

Frederick W. Hopkins MD, MPH
Departments of Obstetrics and Gynecology
Santa Clara Valley Medical Center
Stanford University School of Medicine

Amy Cook Olson, Esq.
Cooper, Rice & Olson, LLC
633 17th Street, Suite 2200
Denver, CO 80202
Direct/Cell: 303.641.1659
Office: 303.607.0077

Re:

Jennifer DeBuhr and Jason DeBuhr, Plaintiffs,
v.
Warren M. Hern, and Boulder Abortion Clinic, P.C.,
a Colorado corporation, Defendants

United States District Court for the District of Colorado
Case No. 15-cv-02613-PAB
Hon. Phillip A Brimmer

My professional opinion in this case is based upon the recommendations of ACOG's (American Congress of Obstetricians and Gynecologist) Committee on Ethics Opinion on Expert Testimony, as well as the following.

- 1) My experience in the field of Obstetrics and Gynecology and expertise in advanced Family Planning procedures such as the procedure in this case, that has been built upon years of training, practice, research and teaching.
- 2) My review of the medical records of this case, the relevant clinical standards and evidence-based medicine guidelines relevant to the medical care received by the plaintiff.
- 3) The performance of medical care for the plaintiff while under the care of Warren M. Hern, MD and Boulder Abortion Clinic P.C., as well as under the care of Dr. Mark Carlson.
- 4) The distinction between medical maloccurrence and malpractice.

Standing as an Expert:

I received my medical degree at Harvard Medical School and my Masters in Public Health at Harvard School of Public Health in 1992. Having completed my residency in Obstetrics and Gynecology at the University of New Mexico in 1996, I entered the Epidemic Intelligence Service at the Centers for Disease Control and Prevention

(CDC). At the CDC, I investigated pregnancy-related and abortion-related mortality in the United States while working in the Division of Reproductive Health, and I achieved the rank of Lieutenant Commander in the United States Public Health Service. After completing my fellowship in epidemiology at the CDC, I returned to Ob/Gyn practice, specializing in Family Planning services, while serving on clinical faculties at U.C. San Diego, U.C. San Francisco, Santa Clara Valley Medical Center and Stanford University's departments of Ob/Gyn from 1998 to the present day.

Currently, I provide care for, contribute to research of, and teach physicians in training advanced Family Planning procedures such as the one performed on Mrs. DeBuhr at the Boulder Abortion Clinic. I have nearly 20 years of experience managing the complications of similar procedures both as a provider and as the Medical Director supervising other physicians in large practices. I have given multiple presentations and have been an invited speaker on panels focusing on complications (prevention and management) of advanced procedures at many national conferences.

Curriculum Vitae

My curriculum vitae is attached to this report.

Opinion:

- 1) There were no deviations in the standard of care by Dr. Hern or Boulder Abortion Clinic, P.C.; no deviations from the standard of care that the plaintiff received.
- 2) The care and treatment rendered by Dr. Hern and the staff at the Boulder Abortion Clinic were reasonable and appropriate and not the cause of any injury or damages to the Plaintiff.

While under the care of Dr. Hern and the Boulder Abortion Clinic, the plaintiff:

- Presented to the Boulder Abortion Clinic for the termination of her pregnancy in its 25th week because of fetal anomalies.
- Received a detailed history and physical examination.
- Underwent extensive counseling regarding the risks and benefits of the procedure.
- Provided informed consent for the procedures occurring 12/3/2013 to 12/6/2013 to terminate her pregnancy.
- Underwent multiple days of cervical preparation.
- Underwent a pregnancy termination procedure on 12/6/2013 with IV sedation without any immediate complications.
- Was given detailed follow-up instructions for the management of any complications that might arise after leaving the Boulder Abortion Clinic.

Evaluation of Care at Boulder Abortion Clinic:

The protocols for Dr. Hern's procedures have been published in medical literature, presented at national medical conferences and provided to physicians referring to and providing after-care for patients at Boulder Abortion Clinic. (1)

The multiple step/day procedures used by Dr. Hern are reasonable and in accordance with National Family Planning Guidelines and evidence-based articles and texts on second trimester surgical and medical pregnancy termination procedures (2,3,4,5). The process used by Dr. Hern of preparing the uterine cervix, reducing risks of infection and prevention of catastrophic amniotic fluid embolism are intended to prevent major complications and maternal death due to hemorrhage, infection and embolism (6,7).

Mrs. DeBuhr's Boulder Abortion Clinic Medical Records demonstrate attention to detail in the initial consultation, multiple day visits and procedure notes. Dr. Hern appropriately noted the increased procedural risks of two prior cesarean sections, and he demonstrated compassionate awareness of the profound effect of caring for a similarly affected son who was institutionalized at the time of the procedure. Notably, in a case like this where in all probability the fetus would not survive the pregnancy or suffer from the same condition of her son, the pregnancy termination procedure carries less risk than a cesarean section delivery, which would have been indicated if the pregnancy was taken to term (9,10).

After extensive counseling regarding her options of terminating the pregnancy or returning to Nebraska and continuing the pregnancy, the patient chose to go forward with termination of the pregnancy. Dr. Hern injected a pharmacologic agent on day 1 of the procedure. On days 2 and 3, Dr. Hern placed serial cervical dilators to induce dilation and softening of the cervix. On the morning of day 4, Dr. Hern performed an amniotomy to drain the amniotic fluid (reducing risks of embolism) and administered uterotonic medicine to further prepare the uterine cervix and reduce blood loss during the procedure. Utilizing IV sedation, and over a 17 minute period, Dr. Hern performed a Dilation and Evacuation procedure without any peri-operative complications such as perforation or post-operative bleeding. Dr. Hern utilized real-time ultrasound to prevent trauma to the uterus and cervix. Dr. Hern utilized operative forceps, uterine curetting and ultrasound to evacuate the uterus. After inspection of the uterus with ultrasound, evaluation of the products of conception and observation that there was no evidence of trauma, bleeding, or infection, the procedure was deemed complete at 2:50 PM.

After the procedure, Mrs. DeBuhr was appropriately observed for a period of 3 hours and repeatedly evaluated for signs or symptoms of complications. At the time of her discharge, there were no recorded complaints or symptoms suggestive of any intra-operative or peri-operative complication.

Upon her discharge from the Boulder Abortion Clinic, Mrs. DeBuhr was provided with instructions to prevent and report post-operative complications. In the month following her procedure, Mrs. DeBuhr returned a self-assessment, and her referring physicians received letters from Dr. Hern regarding her care at Boulder Abortion Clinic and inviting them to contact him if they had any questions regarding her care.

Approximately one month after her procedure at Boulder Abortion Clinic (January 3, 2014) Mrs. DeBuhr saw Dr. Mark Carlson, Ob/Gyn in Omaha, Nebraska, who found no signs of post-operative complications. The practice of actively following patients after they leave the Boulder Abortion Clinic exceeds the community standard of post-operative follow-up only "as indicated" (8).

Dr. Warren Hern's approach to patient preparation for advanced pregnancy termination procedures is reasonable and appropriate and has been published and presented at many national conferences (1). Cervical dilation, while important, is only one of the factors that must be considered while performing such procedures (particularly with patients under moderate sedation). Cervical softness, elasticity, mobility and patient comfort are equally important in completing advanced cases such as this without major complications. The fact that Dr. Hern was able to complete the procedure in a patient with a history of two prior c/sections (which results in a less mobile and elastic cervix) while making intra-operative adjustments confirms his attention and commitment to patient safety. In fact, she had an uncomplicated procedure and went home after several hours of observation and clinical evaluations which confirmed there were no immediate complications.

In the testimony and opinions presented by the Plaintiff's expert witnesses, they are critical of Dr. Hern's documentation regarding:

- 1) cervical preparation/dilation,
- 2) post-operative ultrasound findings,
- 3) fetal tissue examination.

The Plaintiff's expert's opinions and testimony reveal a lack of clinical experience in relevant cases, and these experts are inflated in their findings and simply incorrect:

- 1) Cervical preparation/dilation: Dr. Hern did not document the final dilation at the time of the procedure, and was not required to. With relevant clinical experience, he made a judgement that the procedure could be completed safely, and in fact did so. After 48 hours of cervical preparation, Dr. Hern appropriately adapted his procedure to Mrs. DeBuhr's unique clinical circumstances (this can be demonstrated with the appropriate instruments).
 - a. Forcing further dilation could risk major trauma or perforation.
 - b. Delaying the case may have increased the risk of life threatening infection

- c. Mrs. DeBuhr was experiencing pain, and completing the procedure safely alleviated her suffering.
- 2) Intra- and Post-operative ultrasound assist in providing/completing advanced Family Planning procedures. To complete a procedure, a provider relies on both feeling that the uterus is empty by utilizing forceps and uterine curetting and performing ultrasound, which is what Dr. Hern did in this case. The appearance of a white “hypoechoic” stripe on ultrasound, as was seen in this case, assists the provider in confirming an empty uterine cavity. With an open cervix, air enters the uterine cavity and is seen as “white” on ultrasound. As Dr. Theiler testified in her deposition regarding her own case where she experienced the same complication, a thin fragment can be missed as it conforms to the contour of the uterine cavity. It is a rare, but known complication, and not an indication of medical negligence.
- 3) Inspection of what was removed from the uterus was performed by both Dr. Hern and then again by his staff according to accepted clinical guidelines (2,4). The fragment(s) removed at the time of hysterectomy did not represent a clinically significant portion of the pregnancy as claimed by the plaintiff’s expert witnesses. It is significant that she had no pain, clotting or symptoms of retained products (such as she had in her first miscarriage) at the completion of the procedure or over the course of the next year.

Review of Dr. Hern’s practice and the Boulder Abortion Clinic medical record reveal a reasonable and thorough history and physical exam, detailed pre-procedural counseling, informed consent and a detailed clinical record of the events that took place on the four days that Mrs. DeBuhr received at Boulder Abortion Clinic. Upon completion of her care, the plaintiff was provided with information regarding follow-up and encouraged to contact the clinic with any signs of symptoms of delayed complications. All of this is indicative of reasonable and appropriate care by Dr. Hern and the other providers at BAC.

Evaluation of Care at Methodist Health System:

Mrs. DeBuhr presented again (1/27/15) to Dr. Carlson 1 year after her post-op visit with him. She had symptoms of “bleeding on birth control” and was noted to have an exam showing a NT (“non-tender”) Ut (“Uterus”). No uterine tenderness was noted. After that visit, Dr. Carlson ordered a CBC (complete blood count) and a pelvic ultrasound to assess the level and nature of her bleeding.

Evaluation of her blood counts to assess anemia (blood loss from excessive bleeding) and comparison with prior labs demonstrate:

- Her Hematocrit/Hemoglobin (H/H) levels on 1/27/15 were (40/13.3).

- This H/H (40/13.3) was the highest level that can be found in review of her medical records dating back to her first miscarriage in 2005 (35.7/12.8) and does not reflect an anemia state, which suggests she had not suffered significant bleeding prior to the 1/27/15 with Dr. Carlson.
- Her hematocrit at the time of her procedure with Dr. Hern (12/3/13) was (35.4).
- Her H/H at the time of her post-op visit with Dr. Carlson (1/3/14), one month after her procedure at Boulder Abortion Clinic, was (38/12.6) demonstrating minimal blood loss at the time of her procedure.
- There is no record of her menstrual history over the year following her D&E.
- There is no record of whether she was taking her hormonal birth control pills regularly.

The pelvic ultrasound (1/28/15) revealed:

- Echogenic foci 3.5 cm appears in the lower uterine segment indeterminate but concerning for a foreign body.

Dr. Carlson then scheduled a “diagnostic laparoscopy and hysteroscopy with possible hysterectomy if bleeding/perforation should occur”.

- There was no separate visit to discuss the findings of a “foreign object” in her uterus, but rather a brief meeting before the surgery on 2/5/15.
- There is no concrete evidence that the inert foreign object, that was not noticed by the patient or her physicians for more than a year, was the source of her bleeding.
- A note for her medical record (10/08/2005) by Dr. Kenney noted a history of “some significant bleeding in her uterus”.
- In the (History and Physical) H&P Dr. Carlson noted a uterus that was: “mobile, tender, no uterine masses appreciated”. The finding of “tender” is different than the findings on 1/27/15 that preceded the ultrasound report.
- In the H&P, Dr. Carlson states “She is passing large clots, grapefruit in size.”
 - This statement is refuted by the H/H mentioned above and the fact that Plaintiff in her deposition stated that the symptoms of passing clots was during a miscarriage and not in relation to her bleeding at the time of her hysterectomy.
- There is no record of counseling for risks, benefits and alternatives to an operative hysteroscopy/laparoscopy prior to this surgery. Dr. Hern, Dr. Robertson or local experts (who provided direct care and expert witness testimony for the plaintiff) were not consulted for advice or alternative therapies.
- Alternative treatments for Plaintiff’s condition at that time included Dilation and Evacuation (D&E) and, if unsuccessful, a hysterotomy with excision of “foreign object” via laparoscopy or laparotomy (abdominal incision). Neither

of these procedures remove the uterus, resulting in permanent cessation of fertility.

- After unsuccessfully removing the foreign object with hysteroscopy, Dr. Carlson performed an abdominal hysterectomy on his patient stating that the “patient was 100% convinced that she did not want more babies”.
- In his Operative Report, Dr. Carlson states the patient is certain she has no desire for future childbearing.
- In the History and Physical Exam prior to the hysterectomy and in the consent form suggesting a possible hysterectomy, the two indications for hysterectomy cited by Dr. Carlson were uterine perforation or bleeding, neither which occurred as evidenced by the operative report and his testimony at deposition.
- There is no operative report of the laparoscopy. Normally findings would include inspection of the abdomen and pelvis and any findings related to the hysteroscopy that was being performed simultaneously.
- There are no details reported in Dr. Carlson’s hysteroscopy that are standardly reported such as fluid type and volume of used.
- There is no discussion in the operative report as to why an attempt to perform a dilation and evacuation wasn’t performed (despite having laparoscopy).
- The Pathology report demonstrates a “hole” in the posterior uterus that Dr. Carlson states in his testimony is not the site of a uterine perforation, but rather normal trauma from a tenaculum utilized to grasp the uterus during the hysterectomy. If this is the case, why is there not a corresponding traumatic site on the anterior aspect of the uterus (as tenaculum have two grasping sides)?
- Because there was no bleeding or perforation at the completion of the failed hysteroscopy/laparoscopy, Dr. Carlson should have ended the operation, awakened the patient and consulted an expert in removing foreign bodies from the uterine cavity. He instead performed an emergency hysterectomy that resulted in permanent sterilization “to fully assure ourselves that the foreign object had been removed and if there was a bleeding issue”.

Review of these medical records of Mrs. DeBuhr revealed a finding of a foreign body in the uterine cavity, possibly a residual fragment of fetal calvarium from the procedure by Dr. Hern 14 months earlier. She had no significant pain, clotting or other signs of retained products of conception that included two visits to Dr. Carlson and one to Dr. Robertson. The finding of a possible residual portion had minimal effect on her blood count, as her H/H were at the highest recorded level at the time of the finding.

Dr. Carlson’s decision to perform an urgent hysterectomy in this patient who was in a stable and benign condition at the time of her surgery has nothing to do with the care that was provided for Mrs. DeBuhr by Dr. Hern 14 months earlier. Rather than consult Dr. Hern for advice on how to manage something he had never encountered

and had no experience in managing, Dr. Carlson sent Dr. Hern the pathology report for a hysterectomy that was neither indicated or necessary. Retained Products of Conception following a pregnancy termination is an uncommon, but known complication of pregnancy termination procedures. The recognition and management of this complication require emotional support and can typically be managed with a brief outpatient Dilation & Curettage or Evacuation (D&C or D&E). I have personally managed this complication gently and safely on multiple occasions. In short, the hysterectomy was not caused by Dr. Hern and was not a result of any of the care provided by Dr. Hern.

Dr. Regan Theiler, Expert Witness for the Plaintiff provides an example of this very complication in her own practice during her Expert Testimony. She had a similar complication of retained fetal parts and requested a colleague to manage the brief D&E procedure that removed the retained fetal calvarium fragment without any abdominal surgery.

While it is true that performing a hysterectomy will stop uterine bleeding, it is not in itself an indication for major surgery such as a hysterectomy. There are many medical and surgical options available to manage uterine bleeding including bleeding caused by retained products of conception. Other than hysterectomy, unfortunately for the plaintiff, her treating physician Dr. Carlson did not consult a more experienced provider or offer the plaintiff an opportunity to consult other physicians that may have provided alternatives to hysterectomy, such as a simple D&E or fertility-sparing procedure such as hysterotomy and removal of the fragments.

The fact that Dr. Carlson had immediate access to local, more knowledgeable providers like Dr. Robertson (and was encouraged to and declined to contact Dr. Hern if he had any questions regarding Mrs. DeBuhr's care at Boulder Abortion Clinic) makes Dr. Carlson solely responsible for the hysterectomy and permanent sterilization of Mrs. DeBuhr.

As stated earlier, the care and treatment rendered by Dr. Hern and the staff at the Boulder Abortion Clinic was reasonable and appropriate and not the cause of any injury or damages to the Plaintiff. My opinion and testimony is given in recognition that it can be subjected to peer review by any and all professional organizations that I belong to.

Fredrick Hopkins, MD

Materials in support of this opinion include:

--Jennifer DeBuhr's Medical Records from Boulder Abortion Clinic and Methodist's Women's Hospital supplied to me by defendant's attorneys.

--Deposition materials provided to me by defendant's attorneys.

1. Hern, W., Fetal diagnostic indications for second and third trimester outpatient pregnancy termination, *Prenatal Diagnosis*. 2014 May; 34(5): 438-444.
2. *National Abortion Federation Clinical Policy and Guidelines*, 2013. National Abortion Federation.
3. *National Abortion Federation Clinical Policy and Guidelines*, 2016. National Abortion Federation.
4. Paul, M, et al, editors. *Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care*. 2009, National Abortion Federation and Blackwell Publishing Ltd. Chapters 11, 12, and 15, and Figure 15.4.
5. *Society of Family Planning Clinical Guidelines. Cervical preparation for surgical abortion from 20 to 24 weeks' gestation*. 2008. *Contraception* 77:308-314
6. Bartlett L, et al., Risk Factors for Legal Induced Abortion-Related Mortality in the United States. *Obstetrics & Gynecology*, 2004 April; 103(4)729-737.
7. Zane, S. et al., Abortion-Related Mortality in the United States 1998-2010. *Obstetrics & Gynecology*, 2015 August, 125(2)258-265.
8. Gatter, M. et al., Eliminating the routine postoperative surgical visit. *Contraception*. 2012; 86:397-401.
9. Raymond, E, Grimes, D, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States. *Obstetrics & Gynecology*, 2012, February; 119(2, Part 1)215-219.
10. Creanga, A, et al., Pregnancy-Related Mortality in the United States, 2006-2010. *Obstetrics & Gynecology*, 2015, January; 125(1)5-12.



University of Colorado
Anschutz Medical Campus

Department of Obstetrics and
Gynecology
University of Colorado Anschutz
Medical Campus
12631 E. 17th Avenue
Mail Stop B198-1
Academic Office 1, Room 4006
Aurora, CO 80045

o (303) 724-2034
c (303) 815-9340

f (303) 724-2056

e kristina.tocce@ucdenver.edu

December 5, 2016

Dear Amy E. Cook-Olson Esq.,

I have had the opportunity to review the records that you sent me regarding the care given to Jennifer Debuhr by Dr. Warren M. Hern at the Boulder Abortion Clinic. My written review and opinions are below.

Area of specialization & qualifications:

I am a board-certified Obstetrician/Gynecologist and an Associate Professor in the Department of Obstetrics and Gynecology at the University of Colorado. I serve as the Assistant Director for the Fellowship in Family Planning at the University. I am a fellow of the Society of Family Planning, a member of NARAL Pro-Choice America, and a member of Physicians for Reproductive Choice and Health. I am a Ryan Program Site Reviewer for the National Office of Family Planning. My education, experience, and scholarship are discussed in more detail in my *curriculum vitae*, which is attached.

The medical practice of Family Planning involves the provision of specialized reproductive health care, including providing comprehensive contraception consultation, laparoscopic and hysteroscopic sterilization procedures, and pregnancy termination in the first and second trimesters. My practice of Family Planning in Colorado is based at the University of Colorado Anschutz Medical Center, where I provide clinical and surgical care to patients. As an Associate Professor of Medicine, I educate and train medical students, Ob/Gyn residents, and Family Planning Fellows on termination indications, techniques, and procedures. I am extensively familiar with the practice of pregnancy termination, including the termination of pregnancies in the second trimester due to fatal fetal abnormalities, similar to Jennifer Debuhr's presentation in this case. While pregnancy terminations for fetal and maternal indications beyond 24 weeks are less common, I have performed and taught termination of pregnancy up to 32 weeks gestation.

I am substantially familiar with the medical practice of Warren Hern at the Boulder Abortion Clinic in Colorado. The University of Colorado has referred patients to Dr. Hern, as a reasonable and competent physician, since the time I began my practice at the University (2006). I am familiar with the techniques utilized by Dr. Hern for pregnancy terminations at 24-26 weeks, as his protocols are well-published in the literature. I have personally observed some of

Dr. Hern's techniques pertaining to late abortions. Dr. Hern provides a service and access to pregnancy termination in cases where no other physician in the country may offer or have experience in this area. According to Dr. Robertson, (a maternal fetal medicine specialist), Dr. Hern was the only physician in their referral base available to assist with a pregnancy at this gestational age. This illustrates the limited access to late abortion services, and to providers who have the skill and experience necessary to perform procedures like the one performed on Jennifer Debuhr. I have cared for patients like Jennifer in my career, including providing indicated pregnancy terminations beyond 24 weeks for lethal anomalies.

Materials reviewed:

I have reviewed the medical chart of Jennifer Debuhr from the Boulder Abortion Clinic along with records from her providers, both before and after her pregnancy termination. I have reviewed the Plaintiff's expert endorsements, along with the depositions of her treating physicians and experts. I have reviewed the depositions of Dr. Hern, Jennifer Debuhr, and Jason Debuhr. I will review additional records, documents, and depositions as they become available.

Basis of opinions:

In addition to my review and analysis of the medical records and other documents relating to the case set forth above, my opinions are based upon my education, experience, and scholarship in Obstetrics/Gynecological and Family Planning. I am substantially familiar with the applicable guidelines referenced by Plaintiff's experts including the National Abortion Federation Clinical Policy Guidelines and related textbook [Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care], the Society of Family Planning Clinical Guidelines, and ACOG guidelines regarding abortion care. I may address any of these materials in support of my opinions at trial, along with the publications authored by Dr. Hern as outlined in his C.V. I may refer to any of my studies and publications contained in my C.V. in support of my opinion. I may also refer to numerous peer reviewed publications in support of my opinions. At trial, I may reference, draw, or exhibit any of the instrumentation utilized by Dr. Hern as referenced in his protocols and as used in this procedure. I may draw or use anatomical demonstratives to exhibit the anatomy, and procedure.

Summary of the Case:

On December 3, 2013, Jennifer DeBuhr presented to the Boulder Abortion Clinic for termination of pregnancy. At the time, Jennifer [REDACTED] G5P1122 at 26 weeks gestation by LMP. At the clinic, the BPD measurement was 6.1 cm, consistent with 23 wks, and the FL was 4.5 cm, consistent with 25 wks. Her prior obstetric history was complicated by 2 prior Cesarean sections. Her first child, a boy named [REDACTED] was born in 2007 with severe anomalies due to absence of the corpus callosum. Mr. & Mrs. Debuhr described in their depositions how [REDACTED]'s severe anomalies caused him great suffering. The family institutionalized [REDACTED] for care. [REDACTED] did not have purposeful movements and he required ventilation assistance (tracheostomy), feeding through a G-tube, and diaper changes. Her daughter, [REDACTED] was born in 2011 and is developmentally normal. Jennifer had also suffered two first trimester miscarriages.

Jennifer's medical history was significant for obesity (BMI=35) and endometriosis requiring two laparoscopic surgeries. Her history of endometriosis symptoms included irregular vaginal bleeding and pelvic pain. Detailed fetal ultrasound and MRI done in Nebraska verified that the current pregnancy was male and also affected with absence of the corpus callosum. She was counselled that this fetus may have an even more severe presentation than [REDACTED]. Jennifer and her husband Jason made the difficult decision to terminate this very desired pregnancy. They had the support of their families and Jennifer's mother traveled to Colorado with them for the 4 day procedure.

On December 3rd, 2013, Jennifer underwent the standard informed consent process at the Boulder Abortion Clinic. She received written material and watched a video. This material included the risk of retained tissue after termination of pregnancy. She signed the consent form and Dr. Hern then performed a feticidal injection. On December 4th he placed one #8 laminaria into the cervix. On December 5th he removed the laminaria and placed 6 new ones. On December 6th, at 11:00 am Dr. Hern ruptured membranes and placed 400 micrograms of misoprostol into the lower uterine segment. At 12:29 pm a cervical exam revealed the cervix to be 1-2 cm dilated, thick and high. At 1:08 pm a repeat exam was recorded as 1-2/10% and the cervix was "almost impossible to reach." At 2:48 pm the procedure started and concluded 17 minutes later. A dilation and evacuation (D&E) was performed under ultrasound guidance. A lab technician noted that all fetal parts and placenta were identified. The cavity was felt to be empty by forceps and curette inspection. A transabdominal ultrasound revealed a thin endometrial stripe. After 2 hours of observation post-operatively, another transabdominal ultrasound revealed a thin endometrial stripe and the patient was discharged with minimal vaginal bleeding.

Jennifer then presented to Dr. Mark Carlson for the first time for the recommended follow-up examination 4 weeks after her termination. Dr. Carlson documented a normal exam and no abortion complications or abnormal bleeding. His note states that the patient does not desire future pregnancies. Both Jennifer and Jason state in their depositions that they could tell Dr. Carlson did not approve of their decision to terminate the pregnancy and that they needed to be "fixed." Dr. Carlson revealed in his deposition that he was not supportive of this decision and that he would need to consult his pastor regarding the clinical pregnancy care. He referred them to a Christian agency for counseling.

In March 2014, [REDACTED] died due to his severe anomalies. Around this same time, Jennifer was in contact with her maternal fetal medicine physician, Dr. Andrew Robertson. He discussed her risks for recurrent anomalies in male fetuses (she is thought to be a carrier for an X-linked recessive mutation). They discussed assisted reproductive technology and at this point, both Jennifer and Jason decided they would like to pursue the possibility of having additional children. She received birth control pills (BCPs) from Dr. Robertson at this time. She states that over the course of 2014, she experienced irregular uterine bleeding and her BCPs were changed based on phone contact. Despite this bleeding, she was not anemic. By the end of 2014, she re-presented to Dr. Carlson due to her irregular bleeding pattern. He ordered an ultrasound which revealed a foreign structure in the uterus. On the phone he told her that he thought it was due to the prior termination and scheduled her for surgery. In her deposition, Jennifer stated that she was told that she needed surgery over the phone. She was scheduled for the surgery, which she

assumed would be a laparoscopy. On the day of surgery (2/4/2015), Jennifer was informed that a hysteroscopy would also be done and a hysterectomy may be necessary to completely remove the foreign material. She did not have a preoperative appointment with Dr. Carlson prior to the surgery, nor did she discuss any other alternative treatment options with him.

During the OR case, a diagnostic hysteroscopy was performed and a posterior uterine perforation occurred. Dr. Carlson's operative report indicates that the bone "chipped and it only came off in fragmented pieces" when grasped hysteroscopically. Dr. Carlson made the decision to immediately proceed with total abdominal hysterectomy and bilateral salpingectomy. Jennifer then had some post-operative issues with wound healing, but the hysterectomy was otherwise uncomplicated.

After the hysterectomy, Jennifer sought counseling. In 2009 she was diagnosed with depression and incapacitating migraine headaches, exacerbated by stress. She was now (in 2015) diagnosed with adjustment disorder with mixed anxiety and depressed mood. She was grieving over the loss of her son and deciding how to proceed with her marriage. Jennifer was a victim of verbal and physical abuse; in addition, her husband had been having an affair for the first few years of their marriage. Currently Jennifer and Jason state that their marriage is a "work in progress."

Opinions: I thoroughly reviewed the care rendered in this case. It is my opinion that the care and treatment rendered by Dr. Warren Hern and the staff at the Boulder Abortion Clinic was, at all times, reasonable and appropriate. I disagree with Jennifer Debuhr's expert witness opinions to the contrary. In medical care, it is important to review care without the burden and prejudice of hindsight bias; the mere occurrence of a complication does not indicate that the care was substandard. Complications occur even in the best of medical care, and are not always avoidable. These events, including the loss of her son, verbal and physical abuse by her husband, and her husband's history of infidelity reasonably explain Ms. DeBuhr's reported depression and other symptoms mentioned above.

It is my opinion that termination of pregnancy at 26 wks from LMP, and the referral to Dr. Hern by Dr. Robertson at the request of the patient, was indicated due to the catastrophic fetal anomalies (and the history of similar abnormalities in a prior pregnancy that resulted in the birth of a child, who was institutionalized and died at age 7). Nebraska law prohibits termination of pregnancy at this gestational age, requiring Jessica and her family to travel to Colorado for this procedure.

While the procedure was indicated, it was not without the potential for complication given the patient's multiple risk factors. These including obesity, two prior cesarean section deliveries, no prior vaginal deliveries, and advanced gestational age (presentation at 25 5/7 days at day one of the procedure and 26 1/7 days on the day of surgery). Risks associated with this procedure were reasonably outlined in the written informed consent performed by Dr. Hern, and were extensively discussed in the booklet reviewed by the patient along with the video: Having an Abortion. Dr. Hern reasonably consented the patient to the procedure. Risks of the procedure included hemorrhage, cervical laceration, infection/sepsis, retained fetal tissue, uterine perforation and/or rupture, hysterectomy, and even death. Considering all of the risks involved with the procedure, retained fetal tissue is one of the lesser complications when related to

morbidity and mortality. While rare, retained fetal tissue is a known and recognized complication of abortion at any gestation age. Observational data and several retrospective cohort trials consistently confirm the safety of D&E; major complications occur in less than 1% of D&E cases [Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care] is reported in the literature. A recent review of 54,911 abortions identified a major complication rate of 0.41% for second-trimester or later procedures [Upadhyay UD et al. Incidence of emergency department visits and complication after abortion. Obstet Gynecol. 2015].

While retained fetal bone is a reported complication of D&E, it rarely results in hysterectomy. A search of “retained bone after abortion” in PubMed yields over 10 case reports; in all reports, the bone was removed by minimally invasive means (ultrasound guided D&E and operative hysteroscopy); multiple patients had restoration of fertility after removal of bony fragments. In this case, hysterectomy was not reasonably indicated for the removal of the fetal bone. There was no urgency for definitive surgery; the patient was completely stable. Jennifer does not remember discussing her future fertility desires immediately prior to surgery. If Dr. Carlson was unable to remove all of the bone that day, he should have terminated the procedure, and discussed various options with Jennifer. The pathology report indicates that only a 0.5 cm portion of myometrium had bone imbedded; the bony fragments measured 3 x 2 x 0.1cm. “Chipping” the non-embedded bone out followed by resection of the small imbedded portion by operative hysteroscopy should have been attempted before moving to hysterectomy. Another option would have been increasing cervical dilation and performing an ultrasound guided D&E. Either of these procedures would have been a logical next step, NOT hysterectomy. Jennifer unfortunately experienced a known complication of abortion (retained tissue), that can be rectified with non-invasive means. Neither Dr. Hern nor the staff at the Boulder Abortion Clinic caused the need for a hysterectomy; Dr. Carlson’s rush to hysterectomy without exploring other means for removal of the bony fragments was completely unindicated in this stable patient, who until the day of surgery, did not know that a hysterectomy was a possibility.

Dr. Carlson’s notation that Dr. Kling, his assistant, “could identify by palpation of the anterior uterus with laparoscopic instrument that the bone had penetrated up almost through the serosa.” This is contradictory to the pathology findings of a small 0.5 cm area of bony material wedged into the lower uterine segment; there was no evidence of bony fragment perforation through to the outer lining of the uterus (serosa). Also, laparoscopic instruments do not allow for “palpation”---palpation is a tactile sensation, a sensation which cannot be appreciated/transmitted through metal instruments. Dr. Carlson states in his operative report that “the patient was 100% convinced that she did not want more babies.” All of these factors/discrepancies make the decision to proceed to hysterectomy at that time problematic.

Dr. Hern and the Boulder Abortion Clinic’s care from the time the patient presented by phone requesting the procedure, through the time the termination was completed, was reasonable and appropriate. The patient was reasonably counseled prior to the procedure and informed consent was appropriately obtained. The patient underwent several days of slow cervical ripening with laminaria. On the fourth day of the presentation, Dr. Hern reasonably proceed with surgical evacuation of the uterus. Dr. Hern proceeded with rupturing membranes and placing intrauterine misoprostol—a procedure he has utilized for decades, as is also published in the literature. The

purpose of this approach is to encourage further cervical dilation. In Dr. Hern's Global Library Women's Medicine chapter "Second-Trimester Surgical Abortion," he describes in detail his multi-day technique to atraumatically dilate the cervix. The use of amniotomy with a 12-mm cannula and intrauterine misoprostol is utilized to induce labor; if fetal expulsion does not occur due to poor cervical dilation or uterine atony, the fetus and placenta are then removed with forceps. Dr. Theiler's deposition statement re: the "strange practice" of rupture of membranes before achieving "adequate dilation" shows that she is not aware of Dr. Hern's practice of inducing labor. In many settings, D&E's at less than 24 weeks are often performed immediately after removing overnight laminaria. However, due to the gestational ages that Dr. Hern often manages, he induces labor and performs a D&E if fetal expulsion does not occur. There is nothing in any of Plaintiff's cited guidelines to suggest that this procedure is not reasonable and appropriate.

Drs. Robertson and Theiler both attest that there was failure to achieve adequate dilation for the D&E. Dr. Theiler states that it is "her opinion" that 3 cm of dilation is needed. This is purely her opinion, without basis or support from any guideline or literature. Management of Unintended and Abnormal Pregnancy; Comprehensive Abortion Care's chapter on Dilation and Evacuation does not make any reference as to a number of centimeters required to perform a procedure at a certain gestational age. Experienced operators are often well-equipped to deal with cervical dilation that is less than optimal; the procedure is not postponed or transferred to an Operating Room setting. The minimal dilation needed depends on what forceps are needed to complete the procedure. Due to the diameters of the instruments, Ring forceps require cervical dilation of 10-12 mm, Sopher's 13-15 mm, Hern's 13-15 mm, and Bierer's >15 mm. These forceps allow for decompression of the calvarium and for a BPD that is larger than the cervical dilation to be removed. With cervical dilation of 2 cm, it is very possible to extract a fetus with a BPD consistent with the measurements documented on Jennifer DeBuhr's pre-procedure ultrasound. Cervical preparation clearly reduces the risks of D&E; however, there is no standard approach to cervical preparation. A recent review by Shaw et al [Curr Opin Obstet Gynecol. 2016] summarizes over 8 peer reviewed publications since 2012 reporting various means of cervical preparation prior to D&E: laminaria, Dilapan-S, misoprostol and mifepristone.

Drs. Robertson and Theiler also state that failure to identify the retained bony fragments on the immediate post-operative ultrasound and on the ultrasound performed immediately prior to discharge are consistent with a breach of care/deviation from standard of care. I disagree with these opinions. By direct ultrasound visualization, forceps and curettage inspection of the uterus, the uterus was felt to be empty. The patient's bleeding was normal. Portions of the extracted calvarium were noted by Dr. Hern (during the procedure) and the lab tech (after the procedure concluded) to be present; however, portions of bony tissue, with a maximum size of 3 cm, were retained. At the end of any procedure, the endometrial stripe (a finding consistent with an empty uterine cavity) can appear significantly echogenic ("white" on ultrasound). Flat bony fragments will also appear thin and white on ultrasound (just as the endometrial stripe does). The images captured by the Boulder Abortion Clinic staff appear to show a very normal appearing empty endometrial cavity, and show no evidence of retained tissue. Even in hindsight, the ultrasound images provided do not show any evidence of retained tissue.

Dr. Theiler also implies that Dr. Hern should have delayed the procedure on day 4, until more

cervical dilation was obtained. Dr. Theiler has never performed an abortion over 24 weeks gestation. Dr. Hern is one of the most experienced physician in the nation at performing late terminations. He reasonably proceeded with the procedure on day 4 of presentation. There was no contraindication to proceeding with the termination on day 4; even if 2 cm was the maximum dilation obtained, this is sufficient for a D&E with Beirer's forceps. Rupturing membranes and placing the misoprostol yields greater dilation and less tension when extracting tissue. The dilation was sufficient to avoid other serious complications, such as uterine perforation or cervical tear.

Proceeding with the termination on day 4 was also indicated given the patient's discomfort and symptoms of nausea and vomiting. She presented to the clinic earlier than her scheduled appointment due to these symptoms. It would have been unreasonable to have the patient wait for days or weeks, as suggested by Dr. Theiler, when the procedure could be performed on that day, in the skilled hands of an experienced provider. Delaying the procedure as suggested by Plaintiff's experts could have resulted in increased risk to the patient.

Dr. Theiler also contends that failure to document certain details of the procedure is a deviation from the standard of care. More detailed documentation of the procedure may have been possible; however, the lack of such details did not cause the complication of retained tissue and this certainly did not cause the hysterectomy. Dr. Brianne King, who assisted Dr. Carlson during the surgery, did not produce any operative report for her portion of the surgery (the laparoscopy). This complete failure to document an operative procedure also did not cause the hysterectomy. As stated above, the hysterectomy was caused by Dr. Carlson's decision to proceed with an invasive treatment rather than investigate minimally invasive options that would have preserved Jennifer's fertility.

After discharge, Dr. Hern's follow up was beyond reasonable care as demonstrated by his multiple communications and follow-up with the Nebraska providers and the patient. The patient had also filled out a survey demonstrating her satisfaction with her medical care.

In conclusion, the care rendered by Dr. Hern and his medical staff was reasonable and appropriate and was not the cause of Jennifer Debuhr's hysterectomy or other alleged damages.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Kristina', followed by a long, horizontal, slightly wavy line that extends across the width of the signature area.

Kristina Tocce, MD, MPH
Associate Professor
Department of Obstetrics and Gynecology
Division of Family Planning
Assistant Director, Fellowship in Family Planning