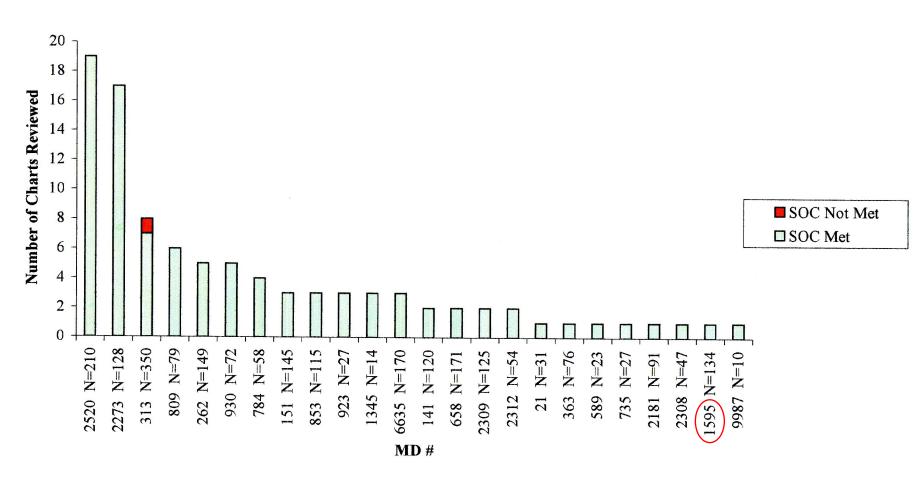
#### **Exhibits**

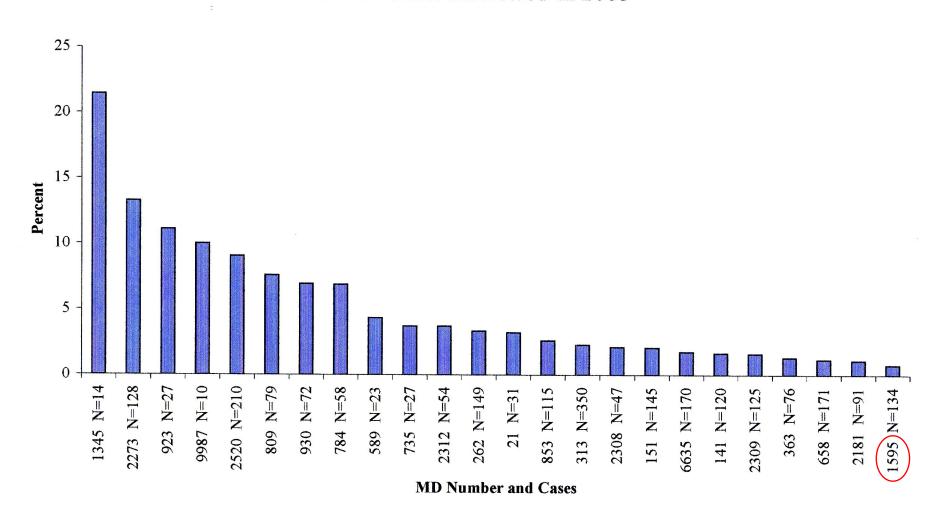
- A. 1-2005 Gyn QA Report from Crouse
  - 2-United Healthcare Premium Rating
  - 3-Letters of recommendation by Dr.'s Cameron and Landas
  - 4-Delivery history analysis 1998-2001
  - 5-CV for James R. Caputo, M.D
  - 6-RateMD's Report showing James R. Caputo, M.D. as #1 rated Ob/Gyn in Syracuse
- B. 1-September 2002 Complaint against Crouse Hospital
  - 2-October 2002 Complaint Response letter from OPMC assigning case #
  - 3-August 2004 Letter from Attorney Michael Ringwood to OPMC requesting status of complaint.
  - 4-September 15, 2010 response letter from Office of Health Systems Management.
- C. State's acknowledgement of Dr. Waldman
- D. Worley RCA Report adulterated version
- E. 1-Worley RCA Report corrected version
  - 2-Worley NYPORTS Report
- F. Worley Emails
- G. 1-Six month Ob review by Aubry
  - 2-Testimony excerpts from 2002 Crouse Hospital MEC Hearing by Richard Aubry, M.D.
  - 3-Forceps limitation penalty excerpts from 2007 Determination and Order
- H. CK letter to Crouse 2007
- I. Card describing Crouse QA as oppressive
- J. Peer Review Flow Chart
- K. DOH requesting pertinent minutes and information in 2008
- L. 1-RCA Report request response from Medical Staff Office
  - 2-NYPORTS Reporting Guidelines
- M. OPMC Reform Bill facesheet
- N. Defenses Request and Motions 2007
- O. Excerpt from D&O establishing Panel's position concerning expert witnesses.
- P. 1-Tactics Characteristic of Sham Peer Review
  - 2-The Psychology of Sham Peer Review
- Q. Page 64 from 2007 Determination and Order
- R. DOH due process inconsistencies.
- S. 1-Temporary Restraining Order against OPMC on 12-13-2007
  - 2-Decision by Judge Teresi on OPMC violation of the law.
- T. Modification Petition Statute
- U. 1-Certified mail receipt for 7/2013 Petition to BPMC
  - 2-July 2013 Petition to BPMC
  - 3-July 2013 Petition to BPMC supporting documents
- V. Determination and Order Marc Feiner
- W. In the Matter of Vito Edward Caselnova, M.D.
- X. Crouse Privilege Suspension Truth

Exhibit A1

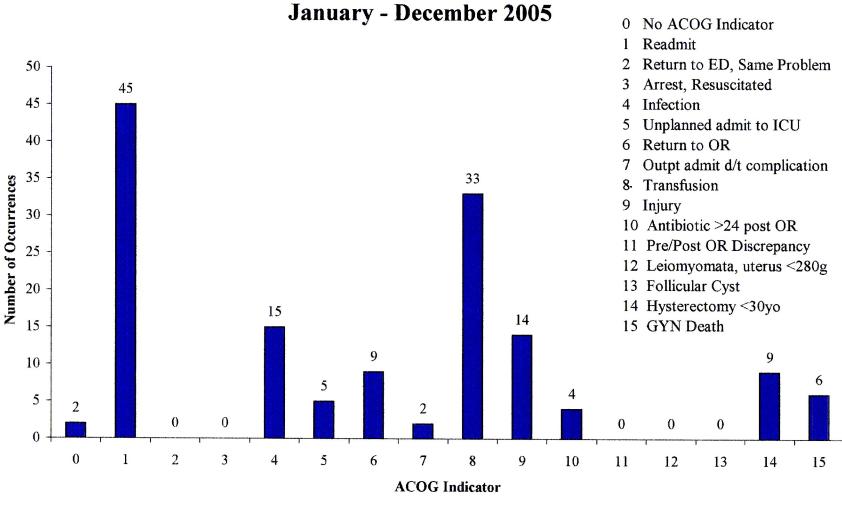
# Crouse Hospital Gynecological Occurrences Reviewed by the GYN QAI Committee January - December 2005



Crouse Hospital
Gynecological QAI Committee Report
Rate of Cases Reviewed in 2005



## Crouse Hospital Gynecological Occurrences Reviewed by the GYN QAI Committee



April 26, 2007

## Exhibit A2



James R Caputo MD 739 Irving Ave Ste 300 Syracuse NY 13210-1663

Dear Dr. Caputo,

Recently we sent you a letter explaining the UnitedHealth Premium® designation program for UnitedHealthcare and Oxford products. This follow-up letter provides you with updated information and your designation status. We continue to be committed to a collaborative process that supports data accuracy, evidence-based expert physician and industry standard performance measures, transparent methodology, and fair reporting to physicians and consumers.

We are pleased to inform you that you have met the UnitedHealth Premium designation program criteria and will receive the UnitedHealth Premium Quality Of Care designation.

Your designation is based on our analysis of claims data from calendar year 2004 through May 2006 against designation criteria. Your designation status will be displayed on the UnitedHealthcare website by the end of May and the Oxford website by the end of 2007. You will be identified as shown below. The next analysis of claims data for redesignation will be performed later this year.

Name	Address	Specialty
James R Caputo, MD	739 Irving Ave Ste 300 Syracuse NY 13210-1663	Obstetrics And Gynecology  ☆ UnitedHealth Premium  Quality Of Care

#### Access your detailed practice report online

We believe that the UnitedHealth Premium designation program data and analysis can serve as a valuable tool to assist physicians in addressing their professional obligations for continuing professional development. As such, we encourage you to access your detailed performance assessment results at www.UnitedHealthcareOnline.com > Clinician Resources > Performance Measurement & Reporting > UnitedHealth Premium Designation > View Ratings/Designation > View Your UnitedHealth Premium Assessment Report. Your user ID and password are provided on the lower right of this letter and can be cut out and kept for future reference. This is a temporary password. After accessing the Web site, you will be prompted to create a permanent password.

## Exhibit A3a

Dr. Scott J. Cameron 435 East 70<sup>th</sup> Street, 17-J New York, New York, 10021

June 9, 2010

To Whom It May Concern:

I am writing in support of James R. Caputo, M.D. I have known Dr. Caputo on a professional basis for approximately four years. I have witnessed him practice both obstetrics and gynecology in Syracuse, I have assisted him with surgical cases in the operating room, and I have collaborated with him at length on a research study. I can also testify to his good character and fastidious personality traits.

Dr. Caputo is a highly skilled medical practitioner. His attention to detail and delivery of quality patient care are second-to-none. Comparing him to several other medical practitioners in the area whom I have also worked with in the clinical environment and in the operating room, I submit that his skill and care are of the highest caliber. He offers a broad array of complex gynecological procedures and navigates the most intricate surgical cases with comfort and with good outcomes that are not matched by many of his contemporaries. He operates extremely competently independently, but also functions well as part of a team.

Without hesitation, I would be encouraged to see patients present to Dr. Caputo to receive the high level of care that he has a reputation for delivering, and I commend him to you most warmly. Please feel free to contact me regarding any concerns.

Yours,

Scott J. Cameron, B.Sc., M.S., M.D., Ph.D.

Select Sans

Exhibit A3b



June 17, 2010

#### To Whom It May Concern:

This letter is in support of James Caputo, MD, a colleague who I have known for five years. Jim is one of the most genuinely friendly, engaging and enthusiastic individuals I have known. He has been a part of our voluntary clinical teaching faculty in the second year medical student pathology course (that I direct), contributing two one-hour sessions per year. These are comprised of wellillustrated clinical vignettes in which he challenges the students to not only recall the facts and associations they have been studying, but also to apply them in clinical context. He has a talent for cultivating the clinical reasoning skills that are vital in these students' future practice and the students are regularly appreciative in their feedback. What impresses me even more about this dynamic young physician, though, is the bond with his patients. I can recall multiple occasions conversing over lunch with Jim when a patient would approach, politely interrupt, and express a wide combination of greeting, gratitude, and good wishes. To say that Caputo's patients are satisfied with his care would be a gross understatement: they absolutely love him, they appreciate his sensitivity, and they rave about the quality of his care. I am pleased to count Dr. Caputo as a colleague and a friend.

Sincerely,

Steve Landas, MD

Professor, Department of Pathology

## Exhibit A4

## Labor and Delivery History

at Crouse Hospital (October 1998 - Nov 2001)

for James R. Caputo, M.D.

Total Deliveries	Vaginal	Vaginal Breech	Total Cesarean	Primary Scheduled	Primary Failed TOL	Repeat	Total Forceps	Kielland Rotations	Mid Forceps	Vacuum	Multiple Gestations	
394	329	6	65	17	19	29	45	13	18	16	14	

Total C-Section Rate => 16.50%

Failed Trial of Labor C-Section Rate => 4.82%

Post C-Section Wound Infection Rate => 0%

Post Partum/Post Operative => 0.25%
Maternal Complication Rate (one case)

## Exhibit A5

**TRAINING** 

### James Richard Caputo, M.D.

#### **Curriculum Vitae**

BIOGRAPHICAL/ Address: 4729 North Street Jamesville, New York 13078

**CONTACT DATA Birthdate:** March 8, 1967

Place of Birth: Rochester, New York

Citizenship: United States Email: jrcaputo@yahoo.com Phone: (315) 382-8778

EDUCATION/ 06/1997 SPECIALTY TRAINING IN OB/GYN

Oakwood Hospital and Medical Center
Department of Obstetrics and Gynecology

18101 Oakwood Blvd Dearborn, Michigan

05/1993 **DOCTOR OF MEDICINE** 

State University of New York Health Science Center @ Syracuse

College of Medicine Syracuse, New York

05/1989 BACHELOR OF SCIENCE IN BIOCHEMISTRY

University of Buffalo Buffalo, New York

LICENSURE New York State – Physician #206065

WORK 5/2009 – Present James R. Caputo, M.D., Ob/Gyn

**EXPERIENCE** 1200 East Genesee Street · Suite 201

Syracuse, New York 13210

Private Practice

4/2008 – 4/2009 Practice restructuring

07/2001 - 4/2008 James R. Caputo, M.D., P.C.

739 Irving Avenue · Suite 300 Syracuse, New York 13210

Private Practice

03/2000 - 07/2001 Jeffrey B. Chick, M.D., P.C.

502 Walnut Avenue Syracuse, New York

Private Practice - purchased practice in July 2001

 $10/1998 - 02/2000 \qquad \textit{Hill Ob/Gyn Associates, P.C.}$ 

1000 East Genesee Street · Suite 500

Syracuse, New York Private Practice

08/1997 – 10/1998 James R. Caputo, M.D., Obstetrics and Gynecology, P.C.

Penfield, New York Private Practice

07/1993 – 06/1997 Oakwood Hospital Department of Obstetrics and Gynecology

Resident Physician

Program Director: Sami Guindi, M.D.

#### TEACHING **EXPERIENCE**

#### 06/2011 Surgical mission trip to Botown, Sierra Leone, Africa

West Africa Fistula Foundation

Provided surgical treatment free of charge for women with various disorders including severe Vesico-Vaginal and Recto-Vaginal Fistulas resulting from obstructed labor and lack of access to cesarean section while collaborating with and instructing local African doctors in both medicine and surgery.

#### 02/2005 - 2008**Ob/Gyn Clinical Correlations Lecture Series**

Gave two separate lectures to second year medical students through the Department of Pathology at SUNY Upstate Medical University. Presented slides of clinical medicine and surgery, correlating them with core topics in the fields of Obstetrical and Gynecological private practice.

#### 1998 - 2008**Clinical Instructor**

Department of Ob/Gvn

SUNY Upstate Medical University – resident education

#### 08/1997 – 06/1998 Clinical Instructor

Highland Hospital of Rochester Department of Family Practice Provided Ob/Gyn clinical instruction for resident physician outpatient clinic.

#### 08/1997 - 05/1998**Clinical Instructor**

University of Rochester Department of Ob/Gyn Supervised resident Colposcopy/LEEP Clinic Highland Hospital, Rochester, New York

#### **CERTIFICATIONS & MEMBERSHIPS**

#### **Board Certified**

November 1999. Certificate # 971289

Diplomate of the American Board of Obstetrics and Gynecology

Certification current

#### Fellow of The American Congress of Obstetrics and Gynecology

Admitted December 2000

#### **National Board of Medical Examiners**

Certificate # 432321

#### CLINICAL PRACTICE INTERESTS & ACCOMPLISHMENTS

Precise delivery of Care Minimally Invasive Surgery Reconstructive Vaginal Surgery Urinary Incontinence

Pelvic Pain Infertility

High Risk Obstetrics

Menopausal Medicine

High patient satisfaction

#### RESEARCH **ACTIVITIES**

1998 – 2008 Private practice research into premature birth – causes and treatment modalities. Compiled data and wrote preliminary abstract with

statistically significant results.

1988 - 1989 Isolated defective genes of temperature sensitive strains of Vaccinia virus

during undergraduate research at University of Buffalo.

1985 Researched new strategies in producing three-dimensional semi-conductors

during summer internship at IBM Corporation.

#### RESEARCH INTERESTS

#### Gestational Diabetes: New strategies in screening and management

Evaluation of new management protocol for optimizing overall

delivery outcome.

#### **Secondary Infertility**

Development of a treatment protocol aimed at restoring a functionally proven system in the absence of new tubal disease.

#### AWARDS Compassionate Doctor Recognition – 2010, 2012-2013 Vitals.com

**Top Ten Doctors** – 2012 Vitals.com

Patient's Choice Award - 2012-2013 Vitals.com

#### **Practice and Performance Highlights**

- Overall Number of Gynecologic Cases: ~2,300 major and minor surgeries. Extensive first assistant experience.
- Gynecologic Surgeries:

*Minimally Invasive*: Advanced Laparoscopy – Level II: Cystectomy, Adnexectomy, Extensive adhesional disease, CO2 laser, Myomectomy, Endometriosis, Ectopic pregnancy, Uterine suspension, Vaginal Vault suspension, Pomeroy tubal ligation, Tuboplasty, LAVH (Traditional/Döderlein Techniques), Laparoscopic Burch, Level II Hysteroscopy/Resectoscope.

*Laparotomy:* Exploratory, TAH, Myomectomy, Adnexal disease, Ectopic/Cornual Pregnancy, Tubal Reanastamosis.

*Pelvic Reconstruction*: Anterior and Posterior (Levatorplasty) Colporrhaphy, Trans Obturator Tape, Kelley Plication, Hymenectomy, Perineoplasty.

Minor Gynecologic Surgery: Diagnostic Hysteroscopy/D&C, Essure, LEEP, CO2 Laser ablation.

- **Special Obstetrical/Gynecologic skills:** VBAC, Vaginal Breech delivery (singleton or second twin), Genetic/Maturity Amniocentesis, Transvaginal/Abdominal Ultrasound performance/interpretation, Obstetrical Forceps (outlet, low, mid, rotation), Shirodkar Cervical Cerclage, External Cephalic Version, Internal Podalic Version, 3<sup>rd</sup> and 4<sup>th</sup> Degree Obstetrical Laceration Repair.
- **Number of Pregnancies/Deliveries:** ~1300 Low and high risk, multiple gestation.
- Primary Cesarean Section Rate: ~5%
- Total Cesarean Section Rate: 16%
- Premature Birth Rate: <3%
- NICU Admission Rate: <5%
- Vaginal Delivery Complication Rate: 0 %
- Cesarean Section Complication Rate: 0%
- **Gynecologic Surgery Complication Rate:** 0.1% (3 in 2,300)
- Number of Ureteral injuries from Gyn surgery: 0
- Blood transfusion rate: <1%
- Post Surgical Wound Infection Rate: 0% (abscesses, dehiscences, wound breakdowns, readmissions)



Find A Doctor By Name

Signup | Login

& Claim Doctor Profile



Share this Doctor: twitter ff facebook

Exhibit A6

Q

#### Dr. James R. Caputo

Gynecologist (OBGYN) (/best-doctors/ny/syracuse /gynecologist-obgyn/) @ (/specialties/gynecologistobgyn/)



#1 of 44 Gynecologists (OBGYN) in Syracuse, New York (/best-doctors/ny/syracuse/gynecologist-obgyn/)

- ♠ Male (/best-doctors) /ny/syracuse /gynecologistobgyn/?gender=m)
- 2 Facilities (/doctors /28853 /Dr-James%2BR.-Caputo-Syracuse-NY.html/credentials/)
- **└** Unavailable
- **♀** View Map & Address
- ✓ Visit Website (http://www.goodlifecentre.com)

### Rate Dr. James R. Caputo



#### Comment

Please leave a comment with more detail about your experience.

★ Rate This Doctor

#### Dr. James R. Caputo's Ratings

₽5



I drive 75 miles to be seen and cared for by this amazing Dr. Always caring and informative, never rushed. He takes time with each patient to correctly diagnose any issues and treat them. I'm happy to have found his practice. 5 ☆☆☆☆☆

Was this rating useful? 0 🖒

flag | Submitted Oct. 29, 2014

**②**5

₽5 Knowledge



Dr. Caputo spent time attending to my concerns related to fertility anxieties. He made me feel comfortable, and not at all embarrassed discussing personal emotional and physical issues that might be

1/2/2015 7:23 AM 1 of 5

challenging to discuss with a less patient and empathic doctor. FIVE stars.

Was this rating useful? 0 🖒

flag | Submitted Feb. 28, 2014











Excellent doctor! Puts his patients best interest first. Takes the time to explain all options for your when discussing health issues. I wouldn't want another doctor for my OB/GYN needs.

Was this rating useful? 0 🖒

flag | Submitted June 9, 2013











Dr. Caputo is an excellent, knowledgable, truly caring doctor. Of all the doctors I've seen in my life, he is the ONE doctor I have stayed with and WILL stay with. The staff at the office are personable and kind, friendly and joyful, and the Doc is just all-around good. Whip-smart, and he takes the time to explain everything to you, with whatever issues you're having. He delivered two of my babies, they were beautiful births, and I continue to see him for regular GYN care. You couldn't find a better doctor, or office. Highly recommend.

Was this rating useful? 0 🖒

flag | Submitted Feb. 16, 2013











DR Caputo and his staff are very professional and have a gift of making you feel as if you are their most important patient. He is extremely knowledgeable and compassionate and I have never felt rushed through my visit. I recently had a surgical procedure performed by Dr Caputo and my recovery was remarkable. He also delivered my youngest 2 children with great skill where as my recovery was unbelievably shorter than from the other children.

Was this rating useful? 0 🖒

flag | Submitted Feb. 12, 2013











I highly recommend Dr. Caputo for many reasons. He safely and successfully delivered all 3 of my girls. He is trustworthy. He takes the time to listen to your concerns, then addresses each one. I had a long-standing problem with my cycle, and after asking detailed, pointed questions and performing a diagnostic test, he diagnosed the problem. He then performed outpatient surgery, and effectively eliminated the problem! Lastly, and most importantly to me, he respects and honors my faith.

Was this rating useful? 0 🖒



flag | Submitted Feb. 10, 2013

2 of 5 1/2/2015 7:23 AM



**Q**4 Punctuality **Q**5
Helpfulness

**♀**5 Knowledge



Dr.Caputo is a WONDERFUL physician !!!! You'll never find another like him that actually CARES about the best for his patients !!! In my eyes, he is a total SAINT for putting up with what he does !!!

Was this rating useful? 0 🖒

flag | Submitted April 16, 2008



**Q4**Punctuality

**Q**5
Helpfulness

**♀5** Knowledge \*\*\*\*

he delivered both of my children. both were emergency c-sections. he was on top of everything. he calmed all my fears and handled ALL my current medical problems very carefully in relation to my health and my 2 unborn babies lives. He's awesome. i wouldnt want anyone else handing my case.

Was this rating useful? 0 🖒

flag | Submitted March 19, 2008



②3

**Q**5

**♀**5 Knowledge



Caring doctor who actually takes all the time you need with questions and concerns. (That's why punctuality is not a 5, but this is not a bad thing!)

Was this rating useful? 0 🖒

flag | Submitted Dec. 19, 2007



②5 Punctuality **Q**5
Helpfulness

**♀**5 Knowledge



Excellent physician and a man of God. He spends a lot of time with patients, so expect a little wait.

Was this rating useful? 0 🖒

flag | Submitted Aug. 7, 2007

3 of 5

Board Certified in Obstetrics and Gynecology

Syracuse, New York 13210 (315)-475-8599

September 21, 2002

New York State Department of Health Office of Professional Medical Conduct 433 River Street, Suite 303 Troy, New York 12180 Exhibit B1

To Whom It May Concern:

I am writing you to file a formal complaint against Crouse Hospital located in Syracuse, the Department of Obstetrics and Gynecology at this hospital, the Chairman/Residency Program director of this department and three other faculty members from this department. I realize this may appear to be an exorbitant complaint, however I assure you there is not only a factual and scientific basis, but a moral and ethical one as well. I plead with you to take this grievance seriously and I will do my best to be right to the point with the facts, as there is quite a bit of information to convey.

I need to establish the history that leads up to the issue at hand. I am a 35 year old, board certified Obstetrician/Gynecologist. I graduated from medical school in 1993 from Upstate Medical University, Syracuse, New York. I completed my residency training in Dearborn, MI and have since returned to Syracuse where I maintain a successful private practice across from Crouse Hospital. I sat for my written boards in June of 1997 and completed my board certification on schedule by passing the oral examination in Chicago in November of 1999. I have been married for ten years and have four young children. Fundamental to understanding not only who I am as a physician but also the substance of how I bring this complaint to you, my residency program in Michigan proves instrumental. I am eternally fortunate to have had a training program that, at its core, symbolizes the virtues of quality, education, order, rule, work ethic and integrity. Despite having gone to medical school in Syracuse, I didn't consider their program because, at that time, they had been mired with problems and other deficiencies such that they were on probation. After residency, it is commonly an uphill struggle for a physician to break into a community where they didn't train because of the unfamiliarity with not only their skills but with who they really are and what they represent. This observable fact undoubtedly did not side-step me at first and has continued to be particularly so with certain faculty members that have taken an antagonistic position without ever having observed me in action, so to speak.

Upon arriving to Crouse Hospital in October of 1998, I immediately observed dozens of aspects to their residency program that would never have existed where I trained. Now these were not subtle regional differences that exist between programs. They were major deficiencies that not only hurt the overall educational objectives and experience for the residents but also had a direct impact on patient care. To be blunt, I couldn't believe what I was seeing. This subject alone is enough for a lengthy letter; however, it serves as the beginning of my problems with this institution and particularly the Chairman and Residency Program Director of the Ob/Gyn Department, Dr Shawky Badawy.

Having spent my first year out of residency in Rochester, I became quite familiar with the ins and outs of their training program, which was completely in line with my own experience. In addition, as a

department member at my admitting hospital, it was commonplace for resident and residency issues to be discussed amongst attending physicians in an open forum. There was a mandatory monthly departmental meeting where the sense of camaraderie and accomplishment was what I had come to expect and respect for that matter. Now, nearly six months at Crouse and having witnessed and experienced the egregious deviation of all that had been imparted to me throughout my own training, I felt compelled to speak up since my own patients' care was being affected. At one of the department meetings, I warily and politely brought up five or six of the most evident issues. It was, first of all, difficult to bring about an engaging discussion since only a fraction of the department's attendings even bother to show up for these apparent non-mandatory meetings. My concerns were essentially brushed off with the response from the Chairman being, "does anyone have anything good to say about the residency program?" I couldn't believe it considering what I had just described as having gone on within his program. I essentially felt as though his attitude was 'how dare you come into my department and question my program' without so much as giving credence to anything I had just said. It was also clearly evident that no one was going to speak up against such commentary regardless of the legitimacy of my issues. I was new and expected this to be tough to impart, but didn't realize how insignificant my opinion was, in addition to the impact this meeting would have on my future with this man.

Another six months went by and I, again, could not sit idle with what I was experiencing with the residency. I had been at the hospital for a year with my abilities and most importantly my demeanor as an attending physician clearly established with all that I had worked with. This time, the Chairman met my issues with downright anger. Frankly, this was the only forum I felt comfortable raising these issues, given such responses. A fellow colleague who had trained under Dr. Badawy pulled me aside afterwards and advised me to avoid the Chairman. Apparently, his history with the residents has been described as dictatorial. If there was an issue with the residents, bring it up with them on an individual basis, he said. This is what I did, only further to my detriment. A few residents must have gone to him after I expressed disapproval on the how they were caring for my patients. Dr. Badawy immediately padded my hospital file with disparaging letters about my person and completely mischaracterized my relationship with the residents. One resident told me that he actually called a meeting to 'warn' them all about me. What in the world had I done to this man? Never did he ever speak to me about the concerns I had about resident care or the specific incidents that prompted me to speak straight to them. I even called his office directly when individual issues with resident care arose, only to never receive a response. Again, as chairman of the department and residency program director, the concerns of one of his attending physicians didn't matter and once more fell on deaf ears. From this point on, any contributions I would try to make in department meetings were met with complete disregard. Everything I have ever brought up, alongside the resident issues, has been in the spirit of making the department better, drawing on my own experiences and principles. While significant, they are beyond the scope of this letter. In summary, this man, as I saw it, despised me because I wanted to essentially help improve matters and make it a better and safer place for patients, residents and attendings in pursuit of the practice of Obstetrics and Gynecology.

This above historical perspective of my personal dealings with this man and his department are critical in understanding what I am about to elaborate on below. In the four years I have been a member of the Obstetrics and Gynecology department at Crouse Hospital, I have delivered over 500 babies and have done hundreds of major and minor gynecologic surgical procedures. I have one of the lowest cesarean section rates in the region and my complication rate on both the ob and gyn side of things is virtually non-existent, despite having taken on many high-risk and complicated cases. In addition, I have repeatedly demonstrated specialized skill in the areas of operative vaginal delivery, vaginal breech delivery and operative laparoscopy. Perhaps my most noteworthy characteristic is that I do not share call

with anyone and in fact look forward to delivering all of my obstetrical patients. This has been the foundation of my practice from day one and specifically why many of my patients come to me. I am very proud of my accomplishments, as they are a testament to my training and to my parents for having instilled in me the sense of compassion, work ethic and the unrelenting pursuit of excellence in everything I do. Anyone, with whom I have worked, including residents, nurses and even the housekeeping staff could corroborate these facts and I have long been unafraid to let my record and case history speak for itself.

On September 16, 2001, I was involved with a delivery that resulted in a stillbirth. It is crucial to understand the specifics of this case, so as to appreciate the substance of my grievance. I apologize for how clinical my account will be but it is necessary to do so. And importantly, the medical record supports every single thing detailed below. This delivery involved a patient that was expecting her first baby. Throughout the course of the gestation, as with most cases, I became close with this couple. After 36 completed weeks of gestation, this patient was seen several times in the office for false labor. She was having such painful contractions that she could not get any relief or rest for that matter. This is despite no change to her cervix; a common yet frustrating condition of late pregnancy. On September 12, 2001, she presented once again to the office, now 36 5/7 weeks gestation. In addition to persistent painful contractions, she now was suffering from cellulitis in her right lower extremity. She was therefore admitted to the hospital for IV antibiotic therapy. She had a good therapeutic response and was started on subcutaneous Heparin therapy for prevention of deep vein thrombosis given multiple risk factors, including an infected, markedly swollen leg, a mother, maternal aunt and maternal grandmother all with a history of DVT, and the fact that she was pregnant and relatively bedridden. On September 15, she was clinically stable with regards to her leg. However, the entire time she was in the hospital, she continued to have painful contractions that were repeatedly documented in the medical record and that required periodic doses of Tylenol with codeine for relief. In addition, there are two separate notes detailing that she was now having bloody show, which is a physiologic declaration of cervical change, specifically softening and thinning, resulting in the release of the protective mucus plug. And in fact, on September 15, a cervical exam revealed that for the first time in over a week of contractions, she was now almost two centimeters dilated and her cervix was indeed soft and thinning. But most significantly, she was writhing in bed from the pain. This patient was **clearly** in early labor and therefore was transferred to labor and delivery, now at 37 2/7 weeks gestation. Sending her home was not an appropriate clinical option.

Once in Labor and Delivery, her water was broken and eventually received a small amount of Pitocin to reach full dilation of her cervix. She had earlier received a labor epidural and the fetal heart rate tracing was reassuring throughout the entire process. Once completely dilated, it was noted that her baby's head was in a straight occiput posterior position and a plus one to two station. What this means is that the fetal head was in a position whereby the face was up towards the ceiling. As a result, the head diameter that needed to negotiate her pelvic outlet was significantly wider than if the face were looking towards the floor. In general, when a patient gets to full dilation and the fetal heart rate tracing is otherwise reassuring, this scenario is the number one reason for cesarean section, citing failure to progress. In addition, at this time, the fetal heart rate tracing now revealed the presence of repetitive variable heart rate decelerations. By definition, this type of heart rate finding is the result of umbilical cord compression, most commonly from the cord being around the neck of the baby, (nuchal cord). In fact, a nuchal cord can be a normal finding in up to 33% of successful vaginal deliveries. In this case, however, the decelerations were classified as moderate to severe in nature while the overall tracing still indicated a healthy baby. However, the natural history of such decelerations, if left unchecked over time, presents a significant risk of fetal compromise.

A clinical decision had to be made. It was now in the middle of the night on September 16, and the patient had been laboring all day and really all week for that matter. She was looking at pushing for at least two hours because of the fetal head position and the fact that she had not delivered before. And given her level of exhaustion, it was questionable whether she would have made it. But more importantly, since there were the above described decelerations of the fetal heart rate, the baby would not have tolerated the time it would have taken the patient to push, even if successful. Therefore, the patient and husband were counseled and consented to the use of special obstetrical forceps to rotate the fetal head to the more favorable position, with eventual delivery aided by conventional forceps, so as to expedite the delivery. The American College of Obstetrics and Gynecology, (ACOG), has indication guidelines for the use of operative techniques to effect delivery. I was completely within these guidelines, on more than one item, to offer this as a legitimate means to address the situation. Furthermore, this is a procedure that, up to this point, I had performed at this institution more than a dozen times in the preceding two years. Everyone had been successful without so much as a scratch on the baby. In fact, during my time at Crouse, I had performed nearly fifty forceps deliveries overall, with absolutely no complications and all perfectly healthy moms and babies. I had unassumingly established myself amongst the nursing staff and residents as one attending completely capable of such otherwise difficult procedures. And as a result, I spared many women the likelihood of a cesarean section.

I need to bring up this clinical history because I take the use of obstetrical forceps very seriously. I am exquisitely sensitive to the relative controversial nature of their usage. Historically, when used properly, they offer the obstetrician a powerful modality to a safe and effective delivery. When I instruct residents on such practice, there is one thing that is made clear. An obstetrician has absolutely no business ever using them unless they are utterly and unequivocally certain as to their placement and operation. I bring this conviction to the table every time I employ them.

In this case, the application was no different than any other rotational procedure I had performed in the past. Typically, the placement of the individual forcep blades offers the greatest challenge and usually takes several minutes before absolute accuracy is achieved. Here it took approximately seven to eight minutes to place the forceps properly before they were engaged and the rotation attempted. During this time, the fetal heart rate electrode, that had been on the scalp of the baby, had come off while applying the instruments, which is a common occurrence. Again, the baby had looked reassuring heading into the procedure and there was no overall concern as to its health. Therefore external monitoring was utilized. Two attempts to rotate the head clockwise were made between the every two-minute contractions. If unable to rotate in one direction, it will customarily go the other way, as there is an inherent fetal reflex to do so when prompted. However, given the time frame of the procedure and the relative difficulty in maintaining an accurate fetal heart rate tracing, I opted to abandon the rotation and deliver the baby in the straight occiput posterior position with the aid of conventional forceps. This was avoided initially so as to reduce the risk of trauma to the patient from delivering with the head in this position. The fetal head was brought to a crowning position and the forceps then removed. An episiotomy was performed and the patient delivered the head with the next contraction. With delivery of the head, I noted the tightest nuchal umbilical cord I had ever experienced in the several thousand deliveries either performed or attended. It had to be slipped over the body with completion of the delivery. Immediately upon delivery, the baby was pale and limp, which was totally unexpected. The neonatal intensive care unit team quickly administered resuscitative efforts to the baby, to no avail. For some unexplained reason, this baby went from healthy on the monitor to stillbirth. I was devastated to say the least. The patient was out of her mind and was wailing along with her husband and other family members in the room. While the patient anguished, I was squatting against the wall with my head in my hands from total disbelief. Not eager to repair the

episiotomy under such circumstances, I called upon the in-hospital attending and asked if he could perform this ten-minute procedure for me. He courteously and understandably obliged.

The scene eventually calmed and I began piecing together any and all information so as to provide an explanation to the family. Within an hour we knew the following. First, there was no apparent trauma to the baby from the delivery itself. Second, laboratory evidence and the resuscitative efforts revealed severe anemia with a loss of more than two thirds of this baby's blood, which is what proved fatal. Third, the placenta delivered immediately after the baby without any provocation and was without any evidence of hemorrhage or premature separation. Fourth, the baby's pH immediately at delivery was a normal 7.22, but within minutes of resuscitation, plummeted to 6.81 resulting directly from the lack of blood able to provide oxygenation.

The in-house attending that night is one of the hospital's high-risk obstetricians, Dr. Robert Silverman. He and the neonatologist did a cursory review of the case immediately following the delivery and discussed with me their certainty that the forceps or I had nothing to do with the outcome of this case. While this was comforting at the time, I wouldn't rest until I had every bit of scientific evidence to draw a complete conclusion. Within two days, I had received word from the medical examiner that the baby exhibited absolutely no trauma or evidence of internal bleeding to account for the massive loss of blood, which was the likely cause of death. An official autopsy report would otherwise take several weeks to complete.

The big question remained, 'where did the baby's blood go?' Every bit of pathologic and physiologic evidence pointed to one thing. There is a rare event that can occur with an extremely tight nuchal umbilical cord whereby the baby can literally pump its blood into the placenta with an inability for it to return to the baby. This is a direct result of the physiologic properties of the umbilical cord vessels themselves. The two umbilical arteries that bring blood from the baby to the placenta are muscular and therefore more resistant to compression, whereas, the single umbilical vein is flimsy and easily compressed. In this case, as the baby's head descended toward delivery, the umbilical cord was subjected to such compressive forces that the umbilical vein became so occluded that there could be no return to the baby of its own blood. This is such a rare event that up until then, I had not only ever seen a case of it, I and others, I posed, had never even heard of it. The official autopsy report, reached this same conclusion.

I was in constant communication with the patient and her family about the scientific findings as they developed. They harbored no ill will towards me despite the obvious outcome, because of the strength of our relationship and my absolute honesty about the situation. She remains my patient today and her mother has even made me her doctor.

The following is the substance of my complaint and I appreciate allowing me to provide the above lengthy history in support of my case. On September 25, 2001, I received a phone call at nine o'clock pm from Dr. Badawy telling me that he was immediately suspending my privileges to perform any and all operative vaginal deliveries, including vacuum assisted deliveries, because of this case. He stated that members of the department's quality improvement committee reviewed the case and he was taking this action. His account of the case from admission to delivery was terribly inaccurate and despite my objection and attempts to provide clarification on not only the facts but on the cause of death, he would have none of it and smugly maintained his position. I immediately began efforts to challenge this action through the hospital's bylaws. Such an action stood to cripple my practice of obstetrics. In addition, there was to be a six-month prospective review of every obstetrical admission I brought to the hospital, as well as some objective to 'properly' educate me on the use of forceps.

I was very upset, as there was no due process or due cause for this action. Not once did anyone from the QI committee or Dr. Badawy, himself, ever sit down with me and talk about this case, not even

to this day. It is his responsibility as Chairman to afford me this right, especially when levying such sanctions. He even had the nerve to speak about these rights shortly after this action, in one of the department meetings. Ironically, the subject of QI committee reviews just happened to come up. I therefore asked him to explain, to the department, the process by which such reviews are carried out, knowing what had already happened to me. He could not and would not provide any specifics as to the process when pressed to do so. However, he adamantly stated that he "always" sits down with the attending to discuss, in detail, any case or issue brought to him before rendering a judgment or opinion. I was flabbergasted, but then again, not surprised. There was no way he was going to talk to me about this case because he finally "had me." And he certainly wasn't going to be a gentleman and scholar in handling it.

I would soon find out the ramifications of his action beyond the mere inability to do a forceps delivery. Whenever a physician has any suspension or revocation of clinical privileges, it sets off a chain reaction of reportings that poses a potential threat to their career and reputation. Specifically, I was reported to the National Practitioner Data Bank, (NPDB), and the New York State Office of Professional Medical Conduct. Additionally, I have been forced to provide a written explanation to participating insurance carriers as well as any institution with whom I am affiliated. I have even been denied participation with one insurance carrier as a result. This has only compounded my resolve in seeing that these actions not go unchecked. I even received a call, a while back, from someone at the OPMC whereby I was not only willing to speak to any of the issues, I encouraged them to please look into the matter.

I was forced to retain the services of an attorney and began the long and arduous process of challenging this action through the hospital's Medical Executive Committee. This is the very committee that upheld Dr. Badawy's recommendations to take this action in their October 16, 2001 assembly. On this date, Dr. Badawy presented a written document of his case review whereby he not only misconstrues the facts, he in essence states that I killed this baby by using forceps in a completely inappropriate and unindicated manner. In addition, a second review document was submitted by Dr. Ronald Stahl. He is in private practice and is on the Ob QI committee. Within the past two years, he was appointed, by the department, to a newly created position of "Director of Low Risk Obstetrics." The only thing I know about this event is that it was a very political process fraught with much bad blood between parties seeking the position. His review is much the same as Dr. Badawy's, however, Dr. Stahl takes it upon himself to offer up further commentary that is not only clinically feeble, he goes one step further by daring to disparage the fact that another doctor repaired the episiotomy, citing my emotional instability in being able to handle a difficult and complicated case. An otherwise healthy baby had just died for no immediately apparent reason. I chose not to repair the patient's episiotomy, given the scene in that room. I was neither incapacitated nor incapable of this repair. This commentary was in such poor taste I couldn't believe it. Interestingly enough, this would not be the last I heard of this diatribe. In essence, these two documents, that were submitted to the hospital's Medical Executive Committee as official departmental reviews of this case seeking to levy sanctions against me, are not only an embarrassment to all that is clinical and scientific, they are an abomination. Nonetheless, when you have a committee of other department heads who, admittedly, know little about obstetrics, this relative ignorance, as I have found out, is easily exploited. They basically reiterated everything that was offered to them in upholding the recommendation for suspension. And as far as they knew, I was an incompetent and imminently dangerous physician.

Following the suspension, Dr. Badawy made absolutely no arrangement on how to deal with any obstetrical scenario I might find myself in where forceps or vacuum would be indicated for either an emergent delivery or to avoid a patient being forced into a cesarean section. Unfortunately, operative

vaginal deliveries are not something that is foreseeable and therefore any obstetrical situation could present a potential for their usage. And surely enough, one such situation presented itself within the first month. Rather than subjecting one of my patients to a major surgical procedure, I approached the on-call faculty member for that day and explained the situation and what I wanted to do. Here I am a board certified physician in my specialty that arguably has more experience doing these types of deliveries than anyone else in the department, having to essentially defend my case and seek supervision. If my attitude here seems coarse, it is directly the result of the position I had been put in with not only my patients but with the staff with whom I had worked so hard to establish the confidence and faith in my ability. My standing in the hospital was hurt very badly, because the majority of those who had heard of the case and the disciplinary action never had the luxury of knowing the true facts. I even had one of my obstetrical patients, at that time, confront me one day in the office on how I had killed a baby at the hospital with forceps. This is after a friend of hers, a nurse in the Neonatal Intensive Care Unit, told her what she had heard. I illuminated the facts, she was satisfied and she went on to have a successful pregnancy and delivery, ironically requiring forceps due to fetal distress.

The above faculty member agreed to stand in the back of the room to oversee the procedure and then write a note in the chart. He wasn't thrilled with having this put on him, and rightfully so. He stated that there had not been any briefing by the Chairman on how to deal with such issues. He observed, the baby was delivered without a mark, and the mother left unscathed. In fact, several more forceps scenarios presented themselves throughout the six-month period following the sanctions. Incredibly, three of them involved having to perform the specialized rotational procedure that I had been labeled a danger in doing. With each case, I had to solicit the approval of the on-call faculty member for that particular day. The only resistance was the fact that they were put in this position. There was absolutely no reservation that the job could and would get done. Each time they were asked and then denied that they had been given any directives on how to deal with this issue. Frustrated, one faculty member specifically approached Dr. Badawy for an answer. Nothing was ever done and I received no written communication as to how this was going to be handled. Since a functional mechanism to deal with the situation had essentially been created out of necessity, it stayed this way for the six months.

In March of 2002, the autopsy report was finally available and the conclusion, as stated previously, showed absolutely no trauma to this baby, especially to account for the stillbirth. The medical examiner's final assessment was an umbilical cord accident. This was the certified exculpatory evidence my attorney and I were waiting months for, so as to schedule a hearing to have my record cleared, specifically the NPDB reporting. Just prior to this report, when we knew it was about to be released, I met with Dr. Badawy in an effort to try and settle this matter man to man, based on nothing but facts and science. Not only was he unwilling to hear anything about it, the manner in which I was treated was nothing short of impudent.

In addition to requesting a hearing in front of the Medical Executive Committee, we immediately called for a voiding of the NPDB report in a effort to avoid creating a circus of the matter. We scheduled a meeting with the hospital's attorney and the new President of the Medical Staff, Dr. Mary Beth McCall. They stated that they didn't have the power to void the report, which was contradictory to the experience of my attorney, who has exquisite experience in this area of healthcare law. In addition, Dr. McCall had the audacity to state that if they voided the report, the hospital would have to answer to the State as to their actions in doing so. It was now clear that the hospital was trying to save face on something they absolutely knew was wrong, at the expense of my name and reputation. In addition, my attorney questioned them on why the NPDB report had continued, for nine months, to represent the fact that a complete suspension of privileges had been levied, (which was the original intention), when in reality they

knew it turned into a restriction with supervision as detailed above. They had no answer, but within one week, the NPDB report was magically amended to reflect this actuality. Interesting how they could change a reporting, which still was based on the recommendation of the Medical Executive Committee but somehow couldn't void it altogether. It was strictly a move on their part to offset their previously unrecognized liability on the issue.

Also in March of 2002, the six-month prospective review of all of my obstetrical admissions was presented as a report to the department. This was the creation of Dr. Richard Aubry, another faculty member under Dr. Badawy, and also on the Ob QI committee. He is a grand-fathered-in perinatologist that has been with the department for decades. My personal dealings with this man had been strained at best. One day in 2000, he actually called me at my office and essentially demanded that I consult him on a triplet pregnancy I had in the hospital with preterm labor. This was completely out of line and I politely let him know it. There was never a problem with this patient that warranted such an action. Now being in the position of scrutinizing my every admission, he certainly took advantage of it. Again, through him, this department produced an official document that not only lacks any modicum of clinical foundation; it proves once and for all that they categorically knew they were wrong by sanctioning me in the first place. He cites three **major** deficiencies in his report, fascinatingly, all dealing with rotational forceps deliveries. There were no criticisms of the deliveries themselves because they all went flawlessly. I was condemned for inappropriate indications for the use of forceps pertaining to these deliveries. This was absurd considering the clarity by which the medical record detailed the cases, especially at a time where I knew I was being watched. But even more amazing was the fact that, in order for me to have been able to do the procedure in the first place, it had to be approved and overseen by one of their own departmental faculty. And what was the action of the department upon receiving such a damning report of my activities with the exact type of delivery I was sanctioned for in the first place? Within a week, as the six months was now up, I got all of my privileges back to perform operative vaginal deliveries without a single restriction.

We were finally granted a hearing date in front of the Medical Executive Committee last month, August 2002. It was a little unorthodox to be conducting such an event almost a year from the inciting event and nearly six months after I had my privileges reinstated. My purpose was to clear my record and to expose the egregious actions of my department. The first of two sessions was on the 6<sup>th</sup>. Minutes prior to the hearing, my attorney detailed me on a potential settlement offer being put forth by the hospital's attorney. They could now magically void the NPDB report but there would remain a disciplinary action that would still require future disclosure, such that my record would continue to be marred. My attorney strongly advised me to consider it because from his experience, Medical Executive Committee proceedings are not held to the same standard as a court of law. He stated that regardless of how strong our case was, we would be asking them to overturn a fellow department head and themselves, for that matter. Believing in the spirit of truth and science, my principles in this affair would take absolute precedence, so I declined and headed into the boardroom.

The hearing was held in two separate sessions, sixteen days apart. What I witnessed and experienced at these proceedings is nothing short of disgusting. Dr. Badawy was the first witness. His evasiveness of the issues and obvious inability to answer the most basic clinical questions regarding this case even made me uncomfortable. Surely, it was just as evident to the others in the room. He was asked flat out whether or not my use of the forceps caused this baby's death. Knowing the truth of the matter, he answered, "no." When asked why his report to the MEC on October 16, 2001 essentially stated that I did, indeed, cause the death of this baby, I got my first glimpse of their dishonorable strategy. He responded by saying that my privileges were suspended because I was an imminent danger to patients for the following reasons. First, there was no indication for delivering this patient in the first place, second there

was no indication for the use of forceps and third, I was a danger because of my emotional instability. The latter being emphasized beyond any comprehendible measure of decency. He then went on to lie about how he handled the makeshift supervisory role of the faculty members during the sixth months of the suspension. He proceeded to confabulate in such a manner so as to avoid appearing ignorant and guilty of perpetrating a lie to the Medical Executive Committee itself. Unable to do a complete justice to his testimony, every word of it was documented by a stenographer.

The next person to testify against me was Dr. Aubry. Upon cross exam, his demeanor was quite hostile. Again, the crux of their argument was focused on issues having nothing to do with my ability to perform an operative vaginal delivery, which is what I was disciplined for in the first place. Their emphasis was that I had no indication to induce the patient and that I was again a danger to patients because a colleague repaired the episiotomy. However, when Dr. Aubry was asked flat out whether the forceps caused the death of this baby, he answered, "yes." Taken back by this and knowing the exact science of what really happened, I asked him to please provide a physiologic explanation of how this could be, in the face of a completely contradictory autopsy report, medical record and testimony from Dr. Badawy himself. This man proceeded to put forth the most counterfeit explication I have ever heard. And he knew it. The distressing thing was, those who wanted to believe him, did. It sounded clinical. So, for all they knew, it was valid. In truth, he manipulated several obstetrical facts to create uncertainty in the minds of the committee in regards to my case. I was up against a senior attending who was cleverly being deceitful to his fellow physicians. Sadly, I was the only one in the room who knew what he was doing.

I then asked him to tell the MEC about another delivery in the department that involved one of the faculty members, within that same year. It was a case where this doctor used forceps on a baby and directly caused a fractured skull. In fact, she had been at the center of several bad outcomes over the past few years that had prompted the obligatory departmental inquiries. Following this fractured skull, I was told a huge departmental investigation ensued, only for there to be no action taken. No limitation or suspension of any privileges was imposed. Despite being on the committee that handled such investigations, he testified that he "didn't recall the case." Again, the full extent of his testimony was recorded, word for word.

Following this utmost display of integrity, Dr. Silverman was next to berate my character. He is the director of the Regional Perinatal Center who has never bothered to become board certified in his subspecialty, despite the obvious loss of academic credibility to this department and residency program. Also a member of the QI committee, he sung the same tune as the others. Again, he was the doctor who sympathetically patted me on the back and said he would gladly do the episiotomy repair, amidst the horrific scene that evening. He also concluded that night, as detailed in the case presentation, I had nothing to do with the outcome of this delivery. When asked about this conversation, he suddenly could not recall it. Having lost all respect for this man and somewhat unclear as to why he was now taking this position, I quickly moved onto the witness I had most been waiting for, Dr. Ronald Stahl.

Dr. Stahl's review of the case was the main focus of my questioning. In addition to the facts of the case being inaccurately detailed, his conclusions displayed an unspeakable lack of clinical acumen. Remember, this man is the so-called "Director of Low Risk Obstetrics" at this hospital. Among his conclusions, as with the others, he continuously maintained that the standard of care had not been met with the use of forceps without first letting the patient push. While this sounded legitimate to those in the room, ACOG's guidelines gave me every right to have proceeded in the manner that I did in this case. Please refer to the clinical indications detailed above. There is no absolute rule or law in obstetrics that states an obstetrician *must* allow pushing in order to perform a forceps delivery, especially in the face of a maternal or fetal indication which was the case here.

Dr. Stahl was unable to legitimately justify why no one had ever talked to me about this case. This is despite his own admission that he was unclear on several points of the case, including the indication for the forceps as well as the exact mechanism of how the forceps were used and the timing of their usage. He also continued to maintain the department's incredibly fraudulent stance that I had no indication for inducing this patient in the first place. As stated above, this patient was clearly in early labor at the time she was transferred to labor and delivery, as detailed all throughout the medical record by not only me, but by the nursing and resident staff. I pressed him very hard on this subject, which left him dumbfounded and unable to maintain continued justification of this position. He even condemned the fact that the patient's use of Tylenol with codeine was excessive, completely discounting the fact that she was in so much pain from uterine contractions so as to require it in the first place. He chose to take this shameful position despite there being a legitimate order on the chart that is consistent with the standard of care in regards to the use of this medication. When asked to explain his use of the term "excessive", he could not even point out how many doses and overall pills she received. In fact, she only received 16 out of a possible 36 pills during the time of her admission before being transferred to the delivery unit. Further, his analysis of the baby's anemia and pH findings is so weak, it clearly illustrates his incomplete understanding of the case. And he is also the one who made a written point of criticizing my emotions of that evening by citing "significant concerns regarding Dr. Caputo's ability to handle stress." I've already been clear on this admonition. His transcribed testimony would provide all that is needed to reveal the exact points of my objection here.

In addition, the department sought the expert opinion of an independent reviewer from the University of Rochester, named Dr. James Woods, Jr. While Dr. Woods is extremely critical of this case, especially me, I have a great deal of respect for how he approached his review. It is clear that he is a man of science and truth. However, not only is his review based on inaccurate data, he is the first to admit that he could not answer many questions given the information provided to him. I desperately wanted to talk to him at the hearing so that he himself could see the veracity of what really happened. Unfortunately, he was not available for any of the dates selected and short of holding a third session so that he could be questioned, I elected to forgo this opportunity in, not only, the interest of time but more importantly the blatant facts of this case.

It was now my turn to present my case. My only witness was Dr. Richard Waldman. Dr. Waldman is a board certified Obstetrician/Gynecologist in the Syracuse area. What qualified him as an expert is the fact that for years, he served on a special committee, commissioned by the American College of Ob/Gyn itself, in the area of case reviews. He was a member of a team of doctors that traveled throughout the country evaluating an array of cases in both obstetrics and gynecology. When asked to speak to this case, his conclusions were very clear and he didn't hesitate to express his viewpoint. He also submitted a written review of this case where it is evident he gives respect to facts and science. He testified by denouncing the department's assertion that this patient was induced when she was, no doubt, in early labor. In addition, he was very disapproving of the criticism founded on the episiotomy issue. He poignantly described a personal experience of his that put the emotions of my case totally in perspective. He was also quick to point out that despite the department's rhetoric on the induction issue, this is not why I had my clinical privileges suspended. While he personally doesn't use forceps and finds my utilization somewhat bold, it plainly doesn't rise to the level of such actions by the department. I was actually flattered to hear him say that my ability with the forceps is what enabled this baby to be delivered as expeditiously as it was. As to the ridiculous theory put forth by Dr. Aubry on how the forceps directly killed this baby, he referred to it as utter nonsense. Clearly I view his testimony with bias towards my case, however I admire him for his professionalism and deliberate manner in dealing with the actuality of what really happened.

Finally, I had the opportunity to present the correct case to the MEC. With greater detail, I gave essentially the same account as described in the paragraphs above. In addition, I provided a diagram of how this baby physiologically bled to death, into its own placenta, as it descended in the pelvis because of the increasingly tight nuchal umbilical cord. I tied together the autopsy report, the medical record, every laboratory study, and the pathology on the placenta to prove my case beyond a doubt. I also pointed out some of my history with my detractors as well as my clinical history within the hospital along with who I was as a person. I knew that some on the MEC had been put off by my approach to the witnesses and I addressed this with them. Knowing how angry I must have appeared to them, I asked them not to necessarily like me but to put themselves in my position so as to understand my reproach. I welcomed all questions and criticisms from the members in attendance. I wanted them to scrutinize me in much the way I wanted them to scrutinize not only those that did this to me but the process as well. Despite more than one of them commenting to me afterwards on the good job I did, two weeks later I learned that they completely upheld their original ruling, siding with everything put forth by the department. I should have known.

Perhaps by reaching this ruling, they felt it would put this issue to rest, once and for all. I am certain one of the prevailing arguments, as previously eluded to by Dr. McCall, was to the liability that would be created if any changes were made to the original decision. Again, I refuse to have my record forever stained because of dishonest behavior on the part of professionals appointed to uphold the integrity by which such institutions and proceeding are supposed to conduct themselves. How could this department justify what it did to me without so much as a shred of evidence and not act on another that directly caused a fractured skull of a baby? And why was it that after my case, a special session of the QI committee was purposely called to review it? And if QI committee reviews are supposed to be anonymous, then why did everyone during this 'special session' know it was my case? I am a firm believer of case reviews for the maintenance of quality and competency within any healthcare institution. There must, however, be some level of due process, due cause and at least an infinitesimal degree of integrity.

Believe it or not, I like practicing at Crouse Hospital very much for many reasons and maintain a level of popularity with those I interact on a regular basis. Those who know me appreciate what I stand for and that's quality in everything I do. I am, however, ashamed to be affiliated with the leadership of the Ob/Gyn department for obvious reasons. My entire family has been put through a lot because of this case and the resultant conduct of Dr's Badawy, Aubry, Silverman and Stahl. My mother, a nurse for more than forty years, has taken it very hard. While on one level she wishes I just let them win and move on, she understands the purpose for why I cannot. I hope this lengthy account has convinced you as well. I have not only myself to face but also my four children. How can I teach them the virtues of right and wrong without validating these things myself? This may come across as a bit self-righteous, but that is how I was raised and will continue to be until I am dead and buried.

Therefore, I plead with you to investigate this case and the actions of this hospital, specifically the Department of Ob/Gyn and the four individuals named herein. The following are the specific areas of inquiry that beg to be revealed. What is the process by which departmental reviews are conducted? Why wasn't I ever involved? What is the history of case reviews and disciplinary action within this department? What factual basis was there in the first place for such sanctions against my practice and record? How consistent is this action with other outcomes within this department? What level of integrity was maintained during the testimony of all that participated in the MEC hearing? How could the hospital summarily change the NPDB report without the recommendation of the MEC, while they concomitantly asserted they could not void it because of any existent mechanism? How could the MEC uphold their decision in the face of overwhelming evidence and testimony to the contrary?

I would also encourage just as much of your analysis to be directed towards me, including all of my cases, if needed. For fear of sounding scandalous, this department apparently has a history of unscrupulous behavior, such that many quality physicians have left for other area hospitals, unwilling to put up with it. I, hereby, stand firm in confronting such deeds, which is what I contend is the motivation for the extent of their actions. While Crouse Hospital, itself, remains financially bankrupt, perhaps this case can bring about enough enlightenment of these critical issues such that it doesn't become morally bankrupt as well. Thank you for the time and patience required to not only read this complaint but to absorb it. I very much look forward to a response.

Very truly yours,

James R. Caputo, M.D.

Exhibit B2

433 River Street, Suite 303

Troy, New York 12180-2299

Antonia C. Novello, M.D., M.P.H., Dr. P.H. Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

October 1, 2002

James Richard Caputo, M.D. 739 Irving Avenue, Suite 300 Syracuse, NY 13210

**RE:** Physicians @ Crouse Hospital OPMC # 02-09-4875

Dear Dr. Caputo:

The Office of Professional Medical Conduct has received your September 17, 2002 correspondence. This office is responsible for investigating allegations of medical misconduct by physicians and physician assistants.

This matter has been forwarded to our Syracuse Area office for investigation at the address below. For any questions regarding this investigation, please contact that office at:

NYS Department of Health

Office of Professional Medical Conduct

Central Field Area Office

APTN: Pauline Frazier

677 South Salina Street

Syracuse, New York 13202-3592

Program Director

(315) 426-7697

Thank you for bringing this matter to our attention.

On Hoerkens
Chares dush T. P. Frazi

Sincerely,

IM Carey

Office of Professional Medical Conduct

Jane Durr Howard Levine

## SMITH, SOVIK, KENDRICK & SUGNET, P.C.

Exhibit B3

JOHN TIMOTHY SMITH (1902-1964) NELSON J. SMITH (1923-1967) MARTIN F. KENDRICK (1917-1983) LAURENCE SOVIK (1904-1998)

WILLIAM E. SUGNET, RETIRED JAMES A. O'SHEA, RETIRED

LAURENCE F. SOVIK
JAMES D. LANTIER
MICHAEL P. RINGWOOD
KEVIN E. HULSLANDER
ERIC G. JOHNSON
STEVEN WARD WILLIAMS
MARY KENDRICK-GAFFNEY
JAMES W. CUNNINGHAM
ROBERT P. CAHALAN
GABRIELLE MARDANY HOPE
KRISTIN L. NORFLEET
PATRICK B. SARDINO
KRISTEN M. BENSON
JENNIFER L. PLOETZ
J. WILLIAM SAVAGE
DAVID A. D'AGOSTINO
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MICHAEL PAUL RINGWOOD Voice Mail Extension 121 mringwood@smithsovik.com

August 9, 2004

J. M. Carey Office Of Professional Medical Conduct 433 River Street, Suite 303 Troy, NY 12160-2299

Re: OPMC #02-09-4875

Dear Mr. Carey:

I am representing Dr. James Richard Caputo to the extent that he is the subject of investigation through your offices regarding a number of patients he cared for within the context of his OB/GYN practice.

During the course of interviews related to those investigations, Dr. Caputo wrote your offices on or about September 17, 2002 with complaints of his own regarding Crouse Irving Memorial Hospital, its OB/GYN residency training program, and other activity of that institution impacting on his practice.

You wrote back to Dr. Caputo by letter dated October 1, 2002 and apparently an OPMC claim number was assigned to his complaint as described above. Dr. Caputo has become somewhat frustrated by way of the fact that he has heard little if nothing regarding the complaint he made and the investigation that he asked be conducted. To that extent he asked me to inquire. I do so via this letter.

Would you please be so kind as to review the file regarding the claim number referred to above and to write both myself and Dr. Caputo regarding the status of the investigation regarding the same.

Very truly yours,

Michael Paul Ringwood

MPR/csw

cc: James R. Caputo, M.D.





## Exhibit B4

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D. Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

September 15, 2010

James Caputo, MD 1200 East Genesee Street Suite 201 Syracuse NY 13210

Dear Dr. Caputo:

I am writing in response to your recent correspondence to Governor David A. Paterson, which was forwarded to the Office of Health Systems Management for a response. In your letter, you expressed your dissatisfaction with the results of the investigation against you by the Office of Professional Medical Conduct (OPMC).

As you are aware, New York State Public Health Law § 230 delineates the roles, responsibilities and procedures that must be followed by OPMC when investigating and adjudicating allegations of medical misconduct. When reviewing allegations of medical misconduct, OPMC relies not only on the opinions of investigators, nurses and supervisors, but also on the medical expertise of board-certified physicians in the same specialty as that of the subject physician. Therefore, the investigations are thorough and carried out consistent with statutory requirements.

If you would like to file a complaint against the OPMC you may send the information directly to the New York State Office of the Inspector General (OIG) at the address provided below. The OIG would more appropriately address the issue(s) you have raised regarding the OPMC.

State Inspector General Empire State Plaza Agency Building 2, 16th Floor Albany, NY 12223

Thank you for bringing this matter to my attention. If you need further assistance, please don't hesitate to contact me, at (518) 474-7028.

Sincerely,

Richard M. Cook

Deputy Commissioner

Office of Health Systems Management

## NEW YORK STATE DEPARTMENT OF HEALTH STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

Exhibit C

IN THE MATTER

OF

JAMES R. CAPUTO, M.D.

5.

PETITIONER'S RESPONSE TO RESPONDENT'S DISCLOSURE DEMANDS

Petitioner makes the following response to Respondent's Disclosure Demands:

- 1. <u>McBarnett v. Sobol</u> (190AD2d 229) provides for disclosure of written complaints in those circumstances in which the complaining witness testifies in the disciplinary proceeding. If a complaining witness testifies in this matter for Petitioner, his or her statements or complaints will be provided.
- 2, 3 Petitioner has previously provided Respondent with the disclosure requested. &4.
  - Petitioner believes that Respondent is already in possession of the written opinion and testimony of Richard Waldman, M.D. before the Medical Staff Executive Committee of Crouse Hospital. Dr. Waldman appeared before the Medical Staff Executive Committee on behalf of Respondent regarding the care of Patient A at the time of her 2001 pregnancy.
- 6. Petitioner's expert will take the same oath as every other witness in these proceedings prior to testifying. No additional oath or deposition is authorized by statute or regulation.

Root Cause Analysis		Action Plan
What happened?	Occurrence Date: 12/7/05 Wednesday 11:30AM	
Sentinel Event (Adverse Occurrence)  What are the details of the event? (Brief description) Include date, day of week, time and the area/service involved	Date: 10/21/2005 - 33 year old 350 lb African American female seen in Prompt Care with possible pregnancy and swollen foot. Serum test was performed in Prompt Care which was positive. Estimating from her last menstrual period, she was estimated to be 19.5 weeks gestation. Her other diagnosis was lower extremity edema. She was discharged to home with understanding the need to follow up with her OB-GYN.  Date: 11/23/2005 – Patient admitted for suction D&C for suspected missed abortion at 8-10 weeks. Findings from the surgery showed a uterus of 10 weeks in size that was retroverted with a moderate amount of products of conception. During the procedure, three passes of the curettes were done and then a sharp curettage was performed until gritty texture was noted. The suction was then placed to remove the uterus of the remaining products of conception. Products sent to lab.  Date: 11/28/05 - Surgical Pathology Report Diagnosis – "Products of Conception – mostly inspissated mucus, associated with small fragments of secretory endometrium and decidualized stroma; no chorionic villi identified"  Date: 12/7/05 – Patient was seen in MD office for increased abdominal pain. There was concern that the Methotrexate and D&C that she had undergone in November was ineffective and that she most likely had an ectopic. She was sent to the hospital for further evaluation. The patient was sent emergently for a pelvic sono which showed a 38.5 weeks full term pregnancy with a fetal heart rate of 140 beats per minute. She was immediately sent to labor and delivery.  Patient delivered a 7 lbs 15 oz infant with APGARS of 9/9. According to MD addendum, a full discussion occurred with patient regarding the circumstances leading to this event. The patient was on birth control pills until she ran out. She had intermittent bleeding every 4-6 weeks until this stopped around Aug 2005. She had no symptoms of pregnancy until a positive HCG in Oct 2005. Sono in the office by transvaginal probe did not show any indication of pregnancy. The patient's	Exhibit D

Why did it happen?	Aspects for Analysis		Risk Reduction	Measures of Effectiveness	
What were the proximate causes? (special cause variation)			Strategies		
What systems and processes underlie those proximate factors? (common cause variation)					
			Implemented		
			YES DATE		_
Policy or Process (System) in which the event occurred	The system in place related to the event is effective	X			
	The system in place related to the event was carried out as intended	X			
	An effective policy is in writing	X			-
	The policy was effectively communicated	X			-
	An effective procedure is in place	X			-
Human Resources Factors & Issues	Staff are properly qualified	X			
	Staff are currently assessed as competent to carry out their responsibilities	X			
	Staffing level plans were in place	X			
	Staffing level plans were appropriate	X			
	Staffing level plans were implemented	X			-

	Staff performance in the relevant processes is evaluated	X					
	Orientation & in-service training are in place	X					
	Human error did not contributed to the outcome	X					
Environment of Care Including equipment & other related factors	The physical environment was appropriate for the processes/treatments being carried out	X					
	A system is in place to identify environmental risk	X					
	Emergency and failure mode responses have been planned	X					
	Emergency and failure mode responses have been tested	X					
Environment of Care (continued)	Controllable equipment factors did not contribute		X	There is not a level of confidence of sonography equipment in the office setting for	Imme diately		Effective immediately, all patients >300 lbs will be sent
(community)	to the event			bariatric patients. Effective immediately, all patients >300 lbs will be sent to a radiological suite for evaluation.	diatery		to a radiological suite for evaluation.
(continued)		X		bariatric patients. Effective immediately, all patients >300 lbs will be sent to a radiological	ulatery		to a radiological suite for
(community)	Controllable environmental factors did not contribute	X		bariatric patients. Effective immediately, all patients >300 lbs will be sent to a radiological	diately		to a radiological suite for
	Controllable environmental factors did not contribute to the event  Uncontrollable external factors (natural disasters, power outages, etc. ) were not a factor in this case  An emergency preparedness plan is in place	X		bariatric patients. Effective immediately, all patients >300 lbs will be sent to a radiological	diately		to a radiological suite for
Information Management & Communication issues	Controllable environmental factors did not contribute to the event  Uncontrollable external factors (natural disasters, power outages, etc. ) were not a factor in this case  An emergency preparedness plan is in	X		bariatric patients. Effective immediately, all patients >300 lbs will be sent to a radiological	diately		to a radiological suite for

	Necessary information was complete	X					
	Necessary information was clear and unambiguous	X					
	Communication among participants was effective	X					
	No barriers to communication were identified	X					
Standard of Care -If no and linked to an individual practitioner, list name and license #	The quality of care and services met generally accepted community standards	X					
Leadership: Corporate culture	Leadership is involved in the evaluation of adverse patient occurrences	X					
Other	Note other factors that influenced or contributed to this outcome	X					
	Note other areas of service impacted	X					

**Results of literature review: (include key citations)** 

**1. Introduction** - All pregnant women in our technology-happy modern society face confusing choices about prenatal testing, its advantages and disadvantages, and its appropriateness for them. Large pregnant women face even more confusion, since prenatal testing can be slightly harder in this population, and the results can be more confusing. However, since they may be at a somewhat increased risk for problems like neural tube defects, they also face greater pressure than others to have these prenatal tests, even though the tests are often difficult to interpret.

#### **Transvaginal Ultrasound**

Vaginal ultrasound is used for very early pregnancy, and sometimes for heavier women with more abdominal fat. This type is done trans-vaginally, using a long 'wand' (transducer) that is covered with a condom (!), lubricated, and placed inside the vagina. A male technician may ask you to insert it yourself (a female attendant should also be present in these cases, or you can request ahead of time to have a female technician instead).

The 'wand' is then moved around your vagina to allow the technician to 'see' up into the uterus and abdomen as needed. Occasionally it needs to be pressed up on either side of your cervix firmly to 'see' the ovaries clearly, which can be a bit uncomfortable for some women, but the discomfort is usually tolerable. Some moms have likened a transvaginal ultrasound to 'having someone driving a stick shift inside.' That's a crude but accurate

description. Having a sense of humor about it makes it easier. However, women who have sexual abuse background may want to request a female technician instead or avoid having an early ultrasound altogether, depending on their comfort level.

Generally speaking, the trans-vaginal ultrasound is used in the first trimester, since the uterus has not yet grown big enough to lift out of the pelvic cavity. It is very useful in getting a clearer picture to determine whether there is an ectopic pregnancy, whether the fetus is viable, if there are multiple fetuses, etc. It is especially useful in heavyset women and women with retrograde uteri.

Because the transducer is right up by the cervix and thus right next to the baby, the ultrasound waves do not have to go through the abdomen before reaching the baby, and the picture is often clearer than with an abdominal ultrasound at this point. However, it also means the transducer is much closer to the baby than with an abdominal ultrasound, and critics worry about the safety of this.

The closeness of the trans-vaginal transducer (and its ability to use somewhat higher frequencies) is a particular advantage in the case of very heavy women with extensive abdominal adiposity.... Thus transvaginal ultrasounds are especially common in women of size early in pregnancy. However, it is also not unusual for women of all sizes (not just heavy women) to have difficulty getting a clear abdominal ultrasound early in pregnancy, so big moms should not feel like they are the only ones having a vaginal ultrasound. When ultrasounds are done in very early pregnancy, they are usually done transvaginally. It is only a little later that there is a difference in ultrasound method due to size and this does not last for long.

#### **Concerns of Larger Women**

#### "They Won't Be Able to See Everything"

Will they be able to see everything? It <u>is</u> harder to do an ultrasound on a big person, and the bigger the tummy, the more difficult it can be to see everything they want. However, other factors are can be more important than the size of the mother. These can include:

- The skill of the technician
- The position of the baby, and perhaps of the placenta too
- The power and quality of the machine
- The gestational age of the baby

Don't assume that any problem *must* be because of your fat. Often the baby is not in the best position for optimal viewing, the u/s tech is not very skilled, or the machine is not powerful enough to get good resolution of what they are looking for. Fat *can* make it harder to get the best view, but there are certainly many other factors that are just as important.

• • •

#### **Ultrasound Summary**

Often ultrasound machines in the doctor's office are less powerful and the ultrasound techs less trained than those found in a business that *specializes* in ultrasounds. Techs in ultrasound centers may also be more experienced with doing ultrasounds on women of size, and more adept at different techniques that can be used to help "visualize" things better if there are any difficulties because of size. So, if you have a choice, you may want to choose an ultrasound at a practice that specializes in ultrasounds and prenatal testing.

**Source 1:** KMom, Large Women and Prenatal Testing; Ultrasounds in Women of Size; 1996 – 2003, last updated March 2003

#### 2. Maternal obesity: a potential source of error in sonographic prenatal diagnosis.

#### Wolfe HM, Sokol RJ, Martier SM, Zador IE.

Department of Obstetrics and Gynecology, Hutzel Hospital, Wayne State University, Detroit, Michigan.

Sonograms from 1622 consecutively scanned singleton pregnancies at a mean gestational age of 28.5 weeks were analyzed to determine whether maternal obesity affected visualization of fetal anatomy. Fetal head (cerebral ventricles), heart (four-chamber view), stomach, kidneys, bladder, diaphragm, intestines, spinal column, extremities, and umbilical cord were classified as visualized or suboptimally visualized. Maternal body mass index was used as a measure of relative leanness. No significant impairment of ultrasound visualization was noted until a body mass index above the 90th percentile, when visualization fell by an average of 14.5%. Reduction in visualization was most marked for the fetal heart, umbilical cord, and spine. Among non-obese women, advancing gestation and decreasing body mass index were the most important determinants of visualization. However, among obese women, body mass index was the best predictor of visualization, with no improvement seen with advancing gestation or duration of examination.

**Source 2:** Wolfe HM, Sokol RJ, Martier SM, Zador IE; . <u>Maternal obesity: a potential source of error in sonographic prenatal diagnosis.</u>; Obstet and Gynecol, 1990 Sep; 76(3 Pt 1): 339-42

#### 3. Pill 'fails more in obese women'

Women who are overweight or obese have a much higher chance of becoming pregnant because their Pill has failed, researchers have found.

Overweight women were 60% more likely to fall pregnant while on the Pill.

Obese women were 70% more likely, found a study in Obstetrics and Gynaecology by a team from the Fred Hutchinson Cancer Research Centre in Seattle.

It suggested that of 100 women on the Pill, an extra two to four would fall pregnant due to being overweight.

The Pill is usually estimated to be over 99% effective. This means that less than one woman in 100 will get pregnant in a year.

However, that figure relates to perfect Pill use. Actual failure rates are estimated to run at around 6%.

Researchers compared the weight and body-mass index (BMI) of 248 women who became pregnant while on the Pill, and compared them to a group of 533 women of the same age who were taking oral contraceptives but who were not pregnant.

BMI is calculated by dividing your weight in kilograms by the square of your height in metres.

A BMI of over 25 is considered overweight and one of 30 or above is considered obese.

It was found that the link between carrying extra weight and contraceptive pill failure became evident in women whose BMI was 27.3 or higher - equivalent to a 5ft, 4in woman who weighs 160lbs (11st 6lb, or 72.5kg) or more.

# 66 This higher risk of pregnancy also translates into a higher number of obesity-related complications of pregnancy

Dr Victoria Holt, Researcher

#### **Complications**

The researchers say their study did not look at why this link should exist.

But they suggest a higher metabolism, linked to extra weight, could be a factor, because it can shorten the duration of a medication's effectiveness, or that hormone levels in the Pill may not be high enough for larger women.

In addition, they said the more overweight or obese a woman is, the more liver enzymes they have to clear medications from the body, causing a drop in the amount of a drug circulating in the blood.

The researchers say another explanation could be linked to the fact that the active ingredients in oral contraceptives, oestrogen and progesterone, are stored in body fat - so the more likely the drug is to become trapped in the fat instead of circulating in the bloodstream.

#### 'Health hazard'

Dr Victoria Holt, who led the study, said: "These results represent yet another reason why obesity is a health hazard.

"Overweight and obese women have a significantly higher risk of getting pregnant while on the Pill than women of normal weight, and this translates into a substantial number of unplanned pregnancies."

She added: "This higher risk of pregnancy also translates into a higher number of obesity-related complications of pregnancy, which range from gestational diabetes and high blood pressure to Caesarean delivery."

Dr Holt said women who are overweight should not ask for a higher dose Pill, because they were already at a higher risk of cardiovascular disease which contraceptive hormones increase even more.

She suggested women who had completed their families should consider a permanent form of birth control such as sterilisation, and those who still wanted to have a family considered using a back-up form of birth control, such as a condom, as well as the Pill.

She added: "I think losing weight, if one is substantially overweight, is a terrific idea for many health reasons and a laudable goal."

But she said "I also acknowledge that it is often difficult to do."

Geoffrey Chamberlain, professor of obstetrics and gynaecology at the University of Wales College of Medicine, said: "The Pill is not so effective in overweight women. The hormones get absorbed into the fat, so the blood concentration and the effect on the ovaries is lower.

"Therefore, it may be advisable for women who are overweight to use other methods of contraception such as barrier methods or an intrauterine device."

- 3. Source: BBC News/Health/Pill 'fails more in obese women'; http://news.bbc.co.uk/2/hi/health/4123433.stm
- 4. Limited by Body Habitus: Economic and Quality Control Issues in the Ability of a Radiology Department to Provide Diagnostic Imaging to a Fattening Population

# **Purpose**

Obesity is a growing medical problem which can influence the ability of radiology department to provide optimum image quality and accurate diagnosis. This paper will address the economic and quality care impact of obesity on the ability of radiology departments to provide quality diagnostic imaging.

Method and Materials

A fourteen year retrospective review of dictated radiology reports with the disclaimer "limited due to body habitus" between the years 1989-2003 was performed from the electronic medical records. Percentages of "limited" radiographic studies were calculated per year. "Limited studies" were also classified based on modality and percentages per modality per year were calculated. Comparisons were made of the calculated percentages between modalities within a year and within each modality across the 5 years. Economic impact was assessed by calculating the cost estimates for the limited studies on a per modality basis, per year. Quality control issues were accessed by examining what technical factors and patient factors resulted in the limitation for each modality.

#### Results

Overall, 0.15% of all studies were limited by body habitus. For all studies from 1989 through 2003, there has been an increase at a rate of 0.010% (95% CI 0.007 – 0.013%) per year (p<.0001). The study most dictated as "limited" is the abdominal ultrasound, followed by the chest radiograph. 1.5% of ultrasounds were reported limited by body habitus. The rate of US cases limited by body habitus for 1989 through 2003 increased at a rate of 0.090% (95% CI 0.045 – 0.134) per year (P<.001). 0.08% CXR were reported as limited with an increase at a rate of 0.007% (95% CI 0.0008-0.013) per year (P<.05). Although the direct economic impact of the "limited studies" is small, the steady rise over 14 years and the additional diagnostic tests and increased hospital stay to make up for the "limited study", also has an economic impact. A review of quality control shows technical factors available for each modality to improve image quality in obese patients.

#### Conclusions

Changes in the American body habitus over 14 years has increasingly affected the ability of radiology departments to provide quality images and accurate image interpretations.

4. Source: http://rsna2004.rsna.org/rsna2004/V2004; Scientific Papers section of the Conference

#### 5. Bleeding During Pregnancy

<u>Pregnancy</u> is a joyful time, but it can also be a time filled with worry and concern for many women. Noticing spotting during pregnancy can set off alarm bells for many pregnant women. Is it a sign of problems? Is it your period, which many women swear they continue to get all through their pregnancy? Or is it something completely different? Bleeding during pregnancy can be cause for concern but it can also be normal. So how do you know when to call your <u>health care provider</u>?

#### **Periods During Pregnancy**

Many women notice bleeding or spotting throughout their pregnancy, particularly during their first trimester. This is a fairly common occurrence, with about 10% of all women experiencing some type of light bleeding during pregnancy. This bleeding, though, is not the same as getting your period.

During pregnancy, your body is focused on nurturing your <u>baby</u> so your brain sends signals to your uterus not to menstruate. Most of the time, light bleeding during pregnancy is normal and doesn't present a danger to you or your baby. However, there are some risks associated with bleeding, especially in later stages of pregnancy. If you are pregnant, it is important to be aware of the factors that can cause bleeding, and the symptoms to watch out for.

# **Bleeding During Early Pregnancy**

Bleeding during early pregnancy is fairly common, with about 1 in 4 women experiencing symptoms during their <u>first trimester</u>. If you are early in your pregnancy and have noticed some vaginal bleeding, you may think you have gotten your period. This blood is not your period, but, in fact, is due to some other cause.

Some women will notice light bleeding about 10 to 14 days after fertilization. This is called <u>implantation bleeding</u>, and is caused by the egg implanting itself in your uterus. As the egg finds a home for itself in your uterus, it may disrupt the lining just a little bit, causing light bleeding. This bleeding should only last a couple of days and be fairly light. Implantation bleeding is nothing to worry about, but if it gets heavy at any time, or continues longer than a couple of days, see a doctor.

#### **Should You Worry?**

During early pregnancy, your cervix changes in order to accommodate your new baby. Your body will provide increased blood flow to your cervix, and sometimes this can result in light bleeding. If your cervix is inflamed slightly during intercourse or a pelvic exam, spotting or bleeding may occur. Again, this is normal and does not necessarily mean that your baby is in any trouble. If your bleeding is abnormally heavy or lingers for more than a few days, visit with your doctor to determine the cause.

Bleeding in the first trimester can sometimes be a signal that there is a problem with your baby. 15% to 20% of pregnancies end in <u>miscarriages</u>. Miscarriages most commonly occur within the first 12 weeks of pregnancy. Bleeding or spotting could be symptoms of a miscarriage, especially if they are associated with cramping, fever, or chills. If you think you are having a miscarriage, or are unsure why you are bleeding, contact your doctor or midwife. Your <u>health care</u> provider will be able to perform a pelvic exam to determine your baby's situation.

Sometimes bleeding during early pregnancy can signal a more serious problem with your baby. <u>Ectopic pregnancies</u> occur in 1 out of every 60 pregnancies, and can be life-threatening to both mom and baby. Serious internal bleeding can occur with ectopic pregnancies, so if you are experiencing heavy bleeding go to the hospital.

## **Bleeding During Late Pregnancy**

Bleeding can also occur during your <u>second trimester</u> and <u>third trimester</u>. Again, this bleeding is not your period, but is a result of other causes.

Bleeding may be a sign of early or preterm labor. If accompanied by contractions or cramps, go to your doctor to find out what's going on. Miscarriage, or stillbirth, is still a possibility at the later stages of pregnancy, however it is less likely. If you are bleeding a lot, see your health care provider or go to the hospital just to be sure. More often, bleeding in the second and third trimesters is caused by an infection in your cervix.

<u>Yeast infections</u> and some <u>sexually transmitted diseases</u> can inflame the cervix causing light spotting or bleeding. Your health care provider can perform a simple exam to determine the cause of infection. If you are experiencing bleeding during the later stages of pregnancy, try not to worry and remain calm. It is important to visit with your doctor or midwife to have a checkup and get to the bottom of any problems. Most bleeding can be solved without any harm to you or your baby.

- 5. Source: http://www.epigee.org/pregnancy/bleeding.html
- **6. Background:** Missed abortion refers to the clinical situation in which an intrauterine pregnancy is present but is no longer developing normally. This can manifest as an anembryonic gestation (empty sac or blighted ovum) or with fetal demise prior to 20 weeks' gestation. The gestation is termed a missed abortion only if the diagnosis of incomplete abortion or inevitable abortion is excluded (ie, the cervical os is closed). Before

widespread use of ultrasonography, the term missed abortion was applied to pregnancies with no uterine growth over a prolonged period of time, typically 6 weeks. Some authorities think that more specific descriptive terms should be used; however, the term missed abortion is still widely used among clinicians and is a commonly used indexing term for MEDLINE and other resources.

**Pathophysiology:** Causes of missed abortion are generally the same as those causing spontaneous abortion or early pregnancy failure. Causes include anembryonic gestation (blighted ovum), fetal chromosomal abnormalities, maternal disease, embryonic anomalies, placental abnormalities, and uterine anomalies. Virtually all spontaneous abortions are preceded by missed abortion. A rare exception is expulsion of a normal pregnancy because of a uterine abnormality.

# Frequency:

• In the US: Frequency closely correlates with frequency of failed pregnancy in general. In clinically recognized pregnancies, spontaneous abortion occurs in up to 15% of cases. The rate is much higher for preclinical pregnancies. Diagnosis is made much more frequently because of increased use of early ultrasonography.

# **Mortality/Morbidity:**

- Associated morbidity is similar to that associated with spontaneous abortion and includes bleeding, infection, and retained products of conception.
- Previously, before the diagnosis of fetal demise could be made and before the condition could be treated easily, disseminated intravascular coagulation (DIC) syndrome associated with prolonged retention of a dead fetus (>6-8 wk) was reported. With early diagnosis and treatment, DIC is extremely rare.

Race: Incidence is similar among all races.

Age: Pregnancy failure rates increase with age and rise significantly in women older than 40 years.

**History:** History is of limited value. Obtaining information about the first diagnosis of pregnancy, any human chorionic gonadotropin (hCG) tests, or abatement of symptoms of pregnancy may help increase the index of suspicion for the diagnosis of missed abortion.

# **Physical:**

• Physical examination is of limited value.

- A uterus that is small for dates or not increasing in size suggests missed abortion.
- Vaginal bleeding is suggestive of missed abortion.
- Loss of fetal heart tones or inability to obtain heart tones at the appropriate time leads to suspicion of the diagnosis.

Causes: Causes of missed abortion are generally the same as those causing spontaneous abortion or early pregnancy failure. Causes include anembryonic gestation (blighted ovum), fetal chromosomal abnormalities, maternal disease, embryonic anomalies, placental abnormalities, and uterine anomalies.

#### **Lab Studies:**

- Quantitative hCG levels
  - o Quantitative hCG levels are useful for very early pregnancy evaluation when no sac is visible in the uterus on sonogram.
  - o If suspicion of ectopic pregnancy exists, levels should be obtained at 48-hour intervals until the discriminatory level is reached. The discriminatory level of hCG is the level at which an intrauterine pregnancy should always be visible on vaginal probe ultrasonography. In most institutions, this is about 1500-2000 mIU/mL when standardized to the International Reference Preparation (IRP).
  - o Once the sac is clearly observed in the uterus, lower-than-expected levels of hCG or progesterone increase the possibility for abnormal pregnancy but are not diagnostic. Therefore, imaging studies are the studies of choice. To make the diagnosis with ultrasonography, the findings may include, but are not limited to, absence of fetal pole, lack of growth of fetal pole, fetal pole with no evident heartbeat, lack of yolk sac at the appropriate gestational age, misshapen yolk sac, or placental separation.
- Coagulation studies are generally not indicated prior to evacuation of the uterus.
- Documenting Rh status and treating appropriately if the woman is Rh negative is important.

# **Imaging Studies:**

- Ultrasonography
  - Once the hCG level has reached the discriminatory level, vaginal ultrasonography replaces blood tests as the primary means of evaluation.

- o If a true intrauterine gestational sac is observed, ectopic pregnancy is ruled out. For naturally conceived pregnancies, the coexistence of ectopic and intrauterine pregnancy is extremely rare (1 out of 30,000 pregnancies). However, with assisted reproduction technology, consider the coexistence of an ectopic and intrauterine pregnancy.
- o After a sac has been demonstrated in the uterus, the next step is to determine if the pregnancy is normal or abnormal. Transvaginal ultrasonography is the best imaging procedure to evaluate intrauterine contents.
- o While some ultrasonography criteria strongly support the diagnosis, most patients and physicians prefer to use repeat ultrasonography to confirm that the pregnancy is a missed abortion and not simply an early normal pregnancy. In most cases, a repeat ultrasonography in 1 week confirms lack of progressive development. In the case of a very early pregnancy where the sac diameter is less than 5-6 mm, repeating the study in 10-14 days may be more effective.
- o Serial ultrasonography is unnecessary if ultrasonography reveals loss of previously documented heart activity.
- o Transvaginal ultrasonography criteria that strongly suggest missed abortion are the absence of cardiac activity in an embryo with a crown-rump length greater than 5 mm or absence of fetal pole when the mean sac diameter is greater than 18 mm.

**Surgical Care:** Surgical evacuation is the standard of care in treating missed abortion, with suction curettage being the most common method. This procedure is typically performed in an outpatient setting. Advantages to surgical evacuation include immediate and definitive treatment with fewer medical visits.

# 6. Source: Lindsey, James L MD, Veronica R Rivera, MD; Missed Abortion; July 18, 2005; emedicine.com

#### 7. Medical Care for Obese Patients

...Results from several studies<sup>5-7</sup> suggest that patients who are obese are less likely to receive certain preventive care services, such as pelvic examinations, Papanicolaou (Pap) smears, and physician breast examinations, than those who are not obese. It is unclear whether this is a result of patient or physician factors. For example, physicians may be less likely to perform pelvic examinations on patients who are obese, because of the difficulty in performing an adequate examination....

7.Source: National Taskforce on the Prevention and Treatment of Obesity; <u>Medical Care for Obese Patients: Advice for Health Care Professionals</u>; American Family Physician, Vol 65/No1 (Jan 1, 2002)

# 8. Methotrexate (MTX) for Early Abortion

Methotrexate (MTX) is a chemotherapy agent that has been used for many years in the treatment of cancer because it affects cells that are rapidly dividing. In a Methotrexate (MTX) Abortion, it stops embryonic cells from dividing and multiplying and is a non-surgical method of ending

pregnancy in its early stages. Within a few days or weeks of receing an injection of Methotrexate (MTX) at the clinic the, the pregnancy ends through an experience similar to an early miscarriage.

... It has been successfully used since 1982 in a single dose to treat ectopic (tubal) pregnancies (where the fertilized egg is embedded in the fallopian tube instead of the uterus). In 1996-97, FWHC participated in clinical trials with the University of Washington to study MTX for Medical Abortion. The study showed MTX alone to be effective and we continue to offer it as an option to women at our clinics.

Methotrexate is given by injection the amount of which is individually calculated by each woman's weight and height. As the medication takes effect, MTX interferes with folic acid and stops fetal cell duplication, and disrupts pregnancy at the stage of implantation in the uterine wall. When given early in pregnancy, it is effective in ending the pregnancy....

The "miscarriage" after the MTX injection occurs anywhere from two to six weeks later, when the uterus expels the fetus. Passing the tissue is unpredictable. It may occur any time, day or night, any place.

#### **Side Effects**

There is limited information on childbearing after taking Methotrexate. Since the medication works on dividing cells and a woman's eggs do not divide until they are fertilized, future pregnancies should not be affected. However, to be extra-safe, women should avoid getting pregnant by using birth control for at least three months after receiving Methotrexate.

When used in early pregnancy Methotrexate safely and effectively induces abortion 90-97% of the time. Women who have chosen a medical abortion said it felt more private and natural than a surgical procedure. If the medication does not induce termination, a surgical suction abortion will be performed at no additional charge. Medical abortion with Methotrexate (MTX) is an option up to six weeks measured since last menstrual period (LMP).

Possible side-effects of Methotrexate include nausea, vomiting, diarrhea, abdominal cramping, sores in the mouth, headache, dizziness, insomnia, and vaginal bleeding. Except for nausea, these side effects are unusual for the single dose given to induce abortion.

#### **Risks**

Vaginal bleeding during the miscarriage caused by MTX may be heavy. In rare situations it could require a surgical abortion and very rarely, a blood transfusion. If a minor under age 18 has complications, their confidentiality cannot be guaranteed as their parents or guardians may need to give consent for care if complications occur.

Studies show MTX abortion has a failure rate of 1-10%. If spontaneous abortion has not started by 6 weeks after injection, a surgical abortion is required.

# 8. Source: http://www.fwhc.org/abortion/mtxinfo.htm

#### **Executive Summary of the Analysis's (note critical findings)**

33 year old morbidly obese African American female who is a poor historian was seen in Prompt Care on 10/21/05 for swollen feet after taking a pregnancy test at home which was positive. According to the dates that she gave the Prompt Care staff, she was approximately 19 weeks. She was discharged to home with the understanding that she would follow up with her Obstetrician. The patient was seen by her OB at the end of October. The patient told her physician that she had run out of birth control pills in May (according to source number 4, the Pill in obese patients is ineffective 70% of the time) and she had had a normal period every 4-6 weeks until August. According to source number 5, it is uncommon but possible for a woman to bleed throughout her pregnancy. A beta HCG was done which was 4600. According to this clinical information, she would be about 8-10 weeks gestation. A transvaginal ultrasound was accomplished in the MD office. There was no evidence of intrauterine pregnancy and therefore it was assumed that she had had a missed abortion. According to the literature, "it <u>is</u> harder to do an ultrasound on a big person, and the bigger the tummy, the more difficult it can be to see everything they want. However, other factors are can be more important than the size of the mother. These can include:

- The skill of the technician
- The position of the baby, and perhaps of the placenta too
- The power and quality of the machine
- The gestational age of the baby

Don't assume that any problem *must* be because of your fat. Often the baby is not in the best position for optimal viewing, the u/s tech is not very skilled, or the machine is not powerful enough to get good resolution of what they are looking for. Fat *can* make it harder to get the best view, but there are certainly many other factors that are just as important." There is also much literature including sources 2 and 4 that state that "among obese women, body mass index was the best predictor of visualization, with no improvement seen with advancing gestation or duration of examination."

Because of the fact that the power and quality of the machine is a factor in visualization, especially in the morbidly obese, patients greater than 300 pounds will now be sent to a radiological suite for all ultrasounds.

Due to the patient's morbid obesity, it was felt that she was a poor surgical candidate and therefore the physician and patient opted to try medicinal evacuation of the uterus with Methotrexate. In November, the patient was seen back in the MD office to repeat her beta HCG which was 4200. Due to the fact that the beta HCG had only gone from 4600 to 4200, it was felt that the Methotrexate was not successful in evacuation of the uterus and therefore a D&C was scheduled. According to source number 8, "studies show MTX abortion has a failure rate of 1-10%."

The patient was admitted on 11/23/05 for a D&C for a suspected missed abortion in the outpatient surgery center. Findings from the surgery showed a 10 week uterus with a moderate amount of products of conception. During the procedure, 3 passes of the curette were done and then a sharp curettage was performed until resistance was felt and a gritty texture was noted. The suction was then placed to remove the remaining products of conception. The pathology report states "products of conception – mostly inspissated mucus, associated with fragments of secretory endometrium and decidualized stroma; no chorionic villi identified."

On 12/7/05, the patient was seen in the MD office with complaints of increased abdominal pain. The concern was that the D&C was ineffective and that she possibly has an ectopic pregnancy. She was sent to the hospital for further evaluation. At the hospital, she was sent for an emergency pelvic sonogram which showed a 38.5 week pregnancy with a fetal heart rate of 140 beats per minute. The patient was immediately sent to labor and delivery, the attending was called in and she delivered a 7 pound 15 ounce infant with APGARS of 9 and 9 at 1 and 5 minutes respectively.

Once again, since the patient was on the Pill until May and was having "periods" until August a clinical decision was made that the patient was between 8 and 10 weeks. The transvaginal ultrasound did not show any evidence of pregnancy and therefore a missed abortion was assumed. Because of the morbid obesity of the patient, Methotrexate was attempted to evacuate the uterus. When this did not work, the patient had a D&C. The patient admitted to never "feeling" the baby move or having any symptoms of pregnancy. The D&C was unsuccessful because of the fact that the patient was so far along in gestation and therefore the curette does not advance as far into the uterus for a full evacuation. The patient came to the hospital and delivered a healthy infant. Both mom and baby had a normal post delivery course and were discharged home on day two.

# List titles of RCA participants (i.e. director of nursing)

Chief Medical Officer
Director of Quality Improvement and Medical Affairs
Chief, Department of Anesthesiology
Attending Physician
Director of Women and Children's Services
Director of Surgical Services
Director of Educational Services
Library Services
Nurse Manager Labor and Delivery
Nurse Manager Outpatient Surgery Center
Quality Improvement Analyst

Yes, no further action
Yes, room for improvement X
No, attributable to systems
No, attributable to an individual practitioner

Root Cause Analysis Action Plan

Exhibit E1

#### What happened?

Sentinel Event (Adverse Occurrence)

What are the details of the event? (Brief description) Include date, day of week, time and the area/service involved Occurrence Date: 12/7/05 Wednesday 11:30AM

10/21/05-33 year old 450-500 pound African American female seen in Prompt Care with a complaint of right lower extremity swelling. She reported that she had also taken a home pregnancy test which was positive. A serum pregnancy test was performed and was positive. She was instructed to follow up with her gynecologist for appropriate prenatal care. For the edema she was instructed to drink plenty of water, restrict salt intake, elevate feet and follow up with her primary care physician. The dictated Prompt Care report was copied directly to the patient's primary care physician.

On 10/31/05 the patient was seen at her gynecologist's office. A quantitative beta hCG was performed and results were 4497. The patient had no nausea or breast tenderness. She reported having bleeding x 1 day in September and believed her last menses to be in August. Based on this information, it was believed that the patient was 8-10 weeks pregnant.

On 11/4/05 the patient returned to the office for another beta hCG. This result was 4265 The resulting decrease was believed to be the result of a first trimester miscarriage. A transvaginal sonogram was scheduled and completed on 11/7/05. Findings revealed no fetal tissue or intrauterine pregnancy. Beta hCG on that date was 4800.

On 11/8/05 the patient went back to the office for discussion with the physician regarding next steps. Based o the fact that the patient had abnormal Beta HCG and negative sonogram for intrauterine gestation, the decision was made to administer methotrexate for medical abortion

On 11/14/05 the patient was seen in the MD office reporting that she felt as though she was about to expel something vaginally. There was no active bleeding but it was believed that the process had begun.

On 11/21/05 the patient called the office reporting that she had not expelled the products of conception. A D&C was scheduled for 11/23/05. On that date the patient presented to the outpatient surgery center at Crouse Hospital and a D&C was performed. The curette was advanced to what was believed to be the fundus of the uterus. Suction curettage was performed using spiraling technique. Tissue obtained was sent to pathology for examination.

On 11/23/05 the physician received the pathology report which showed no chorionic villi and no products of conception. The patient was called to come in for another beta hCG. The patient was not symptomatic with a potential ectopic pregnancy and was informed to call the office if pain developed. The patient did not obtain the beta hCG but did call the office on 12/7/05 complaining of new onset lower pelvic pain. She had difficulty walking and tenderness on the right side. The patient was sent to the Crouse Hospital Emergency Department for examination and potential treatment for ectopic pregnancy.

An ultrasound was performed on the patient and it was discovered that the patient had an intrauterine pregnancy of 38.5 weeks gestation. The patient was in labor and was transferred to labor and delivery. She progressed and delivered a 7 lbs 15 oz infant with APGARS of 9/9.

Why did it happen?	Aspects for Analysis		Risk Reduction	Measures of Effectiveness
What were the proximate causes? (special cause variation)			Strategies	
What systems and processes underlie those proximate factors? (common cause variation)				
			Implemented	
			YES DATE	
Policy or Process (System) in which the event occurred	The system in place related to the event is effective	X		
	The system in place related to the event was carried out as intended	X		
	An effective policy is in writing	X		
	The policy was effectively communicated	X		
	An effective procedure is in place	X		
Human Resources Factors & Issues	Staff are properly qualified	X		
	Staff are currently assessed as competent to carry out their responsibilities	X		
	Staffing level plans were in place	X		
	Staffing level plans were appropriate	X		
	Staffing level plans were implemented	X		

	Staff performance in the relevant processes is evaluated	X					
	Orientation & in-service training are in place	X					
	Human error did not contributed to the outcome	X					
Environment of Care Including equipment & other related factors	The physical environment was appropriate for the processes/treatments being carried out	X					
	A system is in place to identify environmental risk	X					
	Emergency and failure mode responses have been planned	X					
	Emergency and failure mode responses have been tested	X					
Environment of Care (continued)	Controllable equipment factors did not contribute to the event		X	Radiologic image quality is hindered by the body habitus of morbidly obese patients.  Effective immediately the attending MD will send all patients >300 to a radiological suite for evaluation. This information will be shared at the monthly OB/GYN department for consideration by all department members.	Immedi ately		Attending MD will send all patients >300 lbs to radiology suite for ultrasound examinations
	Controllable environmental factors did not contribute to the event	X					
	Uncontrollable external factors (natural disasters, power outages, etc.) were not a factor in this case	X					
	An emergency preparedness plan is in place	X					
Information Management & Communication issues	Necessary information was available	X					

	Necessary information was accurate	X	
	Necessary information was complete	X	
	Necessary information was clear and unambiguous	X	
	Communication among participants was effective	X	
	No barriers to communication were identified	X	
Standard of Care -If no and linked to an individual practitioner, list name and license #	The quality of care and services met generally accepted community standards	X	
Leadership: Corporate culture	Leadership is involved in the evaluation of adverse patient occurrences	X	
Other	Note other factors that influenced or contributed to this outcome	X	
	Note other areas of service impacted	X	

Results of literature review: (include key citations)

- Obesity is a growing medical problem which can influence the ability of radiology department to provide optimum image quality ad accurate diagnosis.
- A fourteen year retrospective review of dictated radiology report with the disclaimer "limited due to body habitus" between the years 1989-2003 was performed from the electronic medical records
- Overall 0.15% of all studies were limited by body habitus For all studies from 1989-2003 there has been an increase at a rate of 0.010% (at 95% CI) per year.
- Conclusions are that changes in the American body habitus over 14 years has increasingly affected the ability of radiology departments to provide quality images and accurate image interpretations.

Uppot, Raul, MD, Sahani, Dushyant, MD Hahn, Peter MD, Kaira Manudeep, MD, Saini, Sanjay, MD, Mueller Peter, MD. Limited by Body Habitus; Economic and Quality Control issues and the ability of a Radiology Department to provide diagnostic imaging to a fattening population. Health Services, Policy and Research (Quality and Safety) Scientific Paper.

- Imaging the obese patient has become a major issue in radiology departments across America. This epidemic has reduced the physician's ability to diagnose and treat patients using standard imaging modalities because of the limitations of current radiology equipment.
- Each modality has its own difficulties with obesity and therefore possible solutions are unique to each one. Safety is also an issue because there are weight limits as to how much weight the machinery can hold.
- Manufacturers and vendors are meeting this need by developing ad marketing new bariatric equipment

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- The obesity epidemic, radiologists nationwide say, increasingly is reducing their ability to diagnose and treat patients using the imaging technology that have become the cornerstone of modern medicine
- Radiologists argue that too much fat makes it difficult or impossible to determine whether a patient has a kidney obstruction, to distinguish a benign fibroid tumor from ovarian cancer or to see whether a fetal heart is developing properly.
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- Equipment manufacturers need to consider design changes to cope with America's larger population
- Siemens Medical Solutions recently rolled out a new MRI with a wider opening and has devised an ultrasound system capable of greater depth penetration.

Boodman, Sandra G. Obesity gets in the way of medical imaging tests. American College of Radiology. Los Angeles Times December 27, 2004

- The prevalence of obesity in the United States has increased dramatically over the past 20 years. Obese women are at increased risk for several pregnancy complications; therefore, preconception assessment and counseling are strongly recommended.
- Potential intrapartum complications include difficulty estimating fetal weight (even with ultra sonongraphy), inability to obtain interpretable external fetal heart rate and uterine contraction patterns, and difficulty performing an emergent cesarean delivery.

Obesity in Pregnancy. ACOG Committee Opinion No315 American College of Obstetricians and Gynecologists. Obstet Gynecol 2005; 106: 671-5

Suspected pregnancy should be confirmed. The earliest signs and symptoms of pregnancy include: absence of expected menses, breast fullness and tenderness, urinary frequency, nausea, and fatigue. The "gold standard" for diagnosis of pregnancy is the detection of the beta subunit of <a href="https://human.chorionic.gonadotropin">human.chorionic.gonadotropin</a> (hCG) in blood or urine using immunologic techniques. The most sensitive enzyme-linked immunosorbent assays (ELISA) can detect hCG approximately one week after fertilization. The hCG concentration doubles every 29 to 53 hours during the first 30 days after conception in a viable, intrauterine pregnancy. Serum hCG reaches peak concentrations of 100,000 IU/L (in relation to the First

International Reference Preparation) at 8 to 10 weeks after the last menstrual period. The concentrations start to decrease after week 12 and stay fairly constant at approximately 30,000 IU/L from about the 20th week until term.

Lockwood, Charles, MD UptoDate 2006. *UpToDate performs a continuous review of over 330 journals and other resources. Updates are added as important new information is published. The literature review for version 13.3 is current through August 2005; this topic was last changed on June 30, 2005. The next version of UpToDate (14.1) will be released in February 2006.* 

The incidence of congenital uterine anomalies is difficult to determine since many women with such anomalies are not diagnosed, especially if they are asymptomatic. Uterine anomalies occur in 2 to 4 percent of fertile women with normal reproductive outcomes]. In one of the better designed studies, the uteri of 679 women with normal reproductive outcomes were evaluated with laparoscopy or laparotomy prior to tubal ligation, and then by follow-up hysterosalpingogram (HSG) five months after sterilization. The incidence of congenital uterine anomalies was 3.2 percent. The type and frequency of abnormality were septate uteri (90 percent), bicornuate uterus (5 percent), and didelphic uterus (5 percent)

A bicornuate uterus refers to a uterus in which the fundus is indented (arbitrarily defined as ≥1 cm) and the vagina is generally normal. This anomaly results from only partial fusion of the müllerian ducts. This leads to a variable degree of separation of the uterine horns that can be complete, partial or minimal (ie, the arcuate uterus merely has an indentation at the center of the fundus)

Iverson, Ronald, MD, DeCherney, Alan, MD, Laufer, Marc MD UptoDate 2006 *UpToDate performs a continuous review of over 330 journals and other resources. Updates are added as important new information is published. The literature review for version 13.3 is current through August 2005; this topic was last changed on June 30, 2005. The next version of UpToDate (14.1) will be released in February 2006.* 

# **Executive Summary of the Analysis's (note critical findings)**

A multidisciplinary team was convened to perform a root cause analysis. A case review was completed that confirmed that the patient had been seen in Prompt Care and was referred to her gynecologist after she reported that she had taken a home pregnancy test that was positive. A serum test confirmed the pregnancy and she was seen by her OB/GYN within 10 days. The first of many quantitative beta hCG tests confirmed pregnancy (4497). The patient (who has a history of irregular periods) claimed that she had her last menses in August. Based on the combination of these two factors a diagnosis of intrauterine pregnancy of 8-10 weeks was made. The next beta hCG was performed four days later and had decreased (4265). Literature review confirms that that the hCG concentration doubles every 29-53 hours during the first 30 days after conception in a viable intrauterine pregnancy. Serum hCG peak concentration reaches peak concentrations of 100,000 IU/L at 8-10 weeks after the last menstrual period (Lockwood). In this case, the levels were not at as expected therefore it was believed that the patient had a non-viable pregnancy.

A transvaginal ultrasound was performed and found no intrauterine pregnancy. The patient is reportedly 450-500 pounds. She was unable to be weighed at the physician's office as a bariatric scale for such a morbidly obese patient was not available. Studies and comments offered by professionals in the field of radiology and obstetrics confirm that "the obesity epidemic increasingly is reducing their ability to diagnose and treat patients using the imaging technology that have become the cornerstone of modern medicine" (Boodman). "Potential intrapartum complications include difficulty estimating fetal weight (even with ultra sonongraphy), inability to obtain interpretable external fetal heart rate and uterine contraction patterns, and difficulty performing an emergent cesarean delivery" (ACOG). During the root cause analysis, the attending OB/GYN

confirmed that reviews of the pictures of the transvaginal ultrasound show no identifiable features of a fetus. The patient's body habitus is one explanation as to why the IUP was not identified.

The beta hCG continued to confirm that there was a human chorionic gonadotropin present and that the patient was pregnant (with a nonviable fetus). The patient was counseled on alternatives including waiting for spontaneous elimination of the products of conception, administration of methotrexate or surgical removal via D&C. The patient opted for treatment with Methotrexate and when that did not work, a D&C was scheduled. During the RCA, the manager and supervisor of the outpatient surgery center reported that there was nothing unusual about the patient presentation or the procedure. They commented that the patient was morbidly obese but the equipment and supplies available to them were able to accommodate the patient. There is no explanation as to how the physician was able to insert the curette and perform the spiral technique and not break the amniotic fluid sac. There is a question as to whether the patient has a uterine anomaly (eg. bicornuate uterus) but there is no evidence of that at this time. The literature confirms that "the incidence of congenital uterine anomalies is difficult to determine since many women with such anomalies are not diagnosed, especially if they are asymptomatic. Uterine anomalies occur in 2 to 4 percent of fertile women with normal reproductive outcomes". (Iverson et al).

The case where systems and processes associated with this case were discussed at the root cause analysis. It was recognized and agreed upon that obesity and medical imaging pose problems related to obtaining true diagnosis. The hospital does have an entire radiology department with the support of board certified radiologists and different and more powerful equipment than available in MD offices. The attending physician determined that he will be sending all patients > 300 lbs to a radiology center for evaluation. This was deemed to be a valuable lesson for all and hence was shared at the January 2006 Department of Obstetrics & Gynecology Department meeting for consideration by other physicians.

The case was also concurrently reviewed by the hospital's OB Quality Improvement Committee. They closely examined the events of this case and determined that the standard of care was met with room for improvement (action step from the RCA). With hindsight it was clear that the beta hCG was in fact trailing off into the 4000 level as she was ending a full term pregnancy-not beginning one. This is a case with a surprising outcome but resulted in the delivery of a healthy newborn.

# List titles of RCA participants (i.e. director of nursing)

Chief Medical Officer
Director of Quality Improvement and Medical Affairs
Chief, Department of Anesthesiology
Attending Physician
Director of Women and Children's Services
Director of Surgical Services
Director of Educational Services
Library Services
Nurse Manager Labor and Delivery
Nurse Manager Outpatient Surgery Center
Quality Improvement Analyst

Yes, no further action
Yes, room for improvement X
No, attributable to systems
No, attributable to an individual practitioner

# Exhibit E2

#### NYPORTS.Net NYSDOH

# **New York State Department of Health** NYPORTS.NET

# **Bureau of Hospital and Primary Care Services Root Cause Report**

Run Date: 2/10/2006

Reported By: dr333777

Area Office: Syracuse Occurrence ID: 06360512002 Submission Date: Facility: CROUSE-IRVING MEMORIAL HOSPITAL

Closure Date:

02/10/2006

#### What Happened

Sentinel Event(Adverse Occurrence) What are the details of the event?(Brief Description) Include Date, day of Week, Time and the Area/Service involved

Occurrence Date: 12/7/05 Wednesday 11:30AM

10/21/05-33 year old 450-500 pound African American female seen in Prompt Care with a complaint of right lower extremity swelling. She reported that she had also taken a home pregnancy test which was positive. A serum pregnancy test was performed and was positive. She was instructed to follow up with her gynecologist for appropriate prenatal care. For the edema she was instructed to drink plenty of water, restrict salt intake, elevate feet and follow up with her primary care physician. The dictated Prompt Care report was copied directly to the patient's primary care physician.

On 10/31/05 the patient was seen at her gynecologist's office. A quantitative beta hCG was performed and results were 4497. The patient had no nausea or breast tenderness. She reported having bleeding x 1 day in September and believed her last menses to be in August. Based on this information, it was believed that the patient was 8-10 weeks pregnant.

On 11/4/05 the patient returned to the office for another beta hCG. This result was 4265 The resulting decrease was believed to be the result of a first trimester miscarriage. A transvaginal sonogram was scheduled and completed on 11/7/05. Findings revealed no fetal tissue or intrauterine pregnancy. Beta hCG on that date was 4800.

On 11/8/05 the patient went back to the office for discussion with the physician regarding next steps. Based o the fact that the patient had abnormal Beta HCG and negative sonogram for intrauterine gestation, the decision was made to administer methotrexate for medical abortion

On 11/14/05 the patient was seen in the MD office reporting that she felt as though she was about to expel something vaginally. There was no active bleeding but it was believed that the process had begun.

On 11/21/05 the patient called the office reporting that she had not expelled the products of conception. A D&C was scheduled for 11/23/05. On that date the patient presented to the outpatient surgery center at Crouse Hospital and a D&C was performed. The curette was advanced to what was believed to be the fundus of the uterus. Suction curettage was performed using spiraling technique. Tissue obtained was sent to pathology for examination.

On 11/23/05 the physician received the pathology report which showed no chorionic villi and no products of conception. The patient was called to come in for another beta hCG. The patient was not symptomatic with a potential ectopic pregnancy and was informed to call the office if pain developed. The patient did not obtain the beta hCG but did call the office on 12/7/05 complaining of new onset lower pelvic pain. She had difficulty walking and tenderness on

> of 10 Page 1

the right side. The patient was sent to the Crouse Hospital Emergency Department for examination and potential treatment for ectopic pregnancy.

An ultrasound was performed on the patient and it was discovered that the patient had an intrauterine pregnancy of 38.5 weeks gestation. The patient was in labor and was transferred to labor and delivery. She progressed and delivered a 7 lbs 15 oz infant with APGARS of 9/9.

	en				
Aspects fo	or Analysis				
F	indings, including Root Ca	use(s)	Risk reduction Strategies Expected Implementation		
Г	Description	Corrective Action	Date	Measures of Effectiveness	
Poli	cy or Process(System) in	which the event occurred			
<b>V</b>	The system in place relat	ed to the event is effective			
<b>V</b>	The system in place relat	ed to the event was carried ou	it as intended		
V	An effective policy is in w	riting			

Hun	Human Resource(Factors and Issues)				
	Staff are properly qualified				
	Staff are currently assessed as competent to carry out their responsibilities				
	Staffing level plans were in place				
	Staffing level plans were appropriate				
	Staffing level plans were implemented				
	Staff performance in the relevant processes is evaluated				
	Orientation & in-service training are in place				

	Human error did not contribute to the outcome
Env	viroment of Care Including Other Related Factors  The physical enviroment was appropriate for the process/treatments being carried out
<b>✓</b>	A system is in place to indentify enviroment risk
<b>✓</b>	Emergency and failure-mode reponses have been planned
<b>✓</b>	Emergency and failure-mode reponses have been tested
<b>✓</b>	Controllable equipment factors did not contripute to the event

Radiologic image quality is of morbidly obese patients. Effective immediately the attending MD will send all patients >300 to a radiological suite for evaluation. This information will be shared at the monthly OB/GYN department for consideration by all

Radiologic image quality is hindered by the body habitus hindered by the body habitus of morbidly obese patients. Effective immediately the attending MD will send all patients >300 to a radiological suite for evaluation. This information will be shared at the monthly OB/GYN department for consideration by all

01/05/2006

Attending MD will send all patients >300 lbs to radiology suite for ultrasound examinations

О	partment members. department members.
<b>✓</b>	Controllable enviromental factors did not contripute to the event
<b>✓</b>	Uncontrollable external factors, (natural disasters, power outages, etc) were not a factor in this case
<b>✓</b>	An emergency preparedness plan is in place
Infor	nation Management and Communications Issue
	Necessary information was available
	Necessary information was accurate

□ Necessary information was complete
☐ Necessary information was clear and unambiguous
☐ Communication among participants was effective
☐ No barriers to communication were indentified
Leadership: Corporate Culture  Leadership is involved in the evaluation of adverse patient care occurrences
Other  Note other factors that influenced or contributed to this outcome as well as other areas of service

#### Literature Review

- Obesity is a growing medical problem which can influence the ability of radiology department to provide optimum image quality ad accurate diagnosis.
- A fourteen year retrospective review of dictated radiology report with the disclaimer "limited due to body habitus" between the years 1989-2003 was performed from the electronic medical records
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- Imaging the obese patient has become a major issue in radiology departments across America. This epidemic has reduced the physician's ability to diagnose and treat patients using standard imaging modalities because of the limitations of current radiology equipment.
- Each modality has its own difficulties with obesity and therefore possible solutions are unique to each one. Safety is also an issue because there are weight limits as to how much weight the machinery can hold.
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Lockwood, Charles, MD UptoDate 2006. UpToDate performs a continuous review of over 330 journals and other resources. Updates are added as important new information is published. The literature review for version 13.3 is current through August 2005; this topic was last changed on June 30, 2005. The next version of UpToDate (14.1) will be released in February 2006.

The incidence of congenital uterine anomalies is difficult to determine since many women with such anomalies are not diagnosed, especially if they are asymptomatic. Uterine anomalies occur in 2 to 4 percent of fertile women with normal reproductive outcomes]. In one of the better designed studies, the uteri of 679 women with normal reproductive outcomes were evaluated with laparoscopy or laparotomy prior to tubal ligation, and then by follow-up hysterosalpingogram (HSG) five months after sterilization. The incidence of congenital uterine anomalies was 3.2 percent. The type and frequency of abnormality were septate uteri (90 percent), bicornuate uterus (5 percent), and didelphic uterus (5 percent)

A bicornuate uterus refers to a uterus in which the fundus is indented (arbitrarily defined as 1 cm) and the vagina is generally normal. This anomaly results from only partial fusion of the müllerian ducts. This leads to a variable degree of separation of the uterine horns that can be complete, partial or minimal (ie, the arcuate uterus merely has an indentation at the center of the fundus)

Iverson, Ronald, MD, DeCherney, Alan, MD, Laufer, Marc MD UptoDate 2006 UpToDate performs a continuous review of over 330 journals and other resources. Updates are added as important new information is published. The literature review for version 13.3 is current through August 2005; this topic was last changed on June 30, 2005. The next version of UpToDate (14.1) will be released in February 2006.

#### **Executive Summary**

A multidisciplinary team was convened to perform a root cause analysis. A case review was completed that confirmed that the patient had been seen in Prompt Care and was referred to her gynecologist after she reported that she had taken a home pregnancy test that was positive. A serum test confirmed the pregnancy and she was seen by her OB/GYN within 10 days. The first of many quantitative beta hCG tests confirmed pregnancy (4497). The patient (who has a history of irregular periods) claimed that she had her last menses in August. Based on the combination of these two factors a diagnosis of intrauterine pregnancy of 8-10 weeks was made. The next beta hCG was performed four days later and had decreased (4265). Literature review confirms that that the hCG concentration doubles every 29-53 hours during the first 30 days after conception in a viable intrauterine pregnancy. Serum hCG peak concentration reaches peak concentrations of 100,000 IU/L at 8-10 weeks after the last menstrual period (Lockwood). In this case, the levels were not at as expected therefore it was believed that the patient had a non-viable pregnancy.

A transvaginal ultrasound was performed and found no intrauterine pregnancy. The patient is reportedly 450-500 pounds. She was unable to be weighed at the physician's office as a bariatric scale for such a morbidly obese patient was not available. Studies and comments offered by professionals in the field of radiology and obstetrics confirm that "the obesity epidemic increasingly is reducing their ability to diagnose and treat patients using the imaging technology that have become the cornerstone of modern medicine" (Boodman). "Potential intrapartum complications include difficulty estimating fetal weight (even with ultra sonongraphy), inability to obtain interpretable external fetal heart rate and uterine contraction patterns, and difficulty performing an emergent cesarean delivery" (ACOG). During the root cause analysis, the attending OB/GYN confirmed that reviews of the pictures of the transvaginal ultrasound show no identifiable features of a fetus. The patient's body habitus is one explanation as to why the IUP was not identified. The beta hCG continued to confirm that there was a human chorionic gonadotropin present and that the patient was pregnant (with a nonviable fetus). The patient was counseled on alternatives including waiting

for spontaneous elimination of the products of conception, administration of methotrexate or surgical removal via D&C. The patient opted for treatment with Methotrexate and when that did not work, a D&C was scheduled. During the RCA, the manager and supervisor of the outpatient surgery center reported that there was nothing unusual about the patient presentation or the procedure. They commented that the patient was morbidly obese but the equipment and supplies available to them were able to accommodate the patient. There is no explanation as to how the physician was able to insert the curette and perform the spiral technique and not break the amniotic fluid sac. There is a question as to whether the patient has a uterine anomaly (eg. bicornuate uterus) but there is no evidence of that at this time. The literature confirms that "the incidence of congenital uterine anomalies is difficult to determine since many women with such anomalies are not diagnosed, especially if they are asymptomatic. Uterine anomalies occur in 2 to 4 percent of fertile women with normal reproductive outcomes". (Iverson et al).

The case where systems and processes associated with this case were discussed at the root cause analysis. It was recognized and agreed upon that obesity and medical imaging pose problems related to obtaining true diagnosis. The hospital does have an entire radiology department with the support of board certified radiologists and different and more powerful equipment than available in MD offices. The attending physician determined that he will be sending all patients > 300 lbs to a radiology center for evaluation. This was deemed to be a valuable lesson for all and hence was shared at the January 2006 Department of Obstetrics & Gynecology Department meeting for consideration by other physicians.

The case was also concurrently reviewed by the Department of OB/GYN Chief. He closely examined the events of this case and determined that the standard of care was met with room for improvement (action step from the RCA). With hindsight it was clear that the beta hCG was in fact trailing off into the 4000 level as she was ending a full term pregnancy-not beginning one. This is a case with a surprising outcome but resulted in the delivery of a healthy newborn.

#### Standard of care met

Chief Medical Officer Director of Quality Improvemer Chief, Department of Anesthes Attending Physician Director of Women and Childre Director of Surgical Services Director of Educational Services Library Services Nurse Manager Labor and Deli Nurse Manager Outpatient Sur Quality Improvement Analyst	oiology en's Services es ivery	
Was the Standard of Care Met	☐ Yes, no further action	☐ No, attributable to systems
	✓ Yes, room for improvement	☐ No, attributeable to an individual practioner
Date facility certifies Root Cause Analysis complete	2/10/2006 12:00:00 AM	
Physician/Physician as	ssistance:	License #:
Physician/Physician as	ssistance:	License #:

<u>Print</u> <u>Close</u>

From: Jennifer Watkins (Jennifer Watkins@crouse.org)

Sent: Fri 2/10/06 3:46 PM

To: James Caputo MD (Caputodoc@hotmail.com)

1 attachment

WorleyLF.doc.pdf (25.0 KB)

Here is what was submitted to the DOH this afternoon

Jennifer Watkins

Director, Medical Affairs & Quality Improvement

telephone 470-7122

beeper 441-4659

Exhibit F

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1 of 1 1/12/2015 11:58 AM

Outlook.com Print Message

<u>Print</u> <u>Close</u>

From: Jennifer Watkins (Jennifer Watkins@crouse.org)

Sent: Fri 2/10/06 11:51 AM

To: Dawn Richey (DawnRichey@crouse.org)Cc: James Caputo MD (Caputodoc@hotmail.com)

1 attachment

WorleyLF2.doc (124.5 KB)

Dawn-can you please submit this as the long form?

Dr. Caputo-the submission is via cutting and pasting the information directly into the website. Once it is entered we will send you the adobe format that we can from the DOH secured website.

Jennifer Watkins Director, Medical Affairs & Quality Improvement telephone 470-7122 beeper 441-4659

----Original Message----

From: James Caputo [mailto:caputodoc@hotmail.com]

Sent: Friday, February 10, 2006 8:54 AM

To: Jennifer Watkins

Subject: RE: long form revisions

Good Morning Jennifer,

I just got done with reading the report. I must say that I am very impressed with your work on this. It not only is more accurate, but represents a quality document from this institution with sound medical references. I did make a few tiny word changes and you should be able to

pick them out if examined. Just simple ones. I also reduced the font size

for the beginning narrative from 10 to 9.5 because it got cut off at the end

of the section and wasn't totally visible.

Otherwise, it should be ready for submission. I would ask that the copy I

have attached back to you be sent since it contains the small word changes.

I am sure you will see it hasn't changed or altered the substance of document in any way. If you are going to send it electronically, please

copy me in as well. Thanks.

1 of 3 1/12/2015 11:55 AM

Once again, nice job.

Jim Caputo

```
>From: "Jennifer Watkins" <JenniferWatkins@crouse.org>
>To: "James Caputo MD" <Caputodoc@hotmail.com>
>Subject: long form revisions
>Date: Thu, 9 Feb 2006 16:37:19 -0500
>
>I will check my email either later tonight or first thing tomorrow
>morning-if there are desired edits, please let me know. I believe we
>will be able to submit tomorrow afternoon
>
>
>
>Jennifer Watkins
>Director, Medical Affairs & Quality Improvement
>
>telephone 470-7122
>beeper 441-4659
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2 of 3 1/12/2015 11:55 AM

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>contact
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> 
> << image001.jpg >>
> << WorleyLF.doc >>
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3 of 3

Outlook.com Print Message

<u>Print</u> <u>Close</u>

From: Jennifer Watkins (Jennifer Watkins@crouse.org)

Sent: Tue 2/07/06 8:05 AM

To: James Caputo MD (Caputodoc@hotmail.com)

Cc: Shawky Badawy MD (badawys@upstate.edu); Ron StahlMD (RonaldStahlMD@crouse.org); Derrick Suehs

(DerrickSuehs@crouse.org)

Dr Caputo- your request it was forwarded directly to Dr. Badawy. As Chief of the Department he informed me yesterday that he had a message out for you to speak with him directly. I will await his guidance before further action.

Jennifer Watkins Director, Medical Affairs & Quality Improvement telephone 470-7122 beeper 441-4659

----Original Message----

From: James Caputo [mailto:caputodoc@hotmail.com]

Sent: Tuesday, February 07, 2006 7:56 AM

To: Jennifer Watkins Subject: RE: Open ASAP

Jennifer,

I waited all day yesterday for your response and heard nothing. No e-mail

and no call. I thought my request was clear. If you are having a problem

with this, then I would be happy to coordinate it myself. Please send

corresponding e-mails for the individuals I listed and I will contact them.

And again, be sure to provide those individuals from the OBQI who were involved with this report. It appears from reading this report that their

input is the most pertinent to address.

James Caputo

>From: "Jennifer Watkins" <JenniferWatkins@crouse.org>

>To: "James Caputo" <caputodoc@hotmail.com>

1 of 4

```
>Subject: RE: Open ASAP
>Date: Sat, 4 Feb 2006 21:25:23 -0500
>The information outlined in the long form is a copilation of all input
>received from the RCA, OBQI and Chief. We can certainly meet on
Monday- I
>will set up a time and page you Monday morning.
>From: James Caputo [mailto:caputodoc@hotmail.com]
>Sent: Sat 2/4/2006 10:37 AM
>To: Jennifer Watkins
>Subject: Open ASAP
>
>
>Jennifer,
>I have just opened the file and have only taken a few minutes to review
>before thoroughly examining it. I am not happy at all with the content
>accuracy of what is described here and wish to relay this to you right
>away.
> This has caused me to call for an iimmediate meeting on this report
SO
>as
>to get it "right". This must be done as soon as possible since its
>completion and availability to me have come so close to the required
> submission date. I am available on Monday after work. I don't want to
>delay this at all since again, I stand to feel the negative effects of
what
>has proven to be innacurate reporting of clinical events concerning my
> of a patient at this institution. If you check your e-mail on
weekends,
>then I would appreciate a prompt response to this communication. If
>not get this until Monday, I would expect an page to discuss this and a
>corrective meeting at the beginning of the day.
>James Caputo
>441-9979
> >From: "Jennifer Watkins" <JenniferWatkins@crouse.org>
```

> >To: "James Caputo MD" <Caputodoc@hotmail.com>

2 of 4 1/12/2015 11:50 AM

- > >Subject: RE: RCA
- > >Date: Fri, 3 Feb 2006 14:03:28 -0500
- > >
- > >That is fine. We try to get them out earlier than they are due so people
- > >can actually read the document.
- > >
- > >Jennifer Watkins
- > > Director, Medical Affairs & Quality Improvement
- > >telephone 470-7122
- > >beeper 441-4659
- > >
- > >
- > >
- > >-----Original Message-----
- > >From: James Caputo [mailto:caputodoc@hotmail.com]
- > >Sent: Friday, February 03, 2006 1:47 PM
- > >To: Jennifer Watkins
- > >Subject: RCA
- > >
- > >Hey Jennifer,
- > >
- > >I recently received the e-mail of the Worley report. Thanks. I have
- > >been
- > >screamingly busy this week and plan on giving it a thorough review this
- > >weekend knowing it has to be in on 2/10/06. I will have my comments to
- > >you
- > >no later than 2/6/06. If there is any problem or you need anything,
- > >please
- > >let me know. Thanks again and have a nice weekend.
- > >
- > >
- > >Jim Caputo
- > :
- > >
- > >
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3 of 4 1/12/2015 11:50 AM

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- >

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4 of 4

# Exhibit G1

## **MEMORANDUM**

TO:

Dr. Badawy, Dept. of OB-GYN

FROM:

Dr. Aubry, Chairman OB-QA Committee, Dept. of OB-GYN

DATE:

March 4, 2002

RE:

QA Review of OB Cases of Provider #

Some months ago following an occurrence of a particularly poor outcome of birth, a process was implemented whereby the OB cases of the provider involved were to be reviewed by members of the OB-QA committee. The process was implemented and the following is our report up to this point.

- 1. Deliveries done and cases reviewed: From the Birth Log a list of 49 deliveries were noted in October 2001 through January 2002. Of these, 44 delivery charts were reviewed by a least two, and as many as four committee members.
- 2. Problems noted:
  - a.) <u>Serious</u>— There were three <u>midforceps</u> done prior to meeting standard indications i.e. 2 hours of second stage pushing without epidural or 3 hours with epidural.
  - b.) Moderate There were 2 vaginal deliveries of nulliporous breech births without CT pelvimetry.
  - c.) Mild There were 3 inductions of labor without documentable medical indications
- 3. Summary—the provider appears to have a pattern of practice that includes an aggressive approach to operative vaginal delivery and perhaps including inductions. This pattern is unwise and potentially modifiable by a targeted educational effort regarding operative vaginal delivery/induction of labor.

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question is, and you may not be right the person to answer this and if that's the case, I'll understand. In your opinion, what was the cause of death in the fetus? THE WITNESS: I believe the fetus died due to do an accident involving a

DR. FRYMOYER: Thank you.

DR. CAPUTO: Can I ask a question? Can I still ask a question?

cord secondary to the forceps delivery.

DR. GREEN: Yes.

#### BY DR. CAPUTO:

In completing that sentence, death to the baby due to an umbilical cord accident secondary to the use of the forceps, can you explain the mechanism by which the forceps in this case could have caused a cord injury, a cord accident, anything that could lead to the death of the baby related to the forceps? you give at least a mechanism, scientific mechanism?

I'll try to be scientific. When Yeah. the forceps are applied and the cord is around the neck or the lower face and the forceps are applied, in this case the forceps were applied -- they didn't -attempts were to do with rotation. They check the

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baby again. The baby was still posterior. Obviously, 2 either the forceps slipped or they were misapplied to 3 start with. The fact of the matter is there was 4 something about the application of that forceps that 5 was not -- it didn't work, and we know forceps can 6 7 fail and so that's not a problem in itself. However, when the forceps are applied and they are in a 8 9 position to compress the cord, if the cord compression occurs, you can get this profound bradycardia due to a 10 sudden increase in the resistance of the pulsopressure 11 going through the cord, so you have a hypertension, so 12 the baby gets a response and gets profoundly 13 14 bradycardic. If the bradycardia occurs long enough given the circumstances, fluid electrolyte imbalance 15 and so on, you can have a cardiac arrest. The cord pH 16 was not acidotic, so it doesn't appear that fetal 17 distress was a problem prior to the baby's death. 18 The baby had, in my judgement, a cardiac arrest due to a 19 profound cord occlusion that occurred as part of the 20 operative vaginal delivery, and this is plenty 21 22 scientific from my point of view. 23

Q. Doctor, if the cord was around the neck, how do forceps compress the cord?

A. If forceps are applied properly and in the

normally and the baby should have come out. It controlled obviously didn't. So the question is, where were the framforceps? Where was the cord? One doesn't know.

- Q. But yet you say the forceps caused the death of this baby?
- A. I was asked my opinion why did this baby
  die, and my opinion is based on the fact that the baby
  up to the point of the operative application was fine.
  The fetal heart was satisfactory. The fetal heart was
  satisfactory. The beat to beat variability was fine.
  In a 15 or 20-minute period of time between when the
  forceps were applied and that baby was delivered, it
  died. It can die due to a sudden bradycardiac episode Show
  leading to a cardiac arrest, and the application of
  forceps under these circumstances cannot be
- Q. So a pH of 7.22 at the time of the birth clearly does not demonstrate birth asphyxia, correct?
  - A. That's right.

disconnected from that baby's death.

- Q. So how do you get cardiac arrest in an otherwise healthy baby with a normal pH by the use of forceps? I'm missing the connection.
  - A. Well, why do we have cardiac arrests?

1 Doctor, I respectfully disagree with you. 2 Q. A cardiac arrest can occur when there's a 3 4 major insult on the cardiovascular dynamics. But apparently not enough of an insult to 5 effect the pH significantly? 6 No. One is a pressure problem, one is an 7 oxygen problem. The oxygen problem was apparently not 8 the problem. It was apparently an acute hypoxic -- or 9 an acute change in the intervascular pressures and 10 cardiovascular dynamics, I believe. 11 12 Q. So a transient cord compression will cause 13 enough of a hemodynamic catastrophe in a baby to cause cardiac arrest? 14 15 Transient, you know, is a relative term. If you're holding your breath for 13 minutes that the 16 forceps were applied initially and however long it 17 took after that to get the baby delivered, that's a 18 19 long time. But holding your breath would produce an 20 acidemia, correct? 21 If somebody is affecting my cardiac output A. 22 in periphery resistance to the point where I get a 23

profound bradycardia (for 15, 20 minutes) it's quite possible I may have a cardiac arrest under those

would also have as well

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circumstances.

DR. CAPUTO: Well, I would respectfully disagree and I will point out in my summation of the case whereby I disagree.

DR. GREEN: Dr. Aubry, I ask you not to discuss this proceeding or your testimony with anyone, including committee members, outside of this forum, and I'll excuse you and thank you for coming in.

(The witness was excused.)

\* \* \*

# Exhibit G3

#### DETERMINATION AS TO PENALTY

The Hearing Committee, pursuant to the Findings of Fact and Conclusions of Law set forth above, unanimously determined that Respondent's license should be suspended for two years; however, after 30 days of actual suspension, the remainder of the period of suspension should be stayed provided that Respondent complies with certain terms of probation. The Committee determined further that Respondent's license to practice medicine as a physician in New York

State should be permanently limited to prohibit him from performing high and midforceps rotations deliveries. This forceps or determination was reached upon due consideration of the full spectrum of penalties available pursuant to statute, including revocation, suspension and/or probation, reprimand, censure and the imposition of monetary penalties.

The Hearing Committee believes that Respondent has the requisite knowledge and skill to practice medicine safely, but that he has repeatedly failed to exercise the care that a reasonably prudent physician would exercise under the circumstances. The Committee sought to fashion a penalty that would permit Respondent to continue to practice his chosen profession while ensuring the safety of his patients.

The Committee feels that 30 days of actual suspension must be imposed to provide a period of time during which Respondent can reflect upon his prior misconduct and redirect his energy and focus towards practicing medicine within accepted standards. In addition, Respondent's inability to practice for that period of time will serve as a penalty by having a significant monetary impact.

A suspension of Respondent's license, stayed after 30 days for the remainder of a two-year period provided Respondent complies with terms of probation, is necessary to ensure that Respondent practices medicine within accepted standards. In spite of his

# Exhibit H

June 13, 2007

Crouse Hospital
736 Irving Avenue
Syracuse, NY 13210
ATTN: Dr. Shawky Badawy

To Whom it may Concern:

My name is Cathleen and I just gave birth to my second son at your Hospital on June 1, 2007. I wanted to write this letter to let you know of an exceptional physician, Dr. James Caputo, affiliated with your Hospital. I am sure you are already aware of this amazing asset that you have.

My first son was born 17 months ago on January 21, 2006 at Crouse Hospital and was premature. I initially started at Community General with an OB-GYN and unfortunately went into labor 9 weeks early. I was rushed to Crouse Hospital where I was released into the care of the Perinatal Center. Given their excellent reputation, I was thankful to have them under the circumstances. However, my second experience at Crouse Hospital with the recent delivery of my second son on June 1, 2007 with Dr. Caputo was so much smoother.

When I was initially brought to Crouse in January 2006, I was met by several different doctors from the Perinatal Center at intermittent and sporadic times. I was scared and confused. I just wanted to know what the game plan was and be reassured my future child would be healthy. Unfortunately, the first doctor that we met with was more interested in talking about a baby book he wrote, and wanting to make sure we had a copy of it. This doctor actually offered a "free" autograph if my husband brought his book to your hospital. This was not the "medical care" we expected or deserved. Once he got past his own self-admiration, the game plan remained unknown and we were left with even more questions. After an extended wait, another doctor came in from the Perinatal Center with no clear opinion on what we should do. Finally, after several other doctors came in and no consensus treatment plan in place, we were told by our nurse what to expect – that we would sit and wait.

My first labor was chaos, never meeting the doctor that would ultimately deliver my son until I was in active labor and still unsure of the plan once delivered. Thankfully, our son was born relatively healthy at 32 weeks and brought to the NICU, where our decision to transfer to Crouse Hospital was validated. I followed up our original experience with a similar letter to the NICU letting them know how thankful we were for the exceptional care ultimately provided.

After the birth of my first son, I later went to the Perinatal Center for my follow up appointment. I was told by another doctor that I had never met before that he did not know the reason why I had a preterm baby, but I would not have another one. They told me I should just find another doctor if I became pregnant again. I did not feel very good about this advice, questioning how they could minimize another complication without

even knowing the reason why I had a preterm baby in the first place. Without being informed of the cause for my preterm child, I was advised that I did not need to see a "high risk" physician or stay with their practice group if I became pregnant again. On my own instincts, I decided I would find an OB-GYN on my own, also affiliated with Crouse Hospital, in the event that I had another preterm baby.

I spoke with some friends that raved and highly recommended their OB-GYN, Dr. Caputo. At this point I did not trust any doctors, my world had been rocked and I was very skeptical about having another baby. I felt that the healthcare system had missed major issues that I was having with my first child, and I was not going to allow it to happen again. Immediately upon meeting with Dr. Caputo, he took my future pregnancy seriously, spent considerable time with me going over what happened with my first delivery, and explained the various options he felt he could do to prevent it from happening again. With the help and reassurance of Dr. Caputo, I went home feeling like I could do this again. I felt comfortable with the preventative measures he planned to undertake to help me go further along with my second pregnancy.

We got pregnant again in September 2006. In January 2007, Dr. Caputo put a cerclage in me to prevent my cervix from breaching early. Dr. Caputo saw me every three weeks to inspect my cerclage. After 20 weeks, Dr. Caputo saw me every two weeks. I felt that he was taking my pregnancy seriously and put my mind at ease. It also became evident that he provided exceptional care for all of his patients, not just the ones with my history.

I had a fairly easy pregnancy with no other issues until I was 34 weeks pregnant. My cerclage was definitely working, and Dr. Caputo was right about my cervix being incompetent. I am thankful everyday that I did not listen to the Perinatal Center's initial advice and get pregnant again without the guidance of a proactive professional like Dr. Caputo. I firmly believe I would have had another preterm baby without Dr. Caputo.

During a regular follow-up exam with Dr. Caputo, I had mentioned in passing that I had a headache. Dr. Caputo immediately sent me for blood work and found that I had pre-eclampsia. Dr. Caputo saw me every other day to monitor my condition and gave me peace of mind. He knew how nervous I was to have another NICU baby and he was doing everything he could to spare us from that experience again. It is hard for a mother to explain the loss of trust that happens when you have a pre-term baby, knowing in your heart it could have been prevented.

I hope you understand how special Dr. Caputo is. I trust him with my life and the life of my child. Due to low amniotic fluid and the pre-eclampsia, Dr. Caputo felt that we should deliver the baby at 35 weeks and 4 days. Before Dr. Caputo, I would have questioned this plan. I completely accepted his decision as I knew unequivocally he was acting in the best interest of my child and myself.

Dr. Caputo delivered my healthy son Jackson at 5:17 A.M on June 1, 2007, and he was perfect. While in the initial stages of my labor, Dr. Caputo sat in my delivery room for hours with me and my husband to provide even more reassurance. My labor was relaxed,

happy and emotional, which I didn't experience with my first delivery. I actually got to hold my son, my husband got to cut the umbilical cord, I got to see first what the sex of my child was and I was able to take my son home with me – all experiences which we did not have with our first child.

My husband and I owe our healthy son to one person and that is Dr. James Caputo. He is an exceptional doctor, father, and person. We not only consider him the best doctor we have ever been involved with, but we also now consider him our friend. Crouse Hospital is a better hospital due to this caring and thorough man. I am sure you are aware of how very lucky you are to have him practicing medicine at your hospital. I hope that my feelings for this man are being translated in this letter, and I will forever recommend Crouse Hospital because of Dr. Caputo and the NICU to every person that will listen.

Milens about a baby book he wrote, and wunting to make sure we had a copy of it. This

was born referively besiden at 22 weeks and brought to the NICU, where our decision to

Thank you, Cathlees

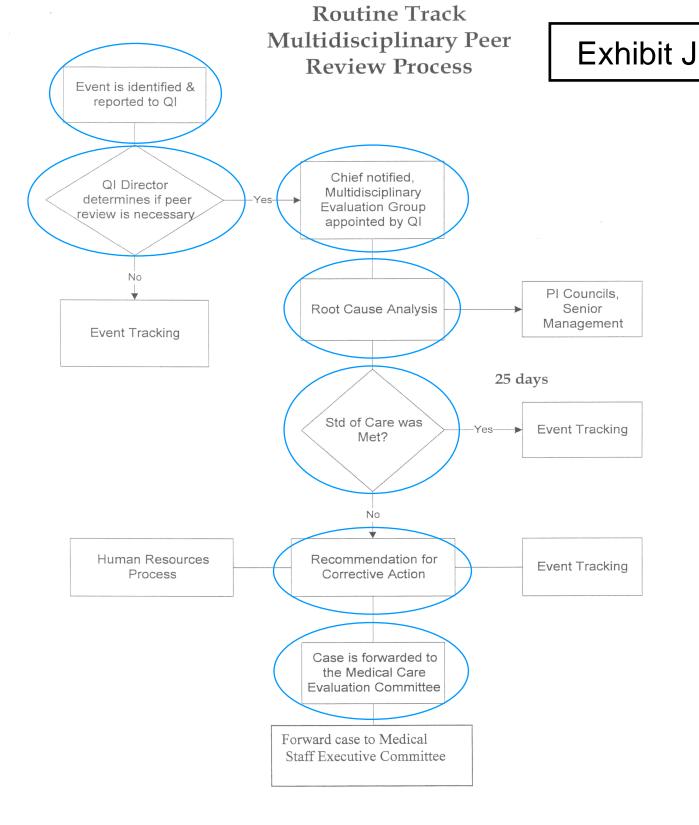
Cc: Joan Dadey
Dr. James Caputo

Cathleen & Michael

# Exhibit I

April 1, 2010 Dean Dr. Capute, I have decenced your ay a meruitar me Know who specializes Placing Physicians CONO OMINE MADE 155000. The Mospital pays all few.

(SOOD LUCK ON your search. I wish I would hecommund bet it is a SMAKE pit that is held history to GA from Cross I have Palacever year blog Best of Louis to year year





#### **Central New York Regional Office**

217 South Salina Street Syracuse, New York 13202

Richard F. Daines, M.D. Commissioner

April 8, 2008

Wendy E. Saunders Chief of Staff

Paul Kronenberg, MD, President/CEO Crouse Hospital 736 Irving Avenue Syracuse, New York 13210

Dear Dr. Kronenberg:

Pursuant to Section 230 of the New York State Public Health law, please provide this office with a <u>complete</u>, <u>certified copy</u> of the materials listed below relating to **James Caputo**, **MD for the time frame of 11/01/07 to the date listed above:** 

- (X) All Meeting Minutes and reviews related to James Caputo, MD, with the **name** of the Committee and the **date** of the meeting (previously sent reviews did not include the name of the Committee or date of the meeting copies attached)
- (X) All Meeting Minutes, with the name of the Committee and the date of the meeting in which the care of patient K B Medical Record # 0205 was reviewed
- (X) The **January 2008 GYN QI Committee meeting minutes** as referenced in the review of case # 0295 by Dr. Byuong Ryu dated 12/26/2007
- (X) All correspondence <u>regarding</u>, and <u>to</u> and <u>from</u> James Caputo, MD including that from outside sources including but not limited to the Committee for Physician Health

Please note that documents/records <u>must</u> be certified as complete. Records are due in this office by April 22, 2008.

Sincerely,

Kathleen P. Alger, RN, BSN

Nurse Investigator

Office of Professional Medical Conduct

(315) 477-8512

# STATE OF NEW YORK DEPARTMENT OF HEALTH

Central NY Regional Office 217 South Salina Street Syracuse, New York 13202

Richard F. Daines, MD Commissioner

### CERTIFICATION

I, Jenniferwatkins	hereby certify that these are true and exact	
copies originals of the	records of Dy James Cape	ito
kept on file during the regular of	course of business and were made at the time of	
such event as recorded or writte	en.	
	Signed: Junger Watkins  Title: Overtor & 1/m50	
	Organization: Crouse Hospital	<del>-</del> 0
	Date: 4-11-05	

# **RE:** report request

Exhibit L1

From: **Jennifer Watkins** (JenniferWatkins@crouse.org)

Sent: Tue 12/09/08 1:54 PM

To: James Caputo (caputodoc@hotmail.com)

Dr. Caputo- no report was submitted to the New York State Department of Health regarding the care and treatment of Ms. K under the NYPORTS reporting programming. The case did not meet the requirement for reporting under their definitions. An internal root cause analysis was performed due to the fact that she had experienced complications during her inpatient stay. The only documents that are generated from these RCAs are lists of action steps with persons responsible for those actions as the purpose of the meeting is to examine opportunities for improved systems and processes in patient care.

Please let me know if I can provide further assistance.

Jennifer Watkins, MS, CPHQ Director, Medical Affairs & Quality Improvement telephone 470-7122 beeper 441-4659

From: James Caputo [mailto:caputodoc@hotmail.com]

Sent: Tuesday, December 09, 2008 10:25 AM

**To:** Jennifer Watkins **Subject:** report request

Jennifer,

Last Winter, I believe February, I participated in a Root Cause Analysis for one of my patients (Karana Barana in regards to her October 2007 admission.

It is my understanding that all RCA's require a written report be submitted to the State Department of Health. This would account for the overhead documentation concurrent with the actual RCA meeting itself. I would like to obtain a copy of the report submitted as a result of the RCA for Mrs. Believe. Please let me know that you received this communication and when I can expect the

1 of 2 3/13/2013 11:55 AM

requested material. Thank you for your time and attention to this matter.

Sincerely,

James R. Caputo, M.D.

Crouse Hospital CONFIDENTIALITY NOTICE: The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer.

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Exhibit L2

#### Appendix 1

Public Health Law Article 28 HOSPITALS S 2805-I.

#### S2805-I. Incident reporting

- 1. All hospitals, as defined in subdivision ten of section twenty-eight hundred one of this article, shall be required to report incidents described by subdivision two of this section to the department in a manner and within time periods as may be specified by regulation of the department.
- 2. The following incidents shall be reported to the department:
  - a. Patients' deaths or <u>impairments of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards;</u>
  - b. Fires in the hospital which disrupt the provision of patient care services or cause harm to patients or staff;
  - Equipment malfunction during treatment or diagnosis of a patient which did or could have adversely affected a patient or hospital personnel;
  - d. Poisoning occurring within the hospital;
  - e. Strikes by hospital staff;
  - f. Disasters or other emergency situations external to the hospital environment which affect hospital operations; and
  - g. Termination of any services vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel, including but not limited to the anticipated or actual termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food or contract services.
- 3 The hospital shall conduct an investigation of incidents described in paragraphs (a) through (d) of subdivision two of this section and shall inform the department of the expected completion date of the investigation. The hospital shall provide to the department a copy of the investigation report within twenty-four hours of completion. Nothing herein shall limit the authority of the department to conduct an investigation of incidents occurring in general hospitals.

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4. The Commissioner shall make, adopt, promulgate and enforce such rules and regulations, as he may deem appropriate to effectuate the purposes of this section.

#### S 2805-m. Confidentiality.

- 1. The information required to be collected and maintained pursuant to sections twenty-eight hundred five-j and twenty-eight hundred five-k of this article, reports required to be submitted pursuant to section twenty-eight hundred five-l of this article and any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions of this chapter shall be kept confidential and shall not be released except to the department or pursuant to subdivision four of section twenty-eight hundred five-k of this article.
- 2. Notwithstanding any other provisions of law, none of the records, documentation or committee actions or records required pursuant to sections twenty-eight hundred five-j and twenty-eight hundred five-k of this article, the reports required pursuant to section twenty-eight hundred five-l of this article nor any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions of this chapter shall be subject to disclosure under article six of the public officers law or article thirty-one of the civil practice law and rules, except as hereinafter provided or as provided by any other provision of law. No person in attendance at a meeting of any such committee shall be required to testify as to what transpired thereat. The prohibition relating to discovery of testimony shall not apply to the statements made by any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting.
- 3. There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any person, partnership, corporation, firm, society, or other entity on account of the communication of information in the possession of such person or entity, or on account of any recommendation or evaluation, regarding the qualifications, fitness, or professional conduct or practices of a physician, to any governmental agency, medical or specialists society, or hospital as required by sections twenty-eight hundred five-j, twenty-eight hundred five-l of this article or any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions of this chapter. The foregoing shall not apply to information which is untrue and communicated with malicious intent.

#### Appendix 2

Effective Date: 10/14/98

Title: Section 405.8 - Incident reporting

#### 405.8 Incident reporting.

- a. Any incident required to be reported pursuant to subdivision (b) of this section shall be reported to the departments investigation and identification information required by the department.
- b. Incidents to be reported are:
  - 1. Patients' deaths in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards. Injuries and impairments of bodily functions, in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards and that necessitate additional or more complicated treatment regimens or that result in a significant change in patient status, shall also be considered reportable under this subdivision;
  - 2. Fires or internal disasters in the facility which disrupt the provision of patient care services or cause harm to patients or personnel;
  - 3. Equipment malfunction or equipment user error during treatment or diagnosis of a patient which did or could have adversely affected a patient or personnel;
  - 4. Poisoning occurring within the facility;
  - 5. Patient elopements and kidnappings;
  - 6. Strikes by personnel;
  - 7. Disasters or other emergency situations external to the hospital environment which affect facility operations; and
  - 8. Unscheduled termination of any services vital to the continued safe operation of the facility or to the health and safety of its patients and personnel, including but not limited to the termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food, or contract services.
- c. The hospital shall conduct an investigation of incidents described in paragraphs (b)(1)-(6) of this section and those incidents in paragraphs (7)-(9) deemed appropriate by the department.
- d. The hospital shall provide a copy of its investigative report to the area administrator within 24 hours of its completion. This report shall document all hospital efforts to identify and analyze the circumstances surrounding the incident and to develop and implement appropriate measures to improve the overall quality of patient care. This report shall contain all information required by the department including:
  - 1. An explanation of the circumstances surrounding the incident;
  - 2. An updated assessment of the effect of the incident on the patient(s);
  - 3. A summary of current patient status including follow-up care provided and post-incident diagnosis;
  - 4. A chronology of steps taken to investigate the incident that identifies the date(s) and person(s) or committee(s) involved in each review activity;
  - 5. The identification of all findings and conclusions associated with the review of the incident;
  - 6. Summaries of any committee findings and recommendations associated with the review of the incident; and
  - 7. A summary of all actions taken to correct identified problems, to prevent recurrence of the incident and/or to improve overall patient care and to comply with other requirements of this Part.
- e. e) This section does not replace other reporting required by this Part.
- f. f) Nothing in this section shall prohibit the department from investigating any incident included in subdivision (b) of this section.

Volume:C

#### Appendix 3

(Commissioner's 2/23/00 Dear Administrator Letter)

State of New York Department of Heath Corning Tower, Empire State Plaza Albany, New York 12237

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ANTONIA C. NOVELLO, M.D., M.P.H. Commissioner February 23, 2000 Phone: (518) 474-2011 Fax: (518) 474-5450

#### Dear Administrator:

Providing the highest quality of care to patients is our most important responsibility. Achieving this goal takes a dedication to quality assurance and a commitment to realizing that when mistakes happen, they should be identified, reported, analyzed and corrected so that they never happen again.

The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is <u>a national model</u> for medical error reporting. Its development was due to the collaboration and hard work of hospitals, consumers and the State Health Department, and to our collective commitment to protecting patients at all costs.

Today we have a reporting system that is based upon objective criteria and information and has clear definitions of what needs to be reported. As a result, reporting is more consistent statewide. And, hospitals know what is expected of them should an incident occur. Most importantly, we have a system that will help improve the quality of care and reduce medical errors in New York State.

A key ingredient of NYPORTS, as a reporting and quality improvement mechanism for reducing medical errors, is hospitals reporting. Recent disturbing events at three hospitals in New York City lead us to reemphasize the importance of prompt reporting, and to stress that failure to report comes with consequences and cannot be tolerated.

The creation of a national reporting system and new agencies to oversee medical quality is being discussed in Washington. We have an <a href="important\_opportunity">importunity</a> in New York State to <a href="reduce medical errors">reduce medical errors</a> and <a href="important-opportunity">importunity</a> in New York State to <a href="reduce medical errors">reduce medical errors</a> and <a href="important-opportunity">importunity</a> in New York State to <a href="reduce medical errors">reduce medical errors</a> and <a href="important-opportunity">importunity</a> of care provided to our citizens, since we in New York have a model that is already developed and working. I will not see that opportunity lost.

The Department stands ready to enforce reporting requirements, and will publicly sanction those facilities that fail to promptly and accurately report incidents that result in patient death, injury or potential injury. The Department also stands ready to assist your facility in meeting the statutory requirements of NYPORTS.

Sincerely,

Antonia C. Novello, M.D., M..P.H. Commissioner of Health

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You know it has happened to other physicians. You do your best, and one day you open the mail to a letter from the New York State Office of Professional Medical Conduct asking for a few charts...

Exhibit M

#### **SUPPORT Senate Bill 5221**

By the Hon. James Seward

#### The OPMC Reform Bill

To make Professional Medical Conduct honest and fair

Currently there is a wellspring of public protest against OPMC investigating and penalizing doctors under suspicious circumstances.

Patients in the thousands have signed petitions and written letters mourning the loss of their doctors when OPMC has prosecuted vendettas among colleagues, ignored exculpatory evidence, or used its police power to aid insurers in dispute with doctors over medical benefits.

The Appellate Division of the State Supreme Court has escalated their criticisms of OPMC behavior.

Other states are refusing to follow OPMC findings against physicians, citing lack of OPMC due process.

What would fix the system so that both the good doctors and the bad doctors would find the justice they deserve?

The American solution, since the Declaration of Independence, is DUE PROCESS.

#### S.5221 would provide due-process and better peer review to doctors:

- More timely notice to doctors of the existence, progress, and the facts behind investigations against them so that they may mediate or settle disputes sooner and improve patient care.
- Give the investigative committees of the Board of Professional Medical Conduct (BPMC) more control over investigations and charges now controlled by unaccountable OPMC staff.
- Miranda-type warning before doctors agree to submit to interview by OPMC investigative staff.
- Opportunity for doctors to appear before the BPMC investigative committees which may result in settlement or remediation more quickly, well before expensive and time-consuming adversarial hearings begin, which can improve patient care sooner as well.
- Rules for the inclusion of <u>medical and scientific literature evidence</u> -- which is currently rarely admitted; <u>exculpatory evidence</u> -- which is currently ignored; as well as <u>newevidence</u> that would clear a good doctor's name -- which is currently not allowed at all!
- Disclosure of the qualifications/experience/affiliations of experts relied on by both parties.
- Require the appeal board (ARB) to send back a case to rehearing when it disagrees with the dismissal of charges by the hearing panel that actually heard the doctor, instead of simply overturning the dismissal as they have.

Due process is the most basic protection against wrongful prosecution that our Constitution guarantees, at the same time, it assures that the full merits for prosecution, and for defense, are clear.

**CONTACT TWO KEY STATE SENATORS TODAY!** 

Hon. Kemp Hannon
Chairman, Senate Health Committee
Room 609 LOB
Albany, NY 12247
Hon. Joseph Bruno
Senate Majority Leader
Room 909 LOB
Albany, NY 12247
Albany, NY 12247

Use the explanations above to frame your message in your own words.

The Assembly bill, A.4274a, by Health Com. Chairman Gottfried, has already passed!

Prepared by Monica Miller for FAIM, see www.healthlobby.com for details

Exhibit N

NEW YORK STATE DEPARTMENT OF HEALTH STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER

**OF** 

DEFENSES, REQUESTS AND MOTIONS OF THE RESPONDENT

JAMES R. CAPUTO, M.D.

James R. Caputo, M.D., with the assistance of his attorneys, Smith, Sovik, Kendrick, and Sugnet, P.C., raises the following defenses, requests and motions for determination prior to and/or during the re-hearing of this matter.

1. Respondent takes the position that State Attorney Timothy J. Mahar is unfairly and improperly biased against him. The bases for these concerns are as follows. He acknowledges observing interaction at the original hearing between hearing panel member.

Ellman and petitioner expert Ponterio and failed to independently bring this misconduct to the attention of the Hearing Officer or respondent. Certain of the improper comments by panel member Ellman suggested testimony to State Expert Ponterio on the subject matter of quality of fetal heart decelerations. Subsequent to executive session regarding Dr. Ellman's improprieties, it appears that Mr. Mahar, via leading questions to the State expert, elicited this very testimony which had been suggested by panel member Ellman. In his post hearing submission Mr. Mahar, on his own and under his own signature announces that Dr. Caputo deserved to have his license permanently restricted to prohibit forceps deliveries and vacuum deliveries and rotations with the exception of outlet deliveries. What motivates this request is his notion that Dr. Caputo "will not

reform his practices with forceps" and "would absolutely manage these three cases the same today". How can this be the sole justification for a penalty when, (a) the hearing panel had yet to make a finding, and (b) Dr. Caputo, when giving this testimony had been told (as were Mr. Mahar and the hearing panel) by Board Certified OB-GYN Steven Burkhart, MD. that there were no deviations on the part of Dr. Caputo. This bias and animus on the part of Mr. Mahar reached its zenith after the panel decision/penalty was promulgated. The panel imposed the very penalty requested by attorney Mahar. Despite this and only after respondent sought ARB review, petitioner under Mr. Mahar's name and signature not only sought ARB review but sought an increased and different penalty to the extent of a permanent prohibition of the practice of obstetrics.

Based upon the above, it is requested that Mr. Mahar be directed to step down from the prosecution of this matter.

2. As to patients A, B, C, and F as designated in the pending statement of charges – a prior hearing panel dismissed all claims of gross negligence, gross incompetence, and incompetence on more than one occasion.

To the extent that both the respondent and petitioner sought ARB review, neither made any claim that the hearing panel determination as to gross negligence, gross incompetence and multiple acts of incompetence was improper or inappropriate. The ARB review did not alter those findings and neither petitioner nor respondent has challenged the ARB decision via Article 78.

Those determinations must be considered the "law of the case" and as such all pending

claims alleging gross negligence, gross incompetence, and multiple acts of incompetence must be dismissed pursuant to provisions and principles of res judicata, collateral estoppel, double jeopardy, waiver, equity, and petitioners failure to exhaust administrative remedies and/or Article 78 remedies.

Therefore specifications 1-12, 14 must be dismissed.

3. The current statement of charges arises out of an ARB decision which found that a hearing panel member demonstrated a pre-judgement on the facts of the case; demonstrated a confrontational attitude toward respondent's expert witness; may have engaged in ex parte communication with Petitioner's expert; may have suggested testimony in his questioning of Petitioner's expert and that said bias pervaded the entire hearing.

The ARB decision ordered that the case be remanded for a new hearing and that said hearing take place before an entire new hearing panel.

There was no authority provided via said decision/order to allow Petitioners to add new and additional alleged theories of deviations from accepted standards of medical care as to Patients A, B, C, & F into this new hearing. In fact there was no invitation within the ARB decision or in law, to authorize Petitioners to draw up, file and serve a new statement of charges in relation to Patients A, B, C & F.

Petitioners, without legal authority to do so, have drawn up, filed and served a new statement of charges dated 5/10/07 which adds new theories under A (1, 2, 5); B(1); F (1, 2, 5).

It is believed that some or all of these new theories are the product of questions posed by the biased panel member and also some questions posed by one of the other panel members (but

ruled inadmissible in subject matter) by the ALJ at the initial hearing. In other words, hearing members became sources of evidence, a practice from which they are prohibited.

The original statement of charges have never been withdrawn, nullified or rendered moot (other than the dismissal of claims alleging gross negligence, gross incompetence and incompetence on more than one occasion), and the re-hearing order was specifically limited to those original charges as drafted.

At no time was Dr. Caputo given the opportunity to be interviewed or provide written submissions regarding these new theories nor any of the other rights and protections outlined in PHL §230.10(A)(iii).

Therefore all those claims per A (1, 2, 5); B(1); and F(1, 2, 5) must be dismissed for lack of jurisdiction, lack of procedural and substantive due process.

4. The ARB decision was finalized 8/23/06. This was the trigger to convene a hearing on the original statement of charges relative to multiple acts of negligence. Per PHL \$230.10(F) said hearing was to be commenced within sixty days. The State did not attempt a new hearing until 5/11/07 when they placed into the mail the new expanded statement of charges.

Based upon PHL §230.10 (f)(J) and 10 NYCRR §51.11(b)(2), 51.11 (d)(10) all the charges must be dismissed based upon unreasonable delay, prejudice, and inconvenience to the respondent. Alternatively, all the claims per Patients A, B, C & F must be dismissed for time violation and delay.

5. PLEASE TAKE NOTICE THAT in the event of a hearing on some or all of these charges, respondent intends to videotape the testimony and proceedings.

- 6. PLEASE TAKE NOTICE that respondent Caputo reserves his right to and intends to examine and/or cross examine witnesses separate and apart from any such examination conducted by his legal counsel.
- 7. Respondent Caputo requests an adjournment of the 6/22/07 hearing date as his schedule will not permit and he had been told by his attorney that 6/22/07 was for the pre-hearing conference.

Dated: June, 2007	
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#### JAMES R. CAPUTO, M.D.

#### TO: NEW YORK STATE DEPARTMENT OF HEALTH

Bureau of Adjudication Hedley Park Place 433 River Street, 5<sup>th</sup> Floor South

Troy, NY 12180

Attn.: Hon. Sean D. O'Brien, Director Bureau of Adjudication

#### NEW YORK STATE DEPARTMENT OF HEALTH

Bureau of Professional Medical Conduct Room 2512, Corning Tower

Albany, NY 12237

Attn.: Timothy J. Mahar, Associate Counsel

# **Exhibit O**

The Department presented testimony by Robert Tatelbaum, Dr. Tatelbaum has been board-certified in OB/GYN since 1975. Over a period of approximately twenty-five years, he has involved each year in one hundred deliveries on average and performed between thirty and fifty GYN surgeries. At present, Dr. Tatelbaum is the chief of the OB/GYN Department at Rochester General Hospital and an Associate Professor of Obstetrics and Gynecology at the University of Rochester School of Medicine and Dentistry. Dr. Tatelbaum had no stake in the outcome of this case and testified in an honest, direct and forthright manner. The Hearing Committee gave great weight to Tatelbaum's testimony. Department also presented the The transcribed prior testimony of David Brittain, M.D., and of Patient F's spouse which the Hearing Committee found to be credible.

Respondent presented the transcribed prior testimony of Steven Burkhart, M.D., as an expert witness on his behalf regarding the care provided to Patients A, B, C and F. Dr. Burkhart is board certified in OB/GYN and has practiced obstetrics and gynecology since 1986. Since then he has averaged between one hundred and one hundred seventy-five deliveries each year. Dr. Burkhart is a Physician and Managing Partner at Genesee Valley Obstetrics and Gynecology, P.C. in Rochester, New York. Dr. Burkhart had no stake in the outcome of this case, and the Hearing Committee also gave his testimony great weight.

# Exhibit P1

#### **Editorial:**

# **Tactics Characteristic of Sham Peer Review**

#### Lawrence R. Huntoon, M.D., Ph.D.

The tactics used by hospitals and others in conducting a sham peer review are remarkably similar throughout the country. The common feature of these tactics is that they violate due process and/or fundamental fairness, and they often represent an attempt to make the incident or event "fit the crime."

Although our legal system is not perfect, it does incorporate sound principles and procedures designed to protect an accused individual's right to due process and fundamental fairness (e.g. an accused person is considered innocent until proven guilty). In evaluating the fairness of peer review, one can often find corresponding principles of due process and fundamental fairness in our legal system.

The following list is not all-inclusive, but represents common tactics of sham peer review.

#### **Ambush Tactic and Secret Investigations**

Hospitals that employ sham peer review typically use the ambush tactic to place the targeted physician at severe disadvantage. An administrative secretary may call the physician's office and request that the targeted physician attend an "informal friendly meeting" in the administrator's office to discuss unspecified "issues." Although the targeted physician typically asks about the specific issues or concerns, the hospital administration often refuses to provide any specific details prior to the meeting.

On arrival at the meeting, the targeted physician often finds himself facing the hospital chief executive officer (CEO), hospital attorney, vice-president of medical affairs, chief of staff, and chief of service. The meeting is anything but informal or friendly. All of the individuals in the room, except for the targeted physician, know precisely what the specific issues or concerns are that will be discussed in the meeting.

As the targeted physician fumbles to recall and explain events or patient cases that occurred weeks or months ago, his inability to recall specifics under highly stressful conditions makes him look "guilty." Catching the physician off guard and making him look "guilty" is, of course, the purpose of the tactic. The ambush tactic is frequently enhanced by imposing an immediate summary suspension on the targeted physician, an action that elicits an expected "shock and awe" effect from the targeted physician.

Physicians who are asked to attend one of these "informal friendly meetings" should take a trusted physician colleague with them to the meeting so there will be an independent account of what was said or done at the meeting. Concealed digital recorders, either audio or audio/visual, can also be utilized depending on state laws. Consent for taping requirements is posted on the AAPS website (http://www.aapsonline.org/judicial/telephone.htm). Physicians should also consult a local attorney to confirm requirements.

Hospitals that employ sham peer review also frequently use secret investigations, which can continue for weeks, months, or even longer. In fact, a secret investigation can remain open almost indefinitely until a formal action is taken or the investigation is formally closed. If the physician resigns or lets his hospital privileges expire while under secret investigation, it is reportable to the National Practitioner Data Bank (NPDB), and the physician's career may be ruined or ended. A secret investigation, however, fails to satisfy the requirement (42 U.S.C. §11112(a)(2)) that a reasonable effort be made to obtain the facts of the matter, because it fails to obtain information from the very person (physician under review) who could provide the most direct information about why a patient was treated a particular way.

# Depriving Targeted Physician of Records Needed to Defend Himself

Although no court of law would permit depriving an accused person of files or records needed to defend himself, as it is fundamentally unfair and in violation of due process, hospitals that employ sham peer review frequently refuse to provide records in a timely manner to the physician under review. Sometimes, hospitals delay providing the needed records to the accused physician until just prior to the peer review hearing or at the time of the hearing, leaving the accused physician inadequate time to prepare his defense. Having inadequate time to prepare a defense places the physician at severe disadvantage and makes him look "guilty" as he fumbles to defend himself at the hearing. Attorneys who represent physicians should document strong objection to this tactic both before and during the hearing.

#### **Guilty Until Proven Innocent**

Even accused serial murders, serial rapists, and serial child molesters are supposed to be considered innocent until proven guilty in a court of law. However, due to unfair provisions of the Health Care Quality Improvement Act (42 U.S.C. §11112(a)(4)), and provisions often found in medical staff bylaws that have been manipulated so as to favor the hospital, targeted physicians are often essentially presumed "guilty" and the burden is shifted to the accused physician to go forward with evidence to prove his "innocence."

#### **Numerator-Without-Denominator Tactic**

Although the numerator-without-denominator tactic can be used against any physician, it is most commonly used against surgeons. Hospitals that use this tactic typically select cases that are specifically designed to highlight complications or negative outcomes. The selection of cases often falls outside the routine protocol used for selecting cases for review of physicians practicing at the hospital. The hospital then presents this select group of cases to peer reviewers as evidence that the targeted physician is a bad doctor or provides unsafe care.

Hospitals that use this tactic specifically omit the denominator (how many cases of that type the physician has performed over a period of time), thus eliminating the possibility of calculating a complication rate that could be used to make a fair comparison with statistics of other colleagues, or statistics published in medical literature. Virtually all surgeons, of course, experience complications, and the only surgeons who have zero complications are those who do not perform surgery, or who do not report their complications.

#### Misrepresenting the Standard of Care

This tactic takes advantage of the fact that it is very common for physicians to hold legitimate differences of professional opinion concerning optimal treatment for a specific patient or condition. Hospitals that employ this tactic frequently hire an outside expert who opines that because the targeted physician did not use the same surgical technique or medical treatment that the expert prefers, the targeted physician must be practicing beneath the standard of care. However, if the accused physician can provide evidence, either from the medical literature or from expert testimony, that justifies the treatment provided, then the issue is clearly a matter of difference of professional opinion and not a standard-of-care issue. In some cases, Medicare billing guidelines have even been misrepresented in peer review as a clinical standard of care.

#### **Trumped-Up and/or False Charges**

Hospitals that use sham peer review frequently bring trumpedup, fabricated, and totally false charges against targeted physicians. Charges are often pretextual, consisting of more "spin" than substance. Some examples and associated characteristics include:

- A "stack" of invalid incident reports or complaints—creating an appearance of a large quantity of actual valid incidents/complaints;
- "Sanitization" of meeting minutes (altering wording so as to show the targeted physician in unfavorable light, or place targeted physician at disadvantage);
- Use of summaries or abstracts (subject to manipulation/editing) prepared by hospital employees;
- Use of hearsay evidence;
- Strategic omissions of fact that place the targeted physician at a disadvantage;
- Highly damaging accusations of alcohol or drug abuse where there is no substantial or credible evidence to suggest that the accused physician has a problem;
- Prosecution choreographed/presented by one person under the hospital's influence or control, with an agenda not in furtherance of quality care;
- Wrongfully attributing the deficiency of the hospital or others solely to the targeted physician; and
- Accusers who are frequently guilty of the same accusations being made against the targeted physician.

In sham peer review, where the hospital controls the entire process and acts as judge, jury, and executioner, the truth or falsity of charges makes no difference, and the truth and the facts do not matter because the outcome is predetermined and the process is rigged.

#### Abuse of the "Disruptive Physician" Label

The definition of "disruptive physician" is highly subjective and subject to manipulation and abuse. Recently, the general and vague definition of "disruptive physician" has been fortified with the more specifically vague and subjective descriptions in the "Code of

Conduct" as promulgated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Nonverbal conduct, such as facial expression and body language, can be used to label a physician "disruptive," and no evidence is required beyond how the accuser feels.

Increasingly, the term "disruptive physician" has become synonymous with "mentally impaired" physician. A physician who is wrongfully labeled "disruptive" because he does not agree with the hospital administration's views, or complains about substandard care in the hospital, can be subjected to inpatient treatment at a facility that specializes in treating "disruptive physicians." "Treatment" at one of these facilities may include treatment with medications, which if the "dissident physician" refuses to take "voluntarily," may result in automatic termination of privileges for failure to comply with the recommended "treatment." Physicians typically emerge from one of these "treatment" facilities with psychiatric diagnoses of narcissistic personality disorder, obsessive-compulsive disorder, or both.

#### **Dredging Up Old Cases to Justify Summary Suspension**

Hospitals that use sham peer review frequently will use cases occurring in the distant past to justify a contemporaneous summary suspension. This tactic suffers from an obvious flaw in logic: If hospital officials truly believed that the physician posed an imminent danger to patients months ago, why did they wait and allow the physician to continue to practice, instead of summarily suspending the physician at the time when the incident occurred, in order to protect patients?

#### **Ex-Parte Communications**

Although no court of law would allow a prosecutor, judge, or witnesses to meet with members of the jury outside the hearing to discuss or influence a case, similar ex-parte communications occur frequently in sham peer review. Although such ex-parte communications taint the entire hearing process and clearly violate fundamental fairness and due process, hearing officers, hired by the hospital, often allow ex-parte communications.

# Hospital Attorney or Conflicted Attorney Used to Influence the Peer Review Process

Hospitals that employ sham peer review often will use an attorney who represents the hospital or who represents both the hospital and medical staff simultaneously (i.e. a conflicted attorney) to influence the peer review process.

The goals and interests of a hospital administration and a medical staff are not identical. The medical staff is the primary entity in a hospital that is responsible for assuring safe and competent care of patients. Although a hospital administration also has responsibility for assuring quality care, the administration also has a fiduciary duty to assure the profitable operation of the hospital, a goal that may conflict with optimal care of individual patients.

Hospital attorneys, or attorneys who have a conflict of interest in simultaneously representing the hospital administration and medical staff, influence the peer-review process and thus violate due process and fundamental fairness. Although a medical staff can hire its own independent attorney to give advice concerning the peer-review process, peer review should be performed by peers (other physicians on staff) and should not be influenced by the hospital administration, or its attorney or a conflicted attorney, prior to the matter reaching the level of the hospital board of directors.

#### **Bias**

Hospitals that employ sham peer review frequently bias the peer-review proceedings in a number of ways, including: stacking the investigative committee or hearing panel with physicians who have personal animus or bias against the accused physician; allowing the prosecution much more time to review records or present the case than the targeted physician; unfairly limiting the time allowed for the physician to present his case; disallowing evidence or testimony that may be favorable to the targeted physician; differential treatment of the physician whereby the targeted physician is treated more harshly than his colleagues for a similar alleged offense; use of the hospital "rumor mill" to spread negative and highly damaging rumors about the targeted physician while the peer-review process continues, and many others.

Hospitals that use the "rumor mill" to damage the targeted physician's reputation, and influence the peer review process, may also file improper or false reports with the National Practitioner Data Bank (NPDB) so as to permanently damage or end a physician's career. Hospitals will also frequently not allow the physician to hire a court reporter to provide an independent record of the peer review hearing, opting instead to provide a record kept by the prosecuting hospital. No court of law, of course, would permit a record of a hearing to be kept solely by the prosecutor, as it would introduce bias and would be patently unfair to the accused.

#### Peer Validation of Tactics Characteristic of Sham Peer Review

The information in this current editorial about tactics characteristic of sham peer review was presented to two large groups of physicians in June and July, 2009 (AAPS meeting in Dallas, Texas,

on Jun 5, and at the Florida Medical Association annual meeting on Jul 25). Following the presentation, a survey question was posed to these two large groups of physicians: "Are any of the tactics reviewed in this presentation fundamentally fair to physicians subject to peer review, and do any of these tactics comply with due process for the accused physician?" Not a single hand in the audience at either meeting was raised, indicating that the tactics reviewed are indeed characteristic of sham peer review, because they do not provide fundamental fairness or due process for the physician under review.

#### Implications for Physicians Who Conduct Peer Review

AAPS supports peer review done in good faith for the purpose of furthering quality care and protecting patients. Physicians who serve on peer-review committees need to be vigilant and diligent in conducting fair peer review. Physicians need to be aware that those who are choreographing the process and presenting the case may have underlying motives that have nothing to do with assuring quality care. Peer reviewers need to ask questions, and personally review cases, complaints, and incident reports, rather than relying on summaries provided by the hospital.

Protecting patients and assuring competent care must be balanced by a process that provides substantive due process and fundamental fairness to the physician under review. Peer reviewers need to recognize that an accused physician's medical career and livelihood are at stake, and any adverse action taken should be justified by full and impartial consideration of all the facts.

**Lawrence R. Huntoon, M.D., Ph.D.,** is a practicing neurologist and editor-inchief of the *Journal of American Physicians and Surgeons*. Contact: editor@jpands.org.

#### Will Your Grandchildren Be Able to See a Private Physician?

The answer to that question probably depends on this one: Will AAPS, the voice for private physicians, remain strong?

AAPS has defended private medicine for more than 60 years—since 1943. AAPS relies on the generosity of its members to survive and thrive. Please remember AAPS in your will or charitable annuity. This is your opportunity to send a Final Message in support of freedom and private medicine. Every gift helps, no matter how small.

For information on making a bequest, call or write: Andrew Schlafly, AAPS General Counsel 939 Old Chester Rd., Far Hills, NJ 07931 (908) 719-8608 or aschlafly@aol.com





# Exhibit P2

#### **Editorial:**

# The Psychology of Sham Peer Review

#### Lawrence R. Huntoon, M.D., Ph.D.

As sham peer review has spread across the nation, it has left behind a trail of broken and ruined lives and careers of good physicians. Although each case is unique, there are certain common features underlying the psychology of sham peer review.

#### Psychology of the Sham Peer Review Process

Sham peer review is a premeditated process that begins long before the actual sham peer review hearings and formal proceedings. It begins in the minds of those who set out to destroy a targeted physician. Improper motives, having nothing to do with furthering quality care, drive the process.

The process of sham peer review frequently involves a progressive series of small attacks leading up to a final formal proceeding designed to end the targeted physician's medical career. Sometimes these trial runs may go unnoticed or seem insignificant to the targeted physician. Meanwhile, the hospital often secretly collects, compiles, and even solicits documentation to be used in the final attack at a later date.

The final attack (formal sham peer review proceeding) is often well planned and well choreographed so as to give the appearance of a legitimate, good-faith peer review action. The appearance of due process and fundamental fairness is given top priority, although substantive due process and fundamental fairness are always lacking in sham peer review.

#### Psychology of the Attackers

Although there are some cases in which one or a few participants in the sham peer review proceedings are lazy and negligent and simply defer to the leaders of the attack in casting their vote against the targeted physician, in most instances those who participate in the sham proceedings know exactly what is going on.

The psychology of the attackers is a combination of the psychology of bullies and that of the lynch mob. The attacks are typically led by one or a few bullies who have gained positions of power over others and who enjoy exercising and abusing that power to attack and harm the vulnerable. Although there is always some improper motive that precipitates the attack, the attack itself often serves to distract attention from the bully's own underlying shortcomings, deficiencies, insecurities, and cowardice.

Sham peer review is by nature a group effort involving collaboration between unethical hospital administrators and unethical physician attackers. The psychodynamics involve both the excitement of the hunt and the raw power of the lynch mob that often develops a life of its own, leading to actions that individuals would likely not take if acting alone. It is the psychology of predators versus prey. Others are drawn into the group hunt via the same type of macabre attraction that often compels people to turn their heads and gawk as they drive slowly by the car wreck, looking for any sign of mangled or dead bodies.

The power to snuff out the career and livelihood of a fellow physician in the blink of an eye provides a certain pathological satisfaction and excitement for some attackers. To share in the "group hunt" is to share in some of the power and excitement. And the nearly absolute immunity the attackers enjoy under the Health Care Quality Improvement Act (HCQIA) and the doctrine of judicial nonintervention further emboldens and enhances the power of the attackers.

#### Psychology of the Physician Victim

Facing superior power and numbers, the targeted physician soon understands that he is the prey and the hunt is on. The final attack is often unleashed quite suddenly and with great fury. The resultant shock and awe often causes a sudden loss of energy and a mental numbness that impairs the physician victim's ability to defend himself effectively. This often further excites the predators as the deer stands motionless, caught in the headlights.

Shock and awe is followed quickly by denial and disbelief. This is frequently accompanied by a strong belief that the truth will save the victim and set him free. Meanwhile, the stigma attached to mere allegations of wrongdoing produces an intended isolation of the targeted physician. As a result, the physician victim often shuns contact with colleagues, further assisting the predators in cutting the prey out from the herd in preparation for the kill.

At this stage, alone and isolated, facing almost certain demise, extreme fear sets in. How will the physician provide for his spouse and children? How will he cope with the bills that are mounting up now that the attack has stopped cash flow? How will he survive?

Constantly living in an adrenaline-soaked fight-or-flight state further depletes the victim's energy and is often accompanied by significant depression, complete with severe sleep disturbance (too much or too little), weight loss, and a pervasive feeling of helplessness and hopelessness. The risk of "death by stress" or suicide is very real at this stage.

Anger emerges as the physician victim comes to recognize that the truth and the facts do not matter at all in sham peer review since the proceedings are rigged and the outcome predetermined. The procedural presumption is that the physician is "guilty" and the burden is shifted to the physician to prove his innocence—a burden that the attackers will never allow him to meet. Anger is often accompanied by a consuming desire to hold the attackers accountable for their evil deeds. This not infrequently leads to many years of litigation, further depleting the victim's energy and resources, and consuming the lives of the ruined physician and his family.

Chronic fear and anger often take a heavy toll on the physician's physical and mental well-being, and on his relationship with family and others. The resulting downward spiral often leaves the physician devastated, still alive physically, but invisible or "dead" to former colleagues and to the profession of medicine. It is a cold and lonely pit that no one could have envisioned upon entering the profession of medicine.

#### Psychology of the Enablers

Enablers are those physician bystanders who are aware that the sham peer review attack is taking place, but who stand by and do nothing to object or to stop it. It is the psychology of the herd that stands placidly by while one of its own is cut out from the herd and killed. Enablers are like the timid sheep who huddle close together, keeping their heads down, in the hope and belief that the predator's appetite will be satisfied with the "kill," leaving the rest of the herd to graze in peace.

In many instances, a few vocal physician bystanders may be all that it would take to stop the bully's attack. Expressing objections to individual physicians could also destroy the psychodynamics that impel a lynch mob.

Although bullies who launch vicious attacks against physician colleagues may be beyond redemption, renewal of professional ethics through education, and urging of the physician bystanders to get involved, may help to stop the spread of sham peer review. It may be the only hope.

Unless ethical physicians stand up and object, and hold the unethical physicians accountable for their actions, the spreading moral malignancy of sham peer review will irreparably harm patient safety, medical excellence, and the integrity of the medical profession.

**Lawrence R. Huntoon, M.D., Ph.D.,** is a neurologist practicing in New York and serves as Chairman of the AAPS Sham Peer Review Committee.

### Exhibit Q

State should be permanently limited to prohibit him from performing high forceps and midforceps rotations or deliveries. This determination was reached upon due consideration of the full spectrum of penalties available pursuant to statute, including revocation, suspension and/or probation, censure and reprimand, and the imposition of monetary penalties.

The Hearing Committee believes that Respondent has the requisite knowledge and skill to practice medicine safely, but that he has repeatedly failed to exercise the care that a reasonably prudent physician would exercise under the circumstances. The Committee sought to fashion a penalty that would permit Respondent to continue to practice his chosen profession while ensuring the safety of his patients.

The Committee feels that 30 days of actual suspension must be imposed to provide a period of time during which Respondent can reflect upon his prior misconduct and redirect his energy and focus towards practicing medicine within accepted standards. In addition, Respondent's inability to practice for that period of time will serve as a penalty by having a significant monetary impact.

A suspension of Respondent's license, stayed after 30 days for the remainder of a two-year period provided Respondent complies with terms of probation, is necessary to ensure that Respondent practices medicine within accepted standards. In spite of his

# SMITH, SOVIK, KENDRICK & SUGNET, P.C.

Exhibit R

ATTORNEYS AT LAW

250 SOUTH CLINTON ST., SUITE 600 SYRACUSE, NEW YORK 13202-1252

315-474-2911 INTERNET www.smithsovik.com

FACSIMILE: 315-474-6015

MICHAEL PAUL RINGWOOD Voice Mail Extension 121 mringwood@smithsovik.com

August 9, 2004

WILLIAM E. SUGNET, RETIRED
JAMES A. O'SHEA, RETIRED
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JOHN TIMOTHY SMITH (1902-1964) NELSON J. SMITH (1923-1967) MARTIN F. KENDRICK (1917-1983) LAURENCE SOVIK (1904-1998)

LAURENCE F. SOVIK
JAMES D. LANTIER
MICHAEL P. RINGWOOD
KEVIN E. HULSLANDER
ERIC G. JOHNSON
STEVEN WARD WILLIAMS
MARY KENDRICK-GAFFNEY
JAMES W. CUNNINGHAM
ROBERT P. CAHALAN
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KRISTIN L. NORFLEET
PATRICK B. SARDINO
KRISTEN M. BENSON
JENNIFER L. PLOETZ
J. WILLIAM SAVAGE
DAVID A. D'AGOSTINO
KAREN M. RICHARDS
NICOLE M. TRUE
MATTHEW H. WOODARD
DANIEL E. DYER

New York State Dept. of Health Office of Professional Medical Conduct 217 South Salina Street Syracuse, NY 13202 Attn: Mr. David Britton

New York State Dept. of Health Office of Professional Medical Conduct 217 South Salina Street Syracuse, NY 13202 Attn.: Harriet Tetley, RN, BPS

Attn.: Harriet Tetley, RN, BPS

Nurse Investigator

Re: OPMC# SY-04-02-0616A James R. Caputo, M.D.

Dear Mr. Britton and Ms. Tetley:

On Friday afternoon 7/30/04, we confirmed that Dr. Caputo will appear for interview regarding patients, B and V and on August 18, 2004 at 9:30 a.m. (I must be finished by 11:30 am at the latest due to another appointment).

At Dr. Caputo's request, I asked Ms. Tetley to see if we can arrange to tape the interview. She indicated this is not allowed. I am a bit surprised at the response. Counter-parts at the Department of Education prefer and always ask the licensees if they will consent to interview taping.

I am asking that you re-consider and get back to me as soon as possible, as this might cause Dr. Caputo to reconsider his decision to be interviewed. I had planned to bring my dictation device for use; preserve the original tape(s) for our mutual use; and prepare a transcript to share. I would be more than happy to finance a stenographer for the work. In any event, please get back to me regarding the request.



SMITH, SOVIK, KENDRICK & SUGNET, P.C.

August 9, 2004 Page 2

May I also ask that you forward copies of the full hospital charts you have on each of these three patients so that Dr. Caputo will have had time to review them in order to be able to participate fully in the interview.

Very truly yours,

Michael Paul Ringwood

MPR/csw

cc: James R. Caputo, M.D.

B.P.S. to Dr. Caputo:

THEY'VE DECLINED MY REQUEST TO TAPE. I'VE PITCHED THEM TO RECONSIDER. PLEASE LET ME KNOW IF THIS IS A MAKE OR BREAK ISSUE. PENDING A FINAL DECISION, PLEASE SCHEDULE THE ENTIRE MORNING OF 8/18/04 TO BE WITH ME STARTING IN MY OFFICE AT 8:00 AM.

Exhibit S1

SUPREME COURT STATE OF NEW YORK

COUNTY OF ALBANY

In the Matter of JOHN DOE, M.D.,

Petitioner.

ORDER AND ORDER
TO SHOW CAUSE

Index No.

Upon reading and filing the Affidavit of John Doe, M.D., petitioner, and upon all papers heretofore served or filed and all proceedings had herein, it is hereby

ORDERED that the Respondent Board of Professional Medical Conduct, SHOW

CAUSE at a Special Term of the Court to be held in and for the Country of Albany at the Albany
Country Courthouse, Albany, New York, on the day of December, 2007, at dooin the
noon of that day or as soon thereafter as counsel can be heard why an order should not be
granted providing for a preliminary injunction staying the penalty imposed by the

Determination and Order of the committee on professional medical conduct and enjoining the

State of New York and Department of Health from publishing the Determination and Order
pertaining to petitioner in any forum and for an Order directing immediate removal of

Determination and Order from the OPMC website, and for an order allowing petitioner to
continue with this proceeding anonymously; and further for an Order and Determination that
petitioner is entitled to an automatic stay pursuant to Public Health Law §230-C(4)(a), and it is
further,

ORDERED that petitioner is hereby granted a temporary restraining order such that the State of New York and the Department of Health are hereby restrained from enforcing the

(except for Michael Forcept Michael Forcept 12/6/07 Hearing Committee Determination and Order and any of the penalties contained therein

and are restrained from making any of the subject matter of the Determination and Order available to the public, absent further, additional or alternative orders of this Court are

forthcoming, and it is further,

ORDERED that service by delivery to the New York State Attorney General's Office in

Albany, New York and on the Office of Counsel to the New York State Department of Health at

Corning Tower in Albany, NY on or before December 23, 2007, shall be deemed good and

sufficient service.

12/07 K

Josephane Due 1

DATED: /2//3/8

Hon. Joseph C.

Justice of the Supreme Court

ENTER:

In Albany County, except for Special Proceedings, original motion papers (and cross motion papers) shall be filed with the Supreme Count Clerk after paying the required motion filing fee to the Albany County Clerk. All answering papers shall be filed with the Supreme Court Clerk. Personal appearance on the motion is not required.

TO: State of New York
Department of Health
Bureau of Professional Medical Conduct
Room 2512, Coming Tower
Albany, NY 12237

New York State Attorney General Department of Law The Capitol Albany, NY 12224-0341

## Exhibit S2

STATE OF NEW YORK SUPREME COURT

COUNTY OF ALBANY

JOHN DOE, M.D.

Petitioner,

-against-

DECISION and ORDER Index No.: 9849-07 RJI No.: 01-07-ST8364

DEPARTMENT OF HEALTH, STATE BOARD OF PROFESSIONAL MEDICAL CONDUCT

Respondent.

Supreme Court of Albany All Purpose Term, January 25, 2008 Assigned to Justice Joseph C. Teresi

#### **APPEARANCES:**

Michael Paul Ringwood, Esq. Smith, Sovik, Kendrick & Sugnet, P.C. Attorneys for Petitioner 250 South Clinton Street Syracuse, NY 13202-1252

Richard Lombardo, Esq.
Office of the Attorney General of the State of New York
Attorneys for Respondent
The Capitol
Albany, NY 12224

Timothy J. Mahar, Esq.
New York State Department of Health
Attorneys for Respondent
Bureau of Professional Medical Misconduct
Room 2512, Corning Tower
Albany, NY 12237

#### TERESI, J

Petitioner, by petition, seeks an order pursuant to Public Health Law §230-c(4)(a), Public Health Law §230-c(5), CPLR §7805, and CPLR Article 63, staying the Determination and Order

("D&O") of the Hearing Committee ("Committee") of Respondent, and enjoining Respondent from enforcing and publicizing the D&O. Respondent opposes the petition.

Petitioner (anonymous status), a medical doctor licensed to practice medicine in the State of New York, was charged with medical misconduct under the Education Law of the State of New York via a Notice of Hearing and Statement of Charges dated May 10, 2007. The Committee held a hearing from June 22, 2007 to August 28, 2007, ultimately finding Petitioner guilty of misconduct. The D&O, dated December 6, 2007, included a penalty ordering a two-year suspension of Petitioner's license. Only the first thirty days of the penalty was effective; the remainder was stayed.

Following submissions by Petitioner, this Court granted a Temporary Restraining Order, dated December 17, 2007, staying the license suspension and enjoining the Respondent from publishing the D&O. Petitioner then brought this action to permanently stay the license suspension pending review by the Administrative Review Board. Petitioner claims that, as the only OB-GYN in his medical practice, the penalty will cause irreparable harm to his patients and his reputation. Additionally, Petitioner has posted non-anonymous comments on a website concerning the D&O.

Public Health Law §230-c(4)(a) provides that "[a]ny penalty imposed by the order of the committee on professional medical conduct, other than a penalty of annulment, suspension without stay or revocation, is stayed by the service of the notice of review upon the administrative review board and remains stayed until the review board renders its determination." Further, Public Health Law §230(10)(g) provides that "[t]he committee's findings, conclusions, determinations and order shall become public upon issuance in any case in which annulment,

suspension without stay or revocation of the licensee's license is ordered."

After a full review of the record, this Court declares that the D&O is stayed, that the Respondent is enjoined from enforcing the D&O, and that the Petitioner has waived anonymous status.

Here, the Committee's D&O includes a two-year suspension, with only thirty days effective. Thus, the penalty was a suspension with a partial stay. Public Health Law does not define the term "suspension without stay," and no case law has directly addressed this issue. However, it is notable that the statute contains the general term "suspension without stay," rather than one of the more specific terms sought by Respondent, such as "actual suspension" or "suspension with partial stay." Further, a suspension with full stay, by its nature, is already stayed without need for the automatic stay provision. Thus, Respondent's interpretation that only a "suspension with full" stay triggers the automatic stay provision actually renders the provision meaningless.

Consequently, a fair reading of Public Health Law §230-c(4)(a) is that a partially stayed suspension is not a "suspension without stay," and thus qualifies for the automatic staying provision. For that reason, the partial suspension of Petitioner's license is stayed, and the Respondent is enjoined from enforcing the penalty, pending review by the Administrative Review Board. However, as Petitioner has compromised his anonymity by making non-anonymous posts on the internet concerning the D&O, Petitioner has waived anonymous status.

All papers, including this Decision and Order, are being returned to the attorney for Petitioner. The signing of this Decision and Order shall not constitute entry or filing under CPLR §2220. Counsel are not relieved from the applicable provisions of that section respecting

filing, entry and notice of entry.

So ordered.

Dated: March 18, 2008

Albany, NY

OSEPH C. TERESI, J.S.C.

#### **PAPERS CONSIDERED:**

- 1. Petition, dated December 17, 2007, with attached Affidavit, of Michael Paul Ringwood, Esq., dated December 17, 2007, with Attached Exhibits A-I
- 2. Verified Answer, of Richard Lombardo, Esq., dated January 18, 2008.
- 3. Affidavit, of Timothy J. Mahar, Esq., dated January 18, 2008, with Attached Exhibits A-F.
- 4. Reply Affidavit, of Michael Paul Ringwood, Esq., dated January 22, 2008, with Attached Exhibits J-K.

§ 230

nal misconctice which an adminisne or more nay include. lical society is shall be be used as ever, in the censee, the ided in this

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issued an e records and the ctor may ensee, for ourt shall ble basis o believe ourt may

f profesf section sixty-five hundred thirty of the education law, the director may direct that charges be prepared and served and may refer the matter to a committee on professional conduct for its review and report of findings, conclusions as to guilt, and determination. In such cases, the notice of hearing shall state that the licensee shall file a written answer to each of the charges and allegations

in the statement of charges no later than ten days mice to the bearing that any charge or allegation not so answered shal the licensee may wish to seek the advice of counsel that the licensee may file a brief and affidavit professional conduct, that the licensee may app committee on professional conduct, may be repres present evidence or sworn testimony in his or her contain such other information as may be consi director. The department may also present evider file a brief at the hearing. A stenographic reco made. Such evidence or sworn testimony offe professional conduct shall be strictly limited to evi ing to the nature and severity of the penalty to be Where the charges are based on the conviction of jurisdictions, evidence may be offered to the commi the conviction would not be a crime in New York professional conduct may reasonably limit the m testimony will be received and the length of time ar to testify. The determination of the committee licensee and the department in accordance with t (h) of this subdivision. A determination pursuant

administrative review board for pr (q) At any time subsequent to the final conclusion of a professional misconduct proceeding against a licensee, whether upon the determination and order of a hearing committee issued pursuant to paragraph (h) of this subdivision or upon the determination and order of the administrative review board issued pursuant to paragraph (d) of subdivision four of section two hundred thirty-c of this title, the licensee may file a petition with the director, requesting vacatur or modification of the determination and order. The director shall, after reviewing the matter and after consulting with department counsel, determine in the reasonable exercise of his or her discretion whether there is new and material evidence that was not previously available which, had it been available, would likely have led to a different result, or whether circumstances have occurred subsequent to the original determination that warrant a reconsideration of the measure of discipline. Upon determining that such evidence or circumstances exist, the director shall have the authority to join the licensee in an application to the chairperson of the state board for professional medical conduct to vacate or modify the determination and order, as the director may deem appropriate. Upon the joint application of the licensee and the director, the chairperson shall have the authority to grant or deny such application.

Reporting of professional misconduct

(a) The medical society of the state of New York, the New York state osteopathic society or any district osteopathic society, any statewide medical specialty society or organization, and every county medical society, every person licensed pursuant to articles one hundred thirty-one, one hundred thirty-one-B, one hundred thirty-three, one hundred thirty-seven and one hundred thirty-nine of the education law, and the chief executive officer, the chief of the medical staff and the chairperson of each department of every institution which is established pursuant to article twenty-eight of this chapter and a comprehensive health services plan pursuant to article forty-four of this chapter or article forty-three of the insurance law, shall, and any other person

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.  Print your name and address on the reverse so that we can return the card to you.  Attach this card to the back of the mailpiece, or on the front if space permits.	A. Signature  X
1. Article Addressed to: Keith W. Servis NYS DOH	D. Is delivery address different from item 1? ☐ Yes If YES, enter delivery address below: ☐ No
433 River Street Suite 1000 Troy, MY 12180-2299.	3. Service Type  ☐ Certified Mail ☐ Express Mail ☐ Registered ☐ Return Receipt for Merchandise ☐ Insured Mail ☐ C.O.D.
(100), 10   (200 - 17)	4. Restricted Delivery? (Extra Fee) ☐ Yes
Article Number     (Transfer from service label)  PS Form 3811, February 2004  Domestic Retains	7013 1090 0001 4724 3820 urn Receipt 102595-02-M-1540

Exhibit U1

Board Certified in Obstetrics and Gynecology

Syracuse, New York 13210 (315) 475-8599

July 10, 2013

Exhibit U2

Keith W. Servis, Director Office of Professional Medical Conduct New York State Department of Health 433 River Street, Suite 1000 Troy, NY 12180-2299

Re: BPMC Order #: 07-271

NYS Medical License #: 206065

Dear Mr. Servis,

Please accept this letter of petition requesting both a vacatur and a modification of a current Board Order with regard to my New York State medical license. This Order was the outcome of a matter adjudicated by the Department of Health between 2002 to 2008. It is with sincerity that the requests being made in this writing be received with true contemplation and understanding as to what is being asked. It will need your careful and perhaps repeated reading of this material to appreciate the level of concern that drives this meritorious effort. As you are aware, a great deal hinges upon your favorable response as the one person who holds the authority to then follow through with the current Chairperson of the State Board for Professional Medical Conduct to act accordingly. Understanding how monumentally busy your schedule must be, several thousand people (who stand to be impacted), are relying on the worthiness of this presentation to stir your heart to act on their, as well as my entire family's, behalf. So given the monumental importance of this matter to so many, your time and attention is honestly and truly appreciated.

The Issue in Summary: As a result of the above referenced Board Order in 2008, there have been a number of effects which have created a great deal of difficulty for my practice of medicine as an Ob/Gyn physician. As can be seen from the Order itself, three separate conditions were imposed upon my license. The first was a limitation to the license itself, particular to the use of high and mid forceps when performing a vaginal delivery. The second was a requirement to carry malpractice insurance coverage limits of \$2 million/\$6 million. And the third was the requirement of a practice monitor. The last two were to be enforced for a period of three years. These individual components will be addressed separately in order to illustrate precisely why, since being so commanded, each one has stifled (and really crippled) my ability to maintain gainful employment as a physician in New York, resulting in a tremendous detriment to my family. As such, pursuant to **Public Health Law**, Section 230(10)(q), it is my position that the petition that is to follow offers both "new and material evidence that was not previously available which, had it been available, would likely have led to a different result" along with "circumstances which have occurred subsequent to the original determination that warrant a reconsideration of the measure of discipline" and thus serve as the basis for the filing of this "petition with the director, requesting a vacatur and/or modification of the determination and order."

In addition to pointed argument and reason, this petition will make both references as well as directly discuss your statements as written in your March 24, 2011 response letter to me when, at that time even, I sought similar help from your office for similar reasons. In responding to some of your points, it will necessitate the occasional reference to already admitted evidence from the hearings, since this "material evidence" is pertinent to the discussion of these previous statements. The actual matter of my previous hearings is certainly over and done with and therefore no further argument of the issues will be entertained. However, given that I am directly entreating the authority of the director of this presiding State Office, some of the facts already in evidence need to be clear so as to appreciate the fairness and appropriateness of what is presently being asked regarding the substantial and moreover disproportionately punitive effects of the Board Order that indeed resulted from these hearings. Particular examples of admitted evidence are offered merely as another means of providing additional weight to the already meritorious contention being so submitted alongside it.

#### License Limitation in the areas of High and Mid Forceps Deliveries

This one component of my Order has created a most profound difficulty at sustaining any gainful employment in medicine. Therefore, submitted in support is new material evidence that is worthy enough to warrant a reconsideration and an appropriate modification to the Order as it pertains to this matter.

First, the degree by which adverse outcome continues to be personally and professionally experienced as a result of this imposed limitation mandates a little perspective to be illustrated. With all due respect to the past hearings, if you can, (for the moment), proportionally consider the real-life insignificance of what this official limitation on my license actually represents to the medical practice of Obstetrics alone (not to mention the addition of the whole of Gynecology), it is then difficult to understand how this clinically negligible restriction on an already rare procedure (which is even more rarely performed) could undermine an entire medical career, as it has in my case. Having been limited from performing a procedure that amounts to less than 0.1% of what is encountered across the entire spectrum of Ob/Gyn, only to have it literally wipeout the remaining 99+% is just plain wrong. The reason that this is the case is because of the actual word "limitation" being associated with my license. It turns out that if the word is there, then you are excluded, denied, shut-out – from almost everything. This is even regardless of the fact that the true "limitation" itself (in this case) is clinically irrelevant for not only me but would be for any Ob/Gyn in being able to fully care for any given patient.

In my case, the impairment experienced in all areas of being able to gainfully work has <u>proven</u> to be from the <u>word itself</u> and not the contextualized inconsequentiality of what the limitation is in reality. Because if the latter were the case, the insignificance of the restriction would be otherwise clearly visible upon suitable explanation of both the facts and clinical relevance such that common sense would then rule and the issue gotten past. While the Board indeed has a duty to protect the public, how its disciplinary action is implemented has shown to be critical to the future employability of any given physician, as will be further explained.

Regardless of whatever issue any given doctor faces with the Department of Health, (DOH), by and large, physicians earnestly offer their best when providing care to their patients and have, (as we all know), invested years of education and training in order to sustain this profession for a lifetime. It should <u>not</u> be an automatic consequence of a Board Order, therefore, to render any doctor, who might otherwise have had an unfavorable interaction with the DOH, essentially unemployable for life due to what boils down to be (in many cases) a labeling issue. Especially when no prior allegation (disputed or not) was ever so odious to warrant such a devastating end result. This is what has been encountered in my experience and by many others I imagine.

When considering just what my limitation is in reality – clinically that is – then the real-life penalty that has literally come with it, (again, due in large part to the word "limitation" itself, which continues to nullify any potential endeavor as a physician), is monstrously out of proportion with what was intended by the DOH as well as what was in evidence leading to this determination in the first place, regardless of which side one might be representing.

In order to be able to sustain any sort of practice of medicine, one needs patients. In order to be able to see patients, one must be participating with any number of various health insurance carriers. Of course, liability insurance is imperative as well. And lastly, depending on a particular physician's specialty, they might also require hospital privileges. All of these requisite components to medical practice require credentialing and are not only encumbered whenever there is a restriction on one's medical license, but in many cases, it becomes impossible to successfully navigate the process at all due to this glaring label. No amount of explanation and appeals are sufficient enough to overcome this hard and fast policy by many institutions, corporations as well as our own Federal Government. If you have any sort of "limitation", you are not welcome – regardless of what the limitation actually is – even if it is clinically irrelevant, as I have mentioned perhaps half a dozen times already – (please forgive the necessary emphasis). The moniker of "damaged goods" is really that profound and far reaching. But more than that, it is unfair and undeserved. And again, what's all the more distressing with my case in particular is that my license restriction is for two procedures that have absolutely no bearing whatsoever on my ability to safely and effectively practice my entire specialty and are pretty much never encountered or ever need to be carried out given the availability of cesarean section as the most widely used alternative. Yet, despite the inconsequentiality of the entire thing, as you will soon understand, my practice has been made nearly impossible to sustain as a result of the stigma which bears this name "limited license".

This last point needs to be expounded upon just a little more in order to truly understand the substance of this component of my petition. Please follow along. Per the Board Order, I have been limited (or restricted) from using "high forceps" and "midforceps" (the latter for both deliveries and rotations of the baby – understandingly very complex issues). For the sake of reference, the level of descent of the baby's head in the birth canal is what determines the type of forceps (mid vs low vs outlet) when implementing these instruments. What's important to understand is that the first restricted type (high forceps) have already been *unofficially* outlawed from within the specialty itself for nearly four decades; they have never been a part of my clinical practice; and they were never mentioned nor the subject of any interest in all of my past interaction with the Department of Health. A restriction from using "high forceps" should therefore not even be listed as a limitation at all since they are already forbidden. All this limitation does is provide more negative perception, especially for those who don't understand these things.

This leaves the midforceps (deliveries and/or rotations) as the one true clinically applicable limitation in my case. In order to tangibly appreciate the (real life) insignificance of this limitation as well, it must be clarified as to just how infrequently encountered this procedure is in all of Obstetrical medicine. This is really critical to understand in all of this. First of all, forceps deliveries are seldomly done anymore anyway – chiefly because no one is being trained in them. So, of all the Obstetricians practicing in NY State alone, an educated guess would be that only 5% are still *actively* implementing forceps as part of their practice. The other 95% either opt for the vacuum device as the only other (and much less effective) alternative for assisted vaginal delivery or just do a cesarean section whenever faced with a clinical situation that would call for these decisions. A decision like this for assisted (or operative) vaginal delivery comes up perhaps once in 10 – 30 deliveries (perhaps more), given the unpredictable and highly variable

nature of Obstetrics. Yet, of those who still use forceps for these limited number of clinical circumstances, the "low" and "outlet" classification of forceps comprise nearly 98% of attempted cases. [Incidentally, my license remains approved for these two types.] This leaves an extremely small number of potential midforceps scenarios that might even be encountered as the only other kind that actually applies to my limitation situation. What's more is that there are even fewer forceps using physicians in the State who possess the skill to even carry-out this advanced option. All others, (those who don't use forceps at all, or just don't use mid forceps or even don't use vacuum), simply perform a cesarean section. And this is a significant percentage of Obstetricians as well. So again, to have two limitations: one from doing something that is already outlawed and a second which is so rarely encountered and even more uncommonly implemented because a more widely acceptable alternative (that being cesarean section for which I have no restriction) is readily available, the only purpose this present limitation is serving is to detriment my ability to work as a duly licensed, board certified physician in New York State simply by the label being there, when in reality it represents essentially nothing clinically relevant to the effective practice of Obstetrics and Gynecology. Please see this point as clearly as it is.

As a result of being restricted from performing a procedure that is so rare that I might have to go two years before having a clinical encounter so as to even apply the limitation in the first place, the damage cannot be understated. I have been directly excluded from six major insurance carriers as a result of this "limitation" being present on my license as their only reason. It is apparently company policy to exclude anyone with such a label. No exceptions. This is even after submitting written statements as to the clinical unimportance of this limitation in being able to fully practice my specialty (as argued above). To add to the difficulty, I have been outright excluded from applying to the medical staffs of two of the three hospital's in my community because they each have a specific policy barring any applications by anyone with a limited license. One of them is actually a New York State owned and run teaching institution where I am not only an alumnus but where I was previously on staff for more than ten years! Now only to be excluded. And this exclusion is not subject to any appellate rights within the institution either. In other words, you're out and you can't even appeal the issue. The same applies for liability insurance carriers as well. The limitation has automatically excluded me from two of the three admitted carriers in NY State. As for jobs themselves, even places that are otherwise eager or desperate for a physician are not even possible options for me. For example, I couldn't even apply for work on an Indian Reservation because the federal government has a strict policy about any limitation on a license being an automatic exclusionary criterion.

Hopefully, you can thus far appreciate the magnitude of the impact and the extensive reach that can result from these otherwise well-intentioned Board Orders. Surely the DOH has a duty to protect the public from bad medicine which I'm not even claiming is applicable to my case, but regardless, somewhere in all of this should also be what is personally *good for* and moreover, *desired by* the public/patient. One significant benefit or desire for any patient is to have their longstanding doctor available to them so long as he/she is deemed fit to practice. I have met this designation of fitness yet due to the limitation on my license, my availability is not only null for a great many patients who wish to return, it is in jeopardy of being indefinitely vanquished for all. Realizing that the Board has their interest in the matter to uphold as well, I request the following *modification* to my Order in this area of license limitation which will then have an effect <u>only</u> on the "appearance" of my license while continuing to satisfy the specific restrictions.

Considering the information from above describing the detriment to my practice, heightened by the actual non-applicability of the imposed limitations to both the full practice of Obstetrical medicine as well as my own practice, I ask that they be removed. They have no bearing

whatsoever on my practice of medicine (or any Obstetrician's for that matter) that they should remain in place on my license. It is like putting a restriction on a particular Nascar driver's license for knitting while he is racing. It's something that he will never do while engaging in his day-to-day profession, so it's meaningless, right? That's until he tries to enter his next race and encounters the hard line policy that states any driver with a limitation on his/her license is ineligible. It matters not if it was for the ridiculous notion of knitting while racing, a limitation is a limitation and thus you are out. Case closed. Strange analogy but it illustrates the point well.

To be clear though, I am not asking for the terms of the license limitation to be abandoned as they are not only straight forward to comply with but also signify the standing decision from the hearing (and thus the Board) itself. However, I am fully prepared to sign whatever statement/agreement necessary (please see attached) that continues to sustain the current forceps limitations and prohibitions to my license while simultaneously removing the wording from the official documentation. The agreement should also require me to eliminate and/or forego midforceps from any and every staff delineation of privilege list or application and provide documentation to the Board for each applicable hospital of this having been done (or established). In essence, I will never be able to perform another midforceps delivery again since there would be both a standing agreement between us as well as no hospital privileges at all for being able to do one. This was the objective of the Determination and will forever be satisfied. As for high forceps deliveries - as stated earlier, they are already outlawed and thus no one has (or ever will have) sanctioned privileges to do them. The agreed upon language should even state that I am to immediately surrender my license if at any time in the future, via any investigative means, I am legitimately found to have violated this accord as it pertains to mid and high forceps – the precise terms currently. With the fundamental purpose of my Board Order being to eliminate a certain type of forceps delivery from my practice while otherwise approving me to move on in my medical career, I urge you to consider this request since it accomplishes all of it. With my current state of affairs, this once intended expectation of simply moving on from my experience with the DOH is monumentally askew from reality and hence the driving force behind this petition.

I do not want to neglect addressing any pertinent points made by you in your previous letter. Pertaining to this issue specifically, you pointed out the ARB's conclusions. Again, this is not the forum to re-contend the allegations. I will say that in evidence is the following. First, at no time in any case where I clinically determined (via my experience, opinion and/or skill level) that the use of forceps was prudent was any mother or baby unduly harmed. Never. Secondly, as for the use of forceps after the hospital limited me for six months, in evidence is the fact that the hospital was indeed compelled to modify this restriction thus allowing supervised performance during the imposed time frame. When the sanctioned term was up, all privileges were returned without limit since no violation of the restriction was alleged by those who imposed it. Nonetheless, as already written, I am not asking for a complete vacatur of these terms of the Order, just a restructuring of how it appears.

Therefore, with the submission of the documents showing repeated denial of participation with both health insurance companies as well as admitting institutions, along with the profound and lasting financial detriment due to my inability to sustain any sort of employment in medicine, I believe that new and material evidence exists and circumstances have occurred subsequent to the original determination that warrant reconsideration of this measure of discipline. It is argued that had the State been able to foresee the fact that five years following the relatively small scale of limitation which was actually imposed upon this subject's license that he would be penniless, jobless and unemployable as a result of it all, then they might very well have opted for a different means to achieving their ends – hence, the submitted proposed agreement. Thus, because of

these circumstances, a reconsideration is warranted as to the measure of the discipline. The proposal put forth herein satisfies both the interests of the State as well as the petitioner in order that your consideration might be received.

#### **Liability Insurance limit requirements of 2M/6M**

Perhaps equally as critical to my present ability to practice medicine has been the matter of liability insurance. In fact, at the present time, it is the most pressing issue. I understand clearly from your previous letter that PHL 230 (18)(b) mandates the limits stated. Yet, the requirement to have double the malpractice insurance coverage has had the greatest impact overall on my ability to sustain my career. It was the very reason why my first attempt at reestablishing a practice following the original Board Order failed after only six months due to the excessive premium, combined with limited patient accessibility due to insurance carrier credentialing denials stemming from the license "limitation" issue detailed above. All of these factors remain in play today and are once again seriously jeopardizing the practice, especially now when a new liability insurance policy is due.

Notwithstanding the differences of opinion as to the clinical arguments set forth during my State hearings which led to the Board Order, there is one fact that remains and is undeniable by either side. And it is this: Not one person or baby has ever been unduly harmed by my practice of medicine and in particular, these very cases involving the Order in question. Nor was one penny awarded to any of the subject patients, three of whom actually availed themselves to testify on my behalf. All the cases involved were of a type that is either very infrequently encountered (and now obsolete for me given the forceps limitation), extremely atypical or even odd. Nevertheless, for each patient case, the outcomes were all good. In other words, (and this is very important) despite the arguments entered at the hearing and the language in the final determination, the bottom line is that no one was negligently hurt nor was there legal liability as a consequence of the care rendered in these cases.

Therefore, outside of the mandate in the law, it is truly difficult to understand why (in this case) there would even need to be a double malpractice limit requirement as a result of these unarguable points. With the likelihood of ever seeing any similar cases as the ones involved in the hearings being remote at best, the imposition of this increased liability insurance requirement seems a bit unsuitable, considering my malpractice history for the entirety of my career as a physician had been otherwise spotless and my clinical performance amongst the best in the community. As stated, this requirement has been the single greatest obstacle to practicing since essentially all other components of running a practice depend upon having a policy in place before those can proceed. I believe that this is an example of where the intention and application of the law can sometimes be a little disengaged from its real-life consequences. This is not a condemnation of the law itself but a specific case where appropriate argument is offered allowing the safeguards in PHL 230 (10)(q) to then be effectively exercised to the satisfaction of all parties.

As it stands, the real-life problem with this double liability insurance portion of the Order is two fold. First is finding anyone who can write for it and second is cost. Perhaps this is not fully appreciated by the Board (or the law) when imposing such a mandate but one cannot just dial up whatever coverage limits he wants and then just pay the premium. There are established industry standards for coverage limits and the double requirement imposed upon me is <u>not</u> one of them. For example, you cannot order a seven cylinder car. They do not exist as part of the normal production platform, regardless of whether some company could physically make one or not. It's the same with insurance policies apparently. Please see accompanying copy of an email from a veteran broker in Philadelphia whose company has extensive experience in this field and

who has helped me in the past when no one else could. She just about sums up the fact that there are literally no carriers but one who will write for 2M/6M coverage with the premium correspondingly coming at a significant cost along with a host of other stipulations. You might well imagine my interest in recently learning from my Probation Official in Albany that many monitored doctors are also experiencing extreme difficulty with these insurance limits.

There are a few rationales as to why I believe the law sees fit to impose these increased insurance limits in these OPMC matters. First, as stated above, the Legislature are likely not aware of how nearly impossible it is in general to obtain such coverage limits. Second, for some reason, by increasing the limits, it is possibly thought that by doing so, it will offer some degree of built in protection for the public. Yet, the current limit minimum of \$1Million/\$3Million has proven effective and sufficient in providing *appropriate* patient damages for years, even for those physicians who have high risk practices and/or who have past performance issues, the likes that grieve underwriters. There are even the enhanced limits available with 1.3M/3.9M coverage. So, it is not clear as to what the intent of the increased limits was in formulating the law. Certain physicians, who are fortunate enough to have specific conditions met, can also obtain excess insurance coverage (in addition to their own policy) through their admitting hospital at no extra charge. By having the required 1.3M/3.9M coverage already in place, the excess consists of an additional 1M/3M coverage. This would therefore give that particular provider over 2M6M coverage.

This third point is where I believe the law and the Board might be unaware of the logistics which surround access to this additional (excess) coverage through the hospital and thus feel it readily obtainable so as to be able to straightforwardly comply with such a component of a Board Order. When meeting with a few members of the Board in person back in 2008 after the Order was imposed, I inquired as to how they might suggest obtaining such limits. Their answer was, "It's quite simple really. Just get your base policy and then with the hospital's excess, this will put you over the requirement." It was quite matter of fact and clearly the main avenue by which the DOH felt this part of the Order was to be satisfied. Seemed simple enough at the time – especially, if you had a policy with one of the "admitted" carriers in the State who are the only ones who have access to the excess funds. This would also require you to be on staff at a hospital as well in order to tap into these funds so long as the other stipulations were met.

These conditions are what I believe the law/Board had (has) in mind as being readily available when these double limits were (are) imposed. The problem is that there is only a narrow set of circumstances whereby one can even qualify for these additional monies through the hospital. First, as mentioned, there are only three, (what is called), "admitted" liability insurance carriers in New York State who then are able to access these excess State funds through the hospital. Two of these three carriers automatically reject any application from me due to the aforementioned license limitation that exists. The third is the insurance pool where the cost is so prohibitively high that it already put me out of business previously as I continue to try and reconstruct this remnant of a once thriving career. Further, in order to qualify for these excess funds, one must also have had 1.3M/3.9M coverage in place for three consecutive years prior to applying for the excess. I do not qualify for this.

Thus, outside of obtaining the double limits via the excess coverage through a participating hospital and one of the three admitted carriers for NY, the only other option for satisfying the Order is to see if there is an RRG (Risk Retention Group) who is licensed in NY who can write for a whopping 2M/6M policy. As stated above, such a policy just doesn't exist. Only one carrier in the nation (with access to the NY market) was capable of fabricating something. Cost and payment options have proven excessively prohibitive and will shut down this practice once

again if a cost effective solution is not found. In order to sustain any sort of policy, I have had to scale back on coverage for certain procedures which then impacts revenue, which in turn again impacts what can be afforded as far as coverage goes. As is clearly visible, this vicious cycle moves in a negative direction. In her letter, the agent at Cornerstone Insurance Brokerage made it clear that if the limits were of a standard amount, even the enhanced limits of 1.3/3.9, then it would be straight forward to find a policy, even with all the past issues. This doesn't mean that the premium wouldn't be affected accordingly; it is just that the policy itself is more attainable. Certainly, if I met the criteria for being able to obtain the hospital based excess coverage, I would do so. It has been rumored, however, that this excess funding might soon be done away with as well.

In my Order, this liability insurance limit stipulation was to be for three years. As it stands, just over half of that time has been actively served even though it has been more than five years since the original decree. The remaining time (over two separate work gaps) has been spent unemployed, unemployable and penniless as a result of this malpractice coverage limit issue. With mounting professional obligations, I am once more staring at the reality of being back in this jobless state. Please consider the following. When combining a strong clinical performance history in all other areas of my specialty throughout my career along with the type of forceps deliveries at the heart of the Determination having been eliminated from my practice (while also being a nonfactor in being able to safely care for patients), coupled with the fact that all of my time thus far served under the Order has been done so with a practice monitor closely examining my patient care with no deficiencies found, there is really little to no added liability to my practice then, above and beyond what it always has been such that I should continue to have this portion of the Order imposed. Knowing the center of the Board's focus is protecting the public's interest, the public is not nor does the record show (a complication rate thirty times lower than the national average) that it has ever been at increased danger by my practice of medicine. Therefore, given all that has been presented in this section, new evidence exists along with circumstances subsequent to the Order such that a reconsideration of the measure of discipline is warranted. Thus, I urge you to modify my Board Order as "time served" on the previous limits and mandate that I maintain 1.3M/3.9M coverage, which is still above the minimum. This will open up a whole world of potential companies and ease the greatest of financial burdens while still providing an enhanced level of coverage. It is asked that this request receive utmost priority given current renewal time frames that I presently find myself in. Understanding that the law states that this insurance mandate must be imposed upon a monitored licensee, it is therefore necessary to address this portion of the Order, which is as follows.

#### **Practice Monitor Requirement**

The third probationary requirement that was imposed on my license in 2008 is that of a practice monitor. I have previously written both the Board as well as my Monitoring Program Official about the difficulties encountered with this one particular component. For both personal reasons (five children) and professional constraints, I have chosen to remain in my longstanding medical community in order to practice, much to my chagrin. Accordingly, after an experience such as this, it was extremely difficult to satisfy this monitor requirement. Literally no one would agree to do it out of literal fear of reprisal from the very same element that befell me. Thus, having this one condition in place puts an exceedingly tight limit on my ability to practice within the State itself. For example, if there was ever a desire to relocate, it makes it almost impossible to do. People are so disinclined to helping others, not to mention a stranger, (even at the physician level), that they would scarcely step up and assist in this monitor capacity. Further, no practice or hospital is going to want to employ anyone with such a condition attached. I know this from first hand experience after being rejected by over thirty different employment opportunities –

some of whom were/are desperate for a physician in my specialty. Even if I desired to do some locum tenens (part-time/fill-in) work somewhere in the State, I am certain to be automatically disqualified due to this practice monitor requirement alone, not to mention that very license limitation that the recruiters *even* recognize as having no real bearing on capacity to practice fully but yet adds to the disqualification criteria nonetheless. It all boils down to the stigma perceived by others and the label that generates it. If present, then it spells automatic ineligibility – no questions asked.

You stated in your previous letter concerning this matter that my inability to obtain a practice monitor was not a criterion for reconsideration of this component of the Order. This is not the same as not wanting to have a practice monitor. Here you have a physician dutifully seeking out his colleagues in an effort to satisfy this condition only to be turned away by everyone. This community has been professionally polluted to the point that no one will help. Yet I am stuck here since (as mentioned) there is little chance of finding anyone elsewhere in the State to step up either, should I even think about moving. Given that my actual experience has been one of not being able to secure anyone to fulfill this role, either locally and more importantly, in some other potential community, it would appear that this alone would be enough for the Board to reconsider some element of this requirement since it has been integral in not being able to work. This is why I tried to come up with some alternative form of monitoring in my last letter. Unless the Department of Health's objective was for me to never work again in New York State, then it would seem only prudent for my petition on this area to also receive due contemplation as new material evidence as well as new circumstances that would warrant reconsideration.

I understand the clinical matters you cited in your letter as the basis for why the ARB imposed these monitoring terms. But please also recognize again that the issues were over the perceived application of written standards where the outcomes were all good. And I already addressed the issue of using forceps during my hospital "suspension with supervision" time frame back in 2001. In fact, this issue was not even one of the listed charges for the hearings yet received a lopsided amount of weight in the determination without even a basis. Nonetheless, all this aside, the concerns for why the ARB imposed a practice monitor are essentially made moot by the forceps restriction itself, since my actions here were the reasons you cited in your letter as to why they did so in the first place. You also stated that my time off was an additional reason for why a monitor should be in place even though this was never stated in the Order as a reason to consider. That said, after having been off work for more than two years, this past year alone has demonstrated that more than a decade of extensive practice experience and applied knowledge does not evaporate overnight even though there may be a substantial layoff. The other question that begs to be asked is the following. For even the greatest of hypothetical doctors, how much time back in practice is enough to reliably erase any concern after he has been out of work for two years. I dare say that three months would seem sufficient with six months being more than adequate. In my case, it has been more than a year back in practice and my skills and knowledge have never been keener.

You also mention that I was once able to secure a monitor at the outset. Well, it was not the "outset" in the truest sense but was, in fact, thirteen months after the Order was imposed. This was because, in addition to the other components listed above, I had a hard time finding even this gentleman to serve as my monitor. He agreed and ultimately provided two quarterly reports to the State. It must be said, however, that these duties were done by him under a cloud of duress given his official position within the adversarial hospital where this all began as well as his ties to the Ob/Gyn community. And despite him not "quitting" as my monitor as far as I know, when asked to resume his role, he repeatedly refused citing a new reason each time. In fact, in order to abrogate one's duties as a monitor, it must be done so in writing to the State along with

notification of the other parties as well. I know I never wrote anything severing this monitor relationship. Whether he wrote anything essentially relinquishing his duties (i.e., quitting), I am not certain. Therefore, despite what you might perceive as being readily able to secure this component of the Order, truthfully, it was the one portion that I was the most concerned about ever being able to satisfy. Sure, I suspect that the majority of physicians under a practice monitor Order have numerous colleagues that they could turn to for this need and have it gladly fulfilled. The difference in my case is that I was an outsider to this town who was in solo private practice. Sure I made some friends. However, the indigenous element that was central to my travails is a real and feared entity that has shown no discrimination in the past. Therefore, those willing to help were non-existent. If one would agree, within a week, there would be a sudden change of heart. But for the only man possible in this entire community to actually fulfill this role stepping up, I would still be out of work. And when I say "only", this is no understatement. He was my last hope and fortunately, we knew each other from medical school on top of what he witnessed happen to my career. We hadn't spoke in years, yet when I asked, he agreed. It wasn't long before he was hounded as to his decision. Still, he has remained steadfast. He just so happens to be considered one of the area's premier physicians in my specialty who also carries a great deal of influence such that he would be safe from any hostile response or retaliation. It all sounds dramatic and unfortunately, it is. This is the nature of this community. Save for my current monitor, there is nary a person elsewhere in this State that would reliably fill this role such that I could even contemplate leaving the very region that appears to have, in a sense, enslaved me.

Further in my defense are the following two points as well. First, as previously stated, my entire body of work and clinical history demonstrably bears out the fact that I practice sound, safe and successful medicine both in the office as well as the hospital. The ruling in my Order had nothing to do with objective issues or outcome, but involved the more subjective "physician judgment" contention for cases that are otherwise rarely encountered. Secondly, for a total of eighteen months across two different practice monitors, all of my work has been closely examined, written up and received approval. And this is with a very meticulous present day monitor who spends countless hours going through my charts in detail. Naturally, there have been some excellent clinical discussions and points made amongst two colleagues in the context of these reviews. Yet, there has been no example of a single significant misstep in patient management during this time. It stands to reason that with eighteen plus months of close scrutiny without a deficiency, combined with more than ten years of similar performance from the same practitioner, that the Board can extrapolate the obvious and be safely satisfied that I am consistently and customarily adhering to the standards of care as set forth by my specialty such that I do not represent any sort of danger to the community and thus a monitor is no longer needed. That my time has been served, especially when considering the totality of what has been presented here. Therefore, as a third component of this letter, it is with this new evidence and these circumstances I urge the Board to reconsider the terms and modify the Order so that the requirement of Practice Monitor would be deemed satisfied.

#### **Time Served and Relative Applicability**

Never being that good at writing a letter such as this when the issues are so critical to the writer, I struggle with just what to say in order to summon consideration. For lack of a better description, this section is simply to address the enormous losses and the length of time I have had taken from me, my family, my career, my patients, my staff, my friends, my church, my life as a result of this matter with the DOH. This has been a non-stop almost twelve year encounter. With all the official writing and paperwork alone, this letter cannot begin to describe what it was like to worryingly live through those thousands of hours over multiple years. Somewhere along the line, I hope the Board hasn't forgotten how many years of hard work it took to reach that

point of career success where it was all in jeopardy over these matters such that I was compelled to defend myself as I did. As a result of this entire experience, I did in fact lose it all. This would include a highly successful practice, a home, a marriage, day-to-day access to my five children, a standup reputation, you name it. While it apparently goes with the territory on a personal level, on a professional one, all I am trying to do is get by. It is contended through this writing that the personal and professional losses combined with the nearly twelve years of constant involvement with this matter has been time enough served, especially when all indicators are that I am no threat to the community. For the State, it was officially over more than five years ago with the three year probationary terms already two plus years past their original expiration date due to the continued undermining effects they have had on being able to practice.

Since my original Order came down in April of 2008, I have only worked eighteen out of those 62 months, all because of the logistical impediments that have been created by my present Board Order. And even though I was finally able to get past those hurdles just enough to get the office reopened in 2012, the continued burden brought on by the Order has resulted in a gross adjusted income last year in excess of -\$55K. That is a negative number, just to be clear. In excess means that it was even lower than that number. In essence, even though I am working full time, I have been relegated to living like a pauper on a nominal benevolent fund for troubled physicians as my only means of survival. Given the massive debt and professional commitments still in place, the only way I can possibly overcome is to work as a physician.

Twenty years out from medical school, I should not be in this position. I didn't deserve all of this. After adjudicating this matter with the State for nearly six years, no one getting hurt, no malpractice involved, catastrophic losses experienced on my part, sound and solid argument offered in this letter addressing the three issues that continue to plague my practice of medicine, five children, a respectable practice history, plenty of time served, I urge the Board to have mercy on this situation. I need help. I need your help. I have contemplated writing to all sorts of State officials seeking some sort of endorsement on this matter. As you know, I even wrote the governor's office on more than one occasion. This is not to be inflammatory by any means. It is merely out of desperation that this plea fall on the desk of someone who actually cares. I do hope you do, especially given the power granted to you. Since time is somewhat important, it is asked that this matter be dutifully considered and the authority of the Board favorably applied in this matter. Thank you.

Respectfully,

James R. Caputo, M.D.

c.c. Diane K. Riley

This is just a proposal and certainly not how one would expect the final wording to be written. It is merely for facilitating a similar document as part of my petition to the director of OPMC.

#### \*Proposed Agreement

On this day	_ in the month of	in the year	, James Richard Caputo, M.D., a
licensed physici	ian in New York State,	does hereby ente	r into agreement with the State of New York
Department of I	Health and its Office of	Professional Me	dical Conduct the following terms. These
provisions are o	offered in exchange for	modification to I	Dr. Caputo's New York State medical license
to no longer ref	lect a formal limitation	. It is therefore a	greed:

- 1. That licensee will voluntarily agree to forever forgo any use of High Forceps or Mid Forceps deliveries and/or rotations as part of his practice of Obstetrics in New York State.
- 2. That, in order to comply with term number 1, licensee will purposefully relinquish any current hospital privileges for the stipulated forceps use, will abstain from applying for said privileges in the future at any New York hospital and will provide appropriate documentation indicating that these things have been accomplished. In essence, no hospital privileges are to be held allowing these procedures.
- 3. That, if at any time in the future, via any proper investigative means, the licensee is legitimately found to have violated this accord as it pertains to mid and high forceps, then licensee agrees to immediately surrender his medical license without contest.

By signing this agreement, both parties acknowledge that the clinical limitations set forth in the original Board Order #07-271 are still being honored. The terms of this agreement survive any and all future interactions between the parties unless otherwise decided upon.

<Notary Public and Signature Section>



Your care. In our hands.

736 Irving Avenue, Syracuse, New York 13210
Phone: (315) 470-7111
www.crouse.org

Exhibit U3

January 25, 2013

James R. Caputo, M.D.

Re: Application for Medical Staff Appointment and Clinical Privileges

Dear Dr. Caputo:

We have received your application for medical staff appointment and clinical privileges dated January 3, 2012 as well as your emails in follow up thereto. For the reasons set forth below, we cannot accept your application at this time.

Pursuant to Section 3.2.2 of the Crouse Medical Staff Bylaws no application for membership shall be accepted in the event you do not have a valid unrestricted state license, or are subject to any form of counseling, monitoring, supervision, educational requirements or any other ongoing review, condition, requirement or restriction of any kind. It is our understanding that your license has been limited to prohibit you from performing high forceps and mid forceps deliveries and you remain on probation with practice monitor. If you have any evidence or information that the information we have relied upon is not accurate please provide it as soon as possible.

Moreover, under Section 5.3.7 of the Bylaws, while you are permitted to submit an application for membership, you must also furnish evidence that the basis for our earlier adverse action dated August 19, 2008, no longer exists and/or of reasonable rehabilitation in those areas which formed the basis for the previous adverse recommendation or action, whichever is applicable. In addition, such application shall not be processed unless you submit satisfactory evidence that all of the specific requirements of the adverse decision have been satisfied. We have enclosed a copy of the letter to you dated August 19, 2008 and the relevant Hearing Body Report which sets forth the limitations on your privileges at Crouse Hospital. To date, we have no evidence that the specific requirements of our adverse decision have been satisfied.

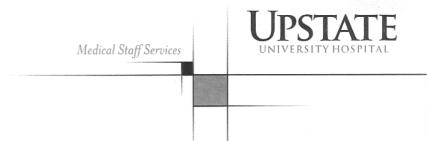
In the event your license is no longer subject to any restrictions and you have satisfied the requirements of our adverse decision in August 2008, if you chose to submit a new application we will conduct a substantive review and make a determination on your qualifications for the privileges you may request.

I have included a copy of Section 3.2.2 and 5.3.7 of the Crouse Medical Staff Bylaws for your reference. We wish you all of the best in your future endeavors. Thank you.

Sincerely

Ronald Stalff, M.D. Chief Medical Officer

cc: Robert Silverman, M.D.



February 1, 2013

James R. Caputo

Dear Dr. Caputo:

We received your application for Medical Staff membership with privileges at both campuses January 15, 2013. Pursuant to Article II, Section 1 (5) of the Medical Staff Bylaws, your application for medical staff membership and privileges at Upstate University Hospital cannot be processed, as you do not meet our eligibility requirements. Specifically, all members of the Medical Staff are required to hold a full legal, unrestricted license in the State of New York. Our information shows that as of 04/12/2008, your New York State license is permanently limited, prohibiting you from performing high forceps and mid-forceps rotations or deliveries. In accordance with MSB X-01, Section 3 (B) (1), our decision not to process your application based on your inability to meet our qualifying criteria does not entitle you to a Professional Review Action Hearing and Appeal Procedure.

Should you have questions regarding this, please feel free to contact Beth Erwin, Director of Medical Staff Services, at 315-464-5733.

Sincerely,

John B. McCabe, MD

Chief Executive Officer of University Hospital Senior Vice President for Hospital Affairs

Enc: MSB A-02, MSB X-01

CC: Howard Weisntein, MD

Robert K. Silverman, MD David Duggan, MD

Bonnie Grossman, MD Bettina Smallman, MD

Medical Staff Services (Credentials / Quality file)

Medical Executive Committee



#### **Certified and Confidential**

November 14, 2012

James Richard Caputo, MD 1200 East Genesee Street Suite 201 Syracuse, NY 13210

Dear Dr. Caputo:

Thank you for your interest in joining HealthNow. The credentials committee has reviewed your application and an administrative decision was made not to process your request for participation at this time.

If you have any questions, please call me at 716-887-7500.

Sincerely,

Many Ferber
Mary Ferber

Manager, Provider Enrollment



Personal and Confidential Certified Mail Return Receipt Requested

December 27, 2012

James Caputo, MD 1200 East Genesee Street, Suite 201 Syracuse, NY 13210

Dear Dr. Caputo:

The MVP Credentials Committee recently reviewed your application for participation including the license action taken against your physician license by the New York State Department of Health, Board for Professional Medical Conduct ("BPMC") which was effective on April 12, 2008, resulting in a license suspension for three years with the first thirty days served as an actual period of suspension and the remainder stayed with probation for three years. Additionally, your license is permanently limited prohibiting you from performing high forceps and midforceps rotations or deliveries. Based on review of this information, the Committee has denied your application for participation.

With respect to the denial of your participation in the MVP Gold program offered by MVP Health Plan, Inc., federal regulations provide that you are entitled to request a review of the Committee's decision. Your request must be in writing and received by MVP Health Plan, Inc. within thirty (30) days of your receipt of this letter. Requests should be addressed to:

Associate Director of Credentialing MVP Health Plan, Inc. 625 State Street, P.O. Box 2207 Schenectady, NY 12301-2207

If you make a timely request, the request will be reviewed within thirty (30) days of our receipt of your request. If you do not request a review, the denial of participation in the MVP Gold program will remain in effect. In any event, you are not authorized to see MVP Gold members in the capacity of a participating physician during the interim.

Sincerely,

Douglas B. Tucker, MD

Vice President, Medical Director MVP East and Quality Administration

MVP Health Plan, Inc.

MVP Health Insurance Company

MVP Health Services Corp.

MVP Select Care, Inc.

Tina Nyland, Associate Director of Credentialing Schelli Servidone, Syracuse PR Manager



May 21, 2012

JAMES CAPUTO 1200 E GENESEE ST STE 201 SYRACUSE NY 13210

Dear Physician or Health Care Professional:

We regret to inform you that on 5/16/2012 the Credentials Committee rejected your credentialing application for UnitedHealthcare and affiliates as we were unable to confirm a current license or certification without restriction exists in the state(s) in which you currently practice. The Credentialing and Recredentialing Plan for United HealthCare Services, Inc., and its affiliates requires practitioners maintain current license or certification without restriction in all states in which they practice.

If you have already signed and returned your physician agreement(s) with the Health Plans, your physician agreements and application will not be processed. If you were applying to join a participating group, your application will not be processed and you will not participate with the Health Plans as part of that group.

If you have any questions about this decision, please contact our National Credentialing Center at 1-877-842-3210 or Network Management at 1-800-339-5380 to be directed to a local representative.

Sincerely,

National Credentialing Center





June 6, 2012

JAMES R CAPUTO MD STE 201 1200 E GENESEE ST SYRACUSE NY 13210-1936

ID: 264662038 NPI: 1619074788

Dear Provider:

We reviewed your provider file and determined that you do not meet the necessary criteria for certification as a TRICARE authorized (certified) provider as specified in 32 CFR 199 and the TRICARE Operations Manual (TOM) because:

	Your specialty () is not eligible for TRICARE reimbursement.
xxx_	Your license in the State of New York is permanently limited.
	You do not meet the TMA educational and/or clinical experience for your specialty.
	The school from which you received your degree is not regionally accredited.
	A conflict of interest exists because of your employment with a

We must deny any claims filed by you or your patients. If you disagree with this determination, you have the right to request a reconsideration. Your written request must state the specific matter you disagree with, and it must be mailed within 90 days of the date of this letter to:

PGBA, LLC
Attn: Appeals has you do no
F P.O. Box 870148 Reserthorized
Surfside Beach, SC 2958749748peration

TRICARE - North Region PGBA, LLC • Fax: 1-888-432-7077 • PO Box 870141 • Surfside Beach, SC 29587-9741 Customer Service: 1-877-TRICARE • www.myTRICARE.com by PGBA

1. at in I wall it is your employment water



#### Certified Mail - Return Receipt Requested

July 2, 2012

#### PERSONAL & CONFIDENTIAL

James Caputo, MD 1200 East Genesee Street Suite 201 Syracuse, NY 13210

Provider ID: PRC10091882

Dear Dr. Caputo:

Thank you for your interest in the Capital District Physicians' Health Plan, Inc. (CDPHP®). The CDPHP credentials committee has carefully reviewed your application and supporting documentation. At its meeting of June 26, 2012, it was the <u>committee</u>'s final decision to deny your application.

Please be advised that the deliberations of the credentials committee are confidential.

Sincerely yours,

Martin R. Symansky, MD

Medical Director & Co-Chair, Credentials Committee

Capital District Physicians' Health Plan, Inc.



August 24, 2012

James Caputo, MD 1200 East Genesee Street, Suite 201 Syracuse, NY 13210

Dear Dr. Caputo:

Fidelis Care has reviewed your correspondence dated August 3, 2012 regarding the denial of your application for initial appointment as a participating provider.

The Committee made an individual credentialing decision based on your information provided during the credentialing process.

At this time, Fidelis' decision is upheld.

Sincerety

Sanjiv Shah, MD, MPH Chief Medical Officer Fidelis Care New York 95-25 Queens Blvd New York, NY 11374



#### New York State Board for Professional Medical Conduct

433 River Street, Suite 303 • Troy, New York 12180-2299 • (518) 402-0863

Antonia C. Novello, M.D.,M.P.H., Dr. P.H. Commissioner NYS Department of Health

Dennis P. Whalen
Executive Deputy Commissioner
NYS Department of Health

Dennis J. Graziano, Director Office of Professional Medical Conduct PUBLIC

Michael A. Gonzalez, R.P.A. Vice Chair

Ansel R. Marks, M.D., J.D. Executive Secretary

Exhibit V

October 3, 2003

#### CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Marc A. Feiner, M.D.

Re: License No. 147174

Dear Dr. Feiner:

Enclosed please find Order #BPMC 03-264 of the New York State Board for Professional Medical Conduct. This order and any penalty provided therein goes into effect October 10, 2003.

If the penalty imposed by the Order is a surrender, revocation or suspension of this license, you are required to deliver to the Board the license and registration within five (5) days of receipt of the Order to the Board for Professional Medical Conduct, New York State Department of Health, Hedley Park Place, Suite 303, 433 River Street, Troy, New York 12180.

Sincerely,

Ansel R. Marks, M.D., J.D.

**Executive Secretary** 

Board for Professional Medical Conduct

Enclosure

cc: James D. Lantier, Esq.

Smith, Sovik, Kendrick & Sugnet, P.C. 250 South Clinton Street, Suite 600

Syracuse, NY 13202-1252

# NEW YORK STATE DEPARTMENT OF HEALTH STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

# OF A SEINER M

CONSENT ORDER

BPMC No. 03-264

MARC A. FEINER, M.D.

Upon the application of (Respondent) Marc A. Feiner, M.D. in the attached Consent Agreement and Order, which is made a part of this Consent Order, it is

ORDERED, that the Consent Agreement, and its terms, are adopted and SO ORDERED, and it is further

ORDERED, that this Order shall be effective upon issuance by the Board, either

- by mailing of a copy of this Consent Order, either by first class mail to
   Respondent at the address in the attached Consent Agreement or by certified
   mail to Respondent's attorney, OR
- upon facsimile transmission to Respondent or Respondent's attorney,
   Whichever is first.

SO ORDERED.

DATED: 10/2/03

MICHAEL GONZALEZ, R.P.A.

Michael Roma

Vice Chair

State Board for Professional Medical Conduct

## NEW YORK STATE DEPARTMENT OF HEALTH STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

# IN THE MATTER OF MARC A FEINER, M.D.

CONSENT
AGREEMENT
AND
ORDER

Marc A. Feiner, M.D., representing that all of the following statements are true, deposes and says:

That on or about July 24, 1981, I was licensed to practice as a physician in the State of New York, and issued License No. 147174 by the New York State Education Department.

My current address is New Hartford, New York 13413, and I will advise the Director of the Office of Professional Medical Conduct of any change of address.

I understand that the New York State Board for Professional Medical Conduct has charged me with two specifications of professional misconduct.

A copy of the Statement of Charges, marked as Exhibit "A", is attached to and part of this Consent Agreement.

I plead no contest to the first specification, in full satisfaction of the charges against me, and agree to the following penalty:

- 1. A censure and reprimand, and
- 2. Three years probation in accordance with the terms set forth in Appendix B, hereto.

I further agree that the Consent Order shall impose the following conditions:

That Respondent shall maintain current registration of licensure with the New York State Education

Department Division of Professional Licensing Services (except during periods of actual suspension), and shall pay all registration fees. This condition shall take effect thirty (30) days after the Consent Order's effective date and will continue so long as Respondent remains licensed in New York State; and

That Respondent shall cooperate fully with the Office of Professional Medical Conduct (OPMC) in its administration and enforcement of this Order and in its investigations of matters concerning Respondent. Respondent shall respond in a timely manner to all OPMC requests for written periodic verification of Respondent's compliance with this Order. Respondent shall meet with a person designated by the Director of OPMC, as directed. Respondent shall respond promptly and provide all documents and information within Respondent's control, as directed. This condition shall take effect upon the Board's issuance of the Consent Order and will continue so long as Respondent remains licensed in New York State.

I stipulate that my failure to comply with any conditions of this Order shall constitute misconduct as defined by New York State Education Law §6530(29).

I agree that if I am charged with professional misconduct in future, this Consent Agreement and Order **shall** be admitted into evidence in that proceeding.

I ask the Board to adopt this Consent Agreement.

I understand that if the Board does not adopt this Consent Agreement, none of its terms shall bind me or constitute an admission of any of the acts of alleged misconduct; this Consent Agreement shall not be used against me in any way and shall be kept in strict confidence; and the Board's denial shall be without prejudice to the pending disciplinary proceeding and the Board's final determination pursuant to the Public Health Law.

I agree that, if the Board adopts this Consent Agreement, the Chair of the Board shall issue a Consent Order in accordance with its terms. I agree that this Order shall take effect upon its issuance by the Board, either by mailing of a copy of the Consent Order by first class mail to me at the address in this Consent Agreement, or to my attorney by certified mail, OR upon facsimile transmission to me or my attorney, whichever is first.

I ask the Board to adopt this Consent Agreement of my own free will and not under duress, compulsion or restraint. In consideration of the value to me of the Board's adoption of this Consent Agreement, allowing me to resolve this matter without the various risks and burdens of a hearing on the merits, I knowingly waive my right to contest the Consent Order for which I apply, whether administratively or judicially, I agree to be bound by the Consent Order, and ask that the Board adopt this Consent Agreement.

DATED 9/19/03

MARC A. FEINER, M.D.

The undersigned agree to Respondent's attached Consent Agreement and to its proposed penalty, terms and conditions.

DATE: 9/19/03

JAMES D. LANTIER, ESQ. of counsel to Smith, Sovik, Kendrick & Sugnet Attorneys for Respondent

TIMOTHY J. MAHAR Associate Counsel Bureau of Professional Medical Conduct

DENNIS J. GRAZIANO

Office of Professional Medical Conduct

NEW YORK STATE DEPARTMENT OF HEALTH STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER

**OF** 

MARC A. FEINER, M.D.

EXHIBIT A
STATEMENT
OF
CHARGES

MARC A. FEINER, M.D., the Respondent, was authorized to practice medicine in New York State on or about July 24, 1981, by the issuance of license number 147174 by the New York State Education Department.

#### **FACTUAL ALLEGATIONS**

- A. Respondent provided obstetrical care to Patient A (the patient is identified in Appendix A hereto) from on or about February 20, 2002 until February 24, 2002 at his office and at Faxton-St. Luke's Hospital in Utica, New York. On August 23, 2002, Respondent delivered Patient A's fetus by forceps, which resulted in, among other things, bilateral subdural hematomas in Patient A's fetus. Respondent's obstetrical care of Patient A failed to meet accepted standards of medical care in the following respects:
  - 1. Respondent failed to perform a competent and/or appropriate forceps delivery of Patient A's fetus.

#### **SPECIFICATION OF CHARGES**

# FIRST THROUGH FOURTH SPECIFICATION GROSS NEGLIGENCE

Respondent is charged with professional misconduct under N.Y. Educ. Law § 6530(4) by reason of his having practiced medicine with gross negligence, in that Petitioner charges:

1. The facts alleged in paragraphs A and A.1.

# SECOND SPECIFICATION GROSS INCOMPETENCE

Respondent is charged with professional misconduct under N.Y. Educ. Law § 6530(6) by reason of his having practiced medicine with gross incompetence, in that Petitioner charges:

2. The facts alleged in paragraphs A and A.1.

DATED:

September 22, 2003 Albany, New York

Deputy Counsel

Bureau of Professional Medical Conduct

#### EXHIBIT "B"

#### Terms of Probation

- 1. Respondent's conduct shall conform to moral and professional standards of conduct and governing law. Any act of professional misconduct by Respondent as defined by New York State Education Law §6530 or §6531 shall constitute a violation of probation and may subject Respondent to an action pursuant to New York State Public Health Law §230(19).
- 2. Respondent shall maintain current registration of licensure with the New York State Education Department Division of Professional Licensing Services (except during periods of actual suspension), and shall pay all registration fees.
- 3. Respondent shall provide the Director, Office of Professional Medical Conduct (OPMC), Hedley Park Place, 433 River Street Suite 303, Troy, New York 12180-2299 with the following information, in writing, and ensure that such information is kept current: a full description of Respondent's employment and practice; all professional and residential addresses and telephone numbers within and outside New York State; and all investigations, charges, convictions or disciplinary actions by any local, state or federal agency, institution or facility, within thirty (30) days of each action.
- 4. Respondent shall cooperate fully with, and respond in a timely manner to, OPMC requests to provide written periodic verification of Respondent's compliance with the terms of this Consent Order. Upon the Director of OPMC's request, Respondent shall meet in person with the Director's designee.
- 5. Respondent's failure to pay any monetary penalty by the prescribed date shall subject Respondent to all provisions of law relating to debt collection by New York State, including but not limited to: the imposition of interest, late payment charges and collection fees; referral to the New York State Department of Taxation and Finance for collection; and non-renewal of permits or licenses [Tax Law section 171(27)]; State Finance Law section 18; CPLR section 5001; Executive Law section 32].
- The probation period shall toll when Respondent is not engaged in active medical practice in New York State for a period of thirty (30) consecutive days or more. Respondent shall notify the Director of OPMC, in writing, if Respondent is not currently engaged in, or intends to leave, active medical practice in New York State for a consecutive thirty (30) day period. Respondent shall then notify the Director again at least fourteen (14) days before returning to active practice. Upon Respondent's return to active practice in New York State, the probation period will resume and Respondent shall fulfill any unfulfilled probation terms.
- 7. The Director of OPMC may review Respondent's professional performance. This review may include but shall not be limited to: a review of office records, patient records and/or hospital charts; and interviews with or periodic visits with Respondent and staff at practice locations or OPMC offices.

- 8. Respondent shall maintain complete and legible medical records that accurately reflect the evaluation and treatment of patients and contain all information required by State rules and regulations concerning controlled substances.
- 9. Within thirty days of the effective date of the order, Respondent shall practice medicine only when monitored by a licensed physician as set forth below, board certified in an appropriate specialty, ("practice monitor") proposed by Respondent and subject to the written approval of the Director of OPMC.
  - a. Respondent shall make available to the monitor any and all records of obstetrical deliveries during the probation term in which forceps or a vacuum extractor was used. The review will determine whether the Respondent's medical practice is conducted in accordance with the generally accepted standards of professional medical care. Any perceived deviation of accepted standards of medical care or refusal to cooperate with the monitor shall be reported within 24 hours to OPMC.
  - b. Respondent shall be solely responsible for all expenses associated with monitoring, including fees, if any, to the monitoring physician.
  - c. Respondent shall cause the practice monitor to report quarterly, in writing, to the Director of OPMC.
  - d. Respondent shall maintain medical malpractice insurance coverage with limits no less than \$2 million per occurrence and \$6 million per policy year, in accordance with Section 230(18)(b) of the Public Health Law. Proof of coverage shall be submitted to the Director of OPMC prior to Respondent's practice after the effective date of this Order.
- 10. Respondent shall enroll in and complete a continuing education program to include the area of obstetrical deliveries by forceps or vacuum extraction for a minimum of 8 credit hours of category I CME. This continuing education program is subject to the Director of OPMC's prior written approval and shall be completed within the first year of probation.
- 11. Respondent shall comply with this Order and all its terms, and shall bear all associated compliance costs. Upon receiving evidence of noncompliance with, or violation of, these terms, the Director of OPMC and/or the Board may initiate a violation of probation proceeding, and/or any other such proceeding authorized by law, against Respondent.

## Exhibit W

1997 WL 34503504 (N.Y.B.P.M.C.)

New York Department of Health Board for Professional Medical Conduct

In the Matter of Vito Edward Caselnova, M.D.

BPMC 97-72 March 19, 1997

#### **Determination and Order**

\*1 A Notice of Violation of Probation, dated September 30, 1996, was served upon the Respondent, VITO EDWARD CASELNOVA, M.D. IRWIN J. COHEN, M.D., Chairperson. RICHARD S. KOPLIN, M.D., and MICHAEL J. BROWN, RPA duly designated members of the State Board for Professional Medical Conduct, served as the Hearing Committee in this matter pursuant to Sections 230(10)(e) of the Public Health Law. CHRISTINE C. TRASKOS, ESQ., ADMINISTRATIVE LAW JUDGE, served as Administrative Officer for the Hearing Committee. The Department of Health appeared by JEAN BRESLER, ESQ., Associate Counsel. The Respondent appeared by the LAW OFFICES OF GARY GREENWALD, MARIE M. DUSAULT, ESQ. of Counsel. Evidence was received and witnesses sworn and heard and transcripts of these proceedings were made.

After consideration of the entire record, the Hearing Committee issues this Determination and Order.

#### PROCEDURAL HISTORY

Date of Notice of Violation of Probation:

Date of Request for Hearing:

October 7, 1996

Date of Hearing:

January 7, 1997

Witness for Department of Health:

Sheila J. Bradwell

Nina Tooker

Witness for Respondent:

Vito E. Caselnova, M.D.

#### STATEMENT OF CASE

This case was brought pursuant to Public Health Law Section 230(19). The statute provides for a hearing where a licensee is charged with a violation of probation.

In the instant case, Respondent was disciplined for professional misconduct in a direct referral proceeding for an admitted violation of 10 NYCRR 80.62(b), in that Respondent dispensed Vicodin to three (3) patients without preparing and maintaining a complete patient record containing information required by said regulation. Respondent's license to practice medicine was

suspended for two years, with said suspension stayed and Respondent placed on probation. The terms of probation included the monitoring of Respondent's practice by a physician, prohibition from writing prescriptions for controlled substances for two years and satisfactory completion of 40 hours of continuing medical education in the area of prescribing and dispensing controlled substances.

By letter dated September 30, 1996, the Director of the Office of Professional Medical Conduct (OPMC) determined that Respondent was in violation of the terms of probation in that it was alleged that Respondent continued to practice medicine without a monitor, failed to comply with insurance coverage requirements of Public Health Law §230(18), failed to submit quarterly submissions and that he continued to prescribe controlled substances.

\*2 A copy of the Notice of Violation of Probation is attached to this Determination and Order in Appendix I.

#### FINDINGS OF FACT

The following Findings of Fact were made after a review of the entire record in this matter. Numbers in parenthesis refer to transcript page numbers or exhibits. These citations represent evidence found persuasive by the Hearing Committee in arriving at a particular finding. Conflicting evidence, if any, was considered and rejected in favor of the cited evidence.

- 1. On or about September 30, 1994, by Stipulation and Order of the New York State Department of Health, the Respondent was found to be in violation of 10 NYCRR 80.62(b), in that from November 1989 to April of 1993, the Respondent dispensed Vicodin to three (3) patients without preparing and maintaining a complete patient record containing information required by said regulation. The Stipulation provided for a Two Thousand (\$2,000) Dollar civil penalty, with One Thousand Five Hundred (\$1,500) Dollars stayed, on the condition that the Respondent commits no further violations of Public Health Law Article 33 or 10 NYCRR Part 80. (Pet. Ex. 1)
- 2. As a result of his admission to the violation of 10 NYCRR 80.62(b), Respondent was referred to OPMC and disciplined for professional misconduct pursuant to Education Law Section 6530(9)(e) through a Direct Referral proceeding held on July 6, 1995. Respondent's license to practice medicine in New York State was suspended for two years. The suspension, however, was stayed and Respondent was placed on probation. The terms of probation required Respondent to have his practice monitored during the period of probation. He was also prohibited from prescribing controlled substances for two years and ordered to complete forty hours of continuing medical education concerning prescribing and dispensing of controlled substances. In its decision, the Hearing Committee noted that "Respondent's failure to take the stand left the Hearing Committee with numerous questions regarding Respondent's knowledge and practice regarding controlled substances." (Pet. Ex. 1, p. 4)
- 3. After repeated written correspondence and telephone conversations with Respondent, OPMC, by letter dated September 30, 1996, advised Respondent that he was in violation of his probation for violation of the terms 1,2,5, 9 and 10 of Determination and Order BPMC-95-22, i.e., failure to secure a monitoring physician; failure to meet quarterly with monitor: failure to comply with insurance coverage of Public Health Law §230(18); prescribing controlled substances and failure to submit quarterly submissions. (Pet. Exs. 3, and 5 through 12, 21,22)

#### **CONCLUSIONS OF LAW**

The following conclusions were made pursuant to the Findings of Fact listed above. All conclusions resulted from a unanimous vote of the Hearing Committee unless noted otherwise.

\*3 The facts in this case are largely undisputed. The terms of probation imposed upon Respondent require that his medical practice be monitored by a physician. Respondent was also prohibited from prescribing controlled substances and required to complete continuing education courses on prescribing controlled substances.

Respondent initially made good faith attempts to obtain a monitoring physician. (T. 114, 117) Respondent, however, incurred difficulty when he realized that pursuant to Public Health Law § 230 (18) (b) he was required to maintain medical malpractice insurance coverage with limits no less than two million dollars per occurrence and six million dollars per policy year. Respondent testified that he could not afford the insurance. (T. 115) When Respondent fully realized that he could not practice medicine without a monitor, he gradually phased out his house call practice. He, however, did not want to abandon any patients without proper medical care. (T. 119) He further testified that he resigned from his part-time job at the Tri-Community Clinic because of the DEA restrictions on his license. (T. 133) Respondent acknowledged prescribing Fastin and Adipex while on probation. because he did not realize that they were Schedule IV controlled substances. (T. 122-123, 145) Respondent further testified that the impact of the probationary terms are "killing" him. (T. 124-125) He has been unable to find a job outside the medical field because he is "too old". (T. 118) He has been treated for a bleeding duodenum and sciatic problems and his wife has suffered major depression. (T. 124-125) Financially, Respondent had to sell his home and move into a 2 bedroom condo and his wife had to resume full time employment. (T. 124)

The Hearing Committee finds that the terms of probation in the Determination and Order are clearly stated. The Hearing Committee also finds that although Respondent appeared to be intelligent, he was often confused in his understanding of the terms of probation. The Hearing Committee believes that Respondent must be responsible to comply with each and every term and condition of his probation if he wishes to practice medicine in New York State. The Hearing Committee concluded that Respondent failed to satisfactorily comply with the terms and conditions of his probation.

#### **DETERMINATION AS TO PENALTY**

The Hearing Committee, pursuant to the Findings of Fact and Conclusions of Law set forth above, unanimously determined that Respondent's period of probation should be extended for an additional period of six (6) months. Therefore, his total time period of stayed suspension with probation is amended from Two (2) years to Two and One-Half (2 1/2) years. This determination was reached upon due consideration of the full spectrum of penalties available pursuant to statute. including revocation, suspension and/or probation, censure and reprimand and the imposition of monetary penalties.

The Hearing Committee re-adopts the original terms and conditions of probation as contained in Appendix II of BPMC Determination and Order No. 95-227 (Pet. Ex. 1). The complete terms of the original probation are contained in Appendix II which is attached to this Determination and Order and incorporated herein. The Hearing Committee further emphasizes to Respondent that the monitor requirement applies to all aspects of his clinical practice.

\*4 The Hearing Committee notes that Respondent was initially disciplined for a record keeping violation and that there was no evidence of risk of patient harm. The Hearing Committee realizes that Respondent has suffered significant humiliation from the loss of his livelihood as well as his home. He appeared to be emotionally stressed when testifying at the hearing. The Hearing Committee recognizes that it will be difficult for Respondent to seek employment in the future with a restricted medical license. Therefore, they believe that there is no justification to outright suspend Respondent's license or extend his probation for more than six months. The Hearing Committee further finds that revocation is not warranted as there is no evidence of patient harm. Therefore, under the totality of the circumstances, extending Respondent's two year stayed suspension with probation for an additional six (6) months is the appropriate sanction in this instance.

#### **ORDER**

Based upon the foregoing, IT IS HEREBY ORDERED THAT:

- 1. The determination by the Director of the Office of Professional Medical Conduct that Respondent is in violation of the terms of probation imposed by BPMC Order No. 95-227 as set forth in Petitioner's Exhibit #1 is **SUSTAINED**;
- 2. Respondent's terms and conditions of probation as set for in Appendix II attached hereto hereby shall be **EXTENDED** for an additional period of **SIX** (6) **MONTHS**.

3. Respondent's total time of stayed suspension with probation is amended from Two (2) years to a period of **TWO AND ONE-HALF (2 1/2) YEARS.** The complete terms of probation are re-adopted from BPMC Order No. 95-227 and contained in Appendix II, which is attached to this Determination and Order and incorporated herein.

Irwin J. Cohen, M.D. Chairperson Richard S. Koplin, M.D. Michael J. Brown, RPA

#### APPENDIX I

#### **APPENDIX II**

#### TERMS OF PROBATION

- 1. Dr. Caselnova shall conduct himself in all ways in a manner befitting his professional status, and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession.
- 2. Dr. Caselnova shall comply with all federal, state and local laws, rules and regulations governing the practice of medicine in New York State.
- 3. Dr. Caselnova shall submit prompt written notification to the Board addressed to the Director, Office of Professional Medical Conduct, Empire State Plaza, Corning Tower Building, Room 438, Albany, New York 12237, regarding any change in employment practice, residence or telephone number, within or without New York State.
- 4. In the event that Dr. Caselnova leaves New York to reside or practice outside the State Dr. Caselnova shall notify the Director of the Office of Professional Medical Conduct is writing at the address indicated above, by registered or certified mail, return receipt requested, of the dates of his departure and return. Periods of residency or practice outside New York shall toll the probationary period, which shall be extended by the length of residency or practice outside New York.
- \*5 5. Dr. Caselnova shall not prescribe controlled substances for patients during his two years period of probation.
- 6. Dr. Caselnova shall satisfactorily complete 40 hours of continuing medical education the area of prescribing and dispensing controlled substances during the two years probationary period.
- 7. Dr. Caselnova's probation shall be supervised by the Office of Professional Medical Conduct.
- 8. Dr. Caselnova shall have quarterly meetings with an employee or designee of the Office of Professional Medical Conduct during the period of probation. During these quarterly meetings Dr. Caselnova's professional performance may be reviewed by having a randomly selection of office records, patient records and hospital charts reviewed.
- 9. For the first year of probation, Dr. Caselnova shall have bi-monthly, and for remaining one year, quarterly meetings with a monitoring physician who shall review practice. The monitoring physician shall be a board-certified family practitioner who been in practice as such for at least five years, selected by Dr. Caselnova and subject to approval of the Office of Professional Medical Conduct. This monitoring physician shall review randomly selected medical records and evaluate whether Dr. Caselnova's medical care comports with generally accepted standards of medical practice. Dr. Caselnova shall not practice medicine in New York State until an acceptable monitoring physician approved by the Office of Professional Medical Conduct.

- 10. Dr. Caselnova shall submit quarterly declarations, under penalty of perjury, stating whether or not there has been compliance with all terms of probation and, if not, specifics of such non-compliance. These shall be sent to the Director of the Office Professional Medical Conduct at the address indicated above.
- 11. Dr. Caselnova shall submit written proof to the Director of the Office of Professional Medical Conduct at the address indicated above that he has paid all registration fees due and is currently registered to practice medicine with the New York State Education Department. If Dr. Caselnova elects not to practice medicine in New York State, then he shall submit written proof that he has notified the New York State Education Department of that fact.
- 12. If there is full compliance with every term set forth herein, Dr. Caselnova may practice as a physician in New York State in accordance with the terms of probation; provided, however, that upon receipt of evidence of non-compliance or any other violation of the terms of probation, a violation of probation proceeding and/or such other proceedings as may be warranted, may be initiated against Dr. Caselnova pursuant to New York Public Health Law Section 230(19) or any other applicable laws.

1997 WL 34503504 (N.Y.B.P.M.C.)

**End of Document** 

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### Exhibit X



736 Irving Avenue, Syracuse, New York 13210 Phone: (315) 470-7646 Fax: (315) 470-7649

June 6, 2002

James Caputo, M.D. 739 Irving Avenue Suite 300 Syracuse, New York 13210

Re: Privilege Status

Dear Dr. Caputo:

This letter confirms that as of March 31, 2002, Dr. Badawy lifted any and all requirements that you seek a consultation prior to undertaking any operative vaginal delivery. Thus, currently your obstetrical privileges are not subject to any restriction or condition.

Likewise, the <u>six-month review</u> of your obstetrical admissions concluded in March of 2002.

Finally, as was identified earlier this month, the letter you received on October 19, 2001 was incorrect. Your clinical privileges for operative vaginal deliveries were never suspended. The noted pre-procedure consultation was required, but the privileges themselves were never suspended. Your privilege sheet as printed from the computer system currently is attached. I will file a correction of this reference with the National Practitioner Databank and the New York State Office of Professional Medical Conduct.

Sincerely,

Daugseth/foreall Uses Marybeth McCall, M.D.

Chief Medical Officer

Cc: Dr. Shawky Babawy