Repudiation of 2007 OPMC Determination and Order – James R. Caputo, M.D.

The following is a comprehensive explanation and clarification of any and all issues regarding my New York State Medical License, including official entanglements with the New York State Department of Health (DOH). As a consequence of several years of involvement with the DOH, this document has become necessary so as to formally counter flawed yet harmful documents that have been posted online by this official State agency pertaining to and resulting from my dreadful encounter with them. Not only are these pages readily available to anyone by a simple internet search, the accessibility of this information has proven to be a substantial obstacle professionally.

Therefore, anyone so interested in reading the following responsorial statement will be able to properly contextualize and clearly see the error in the currently posted documents (entitled *Determination and Order*) once the clinical facts and science are presented. Thus, it must be stated at the outset of this writing that my <u>categorical</u> position is that the charges and determinations contained within these papers are wholly incorrect and furthermore, purposely deceptive in their conclusion. My only defense to this uncompromising and bold statement is to offer a complete elucidation of the facts and circumstances involved in order to thoroughly set the record straight. Understand that the years spent confronting these baseless allegations by the State along with the subsequent license action which ensued were absolutely not done so as a matter of attempting to avoid accountability. This labor has always been about truth, medical science, intellectual honesty and personal integrity. Upon reading this document, it should be abundantly clear that defending phony charges and a litany of other improprieties was clearly warranted.

Central to the counter instruction provided herein is a detailed, case by case, description of the true medical facts that were literally distorted and manifestly misrepresented by the DOH and their Office of Professional Medical Conduct (OPMC) as part of their spurious action against my medical license. This nearly seven year ordeal with OPMC was actually the end result of a little known (and dubious) hospital administrative practice having been deliberately turned loose on my career. This scheme has universally been termed – Sham Peer Review. It is essentially a purposed perversion of the normal hospital quality assurance procedures in order to be used as a weapon against any doctor's practice, name, license, livelihood, etc. Not surprisingly, several national organizations [The Semmelweis Society and Peer Review Justice Center to name a few] have emerged in opposition to this insidious prevarication of the otherwise honorably intended medical peer review system while offering support to those unsuspecting physicians who find themselves being victimized by it. In my case, this deceitful administrative assault was, from the outset, foisted predominantly through the efforts of two high-risk Obstetricians (Perinatologists) within the Department of Ob/Gyn at Crouse Hospital in Syracuse, N.Y. These two men not only greatly influenced an otherwise weak and clinically feeble department chairman (particularly regarding Obstetrical matters), but also turned out to have direct associations with the DOH and moreover, OPMC. Furthermore, one of these men in particular abused his departmental and Quality Assurance committee positions by "selecting" certain patient files (which were seen as distortable) and sending them (under the cloak of anonymity) to Albany along with misleading clinical reviews regarding the medical care rendered. When combining this latter component with the aforementioned connections within the agency, an administrative action was inescapable.

Ultimately, seven cases were compiled as exhibiting some form of medical misconduct with clinical use of Obstetrical forceps as the State's central theme. The mere fact that there were seven separate cases might (and really should) cause anyone to automatically <u>assume</u> that there <u>had</u> to be some wrongdoing worthy of the State taking such action. I would. This is why those doing the prosecuting come with so much volume so that the defending party becomes essentially overwhelmed by the litany of charges and eventually gives up trying to dispute it all. Notwithstanding the baselessness of the entire action by OPMC, understand that these seven cases are a minute fraction of the thousands of patients I have proficiently cared for during my career. They were, however, apparently selected because they represent cases that stand out as unique and therefore are readily subject to factual manipulation towards the appearance of wrongdoing on part of the clinician providing the care. No doctor can claim that he/she has

never had unique or odd cases. They are relatively common if you see enough patients. How they are handled once encountered is another matter. And no physician can ever claim that he/she has never had a complication attributable to their work on or with a given patient. In over 2,500 surgical cases, 1,300 pregnancies (many of which were significantly high risk) and tens of thousands of patient visits, there have been only three true complications where a patient required supplemental care. Hard work, deep pathophysiologic knowledge of the organ system and precise implementation of care are foundational to my practice of Obstetrics and Gynecology. My record unmistakably confirms this.

Naturally, anyone, (me included) would want to know why such an adversarial effort would be put forth by these parties. The reason why I believe such an assault was undertaken towards my practice is several fold. In 1998, I had unwittingly joined a practice in Syracuse that had historically been at interpersonal and professional odds with these two influential Perinatologists who thereafter, evidently ascribed these feelings towards me. Having trained in the Midwest, the stylistic nature of my practice of Ob/Gyn varied considerably with those within the department, especially Obstetrics, which further rubbed these two the wrong way. I honestly was not aware that there was some unwritten expectation of how I was supposed to venerate them. Consequently, they repeatedly tried to impose themselves upon my fledgling Obstetrical practice. I was an outsider who had not trained there under their influence and particularly, their control. Because of these factors, combined with building a very successful and independently comprehensive practice while simply minding my own business, I became the latest subject of their misgivings and long established propensity to abuse their departmental power. During my first three years in Syracuse, they tried to hassle me a number of times. It wasn't until a stillbirth delivery in 2001 did their efforts and desires come to fulfillment, which is detailed extensively below. I would later learn that there have been a number of other regional physicians who have had unexplained State level investigations levied against them, most notably following any type of incongruous interaction with either of these two doctors. It wasn't until after I found myself in the midst of such a situation did I even conceive that such a treacherous system of impropriety existed amongst doctors.

The sentinel case used as part of this process was that of Patient A in 2001 where a stillbirth was experienced. The clinical facts will be elaborated upon below. Following this tragic case, the requisite institutional review that followed was completely devoid of due process (having personally been completely excluded) as well as due cause, ultimately leading to a six month summary suspension of my privileges for operative vaginal delivery. This was because the use of Obstetrical forceps was an incidental (yet not consequential) component of the case. This unfounded action, penalty and national reporting was disputed with the assistance and support of expert testimony from the then American Congress of Ob/Gyn (ACOG) District Chair for Central New York, Richard Waldman, M.D, whose credentials were consummate. Incidentally, Dr. Waldman would eventually go on to become the President of ACOG and currently is in his third year of tenure serving as the immediate past President. Following this acrimonious interaction where no rectification was made, the two primary individuals responsible then turned to their alliances at the DOH as past patient cases were unexpectedly and moreover, anonymously fed to OPMC with dishonest clinical narratives. This led to the six year defense of an even larger number of counterfeit charges from multiple cases. The care provided these patients was never previously the subject of any peer review or standard of care breach and where no patient or baby was unduly harmed, all while remaining patients of my practice.

For the record, when the term "alliances" is used, this refers to the following truths. First, one of these two Crouse Hospital Perinatologists responsible apparently has a brother who holds a position at OPMC. Second, the other doctor involved has personal acquaintances and colleagues within OPMC as evidenced in 2006 by my first hearing's adverse determination being thrown out on appeal. This was because the sole Ob/Gyn physician of the three member panel (jury), who had behaved contemptibly during the hearing and who was literally admonished during the hearing for tampering with the State's expert witness and her testimony, was this Crouse doctor's friend. Somehow (and mysteriously) he was assigned to that panel. This juror's shocking personal association with the one individual central to my troubles was determined after an investigation was made into who this man was and constituted one of the

foundational bases for the appeal, notwithstanding the actual scientific merits of the prosecution as a whole. It should be interesting and moreover troubling to know that the Appellate Division of the DOH made this ruling based on "bias having pervaded the entire proceeding." They acquiesced by remanding the entire thing to a second hearing with all new people instead of addressing the authenticity of the charges which was forefront in the appeal. This remand was the first of its kind in the history of the Department of Health which speaks volumes as to the illegitimate nature of the entire prosecutorial activity.

It must be emphasized that throughout my entire interaction with OPMC, they gave no regard to the following:

- any cooperative efforts on my part
- my plea for reviewers experienced in Obstetrical forceps to be involved with the investigation
- the <u>accurate</u> facts of the cases as represented by the <u>actual</u> medical records
- the abundance of official American Congress of Ob/Gyn (ACOG) written standards of care that were eminently adhered to in all cases
- relevant and scientifically precise expert testimony
- pertinent medical literature submitted as exculpatory evidence
- testimony for the defense by the very patients whose cases were forefront in the State's prosecution
- the plethora of available hospital Quality Assurance (QA) materials/reports evidencing a long-term history of exemplary medical care regarding by my practice of medicine.

Throughout the six long years of defending these matters, the DOH blatantly violated several of their own rules and regulations regarding the process of investigation as well as that of a prosecution before reaching their final determination. Perhaps the most reprehensible example is the manner in which their determination was rendered (see * below). This is important to understand when reading the clinical facts that will be presented, particularly when correlated with the legal obligations of the hearing panel when reaching a determination, for which they were derelict.

The obvious question that should come to the mind of anyone who either learns or reads about my lengthy struggle for the truth with and claims of widespread dishonesty within an official State agency is "why would they do this if it wasn't true?" The answer is not readily clear and moreover perplexing to those who know the truth. But after having witnessed how deliberately depraved their actions were, these are the factors that lend to the "why".

- First, it is well established that the practice of Sham Peer Review is rampant across the country and not limited to just hospitals. State Medical Boards have been implicated in a large number of cases. They are able to compel an adverse determination at will by a combination of denying basic constitutional principles of adjudication within a closed door setting along with an utter lack of oversight concerning their activities. The determination (verdict) is decided upon by only three individuals all of whom are members of the DOH. Only one of them is a physician from the specialty represented by the doctor on trial. The others have essentially no knowledge of the medical matters at hand and rely on the input of a single voice.
- Second, the reputation of OPMC has long been known to be malevolent. This is evidenced by the introduction of New York State Senate Bill 5221 Entitled "The OPMC Reform Bill To make Professional Medical Conduct honest and fair." (This info is attached at the end of this document) Contained within the language of this legislative effort are the exact abuses that were inflicted upon me at both the hospital and State levels. Perhaps the most ironic aspect to my interaction with OPMC is that I was literally warned of this agency immediately

upon moving back to New York State to practice medicine following residency training in Michigan. After what I heard described and given the assiduousness of how I practiced medicine, the thought that they would ever be in my life seemed remote.

- Third is the previous disclosure of the connections between the two Perinatologists from Crouse Hospital and internal members of OPMC.
- Fourth is the anonymous nature of the reports or "complaints" sent to OPMC. The doctor under investigation is never allowed to see just what was written and by who. Such a shadowy assault could be replete with misinformation outside of the clinical facts of the cases themselves and never be capable of being adequately and openly defended. This tactic was clearly evident in my case.
- Fifth and certainly not insignificant is the fact that I pushed back and vehemently defended myself. As effort to introduce material evidence and true scientific facts increased, the more profound the State's efforts were to disregard it all and deviate from the rules in order for an adverse finding to be imposed. There was an ominous feeling concerning my entire experience with OPMC. Despite an overabundance of vindicating evidence as part of my defense and the burden of proof required of the State having narily been met, the outcome was categorically not going to be favorable.

In addressing each of these cases, there will be a detailed clinical narrative as well as a direct rebuttal to the numbered items, statements and all charges as represented on the DOH's 2007 Determination and Order. (The pages referenced will be those annotated on the document itself) When reading these items on the State's determination, please note the selective piece-meal assembly of the clinical material that is blatantly one-sided and agenda driven. Please also bear in mind when reading all rebuttal statements made in this document that they were actual components of the material evidence admitted at the hearing either through documentation and/or witness testimony. In other words, the State received or heard all of this incontrovertible information but essentially disregarded it all.

The writing on each of these cases is quite thorough lending to a rather lengthy document. It is essential that every detail possible be addressed and covered after having experienced the damage that has been incurred by this experience, so that any party reading this account can fully understand the facts whereby a proper conclusion/decision concerning my acumen as an Obstetrician and Gynecologist is without question and found to be fundamentally sound.

This is not an attempt to retry the individual cases. However, for any Obstetrician (and/or lay person) reading this document, the facts should be plainly obvious in addition to an undeniable lack of grounds for any formal State investigation to have ever been initiated or finding of misconduct, incompetence or negligence to have ever been imposed. The patient charts cannot be formally copied in to this document but remain wholly available for verification of the information presented. True – stylistic differences do occur between doctors. However, contrary to how the State of New York exploited this reality, it should never be foundational as a reason to destroy any physician's career and did not warrant their actions of six-plus years that caused great damage to the lives of many.

Before proceeding, a quick word about the first paragraph under, "Findings of Fact." The DOH, by their own rules of the proceeding, is supposed to make a statement about the quality and reliability of the expert witnesses provided by each side. If at any point the State deems the defense's witness to be reliable (or in their own words, gave "great weight" – see page 50) then by law, any charges defended/refuted by that witness must fail. As can be seen, the State did indeed laud the credentials of my primary expert witness (who had previous experience testifying for the State) but thereafter ignored everything he testified to.

* Thereafter, when rendering a determination, the State is required to list the particular charge followed by a ruling on the findings of fact submitted by each side in argument for or against the charge.

See New York State Administrative Procedure Act (SAPA) Article 3 Section:307 –

S 307. Decisions, determinations and orders. 1. A final decision, determination or order adverse to a party in an adjudicatory proceeding shall be in writing or stated in the record and shall include findings of fact and conclusions of law or reasons for the decision, determination or order. Findings of fact, if set forth in statutory language, shall be accompanied by a concise and **explicit** statement of the underlying facts supporting the findings. If, in accordance with agency rules, a party submitted proposed findings of fact, the decision, determination or order shall include a ruling upon **each** proposed finding. A copy of the decision, determination or order shall be delivered or mailed forthwith to each party and to his attorney of record.

In other words, the hearing panel had an obligation to corroborate each charge with all the evidentiary facts and findings then to specifically declare their reasons for choosing one position over the other. Their adherence to this critical stipulation was patently ignored with all testimony and evidence advanced by the defense being minimized in total as "considered and rejected" without any of the offered proof explicitly discussed or a ruling on each having been made – and counter to the "great weight" they had unmistakably given to my expert. Their unilateral determination was made without being accountable to uncontested exculpatory evidence/testimony as well as the literal written standards established by the governing body (ACOG) for the specialty of Obstetrics and Gynecology.

The Cases are as follows:

Case 1: Patient A – 2001 Delivery

History: In 2001, I cared for a mid-twenties woman expecting her first baby. Early on she developed hyperemesis (excessive nausea and vomiting) which required hospitalization that eventually abated by the second trimester. The middle of her pregnancy was otherwise uneventful. When she reached approximately 35 weeks gestation, she developed persistent and painful uterine contractions for which she was seen at the office numerous times. The external monitor demonstrated them to be fairly regular however, she exhibited no cervical change. These contractions were so persistent that she actually was sent to the hospital three times after hours on other days for them. They were also so painful that she could not sleep and was therefore given a small script of Tylenol #3 to help with the pain so that she could rest.

At 36 5/7 weeks, she presented to the office on a Monday with a new complaint of right leg swelling. Upon exam, it was clear that she had developed a significant cellulitis (a dangerous infection of the skin) involving the entire extremity. She was admitted to the hospital for IV antibiotics. She was also started on prophylactic Heparin therapy for multiple risk factors including a family history of DVT (blood clots in the legs). During her hospitalization, she continued to have painful and debilitating contractions demonstrated by external monitoring and documented numerous times in the chart by nursing as well as House Staff (Resident Physicians). However, her cervix remained essentially unchanged. She required Demerol or Tylenol #3 several times for palliation which was nominally effective. She had a difficult time being able to sleep or obtain any appreciable rest during this week. By Saturday of that week, her leg was better and she would otherwise be stable for discharge. However, upon arriving at the hospital late that morning, she was now experiencing an even greater intensity of contractions with an additional finding of idiopathic (unexplained) widespread swelling of both lower extremities as well as her labia.

Upon examination, her cervix had shown significant change in both dilation and especially effacement and consistency. Now at 37 2/7 weeks gestation, the logical decision was made to work towards delivery – given the totality of her case.

This was based on the fact that she was in early labor with intense contractions now having shown cervical change. Adding to this decision was that if she was sent home, not only would she likely return to the hospital given her contractions (as she had done numerous times in the previous two weeks) but she would have to be set up for home (self) administration of prophylactic heparin which had been started and warranted continuation under the present clinical circumstances. All clinical parameters pointed towards keeping her in the hospital and getting her delivered. This was as straight forward a decision as there is in Obstetrics.

She was brought up to labor and delivery and when situated, had her membranes artificially ruptured. She progressed well and required only a nominal amount of augmentation with Pitocin (4mu/min). The record clearly showed that the addition of Pitocin was for augmentation for an already laboring patient. She steadily reached 5cm dilation and received an epidural. For the first time in weeks, she was completely comfortable. Shortly following the epidural, she experienced a prolonged fetal heart rate deceleration lasting 5-6 minutes and dropping to the 50-60 bpm range before slowly returning to baseline. This was <u>not</u> felt to be attributable to a maternal blood pressure issue from the epidural, which is sometimes the case. A fetal scalp electrode was placed for more accurate monitoring at this point, since the deceleration was severe and posed a significant risk to the baby if it were to recur.

Within an hour of the epidural and this prolonged deceleration, the monitor was now revealing significant and repetitive variable decelerations with the fetal heart tones dropping to the 60's. These were recurrent with each and every contraction and not abating with repositioning. She was examined and was fully dilated where after she was asked to push. Having been sleep deprived for more than two weeks and laboring all day, (despite the short rest after her epidural) her expulsive effort was poor. The fetal vertex (head) was also noted to be occiput posterior. For better understanding of those unfamiliar with these terms, the baby was looking up at the ceiling in the birth canal (as opposed to the floor) which was is an unfavorable position for the head to be able to negotiate the dimensions of the maternal pelvis. It was going to require at least two to three hours of pushing in order to deliver this baby with adequate expulsive efforts. Clinically, while there still remained very good fetal heart rate variability between the decelerations, this baby would not have tolerated the repetitive and moderate to severe nature of them for the length of time it was going to require to deliver naturally. Because of the potential for fetal compromise as represented by this clinical picture, I counseled the patient as to the situation and gave her some options. Cesarean section was one option as well as assistance with the use of Obstetrical forceps. The latter was given as a choice since I had extensive training in their application as well as numerous cases on record with the hospital without a single complication or untoward event. I was also the primary practitioner at this hospital for resident education in their use and application. Thus, there was legitimate skill available to provide this as a justifiable option and so it was offered. The patient chose a forceps assisted delivery since she was hoping to avoid a cesarean if possible.

[A brief statement about Obstetrical forceps. It is clear that they have lost considerable relevance in recent decades due to a drastic absence of clinical training. Forceps remain, however, a powerful tool for the Obstetrician under certain clinical circumstances with the American Congress of Ob/Gyn maintaining this very position.

The following is taken from ACOG's Practice Bulletin on *Operative Vaginal Delivery* from the year 2000. Practice Bulletins are considered one of the major resources for the Obstetrician and Gynecologist in establishing a relative standard of care within the specialty. These documents, however, make it clear on page one that they "should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources and limitations unique to the institution or type of practice." This document provides a

tremendous amount of detail regarding the various modalities associated with instrumental delivery, including a thorough discussion on forceps. On page 2 can be found the following:

Indications for Operative Vaginal Delivery

No indication for operative vaginal delivery is absolute. The following indications apply when the fetal head is engaged and the cervix is fully dilated.

- Prolonged Second Stage:
 - Nulliparous women: lack of continuing progress for 3 hours with regional anesthesia, or 2 hours without regional anesthesia.
 - Multiparous women: lack of continuing progress for 2 hours with regional anesthesia, or 1 hour without regional anesthesia.
- Suspicion of immediate or potential fetal compromise.
- Shortening of the second stage for maternal benefit

In this patient's case, while not explicitly required per ACOG's own statement, two of the three possible *Indications* for the use of forceps were met when only one was necessary as part of the recommendation. When contemplating forceps, the practitioner should never use them if there is the slightest doubt of proper application or confidence in obtaining a completely positive outcome when compared to alternate methods of delivery. This has always been foundational to my practice and wholly demonstrable by my clinical record.]

The method of forceps delivery initially planned in this case was that of a Kielland rotation to occiput anterior. In other words, this entailed using a special type of forceps in order to rotate the baby's head from looking up at the ceiling to that of looking downward in order to more favorably negotiate the maternal pelvis. Again, despite being a highly advanced application of Obstetrical forceps, I was trained in this procedure which had been successfully implemented numerous times in my practice without any complication. As the procedure was in progress, it was clear that rotation was not going to be easily accomplished, as sometimes is the case. The heart rate tracing was not continuous throughout the procedure but intermittently was in the normal range. The decision was made provide forceps assistance straight away without the rotation, which is totally acceptable. With two contractions, the vertex (head) was brought to a crowning station whereby the forceps were removed. The patient then delivered the baby via her own expulsive efforts.

When the head was delivered, there was an extremely tight nuchal cord (umbilical cord around the neck) noted. It was too tight, in fact, to reduce (or simply slip) over the head. I had been trained to avoid clamping and cutting the cord at this juncture due to the immediate interruption of blood flow between baby and placenta that this procedure causes. Instead, as usually done, I delivered the anterior shoulder and slipped the cord over and down the baby's body. Upon complete delivery, the infant was unexpectedly and profoundly flaccid and pale despite blood from within the cord being delivered into the baby prior to cutting it. The NICU team was present whereafter resuscitation was employed but to no avail. The baby expired without any immediate understanding or explanation. There were not any inappropriate markings on the baby from the forceps to be found. The Neonatologist was perplexed. It wasn't until a CBC came back revealing a hematocrit of 12 (approximately only 1/4 of the expected blood in a typical newborn) did the etiology of extreme blood loss explain the outcome. The question was where did the blood go?

It was a horrible scene with emotions from all parties present. Within two days, all data were in. The autopsy was completely negative for any trauma from the limited use of forceps. The placenta, which uncharacteristically delivered without any assistance and immediately after the baby, showed no signs of abruption but did histologically reveal what was termed, "focal villous edema" which constituted a rather

acute (and not long-standing) process producing this finding. The pH of the cord was 7.22 but dropped in the baby to 6.8 from the lack of oxygen carrying capacity of the blood due to the severe anemia previously noted by a hematocrit of 12.

The final report from the medical examiner was that of an umbilical cord accident. This is where a little known and quite rare clinical event was uncovered. None of my colleagues had ever heard of this phenomenon nor did any Obstetrical textbooks describe it. The type of neonatal hemorrhage encountered in this case was clearly described in the text Avery's Neonatology: Pathophysiology & Management of the Newborn: 6th Edition (pgs 1172-1174 including Table 46-2). This is a rare entity known as fetoplacental hemorrhage or nuchal cord with placental blood trapping. This catastrophic blood loss was due to the anatomic and physiologic properties of the umbilical cord vessels (two arteries and one vein) when subjected to compression, which was extreme in this case. For clarity, there are several forms of umbilical cord compression that can occur at delivery. There can be mild, moderate and severe degrees of tightness which dictate the management of such a presentation at that moment. In some cases, the cord can be wrapped around the neck of the baby two or even three times. The elements leading to each circumstance are multi-factorial and outside of control of the Obstetrician prior to being encountered upon delivery of the fetal head. Now, relating a severely tight nuchal cord to the vessels within it, the one vein is inherently flimsy and highly susceptible to compression and thus can experience complete obstruction of blood flow – whereas, the two more muscular arteries are less compressible and therefore capable of permitting a degree of blood flow during the same compressive force that is being simultaneously applied to the vein. The net result is blood flowing into the placenta through the two arteries and that is unable to return to the baby through the single vein which is completely occluded. This circulatory aberration is not only possible, it completely explains the totality of all laboratory and pathologic findings in this case and is precisely what the medical examiner concluded in his final report. In other words, the forceps, (again, used for a limited portion of this case to assist the delivery of the head to a crowing position and then removed), had nothing whatsoever to do with the outcome.

The patient, husband and their families were apprised of the scientific findings and (while still grieving) were able to comprehend the unintended and chance nature of the event. This patient would go on to successfully delivery her next two children with me as her sole Obstetrical provider. That one delivery was the only Obstetrical case in over 1300 in my entire career, (including many high risk pregnancies), whereby the baby did not go home from the hospital completely healthy.

One week after the scientific data and the autopsy report were available, the Department of Ob/Gyn neglected to speak to me at all about the case and after ramming the matter through the peer review process without any of the required participation of the attending physician, summarily suspended my privileges to perform all types of operative vaginal delivery – insinuating that the forceps were responsible for the death of the newborn. Having purposefully excluded me from the obligatory involvement concerning the various institutional reviews of this matter, (such as a root cause analysis), erroneous and misleading reports were created and sent to the New York State Department of Health. Further, this was a data bank reportable event. It was at this point that I objected to this action and engaged in what would turn out to be a six and a half year ordeal seeking the clinical truth in this and other cases that would eventually be rounded up and (mis)used in a similar fashion where one colleague of mine termed the entire charade as "prosecutorial overkill".

Addressing now the issues cited by the DOH and OPMC on their Determination and Order from 2007. It would be most helpful to open up this (so called) official State document and follow along, side by side, with what is written below. Please bear in mind that <u>all written entries</u> here are <u>direct references</u> from the actual testimony offered to the State by myself as well as my expert witness and the patient herself yet it was all utterly ignored. Note how many <u>inaccuracies</u> exist between what the State asserts and what can be unmistakably demonstrated by the actual medical records:

Page 4: Patient A – 2001 Delivery – Rebuttal to OPMC Numbered Items.

- 2. This is correct.
- 3. The office records clearly show that these painful contractions started at least a week prior to this date and were the subject of numerous office and hospital visits, which required palliative medication therapy in order for her to obtain any relief and any chance of rest. They persisted as significantly painful through her hospitalization for the right leg cellulitis as repeatedly documented in the chart. These contractions were not associated with cervical change until day 6 of her hospitalization, as described above.
- 4. This date is inaccurate. The patient was admitted on Monday September 10th and received antibiotic therapy for several days. There was never a question or suspicion of deep vein thrombosis. However, prophylaxis was initiated so as to be protective against the high risk for DVT that existed given this clinical presentation combined with family history.
- 5. A cervical exam of 1cm dilated and 50% effaced was highly significant. Her cervix had been long, thick and closed up until this point. If one wishes to classify it as latent phase, then it was more towards the end of a very prolonged latent phase of labor that had been present for over two weeks.
- 6. This was a Saturday and was the day when I saw the patient in the hospital whereby she was writhing in pain from more intense contractions as well as the finding being made of widespread edema of her lower extremities and vulva. Her cervix had notably changed from the previous day and her amniotic sac was bulging. What wasn't disclosed here is that her cervix was also very soft and anteriorly located two parameters indicative of early labor. In addition, her contractions were stronger that ever and she was in considerable pain.
- 7. Given the fact that this patient was in early labor after weeks of a protracted latent phase, had a new onset condition of unexplained edema, was already hospitalized for a week, was still on heparin that would have required being trained on administration if she were sent home, and was experiencing painful contractions with documented cervical change, the logical clinical management was to work towards delivery. By definition, when the fetal vertex (head) is at -3 station, this is the earliest point by which the head IS engaged and therefore safe to artificially rupture the membranes. Of course while there is always a risk when performing this procedure under any circumstance, it is not contraindicated under these conditions.
- 8. This patient was by definition in early labor and spontaneously so. While some practitioners may have elected to send her home or observe her for a period of time, it was not a deviation from any known standard of care to work towards delivery given the entire clinical picture for this patient. Furthermore, the State of New York never introduced a single document establishing any such standard of care that was supposedly being violated. Their entire charge was based on the stylistic opinion of their expert which contradicted the testimony of two other experienced board certified Obstetricians.
- 9. The medical indication was that the patient was in early labor after 37 weeks gestation while having experienced other comorbidities as detailed above. The State's introduction of dysfunctional labor was completely out of place and had no application to the prosecution of this case. The cervical exam revealed, by Bishop scoring, a favorable finding for working towards delivery. In fact, the medical record clearly indicated that she was in labor at the time of admission to L and D and the amniotomy was done as an augmentation measure. To deny the fact that rupturing the membranes is fundamental to augmenting labor is patently disingenuous. And to represent dysfunctional labor as some sort of ominous condition is, again, dishonest since a majority of patients in present day Obstetrics require the use of Pitocin to assist in labor function.
- 10. Correct. Pitocin was indeed used as an augmentative measure to stimulate contraction frequency and intensity so that labor progressed steadily. What was not considered was that this patient required only 4mu/min of Pitocin in order to accomplish the task. This is an extremely small amount when compared to the maximum institutional dose of 32mu/min. In other words, this patient was laboring effectively on her own and in order to optimize her progress, she was given Pitocin just as 80% of patients in this institution receive.

- 11. This significant and concerning deceleration was described above. Though this was an acute event with the fetal heart tones eventually returning to baseline after several minutes, the fact that it occurred indicated a potential utero-placental or umbilical cord problem and required heightened surveillance and vigilance in monitoring the well being of that baby.
- 12. These were the measures taken to increase surveillance of the baby and intrauterine compartment.
- 13. &14 What the State neglects to disclose is the fact that these decelerations were not only recurrent but moderate to severe in nature with the nadir of the decel reaching 60 bpm. There was never a dispute over the presence of heart rate variability (which is a favorable sign) existing between decelerations. The fact concerning moderate to severe variable decelerations is that when recurrent, there is a considerable risk to the baby for hypoxia. Variable decels are caused by umbilical cord compression. The deeper the decel, the more significant the compression and thus the greater the interruption of oxygenated blood flow through the cord when this occurs. Over time, the baby tolerates it less and less resulting in a loss of that ever important variability. Occiput posterior (OP) position is indeed an unfavorable position for spontaneous vaginal delivery. However, the State's insinuation that this condition would have corrected itself in this case is inaccurate. No documentation was ever introduced by the State to authenticate this claim. OP position is one of the main reasons for failure to deliver without some sort of intervention – be it operative vaginal or cesarean section and infrequently resolves in first time mothers. Testimony was also given specific to this patient's exam that there was little room noted for a spontaneous resolution to be realistic. Given the existence of these repeated worrisome decelerations, correlated with how long she had before delivery, the decision was made to assist in shortening the second stage of labor - consistent with the second and third indications from ACOG's Practice Bulletin for Operative Vaginal Delivery.
- 15. The State goes back in time in the course of this patient's labor with this item. It is true that at the time of the prolonged deceleration an hour before she was completely dilated that there was still every reason to believe that a spontaneous vaginal delivery would be possible and anticipated since the heart rate tracing appeared stable. Human labor, however, is never absolutely predictable and it wasn't until an hour later that the recurrent moderate to severe variable decels were noted which changed the clinical management considerably as described in 13&14.. This is not new to Obstetrical management and was clearly testified to by both defense witnesses. The State depicted these clinical events and corresponding decisions as blameworthy when they are fundamental to the specialty.
- 16. The selective description regarding the course of events by the State is clearly evident with this statement which attempts to indict the use of forceps with that of the stillbirth result. They neglect to mention that the forceps were used only until a crowning position of the fetal head and removed where after the patient delivered the baby by her own efforts. They neglect to state that there was no observable trauma to the infant from the forceps. They neglect to acknowledge a comprehensive autopsy revealing no trauma to the baby and concluding that the stillbirth was due to a cord accident.
- 17. Again, no evidence, aside from opinion, was ever introduced by the State to support this first statement. Numerous factors must be considered in order to properly contextualize such a statement. First, there is no clarity or specificity as to what is meant by "start". Nevertheless, this patient was fully dilated and at plus 2 station with a tight pelvis and a clinical determination based on years of experience that the likelihood of a "spontaneous" rotation to a more favorable position for "spontaneous" delivery was remote. Even if it was possible, it would have taken hours that were not available in this situation. The statement regarding the patient being allowed to push was equally irrelevant in the management of this case. The patient testified that she had no ability to push which was integral to the decision making process given the clinical picture previously described. As far as risk to the baby via the use of forceps, such implementation should carry little to no risk to the baby when used properly by a skilled and experienced Obstetrician. As earlier stated, these instruments are never to be applied if there wasn't the expectation of a favorable outcome equal to that of an alternative method of delivery. Therefore, while it is sometimes true that the lower the baby is in the pelvis the less the outward force that may be required to deliver it,

- this baby was at the proper station for forceps to be appropriately employed. This is evidenced once more by the fact that it took little effort to bring the head to the point of crowning and resulted in no trauma at all to the baby.
- 18., 19 & 20. As previously stated, this patient testified that she couldn't push as well as this fact being documented in the chart after I encouraged her to try. True, purely from a maternal standpoint, it may have been prudent to let the patient rest and allow a passive descent of the baby so long as there wasn't any other clinical circumstance that threatened the outcome. This was not the case here. No written standard of care exists or was ever introduced by the State pertinent to this clinical situation whereby the patient was required to push before action could be taken for the sake of the baby. The decision to shorten the second stage of labor, based on fetal indications and the standpoint of the baby being delivered healthy, was a clinical one. It was completely appropriate and within the Obstetrician's right to expedite delivery rather than waiting until the healthy baby worsened by showed signs of hypoxia under known conditions for such an event and while the mother was unable to assist by pushing. To reiterate, ACOG's very own document describing indications for expediting a delivery using forceps clearly states - "Suspicion of immediate or potential fetal compromise." This is what existed here. Furthermore, the State ignored the fact that just one hour prior to these conditions, the baby experienced a serious prolonged deceleration to the 60's for 6 minutes which not only directly correlated with the present findings of moderate to severe variable decelerations but posed a precarious risk of recurrence which would possibly create an emergent situation and an even greater potential for adverse outcome.
- 21. The bottom of the delivery bed had been removed as part of the delivery process. Once the baby is delivered, there is really no other place than the maternal abdomen to place the baby in order to clamp and cut the umbilical cord. This is what was done in this case as well. The State makes the claim that it took "one and a half to two minutes" before the baby was transferred to the NICU team. There is nothing in the medical record establishing this claim. They are going by a comment made by a NICU nurse who was standing by in the room at the time. They purposefully ignored the written statement by the Neonatologist who asserted that it took no extra time at all to receive the baby. As far as the events that took place, the umbilical cord was in fact milked towards the baby in order to optimize as much intravascular blood volume for the newborn as possible given the pale appearance upon delivery all while providing essential stimulation. The baby's father was asked to cut the cord and did so immediately with negligible delay.
- 22. This newborn was transferred as quickly as possible. There was no reason at all not to do this. The State not only manufactured this charge but chose to dispense with the Neonatologist's account to the contrary.
- 23. & 24. It is true that the cord was very tight and incapable of being reduced over the head of the baby upon delivery. This is nothing new in Obstetrics. Once this is encountered, the Obstetrician can either doubly clamp and cut it right there or complete the delivery of the baby and slide the cord down alongside the infant's body in order to free it up. There was roughly a 50:50 preference for either method amongst doctors where I trained. There is nothing written anywhere that requires the Obstetrician to clamp and cut the cord under this circumstance. And the State never produced anything other than expert personal opinion to substantiate this charge. The State's expert was unable to deny the fact that the alternative method was legitimate to perform. His only answer was that this was not how he did it. It has always been my practice to avoid cutting the cord because once done, there is no chance for any blood contained in either the cord or placenta to ever get back to the baby. It is not a deviation from the standard of care whatsoever to utilize this methodology. And when there is a question of anemia in the newborn, as evidence by a pale appearance, this is all the more critical. If the cord was clamped and cut in this case, the resuscitation efforts would have been even less effective. Unfortunately, the loss of blood was so profound that the volume contained within the cord was not enough to make a difference. All of this was presented and testified to by the defense. All of it was ignored. Lastly, the charge concerning any sort of delay in resuscitation has already been answered.

Page 51: OPMC Determination Narrative – Rebuttal: Patient A 2001 Delivery

In describing my role in the proceeding The State states, "Although he appeared sincere, knowledgeable and dedicated to his profession, several aspects of his testimony were troubling. They follow this with two examples that were totally incorrect.

Concerning the allegation that "prohibited actions" were performed, the State chose to once again ignore the evidence that was submitted and sully the proceeding with a dishonest statement. To reiterate, the result of the stillbirth for patient A was in no way due to the use of forceps, which was confirmed by the final autopsy. After disregarding this fact and depriving me of any participation in the review process, the actions of a few within the department of Ob/Gyn at Crouse Hospital led to the six month summary suspension of my privileges for operative vaginal delivery. The problem that materialized was that the chairman had not made any provisions for any circumstance that would invariably arise requiring operative assistance. When this dilemma actually did arise within the first week, the department responded by making a modification to the suspension and allowed the on-duty faculty member to supervise any delivery that would require an operative delivery rather than automatically subject the patient to a c-section. This occurred a handful of times during the six months without incident. After the six months was up, the department reinstated all privileges without limitation. The State was well aware of these details and not only heard it in testimony but had exhibited documentation from the hospital detailing this very condition. They simply did not want to concede these facts.

The second mistruth concerning Patient E's hematocrit was equally handled by the State. This was a prime example of the State attempting to create any possible appearance of misconduct by distorting every element of these cases. A detailed disclosure of the facts concerning this point will be presented below as part of Patient E's discussion.

Pages 52 – 53 OPMC Determination Narrative – Rebuttal pertaining to the charges at the end of the State's document: Patient A 2003 Delivery

Charge A1: This patient was absolutely a candidate for working towards delivery for the plethora of reasons previously stated. Artificially rupturing membranes at -3 station is not a deviation of the standard of care. By indicting this procedure, the State has now created a new standard and therefore has subjected every Obstetrician in New York of being guilty of misconduct. There is absolutely no basis within the specialty for such a charge. Furthermore, by coupling it with the "risk" of umbilical cord prolapse when no such thing even occurred is a clear indication of their overall agenda to manufacture the appearance of as much wrongdoing as possible when truly none existed. This patient was clearly in early labor and it was the sole discretion of her Obstetrician to make these basic clinical conclusions and decisions.

Charge A2: Another attempt by the State to create the pretense of misconduct was their charge of faulty Pitocin management. This point is best understood by an Obstetrician who regularly employs this medication. Patient A never exhibited a problem with the use of Pitocin. In fact, by having to use only 4mu/min of the drug, it is preposterous to insinuate faulty management. The Hearing Panel's conclusion that the State had failed to meet their burden of proof for this charge is interesting for several reasons. First, it goes a long way in revealing just how much clinical acumen and moreover care was utilized by the chart review in establishing the charges levied in the first place. Secondly, it is interesting to see that they clearly knew the burden of proof was on the State (and essentially themselves, being agents of the State) and cited the only evidence presented on the matter. The testimony by myself was corroborated by their witness and therefore they had no other option. This was hardly the norm for the Panel as previously discussed by their complete disregard of any defense testimony when they were obligated to disclose it and rule why it was not considered valid.

Charge A4: The issues surrounding Patient A's pushing in the second stage of labor were thoroughly addressed above. Two very important observations should be obvious to the reader, however. First was the fact that they ignored the testimony of an expert that they claimed to have given great weight to. They secondly blatantly ignore the presence of moderate to severe variable decels that unequivocally placed that baby at risk. This is a fundamental precept in Obstetrical medicine regardless of the presence of variability. The variability only meant that the baby, at that moment in time, was tolerating the conditions that would otherwise place it at risk of hypoxia if not attended to. They once again establish a new standard for the specialty by downplaying this actuality.

Charge A3: My request that these cases be reviewed by someone experienced in forceps doesn't miss the point but goes right to the point. The State continues to declare their agenda by manifestly ignoring the repeated submissions and assertions as to the standard of care regarding indications for Operative Vaginal Delivery as established by the American Congress of Ob/Gyn. Every single case used in their prosecution was well within these guidelines. Furthermore, the very first sentence ACOG uses as part of their statement on Indications – "No indication for operative vaginal delivery is absolute" – provides the Obstetrician with great latitude in clinical decision making.

Charge A5: The State contention that the testimony about the tightness of the cord and the management thereof was "incredible" has no basis. Fact: the cord was extremely tight. Fact: the tightness was severe enough to have caused a rare circulatory event leading to catastrophic blood loss in the baby. Fact: as part of a legitimate option for any Obstetrician, the cord was not clamped and cut which would have further negated any potential for the baby of regaining any of its lost blood. Fact: residents are indeed taught to clamp and cut the cord as one of two options. Fact: I also testified that as a resident, we were alternatively taught that delivering the anterior shoulder enables the cord to be slipped down the baby's body and therefore does not interrupt fetal-placental blood flow. A statement confirmed by the expert the State gave "great weight" to. This point was selectively deleted by the State.

It is evident that OPMC did not exercise due diligence in delivering judgment in this case. An abundance of material evidence, expert testimony and scientific principles was entered. One hundred percent of it was ignored while the only proof used by the State was that of disingenuous testimony by their expert. Not once did they offer anything written to establish the standards for which the charges were based. The burden of proof was on them but yet they never once cited the defense's case and why it was invalid. This was because in order to do so, they would have had to reject in writing, the established standards set forth by the governing body for the specialty (ACOG) as well as the medical record.

Case 2: Patient A – 2003 Delivery

History: After Patient A lost her baby in 2001, she went through a long period of deep depression that her family described as "catatonic" and quite worrisome. This patient and I saw each other on a regular basis and became even closer than before. As stated above, this patient and her husband were completely apprised of all data and findings in the loss of their son. There was no uncertainty as to the etiology for the stillbirth. As an extraordinary sign of trust, other family members became patients of my practice after the tragedy of that 2001 delivery.

The patient eventually became pregnant again and (as expected) was extremely anxious about the gestation and delivery going well. After discussion, we decided that there would be heightened surveillance in the third trimester for her reassurance as well as a planned a primary cesarean section to forgo any form of vaginal delivery. Her pregnancy went well. However, upon routine surveillance via an office non-stress test at 37 ½ weeks gestation (ten days prior to her scheduled c-section) there was a fetal heart rate abnormality noted. Contained within an otherwise normally reactive tracing, there was an isolated deceleration that was characterized as *late* in nature given the presence of regular contractions on

the strip. This was initially noticed by my nurse practitioner who then brought it to my attention. By the time I entered the room where the patient was on the monitor, she was already near hysterical. She sensed that there was a "question" as to the finding and began to emotionally decompensate. I reassured her that the baby was fine but that we would obtain an ultrasound. With a full time certified sonographer in the office, she was brought in for a quick scan.

A complete ultrasound was not felt to be necessary. I was more interested in presentation, visible amniotic fluid level and placental grade. Within the first minute of the scan, for which I was present, it was obvious that there was an abundance of fluid and moreover, that there existed a uniformly grade three (III) placenta. Given this finding, I was confident that, despite being short of her scheduled c-section date of 39 weeks, her baby's lungs would be mature with little to no risk of respiratory distress were it to be delivered early. This was a clinical correlation successfully used numerous times throughout my career which stemmed directly from the influence of the Chief of Perinatology where I did my training, George M. Kazzi, M.D. Dr. Kazzi's research history had been instrumental in establishing the statistically significant reliability of a grade III placental finding by ultrasound with that of fetal lung maturity outside of the necessity of performing an amniocentesis (see attached at the end of this document).

Additionally, the grading of a placenta is an overall indicator of the relative age of the placenta which consequently can affect its function. It is a well established fact that all placentas have a certain lifespan before they wane in their ability to adequately provide for the fetus before ultimately failing. This failure of function is known as placental senescence. As a placenta matures towards this end point, so does the grade increase since grading is based on ultrasonic findings associated with agedness – calcification and breakdown. Therefore, when a grade III placenta is present, the associated risk for functional loss is at hand and thus poses a potential for adverse outcome.

When faced with the responsibility of ensuring a favorable result in any given pregnancy, especially that of patient A, all knowledge and understanding of pregnancy and, in particular, the utero-placental unit is critical. The late deceleration noted was certainly an isolated event and may not have ever occurred again. Nevertheless, it did, in fact, occur which obligated me to correlate it clinically. By definition, a late deceleration, (whether associated with the signs of fetal compromise or not), is caused by utero-placental insufficiency. The pathophysiology of a late decel is not necessary for this point to be understood. Nonetheless, the prudent action for me was to put it into context with the observable findings.

Despite the reassuring fetal heart rate tracing, the decel in conjunction with the placental findings theoretically put that baby at increased risk of adverse outcome. And with a mother who was not only becoming panic-stricken but also experienced a catastrophic loss already, there was very little room for error. However, while the grade III placenta correlated with a potential functional problem as evidenced by the late deceleration, it also provided the reassurance for a lack of respiratory distress were the decision made to move to delivery. The decision was made to delivery her in the overall interest of mother and baby. To look at it another way, if I sent her home without any action since the baby was otherwise healthy at that moment in time due to the reactive tracing and she returned to the office in a few days with a distressed or deceased baby, there would be no defense for such an outcome given the information that was already known days earlier. While this was unlikely in the grand scheme of things, it was a possibility. And since she had already experienced a loss and nearly didn't recover from it, the decision to act that day was appropriate. Obstetricians are faced with a wide range of clinical decisions whereby a baby is deemed better delivered than remaining in the womb. Not all are clear cut but require a logical pathway of clinical thinking in order to be made. This was one such circumstance.

She was sent to the hospital for continuous monitoring until six hours had passed from when she last ate. While awaiting her surgery, the tracing was reassuring without any decelerations. She underwent an uncomplicated cesarean section with a healthy baby. The baby experienced a short lived tachypnea (rapid breathing) which is commonly associated with c-section delivery due to an incomplete wringing out of

amniotic fluid from the lungs when delivered through the abdomen. There was never an issue of respiratory distress, consistent with the preoperative finding of a grade III placenta. Mother and baby went home healthy and very happy on post-op day four.

Page 12: Patient A – 2003 Delivery – Rebuttal to OPMC Numbered Items:

- 25–30. This information is correct and all alluded to in my narrative. The only thing to add is that in addition to establishing a reassuring status of the fetus and the relative state of oxygenation, the objective of an NST is also to identify any potential irregularities with the intrauterine compartment or the utero-placental unit as evidenced by the presence of heart rate irregularities such decelerations. This indeed was the case here.
- 31. The fact that she had five reactive NST's prior to this date simply shows that surveillance of the baby was reassuring.
- 32. There was in fact a maternal indication for increased surveillance in this pregnancy. The patient is just as important an element to ensure a status of well-being as the fetus. The fact that the tracing met criteria for reactivity (as acknowledged by the State) does not preclude the significance of the noted deceleration. The deceleration was plainly consistent with that of a late decel and not a variable decel particularly due to the shape and the offset relation to the contraction just before it. The tracing was more than adequate with little to no loss of continuity and thus, the State's assertion here is incorrect. With the tracing having been reactive, this was all that was necessary to establish the well being or status of the fetus. The State already affirmed that a reactive tracing was (by definition) consistent with no presence of hypoxia or stress. This was not the issue at hand in this case. That there was a late deceleration required further decisions to be made based on more data. The additional testing she received was that of an ultrasound to identify her fluid level as well as the appearance of the placenta. No other testing was required since the present well-being of the baby was not in question.
- 33. Again, there was no question as to the present status of the fetuses condition. The reactive NST affirmed that is was reassuring. Even though she did have further reassuring monitoring in the hospital while awaiting c-section, the same information already known was gleaned by this. A biophysical profile is indicated when a fetal heart rate tracing is **non**-reactive and further testing is required to establish the well-being of the baby. This was not the issue here. The issue was what to do with the identified late deceleration, especially when correlated with an advanced age placenta, which increased the risk of adverse outcome. The deceleration was a sign that the placenta was potentially exhibiting a deficiency in function regardless of whether the finding was recurrent or not or the fetus was showing signs of distress or not. Aside from the patient's anxiety (affirmed by the State) given her history of catastrophic loss combined with the clinical findings which suggested a feasible risk to the baby along with the reassurance of fetal lung maturity by placental grading, the clinical decision to move to delivery was sound and properly made.
- 34. Biophysical profile was not indicated per the reasons cited above. There was no question as to the well being of the baby which is what this test is utilized for when there is ambiguity on the NST.
- 35. To reiterate, the NST did indeed indicate fetal well-being. While continuous fetal monitoring was indeed undertaken and showed that the decels were not recurrent, this was not the issue. The NST is also valuable for aiding in the identification of other pregnancy issues and thus most certainly is sufficient for making management decisions. This was described in detail above. In fact, the NST (external fetal monitor) is what is used in labor and delivery to assess for fetal well-being during labor. Management decisions are made in every single Obstetrical case based on the information obtained from this method of fetal surveillance. Therefore, the NST is more than a screening test. In this case, it revealed a potential placental problem which was confirmed by further testing (ultrasound) with the identification an advanced grade/age placenta which directly correlated with the late deceleration, be it isolated or not.

- 36. A biophysical profile was not indicated or necessary for making a management decision and therefore wasn't done. It was stated above that upon personally viewing the ultrasound, the fluid level was adequate. A formal measurement was left to the sonographer yet wasn't integral in the management of this pregnancy which was already determined upon visualization of the grade III placenta. The State does demonstrate a fundamental lack of understanding when it correlates the presence of satisfactory amniotic fluid level with the absence of fetal hypoxia. While I have not ever claimed that the fetus was hypoxic at any time during the pre-op assessment, the amniotic fluid level is never a direct parameter determining the oxygenation status of the baby. Low fluid can be indicative of poor placental function which can also be associated with hypoxia in certain cases. However, a baby could very well be experiencing hypoxia depending on a number of variables in the face of an otherwise normal fluid level.
- 37. These points have already been answered. It must be pointed out, though, that the State again demonstrates a complete lack of understanding of fetal well-being when ascribing the conclusion of standard of care deviation to the management in this case. A biophysical profile only becomes necessary when NST surveillance is indeterminate. They acknowledge that the tracing was reassuring thereby contradicting themselves. They neglect to establish what is meant by "other monitoring".
- 38. As clearly described in the narrative above, the risk of lung immaturity was completely entertained and ruled to be negligible by the presence of the grade III placenta. No unsubstantiated assumptions were made. See the research articles attached to the end of this document. While lung maturity was clearly a consideration in this case, the patient was being delivered primarily for a fetal indication. Interestingly, when this is the case, the concern of the baby essentially trumps the issue of lung maturity especially when 36 plus weeks gestation. Because the placental risk identified was arguably accompanied with a degree of uncertainty, the ultrasound findings solidified the decision to move towards delivery without a concern regarding lung maturity.
- 39. There was not any deviation from the standard of care by not performing an amniocentesis. The State was presented with an abundance of medical research literature clearly establishing a near 100% presence of lung maturity at 37+ weeks gestation when accompanied by a grade III placenta. This is equal to or even greater than the incidence of lung maturity when delivered at 39 weeks without any foreknowledge of the like.
- 40. The State once again not only completely disregarded the medical literature submitted regarding placental grading and the incidence of lung maturity, they repeatedly rely on the incorrect testimony of their expert when claiming the assessment of placental maturity is restricted to a pathological evaluation. Textbooks as well as the scientific literature is replete with studies on the subject of Sonographic placental grading as a measure of placental aging, maturity, function, lung maturity and fetal risk.
- 41. The baby was delivered completely healthy without any lung maturity issues.
- 42. The baby was delivered at approximately 8pm. There was a transient tachypnea as described in the narrative above from a little trapped fluid in the lung commonly associated with c-section delivery. The State knew this but chose to use selective language in order to falsely insinuate the presence of difficulties from being delivered ahead of schedule. The baby was observed overnight, was reunited with his mother by the next morning and went home on schedule without incident.

Page 54: OPMC Determination Narrative – Rebuttal pertaining to the charges: Patient A 2003 Delivery

Charge A6: The State is patently incorrect here. This patient was clear about her concern with the baby after my nurse practitioner had to seek me out for what she had observed. Her demeanor was clear to everyone in the office that day. It took a concerted effort to settle her down and to reassure her that everything was ok. However, the fact of the matter as far as what the patient was experiencing is irrelevant. There were two clinical findings (the late deceleration and the advanced age placenta) that are associated with fetal risk and increased incidence of adverse outcome and were not negated by the fact

that the present tracing indicated a healthy baby. This was the overall assessment. As far as further testing, the baby's present health status was reassuring by an otherwise reactive NST and did not require a Biophysical Profile which would have added nothing to the clinical scenario.

Charge A7: This case represented a fetal indication with a maternal component. Babies are delivered every day for far less indication when a decision has to be made concerning the best course of action for the most favorable outcome. This was a judgment call based on the totality of material available – taking great care not to disregard the trauma experienced just two years earlier. Besides, the pregnancy was 37 plus weeks and considered term by definition. Therefore delivery took precedence over waiting when all parameters were considered. As far as the charge regarding the reliability of a grade III placenta and lung maturity, the State flat out ignores the multiple studies that were presented. These were not isolated clinical trials but scientific results that have been duplicated by numerous study groups. What value does it offer to the clinician when their own scientific journals are not considered applicable with long-standing data that has been repeatedly proven? The absolute fact is that when a pregnancy after 37 wks gestation is associated with a grade III placenta, fetal lung maturity is present essentially 100% of the time. Despite the fact that other indications existed for moving to delivery, this baby was never put in unnecessary risk yet the State simply refused to accept the evidence. Lastly, the Hearing Committee once again reveals an utter lack of intellect when rendering a decision in this area with the proclamation, "the standard of care was to determine fetal lung maturity by an adequate assessment such as performing a biophysical profile or..." A biophysical profile can never be used to determine fetal lung maturity. This outrageous statement is just one more clear-cut example of why I had asked that individuals with a wealth of clinical acumen be involved with these proceedings. It also provides (along with the imprecision within the entire determination) a further indictment of the fact that only one Ob/Gyn sits on a hearing committee that has great power in deciding the future fate of a physician involved with such a circumstance.

Charge A8: This charge was not sustained and not even commented on. Unlike the other charges, the record could not be distorted nor the State's expert testimony selectively chosen to support it.

Conclusion: In prosecuting this case, the State repeatedly ignored any and all medical science and clinical data that was clearly before them. The management of this pregnancy was properly thought out and implemented with great care concerning a favorable outcome. I had promised this patient that everything within my control would be done to deliver her a healthy baby. The occurrence of that deceleration may have been a blessing for all we know. The management was based in science and the result consistent with everything expected. When this case was used to file charges of misconduct, it was shocking to say the least. The State's selective use of their expert's testimony and lack of fundamental knowledge while completely excluding any and all defense evidence was highly representative of how they operated throughout the entire hearing.

Case 3: Patient B

History: This patient was in her late twenties and was pregnant for the first time. She had a history of a deep vein thrombosis for which she was effectively managed with Lovenox throughout the pregnancy and transitioned to subcutaneous Heparin near term. She was a very slender woman with an appropriately measuring fundal height during her gestation. At 40+ weeks, she presented to the office in early labor. She was admitted to the hospital and eventually had an amniotomy to augment the labor process. She became fully dilated in the early hours of the overnight. I was in house and readily available at any time for the delivery. Since the baby was still relatively high in the pelvis and she was comfortable, the decision to allow passive descent of the fetal vertex (head) was undertaken.

After nearly an hour, she began pushing with the labor and delivery nurse. After several hours of effort, she was still not ready to delivery. An exam was performed and revealed that the fetal head was

experiencing what is termed transverse arrest which precluded it from properly descending further in the pelvis and explained her lack of progress. It seemed clear on exam and from experience that there was room to deliver were the head properly oriented. Her pushing efforts were good but had been incapable of effecting a rotation of the head in order to negotiate the remainder of the birth canal. She was now getting tired from several hours of pushing.

The patient was thoroughly counseled as to the options before her. One was to continue pushing, another was a cesarean section and the third option was assisted delivery with forceps. Given extensive experience in this latter modality, I explained that if she chose this option, a special forceps rotation would be necessary in order to properly align the head where after another type of forceps would be used to finish the delivery. She consulted with her husband and then chose the forceps option.

Anesthesia was called to top off her epidural. The room was set up for delivery. The proper application of the individual forcep blades is the most critical step in undertaking this type of delivery. It requires a high level of precision and unambiguous knowledge of the orientation of the fetal head in order for the instruments to be accurately positioned before an attempt at delivery is made. Sometimes, this aspect of forceps delivery takes more time than the actual implementation of them, once in place. In some cases, the forceps are just not able to be correctly situated and therefore cannot be used. In this particular case, there was difficulty in clearly identifying the sutures created by the bones of the fetal head in order to safely apply the forcep blades. This was due to a combination of the station of the vertex and the slight degree of asynclitism that was present. Asynclitism is when the head is off center with a certain amount of the parietal region of the head presenting in the birth canal. There are differing extents to this finding. In this case, it was mild but enough to obscure the location of certain landmarks for forceps application.

It was decided that a vacuum device would be employed to bring the vertex down as well as maneuver the head in such a way to center it in an effort to better ascertain the information necessary for forceps application. The vacuum was used for one contraction. After it was removed, the head was further down the birth canal and the landmarks readily identifiable. In under two minutes, the Kielland forceps were successfully applied, the head easily rotated to occiput anterior, then Luikart-Simpson forceps implemented to successfully complete the delivery. The patient did not require any stitches and the baby was without a mark.

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- 43. -46. There is no dispute with these statements as described above.
- 47. As per above, the patient was counseled, they made a decision, the epidural was optimized and the delivery room and bed set up for a forceps delivery.
- 48. The patient did push for three hours without being able to deliver due to transverse arrest of the fetal head. There was also a slight degree of asynclitism present as well. By her having pushed for three hours while the baby otherwise looked fine on the monitor, this enabled me to offer an operative vaginal delivery (in this case with forceps) by ACOG's first set of indication standards (as listed in Case 1) due to failure to progress.
- 49. In this numbered item, the State (moreover their expert) once again demonstrates a fundamental lack of understanding into the dynamics of transverse arrest, asynclitism and cephalo-pelvic disproportion (CPD). The first statement that "the findings of transverse presentation and asynclitism would suggest that patient B's pushing efforts were reasonably good in order for the bones to change their configuration" makes absolutely no sense. The findings of the head being transverse and asynclitic have no connection to the effectiveness of pushing but are more related to maternal pelvic architecture and abnormal engagement of the fetal head, respectively. In fact, depending on the case, the persistence of such a finding could be associated with poor maternal effort in that the expulsive forces were inadequate in effectively correcting the malposition. Further, there is never any explanation by the State as to what is meant by the bones changing "their configuration" or "anatomical change" from "the head pushing against the pelvic bone."

One must assume that they are making references to the presence of asynclitism but they are not clear in their wording. As stated in the narrative above, asynclitism is not defined as the bones changing configuration but a skewing of the head off center whereby the parietal region of the fetal head is presenting. This alters the diameter of the presenting part in such a way that it can cause an arrest in the descent of the head. In this statement, the State appears to be misconstruing "asynclitism" with that of "molding". Referring to the latter; in general, as a baby negotiates the birth canal, the bones of the fetal head are biologically not yet fused so that they can overlap and therefore mold in order to fit. The degree of molding is predicated on the size of the head in conjunction with that of the maternal pelvis. In some cases there is considerable molding while in others there is very little. Molding can sometimes be a sign that the head is experiencing some difficulty in making it through the birth canal and needs to be correlated with the overall progress in labor. Molding, however, is NOT the same as asynclitism. In this case, the persistent transverse position of the fetal head was why she was unable to deliver despite having pushed for three hours. When this is the case, there is indeed the potential for what is called cephalo-pelvic disproportion (as named by the State) where the fetal head (the largest part of the baby that needs to be able to deliver) and the maternal pelvis (the fixed boney outlet for the head) are not compatible to allow for effective passage. When considering CPD, one must understand that there are two types. The State did not make this distinction. One type is of the absolute variety and the other is what is called *relative* CPD. The former is when no matter the circumstance, the baby's head and the maternal pelvis are absolutely not compatible for vaginal delivery. In the latter, however, there commonly exist clinical situations where the fetal head is simply out of alignment with the particular boney architecture of the given maternal pelvis. The maternal pelvis can exhibit a number of variations in shape. Depending on the relative size and how the bones are configured, one pelvis may allow virtually any size fetal head to pass while others may require the head to be in just the right position in order to fit. Sometimes this proper alignment is not spontaneously achieved and intervention is needed to effect delivery. In this case, it was determined that the patient had an adequate pelvis to be able to deliver her baby but that due to the persistent transverse position, this caused an arrest of progress. If the head could be properly aligned, then vaginal delivery would most likely be possible. This is what she was counseled about and what was undertaken. And from the record, it was accomplished in under two minutes, thus otherwise sparing her a major abdominal surgical delivery via c-section.

50. The first two sentences for this item are directly from my testimony and consistent with the clinical account above. To reiterate, in order to safely apply the forceps, there must be absolute certainty as to the precise orientation of the head. However, this is not the case with vacuum (see below). Specific to this patient, ACOG's Practice Bulletin for Operative Vaginal delivery also clearly addresses and condones the combined use of two separate modalities (vacuum and forceps) in order to accomplish delivery so long as there is not excessive utilization of each, which was the case here. The State's charge that my use of the vacuum extractor under the conditions in this delivery constitutes a deviation from the standard of care once more demonstrates a lack of understanding of the instrument, a disregard of the written standards as well as an unfair effort to create as many charges as possible in an otherwise properly managed case. It is well understood that forceps deliveries have significantly diminished over the past several decades. This is due to the demanding nature of their application along with the lack of adequate instruction within the nation's training programs. Most doctors are either too uncomfortable or lack the requisite skills to perform a forceps delivery, despite their superior ability in achieving delivery. Thus, vacuum has essentially replaced forceps as the preferred operative vaginal delivery instrument for the vast majority of Obstetricians because of its relative ease of use. Not only is it simple to apply to the top of the fetal head, it does not require the same precise knowledge for placement as that for forceps. This is why it was initially chosen in this case to in order to bring the head into a more determinant position so as to use the far more effective forceps in correcting the transverse arrest and completing the delivery. As can be seen from the record, this was done in minutes without incident and with a healthy result.

Page 55: OPMC Determination Narrative – Rebuttal pertaining to the charges: Patient B

Charges B1-B4:The Hearing Panel's written narrative for this patient presents a paradox of sorts concerning this entire proceeding. Somewhere along the pathway to this prosecution, the State commissioned an expert review which was then required to be presented to an investigation committee, who then approved the charges for prosecution. The looming question should be, how then did every one of these charges fail? How could they have been claimed in the first place and by whom? The State had difficulty during the hearing to completely satisfy their case because their own expert was impeached when trying to sell these charges as those representing misconduct. The only assertion of theirs that appears in the end to stick is that of the use of vacuum without specifically knowing the fetal head suture orientation. This unfounded position was refuted above and would be equally discounted by any practicing Obstetrician. The charge of mismanaging the second stage of labor due to some nebulous requirement that I examine her every hour when she was being properly attended by a skilled nurse failed because the State's expert was not able to finagle it by his testimony.

The paradox is when the Hearing Panel actually deferred (although they refused to specify this in their determination) to the ACOG Practice Bulletin on the matter of multiple operative vaginal delivery devices. This was due to a number of factors. It was irrefutable that the patient met criteria for intervention in the second stage of labor given how long she had pushed. Therefore, they could not argue that there was no indication as they had with the other cases. They had to consequently opt for attacking the use of the instruments themselves. When they were handed the Practice Bulletin which clearly established the legitimate option of what was done, they (and primarily) their expert could not explain away this clear and convincing fact with his emblematic opinions on practice style as he did for every other charge. Note also how the first and fourth charges were dropped and not sustained respectively without so much as a single comment.

There is very little more to add to the discussion of this case. This patient also testified on my behalf at the hearing and was appalled to learn of her delivery being used against her doctor. Every aspect of the care with this patient was well within the standards as outlined by the American Congress of Ob/Gyn. While the style of delivery may be unique to only a small percentage of Obstetricians, it does not give reason for it to be singled out for prosecution. This was an excellent accomplishment for both doctor and patient that has been sullied by the contention that wrongdoing was involved with its execution.

Overall, this case is very illustrative of many of the themes with this entire prosecution. It reveals the lack of care and knowledge by OPMC that went into the review of this (and all of the other) cases when investigating and subsequently compelling charges. With what has already been presented in the first two cases, a pattern should be clear. Alluded to and striking in each case is the lack of any references to defense testimony and especially ACOG Standards when these are what they ought to be utilizing as the material basis for their case. The other less conspicuous but substantially related component here goes back to the fact that all of these cases were purposefully gathered, manipulated and misrepresented by one of the previously cited Perinatologists who thereafter sent them to OPMC while hiding behind a cloak of anonymity. When misinformation is called out by the facts, science, evidence and written standards, this indiscretion is precisely what one should expect to see.

Case 4: Patient C

History: This was a mid 30's well educated woman in her second pregnancy when she presented to my office for prenatal care. She had a history of primary cesarean section for her first baby at term for breech presentation after reaching 7-8 cm dilation. I had not taken care of her during that pregnancy. She came to me seeking to have a Vaginal Birth After Cesarean (VBAC) since her previous doctor has declined her

request. VBAC deliveries have fallen out of favor in Obstetrics given the relative risk of uterine rupture along the previous cesarean scar as well as the liability that accompanies such risk. After confirming her history of a low transverse scar on the uterus, I explained to the patient that in order to safely undertake a VBAC, certain controllable parameters need to be considered and carefully implemented with how I approach such cases. These included but weren't limited to:

- ideally having the baby during a time when full staffing was available in the event of an emergent delivery
- ideally having the baby when I was readily available to be present for as much of the labor as possible, particularly the active phase and the second stage.
- not allowing her baby to get too big particularly since she had previously delivered a 9lb 7oz baby. The larger the baby, the harder the uterus has to work in order to deliver via the contraction forces required which when transmitted across her surgical uterine scar could increase her risk for rupture
- selective use of induction if conditions favorable for delivery presented themselves in order to satisfy the above three concerns regarding staffing, my presence and fetal size.
- use of internal monitors throughout labor to closely monitor the fetal status and uterine pressures in order to minimize adverse outcome from potential uterine rupture.

Her pregnancy was essentially uncomplicated. She then presented at 39 and a half weeks for a routine office visit. She was complaining of fairly regular contractions but nothing overtly painful. Upon exam, she was noted to have an advanced cervical change, namely in regards to effacement. This is the single most important factor in determining readiness for delivery. However, aside from this, her cervix was also 2+cm dilated, soft and anteriorly displaced with the head applied. All of these findings were very favorable for reaching active labor without difficulty. Further, she had shown a significant weight gain over the previous week and her fundal height was measuring slightly larger than expected. It was far and away in this patient's best interest, if successful VBAC was to be accomplished, to consider working towards delivery under the desired controlled circumstances detailed above. After discussing this with the patient, she was eager to proceed. Labor and delivery was called and an appointment made for the next morning to non-aggressively get the process going.

She was admitted and had an amniotomy (artificial rupture of membranes) performed. She soon thereafter entered active labor and received an epidural for pain by midday. She was complaining of persistent low back ache throughout labor and it was determined that the fetal head was occiput posterior. This not only was associated with "back labor" but, if not spontaneously corrected, could also pose a potential issue with continuous descent of the head as she entered the second stage of labor. She received a re-dosing of her epidural when she was 9cm dilated and became fully dilated soon thereafter in the mid afternoon. At this time, she was encouraged to push while I remained in the labor and delivery unit. After initiating her pushing, she continued to complain of the back pain. The nurse worked closely with her on proper technique since this was new for her while also enabling her to remain focused through the pain.

After nearly forty minutes of pushing, I was urgently called to the room. Upon entering, the patient was standing up on the bed screaming and behaving hysterically. It was a shock to see such a sight since she was normally a stoic and highly contained woman. She exclaimed that the pain was just too severe to be able to go on and that she didn't want to have the baby vaginally anymore. She had moved the head to a +2 station but it was lodged in the occiput posterior position still. She had essentially given up and refused to push anymore. I was able to calm her down and get her back in the bed. I discussed a number of options for her at that point which were fully documented in the chart. These included continuing to push, (which she had already stated was not an option for her), performing a cesarean section or offer her forceps assistance. After answering questions on the latter, she and her husband chose forceps. The indications for this offering was based on ACOG's Operative Vaginal Delivery indication criteria number three – shortening of the second stage for maternal benefit. She had reached her end point and aside from

any assistance in the actual delivery – vaginally, she was going to demand a c-section. This case was precisely the sort of circumstance whereby this indication was conceived.

Anesthesia was called to maximize her epidural so she could get some relief. Once comfortable, the Kielland forceps were readily applied and successfully implemented thus rotating the head to occiput anterior. These instruments were then removed and Luikart-Simpson forceps used to bring the head to crowning where after the patient completed the delivery of a 9lb baby by pushing with one contraction.

The baby was completely healthy without a mark from the forceps. The patient did sustain bilateral tears to the vaginal side walls from the forceps. This is a relatively common potential after affect from forceps depending on the bony pelvis of the patient. The ischial spines can be more prominent in some patients which pinch the vaginal mucosa against the forceps blades and thus can cause an avulsion-type tear. This sort of tear is not a reflection of anything but the fact that forceps were used. The lacerations were repaired without difficulty and the patient went home on post partum day two with her baby.

At her six week visit, she was noted to have some granulation tissue at the distal ends of each repair. Granulation tissue is an exaggerated healing response that very commonly involves the vaginal mucosa. It is mainly comprised of fleshy vascular tissue that easily bleeds when touched and can be uncomfortable for the patient when present. Treating it is rather simple by either pulling it off, cauterizing it or a combination of both. Doing so provides an immediate relief of discomfort for the patient. In some cases, it can recur and require a repeat effort in treating it. Once gone, it does not come back outside of any further injury to the area. After the second treatment for a small recurrence of her granulation tissue, it was gone and presented no further issue for this patient.

Page 17: Patient C – Rebuttal to OPMC Numbered Items

- 51. This information if essentially correct and alluded to above. One point to be made is that while the risk to the previous cesarean section scar is greatest once in labor, there is also a limited risk during the pregnancy itself, albeit remote.
- 52. No issues with this statement other than the second sentence should read, "progress of the *pregnancy* had been..."
- 53. The patient had a history of a large baby. Her weight gain was associated with a larger than normal fundal height, which suggested another larger baby. This was all remedied by the presence of her advanced cervical change as it related to labor potential via induction which was already a potential stipulation antecedent to her attempt at VBAC. There is no absolute standard of care when it comes to this clinical situation and the State never once produced a single document establishing anything of the sort. Their entire position was based on the stylistic opinions of their expert who declared himself throughout this whole proceeding by distorting the inherent latitude all physicians have the benefit of in managing their patients. There is no manual for the rigidity that has been claimed and forced upon my practice by the State and their expert in any of these examples of supposed misconduct. Sure, for some Obstetricians, expectant management might very well have been the way they would approach this case. It was, however, not the only way. The clinical considerations that constituted my approach were detailed in the narrative above. These were sound and legitimate reasons to work towards delivery and are far more justifiable than what thousands of Obstetricians cite each day to induce their patients.
- 54. The examination cited by the State was that of the admitting resident and indicative that dilation is often a subjective determination. What is important to note is that the effacement is 90% which, as previously stated, is the most critical parameter for getting a patient into active labor. That she was not contracting is irrelevant.
- 55. The medical indications for why this patient was brought to the hospital for delivery were thoroughly detailed in the narrative above. Labor induction is one of the most common procedures in all of medicine. The reasons for why any given patient would be induced are

- numerous and vary widely. When examined, the literature provides great latitude to the Obstetrician in determining when to induce a patient. The State never once produced any document indicating any sort of parameters or guidelines. The clinical indications for this patient fell well within any parameter within the specialty.
- 56. The State chooses to once again rewrite the standards of care that have been used by Obstetricians since anything has been written on the subject. Rupturing a patient's water at -3 station is categorically <u>not</u> a violation of any sort. For any Obstetrician testifying as an expert to offer such a mistruth constitutes a violation of ACOG's code of conduct. All cases of amniotomy require the operator to exercise care in doing so in order that the umbilical cord is protected. Just because there exists a theoretical risk does not make is wrong to perform. What's more, nothing negative occurred in this or any single case in my career when performing this procedure.
- 57. Once again, the State chooses to prosecute risk and not performance, outcome or critical thinking. There are an enumerable number of risks inherent to the world of medicine. Such a basis for prosecution is preposterous. When assigning wrongdoing with this numbered item, they seem to forget that this patient was admitted for an induction and would therefore not be expected to be contracting. Further, the cervix was, in fact, favorable as previously stated, so they are incorrect with this conclusion as well. However, even if the cervix was not favorable, such a condition is not prohibitive of performing an induction. Unfavorable cervical conditions are commonplace when patients present for induction of labor. For OPMC to insinuate that an induction with this patient's cervical condition constituted misconduct is telling as to clinical acumen and more likely, agenda. As far as infection risk, any patient who has ruptured membranes is exposed to this possibility. This is why all patients are closely watched and when a certain time frame has passed, they all receive prophylactic antibiotics. To add this to a list of charges again speaks to an agenda of throwing any and all possible distortions of the care rendered to see which ones stick enough to result in a conviction.
- 58. This statement is again just plain wrong. The cervix was nearly completely effaced with the head applied to the cervix for protection against cord prolapse. With this accusation, they are trying to legislate the smallest of clinical decisions granted to any Obstetrician. What is perhaps the strongest indictment of this charge is the fact that she immediately went into labor which confirms the fact that the conditions for amniotomy were just right.
- 59. This statement completely contradicts OPMC's very charges in the previous numbered item in that this patient was subjected to an unnecessary prolongation of her labor.
- 60. It is questionable as to why this statement would be made since it is commonplace for epidurals to lose their effectiveness over time.
- 61. At this moment in time, the patient had progressed very well and was 9 out of 10 cm dilated with the head well into the birth canal at 0 station. If the epidural was not optimally functioning, the patient would certainly feel it and therefore the need to "top" it off. At this point in the labor, with an otherwise healthy appearing baby, there was no reason to believe that a normal vaginal delivery could not be expected.
- 62. With the patient fully dilated just after 3pm and being comfortable with her epidural, she was allowed to rest for a short period so that the head could passively descend. She soon had the urge to push and therefore started. As described above, after only thirty minutes, the patient was not only in agony, but was hysterical and recklessly standing on the bed. The remaining point to be made here was adequately described in the case narrative.
- 63. This statement is true. Up until the point where she refused to go on, the head had moved down to a +2 station which enabled a straightforward forceps delivery to be performed.
- 64. The State contentions with this item are totally out of context. There is no way an after-the-fact chart review or prosecution (for that matter) could fully understand the dynamic that existed in that delivery room. The patient had just received a top off to her epidural. She had also refused to push anymore due to the pain she was feeling. An experienced Obstetrician is allowed to correlate such symptoms in his patient with that of a persistent and painful occiput posterior position. This was precisely the case here. For OPMC to dictate what the acceptable standard of

- care should have been is out of line and beyond the scope of their jurisdiction concerning the rights of an Obstetrician to manage his/her patient.
- 65. This statement was made in regards to the first delivery for Patient A and resubmitted here. Again, the State does not provide any study, text book reference or ACOG Practice Bulletin as evidence for this statement. Their sole reliance is once again on that of their expert. When there is a reasonably good sized baby in a primigravid pelvis, the likelihood of spontaneous rotation is tenuous at best and constitutes the basis for a significant percentage of cesarean births for failure to progress in labor. To say that the majority spontaneously rotate is simply not consistent with over a decade and a half of experience in Obstetrics.
- 66. This is correct. There were no fetal indications but there were maternal indications. Again, while ACOG clearly states that no indication is absolute, the third recommendation listed (written above as part of Patient A's narrative) reads, "shortening the second stage of labor for maternal benefit." It was absolutely to this patient's benefit to utilize the methods available to all Obstetricians to assist her in accomplishing not only a healthy vaginal delivery but the goal she set out to achieve from the very beginning that being a successful VBAC.
- 67. This section is completely correct in that the forceps were properly used and resulted in a healthy baby. As written above, forceps can be associated with certain lacerations of the vaginal mucosa as a component of their use. The vagina is capable of great expansion as evidenced by the tremendous variation seen in birthed baby sizes and can easily accommodate the thin bladed forceps. The predominant factor leading to the occurrence of sulcus tears is the prominence of the ischial spines in the maternal pelvis which the forceps can ride against while being used and thus result in a pinning of the vaginal tissue between the two that in some cases causes the injury. This is yet another reason why OPMC failed to exercise due diligence in obtaining a review and expert testimony for these cases by someone with extensive experience with the use of forceps as repeatedly asked and obviously denied. The contention OPMC makes about the forceps injuriously distending the vaginal walls as compared to that of the vacuum as if it was wrong to do so is merely an attempt to further manufacture the appearance of wrongdoing. Whenever a sulcus tear is encountered, then it is repaired where after it heals without scarring.
- 68. Granulaton tissue is not from incomplete healing. In fact, it is an exaggerated response **to** healing, and commonly seen when vaginal mucosa is sutured. This is often seen following hysterectomy after the top of the vaginal is sewn together at the end of the procedure. The sulcus tears healed very well for this patient. When she was seen months later, she complained of a tender spot inside the vaginal. A small amount of granulation tissue was seen and attended to. She did not have any further issue with this thereafter. There is no reason for any of this granulation tissue discussion to have ever made itself to this document.

Page 56: OPMC Determination Narrative – Rebuttal pertaining to the charges: Patient C

Charge 1: This first paragraph again indicts the fact that a sound medical management was undertaken concerning Patient C's desire to have her baby via VBAC. The reasons for working towards delivery have been thoroughly expounded upon in the paragraphs above. There were absolutely no unnecessary risks that this patient was exposed to. Rupturing membranes at -3 station is not a violation of any standard of care and the State never produced a single piece of evidence in support of such a ludicrous claim. Again, by making this charge, OPMC has unilaterally exposed every single Obstetrician in New York State to an investigation for misconduct.

Charge 2: Here again, the State intentionally leaves out the pertinent facts concerning the patient's hysterical state of mind and her unwillingness to continue pushing. Absent this scenario, of course it would have been prudent to allow her to push since she did in fact make some progress over that first half hour. However, this was not the luxury of the situation. By having had a previous cesarean delivery, this patient was allowed to opt for this manner of delivery at any time if she felt she didn't want to have a vaginal delivery for whatever reason. So when she became out of control after 30 minutes of pushing, a

clinical decision had to be made. Either perform a c-section or offer her some other alternative. She was appropriately counseled and made an informed decision to try a forceps delivery which was entirely within the standard of care concerning maternal benefit. This procedure would prove to be very straight forward and resulted in a completely healthy and favorable outcome.

It can be plainly observed that OPMC's continued condemnation of the multitude of basic Obstetrical principles seen in this and every case thus far reveals a profoundly licentious agenda and, more importantly, a highly questionable command of the subject matter they have contended themselves as being the authorities over. This case, like all the others, was deliberately manipulated in order to create the perception of misconduct so that it could be forced through a closed door process whereby career damaging penalty could be imposed. In doing so, the resulting arguments that are used to substantiate OPMC's actions are clinically feeble to say the least.

Case 5: Patient D

History: This case clearly represents the most bizarre clinical encounter of my career. When reading and examining the facts, the order of how information and clinical decisions manifested themselves is critical to understanding just how such a case could occur. Admittedly, and primarily in retrospect, this medical circumstance could have been handled in a different manner. However, once the details are discussed, it should be clear just how it unfolded. In fact, when this case was reviewed by a multidisciplinary team as part of a hospital root cause analysis, (attached at the end of this document), everyone in attendance agreed that it could have happened to anyone once and after the factual evidence was examined. Their conclusion was that no deviation from the standard of care was evident amidst the extraordinary set of circumstances.

The central theme to this case is the fact that Patient D was a morbidly obese early thirties multiparous African American woman whose weight was between 450-500 lbs. She was the largest patient (and individual) I had ever personally seen or ever treated. The significance of this last statement cannot be understated. I had been her doctor for years and had delivered a previous baby without any complications. Our relationship had grown nicely over her time in the practice with considerable trust having been established.

In October of 2005, she presented to the office having just had a positive pregnancy test. Her history revealed menstrual-like bleeding every month before and after she stopped her birth control pills in May of that same year. Given her obesity, her cycles were prone to a degree of irregularity due to ovulatory dysfunction. While on the pill, her bleeding was much more regular and predictable but she did in fact describe a periodic bleeding episode on roughly a monthly basis after she stopped. She stated that she stopped her bleeding at the end of August but didn't know the exact date. Recent to presenting to the office, she did a home pregnancy test which was positive and the reason for the appointment. She was not bleeding and had no complaints.

After she was seen in the office as part of her initial evaluation, she had a Bhcg and serum progesterone obtained to establish a basis of where she was in pregnancy so that she could be further managed. She was otherwise scheduled to return in a week for an ultrasound pending these results. When the lab results came into the office, my nurse practitioner caught me in the hallway while seeing patients and informed me of her Bhcg level. When asked about her progesterone, she responded that it was "high".

In our office, we obtain a serum progesterone level for a number of reasons. First, it establishes the function of the corpus luteum within the ovary from where ovulation occurred since this is the primary source of this critical hormone in the first ten weeks of gestation. If it is lower than expected, then it could signify a defect in the production of progesterone which can and does happen. If caught early

enough, supplementation can be initiated and therefore salvage an otherwise at-risk pregnancy for miscarriage. Second, the level of progesterone can be an adjunctive factor in establishing the risk for ectopic pregnancy if the Bhcg is not rising appropriately in early pregnancy. In my experience, very few practices order testing of this hormone in early pregnancy for reasons that are unclear given the above information that is gleaned. When we obtain a progesterone, it is either described in our office as low, normal or high depending on the result in relation to the desired range of 16-20ng/ml. If it is lower than this range, then it is designated as "low". When it is within this range, then it would be described as "normal". And when it test greater than 20ng/ml, then we often describe it as "high". The higher it is, the better. It is important to understand that anything above 20 is considered desirable. In essence, one can't have too much endogenous progesterone production in pregnancy since it is all good. So it really doesn't matter what the number necessarily is, so long as it surpasses this threshold. Of course, (as in this case) the number can be excessively high for the appreciated gestational age. But without having that correlative understanding, a level of 150 wouldn't be readily seen as suspicious. So devoid of having personally seen the result, when my nurse practitioner stated the progesterone level as "high", it was then interpreted as normal and therefore not a factor for her to be at significant risk for miscarriage based on corpus luteum failure or suspicious for ectopic pregnancy given an abnormally low value. Again, all indication was that she was in the first trimester and without actually having been told the value, wouldn't have questioned the information as it was presented.

The fact that I did not physically see this lab result after the aforementioned description by my N.P. (who then signed off on it) is one of the critical points in how this case played out. As a matter of fact, I never physically saw any serum progesterone levels for this patient during the course of her treatment and clinical decision making. This will be explained in greater detail below. The patient was sent for a repeat of her Bhcg level a few days later in order to confirm that is was doubling every two days. The repeat was roughly the same as the original level which raised the suspicion of a potential problem. The lab who does these tests for us automatically runs a progesterone as part of the typical pregnancy profile for our practice even if a Bhcg was the only thing ordered.

A week later, Patient D came in for what was thought to be a 6-8 week gestational ultrasound based on the Bhcg level being around 5,000. She had a 15-20 minute real-time transvaginal ultrasound performed by a highly skilled and experienced licensed sonographer who worked full-time in our office. She used a \$110K recently purchased G.E. Voluson 730 Pro 3D/4D Ultrasound unit for the exam. Although somewhat limited due to the patient's considerable size, the sonogram revealed a vacuolated uterine cavity without any identifiable gestational sac or fetal pole. There was no identifiable tissue or pregnancy at all. **This is the most critical aspect of this case to consider when reading further.** The information obtained from this sonogram when combined with the blood work as well as her history of what was otherwise menstrual bleeding up until eight weeks earlier led to the presumption of a missed miscarriage in the form of a blighted ovum.

At this point, given the information that was available, there was every reason to believe that this patient had a non-viable pregnancy. The decision at this point was what to do with it. The natural history for a blighted ovum is for the uterus to eventually expel the products of conception. This can be either completely accomplished or (in some cases) incompletely so. For the latter situation, surgical intervention is necessary. Given the poor surgical candidate that this patient represented, the decision was made to chemically assist in the completion of the process. This is where methotrexate was implemented. She was counseled and given the appropriate dose for this early stage of pregnancy. Blood work was ordered thereafter to ensure no hepatic toxicity as part of usual protocol for using this medicine.

Her Bhcg level failed to fall and the patient subsequently complained of mild cramping. Therefore, she was scheduled for a suction dilation and curettage in order to complete the process of uterine evacuation for a non-viable first trimester pregnancy. When she was taken to the operating room, there were several medical personnel present including a senior ob/gyn resident. There was nothing about her presentation that alerted anyone involved. She subsequently underwent a rather straightforward suction dilation and

curettage. Nothing about the procedure was out of the ordinary. The uterus was sounded in usual fashion and the curved suction tip advanced without any difficulty with the appearance of some products having been obtained. There was no excessive bleeding and absolutely no sign of anything other than a first trimester pregnancy.

That weekend, the pathology report from the d&c was received at the office. Within the specimen, there was an absence of chorionic villi, which is the primary component of placental tissue and thus the pregnancy. Under typical circumstances regarding the clinical information known, the lack of pregnancy tissue on this pathology report raised the suspicion of ectopic pregnancy. Repeated attempts were made to contact the patient beginning that Monday in order to come into the office and for repeat Bhcg. She did not return the message until the following week and said she would be in on that Wednesday. She was counseled to call if any pain or bleeding was experienced in the meantime. On the morning of Wednesday, December 7, 2005, she called the answering service complaining of light bleeding and pelvic pain. I called her and instructed her to immediately go to the emergency room, concerned that she had a symptomatic ectopic pregnancy. Once seen there, she was worked up and the E.R. attending physician called me. He informed me that she was found on ultrasound to have a 38 week gestation and that they were sending her up to labor and delivery for being in labor. I instantly said that I thought he had the wrong patient and surely there was some kind of mistake. He assured me of who he was speaking of. I went to the hospital where after she delivered a male infant who was perfectly healthy.

After the delivery, I went straight to my office in order to unravel how this could have happened. I reviewed the history, the sonogram and all laboratory results. It was here that I saw the significantly elevated progesterone levels for the first time. They had been signed off by my nurse practitioner and filed in the chart. Not once prior to this had I known any of them to be greater than 100 ng/ml. Even though the first one had been described as "high", again, in our office, this was meant to be simply greater than 20. By no means did my N.P. intend to misrepresent the value. There simply was not any definitive experience with such a level in order to properly interpret the significance. Had just one of these levels been known by myself, the entire management would have certainly been different given the outright inconsistency with that of a first trimester pregnancy. What clouded this case was the fact that her Bhcg levels were consistent with a first trimester pregnancy for a presumed gestational age indicated by her history. They were also within the extremely wide range for that of a third trimester pregnancy - values which are rarely if ever tested for. The occurrence of this hormone having similar levels at these two extremes of gestation (when combined with her history and especially the ultrasound, in the absence of knowing the progesterone levels) led to the belief that she was in the first trimester.

I sat and discussed the case at length with the patient. She was a bit troubled by how the events unfolded but was grateful for a healthy outcome. She claimed to not have had any clue that she was further along than what she believed when she presented. She had no real indication of fetal movement or other sign of advanced pregnancy, despite having had three other children. She and the baby went home on post partum day two.

After this case, there were several other questions that emerged as part of my obsession to understand how such a misdiagnosis could have occurred, even without knowing the progesterone. There were two primary items that begged for an explanation. First was how did a lengthy sonogram fail to identify any sign of a baby that would have been around 31-32 weeks gestation? Not once did any fetal tissue or part (head, arm, leg, torso, placenta or cord) present on the screen during the ultrasound. There was absolutely no explanation and nothing like this has ever been seen in several thousand third trimester ultrasounds I have personally observed. As previously stated, this patient was extremely obese and clearly stretched the limits of our highly advanced office ultrasound unit. Transvaginal sonography is far superior in the first trimester for visualizing early pregnancy over that of a trans-abdominal approach. And with this patient, there was so much abdominal tissue mass that the abdominal probe was completely ineffectual. The reason the hospital was able to identify the pregnancy on December 7th was because their quarter million

dollar equipment is significantly more powerful and able to penetrate the soft tissue of her abdominal wall.

The second mystery in this case was how an otherwise straight forward dilation and curettage could have been performed whereby tissue was recovered on multiple passes with the curette and no significant bleeding or moreover, rupture of membranes was incurred. Moreover, the uterus sounded to 11 cm. The average pregnant cervix is 4-5 cm. It is inconceivable as to how and why the gestational sac was not disrupted if it was truly present within the operative field of that d&c. Therefore, when these two idiosyncrasies are combined, the possibility that this patient had a mullerian anomaly that contributed to the misdiagnosis was proposed. It could readily explain the ultrasound findings, (or lack thereof) as well as the atraumatic nature of the dilation and curettage.

As stated earlier, this case went before a multi-disciplinary team of clinical providers as part of a requisite root cause analysis for the hospital. As part of this process, the literature is reviewed. When this was done, there were widespread reports nationwide whereby the relative power of radiologic equipment was failing to properly penetrate the soft tissue of morbidly obese patients thus leading to scores of misdiagnoses. Manufacturers were constantly having to redesign their products and hospitals were frequently finding it necessary to upgrade their equipment in order to keep up with this dilemma. When all the clinical information was detailed, particularly focusing on the order by which it was known, there was universal agreement that no deviation in the standard of care had occurred.

The cornerstone to the case was the misdiagnosis. The ultrasound was seen as the primary failure and therefore new policies were adopted to address this issue. Within our office, any patient greater than 300lbs was there after always send to an outside radiology center for ultrasound studies. The power advantage of the equipment was significant enough to make a clinical difference. Also identified as part of this analysis was the fact that this patient had been seen in the hospital's prompt care prior to her first visit with our office. She did not disclose this information and this treatment facility never sent a report of the visit to our office. This matter was addressed and a policy change within the hospital was implemented so as to prevent this in the future.

There was also the issue of certain laboratory results (progesterone) not having been clear early on as well. Our office has always been exceptional in the management of lab studies and correlating them clinically as well as communicating results to patients. In this case, the logistics of an extremely busy office and that of the chart filing duties of the nursing staff were enough for the actual values of this hormone to have been both missed by the physician and the significance misunderstood by those actually seeing them. While there is no overt understanding as to how this information was missed, this was purely an isolated case and was far from being representative of the office as a whole. There has always been an emphasis on excellence that when this occurred, the entire office was mortified over the sheer possibility of it all. Nonetheless, a mistake was made and policy changes were implemented such that all abnormal and pregnancy related lab values required a physician signature in order to be filed.

The findings of the root cause analysis as well as the policy changes made across the board were written up and sent to the New York State Department of Health as part of a mandatory reporting on such incidents. I had already been involved with OPMC for Patients A, B, C and F by this time. Despite a thorough review within the hospital having already been done on the case, it wasn't until the second hearing, (after the original hearing was thrown out on appeal), did the State decide to tack on this case as part of their prosecutorial effort. I cooperated with all their wishes, went to the obligatory interview and provided them with all the facts and details in writing. It did not matter. This case was going to be part of the second hearing.

Page 21: Patient D – Rebuttal to OPMC Numbered Items

- 69. As stated above, this visit was not known to my practice. Promptcare never sent any records regarding this visit. The patient gave us a totally different last menstrual period. All of this was recorded in her office chart.
- 70. & 71. There is no dispute to this point. True, it is important to establish not only the specific interval of the patient's periodic bleeding in order to understand whether it was driven by regular ovulation or dysfunctional ovarian function but also the character of each of the bleeding episodes. This patient was a fairly reliable historian who described somewhat regular interval bleeding. Given her predisposition for some degree of ovulatory dysfunction and the imprecision of her bleeding account, her dates could not be reliably determined by her history but at least put into some context providing other information being obtained. This is why she was sent for Bhcg and scheduled for an ultrasound to establish dates.
- 72. Notwithstanding the fact that Crouse Promptcare never send our office any records indicating this visit, their dating was based solely on the history they obtained from a patient clearly inconsistent with her story but only realized after the fact. The State indicates that the Promptcare dates significantly varied from what we obtained ten days later. Nonetheless, their dates were (understandably) even three months off from where this patient truly was in the pregnancy. It is not out of the question for a patient such as this who presents to a promptcare setting when there is some uncertainty to her dates to have a sonogram ordered. This was not done and otherwise could have saved a lot of trouble in this case given the hospital's superior equipment as alluded to above.
- 73. True she was seen on October 31st. However, just because the chart indicates an inexact date for the patient's last menstrual period, it has nothing to do with the certainty on part of the nurse. She was just writing down the uncertainty of the patient. And true, unless this date is certain, there will always be difficulty in dating a pregnancy without further information via Bhcg and ultrasound.
- 74. Correct. Bhcg doubles roughly every two days and peaks at around 12 weeks gestation. Thereafter, it slowly decreases and levels off at some point in the third trimester.
- 75. As stated in the narrative, the actual level of the progesterone was not known by myself due to a snafu in the office with the unseen report having been filed and the qualitative information having been previously verbally communicated. The lack of actual visualization and quantitative knowledge of this hormone during this case was an extremely atypical oversight that was addressed thereafter so as to eliminate any chance of recurrence. The assertion made here by the State regarding a Bhcg level of 4496 is incorrect. As written above, it is highly consistent with that of an early first trimester pregnancy. After peaking at 12 weeks, whereby the levels can get into the hundreds of thousands, it eventually normalizes and can settle anywhere between 4,000 and 120,000 in the third trimester.
- 76. There is no debating the State's assertion here. However, they are blatantly operating from a hindsight perspective while fully aware of my testimony about not knowing the progesterone levels. Two things are important to understand. While I admittedly was not aware of the progesterone levels, had I been, there would be no question as to the inconsistent nature of them to a first trimester pregnancy. This is fundamental knowledge and was never disputed by me. Nevertheless, the slight decrease in the Bhcg was potentially clinically very significant. If operating from the perspective of a first trimester pregnancy (based initially on history) then such a minimal change or subtle drop would clearly indicate a problem even if the perceived qualitative progesterone level was not felt to be an issue.
- 77. Again, in the absence of the quantitative progesterone information (while all other clinical information pointing towards a first trimester pregnancy), this drop in the Bhcg would absolutely be indicative of a nonviable pregnancy in the first trimester. This is where an important point needs to be made. Notwithstanding the lack of information regarding the actual progesterone values, both the medical personnel present for the root cause analysis at Crouse Hospital and (interestingly) the State's expert witness agreed that despite the factors leading to the misdiagnosis of the true gestational age, all medical decisions and treatments that ensued were consistent with acceptable standards of care. This would include the conclusion that there

- existed a non-viable pregnancy based on the dropping Bhcg's and an absence of an identifiable intrauterine pregnancy by the highly accurate method of transvaginal ultrasound.
- 78. The sonogram was indeed necessary in light of the patient's uncertain dates as well as the dropping Bhcg in establishing the intrauterine presence of the pregnancy and whether or not it was viable. If the actual progesterone levels were known, the sonogram would have lent very little to the "interpretation" of these two hormone levels since it would have been apparent that they were not consistent with a first trimester pregnancy. The sonogram was indeed done but revealed no visualization of a baby consistent with that of a third trimester pregnancy. If this was the case in the face of known progesterone levels, a more powerful ultrasound would have "supplemented" the conclusion that somehow our exceptional unit was incapable of penetrating this patient's body habitus in order to confirm an advanced pregnancy.
- 79. This statement insinuates that the patient's menstrual dating was the sole parameter used in dating her pregnancy. She did give a history of fairly regular periodic bleeding up until the end of August. However, since her history was not definitive, this is why labs and a sonogram were ordered. Again, excluding the issue of the progesterone levels, the sonogram and the labs were consistent with her history.
- 80. The State decides to take a duplication position here which is not readily apparent to the reader. Their expert testified that he has never ordered a serum progesterone when obtaining a Bhcg early in pregnancy to establish dating and viability. He didn't know why such a thing would be done. The benefit of determining a healthy level of this hormone was detailed above but yet an expert in testimony was not conversant of these facts. It wasn't until my testimony on the subject did the State decide to adopt the position as to the significance of obtaining this information. As far as using Bhcg to interpret the relative gestational age in early pregnancy, when there is fairly good dating based on either menstrual period and/or sonogram, it is a very reliable test unto itself to confirm or to correlate the information already at hand. The progesterone is essentially never used as a dating parameter in early pregnancy. It is only used for establishing adequate corpus luteum function (>20) which is critical to the sustenance of the uterine lining up until ten weeks gestation. The fact that the progesterone was excessively high in this case did speak to an inconsistency with that of first trimester levels. However, it has been repeatedly stated that these levels were understood in a qualitative and not a quantitative manner which contributed significantly to the misdiagnosis. OPMC writes as if these levels were known and ignored which is absolutely incorrect.
- 81. These statements are correct. In this particular case, this patient's abdomen was so profoundly large and pendulous that an abdominal probe was completely ineffective in being able to see any intra-abdominal structures.
- 82. There was certainly a relative limitation in being able to fully assess the pelvis of this patient even with the transvaginal probe. The cervix is the closest structure to the probe and therefore most readily measurable. There was a great deal of the intrauterine cavity seen on the study, yet with no visible pregnancy identified. Not every transvaginal ultrasound is capable of visualizing every structure (i.e. the ovaries) in every patient. True, the sono tech was not able to completely obtain all measurements due to the patient's size. However, the information (or lack thereof) contained on the scan and pictorial record was consistent with the patient's dates and Bhcg as being in the first trimester which we now know all to have been deceivingly inaccurate. The failure of what was otherwise a highly advanced ultrasound machine in this tremendously morbidly obese patient was validated by numerous studies indicating that such occurrences had become prevalent across the nation as segments of the population have gotten more and more overweight. This information was revealing to everyone who participated in the root cause analysis. For these reasons and moreover, the outcome of this case, an immediate policy change was made in the office so as to avoid such a misdiagnosis from ever happening again when involving an obese patient.
- 83. Again, the State is operating from a hindsight perspective with their comments made here. Even their own expert testified that all management decisions and actions were within acceptable standards of care once the diagnosis of a first trimester missed miscarriage was made. The lynch

pin in this case was that this conclusion was erroneous based on the misleading information obtained via the patient's history, sonogram and Bhcg. The absence of the exact progesterone levels has been spoken to repeatedly as a cofactor in this misdiagnosis. What was seen on the sonogram was pretty definitive in not identifying a pregnancy, especially one that would have been 31-32 weeks gestation at the time. There has never been an explanation provided as to how this could occur. The State and their expert had an opportunity to view these pictures and offered no rebuttal or differing of opinion as to what was seen (or not seen) on them. To put it another way, when using a transvaginal probe on any patient at 31-32 weeks gestation, one can, with near 100% certainty, expect to see some evidence of the pregnancy occupying the lower segment of the intrauterine compartment – be it a leg, arm, head, torso, cord, placenta, etc. It is not as if there exists a known phenomenon that precludes such an expectation to then prompt an Obstetrician to automatically consider it a third trimester pregnancy anyway when such structures are not identified. For this reason alone, there was no motivation to obtain an abdominal scan on this patient since the transvaginal probe was superior in visualizing the pelvis in such an obese patient and provided the information that it did. It is difficult to accurately explain in written form just how big this patient was in order to illustrate this last point. Certainly, if there had been a cause at that time to send her to a radiology suite where their machines possess far more power to penetrate the abdominal wall in such a patient, then undoubtedly this case would have turned out differently. There was no deviation from the standard of care, nor a gross one for that matter in regards to the use of sonogram in establishing this patient's dates given the circumstances already described. I agree that it is easy to criticize the erroneous nature of the information obtained after the fact. However, one must consider the manner in which these particulars unfolded which thereafter led to management decisions based upon them.

- 84. Again, the absence of knowing the actual progesterone levels has been repeated written about. The Bhcg level having stayed in that range remained consistent with the working diagnosis of a missed miscarriage in the first trimester when correlated with the (now known) inaccurate dates and sonogram information.
- 85. This patient was suspected of having a first trimester nonviable pregnancy. At no time did she ever describe "movement" consistent with that of a baby. She did complain of pressure and cramping which could easily be associated with a missed miscarriage. The fact that her urinary and GI functions were normal did not prohibit this conclusion from being made given the working diagnosis at the time.
- 86. The sensation that this patient was experiencing could most certainly be all the things described by the State in this section in addition to symptoms of an impending miscarriage. Of course, having ultimately learned that she was actually pregnant in the third trimester these symptoms most likely were due to the advanced gestation.
- 87., 88 & 89. The use of methotrexate under the working diagnosis of a missed miscarriage or nonviable gestation in the absence of spontaneous expulsion in the first trimester for this patient was not a deviation from the accepted standards of care as agreed upon by those having reviewed the case at the root cause analysis as well as the State's own expert. The State is indicting this decision as if there was foreknowledge of a third trimester pregnancy which was not the case. Methotrexate has long been used in Obstetrics to expedite the spontaneous expulsion of a missed miscarriage or to treat a nonviable pregnancy when its location is not absolutely determined, such as in suspected ectopic pregnancy. Therefore, the State's statement as to location needing to be absolutely determined is incorrect. To repeat, the clinical information that was considered in making this management decision was a combination of the patient's dates, Bhcg levels and ultrasound findings which pointed towards a first trimester non-viable pregnancy. Obtaining liver function tests (LFT's) in conjunction with using methotrexate is recommended in order to establish normal hepatic operation since this medication is metabolized here. This has always been the standard practice when this medication is used for my patients. Despite being a good clinical exercise, there has never been a case in my experience under these medical circumstances whereby such testing identified a patient with abnormal hepatic function,

particularly in the absence of any symptomatology. In fact, studies have been done looking at the absolute necessity of LFT's prior to using methotrexate and have found an overwhelmingly low incidence of hepatic deficiency thus questioning the true need for such testing. The fact that this patient did not follow through with this testing is not a deviation from the standard on part of the physician and proved ultimately to be inconsequential in the overall management and outcome in this case.

- 90. The use of methotrexate in the first trimester to resolve a nonviable pregnancy is not always effective. This is evidenced primarily by a failure of the Bhcg to significantly decrease as was seen in this case. This is not a new phenomenon and is well established when using this medication for this purpose. Once more, the fact that progesterone levels were continually being done by the lab was not known and not a specific piece of information being sought by my office. This repeated testing of the progesterone was a function of the laboratory automatically running this assay whenever a Bhcg was ordered. The chief interest was in the Bhcg which was the principal information being sought when results were available. The lab would initially fax them to the office. The Bhcg would routinely be sent separate since it is run at once while the progesterone took longer due to batching of the samples. This would account for the two results not initially being seen together. Eventually, hard copies with both would follow a day after the information had already been employed.
- 91. There is little dispute with this numbered item. The dilation and curettage proceeded in typical fashion and nothing appeared out of the ordinary to all personnel in the operative suite. The possibility that this patient had a mullerian anomaly was entertained upon reviewing the totality of this case in particular, the d&c.
- 92. All of these risks are correct. However, the key factor the State leaves out is that this d&c was not *knowingly* performed on an advanced gestational age pregnancy. What's even more astounding is the fact that not one of these risks presented clinically despite the advanced gestational age of the pregnancy. This glaring truth speaks to something out of the ordinary with Patient D's uterine anatomy. Otherwise, given the invasive nature of the surgical procedure, one would have expected bleeding as well as ruptured membranes to have been an almost certainty.
- 93. Absent the quantitative knowledge of the progesterone, the information obtained was reliable and consistent with that of a first trimester pregnancy. The State had more than enough information to see clearly what I and everyone at the root cause analysis saw in order to understand how this conclusion could be made. The State's own expert testified that he never orders a progesterone level in early pregnancy. Therefore, he would have relied on the very same information that was available in this case which all pointed towards a first trimester pregnancy. The only information that spoke against it was the quantitative measurements of that very progesterone their expert said he does not obtain. OPMC saw the sonogram pictures visualizing a uterine cavity devoid of any sign of pregnancy, yet they offered no explanation themselves. Palpating an 8-10 week pregnant uterus in a 500 pound patient is not only impossible, such an exercise is rendered moot when transvaginal ultrasound is available. We now know that she in fact had a 31 week pregnancy which was not even discernible given the enormity of her abdominal adiposity. The State cannot therefore contradict themselves by concluding that there was a gross deviation from the acceptable standards of care by giving methotrexate and subsequently performing a d&c when they agreed that these were appropriate management options under the clinical circumstances that this patient was presumed to be. The fact that a misdiagnosis was made does not negate these conclusions. They assign this determination by insinuating that these clinical management decisions were made on a known third trimester pregnancy.
- 94. This numbered section is true, so long as the pregnancy is intrauterine.
- 95. The State is inaccurate with the facts in this section. The patient called my answering service prior to the office opening. She was sent to the emergency room for evaluation and wasn't seen at the office. The reason the history of oral contraceptive use (up until May) appeared in the chart that day was from questioning of the patient further upon learning of the advanced

gestation. The misdiagnosis was quite distressing, so additional information was eagerly sought in order to understand every aspect of how this could have happened. The fact that she stopped oral contraceptives in May in no way disqualified this patient from being able to properly discern periodic bleeding in order to provide what she thought was the date of her last menstrual period. This assertion by the State is simply incorrect even if the patient was incorrect. The fact of the matter is that her true last menstrual date was somewhere around March despite her having taken oral contraceptives for two months into the pregnancy. Any bleeding she experienced after conception in March was likely due to withdrawal effect from the pill while still on it and from an unstable endometrium during the second trimester once off it. To the patient, this bleeding appeared to be enough for her to think that it was her menstrual cycle, thus leading to the erroneous dates provided. But as stated earlier, these dates were in fact not completely relied upon but were correlated with a Bhcg and a sonogram which were contributing factors in the misdiagnosis. The abdominal scan obtained in the hospital was done on a machine that was far superior to the one in our office despite unto itself being a quality unit. I actually spoke with the technician who stated that their machines cost in the neighborhood of \$250-300K.

- 96. By the grace of God, the outcome of this case was very good. The patient's body habitus was indeed a significant factor in this case purely by the limitations that it imposed on our advanced office ultrasound equipment. So as not to be excessively redundant, the primary data point that contributed to the misdiagnosis was the lack of a quantitative knowledge of the progesterone. Had this been known early on or at any point, additional testing would most certainly have been done. The assertion made by OPMC in this numbered item is that I knew of these values and failed to act on them. This is categorically not correct.
- 97. There cannot be a failure to adequately assess the serum progesterone levels when they are not quantitatively known. This was made absolutely clear to the State who simply continued to ascribe condemnation as if they were known all along. I accept the criticism of somehow not having physically seen them after my appreciation of the first value being qualitatively sufficient. I truly had no idea that they had been repeatedly obtained with each Bhcg since there would have not been any reason to do so once the first one was established as >20 by being told that it was "high". As for the failure to accurately diagnose the true gestational age of the pregnancy, the operative information that was available in making this determination was muddled just enough for it to happen. The clinical decision making was not faulty, the data was. This is very important to understand.

Page 56: OPMC Determination Narrative – Rebuttal pertaining to the charges: Patient D

Charge D1, D2, D3, D4 and D5: This case has been exhaustively described above on all the matters discussed in this section of the determination. The following points will be once more emphasized. The patient provided reasonably good dates at the time in order to establish a rough estimate of her pregnancy's age. There was absolutely no reason to think that what she described as monthly bleeding was in fact periodic bleeding throughout her pregnancy and that she actually got pregnant seven months earlier. Such a presentation is highly irregular and extremely uncommon even for an obese patient with a history of ovulatory dysfunction. When her Bhcg was obtained, it was consistent with her dates as to being around eight weeks gestation. The progesterone that day had been verbally communicated indicating a qualitatively appropriate level. A repeat Bhcg was done which was slightly lower that the first which created concern as to the viability of this pregnancy which for all intents and purposes was still felt to be in the first trimester. When the patient ultimately presented for a sonogram, she was found to have a uterine cavity that was vacuolated but without any identifiable pregnancy – consistent again with the aforementioned suspicion of non-viability in the first trimester. Sure the sonogram was limited by the patient's size and thus affected some of the measurements. This did not negate the information that was gleaned which, again, was in harmony with the above concerns. There was no urgent need under what

appeared to be clear circumstances to obtain an outside abdominal ultrasound. Therefore, this did not constitute a gross deviation from the standard of care.

First trimester missed miscarriages happen all the time in Obstetrics and are accompanied by clinical information just like this case revealed – dates establishing rough gestational age, Bhcg levels not doubling and no identifiable pregnancy on sonogram. The only piece that differed here was the level of progesterone where they were elevated far beyond that expected for a first trimester pregnancy. There was not a failure to consider them in the context of the other information. In order to fail to consider them, one must know of them. This was sadly not the case here. While I did have qualitative knowledge of the first value, there was never a quantitative confirmation of this or any of the others that were subsequently obtained. The misdiagnosis led to all management decisions thereafter. Again, had the diagnosis been correct, all clinical management was deemed appropriate under such circumstances and therefore cannot constitute misconduct.

The State completely mischaracterizes my testimony at the hearing. My statements regarding the misdiagnosis were aimed at clarifying just how it could have occurred in the first place. Their use of the word "blame" was a intended to sully my honest explanation. By pointing out the patient's dates, her size, the sonogram and the miscommunication of the progesterone level, this was done so the committee could understand just what happened since I was already guilty of misconduct in their minds and trying to prove my innocence. I readily accepted that not having a quantitative knowledge of the progesterone was an oversight that prompted in an immediate correction to protocol in the office.

They also repeatedly refer to my attempts to "expel" the pregnancy as if I was on a mission to terminate it when said efforts were meant to assist resolution of a perceived first trimester miscarriage. They surreptitiously word it as though I knew the pregnancy was in the third trimester when they clearly heard abundant testimony to the contrary. The truth is that these clinical efforts under the working diagnosis of first trimester non-viability (right or wrong) were not a deviation from the standard of care. The bottom line is that there was a failure to make an accurate diagnosis for the variety of reasons thoroughly alluded to in this writing.

There are a few additional pieces of information that are essential to the full understanding of this case and how it was adjudicated at both the hospital and State levels. It was already mentioned above that the root cause analysis (RCA) at Crouse Hospital resulted in all members in attendance not only fully understanding the manner in which this case played out in real time but that despite the fact that a misdiagnosis was made, there was no deviation from the standard of care after and based on that presumptive diagnosis. As this meeting was being held, there was an executive secretary contemporaneously documenting the evaluation and conclusions. After receiving a copy upon request, the majority of the content that what was discussed had been noticeably altered by the very Perinatologist mentioned at the beginning of this document whose friend was the basis for my 2005 State hearing being thrown out after he somehow managed to gain access to the panel (jury). The mutation of this report was clearly an attempt to distort the facts as an additional part of the larger campaign against my license that had already gone awry with the failed first State hearing based on an obvious tampering with the process. Recall that Patient D's case was eventually added to the State's action for the 2007 hearing. This RCA report (attached to the end of this document) had to be officially corrected before being sent to the State and consequently this particular misleading effort disrupted.

At the 2007 hearing while defending this case, the Attorney for the State had in his possession, a hostile document with the clear moniker of IPRO. Not once during the assessment or prosecution of this case was there any provision of it or disclosure by the hospital or the State of New York as to the existence of such a report, how it was created and by whom. Nowhere was the original (NYPORTS) document that was the official hospital report on the incident.

One last necessary component to point out is the fact that this very same Perinatologist, while having no official access or authority to do so, visited Patient D while in the hospital and instructed her that she should seek legal action against me. This contemptible act further compounds the aggression by which certain persons of influence sought to cause harm for daring to oppose what they were abusively doing. Patient D revealed this to me while I sat with her to discuss the particulars of the case that have been written about above. She never pursued such a thing.

At the State hearing, the expert for my defense was the Chief Medical Officer for Crouse Hospital who also presided over the Root Cause Analysis

In many ways, this case remains an enigma after having reviewed it so many times. To this day, there has never been an adequate explanation as to the transvaginal sonogram not revealing the third trimester pregnancy or the lack of complication from the suction d&c performed. Again, it was suggested that perhaps she had a Mullerian (Uterine formation) anomaly. Sadly, this patient died approximately three years later, presumably from complications due to her extreme obesity, without ever following through with further studies.

Case 6: Patient E

History: Before proceeding with the factual accounts for Patient E, OPMC's description and determination for this case are an absolutely disgraceful misrepresentation and distortion of the actual events, professional disclosure to the patient and medical science. In keeping with how they treated each case during this proceeding, not one shred of material evidence was submitted in support of their flawed conclusions while simultaneously failing in their duty to formally address each of the defense's counterpoints.

Patient E was a mid-twenties year old primigravida who at approximately 17 ½ weeks gestation called my service one evening at around 9pm seeking to speak to me about her troubled pregnancy after being referred by a close family friend. After a brief history, she was asked to make an appointment at the office. She was seen the next day and gave the following account. At approximately 9 (nine) weeks gestation, she began having intermittent bleeding during the pregnancy. This was addressed with her previous doctor but did not completely abate. During the week preceding my involvement, she had been admitted for a few days at St. Joseph's Hospital for bleeding and mild cramping. After this, she was sent home being told that there was nothing more that they could do. She was instructed to call after her baby delivered, which they said would eventually happen but not clear as to when. She was not comfortable with this plan and sought another opinion on the matter.

Upon examination at my office, she was noted to have good length to her cervix and evidence for a subchorionic bleed, which was consistent with her history. The baby was otherwise ok but she was cramping enough for there to be a risk of outright labor if the uterine activity persisted. She and her husband were brought to my office where we talked for a while about the definition and natural history of subchorionic bleed and how it applied to her circumstance. It was abundantly clear to the patient and her husband that by being remote from viability, this case was not only an extreme Obstetrical circumstance seldom encountered but that any and all efforts were quite possibly not going to result in a favorable outcome. Since her pregnancy had already been written off by her previous doctor, they felt compelled to at least try rather than simply wait for her baby to deliver at home, as she was left to otherwise do. I offered them an option of making the effort so long as it involved utilizing established methods to do so.

[At this time, it is critical to establish the fundamentals of not only what a subchorionic bleed is but also the natural history of such an Obstetrical complication. First is the anatomical structure known as the chorion. The bag of water that the fetus develops within is comprised of two layers – the outermost chorion and the innermost amnion. The two are fused together early in gestation. The chorion is the layer

that is in direct contact with the entire inner surface of the uterus aside from that portion that has the placenta attached. The uterine lining, (endometrium) undergoes a transition early in pregnancy under the influence of elevated progesterone levels and becomes the decidua which is what the pregnancy directly interfaces with. This lush layer of tissue is very vascular and in some patients can experience bleeding. When this is the case, the bleeding is contained either beneath the placenta when this is the location of the event or beneath the chorion when elsewhere. The latter is the more common scenario. When such bleeding occurs, it can be totally contained between the uterine wall and the chorion or the blood can work its way beneath the chorion, traveling via gravity towards the cervix where it escapes the uterine cavity and is seen as clinical bleeding from the vagina. This is also the more common manifestation of this condition.

When a sub-chorionic bleed occurs, the course of the problem can take many potential avenues. When occurring early in the pregnancy (first trimester) it usually is self-limiting so long as the patient takes it easy and the site of bleeding does not get further aggravated. The pressure created by the bag of water from the growing pregnancy against the uterine wall produces a tamponade effect to assist in resolving the bleeding. This effect, however, does not always result in the problem going away. On some occasions, the bleed can persist for a weeks. When this is the case, it can still resolve with patient and pelvic rest but presents the relatively uncommon possibility of a chronic form of the condition which can persist well into the second and even the third trimesters. What dictates the course of the bleed is multifactorial and depends primarily on what exactly is out of order within the uterine wall causing the bleeding. It is far in the best interest of the pregnancy for all conservative efforts to be employed early on so the problem resolves without becoming chronic. Otherwise, when chronic, a vicious cycle can develop whereby the bleeding that is present causes an irritation to the uterine muscle thereby inducing contractions felt mainly as cramping to the patient. Depending on the degree of irritability to the uterine muscle, it can aggravate the bleed which then acts to irritate the uterine muscle thus perpetuating the condition.

The primary goal in managing this condition is to keep the uterus as calm as possible so that the site of bleeding can have a chance to stabilize and hopefully eventually resolve completely. There may be periods of relative calm alternating with episodes of significant bleeding depending on any given case. When the bleed becomes chronic, the net result is a pool of blood constantly being present between the uterine wall and the chorion (membranes). This blood undergoes breakdown while sitting there and when escaping through the cervix can often be seen as any shade of brown as well as bright red depending on the freshness of the bleed. With the longstanding presence of this blood and the consequential breakdown it can result in an erosive effect on the membranes leading to an increased risk of preterm premature rupture. This phenomenon has been seen in virtually every case of chronic subchorionic bleed I have encountered in clinical practice.]

Since it was clear that Patient E was experiencing a chronic subchorionic bleed, she was admitted and eventually started on magnesium sulfate (MgSO4) in order to immediately address the constant uterine cramping that was likely a contributing factor to the persistence of the bleed. In other words, unless the cramping was stopped, the bleeding was unlikely to have a fighting chance to resolve enough to make it to viability – which was the primary goal. While it was unusual to use magnesium sulfate on a pregnancy of this gestational age, it was certainly not an unprecedented application. This was clearly a pregnancy that was for all intents and purposes healthy aside from this one identifiable variable that put it in jeopardy. Were this variable to be controlled long enough (to viability), it most definitely could be expected to produce a baby capable of long-term survival, which is what the patient wanted. The question entering into this endeavor was not whether it was possible but whether it would be actual. The only way to know was to make the effort, knowing full well that it was an uphill battle.

After several days of MgSO4, her uterine contractions finally abated and no new bleeding was identified. She then had a follow-up sonogram which revealed the presence of a significantly foreshortened cervix. This clearly was the result of the repeated contractile activity and now represented another variable threatening the potential of reaching viability. In order to address this problem, the patient was counseled

about the possible use of rescue cerclage to bolster the integrity of the cervix in an effort to optimize the chances of reaching viability. Since at this time, the bleeding was stable and the uterus was without contractions, this was a legitimate option albeit involving a very uncommon Obstetrical condition.

She was brought to the Operating Room where she underwent a successful placement of a Shirodkar cervical cerclage. She was maintained on MgSO4 the entire time which continued to keep the uterus quiet. Four days later, her bleeding and uterine activity had remained stable. Since this was the primary goal of the admission, the possibility of sending her home was entertained, so long as she was able to be successfully transitioned to continuous oral tocolytics and could reliably maintain a strict regimen of bed rest. Her family modified her home so as to accommodate such a condition. Therefore, on a Sunday, she was allowed to go home. She hadn't been home four hours before she once again experienced uterine contractions that were essentially refractory to her oral medication. She was readmitted and restarted on MgSO4 which was effective in controlling her contractions once again.

She remained relatively stable for seventeen more days with intermittent episodes of contractions and some recurrent bleeding. The entire time of her admission, the status of the fetus was reassuring on external monitoring. The patient then had a new complaint of feeling wet. She was a few days shy of 22 weeks gestation. On a follow-up sonogram, her amniotic fluid level was reported as zero. Clearly, this represented a very negative turn in the effort that had thus far been undertaken. Since the patient and the baby were otherwise stable, the decision was made to wait a few days and reassess the fluid as really the only preservation option left. After two days, she was in early labor with circumstances beyond the point of aggressively trying to sustain the pregnancy. The cerclage was removed and she delivered a nonviable baby without complications. She was discharged the next day.

Page 30 – 40: Patient E – Rebuttal to OPMC Numbered Items

- 98. The State provides only a segment of this patient's history that is pertinent to understanding this case. In reality, she had been bleeding since around 9 weeks gestation. This was therefore a chronic condition that was ultimately confirmed to be that of a subchorionic bleed. OPMC's assertion that such bleeding was defined as a "second trimester threatened abortion" is not within the proper context of the clinical diagnosis. There is so much that can be said about this misleading statement which was naively put forth to imply that this was a natural process and nothing could or should be done to mitigate the clinical circumstances involving such a finding. This is absolutely not correct. The designation of "threatened abortion" is a clinical term primarily reserved for first trimester pregnancies that are being threatened, usually by bleeding of unknown significance. The main etiologies here consist of either implantation problems (often due to progesterone inadequacies) or chromosomal abnormalities. The vast majority of actual first trimester losses are due to the latter and rarely are found viable by ultrasound beyond 10-12 weeks gestation. Therefore, by the third month of pregnancy, such a designation as threatened abortion is usually abandoned once the pregnancy has proven itself viable into the second trimester. Most causes of pregnancy loss in the second trimester are due to identifiable circumstances. Even though technically, for the sake of nomenclature purposes, any pregnancy lost prior to 20 weeks is considered an "abortion" and therefore does not count towards the parousness of the patient, it doesn't mean that efforts aimed at preserving the integrity of the gestation cannot be employed. This is what the State would have you believe with this and subsequent statements concerning this element of the case.
- 99. Any bleeding in pregnancy (outside of that seen at term and associated with labor) is considered abnormal. And of course, if bleeding were to continue in any fashion, there would certainly be a concern about the viability and potential loss thereof. The most important objective of any Obstetrician once bleeding is present is to identify the source, nature and extent of it so that an assessment of the pregnancy can be made and an action plan formulated.
- 100. One such management for second trimester bleeding in pregnancy is to instruct the patient to be less active. In fact, this would be essential for all cases. However, to say that this was the only

- management option is simply incorrect. The most important factor lending to management is history and cause. For instance, in this particular case, this patient had been bleeding since 9 weeks and clearly had a chronic problem despite having followed what the State claims was the only option. Furthermore, she had been experiencing uterine contractions which further contributed to the bleeding which then created the vicious cycle described above aggravation of the contraction problem.
- 101. &102. True, the patient was told after two days of inpatient observation that she would have no other option but to go home and essentially lose her baby. The fact that Patient E's previous doctor did not wish to be bothered by the difficult nature of her pregnancy and the risk of loss it represented is irrelevant. For OPMC to claim that nothing could be done for her pregnancy simply because it was less than 24 weeks gestation (and therefore "too immature to survive") is preposterous. There is nothing within the specialty that requires a pregnancy to be 24 weeks gestation before an Obstetrician is allowed to put forth an effort to preserve it. If this were the case, every single case of rescue cerclage for the serendipitous discovery of cervical incompetence prior to 24 weeks would be equally off limits. If this were the case, the use of intravenous tocolysis (MgSO4) post cervical cerclage for contractions induced by the procedure prior to 24 weeks would be equally of limits. If this were the case, the hospitalization and care provided for a patient whose pregnancy was impacted and threatened by a motor vehicle accident prior to 24 weeks would equally be off limits. There are several more examples that could be given. OPMC never once offered anything in writing to substantiate this baseless supposition. The narrow-mindedness and utter lack of understanding possessed by this official governing agency in adjudicating this and every other case detailed in this document is unmistakably evident with such a conclusion. This patient had a subchorionic bleed that had created a cycle of uterine activity which in turn contributed to more bleeding. It was that simple. There is nothing written anywhere that negates an Obstetrician's right at this gestational age to utilize the resources at his/her disposal in an attempt to break such a cycle and thus preserve, potentiate and protect the pregnancy and the life of the unborn child of his patient if this was her desire.
- 103. With this statement, OPMC essentially confirms the basis of why this patient's pregnancy was not only at risk but the purpose of the medical intervention. Lost in the equation is the fact that the subchorionic bleeding in some cases can be attenuated with efforts to control the uterine contractions via established and available methods.
- 104. The State contradicts their own point made in the previous numbered item that if both bleeding and contractions were to stop, then the pregnancy could "conceivably continue." Notwithstanding this obvious line of reasoning, they thereafter contend that nothing other than IV fluids is allowed to be done towards arriving at this desired clinical state, else it be a deviation from their "never" established standard of care.
- 105. This point was already addressed in the answer for numbered item 98.
- 106. The State once again takes testimony out of context. My statements on this case were very clear that this patient had a unique Obstetrical circumstance whereby a known clinical entity (chronic subchorionic bleed) was causing premature contractions that not only jeopardized the pregnancy but could otherwise be amenable to conventional treatments for preterm labor. Any time a patient prematurely contracts, even if after 20 weeks gestation, whereby it is felt that they (the contractions) could be significant enough to lead to cervical change without there actually being cervical change, it is not imprudent for an Obstetrician to initiate medication in an effort to stop them. The fact that this patient just so happened to be prior to 20 weeks is again, irrelevant. By the State's own warped logic, even though they are citing 20 weeks gestation as their benchmark to differentiate threatened abortion from that of preterm labor with the latter being the only indication for legitimate intervention, they contradict their own previously (and newly) established standard whereby any intervention prior to 24 weeks would constitute a breach. The bottom line is that this patient had a clearly identified clinical condition that required her uterus to be calmed in order for the pregnancy to have a chance of reaching viability. The application of methods used for similar circumstances at analogous gestational

- ages was absolutely not a deviation of any standard of care. Just because this case was atypical, it did not translate into a disqualification of medical intervention.
- 107. This is correct. The best known agent for stopping uterine contractions is magnesium sulfate. Therefore, this was the medication used to stop the contractions and thus provide the conditions necessary for the bleeding to potentially stop as well.
- 108. The first two sentences of this numbered item are correct MgSO4 is indeed used in Obstetrics "to relax the uterus and stop contractions." However, to then say that there were no indications for the use of MgSO4 in this case, the State once again contradicts their own conclusion that were the contractions and bleeding to stop, then "the pregnancy can conceivably continue." Stopping the contractions was the indication. It doesn't get more straightforward than that. Further, the State has absolutely no basis for this conclusion concerning the second trimester and offered nothing at all from any official body to substantiate this claim.
- 109. The inclusion of this numbered item is nothing more than an attempt by the State to accentuate the illusion of wrongdoing. MgSO4 is used extensively in the practice of Obstetrics with very strict protocols adopted and applied by any hospital implementing such treatment in order to offset the risk of toxicity. The level of toxicity described by OPMC regarding respiratory depression and "death" is not only extremely rare and requiring of an excessive amount of the drug, it is essentially unheard of in a setting (such as Crouse Hospital) competent with such treatments. The symptoms experienced by this patient are common for this medication. With close monitoring of this medication, Patient E never was at risk for toxicity.
- 110. Again, the State selectively chooses to disclose only a portion of the information concerning the effect of MgSO4 treatment of this patient. True, the patient did have episodes of both contractions and bleeding throughout her two admissions. However, there were also definitive periods of time whereby the medication was successful in stopping the contractions with the bleeding subsequently ceasing as well. Again, this was the objective of the admission and was accomplished.
- 111. This item is correct. The reason the MgSO4 was turned down and eventually off was because her contractions had effectively responded and thereafter stopped. The fact that the contractions recurred indicated that the problem was simply not going to abate with short term treatment but would require additional efforts to keep the uterus quiet.
- 112. This is correct. With the discovery of the shortening of Patient E's cervical length, the persistent contractions had taken their toll on the integrity of this vital anatomical component of the pregnancy unit.
- 113., 114 &115. With these numbered items, the State once more failed to hear/acknowledge/concede what was being testified to when these matters were discussed. The contractions had indeed worn the cervix down such that it was now less than half of its initially assessed length. This posed a new risk of her being able to reach viability for the very reasons cited by the State (in the first two sentences of #113) regarding cervical shortening leading ultimately to dilation and thus an even greater threat of delivery. Nonetheless, the mission at hand had not changed. The goal was to reach viability via whatever methodology legitimately available for such clinical circumstances. When testifying as to the clinical options at this juncture, reference to "cervical incompetency" was made as an illustrative point. Never was the claim made that this patient has an intrinsic abnormality to her cervix. My testimony was clear that her shortening was purely situational and circumstantial from her repeated contractions yet, these observations did not prohibit efforts to be considered in dealing with it. At the time this finding was made, her contractions had been adequately controlled and she was stable. This is why she was able to go down to the radiology suite for the sonogram that revealed this new development in the first place. So, using the very words offered by the State in #114, a cervical cerclage was used "in order to keep the cervix from dilating" and to "keep the cervix closed." At no time did I testify or indicate in the chart that the cerclage was being used as treatment to combat the contractions. This is what the MgSO4 had successfully accomplished by this time. The cerclage was to reinforce the weakness at the cervical level created by the previous contractions in order to mitigate the increased risk of delivery prior to viability. There is a big

difference and the State fully understood this distinction but chose to distort the facts for the purposes of implying some sort of transgression. For the State to follow this with the argument that the only circumstances where a cerclage can be used is when the cervix dilates in the absence of contractions therefore negates any and all cases of true cervical incompetency discovered prior to viability that are associated with contractions. The inherent nature of the uterus is to contract whenever there is advanced cervical change be it from natural processes at term or cervical incompetence remote from term and often prior to viability. If identified in time and the uterus calmed, according to the State, any change to the cervix as a result of this condition is off limits to a cerclage in alleviating this presently identified threat. Another example that would therefore be invalid under this newly and unilaterally established guideline by the State (and not the governing body for the specialty) is the rare circumstance where a pregnancy involving multiple babies is complicated by preterm (and sometime pre-viable) labor resulting in one (or more) of the babies delivering despite efforts to stop the labor only to see the uterus suddenly settle down and the labor stop. There are several documented cases in the literature regarding such a clinical incident whereby a cerclage has been consequently employed following these events in order to successfully sustain the pregnancy housing the remaining babies. The pregnancy and the clinical circumstances for Patient E were clearly atypical and required the application of exceptional measures in order to provide a fighting chance for a favorable outcome. There was no guarantee nor was any such promise of a guarantee ever made to this patient, who was well aware of this from the outset.

- 116. This is correct. To be specific, the type of cerclage used was that of the Shirodkar type which is vastly different from the far more common McDonald type. The advantage of the Shirodkar is that the manner and location by which the ribbon-type suture is placed does not stand to further aggravate the uterus once placed, unlike the McDonald which is typically a thick braided-type suture driven directly into the cervical tissue. In fact, it is not uncommon following the routine placement of a McDonald cerclage in cases of known cervical incompetency to experience the problem of significant uterine contractions thereby requiring the use of a tocolytic agent, such as MgSO4, in order to control them post-operatively. For Patient E, she had been successfully maintained on MgSO4 prior to her Shirodkar cerclage and experienced no increased intensity or frequency following the procedure.
- 117. That this patient had a cerclage under the circumstances clearly established above was absolutely NOT a deviation of any known or formally established standard of care as claimed by the State. Further, at the time of the cerclage placement, the patient was not bleeding or contracting, so this claim is completely false. Not ever did OPMC offer one shred of evidence aside from the testimony of their expert who said that he would not have done such a thing in his practice. There is a much higher evidentiary criterion required when establishing such a rigid principle or standard apart from the opinion of one man whose agenda was clearly disingenuous. In other words, there is not any formal standard of care for extraordinary cases like this one. It is absurd and moreover irresponsible to so rigidly tie the hands of any Obstetrician by pigeon-holing his therapeutic options in such a manner as this when involving an atypical clinical encounter.
- 118. The risk of placing a cerclage in ANY circumstance involves the risks listed in this numbered item. These risks, while remote, were not preclusive to performing the procedure. Once again, the State uses hypothetical risks intrinsic to a given procedure to construct the appearance of misconduct. If this were a proper or legitimate application, then every doctor would be so guilty since every single medical treatment and/or procedure carries built-in risks.
- 119.Again, this is the theoretic possibility with ANY cerclage placement. Note the State's use of the word "could". This is why this patient had been maintained on MgSO4 prior to, during and following the procedure. This is why similar efforts are used in all patients presenting for cerclage so as to limit the potential stimulating effect of the procedure on the uterus. As previously stated, the cerclage in this case resulted in no appreciable increase in uterine activity following its placement.

- 120. This is correct and written about above. She had been transitioned to oral tocolytics and was felt to be stable enough for discharge under orders of strict bed rest at home. She had the necessary family support in place in order to accommodate this important element. Unfortunately, she had the recurrence described which may have been precipitated by the ride home and the limited physical activity required as part of this effort. After the MgSO4 was restarted, it effectively calmed the contractions.
- 121. The uterine activity and bleeding had been significantly attenuated with the use of the MgSO4 in an effort to reach viability. This did not mean that she would or could not experience episodes of increased contractile activity or associated bleeding requiring adjustments to be made to her treatment. This is common in the management for preterm labor. The use of MgSO4 entails many differing doses to be employed as part of the effort to control uterine contractions. As long as the patient is not becoming toxic on the medication, increased doses are sometimes necessary in order to gain an advantage over the uterine myometrium. OPMC's placement of this comment regarding "high doses" is essentially irrelevant absent any untoward affect from the use thereof – as was the case with Patient E. The additional comments made here concerning the "possible accumulation of blood in the uterus" imply that the cerclage absolutely prevented blood from escaping the uterine cavity and that the issue of clinically significant blood loss was not on the minds of anyone involved with this case. Again, note the use of the word, "possible". On the contrary, the patient did indeed continue to have evidence of light bleeding which was noted despite the placement of the cerclage which wouldn't and couldn't have created a hermetic seal at the level of the internal cervical os as depicted by the State. Further, the patient had been followed with serial blood counts and had been maintained on prenatal supplements.
- 122. &123. After her readmission, the patient remained stable for seventeen (17) days before complaining of feeling wet more so than had been experienced with the light bleeding. An ultrasound revealed a markedly low or absent level of amniotic fluid. This was a devastating turn in the case yet, not completely unexpected. As detailed in the case narrative, the natural history of a chronic subchorionic bleed, via the continued presence of blood and the breakdown thereof intimately associated with the membranes, can eventually result in preterm, premature rupture of the membranes. The question was never a matter of *if* such a complication would happen but *when*. Since it did so at just under 22 weeks, it was a sad development.
- 124. After the identification of no amniotic fluid, it was apparent that all efforts up to this point were likely in vain. Since she was otherwise stable, there was no compelling reason to immediately remove the cerclage and have her deliver that very day. While discussed as unlikely to make a difference, if she remained stable, we would reassess the fluid in a couple days and then proceed to delivery if no change for the better. Antibiotics had already been administered as part of the cerclage procedure and were maintained in light of this new development, so the actual risk of clinically significant infection was appreciably reduced. The comment about bleeding again seems out of place since this was consistently a consideration during her admission.
- 125. Soon after clinical evidence of ruptured membranes, she went into labor necessitating removal of the cerclage.
- 126. Again, not having immediately removed the cerclage while the patient was otherwise stable, despite the unlikelihood of improvement was not a standard of care deviation, especially one of a gross nature. There is no overt standard of care for a case like this. This patient had been closely monitored for any complication and was informed that the pregnancy was for all intents and purposes going to be lost. There was absolutely no harm involved or incurred by removing this cerclage at the time that it was. All information and clinical decision making was thoroughly charted so as to indicate precisely what issues were at hand and discussed between doctor and patient.
- 127. This is correct.
- 128. At no time was Patient E or her husband misled about the nature of her complicated pregnancy and the options available to try and save it. When you have premature uterine contractions, there absolutely are options available to pacify them in an effort to prolong, extend or salvage a

pregnancy if the status of the baby and mother are otherwise stable and reassuring. This was the instance here. The fact that it was an isolated and atypical case with uphill odds of success that ultimately didn't work out makes no difference when examining the legitimacy of otherwise making a clinical attempt of saving it. It seems hypocritical for the State to insinuate that the efforts made contributed to the loss of the pregnancy when the patient was originally sent home by her previous doctor to await delivery and thus the death of her baby. According to the State, the only management authorized for this pregnancy was that which would have resulted in the same outcome she was trying to avoid. So to now say that my efforts may have led to what they insisted was the only outcome allowable is nonsensical. After the delivery, it was a life changing event for Patient E. She and her husband wanted a fresh start and moved out West. She was contacted by my counsel who was able to obtain a statement from her regarding her experience. It was far and away a favorable account as to her clinical encounter and interaction with me. The State used snippets of it in an attempt to once more foster a contention of misconduct. While the State chose to use these entries and take them out of context, their failure to cite the very patient record as further "evidence" of their charges is blatantly obvious. This is because the record clearly indicated the extreme and precarious nature of the pregnancy condition and the challenges that were faced in an attempt to salvage it as desired by the patient. Somehow OPMC deemed it inappropriate for me to provide a level of reassurance to the patient at a time of great stress while simultaneously imparting the difficult nature of what was being attempted.

- 129. This statement is patently incorrect. It was not beyond the capacity of an Obstetrician (and specifically this one) to attempt to preserve the pregnancy under these clinical circumstances. Had this particular patient's response to the MgSO4 been an immediate or even eventual cessation of her contractions and bleeding such that she did in fact make it to viability, then there would be no argument at all that the effort was valid. The fact that her case was such that the bleeding and the contractions worked counter to this goal and ultimately failed does not by default make it wrong. There is also a problem with the use of the word "capability". This was never a matter of capability but one of possibility. The methodologies used for this patient had been long established in the field of Obstetrics. Just because the utilization of them is typically seen later in pregnancy, it did not obviate their use at this juncture since a comparable therapeutic effect would otherwise be expected.
- 130. 131, 132, 133 &134. True, this patient did experience a persistent level of bleeding prior to and after her admission. She had been maintained on supplements during her hospitalization with additional iron and her vital signs remaining stable all the while. This patient was a very thin woman who also received considerable volumes of IV fluids during her hospitalization which surely would have resulted in some degree of intravascular dilution that must not be underestimated. Further, as with any delivery, there was an associated loss of blood above and beyond what she had already experienced, thus contributing to her anemia as evidenced in the drop from July 9th to July 10th. One identified problem that did occur in and around the time of these two days is that the hospital lab had been experiencing a problematic lag in making blood work results available to either nursing staff and/or the computer system. This was a fact that was corroborated through testimony at the State hearing by the Chief Medical Officer of the hospital who stated that it was around that time the problem was indeed real and system wide where after it was identified and corrected. At the time of Patient E's discharge, automatic postpartum blood work was not available, yet her vital signs were stable, she was ambulating without difficulty and she was experiencing no perilous effects of her anemia indicative of requiring a blood transfusion. She went home without incident. My office subsequently received a copy of her July 10th CBC revealing the significant level of anemia. Note the lag time of my office having received this lab from when it was drawn and performed. She was immediately called, informed of the results and asked how she was feeling. She had no complaints and was encouraged to take additional amounts of iron for what would have been an ongoing process of red blood cell production/restoration. Her counts recovered readily and she never experienced a complication.

- 135. This is simply not true. This patient had been maintained on vitamin and mineral supplements throughout her entire hospitalization and was instructed to do so as part of the normal discharge instructions given her.
- 136. & 137. The discharge summary was dictated nearly a month after the patient was sent home. It absolutely does reference her low hemoglobin and that she was treated with iron. Nowhere does it say that she was specifically started on iron therapy as part of her discharge instructions although taking a multivitamin supplement was part of my preprinted discharge instructions. At the time of this dictation, I had recalled that this patient was contacted after the lab result was received at the office and therefore instructed to take additional iron therapy. The fact that I included this in the discharge summary was nothing more than providing pertinent information regarding the totality of this patient's care surrounding that hospitalization.
- 138. The discharge summary for this patient was several pages long and provided great detail as to the entire hospitalization for Patient E. By taking merely one paragraph, the State, seeking to once again manufacture whatever appearance of impropriety, alleges deceitfulness on my part when there simply was none.

Page 58: OPMC Determination Narrative – Rebuttal pertaining to the charges: Patient E

Charges 1 & 2: The clinical facts and circumstances in this case have been abundantly established as to why she was admitted and tocolysis initiated. Despite an expert testifying regarding the very same Obstetrical community at times utilizing similar therapeutic uses of tocolysis prior to 20 weeks, the State discounted this evidence as unacceptable when compared to the standard of care in New York – a standard that was never established by the State other than their own deceitful expert saying otherwise. If anything was anecdotal, it was the State's expert opinion. No formal documentation was ever produced to establish their case. Nor were any clinical studies ever submitted as well. Interestingly, if the State, in fact, claims this to be a deviation of the standard of care, then they should be obligated to seek out and investigate every other doctor in this community who was alluded to by Dr. Stahl's supportive testimony. In summary, the State had the burden of proof and offered nothing to establish a basis for making a charge in the first place never mind a conviction.

Charges 3 & 4: The clinical record was replete with documentation as to every step and decision in this case. The reader should find it interesting that the State failed to reference it once in their determination concerning these allegations. The clinical indication for cerclage was detailed extensively in the chart and above. The contractions had stopped prior to the placement of the cerclage. With all the State's claims of impropriety, they act as though my care for this and all these patients was being rendered in a vacuum and that there were no other medical personnel around or clinical guidelines in place to govern the decisions that were made. In order for a patient to be brought to the operating room for a cerclage, her contractions would have had to be absent per hospital protocol. I couldn't just do what I pleased because I said so. This case was never objected to by any experienced nurse nor was it ever the subject of any institutional peer review. The State failed to establish any guideline as to the charges made here other than (again) the limited testimony of their completely inexperienced expert on such matters. There was no negligence in placing the cerclage nor was it "egregiously negligent conduct" weeks later to have waited two days to remove the cerclage in the absence of contractions and infection. This patient was always stable and closely monitored and never experienced a complication from the management decisions employed.

Charges 5 & 6: The discharge summary indicates that the patient's hemoglobin was perhaps artifactually low at the time of discharge given the result from just hours earlier. The patient had received considerable IV fluids during her admission and thus may well have had a dilutional effect. This did not negate the fact that she was significantly anemic. She had been taking a prenatal vitamin and addition iron while in the hospital. Despite the hospital lab having issues with their reporting of results, her final CBC was admittedly missed prior to her discharge. This, unto itself, did not constitute gross negligence. She had been receiving supplements and had a short delay in the re-initiation of them. When the State

decries the six day delay in starting supplemental iron, they once more reveal a fundamental lack of understanding of medical science and physiologic principles. This time it was the function of iron therapy in treating anemia. Their charge implies that had she received these six days of iron, her risk of "shock and death" would have been eliminated. She clearly was stable enough at the time of discharge to NOT warrant a blood transfusion. With her degree of anemia, of course she would be *theoretically* at risk of complications for several weeks were she to have any sort of significant bleeding event during this time. This is regardless of whether or not supplemental iron therapy was initiated six days earlier. This is because iron therapy does not immediately replace blood losses but is a cofactor in the synthesis of new red blood cells which is a self-limited but steady process within the body that takes months to accomplish. This patient was not completely devoid of iron stores for effective erythropoiesis. She just needed to maintain a certain level of supplementation in order for her stores not to be depleted and thus retard the process over the time necessary for her counts to return to normal. The delay in starting supplemental iron was inconsequential and the State knew this but chose to ignore any and all testimony related to it.

In summary, this case was an excellent example of the unpredictable nature of Obstetrical medicine. If every pregnancy was straightforward, then it would be easy. Unfortunately, all sorts of complications periodically arise which therefore call for clinical decisions to be made. Some are far more complicated than others and some call for more extreme measures than others. In this case, Patient E had a very difficult clinical situation. The patient was desperate to try and save the pregnancy which had been written off by her previous doctor. Legitimate measures at pregnancy preservation were used, albeit earlier than usually seen. While a highly atypical case, it was not negligent nor was it a deviation of any standard of care to have made the effort that was made. The fact that it didn't work out matters not. This patient eventually recovered fully and had no regrets. Moreover, she clearly was not the source of this case reaching the Department of Health. As stated above, this case was also never the subject of an institutional peer review. So the question remains, how did it make its way to OPMC? And who provided the distorted narrative that clearly drove the prosecution? The answer should be clear thus far.

Case 7: Patient F

The clinical facts and circumstances concerning this case are very straight forward and should be plainly clear to the reader. The mistreatment of this case by OPMC should be equally evident. Once again, this case was never the subject of any peer review.

History: Patient F was a 52 year old white female, who presented to the office in mid April, 2000. She complained of a two year on-again, off-again history of chronic right lower quadrant pain. By the manner in which she described the pain, it was consistent with pelvic adhesional disease. My practice had been and continues to be particularly proficient with the diagnosis and treatment of all degrees of adhesional disease with hundreds of cases ministered to. Her presentation was clearly suspicious for this pathological process. Furthermore, there was every reason to place adhesional disease high on the differential diagnosis since she had numerous previous abdominal/pelvic surgeries lending to this risk aside from her complaint. One such case was that of a right salpingoopherectomy.

Pertinent to her case was her medical history as well, which included diabetes, hypertension, hypercholesterolemia, atherosclerosis, GERD and obesity. While still being well over two hundred pounds, she had lost more than two hundred additional pounds since having gastric reduction surgery years earlier. Despite being a degree more challenging than someone thinner, I had extensive experience performing laparoscopy on patients with all body types.

As part of her work-up, she had an ultrasound which was not particularly revealing apart from confirming a normal uterus and left adnexae as well as no other abnormality in the area of her complaint. She was counseled as to options but was advised that is she did in fact have adhesional disease causing her pain,

surgical release would likely be necessary in order for definitive resolution. She was apprised of the associated risks, complications, benefits and alternatives of the procedure. She decided to think about it. She would eventually call and indicated that she wanted to proceed. She was sent to her primary doctor to have a pre-op evaluation considering her past medical history. Once cleared, she was scheduled. Our office has a specific preoperative diet and bowel prep regimen prior to any abdominal surgery. Patient F received this information and was instructed to follow it.

Once in the operating room, it was decided that an open laparoscopic approach would be undertaken to reduce the risk of visceral injury upon gaining peritoneal access given her body habitus as well as the potential for adhesional disease beneath the entry point in and around the umbilicus. During the dissection of the infra-umbilical tissue, the layers were opened until the peritoneum was reached. Babcock clamps were used to grasp this layer atraumatically before opening this final layer. Once into the peritoneal cavity, there was a loop of small intestine stuck to the anterior abdominal wall just beneath the umbilicus. Despite using instruments aimed at lessening the risk of trauma, the loop of bowel sustained a very small rent in the outermost serosal layer that was immediately identified. It was surprising to see such an abrasion since the bowel is usually rather hearty and there had been such minimal manipulation to have caused it. The infra-umbilical incision was extended and the loop of bowel freed up and lifted out of the incision. A two layer imbricating repair was performed using only a few stitches. The bowel was then returned to the abdominal cavity and the case continued.

The Hassan trochar was placed and secured at the umbilicus and two more suprapubic ports were placed under direct visualization. At this time, a thorough survey of the abdominal and pelvic cavities was undertaken. There was indeed a number of thin, avascular adhesions involving the right pelvis in the area where she had previously had her tube and ovary removed. After a limited degree of uterine manipulation, a small defect in the uterine fundus was noted from the intrauterine manipulator (which was placed and secured at the very start of the case) having somehow poked through the myometrium. It was unclear as to how this was incurred given how the instrument is carefully designed and utilized. I would eventually gain a better insight as to how and why this occurred after an atraumatic placement in this case. Nonetheless, a small perforation of the uterine fundus is not an all too uncommon event and so long as there is no appreciable bleeding, it heals spontaneously. Furthermore, the tip of the manipulator is designed to be blunt and smooth which (in a case such as this) innately posed no bona fide risk of injury to adjacent pelvic structures. A careful survey of the area and bowel in and around the dome of the uterus was inspected. There was no bleeding from the uterus and there was no trauma at all seen involving the bowel.

The adhesions were, as described, of the thin and filmy type without any distinctive vascularity associated with them. The adhesions involved a short segment of small bowel that had become stuck to the right pelvic sidewall. A blunt probe was used from the left suprapubic port to gently put traction on the bowel in order to put the adhesions on stretch. Once on stretch, such adhesions are able to be taken down easily. This was done in a matter of minutes using the laparoscopic scissors and a small amount of unipolar energy. All loops of bowel involved were completely freed up. The abdomen and pelvis were irrigated, the surgical site re-examined and the peritoneal cavity observed for a few minutes before closing which included the clearly visible and intact suture repair on the small bowel beneath the umbilicus. Since there was no other identifiable issue that required surgery, the case was concluded.

The patient was successfully awaken and eventually sent home with post operative instructions which included making a follow-up appointment. Either the next evening or the second morning later (see #157 below), the patient's husband called stating that she was experiencing some abdominal discomfort and lack of flatus. There was no other problematic information described at that time. She was advised to use milk of magnesia in an effort to stimulate bowel activity since her symptoms were most consistent with that of a post operative ileus commonly a result of the manipulation of the bowel during surgery. He was instructed to call back if there were any further problems. Several hours later, he called again stating that she was not feeling well. Her pain had worsened and she was short of breath. They were instructed to go

to the hospital immediately where I met them right away in the emergency room. This was a Sunday. Upon examination, it was not readily apparent as to what was going on. A thorough history was written detailing the precise events of the surgical case two days earlier, including the small serosal tear that was repaired and intact at the end of the case.

She underwent a battery of tests and studies. She did not have a fever and her CBC was not indicative of anything overtly obvious, yet her blood sugar was elevated. Her abdomen was distended, tympanic and without bowel sounds. She was clearly in some sort of distress as evidenced by a tachycardia and shortness of breath. She was ruled out for pulmonary embolus which she was technically at risk for, specific to her obesity and the fact that she recently had surgery. A CT scan of her abdomen and pelvis was inconclusive with a small amount of air under the diaphragm which was read by the radiologist as likely from her recent laparoscopy. She was admitted and observed while being started empirically on antibiotics. Initial management was palliation of her pain, cathartics aimed at stimulating her absent bowel function and observation. After a day in the hospital, both surgical and medical consultations were obtained.

Her primary physician made some recommendations regarding her medical care while the general surgeon's evaluation was essentially inconclusive. The plan was to repeat the CT scan in another day to observe for changes. When this was done, there was an increase in the free air component previously seen which was indicative of bowel perforation. She was immediately scheduled for surgery and was in the operating room that night. I scrubbed the case.

Upon entering the peritoneal cavity, there were obvious signs of a peritonitis and contamination from a bowel perforation. The process had been somewhat isolated to the right lower quadrant, however. When the general surgeon ran the bowel, the minor repair on the loop of small intestine that had been performed at the beginning of the laparoscopy was still intact and not the source of the problem. While running the bowel, the general surgeon iatrogenically caused approximately five to six small serosal tears simply by handling the tissue during this process. His comment was that despite the peritonitis, this tissue should not behave in such a way that it would be so overtly friable. In other words, this was a highly atypical finding. He did go on to repair them, of course. Eventually, a very small, pencil eraser sized perforation was discovered on the anti-mesenteric border of the portion of ileum which resided in the right lower quadrant. The overall conditions within the peritoneal cavity were such that the surgeon was able to conduct a simple resection of the defect and thereafter perform an end-to-end anastomosis of the affected small bowel after copious irrigation had been carried out. The patient was then closed and eventually went home without any complications from the repair.

Page 41 - 47: Patient F – Rebuttal to OPMC Numbered Items

- 139., 140, 141, 142 &143. Patient F's primary complaint was that of off and on deep discomfort mainly along her right lower abdomen with characteristics consistent with adhesional disease. Given her history of abdominal and pelvic surgery, especially involving the right lower quadrant (RLQ), this was the logical presumptive diagnosis. The State's pathophysiologic description (via their expert) of adhesional disease is accurate enough to illustrate the point. Their mention, however, of the presence of bowel being in the RLQ on sonogram as a diagnostic criterion for adhesional disease is an obtuse contention since not only does the bowel naturally fill these spaces but adhesional disease is not capable of being diagnosed radiologically. It is purely a diagnosis confirmed surgically as indicated by indices of suspicion through history and physical.
- 144. This item is perhaps one of the most disingenuous statements made by the State's expert witness who is obligated by ACOG code of ethics to testify honestly when acting in this capacity. The treatment of adhesional disease involving the female pelvis is absolutely within the realm of the Gynecologic surgeon. This is what we do. Just because this man might be

incapable of performing laparoscopic adhesiolysis does not disqualify the Gynecologic surgeon thus making it solely a general surgery matter. Such surgical cases are an essential component of residency training as well as the armamentarium of most practicing Gynecologic surgeons.

145. This is correct.

- 146. This is correct to the extent that the dissection is carried down to the peritoneum. The peritoneum is then opened as well and the trochar placed directly into the peritoneal cavity.
- 147. This first sentence is correct in reference to the potential risks of laparoscopy as do all surgical procedures in the abdominal cavity. The second sentence is very nebulous as to what the State is trying to say as far as preventing injury. It is just unclear as to whether they are referring to the bowel itself of other structures because of an immobile bowel. There are many cases in which adhesions are noted to involve the bowel that are not related to the surgical task at hand. The relative immobility of the bowel in this example has no bearing on the overall case. If the overall objective of a surgical case requires the bowel to be mobile for issues of exposure to the surgical site, then adhesions under this condition could impede the progress of the case and theoretically increase the risk of complication. Typically when this is the case, the adhesions are addressed, the bowel moved out of the way, the surgical site properly exposed and the procedure allowed to proceed.
- 148. This patient was at increased risk for adhesional disease based on her previous surgical history. The risk for bowel injury is dependent on multiple variables and such a statement cannot with certainty be ascribed by the State. Just because there was the suspicion of adhesions, this did not necessarily increase her risk depending on where they were, what they involved and the character of them. The highest risk of bowel injury during laparoscopy in a patient with adhesions is while gaining access to the abdominal cavity. Blind trochar placement offers the biggest risk. This is why open laparoscopic approaches are chosen under these sorts of circumstances. Once access is gained, unless the adhesions involve the bowel and are of the thick, vascular type, then under the care of a skilled surgeon, the relative risk of bowel injury should be negligible.
- 149. There are many high risk surgical patients given their medical history. This does not preclude them from being subjected to surgery or anesthesia. Anesthesiologists deal with patients such as this on a daily basis. This is why they meet with the patient beforehand as part of the surgical scheduling protocol so that they can be prepared on the day of surgery. This is also why patients are sent to their primary care doctors prior to surgery in order to obtain medical clearance. All of this was done which makes this numbered item nothing more than the State once again creating the appearance that somehow either I wasn't qualified to treat her or that I shouldn't have treated her at all.
- 150. & 151. First, if a Gynecological surgeon feels that there is a concern for bowel injury for each and every surgery he/she performs for pelvic adhesions that may involve the intestines such that he needs to consult with a general surgeon, then perhaps that doctor shouldn't be performing such cases in the first place. Granted, some severe cases do potentially arise whereby one might wish to know that a general surgeon colleague is available should the findings and the treatment thereof pose an increased risk. Otherwise, the vast majority of cases encountered are very straight forward and readily treated by a skilled gynecologic laparoscopist. Adding to this, Surgery for pelvic adhesional disease involving the bowel and other structures is done every day across the country by thousands of Gynecologic surgeons. So to insinuate that such procedures are out of the clinical dominion of the Gynecologist is patently false. Further, there is nothing written anywhere that requires such a surgeon to seek first (or at all) the consultation of a general surgeon in order to proceed with the case. So alleging a deviation of the standard of care for not having done so has no basis at all. One last thing, if such a condition were the standard of care, then explain how the hospital would allow such a case to be scheduled and carried out in the absence of it having been met.
- 152. This was described in detail in the above case narrative. Important to understand here (which will become clearer below) is the fact that this small defect in the small intestine was created

- without very much interaction with it. The significance of this would not be appreciated until the exploratory laparotomy was carried out less than a week later.
- 153. During any laparoscopic procedure, there is invariably going to be interaction with the bowel. Typically this would entail moving it out of the way in order to visualize the pelvic structures which are usually the subject of the surgery. Certainly, when the bowel is involved with adhesional disease, it often necessitates lysis in order to move it out of the way, alleviate pain, and/or simply restore normal anatomy. Whenever any tissue is being operated on, there is always going to be an associated level of risk, even if nominal. The factors lending to this risk are the severity (or lack there of) of the problem and operator experience.
- 154. The surgical work done was described here and in the operative note as being straightforward and involving the thin, filmy, avascular type of adhesion. The State's use of the term "significant" is unclear.
- 155. The small perforation defect noted at the dome of the uterus was detailed in the narrative above. The tip of the Kroner is smooth and blunt. When placed, it is secured in such a way that it cannot advance forward or come out. The key to how and why this most likely occurred was realized based on retrospection. As mentioned above, during the exploratory laparotomy when the general surgeon ran the bowel, there was a highly atypical weakness noted involving the serosal layer of the small entire intestine which led to numerous minor tears having been incurred due to simple manipulation. After this doctor made comments about this unexpected condition, I inquired a little further into this patient's dietary habits. It turns out that after she had her gastric bypass, her diet was significantly devoid of adequate intake of proteins. The corollary was that with such limited protein intake, her overall tissue quality was consequently poor and therefore more susceptible to trauma from otherwise normal handling or interaction. This could retrospectively be evidenced by the following: - the minor injury to the small intestine upon starting the case after nominal interaction; - the latent bowel perforation that most likely resulted from an occult tear in the serosa after normal manipulation of the bowel during adhesion take-down; - the numerous serosal tears by the general surgeon from simply running the bowel; - and by the perforation encountered at the uterine fundus by the ordinarily atraumatic Kroner following minimal movement – which is the subject of this particular numbered item.
- 156. The dietary instructions were given so as to encourage a period of bowel rest specifically due to the small serosal injury that was experienced at the start of the case as an extra effort to avoid any sort of complication that might have stemmed from it. There was no anticipated complication expected. It was simply a matter of doing as much as possible within my control to avoid stressing that repair. By directing the patient to take her temperature, it was just another basic measure by which to identify the clinical manifestations of any surgically associated complication as early as possible.
- 157. The State produced no evidence of such a phone call nor was there a record through my answering service of one being made the day following surgery. I did acknowledge that the patient's husband did call one time prior to the call which resulted in her being sent to the hospital (be it the evening prior or earlier that morning) with complaints of abdominal discomfort and that she had not passed flatus yet. She was encouraged to take milk of magnesia to stimulate a bowel movement and to call back if any further problems. There was no mention at all of a fever even after asking. If there had been, then certainly there would have been a different response and action plan from me, especially since I had specifically given the above mentioned instructions pertaining to taking temperature. Furthermore, the hospital record clearly showed that even when she presented to the E.R., there was no fever present.
- 158. The State is making this statement on unfounded information. As soon as there was an appreciation that this patient needed to be seen for further work-up and care, she was sent to the hospital immediately. I would have absolutely no reason at all not to have acted sooner had there been anything communicated indicating a problem. Furthermore, such a non-action (as alleged by the State) is wholly inconsistent with the entirety of my clinical practice of medicine.

- 159., 160 &161. As written in #158, the State never legitimately established the content of the first phone call. I testified that the only information given me was that of abdominal discomfort and lack of flatus and not that of fever. They are making conclusions based on unsubstantiated information. The record bears this all out. After several years and several hundred cases of laparoscopy, it is not uncommon for some patients to experience a transient paralytic ileus of the bowel thus causing distention due to gas being trapped and consequently, significant discomfort. [A resounding example of this is the following: I once had an Emergency Room attending call me one morning about a patient they had seen overnight who was 36 hours post laparoscopy for a simply tubal ligation. So impressed were they that this patient had had thousands of dollars of radiologic procedures performed and numerous other tests run (all negative) in an effort to diagnose the abdominal pain and distention she complained about upon presentation. Not only did the patient not call my service (which is rare) prior to going to the hospital but the hospital did not call once they triaged her. I then told the attending that it sounded as though the patient had the relatively common post-op complaint of transient ileus and that she needed something to stimulate bowel activity in order to alleviate the problem. This was done and she was soon out the door, no longer in pain.] Therefore, if patients are able to able to regain motility of the bowel and thus move the air, their pain almost completely abates. In order to stimulate this action, milk of magnesia (or in some cases, a rectal suppository) is a tried and true method of doing so. Therefore, yes, the use of this over-thecounter medication is a commonly prescribed practice in overcoming the symptoms associated with a temporary paralysis of the bowel experienced by some following laparoscopic surgery. As far as the patient being directed to go to the emergency room, she was instructed just hours later to do so the moment her symptoms were such that an ileus might not be the causation of her complaint. This was merely after she had tried the recommended cathartic and had no response. There was nothing about the course of her case having been the surgeon present to suggest that she would have sustained a bowel injury. The lysis of adhesions had been as trouble-free as could be and minor repair to the small bowel encountered at the beginning of the case was a completely straight forward repair and shouldn't have (under any circumstance) broken down given my years of experience – which it didn't. So for OPMC to (illegitimately by hindsight) ascribe to me a failure to recognize an occult bowel injury (highly likely (and legitimately by hindsight) due to the chronic malnourished state of the patient) when the only information known was otherwise consistent with the ever more common small bowel ileus, it is frankly intellectually dishonest.
- 162. When this patient presented real-time, (and not from the hindsight position of OPMC) all of these symptoms could most definitely have been associated with the presumptive diagnosis of ileus that has been described at length above. Not to mention that this patient was obese, had lost over two hundred pounds and had led a sedentary life since and prior to her gastric bypass surgery. Therefore, aside from an ileus, any shortness of breath could also have been associated with having recently had general anesthesia as well as post op discomfort. She was definitely in pain and had some abdominal distention, but she was not in acute distress. The State also continues to maintain and assert that the patient had a fever the day prior when, again, this has never been verified or substantiated. Nonetheless, a temperature of 99.6 is not, by definition, a fever as delineated by (amongst others) hospital discharge qualification criteria. While a little elevated above the normal 98.6, it could very well have been from any number of surgery related etiologies.
- 163. The resident rightfully established what is known as a differential diagnosis. This is a fundamental component of any admission when a patient presents with a complaint. The potential etiologies are listed and then systematically eliminated via various studies and tests.
- 164. & 165. The State's description of the patient's status in this numbered item it a complete exaggeration. This patient was not presenting as being as sick as they have embellished, otherwise there would have been a corresponding urgency represented in all aspects of her care and by all involved persons as represented in the patient record. Certainly, all parties know that she ultimately had a bowel perforation, however, it was not clear, even on CT scan and blood

work evaluations. Her pulse was slightly elevated above 100 and her diabetes was not out of control but elevated upon admission and readily controlled. After having received supportive care and bowel rest in the hospital for one day, medicine and surgical consults were obtained. The surgical consult was not predicated on the medicine consult just because it had been alluded to in this report and subsequently carried out later in the same day. Both were contacted with one being completed prior to the other. Surgery was equally perplexed as to her diagnosis given the relative ambiguity of her symptoms. It was not until a repeat CT scan a few days later did her diagnosis become clear.

166. & 167. OPMC makes a general statement here concerning the consequences of bowel injury from surgery causing a potential life-threatening peritonitis even though their wording seems to imply that laparoscopic surgery unto itself causes bowel injury. Given the particular presentation and findings in this patient, as represented by the medical chart and all diagnostics, it was not abundantly clear on hospital day number one that she was in fact suffering from anything more than an associated paralytic ileus. When this item on the differential diagnosis appeared to be less likely, the appropriate surgical consultation was obtained and yet, didn't result in any immediate change in her care or therapy. It wasn't until additional information was obtained did her diagnosis become clear. During this time, she was completely stable and did not show any signs of sepsis. Perhaps the biggest testimony to her relatively stable and contained inflammatory/infectious process stemming from the small perforation was the fact that she was successfully able to have an immediate end-to-end reanastomosis without the need for an ileostomy.

Page 59 – 60: OPMC Determination Narrative – Rebuttal pertaining to the charges: Patient E

Charge F1: With this charge, the State establishes an entirely new standard of care for practicing Gynecologic surgeons with the requisite skill and experience in undertaking corrective surgery for abdominal/pelvic adhesional disease. Nowhere in the literature does it require a qualified surgeon to obtain a pre-operative consultation from another surgeon for clinical matters he or she is otherwise capable of performing. Nor did the State ever produce any documentation supporting such an assertion. The presence of pelvic/abdominal adhesions, even if involving the bowel, does not necessarily imply an increased risk of injury. The bowel is normally a hearty tissue that is capable of considerable handling whenever involved with adhesional disease. When a competent surgeon is treating this condition, it is not expected that a bowel injury would be sustained. If, for some unforeseen reason an injury is sustained, there is any number of options available. One would be to directly make the repair if proficient in doing so. Otherwise, general surgeon would be called and historically available without delay. Note also that in this (and every case) a purposed bowel prep was ordered and performed by the patient. The primary reason is to decompress the intestines to enable better visualization and manipulation during surgery. The added (and certainly not discounted) benefit of this prep is to significantly mitigate the risks to the patient of fecal contamination if the bowel did, for some reason, sustain an open injury. Note also that OPMC initially levied a charge in this case (Charge F2) that this preparation was not done. It wasn't until the patient record was admitted into evidence that this charge was immediately vanquished. While there was never a doubt on part of the defense as to the baselessness of this as well as every other charge, it provides the reader of this document a clear picture of just how much care and diligence went into the State's effort to properly evaluate these cases and accurately establish the facts. Another example of their cursory survey of the facts is found in the very first sentence for Patient F on page 59. The clinical exam revealed the patient's pain to be in the lower right quadrant – consistent with the previous surgical removal of her right tube and ovary. Unless they also wish to establish new anatomical boundaries, this would most definitely be consistent with a gynecologic region.

Charge F3, F4 and F5: (paragraphs 2 & 3) These charges has been extensively addressed above. First, there was no evidence at all during the actual surgical case of the bowel injury that complicated this

patient's post operative course. This was after a complete survey of the operative site and entire peritoneal cavity was carried out prior to concluding the case. Further, the information conveyed to me prior to sending Patient F to the hospital for further evaluation did not specify a fever or complaints inconsistent with that of a transient post op ileus. The recommendation made was appropriate while the patient's husband was instructed to call at once if she was not better. She did not improve, her husband did call back and the patient was immediately sent to the hospital where I met them. The patient's findings upon admission were properly contextualized above yet made (by the State) to look like she was in obvious distress or that her findings were immediately consistent with bowel perforation. Once conservative measures aimed at resting her bowel for a day were unproductive, a surgical consultation was obtained and not constituent with a standard of care breach. If Patient F's symptoms, findings and presentation were so apparently obvious such that a State level investigation and prosecution were called for, they failed to explain why the general surgeon who was consulted wasn't subject to the same scrutiny after he failed to immediately act in accordance with OPMC's mandate on how I should have perceived the exact same parameters. This double standard was symbolic of the entire experience in dealing with this agency.

Clearly this case represented a complication from an otherwise very straight forward surgery. It marked the very first surgical complication of my entire career for which there have only been a total of three in well over two thousand cases. In trying to understand just how such an outcome could have occurred when there was no undue stress or manipulation out of the ordinary to this segment of bowel, the evidence seemed abundantly clear as to the most likely explanation. The numerous examples pointing to a protein deficiency leading to the abnormal tissue fragility in this patient are telling. In fact, I have observed this phenomenon several other times in the years to follow after gaining a heightened awareness of the relatively unknown and unappreciated impact of this nutritional condition. As stated above, the bowel is typically a very sturdy tissue capable of being grasped and manipulated fairly robustly without injury. Somehow in this case, via the normal interaction with the small bowel involved in and around the site of the easily treated adhesions, the serosa must have incurred an injury not immediately recognizable once the surgical site was inspected prior to closure. Some time thereafter, the weakness that was created overtly perforated.

It was an extremely regrettable case since my practice is so focused on precision and therapeutic success not to mention the trouble it caused this very nice woman. Not having been the subject of any type of hospital peer review, it has been enigmatic as to how this case became the object of OPMC. The bottom line is that this patient suffered a known potential complication from an indicated surgical procedure where after her presenting symptoms were initially ambiguous to all parties involved. She was ultimately well cared for and went home with far less morbidity than is characteristic for similar cases. While highly unfortunate to have happened in the first place, it does not nor did it ever justify becoming the subject of a State level investigation or prosecution.

Page 62 – 63: Specifications

(Paragraph 1 and 3): When the assertions in this paragraph are measured against the specification of charges on (document) page 82 (annotated as page 6), note that each numbered item states, "the facts set forth in the following paragraphs:..." The only testimony presented throughout the entire hearing as "facts" by the State of New York that led to any adverse determination were the unsupported, unsubstantiated *opinions* and *clinical inaccuracies* of their expert. After they specifically acknowledged that my expert was given great weight, not one confirmatory position given by him was considered at all. This is in direct violation of the law which states that if the Hearing Panel considers the defense expert's testimony to be valid, trustworthy, or believable – all descriptors that would arguably be synonymous

with having been given "great weight", then where the two experts differed on any given charge, they were prohibited from finding adversely on that charge.

And since my expert was not only supremely qualified, he emphatically asserted that all of my management, especially when the actual patient records were considered, was justifiable and within established standards of care. As far as their treatment of Dr. Stahl's testimony for patient's D and E (which were added to the other five cases that were initially part of the thrown-out 2005 hearing), the State merely dismissed it without ever having provided a basis for why. His testimony was superb and spot on with the clinical facts, findings and records for these two cases.

As far as the "unanimous vote" noted in this section, it must also be re-emphasized that the Hearing Panel had only one Ob/Gyn present of the three who stood in judgment. The other two admitted during the hearing that they were reliant on the input of this one and only voice who was purported to possess the requisite knowledge concerning the subject matter being presented even though he had stopped practicing Obstetrics years earlier and demonstrated an utter lack of insight into the matters at hand. This was certainly not a panel or "jury" of my peers, especially when one's license and livelihood is on the line. And of course, (as stated above), just like the Ob/Gyn who was culpable for the 2005 hearing having been thrown out, this one and only Ob/Gyn on the 2007 Panel was equally connected to parties within the department who had an interest in seeing an adverse outcome at all costs – especially at the expense of any and all integrity and/or legitimacy.

The bottom line is that the State's case was flawed on the facts, flawed on the science, flawed by their expert's testimony, flawed by excluding the testimony of an expert given great weight, flawed on the material evidence submitted (or complete lack thereof), flawed by what was actually contained in the medical record, and flawed on how their determination was reached. These truths combined with the substantial material evidence based argument throughout this document more than rebuts and impeaches their conclusion of gross negligence.

(Paragraph 2 and 4): The second paragraph speaks of gross incompetence for which they did not sustain. I will comment this way. Not only do I ardently agree with this conclusion, OPMC knew throughout this entire six plus year charade that I was completely competent in my practice of the specialty. OPMC also knew full well that they were prosecuting phantom charges that were manufactured via a distortion of the record in order to give the appearance of misconduct. I vehemently defended this attack on my license and (as repeatedly alluded to throughout this document) they were never able to provide any document at all that established any of their positions. So instead of being able to prosecute any form of incompetence, they instead chose to warp the reality of the care provided after the fact in such a way to fit their "negligent application of competence" agenda while either skewing or completely ignoring the evidence. More is presented on this tactic below and how they used the fact that I stood up for myself as substrate to impose punishment.

(Paragraph 5): All charges involving failure to maintain medical records were dismissed. There are two important points to be made here. First, the fact that such allegations were levied in the first place provides yet another example of the "prosecutorial overkill" that was emblematic of this entire ordeal. Secondly, it cannot be denied that the numerous examples of exculpatory evidence contained within the very records that were found to be "adequate" were conspicuously absent from any and all of the State's contentions of misconduct.

Determination of Penalty:

A few critical points must be made at this time before addressing this final section of the State's Determination and Order. For starters, the majority of these cases were highly unique which made the management thereof not typical for the every day practice of Obstetrics and Gynecology. This does not

automatically create, imply or establish anything having been done wrong. Furthermore, not every physician is created equal nor does every doctor feel comfortable practicing outside of a very basic and narrow comfort zone. Again, this does not automatically bring condemnation for those who do. This admonition, however, was the overall tone of OPMC's prosecution that was driven by the anonymous complaint letters covertly written by the elder of the two Perinatologists detailed at the beginning of (and subsequently throughout) this document and not based on anything else – like the copiously aforementioned true Obstetrical science, standards, facts and patient records.

In other words, (as will be seen in OPMC's language under this section of their Determination and Order) my license and career were chastised for "daring" to practice at the highest level and expanse allowable for the specialty, when the "norm" for the area was not to do so. This especially is in reference to this one perinatologist whose hostility was particularly centered on those who were adept with Obstetrical forceps. His history speaks volumes as to his motives along these lines as well as in my case. The prime example of this was imparted to me first hand by one of his past "victims" who was (fortunately) able to overcome an assault waged on his license (years before mine) which was also because he was adept with Obstetrical Forceps. This friend and former practice partner was an eminent member of Ob/Gyn department and community when I joined his practice. Interestingly, he and I both had experience, proficiency and a zeal for the rarely implemented technique of Obstetrical forceps. In fact, after working for only one year with this gentleman and scholar before he retired, my proficiency with forceps experienced significant advancement with just a few minor, yet additional, nuances gained from his expertise. He is one of the two doctor's detailed at the beginning of this document who I had joined upon arriving in Syracuse and who also had long been at odds with the two perinatologists involved with my problems.

Approximately ten years earlier, this one elder and seditious perinatologist made an "anonymous" report to the State's Department of Health regarding by my fellow practice colleague in an attempt to trump up charges and cause his life and career harm. He was able to successfully defend this assault with good and timely counsel and by his case having occurred prior to when OPMC had completely devolved into what it is today. The legal aspects of disclosure were a little looser then as well, so he was able to find out who had initiated this action/complaint – and it was none other than the elder. Having been a member of this community for several years, my friend/colleague/partner gave me a long talk concerning this one particular perinatologist after he and I spoke about my ongoing travails which started two years after his retirement. According to him, for some unknown reason, this perinatologist abhorred anyone who was capable of skillfully using Obstetrical forceps. The reason given me was simply that of jealousy because he apparently lacked the ability. As a self proclaimed and grand-fathered-in Perinatologist without any formal training, his historical self-exaltation was diametrically opposed to anyone else being able to do what he couldn't. I hadn't known or worked with this man long enough to have known all of this, but I was given numerous past accounts as to how my partner had repeatedly been affronted by him specific to this issue of forceps (amongst other things) when such clinical circumstances would arise concerning patient care in labor and delivery. My response to learning this was one of incredulity given how petty and unprofessional such behavior had and continued to be. Yet, at the same time, I was not surprised having personally experienced a few of my own intimidating interactions with him prior to the initial case for Patient A. So clearly, with my experience as well as that of my colleague (along with several other administrative assaults against other Obstetricians I have come to learn of who have dared disagree with him), this perinatologist has used OPMC as his own personal vendetta tool in the very manner specifically called out in the OPMC Reform Bill, (details of which are attached to the end of this document on page XXX).

Secondly, when considering this "Penalty" section of the Determination, it is important to remember that the prosecution of these cases was not driven by the patients involved. And despite the clinical circumstances being idiosyncratic as far as everyday practice goes, none of the results were adverse or outside the realm of possible outcomes for the type of cases they represented. The peculiarity of some of these cases and any associated unconventional care involved did not automatically qualify them to be

subject to prosecution. It did, however, enable them to be manipulated and misrepresented in such a way as to provide substrate for the untoward agenda.

And lastly but probably most importantly in order to understand the dynamic of OPMC's ill-mannered conduct here is how they upped the proposed penalty towards me, my license and ultimately my livelihood as my defense of the charges dared persist beyond any given stage. At the outset in 2002 and leading up to the 2005 hearing, they stated that all they wanted was my forceps privileges to be restricted at the State level based solely on the information being fed them by this one Perinatologist at Crouse Hospital and clearly not on the facts which have been exhaustively argued in this document. Their seeking of my forceps privileges certainly wasn't due to any wrongdoing as far as their use was concerned since there has never been an adverse outcome from my application of forceps throughout my entire career while every single one of them meeting the criteria set forth by the American College (now Congress) of Obstetrics and Gynecology. Remember, the loss of Patient A's first baby was not at all due to their use. As a result of OPMC's aggressive pursuit of limiting my right to utilize this still legal and powerful tool in Obstetrical practice, I adamantly opposed such an unsubstantiated and prejudiced action and chose to defend myself rather than sign a statement of guilt after the proverbial gun was put to my head to do so. After the 2005 hearing's fraudulently adverse determination was appealed as part of my continued defense of this sham (and before it was soon thereafter thrown out by the Appellate Division of the Department of Health), the State's resultant response for daring to challenge this verdict was that they now wanted my entire practice of Obstetrics to be revoked. So, for matters that originally drove them to seek my forceps privileges, they now were supposedly deserved for this new level of punishment. After the 2005 hearing was thrown out on an Appeal that I had to write myself given the financial devastation they had already caused my practice and family by that point, the Appellate division of the DOH (citing the blatant bias that had pervaded the entire proceeding) mysteriously remanded the entire mess to a new hearing rather than recognizing the truth and ending the lie at this point. Because I now decided to push the defense of these spurious charges to this point (another hearing), the State now sought to take my entire license from me. This progressive style and brand of punishment was nothing more than an abject lesson for me as to who was the boss as well as who could (literally) make the rules (on the fly), break the rules (at will) and establish new standards (without base or authority) for the specialty just because they said so. Could anyone reading this imagine what it was like to not only bear witness to such lies, deception and utter corruption? It was ever the more disgusting to have had it directed right at you to the detriment of more than twenty years of grueling and successful work, not to mention an entire family with children? These personal consequences certainly cannot discount the impact to patients having lost access to their doctor or of employees seeing their jobs literally disintegrate before their eyes. For what? Prideful and powerful men behaving very badly, that's what.

Now, getting to what they wrote in this section.

(Paragraph 1): The fact that my license was suspended over these cases when the facts are clear and convincing to the contrary of what they specify as findings of fact is simply disturbing. There is nary a physician in New York State who could survive such a preposterous standard of performance as was applied to my practice. Again, pardon the redundancy, but my entire body of work for over ten years had consistently been exemplary by all state-wide, community, institutional and department standards. The only way such a verdict could be rendered and not (at the same time) implicate any and all other Obstetrician/Gynecologists in the State with this mythical standard was to ignore my record as a whole. This is precisely what they did. I have described the clinical facts which are clear as to no clinical wrongdoing having been committed in any of these cases. Even if there was any transgression and the State desired to make it an issue, there cannot be any justifiable precedence whereby any legitimate punishment could be imposed in the face of hundreds of similar cases having been adeptly managed without incident. In other words, a starting baseball player batting over .300 doesn't get benched for having a bad game. There is no physician (or human) who could withstand such a performance standard of zero tolerance as was exploited by OPMC.

While maintaining my defense of the particulars of each case used in their prosecution, the overall message here is that said cases were isolated and completely atypical to have ever been used as a benchmark for seeking any sort of disciplinary action against my entire license. If every doctor in this State had their unusual and/or weird cases used in such a manner, then there would be none left unpunished. Is this really the function of OPMC? Aren't they supposed to identify doctors who exhibit a pattern of suspect or inappropriate care who therefore put the public at risk? Even if OPMC wishes to continue being misled into believing what they palmed off as misconduct in these cases, there is no pattern here and the community has never been at risk from my practice of medicine. Never, ever! All the fancy language used by this agency will not ever change these absolute truths.

Then, in perfect fashion with how uninformed OPMC has been with all of these issues, they impose a restriction/limitation/prohibition on my license for the performance of **high forceps** and midforceps rotations/deliveries. In reference to the latter - once again, there has never been a single case of misuse, injury or adverse outcome from my clinical application of this operative vaginal delivery modality. Never. However, aside from this fact, OPMC's utter ignorance as to the subject matter before them when acting in any legitimate capacity to be presiding over the prosecution of one's license is clearly demonstrated with their issuance of the former restriction. The topic of **high forceps** is plain and simple. The American Congress of Obstetrics and Gynecology, [the governing body for practice standards within the specialty, (essentially world wide), and who's very standards have already been patently ignored by OPMC as described above], outlawed the use of **high forceps** nearly forty years ago. Any and all Obstetricians are fully aware of this basic tenet of the specialty. And for those who still maintain a practice using forceps, never would they ever entertain such a procedure given this prohibitive status, not to mention the outright risk to both mother and baby – or further, the clinical implications of such an obstetrical condition as far as the overall likelihood of being able deliver vaginally in the first place. Not once has my practice ever crossed this well established line. That OPMC would include such a restriction is very telling on many levels. Again, not only does it speak volumes as to their lack of knowledge in what they were standing in judgment of, but it goes even further in establishing the credibility (or lack thereof) of the one and only Obstetrician who sat on the Hearing Panel and who, (invariably), had the most influence on the other two members (jurors), both of whom admittedly had little to no knowledge at all concerning the very issues they were entrusted to decide. Remember, this sole Obstetrician was literally "recruited" to sit on this panel (as evidenced by his (admitted) very recent appointment to the board) when the Department of Health certainly had many others who could have legitimately filled this role. And also remember, that this Obstetrician was directly connected to adversarial parties in my hospital department who had an interest in seeing this process work unfavorably for me. And lastly, remember that this Obstetrician's presence on the Hearing Panel was objected to the very first day of the Hearing, before it began – only to have the Administrative Law Judge (ALJ) rule against it. Farcically, this decision to keep him on the panel was made by the ALJ after he asked this Obstetrician openly if he felt as though he could remain fair and unbiased. What was he to say to this? No Obstetrician with an ounce of integrity would have stood for or would have ascribed his name to what was done to the facts and science of the specialty during this proceeding. In fact, my expert was so appalled at what he witnessed in the charges alone when compared to the substantial patient records that he expressed his discontent by wanting to "tear up" the actual State documents. The fix was in and clearly evident by the State's shiftily selected Obstetrician's absolute disregard of any and everything valid for the specialty which has already been painstakingly (and painfully, I might add) laid out in this document.

(Paragraphs 2, 3 &4): It is incredulous that the State begins this paragraph commenting about my possession of "the requisite knowledge and skill to practice medicine safely" when they blatantly ignored any and all pleas to consider or even introduce several years and tens of thousands of patient encounters which clearly established this very fact in compounding fashion. Further, if there was possession of requisite knowledge and skill, do not these two important factors also imply that they would thereby give way to appropriate judgment when applying them in a given clinical circumstance? In other words, having skill and knowledge of something would also indicate that the possessor would also know when and how to use it. This was clearly established at the hearing and written to above when discussing each

and every case that was part of this prosecution – especially those involving forceps, to which this determination seems to be focused on. It has been repeatedly stated that <u>not once</u> did OPMC ever establish any standard that I was supposedly in violation of nor did they submit any formal documentation in order to meritoriously state or suggest what a prudent physician would have or could have done under any of the circumstances. Ignoring submitted documentation from ACOG by the defense while blindly accepting the duplicitous testimony (or more accurately – personal opinions) of their dubious expert served as their entire basis of this tribunal. Since when does disingenuous hearsay trump official written standards by a governing body on any subject? Imagine witnessing it.

The imposition of a thirty day suspension for the reasons stated is, frankly, insulting. It is moot for me to raise any further objection to what they have classified as misconduct. Given how they treated me, it was more like I was being cited for "misconduct" for daring to challenge their rail-roading of my license and career via an illegitimate pursuit of wrongdoing. Honestly, after six and a half years of fighting for the truth against what amounted to a steamroller of dishonesty and having my name dragged through the community mud by a newspaper more interested in sensationalism than sincerity, I needed a break. While this may have been a time for some much needed rest, those thirty days sadly proved to be ruinous for a once multimillion dollar practice that had been teetering on the brink of insolvency since public disclosure of this mess was illegally leaked by the Department of Health four months earlier. Moreover, the stigma of having a State level license action with such terminology as "Gross Negligence" in addition to the clinically suave language used to tell (more like "sell") the lie has also resulted in unwarranted marginalization across a broad spectrum of clinical medicine. It has been mind-boggling to experience similar treatment as one who might have otherwise committed murder or perhaps merely contracted leprosy.

New York State then goes on to comment that such a penalty is designed to address medical management that has apparently exposed my patients to unnecessary risk. The problem here is that not once did they ever establish what exactly they are alluding to when using the term, "unnecessary". The clinical indications employed for the three forceps cases were clearly within the bounds of the very standards set by ACOG. Therefore, when forceps are being utilized under acceptable clinical standards, then the only risk present is that which is inherent to the procedure itself. It is undeniable that all medical procedures across all specialties carry innate risk. There cannot be an ascribed "unnecessary" risk, therefore, when a procedure or treatment plan is valid and/or justifiable in regards to the clinical condition for which it is being applied. OPMC provided no basis, documentation of standards or example of how any of these medical treatments or procedures carried any sort of unnecessary risk above and beyond what would be considered customary. They habitually and notoriously attack "medical indications" as part of their modus operandi yet their indictment is conspicuously devoid of anything legitimately supportive other than the "we say so, that's why" which is what was witnessed for six and a half years.

Paragraph 5: Again, there is this reference to restricting high forceps which is completely unbefitting. Nevertheless, the State's subsequent comments concerning my "skill", "satisfaction" and some sort of *bravado* I was accused of supposedly "flaunting" concerning something as serious as implementing a highly technical instrument used to deliver and preserve the life of a newborn is enormously insulting. This sort of rhetoric is wholly illustrative of the very posture of the State and more like that of the one perinatologist who was not only responsible for the anonymous reports but whose personal insecurities towards anyone with the clinical capability to use Obstetrical forceps has been described above. If defending one's self from a baseless attack regarding an aptitude he has repeatedly demonstrated to possess is now being considered braggadocios, then what would they have wanted me to do? The record speaks for itself. All I did was testify to it.

[To look at their accusation in another way, let's say that we take the simple analogy of a baseball pitcher who can throw a fastball more than 100mph. It first requires an understanding that this is a specific skill and ability which indeed sets him apart from a number of his peers. However, it does not make it illegal, inappropriate or wrong for him to include such a technique in the armamentarium of options for his craft,

depending on the circumstances encountered. The reasons why he would not always utilize this capability is because there are indeed potential risks associated, such as a wild pitch, possible injury to his arm/shoulder and/or possible injury to the batter were he to get hit by a pitch with such velocity. Nonetheless, when a given setting calls for it, he readily implements this wherewithal and has repeatedly shown the proficiency necessary to establish himself as a specialist in this one particular area of his profession. He is personally fulfilled as a pitcher and lauded by those who directly benefit from this ability because he can do something in certain situations that enables him to effectively get out of a jam when others would be forced to use other (perhaps riskier) options.

Now, as a result of this talent, another (older) pitcher (who has personal connections to the league office) simply dislikes him because of his own (career long) inadequacies in this area and therefore files a grievance with the league stating that our pitcher in question is unnecessarily exposing risk to those of whom he appropriately directs this ability and who also acts with bravado when doing so, when in fact there has never been a negative incident nor any display of haughtiness for an aptitude he has always been humbly thankful to possess. In this example, the league office is made up of elderly (now administrative) contemporaries of our complainant, who have little familiarity with the actual on-field goings on and therefore relied completely on the information being fed to them by this one disgruntled man. The "risk" in question is not only purely theoretical but even intrinsic to this accepted method yet now garners an investigation into this endowed pitcher's record and career. Soon thereafter, he finds himself being sanctioned by the league for having applied his ability "inappropriately" whereby he vehemently defends himself by simply stating the facts about his legitimate skill and careful implementation. He is now being told that while he may possess the ability to throw the ball 100mph, he lacks the judgment on when he can and should do it. Despite documentation by the team and testimony being offered by others who have expertise in this area thus establishing the rightful use of this technique and further, no one ever getting harmed by it, the league officials punish him because they obtusely say otherwise...because they can. Furthermore, because this pitcher dared defend himself by testifying to his ability and the discretion applied in using it, (as evidenced by any and all records available and submitted), he is additionally admonished for behaving arrogantly because this is precisely the portrait that was viciously painted by the one detractor whose sole purpose was to cause substantial harm to this pitcher's reputation and livelihood while also seeking to eliminate this highly effective and demonstrably safe modality from his skill set. In the end, all truth, morality and justice were set aside in order for those in power to teach this youngster a lesson. This example is absolutely illustrative of what was done over six and a half years to my license, differing only in that the setting was the world of Obstetrical medicine.]

Getting back to paragraph 5, OPMC then continues to assert that I demonstrated impaired judgment by violating what (in reality) was **not** a prohibition on the use of forceps that existed within the hospital subsequent to the summary suspension. True, the initial sanction was that my privileges to perform all forms of operative vaginal delivery were suspended for six months. But, as stated above, by doing so, the department failed to provide any alternative to otherwise forcing a major abdominal surgical procedure upon a patient when (unpredictably) facing any number of clinical circumstances that could have readily and properly been overcome by using an operative vaginal method. You see, it is not as simple as restricting a procedure that is normally scheduled ahead of time. The indication (or incidence for that matter) for the use of operative vaginal delivery is almost always unpredictable and encountered when a decision has to be made right then and there. This, in fact, happened within two weeks of the sanction. The case was that of a first time mother having pushed for three hours who was now too exhausted to go any further. The baby's head was near crowning and a simple application of an operative technique would have resulted in a straightforward vaginal delivery. However, by the imposition of this restriction, my only option was to subject her to a major surgery. Frankly, as an ardent patient advocate, this was unacceptable. I therefore called the Chairman of the department who was the one responsible for compelling this limitation. After appreciating the implication of the situation, he agreed (based on his acute awareness of my long history of safe and appropriate practice, particularly with forceps, as well as his personal realization of the baselessness of the sanction in the first place) that I should be allowed to perform an operative delivery with one of the faculty present for the delivery as a supervisor or proctor, if you will. The point here is that I had the chairman's blessing to proceed. It would have been impossible to simply decide for myself to proceed against an administrative directive, as implied by the State.

Forceps were chosen as the most direct and safest method from my experience and within two minutes, the baby was delivered healthy with the mother and her infant completely unscathed. From this point forward, the sanction for the remainder of the six months was <u>formally</u> modified to specify that whenever any other such circumstance would arise, the faculty on service was to be approached, the clinical indications discussed and, if agreed, the procedure performed with them present in the room. This came up only a handful of times during the six months. Each and every time the faculty (including two such occasions with our antagonistic perinatologist) concurred with the management plan and all deliveries were successfully completed without a single problem. When the six months was up, one last ditch effort (at the time) was made by this one adversarial perinatologist to create added trouble for me via a spitefully derogatory report written concerning this time period. This diatribe was essentially ignored by the Chairman, where after all privileges were restored in full without any restriction or admonition from the department.

All of this information about the institutional modification of the privilege suspension was disclosed to OPMC, yet they patently ignored it and insisted on maintaining that I had repeatedly violated a sanction that didn't exist. If such a restriction was indeed in place and furthermore repeatedly violated, it would have been immediately reported to the Chairman's office and I would have been suspended outright from the department, if not the hospital. The charge here by the State of New York is absolutely (and knowingly) baseless and more importantly, a complete and deliberate lie. How this issue even became fodder for the State is as follows. When the elder perinatologist was unsuccessful in trying to cause further trouble with the above mentioned report of the six month privilege limitation, he simply changed who would be audience to it and added it to the plentitude of other disparaging writings sent to OPMC on my behalf. The redundancy of the efforts by OPMC to sully the proceeding in any way possible is once again demonstrated here by forcing this fraudulent violation upon the record when they knew full well that is was untrue. They took every single written criticism by the elder perinatologist as full-scale, unimpeachable evidence when it was constructed out of nothing more than sheer disinformation and repeatedly discredited throughout the proceeding.

Paragraph 6: I have already well established that the entire attack on my license in the area of Obstetrical Forceps was utterly baseless. Once again, they find it necessary to attack the character of the physician under investigation rather than the facts by dishonorably citing "over-confidence" and an "unwillingness to alter" practice habits (oddly without truly ever establishing what constituted such a claim or what needed to be altered). What precisely was outside the bounds of standard indication and application that needed to be amended, especially when the written standards were in their possession and the specifics of the cases were right before them. Apparently, defending oneself with factual information in the face of a disingenuous agenda constitutes such rhetoric when there is nothing else to offer. Whenever a mendacious entity in an argument finds itself in the position of having no honest basis for their stance, it is standard operating procedure to start with what amounts to "name calling." As adults, this should be readily obvious to any of us who have simply kept our eyes and ears open throughout our lives. OPMC has certainly proven capable of such pettiness.

The fact remains that not only did I never have an adverse outcome from the use of forceps, on top of the fact that they were only used when absolutely necessary, and that I took them very seriously when deciding to implement them, but because of the judicious implementation of this technique, my primary cesarean section rate (not overall rate) was a drastically low 4%. This is compared to the community average of over 16%. These stats are not, in and of themselves, an absolute justification for their use. However, outside of the otherwise legitimate and safe option forceps represent to both the patient and Obstetrician, there are additional benefits as well – i.e., the avoidance of a major abdominal surgery. The assertion by OPMC to simply perform a cesarean section in lieu of implementing what I had been accustomed to practicing did two things. First, it denigrated the importance of the patient by legislating

that she simply be subjected to a major surgery when there was an alternative that she might otherwise choose for herself. Secondly, it stemmed to stratify me with everyone else in the community so that I was put in line with those who were incapable of offering this option.

I have already alluded to the inane/childish mission of the elder perinatologist to strike down anyone who is capable of doing what he cannot – with mid-forceps deliveries historically having been one of the most significant procedures to gain his ire. Isn't it interesting to consider all of this in the context of the absolute fact that he was responsible for my entire ordeal and the fact that only mid-forceps privileges were limited by the State? The anatomically driven difference between mid-forceps and the next category (low forceps) is so arbitrarily determined by any particular clinician performing such procedures that to limit one and not any other is once more very telling as to the committee's agenda and overall competence in what was being adjudicated. Also, note that each of the cases that were "gathered" as material for prosecution just so happened to involve only mid-forceps. For an Obstetrician, who in the eyes of the State was so filled with "bravado" as to the implementation of Obstetrical forceps such that he needed to be taught a lesson regarding his inability to "alter his use", certainly there should have been other cases involving low or outlet forceps as well that fell outside of the phantom standard that the State created for this prosecution. Given that there was 80-100 forceps cases performed throughout my tenure at Crouse Hospital, shouldn't the State have been a little more protective of the public interest and properly investigated all of my forceps cases? How are they protecting the public from danger? Do I only improperly utilize forceps whenever I choose to honestly disclose for the record that they are of the midtype? Do I magically and suddenly right my clinical decision making ship when the baby's head is 1cm lower in the pelvis such that I am now not considered a danger and therefore need not be limited? Of course these sardonic points are meant to further ridicule this entire proceeding specific to the forceps issue for which it was predominantly based.

The bottom line is that ACOG's standards are as plain as day and every one of these cases on trial were well within the guidelines, regardless of the State's deliberate decision to ignore them. The reader of this document need not forget that not only do I stand by every single case and application of forceps throughout my career, but that I repeatedly asked OPMC to review every one of them along with my entire record as a physician in order to prove that my practice of medicine NEVER EVER approached anything that could be considered a danger to the public. Six years were spent by this agency (not to mention perhaps \$100+K of taxpayer money) to prosecute what originated as a complete assault on my forceps rights. I categorically refused to allow them to do such a thing based on a lie. As stated above, my penalty for daring to fight was increased from initially my forceps privileges to my entire license. In the end, however, only a remotely used aspect of forceps deliveries was limited. Just enough so that our "gentleman and scholar" could see to it that no one was going to be performing mid-forceps so long as he was around.

Paragraph 7: Hopefully by now, with all that I have written and reiterated, this entire proceeding is capable of being seen for what it truly was. A longstanding record of exemplary performance was ignored and then destroyed by a few men who possessed the power and connections to do so by utilizing and abusing the hospital peer review system and then a State level agency to accomplish their agenda. There was no gross negligence nor was there any repeated negligence involving any of these patients. The cases and the arguments provided more than establish this position. Were there some things that could have been done differently so as to avoid the course of some of the events? Certainly. This is inherent to not only medicine for every physician but to life for every human. Recognizing idiosyncrasies and making corrections is never a bad thing, especially in medicine. This is why physicians engage in what is called a "practice." We are to practice our craft with the purpose of (hopefully) getting better. Sure, some of these cases were not typical. But what is even more important to consider is that they were also isolated. In the end, no one was unduly harmed and none of these cases represented any sort of overall picture of my practice of medicine to have been used in a prosecutorial manner to suspend a license and consequently destroy a career. This latter point is further compounded when my entire body of work is considered which then reduces any issue with any of these cases to a statistical nonentity.

When contemplating the exact role of OPMC as existing to protect the public, then this entire six year ordeal was a failure to their stated mission and a huge stain on the integrity of the agency.

I won't comment on the remaining portion entitled "Order." Enough has been argued already as to this material.

In conclusion and summary, it was an arduous task to write about and provide the true facts for each of these cases. It was painful enough to have endured six and a half years of seeking the truth in these matters, thus going through them again was not fun, to say the least. When following the State's document alongside this one, it should be plainly obvious that there is a stark contrast and major disconnect. There is a reason. In adjudicating this proceeding, the State ignored submitted and moreover, vindicatory evidence especially that from the actual patient charts, ACOG practice standards, fundamental Obstetrical medicine and research journals. They disregarded highly qualified expert testimony, suppressed other exculpatory evidence, used secret evidence, empanelled biased jurors (twice), limited cross examination of their expert when their testimony was being impeached, presumed me to be guilty while having to prove my innocence and violated too many of their own rules to even list. These facts are tantamount in establishing the Kangaroo Court that was inflicted upon my license, livelihood, life, patients, employees and family.

Consider the following as a final illustration and example of the Department of Health's and particularly, their Office of Professional Medical Conduct's failure to properly exercise the authority granted them. The Hearing Panel clearly stated in their summary on page 50 of the determination that my primary expert was given great weight. Yet, not a single one of his opinions, which fully supported my defense, were given any mention. This was an unmistakable violation of how these matters are to be adjudicated. I encourage anyone to read the *Findings of Fact* which was penned by my attorney as a formal written closing statement at the end of the 2007 hearing. In it, he notably points out that when the State makes such a statement about the defense expert, they are essentially prohibited from finding adversely on any charge for which that expert testified against. This was not done which makes six-plus years, tens of thousands of dollars and OPMC's resultant Determination and Order unconditionally fraudulent and invalid.