71320-5

71320-5

NO. 713205-1

COURT OF APPEALS
DIVISION I
STATE OF WASHINGTON

SNOHOMISH COUNTY SUPERIOR COURT NO. 13-2-07244-9

JULIA MITCHELL, STEPHONE MITCHELL

Appellants/ Plaintiffs

VS

BOURNE RANDOLPH

Respondent/ Defendant

APPELLANT'S REPLY BRIEF

Julia and Stephone Mitchell
P O Box 1913
Lynnwood, WA 98046
Appellants/Plaintiffs Pro se

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(Included in Appendix A are exhibits from the clerk's papers and other records from Department of Health for the ease of this court)

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I. INTRODUCTION RESPONSE

Julia and Stephone Mitchell's complaint pleads discovery of the injury (normal pregnancy) from Department of Health's findings, fraud and lack of informed consent.

Dr. Bourne alleges that all facts were construed in light most favorable to the Mitchell's however, a review of the evidence indicates fraud that resulted in destruction of the key element for a cause of action. Dr. Bourne misrepresented the uterine tissue as ectopic tissue which resulted in a karyotype analysis not being performed by the pathologist. [Appendix, EX:1], Note: clinical information he sent to the pathologist reads: "ectopic pregnancy, site not stated", the copy of this is attached in the appendix for the ease of this court. Dr. Bourne already admitted this to the lower court [CP 119 qn 8, 77].

In his brief, Dr. Bourne alleged that "Mitchell's administrative complaint explains in detail why she believes he was negligent and how his alleged negligence caused her injuries" This is the same response that Dr. Bourne used with the lower court and is using with this court. This response is referring to termination of a supposed failed uterine pregnancy based on the then missing ultrasound whereas the Mitchell's are referring to termination of a "normal pregnancy" based on the findings from Department of Health's investigative report.

At the time of filing a complaint with Department of Health in 2011, the Mitchell's had learned of the presence of the yolk sac on the missing ultrasound however, they did not know of their injury (termination of a normal pregnancy) because no karyotype analysis was performed on the tissue that Dr. Bourne obtained from Julia's uterus. Department of health also felt that there was insufficient evidence for them to come to a conclusion in March 2012 thereby requested more additional information from Dr. Bourne and also responses in "his own handwriting" [CP 75]. Dr.Bourne attempted to disagree with Department of Health about the pregnancy hcg levels being normal and referenced a conversation he had with Dr. Rogers regarding hcg levels and ectopic pregnancies.[CP 30]. Fortunately, there were two obstetricians on the investigating committee and they believed the hcg levels were within the "normal range" for a 7 to 8 week pregnancy [CP 29]. Dr. Bourne states the Mitchell's complaint to the Department of Health indicates how his negligence caused Julia's injuries. Dr. Bourne however fails to state where Julia may have complained of her injury relating to termination of a "normal pregnancy" because there was never such a complaint since Julia did not know of "this injury". This is simply because the injuries known at that time were termination of "a pregnancy" and not a "normal pregnancy" [CP 87]. Negligence resulting into termination of a failed pregnancy is not a cause of action for a civil suit as their are no injuries

suffered. On the other hand, negligence relating to termination of a "normal pregnancy" results into injury and this is what the Mitchell's complaint is about.

Julia a nurse did not know that her pregnancy was normal at the time of filing a complaint with Department of Health in 2011. She had one ovary after Dr. Bourne removed one and had been experiencing fertility issues. During her consults with specialists in fertility and obstetrics, Julia informed the physicians as part of her medical history that she had a failed pregnancy because that was what she had been made to believe she had [CP 64] until Department of health notified her on November 20, 2012 of their findings.The complaint to Department of Health does not state anywhere negligence due to termination of a "normal pregnancy". Julia exercised due diligence by filing a complaint with Department of Health in August 2011 and in November 2012, "discovered the injury" she sustained that she presents before this court. On November 20, 2012 Julia and Stephone Mitchell learned that the pregnancy with their first child was normal and was terminated by Dr. Bourne. They then filed a civil suit against Dr. Bourne on September 5, 2013 which is well within the one year deadline for discovery claims. Under de novo review, the trial court's summary judgment should be reversed.

II. RESPONSE TO RESTATEMENT OF THE ISSUES ON APPEAL.

1. The alleged negligence occurred in 2008. However, the injury before this court

(termination of a normal pregnancy) was unknown till November 2012 . Did the lower court properly grant summary judgment dismissing Julia and Stephone Mitchell's claim even though they did not learn of this injury prior to November 2012?

2. In response to tolling of the statute of limitations based on intentional concealment, Julia and Stephone Mitchell did not learn of the key fraud in this case as there were a series of them. The key fraud scheme in this case was relating to the hcg levels since the tissue was no longer available for testing. Dr. Bourne fraudulently informed Julia that her hcg levels were not rising [CP 22]. If Julia and Stephone Mitchell had known that the hcg levels had actually risen to the normal level, Julia would not have ever signed the consent to surgery. Julia's primary obstetrician Dr. Bray had even made a note in reference to the hcg and ultrasounds "warning to be cautious while treating Julia as this was a highly wanted pregnancy" [Appendix, EX: 5]. Dr. Bray also charted that he did not expect to see the hcg levels double since they were high up in the thousands and he was hopeful that the next ultrasound would show a little more since the pregnancy was quite young [Appendix, EX: 5]

III. RESPONSE TO RESTATEMENT OF THE CASE

RESPONSE TO RESTATEMENT OF PERTINENT FACTS.

Appellant Julia Mitchell's profession was mentioned to the lower court as is to this

court. Julia Mitchell would like to inform the court that she at the time of the surgery was a medical / orthopedic nurse and not obstetric nurse. Her knowledge of obstetrics was so limited and that she had trusted Dr. Bourne to treat her within the standard of care of an obstetrician. What was interpreted as vaginal bleeding was actually implantation bleeding and at the time Dr. Bourne performed surgery on Julia Mitchell, Julia had no spotting, no bleeding, no pain and all vital signs were stable. Dr. Jeffrey Bray, Julia's primary obstetrician was less suspicious that Julia had an ectopic and assumed there was a uterine pregnancy [Appendix, EX: 5] and believed the pregnancy was too young to make a conclusion hence the series of ultrasounds ordered.

Bare in mind that the pregnancy was still very young and Julia's uterus was retroverted (tipped) which often obscures visibility. When a uterus is tipped, the fetal pole is often not seen in many of these pregnancies not until later in the pregnancy and this varies depending on the skill of the technician and ultrasound machine being used.

Regarding the consent form Dr. Bourne had Julia sign prior to the surgery, the consent form states in relevant part that:

"I recognize that during the course of the operation..... unforeseen conditions may necessitate additional or different procedures than those above set forth .....
The authority granted under this paragraph shall extend to the treatment of all conditions that require treatment and are not known to my physician at the time the medical or surgical procedure is commenced". [CP24, EX:4]

Dr. Bourne however stated in his October 20, 2008 preoperative note that the right ovary appeared to be abnormal and had a cystic mass [CP 22, EX: 4]. He was aware of this when he reviewed the October 17, 2008 ultrasound but did not tell Julia and Stephone Mitchell about this finding in his pre-operative counseling on October 20, 2008. He proceeded to cut the entire ovary out on October 21, 2008 without consent from Julia or Stephone.

Dr. Bourne continues to argue in his response that he removed a "failed pregnancy" and not a "normal pregnancy". Department of Health did not agree with him and thereby took disciplinary action against him. Dr. Bourne also removed Julia's entire right ovary because Julia had a dermoid cyst which is normally resected. Apparently Julia had informed Dr. Bray that she comes from a family with a history of dermoid cysts and fibroids.Knowing what Dr. Bourne stated regarding the October 17 ultrasound showing an abnormally shaped right ovary/ cystic mass and family history of dermoid cysts from Dr. Brays history and physical intake, Dr. Bourne would have known that Julia had a dermoid cyst.

Dr. Bourne again references Julia's complaint that she claims she had not consented to terminating a normal pregnancy and removing her right ovary. The consent clearly reads a diagnosis of a blighted ovum (failed pregnancy and ectopic pregnancy)

to which treatment included a dilation and curretage (removal of the failed pregnancy), salpingestomy and salpingectomy (opening and removal of the fallopian tube). Dr. Bourne had informed Julia at the preoperative visit that "she had nothing in her uterus but a fluid filled sac" [CP 22, EX: 4]. This is not the same as a yolk sac and as a matter of fact, the yolk sac is attached to the embryo and provides nutrients to the embryo. Even when given benefit of doubt that Dr,Bourne looked at the October 17 ultrasound film as he claims instead of the October 20 ultrasound, he avoids the fact that the October 17 ultrasound film indicated an abnormal ovary with a cystic mass.

Dr Bourne acknowledges in his response "Mrs. Mitchell explains that Dr. Bourne was negligent because he allegedly did not fully disclose information and findings contained in the the October 20 ultrasound, namely that there was a visible yolk sac. CP 88). she also complained that she had not consented to terminating a pregnancy and removing her right ovary. (CP 88). [Respondents reply page 5]. This was the complaint to Department of Health however, the complaint in this civil suit is about findings from Department of Health which include termination of the normal pregnancy, fraud/intentional concealment and lack of informed consent to remove the right ovary (unnecessary removal of the ovary)

Dr. Bourne also states that during the surgery for what he believed to be a

laparascopy for a probable ectopic pregnancy, he discovered the almost six-centimeter cystic teratoma [Respondents brief, page 6]. This is inconsistent with what he stated in his review of the October 17 ultrasound that "the right ovary looked abnormal". He further states that the cyst could turn malignant and posed an imminent risk of ovarian torsion. By attempting to cut the cyst out without knowing if it was malignant, Dr. Bourne was actually putting Julia at risk for spread of the cells and if it was indeed malignant, he could have caused the malignant cells to migrate to other areas of the pelvis hence spreading cancer cells. He further talks about imminent risk of ovarian torsion then on the other hand talks about probable emergency surgery in the future. This would have been up to Julia to make that decision since she had no problems with this ovarian cyst that she probably had for several years and her main concern was avoiding complications of an ectopic pregnancy that she did not even have.

In attempting to remove the ovarian cyst, Dr. Bourne stated to the superior court that owing to bleeding, he had to remove the entire ovary. Dr. Bourne however stated in his operative note and to Department of Health that there was an estimated blood loss of 150 ml. This is a very small amount of blood loss to warrant removal of an entire ovary. Julia had the uterine fibroid which was the size of some premature babies removed in 2011 and had a blood loss of 2000 ml (2 liters). Both the uterus and ovary happen to

receive their blood supply from the descending aorta (large blood vessel from the heart pumping large amounts of blood to the lower part of the body). Julia's uterus was not removed due to the 2000 ml blood loss however, Dr Bourne removed her ovary for only 150 ml of blood loss which is not even a tenth of what she lost when she had the fibroid removed. The bleeding was only controlled with application of pressure during that surgery however, Dr. Bourne argued to Department of Health that the kind of bleeding he encountered could not be controlled with pressure application. On the other, Dr. Bourne acknowledged to Department of Health that removal of an ovary due to a cyst is uncommon [CP 28, EX: 6].

Dr, Bourne argues that Julia consented to termination of an abnormal pregnancy. He further states that his partner, Dr. Rogers spoke at length with Julia about her elevated hcg levels and that the pregnancy was clearly not a normal intrauterine pregnancy. Dr.Bourne further states that even with the presence of a yolk sac, an eight week pregnancy with an hcg level of almost 60,000 is not a normal pregnancy [Respondents reply page 7]. This response answer's the question of whether the lower court made an error in dismissing Julia and Stephone's claim to which the answer is yes. This is so because first, Dr. Bourne is acknowledging that the consent he obtained was for an abnormal pregnancy. Julia and Stephone's claim is about termination and lack of

informed consent to terminate a normal pregnancy based on Department of Health's findings.

Second, the discussion between his partner Dr. Rogers, Julia and Stephone is irrelevant because Julia and Stephone declined any treatment from her and requested for another opinion with the hope that Dr. Bray would have been back from vacation for them to follow up with him. Also the discussion between Dr. Rogers, Julia and Stephone is again irrelevant because Dr. Rogers is not the one who ordered the October 20, ultrasound and she is not the one that did the preoperative counseling need to say she is not the one that took Julia to surgery and terminated a normal pregnancy as well as removing her ovary without consent.

Third and foremost, Dr. Bourne is arguing that an hcg level of 60,000 is not normal for an eight week pregnancy and he attempted to use this with Department of Health however they did not agree with him [CP29, EX: 6]. The normal range of hcg levels for a 7-8 week pregnancy is 500 - 200,000. Dr. Bourne further states that because the hcg was 60,000, the pregnancy would have resulted in an "anembryonic gestation" (failed pregnancy). Dr. Bourne is here by saying that regardless of the pregnancy showing a yolk sac, the pregnancy was going to fail however, if this were true it does not give him a right to terminate the pregnancy without Julia or Stephone's consent.

This medical malpractice case has been made complex by the the twists and turns that have occurred right from the time Dr. Bourne first met Julia and Stephone Mitchell for what was supposed to be a follow up antenatal visit while Dr. Bray, Julia's obstetrician was out on vacation. It is evident that Dr. Bourne lied to Julia and Stephone that the pregnancy had failed but in addition to that, he informed them that Julia had an ectopic pregnancy making them think her life was in danger. Instead he put her life in danger by cutting into her ovary then removing it and most heartbreakingly terminated a normal pregnancy making them think she had already lost the pregnancy when this was not even true.

Finally, Julia and Stephone Mitchell agree that the Appellate court reviews summary judgment decisions de novo however, they disagree with Dr. Bourne's allegation that "(Mrs. Mitchell is relying on speculation, argumentative assertions that unresolved matters remain" The specific facts with evidence have been provided in the Appellants opening brief and this Appellants reply brief. Dr. Bourne actually argumentatively asserted that Julia's hcg levels were not normal to the Department of Health Medical Quality Assurance Commission that investigated him. This is the same organization that has experts in the field of medicine and is the same organization that grants him a license to practice medicine in the state of Washington. Dr. Bourne continues to argumentatively challenge Julia and Stephone Mitchell in the courts given

he is a physician even when facts all evidently show he exercised fraud and intentional concealment in this medical malpractice case. Dr. Bourne through his spoilation of evidence / tampering with evidence sent the uterine tissue with clinical information "ectopic pregnancy" and he as a physician knows clearly that a karyotype analysis is insignificant when the pregnancy is ectopic. In addition, Dr. Bourne stated he did not see any chorionic villi during surgery however, the pathologist indicated in his report that there was some chorionic villi seen. Dr. Bourne fails to respond to Julia and Stephone Mitchell's complaint that he ordered the October 20 ultrasound in his response. Department of Health requested of him all medical records unredacted prior to the start of their investigation and the copy of the order he wrote was not submitted even though the nurse Cathy Bently RN did state in her notes that she faxed the order to Stevens radia where the ultrasound was done and the ultrasound report indicates the report was sent to the ordering provider Bourne Randolph. (Note:This ultrasound order/copy is no where to be found to this date)

Dr. Bourne also states in his response [respondents brief 14] that the Department of Health investigative report is five pages - not 300. This is because Julia and Stephone submitted only the pages that addressed the issues they were presenting to avoid burdening the court having to read through 300 pages. If required by the Appellant court,

the 300 pages of the investigative report is available for submission by Julia and Stephone. Second, Dr. Bourne states the word "normal" appears nowhere in the report when it actually appears and reads:

"Question 3: The commission's concern given the above is 1) the patient may have been denied the choice of continuing the pregnancy normal or not, and 2) the risk to the patient if the surgery was delayed until the ultrasound results were available was not sufficient enough that you could not have waited until the results were obtained" [CP 26, EX: 6]

"Question 2: The medical records suggest, and you acknowledged, that you decided to go ahead with a pre-operative evaluation including informed consent on 10/20/2008 and then performed a D&C and laparascopy on 10/21/2008 without benefit of the information that the ultrasound of 10/20/2008 would have provided, and despite the fact that the patient was not bleeding or in pain. The commission finds that though the HCG levels were in the low normal range, they had increased and were in the normal range for a 7-8 week pregnancy, and a level of 53,000 was too high to suggest an ectopic pregnancy" [CP 29, EX:6]

Despite his responses which argued otherwise, Department of Health proceeded to take disciplinary action against Dr. Bourne and this record cannot be expunged. The findings by Department of Health were serious enough for them to take action and it is from these findings that Julia and Stephone discovered their injury. Had it not been for Department of Health carrying out an investigation and obtaining Dr. Bourne's responses in addition to the medical records, this medical malpractice case involving intentional concealment / fraud and lack of informed consent would have gone unnoticed / unknown.

IV. LEGAL ARGUMENT

Julia and Stephone Mitchell's claim was improperly dismissed by the lower court because they filed the civil suit well within one year of discovering the injury of termination of a normal pregnancy and the fraud / intentional concealment relating to the hcg levels. Also because Dr. Bourne never obtained informed consent to remove Julia's ovary or even perform a cystectomy when he was aware that the right ovary had a cyst prior to surgery, dismissal of Julia and Stephone's claim for lack of informed consent was improper.

The statute of limitations that was applied to this case was RCW 4.16.350. The statute clearly states in regard to actions based on the discovery rule:

> Medical negligence shall be commenced ..... or one year of the time the patient ..... discovered or reasonably should have discovered that the injury or condition was caused by said act. RCW 4.16.350(3)

This provision "is triggered by the discovery of the injury or condition that was caused by the action of a medical provider. Courts interpreting this statute have consistently found that the time limit begins to run when the plaintiff discovers his or her injury, Reichelt v. Johns- Manville Corporation, 107 Wn.2d 761,733 P.2d 530 (1987) . The discovery rule applies here because Julia and Stephone had no knowledge of the

injury relating to termination of the normal pregnancy by Dr. Bourne until November 20, 2012. They then had until November 20, 2013 to file suit under the discovery rule. Julia and Stephone filed a civil suit against Dr. Bourne on September 5, 2013.

In Julia's complaint to Department of Health, she mentioned the ultrasound dated October 20 and no where did she mention her hcg levels because she was unaware they were within the normal range. On investigating Julia's complaint based on the ultrasound, Department of Health reviewed the hcg levels and the ultrasound. Disciplinary action against Dr. Bourne was not based on the ultrasound alone and it took a year of investigation and reviews. If the October 20 ultrasound alone was sufficient to conclude the investigation, any jury would clearly see that Department of Health would have taken action much earlier and not wasted their time going back and forth with Dr. Bourne to obtain more information from him including requests for responses in his own handwriting.

In their superior court complaint, Julia and Stephone indicated they did not discover that they had a legal cause of action until Department of Health (MQAC) sent them a 300 page copy of the investigation on November 20, 2012. The cause of action referred to was the injury of termination of a normal uterine pregnancy and not an abnormal pregnancy/ blighted ovum as they had been informed by Dr. Bourne. Under

the law, it is not sufficient to merely state that certain events occurred that entitle a plaintiff to file suit in the courts. The cause of action comprises of elements to which injury is one. Dr. Bourne contends that Julia and Stephone's claim was barred by the statute of limitations even when evidence shows that the injury element of a claim was unknown till later. In Reichelt v. Johns- Manville corporation, the court went on to remand the case to the lower court to make factual findings to determine when Mrs. Reichelt first "discovered" her injuries.

Under the discovery rule in reference to Estates of Hibbard, 118 Wash.2d 737, 826 P.2d 690 (1992):

> "Application of the rule is limited to claims in which the plaintiffs could not have immediately known of their injuries due to professional malpractice, occupational diseases, self reporting or concealment of information by the defendant. ....."

Finally, Julia's October 20, 2008 surgery by Dr. Bourne should never have taken place to begin with. Dr. Bourne never consulted with Dr. Jeffrey Bray, Julia's obstetrician or Dr. Karen Hibbert, Julia's primary care physician who made the obstetrical referral to Sound women's care; regarding his decision to take Julia to surgery. Dr. Bourne ordered the October 20 ultrasound and according to records obtained by Department of Health, evidence showing he ordered the ultrasound was documented by the nurse [CP 20] and the report was faxed by the radiology department to the ordering physician Dr. Bourne

[CP 60,61. EX: 7]. The actual order slip is however missing and was not included in the records Dr. Bourne submitted to Department of Health despite their request for unredacted records. Dr. Bourne never looked at the actual images for the ultrasound even as an obstetrician who is trained to interpret ultrasound films. He proceeded to obtain consent from Julia under the pretence that he had looked at her ultrasound and most importantly informed her that her hcg levels were not rising in addition to having nothing in her uterus. Evidence of this is documented in his pre-operative counseling [CP 22]. Department of Health disclosed in their investigative report that the levels had risen and were in the normal range [CP 29]. Dr. Bourne informed Department of Health that had he known there was a yolk sac on the ultrasound, he would never have taken Julia to surgery [CP 26, EX:6] however, he informed her "the ultrasound you had today showed nothing in your uterus" (Note: Dr. Bourne ordered this ultrasound on October 20 some time prior to 12:30 pm when Julia had the ultrasound, then he saw her in the afternoon of the same day October 20, 2008). Dr. Bourne claimed he never received the ultrasound report dated October 20, 2008. (Note: Department of Health concluded this was inconsistent with information from the radiology department because the report showed it was faxed to the ordering provider Dr. Bourne on October 20, 2008 at 13:27 pm prior to him seeing Julia at 14:30 pm for the follow up antenatal visit which he turned into a

pre-operative counseling). [Appendix, EX: 8],

The pathologist report indicates clinician as Dr. Bourne and the clinical information above GROSS DESCRIPTION indicates "CLINICAL INFORMATION : ectopic pregnancy". [Appendix, EX: 1]. (Note: Dr. Bourne sent this information. He performed the surgery independently without an assistant who could have mistakenly provided this wrong information to the pathologist. Dr. Bourne admitted to doing this to the Snohomish Superior Court [CP 77, answer #8]). Dr. Bourne obtained the tissue from the uterus and reported it as ectopic pregnancy tissue (outside the uterus) therefore, non-viable which resulted in no karyotype analysis and discarding of the tissues / evidence. This constitutes fraud / spoilation of evidence and tampering with evidence. Dr. Bourne informed Department of Health that he did actually find out about the results of the October 20, 2008 ultrasound sometime after the surgery [CP 38, EX: 9]. On the post-operative appointment with Dr. Bourne, Julia and Stephone arrived at the clinic to see Dr. Bourne and he avoided them. He was aware they were coming as evidenced by his charting obtained by Department of Health [CP32,EX: 10]

In light of all the fraud Dr. Bourne engaged in that resulted in delay of the discovery of his terminating a normal pregnancy, the fraud/ intentional concealment and lack of nformed consent to remove an ovary, a rational jury would find that the lower

court erred in dismissing Julia and Stephone's claims. Dr. Bourne argues that "Julia knew the factual basis of this lawsuit and that whether or not she actually knew this information was enough to establish a legal cause of action is irrelevant". This argument / defense is misplaced along with the case laws Dr. Bourne referenced because he is talking about what transpired prior to Department of Health concluding their investigation while Julia and Stephone are talking about the findings of Department of Health which were not known to Julia and Stephone until the conclusion of the investigation. Julia and Stephone have to the best of their ability explained their stand on the discovery of the injury to which they have provided evidence provided to them by Department of Health whereas Dr. Bourne has continued to talk about the statute of limitations regarding the three year limit. Considering Dr. Bourne is a board certified obstetrician and Julia is a nurse, a rational jury would also be interested in medical experts opinions in order for justice to be served in this complex medical malpractice case involving fraud / intentional concealment and lack of informed consent. (Note: Department of Health had two medical experts in obstetrics on the committee that investigated Dr. Bourne hence resulting in disciplinary action against him).Julia provided a copy of her ultrasounds she obtained from Stevens hospital and Stevens radia to Department of Health of which they used as part of their investigation that resulted into disciplinary action against Dr. Bourne's

medical license. Department of Health retained the copies for their records. Julia requested for more copies from the hospital and radia for the purposes of this legal suit. However, in attempting to read the ultrasound films, the medical experts who would be used for this legal suit (an obstetrician who is also a professor in obstetrics and a radiologist) report that the ultrasound is not partially readable because there are no markers that were initially used to read the films by the reading radiologists in 2008. Department of Health had requested Dr. Bourne's responses preferably in his own handwriting for specific reasons. Dr. Bourne however did respond through his attorney who had the responses typed.

V. CONCLUSION

For the foregoing reasons, Appellants Julia and Stephone Mitchell respectfully request that the Court of Appeals reverse the trial court's summary judgment dismissal of their civil complaint based on the discovery rule, lack of informed consent and tolling of the statute of limitations due to fraud/ intentional concealment.

Respectfully submitted this 1 day of May, 2014.

J.M. Mitchell
Julia K, Mitchell

J.M. Mitchell (for Stephone Mitchell)
Stephone Mitchell

Julia K, Mitchell & Stephone Mitchell
Appellants Pro se

APPENDIX A

EXHIBITS

EXHIBIT 1

CELLNETIX
PATHOLOGY & LABORATORIES

21601 76th Avenue West
Edmonds, WA 98026
(425) 640-4889

1124 Columbia Street, Suite 200
Seattle, WA 98104
(866) 236-8296

Alan C. Boudousquie, MD
Barry T. Kahn, MD
Charles Sturgis, MD
Deirdre P. McDonagh, MD
Donald T. Tran, MD
Ernest Kawamoto, MD
Kirstine Y. Oh, MD
Martin J. Pointon, MD
Tajinder S. Bisla, MD
William J. Monteforte, Jr., MD

Patient Name:	[redacted]	Pathology No.:	**S08-039343**
Patient ID:	468900	Collection Date:	10/21/2008
		Received Date:	10/22/2008

SURGICAL PATHOLOGY REPORT

FINAL DIAGNOSIS:

A. Specimen Designated "Retained Products of Conception", Site not Stated:
Small amount of chorionic villi seen.
Abundant decidua and abundant gestational endometrial tissue also seen.

B. Segments of Right Ovary:
Mature cystic teratoma (dermoid cyst) seen; no immature / malignant cellular elements seen.
Corpus luteum of pregnancy also seen.

CLINICAL INFORMATION:
Ectopic pregnancy. ICD-9 code: not provided.

GROSS DESCRIPTION:
A. Received in formalin, labeled "[redacted]" and designated **"retained products of conception"**, is a 6.5 x 6.5 x 1 cm aggregate of red-tan tissue fragments and blood clots. Villi are present but no fetal parts are identified. Representative sections are submitted in A1 and A2.

B. Received in formalin, labeled "[redacted]" and designated **"dermoid from right ovary"**, are two portions of possible ovarian tissue, 4.5 x 1.5 x 1.5 cm and 3 x 2.5 x 2 cm. Both portions of tissue have inner cavities containing blood clot, hair, and bony tissue. Representative sections are submitted in B1-B4. (axp/cm)

MICROSCOPIC DESCRIPTION:
A. The representative histologic sections of specimen A show a small number of chorionic villi, abundant decidua, and abundant gestational endometrium.

B. The representative sections of specimen B show ovarian tissue containing a corpus luteum of pregnancy and containing a mature cystic teratoma (dermoid cyst). The cystic teratoma has a cavity lined by benign stratified squamous epithelium. The wall of the cyst contains a collection of benign melanin-laden spindle cells and neural tissue. No immature / malignant elements are seen in the cystic teratoma.

Patient:	[redacted]	Clinician:	**Randolph Bourne, MD**
Patient ID:	468900		**Sound Womens Care**
Date of Birth:	2/17/1968 Age: 40		**21616 76th Ave. W**
Gender:	F		**Ste. 205**
Location:	Stevens Hospital Outpatient		**EDMONDS, WA. 98026**
Reference No:	1014209892		
Referring Clinician:	Randolph Bourne, MD		
Copies To:	Karen E Hibbert, MD		

Ernest H. Kawamoto, M.D. Electronically signed 10/23/2008

EXHIBIT 2

I obtained my records from Stevens hospital medical records located on the fourth floor however, the ultra sound dated October 20th, 2008 was missing. I informed the lady that I had four ultrasounds and she stated there were only three on file. I had worked the night before and was in my uniform and also had my badge on. The lady let me go through the file with her and indeed there were only three ultrasound reports on file. I went to the x-ray department and talked to the receptionist who remembered me and she said that is strange. She then pulled up my records on the computer and gave me a copy. I was shocked to learn that the missing ultrasound report dated October 20th, 2008 actually indicated a uterine pregnancy with a visible yolk sac and a fibroid as well as the right ovarian dermoid cyst. Also the pathology report indicated that DR. Bourne reported the tissue being ectopic pregnancy tissue however he did not state the site. It further showed gestational tissue with some chorionic villi. I questioned why he would state it was ectopic tissue when for a fact he obtained it from my uterus. Knowing I had a retroverted uterus with a large dermoid, and the pregnancy being young I decided to get a second opinion from various doctors. It was with dismay that I learned that I did not have a true blighted ovum since there was a yolk sac seen as the pregnancy progressed and my hcg levels had gone up. According to three different physicians I have talked to about my case, they informed me that the pregnancy was still young for DR. Bourne to conclude that it had failed especially since there was a yolk sac. I was not even 8 weeks pregnant and we will never know if he had waited till then we could have seen the embryo. There have been many cases where the embryo is not identified until later according to my current obstetrician with the UW medical center.

I am now forwarding the details of the incident along with the ultrasound reports and films to the Washington State Department of Health to look into the matter because I believe that DR. Bourne was negligent in treating me. First he did not fully disclose information of my ultrasound report dated October 20th, 2008 to me. Looking at his dictation as proof, he does not even seem to have looked at my ultrasound report or even the films because he states he just realized that I had a dermoid cyst when he cut the corpus luteum off my right ovary. The radiologist indicated that I had a right dermoid cyst. Secondly, he stated that there was no yolk sac visible on that same ultrasound when indeed there was one. He terminated a pregnancy making me believe I had just a uterine cyst and an ectopic some where. I would never have accepted to have surgery if he had told me I had a uterine pregnancy. Thirdly, when he sent the uterine tissue to pathology he indicated that it was ectopic tissue when he actually obtained it from my uterus. The pathology report clearly showed "red tan tissue fragments" which indicated it was gestational tissue with some chorionic villi. Lastly, I had not given him consent to terminate a uterine pregnancy or even remove my right ovary. He failed to fully disclose information to me which resulted in him terminating a pregnancy and removing my right ovary. Also if he was planning on cutting my right ovary, he should have ordered some labs to at least check my clotting factors. Ever since the surgery, I have suffered from cardiac arrhythmias and had to

EXHIBIT 3

MITCHELL, JULIA
Maternal & Infant Record Authenticated
Service Date: Jul-11-2011
Dictated by Cheng, MD , Edith on Oct-04-2011

MICC High Risk Return OB
DOS: 7/11/2011

GA: 8w4d
EDC: 2/12/2012

Primary MFM: Edith Cheng, MD

NOB H+P = 6/27/2011 Note

2. H/O prolonged bleeding: With regard to her concern for bleeding abnormalities, she notes that at the time of her pregnancy in 2008, she had a D&C because of an abnormally rising HCG and because apparently the villi or products of the D&C were not consistent with an intrauterine gestation, she underwent a diagnostic laparoscopy and it was at that time apparently that an ovarian cyst consistent with a teratoma was identified. She underwent a mini-laparotomy and per the patient's report, there was extensive bleeding to the point where she had to undergo a right oophorectomy for control of the bleeding. Prior to this, she had not had any history, as far as she knows, of easy bruising or bleeding after cuts or any menorrhagia.

3. Maternal anxiety: See previous notes by me and Dr. Chiang. Pt. continues to have anxiety re: trust in medical providers. Her D+C in 2008 was complicated by the fact that she "woke up" from general anesthesia to find that she had had a laparotomy and that her right ovary was removed. She had not anticipated this outcome and remains traumatized by this event which does continue to bring up when seeing new providers.

PAST OBSTETRICAL HISTORY

1. 2008 with suspected ectopic. She underwent D&C and then diagnostic laparoscopy and exploratory laparotomy for right oophorectomy secondary to a teratoma.
2. 2009 missed AB -> D+C

PAST SURGICAL HISTORY

1. as in problem list
2. wisdom teeth extraction

PRENATAL LABS; Pending
Pap 3/28/2011 = Negative

MEDICATIONS: prenatal vitamins, folate, tums

ALLERGIES: NDKA, denies allergies to iodine or latex
? sulfites --> reports h/o "anaphylactic reaction" in 2009 for which she was treated at HMC. She reports that this happens when she eats nonorganic fruits, especially apples. She now washes all her fruits with and soap and she has not had a recurrence.

REVIEW OF SYSTEMS: Pertinent findings are noted in the above HPI. All other systems were reviewed and are negative.

PHYSICAL EXAMINATION
VITAL SIGNS: BP: 116/62 WT: 67.1 kg HR:68
GENERAL: Well appearing female; No acute distress
NEURO : ambulatory, gait normal
PSYCH: alert and oriented x3. Mood - very anxious
HEAD/FACE : normocephalic, no dysmorphic features, no facial asymmetry
RESPIRATORY : Effort normal,
ABDOMEN: non-tender,gravid, about 12 week size. Anterior fibroid is palpable just above the pubic symphysis.
FHT: office ultrasound today confirms viable IUP at about 8 weeks by CRL.. Fetal heart beat is seen
EXTREMITIES: no joint deformities, no asymmetry
SKIN : no rashes

MITCHELL, JULIA (
Fertility - Outpt Record Authenticated
Service Date: Jan-10-2011
Dictated by Zarutskie, MD , Paul on Jan-10-2011

FERTILITY CLINIC NOTE

IDENTIFICATION
Couple seen back in consultation today following pregnancy attempt for the past 2 months.

4. Records from Stevens Radio-imaging Center (October 20, 2008): OB ultrasound was listed showing an absent fetal heart tone. Complex right adnexal mass was noted, with a large left adnexal cyst seen on prior ultrasound was noted.
5. Surgical path report (October 21, 2008): Specimen shows no clear site of origin noted. For "retained products of conception" 2, segment of the right ovary shows a mature cystic teratoma (dermoid cyst). In further review of the gross descriptions for (a) labeled retained products of

conception, they described 10 tissue fragments of blood and clot that were present, but no fetal parts were identified.

6. The couple expressed extreme concern about review of the records from Stevens Hospital and my interpretation. I gave no impression at this time of the findings, other than recording them and suggesting that we keep them as part of our file here, in light of her description of a dermoid tumor and missed pregnancy. It was my impression that there was no confirmation of an ectopic at the time of the laparoscopy, rather the finding of the dermoid structure. Review of the pathology report today demonstrates that villi were observed, but no decidua were described in that path specimen.

EXHIBIT 4

ULTRASOUND CONTINUED
PELV OB TVAG 10/06/08 15:10 DICT DR:
is recommended. Differential considerations include endometrioma, teratoma, TOA.
3. Large lower uterine segment fibroid blocking the exit canal in the precervical anterior subserosal right-sided region.
4. Left ovarian large cyst.
5. Report called and verified.
Transcribed Date:10/06/2008
Reading Radiologist:CASTAGNO ARTHUR
Reading Time:10/06/2008

HIST & PHYS
H&P Pre-Op 10/20/08 18:07 DICT DR: BOURNE ,RANDOLPH, MD

PRE-OPERATIVE HISTORY AND PHYSICAL EXAMINATION

DATE OF ADMISSION: 10/21/2008

CHIEF COMPLAINT:

HISTORY OF PRESENT ILLNESS:
The patient is a 40-year-old gravida 1, para 0, who is approximately 7 weeks 2 days pregnant by last menstrual period of August 30. She is here because she has been followed with quantitative hCGs as well as ultrasound. Her hCG a week ago was 32,000; the repeat on 10/17 was 51,000 and today, 10/20, it is 53,000. She has nothing in her uterus. Several ultrasounds, including one today, have revealed a small cystic structure in the uterus, yolk sac is not visible, no embryonic pole visualized, and they should be by this point. There is a large anterior fibroid, complex cystic mass noted in the right ovary. Large simple cyst in the left adnexa which appears unchanged. Given all of these things, the most likely diagnosis is ectopic pregnancy. It is also possible, however, that she has a blighted ovum, or even a molar pregnancy. A normal pregnancy has been ruled out by the fact that she has had multiple ultrasounds and her hCG is no longer rising; therefore, this needs to be evaluated from a tissue standpoint. Therefore, my plan is to take her to the operating room, perform a dilation and curettage, and float the tissue. If there is no obvious placental tissue present, then I will perform a diagnostic operative laparoscopy with a possible salpingostomy or salpingectomy; more likely on the right than on the left.

Of note, the patient does not have any pain at this time and is completely stable.

PAST MEDICAL HISTORY:
None.

PAST SURGICAL HISTORY:
None.

Text Continued on Next Page

HIST & PHYS CONTINUED
H&P Pre-Op 10/20/08 18:07 DICT DR: BOURNE ,RANDOLPH, MD

ALLERGIES:
SULFA.

OB HISTORY:
None.

GYN HISTORY:
Menarche at age 12. No history of STDs or PID.

SOCIAL HISTORY:
She works as a nurse at Stevens on the 5th floor. She denies tobacco, alcohol, or drugs.

PHYSICAL EXAMINATION:
VITAL SIGNS: Height 5 feet 7 inches. Weight 128 pounds. Blood pressure is 120/60.
GENERAL: She is a well-developed, well-nourished female who is in no acute distress.
ABDOMEN: Soft. Nontender, nondistended. She does not have any pain on physical examination.

LABORATORY DATA:
Quantitative hCG today is 53,000, rising from a first-known hCG of 26,000 on 10/07/2008. This is clearly a very slow rise.

ASSESSMENT/PLAN:
A 40-year-old female gravida 1, para 0, at some 7 weeks 2 days by last menstrual period with a quantitative hCG of 53,000. The likelihood that she has an intrauterine pregnancy is essentially zero at this point, has been ruled out by the fact that it is not rising appropriately. She does not have any pain which is concerning. It is also possible that she simply has a blighted ovum. I am going to perform a dilatation and curettage followed by possible laparoscopy with salpingectomy/salpingostomy.

I talked to the patient at great length about this. She had previously been talked to about methotrexate; however, I told her that methotrexate had a very low likelihood of working in somebody with an hCG about 10,000, particularly when the hCG was as high as 51,000. She voiced understanding of this. The consent form was signed for the above procedures.

Job Number: 391110

cc: RANDOLPH, MD BOURNE, MD

06:01 11/16/08 FROM 9H3U,ZRPRTGF1

PA3947

Stevens Healthcare

SPECIAL CONSENT TO OPERATION, POST OPERATIVE CARE MEDICAL TREATMENT, ANESTHESIA, OR OTHER PROCEDURE

Patient: _____ Patient No.: _____

Washington State law guarantees that you have both the *right* and *obligation* to make decisions concerning your health care. Your physician can provide you with the necessary information and advice, but as a member of the health care team, you must enter into the decision making process. This form has been designed to acknowledge your acceptance of treatment recommended by your physician.

1. I hereby authorize Dr. Bourne and / or such associates or assistants as may be selected by said physician to treat the following condition(s) which has (have) been explained to me: *(Explain nature of condition(s) in professional and lay language.)*

Ectopic Pregnancy versus
Blighted Ovum

2. The procedures planned for treatment of my condition(s) have been explained to me by my physician. I understand them to be: *(Describe procedures to be performed in professional and lay language.)* RIGHT LEFT BOTH SIDES N/A

Suction Dilation and Curettage
Laparoscopy, Possible Salpingectomy
or Salpingostomy

2. I recognize that, during the course of the operation, post operative care, medical treatment, anesthesia or other procedure, unforeseen conditions may necessitate additional or different procedures than those above set forth. I therefore authorize my above named physician, and his, or her assistants or designees, to perform such surgical or other procedures as are in the exercise of his, her or their professional judgement necessary and desirable. The authority granted under this paragraph shall extend to the treatment of all conditions that require treatment and are not known to my physician at the time the medical or surgical procedure is commenced.

2. I have been informed that there are significant risks such as severe loss of blood, infection and cardiac arrest that can lead to death or permanent or partial disability, which may be attendant to the performance of any procedure. I acknowledge that no warranty or guarantee has been made to me as to result or cure.

IMPORTANT: HAVE PATIENT SIGN FULL OR LIMITED DISCLOSURE BOX AND SIGNATURE LINE AT BOTTOM.

FULL DISCLOSURE

I certify that my physician has informed me of the nature and character of the proposed treatment, of the anticipated results of the proposed treatment, of the possible alternative forms of treatment; and the recognized serious possible risks, complications, and the anticipated benefits involved in the proposed treatment and in the alternative forms of treatment, including non-treatment.

X _____

Patient / Other Legally Responsible Sign If Applicable

LIMITED DISCLOSURE

I certify that my physician has explained to me that I have the right to have clearly described to me the nature and character of the proposed treatment; the anticipated results of the proposed treatment; the alternative forms of treatment; and the recognized serious possible risks, complications, and anticipated benefits involved in the proposed treatment, and in the alternative forms of treatment, including non-treatment.

I do not wish to have these facts explained to me.

X _____

Patient / Other Legally Responsible Sign If Applicable

Any sections below which do not apply to the proposed treatment may be crossed out. All sections crossed out must be initialed by both physician and patient.

5. I consent to the administration of anesthesia by my attending physician, by an anesthesiologist, or other qualified party under the direction of a physician as may be deemed necessary. I understand that all anesthetics involve risks of complications and serious possible damage to vital organs such as the brain, heart, lung, liver and kidney and that in some cases may result in paralysis, cardiac arrest and / or brain death from both known and unknown causes.

6. I understand that all blood and blood products involve risk of allergic reaction, fever, hives, and in rare circumstances infectious diseases such as hepatitis and HIV/AIDS. I understand that precautions are taken by the blood bank in screening donors and in matching blood for transfusion to minimize those risks.

2. Any tissues or parts surgically removed may be disposed of by the hospital or physician in accordance with accustomed practice.

PHYSICIAN'S STATEMENT

The medical procedure or surgery stated on this form, including the possible risks, complications, alternative treatments (including non-treatment) and anticipated results, was explained by me to the patient or his/her representatives before the patient or his/her representative consented.

Physician's Signature M. Bourne Date _____ Time _____

PATIENT OR PATIENT REPRESENTATIVE'S ACKNOWLEDGEMENT

I acknowledge that I have read (or have had read to me) and fully understand the above consent, the explanations referred to were made, and that all blanks/spaces have been filled in before I affixed my signature.

_____ Witness: _____

Patient / Other Legally Responsible Sign Witness to Signature

_____

Relationship of Legally Responsible Person to Patient

Date: _____ Time: _____ 120

DISTRIBUTION OF COPIES: WHITE - HOSPITAL CHART YELLOW - PHYSICIAN CHART PINK - PATIENT LEG 106 S (REV. 6/01)

EXHIBIT 5

DATE

10-7-08 Continued from previous page

LABORATORY DATA:
Reviewed. Quantitative HCG is 26,000, and the ultrasound does reveal a 5 mm sac that is somewhat irregular in size and shape. I did review these pictures myself. The left adnexa has a large simple cyst, which certainly is not an ectopic. The right ovary can be seen, and there is what appears to be a hemorrhagic cyst within this. I would agree with Dr. Castagno's evaluation on his report. It does not look certainly like a typical ectopic would, and the patient's pain is not significant either.

ASSESSMENT AND PLAN:
My assumption of this is that it is likely an intrauterine pregnancy. However, there is a large fibroid on the ultrasound, and this is implanted very near it. I did discuss I am little concerned about a miscarriage. The patient does report some bleeding over the last few days. Nonetheless, we are not going to know for sure until we repeat an ultrasound in a few days. I have ordered another quantitative HCG tomorrow, although at 26,000 doubling may not occur because it is too high to necessarily double. Ectopic precautions were discussed in detail, and she knows to go to the emergency room if she has any increase in pain, rapid onset of pain, or other signs and symptoms of ectopic. Looking at the pictures I am less suspicious, but discussed that I certainly cannot ever guarantee. This is a highly desired pregnancy, so we must watch it closely. In three days she will get an ultrasound, which will be four days from her previous, and hopefully we can see a little bit more with this intrauterine fluid collection. If her quantitative HCG is declining, then we very well may need to think about methotrexate, as an ectopic cannot be completely ruled out. However, the patient is very reticent to do this, and if it is declining rapidly, this may not need to be done. Questions were answered, and the patient agrees with the plan.

Jeffrey F. Bray, MD/rd

cc: Karen Hibbert, M.D. ~~Faxed~~ 10/8/08

— OUT OF SEQUENCE —

10·10·08 See phone note from 10·8·08. — CBentley RN

10·10·08 JB aware – pt. U/S today @ Stevens ~~for~~ Radiology at 2pm. — CBentley RN

Date 10/10/08 Time 4:27 — 3 - Healthcare Information Readily Identifiable to a Person - RCW 42.56.360(2), RCW 70.02.020(1), RCW 42.56.070(1)

Provider JB/ CBentley ✓ ☐ Phone Follow-up ☐ Rx Refill ____ Pharmacy # ____

☐ Medications ☐ Referral ☐ Test Results ☒ Please call back

Message: Had US today @ 2:00

Let RB know about pt's U/S today and her quants and so on b/c it is unclear if JB called pt & result already today before triage reviewed phone note. He (RB) will call pt.

Other

Rec'd By TOLLIVER, K. Date 10/10/08 Time 5:58pm Initials CBentley RN

	Cystitis	New rx	Irreg bleeding/mass, bx		Phys Exam	6-11	12cr>	Comprehensive
Estab	15	25	40					
New	30	45	60					

FCH1
H:

PAGE

SWC 114 (REV. 7/02)

EXHIBIT 6

anembryonic gestation or incomplete miscarriage, then she would have been subjected to a potentially toxic drug to treat a self-limited problem.

Dr. Bourne would recommend surgical management. In his opinion, surgery poses the least harm, (the pregnancy, wherever it should turn out to be, clearly is not viable) with the best likelihood of treating a potentially fatal disease (ruptured ectopic pregnancy with exsanguination).

Whenever obtaining consent from a patient for any potentially injurious procedure, Dr. Bourne always starts by saying that she is an adult and must make her own decisions. He also states that he is not the person with the pain, abnormal pregnancy, heavy bleeding, etc, and that the final decision must lie with her. He then details the risks involved in the procedure. In this case that would be bleeding, infection, and damage to adjacent organs. Specifically, Dr. Bourne would talk about uterine perforation, bladder, bowel, and fallopian tube injury. Since this complaint, Dr. Bourne has specifically added to all of his consents the potential for removal of abnormal or diseased tissue. He is going to go into further detail about what the exact risks are. The loss of the ovary is an uncommon, but not unheard of complication of attempting to remove an adnexal mass. In mentioning to patients the desire to remove diseased tissue he explains that there may be unforeseen events or abnormal findings that indicate further intervention. This may lead to removal of diseased tissue. Dr. Bourne explains to patients that without this consent he would need to wake them up prior to proceeding with the correct care.

Question 3C: Your statement notes that the ultrasound was faxed to your office but for some unknown reason was not in the patient chart. How are you going to address this?

Answer 3C:

As stated in response to question 3A, Dr. Bourne's clinic now has an electronic medical record. He is hopeful that this will avert this problem in the future, because any study ordered by any provider in his clinic will automatically show up in the patient's medical record. Dr. Bourne certainly would have reviewed this (as he did her paper chart) prior to going to the OR and found the most recent ultrasound report.

Sincerely,

Tammy L. Williams

TLW/ng

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March 22, 2012

Denise Gruchalla, PA-C
Healthcare Investigator
Medical Quality Assurance Commission
P.O. Box 47866
Olympia, WA 95408-7866

Re: *In Re Randolph Bourne, MD*
Case #2011-159469MD

Dear Ms Gruchalla,

In answer to your questions:

Question 1: Explain how you came to provide care to [redacted] given that she had been seen previously by Dr. Bray and Dr. Rogers?

Answer 1:

The practice that Dr. Bourne is a partner in, Sound Women's Care, is a collaborative one. The doctors work together, frequently taking over care for one another when a patient's primary doctor is unavailable. Dr. Bray was Ms [redacted]'s primary obstetrician. Dr. Rogers was covering for him while he was away and she was on call. Dr. Bourne then followed her on call and, as is their usual practice, when on call he took over the care of this concerning patient, whose medical situation could not be left until Dr. Bray was available to manage it. Dr. Bourne does not remember where Dr. Bray was at that time.

Question 2: The medical records suggest, and you acknowledged, that you decided to go ahead with a pre-operative evaluation including informed consent on 10/20/2008 and then performed a D&C and laparoscopy on 10/21/2008 without benefit of the information that the ultrasound of 10/20/2008 would have provided, and despite the fact that the patient was not bleeding or in pain. The Commission finds that though the hCG levels were in the low normal range, they had increased and were in the normal range for a 7-8 week pregnancy, and a level of 53,000 was too high to suggest an ectopic pregnancy.

=7

Answer 2:

With all due respect, Dr. Bourne does not agree with the Commission's assertion that 53,000 is low normal and is not consistent with an ectopic. Dr. Bourne has personally performed an exploratory laparotomy and salpingectomy for a ruptured ectopic that had a last known HCG of 67,000. That patient lost approximately three liters of blood and was transfused multiple units of packed red blood cells. His partner, Dr. Rogers, told Dr. Bourne that she performed a salpingectomy for an ectopic this past weekend and that in that case the HCG was 30,000. HCG is notoriously variable and cannot be depended on to determine where a given pregnancy is. The only thing that has been consistently shown is that once the HCG level rises above 2,000, there should be evidence of an intrauterine pregnancy on ultrasound. If there is no evidence, then the pregnancy is abnormal. There was evidence

Additionally, if a pregnancy has been observed on multiple occasions without any change in the findings on ultrasound it can be assumed to be an abnormal pregnancy. It should also be noted that in Dr. Rogers' note dated 10/17/08, she states that the patient and her husband are *"aware that this is essentially an abnormal pregnancy."* In the ACOG Practice Bulletin, the clinical guidelines for Obstetricians and Gynecologists, number 94, from June 2008, it states that an HCG greater than 2,000 predicts visualization of an intrauterine pregnancy on ultrasound. It further states, *" If necessary, endometrial sampling can be used to differentiate between a failed intrauterine pregnancy and ectopic pregnancy by confirming the presence or absence of intrauterine chorionic villi."* Indeed, if we were to present a case to a second year OB/GYN resident, in which a patient has a very high HCG (of perhaps 50,000), no intrauterine pregnancy on ultrasound, and a complex adnexal mass, Dr. Bourne would be shocked if any of them would not diagnose an ectopic. That this is an ectopic until proven otherwise, is a standard medical practice. The risk of a D&C, when the patient clearly has an abnormal pregnancy is negligible compared with the risk of a ruptured ectopic pregnancy.

failed US 100 case to see major changes

There was an IUP.

There was an IUP

Should we requested another US and another opinion then seeing Dr Bourne

Question 2A: Please explain your clinical rationale for that decision given the fact that the patient was asymptomatic and why you did not allow the patient the "choice" of waiting until she was either symptomatic or had a spontaneous miscarriage.

Answer 2A:

Dr. Bourne would never tell any patient what they have to do. He offers options and lets them make the decision. In general, if Dr. Bourne thinks one option is better, then he will say that. Dr. Bourne will make a recommendation as to what course he think is best. So, in this case, he would recommend that, as she was at significant risk of an ectopic, and clearly did not have a normal pregnancy (to his knowledge at the time, multiple ultrasounds showing no pregnancy in the uterus, a large adnexal mass and an elevated HCG), she should have treatment for a presumed ectopic pregnancy. Given that he could not be certain that this abnormal pregnancy was an ectopic, and that it was possible that she actually had an an-embryonic gestation (blighted ovum) or an inconiplete miscarriage, Dr. Bourne would perform a D&C to ascertain if this had ever been an intrauterine pregnancy. If no evidence of IUP was found on D&C, then he would have to assume that this abnormal pregnancy was indeed an ectopic pregnancy and should be treated as such. This management approach is in agreement with ACOG practice guidelines.

Question 2B: Who ordered the ultrasound that was done on 10/20/2008?

Answer 2B:

Dr. Bourne does not know who ordered the ultrasound.

Question 2C: Did you know that an ultrasound was being done or had been done on 10/20/2008?

Answer 2C:

In his pre-op note from 10/20/08, Dr. Bourne stated that, *"She has nothing in her uterus. Several ultrasounds, including one today, have revealed a small cystic structure in the uterus, yolk sac is not visible, no embryonic pole visualized, and they should be at this point."* Obviously, Dr. Bourne did not know about the yolk sac within the uterus. As was stated in the prior response to this complaint, Dr. Bourne signed off the ultrasound report from 10/17/08 on 10/20/08. Presumably, he thought that he had just reviewed the most recent ultrasound. Had he known that there was a yolk sac seen on Ms. [redacted]'s ultrasound, Dr. Bourne would never have proceeded to a D&C, much less laparoscopy. Dr. Bourne only proceeded with these procedures because he believed that she was potentially in grave danger from a ruptured ectopic.

Question 2D: During your informed consent of the patient, what information did you provide to the patient regarding the findings of the 10/20/2008 ultrasound?

Answer 2D:

In his pre-operative note, Dr. Bourne documented that he thought she had a very small cystic structure within her uterus, with no yolk sac visualized, and a complex adnexal mass. This is what was communicated to her. Dr. Bourne may have also mentioned that she had a large anterior fibroid on her uterus.

Question 2E: Was there an y discussion between you, Dr. Bray or Dr. Rogers regarding Ms. [redacted] s care?

Answer 2E:

Dr. Bourne recalls speaking with Dr. Rogers about this patient briefly prior to assuming care. She told him to read the note she had dictated about the patient, which he did. Following the case, when Ms. [redacted] and her husband came into clinic on 11/5/08, Dr. Bourne recalls speaking with Dr. Bray about her. Dr. Bray told him that she and her husband were angry and that he had explained everything to her. Dr. Bourne told Dr. Bray about his experience in the OR and how she came to lose her ovary along with the teratoma.

Question 3: The Commission's concern, given the above is 1) the patient may have been denied the choice of continuing the pregnancy, normal or not, and 2) the risk to the patient if the surgery was delayed until the ultrasound results were available was not sufficient enough that you couldn't have waited until the results were obtained.

Question 3A: Please explain what changes you would make in your approach to the care of patients having a similar presentation in the future.

Answer 3A:

Given what was known at the time, that there was no evidence of an intrauterine pregnancy, and there was a large complex adnexal mass and an elevated HCG, Dr. Bourne would not alter his practice. A woman with this high of an HCG and no documented intrauterine pregnancy has an ectopic pregnancy until proven otherwise. She is therefore at significant risk of fallopian tube rupture and massive internal bleeding. Despite her lack of overt symptoms, she was still at significant risk. As stated in the prior response, Dr. Bourne had seen an ultrasound report. He signed it off on 10/20/08. Unfortunately, it was the report from the ultrasound exam done on 10/17/08 that did not show an intrauterine yolk sac. It was therefore Dr. Bourne's belief that he had seen the most recent ultrasound report and was not rushing to surgery without allowing sufficient time for the ultrasound results to come back. Dr. Bourne has reviewed Dr. Rogers's note from 10/17/08, in which Dr. Rogers states that the patient has had twinges of pain in the right adnexal. Had Dr. Bourne known the results of the 10/20/08 ultrasound, he would most likely only give the patient miscarriage precautions and have her follow up with Dr. Bray without any further intervention being made.

Additionally, Dr. Bourne will review all ultrasounds himself prior to going to surgery. In general this has always been his practice. In Ms. [redacted]'s case, he does not know why he did not review the images from the 10/20 study. This issue can hopefully be averted in the future, as the clinic has converted to an electronic medical record. As a result any study ordered by any provider in his clinic will automatically show up in the patient's medical record.

Dr. Bourne ordered the 10/20 ultrasound

Question 3B: What changes would you make in your practice with regards to communicating information to patients and documenting the counseling and information given?

Answer 3B:

In counseling a patient in a situation like this, it is Dr. Bourne's general practice to explain slowly and carefully, what he thinks is happening. He frequently draws diagrams of the uterus and fallopian tubes with possible locations for the pregnancy. He generally explains the concept of the discriminatory zone (an HCG over 2000 should show ultrasonic evidence of an intrauterine pregnancy). He would express empathy regarding the loss of the pregnancy and then describe options. In a case like this, in which to Dr. Bourne's knowledge at the time, the patient had a very high HCG, with no evidence of a pregnancy in the uterus, and an adnexal mass. These would be 1) watchful waiting, 2) methotrexate management, or 3) surgical intervention. Dr. Bourne would recommend against watchful waiting, as this is clearly not a normal pregnancy, and while it is not necessarily clear that this is an ectopic pregnancy, it is clear that it will not turn into a baby. In Dr. Bourne's view, should the pregnancy turn out to be an anembryonic gestation or an incomplete miscarriage, then the risk of a D&C is certainly outweighed by the risk a potential ectopic poses.

Dr. Bourne would recommend against methotrexate management as the HCG is too high for this medication to be effective. Methotrexate is only effective in patients with an HCG that is less than 10,000. Additionally, should this abnormal pregnancy turn out to simply be an

EXHIBIT 7

Stevens Radia Imaging Center

21700 - Highway 99
EDMONDS, WA. 98026
(425) - 640-4949

Accredited by:
American College of Radiology
Commission on Quality and Safety
for MRI, CT and Ultrasound

Patient Name: [redacted]
Date of Birth: [redacted] **Age:**40Y **Sex:** F
Patient Phone: -
Medical Record Number: 468900

PROCEDURE: EUS 6030 EUS PELVIC OB COMP W TRANSVAG
DATE: Oct 20 2008 12:18 PM **ACCESSION NUMBER:** 1703924

OBSTETRIC ULTRASOUND

INDICATION: Absent fetal heart tones. Complex right adnexal lesion and large left adnexal cyst seen on prior ultrasound. An ectopic pregnancy could not be excluded. Rising hCG. No pain or bleeding.

COMPARISON: 10/17/2008 OB ultrasound from Stevens Hospital.

TECHNIQUE: Transabdominal images were obtained for global visualization. Transvaginal images were obtained for better detail of pelvic structures.

FINDINGS: Is a large transmural fibroid noted anteriorly measuring 6.6 x 5.7 x 7.2 cm. This causes mass-effect on the endometrial stripe. There is a left posterior intramural fibroid measuring 2.0 x 1.5 x 2.3 cm.

There is an intrauterine gestational sac measuring 2.5 x 1.8 x 2.2 cm. The mean sac diameter is 2.2 cm which corresponds to a gestational age of 7 weeks, 2 days. This has increased compared to the prior ultrasound. There is a yolk sac seen within the intrauterine gestational sac. The contour of the gestational sac is slightly irregular and the choriodecidual reaction around the sac is heterogeneous. There is a small area of hypoechogenicity noted laterally concerning for a small perigestational bleed. The intrauterine gestational sac is implanted on the right side.

The right posterior cul-de-sac complex mass including the right ovary measures 6.1 x 3.4 x 6.8 cm. This appears to be partially complex cystic mass with a dermoid plug most suggestive for a large dermoid. Flow is demonstrated in what appears to be right ovarian tissue and there is an oval shaped avascular heterogeneous area in the right ovary suggestive for a corpus luteum cyst.

There is a simple cyst in the left ovary measuring 3.5 x 5.0 x 3.4 cm. Overall the left ovary including this cyst measures 5.3 x 3.5 x 3.9 cm. Low resistance arterial waveform is demonstrated in the left ovarian parenchyma.

No significant free fluid.

IMPRESSION:

1. The intrauterine gestational sac has increased compared to the prior ultrasound. A yolk sac is seen on today's exam. No embryo is identified.
2. Findings are most suggestive for a large right dermoid.
A 5 cm simple left ovarian cyst is also again noted.

Transcribed By: PSC: 10/20/2008 1:12PM
Reading Radiologist: ALICE B JOSAFAT, MD

Final Report

Stevens Radia Imaging Center
21700 - Highway 99
EDMONDS, WA 98026
(425) - 640-4949

Accredited by:
American College of Radiology
Commission on Quality and Safety
for MRI, CT and Ultrasound

Patient Name: [redacted]
Date of Birth: [redacted] **Age:**40Y **Sex:** F
Patient Phone: -
Medical Record Number: 468900

3. Large right anterior transmural fibroid causing mass-effect on the endometrial stripe. Small left intramural fibroid.

4. The estimated gestational age by gestational sac size is 7 weeks, 2 days with an ultrasound EDC of 06/06/2009. By the gestational sac size of the first ultrasound from 10/06/08, the gestational age by dates is 7 weeks, 5 days.
5. With an intrauterine pregnancy present, an ectopic pregnancy is most likely not present.

Distribution: Ordering Provider: RANDOLPH BOURNE

Transcribed By: PSC: 10/20/2008 1:12PM
Reading Radiologist: ALICE B JOSAFAT, MD

Final Report

EXHIBIT 8

and they should be at this point". He noted additional findings including a cystic structure in the uterus, a large anterior fibroid, a complex cystic mass in the right ovary and a simple cyst in the left adnexa. The respondent's conclusion was that all things considered, the most likely diagnosis was ectopic pregnancy. **(Pages 26 – 27)**

In his statement, the respondent also stated that though he "did not know the results of the October 20 ultrasound during the October 20 pre-operative visit or the October 21 surgery, he acted in good faith by diagnosing and treating what he believed to be an ectopic pregnancy."

Note: There is an inconsistency in this statement versus what was dictated in the 10/20/2008 Pre-op H&P note.

The respondent further stated that during the pre-operative visit the complainant consented to a D&C and possible laparoscopic salpingectomy or salpingostomy for probable ectopic pregnancy. (Pages 28 – 30)

On October 21, 2008 the complainant had surgery. The Operative Report notes that the respondent looked at the tissue obtained from the D&C, floated the tissue and did not see any chorionic villi; he determined there was no evidence of an intrauterine pregnancy and proceeded with laparoscopy. During the laparoscopy a large right ovarian mass was observed and determined to be a teratoma; he then proceeded with removal. Ovarian bleeding necessitated right oophorectomy. **(Pages 33 - 34)**

In his statement, the respondent also addressed the complainant's specific allegations regarding:

A. Review of Ultrasound - Multiple ultrasounds were performed on 10/6/2008, 10/10/2008, -respondent states that he reviewed all films and reports available and in retrospect cannot explain why the 10/20/2008 report was not available on either 10/20 or 21/2008 and wasn't in the patient's chart at the patient's post-operative visit. The date on the 10/20/2008 report shows that it was faxed to Sound Women's Care on 10/20/2008 at 1:27 PM **(Page 47, Attachment A)**

B. Consent to Removal of Right Ovary - The type of bleeding the patient experienced was a result of high pressure vessels originating from the aorta to the ovary and teratoma and required treatment with pressure, coagulation or ligation with suture. This type of bleeding would not have responded to clotting factors as the complainant suggests.

C. Consent to Terminate Pregnancy - The complainant did consent to termination of an abnormal pregnancy. The respondent stated that on 10/17/2008, Dr. Rogers, discussed with the complainant the existence of an abnormal pregnancy and ectopic pregnancy.

D. Cardiac Arrhythmias – The patient's dysrhythmias were diagnosed 22 months after the surgery, are not related to the surgery or her not receiving clotting factors for bleeding during surgery. -The blood loss was estimated at 150 ml.

EXHIBIT 9

Data on the October 20 report shows it was faxed to Sound Women's Care the same day, at 1:27 p.m.; we simply cannot explain why the report was not available to Dr. Bourne on October 20 or 21, and why it was not in the patient's chart on the date of the patient's post-operative visit. Dr. Bourne does not recall the specific date, but sometime after surgery he did receive and review the October 20 report, as evidenced by his undated initials.

If Dr. Bourne had seen a yolk sac, ~~or had read in a report that there was a yolk sac~~, he would not have proceeded with surgery. Dr. Bourne's October 20 preoperative report states, "Several ultrasounds, **including one today**, have revealed a small cystic structure in the uterus, yolk sac is not visible, no embryonic pole visualized, and they should be by this point. There is a large anterior fibroid, complex cystic mass noted in the right ovary. There is a large simple cyst in the left adnexa which appears unchanged. Given all of these things, the most likely diagnosis is ectopic pregnancy. It is also possible, however that she has a blighted ovum, or even molar pregnancy." (Emphasis added.) The "one today" ultrasound report referred to by Dr. Bourne is the October 17 report, which he reviewed on October 20 according to the stamp on the report.

B. CONSENT TO REMOVAL OF RIGHT OVARY

The patient claims that she did not consent to removal of her right ovary, but removal of the right ovary became necessary as Dr. Bourne excised the cystic teratoma. During what he believed to be a laparoscopy for a probable ectopic pregnancy, Dr. Bourne discovered the almost six-centimeter cystic teratoma. The standard of care requires that a teratoma be removed when found, and this was a particularly large abnormality that could turn malignant and posed an imminent risk of ovarian torsion. Ovarian torsion occurs when an ovary "flips" on its blood supply and gets stuck in this position, causing the blood flow to and from the ovary to become compromised. Torsion of this kind of mass would lead to severe pelvic pain, possible ovarian death and probable emergency surgery in the future.

Dr. Bourne attempted to remove the teratoma separately from the ovary. Unfortunately, as is often the case, the way in which the teratoma had grown caused unexpected bleeding; Dr. Bourne was unable to remove the teratoma without the ovary. He did not discuss the removal of the ovary with the patient, as this would have required stopping the surgery, waking her up (as stated in her letter, she consented to general anesthesia), and exposing her to the risk of a second procedure. In addition, the patient had already consented to allow Dr. Bourne to "perform such surgical procedures as are in the exercise of his professional judgment necessary desirable." The consent further states, "The authority granted under this paragraph shall extend the treatment of all conditions that require treatment and are not known to my physician at the time the medical or surgical procedure is commenced."

C. CONSENT TO TERMINATE PREGNANCY

The patient claims she did not consent to terminate a uterine pregnancy, but the patient did in fact consent to termination of an abnormal pregnancy. On October 17, 2008, Dr. Bourne's partner, Dr. Rogers, spoke at length with the patient about her elevated hCG levels. They also discussed that, while the pregnancy might or might not be an ectopic pregnancy, it was clearly

EXHIBIT 10

Date	Time
10-27-08	11:43

Provider RB ☐ Phone Follow-up ☐ Rx Refill Pharmacy #

☐ Medications ☐ Referral ☒ Test Results ☒ Please call back

Message

(HCG + pathology report)

Pt states:

Pain

"really light flow"

Febrile FLU

Night sweats q HS 11105

(CR + See HCG Quant + path report

attached

Pt has not been called by triage.

Rec'd By [illegible] Date Time Initials

10/28/08 Called [illegible], left message to call for thursday. RB

10/31/08 [illegible] Came by. Having problem with breathing. Has pleural effusion. Being managed by PCP. I will follow up PRN. RB

2 out of 3	low[3]	mod[4]	high[5]
Data	2	3	4
Diagnosis / mgmt	Estab prob worse	New problem	New prob w/ workup
Risk	Minor surg	Minor surg w/risk	Major surg
	Rx renew	Major surg w/o risk	
	Cystitis	New Rx	
		Irreg bleeding/mass, dx	
Estab	15	25	40
New	30	45	60

	99213	99214	99215
ROS	1 system	2-9	10-14
PFSH		1 of 3	2 of 3
Phys Exam	6-11	12<r>	Comprehensive

SWC NO:7013028
FCH1

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