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BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: MICHAEL KAMRAVA, M.D. 9730 Wilshire Boulevard, Suite 211 Beverly Hills, California 90212 Physician's and Surgeon's Certificate No. G 41227, Respondent.	Case No. 06-2009-197098 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Barbara Johnston (Complainant) brings this Accusation solely in her official capacity as the Executive Director of the Medical Board of California (Board).

2. On or about November 26, 1979, the Board issued Physician's and Surgeon's Certificate number G 41227 to Michael Kamrava, M.D. (Respondent). That certificate was in effect at all times relevant to the charges brought herein and will expire on November 30, 2011, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code ("Code") unless otherwise indicated.

4. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Board deems proper.

5. Section 2234 of the Code states:

"The Division[1] of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

"(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter [Chapter 5, the Medical Practice Act]."

"(b) Gross negligence."

"(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

"(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

"(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care."

". . ."

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[1] California Business and Professions Code section 2002, as amended and effective January 1, 2008, provides that, unless otherwise expressly provided, the term "board" as used in the State Medical Practice Act (Cal. Bus. & Prof. Code, §§§§ 2000, et seq.) means the "Medical Board of California," and references to the "Division of Medical Quality" and "Division of Licensing" in the Act or any other provision of law shall be deemed to refer to the Board.

6. Section 2266 of the Code states:

"The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

INTRODUCTION

7. Respondent is an obstetrician/gynecologist with a subspecialty in reproductive endocrinology. He maintains a private practice in Beverly Hills, California. He is not board certified in any specialty. The acts or omissions alleged herein occurred in the scope of Respondent's clinical practice.

8. Patient N.S.[2], age 21 at her initial presentation, was under the care of Respondent from 1997 through 2008.

9. At the patient's first consultation with Respondent in 1997, she was electing to use donor sperm to conceive. She underwent intrauterine insemination (IUI) in April 1997, but failed to conceive. The patient underwent another attempt of IUI in November 1998, which was also unsuccessful.

10. On April 13, 1999, N.S., now 23 years old, consulted with Respondent to discuss in vitro fertilization (IVF). The patient underwent her first oocyte[3] retrieval on May 4, 1999. On May 9, 1999, a hysteroscopic trans-uterine fallopian tube transfer was performed resulting in an ectopic pregnancy[4].

11. On July 13, 2000, the patient began hormone therapy as a precursor to IVF. The cycle was cancelled without egg retrieval. She resumed hormone therapy on August 15, 2000, and underwent egg retrieval on August 29, 2000. Intrauterine transfer of blastocysts[5] was performed on September 3, 2000; the remaining blastocyst embryos were apparently frozen. A singleton[6] term delivery resulted on May 18, 2001.

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[2] In this Accusation, the patient is referred to by initial. The patient's full name will be disclosed to Respondent when discovery is provided pursuant to Government Code section 11507.6

[3] An immature ovum or egg cell.

[4] An abnormal pregnancy that occurs outside the uterus.

[5] A structure formed in early embryogenesis after the formation of the morula (an early stage embryo), but before implantation.

[6] One baby.

12. Four months following delivery of her first child, N.S. returned to Respondent for consultation to pursue pregnancy again. The patient was now age 26. She began hormone therapy as a precursor to IVF on September 23, 2001. Egg retrieval was performed on October 8, 2001 and embryo transfer was performed on October 13, 2001. The unused blastocyst embryos were frozen. A pregnancy resulted from this IVF cycle and a singleton was delivered on June 30, 2002.

13. Four months following the delivery of her second child, N.S. consulted with Respondent to pursue pregnancy again. Despite the fact that she had frozen embryos, Respondent began the patient on hormone therapy as a precursor to IVF on October 30, 2002. She underwent egg retrieval on November 27, 2002 and embryo transfer was performed on December 3, 2002. The unused blastocyst embryos were frozen. This cycle of IVF resulted in pregnancy; a singleton was delivered on August 20, 2003.

14. Four months following the delivery of her third child, N.S. again consulted with Respondent to pursue another conception. Even though she had frozen embryos available, Respondent initiated N.S. on hormone therapy as a precursor to IVF on June 28, 2004. N.S. signed consent forms for oocyte aspiration, embryo implantation and embryo disposition; however, Respondent did not sign the consent forms. Oocyte retrieval was performed on July 13, 2004 and blastocyst embryos were transferred on July 18, 2004. The remaining blastocyst embryos were frozen. A positive pregnancy test was obtained and N.S. delivered a fourth singleton on April 6, 2005.

15. Three months later, on July 5, 2005, N.S. consulted with Respondent to pursue pregnancy. Although N.S. had many frozen embryos available, Respondent began the patient on hormone therapy as a precursor to IVF on October 3, 2005. N.S. signed all the related consent forms, however Respondent failed to do so. Oocyte retrieval was performed on October 21, 2005 and embryo transfer was performed on October 27, 2005. This IVF cycle resulted in a biochemical pregnancy[7].

[7] Where the human chorionic gonadotropin pregnancy test is positive after a missed period, however no pregnancy is documented on ultrasound.

16. Rather than utilizing the available frozen embryos, Respondent began N.S. on another IVF cycle for retrieval of fresh embryos on December 19, 2005. N.S. signed all the related consent forms, however Respondent did not sign the consent forms. Oocyte retrieval was performed on January 15, 2006. On January 20, 2006, blastocyst embryo transfer was performed. The number of blastocyst embryos transferred to N.S. by Respondent was in excess of the American Society of Reproductive Medicine (ASRM) recommended number of blastocysts to be transferred in a woman under the age of 35[8]. The unused blastocyst embryos were frozen. This cycle of IVF resulted in a twin pregnancy.

17. N.S. returned to Respondent for consultation on January 8, 2007. At this point the patient was 31 years old with six children born from IVF. Despite that N.S. had numerous frozen embryos available for implantation, Respondent placed her on hormone therapy as a precursor to IVF on February 28, 2007. N.S. signed all the related consent forms, however Respondent did not sign the consent forms. Oocyte retrieval was performed on March 16, 2007, and embryo transfer took place on March 21, 2007, with Respondent transferring a number of blastocyst embryos in excess of the ASRM recommendation. This IVF cycle did not result in a pregnancy.

18. N.S. consulted with Respondent on August 13, 2007; she requested another IVF cycle. Despite the fact that N.S. had numerous frozen embryos, Respondent commenced another IVF cycle with a fresh embryo retrieval in November 4, 2007. Once again, N.S. signed all the related consent forms, however Respondent did not sign any of the consent forms. No embryo transfer was performed; all the blastocyst embryos were frozen.

19. N.S. consulted with Respondent on January 8, 2008 for another IVF cycle. Despite the fact that N.S. had numerous frozen embryos, Respondent commenced yet another IVF cycle with a fresh embryo retrieval on January 20, 2008. Once again, N.S. signed all the related consent forms, however Respondent did not sign any of the consent forms. Embryo blastocyst transfer took place on January 26, 2008, with Respondent transferring a number of blastocyst

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[8] ASRM recommends the transfer of one to two blastocyst embryos. See also paragraphs 22 and 23, *infra*.

embryos in excess of the ASRM recommendation. The unused embryos were frozen. This IVF cycle did not result in pregnancy.

20. N.S. now age 33, consulted with Respondent on May 7, 2008 where Direct Endometrial Embryo Delivery[9] and Hysteroscopic Endometrial Embryo Delivery[10] were discussed. The patient agreed to undergo the new procedure. Once again, despite the fact that N.S. had numerous frozen embryos, Respondent commenced another IVF cycle with a fresh embryo retrieval on July 14, 2008. N.S. signed all the related consent forms, however Respondent did not sign any of the consent forms. Embryo blastocyst transfer took place on July 19, 2008, with Respondent transferring a number of blastocyst embryos far in excess of the ASRM recommendation and beyond the reasonable judgment of any treating physician. This IVF cycle resulted in the development of an octuplet pregnancy.

21. At no time while N.S. was under the care of Respondent, especially from July 5, 2005 up to July 19, 2008, did Respondent ever recommend or refer the patient to consult with a mental health professional. Respondent knew that N.S. was a single woman with four children all conceived through IVF. She repeatedly returned for consultation approximately every four months following the delivery of her baby without any period of delay. Respondent provided IVF treatment without consideration regarding potential harm to N.S.'s future children.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

(Number of Embryos Transferred)

22. The standard of care in assisted reproductive technology (ART) has been established by ASRM. The guidelines established by ASRM for the number of embryos transferred were published in *Fertility and Sterility Journal* in 2004, 2006, and 2008. In 2004 the guidelines stated:

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[9] Direct insertion of embryo(s) into the endometial stroma (connective tissue that lies between the glands of the endometrium).

[10] Visually confirmed placement of the embryo(s) at a specific area on the surface of the uterus.

"In patients under the age of 35, no more than 2 embryos should be transferred in the absence of extraordinary circumstances. For patients with the most favorable prognosis, consideration should be given to transferring only a single embryo."

That recommendation referred to cleavage stage embryos[11] and it is specifically stated that, "These guidelines should be modified to replace fewer embryos when transferring embryos at a more advanced stage of development (i.e., blastocysts)."

23. In 2006 ASRM updated its guidelines for embryo transfers as follows:

"For patients under the age of 35 who have a more favorable prognosis, consideration should be given to transferring only a single embryo. All others in this age group should have no more that 2 embryos (cleavage-stage or blastocyst) transferred in the absence of extraordinary circumstances."

24. Respondent demonstrated gross negligence in transferring excessive blastocyst embryos to N.S. on December 3, 2002, July 18, 2004, October 27, 2005, January 20, 2006, March 21, 2007, January 26, 2008 and July 19, 2008[12].

25. The number of blastocyst embryos Respondent transferred to N.S. on July 19, 2008, should not be transferred into any woman, regardless of age. The number of blastocyst embryos transferred not only was in violation of the standard of care, but is beyond the reasonable judgment of any treating physician.

26. Respondent demonstrated a pattern of transferring excessive numbers of blastocyst embryos with every IVF cycle in patient N.S., placing her at risk of higher-order gestation with each transfer from December 3, 2002 to July 19, 2008.

27. Respondent's treatment of N.S.as set forth above includes the following acts and/or omissions which constitute extreme departures from the standard of practice.

A. His systematic transfer of a number of blastocyst embryos that exceeds the number recommended for the patient's age and history.

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[11] The cleavage stage is when the embryo is actively dividing from day 2-3.
[12] On these dates Respondent transferred more than two blastocyst embryos to N.S.

B. His transfer of an excessive number of blastocyst embryos to N.S. on December 3, 2002, July 18, 2004, October 27, 2005, January 20, 2006, March 21, 2007, January 26, 2008 and July 19, 2008.

28. Respondent's acts and/or omissions as set forth in paragraphs 22 through 27, inclusive, above, whether proven individually, jointly, or in any combination thereof, constitute gross negligence pursuant to section 2234 (b) of the Code. Therefore cause for discipline exists.

SECOND CAUSE FOR DISCIPLINE

(Gross Negligence)

(Repeatedly Initiating a Fresh Cycle of Oocyte Retrieval when Frozen Embryos were Available)

29. In conformance with the standard of care, it is customary for a physician to recommend the cryopreservation[13] of unused embryos after a fresh embryo transfer. This affords the patient the opportunity to attempt conception if the fresh cycle retrieval and transfer were to fail. With cryopreservation, the risks associated with ovarian stimulation and oocyte retrieval can be avoided, as well as the substantial cost of another fresh IVF cycle.

30. Following the September 3, 2000, October 13, 2001, December 3, 2002, July 18, 2004, January 20, 2006, November 4, 2007, and January 26, 2008, fresh oocyte retrievals, Respondent cryopreserved the unused embryos from each procedure. Notwithstanding this, Respondent failed to recommend that N.S. forgo a fresh IVF cycle and use cryopreserved embryos.

31. By initiating N.S. to a fresh IVF cycle from October 2002 to January 2008, Respondent placed the patient at an increased medical risk with each successive fresh IVF stimulation cycle.

32. Moreover, there is a stockpile of N.S.'s cyropreserved embryos which serve no clinical purpose.

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[13] Freezing or frozen.

33. Respondent's treatment of N.S. as set forth above includes the following acts and/or omissions which constitute an extreme departure from the standard of practice.

A. His failure to use any of the cryopreserved embryos during his course of treatment of N.S. between October 30, 2002 to July 19, 2008.

B. His failure to recommend that N.S. use any of the cryopreserved embryos during his course of treatment of her from October 30, 2002 to July 19, 2008.

34. Respondent's acts and/or omissions as set forth in paragraphs 29 through 33, inclusive, above, whether proven individually, jointly, or in any combination thereof, constitute gross negligence pursuant to section 2234 (b) of the Code. Therefore cause for discipline exists.

THIRD CAUSE FOR DISCIPLINE

(Gross Negligence)

(Failure to Refer the Patient for a Mental Health Evaluation)

35. During Respondent's treatment of N.S. he never referred her or recommended that she consult with a mental health professional. N.S. was a single woman who had multiple children, all conceived from IVF. Shortly after giving birth, N.S. repeatedly returned to Respondent for consultation on more IVF cycles for additional pregnancies, without any period of delay.

36. When N.S. returned to Respondent in July 2005 following the birth of her fourth child and again in January 2007, following the birth of the twins (her fifth and sixth children), Respondent failed to exercise appropriate judgment and question whether there would be harm to her living children and any future offspring should she continue to conceive.

37. Respondent's treatment of N.S. as set forth above includes the following acts and/or omissions which constitute an extreme departure from the standard of practice.

A. His failure to recognize that N.S.'s behavior was outside the norm and that her conduct was placing her offspring at risk for potential harm.

B. His failure to recommend a mental health referral for N.S.

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38. Respondent's acts and/or omissions as set forth in paragraphs 35 through 37, inclusive, above, whether proven individually, jointly, or in any combination thereof, constitute gross negligence pursuant to section 2234 (b) of the Code. Therefore cause for discipline exists.

FOURTH CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

39. Respondent is subject to disciplinary action under section 2234, subdivision (c) of the Code in that his care and treatment of patient N.S. constituted repeated negligent acts. The circumstances are as follows:

40. The allegations of the First Cause for Discipline are incorporated herein by reference as if fully set forth.

41. The allegations of the Second Cause for Discipline are incorporated herein by reference as if fully set forth.

42. The allegations of the Third Cause for Discipline are incorporated herein by reference as if fully set forth.

High Doses of Gonadotropins[14]

43. One of the risks associated with IVF is ovarian hyperstimulation syndrome. This complication is associated with excessive stimulation of the ovaries during IVF. Gonadotropin dosing for the purpose of IVF stimulation is dependent on a number of factors including maternal weight, ovarian antral follicle count as determined by transvaginal ultrasonography, and basal follicle stimulating hormone level.

44. Clinical judgment is necessary to determine an appropriate level of responsiveness keeping in mind that gonadotropin stimulation may negatively influence oocyte quality during IVF and the negative effect of gonadotropin stimulation on endometrial receptivity during a fresh autologous IVF treatment cycle.

45. During several IVF stimulation attempts, especially the July 2005 IVF stimulation, N.S. was given higher doses of gonadotropins than what was clinically indicated.

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[14] Gonadotropins are protein hormones secreted by the pituitary gland.

46. Respondent's treatment of N.S. as set forth above includes the following acts and/or omissions which constitute departures from the standard of practice.

A. His systematic transfer of a number of blastocyst embryos that exceeds the number recommended for the patient's age and history.

B. His transfer of an excessive number of blastocyst embryos to N.S. on December 3, 2002, July 18, 2004, October 27, 2005, January 20, 2006, March 21, 2007, January 26, 2008 and July 19, 2008.

C. His failure to use any of the cryopreserved embryos during his course of treatment of N.S. between October 30, 2002 to July 19, 2008.

D. His failure to recommend that N.S. use any of the cryopreserved embryos during his course of treatment of her between October 30, 2002 to July 19, 2008.

E. His failure to recognize that N.S.'s behavior was outside the norm and that her conduct was placing her offspring at risk for potential harm.

F. His failure to recommend a mental health referral for N.S.

G. His administration of high does of gonadotropins to N.S. than what was clinically indicated.

47. Respondent's acts and/or omissions as set forth in paragraphs 40 through 46, inclusive, above, whether proven jointly, or in any combination thereof, constitute repeated negligent acts pursuant to section 2234 (c) of the Code. Therefore, cause for discipline exists.

FIFTH CAUSE FOR DISCIPLINE

(Inadequate Records)

48. Respondent is subject to disciplinary action under section 2266 of the Code in that respondent failed to maintain adequate records of his care and treatment of patient N.S. The circumstances are as follows:

49. The consenting process is a critical aspect of care in counseling patients who are embarking in the IVF process due to the multitude of risks associated with IVF that range from, but are not limited to, ovarian stimulation risk to the woman, IVF birth defect risk, to multiple gestation risk.

50. Obtaining informed consent requires dialogue and documentation by the physician that a discussion regarding the potential risks of undertaking IVF has occurred.

51. In reviewing Respondent's chart on N.S., all of the IVF related consents are signed by the patient, usually, but not always with a staff witness. Respondent however failed to sign the consent forms. There was no clear documentation from the records that Respondent discussed the specific risks and benefits associated with IVF stimulation and embryo transfer with the patient.

52. There is also no clear documentation that Respondent discussed with N.S. the risk of multiple gestation despite the transfer of excessive blastocyst embryos or her willingness to undergo multi-fetal reduction if faced with a higher order multiple pregnancy. At the very least, the documentation of such discussions was extremely poor.

53. Respondent also failed to appropriately document the patient's social situation. Respondent should have documented, prior to authorizing any further infertility treatment, that a referral to a mental health professional was considered or that such a referral or recommendation was made to the patient.

54. It is also not clear from the record, between October 30, 2002 to July 19, 2008, that Respondent had any discussion with N.S. whether to use cryopreserved embryos. If it was deemed that the embryos were not viable or "not as viable as fresh embryos," then this thought process should have been noted in the patient's chart.

55. It is not clear from the records what the disposition of the stockpile of cryopreserved are, if they are not to be used.

56. Respondent's acts and/or omissions as set forth in paragraphs 48 through 55, above, constitute the maintenance of inadequate records within the meaning of section 2266 of the Code. Therefore, cause for discipline exists.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate No. G 41227, issued to Michael Kamrava, M.D.;

2. Ordering him to pay the Board, if placed on probation, the costs of probation monitoring;

3. Prohibiting him from supervising physician assistants pursuant to section 3527 of the Code; and

5. Taking such other and further action as deemed necessary and proper.

DATED: December 22, 2009

BARBARA JOHNSTON
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant