State of New Jersey
OFFICE OF ADMINISTRATIVE LAW

INITIAL DECISION
OAL DKT. NOS. BDS 12006-10 and
BDS 16372-12
(CONSOLIDATED)

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

Jeri L. Warhaftig and Joshua M. Bengal, Deputies Attorney General, for complainant Attorney General of New Jersey (John J. Hoffman, Acting Attorney General, attorney)

Joseph M. Gorrell, Esq., for respondent Steven G. Brigham, M.D. (Brach Eichler, attorneys)

Record Closed: July 25, 2014 Decided: August 13, 2014

BEFORE **JEFF S. MASIN**, ALJ:

Steven C. Brigham is a physician licensed to practice in the State of New Jersey. On September 8, 2010, the Attorney General of New Jersey, acting as the statutory complainant under the Practice Act, N.J.S.A. 45:1-18, filed with the New Jersey Board of Medical Examiners a Complaint and Order to Show Cause Complaint against Dr. Brigham, seeking a temporary suspension of his New Jersey license to practice medicine. On that date, the Board approved a Consent Order requiring that Brigham cease and desist practice while he prepared to resist the Order to Show Cause. On September 17, 2010, the Attorney General filed a First Amended Verified Complaint, seeking to have the Board impose sanctions against Dr. Brigham's medical license, including the possible revocation of that license and of Brigham's ability to practice medicine in this State. The charges involved Dr. Brigham's practice, in which he

performed terminations of pregnancy procedures (TOPs). The terms "termination of a pregnancy" and "procedure" each appear in a provision of the New Jersey Administrative Code, N.J.A.C. 13:35-4.2, and the precise meaning of the terms as used therein is a matter of major dispute in this case. The Attorney General argues that Dr. Brigham's practices in connection with the performance of TOPs violated certain restrictions in regard to where and by whom such procedures can be performed in this State. In part, the case involves medical practice that occurred in New Jersey; in part, medical practice that occurred in the State of Maryland. The complainant seeks to hold Brigham liable for actions occurring in both States, as it believes his conduct in Maryland, which it characterizes as the unlicensed practice of medicine, involved violations of standards of care and of law that properly affect his qualification to practice in New Jersey.

For his part, Dr. Brigham argues that the Attorney General's understanding of exactly what the TOP regulation addresses is flawed. He denies any violation of any element of the regulations in New Jersey or Maryland. He denies that his practices violate any professional standards of care.

After the Complaint was filed with the Board, Brigham moved to dismiss the Complaint. The Board conducted an oral argument and received testimony from witnesses. On October 13, 2010, the Board denied the motion to dismiss and ordered that the doctor's license be suspended pending the outcome of the administrative process. Orders denying the motion and imposing a temporary suspension of license were issued nunc pro tunc on that date. The contested case was then transferred for hearing to the New Jersey Office of Administrative Law (OAL), where it was made inactive by Order issued on March 11, 2011, pursuant to an agreement between the parties, due to a criminal indictment then pending in Maryland against Dr. Brigham, involving charges arising out the treatment of D.B., one of his patients. This treatment also figures in the allegations in this disciplinary hearing. The Maryland indictment was eventually withdrawn before any trial, and the present case was reactivated, over the objection of respondent, who was concerned that Maryland might revive the charges against him. See Order dated July 3, 2012. During the course of extended discovery, the Attorney General filed a Second and then a Third Amended Complaint (hereinafter

referred to as the "Complaint").[i] A motion for partial summary decision was filed by the complainant on June 7, 2013, but the motion was denied on August 27, 2013. Hearings were conducted beginning on October 2, 2013 and continued over eighteen days, concluding on January 9, 2014.[ii]

The parties filed extensive briefs, appendices and reply briefs, and the record closed on March 31, 2014. Due to the extensive record, the complex factual and legal issues involved, the need to address other pending cases and administrative duties, and a previously scheduled vacation falling within the statutory time for the issuance of the initial decision, an extension of that time was requested and granted. N.J.S.A. 52:14B10(c) and N.J.A.C. 1:1-18.8- The record was reopened on June 30, 2014, to allow for additional testimony relevant solely in relation to the level of any sanctions that might be imposed. A hearing was scheduled and heard on July 25, 2014, after which the record closed.

At the outset, it is necessary to say something regarding the terminology that the issues in this case necessarily involves. Dr. Brigham's practice involved what are commonly termed abortions. As will be detailed, in the regulation that is at the heart of the case, that term never appears. Instead, the regulation, N.J.S.A. 13:35-4.2, speaks of "termination of a pregnancy." Expert witnesses and regulators, as well as attorneys for both parties, have testified and argued about the meaning of this term, and the intended reach of the regulation. Whether this regulatory term is synonymous with "abortion," at least as that term is commonly understood, or has a specialized meaning within the medical community, may or may not be. However, as it is central to the case, that regulation, N.J.A.C. 13:35-4.2 provides, in pertinent part

> (a) This rule is intended to regulate the quality of medical care offered by licensed physicians for the protection of the public, . . .
>
> (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. "Procedure" within the meaning of this

[i] The Third and final Amended Complaint dropped certain portions of Count I of the prior Complaints and entirely eliminated Count IV, while adding Counts VII and VIII.

[ii] Hearings were held on October 2, 10, 11, 16, 17, 18, 24, 29, 30, 31, November 12, 13, 14, 18, 19, 22, and December 16, 2013, and January 9, 2014.

subsection does not include the issuing of a prescription and/or the dispensing of a pharmaceutical.

(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 and Senior Services. The physician may perform the procedure in an 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.

The Charges[iii]

Initially, the Complaint notes that as of the time it was filed, Dr. Brigham conducted his medical practice at several addresses within New Jersey and under several business names, including American Women's Services, American Wellness Center, American Women's Center, Grace Medical Care and Grace Medical Services. None of the doctor's New Jersey practice is conducted in a Licensed Ambulatory Care Facility. Dr. Brigham is not a gynecologist, nor is he an obstetrician. He has a medical

[iii] Evidence as to Count V, referencing a patient , J.P., was not specifically presented.

degree and served an internship and residency. These facts are not disputed by Dr. Brigham.

In various portions of the Complaint, the Attorney General charges that in his New Jersey office in Voorhees Township, Camden County, Dr. Brigham treated various patients, identified in the Complaint and the record of this hearing by initials, who were seeking terminations of their pregnancies. Over several days, in New Jersey, Brigham inserted laminaria, a device that is derived from seaweed or the dogwood tree and which has the property of becoming swollen and therefore causing the cervix to dilate. He also provided drugs, such as Misoprostal, also used as a dilative agent, and Digoxin, which causes fetal demise. Then, on a subsequent day, he had these patients travel by automobile to a facility he operated in Elkton, Maryland, where he, or in some instances, another physician acting under his supervision, performed a dilatation and evacuation (D&E), a surgical procedure, on the patient. Again these facts are not disputed. The D&E was intended to remove all of the fetal remains and products of conception from the woman's uterus.

The First Count of the Complaint addresses the above scenario in the case of D.B., a patient who, after undergoing the D&E in Elkton, suffered a perforated uterus, which caused her to be taken from the Elkton facility to the emergency room of the nearby Union Hospital in Elkton. It is important to note here that the D&E was not performed by Dr. Brigham. It was actually performed in the presence of Dr. Brigham by a Dr. Nicola Riley, a licensed Maryland physician. D.B was subsequently transported to Johns Hopkins Medical Center in Baltimore for additional treatment. It was this incident that caused police involvement by the Elkton, Maryland Police Department, and eventually led to the aforementioned Maryland indictment. It also brought Dr. Brigham to the attention of the New Jersey Board of Medical Examiners and the Maryland Board of Physicians, although, as will be detailed, the New Jersey Board, the Attorney General and Dr. Brigham were not strangers to each other. In the case of D.B., and other identified patients as well, the Complaint contends that this procedure of performing certain acts in New Jersey and others in Elkton, Maryland, violated N.J.A.C. 13:35-4.2. More specifically, it claims that either the insertion of laminaria or the consumption of misoprostol by D.B. on August 12 and 13, 2010, respectively, each of which occurred in

New Jersey, involved the commencement of the "termination of D.B.'s pregnancy." Contending that in D.B.'s case she was at least mislead as to the actual location where her "abortion would be completed," the First Count concludes by charging, in conclusory terms, that the medical treatment provided to "patients identified herein" violated professional standards and involved repeated acts of malpractice, gross malpractice and negligence, all grounds for the imposition of sanctions, including possible revocation of the doctor's medical license.

Count II charges that Dr. Brigham, who has no Maryland medical license, performed approximately fifty terminations of pregnancy in the Elkton office of American Women's Services, mainly second trimester, including so-called, "later cases" involving women beyond twenty weeks LMP. Each began in some location other than Elkton. It is charged that Brigham created or allowed to be created medical records that were false, misleading or confusing, and which failed to convey to patients necessary information required by standards of good medical practice. In addition, it notes that on August 25, 2010, the Maryland Board of Physicians issued a Cease and Desist Order directing Dr. Brigham to stop the unlicensed practice of medicine in Maryland. The Count claims that Brigham's conduct involved the unlicensed practice of medicine and thus was a "crime or offense relating adversely to the practice of medicine," involving repeated professional misconduct, acts of dishonesty, fraud, deception and misrepresentation, as well as the failure to maintain patient records that conform to the requirements of N.J.A.C. 13:35-6.5.

Count III addresses the doctor's treatment of patients S.D. and N.C., each of whom were patients at Voorhees and then had D&E's performed in Elkton on the same date as was D.B.'s treatment. Each was more than fourteen weeks LMP. Indeed, S.D. was twenty-five weeks pregnant with twins. The Count charges that Brigham's treatment of these two "is part of a wide-scale pattern of practice whereby terminations of pregnancy that cannot be legally performed by Respondent Brigham in his New Jersey office are begun by him and/or at his direction in New Jersey and completed in Maryland." Again, similar allegations of violations of standards of practice and of dishonesty, are claimed, as well as violations pertaining to inappropriate records.

Count VI addresses the treatment of patient M.L., largely repeating the allegations of fact and of legal violations that are asserted in Count III. Count VII then asserts much the same in the cases of sixteen listed patients. In each case it is again claimed that Brigham "was ineligible to perform the procedures . . . under applicable New Jersey law."

Count VIII mentions autopsies performed in Maryland upon fetal remains and charges that the fetal death of each was initiated by Dr. Brigham in New Jersey, in violation of New Jersey law. Again, this conduct is alleged to have involved gross negligence and repeated acts of negligence, as well as repeated acts in violation of N.J.A.C. 13:35-4.2.

While the charges in the Complaint present a series of allegations concerning Dr. Brigham's practice and condemn what might be referred to as his arrangements for delivery of medical treatment to patients, there is no specific mention in the charges about the physical characteristics, conditions or equipment either utilized at or absent from the Elkton office. During the hearing much testimony was presented on these matters, focused upon a series of photographs of the Elkton office that the complainant's expert reviewed. Presumably, the contention is that the conditions at Elkton were such as to violate the professional standards appropriate for such a facility where procedures such as D&E's are performed. No objection was made regarding the relevancy of this testimony, although, as will be noted later, the focus of the parties in reviewing the record and briefing the matter appears to place little significance on this testimony or on the legal ramifications that might arise from what they purportedly show.

The following is a list of persons prominently involved in this case. In addition, several patients and employees of the doctor testified, but are identified only by initials in order to protect their medical privacy or for other sufficient reasons.

Steven Chase Brigham, M.D., graduated from the Massachusetts Institute of Technology with degrees in Physics and Applied Biology. He graduated from the Columbia University Medical School/Physicians and Surgeons, in a combined medical school and graduate school program that resulted in both M.D. and PEdD degrees.

Although he had desired to be a pediatric oncologist, certain experiences led him to a different path. After graduating from medical school in 1986, Dr. Brigham interned for one year, during which time he did a clinical rotation in obstetrics and gynecology. He assisted on some second trimester abortions, but not on D&E's or D&X procedures. Licensed to practice in 1988, he performed emergency room service in several hospitals. In 1988, he began work relating to terminations of pregnancy. He worked at several facilities in New York, and observed and performed both first and second trimester abortions. He performed terminations of pregnancy for Planned Parenthood in New York City and later at facilities in New York, Pennsylvania and New Jersey. Dr. Brigham explained at some length his experiences with protests and threats surrounding facilities at which he worked, as well as at which others worked, and some of this will be discussed below.

Dr. Brigham noted training he had received over the years from several practitioners in the abortion field. He was "always cognizant" that he was not an ob/gyn. He sought more and more knowledge from persons with expertise in the field. He began practicing in New Jersey in 1992, in Voorhees Township. He was aware of N.J.A.C. 13:35-4.2. He discussed as background his experiences with the issue of the insertion of laminaria, and his establishment of American Women's Services, a name that was utilized by a long-standing multistate practice started in the 1920's in Ashland, Pennsylvania. As of 2009, Dr. Brigham had performed between 40,000 and 50,000 terminations of pregnancy. The majority of these were first trimester, perhaps 3,000 were second trimester. He has never had a patient die, nor has any patient died who was treated by those who have worked for Brigham or in any facility that he has owned. He has had several patients suffer significant complications.

Christine A. Farrelly is the Acting Executive Director of the Maryland Board of Physicians. Ms. Farrelly holds a Bachelors Degree in History and has eighteen credits towards her Masters in Management (Health Programs of Public Health), performing investigations of facilities and practitioners. She has been a private consultant in vital records management. She was a Long Term Care Obdsbudsmen and started her employment with the Maryland Board of Physicians in 2007 as an administrative liaison for nursing homes. She worked for three years as a compliance analyst and was then

assigned to the Brigham investigation. In 2012 she became a Compliance Manager and remains in that title, while serving since September 2012 as Deputy Director of Allied Health, Compliance and Licensure, and since June 2013, as the Acting Executive Director.

E. Steve Lichtenberg, M.D., is a Board Certified Obstetrician/Gynecologist, licensed in Illinois and California. He received his B.A. degree from Cornell University and his M.D. from the University of Pennsylvania. He holds a Masters Degree in Public Health in Epidemiology from the University of California, San Francisco. He is employed by Family Planning Associates Medical Group in Chicago, Illinois and Long Beach, California. He serves as the Medical Director and is an owner of the business. Dr. Lichtenberg is on the staff of Northwestern Memorial Hospital in Chicago, where he serves as an Associate Professor of Clinical Obstetrics and Gynecology. Dr. Licthenberg has performed approximately 70,000 first trimester abortions in his career; and at least 30,000 second trimester. The doctor currently does about four weeks of clinical work in Chicago a year and during the remainder of the year he teaches, does research, and engages in political advocacy. Dr. Lichtenberg was a board member of the National Abortion Federation (NAF) from 1999 through 2005, and was chair of the Medical Standards and Guidelines Committee for Planned Parenthood in 2010-2012. He also served five years on the Board of the American Civil Liberties Union in Illinois. He has written extensively on complications in abortion, has been the associate editor of a 2009 book, "Management of Unintended and Abnormal Pregnancy, Comprehensive Abortion Care", and an earlier book, "A Clinician's Guide to Medical and Surgical Abortion." Dr. Lichtenberg was admitted as an expert in obstetrics and gynecology, with a specialty in family planning, contraception, and abortion in all trimesters. [iv]

[iv] Respondent has noted Dr. Lichtenberg's role in advising the Maryland legal authorities regarding Brigham's activities and his role in barring Brigham's involvement in professional associations as an indication of bias on Lichtenberg's part, bias which should affect the credibility of his professional opinions regarding Brigham and his practice. While it is clear enough that Lichtenberg does not approve of elements of Brigham's practice (he noted that he could not opine as to the doctor's technical skills), I found Lichtenberg to be an honest advocate of his positions and not in any sense an inappropriately zealous advocate against what he truly felt were the shortcomings and professional misdeeds of the respondent. That said, of course, the normal process of weighing the quality and overall credibility of the expert's opinions has been applied in assessing the value and meaning of his testimony.

Detective Sergeant Holly Smith is a police officer employed by the Elkton, Maryland Police Department. Detective Smith has been a police officer for twenty years, and a sergeant supervising the Detective Division. On Friday, August 13, 2010, she was dispatched to 126 East High Street in Elkton, in connection with a matter referred from Union Hospital regarding D.B. Thereafter, Detective Sergeant Smith was involved in the investigation of Dr. Brigham's activities in Elkton and Voorhees..

M. Natalie McSherry, Esq., is admitted to the Bar of the State of Maryland. She graduated from the University of Maryland School of Law in 1974. She is a litigator, now a partner in the law firm of Kramon & Graham in Baltimore, Maryland, with substantial experience in the malpractice field. She has conducted medical malpractice defense and has practiced for twenty years before the Board of Physicians and has handled cases involving standard of care, unprofessional conduct, inappropriate behavior and credentials matters. She has served as an adjunct faculty member of the University of Maryland School of Law. Ms. McSherry was admitted as an expert in Health Law and the Health Law in Maryland.

George Shepard, M.D., now retired, was, according to his Certification dated October 8, 2010, then licensed by the State of Maryland as a physician, and was Board Certified in Obstetrics and Gynecology and a Fellow of the American College of Obstetricians and Gynecologists. He has been identified by Dr. Brigham, and self-identifies in his Certification, as the Medical Director of American Women's Services, and he was present at the Elkton, Maryland facility at the time at which many D&E procedures were performed on patients. He also purportedly was on an open telephone line from his home in Delaware while listening and commenting during some of the other D&E procedures performed at Elkton. Dr. Shepard, who surrendered his Maryland medical license subsequent to the initiation of the investigation of the Elkton facility, did not testify in this proceeding.

Richard Lizzano is an investigator with the Enforcement Bureau of the New Jersey Division of Consumer Affairs. He has worked for this agency since 2001. He was formerly a police officer and retired in 2001 as a detective lieutenant. He was assigned to investigate matters concerning Dr. Brigham.

Gary Mucciolo, M.D., is an obstetrician/gynecologist who graduated from Queens College and New York University Medical School. He began his practice in July 1980. Dr. Mucciolo is a Clinical Associate Professor of Obstetrics and Gynecology at N.Y.U. Medical School and is on the Quality Assurance Committee of the Department. His practice is 60 percent obstetrical and 40 percent gynecological. He operates upon an array of gynecological issues. Since his early days in practice, Dr. McCool has worked at several clinics where first and second trimester abortions were performed. He has performed several thousand D&E procedures and tens of thousands of first and second trimester abortions. Dr. Mucciolo was admitted as an expert witness for Dr. Brigham, in obstetrics and gynecology and termination of pregnancy procedures.

Greg Lobel, M.D., also testified as an expert witness on rebuttal for the complainant. Dr. Lobel is Board Certified in Anesthesiology and licensed in New Jersey. He was educated at Brandeis and Mt. Sinai Medical School in New York City. He serves as an Assistant Clinical Professor of Anesthesiology at Mt. Sinai and was a member of the Credentials Committee for three years at Englewood Hospital, which is associated with Mt. Sinai. He also served as a member and as Chair of the Medical Executive Committee, and as Vice President of the medical staff since January 2014.

Termination of Pregnancy/Abortion
What does N.J.A.C. 13:35-4.2 Regulate?

While the terminology involved regarding the subject may differ, and in some instances with significant legal, if not also medical, implications, it is first important to note that there are several types of intentional procedures or natural occurrences commonly referred to as “abortions.” A pregnant woman may sometimes experience a “spontaneous abortion,” where ”fetal demise” and “miscarriage” occur for some reason that is not related to any intentional human intervention,. There is also an “induced abortion,” sometimes referred to simply as an “abortion,” which occur in the second and third trimesters. According to Dr. Lichtenberg, a “medical abortion is an induced abortion that’s designed to complete the emptying of the uterus using only medications, devices or both.” This may occur in either the second or the third trimester. A “surgical

abortion" involves removal of the fetus and products of conception, accomplished by the use of hands and instruments. Dr. Lichtenberg described a dilatation and evacuation or extraction (D&E) as a "surgical abortion performed beyond the first trimester," which in New Jersey means beyond fourteen weeks.

As previously noted, an essential question raised by the differing positions of the parties in the current matter involves the meaning of the regulatory phrase "termination of a pregnancy." Essentially, the complainant contends that the insertion of laminaria, and/or, at the very least, the initiation of fetal demise, is a part or portion of the "termination of a pregnancy" "procedure" that is governed by N.J.A.C. 13:35-4.2 and thus restricted in certain ways as to the location where termination can be performed and the practitioner who can perform the termination. As it is undisputed that Dr. Brigham caused fetal demise to occur in New Jersey even before any of the patients went to Maryland for the D&E, his conduct would then fall with the reach of the regulation. But Dr. Brigham contends that the terminology used, and thus the regulation itself, only addresses the D&E, or other such "procedures," which are, essentially by definition, surgical in nature, and which are, in his and his expert's view, that which constitute a "termination of a pregnancy." He contends that while the insertion of laminaria, and even the institution of fetal demise, are part of the process that is involved in preparing a patient to undergo a "termination of a pregnancy," these are not properly equated with, or subsumed under, the "termination of a pregnancy" label and thus are not addressed by the restriction contained in this regulation. Thus, the "termination of a pregnancy" that occurred in these cases, occurred in Maryland, and not in New Jersey. In this vein, Dr. Lichtenberg, the complainant's expert, offered that the "termination of a pregnancy" is itself a "process," and in his opinion the term includes all the events from at the very least the patient's first encounter with the physician from whom she seeks treatment, through the several stages of counseling, preparation and ultimate removal of the fetus and other products of conception. .

The question of what is or is not addressed by N.J.A.C. 13:45-4.2 is not a topic that is new to these parties. Any consideration of the charges brought against Brigham and his defense thereto must necessarily acknowledge that Dr. Brigham is no stranger to the Board of Medical Examiners. In the early 1990's the Attorney General brought a

series of administrative charges to the Board, arguing that Dr. Brigham's practices regarding terminations of pregnancy were in violation of the Board's regulations, amongst which was N.J.A.C. 13:45-4.2. A lengthy administrative hearing was conducted before Honorable Joseph F. Fidler, ALJ, which resulted in a ninety-seven-page initial decision issued by Judge Fidler on April 12, 1996. In the Matter of the Suspension or Revocation of the License of Steven Chase Brigham, M.D., BDS 1303-94 and BDS 2468-95 ("Brigham I"). The Board of Medical Examiners issued its Final Decision regarding Brigham I on August 28, 1996, nunc pro tunc, August 14, 1996. The Board accepted and adopted Judge Fidler's determination that "all allegations in the complaint be dismissed," with an exception for certain allegations pertaining to "misleading advertisement" as its decision. Because Brigham I involved issues that touched on the meaning of N.J.A.C. 13:45-4.2, we must examine Judge Fidler's ruling.

Judge Fidler was confronted, in part, by allegations that Dr. Brigham was acting in violation of the restrictions imposed by N.J.A.C. 13:35-4.2 regarding termination of pregnancy. The complainant in Brigham I contended that the insertion of laminaria in a patient who intended to have an abortion, that is, to purposely avert the possibility of carrying a live fetus to full term, was "the commencement of the abortion procedure." As Judge Fidler noted, the regulation said nothing about the insertion of laminaria for the purpose of dilating the cervix preparatory to the removal of the fetus and the placenta. The evidence offered in Brigham I, as here, was that the insertion of laminaria, by itself, does not commit a woman to ending the pregnancy, for laminaria can be removed and the woman can still have a successful delivery, at least in some, if not most, cases. In the situation addressed in 1996, the laminaria were inserted in New Jersey and the D&E was to be performed in New York in a setting legal in that State.

Judge Fidler determined from the expert evidence offered that, "[i]t is clear that insertion of laminaria does not terminate a pregnancy." It is a "necessary step" to achieve adequate cervical dilatation, itself necessary to allow for safe removal of the fetus and placenta. As for whether this "necessary step" was "a termination process" under the regulation, Judge Fidler wrote

> 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.

As a result of his ruling, Judge Fidler dismissed the allegation that the doctor had acted in a manner subjecting him to discipline. Having concluded that the regulation as it existed did not address the subject of the insertion of laminaria, Judge Fidler found Dr. Brigham "did not intentionally or negligently violate N.J.A.C. 13:35-4.2." As previously mentioned, the Board adopted this ruling of Judge Fidler, without modification.

Subsequent to the completion of Brigham I, an attorney representing Dr. Brigham, or, more properly, a group of physicians, engaged in correspondence with a representative of the Board that again touched on the subject of the insertion of laminaria in New Jersey. The letters are collectively referred to as the "Phillips Letters," as Stuart J. Phillips was Brigham's attorney who wrote the initial letter. That letter, dated January 26, 1999, was addressed to Judith I. Gleason, then the Executive Director of the Board of Medical Examiners. Mr. Phillips inquired, on behalf of "a group" of New Jersey medical practitioners who performed "second-trimester abortion procedures" about the Board's "termination of pregnancy" regulation, N.J.A.C. 13:35-4.2. Phillips describes that the doctors used "D&E" procedures in which laminaria were inserted in the patient's cervix in the doctor's office. One or two days later "the abortion procedure is performed either in a hospital or a licensed/approved facility." Phillips describes the method for laminaria insertion, noting that patients sometimes change their mind after the laminaria have already been inserted and removal of the laminaria can occur and normal delivery can still occur. After referencing the Board proceedings brought against Brigham, "on charges of violating N.J.A.C. 13:35-4.2 . . . for inserting laminaria in an office setting, prior to performing an abortion," and his exoneration, Phillips offered that his client

> "nevertheless does not want to run afoul of this Board, and 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 restriction against the actual performance of 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."

Phillips added that in his professional opinion, the insertion of laminaria in the office did not violate the regulation. However, he sought to allow the Board an opportunity to correct him if it disagreed with his understanding.

On October 21, 1999, Phillips wrote to Gleason, noting that he had received no reply to the January 26, 1999, letter. Executive Director Gleason replied, in a letter date stamped as received on November 8, 1999. She advised that she had discussed his inquiry "yesterday" with the Board's Executive Committee.

> The members 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, however, 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.

Thus, it is at least fair to conclude that in the mind of the Board, as expressed in writing to Attorney Phillips, at least as of November 1999, insertion of laminaria by itself was a "prefatory" act, not part of the regulated "termination of a pregnancy" "procedure" addressed by the regulation.

Despite the above, the Attorney General here argues that the Board did actually consider that the insertion of laminaria was encompassed by "the applicable New Jersey law," by which the complainant must mean this regulation. This argument is premised on language included by the Board in an Interim Order issued by the Board in December 1993, following a hearing on an application by the Attorney General for an order of temporary suspension prior to the hearings later held before Judge Fidler. The

Board then determined that Brigham's practice posed a clear and imminent danger to the public and decided to limit his practice. In the Final Decision and Order issued following the full administrative hearing before Judge Fidler, the Board recited a procedural history of the case, including the filing of the original Complaint and the Attorney General's applications for Orders to Show Cause and for Temporary Suspension. It quoted restrictions imposed, including a bar on the initiation or participation in second trimester abortions, encompassing the insertion of laminaria in patients for the purpose of cervical dilatation preceding evacuation of the uterus. Here, the Attorney General cites these references from the Interim Order as proof that the Board's earlier position expressed in its 1996 Final Decision and Order is consistent with the "determination that the TOP [termination of pregnancy] regulation applies to more than the evacuation of the uterus."

However, it is not appropriate to rely upon the quoted language as establishing that proposition. The order for temporary suspension sought by the Attorney General was, of course, an interim order. It was sought to be issued well before the full administrative hearing that would consider all of the relevant evidence concerning the range of issues regarding Brigham's practice, including this issue of the insertion of laminaria. Once the record was closed, Judge Fidler ruled and the Board issued its Final Decision, accepting Judge Fidler's commentary, in which he very clearly noted that the rule did not specifically address laminaria insertion. That said, Judge Fidler wrote, "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." In light of the fact that the Board did not choose to even comment on this language, it is fair to conclude that the Board itself did not believe, at least to the degree that it was willing to publicly disagree with the judge, that the rule did specifically address the use of laminaria. And thereafter, no doubt well aware of Judge Fidler's comment that the Board could, of course, "interpret the scope of its rule on termination of pregnancy, in accordance with reason, fairness, and adequate notice to those who are regulated," the Board did not choose to revise the language of the regulation, and also responded as it did to Mr. Phillips, telling him that, "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." Given this history, there is no basis for determining the Board's position on this issue from the language of the Interim Order relied upon here by the complainant.

That said, neither the decision rendered in Brigham I nor the Phillips' correspondence, including Ms. Gleason's reply of November 8, 1999, specifically addressed the issue and import of fetal demise, that is, whether the initiation of that condition is simply another "prefatory" act prior to the termination-of-pregnancy procedure, or whether instead it is an integral part of that termination-of-pregnancy procedure and, therefore, actions to cause fetal demise undertaken in New Jersey come within the regulation. In this respect, it is noted that the Attorney General nevertheless contends that Mr. Phillips' letter noted that the insertion of laminaria did not kill the fetus, and thus the complainant sees Phillips as having distinguished between the "prefatory," non-fatal insertion and the fatal action that the complainant contends this letter admits was a subject of regulation under the provision. In addition to this, some testimony was offered for the proposition that the administration of certain drugs, most particularly Misoprostol, given to women in conjunction with the insertion of laminaria and for the same purpose of promoting cervical softening and dilation, poses risks that make it less certain that the woman can simply reverse her decision to have an abortion without concern that she may go into labor, even do so without being aware that she is in labor and could deliver. There was even testimony concerning the risks that can arise when laminaria are removed. Thus, to the extent that this case requires some determination of the breadth of conduct that comes within the regulation's coverage, the 1996 decision and the letter exchange only go so far in defining that reach. This case then touches on elements of the full picture surrounding the process of intentionally ending a pregnancy that those prior matters did not.

Dr. Lichtenberg testified that "termination of pregnancy" is a "medical phrase," involving an induced abortion, as distinct from a miscarriage or a spontaneous abortion. He noted that the term "fetal demise" often used in this record, is itself a "loose usage," as, if the demise occurs at the hands of the woman herself or of a practitioner, the proper term is "feticide." A "medical abortion" is an induced abortion designed to completely empty the uterus, by either the use of medicines or the use of devices, or

both. These drugs can be uterotonic, increasing the tone in order to start the contractions and also to help decrease bleeding after the uterus is emptied. Devices such as laminaria are used, and feticidal agents, such as Digoxin, can cause the death of the fetus and cause the uterus to begin labor. In a "surgical abortion," instruments, or hands or both, are utilized to accomplish the delivery of the fetus, placenta and other products of conception. Various vacuum, scraping and extracting devices may be used for this purpose.

Addressing New Jersey's regulation on "termination of a pregnancy," N.J.A.C. 13:35-4.2, Dr. Lichtenberg first noted that "gestational age" in medicine is a means of dating the pregnancy. It can be dated from the last menstrual period (LMP). Some laws refer to fetal age, which refers to the moment of conception. This adds two weeks to the timing as measured by "gestational age." Dr. Brigham's records show that he used gestational age as the measure for dating the pregnancies of his patients. The period of pregnancy is divided into twelve and fourteen weeks LMP. Thus the second trimester ends at twenty-eight weeks, but there is some variation from locale to locale. Cases referred to as "later cases" generally refer to cases after twenty weeks LMP.

Dr. Lichtenberg described in detail the steps involved in a surgical "D&E" abortion, performed beyond the first trimester. These steps include counseling of the patient, as to possible choices (abortion, carry to full term, adoption) and the process and risks of the procedure, obtaining consent, cervical preparation, and extraction of the products of conception. The doctor noted that some elements of cervical preparation are generally reversible; others are not. Essentially, the application of Digoxin, which causes feticide, "will cause a process that will irreversibly result in labor and delivery over time if it isn't facilitated by a medical practitioner." And, if the woman were to change her mind about the abortion after the irreversible step has been taken, "[s]he won't be able to have a live birth" and "[i]n all, but the exceptional case, she would probably go into labor and deliver within a day or several days." According to Lichtenberg, and central to his thesis, all of these steps are part of the termination of pregnancy "process." Indeed, he emphasized that it is a "process," and at one point, I asked him if, under his "process" definition, it was also true that the woman's initial contemplation and decision-making about even seeking an abortion was not part of the

process he defined. He agreed that it was. Yet, Lichtenberg acknowledged that in the regulation, the term used to describe the termination of a pregnancy was "procedure." He, and other expert witnesses in the case, acknowledged that this term is generally understood in the medical community to refer to surgery, to a surgical procedure, as indeed a D&E is. However, Dr. Lichtenberg added that the term could also apply to such matters as the insertion of laminaria or of an IUD. "[T]he meaning of the word 'procedure' does depend heavily on context."

> The Court: Now, when we've been talking about the question of where the procedure was going to take place, what did you mean by the "procedure" in that context?
>
> A. That is the surgical removal of the pregnancy.
>
> The Court: That's the D&E; is that right?
>
> A. That's the portion of the D&E in which the pregnancy is removed.. . .
>
> Q. By that you mean the evacuation of the fetus, correct?
>
> A. The fetus, the placenta, the decidua, the blood.

Lichtenberg agreed that the regulation does not contain any definition of "termination of pregnancy."

> There is no distinction in this regulation that lets us know whether termination refers to the actual final end-stage evacuation of the uterus or more broadly to the entire process that leads to and includes it. I would - - as a physician, I would assume that it refers to the entire process if, in fact, that was a consideration at all. And frankly, I'm not sure whether the person who drafted this actually thought about the question that is being raised here. . . . But this regulation clearly does not specifically deal with the question of when an abortion begins.

Lichtenberg noted that when the Board was examining Brigham's practices in Brigham, I, involving the insertion of laminaria, it was looking at a regulation that did not "specifically address this question" of when an abortion began.

> So what the board was confronted with doing was interpolating and trying to understand the regulation, which didn't specifically address this question, and trying to use its best medical or legal judgment as a board on which there may not have been an obstetrician/gynecologist, but even if there had been someone involved in OB/GYN, that person . . . may have had little or no familiarity with abortion procedures, much less D&E procedures. . .They did not appreciate the fact . . . that the procedure actually begins with counseling, consents and cervical preparation.

Given what he thought might have been the Board's lack of specific knowledge "about this area of medicine," Lichtenberg "understood . . . why in 1995 . . . they might have made that mistake."

> I would simply say . . . that medicine has got more sophisticated since 1995, and this specific area of D&E abortion and cervical preparation has gotten more sophisticated, and I would imagine that the Board . . . could well come to a different conclusion in light of what we've learned and in light of the composition of the board.

Counsel asked the doctor

> Q. Would you agree that reasonable physicians could disagree reasonably concerning when an abortion begins - - termination of pregnancy begins?
>
> A. If they're thinking about the process, then they would not disagree with each other. It depends on whether their focus - - whether you or anyone else directs their focus to the actual moment of evacuation of the uterus or not. And the reason I make this point is because doctors can be very literal, as can we all. We are talking in conference about medical complications, for example. And we've gotten to the point where we're talking about serious complications that can occur from a D&E, like in the case of "D.B." Evidence focus will be on the actual operation itself. So if you were to intrude on that conversation, you will find the doctors talking about actuality of the surgery, what happened, what could have been done, how it could have been diagnosed and treated. But if on the other hand, the discussion that you came upon in mid-discussion was a discussion of consent and what should go into a consent form, then the scope of the discussion would include the consideration of abortion as a process, which is all a matter of consent.

Dr. Lichtenberg agreed that in this context, he used the word "operation" as synonymous with "procedure." The word "process" is not included in the regulation.

Additionally, Dr. Lichtenberg was questioned about practices in his own Chicago facility where non-physicians insert laminaria and provide ultrasounds for patients who are having their pregnancies terminated. He was unaware of New Jersey's regulations about who could insert laminaria or perform ultrasounds. He understood that Brigham actually inserted laminaria, but he recognized that it was the case in most states that ultrasounds are not performed by physicians. If it were the case that New Jersey permitted ultrasounds for these patients to be performed by non-physicians, and as he considered that an ultrasound was "part of the process of termination of pregnancy, as you understand it," then, again, he would

> "believe that the drafters of this language were not aware of the distinction between actual final evacuation of the uterus and the process leading up to it. . . Clearly, it is a process because the consent forms reflect that it's a process. The only way to interpret that and this sentence, "The termination of a pregnancy at any stage of gestation is a procedure which may be performed only by a physician licensed," is that termination of pregnancy in this context means the actual act of evacuating the uterus."

Testifying on Dr. Brigham's behalf, Dr. Mucciolo rejected any idea that the insertion of laminaria, use of Misoprostol and induction of fetal demise "constitutes a performance of the termination of pregnancy."

> I think that is completely incorrect. I think the definition of an abortion is the evacuation, the emptying of the uterus of pregnancy contents.

As for the fact of fetal demise, he explained

> Once again, whether the fetus is alive or not, if it is in the uterus an abortion has not been completed; you have to remove the pregnancy and all of its contents, placenta, amniotic sac, everything, to constitute an abortion.

N.J.A.C. 13:35-4.2 is located in the Administrative Code in Subchapter 4 of Title 13, Chapter 35. That Subchapter is entitled "Surgery." It contains two subparts; 4.1 deals with "Major surgery"; 4.2 deals with "Termination of pregnancy."

During the hearing, reference was made to medical expert opinion offered in testimony during Brigham I, by Nicholas Kotopoulos, M.D., which was admitted in evidence in the current proceeding. Dr. Kotopoulos was asked whether there were any differences in the technique used to perform a second trimester procedure if the fetus was demised or if it was not. He said the procedure was similar. The removal of a demised fetus was an abortion. The basis of this opinion was that the "medical definition" of

> pregnancy is. . . 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.

Dr. Kotopoulos was also asked to define "abortion."

> Abortion is a termination of a pregnancy before the fetus reaches viability or 24 weeks for the State of New Jersey.

The doctor was then asked about the equipment and procedure utilized "to perform an abortion in the first trimester."

> Termination of pregnancy for the first trimester includes first the dilation of the cervix. After the proper preparation of the patient and the proper anesthetizing agent is given . . . then the surgeon proceeds, with, as I said, the dilation of the cervix and the evacuation of the uterine content. During this procedure, many inflexible instruments are used.

Dr. Lichtenberg was shown a document entitled "Clinical Guidelines, Induction of fetal demise before abortion," published by the Society of Family Planning (SFP), released in January 2010[v] (R-22). He acknowledged that this group is one of the organizations that establishes commonly accepted medical standards. He was asked whether he agreed with the following quotes from that publication

[v] A determination as to the admissibility of this document in evidence was withheld at hearing pending further review. It is now admitted as Exhibit, R-22 in evidence. The document advises that "This guideline has been developed under the auspices of the Society of Family Planning for its fellows and for any physicians and other clinicians who perform surgical abortions 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 is to review the medical literature evaluating common means and goals of inducing fetal demise before pregnancy termination. This evidence-based review should guide clinicians, although it is not intended to dictate clinical care."

> "for decades, the induction of fetal demise has been used before both surgical and medical second trimester abortion."
>
> "providers have begun to induce and document fetal demise before an abortion begins, to avoid any potential accusations of intending to violate the law."
>
> "By ensuring demise before the termination has begun, live birth cannot occur, thus avoiding entirely the problem that faces the provider, the team of caregivers, and the patient undergoing induction of D & E if the patient were to expel the fetus with signs of life."
>
> "Some patients may prefer to have fetal demise induced before the abortion procedure begins."

Dr. Lichtenberg agreed with each of these statements. The emphasis in each quote is not in the original document, but added here to emphasize the consistent reference to fetal demise as an event that occurs before the "abortion", before the "termination of pregnancy."

In Requests for Admissions, the complainant referred to testimony that Dr. Brigham gave during the proceedings that led to Brigham I. Dr. Brigham was being questioned by the deputy attorney general who prosecuted that case, and she asked him,

> Q. The termination of pregnancy results from what?
>
> A. The death of the fetus.

In his testimony in the current hearing, Dr. Brigham explained that he

> "wouldn't testify in this way now. . . I think that I would actually be more aligned to testify in concordance with what Dr. Kotopoulos said. I think that there is a - - there are elements of truth to both testimonies. I think that what this really gets down to is what is a pregnancy, and I think what's - - the question of if the fetus dies has the pregnancy terminated, this is a difference of opinion between Dr. Kotopoulos and I [sic] in that in the 90's . . . when I made this testimony, this was my first case of fetal demise. You

> have to remember I'm not an OB/GYN. So I hadn't thought this through all that carefully, but I think you can look at pregnancy from two perspectives. There is the perspective of the fetus and the perspective of the woman. So if you look at - in fact, that clash of views is what underlies the culture war that surrounds abortion. There are people who are pro-life, who are anti-choice, who argue that the pregnancy is the fertilized egg, is the embryo, it's growth of the fetus, and the purpose of the pregnancy is to give rise to a baby, and that is also, I would say, almost a common way of viewing it. And then the other view is that the pregnancy - - you can look at it from the perspective of the woman, and the pregnancy is a condition of the woman. So I would agree with Dr. Kotopoulos at this point . . . I would say that the pregnancy is a condition of the woman . . . the woman is pregnant . . . in the normal process of pregnancy the fetus grows and continues to grow and develop . . . when the fetus dies, that process is terminated . . . but the question is the woman still pregnant . . . is the woman pregnant if you have a demised fetus, and this is where Dr. Kotopoulos, I think he states it very clearly, because the uterus is impregnated by a fetus, that woman's uterus is impregnated.

Dr. Brigham observed that the termination of pregnancy regulation was designed to protect the patients and the public. If the intention was to protect the fetus, which of course in the case of an abortion will not survive an induced termination of pregnancy, then abortion must be outlawed. If the regulation is meant to protect the woman from medical harm, then the harm is most likely to arise to the woman in the evacuation procedure.

In the course of this hearing, I noted that the case involved medical and legal definitions of a topic that is of sometimes intense interest and concern, not only to practitioners, patients and regulators, but, as is of course quite obvious, to many in the general public, and political and legal spheres. "Abortion" is the subject of much, often passionate, indeed, as this record notes, sometimes even violent, discourse and action. In discussing the terminology that doctors utilize, and in regard to the regulation at hand, it may be wise to note that the common interest and concern of most of this public interest, debate, and legal and political controversy, is clearly in respect to the moral, legal, social, religious, womens' rights, and even criminal aspects of the purposeful causation of the demise of a fetus. While the record contains no evidence on this point, it seems apparent that the focus of so very much of all this is on whether or not such intentional feticide should be permitted, or be banned, or how the ability to cause fetal

demise should be regulated. The whole, or at least nearly all, of the concentration, outside of the medical and medical regulatory community, is not on the subsequent need of women, whether their fetus is dead through legal or illegal means, much less through purely spontaneous demise, to have the contents of the uterus evacuated. As this record explains, that part of the process involves medical issues that may endanger women and that must be properly be regulated by the medical and legal communities. But as a general matter, people who speak about "abortion" are not generally focusing on this aspect at all. Few discuss the issues in terms of "termination of a pregnancy." "Abortion" is the word that is thrown about. Yet, the evidence here demonstrates that in this milieu, "termination of a pregnancy" is used in regulation and its proper meaning, or perhaps what meaning it was meant to have, is subject to some debate as to the extent of activity the term properly covers.

The evidence is that induced fetal demise is not necessarily immediately followed by evacuation of the uterus. Dr. Brigham's process involved demise being induced on one day, and the D&E taking place thereafter, generally the next day. If the Attorney General's position is accepted, it would appear that the very same restrictions on the location of second trimester D&E's would apply to the inducement of fetal demise.

In the end, the understanding of the meaning of the regulation's language must first be obtained from the very words of the regulation itself. The common understanding of the words of a regulation affecting medical practice must be understood given the common understanding of the persons subject to the regulation. On its face, the regulation refers to the termination of pregnancy as a "procedure." Even Dr. Lichtenberg agreed that in medical terminology, this refers to a surgery. D&E is a surgical event, the placement of laminaria and the inducement of fetal demise are not. Thus, the very reference to the "termination of a pregnancy" as a "procedure" would appear to limit the action covered by the term. Further, given that pregnancy clearly does not end with fetal demise, but only when the fetus and products of conception are removed from the uterus made pregnant by its very impregnation by the fetus, the pregnancy cannot be deemed terminated until the D&E occurs. The "procedure" that "terminates" the "pregnancy" is the D&E. It is not the placement of laminaria; it is not the inducement of or the fact of fetal demise. Any other reading, one

that accords with Dr. Lichtenberg's by no means inappropriate theory of the "process" of termination, expands the usual meaning of the terms to encompass matters that are not medically understood as falling within the terms used in the regulation. Thus, the regulation, as currently written, only refers to the D&E.[vi] Rewritten, it could encompass more, but not as it presently reads.

Even Dr. Lichtenberg acknowledged that the Society of Family Planning, in the article concerning clinical guidelines published in 2010, conceived of the institution of fetal demise as occurring "before" abortion, even "second-trimester abortion."

> During the past three decades, many modalities for causing fetal demise (often described as "feticide" in the medical literature) have been used. In the last several years, induction of fetal demise has been more common before second-trimester abortion, as well as for selective fetal reduction. . . . In addition, since the Supreme Court of the United States upheld the case of Gonzalez v. Carhart—affirming the constitutionality of the Partial-Birth Abortion Ban Act of 2003 (the Act)—many abortion providers have begun to induce and document fetal demise before an abortion begins, to avoid any potential accusations of intending to violate the law.

Here again, a respected professional organization, in its clinical guidelines, distinguishes between that which occurs "before" the abortion and the abortion itself. Fetal demise occurs before the abortion. While, as noted, it is common to consider that the action causing the death of the fetus is the abortion, this clinical guideline makes the case that from the purely medical viewpoint, that is not so. And as the regulation does not even use the word "abortion," but instead speaks of a "procedure" termed "termination of a pregnancy," which term connotes both a surgical act and an act that

[vi] The complainant's contention that Dr. Brigham admitted, through the Phillips' letter, that, as opposed to the placement of laminaria, fetal demise was included within the regulated activity, is without merit. First, the words of the regulation control, not what Brigham may have thought, and those words, without the benefit of further definition in the regulations themselves, do not bear the meaning that the complainant seeks. Further, as Brigham testified, his understanding now is different than when he testified in Brigham I, and is in line with Dr. Kotopoulos' position. Finally, the whole context of the Phillips' letter was geared to the subject of the insertion of laminaria, and the reply from Gleason as well, and it would not be appropriate in that context to read the letter as admitting anything about a legally significant distinction between the insertion of laminaria and the initiation of fetal demise. as opposed to evacuation, which as explained, is, as opposed to the insertion of laminaria and the provision of a feticide, clearly a surgical "procedure" that eliminates that which caused the woman to be in, and to remain even after insertion of laminaria and demise of the fetus, in a pregnant state.

removes that which makes and, so long as it remains, maintains a woman in a pregnant state, any inclusion of the induction of fetal demise within the regulated activity denominated as "termination of a pregnancy" cannot stand, at the very least, in the absence of language within the regulation itself that clearly defines the activity intended to be regulated as including as within its reach this, and perhaps other elements, such as the insertion of laminaria. In fact, in its closing statement, the clinical guideline itself refers to its purpose as, ‘‘to review the medical literature evaluating common means and goals of inducing fetal demise before pregnancy termination," thus utilizing the very "termination" language found in N.J.A.C. 13:35-4.2.

It would be foolish to ignore the fact that in its Order Imposing Temporary Suspension of License, the Board commented upon Dr. Brigham's argument that all of the treatment he provided in New Jersey was prefatory to "an abortion." While the Board there, after a hearing conducted in a rapidly scheduled preliminary proceeding prior to the full discovery permitted under the Administrative Procedure Act in a serious matter such as this case, described Dr. Brigham's position as "patently specious," it offered little in the way of analysis of the legal issues involved. Instead, it noted that the injection of Digoxin to cause intra-uterine fetal demise "placed each patient at a point where they had no viable option other than to have an abortion procedure completed, and thereby committed those patients to abortions which he could not legally perform in New Jersey." This comment is itself interesting, although given the evidence and analysis presented here, I must humbly conclude that from a legal standpoint in respect to the regulation as currently worded the position is not specious at all. Indeed, given the evidence, it appears that it is not specious even from a medical standpoint. What is interesting is that it may well be that the "inevitability" element that the Board zeroed in on and the Attorney General advocates here, would reasonably support a regulation that, for regulatory, policy-oriented reasons that may exist even separate from the strictly medical reasons, expressly defines the "termination of a pregnancy" "procedure" as including the induction of fetal demise, or even perhaps the insertion of laminaria and the administration of Misoprostol. If the Board believes that it can, in light of the medical facts and concerns and appropriate policy considerations, reasonably and fairly include these elements within its regulation controlling where and by whom the "termination of a

pregnancy" "procedure" can be performed, then, as Judge Fidler said eighteen years ago, it can amend the regulation, with adequate notice to those who are regulated.[vii]

Counsel for the respondent contends that if the Board were in this case to hold Dr. Brigham in violation of the existing regulation for his actions involving laminaria and/or fetal demise, its action would involve a violation of the Metromedia standards. Metromedia, Inc. v. Director, 97 N.J. 313 (1984). It is of course premature to assume that the Board will do so in this case. But given the language as it currently exists, the past acknowledgement of the existence of acts "prefatory" to the "termination of pregnancy procedure," including the insertion of laminaria, and the evidence that reasonable practitioners and reasonably authoritative groups in the field understand that the "termination of a pregnancy," indeed, the "abortion," occurs after fetal demise, much care must be exercised before prematurely imposing this view prior to fair notice and adoption proceedings.

I **CONCLUDE** that N.J.A.C. 13:35-4.2 regulates the D&E "procedure" and does not regulate the entire "process" that starts at the very least with consultation and counseling and proceeds through steps that are "prefatory" to the surgical procedure, including the initiation of fetal demise. Thus, in the cases at issue in this matter, Dr. Brigham did not perform any "terminations of a pregnancy" "procedure" in New Jersey.

[vii] Perhaps the word "procedure" might be removed, and a more expansive word or phrase substituted to avoid the limitation that the term "procedure" appears to have within the medical community.

The Maryland Practice Exception

At the time of the incidents that are under review in this matter, the Maryland statute regarding the practice of medicine included a provision that allowed for the possibility of practice within Maryland by a physician who does not hold a Maryland medical license. Md. Code, Health Occupations, §14-320, provided that "subject to the rules, regulations, and orders of the Board, the following individuals may practice medicine without a license: . . . (2) a physician licensed by and residing in another jurisdiction, while engaging in consultation with a physician licensed in this State." Expert witnesses, legal and medical, testified as to the meaning of "consultation," a term that, at least in the context of this regulation, has apparently not been the subject of any formal definition by either the Maryland Board of Physicians or the Maryland courts. Dr. Brigham asserts that his involvement with Dr. Shepard was entirely appropriate, and legitimately within the meaning of "consultation," and therefore his practice in Maryland was legal. As will be detailed, Dr. Mucciolo, an expert witness for Dr. Brigham, testified that any discussion about a patient's case between doctors could be a consultation. However, Dr. Lichtenberg, the complainant's expert witness, contended that the term had a much more focused meaning than the mere discussion of cases between doctors and that there was no legitimate "consultation" between Drs. Brigham and Shepard, at least as far as is contemplated by the regulation in light of the understandings as what medical "consultation" is.

Undisputed evidence establishes that at the time when Dr. Brigham was performing D&E procedures at the Elkton facility, Dr. Shepard was in his mid-eighties and had previously suffered a stroke which limited his ability to use his dominant side. He could not have reasonably been expected to, and quite possibly could not have, physically performed the surgical procedures that he was present at. Dr. Shepard lived in Seaford, Delaware, located nearly two hours from Elkton, and he either drove, or in some instances was driven, from his home to Elkton on days when procedures were scheduled to be performed. Despite his age, Dr. Shepard had young children, and testimony of staff at the Elkton facility indicated that Shepard would leave that facility to attend to his children when they got out of school. On some occasions, the number of which was not established, Shepard's participation in the activity occurring at Elkton

was limited to telephone contact on a speaker phone, as he was not present at the facility even though procedures were occurring at that time. Shepard did not himself perform any D&E's, nor did he assist in the actual performance, although testimony from staff, Dr. Brigham, and patients indicates that at times he monitored blood pressure and/or pulse/oxygen saturation and observed the activities, while attempting to make the patients as comfortable as possible. Shepard never met with patients at Voorhees and only met patients at Elkton at the time for their D&E's.

Subsequent to D.B'.s treatment and the involvement of the Elkton Police Department in the initial investigation of the activities at the Elkton facility, the Maryland Board of Physicians became involved in considering the activities of Drs. Brigham and Shepard. On August 25, 2010, the Board issued a Cease and Desist Order to Dr. Brigham. It noted that this unlicensed [in Maryland] individual had performed surgical procedures in Elkton "on a regular basis;" two or three procedures on each visit approximately twice a week "for at least several months prior to the date of this Order." It noted the August 13, 2010, procedure that required "urgent" completion. It offered that "the health of Maryland patients is being endangered." In its Conclusions of Law, the Board stated that the practice of surgery, the assisting or directing of the practice of surgery by another, and the initiation of a procedure which required completion on an "urgent basis," constituted 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 . . . ." As such, the Board ordered that Brigham cease and desist from the practice of medicine in Maryland upon the issuance of the Order, which was subject to challenge if Brigham chose to do so.

On November 18, 2010, Dr. Shepard entered into a Consent Order that he had "is guilty of: unprofessional conduct in the practice of medicine, in violation of [Health Occupations] § 14-404(a)(3)(ii); and, practices medicine with an unauthorized person or aids an unauthorized person in the practice of medicine, in violation of H.O. § 14-404(a)(18)."

Dr. Lichtenberg testified that the only reason that Dr. Brigham involved Dr. Shepard in the Elkton activities was that Brigham needed Shepard "for legal reasons." As Shepard was not capable of performing the procedures due to his affliction, had no recent experience performing second trimester abortions, was not able to lend any substantial assistance to Brigham as Brigham had substantial experience in the field and was not learning substantive new information from Shepard, the two were not capable of filling the roles of persons who were in actual "consultation," as that term is properly understood in the medical context.[viii] Consults are indeed performed, frequently occurring in an institutional setting, such as in medical schools. As such, doctors instinctively understand what a "consultation" is. It is a "deeply embedded concept." More precisely, Lichtenberg defined "consultation" as having two "common" meanings,

> The first is in-house consultation when one clinician consults another clinician for confirmation of expert opinion or diagnosis or advice for treatment. And consultation is done with the understanding that the physician who is being consulted is expert and practices in the area in which they're being consulted, and therefore can lend perspective and further detail to the diagnosis and treatment of a given patient.
>
> The second is an example in which an institution invites an expert from outside the institution to come to the institution to impart wisdom . . . by lectures or conferences; sometimes by practicum, that is demonstration of a technique, or even on occasion in collaboration in performing a technique or a surgery. . . the assumption is that the person who is coming from the outside is a renowned expert . . . .

Brigham's action in misrepresenting that Shepard was engaged in a legitimate "consultative" role amounted to a gross violation of standards.

Commenting further on why he believed that the interaction reported by Brigham and staff members present at the D&E's was not truly "consultation," Lichtenberg characterized the reported dialogue between the two as "fairly general, not too substantive and not very useful, as I view it as an expert." This opinion was based in part on his acceptance of Brigham's representation that he had performed over 40,000

[viii] Dr. Lichtenberg had no information as to Dr. Shepard's mental acuity.

abortions, 90 percent of which were first trimester, and between 1,000 and 1,500 second trimester D&E's.

> Given that experience on his part and given that I was able to deduce from the characterizations in all three of those testimonies, the testimony by Dr. Brigham, by Dr. Shepard, and by employee "K.G.," not much in the way of substantive medical information was passing from Dr. Shepard to Dr. Brigham. . . . Probably of a very minor and transitory sort . . . I think the patient might need a little more medication, Doctor, or yeah, you know, I once had a case like this a long time ago.

Dr. Lichtenberg characterized Dr. Brigham as having committed a gross deviation from the standard of care in regard to his representations that Shepard was "capable of acting as a consultant. Dr. Shepard was not able to impart any new substantive information to Dr. Brigham, and that misrepresentation constitutes a gross violation."

On cross-examination, Dr. Lichtenberg was asked if he could accept the definition of a consultation that had been included in the expert report of M. Natalie McSherry, Esq., a Maryland attorney practicing in the health care field.

> Q. Doctor, would you accept the definition of a consultation as one physician providing an opinion or assistance to another physician?
>
> A. Yes.

K.G., an employee of Dr. Brigham and a graduate of Ultrasound Diagnostic School, started work at American Women's Services in King of Prussia, Pennsylvania, and then transferred to the Voorhees Township office in 2001. She served as an ultrasound technician and then as assistant manager of the Voorhees office. In about 2006, she became the office manager of that facility. Part of her responsibilities involved assuring that the Elkton office was staffed and supplied with proper inventory. In this regard, she testified that Dr. Shepard would advise her if that office was low on any items needed. He would walk around the Elkton facility to see if anything was needed. K.G. made between fifteen and eighteen trips to Elkton when patients were to be treated there.

Commenting upon Dr. Shepard, K.G. identified him as the medical director of the Elkton facility, and indeed when he greeted patients who had arrived in Elkton, he would identify himself as such. He was at Elkton on all but one occasion when she was there. "He took charge," visited with each patient in their particular cubicle, checked to see if they were in too much pain. He would decide which patient "he wanted to see first." He would check the patient physically and "give me an order of which to set up first." Shepard and Brigham would sit at a desk and go through paperwork. Brigham would tell Shepard how many laminaria had been inserted, how much medication the patient had received. In the procedure room, Shepard would again identify himself to the patient as the medical director, ask how the patient felt and about their pain. He would "instruct Brigham that he could begin the procedure," he could give pain medication." During the procedure, Shepard would

> adjust the patient, the pillow, the head, to make sure they were comfortable. He would check the pulse-ox, he would check to see what their pain medication level was, if they were in a lot of pain he would call, Steve, stop, I think you need to give the patient more pain medication. . . . He did blood pressures a couple of times that I saw . . . I heard him talking about if complications would arise that he . . . that Doctor Shepard would instruct Dr. Brigham what to do in case of an emergency. . . . he would show him maneuvers . . . he showed him how to do a uterine massage, he showed him how to maneuver a fetus, if necessary. I saw him show how you insert the Misoprostol rectally.

After the procedure was completed, Shepard would assist the patient in getting off of the table and into a wheelchair. Brigham and Shepard would then go to a table and fill out paperwork. Later, he would check on the patient in the recovery room.

K.G. reported that the two physicians' conversation during procedures involved a lot of medical terminology she did not understand.

Dr. Mucciolo defined "consultation " in a "medical sense," as

> I think there are several things you can do when you use that word medically. If I need an opinion or help I can call up a consult over the phone . . . If I have somebody in the hospital I may want

> somebody there in person and it's a face-to-face consult, if I'm in the operating room you need help or you need somebody to do something outside of your field of OB/GYN, I will call somebody into the operating room. I think that there are varying levels of consultation, and probably the last one is sending a patient to see somebody else who will send you a written report, and I think it is any of those things.

Given a hypothetical where Brigham performed the termination procedure and another doctor was present with whom Brigham discussed in advance whether to accept the case and who reviewed the patient's records, then monitored the patient's blood pressure, oxygen saturation and pulse, discussed the progress of the case with Brigham as the termination was proceeding, discussed potential complications and possible need to increase medication to deal with pain levels, and sometimes "instructed" Brigham in obstetrical maneuvers and uterine massage, Dr. Mucciolo opined that such "was pretty extensive in terms of what you would expect from a consult" and "that together in the operating room, it's advice given with the patient as you are treating her, the doctor essentially becomes a consult and a treating physician."

M. Natalie McSherry, Esq., testified that she is familiar with the exceptions to the requirement for licensure of doctors who practice in Maryland, although she acknowledged that she is even more aware of them as a result of this case. Typically, there is little legislative history in regard to Maryland legislation and there are no reported cases by the Board or the courts, or any regulations regarding this "consultation" exception. Given this, the ordinary meaning would be examined to determine the meaning. In her experience, in medical circles, as health care providers use it, it involves a process in which one health care provider speaks with and obtains information from another health care provider. Interaction between physicians in this manner is within the meaning of the term.

Ms. McSherry was provided with a copy of a form that was included on the website of the Board of Physicians, under the "forms" label. It is entitled "Application For Exceptions From Licensing." She was unaware of the form until Dr. Brigham's attorney pointed it out to her, and in fact, at least at the time of the events in question, and despite evidence from the Board's Executive Director that the Board did actually

receive these forms, nevertheless, there was no rule of the Board of Physicians or any statute of the State of Maryland that referred to the form or that mandated that this form be filed by any practitioner. Its existence did not change McSherry's opinion. Her conversations with three colleagues, each at least as experienced in the field as she, revealed that they did not know of the form, which they dubbed the "secret form." To the extent that it was known to exist, she believed that the several large teaching hospitals in Maryland might be the source of such applications that were filed.

During its 2013 session, the Maryland General Assembly amended the Maryland Health Occupations statute, in an emergency measure, pursuant to House Bill 1313, which became 2013 Maryland Laws Ch. 583. The amended statute, Md. Health Occup § 14-302, provides

> Subject to the rules, regulations, and orders of the Board, the following individuals may practice medicine without a license: . . .
>
> (2) A physician licensed by and residing in another jurisdiction, if the physician;
>
> > (i) Is engaged in consultation with a physician licensed in the State about a particular patient and does not direct patient care; . . . . .

Ms. McSherry was aware that the Maryland Board of Physicians issued a Cease and Desist Order to Dr. Brigham, in which it referred to his "apparent practicing . . . without a license." She noted that while Brigham did not challenge that order, no charge of practicing medicine without a license was ever filed against Brigham, and there was never any actual adjudication that he had violated the Maryland statute as it existed at the time of the events under inquiry.

Ms. McSherry offered her opinion that if Dr. Brigham, in the course of his activity in Maryland, was providing advice and engaging in professional discussions and training activities with Maryland physicians, as described in letter from Dr. Brigham's Maryland attorney, Marc Cohen, then he was engaging in "consultation" within the meaning of the then existing Maryland statute. She viewed consultation as a "two-way street," and not so narrowly as to mean both that Brigham brought his expertise to

Maryland and that he received "consultation," that is, he received expert advice and information as well from a licensed Maryland physician. It sounded to her that Dr. Shepard was providing not only obstetrical expertise but also "input on the conscious sedation levels and that sort of thing . . . so you have two physicians with slightly different areas of expertise coming together to render care for one patient."

Dr. Brigham described how it was that he first came to perform procedures in Maryland. At first he had only instructed doctors in Maryland and did not touch the patients. Thereafter, after some issues arose, he consulted with Marc Cohen, a Maryland attorney, as to what he could do in Maryland as a physician without a Maryland license. He understood that as long as he was in consultation with a Maryland doctor, he could perform the procedures himself. Dr. Brigham knew Dr. Shepard as a physician who had previously worked with AWS in its Baltimore office. Shepard had performed termination of pregnancy procedures in Baltimore and had been the medical director in State College, Pennsylvania. He told Shepard of his thoughts of opening a facility in Elkton and asked Shepard if he would be the medical director of that facility. Shepard said, "Sure." The original plan was not for Brigham to be the physician in Elkton for any length of time; he would merely start the facility and bring in a Maryland doctor, with Shepard supervising and Brigham "bowing out." During this "start-up" period, Brigham wanted Shepard to be at Elkton when he saw patients, as it was good to have a doctor with "excellent skills" that complimented his own. He wanted there to be no question that he was in consult with a Maryland physician. This plan was discussed with Mr. Cohen, and Brigham understood that it was "perfectly lawful." A signed "Consultation Engagement Agreement," dated September 8, 2009, with signatures of Brigham, and he testified, of Shepard, provided that, for the term of two years, "Dr. Brigham shall at all times remain engaged in consultation with Dr. Shepard." Brigham agreed that "he shall be engaged in consultation with Dr. Shepard regarding the care and treatment of patients." Another document, entitled "Medical Director Engagement Agreement" signed by Brigham and purportedly by Shepard, and bearing the typed month and year, "September 2009," but no specific date, provided that for a term of two years, Shepard would serve as Medical Director of AWS and Grace "in an administrative capacity." Brigham described Shepard's role in New Jersey

under this, as a "much smaller role," as Shepard's New Jersey license was inactive and he would not be responsible for patient care.

Dr. Brigham testified that he opened the Elkton office in September 2009, and found a physician, Dr. Walker, who had done an Ob/GYN residency and was nearly eligible for Board certification. She observed and he transmitted his knowledge. She received her license, but not before the D.B. case. For some reason, she always represented that she was two to three weeks away from licensure, but it seemed that this event kept getting postponed. He then found Dr. Riley and started to train her.

Dr. Brigham required that potential patients provide certain information before he would accept them as patients for a termination of pregnancy. They would fill out an application form and they had to present documentation from family and/or genetic counselors. in addition, Brigham wanted medical records, including an ultrasound. Dr. Shepard had to accept each patient, so that the decision to take on a patient had to be a joint one. As Grace patients, that meaning for the most part those beyond twenty-four weeks LMP, sometimes came from far away, Brigham would present the case to Shepard before agreeing to take on the patient. The process changed over the eleven months that the Elkton office operated. Initially Brigham would call Shepard. They had a set of rules and as such, he had a generally good idea of who they would accept. Some were easy decisions, as, for instance, an anencephalic fetus, that is, one with no brain. Others were not so easy, such as cases involving depression, or suicidal persons. Cases such as one with a thirty-five week pregnant woman who broke up with a boyfriend and wanted an abortion, they would not accept. Shepard would tell him if he wanted to turn down a case. Brigham was more accepting of cases involving mental health issues with a normal fetus; Shepard was not so accepting to these. Shepard was more accepting of cases with fetal issues than Brigham was.

Brigham explained that when he, staff and patients would arrive at Elkton, Shepard was sometimes there before they arrived; sometimes he arrived after they did. Shepard greeted each patient in her private waiting bay, "eyeballed" them, and decided which patient to take first. He and Brigham generally agreed on the order. Then he and Shepard went to a storage area where they would put the chart on an exam table that

was in that room. They would review the chart and later, after the procedure, they would do the same. Brigham would fill Shepard in on the number of laminaria used and the amount of Mesoprostol utilized. Shepard would introduce himself to the patients and have "his own little talk" with them, referring to himself as the medical director. He had a very calming effect, very gentle and reassuring. Shepard would monitor how the patients were doing during the surgery, as they were sedated but were not asleep, although sometimes the patient would fall asleep and Shepard would shake them and tell them to "breathe."

Dr. Brigham identified three levels of interaction that he had with Dr. Shepard. First, they both participated in each case. Shepard played the same role as an anesthetist would: how much medicine to give, as part of the team effort. Secondly, Brigham would try to learn things from Shepard, as Shepard was an OB/GYN and in regard to the particular patient under care. Third, he would teach things to Shepard, what and why he did things, as they had very different skill sets. Shepard was a Board Certified OB/GYN and had been the Chair of Obstetrics and Gynecology at a major teaching hospital. Brigham, on the other hand, was a "super specialist," that is, he could do one thing. In the case of the Grace patients, Brigham was "very concerned," as, due to the age of the fetus, these could involve more obstetrical issues and he was not an OB/GYN. However, Shepard did not perform these late term cases. Brigham wanted Shepard to be aware of the procedures that he utilized for such time as other doctors performed procedures with Shepard present.

Dr. Shepard would discuss several serious complications that could arise, things that he had faced and that Brigham had never encountered, but dreaded the prospect of ever seeing. From lectures and reading, Brigham was aware of such matters as amniotic embolism, uteric inversion, placenta acreta, placenta increta. He knew his limitations and weaknesses and felt that having a former Chairperson of Obstetrics in the room for 98 percent of the procedures was "as good as it gets." Shepard told him about the administration of Misoprostol rectally, which Brigham had never done and understood to be a very good suggestion. He explained various obstetrical maneuvers and techniques for delivering the placenta, and also uterine massage, which he was able to view from an obstetrical perspective. Brigham learned from Shepard about

coughing being a first sign of amniotic fluid embolism, a condition the occurrence of which Brigham feared. Of course, on the occasions when Shepard was only present by speaker phone, his participation was more limited. He would still try to assess pain and medicine levels while on the phone, but could not assist with complications or hold the patient's hand. Even when Shepard was not physically present, there was always a trained medical professional present besides Brigham.

Dr. Brigham testified before the Board of Medical Examiners in October 2010, in the proceedings that resulted in the interim suspension of his license. While he "thought there was a lot of benefit to having him there," Brigham testified in this hearing in regard to his answer to that question posed to him in 2010, that "I would say that - - no. I mean, it wasn't necessary. I was capable of doing the procedure without him there." However, Brigham denied any truth to the idea that Shepard could not impart to him information that was new to Brigham, about techniques, preventing and treating complications, and about particular patients. It was an "absurd idea" that he could not learn from Shepard. As for Shepard's own medical condition, Brigham understood that he had a "slight weakness" in his right arm, and he might have been capable of performing simple procedures with a lot of support. There was no sign of any loss of dexterity. Shepard never said that he could not perform, he just did not, and Brigham cannot say if he could have.

Dr. Shepard did not testify in these proceedings. The record indicates that when Shepard was subpoenaed to appear at proceedings in Maryland regarding Dr. Nicola Riley, his counsel moved to quash the subpoena, arguing that an appearance risked a negative impact to Shepard's health. Administrative Law Judge William C. Herzing, sitting in the Maryland Office of Administrative Hearings, granted the motion to quash, noting in his Order, issued June 5, 2012, that Shepard had suffered a subdural hematoma in May 2011, necessitating a craniotomy, and suffered seizures as a result of the hematoma, resulting in "significant memory loss," an "inability to recall events in question," "advanced age," and "poor health." However, prior to this Dr. Shepard had executed a Certification dated October 25, 2010, and was also interviewed by police authorities. In the Certification, Shepard confirms his engagement as the medical director of AWS, his duties and responsibilities in that position, his understanding that

"Brigham was engaging in consultation with me or another Maryland licensed physician at all times while any care was being delivered at the Elkton office, as permitted under Maryland law."

Detective Holly Smith testified that after learning of Dr. Shepard's connection to the Elkton facility (his DEA license was on the wall and his name in logs), she interviewed him on August 19, 2010, at his home in Seaford, Delaware, a two-hour drive from Elkton. This was an unscheduled interview and she arrived at his house and knocked on the door. She was not in uniform, but was armed and Shepard could see her weapon. His wife answered the door and a teenage boy was present. Smith advised that she was conducting a criminal investigation regarding a possible murder. Shepard was told that he was not under arrest, free to leave and could tell Smith to leave. In fact, D.B., whose treatment was the source of the investigation, had said nothing about Shepard and Smith told him that he was not in trouble and did not Mirandize him. Shepard agreed to speak with her. He was cordial, appeared to be quite old, and his wife was "very protective" of him. He walked slowly and did not move very much. He did not appear to be very vigorous. His mental state and hearing appeared to be "okay." He sat slowly and his wife appeared to assist him in getting up and down.

Dr. Shepard told Detective Smith that he was employed by Brigham. He would go to the Elkton office twice a week. He knew that the patients originated out of the Voorhees Township, New Jersey office. He thought that their fetuses were dead by the time that the patients came to Elkton. He had not performed any abortions for years, and Brigham performed the D&E procedures at Elkton. The word "consulting" was not used by Shepard. Shepard then discussed his role at Elkton. At the beginning of the interview, Shepard was asked about his "responsibility when you go to Elkton." He explained

> My responsibility is just to make sure that the facility is clean, and they treat the patients well, and they pay attention to 'em, and they make sure that nobody leaves that says they're not feeling well or anything like - - everybody that leaves has to be well.

He denied that he had any hands-on role, as he did not touch the patients. He asked how they felt, assured them they would feel "much better" when they left. He did not assist Brigham or hand him anything during the procedures. He denied that he instructed any doctors.

> Q. No. So it's not like they hired you to help them to learn?
>
> A. No, no, they didn't hire me like that.
>
> Q. Okay. Would it shock you to find out that their medical records are showing you as the doctor who's doing the procedures?
>
> A. That would shock me as doing the procedures, but I think I saw some forms saying the procedure was done, and it was done as I feel, legally, anyhow - - . . . or that there were no complications or anything.
>
> . . .
>
> Q. I read only one document, and that's the patient's blood pressure, temperature, weight and whatnot, and are you taking any medications . . . what are you feeling at that point and that's all.

The doctor appeared to acknowledge that he was present during procedures, but said that he just sat there and did not see what Brigham was doing. He did note that Brigham would instruct Drs. Walker or Riley, showing them what he did and what to do or not to do, while Shepard was "just sitting there waiting, how long is this going to take."

Later in the interview, Detective Smith told Dr. Shepard that she believed Dr. Brigham was taking advantage of Shepard, that

> "they're using your name for a lot more than you even know," and that I would really hate to see bad things happen like what happened to that girl Friday [D.B.] have been blamed on you."

Dr. Shepard was also interviewed by telephone by Christine Farrelly. He explained that while he had the title of medical director at Elkton, he was "not actually a director, I can't hire or fire anybody. I can just tell them what I think - - you know, you're doing this right or you're not doing this right."

The Attorney General has charged that Dr. Brigham violated the law of the State of Maryland when he practiced medicine in that State without a license to practice issued by the Maryland Board of Physicians. If he did violate that law, then the complainant seeks sanctions for that misconduct from the Board that has licensed Dr. Bingham's practice. In regard to Dr. Brigham's contention that his practice in Maryland was lawful, as it came within an exception to the requirement for licensure, the Attorney General answers that the attempt to have it appear as if the doctor's practice came within that "consultation" exception involved an illegitimate scheme, a "sham" in which there was in fact no "consultation," as that word is used in the statute. Resolution of this issue involves a determination of what is or is not permitted by the law of a sister state. Whether the inquiry is to determine if a crime was committed, or a civil offense against the civil statutes and regulations of Maryland, the need is to understand what the statute means, or, since it has since been amended, what it meant at the time of the events in question.

The parties have presented clashing expert views on what "consultation" means, zeroing in on the medical communities understanding of that term. But the parties have agreed that the meaning of the term, as used in this statute, has not been the subject of any decision of the courts of Maryland nor of its Board of Physicians. Generally, it is proper for the courts of a state to determine the meaning of a sister state's law where that question is relevant to deciding legal issues before the forum state court. The Federal courts likewise do this where they must interpret the meaning of state law. The first inquiry is whether the highest court of the sister state has spoken on the issue at hand. If it has, then the forum court is bound to follow that court's decision. Gares v. Willingboro, 90 F.3d 720, 725 (3rd Cir. 1996). If the highest court has not addressed the issue, reference is made to the decisions of the sister state's intermediate appellate courts. If the forum court is not persuaded that the sister state's highest court would decide otherwise, the forum state court is bound by the intermediate court's ruling. Ibid. If the appellate courts have not addressed the issue, and it involves a statute or regulation that falls within an area of regulation, reference to the interpretations of the relevant sister state administrative agency with jurisdiction over the subject matter of the statute or regulation in question may be had, as appellate courts will give deference to the interpretations of agencies regarding the statutory and regulatory provisions that

they administer. Again, if the forum court is convinced that the sister state's highest court would decide the issue in a manner other than that determined by the sister state administrative agency, the forum court is not bound to follow that agency's understanding. Finally, if none of these authorities in the sister state have determined the question, the forum state court must then attempt to predict how the sister state's highest court would decide it. In doing so, the forum court will try to "predict how, in light of developing law both within and without the state to date," that highest court would decide the question. Fantis Foods, Inc. v. North River Ins.Co., 332 N.J. Super. 250, 260-61, certif. denied, 165 N.J. 677 (2000) (Kestin, J.A.D.). In this matter, it is necessary for the Board of Medical Examiners, as the administrative adjudicator in this case, and for this judge, sitting for the Board as the trial judge, to do as these cases provide in the case of the judiciary.

The first means of understanding the meaning of any provision of statute or regulation is the plain meaning of the words used by the enacting body. Scoville Serv. Inc. v. Comptroller, 269 Md. 390, 306 A.2d 534 (1973). If the reasonable meaning is ascertainable by that review, the inquiry is at an end. But if the word or words used are susceptible to more than one reasonable meaning, the inquiry must go further. In order to determine the intent of the Legislature, such methods of statutory construction as review of the Legislative history and consideration of the words in context of the remainder of the enactment, in pari materia, are means that may explain the meaning intended. "Statutes are to be construed reasonably with reference to the purpose sought to be accomplished and in accordance with declared legislative policy." Becker v. Crown Central Corp, 26 Md. App. 596, 608, 340 A.2d 324, 332 (Ct. Special App. 1975). And subsequent action by the enacting body to revise or amend the provision containing the word(s) in question may also serve to clarify the meaning that was intended by that body when it first enacted the provision. Singer and Singer, Statutes and Statutory Construction, § 22.31, 22.24 (7th ed. 2009); Connolley v. Collier, 39 Md. App. 421,385 A.2d. 826 (1978) (citing 2A, Sutherland, Statutes and Statutory Construction, § 49.11 (Sands ed 1973)), aff'd, 285 Md. 123, 400 A.2d 1107 (1979). In any instance, the goal is to understand the legislative intent.

Merriam-Webster defines "consultation" as "a meeting in which someone (such as a doctor or lawyer) talks to a person about a problem, question, etc." and as "a discussion about something that is being decided." However, it also offers a "medical dictionary" definition, "**:** a deliberation between physicians on a case or its treatment." This latter definition is, of course, of most importance in understanding what the term means as used by the Maryland Legislature. Dr. Lichtenberg argued that outside of the institutional setting, the "common" meaning of the term was

> "in-house consultation when one clinician consults another clinician for confirmation of expert opinion or diagnosis or advice for treatment. And consultation is done with the understanding that the physician who is being consulted is expert and practices in the area in which they're being consulted, and therefore can lend perspective and further detail to the diagnosis and treatment of a given patient."

Evident in his criticism of the alleged consultative relationship between Brigham and Shepard was Lichtenberg's notation of the fact that Shepard was retired and at least somewhat disabled, at least in terms of performing D&E's, and that he was not providing Dr. Brigham with any real substantive training or information. Of course, Brigham argued that he learned from this highly experienced OB/GYN, who, when he practiced, did so in an area of medicine that, while including terminations of pregnancy for which Brigham was himself arguably expert, also included elements of obstetrics that Brigham had no qualification in, let alone any expertise. Brigham, and some of the employee witnesses, offered that as Brigham performed D&E's, Shepard and he did deliberate between physicians on a case or its treatment. The dictionary's definition of the word does not include on its face the further refinements of the term Lichtenberg added, that is, the idea that the consulted doctor is an expert, and perhaps the idea that the doctor consulted actually practices in the area, rather than perhaps being retired from practice, although it may be that Lichtenberg did not mean to imply this need to be an active practitioner, at least presuming that the retiree is up to speed on the current practices in the area in question. The dictionary definition does appear to be more in line with Dr. Mucciolo's definition, which eschews the "expert" element, as the doctor "consulted" may be simply more familiar with a particular issue than the doctor seeking the consult. In the end, Dr. Lichtenberg appears to have accepted that at least one

acceptable definition of "consultation" simply is, "one physician providing an opinion or assistance to another physician," a definition which is certainly in line with Dr. Mucciolo's concept.

Thus, as used in the statute, the word "consultation," must be seen in a medical context, for that is the subject of regulation. Its meaning may vary, but one acceptable meaning for it is simply this idea of a doctor providing an opinion or assistance to another physician. While it seems clear this does not mean serving simply as one to sit and monitor vital signs, it can well mean to discuss the details of the patient's case, exchange ideas and discuss concerns, techniques, etc. In this sense, it seems hard to deny that on the surface meaning of the term, if the facts are as stated in the hypothetical offered to Dr. Mucciolo, then a consultation was occurring between an out-of-state licensee and a Maryland-licensed physician. But, it may be asked, was this the sort of consultation that the Legislature had in mind when they allowed for an exception to the general rule that one seeking to practice medicine in Maryland had to be licensed by that state? Does this meaning of the term convey that which the legislators thought they were allowing?

The "consultation" provision is an exception to the general requirement for a physician engaging in the practice of medicine in Maryland, to be licensed by that state's medical licensing authority. As an exception to the general rule, the exception must have been enacted to allow something that was deemed necessary to permit for exceptional circumstances, for unusual events or needs, and certainly not as a means for circumventing the general requirement that to practice in Maryland a physician had to hold that state's license to do so. The idea most certainly was not to permit a doctor, licensed and living elsewhere, to establish a practice of medicine in Maryland. Instead, it no doubt was intended to allow non-Maryland licensees to practice in Maryland in limited circumstances deemed beneficial to Maryland-licensed physicians and patients of Maryland-licensed physicians. Taking this as the purpose and intent of the statutory exception, we can look at Dr. Brigham's activities to see if they complied with this narrow purpose. We can then look at what the Maryland Legislature did when it amended the exception to see if that revision clarifies what the Legislature actually

meant in using the term "consultation" in the version of the statute in force when Brigham allegedly consulted with Shepard.

Dr. Brigham was a New Jersey-licensee, living outside of Maryland. He had a practice in New Jersey, although he may have had interests in facilities and practices outside New Jersey. He undertook the insertion of laminaria and the induction of fetal demise in New Jersey, steps which, if not themselves part of a "termination of a pregnancy" "procedure," certainly were at the very least prefatory elements that themselves were directed and supervised by Brigham in his role as a physician treating these patients. For reasons that appear to solely arise from legal limitations on the nature of the facilities permitted for performing certain termination procedures involving post-fourteen-week cases, and perhaps as well the requirements to be able to practice in those facilities, Dr. Brigham chose to seek a location outside of New Jersey to perform the D&E's. While the record contains some suggestions as to the economic motivations that might have been considered, I am persuaded that Dr. Brigham had a sincere desire to provide a service to women seeking such procedures, procedures the availability of which in certain situations was limited by legal and possibly financial considerations. Thus, Dr. Brigham created, for reasons that he deemed appropriate to allow him to carry out these terminations, a sort of split practice, part of the treatment occurring in the state in which he was licensed and part in another state, Maryland, where he was not licensed. In effect, Brigham opened a medical practice in Maryland. He intended, at least, according to his testimony for a short time, to have his New Jersey-treated patients also treated in Maryland. He was the physician who had treated, or at the very least directed the treatment, of these patients, and he was the doctor who directed the treatment of the patients in Maryland. This was so even if one credits the evidence offered to support that Shepard was medical director in Elkton, or even in Voorhees Township. And this was so, even if at some point some other doctor was going to engage in a form of training in the D&E's under Brigham's supervision. As such, Brigham was, at least for some period of time, establishing a medical practice in Maryland. The record does not suggest that he was asked to do so by any Maryland physicians as a means of training Maryland licensees, and surely not by Dr. Shepard. In summary, if the purpose of the consultation exception was to allow for the unusual need, the limited circumstance warranting the practice by an out-of-state licensee, for

the benefit of Maryland physicians and patients, then it is hard to see how Brigham's practice in Elkton came within the purpose of the exception. It might have provided some training as an ancillary feature, it might have been the case on some future date that Brigham could have stopped his personal practice in Maryland, but that is speculative.

In the record, there is some speculation that the Maryland Legislature was responding to the events in Elkton when it chose to amend the language of the "consultation" exception in H.B. 1313. That bill, enacted and effective May 16, 2013, is by its very terms, enacted as "an emergency measure," "necessary for the immediate preservation of the public health or safety." The bill does not state why exactly this is so, or what the motivating cause for the Legislature's action was. It is true that the events surrounding the sudden emergency treatment rendered at Union Hospital to D.B. in 2010, and the subsequent criminal indictment of Dr. Brigham, generated publicity. The Board of Physicians took immediate action to stop Brigham's activities, although as previously noted the uncontested Cease and Desist Order does not constitute any actual adjudication of Brigham's contention that his activities fell within the existing "consultation" exception. The gap between these events and the enactment of the "emergency" legislation may or may not suggest that the action was in direct response to the Brigham matter. Nevertheless, in this bill the Legislature chose to define precisely what sort of "consultation with a physician licensed in the State of Maryland" it was permitting. It required that such consultation be "about a particular patient" and that the "non-licensed physician not direct patient care." Surely, under this language, what Dr. Brigham did at Elkton was not the sort of activity the Legislature was permitting, as he surely did direct patient care.

The Maryland courts have recognized that at times the meaning of a word or phrase in legislation that is itself ambiguous or doubtful can be understood by examining a subsequent amendment. Maryland's Court of Special Appeals cited the following authority in regard to this principle in Connolley v. Collier, supra, at 39 Md. App. 421,427-28, 385 A.2d 826, 829-30. The court cited 2A. Sutherland, Statutes and Statutory Construction, § 49.11 (Sands ed. 1973).

> Where a former statute is amended, or a doubtful meaning of a former statute rendered certain by subsequent legislation a number of courts have held that such amendment or subsequent legislation is strong evidence of what the legislature intended by the first statute. But a subsequent legislative construction of a statute is not conclusive of the meaning of the former statute . . . . It has been judicially declared that 'If it can be gathered from a subsequent statute in pari materia what meaning the legislature attached to the words of a former statute, they will amount to a legislative declaration of its meaning, and will govern the construction of the first statute.'
>
> . . .
>
> "Whether or not a subsequent statute sheds light upon the meaning of a former statute depends upon a number of circumstances. Where the original law was subject to very serious doubt, by permitting subsequent amendments to control the former meaning a great deal of uncertainty in the law is removed. And the legislature is probably in the best position to ascertain the most desirable construction. In addition it is just as probable that the legislature intended to clear up uncertainties, as it did to change existing law where the former law is changed in only minor details. Thus it has been asserted that 'one well recognized indication of legislative intent to clarify, rather than change, existing law is doubt or ambiguity surrounding a statute.'" (Footnotes omitted).

Here, the Maryland Legislature, having first chosen to permit what had to have been expected to be a limited exception to the requirement for licensure in Maryland for physicians practicing in Maryland, chose, subsequent to the exposure of the Elkton activities, to amend the consultation exception to more explicitly indicate that it was intended to address the care of particular patients and that the out-of-state licensee was not to be in charge of and was not to be directing the care of any such "particular" patient. Since this amendment can reasonably be seen as addressing any doubt about whether the sort of activity Brigham was engaged in was within the limited exception intended by the Legislature in the first place, as authorized in the first statute, this amendment can properly be seen as "intended to clear up uncertainties" and not as a "change to existing law." The amendment can be seen simply as the Legislature's re-assertion of the primacy of licensure by Maryland authorities for those who choose to practice medicine in that State, which was always implied by the fact that the

"consultation" situation authorized in the first statute was but an exception and not a normal avenue for practice in the state.

In view of the above, it appears that the Maryland Court of Appeals, and on the administrative level, the Maryland Board of Physicians, would each determine that the consultation provision allowed only a very narrow exception to the general licensure requirement, and that it was always the intention of the Maryland Legislature to restrict such practice in line with the understanding that a Maryland physician and patients being treated in Maryland would benefit by the ability of Maryland doctors to benefit from the ability to consult about the treatment of their patients with out-of-state licensees who had some expertise or at least some special knowledge that could assist the Maryland doctor in that physician's care of his or her patient, care that the Maryland physician directed and was ultimately responsible for.

It seems clear that Dr. Brigham's activities in Elkton did not comply with the understanding of "engaging in consultation with a physician licensed in this State." Dr. Shepard, the physician with whom he purports to have been engaged in such consultation as would make Brigham's unlicensed practice in Maryland legal, had no patients of his own. He did not treat the Elkton patients in New Jersey. He did neither the prefatory acts (under one view) or the early portions of the termination of pregnancy procedure (under another view). He did not, and likely could not, perform the D&E's that Brigham, or Walker, did in Elkton. He was not in need of Brigham's expertise. At most, it might be argued that he was imparting his expertise in OB/GYN to a New Jersey-licensed doctor who was treating the New Jersey-licensed doctor's patients, whose treatment was initiated in New Jersey, in Maryland. There is simply no reason to believe that the Maryland Legislature, under even the first legislation, intended to permit this sort of run around of the Maryland licensing requirement for doctors treating their patients in Maryland. And the amendment of the consultation provision is reasonably understood as merely clarifying the original intent of the first provision, not as a significant change thereof.

For these reasons, I **CONCLUDE** that Dr. Brigham was not authorized under Maryland law to practice medicine in that state. The activity that he undertook in Elkton was therefore in violation of that State's law regarding the practice of medicine.

It seems abundantly clear that Dr. Brigham, for what may well have been, at least in regard to the provision of a generally lawful service to women who chose to terminate their pregnancies, a well-intentioned desire to provide them with an available means to accomplish that end, chose to find a way that he could complete the terminations himself, in a location that he believed was lawful for a doctor with his level of training and certification. I accept that he sought legal advice about his ability to do so in Maryland. I **FIND** that he obtained the cooperation of Dr. Shepard strictly for legal reasons, and that while it would be impossible to completely ignore that he may have received some information and advice from Shepard on technical matters, the real reason that Shepard was involved had nothing to do with any perceived need by Brigham for his medical services, or frankly, for his input, which, had Brigham sought to enhance his own knowledge in OB/GYN matters he could have presumably discussed with experienced OB/GYN's, including even Dr. Shepard himself, without the attempt to make it appear as if Shepard was actually engaging in "consultation" about the patients who were undergoing the D&E's he sat in on, whether physically present or on the telephone. Shepard was simply the necessary vehicle for what Brigham perceived as a means to allow him to practice in Maryland. Defining what occurred as a "consultation" was, at best, a stretch, albeit perhaps slightly within a broad understanding of the concept. However, even recognizing that under the original statute, "consultation," at least as I conclude the Legislature actually meant it, might have had a somewhat unclear meaning, I **FIND** that what Brigham created was not a medical consultation in any real sense, and, frankly, I do not think it was truly meant to be that. And, given the conclusions about what the Legislature did mean, as clarified by the later amendment, there was simply no legally acceptable "consultation." In summary, I **FIND** that Dr. Brigham knowingly effectuated a scheme to allow himself to practice in Maryland, possibly but in no sure sense for a limited time, and with no illusions that he had any actual need for medical consultation with Dr. Shepard on the specific cases he was treating, later rationalizations to the contrary.

The Board of Medical Examiners can respond to this serious breach of the law of another state committed by its licensee, regardless of whether that State would, or did, consider the violation to be criminal in nature.

Criticisms Concerning Details of Brigham's Practice

Aside from the large questions about "termination of a pregnancy" and "consultation," the Complaints allege, in somewhat general terms, that other elements of Dr. Brigham's practice violated professional standards. These violations are broadly alleged as involving misrepresentation, fraud, dishonesty, and false pretense. Additionally, it is alleged that Brigham failed to properly maintain patient records. The detail of the alleged breaches of trust and of concerns about alleged gross negligence, gross malpractice and/or repeated acts of such caliber, while in part based on certain facts asserted in narrative in the Complaint, were largely supplied by expert testimony from Dr. Lichtenberg, supplemented by testimony from others. Broadly stated, the criticism, which the complainant labels, at least in part, as relating to the doctor's "blueprint for patient care", centered upon

1) Inaccurate and confusing consent forms,

2) Breach of trust arising from the provision of either false or inadequate information, such as

    a) the alleged failure to advise patients as to where their D&E's would be performed,

    b) by what doctor,

    c) what type of procedure would be performed,

3) the risks involved in the transportation of patients whose fetuses were already dead from Voorhees Township to Elkton,

4) Deficiencies in record keeping, including

    a) confusing and contradictory entries on patient records concerning the type of procedure performed,

    b) failure to record serial measurements of blood pressure, oxygen saturation, pulse

    c) failure to record measurements or estimates of blood loss,

5) the physical and aesthetic conditions of the Elkton facility.

Standard of Care

Dr. Lichtenberg defined the standard of care that he was applying in rendering his professional opinion concerning Dr. Brigham's practice as the performance of medical duties up to the level expected of a reasonably competent physician, with the standard viewed in a national context due to the availability of national guidelines and nationally recognized practices. He explained that there exists an aggregate sense of what constitutes reasonable and competent practice. Thus, Lichtenberg believes that all doctors practicing in the United States in a particular field are bound by the same standards of care. However, the accepted practices are constantly evolving. In the field of family planning, including abortion, there are several groups who have produced guidelines that assist in and help to form the acceptable standards. These include the American College of Obstetricians and Gynecologists, the National Abortion Federation (NAF), Planned Parenthood, and the Society of Family Planning (SFP). There exist several layers of what might overall be termed acceptable ways of practice. These include standards, which all must perform; recommendations, which all should perform, but to which there can be exceptions that must be documented when employed; and options, which are completely discretionary. Additionally, there are local laws and regulations which may restrict what can be done, and by whom or where different matters can be performed. These laws and regulations can impact the standard of care applicable in a given jurisdiction.

Before considering these allegations relating to the doctor's practice and his "system," it is appropriate to note that the record is replete with information concerning the often well-documented history of protests, demonstrations, obstruction and occasional outbreaks of violence that have occurred in various parts of the United States in the vicinity of, and on occasion, directly within, premises on which abortions occur. This history, which has included among other elements, picketing, direct confrontations with patients and staff, abusive language, and, on a more dangerous level, bombings, arson, and the like, also has included the murder of several physicians who provided abortions, most notably in regard to this record, Dr. George Tiller, who

practiced in Kansas, but also Dr. Slepian in New York State and two physicians in Florida. Dr. Brigham testified about both his own experiences with protests, physical obstruction to buildings, and of patients and staff, and threats made to providers where he worked. He also explained his interaction with other providers, including Dr. Tiller, and the impact that his knowledge of all this history upon his own decisions regarding where and how he practiced. He noted that Dr. Tiller conducted a very open and obvious practice, whereas a practitioner such as Dr. McMahon in California did not advertise and conducted his practice in as discreet a fashion as he could. Brigham explained that the Elkton facility was purposely not identified on the outside, that the intention was to shield patients and staff as much as possible from the risk of publicity and of protests. Staff of his practice in Voorhees and Elkton, as well as patients, testified about their experiences, fears and concerns regarding the threat of protests and/or violence to them as either workers at, or patrons of, Brigham's practice. Whatever the outcome of the assessment of the details of the criticisms of that practice, I recognize that it would be foolhardy to dismiss these concerns or to downplay the risks that persons who are involved in, or become involved with, the provision of abortion services must consider. That said, I also recognize that the protests and violence are not everyday occurrences at every such facility, and abortion services are provided in locations without any active problems. And the existence of these unfortunate realities that may, or occasionally due, impact providers cannot justify deviation from the standards of care that are rightfully imposed.

Consent Forms

The "Informed Consent for Abortion after 14 Weeks" forms utilized by Dr. Brigham and signed by the several patients whose records were made part of this record are criticized by Dr. Lichtenberg as inaccurate and confusing. Examining the records related to the care of patient S.D. (P-18), whose D&E was performed at Elkton on August 13, 2010, and who is listed as having been twenty-five weeks pregnant, Dr. Lichtenberg observed that the "Informed Consent for Abortion after 14 Weeks" form that this patient, as well as other, signed, states, in its first sentence

> "I _____ hereby request that I receive a abortion (sometimes known as a "medical abortion" from Dr. _____, . . . an independently contracted physician working with Grace Medical Care (GRACE)"

However, the abortion or termination of pregnancy procedure that Brigham was to perform under the authorization of this form was actually a "surgical abortion," one that was contemplated to involve the use of forceps and obstetrical maneuvers, a D&E. The last paragraph of the first page of the form, page 1 of 4, which lists medications that might be used "to cause an abortion," could be construed as including the possibility of a termination of pregnancy without the use of forceps and maneuvers, since these are not mentioned therein. If the patient knew she was to have a D&E, then the form would presumably not be confusing. However, the reference to a "medical abortion" involves misleading terminology. None of the several patients involved here were expected to have a "medical abortion." That is, each was expected to undergo a D&E, a surgical abortion procedure. Later in the form there is a reference to "a late abortion" being "different than an early surgical abortion . . . ." Even further on, there is reference to a permission given for the use of a "suction canula to aspirate blood, amniotic fluid, or placenta" and to the use of "a sharp curette to remove adherent placental parts." And this statement appears

> Although I have requested my doctors to conduct an abortion, and my Doctor's intentions are to prefer non-surgical methods, nevertheless, surgical techniques may be necessary and I consent to the use of surgical abortion techniques.

Quite clearly, this form requires that the patient give her consent to a surgical abortion, but it suggests that the abortion might be "medical," when in fact that approach seems not to have been within the contemplation of Dr. Brigham in regard to these patients. It is thus the case that the form might be considered at least misleading or confusing, especially to persons who were not familiar with the terminology, or to those whose level of understanding was limited by educational or other limitations It seems evident, however, that any patient who was properly counseled about the contents of the form and the procedure that was anticipated, which was certainly a D&E, had received both

written information of the prospect of a surgical abortion, as well as oral counseling about that prospect. As such, the actuality of confusion in the patient population is somewhat doubtful. Nevertheless, even Dr. Mucciolo, who felt that the contents of the form extensively identified risks, including death, and as an overall matter met the standard of care, nevertheless appeared to agree that it was facially confusing.

I **FIND** that the "Informed Consent for Abortion after 14 Weeks" form is not appropriately clear and that clarity is an important element of any consent process. Thus, it fails to meet all of the necessary elements of the standard of care. However, it nevertheless is detailed enough that it delivers to the patient adequate information as to the prospect of a surgical abortion and the risks attendant thereto. As such, I **CONCLUDE** that this as a minor violation of standards.

Concerns Regarding Travel to Elkton

As will be recalled, patients ultimately undergoing D&E's at Elkton were first treated, with laminaria and the induction of fetal demise, in New Jersey. However, as the record details, on the day when the D&E was to be performed patients were instructed to appear at the Voorhees office, accompanied by someone who would drive them, either both to and/or from, a facility described as about one hour away.[ix] Evidence from some patients indicates that they were told to have money with them for bridge tolls. A caravan would then depart from Voorhees, including vehicles containing staff, patients and those driving, and Dr. Brigham.

Dr. Lichtenberg explained that the respondent had violated the trust relationship that must inherently exist with a patient, a relationship that is an element of a practice conducted within the standard of care. This breach arose from several factors, but a significant element in that breach was the lack of information, or of specificity, as to where the completion of the process would occur. Additionally, Lichtenberg appeared to question the propriety of such a journey for women who had already had fetal demise induced, noting the risks that existed for them at that point in the process.

[ix] D.B. testified that she was accompanied by someone who would be in Elkton to drive her home after transportation was provided for her by the practice.

According to Dr. Brigham and staff witnesses, the caravan proceeded south, over the Delaware Memorial Bridge, through Delaware and then over the Maryland border to Elkton. Patient witnesses described the cramping and pain that they suffered while on this journey, and the evidence is that these were normal and expected results of the medication and the fetal demise that had occurred. Some expressed their concern about what would happen if they got lost, or if "something happened." Dr. Lichtenberg, noting that once fetal demise occurred, the risk of a woman going into premature labor was present, and that women undergoing abortions were likely to be under considerable emotional distress, argued that this procedure of traveling to Elkton was itself fraught with risk, such as, someone getting lost or having a mechanical failure and the like, and that the failure to tell patients where they were going was a breach of Brigham's ethical responsibility to his patients. He wondered about what care was available in such contingencies. Patients should know where they are having surgery and generally, by whom the surgery will be performed. Patients also needed to know where to go if they went into contractions en route. These concerns arose due to what the doctor labeled as a "serious deviation from standards."

Dr. Lichtenberg was asked about the practice in his own facility in Chicago, where patients who have had laminaria inserted are told that they can drive to places that might be an hour from the facility. While he explained that they "probably" are not driving, as the instructions usually are to come with a chaperone, nevertheless, he agreed that the patient may have cramping and pain, and that there is a "small chance" that the patient might go into labor. He agreed that when these patients travel that distance over that period of time, there is no nurse with them or following them, there is no stat kit available. If something occurred while travelling, a call could be made to his facility for instructions, twenty-four hours a day.

K.G., the manager of the Voorhees office, testified that the patients who arrived at Voorhees on the day scheduled for their D&E's were first examined by Brigham to see if they needed more laminaria inserted or more medication, and then as they prepared to depart for Elkton, it was determined if all had the necessary money for gas and tolls. If necessary, the cars would pull off of the road in order to make sure all

made the proper turns, and at tolls, to make sure all had gotten through. There never was any problem in this transportation element during the approximately fifteen to eighteen trips that she made to Elkton. K.G. recalled three of the patients who were treated first in New Jersey asked where they were going on the day of their D&E's. One, who she was pretty certain was a Grace patient, wanted to put the address into her car's GPS. K.G. provided the address. A second, a Grace patient whose brother was a doctor in Columbia and who was flying in to be with her, needed the address. Again, it was given to her. A third, either a Grace or an AWS patient, gave the address to her husband over the phone so that he could pick her up in Maryland. K.G. did not recall that either D.B., her mother or D.B.'s boyfriend asked her about where they were going.

K.G. testified that a complete stat kit, which K.G. herself examined and determined to be full, was always transported with the caravan to Elkton. This stat kit was a different one from the stat kit kept at the Elkton facility. She was told that the reason for taking it back and forth was in case of an emergency occurring on the way to Elkton.

D.B., a 2010 high school graduate who is attending college, testified regarding the circumstances of the abortion that she underwent in August 2010. She recalled that she had not researched Dr. Brigham and he had not been recommended to her, but she assumed that he was competent. She was told on her first visit to Voorhees on August 9, of the multi-day schedule for the process. She was told that a "late term" "procedure," which she understood would be "surgical," was not done at Voorhees and had to be done at a "bigger facility in Philadelphia." She was told that transportation would be provided and that she would have to have someone follow in another vehicle. She assumed that this was for "safety reasons to drive me back home." She met Dr. Brigham on the August 12, three days after that first visit to Voorhees. Laminaria were then inserted and she went home. At this second visit, she believes she was again told "we'd be going to Philadelphia." Nothing was said at that time about bringing money for tolls or having a full tank of gas, or about having a cell phone with her. Then, on the 13th, when D.B. was in "a lot of pain" in the cervix area and experiencing "just like labor pains," she realized transportation was not provided for her and she was to travel in her

own car with her mother and boyfriend. She still thought that they were going to Philadelphia, but, as she was from South Jersey, she soon realized that the route they were taking was not going to Philadelphia. The trip took "more than one hour" and D.B. was in pain as they travelled, eventually arriving in Elkton. Other than her pain, the trip did not pose any problem.

A.C., a twenty-five-year-old medical and surgical assistant who had an abortion in August 2010, testified that she was told that as she was too far along, it would be necessary for her to go to a different location for the completion of her treatment and that she understood it was to be a surgical procedure (It must be noted that A.C. had had a previous abortion, and thus presumably had some advance understanding about the procedure that others may not have had). This location was described as being about one hour away from Voorhees. She was not concerned where, and was happy that protestors could not find where she was being treated, as she had a fear of demonstrations, about which she had heard "horror stories."

S.B., another patient, testified that she was told that she would be travelling about one hour from Voorhees for the abortion, which she understood would be "surgical." She did not ask where she was going, and was not concerned, as she believed that she was in the hands of persons who had her best interests at heart.

Dr. Mucciolo discussed the procedure for his patients undergoing terminations of pregnancy. His office is located on 78th Street and Madison Avenue in Manhattan. The hospital is on 34th Street. Laminaria are inserted and patients go home. Insertions may occur on a Monday and again on Tuesday, with the "procedure" on Wednesday. Fetal demise is induced on Monday. Patients go home Monday and Tuesday nights. Many of his patients come from Long Island, Westchester County, Connecticut, and a sizeable number from Lakewood, New Jersey. The travel time from Lakewood to his office or the hospital is about one and one-half hours. It is within the standard of care for a patient who has had laminaria inserted and who has had fetal demise induced to travel for an hour or more to the facility where further events in the process will take place.

Dr. Brigham did not recall that any patient ever asked him specifically where the final procedure would be performed. As for D.B., as patients were specifically told that they would be travelling about one hour from Voorhees and to have bridge toll money with them, he thought that D.B must have thought that they were going to Philadelphia. A stat kit was transported with the caravan in case of any emergency, but he never encountered any problems concerning the condition of the patients during the journey to Elkton. Eight hospitals had been identified as "along the way" to Elkton, and Brigham described his conversation with the medical director at one, Christiana Hospital, in Delaware about ten or fifteen minutes from Elkton, in which he told that doctor that he wanted to sign an agreement for Christiana to accept his patients if necessary. He was told there would be no problem, they would take patients in cases of emergency or complications. However, due to the nature of the procedures that Brigham's patients were undergoing, that is, abortions, the medical director was reluctant to actually sign any agreement. Thus, he said, a verbal agreement would suffice.

Dr. Lichtenberg's criticism of the travel necessitated by Dr. Brigham's arrangements for providing terminations of pregnancy certainly emphasizes that patients were not told exactly where they were going, other than a statement that it was about one hour from Voorhees Township. From there, the doctor moves on to his criticism of Brigham for taking patients to a state in which he was not licensed, a fact that he also did not reveal to his patients. Thus, Lichtenberg sees in all this a breach of trust, but with regard to the travel itself, Lichtenberg did note concerns about what arrangements were made to deal with any emergency that might occur, especially as the women, having already received Digoxin and already in pain from cramping, were at risk for the onset of labor. While the record reveals no evidence that any such emergency situation ever actually occurred en route to Elkton, it is true that the journey did involve some risk of something happening that could require immediate attention before the arrival at Elkton. But the evidence also demonstrated that it is not that unusual for women who are to undergo termination of pregnancy procedures to travel after laminaria are inserted and even after fetal demise is induced. Indeed, Dr. Lichtenberg and Dr. Mucciolo each testified that their patients travelled from their facilities after receiving laminaria, and at least in Mucciolo's case, after fetal demise had occurred, and in their cases their practices were in large metropolitan areas, Chicago

and Manhattan. Mucciolo noted that his patients were spread throughout the New York, New Jersey, Connecticut region, and that their travel time was often at least as great as that involved in the trip from Voorhees Township to Elkton. Perhaps in some of those trips, the mileage was less, but the traffic may well have been much greater than that generally encountered between Voorhees Township and Elkton, and thus the travel time was as great or even greater than that experienced by Brigham's patients. And Lichtenberg did not suggest that there was any negligence or malpractice involved in allowing the patients who had received Digoxin to go home or to wherever they were staying and then travel on the next day to Voorhees. The evidence that Brigham had a full stat kit with the vehicles traveling to Elkton was credible.

While the criticisms expressed by Dr. Lichtenberg regarding the entire circumstances surrounding the Maryland portion of Dr. Brigham's activities are extensive, I **CONCLUDE** that considering only that portion involved in the actual travel from Voorhees to Elkton, no violation of the standard of care has been proven.

The primary evidence regarding an allegation of dishonesty involving the travel was D.B.'s testimony that she was told that the procedure would be performed in Philadelphia. She was aware of the need to travel, but said that on two occasions Philadelphia was specified as the place where they would be travelling. No other witness testified that they were told of a Philadelphia location. There seems to be little reason why, if anyone in Brigham's office were telling D.B. where the procedure would occur outside of New Jersey, they would have specified Philadelphia. References that might have been made to the need for bridge tolls, which comments D.B. denies hearing, might suggest to someone aware of the proximity of Voorhees Township to Philadelphia, that the bridge involved was the Ben Franklin or the Walt Whitman or the Tacony-Palmyra, common entry points from the Camden County/Burlington County area (in which I live) to Philadelphia. Someone from outside the area might well not know the names of the bridges, but if they came over them to Voorhees Township, perhaps from Philadelphia International Airport, or by car from somewhere outside the Philadelphia area, they would have crossed a bridge into New Jersey. It might well be that mention of bridge tolls was less likely to suggest to someone the more remote Delaware Memorial Bridge, approximately forty miles from Voorhees Township. In any

case, I am persuaded that D.B., who surely suffered enough, simply is incorrect in her recollection of Philadelphia as the place she was told about. She mentioned Philadelphia in her statement, made shortly after the event, and this might tend to strengthen the likelihood that she was correct in her recall, but there is no other fact here that would tend to support her. Brigham and others credibly testified that if someone asked for the location, they gave it, even though they did not volunteer it. While Brigham is criticized for not revealing the location up front, for keeping it a secret, it is another thing altogether to conclude that when asked, he purposely lied about the location. Of course, he might have done that if he felt the question might compromise the attempt to make the Elkton site as "private" and unobtrusive as he desired. But I am not persuaded that Brigham or his staff had any reason to mislead D.B. I simply must conclude that she was mistaken. I **FIND** that she was not misinformed about where her procedure would occur and **CONCLUDE** that no dishonest action was involved.

More generally, Dr. Lichtenberg complained that the failure to tell patients as a matter of course where the procedure would occur was a breach of trust. Dr. Brigham and others, including patients, have testified as to the concerns they had about protests. Brigham had decided to take a low-key approach, not to trumpet or to make obvious what was occurring in Elkton. While I fully agree that the determination of professional standards and of violations of those standards is not controlled by the reactions of patients to matters that they, as lay individuals and in many instances, given their medical needs, vulnerable persons, may not appreciate for their importance, it is true that these patients, trusting Brigham to be a competent physician who could provide them with appropriate medical care, did not concern themselves with exactly where they were to be treated "about one hour away." It seems that to Lichtenberg the real issue here is that the physician offering to treat these patients was taking them to a place in which he was not licensed, and, to the extent that he criticizes the Elkton facility, to a place he deemed inadequate for the procedures to be accomplished there. But taken alone, I **CONCLUDE** that while it might well have been a better practice to be specific with patients up front about exactly where they were going, the failure to actively identify to the patients who did not themselves ask the location where the D&E would occur did not violate professional standards.

While the ability of Dr. Brigham to practice medicine in Maryland is primarily a legal question, in the context of his attack upon Dr. Brigham's honesty and what he deemed the breach of trust with the doctor's patients, Dr. Lichtenberg was asked for a medical prospective concerning the questions arising from the fact of Dr. Brigham's lack of Maryland licensure. He proposed that a patient seeking medical care for a termination of pregnancy at, say, twenty-four weeks, who is in a stressful situation and understands that she will have to go through a lengthy process with some danger associated with it, would "presume that she was in the care of a competent physician. And she would further presume that the physician were licensed to perform the procedure that she was contemplating in the location that it was to be performed at." From the medical, as opposed to the legal perspective, regarding the right of a physician to practice and the need for a license in any jurisdiction,

> "I would opine that the counseling involved includes inherently the assumption by the patient that the doctor who represents himself or herself as being competent to perform the anticipated procedure would have a license . . . That they've been judged by the authorities, who are vested by the state . . . for vetting practitioners in medicine, having found this person unworthy of a license would, I think, instill alarm and chagrin in the average patient."

Indeed, Dr. Lichtenberg opined that there would be a breach of trust even where the doctor could not perform the abortion in New Jersey, but could do it in Maryland under that state's law, "because the patient assumed they were being done in New Jersey by someone licensed to do them in New Jersey." He also expressed that if the unlicensed physician was not engaged in proper counseling in Maryland under that state's exception to licensure, that the concern was in regard to the issue of "competent counseling" of the patient.

> "counseling is the encounter with the patient that establishes trust, that counseling involves a discussion of risks and options and benefits, and that inherent in counseling is the fact that one - - that the patient is being presented with the prospect of having her procedure performed by a licensed physician. And that seems to me as the only physician[x] in our virtual room to be an assumption that is indisputable."

[x] Dr. Lichtenberg was referring to the fact that he was testifying via video conference.

He found the deviation from accepted standards to be “gross and serious.”

Several patient witnesses testified that if Dr. Brigham had a medical license in New Jersey, the lack of a license specifically permitting practice in Maryland was not of consequence to them. A.C. commented that as Brigham was licensed in New Jersey, the lack of a Maryland license did not mean that he had lost his skills. She had been told that the surgery could not be performed in New Jersey, but not why. She assumed that the reason had something to do with New Jersey laws. She did not care that it could not be done in New Jersey.

Dr. Lichtenberg’s position on this matter raises some interesting questions. Dr. Brigham was a licensed physician in the State of New Jersey, highly experienced in the performance of termination of pregnancy/abortion procedures. While there are serious concerns expressed in this record about aspects of his ”system,” it must be noted that there is no evidence that Dr. Brigham personally failed to comply with professional standards in regard to the technical aspects of performing these procedures. His record keeping is questioned, his attempt to practice in Maryland is questioned, his honesty and issues of trust are implicated, but there is no attack on his technical competence in the performance of the surgeries. Indeed, Dr. Lichtenberg specified that given the records he had reviewed he could not comment on that subject, and the serious problem that affected D.B. was not at Brigham’s own hand, but that of Dr. Riley. Given this, there is no basis to conclude that Brigham did not know how to competently perform the termination of pregnancy procedure. That he was not permitted to do it in New Jersey does not tell us that he could not do it with technical competence. And, there is no evidence that were he licensed in Maryland, he could not have performed the procedures that he did in Elkton at that very facility.

Surely, a patient who goes to a doctor expects that the physician is permitted by some recognized authority to practice medicine. No patient in any but perhaps the most dire, life-threatening emergency is likely to want to be treated by a doctor unlicensed to practice in any jurisdiction. The patient assumes that a licensed physician is competent. He or she trusts in that assumption. If the doctor has a license, a patient seeking that doctor’s medical care, while not necessarily concerned about the doctor’s lack of a

license in another state where treatment is to be rendered (and here I speak not of where the doctor has had his license revoked), most probably is not interested in becoming any part of some potentially illegal situation. As such, if the doctor knowingly involved the patient in such a circumstance, most especially but not exclusively without first advising the patient of the circumstance, there then certainly would be a breach of trust. Thus, the real issue here is not so much that there was a breach because the patient was not told that Brigham did not have a Maryland license, but whether Brigham can be said to have withheld that this practice in Maryland was known to him to be outside of the accepted exception that he claims to have been practicing under. If his claim to meet the exception was correct, then his practice in Maryland was legal, and in that case, no breach of trust can be said to have occurred. The facts as developed in this case, and as analyzed here, point to the conclusion that Dr. Brigham knowingly engaged the services of Dr. Shepard solely so as to attempt to fit within the legal requirements for permissible practice by a non-Maryland-licensed physician, and that he knew that he did not need Shepard's involvement for actual medical reasons. Thus, he knew that he was at the very least skirting the edge of what was authorized. Involving his patients in this attempt did expose them to the prospect that they might in some fashion become entangled in Brigham's own legal and ethical problems. There is in this a lack of candor and responsibility towards his patients, and in that sense, I **CONCLUDE** that Brigham did breach the trust that his patients inherently placed in him.

Record Deficiencies

According to his report of February 7, 2011, Dr. Lichtenberg reviewed twenty-one patient charts of Dr. Brigham's patients treated in Voorhees and Elkton. In the report and in his testimony, Dr. Lichtenberg identified several repeated deficiencies regarding information that was either not in the chart as it should be, or was in the chart, but in a manner that was confusing and perhaps incorrect. Regulations of the Board of Medical Examiners address certain chart requirements, but Lichtenberg was unaware if the Maryland Board of Physicians had any such regulations.

As part of his report to the complainant, Dr. Lichtenberg prepared a chart of the deficiencies he noted on review of twenty-one patients' charts. The doctor observed that

vital signs were apparently taken, but the record shows no time when these recordings occurred. The doctor testified that the records regarding M.L., treated on August 4, 2010 at Elkton, contained an "Abortion Record" that he described as "extremely lacking." All that the first page of the two-page form contained were single entries for blood pressure, pulse and oxygen saturation. No intra-operative vitals signs are recorded. The record does not indicate any recording of blood pressure, pulse and oxygen saturation during the D&E, although he must assume that there were others in the room at the time besides Dr. Brigham who could have made the recordings. Periodic recording is not difficult and the standard of care requires it. Dr. Lichtenberg asserted that under the standard of care, these measures are typically monitored every five to ten minutes and then taken post-operatively until the patient is alert and awake. Lichtenberg's review of patient records showed that the dosages of anesthetics administered were consistent with IV conscious sedation, a form of sedation that is often used within the standard of care in a second or a third trimester abortion. The records show that three medications were administered, Lidocaine, Vasopressin and Oxytocin. However, the records fail to record the amount of each utilized. Monitoring of these several measures should have been occurring. A failure to monitor a patient who is not alert and responsive is a violation of the standard of care. Recovery room records maintained by the practice did not comment upon the patients' responsiveness, merely providing vital signs, limiting the ability to determine if in fact the level of sedation utilized.

In his report and testimony, the doctor noted that while twelve Abortion Records (which in his report he described as "operation records"), lacked serial intraoperative oxygen saturation, pulse and blood pressure readings, (including D.B.'s where Dr. Riley performed the procedure), in the remaining nine charts, those intraoperative readings were present.

Another concern was that the records did not document estimated blood loss. If this is greater than a doctor should expect in a particular instance, the doctor needs to know of the increase and must determine why it is occurring. Treatment varies depending upon the cause. The recovery room needs to know of the issue, to better monitor the patient in recovery. And post-operatively, where there is excessive

bleeding, the need for monitoring of hematocrit or hemoglobin is "all the more necessary, perhaps on a serial basis." Monitoring of these levels are necessary to meet the standard of good medical care. And finally, if the excessive bleeding continues, the patient must be transported to another healthcare facility. The records of Brigham's patients do not note any post-operative hematocrit or hemoglobin monitoring.

Dr. Lichtenberg characterized the absence of an abortion record and the absence of serial recordings of oxygen saturation as "serious deviation(s)" from standards. The absence of a signature of the physician on an abortion record is a "minor" deviation, "if it occurs sporadically." The absence of serial recordings of intraoperative records, the absence of estimated blood loss and the absence of recording of hematocrit and hemoglobin are each a "concerning issue, a concerning deviation," that is, one that would make one concerned that there are other deviations in the record. The latter two are important entries as they assist with the care of the second and third trimester patient later on, and the entry of hematocrit and hemoglobin recordings provide a "benchmark in the case of complications. So, once again, it's the kind of deviation that has cause to concern someone reviewing the chart."

Dr. Lichtenberg pointed to the record for another problem that he observed with many of the "Abortion Record" forms that he reviewed from Elkton. The form contains a sentence, reading

> "**The patient [ ] did [ ] did not, spontaneously deliver the fetus and placenta."**

In S.D.'s Abortion Record the box for "did" is checked. This would mean that she delivered without assistance from a surgeon. Yet, clearly, this was not the case, as in her and others cases, the patient was undergoing a D&E procedure for the very purpose of removing the dead fetus, placenta, and other products of conception. And the very Abortion Record itself contains a pre-printed list of equipment that may be utilized in the evacuation process, such as those checked as having been employed in S.D's procedure, including obstetrical maneuvers, forceps, sharp curettage of the endometrium, vacuum aspiration of the amniotic fluid, blood, parts, etc, CNS

decompression, and other items. The form then is, on its face, contradictory, as either she had a spontaneous delivery without surgical intervention or she did not and had a surgical procedure to evacuate the uterus. Since everything checked off as having been utilized would clearly indicate the surgery occurred, there is no apparent reason for the indication of a spontaneous delivery. The record then cannot be viewed as an accurate recordation of what occurred, or at the very least, it presents a confusing picture. There is no record for this patient of any post-operative hematocrit or hemoglobin measurement. The lack of recordation may also indicate an actual lack of monitoring.

Dr. Lichtenberg characterized the deviations in charting as "serious," explaining that these are "such widespread practices" that whether they appear in some form of manual or guideline is "really beside the point." They are "part of standard practice in surgery as a whole and in particular in this field . . . where an abortion is done in the second trimester or beyond. . . " The National Abortion Federation Clinical Policy Guidelines for 2010, page 24, (P-46), referring to "Anesthesia", provide that when moderate sedation is used [he characterized this level as equivalent to IV conscious sedation] "monitoring must be of a degree which can be expected to detect the respiratory, cardiovascular, and neurological effects of the drugs being used." Recommendation 7.01 reads "Pulse oximetry should be used to enhance this monitoring." Lichtenberg was also aware that similar guidelines existed in the standards of the American Society of Anesthesiologists.

The doctor could not tell from the records whether an IV was running during the surgery, the absence of which would violate standards of practice requiring that IV access be maintained. Lack of information in the record, such as this, can be important if the patient has complications and especially, if she has to be referred to another healthcare provider, as in the case of D.B.

On cross-examination, the doctor was referred to a book he edited, "Management of Unintended and Abnormal Pregnancy." In part, the book addresses "abortion follow up," including the follow-up visit of the patient to the doctor. The doctor did not think that he edited this particular chapter, but he acknowledged that it said

nothing about any standard or recommendation regarding hematocrit or hemoglobin being taken at a follow-up visit.

In reviewing other patient records in evidence, Lichtenberg noted that in some, as for instance, patient S.W., (P-28) the Maryland Abortion Record form does contain entries indicating some periodic monitoring of blood pressure, pulse and oxygen saturation. But in her case, the same confusing indication of a spontaneous delivery is followed, as in the space just below the pre-printed line quoted above, is a handwritten entry, "D&X & delivery," and the list of equipment used contains several check marks indicating a surgical procedure, as well as a check for a CNS decompression, and an entry that confirms the use of a process, described in detail in the record, that absolutely cannot be termed as a "spontaneous" delivery. However, in characterizing these deviations, that is, the confusion as to the means of delivery and the lack of dosages, Lichtenberg said they were "not serious deviations." The same recordings, and the same confusing entries regarding the type of delivery, are found in the records of D.M. (P-23). Again, these deviations were "not serious."

Dr. Lichtenberg concluded that while the "system" that Dr. Brigham had established to perform "these abortions," and the records which he had reviewed, showed that Brigham lacked good clinical judgment, nevertheless, this did not suggest that the Lichtenberg could comment on how the Brigham functioned "as a clinical doctor from day-to-day." "I can't make a judgment about his technical competence based on the records before me." However, the flaws in judgment that Lichtenberg could identify constituted a serious deviation from acceptable standards.

D.B. testified that she was under the impression that Dr. Brigham would be performing the procedure. Dr. Riley introduced herself as a doctor who would be assisting Dr. Brigham. D.B. was the second patient treated that day. Dr. Riley administered anesthesia in her arm either by IV or a needle. When she was falling asleep, she saw Riley "in front" of her. Brigham was on her right side. She recalls nothing else from the procedure room, and next recalls waking up in the hospital, where she was told that the abortion was not finished. She was airlifted to Johns Hopkins.

D.B. did not know that Dr. Brigham was not licensed in Maryland, or that Dr. Riley had been licensed in Maryland for less than one month. D.B. eventually obtained $150,000 from Dr. Riley for the damages she suffered, but nothing from Dr. Brigham, for whom she still has some anger.

Shown the consent form that she signed for the procedure, D.B. acknowledged that the name of the doctor was left blank, but she did not ask about this and was not concerned about the absence of the name.

Dr. Mucciolo discussed the need to write down an estimate of blood loss. Physical measurement of blood loss is not generally made. If the procedure is a minor one, and blood loss is generally small, with no signs of excessive bleeding or changes in vital signs, "I don't think that it's absolutely necessary that you have to document it, understanding it's an estimate anyway and it is not something that you have specifically measured."[xi] He based this opinion on "countless" personal experiences and his reading of "countless" operative reports of major surgeries.

> "I think it is nice if you can give a gross estimate . . . but in the final analysis it's, is there evidence of abnormal bleeding? And it there is not and in the surgeon's opinion this is an acceptable norm of a first or second trimester procedure or even an early third, I don't think that's a transgression.

The doctor offered that if there is no "evidence of extraordinary bleeding" "we do not do post-op hematocrits at all." It is not done at the hospital, NYU, or at Lenox Hill Hospital, where he practiced for ten weeks when NYU was shuttered due to damage from Hurricane Sandy.

As for the consent form, Mucciolo thought it was "pretty much within the standard" and not "confusing." "I think it gives the patient the obvious options on how to terminate a pregnancy, they should know this." He considered it "more extensive than the one I show a patient at NYU."

[xi] The witness noted that the American College of Obstetricians and Gynecologists considered abortions to be minor procedures, even in the third trimester, although "obviously with significant risks." He was not aware of New Jersey's regulations in regard to this issue.

Regarding the Abortion Record, the expert did see it as "a little confusing by using the word "spontaneous" but writing that it occurred "Via D&E." The addition of this term clarifies what occurred.

Dr. Brigham noted that in regard to the alleged contradictions in the "Abortion Record," a review of the record would make it clear what actually happened, but he acknowledged that "probably" the use of the word, "spontaneously," was a "poor choice of words," as clearly, adjunctive measures were employed in the procedure. As for criticism that he did not record blood loss, he explained that there was very little, given the technique that he employed using Pitressin, known also as Vasopressin, which causes the blood vessels of the uterus to clamp down. The uterus is "like - - bone dry." As such, they did not document the "minimal loss," which Brigham described as "not clinically significant." In D.B.'s case, where there was perforation of the uterus, even she was not bleeding, for the reason just described. Brigham acknowledged that in other facilities in which he had worked, he had documented blood loss.

As for Lichtenberg's criticism about not documenting post-operative hematocrit and hemoglobin, Brigham described this as "a very unfair criticism," noting that it was not the standard of care to document these, not according to the National Abortion Federation Guidelines, nor according to the practice at Planned Parenthood, or from his experience in the field. It is not done in routine procedure. Indeed, he described it as "clinically useless." And to do so two weeks later, at a follow-up examination, is a "non-issue." Again, there is no such standard of practice.

Dr. Brigham insisted that IV access was always maintained through a intravenous butterfly. As for documentation of post-operative oxygen saturation, Brigham again disputed that this was required by the standard of care, noting that the NAF Guidelines did not require this measure to be done in the recovery room, despite requiring other measuring of blood pressure. It is a "good practice" with which Brigham would not argue, but while Brigham testified that "we did it" with "fancy pulse oximeters," it was not required by the standard of care.

Brigham termed Lichtenberg's concerns about the lack of documentation of dosages of Lidocaine, Vasopressin and Oxytocin as "fair criticism" from the perspective of someone who was reviewing a record later on, although clinically the doctors knew that they gave the same dosage to every patient, so that it was "not clinically significant to us as providers." It is "better practice to actually note the dose."

The respondent addressed the overall criticism of his "clinical judgment." He believe that the system he utilized was effective, it "worked." He referred to this in regard to the testimony about the history of providers of abortions: the "very public and open" practice of the murdered Dr. George Tiller, and by Dr. Hern, and the "very discreet, private, low-key approach" which he had seen used by Dr. McMahon, who had no security problems and no protesting, which was better for the patients. He believed the success of the practice for the patients demonstrated his good clinical judgment.

N.J.A.C. 13:35-6.5(b) provides in pertinent part:

> (b) Licensees shall prepare contemporaneous, permanent professional treatment records . . . All treatment records, bills and claim forms shall accurately reflect the treatment or services rendered. . . .
>
> 1. To the extent applicable, professional treatment records shall reflect:
>
> i. The dates of all treatments;
>
> ii. The patient complaint;
>
> iii. The history;
>
> iv. Findings on appropriate examination;
>
> v. Progress notes;
>
> vi. Any orders for tests or consultations and the results thereof;
>
> vii. Diagnosis or medical impression;
>
> viii. Treatment ordered, including specific dosages, quantities and strengths of medications including

> refills if prescribed, administered or dispensed, and recommended follow-up;
>
> ix. The identity of the treatment provider if the service is rendered . . . .

Based upon the evidence, I **FIND** that it is apparent that the Abortion Record maintained by Dr. Brigham in respect to the patients whose care has been the subject of this case were, at least upon facial examination, confusing. Even Dr. Mucciolo agreed with this, and Dr. Brigham himself noted that the forms demonstrated at least a "poor choice" of words. The indication that the patient had experienced a spontaneous delivery of the fetus and placenta was of course incorrect. The identification on the very same page of equipment and methods used to effectuate what was anything but a spontaneous delivery makes the Record seem as if it might combine the information of two different patients on one Record, one who had a spontaneous delivery and one who did not. Of course, each Record only dealt with one patient, and none had a spontaneous, unassisted delivery.

While surely the confused nature of the Abortion Record violates the regulatory mandate that physicians maintain accurate records, I **CONCLUDE** that Dr. Lichtenberg's characterization of this particular series of deviations from the proper professional standard regarding keeping of accurate records as, "not serious," to be quite appropriate. Anyone who had reason to examine the record could readily see that it was not a record of spontaneous delivery, and the specific means utilized to effectuate the delivery are readily identified.

The various records identified show that in some cases the serial recording of pulse, blood pressure and oxygen saturation is listed, and on others it is not. While Dr. Lichtenberg generally commented that where recording of some expected monitoring is absent there can be suspicion as to whether the actual monitoring occurred, given that there are records here that show the recording, I have no reason to believe that it was not generally performed. Why exactly it was not recorded in some instances and was in others cannot be explained from this record. However, to the extent there is a lack of such recordings, the regulation does not require that the specific numbers be noted, only that findings, diagnosis or medical impression that might be gained or influenced by

such reading be recorded. Nothing here suggests that the failure to list these constitutes a violation of professional standards. It surely would not be wrong to list them, indeed it might even be a very good idea, but the absence of the numbers simply does not rise to the level of professional misconduct, much less to the higher level of gross malpractice or gross negligence.

Dr. Lichtenberg's criticism that the failure to record blood loss violates professional standards of care fails to impress. Dr. Mucciolo's credible testimony was that there is no general need, or requirement, to do so in the cases at issue, and that this is not the practice he has seen in his institutions or in the records he has so frequently reviewed. Again, he did not say it could not be done, in fact it might be a good idea, but such recording is not required by the standard of care in any general sense. It might be necessary and indeed required in cases where unusual blood loss is observed or suspected, but there is no such case here. Dr. Lichtenberg has not provided any evidence that his own belief about this subject rises to the level of a recognized professional standard. I **CONCLUDE** that the lack of recordation of estimated blood loss is not a violation of generally applicable professional standards.

A similar conclusion obtains regarding the taking of post-operative hematocrit and hemoglobin readings. The NAF standards do not provide for this, Dr. Mucciolo credibly denied that it was required by the standard of care. I **CONCLUDE** that no violation of standards is proven.

Conditions at Elkton

Dr. Lichtenberg was shown a series of photographs (P-16) taken both in and outside of the Elkton facility at 126 E. High Street and was asked to comment on what he saw that was troubling to him from the standard of the maintenance of professional standards of care. He opined that they did not "depict a facility of the level of equipment and safety . . . for procedures 24 weeks and beyond. "

The photographs considered by Dr. Lichtenberg were taken on August 17, during the time when the police were inside the facility, acting pursuant to a search warrant

obtained sometime after police were first summoned concerning the patient, D.B., who had suddenly appeared with staff from the clinic at the Union Hospital emergency room. Detective Holly Smith testified that to her knowledge, the facility, which had been secured on the 13th, was observed from the outside from August 13 to 17. The photos were taken while the police "stood by," and she had no knowledge of the police doing anything until the pictures were taken. As an example, she identified a picture of a freezer which she had opened and which contained what appeared to be fetal remains, and she explained that the police neither placed anything inside the freezer nor removed anything from it. A diagram of the inside of the building was also prepared and admitted into evidence (P-59). She also explained that a number of photos that show packages of drugs, such as Dilaudid and Misoprostol, do not reflect the condition in which these were discovered when the police first examined the building or when they returned with a search warrant, as these drugs were removed from a safe or drawers where they had been stored out of sight, for the purposes of photographing them.

Dr. Lichtenberg's testimony regarding the photographs included his critique that the facility was "a barren setting," one that shows a lack of maintenance, with stains on the ceiling, and rust on a piece of equipment (Berkeley Vacuum Curettage System pump, P-16, photos 6034 and 6147). He noted open bottles of Ketamin (P-16, photo 6052). He observed that a stat kit, shown in photo 6142, was not complete. This is a set of emergency equipment and medications, vital to have available in a facility were procedures such as D&E's are performed. He noted the absence of Epinephrine. If several procedures were occurring at this facility and if the stat kit were not complete, such would violate the standard of care, although he did not know of a specific citation for such a requirement. He was positive that any Department of Health would cite the lack of a full stat kit as a violation. He noted that Dilaudid, a Schedule III narcotic, which in Photo 6065 was not secured, should be in a locked compartment with restricted access. Additionally, the doctor contended that there was no evidence of an ambu bag at the facility.

Dr. Lichtenberg explained that there were medical reasons requiring that terminations of pregnancy for patients twenty-four weeks and beyond be "performed in facilities of a higher quality with more equipment and more resuscitative measures and

higher quality staff to handle possible complications." Based on his review of the photographs, he opined that they did not depict a facility "of the level of equipment and safety" such as he had described to be necessary for such cases. He deemed the deviation from acceptable standards to be "serious."

On cross-examination, Dr. Lichtenberg acknowledged that photographs did appear to show at least one, if not two, ambu bags and he agreed that his "criticism was misplaced." Also, the witness had noted in his report a concern about syringes that he saw on one side of the photographs that appeared to have been used "in prior abortions and were not properly disposed of." Shown photograph 6058, which "could very well have been this slide," Lichtenberg advised that he thought that they "may contain varying amounts of liquid and that's the basis on which I inferred" that they had been used. However, he could not say so "with absolute certainty," and, if his opinion had been based on this slide, he retracted his statement.

As for the stained hallway, Dr. Lichtenberg claimed that the setting was "very stark for anyone who's just been transported to a place that they've never been to in which they're going to have a fairly serious operation at often advanced gestations." He characterized the "location" where Brigham was performing these procedures as "not very welcoming," "barren and threadbare" and "equipped in the most basic ways, and not possessing much in the way of amenities for patients." "It doesn't improve their anxiety, and in some cases I would venture that it increased their anxiety."

Reviewing the photos of the room in which he observed the suction pump that appeared to be rusted, Lichtenberg explained that he believed it was a room to which patients had access, as "given the way it was outfitted, it strains credibility to think that no patient ever saw this room for a procedure because it's outfitted for one." However, credible testimony of several employees and of Dr. Brigham was that while the building in which they conducted their business contained a number of rooms and corridors, they only utilized a portion of the building for their business and patients, who had access to even less of the building than the staff used, never had reason to enter into a number of areas that were actually within the business area itself. Included within these non-patient areas was that portion observed in photos as having water stains on the ceiling.

Detective Smith noted that during the police investigation she learned that some portions of the building were not part of Dr. Brigham's space.

Dr. Lichtenberg had never been to the facility, and no other witness contradicted the testimony regarding the spaces that patients had no access to. I **FIND** that as there is no evidence that supports that patients ever had any contact with these areas or that the rusted equipment was actually utilized, neither the presence of the rusty pump or the stain on the ceiling constituted a violation of the standard of care.

As previously noted, testimony from several witnesses, including Dr. Brigham, was that a complete stat kit was maintained and was transported with the caravan each time it went to Elkton and then back to the Voorhees facility where it was kept complete. I **FIND** that this testimony, while offered by the respondent and persons affiliated with him whose credibility must, as with all witnesses, be assessed with due consideration for their interests and biases in the matter, was credible. There is no reason to believe that Dr. Brigham was not cognizant of the need for the presence of such emergency items, both on the road and in Elkton. The fact that another stat kit was present and was not complete is not evidence that precludes the existence of the travelling kit. I **FIND** no violation of the standard of care in regard to the stat kit has been established.

I **FIND** that Dr. Lichtenberg's critique of the "barren" appearance of the Elkton facility is not grounded in any evidence of any standards applicable to the decor of such a place. Of course, persons present there for termination procedures are under stress, and one would like to think the atmosphere of the facility might at least not add to their stress. But the doctor did not offer any evidence that there is any standard other than his own taste, and more depressing sights such as stained ceilings and rusty equipment (with no evidence of its actual use), were not exposed to patient view. Therefore, I **FIND** that this criticism simply does not rise to the level of a violation of professional standards.

While there certainly are concerns regarding whether Dr. Brigham's activities in Elkton constituted a violation of Maryland's law concerning the unlicensed practice of medicine, there is no evidence that in the actual management of the patients treated

there Dr. Brigham acted negligently or committed malpractice in regard to any of the D&E's that he personally performed. The unfortunate injury to D.B. was at the hands of Dr. Riley, although of course Dr. Brigham was supervising her. I **FIND** that the criticisms that Dr. Lichtenberg has offered about the Elkton facility itself, its decor, its ambiance or lack thereof, and his commentary on the conditions based upon photographs that in at least some instances do not depict what the conditions were before the police arrived, or involve assumptions as to the actual practices within the building, simply do not possess enough credibility to support claims of violations of the standards of practice.

Summary

Count I of the Complaint, which addresses the treatment of D.B., presents a series of statements as alleged facts and then concludes with general assertions of unspecified acts of gross or repeated negligence, as well as a violation of N.J.A.C. 13:35-4.2, the termination of pregnancy regulation. Similarly, Counts II, VI and VII involve charges of similar violation of this regulation.

Based upon the record, I **CONCLUDE** that given the proper understanding of the meaning and scope of N.J.A.C. 13:35-4.2, as now written, Dr. Brigham did not violate that regulation by inserting laminaria or inducing fetal demise in New Jersey. Any desire on the part of the Board to include these matters within the regulatory definition of "termination of a pregnancy" "procedure", or to otherwise redefine the coverage of the provision, must be accomplished by proper means dictated by the Administrative Procedure Act, N.J.S.A. 52:14B-1 to - 31. As currently written and properly understood from a medical viewpoint, reference to "termination of a pregnancy" as a "procedure" is reasonably understood to mean the evacuation of the uterus of fetal remains and other products of conception by surgical means. Other parts of what Dr. Lichtenberg understandably conceives of as a "process" are prefatory, at least as the existing regulation must for now be understood. For the reasons expressed these charges are **DISMISSED**.

Count II expressly addresses the alleged impropriety of Dr. Brigham's actions in Maryland, where the terminations of pregnancy of the several named patients did occur. I **CONCLUDE** that Dr. Brigham's unlicensed practice of medicine in Maryland did not come within the intent of the Maryland General Assembly in permitting a physician unlicensed in Maryland and living in another state to practice "while engaging in consultation with a physician licensed in this State." The purpose of his having Dr. Shepard involved in the Elkton practice, and in any manner in the Voorhees practice, was strictly done for "legal", and not for "medical" purposes. While general "consultation" with Shepard over matters of interest to Brigham as a provider of abortions and as a non-OB/GYN might possibly have been of some value to Brigham, Shepard did not need the services of a consultant for Shepard's practice of medicine, and Shepard's involvement was simply a pretense to provide cover for Brigham to maintain a Maryland practice. In a broad sense, it may perhaps be said that they were at least occasionally consulting, and that might be seen as a mitigating factor in regard to the violation deemed to have existed given the proper understanding of the intent of the exception as later clarified by the amendment, but overall, it must be said that Brigham was really trying to create a picture that might pass for legitimate consultation, when in fact he knew that the reason for it all was legal, and not, at least as it existed, for any significant medical reason. As such, Dr. Brigham's conduct involved violation of the law of Maryland, and conduct that was improper for a licensed New Jersey physician. I **CONCLUDE** that this conduct constituted a major violation of professional standards in each of the multiple instances in which he so practiced.

Counts II, III, and VII each charge that Dr. Brigham failed to maintain patient records in accordance with N.J.A.C. 13:35-6.5. I **CONCLUDE** that the Consent Form and the Abortion Records that were offered in evidence demonstrate confusing terminology and entries that are not appropriate under professional standards. It is nevertheless reasonable to conclude that the Abortion Record, despite the internal inconsistency, does provide information that allows for an understanding of the surgical nature of the abortion it records. And the Consent Form is comprehensive enough, despite its flaws. I **CONCLUDE** that these violations are therefore relatively minor.

I **CONCLUDE** that the criticisms in several Counts that relate to criticisms about alleged missing equipment, such as an ambu bag, an incomplete stat kit at the Elkton premises, a lack of ambiance, including stains and rusty equipment, a failure to record hematocrit and hemoglobin levels, to record blood loss as a general requirement, all fail to establish any violation of professional standards. These charges are **DISMISSED**.

I **CONCLUDE** that the criticism concerning the transport of patients who have had induced fetal demise likewise fails to establish a violation of professional standards. This charge is **DISMISSED**.

Sanctions

Prior Disciplinary History and Mitigation Evidence

Prior to the closing of the record, the parties were afforded the opportunity to present evidence that they believed might be relevant solely in relation to the level of any sanctions that might be imposed. The Attorney General offered exhibits related to Dr. Brigham's past disciplinary history and Dr. Brigham offered some limited explanatory testimony concerning certain matters arguably of a mitigating nature. Certain other exhibits that the Attorney General offered were rejected as not proper evidence, particularly with respect to a previous matter in New York State that was addressed in the decisions of Judge Fidler and the Board in the mid-1990's, as well as regarding certain Pennsylvania Department of Health inspection notices requiring corrective action plans that were deemed not to be disciplinary matters. Additionally, Dr. Brigham's Voluntary Retirement from Practice in Pennsylvania pursuant to which he agreed never to apply for reactivation, renewal, reinstatement or reissuance of his license is not considered as evidence of a disciplinary history, as it involved no adjudication or any stated admission of wrongdoing. Finally, P-80, a Stipulation and Settlement Agreement entered into with the Department of Health of the Commonwealth of Pennsylvania in July 2004, the admission of which was held in abeyance, is rejected as it does not involve any stated discipline or any stated admission, only incorporating agreements to govern future conduct.

The items offered and accepted in evidence include the following:

A decision of the Commonwealth Court of Pennsylvania, issued June 15, 2011, Steven Chase Brigham, M.D., et al. v. Department of Health, Bureau of Community Licensure and Certification, No. 1582 C.D. 2010 (unpublished), affirming an Adjudication and Order of the Deputy Secretary of the Pennsylvania Department of Health, In essence, the Adjudication and Order determined that the respondents had violated a prior Settlement Agreement which had imposed upon them a duty to verify the licensure status of employees and failed to report that an individual had provided nursing services despite her not having an LPN license. The sanctions imposed included that the registrations of AMA and AMS to operate freestanding abortion facilities in Pennsylvania be revoked; that each entity be precluded from registering any facility as a freestanding abortion facility under the Commonwealth's Abortion Control Act; and that Dr. Brigham be precluded from registering any facility as a freestanding abortion facility under the Act either directly or indirectly through any professional corporation, nonprofit or any other entity in which he had either a controlling or equity interest.

A decision of the Supreme Court of New York, Appellate Division, Third Department, entered December 23, 1999, The People of the State of New York v. Steven C. Brigham, 201 A.D.2d 43; 702 N.Y.S.2d 119, affirming a conviction for two counts of failure to file corporate tax returns. The decision also reversed a conviction for fraud in the first degree. Dr. Brigham was sentenced to 120 days in jail, of which he testified to serving 10-14 days and then having served additional days on work release, until his release from jail after deduction of good time.

The Final Decision of the New Jersey Board of Medical Examiners rendered on August 28, 1996, in 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, BDS 1303-94 and BDS 2468-95 (referred to previously in this decision as "Brigham I"). This Final Decision required that Dr. Brigham cease and desist from certain advertising that misleads or has the capacity to mislead, and from the use of certain words in advertising.

A Final Order of the Florida Agency for Health Care Administration (Agency), dated June 25, 1996. This Order revoked Dr. Brigham's license to practice medicine in Florida. It was based upon a finding that Brigham had violated portions of the Florida statutes, arising from findings made by a Hearing Officer of the Florida Division of Administrative Hearings. The Hearing Officer determined that, based upon a series of admissions arising from a Request for Admissions filed by the Agency, Brigham had agreed to a series of facts, as follows:

1) his Voluntary Retirement from Practice in Pennsylvania pursuant to which he agreed never to apply for reactivation, renewal, reinstatement or reissuance of his license;

2) a determination of the New York Department of Health, State Board of Professional Medical Conduct, that his continued practice of medicine in New York State constituted an imminent danger to the health of the public and Brigham's failure to notify the Florida Board Medicine in the required time frame of the interim action of the New York licensing authority;

3) the finding by New York State that his license should be revoked due to a finding of gross negligence;

4) the action of the New Jersey State Board of Medical Examiners on February 3, 1994, instituting an interim limitation on Brigham's practice based upon its determination that his continued practice in regard to second trimester abortions and certain elements of his procedures demonstrated a clear and imminent danger to the public, and Brigham's failure to notify the Florida Board of Medicine in the requisite time frame of this action of the New Jersey Board;

5) The January 13, 1995 Order of the New Jersey Board of Medical Examiners directing that Brigham refrain from practice effective as of December 14, 1994; and

6) Brigham's' having indicated on a license renewal form completed on March 22, 1994, that he was exempt from financial responsibility requirements "due to his not practicing in the State of Florida" and his expression on March 1994, that he had no intention to practice medicine in Florida, when, in fact, beginning in September 1994, and until February 3, 1995, he provided medical care and performed terminations of pregnancies in Pensacola, Florida, doing so without notifying the Agency of his primary place of practice within the State of Florida prior to engaging in practice therein. As a result, he failed to comply with Florida's financial responsibility law or show exemption therefrom prior to his initiating the practice of medicine in Florida.

The Attorney General proffered evidence pertaining to a decision of the New York State Department of Health regarding the treatment of two patients that resulted in disciplinary action in New York. However, as was discussed on the record, the treatment of those two patients was considered at the hearing before Judge Fidler after the Board declined to apply collateral estoppel in favor of the Attorney General regarding the New York decision. Judge Fidler ruled that the Attorney General failed to meet its burden in regard to allegations of professional negligence regarding these two patients, and the Board accepted the judge's decision. Under these circumstances, it would not be appropriate to allow the New York disciplinary action based upon the treatment of these two patients to impact the determination of the sanctions to be imposed in the present matter. To the extent that the New York sanction arising from the New York determination of gross negligence is mentioned in regard to the action of the Florida Health Care Administration, it is noted for historical purposes, but again, that New York sanction will not be considered in regard to the nature of the sanctions imposed herein. Similarly, I did permit the introduction of Pennsylvania matters that by their very specific terms were not to be treated as disciplinary in nature or that merely recorded agreements to act in a certain manner in the future without any adjudication or admission of alleged past wrongdoing.

Dr. Brigham presented testimony from Julia Gabis, Esq., an attorney admitted to practice in Pennsylvania, who represents Dr. Brigham in matters in that State, concerning certain matters currently pending administrative appeal in that State, in order to clarify that no final administrative action has yet occurred in connection with

these matters involving a revocation of a clinic's registration to operate in Allentown and Pittsburgh, Pennsylvania. Dr. Brigham also offered testimony from Donna Marie Smith, district manager for the Allentown and Phillipsburg clinics operated by American Women's Services, regarding Dr. Brigham's limited role, at most, in the Allentown operation and the corrective actions plans filed in Pennsylvania. Dr. Brigham also explained certain aspects of other matters that did result in disciplinary action.

Discussion and Order

N.J.S.A. 45:1-25 provides

> a. Any person who engages in any conduct in violation of any provision of an act or regulation administered by a board shall, in addition to any other sanctions provided herein, be liable to a civil penalty of not more than $ 10,000 for the first violation and not more than $ 20,000 for the second and each subsequent violation. For the purpose of construing this section, each act in violation of any provision of an act or regulation administered by a board shall constitute a separate violation and shall be deemed a second or subsequent violation under the following circumstances:
>
> (1) an administrative or court order has been entered in a prior, separate and independent proceeding;
>
> (2) the person is found within a single proceeding to have committed more than one violation of any provision of an act or regulation administered by a board; or
>
> (3) the person is found within a single proceeding to have committed separate violations of any provision of more than one act or regulation administered.
>
> . . .
>
> d. In any action brought pursuant to this act, a board or the court may order the payment of costs for the use of the State, including, but not limited to, costs of investigation, expert witness fees and costs, attorney fees and costs, and transcript costs.

The purpose of imposing sanctions on a physician found to have violated professional standards is both to deter others from such misconduct as well as to punish the offending physician. In the Matter of the Suspension or Revocation of the License of Peter T. DeMarco, 83 N.J. 25 (1980).

Dr. Brigham's license to practice medicine in the State of New Jersey has been suspended since October 13, 2010, a period of nearly forty-six months. It will no doubt remain suspended pending the issuance by the Board of Medical Examiners of a Final Decision in this contested case. The major violation of professional standards proven against him is his unlawful practice of medicine in the State of Maryland, a practice that was at the heart of his performance of terminations of pregnancies that he could not, or if he could have, would not, perform in New Jersey for these patients who began his treatment with them in New Jersey, where he was licensed. This violation of a sister-state's law governing the practice of medicine is a legitimate basis for New Jersey's regulatory authority to sanction its licensee. Importantly in this regard, his Maryland practice was not isolated from his New Jersey practice. Indeed, it was part and parcel of the New Jersey practice, a continuation in Maryland of the treatment he rendered to the patients in his New Jersey facilities.

The record of Dr. Brigham's past conduct is troubling. He has suffered license revocations. He has run afoul of the licensing authorities in New York, Pennsylvania and Florida. Indeed, part of the Florida discipline, similar to the current case and the violation of Maryland law, involved his practicing in that State in violation of the rules governing eligibility to practice. He has a conviction for failure to file income taxes. And here, he demonstrated a willingness to play fast and loose with the law in Maryland that governed his right to practice medicine. While the record does not contain evidence that he personally mishandled the actual hands-on treatment of patients (recall that he did not cause the perforated uterus, although he was the physician in charge of that treatment and therefore could bear some responsibility for the result), and it cannot be fairly said that his hands-on treatment of patients has been shown to threaten the public safety and health, nevertheless, whether he should be permitted to practice in this State is at best questionable. While I have considered extending the long-standing suspension of his license and then allowing him to return to practice after the conclusion of an extended suspension, with limitations imposed on his practice, given his overall disciplinary history, I am persuaded that by now Dr. Brigham has clearly demonstrated that, regardless of his technical competence, he simply is not willing to carefully follow the licensing rules and regulations that govern his practice of medicine. I recognize the

difficult and controversial nature of the area in which he practices, and the validity of the concerns about access and safety that were a part of the record. Possibly, in part his conduct has been influenced by what he may perceive, rightly or wrongly, as inappropriate roadblocks to access for patients. However, it seems that Dr. Brigham has finally cut enough corners. As such, I **CONCLUDE** that the proper sanction is revocation. Given the length of his suspension from practice prior to the issuance of Final Decision in this case and the license revocation issued herein, and taking into account that there were multiple violations of the Maryland practice statute and of the rather less serious records provisions, I **CONCLUDE** that a single civil penalty of $20,000 shall be imposed for the violation stemming from the unauthorized practice in Maryland, and a single $10,000 civil penalty shall be imposed for the various minor violations of record keeping requirements. In addition, as to the payment of costs and fees authorized by the statute, I recognize that Dr. Brigham has had to defend against a serious and detailed charge regarding N.J.A.C. 13:35-4.2, a charge of which he is herein exonerated. Having been found guilty of one of the two most serious charges in this matter and of some lesser charges, I **CONCLUDE** that Dr. Brigham shall be responsible for two-thirds of the cost and fees arising from the investigation and prosecution of this administrative proceeding. These sanctions will adequately serve the twin functions of punishment and deterrence.

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 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 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.

August 13, 2014
DATE

JEFF S. MASIN, ALJ

Date Received at Agency: August 13, 2014

Date Mailed to Parties: August 13, 2014

mph

LIST OF WITNESSES:

For the complainant:

Christine Farrelly
E. Steve Lichtenberg, M.D.
Detective Holly Smith
D.B.
C.B.
Richard J. Lizzano, F.N., M.D.

For the respondent:

Steven Chase Brigham, M.D.
Gregg Lobell, M.D.
L.M.
Gary Mucciollo, M.D.
S.B.
S.A.
M. Natalie McSherry, Esq.
A.C.
K.J.
K.G.
V.O.
A.H.
Todd Stave
C.R.
B.W.
Julia Gabis, Esq.
Donna Marie Smith

LIST OF EXHIBITS:

For the complainant:

P-1 Curriculum Vitae of Christine Farrelly
P-2 Investigative Memorandum, dated August 16, 2010
P-3 Tissue and regulated Medical Waste and Recovery Room Log sheets
P-4 Transcript, Telephonic Interview with George Shepard, Jr., M.D., August 19, 2010
P-5 Transcript Interview with Dr. Shepard, dated August 30, 2010
P-6 Order for Summary Suspension of License to Practice Medicine, In the Matter of George Shepard, Jr., M.D., Maryland Board of Physicians, Case Number 2011-0134
P-7 Cease and Desist Order, In the Matter of Steven Chase Brigham, M.D., Maryland Board of Physicians, Case Numbers 2007-0448, 2010-0304, 2011-0117
P-8 Letter, September 4, 2010
P-9 Consent Order, In the Matter of George Shepard, Jr., M.D., Maryland Board of Physicians
P-10 Maryland Health Occupations Code Ann. § 14-302 (2010)
P-11 Instructions for Application for Exceptions from Licensing and Application for Exceptions from Licensure
P-12 Curriculum Vitae of E. Steven Lichtenberg, M.D., MPH
P-13 Report dated February 7, 2011
P-14 Report dated September 3, 2013
P-16 Photos of Elkton, Maryland office
P-17 Patient records of D.B.
P-18 Patient record of S.D.
P-19 Patient record of N.C.
P-21 Patient record of M.L.
P-22 Patient record of J.H.

P-23 Patient record of D.M.

P-24 Patient record of V.O.

P-25 Patient record of M.P.

P-26 Patient record of E.C.S.

P-27 Patient record of D.S

P-28 Patient record of S.B.-W.

P-29 Patient record of M.R.

P-30 Patient record of N.M.

P-31 Patient record of A.C.

P-32 Patient record of M.P.

P-33 Patient record of C.G.

P-34 Patient record of S.A.

P-35 Patient record of D.D.

P-36 Patient record of S.B.

P-37 Patient record of K.J.

P-38 Recovery Room Log for Elkton

P-39 Regulated Medical Waste log for Elkton

P-40 Autopsy reports

P-41 Information form completed by Dr. Shepard

P-45 Chart Representing Patient Record Deficiencies

P-46 2010 Clinical Policy Guidelines

P-47 Union Hospital security video August 13

P-48 Transcript of interview with Dr. Shepard by Detective Smith, August 19, 2010

P-49 Transcript of interview of Dr. Walker by Detective Smith, December 12, 2010

P-50 Transcript of interview of K.G. by Detective Smith, December 15, 2010

P-53 Interview of Christine Rodriquez

P-54 Search warrant inventory for Elkton

P-55 Search warrant inventory for Voorhees

P-56 Documents obtained in search warrant

P-57 Cover pages and Indictment of Steven Chase Brigham, State of Maryland, Cecil County

P-58 Transcript of interview of K.G., July 8, 2011

P-59 Diagram of Elkton office building

P-60 Certification of Christine Farrelly, October 9, 2013

P-61 Insurance communications

P-64 Patient record of C.S.

P-65 Patient record of W.B.

P-70 Notice of Offer of Respondent's Admissions as Evidence in the Pending Matter Revised-10/7/13

P-71 Not in evidence

P-72 Letter, August 12, 2010, Dr. Brigham to Roeder

P-73 Hospital record of P.J.

P-74 Letters between Phillips, Esq., and Executive Director Gleason, dated 1/26/99, 10/21/99 and 11/8/99

P-75 Letter, June 30, 2010, Dr. Brigham to DAG Krier

P-76 Certification of Gezim Bajrami

P-77 Order of Motions to Quash Subpoenas, State Board of Physicians v. Nicola Riley, M.D.

P-78 CD of interview of Dr. George Shepard, M.D.

P-79 Report of Gary Mucciolo, M.D., FACOG

P-86 Opinion of the Commonwealth Court of Pennsylvania, Brigham, et al. v. Department of Health, Bureau of Community Licensure and Certification, No. 1582 C.D. 2010 (June 15, 2011).

P-90 Opinion, The People of the State of New York v. Steven C. Brigham, 261 A.D.2d 43; 702 N.Y.S.2d 119, 1999 N.Y. App. Div. LEXIS 13538 (December 23, 1999).

P-91 Final Order, Agency for Health Care Administration, Board of Medicine v. Steven Chase Brigham, M.D., (June 28, 1996), with attachments.

P-92 Final Decision and Order, In the Matter of the Suspension or Revocation of the License of Steven Chase Brigham, M.D., BDS 1303-94 & BDS 2468-95 (Board of Medical Examiners, August 14, 1996).

P-93 Letter of January 17, 2001, with attached Administrative Consent Order, In the Matter of the Suspension or Revocation of the License of Steven Chase Brigham, (Board of Medical Examiners), dated July 12, 2000.

For the respondent:

R-1 E-mail, August 25/26, 2010
R-2 E-mail October 14, 2010
R-3 Letter dated July 1, 2009, from Maryland Board of Physicians, with Information Sheet
R-4 Letter dated August 5, 2009 from Marc K. Cohen, Esq.
R-5 Letter dated August 20, 2010 from Christine A. Farrelly
R-6 Letter dated August 25, 2010, Sammons to Cohen, Esq.
R-7 Letter dated September 15, 2010, with attached Notice of Appeal, Request for Case Resolution Conference and Hearing
R-8 For identification only
R-9 For identification only
R-10 For identification only
R-11 Letter, March 3, 2011, Farrelly to Dunne and Gilbert, Esqs.
R-12 For identification only
R-13 For identification only
R-14 Letter, February 27, 2013, Henderson, M.D., Board Vice Chair, to Brigham, M.D.
R-15 Screen Shot, web page of Maryland Department of Health and Mental Hygiene, Maryland Board of Physicians
R-17 Web page, Grace Medical Care
R-18 For identification only
R-19 For identification only
R-20a Website Listing, “The Assassination of Dr. Tiller”
R-20b Video, “The Assassination of Dr. Tiller”
R-21 No exhibit
R-22 Clinical Guidelines “Induction of fetal demise before abortion”, SFP Guideline 20101 (Society of Family Planning)
R-23a Photographs of Atrium, Mt. Laurel
R-24 Pulse Oximeter
R-25 Resume of M. Natalie McSherry, Esq.

R-26 Letter of February 7, 2011, from McSherry, Esq., to Gorrell, Esq.

R-27 Letter of March 4, 2011 from McSherry, Esq. to Gorrell, Esq.

R-28 Letter dated February 22, 1994 from Tiberius Dengelegi, M.D.

R-29 Letter dated March 5, 1992 from James T. McMahon, M.D., with attachments

R-30 Letter, dated June 24, 1993, from Harold Ticktin, M.D.

R-31 Letter dated July 3, 1993 from G.J. Campana, M.D.

R-32 Verified Complaint, filed November 24, 1993, In The Matter of the Suspension or Revocation of the License of Steven Chase Brigham, New Jersey Board of Medical Examiners

R-33 Initial Decision of Honorable Joseph F. Fidler, ALJ, April 12, 1996, In the Matter of the Suspension or Revocation of the License of Steven Chase Brigham, OAL Docket Nos. BDS 1303-94 & 2468-95

R-34 Final Decision of the Board of Medical Examiners, In the Matter of the Suspension or Revocation of the License of Steven Chase Brigham, OAL Docket Nos. BDS 1303-94 & 2468-95, dated August 14, 1996

R-35 Portions of testimony of Dr. Nicholas Kotopoulos given in Brigham I on November 17, 1994

R-36 Medical Director Engagement Agreement

R-37 Consultation Agreement

R-38 Chart

R-39 Picture of Stat Kit

R-40 Handwritten narrative on form intended for Christiana Medical Center

R-41 Medical Director's Elkton Facility Quality Assurance Review

R-42 Certification of George Shepard, M.D., dated October 8, 2010

R-44 Supplemental Report of Detective Holly Smith

R-45 Curriculum Vitae of Gary Mucciolo, M.D., FACOG

R-46 Report of Gary Mucciolo, M.D., FACOG

R-47 Curriculum Vitae of Gregg P. Lobel, M.D., FAAP

R-48 Letter report of Gregg P. Lobel, M.D., FAAP