



State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY

DIVISION OF LAW
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September 20, 2010

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Director

New Jersey State Board of Medical Examiners
140 East Front Street - 2nd Floor
Trenton, New Jersey 08625

Re: IMO Steven Chase Brigham, M.D.

Honorable Members:

Please accept this letter brief in support of the Attorney General's Temporary Suspension application scheduled to be heard by the Board of Medical Examiners on October 13, 2010. The application is embodied in the Amended Verified Complaint filed on September 17, 2010 and the exhibits thereto. It is also supported by the expert opinion of Dr. Gary Brickner whose written opinion and curriculum vitae are attached hereto as Exhibit 1.

Preliminary Statement

Respondent Steven Chase Brigham, M.D., a licensed physician in the State of New Jersey, has flagrantly disregarded the regulations of the State Board of Medical Examiners ("Board") and repeatedly placed his patients' health and well being in jeopardy. Respondent Brigham has undertaken and participated in terminations



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of pregnancy for patients in the second and third trimesters of pregnancy, far beyond the 14 week limit which is permitted by virtue of his medical training and practice setting. His decision to engage in conduct which violates Board regulations and to place his patients at risk of serious harm, warrants the immediate temporary suspension of his license.

The documents amassed by the Attorney General demonstrate that Respondent Brigham practices in an office setting, not a Licensed Ambulatory Care Facility (LACF) and not a hospital. In an office setting, terminations of pregnancy can be performed through 14 weeks LMP (last menstrual period). After 14 weeks and through 18 weeks, a termination must be completed in a hospital, or if planned as a dilatation and evacuation procedure (D&E) in an LACF. Despite these rules, Respondent has begun D&E terminations in an office setting far beyond 14 weeks. Additionally, Respondent is ineligible to perform the procedures beyond 14 weeks because he is not specially credentialed as required by N.J.A.C. 13:35-4.2(e) nor is he Board certified as an ob/gyn as required by N.J.A.C. 13:35-4.2(f). Even if he was so credentialed, he would still be required to perform the procedures in a hospital or LACF.

Respondent flouts this regulation and the records herein show that in a mere office setting, absent any hospital privileges or the facilities of an LACF, he has undertaken terminations of pregnancy for patients as much as 33 weeks LMP.

The patient records filed as exhibits to the Amended Verified complaint show that Respondent begins terminations of pregnancy in New Jersey with the plan that they will be completed out of state. By dint of his New Jersey based treatment, the patients are placed at a point of no return. The abortion has begun, there is no turning back, and despite their stage of pregnancy the procedure has commenced in an office setting, in violation of Board regulations designed to protect patients' safety. They are then forced to travel a considerable distance out of state, without the protections afforded by this Board. Respondent Brigham's choice to violate Board regulations and to place his patients at risk of harm, warrants the immediate temporary suspension of his license.

Proofs herein will also show that Respondent has engaged in acts of dishonesty apparently designed to obfuscate the illegality of his conduct. He has caused inaccurate and false medical records to be created, engages in unlicensed practice and made a material misrepresentation to this Board when he swore that he did not perform terminations of pregnancy beyond 14 weeks. Exhibit L.

Statement of Facts

The Attorney General alleges that Respondent's care of the five patients described in the Amended Verified Complaint demonstrates his grossly negligent and dangerous pattern of practice. All five of his patients were more than 14 weeks pregnant. As explained more fully in the Legal Argument, the

performance of post-14 week terminations of pregnancy requires that the physician first place on file with the Board his proof of compliance with Board pre-requisites. Respondent has no such proof on file. Even if he had such proof on file, however, the procedures were performed in violation of the regulations requirement that terminations by non-D&E methods must take place in a hospital, and D&E procedures must take place in a hospital or LACF. All of respondent's practice is in an office setting and all of these procedures were commenced in New Jersey offices with the intention that they would be completed out of state in another medical office.

Patient D.B.

D.B. sought an abortion at American Women's Services in Voorhees, New Jersey. According to her patient record she was first seen on August 9, 2010. Exhibit B¹, medical record of D.B. On that day, she was told that since she was 21 weeks pregnant, her abortion would be performed in a different clinic office. Exhibit A, Interview of D.B., page 6. She returned to the office on August 12, 2010, when she signed an informed consent form for "Abortion after 14 weeks" which stated that she was 21 weeks (LMP) pregnant. (The Obstetrical Sonogram Report in her chart reflects that she was

¹Exhibits A through T, referenced herein, are attachments to the First Amended Verified Complaint filed September 17, 2010.

21.5 weeks pregnant on August 13, 2010, the final day of her procedure). Exhibit B.

On August 12, 2010, D.B. underwent the insertion of laminaria in a procedure performed by Respondent Brigham in New Jersey. Exhibit A, page 8. The insertion of laminaria begins the termination of pregnancy. It is used to soften and dilate the cervix as an aid to the ultimate evacuation of the uterus. The instructional sheet given to DB on that day stated "Remember that your abortion really begins when the laminaria is inserted into your cervix." She was instructed to return to the New Jersey office on the following day. Exhibit B.

D.B. was under the impression that on August 13, 2010 she would be transported to Philadelphia for the completion of the abortion. Exhibit A, page 7. She arrived at the Voorhees, New Jersey office at 8:00 a.m., accompanied by her boyfriend and her mother. Id. at page 12. She was joined in the office by patients S.D. and N.C. At 8:45 a.m. while in the Voorhees office, D.B. was administered Cytotec (also called misoprostol). According to Respondent's own medical record for D.B., this drug is considered dangerous to pregnant women because it causes softening of the cervix and uterine contractions which can expel the pregnancy. Exhibit B. It is administered to induce labor. Exhibit 1 to this Letter Brief, Report of Gary Brickner, M.D. dated September 21, 2010.

Contrary to her expectations, D.B. was not transported to Philadelphia from Voorhees. Instead, Respondent Brigham directed her to her personal vehicle and, driven by a family member, she traveled in a caravan of five cars occupied by fellow patients N.C. and S.D., clinic staff, and Respondent Brigham, to a second location. She was not provided with the address of their destination or any emergency contact information. Exhibit N, Sworn Statement of D.B. dated September 9, 2010. Ultimately D.B. and the caravan arrived in Elkton, Maryland.

D.B., N.C. and S.D. all underwent terminations of pregnancy completed by Nicola Riley, M.D. in the Elkton, Maryland office, with Respondent Brigham present. D.B.'s abortion was the second procedure undertaken at the Elkton Clinic that day. As noted in the procedure note created by Dr. Riley (Exhibit C), the D&E procedure was stopped when extra-uterine tissue was noted in the vaginal vault, a sign of a serious medical complication necessitating emergency surgery. No ambulance was summoned. Instead, the patient was transported by Dr. Riley and Respondent Brigham in a private automobile drive by Respondent. Exhibit I, pages 20,33. They brought D.B. to the emergency room at Union Hospital where the patient was stabilized, and diagnosed with uterine perforation. Exhibit E, Union Hospital Record.

After D.B. was treated at Union Hospital, she was transported by air to Johns Hopkins Hospital. Id. Ultimately, it was determined

that D.B. has suffered both a uterine perforation and a bowel injury in the course of a D&E and she underwent surgery to repair those injuries. Exhibit D, medical records of D.B.'s admission to Johns Hopkins Hospital, August 13, 2010. The abortion was completed during the surgery performed at Johns Hopkins.

Patient S.D.

S.D. was also in the caravan of patients who traveled with D.B. and N.C. from the Voorhees, New Jersey office to the Elkton, Maryland Clinic. Although D.B. and her accompanying family members did not know S.D.'s name, D.B.'s mother, C.B., reports that the other patients present on the morning of August 13, 2010 included an "Indian couple." Exhibit J, page 3. It is important then to note, that S.D. has an Indian surname and reports India as her place of birth in her medical records. Exhibit O. Further, the medical records created for S.D. in Voorhees, New Jersey reflect that she was pregnant with twins. Id. The tissue records maintained for the Elkton office reflect that on August 13, 2010, the day the termination of pregnancy was performed on S.D., a patient with those initials produced tissue corresponding to twins. Exhibit H. Thus, the proofs establish that S.D.'s termination of pregnancy was begun in New Jersey. She was present in the Voorhees office when Dr. Brigham arrived on the morning of August 13, 2010 and directed the caravan of cars to proceed to Elkton, Maryland.

Her pregnancy was terminated in Elkton by Dr. Riley, in Dr. Brigham's presence. Exhibit I, Interview of Dr. Riley, pages 9, 17.

S.D. was 25 weeks pregnant with twins. Exhibit O, patient record of S.D. from Grace Medical Care; Exhibit H, second page. She was first seen on August 11, 2010 at which time she underwent the insertion of six laminaria, and digoxin was administered via spinal needle directly into the fetuses for the purposes of causing fetal demise. Exhibit O.

On August 12, 2010, S.D. returned to the office where the records reflect intrauterine fetal demise for fetus A but possible cardiac and fetal movement for fetus B. Additional laminaria were inserted and a second injection of digoxin was administered to fetus B. Subsequently, fetus B underwent intrauterine fetal demise. All of this treatment took place in New Jersey.

On August 13, 2010, S.D. traveled in the caravan to Elkton, Maryland where the termination procedure was completed by Dr. Riley. In her interview with Maryland Board authorities, Dr. Riley reported that as a matter of protocol the physician in Elkton ascertains that there has been fetal demise before the patient arrived at the Elkton Clinic. Exhibit I at page 31. During the termination, Dr. Brigham was present to "advise" Dr. Riley. Exhibit I at page 9.

Patient N.C.

The proofs establish that Patient N.C. was the third woman present in Voorhees, New Jersey office on the morning of August 13, 2010. D.B.'s mother, C.B., reports that one of the two other patients who traveled in the caravan from Voorhees, New Jersey to Elkton, Maryland was "Spanish mixture." Exhibit J, statement of C.B., pages 3, 4. N.C. speaks Spanish and her record states that she was born in Mexico. Exhibit P, medical record of N.C. N.C.'s medical record reflects both that she was treated in the New Jersey office and that her termination of pregnancy was completed on August 13, 2010 by Nicola Riley, M.D. who was in the Elkton, Maryland office. Exhibit P. Thus, it is clear that N.C., who was 18.4 weeks pregnant, underwent an abortion which was begun in the New Jersey office and completed in the Maryland clinic. This is also confirmed by the tissue and medical waste log entry for August 13, 2010 which reflects a patient with the initials N.C. who was 18.4 weeks pregnant. Exhibit H, second page.

N.C. first treated at American Women's Services on August 12, 2010 when she underwent the insertion of laminaria. On August 13, 2010, N.C. arrived at American Women's Services in Voorhees, New Jersey, where prior to traveling to Maryland, she was administered Cytotec (also known misoprostol). N.C.'s record confirms that this occurred in the Voorhees office in part because there were issues

regarding her need to bring the balance of her payment to the office. Exhibit P. N.C. was the third patient in the August 13, 2010 caravan from New Jersey to Maryland.

Patient J.P.

J.P. is a 20 year old female who on June 9, 2010 was approximately 24 weeks pregnant. On that day, she underwent insertion of laminaria in the New Jersey offices of American Women's Services. According to her records, her care was provided by an entity called Grace Medical Care, a practice name which appears in several patient's records. J.P. was referred to the New Jersey office by "Women's Services" in Pittsburgh, Pennsylvania.

On June 9, 2010, J.P. underwent the insertion of laminaria and an injection into the fetus of digoxin in order to cause fetal demise. Exhibit Q. On June 10, 2010, J.P. returned to the New Jersey office where she underwent the insertion of additional laminaria. Her chart reflects a plan for her to return on June 11, 2010 and to travel to "MD" (presumably Maryland). Id.

J.P. never presented to the medical office on June 11, 2010 because in the early hours of that day she experienced difficulty urinating and contacted Respondent Brigham through the call center "Appointment Hotlines, Inc." The call center record states that the patient reported having been treated in Voorhees, New Jersey and that she was experiencing difficulty urinating. Respondent Brigham arrived at her hotel room in New Jersey and cared for her

in that room. Id.

J.P.'s termination of pregnancy was commenced by Respondent Brigham in New Jersey by the insertion of laminaria and the administration of digoxin. He intended that her termination would take place out of state as indicated in his correspondence with the Board dated August 12, 2010. Exhibit R, Letter from Respondent Brigham of August 12, 2010; Exhibit RA. In fact, the patient was emergently admitted to Virtua-West Jersey Hospital of Voorhees, New Jersey where the fetus was delivered. Exhibit T, hospital record for J.P.; Exhibit 1, Report of Dr. Brickner.

Patient M.L.

Patient M.L., a 35 year old woman, underwent a termination of pregnancy under Respondent Brigham's care. M.L., a Canadian, was 33 weeks pregnant. Exhibit S, patient record of M.D. Her records reflect care rendered in the offices of "Grace Medical Services" but there is no information which identifies the practice location of Grace. Nonetheless, it is clear from the records that M.L. was first seen in New Jersey in an office referred to throughout the records as "Wellness."

On August 2, 2010, M.L. underwent the insertion of laminaria and an injection of digoxin into the fetus to cause fetal demise, in a procedure performed by Respondent Brigham. On August 3, 2010, M.L. returned to the office where ultrasonography revealed no fetal heartbeat or movement, and a determination is reflected in the

record of "probable IUFD" (intra-uterine fetal demise). Additional laminaria were inserted that day and M.L. was directed to return to the "Wellness Office" on August 4, 2010 at 8 a.m. and "then to MD" (presumably Maryland). Exhibit S.

M.L.'s abortion record does not reflect a physician's initials or signature. The termination of pregnancy was performed in Maryland on Wednesday, August 4, 2010, approximately 5 days after Dr. Riley began her employment at the Maryland Clinic. However, Dr. Riley testified that she worked in the Maryland clinic only on Fridays. Exhibit I at page 38. August 4, 2010 was a Wednesday. Therefore, the identity of the attending physician is unknown. The tissue record for Maryland reflects a termination of pregnancy for patient M.L. on August 4, 2010 at 33 weeks of pregnancy. That tissue record bears the name of Dr. George Shepard. Exhibit H.

DRS. NICOLA RILEY, GEORGE SHEPARD, AND KIMBERLY WALKER.

On July 30, 2010 Dr. Riley, a family practice doctor, was first employed by American Women's Services to perform first and second trimester abortion procedures and to train in third trimester procedures.² Exhibit I, page 4, 37. Dr. Riley had no prior training in third trimester procedures. Id. at page 10. She performed terminations of pregnancy on Fridays in the Elkton, Maryland clinic with Respondent Brigham present to "consult." Id.

²Dr. Riley's license to practice medicine was summarily suspended by the Maryland Board on August 31, 2010.

at page 9. Dr. Riley completed the terminations of pregnancy for patients N.C., D.B. and S.D. on August 13, 2010. Id. at page 17.

Dr. George Shepard works at the Elkton, Maryland clinic on Wednesdays and Fridays.³ Exhibit F, Interview of Dr. Shepard, pages 2 - 3. Dr. Shepard's title is "Medical Director" but he appears to have no actual authority. Id. at page 11.

In his interview on August 19, 2010, Dr. Shepard confirms that Dr. Riley began her employment on July 30, 2010 and that Dr. Walker was present at the clinic as an "observer." Id. at pages 6 - 7. He also confirms that Dr. Walker observed Respondent Brigham perform abortions in Elkton, Maryland. Id. at pages 8 - 9. Dr. Shepard estimates that Respondent Brigham was present in Elkton, Maryland, and performing abortions there, approximately two times a week from in or about September 2009. Id. at page 13 - 14. Dr. Shepard has "no clue" as to how abortions were actually performed. Id. at page 23. He does not practice medicine due to a handicap. Id. at page 24.

Dr. Kimberly Walker is an unlicensed medical school graduate. Exhibit G, Interview of Kimberly Walker, M.D. on August 23, 2010. Beginning in January 2010, Dr. Walker was an observer in the Elkton, Maryland clinic. Id. at page 5. She hoped to work in the clinic after she was licensed in Maryland. Id. at page 7. Dr.

³Dr. Shepard's license to practice medicine was summarily suspended by the Maryland Board on August 31, 2010.

Walker observed Respondent Brigham perform approximately 50 abortions in Maryland. Id. at page 9. Respondent Brigham does not have a license to practice medicine and surgery in Maryland.

Approximately 30 percent of the abortions that Dr. Walker observed Dr. Brigham perform were beyond twenty weeks. Id. at page 13. Typically these patients had been pre-treated elsewhere with laminaria and/or misoprostol. Id. at page 20. Dr. Walker confirms that neither she nor Dr. Sheppard performed abortions in Elkton, Maryland. Id. at pages 24-25.

Legal Argument

I

RESPONDENT BRIGHAM'S MEDICAL CONDUCT
DEMONSTRATES A FLAGRANT DISREGARD FOR THE
BOARD'S REGULATIONS REGARDING TERMINATION OF
PREGNANCY AND THUS PRESENTS A CLEAR AND
IMMINENT DANGER TO THE PUBLIC.

Terminations of pregnancy are regulated by N.J.A.C. 13:35-4.2.⁴ The purpose of the rule is to "regulate the quality of medical care offered by licensed physicians for the protection of the public." N.J.A.C. 13:35-4.2(a). The provisions of the rule are expressed in terms of "weeks LMP." N.J.A.C. 13:35-4.2(c). This refers to the number of weeks that have elapsed from the start of the patient's last menstrual period. The regulation provides the

⁴NJAC 13:35-4.2 is attached hereto as Exhibit 2.

following example: the stage of pregnancy at 12 weeks' gestational size, as determined by a physician, is the equivalent of 14 weeks from the first day of the last menstrual period (LMP)." N.J.A.C. 13:35-4.2(c).

Beyond 14 weeks LMP, any termination of pregnancy procedure other than dilatation and evacuation (D&E) must be performed only in a licensed hospital. N.J.A.C. 13:35-4.2(d). This includes a "medical" abortion which is performed through pharmacological intervention. A D&E procedure performed after 14 weeks must occur either in a licensed hospital or in a licensed ambulatory care facility. None of the abortions at issue in the Amended Verified Complaint were performed in either authorized setting in New Jersey or elsewhere.

In order to be authorized to perform a D&E termination of pregnancy after 14 weeks, a physician must be credentialed by the Medical Director of the LACF in which he intends to perform the procedure. Physicians who undertake D&E procedures later than 18 weeks must have first filed with the Board "a certification signed by the Medical Director that the physician meets the eligibility standards" as set forth in the regulations. N.J.A.C. 13:35-4.2(f). In addition to the fact that Respondent Brigham did not perform any procedures in a LACF, he would be ineligible to have such a certification on file with the Board because one of the eligibility standards is that the physician be Board certified or Board

eligible by a Board of Obstetrics and Gynecology, a certification for which Respondent Brigham is ineligible since he is not an OB/GYN by training.

The rules surrounding the performance of abortions are not ministerial. They regulate a potentially dangerous medical procedure by providing accessibility without undue restriction in a location that provides appropriate medical oversight. Dr. Brickner, the Attorney General's expert, observes that the requirement that post-14 week procedures take place in a hospital or LACF is mandated by the Board for patient safety. Exhibit 1, page 3.

The risks of abortion are undisputable. See, Planned Parenthood v. Verniero, 41 F. Supp.2d 478, 483, fn1 (D.N.J. 1998) aff'd 220 F.3d 127 (3d Cir.2000) ("... the risk of death from abortion increased about thirty percent (30%) with each week of gestation from eight weeks lmp to twenty weeks lmp.... the risk of major medical complications increases about twenty percent (20%) with each week of gestation from seven weeks lmp to full term.").

Respondent Brigham's conduct demonstrates clear violations of the Board's regulation dictating the safe practice circumstances and physician eligibility requirements for the performance of terminations of pregnancy in New Jersey. He administered pharmacological interventions which could potentially result in medical abortions after 14 weeks, outside of the required hospital

setting even though both laminaria and misoprostol are known to cause intense labor often associated with significant bleeding. Exhibit 1, page 3. In addition, Respondent Brigham also proposed to undertake D&E procedures outside of either a licensed ambulatory care facility or hospital. Either of these factual scenarios constitute a violation of the regulation and thus are grounds for discipline pursuant to N.J.S.A. 45:1-21(h).

II

RESPONDENT'S TREATMENT OF D.B., N.C., S.D., J.P. AND M.L. DEMONSTRATES A RECKLESS DISREGARD FOR THEIR WELLBEING AND FURTHER DEMONSTRATES THAT HIS CONTINUED PRACTICE OF MEDICINE CONSTITUTES A CLEAR AND IMMINENT DANGER TO THE PUBLIC HEALTH, SAFETY AND WELFARE.

N.J.S.A. 45:1-22 authorizes the Board to temporarily suspend a physician's license upon a showing that the physician's continued practice would constitute a clear and imminent danger to the public. The statute states, in relevant part:

A board may, upon a duly verified application of the Attorney General that ... alleges an act or practice violating any provision of an act or regulation administered by such board, enter a temporary order suspending or limiting any license issued by the board pending plenary hearing on an administrative complaint; provided, however, no such temporary order shall be entered unless the application made to the board palpably demonstrates a clear and imminent danger to the public health, safety and welfare and notice of such application is given to the licensee affected by such order.

Such authority is granted to the Board because "the State has a substantial interest in the regulation and supervision of those who are licensed to practice medicine." In re Polk, 90 N.J. 550, 566 (1982). The State, through the Board, "acts as a guardian to protect these interests fully." . The Board's obligations in this respect are paramount to the qualified right of the individual practitioner claiming the privilege to pursue his or her licensed profession. See . The Legislature, moreover, has granted the Board "broad authority" to regulate the practice of medicine. In re Zahl License Revocation, 186 N.J. 341, 352 (2006) *citing Polk, supra*, 90 N.J. at 565.

The Board may use its "experience, technical competence, and specialized knowledge" in evaluating whether a physician is competent to practice medicine. In re Silberman, 169 N.J. Super. 243, 256 (App. Div. 1979), aff'd o.b. 84 N.J. 303 (1980) (internal citation and quotation marks omitted), In re Heller, 73 N.J. 292 (1977) .

The Board's expertise is sufficient to inform the Board that Respondent Brigham's failure to adhere to the regulation governing terminations of pregnancy constitutes a clear and imminent danger to his patients and to the public at large. The regulations are reasonable and allow the citizens of New Jersey functional access to termination of pregnancy. Respondent Brigham's decision to flout those regulations and to attempt to transport his patients to

distant locations for the purposes of performing terminations which do not conform to New Jersey regulatory requirements is arrogant and dangerous.

In addition to the Board's own expertise, the Board can be guided by the expert opinion of Dr. Gary Brickner, a Fellow of the American College of Obstetrics and Gynecology and practicing OB/GYN in the State of New Jersey. Exhibit 1, Dr. Brickner's report and curriculum vitae. Dr. Brickner opines that Respondent Brigham has repeatedly violated New Jersey law by choosing to perform non D&E terminations beyond 14 weeks in an out-of-hospital setting. In particular, Dr. Brickner highlights Respondent's performance of extremely risky third trimester procedures (S.D. and M.L.) outside an appropriate facility. Respondent Brigham's decision to transport his patients out of state at great distance for the completion of the abortion procedures, according to Dr. Brickner, constitutes multiple acts of gross medical negligence by virtue of the risks of sudden labor and/or hemorrhage that his treatment presents. Further, Dr. Brickner finds that Dr. Brigham placed his patients, who sought late second trimester abortions, in the hands of an unqualified contracted physician.

Dr. Brickner also criticizes Respondent Brigham's failure to have emergency arrangements in place as demonstrated by his treatment of the complications suffered by D.B. in the Elkton, Maryland clinic. Dr. Brickner concludes that Dr. Brigham was

grossly negligent for failing to have sufficient emergency arrangements since that deficiency placed D.B. at an even greater risk of harm.

The Amended Verified Complaint demonstrates that in regard to his care of at least five patients Respondent Brigham engaged in grossly negligent medical practice. His pattern, as demonstrated by these five patients, is to begin second trimester abortions in his New Jersey office - not a hospital and not a LACF. He brings his patients to the point of no return by administering misoprostol or digoxin, causing them to enter an irreversible state which mandates that the termination of pregnancy must go forward. He then causes them to be transported from his New Jersey office to a distant office (most recently Maryland) where the termination is completed. And, at least with regard to patients D.B., N.C. and S.D., the termination is completed by an inadequately trained physician, Dr. Nicola Riley, who was under contract to Respondent Brigham.

CONCLUSION

The extraordinarily poor medical judgment which enabled Respondent Brigham to believe that this medical care meets or exceeds the standard of care in New Jersey warrants the immediate temporary suspension of his license to practice medicine pending a Plenary Hearing. No mere limitation of this doctor's practice will

September 21, 2010

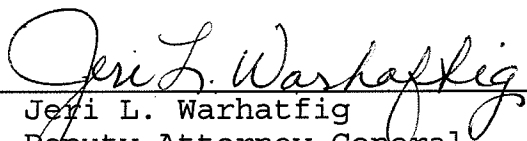
Page 21

protect the public, in particular because the proofs herein show that he is unwilling to abide by the letter of the law. Every aspect of the medical care rendered to his patients bears evidence of devious attempts to circumvent and avoid lawful regulatory oversight.

For the reasons expressed herein, including but not limited to the legal argument, verified proofs, and expert opinion of Dr. Brickner, the Attorney General urges the Board to find that a palpable demonstration has been made of a clear and imminent danger to the public which warrants the immediate temporary suspension of the medical license issued to Steven Chase Brigham, M.D.

Respectfully submitted,

PAULA T. DOW
ATTORNEY GENERAL OF NEW JERSEY

By: 
Jeri L. Warhatfig
Deputy Attorney General

JLW/ahc

cc: Joseph Gorrell, Esq.

Exhibit 1

BRICKNER•MANTELL

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September 21, 2010

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IMO Steven C. Brigham, MD

Dear Ms Warhaftig:

At the request of the NJ State Board of Medical Examiners ("the Board") I have prepared this report assessing the quality of medical care provided by Steven Chase Brigham, MD to patients under his care. In doing so I have relied on the following documents and materials:

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, MD 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 Johns 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 June 2010
16. Medical Records from Grace Medical Services for ML

Patient Summaries:

1. **Patient DB** was first seen at American Women's Services in Voorhees, New Jersey on August 9, 2010 requesting a termination of pregnancy. An ultrasound performed on that date revealed a viable fetus at 21.5 weeks. She was instructed to return on August 12 to begin the termination of her pregnancy. On that date she signed an extensive consent form that among other things informed her that she would have laminaria inserted into her cervix and that this would be the beginning of the abortion. She had the laminaria placed on August 12 by Dr. Bingham and was instructed to return the following day when she would be given medication to continue the abortion process. Despite the consent indicating that her doctor preferred to complete the abortion without the need for surgery, DB said that she was given to understand a D & E would be done to complete the abortion and that this would be done in Philadelphia on August 13.

The following day DB returned to American Woman's Services where she was prescribed misoprostol (Cytotec) by Dr. Bingham to induce labor. She was then directed by him to drive in her personal car, as part of a caravan of three patients, to Elkton, Maryland, a distance of sixty miles. On arrival she was informed that, although Dr. Bingham was present, her abortion would be completed by Dr. Nicola Riley.

Shortly after arrival in Elkton, Dr. Nicola Riley, a Maryland licensed physician, performed the D & E on DB. During the procedure a serious uterine perforation occurred with extrusion of bowel into the vaginal vault and expulsion of the fetus into the abdominal cavity. In response to this emergency, the patient was driven by Drs. Riley and Bingham by car to Union Hospital several blocks from the clinic.

After evaluation in the ER at Union Hospital the patient was transferred by air to Johns Hopkins Hospital in Baltimore where she underwent emergency surgery to repair her uterus and small intestine.

2. **Patient SD** presented for an abortion to American Women's Services in Voorhees, NJ on August 11, 2010 where an US showed a viable 25-26 week twin pregnancy. She was administered intra-amniotic Digoxin to induce fetal demise in both twins but twin B required a repeat Digoxin dose the following day to produce fetal death. The patient also had laminaria inserted that same day. On August 13 she was sent by personal auto to Elkton, MD in the same caravan as patient DB. She underwent a D & E by Dr. Riley without apparent problem.

3. **Patient NC** was seen at American Women's Services in Voorhees, NJ on August 12, 2010 where an US showed an 18+ week viable pregnancy. Laminaria were inserted by Dr. Bingham on that day and she returned on August 13 for misoprostol administration. Dr. Bingham then had her drive by personal car to Elkton in the same caravan as patients DB and SD. She underwent D & E in Elkton by Dr. Riley without apparent problem.

4. **Patient JP** was referred to Grace Medical (a DBA of American Women's Services) on June 9, 2010 at 24 weeks of pregnancy. On June 10 she had Digoxin infused intra-amniotically to induce fetal death followed the same day by insertion of 15 laminaria. She was due to return to the clinic June 11 but the night of June 10 she went into labor associated with significant bleeding and was emergently admitted to Virtua Memorial Hospital where she delivered an hour later.

5. **Patient ML** presented to Grace Medical on August 2, 2010 for an abortion at 33 weeks of pregnancy. The fetus was viable but had Down Syndrome (Trisomy 21). She had Digoxin infusion on August 3 to induce fetal death and on the same day had laminaria inserted. She was instructed to drive by personal car to Elkton, MD on August 4 where the abortion was completed by D & E.

Findings:

1. Dr. Brigham performed abortions on DB, SD, NC, JP and ML in New Jersey at gestational ages ranging from 18 to 33 weeks by the insertion of laminaria into the patient's cervix along with either oral misoprostol or Digoxin intra-amniotic infusion.
2. These abortions were not performed in either an accredited hospital (for medical abortions over 14 weeks) or a licensed ambulatory care facility (LACF) (for D&E abortions over 14 weeks) which the Board has mandated for patient safety.
3. Laminaria and misoprostol, when used in the late second trimester, are designed to rapidly put the patient into an intense labor often associated with significant bleeding. This is why the Board requires that they be used in the safety of a hospital or LACF.
4. Dr. Bingham performed a very late third trimester abortion on ML beyond the stage of fetal viability in a pregnancy that did not involve a fetus with a lethal defect or a condition dangerous to the mother's health.
5. Dr. Brigham required his patients, after the initiation of their abortions, to travel by personal auto sixty miles in order to have their terminations completed by D&E.
6. Dr. Brigham contracted with, and then referred his patients to, a doctor he knew was poorly trained in, and unqualified to perform, late second trimester terminations by D&E.
7. Dr. Brigham was present in the clinic at the time of DB's uterine perforation and elected to drive the patient to the local hospital in a vehicle not equipped with appropriate medical support.
8. There was no transfer arrangement in effect between the Elkton, MD clinic and Union Hospital for emergency cases.

Conclusions:

1. Dr. Brigham repeatedly violated Board regulations in the performance of pregnancy terminations by:
 1. planning and initiating medical terminations (those not done by D&E) greater than 14 weeks in an out of hospital setting.
 2. abetting the performance of D&E abortions beyond 14 weeks in a non-LACF setting
2. Dr. Brigham's disregard for the Board's safety regulations concerning second trimester abortions exposed his patients to considerable risk for harm.
3. Third trimester terminations by D&E abortions are extremely risky to the mother and should never be performed, as it was in this case, in a facility that does not have the capability of doing immediate major surgery.
4. Dr. Brigham's induction of fetal death in ML's viable 33 week pregnancy that did not involve a fetus with a lethal defect or a condition dangerous to the mother's health seriously violated medical standard of care and, to my knowledge, is not sanctioned by any statute or regulation.
5. 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.
6. Dr. Brigham repeatedly committed gross medical negligence by allowing a contracted physician he knew was unqualified to perform late second trimester D&E's on his patients.
7. Dr. Brigham repeatedly committed gross medical negligence by failing to have an arrangement in place with an accredited hospital for emergency care of patients undergoing high-risk procedures in his Elkton, MD clinic.
8. There is compelling evidence that Dr. Brigham committed the above acts in his management of other patients under his care.

My opinions in this matter are based on the information contained in the documents listed at the beginning of this report, my knowledge and experience gained in 30 years of clinical practice in New Jersey as a board certified obstetrician-gynecologist and the application of the accepted standards of care for my field. I reserve the right to amend these findings if additional information regarding this matter comes to my attention.

Sincerely,

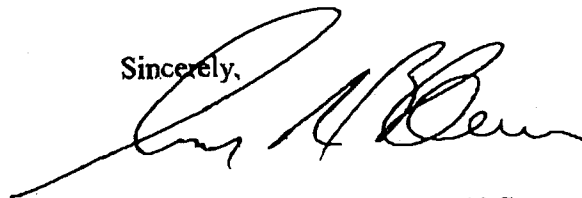
Gary R. Brickner, MD, FACOG

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Sincerely,



Gary R. Brickner, MD, FACOG

CURRICULUM VITAE

GARY R. BRICKNER, M.D. FACOG

September 20, 2010

Office Address: Brickner-Mantell Center for Women's Health
Quakerbridge Plaza, Building 1A
Hamilton, New Jersey 08619
Tel: 609-689-9991
Fax: 609-689-9992

Citizenship: United States

Date of Birth: May 31, 1950

Place of Birth: Brooklyn, New York

Education:

1967-1971: B.A., Psychology, State University of New York at Buffalo, Buffalo, New York

1971-1975: M.D., University of Pittsburgh, Pittsburgh, Pennsylvania

1975-1976: Internship- Rotating, Pennsylvania Hospital, Philadelphia, Pennsylvania,

1976-1979: Residency- Obstetrics and Gynecology, Pennsylvania Hospital, Philadelphia, Pennsylvania

Academic Appointments:

1978-1979: Assistant Instructor, Department of Obstetrics and Gynecology, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania

Presentations:

1999: "Course on First Assisting on Cesarean Sections" Given to Certified Nurse Midwives at Princeton New Jersey

1996: "Course on the Performance of Newborn Circumcisions" Given to Certified Nurse Midwives at the New Jersey Medical School, Newark, and New Jersey

1993: "Dysfunctional Uterine Bleeding" Given at the Nurse-Midwife Clinical Workshop at Mercer Medical Center

1979: "Morbidity of Cesarean Sections-Differences Between Patients on the Private and Teaching Services at Pennsylvania Hospital" Given during the S. Leon Israel Lectureship Series at Pennsylvania Hospital

Awards and Honors:

2009: Meritorious Unit Citation, 206th Area Support Medical Company for service in Iraq

2008: Dr. Martin Epstein Award for Humanitarian Service by Capital Health System

2007: Army Commendation Medal for meritorious service in Iraq

2007: Army Achievement Medal for meritorious service in the Global War on Terrorism

2005: Combat Medical Badge (Army) for action "under fire" in Afghanistan

1999: Central New Jersey Maternal and Child Healthcare Consortium Recognition Award for Leadership on Women's Health Issues

1998: Women's Political Caucus of New Jersey "Good Guy" Award for advancing women's health care in New Jersey

1981: Diplomate, American Board of Obstetrics and Gynecology

1976: Diplomate, National Board of Medical examiners

1971: Phi Beta Kappa

Professional Societies:

Fellow, American College of Obstetrics and Gynecology
The New Jersey Medical Society
Veterans of Foreign Wars
American Legion

Professional Activities:

2002- Officer NJ Army National Guard Medical Corps—Present Rank Lt Colonel
2007: Active military duty in Iraq in support of "Operation Iraqi Freedom"
2004-2005: Active military duty in Afghanistan in support of "Operation Enduring Freedom".
2000-2003: Member, New Jersey Maternal Mortality Review Committee
1996-1999: Member, New Jersey State Board of Medical Examiners—Appointed by
 Governor Christine Todd Whitman
1997-1999: Member, *ex officio*, New Jersey Medical Practitioner Review Panel of the
 New Jersey State Board of Medical Examiners
1998: Member, New Jersey State Board of Medical Examiners Executive Committee
1992-2003: Member, New Jersey State Board of Medical Examiners Certified Nurse-
 Midwife Liaison Committee
 1996-1999: Chairman of Committee
1991: Member, Certified Nurse-Midwife Prescriptive Practices Task Force of the New
 Jersey State Board of Medical Examiners
1996-2001: Member, Board of Directors RWJ Healthcare Corporation at Hamilton
1994-1996: Member, Board of Directors Visiting Nurse Association of the Delaware
 Valley
1987-1992: Medical Director for Obstetrics and Gynecology, Medigroup Central HMO,
 Trenton, New Jersey
1981-1996: Member, Medical Advisory Committee of the Visiting Nurse Association of
 the Delaware Valley
1981-1987: Member, Board of Directors of Planned Parenthood of Mercer County
 1981-1987: Co-Chair of the Medical Committee

Work History:

2005-Present: Member, CHS Women's Health Group at Capital Health System. Trenton,
 New Jersey
2001-Present: Founding Member, Brickner-Mantell Center for Women's Health, Hamilton, New
 Jersey A private medical group dedicated to the care of
 women
1996- 2001: Director and Chairman, Department of Obstetrics and Gynecology, Robert Wood
 Johnson University Hospital at Hamilton
 Director, Robert Wood Johnson Ob-Gyn Group at Hamilton
1981-1995: Founding Member and President, Lawrence Ob-Gyn Associates,
 Lawrenceville, New Jersey, an Ob-Gyn group practice
1979-1980: Member, Tormed Women's Medical Group, Torrance, California,
 an Ob-Gyn group practice

Current Hospital Affiliations:

1981-Present: Capital Health System, Trenton, New Jersey

Licensure:

New Jersey: MA38319
Pennsylvania: MD018245E (inactive)
California: G39063 (inactive)

Exhibit 2

N.J.A.C. 13:35-4.2

NEW JERSEY ADMINISTRATIVE CODE
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THE ***
*** NEW JERSEY REGISTER, VOL. 42, NO. 18, SEPTEMBER 20, 2010 ***

TITLE 13. LAW AND PUBLIC SAFETY
CHAPTER 35. BOARD OF MEDICAL EXAMINERS
SUBCHAPTER 4. SURGERY

N.J.A.C. 13:35-4.2 (2010)

§ 13:35-4.2 Termination of pregnancy

(a) This rule is intended to regulate the quality of medical care offered by licensed physicians for the protection of the public, and is not intended to affect rules of the Department of Health establishing institutional requirements. To the extent that rules of the two agencies may overlap, the Medical Board recognizes and relies upon the regulatory procedures of the Department of Health in establishing minimum acceptable standards for non-physician personnel, equipment and resources, the adequacy of the physical plant of the facility in which surgical procedures shall be performed, and the facility's interrelationship with an adequate network of health care-related resources such as ambulance service, etc.

(b) The termination of a pregnancy at any stage of gestation is a procedure which may be performed only by a physician licensed to practice medicine and surgery in the State of New Jersey.

(c) Provisions of this rule referring to stage of pregnancy shall be in terms of weeks from start of last menstrual period or "weeks LMP." For example, the stage of pregnancy at 12 weeks' gestational size, as determined by a physician, is the equivalent of 14 weeks from the first day of the last menstrual period (LMP).

(d) After 14 weeks LMP, any termination procedure other than dilatation and evacuation (D & E) shall be performed only in a licensed hospital.

(e) Fifteen weeks through 18 weeks LMP: After 14 weeks LMP and through 18 weeks LMP, a D & E procedure may be performed either in a licensed hospital or in a licensed ambulatory care facility (referred to herein as LACF) authorized to perform surgical procedures by the Department of Health. The physician may perform the procedure in an LACF which shall have a Medical Director who shall chair a Credentials Committee. The Committee shall grant to operating physicians practice privileges relating to the complexity of the procedure and commensurate with an assessment of the training, experience and skills of each physician for the health, safety and welfare of the public. A list of the privileges of each physician shall contain the effective date of each privilege conferred, shall be reviewed at least biennially, and shall be preserved in the files of the LACF.

(f) Nineteen weeks through 20 weeks LMP: A physician planning to perform a D & E

procedure after 18 weeks LMP and through 20 weeks LMP in an LACF shall first file with the Board a certification signed by the Medical Director that the physician meets the eligibility standards set forth in (f)1 through 7 below and shall comply with its requirements.

1. The physician is certified or eligible for certification by the American Board of Obstetrics-Gynecology or the American Osteopathic Board of Obstetrics-Gynecology, and the physician satisfactorily completes at least 15 hours of Continuing Medical Education each year in obstetrics-gynecology.
2. The physician has admitting and surgical privileges at a nearby licensed hospital which has an operating room, blood bank, and an intensive care unit. The hospital shall be accessible within 20 minutes driving time during the usual hours of operation of the clinic.
3. The procedure shall be done in a location which is designated by the Department of Health as a licensed ambulatory care facility (LACF) authorized to perform surgical procedures as in subsection (e) above. The LACF shall be licensed by the Department of Health as an ambulatory care facility authorized to perform surgical procedures. The facility shall be in current and good standing at all times when surgical procedures are performed there. The LACF shall have a written agreement with an ambulance service assuring immediate transportation of a patient at all times when a patient has been admitted for surgery and until the patient has been discharged from the recovery room.
4. The procedure shall be done in an LACF which shall have a Medical Director and a Credentials Committee which have duly evaluated the training, experience and skill of the physician at continuous and successive levels of complexity of the D & E procedure in pregnancies advancing in stages from 18 weeks LMP through 19 weeks LMP through 20 weeks LMP, and the physician has been granted successive practice privileges consistent with management of the increased risk to the health and safety of the patient at that stage documented in the personnel file maintained for that physician. (Where the applicant physician is also the Medical Director, the physician shall submit a certificate from the Administrator or Chief of Department of a hospital or the Medical Director of an LACF where the applicant has been evaluated and credentialed in a comparable manner.) The physician new to the LACF shall have his or her operating technique evaluated initially and at least yearly by the Medical Director or his or her designee who shall possess appropriate experience with D & E procedures at least as advanced as those for which the applicant physician seeks approval. The applicant shall be evaluated during that number of procedures which shall be adequate to achieve a sufficient professional skill, and the evaluation procedure shall be documented in the personnel file maintained for that physician. The Medical Director shall agree to review the charts of all patients who suffer complications and in addition shall review charts at random, and shall calculate the complication rate of each physician.
5. The physician shall perform the procedure only on a patient who has been examined and found to be within the eligibility criteria established for advanced D & E procedures in the LACF setting.
6. The procedure shall be performed in an LACF providing adequate staff support and resources for the operative procedure as well as interim follow-up and post-operative care, and where a physician is available and readily accessible 24 hours/day to

respond to any postoperative problem.

7. The physician shall cooperate with the Medical Director to maintain contemporaneous and cumulative statistical records demonstrating the utilization and safety record of each stage procedure and of each surgeon. Said records shall be available for inspection by the Board and copies shall be submitted to the Board semi-annually. These records shall include the following information and data shall be maintained in records compiled monthly, but individual patients comprising the lists shall be identified only by date and by initials and/or case number:

- i. Number of patients who received termination procedures;
- ii. Number of patients who received laminaria or osmotic cervical dilators who failed to return for completion of the procedure;
- iii. Number of patients who reported for postoperative visits;
- iv. Number of patients who needed repeat procedures;
- v. Number of patients who received transfusions;
- vi. Number of patients suspected of perforation;
- vii. Number of patients who developed pelvic inflammatory disease within two weeks;
- viii. Number of patients who were admitted to a hospital within two weeks of the procedure;
- ix. Number of patients who died within 30 days.

Subparagraphs ii. through ix. above shall be summarized by number and percentage of monthly total for post-18 week procedures. The Board shall inspect such reports monthly for the first five months and at such further monthly intervals as it deems necessary.

(g) After 20 weeks: A physician may request from the Board permission to perform D & E procedures in an LACF after 20 weeks LMP. Such request shall be accompanied by proof, to the satisfaction of the Board, of superior training and experience as well as proof of support staff and facilities adequate to accommodate the increased risk to the patient of such procedure.

(h) The physician shall make suitable arrangements to insure that all tissues removed shall be properly disposed of by submission to a qualified physician for pathologic analysis or by incineration or by delivery to a person/entity licensed to make biologic and/or tissue disposals in accordance with law including rules of the Department of Health applicable to an LACF.