IN THE MATTER OF	*	**BEFORE THE**
JAMES I. DAMALOUJI, M.D.	*	**MARYLAND BOARD**
Respondent	*	**OF PHYSICIANS**
License No. D29821	*	**Case No. 2001-0785**

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CONSENT ORDER

PROCEDURAL BACKGROUND

On May 22, 2003, the State Board of Physician Quality Assurance (the "Board")[1] charged James I. Damalouji, M.D. (the "Respondent") (D.O.B. 05/15/57), License Number D29821, under the Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") § 14-101 et seq. (2000).

Specifically, the Board charged the Respondent with violating the following provisions of the Act under H.O. § 14-404(a):

> (22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State;

On December 3, 2003, a Case Resolution Conference was convened in this matter. Based on negotiations occurring as a result of this Case Resolution Conference, the Respondent agreed to enter into this Consent Order, consisting of Procedural Background, Findings of Fact, Conclusions of Law, and Order.

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[1] As of July 1, 2003, pursuant to Senate Bill 500, the State Board of Physician Quality Assurance was renamed and reconstituted as the Maryland Board of Physicians. Throughout this document, the State Board of Physician Quality Assurance and the Maryland Board of Physicians will be referred to interchangeably as the "Board."

FINDINGS OF FACT

The Board finds the following:

1 At all times relevant, the Respondent was and is licensed to practice medicine in the State of Maryland. The Respondent was initially licensed to practice medicine in Maryland in 1983, having been issued License Number D29821.

2 At all times relevant, the Respondent specialized in the practice of general surgery, and maintained an office at the following location: West Shore Surgical Associates, 2403 S. Three Notch Road, Hollywood, Maryland 20636.

3 At all times relevant, the Respondent maintained privileges at the following hospitals: Calvert Memorial Hospital; St. Mary's Hospital, located in Leonardtown, Maryland ("St. Mary's"); and the Southern Maryland Hospital Center.

4 On or about November 9, 2000, a claim (hereinafter "the Claim") was filed against the Respondent before the Maryland Health Claims Arbitration Office. The Claim alleged that the Respondent, who had performed a laparoscopic cholecystectomy on a patient (hereinafter "Patient A")[2] on March 1, 1999, was negligent in failing to diagnose the patient's chronic post-operative bleeding, which ultimately resulted in her death on March 20, 1999.

5. Thereafter, the Board reviewed this Claim, and initiated an investigation of this matter.

6. Pursuant to its investigation, the Board, on or about February 18, 2002, referred this matter for review to the Peer Review Management Committee (the "PRMC") of the Medical and Chirurgical Faculty of Maryland ("Med-Chi").

[2] To ensure confidentiality, the patient's name is not used in this document. The Respondent is aware of the identity of the patient, however.

7 On or about June 25, 2002, the Med-Chi PRMC referred this matter for investigation to the Med-Chi Peer Review Committee (the "PRC").

8 Thereafter, the PRC investigated this matter, and on or about November 27, 2002, submitted a written report of its findings to the Board, in which it concluded that the Respondent failed to meet appropriate standards for the delivery of quality medical and surgical care with respect to Patient A. The reasons for this are set forth infra.

PATIENT-SPECIFIC FINDINGS

PATIENT A

9. Patient A, then a 65 year old woman, was first evaluated by the Respondent on February 5, 1999 for a two-to-three month history of intermittent post-prandial right upper quadrant ("RUQ") abdominal pain. On this visit, the Respondent assessed Patient A as having symptomatic cholecystitis, and recommended that she undergo laparoscopic cholecystectomy.

10. Prior to undergoing surgery, Patient A's hematocrit was measured as 33.6% (with a reference range for normal being 35.0% to 45.0%).

11. On or about March 1, 1999, the Respondent performed a laparoscopic cholecystectomy on Patient A at St. Mary's.

12. On or about March 8, 1999, Patient A returned to the Respondent's office for a post-operative examination, at which time her abdominal staples were removed. During this visit, the Respondent noted that Patient A appeared to be "doing well."

13. After returning home on March 8, 1999, Patient A developed the acute onset of abdominal pain and vomiting.

14. Patient A was then transported by ambulance to the emergency department at St. Mary's, where she was assessed at 5:19 p.m. Blood studies taken at that time indicated leukocytosis and hypokalemia with a mild elevation in liver enzymes.

15. Patient A then underwent a computed tomography (CT) scan, which revealed a perihepatic hematoma, and small to moderate ascites around the liver with hypoventilation changes in both lung bases. In addition, Patient A's blood studies collected on March 8, 1999 at 7:04 p.m. indicated that her hemoglobin level was 9.1 g/dl (with a reference range for normal being 11.4 to 14.6 g/dl); and her hematocrit had dropped to 26.0%.

16. While in the emergency room, Patient A had an episode of unresponsiveness, followed by a period of disorientation for ten minutes, during which she was incontinent of urine. Patient A's pulse oximetry reading during the episode indicated an oxygen saturation level of 85%. Patient A reportedly responded favorably to administration of intravenous ("IV") fluids and nasal oxygen. A later review of this episode by a neurology consultant suggested that it was most likely due to transient hypotension.

17. The Respondent then admitted Patient A for hospitalization, with a diagnosis of possible intra-abdominal abscess versus postoperative bleeding. In his admission note, the Respondent noted that Patient A had a temperature of 100.2° F, had decreasing hemoglobin and hematocrit levels, and commented that she "may

require transfusion and may require either percutaneous drainage, re-exploration or possible endoscopic retrograde cannulation of pancreatic duct depending on further clinical course of the patient's admission."

18. Patient A then underwent further blood studies on March 9, 1999 at 3:50 a.m., which indicated that her hemoglobin had fallen to 8.9, and her hematocrit had fallen to 20.7%.

19. On March 9, 1999 at 1:30 p.m., hospital staff encountered some difficulty setting up IV access, but did obtain access in Patient A's right foot. At 3:00 p.m., Patient A signed a consent for a blood transfusion. At 4:15 p.m., Patient A's temperature was noted to be 101° F.

20. Patient A was transfused with one unit of red blood cells ("RBCs") at 8:00 p.m. on March 9, 1999. This transfusion was administered approximately 17 hours after Patient A's blood studies were drawn which indicated anemia. Patient A was then transfused with another unit of RBCs at 3:25 a.m. on March 10, 1999.

21. On March 10, 1999, at 7:56 a.m., Patient A's hemoglobin and hematocrit levels were 10.0 and 27.1%, respectively; and her white blood cell count ("WBC") was 15.6 (with a reference range for normal being 4.5 – 11.0).

22. From March 10, 1999 through March 17, 1999, the Respondent did not record any progress notes with respect to Patient A. During this period, Patient A was seen by other members of the Respondent's surgical practice.

23. On March 11, 1999, Patient A experienced two additional episodes of vomiting; her WBC was 13.2; and her hemoglobin and hematocrit were 9.6 and 27.6% respectively.

24. On March 11, 1999, Patient A underwent a repeat abdominal CT scan, which revealed "infiltration of the subhepatic process into the right paracolic gutter to the level of the true pelvis."

25. On March 12, 1999, Patient A's WBC was 20.1; and her hemoglobin and hematocrit were 9.5 and 28.1%, respectively.

26. On March 13, 1999, Patient A's temperature was 101.2; her WBC was 11.5; and her hemoglobin and hematocrit were 9.8 and 26.3%, respectively.

27. On March 14, 1999, Patient A's WBC was 18.0; and her hemoglobin and hematocrit were 8.6 and 24.4%, respectively.

28. On March 15, 1999, at approximately 6:45 a.m., Patient A had another episode of unresponsiveness which lasted approximately seven minutes, during which time she again lost urinary control. A neurology consultation was requested, and orders were given by the on-call physician that Patient A undergo a CT scan of the head. The neurologist determined that Patient A had a prolonged syncopal episode secondary to anemia and poor oxygenation with no evidence of an epileptiform disorder.

29. On March 15, 1999, Patient A's WBC was 21.5; and her hemoglobin and hematocrit had declined to 7.8 and 22.9%, respectively.

30. During the day on March 15, 1999, Patient A had a temperature of 100.4° F; reported increased pain; her abdomen was protuberant and distended; and she had diffuse RUQ and epigastric tenderness. The physician covering for the Respondent ordered a repeat abdominal CT scan and noted that drainage versus exploration would be decided based on CT results.

31. On March 15, 1999, Patient A underwent a repeat abdominal CT scan, which revealed increasing ascites within the cul-de-sac and lower pelvis. The radiology report noted that "[t]he common duct is dramatically distended and filled with debris worrisome for obstruction at the level of the common duct;" and that "[a] previously described perihepatic hematoma appears to be undergoing a degree of liquefaction and possible slight enlargement."

32. On March 15, 1999, Patient A also underwent an abdominal ultrasound. The radiology report indicated "[e]xtensive debris without significant shadowing is seen within the common duct which could be consistent with inspissated bile or blood products." The radiologist's impression was "[s]ignificant dilatation common bile duct. If appropriate, ERCP is suggested." The radiologist further noted that these findings were discussed with the Respondent.

33. On March 16, 1999, one of the physicians covering for the Respondent noted that Patient A's abdominal sonogram showed a rise in ascites and common bile duct dilation; and that Patient A had a probable common bile duct obstruction. This physician noted Patient A's decreasing hemoglobin and hematocrit, and ordered two units of RBCs for transfusion and that she be evaluated by a gastroenterologist.

34. On March 17, 1999, Patient A was administered two RBC transfusions: one unit at 1:05 a.m.; and one unit at 6:15 a.m. On this date, Patient A's temperature was noted to be 100.0° F.

35. On March 17, 1999, Patient A's WBC was 17.0; and her hemoglobin and hematocrit were 8.9 and 24.1%, respectively.

36. On March 17, 1999, the gastroenterologist consultant evaluated Patient A, and determined that since Patient A's LFTs were improving, an ERCP should be deferred unless Patient A had a worsening LFTs with increased abdominal pain or a rise in temperature.

37. On March 18, 1999, Patient A's WBC was 24.3; and her hemoglobin and hematocrit were 8.0 and 22.7%, respectively.

38. On March 18, 1999, the Respondent evaluated Patient A. The Respondent noted that Patient A was feeling "OK," but was complaining of some nausea; and that her abdomen was mildly distended. The Respondent noted that blood studies were "pending."

39. On March 18, 1999, Patient A was again evaluated by the gastroenterologist, who recommended that Patient A undergo repeat ultrasound of the upper abdomen for re-evaluation of hematoma, "as well as CBD [common bile duct]."

40. On March 19, 1999, the Respondent evaluated Patient A, and noted that she "feels better." The Respondent continued to note that Patient A's abdomen had "mild distention." The Respondent commented on Patient A's blood chemistry findings, and noted that a "CBC [complete blood count] pending." The Respondent noted Patient A's decreasing hemoglobin and hematocrit levels, but stated that "clinically patient is not acting like she is bleeding."[3]

41. On March 19, 1999, at 12:45 p.m., Patient A's WBC was 27.8; and her hemoglobin and hematocrit had declined to 6.8 and 17.9%, respectively. According to

[3] In Patient A's death summary, dictated May 5, 1999, the Respondent stated that on March 19, 1999, it was his impression that "[h]er hemoglobin and hematocrit was (sic) felt to be dwindling slowly but clinically the patient was not felt to be actively bleeding."

the St. Mary's hematology laboratory report, both levels were designated as "panic levels."

42. On March 19, 1999, the gastroenterology consultant again evaluated Patient A, and noted that Patient A's hemoglobin and hematocrit had dropped and ordered that two units of blood be transfused. The consultant also noted that Patient A might need re-exploration for perihepatic hematoma; he also noted that he was not able to contact the Respondent but would continue to try to do so.

43. On March 19, 1999, at 9:30 p.m., nursing staff noted that Patient A's temperature was 101.6° F. According to the nurse's note, a house doctor was contacted, and cleared Patient A for transfusion.

44. On March 19, 1999, at 9:45 p.m., Patient A was found unresponsive, with slow and agonal breathing. Patient A was frothing at the mouth. Nursing staff present were unable to obtain a blood pressure. Patient A was suctioned repeatedly and the house doctor and nursing supervisor were paged. A "Code Blue" was called. Patient A responded to resuscitation and was transferred to the Intensive Care Unit ("ICU").

45. On March 19, 1999, at 10:15 p.m., the ICU transfer note documents that Patient A was in respiratory distress with hypotension but alert and oriented. Patient A's abdomen was distended, a subclavian line was placed, and a dopamine infusion was initiated.

46. On March 19, 1999, at 11:00 p.m., Patient A's WBC was 30.4; and her hemoglobin and hematocrit were measured as being 4.2 and 12.1%, respectively. Again, both were designated as "panic levels."

47. Patient A was then administered a series of four RBC transfusions: one unit at 11:10 p.m.; one unit at 11:30 p.m.; one unit at 12:30 a.m. on March 20, 1999; and one unit at 1:40 a.m. on March 20, 1999.

48. On March 20, 1999, at 2:00 a.m., Patient A complained of abdominal pain, and was administered one additional unit of RBC, simultaneous with a unit of fresh frozen plasma. By this point, Patient A had been administered nine units of RBCs.

49. On March 20, 1999, at 4:45 a.m., ICU staff noted that they were unable to obtain an automatic blood pressure.

50. On March 20, 1999, at 5:25 a.m., ICU staff called a "Code Blue." Patient A was unresponsive and could not be resuscitated.

51. On March 20, 1999, at 5:49 a.m., Patient A was pronounced dead.

52. On March 20, 1999, an autopsy was performed on Patient A. Patient A's cause of death was listed a "hypovolemic shock due to disseminated intravascular coagulopathy." The autopsy report stated that after undergoing laparoscopic cholecystectomy, Patient A developed a blood clot within the gallbladder fossa; and that she subsequently developed chronic bleeding into the perihepatic fossa and peritoneal cavity which led to disseminated intravascular coagulopathy. This led to hypovolemic shock and cardiac arrest. The pathologist noted the presence of 3000 cc's of organized blood clot occupying the gallbladder fossa and extending through the common bile duct lumen.

53. *The Respondent failed to recognize or appropriately address Patient A's* persistently declining hematocrit levels identified during the course of her

hospitalization. When Patient A was re-admitted after undergoing surgery, her hematocrit level had significantly decreased relative to pre-surgical levels. Then, during her hospitalization, Patient A's hematocrit levels declined on numerous occasions, necessitating that she be transfused on multiple occasions. Notwithstanding continued transfusions, Patient A's hematocrit levels continued to decline, at times falling to dangerously low levels. The Respondent failed to address Patient A's persistently declining hematocrit levels/anemia through radiologic intervention and/or surgical re-exploration to determine the source of Patient A's chronic internal bleeding.

54. The Respondent failed to diagnose in a timely manner the source of Patient A's chronic internal bleeding. In addition to Patient A's persistently declining hematocrit, Patient A's radiographic/imaging studies indicated increasing ascites, significant dilatation of the common bile duct, subhepatic and perihepatic hematomas, and blood collection in the gallbladder fossa. Patient A also experienced at least two episodes of loss of consciousness, due to either transient hypotension or anemia and poor oxygenation. Also during her hospitalization, Patient A had recurrent abdominal tenderness and abdominal protuberance/distension. Notwithstanding the presence of these factors, the Respondent failed to recognize, diagnose, or address these findings or source of Patient A's chronic internal bleeding.

55. The Respondent failed to perform or institute appropriate surgical and/or radiologic procedures to address Patient A's declining hematocrit/anemia.

56. The Respondent failed to address Patient A's lack of response to transfusions administered during the course of her hospitalization.

57. The Respondent failed to institute blood transfusions in a timely manner after laboratory documentation of Patient A's declining hematocrit/anemia.

58. The Respondent failed to document and/or failed to recognize the significance of Patient A's declining hematocrit and syncopal episodes.

59. The Respondent failed to undertake surgical exploration to determine and correct the source of Patient A's chronic internal bleeding.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent failed to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State, in violation of Md. Health Occ. Code Ann. § 14-404(a)(22).

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 5th day of February, 2004, by a quorum of the Board considering this case:

ORDERED that the Respondent be and hereby is **REPRIMANDED**; and be it further

ORDERED that the Respondent shall be placed on **PROBATION** for a **PERIOD OF TWO (2) YEARS** from the date this Consent Order is executed by the Board, subject to the following terms and conditions:

1. Within one (1) year of the date the Board executes this Consent Order, the Respondent shall undergo peer review(s). The Respondent's practice

shall be subject to peer review(s) by an appropriate peer review society, or chart review(s) by a Board designee, to be determined at the discretion of the Board. After any chart review(s) performed, the Board may recommend peer review(s). The chart and peer review(s) may focus on, but shall not be limited to: (1) surgical cases that occurred before the case which was the basis of the charges issued in this case; and (2) nonsurgical and surgical cases that occurred after the case which was the basis of the charges issued in this case.

2. The Respondent shall comply with the Maryland Medical Practice Act, and all laws, statutes, and regulations pertaining to the practice of medicine.

AND BE IT FURTHER ORDERED that if the Respondent violates any of the terms or conditions of this Consent Order, after notice and a hearing, and a determination of the violation, the Board may impose any other disciplinary sanctions it deems appropriate, said violation being proved by a preponderance of the evidence; and be it further

ORDERED that after the conclusion of the entire **TWO (2) YEAR** period of probation set forth above, the Respondent may file a written petition for termination of such terms and conditions without further conditions or restrictions, but only if the Respondent has satisfactorily complied with all conditions of this Consent Order, including the expiration of the two (2) year period of probation set forth above, and if there are no pending complaints regarding the Respondent before the Board; and be it further

ORDERED that the Respondent shall not petition the Board for early termination of the terms of this Consent Order; and be it further

ORDERED that on or before the date the Board executes this Consent Order, the Respondent shall notify the Board in writing of the type of practice in which he is currently engaged. In the event that the Respondent intends to resume the practice of surgery, or has resumed such practice, he shall so notify the Board. Prior to the resumption of such practice, the Respondent shall obtain a Board-approved physician who is Board-certified in the practice of general surgery to supervise his practice. The Respondent shall obtain prior approval from the Board of the physician supervisor before entering into this supervisory arrangement. As part of the approval process, the Respondent shall provide the Board with the curriculum vitae and any other information requested by the Board regarding the qualifications of the practitioner who is submitted for approval. The supervisory arrangement shall remain in full force and effect for a period of **TWO (2) YEARS**, subject to the following:

a) The Respondent shall have no current or pre-existing business, personal, or professional relationship or affiliation with the supervising physician.

b) The supervising physician shall notify the Board in writing of his/her acceptance of the supervisory role with the Respondent.

c) The Respondent shall provide to the supervising physician a copy of the charging document, Consent Order, and any other documents that the Board deems relevant.

d) The supervising physician shall meet with the Respondent at the Respondent's office on a bi-weekly basis, *i.e.* twice per month. The supervising physician shall randomly select a minimum of ten (10) surgical records of the Respondent's patients and review and discuss with the Respondent his treatment plan, medical decisionmaking, and compliance with appropriate standards of care.

e) The supervising physician shall review the patient records and discuss his/her assessment of the Respondent's practice

performance with the Respondent.

f) The supervising physician shall submit written reports to the Board on a quarterly basis regarding his/her assessment of the Respondent's compliance with appropriate standards of care and his medical judgment/decisionmaking.

g) The Respondent shall have sole responsibility for ensuring that the supervising physician submits the required quarterly reports to the Board in a timely manner.

h) In the event that the Respondent resumes the practice of surgery and begins receiving supervision set forth above, but then interrupts his practice for any reason, or does not continue his surgical practice, he shall so notify the Board. The supervision requirement mandated under this provision shall then be tolled. The Respondent shall then have a continuing duty to notify the Board of his practice status, and shall be subject to supervision for the remaining balance of time under this condition, should he resume the practice of surgery;

AND BE IT FURTHER ORDERED that the Respondent shall be responsible for all costs incurred in fulfilling the terms and conditions of this Consent Order; and be it further

ORDERED that this Consent Order is considered a **PUBLIC DOCUMENT** pursuant to Md. State Gov't. Code Ann. § 10-611 et seq. (1995).

2/5/04
Date

C. Irving Pinder, Jr.
Executive Director
Maryland Board of Physicians

CONSENT

I, James I. Damalouji, M.D., acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent, I admit to the Findings of Facts and Conclusions of Law, and agree and accept to be bound by the foregoing Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections as provided by law. I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce the Consent Order. I also affirm that I am waiving my right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order after having had an opportunity to consult with counsel, without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order, and understand its meaning and effect.

12/23/03
Date

James I. Damalouji, M.D.
Respondent

STATE OF MARYLAND
CITY/COUNTY OF: St. Mary's

I HEREBY CERTIFY that on this 23 day of December, 2003, before me, a Notary Public of the State and County aforesaid, personally appeared James I. Damalouji, M.D., and gave oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

AS WITNESS, my hand and Notary Seal.

Carol A Nelson
Notary Public

My commission expires: 6/01/06