 14-302 of the Health Occupations Article, Dr. Brigham was expressly authorized to "practice medicine without a license" . . . "while engaging in consultation with a physician licensed in this State." The Respondent is a well educated and highly trained physician. He is especially skilled in gynecology and difficult and challenging abortion procedures. His abilities and expertise in this area are acutely needed by both doctors and patients facing, often desperately, the need for procedures in this area. The Respondent denies that he has improperly and independently performed any surgical procedures prohibited by law in this state.

Additionally, Petitioner contests the Conclusions of Law in the Cease and Desist Order, which stated that his action constituted the unauthorized practice of medicine in Maryland and that his actions were detrimental or illegal.

The Respondent also contests the terms the Order. This Order is both unsupported by applicable law or reference to any stated allegations that support prohibiting a licensed physician from performing surgical procedures or assisting in the provision of any surgical procedures to the extent such activities are authorized by Section 14-302(2) of the Health Occupations Article. The Order, at a minimum, must allow the Respondent to continue providing demonstrations, training and assistance to Maryland doctors who seek his expertise and guidance.

WHEREFORE, the Respondent requests a Case Resolution Conference, as provided by COMAR 10.32.02.03, and, if not then resolved, a hearing to contest the terms and restrictions of this Cease and Desist Order, including the restriction on the right to continue to practice medicine in the state as permitted under Section 14-302(2).

Respectfully submitted,

Ober, Kaler, Grimes & Shriver

Marc K. Cohen
Kevin A. Dunne
120 E. Baltimore Street
Baltimore, Maryland 21202
410-685-1120
410-547-0699 (fax)

EXHIBIT 7

Kotopolous Direct

OFFICE OF ADMINISTRATIVE LAW
OAL DOCKET NO. BDSME 1301-94
DIVISION OF CONSUMER AFFAIRS
BOARD OF MEDICAL EXAMINERS

IN THE MATTER OF THE SUSPENSION OR REVOCATIO OF THE LICENSE OF

STEVEN C. BRIGHAM, M.D.
LICENSE NO. 51068

TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY

Transcript of Trial

November 17, 1994

BEFORE:

THE HONORABLE JOSEPH F. FIDLER, A.L.J.

APPEARANCES:

NATHAN L. DEMBIN ASSOCIATES,
Attorney for Steven Brigham, M.D.,
BY: NATHAN L. DEMBIN, ESQ.

ATTORNEY GENERAL'S OFFICE
Attorney for the State,
BY: LINDA S. ERSHOW-LEVENBERG, DAG.

FRIIS ASSOCIATES
Certified Shorthand Reporters
P.O. Box 84
WOODBRIDGE, NEW JERSEY 07095
(908) 548-2222

giving up their time, and this may well arise some time during respondent's case. I don't know. But I'm doing my best to try to get this case moved along, and I recognize the problems both parties have of the consequences of unexpected delays and other problems. I don't find that a problem in front of me to make a ruling on, but I'm just telling you that it's a concern I take seriously.

Is there anything else we need to talk about before we take a short break?

MS. ERSHOW-LEVENBERG: No.

MR. DEMBIN: No.

JUDGE FIDLER: Off the record.

(Short recess was taken.)

JUDGE FIDLER: Ms. Ershow-Levenberg, are ready to resume?

MS. ERSHOW-LEVENBERG: Yes, Your Honor.

JUDGE FIDLER: Please go ahead.

MS. ERSHOW-LEVENBERG: Your Honor, at this time I would call my next witness, Nicholas Kotopoulos, M.D.

JUDGE FIDLER: Please remain standing for the oath.

Swear in the witness, please.

N I C H O L A S K O T O P O U L O S, having

been duly sworn by the Officer, testified as follows:

DIRECT EXAMINATION BY MS. ERSHOW-LEVENBERG:

JUDGE FIDLER: Please have a seat.

Would you state your full name and spell your last name, please?

THE WITNESS: Nicholas Kotopoulos, K-o-t-o-p-o-u-l-o-s.

JUDGE FIDLER: Thank you.

Ms. Ershow-Levenberg?

Q Dr. Kotopoulos, where are you presently practicing medicine?

A In Englewood, New Jersey.

Q At what location?

A 400 Eagle Street.

Q Is there a name for your practice?

A Metropolitan Medical Associates. And also at 70 Grand Ave nue. That is my private office.

Q Where did you receive your education?

A I finished medical school in Athens, Greece. I had residency for one year and was elected to educate the new officers of the Medical Corps of the Greek Army. Then I came to the United States. It was in 1971. I had one year internship pertaining mainly to pediatrics and four years

actual technique used to remove it, or are those differences pertaining to the overall medical management?

A Overall medical management.

Q Are there any differences in the technique that's used to perform that procedure as compared to a procedure where it's not a demised fetus?

A The procedure is similar.

Q In your opinion, does the removal of a demised fetus from a patient constitute an abortion or not?

A It's an abortion.

Q And what's the basis for that opinion?

A That pregnancy is defined that the uterus is impregnated by a fetus, and unless the fetus or whatever is in the uterus is removed from this uterus, the uterus is still impregnated with that fetus and it's still a pregnancy. Termination of pregnancy is only when the uterus is evacuated from its contents.

MR. DEMBIN: I was going to request whether that's a legal definition or medical, but I think his response is referring to his medical opinion.

JUDGE FIDLER: Is that correct?

THE WITNESS: I don't know, Judge. You have to give me the two again. I don't know what Mr. Dembin is referring what is the legal definition and what is the medical definition.

JUDGE FIDLER: What is the basis of your opinion?

THE WITNESS: It's the medical definition. I'm not familiar with the legal system, Judge.

Q Where can a patient obtain a second trimester abortion in New Jersey?

A In various outpatient facilities and in various hospitals.

Q What about medicaid patients?

A That applies to medicaid patients, too.

Q Is there a shortage, in your opinion, of qualified physicians to perform abortions in New Jersey?

A No. Absolutely not.

Q And what's the basis for your saying that?

A I can mention like offhand so many clinics that they cover, geographically cover, and hospitals that cover this area of care that I'm

C E R T I F I C A T E

I, KELLY A. MC ARDLE, a Notary Public and Certified Shorthand Reporter of the State of New Jersey, do hereby certify that the foregoing is a true and accurate transcript of the testimony was taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employ nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

KELLY A. MC ~~ARDLE,~~ C.S.R.
Certified Shorthand Reporter

EXHIBIT 8

Google maps

Directions to 126 E High St, Elkton, MD 21921
53.7 mi – about **1 hour 6 mins**

Super Suppers Cherry Hill-Vorhees
1 Alpha Ave, Echelon, NJ 08043

	1. Head **north** on **Alpha Ave** toward **W Evesham Rd**	go 144 ft total 144 ft
	2. Take the 1st **left** onto **W Evesham Rd** About 2 mins	go 0.9 mi total 1.0 mi
	3. Turn **right** at **White Horse Pike** About 2 mins	go 1.5 mi total 2.5 mi
	4. Turn **right** at **Copley Rd**	go 0.1 mi total 2.7 mi
295	5. Turn **left** to merge onto **I-295 S** About 3 mins	go 2.7 mi total 5.4 mi
	6. Take the **I-295 S** exit toward **NJ-42 S/Del Memorial Bridge/Atlantic City** About 2 mins	go 1.2 mi total 6.6 mi
295	7. Keep **right** at the fork, follow signs for **I-295 S/Del Mem Br** and merge onto **I-295 S** Partial toll road Entering Delaware About 33 mins	go 31.9 mi total 38.5 mi
95	8. Merge onto **I-95 S** Partial toll road Entering Maryland About 14 mins	go 11.6 mi total 50.2 mi
	9. Take the **MD-279 N** exit toward **Newark Del**	go 151 ft total 50.2 mi
	10. Keep **left** at the fork to continue toward **MD-279 W/Elkton Rd**	go 0.2 mi total 50.4 mi
	11. Take exit **109A** for **MD-279 S** toward **MD-213/Elkton**	go 0.3 mi total 50.7 mi
279	12. Merge onto **MD-279 W/Elkton Rd** About 4 mins	go 2.1 mi total 52.8 mi
	13. Turn **left** at **North St** About 2 mins	go 0.8 mi total 53.6 mi
	14. Turn **left** at **E High St** Destination will be on the right About 1 min	go 0.1 mi total 53.7 mi

126 E High St, Elkton, MD 21921

route.

Map data ©2010 Google

Directions weren't right? Please find your route on maps.google.com and click "Report a problem" at the bottom left.

EXHIBIT 9

Google maps

Directions to 6930 Austin St # 101, Flushing, NY 11375-4222
100 mi – about **1 hour 58 mins** – up to 2 hours 50 mins in traffic

Super Suppers Cherry Hill-Vorhees
1 Alpha Ave, Echelon, NJ 08043

	1. Head **north** on **Alpha Ave** toward **W Evesham Rd**	go 144 ft total 144 ft
	2. Take the 1st **right** onto **W Evesham Rd** About 1 min	go 0.2 mi total 0.2 mi
	3. Take the 3rd **left** onto **Burnt Mill Rd** About 3 mins	go 1.3 mi total 1.5 mi
	4. Turn **left** at **Berlin Rd** About 1 min	go 0.2 mi total 1.7 mi
295	5. Take the ramp onto **I-295 N** About 5 mins	go 4.3 mi total 6.0 mi
73	6. Take exit **36A** to merge onto **NJ-73 S** toward **Berlin** About 1 min	go 0.6 mi total 6.6 mi
	7. Take the ramp to **Turnpike Entrance** Toll road About 1 min	go 0.5 mi total 7.0 mi
	8. Keep **left** at the fork, follow signs for **New York N** and merge onto **New Jersey Turnpike N** Toll road About 27 mins	go 26.3 mi total 33.4 mi
95	9. Continue onto **I-95 N** Toll road About 39 mins	go 38.0 mi total 71.4 mi
278	10. Take exit **13** to merge onto **I-278 E** toward **Goethals Bridge/Verrazano Bridge** Partial toll road Entering New York About 30 mins	go 24.0 mi total 95.4 mi
	11. Take exit **35** toward **I-495 E/48 St**	go 0.2 mi total 95.6 mi
	12. Take exit **35E** toward **I-495 E/Eastern Long Is/Riverhead**	go 0.1 mi total 95.7 mi
	13. Merge onto **Queens Midtown Expressway Lwr Deck En** About 1 min	go 0.5 mi total 96.2 mi
495	14. Merge onto **I-495 E** via the ramp to **Eastern Long Is** About 2 mins	go 1.4 mi total 97.6 mi
	15. Take exit **19** for **NY-25** toward **Woodhaven Blvd/Queens Blvd**	go 0.3 mi total 97.9 mi
	16. Keep **right** at the fork to continue toward **Eliot Ave/Horace Harding Blvd**	go 0.4 mi total 98.3 mi

17.	Keep **left** at the fork, follow signs for **I-495 E/NY-25/Queens Blvd**	go 0.1 mi total 98.5 mi
18.	Keep **right** at the fork to continue toward **Eliot Ave/Horace Harding Blvd** and merge onto **Eliot Ave/Horace Harding Blvd**	go 0.2 mi total 98.6 mi
19.	Turn **right** at **Hwy 25 Service E/New York 25 Service E/Rte 25 Service E/ State 25 Service E/State Hwy 25 Service E/State Route 25 Service E** About 3 mins	go 1.3 mi total 100.0 mi
20.	Turn **right** at **69th Rd**	go 341 ft total 100 mi
21.	Turn **left** at **Austin St** Destination will be on the right	go 33 ft total 100 mi

6930 Austin St # 101, Flushing, NY 11375-4222

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.

Directions weren't right? Please find your route on maps.google.com and click "Report a problem" at the bottom left.

EXHIBIT 10

ATTORNEYS AND COUNSELLORS AT LAW
SAGOT, JENNINGS & SIGMOND
THE PENN MUTUAL TOWERS, 16TH FLOOR
510 WALNUT STREET
INDEPENDENCE SQUARE
PHILADELPHIA, PA 19106-3683

(215) 922-6700
FAX (215) 922-3524
MY PRIVATE NUMBER IS:
Please Respond to NJ Office

THOMAS W. JENNINGS
RICHARD B. SIGMOND▲◇
KENT CPREK
SANFORD G. ROSENTHAL
RICHARD C. McNEILL, JR.◇
STEPHEN J. HOLROYD*
SUSAN A. MURRAY*◇
MAGDELINE D. COLEMAN
LINDA S. FOSSI*
BETH N. FORMAN*
JENNIFER B. LIEBMAN*
NEIL SAGOT
THOMAS H. KOHN◇◇
JACK B. KATZ
ERIC G. MARTTILA
JONATHAN KRINICK
STUART J. PHILLIPS*†
DAVID G. PASCUCCI
PAUL J. STACOM
ILANA BERMAN FELDMAN*
WILLIAM E. DENGLER*
JOHN H. CHO

NEW JERSEY OFFICE
ASHLAND OFFICE CENTER
1 ALPHA AVENUE-SUITE 33
VOORHEES, NJ 08043-1054
(609) 427-0465
FAX (609) 427-9285

COUNSEL TO THE FIRM:
GARY M. LIGHTMAN
2705 N. FRONT STREET
HARRISBURG, PA 17110-1221
(717) 234-0111
FAX (717) 234-8964

EDWARD DAVIS 1893-1987
M. H. GOLDSTEIN 1904-1971

* ALSO NJ BAR
◇ ALSO DC BAR
▲ ALSO NY BAR
◇ ALSO VA BAR
† MANAGING ATTORNEY NJ OFFICE

January 26, 1999

Judith I. Gleason, Executive Director
Department of Law and Public Safety
Division of Consumer Affairs
New Jersey State Board of Medical Examiners
140 East Front Street
Trenton, NJ 08608

RE: Laminaria insertion in the office

Dear Ms. Gleason:

I am writing for clarification from the New Jersey State Board of Medical Examiners regarding its' regulation, N.J.A.C. 13:35-4.2, entitled "Termination of Pregnancy."

I represent a group of physicians who practice in New Jersey, and who, from time to time, will perform second trimester abortion procedures. My client generally uses a "D & E" procedure in which my client inserts laminaria into the patient's cervix in the office, and then one or two days later the abortion procedure is performed either in a hospital or a licensed/approved facility.

My client informs me that laminaria insertion is a simple, 30 second, "in-office" procedure with the patient awake and often not even requiring a local anesthetic. The physician merely grasps a pre-packaged laminaria "stick" and slides it into the patient's cervix. The patient rarely experiences any discomfort, and afterwards the patient sits up, walks out of the exam room, and goes home.

My client further informs me that it is standard practice amongst physicians in New Jersey and in other states to insert laminaria in the office setting. Nurse practitioners often insert laminaria although they cannot perform abortions. My client states that laminaria insertion involves only the cervix, not the uterus, and that it neither kills the fetus nor evacuates the uterus. Hence, laminaria

insertion does not cause, and is not, an abortion. Patients have been known to change their minds after laminaria insertion, and for those patients the laminaria can be removed and the patient will go on to deliver a baby, with no ill effects from the laminaria. Indeed, this is well documented in the literature (please see the enclosed two published papers).

Furthermore, it is well established that laminaria can be, and are, routinely inserted into the cervix for purposes other than abortion. Such "non-abortion" uses of laminaria can arise any time a physician seeks to achieve passive dilation of a patient's cervix. These include insertion of laminaria preparatory to hysteroscopy, prior to uterine biopsy, prior to any transvaginal intrauterine surgery such as for the removal of fibroid tumors, and as an adjunct to achieving cervical dilation in preparation for a full-term vaginal delivery. It is important to note that there is no regulation prohibiting the insertion of laminaria in an office setting for any of these purposes.

For all of the above reasons, my client has always felt that it was perfectly appropriate to insert laminaria in the office and to then perform the abortion in the hospital the next day. My client believes that there is almost no risk whatsoever to the procedure of laminaria insertion (and hence no need for the emergency capabilities of a hospital or a licensed surgical center), as compared with the very real, potentially serious risks associated with a second trimester surgical abortion procedure, for which the requirement of emergency capabilities would be quite appropriate.

My client has become aware, however, that several years ago, a New Jersey licensed physician, Dr. Steve Brigham, was brought up on charges of violating N.J.A.C. 13:35-4.2 before the New Jersey Board, for inserting laminaria in an office setting, prior to performing an abortion. My client further understands that Dr. Brigham was ultimately exonerated on this charge by the unanimous vote of the New Jersey Board. Nevertheless, my client does not want to run afoul of this Board, and has therefore sought my advice and guidance regarding laminaria insertion, and whether or not I was of the opinion that my client could continue this practice of in-office laminaria insertion.

My client is seeking this opinion regarding only the insertion of laminaria in an office. My client is well aware of the Board's restrictions against the actual performance of a second trimester abortion, except in hospitals or licensed surgical centers. It is my client's absolute intention to adhere to these regulations, and that (except in an emergency to save a patient's life) they have no intention to perform any elective second-trimester abortions, except in a hospital or a licensed/approved facility.

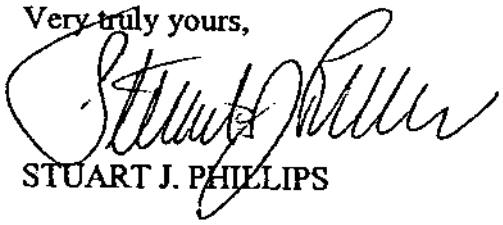
In order to render an opinion for my client, I have reviewed N.J.A.C. 13:35-4.2, some of the documents from the case of Dr. Brigham (including the decision of the Administrative Law Judge and Order of the Board), the enclosed published papers, and I have further discussed this issue at length with my client.

Please kindly take notice that I have advised my client that based upon all of the preceding points, as well as a review of the documents, and the case of Dr. Brigham, it is my professional opinion that insertion of laminaria in the office does not violate N.J.A.C. 13:35-4.2. Therefore, absent any contrary opinion from the Board, I am advising my client that it may continue this practice.

Nevertheless, I am writing to the Board in order to give the Board an opportunity to correct me if it disagrees with my interpretation of this regulation. If you believe I am wrong in this interpretation of N.J.A.C. 13:35-4.2, then I am requesting that the Board please notify me immediately to that effect, and I will quickly counsel my client to immediately cease this practice of inserting laminaria in the office. If I do not hear from the Board one way or another, then I will assume that the Board stands by its findings in the Brigham case, that it agrees with my interpretation of the regulation, and that my client can properly continue this practice.

Thank you very much for your consideration of this letter.

Very truly yours,



STUART J. PHILLIPS

SJP:ri
CERTIFIED MAIL
R.R.R., #Z044 365 155

cc: Regular First Class Mail

bcc: American Medical Services, P.C.

mortality in the United States, epidemiologic surveillance, 1972-1974. JAMA 1977;237:452-5.
5. Grimes DA, Kafrissen ME, Oreilly KR, Binkin NJ. Fatal hemorrhage from legal abortion in the United States. Surg Gynecol Obstet 1983;157:461-6.
6. Grimes DA, Cates W. Complications from legally-induced abortion: a review. Obstet Gynecol Surv 1979;34:177-91.
7. Buehler JW, Schulz KF, Grimes DA, Hogue CJR. The risk of serious complications from induced abortion: do personal characteristics make a difference? AM J OBSTET GYNECOL 1985;155:14-20.
8. Grimes DA, Flock ML, Schulz KF, Cates W Jr. Hysterectomy as treatment for complications of legal abortion. Obstet Gynecol 1984;63:457-62.
9. Grimes DA, Schulz KF, Cates W Jr, Tyler CW Jr. Local versus general anesthesia: which is safer for suction curettage abortion? AM J OBSTET GYNECOL 1979;135:1030.
10. MacKay HT, Schulz KF, Grimes DA. Safety of local versus general anesthesia for second trimester dilatation and evacuation abortion. Obstet Gynecol 1985;66:661-5.
11. Grimes DA, Schulz KF. Morbidity and mortality from second trimester abortions. J Reprod Med 1985;30:505-14.
12. Cates W Jr, Smith JC, Rochat RW, Patterson JE, Dolman A. Assessment of surveillance and vital statistics data for monitoring abortion mortality: United States, 1972-1975. Am J Epidemiol 1978;108:200-6.
13. Kaunitz AM, Hughes JM, Grimes DA, Smith JC, Rochat RW, Kafrissen ME. Causes of maternal mortality in the United States. Obstet Gynecol 1985;65:605-12.

Successful pregnancy outcome after cervical dilation with multiple laminaria tents in preparation for second-trimester elective abortion: A report of two cases

Linda Van Le, M.D., and Philip D. Darney, M.D., M.Sc.
San Francisco, California

Two patients at 22 weeks' gestation underwent extensive cervical dilation with laminaria tents for elective abortion but continued their pregnancies instead. Both had normal deliveries. For the unusual patient who chooses not to carry out an abortion initiated with cervical dilation, successful pregnancy is possible and therapeutic intervention such as cervical cerclage seems inadvisable. (AM J OBSTET GYNECOL 1987; 156:612-3.)

Key words: Abortion, cervical dilation, pregnancy outcome

The decision to terminate a pregnancy is often difficult. The maximum gestational age at which termination is possible is determined by state law and institutional policy but usually does not extend beyond 24 weeks. Laminaria tents have been shown to be safe and effective for cervical dilation preceding second-trimester abortion by instrumental evacuation.[1] Two or three sets of multiple laminaria tents are used to achieve 2 to 3 cm of cervical dilation for abortions beyond 18 weeks' gestation.[2] Occasionally women who have decided to terminate a pregnancy change their minds after multiple laminaria tents have achieved considerable cervical dilation. Risks of infection or spontaneous abortion are unknown but are presumed to be high, perhaps without foundation.

From the Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, and the San Francisco General Hospital.
Received for publication July 29, 1986; accepted September 26, 1986.
Reprint requests: Philip D. Darney, M.D., M.Sc., Department of Obstetrics and Gynecology, San Francisco General Hospital, San Francisco, CA 94110.

Two patients who sought abortions at 22 weeks and subsequently changed their minds were [illegible] up to uneventful delivery. In both cases many [illegible] tents were placed in the cervix and later removed without complications. These two case histories provide some reassurance that normal pregnancy is possible for women who choose not to carry out an elective [illegible] already begun with laminaria insertion.

Case reports

Case 1. M. C., a 23-year-old woman, gravida 4, para 1, elective abortions 2, was a heroin addict with unknown gestational age. She was initially [illegible] desired termination of her pregnancy. [illegible] showed a biparietal diameter consistent with 22 weeks' gestation. Six medium laminaria tents were placed, followed by six additional tents the next day. Metronidazole was given for trichomonal vaginitis; gonorrhea culture was negative. The patient was released from jail and, despite many urgent messages, refused to come to the clinic. Six days later she returned stating that the laminaria tents were expelled on the second. She denied having had passage of fluid from [illegible]

gina; the membranes were intact, and she had no fever or contractions. The temperature was 97.4° F, and the abdomen was nontender. No laminaria tents were seen and the cervix was long and closed. She still desired an abortion but failed to keep her next appointment.

At 37 weeks' gestation, with no prenatal care, she presented in labor and was rapidly delivered of a healthy 2790 gm female infant with Apgar scores of 8 and 8. Labor and the postpartum course were uncomplicated although the patient left against medical advice.

Case 2. B. M., a 27-year-old woman, gravida 6, para 3, spontaneous abortions 2, presented at 22 weeks' gestation with confirmation by sonography. She desired termination of her pregnancy because of the home situation. She had 17 small laminaria tents placed during the course of 2 days, but on the day of her scheduled abortion she requested that the laminaria be removed because she wished to continue the pregnancy. All the laminaria were removed; the membranes were intact. The cervix was 2 cm dilated and soft. There was no bleeding or fever, and sonographic evaluation showed cardiac motion and adequate amniotic fluid. She was given erythromycin, 500 mg three times a day orally for 7 days. The pregnancy continued without complication and at 40 weeks' gestation she was spontaneously delivered of a 3080 gm male infant with Apgar scores of 9 and 9.

Comment

Approximately 30,000 elective abortions requiring laminaria insertion for uterine evacuation were performed in 1981 according to the Centers for Disease Control. An unknown but probably very small proportion of these women (in our experience about one in 500) decide not to carry out the abortion after the laminaria tents have already been placed. The assumption has been that these pregnancies were in jeopardy because of a high risk of amnionitis and spontaneous abortion. There are, however, no data to support these negative assumptions or to guide clinicians regarding the treatment of patients who ask to have laminaria tents removed from the cervix. These two cases demonstrate that an adverse outcome is not inevitable.

Safe, rapid uterine evacuation for elective abortion in the latter second trimester requires 2 to 3 cm of cervical dilation. Since multiple laminaria tents remained in the cervix for 3 days in one case and 2 days in the other, this degree of dilation was achieved. A comparable spontaneous cervical change at 22 weeks in a desired pregnancy would be worrisome, but in both patients the cervix returned to normal within 1 week. Placement of a cervical cerclage would have been unwise. Prenatal care is especially important for these ambivalent patients. One patient sought care but the other did not.

Patients who decide not to end a pregnancy after having laminaria tents placed may be at higher risk for preterm labor and infection, but these did not occur in the two patients described here. Such vacillation about a critically important decision is fortunately a rare occurrence; after counseling the vast majority of women are firm in their decision to continue or not to continue a pregnancy and follow through accordingly. For the women who change their minds about abortion, removal of laminaria tents, consideration of antibiotic treatment, and referral for prenatal care seems the best course. Management should be expectant, and patients should receive documented warnings about the possibility of amnionitis and premature labor.

REFERENCES

1. Schulz KF, Grimes DA, Carter W Jr. Measures to prevent cervical injury during suction curettage abortion. Lancet 1983;1:182.
2. Hern W. Serial multiple laminaria and adjunctive urea in late outpatient dilatation and evacuation abortion. Obstet Gynecol 1984;63:543.

Outcome of Continued Pregnancies After First- and Second-Trimester Cervical Dilatation by Laminaria Tents

D. SCHNEIDER, MD, A. GOLAN, MD, R. LANGER, MD, E. CASPI, MD, AND I. BUKOVSKY, MD

In 21 pregnant women (seven in the first trimester and 14 in the second trimester), laminaria tents inserted for induction of elective abortion were removed after dilatation had been achieved, but upon the patient's request, the abortion was not carried out. Four patients again changed their minds and had uncomplicated induced abortion after reinsertion of the laminaria tents. Seventeen patients continued their pregnancies: Fourteen had term deliveries, two had premature deliveries, and one had a spontaneous abortion at 10 weeks' gestation, 2 weeks after laminaria removal. None of the patients suffered infectious morbidity, including three untreated patients with positive cervical cultures for chlamydia, who experienced normal pregnancies and deliveries. *Obstet Gynecol 78:1121, 1991)*

Patients scheduled for induction of abortion often change their minds and do not proceed. However, reconsideration after successful dilatation of the cervix by laminaria is uncommon. The frequency of this is unknown and the outcome of such pregnancies is rarely documented, with only one report of two cases published to date.[1] We report 21 such patients who elected to reconsider the fate of their pregnancies and had the laminaria tents removed after completion of ripening and dilatation of the uterine cervix.

Materials and Methods

During the years 1978–1990, 1325 early (6–13 weeks) and 515 late (14–18 weeks) elective induced abortions were performed at our medical center using laminaria cervical dilatation and suction. Before late abortion, all patients had biparietal diameter measurements by ultrasound to confirm the gestational age. Confirmation of the gestational age became mandatory for early abortions from 1986; this was determined by crown-rump length measurements. One *Laminaria japonica* was used for all the early terminations, whereas two or three were usually used for second-trimester terminations. The laminaria were inserted as described by Hale and Pion[2] the evening before the operation. All patients received doxycycline 100 mg at the time of insertion and 100 mg/day for 5 days after evacuation. Suction evacuation was performed immediately after removal of the laminaria tents, using the 15.8-mm suction cannula for the late terminations. Forceps was used whenever the diameter was too narrow for fetal parts.

Twenty-one women asked to have the laminaria removed without evacuation. In these cases, the internal tip of the laminaria and the cervical canal were usually cultured. The antibiotics were discontinued at that point. The first five women were kept under observation for 24 hours and then discharged. The following 16 women were discharged immediately after removal of the laminaria tents. All women who carried to term had antenatal care in our high-risk pregnancy clinic and delivered in our institution. Information was retrieved from the medical records.

Results

About 1.1% (21 of 1840) of the women asked for removal of the laminaria and reconsidered termination. This was more common before late abortion (2.7%, 14 of 515) than before early abortion (0.5%, seven of 1325).

Seventeen patients elected to continue their pregnancies. Fourteen had term deliveries, two had premature deliveries, and one had a spontaneous abortion (at 10 weeks' gestation). The early spontaneous abortion

From the Department of Obstetrics and Gynecology, Assaf Harofeh Medical Center, Zerifin, affiliated to the Sackler School of Medicine, Tel Aviv University, Israel.

0029-7844/91/$3.50

removal of the laminaria, and no clinical or histologic evidence of infection was noted. In four cases, laminaria were reinserted and abortion was finally performed upon the patient's request.

Cultures were obtained from the cervix and the internal tip of the laminaria in 18 cases. Eight of the cultures were positive for one or more organisms (two chlamydia, two chlamydia and *Ureaplasma urealyticum*, three *Mycoplasma hominis*, and one *U urealyticum*). All four women with a positive chlamydia culture delivered at term, but only one was treated with antibiotics. Of the three patients with chlamydia who did not receive antibiotics, two refused treatment and in one case the results were overlooked. Of the two patients with *M hominis* who continued the pregnancy, only one was treated with antibiotics; the patient with *U urealyticum* infection also did not receive any treatment. All three patients had an uneventful term delivery and puerperium.

Both patients with premature delivery had negative cultures. One presented with regular contractions at 36 weeks, and cesarean delivery was performed because of a history of two previous cesareans. The other woman had severe pregnancy-induced hypertension, and labor was induced at 35 weeks. The four women who reelected abortion 1 week after removal of the laminaria had closed and unripe cervices on examination and required reinsertion of laminaria for preevacuation dilatation. One of these had *M hominis* infection. All received doxycycline and had uncomplicated terminations.

Discussion

Unlike the one-phase, acute dilatation and evacuation or amnioinfusion techniques for abortion, after laminaria dilatation the laminaria can be removed and no evacuation performed if the patient desires. Little experience has been gained and reported[1] with such cases even though these situations are probably not rare. Such reconsideration occurred in 1% of all abortions (2.7% among the late and 0.5% among the early abortions) in our medical center, probably reflecting the incidence at other institutions. Darj et al[3] reported a dropout rate of 0.4% after counseling before early abortion, but no laminaria was used in their cases. A better abortion counseling service, especially for late aborters, may help identify women at risk and thus avoid dropouts after laminaria insertion.

The possible immediate complications are spontaneous abortion and infection. Only one patient developed early spontaneous abortion, 2 weeks after removal of the laminaria. This case occurred in 1981, when ultrasound evaluation before laminaria insertion for early abortion was not routine. Thus, the possibility of missed abortion cannot be ruled out. A recent report[1] documented two cases of extensive cervical dilatation by means of multiple laminaria tents for late abortion not followed by evacuation. Both women had good outcomes, supporting our observation that abortion is not expected after dilatation and ripening of the cervix. Our two cases resulting in premature labor were probably unrelated to cervical integrity or infection. The infectious morbidity associated with abortion is not increased by laminaria tents.[4] Moreover, a low rate of infectious morbidity was reported in second-trimester abortions with laminaria without the use of prophylactic antibiotics[5] even though about 11% of women seeking an abortion may harbor *C trachomatis*.[6] As doxycycline is contraindicated in pregnancy, it was discontinued after removal of the laminaria. None of the patients developed infection or premature rupture of the membranes, including those who carried chlamydia or *M hominis*. The role of the incidental presence of chlamydia and *M hominis* in cervical culture on adverse pregnancy outcome is still controversial.[7,8] Some studies have identified subgroups of chlamydia-positive patients who were also immunoglobulin M (IgM) seropositive and who had an increased risk for premature rupture of membranes[7,9]; it was suggested that they be treated. This may explain why most patients with chlamydia, including ours, do not develop premature rupture of membranes.

Because nearly 3% of women electing induced late abortion may change their minds after laminaria insertion, a prophylactic antibiotic such as doxycycline, which is contraindicated in pregnancy, might not be the optimal choice. Therefore, doxycycline should be used only after the completion of abortion, or other antibiotics should be considered.

References

1. Van-Le L, Darney PD. Successful pregnancy outcome after cervical dilation with multiple laminaria-tents in preparation for second trimester elective abortion: A report of 2 cases. Am J Obstet Gynecol 1987;156:612–3.
2. Hale RW, Pion RJ. Laminaria: An underutilized clinical adjunct. Clin Obstet Gynecol 1972;15:829–59.
3. Darj E, Starlin EB, Nilsson S. The prophylactic effect of doxycycline on postoperative infection rate after first-trimester abortion. Obstet Gynecol 1987;70:755–8.
4. Levallois P, Rioux JE. Prophylactic antibiotics for suction curettage abortion: Results of a clinical controlled trial. Am J Obstet Gynecol 1988;158:100–5.
5. Altman AM, Stubblefield PG, Schlam JF, Loberfeld R, Osathanondh R. Midtrimester abortion with laminaria and vacuum evacuation on a teaching service. J Reprod Med 1985;30:601–6.
6. Levallois P, Rioux JE, Cote L. Chlamydial infection among females

attending an abortion clinic: Prevalence and risk factors. Can Med Assoc J 1987;137:33–7.
7. Sweet RL, Landers DV, Walker C, Schacter J. Chlamydia trachomatis infection and pregnancy outcome. Am J Obstet Gynecol 1987;156:824–31.
8. Hardy PH, Hardy JB, Nell EE, Graham DA, Spence MR, Rosenbaum RC. Prevalence of six sexually transmitted disease agents among pregnant inner-city adolescents and pregnancy outcome. Lancet 1984;ii:333–6.
9. Harrison HR, Alexander ER, Weinstein L, Lewis M, Nash M, Sim DA. Cervical *Chlamydia trachomatis* and mycoplasmal infections in pregnancy. Epidemiology and outcomes. JAMA 1983;250:1721–7.

Reprints are not available.

Received May 29, 1991.
Received in revised form August 13, 1991.
Accepted August 14, 1991.

ATTORNEYS AND COUNSELLORS AT LAW
SAGOT, JENNINGS & SIGMOND
THE PENN MUTUAL TOWERS, 16TH FLOOR
510 WALNUT STREET
INDEPENDENCE SQUARE
PHILADELPHIA, PA 19106-3683

(215) 922-6700
FAX (215) 922-3524
MY PRIVATE NUMBER IS:

THOMAS W. JENNINGS
RICHARD B. SIGMOND▲°
JACK B. KATZ
SANFORD G. ROSENTHAL
STUART J. PHILLIPS*†
SUSAN A. MURRAY*°
STEPHEN J. HOLROYD*
LINDA S. FOSSI*
PAUL J. STACOM▲
BETH N. FORMAN*

NEIL SAGOT
KENT CPREK
ERIC G. MARTTILA
RICHARD C. McNEILL, JR.*
JONATHAN KRINICK
MAGDELINE D. COLEMAN
JENNIFER B. LIEBMAN*
DAVID G. PASCUCCI
ILANA BERMAN FELDMAN*
WILLIAM E. DENGLER*

NEW JERSEY OFFICE
ASHLAND OFFICE CENTER
1 ALPHA AVENUE-SUITE 33
VOORHEES, NJ 08043-1054
(856) 427-0465
FAX (856) 427-9285

COUNSEL TO THE FIRM:
GARY M. LIGHTMAN
2705 N. FRONT STREET
HARRISBURG, PA 17110-1221
(717) 234-0111
FAX (717) 234-8964

EDWARD DAVIS 1893-1987
M. H. GOLDSTEIN 1904-1971

* ALSO NJ BAR
° ALSO DC BAR
▲ ALSO NY BAR
† MANAGING ATTORNEY NJ OFFICE

Please Respond to NJ Office

October 21, 1999

Judith I. Gleason, Executive Director
Department of Law & Public Safety
Division of Consumer Affairs
New Jersey State Board of Medical Examiners
140 E. Front Street
Trenton, NJ 08608

RE: "In Office" Insertion of Laminaria

Dear Ms. Gleason:

Enclosed please find correspondence, dated January 26, 1999, previously provided to the Board, along with a copy of the receipt evidencing its delivery, January 29, 1999, where I requested clarification of the Board's interpretation of N.J.A.C. 13:35-4.2, regarding termination of pregnancy, and specifically, as regarding insertion of laminaria in an office setting.

To date, I have received no reply to that correspondence or any indication from the Board that it differs with or opposes in any manner the legal opinion express therein.

In my letter, I specifically requested that the Board please notify me if it disagreed with my opinion or was of the position that my client's practice violated its regulations.

It has now been approximately nine months since I corresponded with the Board and have received no reply or any indication that the Board disagrees with my client's practice as previously outlined.

Please, therefore, accept this letter as a second notice to the Board and an additional request that any disagreement by the Board as to the legality of this practice be immediately brought to my

attention. My client informs me that the laminaria insertion as described has been performed for many patients, safely and effectively without any mishap or adverse complication. Nonetheless, my client does not wish to litigate this issue and has assured me that should the Board dispute my opinion, my client will immediately stop inserting laminaria in an office setting, and would only do so in an otherwise approved facility.

Absent a contrary response or opinion of the Board, I will presume that the Board stands behind its prior ruling in the Brigham decision, and that the practice and procedure described in my letter to the Board of January 26, 1999, is considered to be legal and not violative of N.J.A.C. 13:35-4.2.

Thank you for your kind attention to this matter.

Respectfully submitted,

STUART J. PHILLIPS

SJP:jc
Enclosure
CERTIFIED MAIL
R.R.R. #Z 522 784 051

cc: John J. Farmer, Jr., Attorney General
Sharon Joyce, Deputy Attorney General

Is your RETURN ADDRESS completed on the reverse side?

$ ▪ ▪ ▪

card to you.
- Attach this form to the front of the mailpiece, or on the back if space does not permit.
- Write "*Return Receipt Requested*" on the mailpiece below the article number.
- The Return Receipt will show to whom the article was delivered and the date delivered.

e the
or an

1. ☐ Addressee's Address
2. ☐ Restricted Delivery
Consult postmaster for fee.

3. Article Addressed to:
Ms. Judith I. Heaven, Executive Director
Department of Law & Public Safety
Division of Consumer Affairs
N.J. State Board of Medical Examiners
140 E. Front St. CN 183 Trenton NJ 08625

STATE OF NEW JERSEY
CAPITOL POST OFFICE

4a. Article Number
Z 522 784 051

4b. Service Type
☐ Registered ☑ Certified
☐ Express Mail ☐ Insured
☐ Return Receipt for Merchandise ☐ COD

7. Date of Delivery
OCT 25 '99

5. Received By: *(Print Name)*

6. Signature: *(Addressee or Agent)*
X

8. Addressee's Address *(Only if requested and fee is paid)*

Thank you for using Return Receipt Service.

PS Form **3811**, December 1994 102595-98-B-0229 Domestic Return Receipt

Z 522 784 051

US Postal Service
Receipt for Certified Mail
No Insurance Coverage Provided.
Do not use for International Mail *(See reverse)*

Sent to	
Street & Number	
Post Office, State, & ZIP Code	
Postage	$
Certified Fee	
Special Delivery Fee	
Restricted Delivery Fee	
Return Receipt Showing to Whom & Date Delivered	
Return Receipt Showing to Whom, Date, & Addressee's Address	
TOTAL Postage & Fees	$
Postmark or Date	

PS Form **3800**, April 1995

EXHIBIT 11

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
140 EAST FRONT STREET, 2ND FLOOR
TRENTON, NJ

CHRISTINE TODD WHITMAN
Governor

JOHN J. FARMER, JR.
Attorney General

MARK S. HERR
Director

Mailing Address:
P.O. Box 183
Trenton, NJ 08625
(609) 826-7100

Stuart J. Phillips, Esq.
Ashland Office Center
1 Alpha Avenue, Suite 33
Voorhees,N.J. 08043-1054

Re: IN-OFFICE INSERTION OF LAMINARIA

Dear Mr. Phillips:

I am in receipt of your October 21, 1999 letter and apologize for not having replied to your earlier correspondence. I did have occasion to discuss your inquiry yesterday with the Executive Committee of the Board of Medical Examiners. The members present share your view of the applicability of N.J.A.C. 13:35-4.2. Accordingly, there would appear to be no problem with regard to the insertion of laminaria prefatory to a termination of pregnancy whether in an office setting or in a licensed ambulatory care facility. Certainly, your client would be well counseled, howwever, to assure that there are mechanisms in place to follow up in the event that a patient in whom laminaria had been inserted does not appear for the termination procedure as scheduled. You should also be aware that to the extent that the patient is a minor, laminaria should not be inserted until after the physician has discharged his obligation to notify a parent under the new rules of the Department of Health & Senior Services, N.J.A.C. 8:72-1.1. (The requirements of this regulation and the statute which it implements are presently stayed by order of the New Jersey Supreme Court.)

I hope this response is helpful and, again, please accept my apologies for the late reply.

Very truly yours,

STATE BOARD OF MEDICAL EXAMINERS

By: Judith I. Gleason
Judith I. Gleason
Executive Director

JIG:k

EXHIBIT 12

Contraception
an International Journal

JOURNAL HOME
CURRENT ISSUE
BROWSE ALL ISSUES
ONLINE FIRST
SFP GUIDELINES
SEARCH THIS JOURNAL
JOURNAL INFORMATION
- Aims and Scope
- Editorial Board
- Author Information
- Info for Advertisers
- Abstracting/Indexing
- Contact Information
- Society Information
- Pricing Information

SUBMIT MANUSCRIPT
SUBSCRIBE TO JOURNAL
CAREER OPPORTUNITIES
RSS

More periodicals:
FIND A PERIODICAL
FIND A PORTAL
GO TO PRODUCT CATALOG

Volume 77, Issue 4, Pages 308-314
(April 2008)

previous 18 of 18

Cervical preparation for surgical abortion from 20 to 24 weeks' gestation

ABSTRACT
FULL TEXT
FULL-TEXT PDF (119 KB)
CITATION ALERT
CITED BY
RELATED ARTICLES
EXPORT CITATION
EMAIL TO A COLLEAGUE
RIGHTS/PERMISSIONS
NEED REPRINTS?
BOOKMARK ARTICLE

SFP Guideline #20073. Release date 12 December 2007

published online 20 February 2008.

Abstract

Although less than 2% of abortions in the United States occur after 20 weeks, procedures performed at more advanced gestations are associated with increased morbidity and mortality. Adequate cervical preparation before dilation and evacuation (D&E) at 20 or more weeks' gestation reduces procedural risk. However, few clinical trials have included sufficient information on best practices for cervical preparation in this gestational age range. For procedures at 20 or more weeks' gestation, at least 1 day of cervical preparation is recommended. Evidence is less clear that the procedure is faster or safer with the use of either serial dilation over more than 1 day or adjuvant misoprostol. Osmotic dilators are preferable to misoprostol, but there are insufficient data to support either laminaria or Dilapan as the preferred dilator. Fewer Dilapan are needed to gain the same amount of dilation as laminaria. The Society of Family Planning recommends preoperative cervical preparation before D&E between 20 and 24 weeks. Further studies are needed to clarify the best means to prepare the cervix to minimize abortion complications and improve outcome in this gestational age range.

Keywords: Dilation and evacuation, Cervical dilation, Dilator, Laminaria, Dilapan, Lamicel, Misoprostol, Induced abortion, Second-trimester abortion

Article Outline

Background

return to article outline

In the United States, 1.4% of abortions take place after 20 weeks' gestation [1]. The majority of these procedures are performed from 20 to 23 weeks' gestation [2]. Most second-trimester abortions in the USA (87%) are accomplished by dilatation and evacuation (D&E) [1]. Cervical preparation before surgical abortion at 20–24 weeks is essential to reduce complications since the fetal parts are both larger and more calcified as compared to earlier gestations.

Procedural complications increase with advancing gestational age [1], [2]. Morbidity and mortality of induced abortion increase an average of 20% per week [3]. A rare but serious D&E complication, uterine perforation, occurs in only 0.2–0.4% of surgical abortions between 12 and 26 weeks [4] with an increase in relative risk of 1.4 with each additional 2 weeks of gestation [5]. In a review of almost 12,000 patients undergoing D&E between 12 and 26 weeks, blood loss exceeding 500 ml and cervical laceration were the most common complications, each affecting approximately 0.9% of the patients [4]. In those women with 19–26 weeks' gestation, cervical laceration was significantly reduced ($p<.05$) when laminaria were used.

Three methods can be used to open the cervix in this gestational age range: mechanical dilation alone with graduated rigid dilators, preoperative placement of osmotic dilators and preoperative use of ripening agents. In some circumstances, the latter two options may include subsequent use of mechanical dilation.

Mechanical dilation

return to article outline

Early in the development of D&E, mechanical dilation without cervical preparation was observed to increase both the short- and long-term morbidity of procedures requiring significant dilatation such as advanced second trimester gestations. Mechanical dilation using graduated Pratt, Denniston or other dilators may be used at 20–24 weeks for augmenting the dilatation obtained by osmotic dilators and/or cervical ripening agents.

Osmotic dilators

return to article outline

Laminaria

A tent composed of dried, compressed seaweed stem, absorbs fluid to expand gradually and also assists in ripening the cervix by endogenous prostaglandin release [6]. A clinical effect is measurable in 3 h but does not achieve full potential until 12–24 h [7], [8], [9].

Dilapan

A hygroscopic rod dilator made from hydrophilic polymers, is superior to laminaria in dilating properties [10], but initially was prone to fracture [11], [12]. In 2002, the initial formulation was

replaced by Dilapan-S, which dilates at a faster rate and to a larger extent than laminaria and is synthesized with a stronger core intended to reduce fragmentation.

Lamicel®

A sterile polyvinyl sponge with magnesium sulfate, does not elicit cervical wall tension. In contrast to laminaria and Dilapan, its action is largely chemical. While the manufacturer claims that it softens the cervix in 30 min and achieves adequate cervical dilation in a few hours, it is not believed to achieve adequate dilation alone for procedures at 20–24 weeks' gestation when at least 2 cm of dilation is commonly recommended [13].

Ripening agents

return to article outline

Prostaglandins

Prostaglandins were first used in 1970 to soften and dilate the cervix before uterine evacuation [14], [15]. Prostaglandin receptors are present throughout pregnancy and help initiate uterine contractions [16]. Misoprostol, a PGE_1 analogue that can be administered orally, vaginally or buccally, has become the most commonly used prostaglandin analogue. Misoprostol offers a relatively inexpensive and chemically stable agent for cervical ripening [17].

Antiprogesterones

Antiprogesterones, such as mifepristone, are synthetic steroids that bind to progesterone receptors and prevent endogenous progesterone from reaching its target [18], [19]. Mifepristone elicits significant cervical dilatation and softening without initiating contractions, leading to less concern about precipitating labor induction when preparing a cervix for D&E. No studies have examined its use before D&E at 20–24 weeks' gestation, either alone or as an adjuvant to other cervical ripening agents.

Despite common recommendations for cervical dilation or preparation before D&E [20], [21], a number of questions remain unanswered. This document reviews current evidence on cervical preparation for D&E at 20–24 weeks' gestation.

Clinical questions and recommendations

return to article outline

1. Does the use of osmotic dilators decrease the risk of complications with D&E at 20–24 weeks' gestation?

Adequate pre-procedure cervical dilation reduces D&E morbidity. Mechanical dilation alone is associated with more complications than osmotic dilation with laminaria [20], [21], [22], [23], [24]. Cervical laceration with hemorrhage is one of the most commonly cited serious D&E complications [4], [20], [25], [26]. Data from retrospective studies suggest that cervical preparation with osmotic dilators decreases the risk of cervical laceration at 20–24 weeks' gestation [4].

One of the largest series describing how to decrease cervical injury from abortion only included procedures performed at less than 12 weeks' gestation [20], [27]. Prospective series with women greater than 12 weeks' gestation include little to no information specifically about the 20–24 weeks range [28]. A retrospective series of 11,747 D&E procedures completed between 1972 and 1981 evaluated the incidence of cervical laceration requiring repair [4]. Between 20 and 26 weeks' gestation, 10% of cases using mechanical dilation alone required repair, the majority of which were reported to be in the distal cervical canal and were less than 2 cm long. After the introduction of laminaria tents for cervical preparation, the incidence of cervical laceration requiring repair decreased significantly to 1.2% ($p<.05$) for procedures between 20 and 26 weeks. No studies have evaluated the long-term effects of cervical laceration, if any, on future pregnancy outcome.

The associations between gestational age, parity, provider experience and the use of cervical dilators to decrease procedure risk are still poorly understood, especially for procedures at 20–24 weeks. Although conventional wisdom holds that cervical injuries are more common in teenagers [21], [29], no data examine this risk for teens having abortions at 20–24 weeks' gestation. Additionally, the association between cervical injury and parity is unclear [20], [23],

[27], [30], [31]. Although studies suggest that nulliparous women benefit more from laminaria placement before surgical abortion between 13 and 16 weeks' gestation than do parous women [32], research has not investigated this association independently above 17 weeks' gestation. Cervical preparation with osmotic dilators results in a nonsignificant trend towards a reduced risk of uterine perforation above 19 weeks' gestation [5], [27]. Additionally, evidence suggests higher rates of cervical injury and uterine perforation when abortions are performed by inexperienced providers [21], [27].

No studies have examined whether osmotic dilators before D&E at 20–24 weeks increase or decrease the risks of infection or hemorrhage. Retrospective evidence suggests that cervical preparation with osmotic dilators before surgical abortion at 20–24 weeks may reduce the risk of cervical laceration.

2. What are the risks of using osmotic dilators as cervical preparation before D&E at 20–24 weeks' gestation?

No significant clinical risks of using osmotic dilators before D&E at 20–24 weeks' gestation have been documented. Onset of labor is a potential rare complication after placement of osmotic dilators. The exact incidence is not known. Labor onset occurred in about 1 in 500 cases in a series of 1000 D&E procedures performed between 17 and 25 weeks' gestation using serial laminaria and adjunctive urea [25]. This rate is slightly higher than estimates of 1 in 2000 to 3000 abortions at 14–18 weeks' gestation [13]. Still, the relative infrequency of labor demonstrates that inpatient hospitalization for observation is not necessary following dilator placement. No data address whether the risk of labor changes in women at 20–24 weeks' gestation when more dilators are placed or when serial placement is used.

Other possible immediate and long-term risks of osmotic dilators include difficult removal, fragmentation and displacement of the dilators within the uterus [11], [33], hypersensitivity reactions [34], infectious morbidity [11], [35], [36], vasovagal reactions, incidental rupture of amniotic membranes during placement, perforation of the cervix, and possible future cervical incompetence [12], [13], [26], [37], [38], [39]. Information regarding these potential risks of cervical osmotic dilator placement has been addressed by the Society of Family Planning in two previous reviews [40], [41].

Interesting data exist about future pregnancy risk when focusing on procedures from 20 to 24 weeks' gestation. In a retrospective review of 600 patients who underwent D&E between 14 and 24 weeks after approximately 24 h of cervical preparation with laminaria, 96 subsequent pregnancies were identified. Increased risk of subsequent cervical incompetence or preterm delivery was not identified after second-trimester cervical dilation and surgical abortion. However, subsequent preterm delivery appeared to be correlated with a lower gestational duration at the time of previous second-trimester surgical abortion. Specifically, women who had had a previous surgical abortion completed with a median gestational age of 20 weeks had a significantly lower risk of preterm delivery compared to those at a median of 18 weeks. These findings led the authors to hypothesize that future cervical incompetence may be related to the degree of cervical trauma that occurs during the abortion itself rather than to the amount of cervical dilation obtained through osmotic dilation [42].

The benefits of cervical dilation by osmotic dilation appear to outweigh any risks associated with their placement. Placement of osmotic dilators is generally safe and recommended before D&E at 20–24 weeks' gestation.

3. Which osmotic dilator is preferred for preparation of the cervix for D&E at 20–24 weeks' gestation?

Data comparing osmotic dilators used for cervical preparation before surgical abortion at 20–24 weeks' gestation are scant. The largest trial comparing overnight laminaria to overnight Dilapan included 1001 subjects between 13 and 25 weeks' gestation [11]. Laminaria or Dilapan were used for cervical preparation on an every-other-case basis. Women were excluded if they had a history of cervical surgery or multiple cesarean sections, presence of cervical scarring, serious current illness or active vaginal bleeding. Additionally, any woman who was "judged to require multiple applications of dilators" was excluded from the study. The data were not stratified by gestational age; thus, it is not clear which results pertain to cases performed at 20 weeks or greater. No differences were found in procedure time, blood loss or need for additional dilation. Approximately twice as many laminaria were required to achieve

the same amount of dilation achieved with Dilapan, but women were more likely to have "cervical dilation deficiency" (defined as "poor to no dilation" or "fractured or retained dilator") when Dilapan were used.

Earlier data indicated that patients might experience more pain after placement of Dilapan, presumably due to rapid dilation [43]. When Dilapan expands in an hourglass shape, removal may be more difficult. Based on anecdotal experience, some providers recommend placing a laminaria tent or Lamicel with Dilapan to facilitate removal [12], [44]. No data exist to validate this approach. Additionally, no studies have directly compared laminaria to Dilapan-S for use at 20–24 weeks' gestation since its reformulation and reintroduction to clinical practice.

Overall, evidence is insufficient to recommend one osmotic dilator over another before D&E from 20 to 24 weeks. However, fewer Dilapan than laminaria may be needed to achieve equivalent dilation.

4. How many osmotic dilators should be placed?

No data address the question of how many osmotic dilators to use before D&E at 20–24 weeks' gestation nor whether specific sizes of dilators should be used. Additionally, no evidence addresses these questions for nulliparous women and teens, both groups at higher risk of complications with D&E [20], [21], [27], [30], [45], [46], [47]. Some experts recommend placing as many dilators as possible until resistance is met or until they fit snugly [11], [34]. Most suggest a larger number of dilators as gestational age advances since the cervix must accommodate larger forceps [44].

One study including second-trimester surgical abortion patients suggested that a given number of laminaria will create greater dilation at later gestations, presumably because of increasing cervical compliance as the pregnancy advances [48]. A retrospective review in 147 women examined the degree of dilatation achieved with overnight Dilapan-S, with or without misoprostol, before abortion between 20 and 24 weeks. The results suggested that two or three dilators were superior to a single dilator. Women with a single dilator were almost 1.8 times (95% CI 1.4–2.3) as likely to require additional mechanical cervical dilation [49]. No differences were noted in complications between the two groups, but the study was not powered to determine differences in complications [22].

Overall, sufficient data do not exist for guidance about the exact number of dilators that should be used when preparing the cervix for late second-trimester D&E or about the significance of this number in correlation to important clinical outcomes.

5. How long should osmotic dilators be left in situ before D&E at 20–24 weeks' gestation?

No evidence-based recommendations can be made about how long dilators should be left in place. Some experts recommend leaving a single set in place for 18–48 h or replacing them with a second set after 18–24 h [13]. No studies have addressed the theory that increased cervical softening may occur with longer duration of dilator retention.

In a small retrospective review, women treated with two to three Dilapan-S with or without adjuvant misoprostol the day before a 20–24 week D&E had no more complications than women treated with one to two Dilapan-S dilators with or without misoprostol on the same day of the procedure [49]. In this retrospective chart review of 147 abortion cases, there was a nonstatistically significant overall risk reduction of 2.63% (95% CI −7.9% to 13.2%) between cervical preparation achieved with overnight Dilapan-S with or without misoprostol compared to cervical preparation achieved with same-day Dilapan-S with or without misoprostol. The small size, retrospective nature and variation in cervical preparation protocols make it difficult to draw any definitive conclusions from this study. This study is an example of the insufficient literature available to address these clinical issues.

The evidence is insufficient to determine an optimal time for osmotic dilators to be left in situ before D&E at 20–24 weeks.

6. Are multiple days of cervical preparation warranted before procedures at 20 weeks or greater gestation and if so, when?

Expert opinion holds that at least 1 day of cervical preparation is necessary for late second-trimester surgical abortions and several experienced providers have published recommendations [11], [13], [26], [44]. No randomized trials have explored this topic. Based on results from studies in earlier gestations, serial laminaria appear safe [50]. In 172 women at 18–22 weeks' gestation who had two sets of laminaria placed the day before D&E (the second set 6 h after the first), 92% had at least 18 mm of dilation and none experienced cervical injury [51].

Some providers describe that two or three sets of dilators are helpful especially for patients with noncompliant cervices, such as younger or nulliparous women [13], [21]. Overall, there is no evidence to determine whether multiple days of cervical preparation leads to a reduction in abortion complications.

7. Should misoprostol be used as an alternative or adjunct to osmotic dilators for cervical preparation before D&E at 20–24 weeks' gestation?

Data suggest that misoprostol is best used as an adjunct to osmotic dilators rather than alone as cervical preparation for surgical abortion at 20–24 weeks. In a previously described trial, the addition of misoprostol to Dilapan-S did not significantly increase or decrease the number of procedure-related cervical or uterine complications [49]. Moreover, the additional misoprostol did not decrease the need for further cervical dilation. The study did not evaluate other outcomes such as the need for additional dilation, procedure time or blood loss.

A retrospective study of 2218 elective D&E procedures between 12 and 23 6/7 weeks (19% of which were ≥20 weeks' gestation) found that the use of buccal misoprostol with or without laminaria is effective and safe [5]. Additional dilatation was required more frequently when buccal misoprostol was used alone compared with the combination of buccal misoprostol and laminaria (70% vs. 13%, p<.001). When the results were stratified by gestational age, additional dilation was needed between 18 and 23 6/7 weeks 28% of the time when buccal misoprostol was used alone and only 12.3% of the time when buccal misoprostol was used with laminaria (RR 0.44, 95% CI 0.27–0.72), representing a 56% reduction in need for additional mechanical dilation. Paradoxically, women who received a 400-mcg dose of buccal misoprostol were 94% less likely to need additional dilation compared to patients who received a 600-mcg dose (RR 0.06, 95% CI 0.03–0.12). Because this trial was not randomized, strict conclusions about the clinical relevance of this finding cannot be made.

In a randomized controlled trial comparing cervical preparation with laminaria alone to cervical preparation with laminaria plus 400 mcg buccal misoprostol between 13 and 20 6/7 weeks, a subanalysis of gestations between 19 0/7 and 20 6/7 weeks (n=29) demonstrated that adjunctive misoprostol resulted in a significant improvement in dilation over placebo (p=.01) [52].

Overall, limited data suggest that misoprostol as an adjunct to osmotic dilators may result in greater cervical dilation compared to misoprostol alone. The optimal dose and route of adjuvant misoprostol are unknown. Moreover, whether this additional treatment decreases patient risk has not been determined.

8. What are the risks of using osmotic dilators with misoprostol for cervical preparation between 20 and 24 weeks for women with a uterine scar?

A case report of a uterine rupture after overnight laminaria and two doses of 400 mcg misoprostol before a planned 23-week D&E in a patient with two previous cesarean deliveries [53] suggests possible risk. However, there are little prospective data to demonstrate that women with a uterine scar have an increased risk of uterine complications after using osmotic dilators with adjuvant misoprostol as cervical preparation for D&E. A large retrospective study of D&E procedures using buccal misoprostol alone or in conjunction with laminaria between 12 and 23 6/7 weeks (19% of which were≥20 weeks' gestation) found that women with a history of cesarean delivery were three times as likely to experience some adverse event (OR 3.11, 95% CI 1.14–7.98), none of which was explained by uterine rupture or scar dehiscence [5].

Although few studies have examined the use of misoprostol before a D&E in women with a uterine scar, we can look at second-trimester misoprostol induction abortion literature to extrapolate about relative safety, especially since women undergoing induction abortion are likely to receive a larger total dose of misoprostol than would be used for cervical preparation

before D&E. The majority of studies addressing risk of uterine rupture or scar dehiscence in the second trimester before misoprostol induction termination find no associated risk. Bhattacharjee et al. [54] found no uterine rupture or scar dehiscence among 80 patients with prior uterine scars undergoing induction termination with misoprostol between 13 and 26 weeks. Similarly, Daskalakis et al. [55] found no uterine rupture or scar dehiscence among 108 misoprostol induction termination patients between 17 and 24 weeks nor did Dickinson [56] who looked at 720 similar patients between 14 and 28 weeks. These results were also observed by Rouzi [57] in 10 patients undergoing medical induction for fetal demise at a mean gestation of 20 weeks. In addition to case reports of uterine rupture [53], [58], one retrospective study of second-trimester induction termination found a significantly higher risk of both blood transfusion (OR 2.3; 95% CI 1.1–5.0) and uterine rupture (OR 20.9; 95% CI 41.1–104) among women who had a prior cesarean [59]. Other studies mention second-trimester uterine rupture and increased induction complications in women with previous uterine scars [22], [60].

Overall, no data suggest that using misoprostol in conjunction with osmotic dilators as cervical preparation for surgical abortion at 20–24 weeks in women with a uterine scar markedly increases D&E risks such as cervical laceration or uterine perforation, rupture, or dehiscence. However, more definitive studies of the safety of adjuvant misoprostol are needed.

Conclusions and recommendations

return to article outline

The following recommendation is based on good and consistent scientific evidence (Level A):

1. The safety of D&E procedures at 20–24 weeks' gestation is improved by preoperative cervical preparation.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

1. Buccal misoprostol 400 mcg is an adequate dose for cervical ripening when used as an adjunct to osmotic dilation before D&E at 20–24 weeks' gestation. Use of adjuvant misoprostol may decrease the need for additional dilation in these procedures. Higher doses of buccal misoprostol do not appear to decrease the need for additional dilation.

2. Using adjuvant misoprostol with osmotic dilators before D&E at 20–24 weeks' gestation is not associated with significant procedure-associated risks and may aid in cervical dilation.

The following recommendations are based primarily on consensus or expert opinion (Level C):

1. More osmotic dilators are needed for cervical preparation before D&E as the gestational age advances between 20 and 24 weeks.

2. Decisions about the number of dilators to place should be individualized, taking into consideration factors such as a woman's cervical compliance, parity and gestational duration. Decisions about additional time for dilator retention, serial dilator placement or adjuvant misoprostol also should be individualized.

3. Approximately half the number of Dilapan are necessary to achieve a given amount of cervical dilatation as compared to laminaria.

Important questions to be answered

return to article outline

Additional research is needed to determine the best approach to obtaining adequate cervical dilation before D&E at 20–24 weeks. Little high-quality evidence is available to guide clinical decision making. Better designed studies are needed comparing types of osmotic dilators and the effects of serial dilators. Other studies should address the efficacy and safety of adjuvant treatments such as misoprostol or mifepristone in improving cervical preparation, including women with a prior uterine scar. Although a more dramatic change in D&E clinical practice and patient convenience, with possible resultant increased risk, would result from research into same-day cervical preparation with Dilapan-S and/or misoprostol, current clinical consensus recommends at least 1 day of cervical preparation for D&E procedures at 20–24 weeks.

To further complicate research efforts aimed at guiding decisions about cervical preparation

before D&E at 20–24 weeks' gestation, US researchers may be concerned that serial applications of osmotic dilators or adjuvant misoprostol use may be interpreted as intent to perform a "partial birth abortion," which is a federal crime [61], [62]. The federal ban creates an obstacle to research on this topic. Investigators who use preoperative feticidal agents introduce a confounder because feticide itself may have an impact on the safety of D&E at 20–24 weeks, including the safety and efficacy of cervical preparation.

Sources

return to article outline

MEDLINE and EMBASE databases were searched from 1966 to 2007, including the following MeSH terms and text words: induced abortion, surgical abortion, termination, second-trimester, midtrimester, evacuation, hygroscopic tents, priming, cervical ripening, cervical dilation, osmotic dilator, meteneprost, dinoprostone, hydrophilic polymer, sulprostone, laminaria, Dilapan, Lamicel, hypan, gemeprost, prostaglandin and misoprostol. English-language abstracts were reviewed for relevance, with articles and contemporary chapters reviewed for any additional references. An automatic e-mail notification update was created on this topic to continue to review any new articles published during the course of preparing the guidelines. Non-English articles were excluded.

Authorship

return to article outline

These guidelines were prepared by Sara Newmann, MD, MPH; Andrea Dalve-Endres, MD; and Eleanor A. Drey, MD, EdM; and were reviewed and approved by the Board of the Society of Family Planning.

Conflict of Interest Statement

return to article outline

Sara Newmann, MD, MPH; Andrea Dalve-Endres, MD; and Eleanor A. Drey, MD, EdM, report no significant relationships with industry relative to these guidelines. The Society of Family Planning receives no direct support from pharmaceutical companies or other industries.

Intended Audience

return to article outline

This Society of Family Planning guideline was developed for its members and other clinicians who perform surgical abortion procedures at 20–24 weeks or who care for women undergoing these procedures. This guideline may be of interest to other professional groups that set practice standards for family planning services. The purpose of this document was to review the medical literature evaluating common means of cervical preparation for second trimester surgical abortion from 20 to 24 weeks' gestation. This evidence-based review should guide clinicians in preparing the cervix prior to D&E, although it is not intended to dictate clinical care.

References

return to article outline

[1]. Strauss LT, Gamble SB, Parker WY, Cook DA, Zane SB, Hamdan S. Abortion surveillance — United States, 2003. *MMWR Surveill Summ*. 2006;55:1–32[Evidence Grade: II-3].

[2]. Finer LB, Henshaw SK. Abortion incidence and services in the united states in 2000. *Perspect Sex Reprod Health*. 2003;35:6–15[Evidence Grade: II-3]. MEDLINE | CrossRef

[3]. Tietze C, Pakter J, Berger GS. Mortality with legal abortion in New York City, 1970–1972. A preliminary report. *Jama*. 1973;225:507–509[Evidence Grade: III]. MEDLINE

[4]. Peterson WF, Berry FN, Grace MR, Gulbranson CL. Second-trimester abortion by dilatation and evacuation: An analysis of 11,747 cases. *Obstet Gynecol*. 1983;62:185–190 [Evidence Grade: II-3]. MEDLINE

[5]. Patel A, Talmont E, Morfesis J, Pelta M, Gatter M, Momtaz MR, et al. Adequacy and safety of buccal misoprostol for cervical preparation prior to termination of second-trimester pregnancy. *Contraception*. 2006;73:420–430[Evidence Grade: II-3]. Abstract | Full Text | Full-Text PDF (158 KB) | CrossRef

[6]. Herczeg J, Sas M, Szabo J, Vajda G. Pre-evacuation dilatation of the pregnant uterine cervix by laminaria japonica. *Acta Med Hung.* 1986;43:145–154[Evidence Grade: II]. MEDLINE

[7]. Eaton CJ, Cohn F, Bollinger CC. Laminaria tent as a cervical dilator prior to aspiration-type therapeutic abortion. *Obstet Gynecol.* 1972;39:535–537[Evidence Grade: II-3]. MEDLINE

[8]. Krammer J, O'Brien WF. Mechanical methods of cervical ripening. *Clin Obstet Gynecol.* 1995;38:280–286[Evidence Grade: III]. MEDLINE | CrossRef

[9]. Newton BW. Laminaria tent: relic of the past or modern medical device?. *Am J Obstet Gynecol.* 1972;113:442–448[Evidence Grade: II-3]. MEDLINE

[10]. Gilson GJ, Russell DJ, Izquierdo LA, Qualls CR, Curet LB. A prospective randomized evaluation of a hygroscopic cervical dilator, Dilapan, in the preinduction ripening of patients undergoing induction of labor. *Am J Obstet Gynecol.* 1996;175:145–149[Evidence Grade: II-1]. Abstract | Full Text | Full-Text PDF (479 KB) | CrossRef

[11]. Hern WM. Laminaria versus Dilapan osmotic cervical dilators for outpatient dilation and evacuation abortion: Randomized cohort comparison of 1001 patients. *Am J Obstet Gynecol.* 1994;171:1324–1328[Evidence Grade: II-3]. Abstract | Full Text | Full-Text PDF (1004 KB)

[12]. Lichtenberg ES. Complications of osmotic dilators. *Obstet Gynecol Surv.* 2004;59:528–536[Evidence Grade: III]. MEDLINE | CrossRef

[13]. Darney PD. Preparation of the cervix: hydrophilic and prostaglandin dilators. *Clin Obstet Gynaecol.* 1986;13:43–51[Evidence Grade: III]. MEDLINE

[14]. Karim SM, Sharma SD. Therapeutic abortion and induction of labour by the intravaginal administration of prostaglandins e 2 and f 2. *J Obstet Gynaecol Br Commonw.* 1971;78:294–300[Evidence Grade: II]. MEDLINE

[15]. Wiquist N, Bydgeman M. Therapeutic abortion by local administration of prostaglandins. *Lancet.* 1970;2:716–717[Evidence Grade: II]. MEDLINE

[16]. Mitchell MD, Flint AP, Turnbull AC. Stimulation of uterine activity by administration of prostaglandin f-2alpha during parturition in sheep. *J Reprod Fertil.* 1976;48:189–190[Evidence Grade: II]. MEDLINE | CrossRef

[17]. Goldberg AB, Greenberg MB, Darney PD. Misoprostol and pregnancy. *N Engl J Med.* 2001;344:38–47[Evidence Grade: III]. MEDLINE | CrossRef

[18]. Baulieu EE. Ru 486 (mifepristone). A short overview of its mechanisms of action and clinical uses at the end of 1996. *Ann N Y Acad Sci.* 1997;828:47–58[Evidence Grade: II]. MEDLINE | CrossRef

[19]. Cadepond F, Ulmann A, Baulieu EE. Ru486 (mifepristone): mechanisms of action and clinical uses. *Annu Rev Med.* 1997;48:129–156[Evidence Grade: II]. MEDLINE | CrossRef

[20]. Harlap S, Shiono PH, Ramcharan S, Berendes H, Pellegrin F. A prospective study of spontaneous fetal losses after induced abortions. *N Engl J Med.* 1979;301:677–681[Evidence Grade: II]. MEDLINE | CrossRef

[21]. Schulz KF, Grimes DA, Cates W. Measures to prevent cervical injury during suction curettage abortion. *Lancet.* 1983;1:1182–1185[Evidence Grade: II-2]. MEDLINE

[22]. Autry AM, Hayes EC, Jacobson GF, Kirby RS. A comparison of medical induction and dilation and evacuation for second-trimester abortion. *Am J Obstet Gynecol.* 2002;187:393–397[Evidence Grade: II-2]. Abstract | Full Text | Full-Text PDF (49 KB) | CrossRef

[23]. Grimes DA, Schulz KF. Morbidity and mortality from second-trimester abortions. *J Reprod Med.* 1985;30:505–514[Evidence Grade: II-3]. MEDLINE

[24]. Wright CS, Campbell S, Beazley J. Second-trimester abortion after vaginal termination of pregnancy. *Lancet*. 1972;1:1278–1279[Evidence Grade: III]. MEDLINE

[25]. Hern WM. Serial multiple laminaria and adjunctive urea in late outpatient dilatation and evacuation abortion. *Obstet Gynecol*. 1984;63:543–549[Evidence Grade: II-3]. MEDLINE

[26]. Jacot FR, Poulin C, Bilodeau AP, Morin M, Moreau S, Gendron F, et al. A five-year experience with second-trimester induced abortions: no increase in complication rate as compared to the first trimester. *Am J Obstet Gynecol*. 1993;168:633–637[Evidence Grade: II-3]. MEDLINE

[27]. Grimes DA, Schulz KF, Cates WJ. Prevention of uterine perforation during curettage abortion. *JAMA*. 1984;251:2108–2111[Evidence Grade: II-2]. MEDLINE

[28]. Cates W, Grimes DA. Deaths from second trimester abortion by dilatation and evacuation: causes, prevention, facilities. *Obstet Gynecol*. 1981;58:401–408[Evidence Grade: II-3]. MEDLINE

[29]. Cates W, Schulz KF, Grimes DA. The risks associated with teenage abortion. *N Engl J Med*. 1983;309:621–624[Evidence Grade: II-2]. MEDLINE | CrossRef

[30]. Atienza MF, Burkman RT, King TM. Midtrimester abortion induced by hyperosmolar urea and prostaglandin f2 alpha in patients with previous cesarean section: clinical course and potential for uterine rupture. *Am J Obstet Gynecol*. 1980;138:55–59[Evidence Grade: II-3]. MEDLINE

[31]. Gold J. The safety of laminaria and rigid dilators for cervical dilation prior to suction curettage for first trimester abortion: a comparative analysis. In: Naftolin F, Stubblefield P editor. Dilation of the uterine cervix. New York: Raven Press; 1980;p. 363–369[Evidence Grade: III].

[32]. Goldberg AB, Drey EA, Whitaker AK, Kang MS, Meckstroth KR, Darney PD. Misoprostol compared with laminaria before early second-trimester surgical abortion: a randomized trial. *Obstet Gynecol*. 2005;106:234–241[Evidence Grade: I]. MEDLINE

[33]. Borgatta L, Barad D. Prolonged retention of laminaria fragments: an unusual complication of laminaria usage. *Obstet Gynecol*. 1991;78:988–990[Evidence Grade: III]. MEDLINE

[34]. Chanda M, Mackenzie P, Day JH. Hypersensitivity reactions following laminaria placement. *Contraception*. 2000;62:105–106[Evidence Grade: III]. Abstract | Full Text | Full-Text PDF (34 KB) | CrossRef

[35]. Acharya PS, Gluckman SJ. Bacteremia following placement of intracervical laminaria tents. *Clin Infect Dis*. 1999;29:695–697[Evidence Grade: III]. MEDLINE | CrossRef

[36]. Sutkin G, Capelle SD, Schlievert PM, Creinin MD. Toxic shock syndrome after laminaria insertion. *Obstet Gynecol*. 2001;98:959–961[Evidence Grade: III]. MEDLINE | CrossRef

[37]. Grimes DA, Ray IG, Middleton CJ. Lamicel versus laminaria for cervical dilation before early second-trimester abortion: a randomized clinical trial. *Obstet Gynecol*. 1987;69:887–890 [Evidence Grade: I]. MEDLINE

[38]. Hogue CJ. Impact of abortion on subsequent fecundity. *Clin Obstet Gynaecol*. 1986;13:95–103[Evidence Grade: II]. MEDLINE

[39]. Lauersen NH, Den T, Iliescu C, Wilson KH, Graves ZR. Cervical priming prior to dilatation and evacuation: a comparison of methods. *Am J Obstet Gynecol*. 1982;144:890–894[Evidence Grade: II-1]. MEDLINE

[40]. Allen RH, Goldberg AB. Cervical dilation before first-trimester surgical abortion (<14 weeks' gestation). SFP guideline 20071. *Contraception*. 2007;76:139–156[Evidence Grade: III]. Abstract | Full Text | Full-Text PDF (288 KB) | CrossRef

[41]. Fox , Hayes . Cervical dilation before second trimester surgical abortion (15-19 week's gestation). SFP guideline 20072. *Contraception*. 2007;76:486–495[Evidence Grade: II]. Abstract | Full Text | Full-Text PDF (162 KB) | CrossRef

[42]. Kalish RB, Chasen ST, Rosenzweig LB, Rashbaum WK, Chervenak FA. Impact of midtrimester dilation and evacuation on subsequent pregnancy outcome. *Am J Obstet Gynecol*. 2002;187:882–885[Evidence Grade: II]. Abstract | Full Text | Full-Text PDF (51 KB) | CrossRef

[43]. Hern WM. Cervical treatment with Dilapan prior to second trimester dilation and evacuation abortion: a pilot study of 64 patients. *Am J Gynecol Health*. 1993;7:23–26 [Evidence Grade: II-2].

[44]. Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG. A clinician's guide to medical and surgical abortion. 1st ed. Philadelphia, PA: Churchill Livingstone; 1999;[Evidence Grade: III].

[45]. Buehler JW, Schulz KF, Grimes DA, Hogue CJ. The risk of serious complications from induced abortion: do personal characteristics make a difference?. *Am J Obstet Gynecol*. 1985;153:14–20[Evidence Grade: II-2]. MEDLINE

[46]. Herczeg J. Pretreatment of the cervix prior to surgical evacuation of the uterus in the late first and early second trimester of pregnancy. *Baillieres Clin Obstet Gynaecol*. 1990;4:307–325 [Evidence Grade: II-2]. MEDLINE | CrossRef

[47]. Stubblefield P. Laminaria and other adjunctive methods. In: Berger G, Brenner W, Keith L editor. Second trimester abortion: perspectives after a decade of experience. Boston, MA: John Wright PSG; 1981;p. 135–161[Evidence Grade: III].

[48]. Munsick RA, Fineberg NS. Cervical dilation from multiple laminaria tents used for abortion. *Obstet Gynecol*. 1996;87:726–729[Evidence Grade: II-2]. MEDLINE | CrossRef

[49]. Poon LC, Parsons J. Audit of the effectiveness of cervical preparation with Dilapan prior to late second-trimester (20–24 weeks) surgical termination of pregnancy. *BJOG*. 2007;114:485–488[Evidence Grade: II-3]. MEDLINE | CrossRef

[50]. Stubblefield PG, Altman AM, Goldstein SP. Randomized trial of one versus two days of laminaria treatment prior to late midtrimester abortion by uterine evacuation: a pilot study. *Am J Obstet Gynecol*. 1982;143:481–482[Evidence Grade: I]. MEDLINE

[51]. Schneider D, Halperin R, Langer R, Caspi E, Bukovsky I. Abortion at 18–22 weeks by laminaria dilation and evacuation. *Obstet Gynecol*. 1996;88:412–414[Evidence Grade: II-3]. MEDLINE | CrossRef

[52]. Edelman AB, Buckmaster JG, Goetsch MF, Nichols MD, Jensen JT. Cervical preparation using laminaria with adjunctive buccal misoprostol before second-trimester dilation and evacuation procedures: a randomized clinical trial. *Am J Obstet Gynecol*. 2006;194:425–430 [Evidence Grade: I]. Abstract | Full Text | Full-Text PDF (141 KB) | CrossRef

[53]. Berghahn L, Christensen D, Droste S. Uterine rupture during second-trimester abortion associated with misoprostol. *Obstet Gynecol*. 2001;98:976–977[Evidence Grade: III]. MEDLINE | CrossRef

[54]. Bhattacharjee N, Ganguly RP, Saha SP. Misoprostol for termination of mid-trimester post-caesarean pregnancy. *Aust N Z J Obstet Gynaecol*. 2007;47:23–25[Evidence Grade: II-2]. MEDLINE | CrossRef

[55]. Daskalakis GJ, Mesogitis SA, Papantoniou NE, Moulopoulos GG, Papapanagiotou AA, Antsaklis AJ. Misoprostol for second trimester pregnancy termination in women with prior caesarean section. *BJOG*. 2005;112:97–99[Evidence Grade: II-3]. MEDLINE | CrossRef

[56]. Dickinson JE. Misoprostol for second-trimester pregnancy termination in women with a prior cesarean delivery. *Obstet Gynecol*. 2005;105:352–356[Evidence Grade: II-3]. MEDLINE

[57]. Rouzi AA. Second-trimester pregnancy termination with misoprostol in women with previous cesarean sections. *Int J Gynaecol Obstet.* 2003;80:317–318[Evidence Grade: II]. Full Text | Full-Text PDF (33 KB) | CrossRef

[58]. Chen M, Shih JC, Chiu WT, Hsieh FJ. Separation of cesarean scar during second-trimester intravaginal misoprostol abortion. *Obstet Gynecol.* 1999;94:840;[Evidence Grade: III]. MEDLINE | CrossRef

[59]. Chapman SJ, Crispens M, Owen J, Savage K. Complications of midtrimester pregnancy termination: the effect of prior cesarean delivery. *Am J Obstet Gynecol.* 1996;175:889–892 [Evidence Grade: III]. Abstract | Full Text | CrossRef

[60]. Mazouni C, Provensal M, Porcu G, Guidicelli B, Heckenroth H, Gamerre M, et al. Termination of pregnancy in patients with previous cesarean section. *Contraception.* 2006;73:244–248[Evidence Grade: II]. Abstract | Full Text | Full-Text PDF (91 KB) | CrossRef

[61]. Partial-birth abortion ban act of 2003. 18 U.S.C. §1531 (2003).

[62]. Gonzales v. Carhart 127 S.Ct. 1610 (2007).

PII: S0010-7824(08)00031-0

doi:10.1016/j.contraception.2008.01.004

previous 18 of 18

EXHIBIT 13

Gary Mucciolo, M.D., FACOG

40 EAST 88TH STREET, NEW YORK, NY 10128
TEL 212 722-9196 FAX 212 722-0911

gmucciolo@gmail.com

October 5, 2010
Joseph M. Gorrell
Brach Eichler L.L.C.
101 Eisenhower Parkway
Roseland, NJ 07068

Dear Mr Gorrell,

At your request I have read the information provided me regarding the medical care Dr. Brigham rendered to the patients discussed herein. I have relied on the following documents and thirty years of practice at NYUniversity - Tisch Hospital, and currently as a clinical associate professor of obstetrics and gynecology at NYU School of Medicine. The documents before mentioned are:

1. Verified Complaint by the NJ Attorney General against Steven Chase Brigham, MD

2. Order for Summary Suspension of License by Maryland Board of Physicians against George Shepard Jr., MD

3. Order for Summary Suspension of License by Maryland Board of Physicians against Nicola I. Riley, MD

4. Interview of patient DB by investigator for Maryland Board of Physicians held August 18, 2010

5. Interview of George Shepard Jr., MD by investigator for Maryland Board of Physicians held August 19, 2010

6. Interview of Kimberly Walker by investigator for Maryland Board of Physicians held August 23, 2010

7. Interview of Nicola I. Riley, M.D. by investigator for Maryland Board of Physicians held August 24, 2010

8. Medical records of patient DB for care rendered at American Women's Services covering August 9 to 13 2010

9. Statement of Nicola I. Riley, MD summarizing the care rendered to patient DB in Elkton, MD on August 13, 2010

10. Medical records of DB from Union Hospital, Elkton, MD for August 13, 2010

11. Medical Records of DB from John Hopkins Hospital

12. Medical Records from American Women's Services for SD August 2010

13. Medical Records from American Women's Services for NC August 2010

14. Medical Records from Grace Medical Services for JP June 2010

15. Virtua Memorial hospital Records JP 2010

16. Medical Records from Grace Medical Services for ML

DB was seen at American Women's Services in Voorhees, NJ on august 9, 2010 requesting a termination of pregnancy. Ultrasound revealed a pregnancy at 21.5 weeks. She returned on August 12, 2010 for a laminaria insertion. These are osmotic dilators placed in the cervix prior to any abortion to slowly and safely dilate the cervix and avoid mechanical dilatation when the abortion is performed at a late time. In this case seven laminaria were inserted, prophylactic doxycyline was prescribed, tylenol #3 was given for pain and the abortion was scheduled for August 13, 2010. On August 13, 2010 DB returned to American Women's Services where cytotec was prescribed. This is a prostaglandin class drug which has many uses. In this case it was (and is currently routinely) used to cause cervical softening to allow the laminaria to work more effectively and the cervix to dilate easier. Its purpose in this context is not to induce labor, which rarely occurs in the dosage utilized by Dr. Brigham. This is done to increase the safety of the abortion performed later at the Elkton location by Dr. Riley.

An abortion is the termination of a pregnancy, evacuating the products of conception (i.e., the fetus and placenta) from the uterus. This is done by an abdominal operation - a hysterotomy (as in a cesarean section), induction of labor with a vaginal delivery or evacuating these productions of conception vaginally. The later two procedures can only be done if the cervix is dilated first. An abor-

tion is not dilatation of the cervix. Moreover, induction of fetal demise by digoxin and/or utilization of cytotec is prefatory to, but does not constitute an abortion. In many other circumstances the cervix is dilated where no abortion is done and no pregnancy exists. Laminaria are routinely used in multiple day procedures where patients return home and will return to the location where the abortion is performed. The time between insertion and abortion can be about 24 hours.

Digoxin, as utilized by Dr. Brigham, and the resultant fetal demise does not increase the risk of hemorrhage. The interval between the fetal demise and the subsequent abortion is too short to allow any coogulopathy to develop. Moreover, in cases of multiple gestations, fetal demise is routinely done to cause fetal reduction where delivery does not occur for many months. The use of digoxin in the office with the patient later coming to an approved facility is standard practice. An interval of days regardless of travel allows the fetal boney parts to soften and increases the safety of the abortion. Several hours of travel time would have no deleterious affects on the patient. Misoprostol in the doses used by Dr. Brigham and use of laminaria when used in the late second trimester are not designed to induce labor, nor are they associated with significant bleeding. Rather they are designed to prepare for the abortion by gently dilating the cervix without labor.

Patient DB suffered a uterine perforation. She was taken 1 1/2 blocks to Union Hospital at the direction of the physician who performed the abortion, Dr Riley. It was appropriate, under the circumstances of DB's condition, and the immediate proximity of the hospital for Dr. Riley to direct Dr. Brigham to drive the car with her and the patient to Union Hospital with her being in continual phone contact with the emergency room physician, especially when accompanied by another physician, namely Dr. Brigham. She undoubtedly arrived at the hospital faster than would have if they had waited for an ambulance for transportation. She was then transferred to Johns Hopkins Hospital where a uterine perforation and small bowel injury were repaired. Her hematocrit was 34 prior to the abortion and on post operative day #1 at Johns Hopkins Hospital is was 26.9. no transfusion was given and there were no complications.

Patient SD had a twin pregnancy at 25-26 weeks. Intra amniotic digoxin was used twice to induce fetal death. Six #10 laminaria were inserted on August 11, 2010. She returned on August 12 where these were removed and nine #10 were reinserted. Doxycycline was used prophylactically. On August 13, 2010 she went to Elkton MD where Dr. Riley performed the abortion without incident. SD 's followup exam on September 2, 2010 at Grace Medical Care was normal.

Patient NC was seen at American Women's Services on August 12,2010 where an ultrasound revealed an 18 week pregnancy. Four laminaria were inserted,

two #10, one #5 and one #4. Prophylactic doxycycline was given and she returned on August 13,2010 for cytotec administration - again used to induce cervical softening and enhance the dilatation with the laminaria. The abortion was done thereafter in Elkton without incident.

Patient JP was seen at Grace Medical on June 9, 2010 and found to be 24 weeks pregnant. Intra-amniotic digoxin was used to induce fetal death. Seven #10 laminaria were inserted. Prophylactic amoxicillin was given. She returned on June 10, 2010 where the laminaria were removed and fifteen more were reinserted, thirteen #10, two #6. Again, prophylactic amoxicillin was used.

Later that evening she developed abdominal pain caused by urinary retention and Dr. Brigham responded immediately. He went to her hotel room where he removed the vaginal gauze that is routinely placed in the vagina to help hold the laminaria in place. The patient was then able to urinate without problems and she reported significant improvement of her pain. The treatment rendered by Dr. Brigham was not intended to induce labor. Against her wishes the patient was transported to the hospital where she delivered without incident. There were no complications. There was no significant bleeding as alleged by Dr Brickner, and no transfusions were given. Her hematocrit was 32 pre-abortion and 31.8 at the hospital.

Patient ML was 33 weeks pregnant with a fetus with trisomy 21 (Down's syndrome) and multiple fetal abnormalities. Ultrasound revealed skeletal anomalies - (abnormal femur) abnormal brain blood flow, abnormal MCA (middle Cerebral artery), marked polyhydromnia and duodenal atresia. The amount of fluid was so abnormal that an amniocentesis for fluid reduction was performed and cytogenetics revealed trisomy 21. Ultrasound also revealed abnormal fetal placental blood flow in the umbilical cord. These anomalies could easily have been fatal if the pregnancy was allowed to continue.

On August 2, 2010 ten #10 laminaria were inserted and on August 3, 2010 they were removed and reinsertion with fifteen #10 were performed. Doxycyline was prophylactically given. The abortion was performed on August 4, 2010 at Elkton without complications.

In summary, Dr. Brigham treated the above patients completely within the standard of care and demonstrated concern and attentiveness to his patients. He performed no D&E abortions in New Jersey, they were all performed in Elkton MD.

Patient ML did have multiple fetal abnormalities, was chromosomally abnormal, all of which would probably have been lethal if the pregnancy was allowed to

continue. Dr. Brigham's treatment was completely within accepted norms of preparing patients for late term abortions. There was no risk of sudden labor or hemorrhage(none of these patients received blood transfusions).

Whenever laminaria and cytotec are used at any gestational age there is a miniscule risk of spontaneous labor. However, the softening these agents provide in avoiding mechanical trauma to the cervix and uterus far outweigh the risk of labor, and thus their use prefatory to an abortion is standard medical practice.

It should be mentioned that Dr. Riley was not unqualified to perform late term abortions, as she had been performing second trimester abortions for five years. The only factor that changes with advancing gestational age is increased fetal size requiring more cervical dilatation. The techniques of evacuations are the same. The only complication mentioned in any of these cases was NOT a late 2nd trimester abortion but rather DB at 21.5 weeks.

Dr. Brigham did not commit any acts of negligence and should be allowed to continue o provided necessary and legal abortion services in New Jersey.

Sincerely yours,

Gary Mucciolo. M.D.

CURRICULUM VITAE

NAME:	Gary L. Mucciolo, M.D.
PRIMARY OFFICE:	40 East 88th Street New York, NY 10128
DATE OF BIRTH:	November 7, 1950
RESIDENCE:	601 Nottingham Court Norwood, NJ 07648
EDUCATION:	Archbishop Molloy High School Queens, New York, 1968
	CUNY – Queens College, B.A., 1968-1972
	New York University School of Medicine, M.D. 1972 – 1976
INTERNSHIP AND RESIDENCIES:	New York University – Bellevue Hospital Department of Obstetrics and Gynecology 1976 – 1980
LICENSURE AND BOARDS:	Diplomate, National Board of Medicine Examiners, 1977
	Medicine and Surgery – New York State #131722, 1977
	American Board of Obstetrics and Gynecology, 1983
ACADEMIC APPOINTMENTS:	Clinical Associate Professor in Obstetrics and Gynecology, 1999 New York University School of Medicine
HOSPITAL APPOINTMENTS:	Attending – New York University – Tisch Hospital

Gary L. Mucciolo, M.D.

SOCIETIES:

American College of Obstetricians and Gynecologists
Fellow, 1983

New York County Medical Society, 1980

New York State Medical Society, 1980

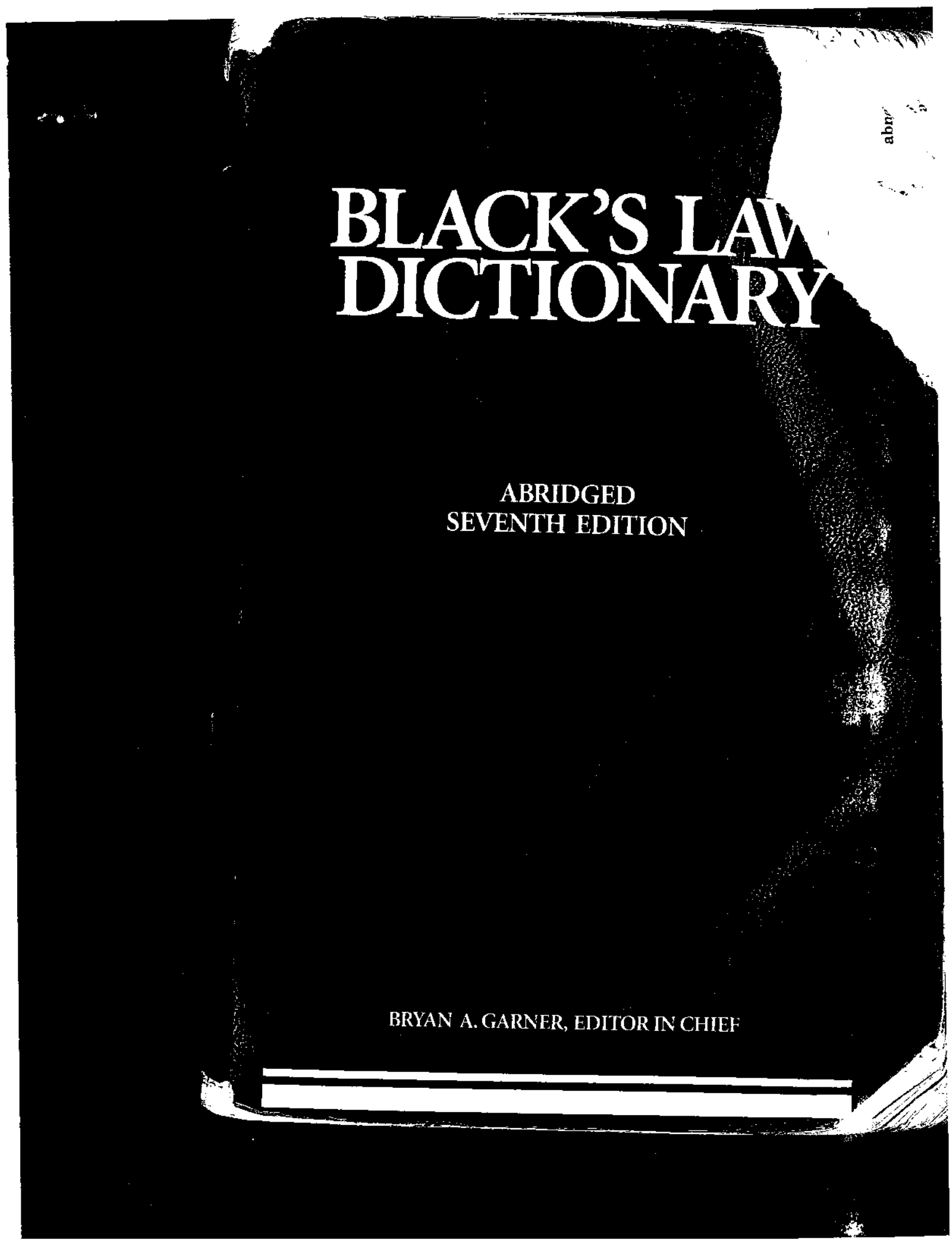
Bellevue Obstetrical and Gynecological Society, 1980

Phi Beta Kappa, 1972

HONORS:

CUNY - Queens College
Honors in Biology, 1972
Magna Cum Laude, 1972

EXHIBIT 14


BLACK'S LAW
DICTIONARY
ABRIDGED
SEVENTH EDITION
BRYAN A. GARNER, EDITOR IN CHIEF

...The law as it applies to persons under legal disabilities such as ...nage, insanity, criminality, and ...coverture.

...nally dangerous activity. An underthat cannot be performed safely even ...reasonable care is used while performing ...and for which the actor may face strict ...liability for any harm caused; esp., an activity (such as dynamiting) for which the actor is held strictly liable because the activity (1) involves the risk of serious harm to persons or property, (2) cannot be performed without this risk, regardless of the precautions taken, and (3) does not ordinarily occur in the community. • Under the *Restatement (Second) of Torts*, determining whether an activity is abnormally dangerous includes analyzing whether there is a high degree of risk of harm, whether any harm caused will be substantial, whether the exercise of reasonable care will eliminate the risk, whether the activity is a matter of common usage, whether the activity is appropriate to the place in which it occurs, and whether the activity's value to society outweighs its dangerousness. Restatement (Second) of Torts § 520 (1977). — Also termed *ultrahazardous activity*. See *strict liability* under LIABILITY.

abode. A home; a fixed place of residence. See DOMICILE.

abolish, *vb.* To annul or destroy, esp. an ongoing practice or thing.

abolition. **1.** The act of abolishing. **2.** The state of being annulled or abrogated. **3.** (*usu. cap.*) The legal termination of slavery in the United States. **4.** *Civil law.* A sovereign's remission of punishment for a crime.

abominable and detestable crime against nature. See SODOMY.

aboriginal cost. See COST (1).

aboriginal title. See INDIAN TITLE.

abortee (ə-bor-**tee**). A woman who undergoes an abortion.

abortifacient (ə-bor-tə-**fay**-shənt), *n.* A drug, article, or other thing designed or intended to produce an abortion. — **abortifacient,** *adj.*

abortion, *n.* **1.** The spontaneous or artificially induced expulsion of an embryo or fetus. • In *Roe v. Wade*, the Supreme Court first recognized a woman's right to choose to end her pregnancy as a privacy right stemming from the Due Process Clause of the 14th Amendment. 410 U.S. 113, 93 S.Ct. 1409 (1973). **2.** *Archaic.* At common law, the misdemeanor of causing a miscarriage or premature delivery of a fetus by means of any instrument, medicine, drug, or other means. • Many American states made this a statutory felony until the *Roe v. Wade* decision. — Also termed *procuring an abortion*. — **abort,** *vb.* — **abortionist,** *n.*

therapeutic abortion. An abortion carried out for medical reasons.

above, *adv.* In a higher court <the court above>. Cf. BELOW.

above-mentioned, *adj.* See AFORESAID.

above-stated, *adj.* See AFORESAID.

above-the-line, *adj.* (Of a deduction) taken after calculating gross income ...fore calculating adjusted gross income ...amples of above-the-line deductions ...RA contributions and moving expenses ...erly, individual tax returns list ...ine above which these deductions ...en. Cf. BELOW-THE-LINE.

abridge, *vb.* **1.** To reduce ...gh <abridge one's civil liberties ...n- dense (as a book or other ...ne author abridged the treatise ...nal publication>. — **abridgment,** *n.*

abridgment of damages. The ...a court to reduce the damages in ...s. Cf. REMITTITUR.

abroad, *adv.* Outside a country; esp. ...her than in a forum country.

abrogate (**ab**-rə-gayt), *vb.* To abolish ...w or custom) by formal or authoritative ...n; to annul or repeal. — **abrogation,** ...B- ROGATE.

ABS. See *able-bodied seaman* under SEAMAN.

abscond (ab-**skond**), *vb.* **1.** To depart secretly or suddenly, esp. to avoid arrest, prosecution, or service of process. **2.** To ...place, usu. hurriedly, with another's ...

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF **STEVEN C. BRIGHAM, M.D.** TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	STATE OF NEW JERSEY DEPARTMENT OF LAW & PUBLIC SAFETY DIVISION OF CONSUMER AFFAIRS STATE BOARD OF MEDICAL EXAMINERS

BRIEF IN SUPPORT OF RESPONDENT'S MOTION TO DISMISS COUNTS I, III, IV, V AND VI OF THE VERIFIED COMPLAINT

BRACH EICHLER L.L.C.
101 Eisenhower Parkway
Roseland, New Jersey 07068
(973) 228-5700

OF COUNSEL:
JOSEPH M. GORRELL, ESQ.

ON THE BRIEF:
JOSEPH M. GORRELL, ESQ.
ERIC W. GROSS, ESQ.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

PRELIMINARY STATEMENT

These proceedings have their genesis in the persistent investigation into Respondent, Steven Brigham, M.D.'s practice for years by the Attorney General's ("Complainant") office. The repeated investigation and harassment by Complainant, even after Respondent was exonerated by the New Jersey State Board of Medical Examiners ("BME") in 1996 for the very same alleged wrongdoings that are now claimed again, raises real questions as to the good faith of Complainant's allegations.

In 1993, a Verified Complaint was filed by Complainant seeking the summary suspension of Respondent's license to practice medicine based on alleged violations of N.J.A.C. 13:35-4.2. (Gross Cert. Exh.1). After extensive proceedings that matter was dismissed by the BME in 1996. (Gross Cert., Exh. 2). Now, in the Verified Complaint currently pending before the BME, Complainant alleges a violation of the same regulation. N.J.A.C. 13:35-4.2(d) provides that "after 14 weeks LMP (last menstrual period), any termination procedure other than a dilation and evacuation (D and E) shall be performed only in a licensed hospital." The text of N.J.A.C. 13:35-4.2 is currently the same as it was in 1993 and therefore Complainant is now alleging a violation of the same exact regulation.

In both matters, Complainant alleged that Respondent violated N.J.A.C. 13:35-4.2 by commencing abortions on patients after 14 weeks in his New Jersey office and then completing them out of state. In the 1993 Complaint, Complainant alleged "the insertion of laminaria in a patient who is past 14 weeks LMP constitutes the commencement of an abortion in the second trimester." (Gorrell Cert., Exh. 1, Count I, ¶ 15). That allegation was rejected by this Board. In the current Complaint, Complainant alleges that the termination of pregnancy was "commenced" by Respondent in his Voorhees, New Jersey Office either when the laminaria were inserted, upon

consumption of misoprostol or injection of digoxin. (emphasis added). Therefore the issue in 1993, and the issue now, is what act constitutes an "abortion" or in other words a "termination of a pregnancy."

In the 1993 matter, after 29 days of hearings, the Honorable Joseph Fidler, A.L.J., issued a 95 page written decision which dismissed all counts related to Respondent's treatment of patients, and the alleged violation of N.J.A.C. 13:35-4.2. (Gross Cert., Exh. 3, p. 3, 22, 77). The 1993 Complaint made allegations with respect Respondent's treatment of several patients in the 1993 matter, all of which were dismissed by the BME. However, only the allegations in the 1993 Complaint as to patients J.K. and B.A. are relevant to this matter.

J.K. was 24 weeks pregnant when she was examined by Respondent on July 14, 1992. (Gross Cert., Exh. 3, p. 12). As to patient J.K., Complainant made the following relevant allegations as to Respondent's treatment of J.K.:

- By inserting laminaria in J.K. on July 14, 1992, Respondent violated N.J.A.C. 13:35-4.2, which restricted the performance of second trimester abortions to licensed ambulatory facilities and hospitals and further restricts the performance of abortions past 20 weeks, L.M.P. to specified circumstances with specific approval of the Board. Complainant contended that the insertion of laminaria in a patient who intends to have an abortion, when the laminaria are inserted for the purpose of dilating the cervix preparatory to the removal of the fetus and placenta, is the commencement of the abortion procedure. (Gross Cert., Exh. 3, p. 76).

- Respondent's care plan for J.K. was a gross deviation from generally accepted standards for a two day termination of late stage pregnancy, in that he inserted laminaria in a patient who had to travel over an hour to and from his office each day and he further intended to transport her an additional two hours to the clinic in New York for the actual completion of the procedure. Complainant further alleged that Respondent's subjected J.K. to enhanced risk of hemorrhage and all risks which flow from that. (Gross Cert., Exh. 3, p. 16).

- Respondent's conduct subjected J.K. to enhanced risk of hemorrhage and infection and all risks which flow from that. (Gross Cert., Exh. 3, p. 11, 12).

As with patient J.K., Complainant also alleged with respect to B.A., who was 23 weeks pregnant when she met with Respondent, that Respondent commenced an abortion on November

11, 1992 by inserting laminaria in his New Jersey office and therefore violated N.J.A.C. 13:35-4.2. (Gross Cert., Exh. 1, Count V, ¶ 2).

In rebuttal to Complainant's allegations, Respondent and his experts made the following contentions during the hearing before Judge Fidler:

- The insertion of laminaria did not constitute an abortion and abortion was defined as the "evacuation of the uterus." (Gross Cert., Exh. 3, p. 76).
- Respondent's management of J.K. and B.A. was within the generally accepted standard of care. (Gross Cert., Exh. 3, p. 17).
- Every physician he knows who does late term abortions sends the patient home after insertion of laminaria, to return the next day to complete the procedure. (Gross Cert., Exh. 3, p. 17).
- Respondent stated that the plan he had for the remainder of J.K.'s care after the insertion of laminaria was also within the accepted standards of care. (Gross Cert., Exh. 3, p. 17).
- Respondent further characterized "as ridiculous" that the assertion that insertion of laminaria in J.K. or B.A. was the performance of an abortion, and he noted that if he had thought insertion of laminaria in J.K. or B.A. violated the regulation "he would not have done it." (Gross Cert., Exh. 3, p. 17).
- Respondent further asserted that "J.K.'s situation was no different than that of a patient who had an induced fetal demise with digoxin in preparation for a late abortion." (Gross Cert., Exh. 3, p. 21).
- Respondent further asserted that the management of a patient with a late second term intrauterine fetal demise is acceptable as an outpatient D&E procedure. (Gross Cert., Exh. 3, p. 22).

Judge Fidler agreed with all of Respondent's contentions and held that Complainant failed to meet her burden. (Gross Cert., Exh. 3, p. 22, 77). Judge Fidler thus held that the insertion of laminaria in Respondent's medical office in New Jersey: (1) did not constitute the performance of an abortion; and (2) did not violate the BME's termination of pregnancy regulation (N.J.A.C. 13:35-4.2). (Gross Cert., Exh. 3, p. 77). Judge Fidler made the following specific findings relevant to the current matter before the BME:

1. Respondent's treatment plan for J.K. was consistent with generally accepted standards of care, and the medical judgment exercised by Respondent was sound and reasonable. (Gross Cert., Exh. 3, p. 22).

2. It is clear insertion of laminaria is a necessary step in achieving adequate cervical dilation so the evacuation of the uterus can be performed safely and does not terminate a pregnancy and that Respondent did not violate N.J.A.C. 13:35-4.2. (Gross Cert., Exh. 3, p. 77).

The BME, in its 1996 Order, "based upon due consideration of the Administrative Law Judge's decision and the underlying record in this case" adopted all of the above findings of Judge Fidler as to patient J.K. and B.A. (Gross Cert., Exh. 2).

Now, in 2010, in Counts I, III, V and VI of the current Complaint, Complainant alleges that Respondent violated N.J.A.C. 13:35-4.2 by commencing abortions in his New Jersey office and that his care plan for such patients was negligent and/or grossly negligent. However, these allegations are barred by the legal doctrine of collateral estoppel, as these issues were fully aired and litigated in Respondent's favor. As set forth below, that decision by this Board now bars Complainant from obtaining a summary suspension of Respondent's license and mandates that these same allegations in the present Complaint be dismissed.

PROCEDURAL HISTORY

On August 25, 2010 the Maryland Board of Physicians ("Maryland Board") issued a Cease and Desist Order against Respondent, Steven Brigham, M.D. from practicing medicine in Maryland without a license. (Gross Cert., Exh. 5). This action was taken without a hearing or any chance of Respondent to respond to any allegations, and contains no findings against Respondent. Rather, the Cease and Desist Order claims that the "Board has probable cause to believe" that certain facts are true. Indeed, several of the "facts" contained therein are untrue. Subsequently, Respondent filed an appeal of the Maryland Cease and Desist Order and requested a hearing. (Gross Cert., Exh. 6). That matter is currently pending in Maryland. (Gross Cert., Exh. 6).

Subsequent thereto, on September 8, 2010, a Verified Complaint and Order to Show Cause was filed by the Attorney General of the State of New Jersey with the New Jersey State Board of Medical Examiners ("BME") seeking the summary suspension of Respondent's license to practice medicine based on treatment provided in 2010 to 5 patients namely, D.B., S.D., N.C., J.P. and M.L.

The original return date for the Order to Show Cause was September 15, 2010, which only allowed Respondent 7 days to prepare a defense. Respondent denied the conduct set forth in the Verified Complaint, but requested additional time to prepare his defense. In exchange for such time, Respondent agreed to cease practicing medicine until Complainant's application is considered by the BME on October 13, 2010. (Gross Cert., Exh. 4).

Subsequent thereto on September 17, 2010, Complainant filed an Amended Verified Complaint with the BME ("Complaint"). Respondent filed an Answer on September 24, 2010.

STATEMENT OF FACTS

A. THE FIVE PATIENTS

1. Patient D.B. (Count I)

Patient D.B. is an 18 year old female who presented to Respondent's office, American Healthcare Services, P.C., ("AHS"), located at 1 Alpha Avenue, Suite 20, Voorhees, New Jersey 08043 ("Voorhees Office"), on August 9, 2010 seeking a termination of her pregnancy. (Exh. B, p.4). On that date, D.B. was 21 weeks pregnant. (Exh. B, p. 8, 20) Based on this information, patient D.B. was told by Respondent's office that the abortion could not be performed in the Voorhees office and needed to be performed at another location. (Exh. A, p. 6).

On August 12, 2010, D.B. returned to the Voorhees Office and Respondent inserted seven laminaria into D.B. to dilate her cervix. (Exh. B, p. 22) D.B. was instructed to then return the next morning on August 13, 2010 for the dilation and extraction procedure ("D and E"). (Exh. A, p. 8).

On August 13, 2010, patient D.B. returned to the Voorhees office and ingested two tablets of misoprostol (Cytotec) to dilate her cervix and uterus. (Exh. B, p. 30) (Exh. G, p. 19). A few minutes later, D.B. was then driven by her boyfriend and mother to American Medical Services, P.C. ("A.M.S."), located at 126 East High Street, Elkton, Maryland 21992 ("Elkton Facilty"). The Elkton Facility is located 54 miles from the Vorhees Office and it takes at less than one hour to drive between the two locations. (Gross Cert., Exh. 8).

Nicola Riley, M.D., a Maryland licensed physician, is an independent contractor of AMS who performs abortions at the Elkton Facility. Dr. Riley is a board certified family physician and is also licensed to practice medicine in Wyoming and Utah. (Exh. I, p.3). Dr. Riley began performing abortions at the Elkton Facility in July of 2010 but had been performing abortions for

the previous 5 years at a woman's clinic in Utah and is the medical director of such clinic. (Exh. I, p. 4, 7).

Before she began working at the Elkton Facility, Dr. Riley surveyed the facility and verified the appropriate emergency equipment was present. (Exh. I, p. 11). Dr. Riley was also assured of the Elkton's Facility capability to appropriately respond to an emergency because it was located only two blocks from Union Hospital. (Exh. I, p. 11). When Respondent's patients are brought from the Voorhees Office to the Elkton Facility for abortions to be performed by Dr. Riley, Respondent's custom and practice is to bring the entire medical record with him down to the Elkton Facility to allow for Dr. Riley to review the chart and confirm the information with her physical examination findings. (Exh. I, p. 12-15). Dr. Riley then talks to the family, verifies the risks and benefits, and goes over the consent form with the patient. (Exh. I, p. 15).

After D.B. arrived at the Elkton Facility, Dr. Riley introduced herself to D.B. and her family and performed an examination. (Exh. B, p. 33). The D and E procedure was performed by Dr. Riley. (Exh. B, p. 33). Dr. Riley began the D and E procedure using suction, with a 16 cannula and forceps. (Exh. I, p. 20). Dr. Brigham was present during the procedure as a consulting physician. (Exh. B, p. 33). As stated by Dr. Riley during her interview with the Maryland Board of Physicians:

A: He was in consult. For example, when I had a question, I would have him observe and he would give recommendations.

Q. So Dr. Brigham is there in your opinion as a consulting physician?

A. Yes

Q. Now why is he only there as a consulting physician?

A. Oh, it was my understanding that because he didn't have a Maryland license.[1] . (Exh. I, p. 9).

During suction, Dr. Riley stopped and observed extra uterine tissue in the vaginal vault. (Exh. I, p. 20). Thereafter, Dr. Riley felt it was necessary for D.B. to go to Union Hospital, which was located two blocks away from AMS. (Exh. B., p. 33). D.B. was stable at that time. (Exh. I, p. 30).

Dr. Riley, as the attending physician, controlled the transfer of the patient to Union Hospital. At the direction of Dr. Riley, D.B. was dressed by the Elkton Facility staff, placed in a wheelchair and was driven by Respondent to Union Hospital. (Exh. I, p. 33). Dr. Riley was in the back seat of the vehicle with D.B. and was in communication with the emergency room physician throughout. (Exh. B, p. 33). Dr. Riley was adamant during her conversation with the Maryland Board that D.B. was her patient and was her responsibility as the Maryland licensee. ("I took control of the situation and I got my patient to the emergency room.") ((Exh. I, p. 24) (emphasis added). D.B. arrived at the emergency room at Union Hospital approximately 10 minutes after the extra-uterine tissue was noticed by Dr. Riley. (Exh. I., p. 21).

D.B. was admitted through the Union Hospital Emergency Department and was later transferred to Johns Hopkins Hospital, where it was determined that D.B.'s uterus had been perforated. (Exh. D, p. 1). At John Hopkins Hospital, the termination of the pregnancy was completed and the perforation was repaired. (Exh. B, p. 33) (Exh. D, p. 1).

2. Patient S.D. (Count III)

Patient S.D. is a 32 year old woman who presented at the Voorhees Office on August 11, 2010 seeking a termination of her pregnancy. (Exh. O, p. 1). On that date, patient S.D. was 25

[1] This arrangement between Respondent and Dr. Riley was perfectly legal under Maryland law. Maryland explicitly permits "a physician licensed by and residing in another jurisdiction, while engaging in consultation with a

weeks pregnant with twins. (Exh. O, p. 6). Patient S. D. was diagnosed as carrying a twin pregnancy in which one the fetuses suffered from intrauterine growth retardation ("IUGR"), and both fetuses had oligohydraminos. (Exh. O, p. 18, 19). Patient S.D. indicated in a form that she wanted to terminate he pregnancy for the following reasons:

> Got pregnant with IVF using donor sperm insemination. At that time IVF people did not give us [sic] the consequences. As the pregnancy days goes on mentally getting stressed, since we did not tell anyone. This lie is making isolated from social life, family, friends, we are not confident that we can provide good care to children and also will be guilty and cannot keep this secret. Worried about the problems that children will have in future. (Exh. O, p. 22).

Patient S.D. also indicated that she was depressed about being pregnant and that she believed her life or mental health would be at risk if she did not receive the abortion. (Exh. O, p. 23).

On August 11, 2010, the fetuses were administered digoxin by Respondent to cause fetal demise. (Exh. O, p.9). Additionally, six laminaria were inserted by Respondent to dilate her cervix. (Exh. O, p. 9). S.D. was then directed to return to the Voorhees office the next day. (Exh. O, p. 9).

On August 12, 2010, an ultrasound revealed an intrauterine fetal demise ("IUFD") for fetus A, but possible cardiac and fetal activity for fetus B. (Exh. O, p. 12). Digoxin was again injected by Respondent to ensure the demise of fetus B. (Exh. O, p. 12). An ultrasound then revealed IUFD for fetus B. (Exh. O, p. 12). Additional laminaria were also inserted by Respondent and S.D. was instructed to return to the Voorhees Office the following morning. (Exh. O, p. 12).

---

physician licensed in this State" to practice without a license to practice medicine in Maryland. (Maryland Code, Health Occupations, § 14-302.

On August 13, 2010, patient S.D. was transported to the Elkton Facility and underwent a termination of her pregnancy by Dr. Riley. (Exh. O, p. 5). Respondent was present during the procedure as a consulting physician. (Exh. K, p. 1) (Exh. I, p. 9). The procedure was completed without incident. (Exh. O, p. 5).

3. Patient N.C. (Count III)

Patient N.C. is a 23 year old woman who presented to an office of AHS on August 12, 2010 seeking a termination of her pregnancy. (Exh. P, p. 6). On that date, Patient N.C. was 18.4 weeks pregnant and she underwent the insertion of laminaria by Richard H. Blum, M.D., F.A.C.O.G. (Exh. P, p. 1,4). N.C. neither met with nor received treatment from Respondent on that day.

On August 13, 2010, Patient N.C. went to the Voorhees Office and ingested misoprostol at the direction of Respondent. (Exh. P, p. 23). Soon thereafter she was transported to the Elkton Facility and she underwent a termination of pregnancy performed by Dr. Riley. (Exh. P, p. 1, 2). Dr. Brigham was present as a consultant during the procedure. (Exh. P, p. 2). The procedure was completed without incident. (Exh. P, p. 1).

4. Patient J.P. (Count V)

Patient J.P. is a 20 year old female who presented to the Voorhees Office on June 9, 2010 seeking a termination of her pregnancy. (Exh. Q, p. 1). J.P. is a law student and indicated in a form that she wanted to terminate the pregnancy because:

> I feel I would be better suited to terminate pregnancy. It would effect [sic] my school and career if it was not done. (Exh. Q, p. 22).

J.P. also indicated in a form that she thought her life or mental health would be at risk and she might try to abort herself, harm the fetus or cause herself to have a miscarriage if she did not receive the abortion. (Exh. Q, p. 23).

On June 9, 2010, she was approximately 24 weeks pregnant and underwent an injection of digoxin to cause fetal demise and Respondent inserted laminaria to dilate the cervix. (Exh. Q, p. 8).

The next day, J.P. returned to the Voorhees Office and additional laminaria were inserted by Respondent. (Exh. Q, p. 7). An ultrasound reflected IUFD. (Exh. Q, p. 7). J.P. was then instructed to return to the Voorhees Office the following morning. (Exh. Q, p. 7).

In the early morning of June 11, 2010, J.P. called the office of Respondent to report difficulty urinating. (Exh. Q, p. 9). Respondent was paged at 12:04 a.m. and called J.P. two minutes later. (Exh. Q, p. 9)

J.P. was staying in a hotel room near the Voorhees Office. (Exh. Q, p. 10). Respondent counseled her on the phone to remove the gauze from her vagina which would allow her to urinate. (Exh. O, p. 10). Respondent called her 10 minutes later and J.P. indicated that she still could not urinate because she could not remove the gauze herself and she asked the Respondent to assist her. (Exh. Q, p. 10). Respondent then went to the hotel room and treated her there. (Exh. Q, p. 10). Upon arrival, Respondent saw the EMS and police had arrived. (J.P.'s mother also called 911). (Exh. Q, p. 10). Respondent then removed the gauze and J.P. was able to urinate and she was greatly relieved. (Exh. Q. p. 10).

Nonetheless, at the demand of the EMS and police, J.P. went to Virtua West Hospital in Voorhees where she was treated. (Exh. Q, p. 10). Respondent did not treat her after that and was not involved in any procedure thereafter. (Exh. Q, p. 10).

At Virtua West Hospital, the laminaria were removed and J.P.'s cervix was noted to be 4 to 5 centimeters dilated due to the laminaria. (Exh. T, p. 6). At the hospital, J.P. was experiencing abdominal pain. (Exh. T, p. 6). However, contrary to the assertion of

Complainant's expert, Dr. Brickner, no where in the hospital record does it indicate she was in labor. (Exh. T, p. 6). A demised fetus was delivered without complication. (Exh. T, p. 6)

5. Patient M.L. (Count VI)

Patient M.L. is a 35 year old woman who presented at the Voorhees Office seeking a termination of her pregnancy on August 2, 2010. (Exh. S, p. 20). On that date, M.L. was 33 weeks pregnant. (Exh. S, p. 20)

Diagnostic testing, including a cytogenetic lab report, indicated that the fetus was diagnosed with down syndrome, possible macrocephaly and duodenal atresia. (Exh. S, p. 20, 29, 31, 32, 34).

In describing why she wanted to terminate the pregnancy, M.L. stated as follows:

> Baby has down syndrome and intestinal problem that will require surgery or surgeries. There are also many other medical issues that could arise. We are 35 and 37, our parents are older, limited support system. Our intention was to have only one child. Emotionally, we don't feel we can deal with down syndrome child and the medical conditions he has and that could potentially come with it. (Exh. S, p. 21).

On August 2, 2010, M.L.'s fetus was injected with digoxin by Respondent and 10 laminaria were inserted. (Exh. S, p. 10).

On August 3, 2010, an ultrasound indicated IUFD. (Exh. S, p. 7).

On August 4, 2010 the demised fetus was extracted at the Elkton Facility. (Exh. S, p. 5).[2]

B. THE COMPLAINT

In the Complaint, Complainant seeks the summary suspension of Respondent's license to practice medicine in the State of New Jersey pursuant to N.J.S.A. 45:1-22, alleging that

[2] Maryland law provides that abortions can be performed at "any time" during the pregnancy if "the fetus is affected by genetic defect or serious deformity or abnormality." Maryland Health General Law § 20-209(2)(ii). Maryland law does not require the genetic defect to be "lethal" for a late-term abortion to be performed. Therefore,

Respondent poses a clear and imminent danger to the public. More specifically, the allegations set forth in the Complaint primarily relate to the treatment rendered to five (5) patients from June of 2010 through August of 2010.

In Counts I, III, V and VI (Patients D.B. S.D., N.C., J.P. and M.L.) , Complainant alleges that Respondent violated N.J.A.C. 13:35-4.2, because the termination of her pregnancy was commenced by Respondent in his New Jersey office by the insertion of laminaria, the administration of misoprostol and/or injection of digoxin which constituted the performance of an abortion.

Also in Counts I, III, V and VI, Complainant alleges that Respondent's care plan of inserting laminaria in his office on one day and directing the patient to return the following day to his office to ingest misoprostol and travel one hour to the Elkton Facility constitutes repeated acts of negligence and/or gross negligence.

Additionally, as to patient D.B., Complainant alleges that the evacuation of the fetus (although performed by Dr. Riley) on August 13, 2010, which resulted in a uterine perforation, constituted repeated negligence and/or gross negligence on the part of Respondent.

Counts I, II, III, V and VI further alleges that Respondent conducted the unlicensed practice of medicine in Maryland.

Count II also alleges that Respondent falsely created medical records which reflected that procedures performed at the Elkton Facility were in fact performed by Dr. George Shepard and/or Kimberly Walker.[3]

---

due to the fetus' diagnosis of Down syndrome, the performance of the third trimester abortion for patient M.L. was legal under Maryland law.

[3] Respondent does not address these allegations in this motion as such allegations are clearly not a basis upon which to summarily suspend his license to practice medicine.

Count IV alleges that Respondent lied in the statement he provided to the BME dated June 20, 2010 wherein he indicated "we are not performing an abortion beyond 14 weeks in New Jersey."

C. THE 1996 BOARD ORDER

In 1996 the BME issued a Final Decision and Order ("1996 Order") with respect to Respondent wherein several of the issues that are now alleged in the current Complaint were fully litigated, explored and resolved in favor of Respondent. (Gross Cert. Exh. 2). By way of background, the First Administrative Complaint was filed on November 24, 1993, ("1993 Complaint"). (Gross Cert., Exh. 1). A second and third complaint were also filed, but the issues contained therein are not relevant to the current matter. The matter was fiercely litigated by both Respondent and Complainant before the Honorable Joseph Fidler, A.L.J. during 29 days of hearings. (Gross Cert., Exh. 3, p. 3). Two experts testified for Complainant, 6 for Respondent. (Gross Cert., Exh. 3, p. 3-8).

Only the allegations in the 1993 Complaint as to patients J.K. and B.A. are relevant to this matter. All claims related to these patients were dismissed by Judge Fidler and later by the BME in the 1996 Order.

1. Patient J.K.

J.K. was 24 weeks pregnant when she sought an abortion at All Woman's Medical Pavilion in Queens, New York. (Gross Cert., Exh. 3, p. 12). Ultrasound confirmed fetal heartbeat and a 24 week gestation. (Gross Cert., Exh. 3, p. 12). She could not afford to have an abortion there, and got Respondent's name from someone in the office. J.K. lived over 50 miles away from the Voorhees Office. (Gross Cert., Exh. 3, p. 12).

J.K. was examined by Respondent on July 14, 1992. (Gross Cert., Exh. 3, p. 12). No fetal heartbeat was detected and Respondent concluded that fetal demise had already occurred. (Gross Cert., Exh. 3, p. 12). On July 14, 1992, Respondent inserted 8 laminaria and prescribed doxycyline. (Gross Cert., Exh. 3, p. 12). Respondent's care plan was to insert laminaria to dilate her cervix for two days and on the third day he would do the abortion at the Queens facility. (Gross Cert., Exh. 3, p. 12). All Woman's Medical Pavilion is 100 miles away from the Voorhees Office and it takes approximately two hours to travel between the two locations without traffic. (Gross Cert., Exh. 9).

A complication arose after laminaria was inserted on July 14, 1992 so the abortion was never performed by Respondent in Queens. The abortion was completed at Robert Wood Johnson Hospital at 5:00 a.m. on July 15, 1992. (Gross Cert., Exh. 3, p. 13).

Complainant made the following relevant allegations as to Respondent's treatment of J.K.:

> 1. By inserting laminaria in J.K. on July 14, 1992, Respondent violated N.J.A.C. 13:35-4.2,[4] which restricted the performance of second trimester abortions to licensed ambulatory facilities and hospitals and further restricts the performance of abortions past 20 weeks, L.M.P. to specified circumstances with specific approval of the Board. (Gross Cert., Exh. 1, Count I, ¶ 15). Complainant contended that the insertion of laminaria in a patient who intends to have an abortion, when the laminaria are inserted, for the purpose of dilating the cervix preparatory to the removal of the fetus and placenta, is the commencement of the abortion procedure. Complainant further contended that the insert of laminaria was the initial medical procedure toward J.K.'s abortion because there was no other purpose for the laminaria insertion in J.K. Complainant argued that to the extent that laminaria might be removable from a patient and the process of D and E interrupted, Respondent no doubt knew he would not be removing the laminaria and thus stopping the process in J.K. who had a fetal demise. (Gross Cert., Exh. 3, p. 76).

[4] N.J.A.C. 13:35-4.2 has not been amended since October 16, 1989. (See 21 N.J.R. 2226(b), 21 N.J.R. 3307(a). Therefore, the text of the regulation is unchanged from 1993 when Complainant initially alleged Respondent violated it to now.

2. Respondent's care plan for J.K. was a gross deviation from generally accepted standards for a two day termination of late stage pregnancy, in that he inserted laminaria in a patient who had to travel over an hour to and from his office each day and he further intended to transport her an additional two hours to the clinic in New York for the actual completion of the procedure. Complainant further alleged that Respondent's subjected J.K. to enhanced risk of hemorrhage and all risks which flow from that. (Gross Cert., Exh. 1, Count I, ¶ 16).

3. Respondent's conduct subjected J.K. to enhanced risk of hemorrhage and infection and all risks which flow from that. (Gross Cert., Exh. 3 p, 11, 12).

Respondent testified that his management of J.K. was within the generally accepted standard of care. (Gross Cert., Exh. 3, p. 17). Respondent testified that every physician he knows who does late abortion sends the patient home after insertion of laminaria, to return the next day to complete the procedure. (Gross Cert., Exh. 3, p. 17). Respondent stated that the plan he had for the remainder of J.K.'s care after the insertion of laminaria was also within the accepted standards of care. (Gross Cert., Exh. 3, p. 17).

Respondent further characterized "as ridiculous that the assertion that insertion of laminaria in J.K. was the performance of an abortion, and he noted that if he had thought insertion of laminaria in J.K. violated the regulation he would not have done it." (Gross Cert., Exh. 3, p. 17). Respondent further asserted that "J.K.'s situation was no different than that of a patient who had an induced fetal demise with digoxin in preparation for a late abortion." (Gross Cert., Exh. 3, p. 21). Respondent further asserted that the management of a patient with a late second term intrauterine fetal demise is acceptable as an outpatient D&E procedure. (Gross Cert., Exh. 3, p. 22).

Judge Fidler characterized Respondent's testimony as sincere and credible. (Gross Cert., Exh. 3 p. 17).

Dr. Jeffrey Moscowitz, one of the experts that testified for Respondent, disagreed with Complainant's contention, and testified that the insertion of laminaria did not constitute an abortion, which he defined as the "evacuation of the uterus." (Gross Cert., Exh. 3, p. 76).

Judge Fidler agreed with all of Respondent's contentions and held that Complainant failed to meet her burden. (Gross Cert., Exh. 3, p. 22). Judge Fidler thus held that the insertion of laminaria in Respondent's medical office in New Jersey: (1) did not constitute the performance of an abortion; and (2) did not violate the BME's termination of pregnancy regulation (N.J.A.C. 13:35-4.2). Judge Fidler made the following specific findings relevant to the current matter before the BME:

> 1. Respondent's treatment plan for J.K. was consistent with generally accepted standards of care, and the medical judgment exercised by Respondent was sound and reasonable. (Gross Cert., Exh. 3, p. 22).
>
> 2. It is clear insertion of laminaria is a necessary step in achieving adequate cervical dilation so the evacuation of the uterus can be performed safely and does not terminate a pregnancy and that Respondent did not violate N.J.A.C. 13:35-4.2. (Gross Cert., Exh. 3, p. 77).

The BME, in its 1996 Order, "based upon due consideration of the Administrative Law Judge's decision and the underlying record in this case" adopted all of the above findings of Judge Fidler as to patient J.K. (Gross Cert., Exh. 2).

2. Patient B.A.

On November 11, 1992, Patient B.A. and her husband met with Respondent at the Voorhees Office. (Gross Cert., Exh. 3, p. 48); Exh. 1, Count V, ¶2). Respondent indicated to the couple that because she was 23 weeks pregnant, in order to have an abortion, he would insert laminaria in the Voorhees Office, and perform the abortion at All Woman's Medical Pavilion in Queens, New York. (Gross Cert., Exh. 1, Count V, ¶5). On that day, Respondent inserted laminaria. (Gross Cert., Exh. 1, Count V, ¶5). (Gross Cert., Exh. 3, p. 62). The next morning,

B.A. and her husband drove to All Woman's Medical Pavilion in Queens, New York where the abortion procedure was performed. (Exh. 3, p. 65, 67).

Again as with patient J.K., Complainant alleged that Respondent commenced an abortion by inserting laminaria and therefore violated N.J.A.C. 13:35-4.2. (Gross Cert., Exh. 3, p.74). However, for the same reasons discussed above as to patient J.K., Judge Fidler dismissed Complainant's claim and the Board adopted Judge Fidler's findings in whole. (Gross Cert., Exh. 3, p. 78; Exh. 2).

D. NOVEMBER 8, 1999 IN-OFFICE INSERTION OF LAMINARIA BME LETTER

In a letter dated January 26, 1999, almost 3 years after the BME's 1996 Order, Stuart Phillips, Esq. wrote Judith Gleason, the Executive Director of the BME at the time, seeking confirmation of the BME's interpretation of N.J.A.C. 13:35-4.2. (Gross Cert., Exh. 10). Mr. Phillips explained that a group of physicians, who practiced in New Jersey, performed second trimester abortion procedures. Mr. Phillips indicated that typically laminaria will be inserted into the patients' cervix in the office, and then one or two days later the abortion procedure is performed in a hospital or a licensed/approved facility. (Gross Cert., Exh. 10). Mr. Phillips explained that his client felt it was perfectly legal and safe to do so.

Mr. Phillips stated, however, that his client had become aware of the fact that several years ago, "Steven Brigham, was brought up on charges of violating N.J.A.C. 13:35-4.2 before the New Jersey Board, for inserting laminaria in the office setting, prior to performing an abortion" but was exonerated by the Board. However, he stated his client did not want to violate N.J.A.C. 13:35-4.2 and was seeking the BME's further guidance. Based on his review of the regulation, and materials for Respondent's previous matter, Mr. Phillips indicated to the BME that he believed the insertion of in-office laminaria does not violate N.J.A.C. 13:35-4.2.

On November 8, 1999, Ms. Gleason responded to Ms. Phillips in a letter and stated as follows:

> I am in receipt of your October 21, 1999 letter and apologize for not having replied to your earlier correspondence. I did have occasion to discuss your inquiry yesterday with the Executive Committee of the Board of Medical Examiners. The Members present share your view of the applicability of N.J.A.C. 13:35-4.2. Accordingly, there would appear to be no problem with regard to insertion of laminaria **prefatory** to a termination of pregnancy whether in an office setting or in a licensed ambulatory care facility." (emphasis added)(Gross Cert., Exh. 11).

Thus, not only did the BME confirm its previous decision as to Respondent, but it clearly indicated that in the BME's opinion the insertion of laminaria was "prefatory" to a termination of pregnancy, and therefore does not constitute the abortion, itself, with the meaning of the regulation.

LEGAL ARGUMENT

POINT I

COMPLAINANT'S CLAIM THAT RESPONDENT VIOLATED N.J.A.C. 13:35-4.2 IS BARRED BY THE DOCTRINE OF COLLATERAL ESTOPPEL

The doctrine of collateral estoppel operates to foreclose relitigation of an issue when the party asserting the bar can demonstrate the following five elements:

> (1) the particular issue to be precluded is identical to the issue decided in the previous proceeding;
>
> (2) the issue was actually litigated in the prior action, i.e., there was a full and fair opportunity to litigate the issue in the prior action;
>
> (3) a final judgment on the merits was issued in the prior proceeding;
>
> (4) the determination of the issue was essential to the prior judgment; and
>
> (5) the party against whom preclusion is asserted was a party to or in privity with a party to the earlier proceeding. Monek v. Borough of S. River, 354 N.J.Super. 442, 454 (App.Div.2002) (citing In re Dawson, 136 N.J. 1, 20-21 (1994)).

Under New Jersey law, an adjudicative decision of an administrative agency is "accorded the same finality that is accorded a judgment of a court." Bressman v. Gash, 131 N.J. 517, 527 (1993). Therefore, it is clear under New Jersey law that the judicial rule of collateral estoppel is applicable to administrative agencies. Hackensack v. Winner, 82 N.J. 1, 28-29 (1980). New Jersey courts have stressed the importance and the benefits of this doctrine, such as "finality and repose; prevention of needless litigation; avoidance of duplication; reduction of unnecessary burdens of time and expenses; elimination of conflicts, confusion and uncertainty; and basic fairness". Hennessy v. Winslow Township, 183 N.J. 593, 600 (2005), quoting Hackensack v.

Winner, supra, 82 N.J. at. 32-33) (stating that such principles "have an important place in the administrative field.").

In this instance, Judge Fidler's Initial Decision and the Board's 1996 Order adopting the findings of the Initial Decision meet all five of the above stated elements and therefore Complainant's claim that Respondent violated N.J.A.C. 13:35-4.2 is barred by the doctrine of collateral estoppel.

First, the issue in the 1993 matter and this matter are the same. N.J.A.C. 13:35-4.2(d) provides that after "14 weeks LMP, any termination procedure other than dilation and evacuation (D and E) shall be performed only in a licensed hospital." N.J.A.C. 13:35-4.2(a) states the "termination of a pregnancy is a procedure." The text of N.J.A.C. 13:35-4.2 is currently the same as it was in 1993 and therefore Complainant is now alleging a violation of the same exact regulation as it did in 1993.

In both matters, Complainant alleged that Respondent violated N.J.A.C. 13:35-4.2 by commencing abortions on patients after 14 weeks in his New Jersey office and then completing them out of state. In the 1993 Complaint, Complainant alleged "the insertion of laminaria in a patient who is past 14 weeks LMP constitutes the commencement of an abortion in the second trimester." (Gross Cert., Exh. 1, Count I, ¶ 9)(emphasis added). In the current Complaint, Complainant alleges that the termination of pregnancy was "commenced" by Respondent Brigham in the Voorhees Office either when the laminaria were inserted, upon consumption of misoprostol or injection of digoxin. (emphasis added). Therefore the issue in 1993, and the issue now, is what act constitutes an "abortion" or in other words a "termination of a pregnancy."

In the 1993 matter, Respondent challenged Complainant's assertion "as ridiculous that the assertion that insertion of laminaria in J.K. was the performance of an abortion, and he noted

that if he had thought insertion of laminaria in J.K. violated the regulation he would not have done it." (Gross Cert., Exh. 3, p. 17). Respondent further asserted that "J.K.'s situation was no different than that of a patient who had an induced fetal demise with digoxin in preparation for a late abortion." (Gross Cert., Exh. 3, p. 21). Dr. Jeffrey Moscowitz, one of the experts that testified for Respondent, testified that the insertion of laminaria did not constitute an abortion and defined abortion as the "evacuation of the uterus." (Gross Cert., Exh. 3, p. 76).[5]

Judge Fidler agreed with all of Respondent's contentions and held that Respondent did not perform an abortion in New Jersey in violation of N.J.A.C. 13:35-4.2 by inserting laminaria in New Jersey. (Gross Cert., Exh. 3, p. 22). Judge Fidler reasoned that "a necessary step in achieving cervical dilation so that evacuation of the uterus can be accomplished safely" such as inserting laminaria, does not constitute an abortion. (Gross Cert., Exh. 3, p. 77). As noted by Judge Fidler, the BME was free to reject his findings and "interpret the scope of its rule on termination of pregnancy, in accordance with reason, fairness, and adequate notice to those who are regulated." (Gross Cert., Exh. 3, p. 77). Indeed, the BME had over 4 months to review the Initial Decision and indicate where it disagreed with his decision. However, the BME chose by unanimous vote to adopt the findings and decision of Judge Fidler.

By adopting the Initial Decision of Judge Fidler, that abortion and "termination of pregnancy" is defined as the evacuation of fetus from the uterus, the BME held that treatment "prefatory" to the evacuation of the uterus does not constitute an abortion and therefore can be

---

[5] Indeed, in his testimony before Judge Fidler, Complainant's own expert Nicholas Kotopolos, M.D., testified that:

> pregnancy is defined as that the uterus is impregnated by a fetus, and unless the fetus or whatever is in the uterus, the uterus is still impregnated with that fetus and it's still a pregnancy. Termination of pregnancy is only when the uterus is evacuated from its contents. (Gross Cert., Exh. 7).

conducted in an office setting. Not only is the BME bound by its prior decision involving Respondent with respect to the insertion of laminaria, but it applies equally to the use of digoxin to induce fetal demise and of misoprostol.

In 1996, this Board adopted the findings of Judge Fidler that he was in agreement with Respondent and Respondent's expert, Dr. Moscowitz, that an abortion is the procedure of "evacuation of the uterus" and that none the of prefatory steps prior to that action meet that definition. Therefore, as with the insertion of laminaria, both the injection of digoxin and the ingestion of misoprostol are clearly prefatory and separate from the evacuation of the uterus and therefore do not constitute an abortion.

Furthermore, the ingestion of misoprostol in a small, one time dose, as taken by patients D.B. and N.C., simply primes and dilates the cervix and is therefore no different than insertion of laminaria, which serves the same purpose. Misoprostol is a prostaglandin. (Gross Cert., Exh. 12). Insertion of laminaria causes the release of the body's own prostaglandins, an effect no much different than the administration of exogenous prostaglandins such as misoprostol. (Gross Cert., Exh. 12). Only when misoprostol is given repeated regular doses does it usually cause a woman to go into labor. (Gross Cert., Exh. 13).

Indeed, Judge Fidler's decision is consistent with the definition of "termination of pregnancy" set forth in N.J.A.C. 13:35-4.2 and the universal meaning of "abortion." As defined by N.J.A.C. 13:35-4.2(a), the "termination of a pregnancy is a procedure", not the other prefatory steps in the process as Complainant asks the Board to believe. Black's Law Dictionary defines abortion as "the spontaneous or artificially induced expulsion of an embryo or fetus." (Gross Cert., Exh. 14).

Next, Respondent meets the second element for collateral estoppel because in the 1993 matter, Complainant was afforded a full a fair opportunity to litigate this issue and present all pertinent evidence during the 29 days of the hearing. Two experts testified on behalf of Complainant, and Complainant had the full opportunity to cross-examine all of Respondent's six expert witnesses. The issue was extensively briefed by both parties. Moreover, Complainant presented exceptions to Judge Fidler's decision to the BME and had the opportunity to argue before the BME itself why it should not adopt the decision of Judge Fidler. Nonetheless, Complainant was not successful.

Next, Respondent meets the third element for collateral estoppel. In the 1996 Order, the BME adopted the decision of Judge Fidler in its entirety as to the alleged violation of N.J.A.C. 13:35-4.2. The 1996 Order was final, as Respondent's license to practice medicine in New Jersey was fully reinstated effective August 14, 1996.

Lastly, clearly the last two elements are met as the determination of the issue was essential to the 1996 Order and Complainant was a party to the 1993 matter.

Moreover, it would be grossly inequitable if Respondent was not permitted to rely on the prior word of the BME. The BME's prior dismissal of the 1993 Complaint against Respondent with respect to the J.K. and B.A. cases was an unequivocal proclamation by the BME that it found his care to be within acceptable standards.

Moreover, an attorney for Respondent actually wrote to the BME in November of 1999 and directly asked the BME if it believed the insertion of laminaria in an office setting and then the performance of the abortion one or two days later at an "approved facility" was a violation of N.J.A.C. 13:35-4.2. The attorney for Respondent asserted that he believed it did not violate the

regulation. Although the BME is not required to respond to requests for legal guidance, the BME explicitly approved this position in its response back to his attorney. The BME stated:

> I am in receipt of your October 21, 1999 letter and apologize for not having replied to your earlier correspondence. I did have occasion to discuss your inquiry yesterday with the Executive Committee of the Board of Medical Examiners. The Members present share your view of the applicability of N.J.A.C. 13:35-4.2. Accordingly, there would appear to be no problem with regard to insertion of laminaria **prefatory** to a termination of pregnancy whether in an office setting or in a licensed ambulatory care facility." (emphasis added)(Gross Cert., Exh. 11).

In sum, New Jersey licensed physicians should be able to rely upon the formal orders and opinions of the BME. The BME, of course, was free to change its' opinion on this issue and promulgate new regulations, but it did not. To sanction Respondent for actions specifically approved by this Board would be unconscionable. Therefore, Counts I, III, IV[6], V and VI must be dismissed.

POINT II

COMPLAINANT'S CLAIM THAT RESPONDENT'S TREATMENT PLAN OF INSERTING LAMINARIA ON ONE DAY AND PERFORMING AN ABORTION THE FOLLOWING DAY IS GROSSLY NEGLIGENT IS BARRED BY THE DOCTRINE OF COLLATERAL ESTOPPEL

Complainant's claim that Respondent's treatment plan is grossly negligent is also barred by the doctrine of collateral estoppel.

In the 1993 Complaint, Complainant argued that "Respondent's management plan for J.K. was a gross deviation from generally accepted standards for a two-day termination of a late-stage pregnancy, in that he inserted the laminaria in a patient who had to travel over an hour to

[6] Count IV, which alleges that Respondent lied in his June 30, 2010 letter to the BME by stating he was "not performing any abortions beyond 14 weeks in New Jersey", should also be dismissed. As stated in Point I,

and from his office each and he further intended to transport her an additional two hours to the clinic in New York for the actual completion of the procedure... ." In this matter, although not explicitly alleged in the Complaint, Complainant's expert Dr. Brickner, states in his report that "Dr. Brigham repeatedly committed gross medical negligence by causing patients, already placed at risk for sudden labor and/or hemorrhage by his treatment, to travel by personal auto a great distance to continue/complete their procedures thus risking medical emergencies remote from immediate care."

In the 1993 matter, with patients J.K. and B.A., Respondent's treatment plan involved the insertion of laminaria to dilate the cervix and having them drive 100 miles to Queens, New York the following day to have the D and E procedure performed. Judge Fidler held that the treatment plan was consistent with generally accepted standards of care... ." (Gross Cert., Exh. 3, p. 22). Furthermore, in the case of J.K., Judge Fidler agreed with Respondent's contention that a recent fetal demise did not increase risk of complication. (Gross Cert., Exh. 3, p. 21, 22). The BME adopted his findings in the 1996 Order. Similarly, in this matter, the issue is whether Respondent's treatment plan of inserting laminaria one day and having the patient ingest misoprostol and drive only 54 miles to the Elkton Facility the following day constituted repeated acts of negligence and/or gross negligence. Indeed, the treatment plan in this matter is safer than the treatment plan in the 1993 matter, as the patients were only asked to drive to a location that was 54 miles away and one hour driving distance from the Voorhees Office, as opposed to the 1993 case where the Queen facility was over 100 miles and 2 hours (without traffic) from the Voorhees Office.

Respondent was not performing abortions in his office beyond 14 weeks in New Jersey, as he was only inserting laminaria, directing patients to ingest misoprostol and/or injecting digoxin.

Complainant may argue that the issue in this matter is different because in two instances (D.B., N.C.), Respondent had the patients ingest misoprostol at the Voorhees Office shortly before having the patient drive one hour to the Elkton Facility. However, as set forth above, misoprostol, in the dosage that was given to the patients, simply primes and dilates the cervix prior to D and E. It is only when misoprostol is given to a patient several times on a regular basis does it induce labor. (Gross Cert., Exh. 3). Furthermore, in the case of D.B. and N.C. cases, a review of the medical records demonstrate that these two patients both received a single dosage of two tablets of misoprostol at 8:45 am, on August 13, 2010, about 5 minutes before leaving New Jersey and driving to Maryland, where they arrived approximately 60 minutes after taking the medication. (Exh. B, p. 30) (Exh. P, p. 23). Furthermore, the Board's review of the enclosed published papers and expert report demonstrate that administration of misoprostol 90 to 120 minutes before the procedure is commonly used as a method of "cervical ripening" or "cervical priming" and not as a labor-inducing regimen. (Gross Cert., Exh. 12, Exh. 13). Indeed, the two patients who received misoprostol in New Jersey, D.B. and N.C., both underwent D&E surgical uterine evacuation procedures. Neither of them underwent the non-surgical delivery of the fetus.

Moreover, the treatment plan was also approved by the BME in its November 1999 letter to Respondent's counsel. Respondent's described a treatment plan of "inserting laminaria into the patient's cervix in the office, and then one or two days later the abortion procedure is performed in a hospital or licensed/approved facility." The BME made no comment as to this plan in its declaration that such a plan did not violate N.J.A.C. 13:35-4.2.

As set forth above, the other elements of collateral estoppel clearly apply, as well. Therefore, the issue is no different than the issue in the 1993 matter and the Complainant is

POINT III

ALL ALLEGATIONS RELATED TO THE TREATMENT PROVIDED TO PATIENT D.B. IN THE STATE OF MARYLAND MUST BE DISMISSED

Count I alleges that the treatment provided to patient D.B. at the Elkton Facility was negligent and/or grossly negligent as "she suffered a uterine perforation and small bowel injury" when the abortion performed by Dr. Riley. However, it is in undisputed that the D and E procedure was performed by Dr. Riley, as it was her patient. Respondent only watched and served as a consultant. Moreover, it is undisputed that Dr. Riley took complete control of the situation once she had determined D.B. needed to transported to Union Hospital and Respondent had no part in the decision to drive D.B. to the hospital. Therefore, it is impossible for Respondent's actions to have constituted negligence and/or gross negligence and this allegation must be dismissed.

CONCLUSION

In sum, based on the foregoing, Counts I, III, IV, V and VI of the Verified Complaint should be dismissed by the Board in its entirety.

Respectfully submitted,

By:_____
Joseph M. Gorrell, Esq.

Dated: October 6, 2010