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

In the Matter of the First Amended Accusation Against: **MICHAEL KAMRAVA, M.D.,** Physician's and Surgeon's Certificate No. G 41227, Respondent.	Agency Case No. 06-2009-197098 OAH Case No. 2010010877

DECISION AFTER NONADOPTION

Daniel Juárez, Administrative Law Judge (ALJ), Office of Administrative Hearings, heard this matter on October 18, 19, 20, 21, 25, 26, and November 17 and 18, 2010, in Los Angeles, California.

Judith T. Alvarado, Deputy Attorney General, represented Linda K. Whitney (Complainant), Executive Director of the Medical Board of California (Board).

Fenton & Nelson, and Henry Fenton, represented Michael Kamrava, M.D. (Respondent). Respondent was present on each day of hearing.

At hearing, Complainant amended the Accusation. On page 5, line 4, "December 10, 2005" was deleted and replaced with "December 31, 2005." On page 5, lines 20 and 25, and page 6, line 9, "embryo" was deleted and replaced with "oocyte." On page 11, line 24, "using known a directed donor" was deleted and replaced with "using a known directed donor."

Complainant also amended the Accusation at hearing by adding three causes for discipline, each to conform to proof at hearing. An eighth cause for discipline was added, alleging that Respondent committed acts of incompetence by the acts already asserted within the Accusation. A ninth cause for discipline was added, alleging that Respondent committed negligence by using a procedure known as "HEED," "DEED," and "SEED" (defined post) without the informed consent of the involved patients. A

tenth cause for discipline was added, alleging that Respondent committed dishonest and corrupt acts when he performed clinical studies on patients without obtaining those patients' informed consent. Respondent opposed all three amendments, claiming a violation of due process. In accordance with Government Code section 11507, the ALJ noted and accepted Complainant's amendments, but also allowed Respondent the opportunity to request additional time to prepare a further defense to the amendments. At no time during the hearing, however, did Respondent request additional time to prepare a further defense to the additional causes for discipline.

The parties submitted the matter for decision on November 18, 2010.

The proposed decision of the Administrative Law Judge was issued on December 20, 2010, and after due consideration thereof, the Board declined to adopt said proposed decision and thereafter on February 9, 2011 issued an Order of Non-adoption. Thereafter, on April 7, 2011, the Board issued an Order Fixing Date for Submission of Argument. Written argument having been received from Complainant and Respondent, and having received oral argument from both parties on May 5, 2011, and the time for filing written argument in this matter having expired, and the entire record, including the transcript of said hearing having been read and considered, the Board, pursuant to Section 11517 of the Government Code hereby makes the following decision:

STATEMENT OF THE CASE

Respondent is a physician who practices gynecology and infertility treatment. This case involves Respondent's care and treatment of three patients identified herein by their initials, N.S., L.C., and H.L. Complainant contends Respondent's medical license should be revoked.

Regarding N.S., Complainant specifically contends Respondent committed gross negligence, repeated negligent acts, and incompetence when he transferred what is alleged to be an excessive number of embryos into N.S. in multiple attempts to achieve pregnancy through in vitro fertilization (IVF) between December 2002 and July 2008. Complainant further contends the following acts by Respondent also constituted acts of gross negligence and repeated negligent acts: the "systematic transfer" of embryos that exceeded the recommended number for the patient's age and history; his failure to recommend the use of, and his failure to use, N.S.'s frozen embryos between October 2002 and July 2008; and his failure to recognize that N.S.'s overall behavior was "outside the norm" and to refer N.S. to a mental health professional. Complainant also alleges that Respondent's administration of high doses of hormones, known as gonadotropins, constituted repeated negligent acts.

Complainant contends Respondent's written records of N.S.'s care and treatment were inadequate because Respondent failed to sign the treatment consent forms, and failed to document that he discussed with N.S. the following: the risks and benefits of IVF transfers, the risks of multiple gestations, whether to use frozen

embryos, and the disposition of N.S.'s frozen embryos. Additionally, Complainant contends Respondent's records were inadequate because they failed to set forth N.S.'s "social situation."

Regarding L.C., similar to N.S.'s case, Complainant contends Respondent committed gross negligence, repeated negligent acts, and incompetence when he transferred what is alleged to be an excessive number of embryos into L.C. in one attempt to achieve pregnancy through IVF in September 2008. Complainant further contends Respondent's failure to refer L.C. and her family to a mental health professional also constituted gross negligence and repeated negligent acts. Complainant contends Respondent's written records of L.C.'s care and treatment were inadequate because Respondent's records did not appropriately document the IVF process at the initial consultation, did not document the significance of using a directed donor (in this case, the patient's daughter), did not clearly describe the stimulation protocol used, and did not document that he discussed with L.C. the number of embryos Respondent intended to transfer and L.C.'s consent to that transfer.

Regarding H.L., Complainant contends Respondent committed repeated negligent acts when, after becoming aware of an abnormal cytology report, he failed to perform testing to rule out ovarian cancer and failed to refer H.L. to a specialist to rule out cancer.

Complainant also contends that Respondent's written records of H.L.'s care and treatment were inadequate for the following reasons: Respondent did not document discussions regarding infertility treatment options; he did not document the plans for artificial insemination and IVF therapies or when the plans for these therapies was made; the records were unclear as to what stimulation protocol was used or the number of IVF cycles undergone by H.L.; Respondent failed to sign the consent forms; the documents are unclear as to whether Respondent discussed the existence of cystic masses on H.L.'s ovaries at any time; there was no documentation as to H.L.'s consent to the aspiration of her ovaries in January 2009; and there is no documentation that Respondent discussed the results of an abnormal cytology report with H.L., including that she might have cancer.

Respondent contends he acted within the standard of care in his treatment of all three patients and produced adequate medical records that met the standard of care. He conceded that in hindsight, his transfer of numerous embryos into N.S. was erroneous, but argued that such an error was only appreciable after N.S gave birth to octuplets. He further argued that any error in judgment that he made in transferring numerous embryos into N.S. and L.C. did not rise to the level of gross negligence, repeated negligent acts, or incompetence. As such, he contends his medical license should not be revoked.

This matter solely assesses whether Respondent's care and treatment of each of the three patients, and his documentation for each patient, was within or below the

standard of care for a physician practicing gynecology and infertility treatments. The serious and weighty bio-medical ethical issues inherent in the transfer of numerous embryos involve separate analyses that cannot and should not be assessed here, as the evidence and argument in this matter relate solely to the question of the standard of care.

FACTUAL FINDINGS

1. On June 30, 2010, Complainant, in her official capacity, filed the First Amended Accusation. On or about July 16, 2010, Respondent signed the Notice of Defense. The three causes for discipline added at hearing, were deemed controverted by Respondent, pursuant to Government Code section 11507.

Respondent's Background and Certification

2. Respondent received his Bachelor of Science from the University of Illinois in 1972, and his medical degree from Case Western Reserve University School of Medicine in 1976. He completed an internship in obstetrics and gynecology at the University Hospitals of Cleveland in Ohio, in 1977, and his residency, also in obstetrics and gynecology, at the Mount Sinai Hospital of Cleveland in 1980. In 1982, Respondent completed a fellowship in reproductive endocrinology and infertility at Beth Israel Hospital through Harvard Medical School. He is a Diplomate of the National Board of Medical Examiners. He holds medical licenses in Ohio (1976), California (1979), and Massachusetts (1980).

3. Since 1982, Respondent has been in private practice in endocrinology and infertility in Los Angeles; he is currently the Director of West Coast IVF Clinic, Inc. in Beverly Hills, California. Currently, his practice is 25-30 percent gynecology and the remainder is IVF. Since 1986, he has been an attending physician in obstetrics and gynecology at Cedars Sinai Medical Center (Cedars Sinai) in Los Angeles.

4. From 1982 through the present, Respondent has published several articles and presented lectures on obstetrics and reproductive science nationally and internationally. Since 2004, Respondent has been an ad hoc reviewer for the "Fertility and Sterility" medical journal.

5. The California Medical Board (the Board) issued physician and surgeon certificate number G 41227 to Respondent on November 26, 1979. The license expires on November 30, 2011, unless renewed.

6. The Board has never disciplined Respondent's medical license.

Patient N.S.

N.S.'s Pre-IVF Care and Treatment

7. Respondent first met N.S. in April 1997; N.S. was 21 years old at that time. N.S. met with Respondent to discuss sex selection of her intended future pregnancy, a pregnancy she expected to create through artificial insemination. N.S. told Respondent she had had a first trimester miscarriage in approximately 1995, and was having difficulty becoming pregnant. N.S. had been taking clomiphene citrate, a medication used to stimulate ovulation, with no pregnancy success.

8. N.S. was single but had a male partner who, at later appointments with Respondent, would sometimes accompany N.S. Respondent documented the existence of N.S.'s partner as well as his presence at various appointments.

9. Respondent initially recommended to N.S. that she attempt pregnancy through artificial insemination, as he explained to N.S. that this was a less expensive and less invasive procedure than IVF. Respondent performed artificial insemination procedures on N.S. in April 1997, and November 1998, but those attempts at pregnancy were unsuccessful.

10. In October 1998, Respondent documented in N.S.'s medical records, among other things, that N.S. had been trying to get pregnant for four years with no success. Based on this information, Respondent considered N.S. infertile. At hearing, Respondent explained that he defines infertility as an inability to become pregnant after engaging in unprotected sex for at least one year. The parties did not dispute this general definition of infertility. In discussing her pregnancy wishes, N.S. immediately informed Respondent that she intended to have a very large family, approximately 10 children. That intention by N.S. never changed throughout the entirety of her doctor/patient relationship with Respondent. Respondent did not react positively or negatively to N.S.'s desire to want a large family. He believed he could assist her to have children and agreed to treat her. Respondent described N.S. during these initial appointments as "intelligent" and "knowledgeable"; he did not observe anything that would have made him believe N.S. was psychologically unsound.

11. Respondent suggested N.S. return to Kaiser Permanente, where N.S. was receiving regular health care, to proceed with the examination of her fallopian tubes. After diagnostic testing, Kaiser Permanente found "bilateral tubal patency" but also "pelvic adhesions." In December 1998, N.S. underwent surgery to address the adhesions, specifically "[h]ysteroscopy, laparoscopy, hydrochromotubation, and lysis of pelvic adhesions." N.S. continued seeing and consulting Respondent thereafter.

12. In January 1999, Respondent prescribed N.S. clomiphene citrate and suggested that she attempt to become pregnant naturally. In that same month, he diagnosed N.S. with mild endometriosis.

13. Respondent saw N.S. in April 1999, and noted that she was still not pregnant.

N.S.'s IVF Care and Treatment

14. In April 1999, N.S. agreed to undergo an IVF procedure. Respondent explained IVF to N.S., describing it as an inexact science and recommending that she limit the number of embryos transferred. He explained that in the IVF process, there is a need to balance the number of embryos transferred with the potential outcome in babies. He informed N.S. about the risk of developing a multiple pregnancy. Respondent explained to N.S. the process of a multi-fetal reduction as a means to control the number of embryos that develop into babies. Multi-fetal reduction is a process whereby multiple embryos that properly attach and begin to develop into fetuses are terminated early to reduce the eventual number of babies to be born. Respondent explained to N.S. that if she was willing to agree to multi-fetal reduction, a greater number of embryos could be transferred; however if she was not so willing, then he would recommend that less embryos be transferred. N.S. agreed to multi-fetal reduction at the outset and thereafter at each embryonic transfer performed by Respondent.

15. In overly simple terms, to begin an IVF cycle, Respondent would administer gonadotropins (hormones) to the patient to stimulate the production of eggs, known as "ooctyes." Respondent would then retrieve the oocytes and fertilize them. Thereafter, Respondent would implant, otherwise referred to as "transfer," the fertilized oocyte (embryo) into the patient. The embryos are classified, based on their maturation. A less mature embryo is known as a "cleavage stage" embryo; a more mature embryo is known as a "blastocyst" embryo.

16. Respondent performed 14 ovarian stimulation cycles and 10 embryo transfers on N.S. between April 1999 and June 2008. Some of the transfers were successful, while others resulted in no pregnancy. Each stimulation cycle and embryo transfer is described in Factual Findings 20-22, 24, 25, 28-32, 35, and 37. Before each of these cycles and transfers, N.S. approached Respondent, requested Respondent's assistance, and asserted her agreement to the stimulation cycles and embryo transfers. In general, N.S. wanted the maximum chance to become pregnant, and informed Respondent of this desire.

17. Throughout his treatment of N.S., Respondent would determine each embryo's development, noting that some blastocyst embryos were of better quality than other embryos, and the better quality embryos would have a better chance of developing into a fetus. At each embryonic transfer, Respondent discussed with N.S. how many embryos should be transferred. Respondent's overall clinical success in IVF had been poor in 1999, and Respondent took his clinic's low pregnancy rate into consideration when opining as to the number of embryos that should be transferred in N.S.'s case. Respondent's understanding, then and now, based on his experience and professional judgment, is that greater quality embryos are more likely to result in a pregnancy than lesser quality embryos. Respondent did not think he could refuse to transfer less embryos than those to which N.S. would agree because he believed at the time that the ultimate decision should be largely driven by the patient's wishes.

18. N.S.'s stimulation cycles were unusual in that she required a greater dose of gonadotropins over more days than other patients her age to render oocytes. Respondent took this fact into consideration when determining the number of embryos to transfer into N.S. Respondent further considered each oocyte's development, the condition of the embryo on the day of each transfer, N.S.'s stated desire for a large family, the length of time N.S. had attempted to become pregnant before the first stimulation cycle began and the fact that N.S. had agreed to multi-fetal reduction.

19. Respondent informed and advised N.S. regarding the risks, benefits, alternatives, and side effects of the IVF and related procedures throughout his treatment and care of N.S. Respondent documented these consultations on N.S.'s medical records, using his own abbreviations. For example, on May 2, 1999, N.S.'s medical records contain the following notation, "Discussed alt's [alternatives], benefit, risks & SE'x [side effects]." On May 6, 1999, N.S.'s medical records read, "Discussed Findings—A's [alternatives] B's [benefits] R's [risks] SE'x . . . tx [treatment]." Respondent documented similar notations throughout N.S.'s medical records, including on the following dates: May 9, 1999; June 10, 1999; August 16, 1999; October 25, 1999; July 24, 2000; October 13, 2001; October 16, 2002; November 27, 2002; December 2, 2002; December 3, 2002; January 7, 2004; June 17, 2004; July 13, 2004; July 18, 2004; October 27, 2005; January 13, 2006; January 20, 2006; February 12, 2007; March 17, 2007; March 21, 2007; April 9, 2007; August 13, 2007; January 15, 2008; January 26, 2008; and July 19, 2008. Throughout his care and treatment of N.S., Respondent properly advised N.S. regarding the alternatives, risks, benefits, and side effects of the oocyte retrievals and embryo transfers, including information on multiple gestations and multi-fetal reduction. While he used abbreviations that were objectively difficult to decipher, once explained by Respondent, those abbreviations were understandable.

20. On April 18, 1999, N.S. underwent the first ovarian stimulation cycle with gonadotropins. In May 1999, Respondent transferred six blastocyst embryos; however, this procedure resulted in an ectopic pregnancy. In an ectopic pregnancy, the pregnancy occurs in the fallopian tubes and must be terminated.

21. In September 1999, and July 2000, N.S. underwent a second and third ovarian stimulation cycle, but each of those cycles was cancelled.

22. In August 2000, N.S. underwent a fourth ovarian stimulation cycle and in September 2000, Respondent transferred five blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s first baby.

23. Respondent described determining the number of embryos to transfer in 2000 as "complex." Based on his experience treating her, Respondent opined that N.S. had low quality embryos and that her uterus was in what he described as "less than optimal condition." Earlier tests, and N.S.'s historic difficulty in the stimulation cycle, requiring greater doses of gonadotropins for longer periods of time, led Respondent to further opine that N.S. might be experiencing premature menopause. It is unclear

whether Respondent continues to believe N.S. was experiencing premature menopause; however, he credibly established that his opinion in 2000 was that he believed she was experiencing such a condition. Respondent considered these factors, in addition to those set forth in Factual Findings 18 and 33, to suggest and ultimately determine the number of embryos to transfer in 2000 and every embryo transfer thereafter.

24. In September 2001, N.S. underwent a fifth ovarian stimulation cycle and in October 2001, Respondent transferred five blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s second baby.

25. In October 2002, at the age of 27, N.S. underwent a sixth ovarian stimulation cycle and in December 2002, Respondent transferred four blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s third baby.

26. In June 2004, N.S. met with Respondent and informed him that she wanted to have twin babies. Respondent documented N.S.'s desire; he recommended against N.S. attempting to have twin babies, and wrote in N.S.'s medical records, "Not recommended." Thereafter, N.S. agreed to attempt a single baby. Respondent further advised N.S. to wait a longer period of time before beginning a new stimulation cycle. N.S. complied.

27. In approximately January 2004, N.S. met with Respondent and informed him that she wanted to pursue another pregnancy, but this time with a surrogate. Respondent spoke with N.S. about this and in a note he drafted in her medical records, dated January 7, 2004, Respondent wrote that he advised N.S. "extensively against surrogacy." He explained at hearing that he had counseled N.S. against using a surrogate because, in his opinion, that process was complicated, expensive, could develop its own legal problems, and generally was a process that she should not take lightly. N.S. did not pursue surrogacy thereafter.

28. In June 2004, N.S. underwent a seventh ovarian stimulation cycle and in July 2004, Respondent transferred four blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s fourth baby.

29. In October 2005, N.S. underwent an eighth ovarian stimulation cycle and in that same month, Respondent transferred three blastocyst embryos. This procedure resulted in a biochemical pregnancy. A biochemical pregnancy is one where the pregnancy hormone is detected in the blood, but the pregnancy terminates early on its own.

30. In November 2005, N.S. underwent a ninth ovarian stimulation cycle, however that cycle was cancelled.

31. In December 2005, N.S. underwent a tenth ovarian stimulation cycle and in January 2006, Respondent transferred six blastocyst embryos. This procedure

resulted in a twin pregnancy, her fifth and sixth babies. Neither Respondent nor N.S. intended a twin pregnancy.

32. In February 2007, N.S. underwent an eleventh ovarian stimulation cycle and in March 2007, Respondent transferred six blastocyst embryos. This procedure did not result in a pregnancy.

33. In February 2007, based on earlier laboratory results, the failed IVF procedures in 1999, 2005, and 2007, and her difficulty responding to the gonadotropin hormones, in Respondent's on-going opinion, N.S. appeared pre-menopausal although she was only 31 years old at the time. Respondent considered this information, in addition to the factors set forth in Factual Findings 18 and 23, in suggesting and ultimately determining the number of embryos to transfer in February 2007 and thereafter.

34. In February 2007, Respondent was concerned that she would have significant difficulty having any more children, and as he was aware she continued to want more babies, he informed N.S. of his opinion as to her problematic fertility. Respondent described N.S. as "alarmed" upon hearing his opinion.

35. In October 2007, N.S. underwent a twelfth ovarian stimulation cycle but Respondent did not transfer any embryos. Instead, upon N.S.'s direction, Respondent froze all (in this instance, eight) embryos.

36. Over the time of all of her IVF treatments through 2008, N.S. directed Respondent to freeze a total of 29 embryos. They remain frozen to date. Respondent felt obligated to freeze them, as he believed he did not have the authority to dispose of them otherwise, as N.S. signed consent forms to authorize the freezing of her embryos and their disposition in certain specified circumstances, but N.S. did not authorize Respondent to ultimately dispose of the embryos. According to Respondent at hearing, on January 4, 2008, Respondent suggested to N.S. that she use frozen embryos instead of fresh embryos, and further informed her that frozen embryos are generally much less successful in resulting in a pregnancy. Respondent did not document his asserted suggestion in N.S.'s medical records. N.S. chose to use fresh embryos throughout all of her embryo transfers.

37. In January 2008, N.S. underwent a thirteenth ovarian stimulation cycle and in that same month, Respondent transferred eight blastocyst embryos. This procedure did not result in a pregnancy.

38. When transferring what Respondent acknowledged was a great number of embryos in January 2008, he considered what he opined was N.S.'s debilitating ovaries, N.S.'s history of failed IVF over the years, including the failed attempt in February 2007, the fact that N.S. had given birth to only one set of twins before, despite the number of embryos transferred in each IVF attempt (that is, all previous

successful transfers had resulted in a single baby with the exception of one set of twins), and the factors set forth in Factual Findings 18, 23, and 33.

39. At all embryonic transfers for N.S., beginning in 2004, Respondent considered the guidelines on the number of embryos to transfer in IVF procedures set forth by the American Society for Reproductive Medicine (ASRM), but understood those guidelines to be flexible depending on the factual circumstances presented in each patient's case. The Practice Committee of the Society for Assisted Reproductive Technology (SART) and the ASRM have published these embryo transfer guidelines in the journal of "Fertility and Sterility." These guidelines are referred to herein as the "ASRM guidelines." (The pertinent portions of the 2004, 2006, and 2008 ASRM guidelines are set forth in Factual Findings 8593.)[1]

40. In June 2008, N.S. underwent a fourteenth ovarian stimulation cycle and in July 2008, Respondent transferred twelve blastocyst embryos, utilizing the HEED procedure. (HEED is described in Factual Finding 43.) This procedure resulted in an octuplet pregnancy.

41. In July 2008, N.S. insisted on transferring all 12 fresh embryos and she would not accept anything less. Respondent suggested that he only transfer four embryos, but felt bound to honor her wishes, after considering her insistent direction and the factors set forth in Factual Findings 18, 23, 33, and 38. Respondent wrote the following note in N.S.'s medical records on July 19, 2008: "[h]ave explained, [d]iscussed—A's [alternatives], B's [benefits] R's [risks] SE'x [side effects] of embryo transfer by implantation or HEED, alt's [alternatives], B's, R's, SE'x of freezing & [r]eduction (fetal)—Pt. [patient] insists and wants all embryos transferred by HEED . . . consequences to the babies of un-compliance [sic] were explained & Pt. understands and wishes to proceed with the HEED Tx [transfer] of all embryos—. . .–own recommendation—4 [a]dvanced embryos by HEED." This notation was signed by N.S. and a witness.

42. Respondent did not see N.S. thereafter and only heard from her briefly after her octuplet delivery. N.S. did not testify.

43. At hearing, Respondent defined HEED as "hysteroscopic endometrial embryo delivery" and explained it as the mechanical insertion of embryos into the endometrium under direct visualization. That is, Respondent would use a hysteroscope to see where to implant the embryos during an IVF transfer. The evidence also established two other similar acronyms: SEED ("sub-endometrial embryo delivery") and DEED ("direct endometrial embryo delivery"). The evidence failed to distinguish the three acronyms, and the parties largely used all three acronyms interchangeably. Consequently, HEED, DEED, and SEED are considered

[1] A 2010 "Fertility and Sterility" article, described further in Factual Finding 94, notes that, as early as 1998, the ASRM and SART published the first recommended guidelines on the transfer of embryos in IVF; however, the earliest guidelines offered into evidence by Complainant are those of 2004.

substantially similar for purposes of this matter and are referred to together throughout this Proposed Decision.

44. Respondent explained at hearing that he developed HEED/DEED/SEED, and believes it is an appropriate embryo transfer method. He concedes he is the only physician he knows who has used HEED/DEED/SEED, but argued that it is not an experimental process and only a distinct method of embryo implantation.

45. Respondent felt compelled to transfer all 12 embryos in July 2008, because he believed that the patient's wishes should largely dictate the number of embryos to transfer, even if he opined differently. Respondent pointed to his July 2008 note showing that he recommended to N.S. that only four embryos be transferred. As part of his consultation with her, Respondent told N.S. that there was no guarantee she would become pregnant, however, there was a significant risk of having a multiple pregnancy. N.S. agreed in no uncertain terms to multi-fetal reduction, and based on this, he figured that if a multiple pregnancy resulted, the multi-fetal reduction procedure would limit the number of babies to be born.

46. Respondent explained at hearing that while he had referred other patients to psychologists in the past, he did not observe N.S. to be in such a condition as to warrant a referral to a mental health professional. When asked at hearing about N.S.'s overall pregnancy-seeking behaviors, Respondent stated that he refused to pass judgment on N.S.'s familial desires. For this reason, as N.S. continued to consistently return to him after each cycle and transfer, whether successful or unsuccessful, he did not consider her returning to him to seek additional IVF procedures as behavior that warranted a mental health referral. He did not think N.S.'s desire to have a large family of approximately 10 children, her request for twins, or her request to use a surrogate were behaviors that warranted a mental health referral.

47. Respondent asserted that at each embryonic transfer, despite the number of embryos transferred, it was always his goal and intention to have his actions result in a single, healthy baby. This was his intention with the 2008 transfer of 12 embryos, and Respondent believed that given her failed pregnancies in March 2007, with six embryos transferred, and January 2008, with eight embryos transferred, that 12 embryos appeared reasonable to him at that time. Looking back now, Respondent agreed that transferring the 12 embryos was "wrong." He is sorry that the IVF process resulted in octuplets and he wishes he had never done the procedure. At the time in 2008, he thought it was the right thing to do, but at hearing, he readily conceded that, in hindsight, it was not.

48. Respondent testified with emotion, but also in an unhesitating manner, with factual consistency, and providing each counsel and the ALJ with direct eye contact. Consequently, Respondent's overall testimony was deemed credible.

49. Respondent documented his discussions with N.S. regarding the use of HEED/DEED/SEED as the embryonic transfer method. For example, on May 7, 2008,

Respondent wrote, "Option of regular ET [embryo transfer] vs. DEED, vs. SEED was given. Possible scratch/bleeding of endometrium with possible impact on non implantation was explained." Respondent documented similar notations on July 19, 2008. Respondent discussed the use of HEED/DEED/SEED procedures with N.S. before using those procedures throughout his care and treatment, and those discussions are encompassed in his notations showing his discussions of embryo transfers generally. For example, on October 27, 2005, Respondent wrote in a note in N.S.'s medical records, "ET done by hysteroscopic embryo implantation. Alternative of regular embryo transfer given prior to preparation. . . Option of regular ET was given. Possible scratch/bleeding of endometrium with possible impact on non implantation [sic] was explained." Similar notations are found in N.S.'s records in 2007, 2006, 2004, 2002, and 1999. Furthermore, Respondent reviewed a video with N.S. regarding HEED/DEED/SEED. N.S. signed two consent forms that included HEED procedures. On July 14, 2008, N.S. signed a "Consent to Medical or Surgical Care and Treatment" that included "[h]ysteroscopic Embryo Transfer" and a consent form authorizing Respondent to perform a "[h]ysteroscopic transuterine fallopian tube transfer," in May 1999.

Dr. V.Y. Fujimoto's Opinions regarding N.S.'s case

50. Complainant presented the opinions of Victor Yutaka Fujimoto, M.D. (Fujimoto). Fujimoto is an Associate Clinical Professor in obstetrics, gynecology, and reproductive sciences at the University of California at San Francisco. He received his Bachelor of Science in bioengineering from the University of California at San Diego in 1982, and his medical degree from the University of California at San Diego, School of Medicine in 1986. He completed his residency in obstetrics and gynecology at the Mayo Graduate School in Rochester, Minnesota in 1990, and a postdoctoral fellowship in reproductive endocrinology and infertility at the University of California at San Francisco in 1993.

51. Fujimoto is a Diplomate of the National Board of Medical Examiners (1987), and Diplomate of the American Board of Obstetrics and Gynecology, in general OB/GYN (1994), and in reproductive endocrinology (1996). The American Board of Obstetrics and Gynecology recertified Fujimoto in 2005 and 2009.

52. Fujimoto has hospital privileges at Chinese Hospital in San Francisco, and the University of California at San Francisco Medical Center. He was the Director of the UCSF In Vitro Fertilization Program from 2000 through 2009, and was heavily involved in the development and growth of IVF practice. Since the early 1990s, Fujimoto has received numerous awards and honors, including from the ASRM, and presented lectures, and published in the areas of obstetrics, gynecology, and reproductive sciences. He has been an ad hoc reviewer for "Fertility and Sterility," among other professional journals. He has been a member of the ASRM since 1993, and a member of SART since 1995.

53. From 1993 to the present, he has held various professorships in obstetrics and gynecology, reproductive endocrinology, and reproductive sciences at the University of California at San Francisco and the University of Washington in Seattle.

54. Fujimoto reviewed the patient cases in this matter, including each patient's medical records. In the case of N.S., he opined that the number of embryos Respondent transferred exceeded the number recommended for patients like N.S., considering her age and history. He asserted that the recommended number of embryos and the overall standard of care in embryonic transfers are set by the ASRM. According to these guidelines, Respondent should have transferred no more than two embryos from 2004 to 2008. In his report, dated October 14, 2009, he described Respondent's transfers with regard to N.S. as a "systematic pattern of excessive number of blastocyst embryos." He stated that his greatest concern was the systematic transfer of blastocyst embryos over the course of 10 fresh IVF stimulation embryo transfer cycles." He found that "[a] total of 60 blastocyst embryos were transferred over the 10 fresh embryo transfers, representing an average number of embryos transferred to be 6. As a result, every embryo transfer performed carried significant risk for higher-order multiple gestation."

55. Fujimoto concluded that Respondent transferred into N.S. an excessive number of embryos and those acts constituted an extreme departure from the standard of care.

56. As to the 2008 transfer of 12 embryos, Fujimoto wrote, "[t]here is no question that transferring 12 fresh blastocyst embryos in any woman regardless of age is a violation of ASRM guidelines and beyond the reasonable judgment of any treating physician especially in light of the social circumstances surrounding this case and prior pregnancies achieved."

57. Fujimoto further opined that Respondent should have referred N.S. to a mental health professional, given what he found to be "out of the norm" behavior in seeking the many embryo transfers, in relatively quick order, and insisting on the 12 embryo transfers in 2008. Fujimoto specifically opined that a referral to a mental health professional was warranted and "necessary" once N.S. had four children in 2005, and that his failure to do so was an extreme departure from the standard of care. Fujimoto described N.S.'s desire for additional IVF as, "unusual requests from a single woman with multiple children already conceived from prior IVF treatment." He opined that he "found it quite abnormal and outside the norm for a single woman with 4 children conceived from IVF to request further IVF treatment for more children as this patient did in 2005. It is particularly worrisome that the patient requested conceiving shortly after delivery of her children without any period of delay."

58. Fujimoto conceded that the ASRM does not have standard of care guidelines for when to refer patients for mental health evaluations, but noted that in a 2009 reissue of a 2004 article, the ASRM wrote that the "well-being of offspring is an

overriding ethical concern" that a physician should take into account "in determining whether to provide infertility services." According to Fujimoto, Respondent should have referred N.S. to a mental health professional once N.S. returned to him for further IVF procedures in 2005. Fujimoto considered N.S.'s requests for further IVF procedures beginning in 2005, as "out of the norm" and unsound. Throughout his testimony, Fujimoto emphatically asserted that a factor he took into consideration in reaching this opinion was that N.S. was unmarried and that it was unclear from N.S.'s medical records whether she in fact had a partner of any sort. By his assertions at hearing and the emphasis with which he made these assertions, it was apparent that Fujimoto was greatly impacted by his uncertainty of whether N.S. had a life partner. He noted this concern in his report. Fujimoto wrote, "after she [N.S.] delivered twins resulting in six children, appropriate judgment should be been [sic] used to question why this woman wanted more children as a single parent with concerns raised regarding potential harm to her offspring and future children." He also wrote that "concerns should have been raised with [N.S.] regarding her persistent desire to have more children despite being single and having four children," and he criticized Respondent for failing to consider the "social context associated with her [N.S.'s] family situation." (See also Factual Finding 57.) According to Fujimoto, N.S.'s social situation included her economic/employment status, her household, the number of children in her family, and her marital or partner status.

59. Regarding Respondent's transfer of only fresh embryos into N.S., Fujimoto opined that Respondent should have used N.S.'s frozen embryos to avoid greater costs to the patient and the risks of ovarian stimulation from using fresh embryos. It remained unclear why none of the 29 frozen embryos were ever used and Fujimoto questioned Respondent's judgment in recommending only fresh IVF stimulation treatment plans for N.S. in light of the frozen embryos.

60. However, Fujimoto could not articulate a clear standard of care in regard to using frozen embryos. In his report, he wrote, "[w]hile there is no standard of care nor guidelines for the utilization of human embryos that have been frozen, the apparent stockpiling of embryos totaling 29 embryos serves no clinical purpose with added medical risk to the patient with each successive fresh IVF stimulation cycle in which more embryos are generated." He concluded that the "non-utilization of any frozen embryos during the entire course of treatments" was an extreme departure from the standard of care.

61. Regarding Respondent's medical record keeping for N.S., Fujimoto opined that Respondent did not document having informed N.S. about the risks of bleeding, pain, infection, and anesthesia from the procedures in May 1999. Fujimoto noted that Respondent had not signed the embryo cryopreservation consent, although N.S. did. The absence of Respondent's signature on other consent forms, while containing N.S.'s signature, was also noted in July 2000, December 2003, July 2004, and Respondent's multiple IVF and embryo transfer consents and embryo disposition consents. Fujimoto found that there was "a lack of documentation with respect to [N.S.'s] willingness to undergo multi-fetal reduction if faced with a higher order multiple

pregnancy," and also noted that it was unclear from the records "whether a discussion regarding the risk of multiple gestation occurred despite the transfer of 4-12 blastocyst embryos with any given embryo transfer from 1999-2008. At the very least, the documentation of such discussions was extremely poor." Fujimoto opined that these documentary problems and the lack of documentation regarding N.S.'s "social situation" and "unusual behavior" constituted an extreme departure from the standard of care.

62. Fujimoto's opinions as to Respondent's medical record keeping was given less weight because, at hearing, when asked to read Respondent's notes, similar to the ones quoted in Factual Findings 19 and 41, Fujimoto appeared overly confused by Respondent's abbreviations, even after being told, for example, to what the "A's" and "B's" notations referred. Fujimoto's inability to decipher Respondent's abbreviations appeared to the ALJ to be exaggerated in an effort to highlight their idiosyncratic nature.

63. Fujimoto also opined that Respondent engaged in a simple departure from the standard of care by using high doses of gonadotropins to stimulate the production of oocytes in N.S and thus risked causing what is known as ovarian hyperstimulation syndrome, the excessive stimulation of the ovaries. However, in his report Fujimoto conceded that it was "difficult to conclude that the stimulation practice [was] clearly outside the standard of care since there remains controversy on the 'optimal' dosing used in IVF cycles."

64. Although he did not so opine in his written report, at hearing, Fujimoto opined that Respondent acted incompetently in his overall care and treatment of N.S. However, Fujimoto failed to define incompetence, as he used the term. He did not refer, for example, to Business and Professions Code section 2234, subdivision (d) (see Legal Conclusion 2), nor did he explain why or how he reached his opinion.

Dr. J. Steinberg's Opinions regarding N.S.'s Case

65. Respondent presented the opinions of Jeffrey Steinberg, M.D. (Steinberg). Steinberg received his undergraduate degree from the University of California at Los Angeles and his medical degree from the Autonomous University of Guadalajara, in Guadalajara, Mexico. He completed an internship in obstetrics and gynecology at the Regina General Hospital through the University of Saskatchewan, School of Medicine in 1978, and a residency in obstetrics and gynecology at St. Luke's Hospital in Chicago, Illinois, through the Rush Medical College. Steinberg completed a fellowship in reproductive endocrinology and infertility at the University of California at San Diego, School of Medicine, and a fellowship in IVF at Cambridge University in Cambridge, England. He is board certified by the American Board of Obstetrics and Gynecology (1983).

66. Steinberg is currently the Medical Director, Laboratory Director, and Tissue Bank Director of his two practice clinics: the Fertility Institutes in Encino,

California, and New York, New York. He is the attending gynecologist for the Student Health Center at California State University, Northridge, in Northridge, California. He has practiced IVF for the past 35 years, since its approximate inception. His current practice includes approximately 200 to 480 IVF cases per year.

67. Steinberg reviewed the medical records of N.S., L.C., and H.L., and met with Respondent to discuss his treatment and care of all three patients.

68. Steinberg did not agree with Fujimoto that the ASRM guidelines establish the standard of care for the number of embryos to implant in an IVF procedure. Steinberg opined that there is no standard of care as to the number of embryos to implant, as there is a "long-standing dictum" in the practicing community that the number of embryos to implant is a decision that a physician must make, while considering the medical circumstances of the patient and importantly, in Steinberg's opinion, the patient's wishes. In support of his opinion, Steinberg highlighted the wording in the ASRM guidelines that indeed state the guidelines are not rigid limits. (See Factual Findings 85, 86, 88, and 90.)

69. Steinberg noted a number of N.S.'s circumstances: her miscarriage two years before she first met Respondent, the fact that in 1999, she had been trying unsuccessfully to get pregnant while on clomiphene citrate, that she had not gotten pregnant after four years of trying, her pelvic adhesions, what he considered an appropriate diagnosis of endometriosis, very low estrogen levels overall, low egg quality, a system that was difficult to stimulate with gonadotropins, and low embryo quality. Steinberg opined that all of these factors would lead him to accurately describe N.S. as infertile and made N.S.'s case an "unusual" case, given her younger age, wherein "aggressive" IVF treatment was warranted.

70. Steinberg opined that the number of embryos Respondent transferred into N.S. were all within the standard of care, with the exception of the 2008 transfers of eight and 12 embryos. He did not specifically state that the 2008 transfers were outside the standard of care, but asserted that he could not say those transfers were within the standard of care. He further asserted that it was clear to him that in those two instances, Respondent was undoubtedly "trying very hard" to help N.S. get pregnant and defined those instances and all of Respondent's IVF procedures with N.S. as "aggressive management." Despite this, on cross-examination, Steinberg agreed that Respondent's transfer of 12 embryos was wrong and an error or lapse in judgment, although he was adamant that the 2008 transfers did not constitute incompetence or gross negligence, given the existent factors and circumstances at issue, as delineated in Factual Finding 69.

71. Steinberg explained further that in all IVF procedures, a reasonable physician's goal is the birth of a single healthy baby and that infertility physicians must use their good, professional judgment in determining the use of hormones, the retrieval of oocytes, and the transfer of embryos. Steinberg opined that, generally, Respondent used good judgment in his care and treatment of N.S., noting that Respondent was

originally concerned with N.S.'s desire to have him implant all 12 embryos in July 2008, as set forth in Respondent's written notation (Factual Finding 41), and that Respondent recommended to N.S. that he only transfer four embryos. However, Steinberg conceded that the ultimate transfer of 12 embryos was not good judgment.

72. Despite his concessions regarding the 2008 transfers, Steinberg opined that it was reasonable for Respondent to rely on N.S.'s original agreement to a multi-fetal reduction procedure. In Steinberg's opinion, it is "extraordinarily unusual" for a patient to refuse that procedure. In Steinberg's 35 years of practice, a patient has only refused multi-fetal reduction once after agreeing to it.

73. In regard to Fujimoto's opinions that the standard of care required Respondent to consider N.S.'s social/familial situation, Steinberg did not agree. In contrast to Fujimoto, Steinberg opined that an IVF physician has no particular responsibility to the patient's existing children. He believes that responsibility lies squarely with the children's mother. In that same vein, he does not believe an IVF physician has a particular responsibility to the patient's future children. Instead, Steinberg opines than an IVF physician must primarily take responsibility to protect the best interests of the patient.

74. Steinberg did not agree with Fujimoto that Respondent was required to refer N.S. to a mental health professional. Steinberg agreed that in hindsight, it appears that N.S. would have benefited from counseling, but that at the time Respondent was treating her, there were no signs that would have required a reasonable IVF physician to refer her, as Complainant contends. Steinberg considered the number of babies N.S. wanted and did not think that this was sufficient reason to make a referral, noting that a portion of society considers large families appropriate and desirable and that patients seeking large families through IVF treatment are not uncommon. He considered N.S.'s desire for twins, and noted first, that Respondent had successfully counseled against twins, and second, that in his own practice between approximately 30 to 50 percent of his patients desire twins. Steinberg opined that N.S.'s proposal to use a surrogate was not uncommon and he saw nothing inherently suspect or "out of the norm" by her proposal. He also noted that Respondent had successfully counseled N.S. against surrogacy. Additionally, Steinberg explained that 10-16 IVF cycles for a patient are not uncommon in the practice. As Steinberg found that N.S.'s overall behavior was not uncommon in IVF patients, he described the viewpoint that Respondent should have referred N.S. to a mental health professional as an "ivory tower" opinion that is "out-of-touch" with what happens in the community.

75. When explaining how he would have dealt with N.S., Steinberg agreed that by February 2007, he would have been concerned about N.S.'s repeated requests for IVF, as she was focused on IVF treatments in short order. Steinberg asserted that he would have been "irked" by the number of babies she sought to have, but he nonetheless would not have referred her to a mental health professional, had he had the same information Respondent did.

76. Steinberg opined that Respondent's use of gonadotropins on N.S. was appropriate and within the standard of care, given N.S.'s sluggish responses to the hormones.

77. Steinberg opined that IVF physicians prefer to use fresh embryos in transfers because fresh embryos are more likely to result in a pregnancy, and an IVF physician should attempt to give the patient the best chance to become pregnant. He explained that the rate of pregnancy using frozen embryos is very low. Therefore, it was reasonable for Respondent to advise N.S. that the using fresh embryos increased her chance of pregnancy and to ultimately use fresh embryos at each transfer. Steinberg took exception with Fujimoto's assertion and Complainant's allegation that there is an increased medical risk in using fresh embryos, especially with young women. Steinberg further opined that embryos, as fertilized oocytes, belong to the patient and that N.S. was therefore able to do with them as she pleased. This included freezing the embryos upon her direction.

78. As to the criticisms of Respondent's record keeping, Steinberg noted that Respondent repeatedly documented his consultations and advice to N.S., including the numerous notations where he documented his informing N.S. of the alternatives, risks, benefits, and side effects of the IVF procedures. He further noted that N.S. had signed all of the consent forms, and opined that this was sufficient to meet the standard of care, as in his opinion, the standard of care does not require a physician to sign the consent form. Steinberg explained that the consent form is meant to inform the patient of the procedure at issue, the risks, and side effects, among other things, and that the importance of the consent forms is that the patient understand the procedure or treatment and consent knowingly; the physician's signature is not nearly as important, in his opinion. Steinberg was able to read and understand Respondent's salient notations and opined that Respondent's documentation in N.S.'s medical records was within the standard of care.

79. Steinberg further opined that Respondent's failure to document N.S.'s "social situation" was not below the standard of care, as it was not required in Steinberg's opinion. He explained that such things as a patient's marital status, economic health, household membership, or whether the patient has a life partner of some kind is not information that must be recorded. Steinberg asserted that an IVF physician cannot withhold IVF treatment based on a patient's marital status, or disability status, and thus, such personal information need not be recorded, as it would be irrelevant to the patient's IVF care and treatment.

80. Steinberg conceded that Respondent's operative note did not mention use of a hysteroscope. Steinberg agreed an operative note should include the number of embryos transferred and how the patient tolerated the procedure, but his testimony was unclear whether the standard of care required it. He did not find any consent form that provided for N.S. to be in any research or clinical study by Respondent.

81. Regarding HEED/DEED/SEED, Steinberg conceded that he did not know of any physician in the community that uses HEED/DEED/SEED as an embryonic implantation method, but opined that that fact alone did not mean HEED/DEED/SEED was experimental.

82. Steinberg opined that Respondent was not incompetent by any of his care and treatment of N.S., explaining that incompetence would mean generally that Respondent did not have the knowledge to execute the IVF tasks necessary to properly care and treat N.S. In Steinberg's opinion, Respondent had that knowledge and largely cared and treated N.S. appropriately (excepting his statements regarding the 2008 transfers).

The ASRM Guidelines on Embryo Transfers

83. Complainant argued at hearing that the standard of care regarding the number of embryos a physician could transfer into an IVF patient is set by the ASRM guidelines in "Fertility and Sterility."

84. To the contrary, Respondent argued that the ASRM guidelines are solely recommended guidelines and do not establish definitive limits on the number of embryos a physician may transfer.

The 2004 ASRM Guidelines

85. In a September 2004 "Fertility and Sterility" article, entitled "Guidelines on the number of embryos transferred," the ASRM recommends that in patients under the age of 35, no more than two embryos should be transferred "in the absence of extraordinary circumstances." In setting forth these and all transfer guidelines, the article begins with the following qualification: "[i]n the absence of data generated by the individual program and based on data generated by all clinics providing ART [assisted reproductive technology] services, the following guidelines are recommended." For patients with the most favorable prognosis, the ASRM recommends that, "consideration should be given to transferring only a single embryo." It defines the most favorable prognosis as including factors such as good quality embryos, excess embryos of sufficient quality to warrant cryopreservation, and previous success with IVF. For women between the ages of 35 and 37 with favorable prognoses, the ASRM recommends that a physician transfer no more than two embryos, and for all other women between the ages of 35 and 37, no more than three embryos. For women ages 38 through 40 with favorable prognoses, the ASRM recommends that a physician transfer no more than three embryos, and for all other women, no more than four embryos. For women over 40, the ASRM recommends that a physician transfer no more than five embryos.

86. The 2004 ASRM guidelines further provide that for patients with two or more previous failed IVF cycles, and those having a less favorable prognosis, regardless of age, "additional embryos may be transferred according to individual circumstances after appropriate consultation." The article reads, "[t]hese guidelines are

intended to assist ART programs and patients in determining the appropriate number of cleavage stage . . . embryos to transfer. Strict limitations on the number of embryos transferred, as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient's own unique circumstances. Accordingly, these guidelines may be modified, according to individual clinical conditions, including patient age, embryo quality, and the opportunity for cryopreservation, and as clinical experience with newer technologies accumulates."

87. The ASRM provided that the 2004 guidelines "should be modified to replace fewer embryos when transferring embryos at a more advanced stage of development (i.e., blastocyst)."

88. On the issue of determining the doctor and patient mutually determining the number of embryos to transfer, the ASRM wrote, "[t]he number of embryos transferred should be agreed upon by the physician and the treated patient(s), informed consent documents completed, and the information recorded in the clinical record."

89. Regarding the issue of multiple gestation, the ASRM noted that a multiple gestation (three or more babies) is an "undesirable consequence" because it leads to the "increased risk of complications in both the fetuses and the mother." The ASRM further noted that multi-fetal reduction does not completely eliminate the risks, as a multi-fetal reduction procedure can lead to losing all the fetuses and emotional issues.

90. Salient to the issues assessed in this matter, the ASRM wrote in 2004, "[w]hile this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations."

The 2006 ASRM Guidelines

91. The November 2006 ASRM guidelines include all of the same statements, as quoted in Factual Findings 85-90, with the exception of the quotation in Factual Finding 87. For 2006, the recommended number of embryos for transfer are the same as the numbers set forth in the 2004 guidelines. The 2006 guidelines, however, further define embryos as either cleavage or blastocyst stage.

92. The 2006 ASRM guidelines provide that a physician should transfer no more than one embryo into women less than 35 years of age with favorable prognoses, and for all other women less than 35, no more than two embryos (cleavage or blastocyst). For women between the ages of 35 and 37 with favorable prognoses, a physician should transfer no more than two cleavage embryos, and for all other women between the ages of 35 and 37, no more than three cleavage embryos or two blastocyst embryos. For women ages 38 through 40 with favorable prognoses, a

physician should transfer no more than three cleavage embryos or two blastocyst embryos, and for all other women, no more than four cleavage embryos or three blastocyst embryos. For women over 40, a physician should transfer no more than five cleavage embryos or three blastocyst embryos.

The 2008 ASRM Guidelines

93. The November 2008 ASRM guidelines set forth all of the same statements contained in the 2004 and 2006 guidelines, as delineated in Factual Findings 85-90, with the exception of the quotation in Factual Finding 87, and contain the same number of recommended embryos that should be transferred as contained in the 2006 guidelines.

The 2010 "Fertility and Sterility" Article regarding Survey of Transfer Guideline Compliance by IVF Practitioners

94. In a September 2010 "Fertility and Sterility" article entitled, "Embryo transfer practices in the United States: a survey of clinics registered with the Society for Assisted Reproductive Technology,"[2] the authors conducted a national survey of clinicians practicing IVF who were registered with SART. The survey was conducted in 2008 and 2009. The authors described the ASRM guidelines as "voluntary guidelines" and found that only nine percent of responding physicians strictly adhered to the guidelines, while 55 percent of responding physicians would deviate from the guidelines "at patient request"; 55 percent would deviate from the guidelines if using frozen embryos; and 75 percent would deviate from the guidelines for patients with previously failed IVF cycles. The authors concluded, however, that while the majority of physicians deviate from the guidelines, the authors were supportive of the transfer guidelines, and agreed that "strong medical justification" should be required to deviate from those guidelines.

Patient L.C.

95. In May 2008, L.C. was a 48-year-old woman in a second marriage who sought IVF, using eggs donated by her daughter, a 28-year-old woman. Respondent discussed IVF with her and noted thereafter that L.C. intended to use her daughter as the oocyte donor. In July 2008, Respondent discussed with L.C. the risks associated with the IVF process, including ovarian hyperstimulation syndrome, multiple gestation, and multi-fetal reduction. Respondent generally described these discussions with L.C. in her medical records, dated May 1, 2008.

96. Respondent met L.C., L.C.'s daughter and L.C.'s husband and concluded that there were no emotional or psychological issues that required him to refer L.C. or

[2] The authors are E.S. Jungheim, M.D.; G.L. Ryan, M.D.; E.D. Levens, M.D.; A.F. Cunningham, M.P.H.; G.A. Macones, M.D., M.S.C.E.; K.R. Carson, M.D.; A.N. Beltsos, M.D.; and R.A. Odem, M.D.

her family to a mental health professional or other type of counseling. At hearing, Respondent explained that he did not react positively or negatively to L.C.'s decision to use oocytes donated by her daughter.

97. As a result of Respondent's treatment, L.C. produced seven embryos. Respondent recommended to L.C., that he transfer only four embryos and she agree to freeze the remaining three. Respondent informed L.C. that three of the embryos were of poor quality and the sperm used was of low quality. However, Respondent maintained that for L.C., transferring four embryos and freezing the remainder was appropriate. L.C. told Respondent she wished him to transfer all seven embryos. L.C. explained that due in part to her age, she intended to proceed with IVF only once, and so wanted all seven embryos transferred to increase her chances of becoming pregnant. L.C. agreed to a multi-fetal reduction procedure, understanding that such a procedure could result in losing all fetuses.

98. Respondent performed an oocyte retrieval on September 22, 2008, and on September 27, 2008, he transferred seven embryos into L.C. using the HEED procedure. Respondent explained that due to L.C.'s age, it appeared reasonable to transfer all seven embryos. Respondent asserted that his intention at all times with L.C. was to produce a single, healthy baby.

99. Respondent documented his discussion with L.C. regarding the risks, including multiple gestation, the benefits, and limitations of the IVF procedure, the embryo transfer process, including HEED, and multi-fetal reduction, in L.C.'s medical records, dated September 25 and 27, 2008.

100. In October 2008, Respondent determined that L.C. had quadruplet fetuses. Thereafter, Respondent recommended multi-fetal reduction and referred L.C. to a specialist in that procedure.

101. However, in November 2008, L.C.'s son was in a serious motorcycle accident and remained in a hospital intensive care unit for four weeks. L.C. became worried that her son might die. She did not want to risk losing all four of the proposed embryos due to multi-fetal reduction. L.C. subsequently refused multi-fetal reduction.

Dr. Fujimoto's Opinions regarding L.C.'s Case

102. Like with N.S., Fujimoto opined that Respondent transferred an excessive number of embryos and that the transfer of all seven embryos was an extreme departure from the standard of care. Fujimoto noted that according to the 2008 ASRM guidelines, the age of the donor should be used to determine the appropriate number of embryos to transfer, and as the donor in L.C.'s case was 28, the appropriate number of embryos to transfer was only two blastocyst embryos.

103. Fujimoto further opined that Respondent should have referred L.C. and her husband and daughter to a mental health professional. In his view, a physician

should always refer the patient and involved family members for mental health counseling when family members are donors or surrogates. He cited no direct authority for his opinion, conceding that his opinion comes from his professional judgment, but pointed to a 2003 ASRM article that suggests such referrals in situations like L.C.'s. (See Factual Findings 109-111.) In his written opinion, dated July 23, 2010, Fujimoto noted the concerns in cases like L.C.'s include coercion. That is, a family member may feel coerced into donating oocytes by virtue of the relationship. Fujimoto further noted the unusual relationship that develops from the use of a family member donor and a successful pregnancy; he wrote, "the recipient patient is both the mother and 'genetic grandmother' of these children while her daughter is the sister and 'genetic mother' of these children." Fujimoto concluded, "the failure to recognize and recommend mental health referral [sic] for the unusual circumstances and request of [L.C.] to use her daughter as an egg donor is an extreme departure from the standard of care."

104. As to Respondent's medical record keeping in L.C.'s case, Fujimoto explained that by law, the United States Food and Drug Administration (FDA) requires an infectious disease risk assessment for donors like L.C.'s daughter. According to Fujimoto, a physician screens donors via a questionnaire, a physical assessment, and blood testing. Fujimoto noted that there was a lack of documentation regarding whether L.C.'s daughter was so screened. Fujimoto did not clearly define the requirement to document the assessment. In his report, Fujimoto wrote, "[i]mplicit in their [FDA] requirements was the importance of documenting this evaluation for every egg donor cycle performed by all clinics." (Italics added.) Fujimoto opined that the lack of documentation in the patient's records regarding L.C.'s daughter's FDA eligibility status was an "extreme departure from the standard of care." There was no evidence other than Fujimoto's opinion regarding such a requirement and no citation to legal authority requiring such screening.

105. Like with N.S., Fujimoto opined that Respondent acted incompetently in his care and treatment of L.C. However, also as with N.S., Fujimoto failed to define incompetence, as he used the term, or explain why or how he reached his opinion.

Dr. Steinberg's Opinions regarding L.C.'s Case

106. Steinberg opined that Respondent's failure to refer L.C. to a mental health professional was not below the standard of care. Steinberg explained that there was nothing particular about L.C.'s desire for IVF or her intention to use her daughter's eggs that would require an IVF physician to refer L.C. for counseling. Steinberg explained further that the decision to refer a patient to a mental health professional in the case of a family member donor should depend on particular behaviors noted or concerns that arise as the physician observes or hears the patient or involved family members during examinations and consultations. The familial ties between donor and patient, according to Steinberg, should not prompt a referral in and of themselves. Steinberg further explained that the decision to make a referral is solely based on the

physician's professional judgment and he saw no reason, based on L.C.'s records, to believe a referral was necessary.

107. Having defined incompetence, as set forth in Factual Finding 82, Steinberg opined that none of Respondent's actions in his care and treatment of L.C. constituted incompetence.

108. Similar to his analysis in N.S.'s case, Steinberg explained that since L.C. initially agreed to a multi-fetal reduction procedure, the transfer of seven embryos was understandable given L.C.'s age and Respondent's understanding that the IVF procedure would likely be her only attempt at pregnancy. Like in N.S.'s case, Steinberg found it extremely unusual that L.C. refused multi-fetal reduction. He described Respondent's treatment as "aggressive treatment," but would not specifically state that the transfer of seven embryos was below the standard of care. He also did not agree that the transfer constituted gross negligence. However, also like with N.S.'s 2008 transfers, Steinberg would not opine that the transfer of seven embryos into L.C. was within the standard of care. He noted that Respondent recommended the transfer of only four embryos, but agreed at hearing that the transfer of seven embryos was "probably" wrong. Steinberg also opined that Respondent's documentation of L.C.'s medical records was adequate.

The ASRM on Family Member Surrogacy

109. In a 2003 "Fertility and Sterility" article, entitled "Family members as gamete donors and surrogates," the ASRM, described unique problems arising from family members as "ovum donors," such as "undue influence" (meaning donors feel coerced to donate) and "confused parentage" for the resulting children.

110. The ASRM affirms that the use of family members is "ethically acceptable," but notes that in circumstances, like in the case of L.C., where the patient is a mother in her second marriage, and the patient's daughter is the intended ovum donor, concern regarding the donor's coercion is significant, and a physician should also examine the relationship between the daughter and the stepfather. The ASRM states, "providers should be prepared to spend more time screening and counseling participants" and further notes that "the involvement of multiple professionals, including . . . counselors may be necessary for a thorough assessment." The ASRM suggests, "[IVF] [p]rograms should encourage prospective participants, including partners of donors and surrogates, to undergo psychological counseling by a professional experienced in surrogacy or gamete donation."

111. Additionally, the ASRM notes that there are potential emotional consequences to the children and families involved in IVF. The ASRM suggests that involved physicians should obtain informed consents from all family participants and ensure there is no undue influence. It further suggests that if a physician finds undue pressures on the donor or surrogate or an unhealthy family dynamic, IVF programs should "feel free to deny these procedures."

Patient H.L.

112. H.L. is a woman who began seeing Respondent for regular gynecological check-ups in approximately October 1995.

113. In 2009, at the age of 43, H.L. sought pregnancy by IVF and discussed the process with Respondent. H.L. had a history of melanoma.

114. A transvaginal ultrasound performed in November 2008, found a right ovarian cyst measuring 3.8 centimeters, confirmed by a second ultrasound in December 2008, and a left ovarian cyst measuring 2.1 centimeters. Respondent initially presumed the cystic masses were benign and further presumed endometrioma.

115. In January 2009, Respondent performed a transvaginal cyst aspiration. The cyst drainage was examined. The cytologic report, dated January 15, 2009, found the aspirated fluid from the left ovarian cyst to contain "hemosiderin-laden macrophages and scattered clusters of atypical epithelial cells." Despite these findings, Respondent explained at hearing that he continued to opine that H.L. had endometriosis and he was not concerned that she had cancer. Respondent proceeded with an oocyte retrieval on January 27, 2009, noting H.L.'s "endometriotic cysts." Respondent proceeded with an embryo transfer, using the HEED procedure, on January 29, 2009. On that same day, Respondent wrote the following note in H.L.'s medical record, "ET [embryo transfer] done by hysteroscopic embryo transfer (HEED). Alternative of regular embryo transfer given prior to preparation and embryo transfer intrauterine," and "[o]ption of regular embryo transfer was given and discussed . . . Implantation vs. [h]ysteroscopic endometrial embryo delivery (HEED) was also discussed; [b]enefits and risks involved with each procedure were also discussed."

116. On January 27, 2009, H.L. signed consent forms indicating that she was advised regarding IVF and the embryo transfer process, among other things, and that she agreed to the procedures. Respondent did not sign these consent forms.

117. Respondent saw H.L. again on February 12, 2009, for a pregnancy test.

118. In April 2009, H.L. underwent laparoscopic surgery by another physician, who found stage three ovarian cancer. H.L. underwent cancer surgery in May 2009.

119. On June 23, 2009, Respondent placed a telephone call to H.L. to follow up with her; he left her a message. Respondent never spoke to H.L. again after approximately February 2009.

120. At hearing, Respondent explained that, by his June 2009 telephone call to H.L., he intended to speak with her to discuss, among other things, the cytology findings and see how she was doing. He conceded, however, that he could have discussed the cytology findings with H.L. and referred her to another physician to rule out ovarian cancer on January 27, 29, or February 12, 2009, but did not. Respondent

explained that, due to the intense media publicity he encountered regarding N.S.'s octuplets, he became overwhelmed and preoccupied and failed to follow up with H.L. He conceded that he should have referred H.L. to a gynecological oncologist and pursued blood and other diagnostic tests to confirm or rule out the possibility of ovarian cancer.

Dr. Fujimoto's Opinions regarding H.L.'s Case

121. Fujimoto opined that failing to follow-up for a suspicious ovarian cyst was a simple departure from the standard of care. Fujimoto agreed that the standard of care in screening for ovarian cancer has not been established and routine screening has not been recommended by any society. However, he noted that the American College of Obstetrics and Gynecology states "a woman with a suspicious or persistent complex adnexal mass requires surgical evaluation by a physician trained to appropriately stage and debulk ovarian cancer." According to Fujimoto, the cytology findings should have been a "red flag" indicating a potential malignancy with at least one ovarian cyst, and Respondent should have stopped the IVF process until he further evaluated the risks, and considered surgery to remove H.L.'s left ovarian cyst. The standard of care, according to Fujimoto required Respondent to refer H.L. to an oncologist and move forward aggressively to remove the cyst. Fujimoto explained at hearing that the aspiration that H.L. underwent was not enough because the source of the cyst remained.

122. Fujimoto opined that the use of gonadotropins in H.L. did not worsen the severity of H.L.'s preexisting ovarian pathology. In his report, dated July 23, 2010, he wrote that "[w]hile the use of gonadotropins in the presence of malignant ovarian neoplasm would be considered a simple departure, there is little evidence that the use of these drugs worsened the condition for this patient [H.L.]."

123. Despite the absence of any written opinions by Fujimoto regarding Respondent's medical record keeping for H.L., Fujimoto opined at hearing that H.L.'s medical records were unclear about whether Respondent discussed the cytology findings with H.L. and the records failed to document whether Respondent ever followed up with H.L. regarding the cysts.

124. Like with N.S. and L.C., Fujimoto opined that Respondent acted incompetently in his care and treatment of H.L. Fujimoto failed to explain how or why he reached his opinion and failed to define incompetence, as he used the term.

Dr. Steinberg's Opinions regarding H.L.'s Case

125. Steinberg opined that the color of the fluid collected from the aspirated cyst was consistent with endometriosis, and therefore Respondent's opinion of endometrioma was appropriate. Steinberg agreed that the cytology report contained abnormal findings, but he did not agree that the findings alone suggested cancer. From the cytology report's findings alone, Steinberg opined that it was not obvious that

H.L. was likely to have cancer. As such, there was nothing inappropriate in Respondent continuing the IVF procedure in light of the cytology report. Steinberg opined that the standard of care requires a physician to inform a patient of any abnormal test results as soon as possible. However, he opined that it was best described, not as incompetence, but as an "oversight" on Respondent's part not to make further referrals, although Respondent should have immediately informed H.L. of the abnormal cytology results, at the latest, on any of H.L.'s three later appointments in January and February 2009. Steinberg opined that Respondent's attempt to reach H.L. by telephone constituted follow up on Respondent's part, albeit belated. He opined that the publicity pressures brought forth in the case of N.S. did not excuse Respondent's failure to follow up with L.C.

Dr. S.A. Achar's Opinions regarding Respondent's Overall Record-Keeping

126. Respondent offered the opinions of Suraj Arthur Achar, M.D. (Achar). Achar is Associate Clinical Professor at the University of California at San Diego (UCSD), School of Medicine and Medical Director at the UCSD La Jolla Family and Sports Medicine Department, where he is currently a member of the risk management committee (since 2009) and the clinical quality assurance committee (since 2007). His work is affiliated with the Physician Assessment and Clinical Education (PACE) program at the UCSD, a nationally regarded remedial program for physicians.

127. Achar received his Bachelor of Arts in French Literature from the University of California at Santa Cruz and University of Poitiers, in France. He received his medical degree from the State University of New York at Buffalo, School of Medicine in 1993. He completed his internship and residency in family and preventative medicine at the UCSD in 1996, and a fellowship in sports medicine at the UCSD School of Medicine in 2001.

128. Achar is a Fellow of the American Academy of Family Physicians. He is a Diplomate of the American Board of Family Practice (1996; recertified in 2003). He has published a number of articles in numerous journals and textbooks on sports medicine. Achar was an expert reviewer for the Board from 2004 through 2009.

129. Achar reviewed the pertinent medical records of N.S., L.C., and H.L and opined that Respondent had appropriately documented all three patient's medical records, and consequently, all of those records were within the standard of care.

130. In the case of N.S.'s records, Achar saw sufficient documentation of N.S.'s social circumstances, and found that Respondent adequately documented his consultations and other discussions with N.S. He explained that all physicians use their own abbreviations within their notes, so that for example, Respondent's use of "A's" and "B's" to refer to alternatives and benefits was appropriate and within the standard of care, as long as Respondent could accurately decipher his notations. Achar acknowledged that while he teaches physicians and medical students to use

complete words in their notes, and not abbreviations, the majority of physician notes he reviews contain abbreviations.

Respondent's Clinical Studies

131. Complainant proffered the testimony of Donna Tartagliano Besone (Tartagliano), an investigator for the FDA. Tartagliano conducted a five-day inspection of Respondent's clinic in August and September 2010, and concluded, based in part on Respondent's responses to Tartagliano's inspection-related questions, that N.S. was part of a clinical study conducted by Respondent. During the inspection, Tartagliano asked Respondent for a copy of the consent form N.S. signed to participate in the study, but failed to receive an appropriate form.

132. Respondent argued that N.S., L.C., and H.L. were not human test subjects for his IVF work, and that none of his actions in his IVF care and treatment of N.S., L.C. or H.L. were part of any clinical study. Respondent further argued that the consent forms in N.S.'s, L.C.'s, and H.L.'s medical records were appropriate and contained each patient's agreement to all of his IVF-related actions, including HEED/DEED/SEED.

Evidence of Respondent's Character and Reputation

133. Respondent proffered Parviz Daniels, M.D. (Daniels) as a character witness. Daniels is board certified in general surgery. He completed medical school in Belgium and his residency in New York in approximately 1981. He has known Respondent professionally for approximately 25 years, having had contact with him at Cedars Sinai Medical Center, and having treated mutual patients. He is aware that, in the past, Respondent has referred patients to mental health professionals when necessary. Daniels described Respondent as a caring and professional physician with an excellent reputation for providing quality care to patients at Cedars Sinai.

134. Respondent also proffered Lawrence Platt, M.D. (Platt) as a character witness. Platt received his medical degree from Wayne State University, School of Medicine in 1972. He is a Diplomate of the National Board of Medical Examiners (1976), and a Diplomate of the American Board of Obstetrics and Gynecology (1979). He has a sub-specialty certification in Maternal-Fetal Medicine from the American Board of Obstetrics and Gynecology. Platt acts as reviewer for a number of medical journals, including "Fertility and Sterility," the American Journal of Obstetrics and Gynecology, and the International Journal of Gynecology and Obstetrics. His practice includes high-risk obstetrics. He is on the staff at Cedars Sinai and was Chair of obstetrics and gynecology at Cedars Sinai from 1990 to 2001. He has known Respondent professionally for approximately 20 years. He regards Respondent highly as a physician and a person, and knows that Respondent is highly respected by colleagues and patients alike at Cedars Sinai.

Respondent's Recent Activity

135. The ASRM revoked Respondent's ASRM membership in 2009; the evidence did not establish the specific reasons.

136. Respondent changed several aspects of his practice in January 2010, as a result of the N.S. case. He changed his office personnel, including his clinic embryologist and the staff in his front and back offices. He has also changed some of his IVF practices. For example, if a patient insists on the transfer of an excessive number of embryos, as N.S. did, he would now refuse to treat that patient.

137. In his direct examination, Respondent asserted that he now strictly follows the ASRM guidelines (since January 2010); however, on cross-examination, he asserted that he would still deviate from the guidelines, based on patient circumstances.

138. Respondent has upgraded his record-keeping, having taken the medical record keeping course through PACE at UCSD, on October 28 and 29, 2010, for 17 continuing medical education credits.

139. Respondent has completed a number of other continuing medical education credits: the Institute for Medical Qualify "Professionalism" course, for 22 credits, on August 21-22, 2010, in El Segundo, California; the Women's Health Annual Visit, by Omnia Education in Pasadena, California, on June 11, 2010 (6.25 credits); Luteal support in reproduction, by the ASRM (1 credit); the City of Hope's 4th Annual Conference on Breast and Gynecologic Cancers: Advances in Prevention, Diagnosis and Treatment, on June 13, 2009 (8 credits); Operative Hysteroscopy System, by Smith and Nephew, in Marina Del Rey, California, on August 20, 2009; the Role of RANK/RANK-Ligand/OPG Pathway in Bone Loss and Associated Diseases, by Education Outcomes Science, on April 24, 2007 (1 credit); Irvine Scientific Vitrification System—Hands-on Workshop; Achieving Success Using Ultra-Rapid Cryo, by the American Board of Bioanalysis Professional Enrichment Educational Renewal, on January 3, 2007, May 20, 2006, and January 23, 2005 (1.8 credits); Preservation of Fertility Through Advances in Cryobiology, by the American Board of Bioanalysis Professional Enrichment Educational Renewal, on January 22, 2005 (0.6 credits); Use of Progesterone in Management of Secondary Amenorrhea, by the ASRM, on January 8, 2009 (0.5 credits); Progesterone Use in Assisted Reproductive Technology by the ASRM (0.5 credits); Practical Considerations for Office-Based Endometrial Ablation, by CME Consultants, on June 21, 2008 (2 credits); 15th World Congress on In Vitro Fertilization, in Geneva, Switzerland, by the International Society for In Vitro Fertilization, from April 19-22, 2009; the Royan International Twin Congress, 10th Congress on Reproductive Biomedicine, 5th Congress on Stem Cells Biology and Technology, on September 23-25, 2009, in Tehran, Iran.

140. Respondent continues to have privileges at, and practices at, Cedars Sinai. Cedars Sinai's Credentialing Committee re-credentialed Respondent in 2007, and commended him for 25 years of "distinguished service" in 2009.

LEGAL CONCLUSIONS

Statutory Law

1. Business and Professions Code section 2227 states in pertinent part:

(a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code . . . and is found guilty . . . may, in accordance with the provisions of this chapter:

(1) Have his . . . license revoked upon order of the division.

(2) Have his . . . right to practice suspended for a period not to exceed one year upon order of the division.

(3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the division.

(4) Be publicly reprimanded by the division.

(5) Have any other action taken in relation to discipline as part of an order of probation, as the division or an administrative law judge may deem proper.

2. Business and Professions Code section 2234 states in pertinent part:

The Division 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:

[¶]. . . [¶]

(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.

[¶]. . . [¶]

(d) Incompetence.

(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.

Case Law

The Standard of Proof

3. Complainant must prove her case by clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) Clear and convincing evidence means the evidence is "so clear as to leave no substantial doubt" and is "sufficiently strong to command the unhesitating assent of every reasonable mind." (*Mathieu v. Norrell Corporation* (2004) 115 Cal.App.4th 1174, 1190 [citing *Mock v. Michigan Millers Mutual Ins. Co.* (1992) 4 Cal.App.4th 306, 332-333].)

Negligence

4. "[A] physician is required to possess and exercise, in both diagnosis and treatment, that reasonable degree of knowledge and skill which is ordinarily possessed and exercised by other members of his profession in similar circumstances." (*Landeros v. Flood* (1976) 17 Cal.3d 399, 408; see also, *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 997-998.)

5. "'Negligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.' [Citation.] Thus, as a general proposition one 'is required to exercise the care that a person of ordinary prudence would exercise under the circumstances.' [Citations.] Because application of this principle is inherently situational, the amount of care deemed reasonable in any particular case will vary, while at the same time the standard of conduct itself remains constant, i.e., due care commensurate with the risk posed by the conduct taking into consideration all relevant circumstances. [Citations.]" (*Flowers v. Torrance Memorial Hospital Medical Center*, supra, 8 Cal.4th at 997.) "Since the standard of care remains constant in terms of 'ordinary prudence,' it is clear that denominating a cause of action as one for 'professional negligence' does not transmute its underlying character. For substantive purposes, it merely serves to establish the basis by which 'ordinary prudence' will be calculated and [Respondent's] conduct evaluated." (Id., at 998.)

6. "The fact that another physician or surgeon might have elected to treat the case differently or use methods other than those employed by [Respondent] does not of itself establish negligence." (*Williamson v. Prida* (1999) 75 Cal.App.4th 1417, 1425-1426.)

Gross Negligence

7. Gross negligence is defined as "the want of even scant care or an extreme departure from the ordinary standard of conduct." (*Eastburn v. Regional Fire Protection Authority* (2003) 31 Cal.4th 1175, 1185-1186.)

Incompetence

8. Incompetence means "an absence of qualification, ability or fitness to perform a prescribed duty or function." (*Pollack v. Kinder* (1978) 85 Cal.App.3d 833, 837.) Incompetence is distinguishable from negligence, in that one may be competent or capable of performing a given duty but negligent in performing that duty. (*Id.*, at 837-838.) Thus, "a single act of negligence . . . may be attributable to remissness in discharging known duties, rather than . . . incompetency respecting the proper performance." (Id., at 838 [citing *Peters v. Southern Pacific Co.* (1911) 160 Cal. 48, 62].)

9. "It [incompetence] is commonly defined to mean a general lack of present ability to perform a given duty as distinguished from inability to perform such duty as a result of mere neglect or omission. (Footnote omitted.) Such an interpretation is totally consistent with the declared legislative objective of public protection by requiring a minimum standard of professional conduct on the part of those licensed to engage in regulated activities." (*Pollack v. Kinder, supra*, 85 Cal.App.3d at 837-838.) "[T]he terms negligence and incompetency are not synonymous; a licensee may be competent or capable of performing a given duty but negligent in performing that duty." (*Id.*, at 838.)

Expert Testimony

10. "The standard of care against which the acts of a physician are to be measured is a matter peculiarly within the knowledge of experts . . . and can only be proved by their testimony [citations], unless the conduct required by the particular circumstances is within the common knowledge of the layman." (*Landeros v. Flood, supra*, 17 Cal.3d at 410.)

11. The trier of fact may "accept part of the testimony of a witness and reject another part even though the latter contradicts the part accepted." (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 67.) The trier of fact may also "reject part of the testimony of a witness, though not directly contradicted, and combine the accepted portions with bits of testimony or inferences from the testimony of other witnesses thus weaving a cloth of truth out of selected available material." (*Id.* at 67-68 [citing *Nevarov v. Caldwell* (1958) 161 Cal.App.2d 762, 767].) Further, the fact finder may reject the testimony of any witness, even an expert, although uncontradicted. (*Foreman & Clark Corp. v. Fallon* (1971) 3 Cal.3d 875, 890.)

12. The fact that a trier of fact "may disbelieve the testimony of a witness who testifies to the negative of an issue does not of itself furnish any evidence in

support of the affirmative of that issue and does not warrant a finding in the affirmative thereof unless there is other [supportive evidence]." (*Hutchinson v. Contractors' State License Board* (1956) 143 Cal.App. 2d 628, 632 [citing *Marovich v. Central California Traction Co.* (1923) 191 Cal. 295, 304].)

Patient N.S.

Gross Negligence and Repeated Negligent Acts

13. As to the embryo transfers in January and July 2008, Fujimoto opined that they were extreme departures from the standard of care due to the excessive number of embryos transferred. Saliently, Steinberg could not say the transfers were within the standard of care. Further, Steinberg described those two embryo transfers as wrong and a lapse in judgment. With no expert testimony to the contrary, the evidence was clear and convincing that N.S.'s embryo transfers, in January and July 2008, were below the standard of care, and as Fujimoto opined, extreme departures from the standard of care. As such, the transfers constituted gross negligence, and as two acts, the transfers constituted repeated negligent acts.

14. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for an excessive number of embryo transfers in the case of N.S. on two occasions in January and June 2008, as set forth in Factual Findings 1-94, and Legal Conclusions 1-3, 7, and 10-13.

15. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for an excessive number of embryo transfers in the case of N.S. on two occasions in January and June 2008, as set forth in Factual Findings 1-94, and Legal Conclusions 1-6, and 10-13.

16. As to all the other embryo transfers, Steinberg opined contrary to Fujimoto. Whereas Fujimoto opined that the embryo transfers between December 2002 and 2007 were all below the standard of care, by sheer number, Steinberg explained that when an IVF physician considers, as Respondent did, the factors delineated in Factual Findings 17, 18, 23, 33, and 38, the number of embryos transferred is less pertinent than the analysis used by the IVF physician in considering the circumstantial patient data. Additionally, the ASRM guidelines do not set forth rigid limitations, as Fujimoto implicitly opined. In the ASRM's own wording, the guidelines are "recommended," "may be modified," and are "not intended to be the only approved standard of practice or to dictate an exclusive course of treatment." (Factual Findings 85, 86 and 90.) Furthermore, pursuant to a 2008/2009 national survey the majority of IVF practitioners nationwide deviate from the ASRM guidelines. (Factual Finding 94.) This survey corroborated Steinberg's similar assertions at hearing.

17. The evidence established, as to the embryo transfers between December 2002 and 2007, that Respondent considered the various factors set forth in Factual Findings 18, 23, 33, and 38, and consulted with N.S. to determine the number of embryos to transfer on each occasion. N.S.'s continuous and successive requests for IVF treatment were in objectively short order, but there was no evidence that the standard of care limits an IVF physician's ability to treat a patient who seeks IVF treatment in as continuous and as successive an order as N.S. did. As the ASRM guidelines provide for flexibility in determining the appropriate number of embryos to transfer, and with evidence that Respondent considered the appropriate factors and used his professional judgment to ultimately determine the number of embryos to transfer on each occasion between December 2002 and 2007, Respondent's embryo transfers between those dates were not extreme departures from the standard of care and thus did not constitute gross negligence or repeated negligent acts.

18. Fujimoto opined that Respondent should have referred N.S. to a mental health professional as soon as 2005, when she had four children and wanted further IVF treatment. However, nothing in the evidence, other than Fujimoto's opinion, supported that position. Fujimoto could point to nothing other than his own professional opinion as to why obtaining four children via IVF was the rational limit of children for N.S. to bear through IVF, without then requiring psychological counseling. Steinberg was persuasive that it is not up to the physician to decide how many children an IVF patient may have. Steinberg noted that, in hindsight, N.S. might have benefited from psychological counseling, but further noted that that viewpoint was not readily apparent in 2005. Whether N.S.'s behavior was abnormal in 2005, is an arguable matter that is not objectively established by the standard of care for an IVF physician. Respondent's failure to refer N.S. to a mental health professional, therefore, was not an extreme departure from the standard of care or otherwise negligence.

19. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for failing to refer N.S. to a mental health professional, as set forth in Factual Findings 1-94, and Legal Conclusions 1-3, 7, 10-12, and 18.

20. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for failing to refer N.S. to a mental health professional, as set forth in Factual Findings 1-94, and Legal Conclusions 1-6, 10-12, and 16-18.

21. Respondent's failure to recommend that N.S. use her frozen embryos was not a departure from the standard of care. Fujimoto's opinion on this was based solely on his professional judgment and he could not point to any standard in IVF practice. Steinberg credibly opined to the contrary, noting that the embryos belong to the patient, who may direct the physician to do with them as the patient sees fit. Moreover, the evidence established that Respondent advised N.S. regarding the use of frozen embryos, advising her, in concert with Steinberg's opinion, that frozen embryos are less successful than fresh embryos.

22. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for failing to recommend and use N.S.'s frozen embryos, as set forth in Factual Findings 1-36, 59, 60, 77, and Legal Conclusions 1-3, 7, 10-12, and 21.

23. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for failing to recommend and use N.S.'s frozen embryos, as set forth in Factual Findings 1-36, 59, 60, 77, and Legal Conclusions 1-6, 10-12, and 21.

24. While Fujimoto ultimately concluded that Respondent's use of high doses of gonadotropins was below the standard of care, he could not identify the standard of care. Moreover, Fujimoto conceded that the optimal dosing of gonadotropins remains unclear. Steinberg opined that the use of hormones was appropriate, given N.S.'s delayed responses to hormonal stimulation. Therefore the evidence was not clear and convincing that Respondent's use of gonadotropins on N.S. was below the standard of care.

25. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for the excessive dosing of gonadotropins in the case of N.S., as set forth in Factual Findings 1-40, 50-53, 63, 65-66, 76, and Legal Conclusions 1-3, 7, 10-12, and 24.

26. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for the excessive dosing of gonadotropins in the case of N.S., as set forth in Factual Findings 1-40, 50-53, 63, 65-66, 76, and Legal Conclusions 1-6, 10-12, and 24.

Incompetence

27. Respondent's overall care and treatment of N.S. was not established to be incompetent. Fujimoto's opinion that Respondent was incompetent merited little weight, as he failed to define incompetence and failed to set forth the analyses he used to reach his opinion. In contrast, Steinberg defined incompetence similar to the case law. (*Pollack v. Kinder, supra*, 85 Cal.App.3d at 837-838.), and opined that Respondent had the knowledge and skill to practice IVF and was therefore, not incompetent.

28. Even when considering the portions of Respondent's care and treatment of N.S. that constituted gross negligence and repeated negligent acts, the evidence did not establish that Respondent's IVF care and treatment showed an absence of

qualification, ability, or fitness. (*Pollack v. Kinder, supra*, 85 Cal.App 3d at 837.) Thus, Respondent did not act incompetently in his care and treatment of N.S.

29. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (d), for incompetence, in his care and treatment of N.S., as set forth in Factual Findings 1-94, and Legal Conclusions 1-3, 8-12, 27, and 28.

Patient L.C.

Gross Negligence and Repeated Negligent Acts

30. For similar reasons as explained in Legal Conclusion 13, the number of embryos Respondent transferred into L.C. was below the standard of care, as Fujimoto opined. Like in the case of N.S., Steinberg failed to opine that the transfer of seven embryos was within the standard of care. The flexible nature of the ASRM guidelines does not, in this patient's case also, mean that the seven-embryo transfer into L.C. was appropriate. Steinberg's opinions neither discredited nor weakened Fujimoto's opinion. Thus, there was clear and convincing evidence that the Respondent's seven-embryo transfer into L.C. was an extreme departure from the standard of care, and consequently, gross negligence.

31. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for an excessive number of embryo transfers in the case of L.C., as set forth in Factual Findings 1, 5, 95, 97, 98, 100-102, 108, and Legal Conclusions 1-3, 7, 10-12, and 30.

32. The embryo transfer, when considered with Respondent's negligent acts in the case of N.S., constitutes repeated negligent acts.

33. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for an excessive number of embryo transfers in the case of L.C., as set forth in Factual Findings 1, 5, 95, 97, 98, 100-102, 108, and Legal Conclusions 1-6, 10-12, and 32.

34. Respondent's failure to refer L.C. to a psychological professional was not a departure from the standard of care, as Steinberg persuasively opined that the standard of care did not absolutely require it. On this issue, Steinberg and the ASRM contradicted Fujimoto's opinion. The 2003 "Fertility and Sterility" article affirms the acceptability of family member ovum donation, and while it suggests that IVF physicians examine the family dynamics of involved family members, and suggests counseling for those participants, it does not mandate a mental health referral. While Fujimoto asserted that it was his practice to always refer patients and involved family members to counseling in situations like L.C.'s, and while such a practice may be

optimal, the ASRM's language in the article is not compulsory. A reading of the ASRM article in whole renders the reasonable conclusion that the decision whether to refer a patient and her involved family members to a mental health professional is in the professional judgment of the physician. L.C.'s case provided no evidence that L.C. or her daughter required such a referral. Respondent credibly asserted that he observed and otherwise perceived no such issues. Therefore, the absence of a referral to a mental health professional, in the case of L.C., was not gross negligence or repeated negligent acts.

35. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for his failure to refer L.C. or her family to a mental health professional, as set forth in Factual Findings 1, 5, 95-101, 103, 106, 109-111, and Legal Conclusions 1-3, 7, 10-12, and 34.

36. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for his failure to refer L.C. or her family to a mental health professional, as set forth in Factual Findings 1, 5, 95-101, 103, 106, 109-111, and Legal Conclusions 1-6, 10-12, and 34.

Incompetence

37. The analysis and conclusions reached regarding the allegation of incompetence in the case of N.S. are equally applicable to the case of L.C. Therefore, Respondent did not act incompetently in his care and treatment of L.C. for the reasons set forth in Legal Conclusions 27 and 28.

38. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (d), for incompetence, for his care and treatment of L.C., as set forth in Factual Findings 1, 5, 95101, 105, 107, and Legal Conclusions 1-3, 8, 9, 10-12, and 37.

Patient H.L.

Repeated Negligent Acts

39. Respondent's failures to perform testing on H.L. and refer her to a specialist to rule out cancer were repeated negligent acts, two simple departures from the standard of care, as opined by Fujimoto. Fujimoto persuasively opined that the abnormal cytology report should have prompted Respondent to perform further testing and refer H.L. to a specialist. Steinberg's opinion, that the abnormal cytology report did not of itself establish H.L.'s cancer, was credible, but the important factor to consider in H.L.'s case, as opined by Fujimoto, was that the cytology report was abnormal. Whether the findings in that report pointed to conditions as serious as cancer, or other less serious conditions, it was Respondent's duty to pursue the

abnormalities in the cytology report by testing and referral. Even Respondent conceded he should have, but neglected to do so because of the publicity pressures he experienced in N.S.'s case. Respondent further conceded, similar to Steinberg's opinion, that those pressures should not have deterred Respondent from his professional obligations.

40. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for failing to perform testing on H.L. and failing to refer her to a specialist to rule out cancer after obtaining abnormal cytology report findings, as set forth in Factual Findings 1, 5, 112-122, 125, and Legal Conclusions 1-3, 4-6, 10-12, and 39.

Incompetence

41. The analysis and conclusions reached regarding the allegation of incompetence in the cases of N.S. and L.C. are equally applicable to the case of H.L. Therefore, Respondent did not act incompetently in his care and treatment of H.L. for the reasons set forth in Legal Conclusions 27 and 28.

42. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (d), for incompetence, in his care and treatment of H.L., as set forth in Factual Findings 1, 5, 112125, and Legal Conclusions 1-3, 8-9, 10-12, and 41.

The Patients' Informed Consent to Respondent's Use of HEED/DEED/SEED

43. Respondent obtained the informed consent of N.S., L.C., and H.L., with respect to the use of HEED/DEED/SEED and documented that consent in the patients' records. (Factual Findings 41, 49, 99, and 115.)

44. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivisions (b) or (c), for gross negligence or repeated negligent acts, for using HEED/DEED/SEED without the informed consent of patients N.S., L.C., and H.L., as set forth in Factual Findings 1, 5, 41, 49, 99, 115, and Legal Conclusions 1-7, 10-12, and 43.

Respondent's Alleged Clinical Studies

45. The evidence established Respondent engaged in IVF clinical studies, and that N.S. participated in at least one such study. However, there was no persuasive expert opinion establishing the standard of care with regard to patient consent in clinical studies. There was no evidence conclusively establishing the legal requirement for consent forms within clinical studies and, for example, whether any exemptions, exclusions, or alternatives to consent forms exist. Further there was insufficient evidence establishing that any portion of the IVF care and treatment of

N.S., L.C., or H.L. at issue in this case was a part of, or otherwise constituted, a clinical study.

46. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (e), for dishonest and corrupt acts, for performing clinical studies on patients without their informed consent, as set forth in Factual Findings 1, 5, 80, 131, 132, and Legal Conclusions 1-3, 1012, and 45.

Respondent's Record-Keeping

47. Business and Professions Code section 2266 states in pertinent part:

> 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.

48. Respondent maintained adequate records in the cases of N.S., L.C., and partially in the case of H.L.

N.S.'s Medical Records

49. N.S.'s records contain Respondent's numerous notations documenting his discussions and consultations with her, discussing the alternatives, benefits, risks, and side effects of the IVF process and related procedures. According to his notations, these discussions included the topics of multiple gestation and multi-fetal reduction. Based on the consent forms on the freezing and disposition of N.S.'s embryos, and Respondent's credible testimony, Respondent spoke with N.S. regarding those topics and obtained N.S.'s authorization and direction. Although as to the disposition of her frozen embryos, N.S.'s consents were limited to certain specified circumstances, Respondent's documentation adequately memorializes the pertinent IVF-related topics. The fact that Respondent did not sign the consent forms is of limited consequence, as Steinberg opined. The patient's signature is the primary concern. Fujimoto failed to set forth any valid reason why Respondent's signature would be so important as to make its absence a departure from the standard of care.

50. There was little, if any documentation regarding N.S.'s "social situation," which was understood to mean facts that would describe her personal and social circumstances. However, the evidence did not establish that the standard of care required the documentation of such information. On this, Steinberg's opinion was persuasive. Fujimoto's point that an IVF physician should consider the patient's children when treating an IVF patient is reasonable. But Steinberg's opinion, that an IVF physician's primary responsibility is to protect the best interests of the patient, is also reasonable. Steinberg further opined that it is the IVF patient who bears the responsibility to care for and consider her children and future children when pursuing IVF, and that the patient's other social circumstances are irrelevant to the physician's

IVF care and treatment. This opinion has merit. Furthermore, to find as Fujimoto opined would risk placing IVF physicians in the role of those who would pass moral judgment on the social circumstances of patients, including for example whether a patient who is single, divorced, rich, poor, or has a disability should have children, or only a specified number of children, via IVF. As Steinberg more convincingly opined, the patient's social situation is not relevant to the patient's care, and thus need not be documented in the patient's medical record. Taken as a whole, the expert evidence did not establish, by clear and convincing evidence, that the standard of care for an IVF physician requires him or her to document the social aspects of the patient's life. Respondent's documentation of N.S.'s records was therefore adequate.

51. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2266, for maintaining inadequate or inaccurate records as to patient N.S., as set forth in Factual Findings 1, 5, 8, 19, 26, 27, 41, 49, 50-53, 61, 62, 65, 66, 78-80, 126-130, and Legal Conclusions 1-3, 10-12, and 47-50.

L.C.'s Medical Records

52. Respondent documented L.C.'s records, showing that he discussed all IVF-related procedures with her on September 25 and 27, 2008. However, Respondent performed an oocyte retrieval on September 22, 2008. Respondent failed to document any IVF-related discussions at the initial consultation or otherwise before the oocyte retrieval.

53. However, Fujimoto's opinion, in light of the subsequent documentation on September 25 and 27, 2008, and the contrary opinions of Steinberg and Achar, and giving Achar's opinions less weight[3], Fujimoto's opinion alone did not establish by clear and convincing evidence that Respondent's omission constituted inadequate records that merited license discipline, pursuant to Business and Professions Code section 2266.

54. Respondent documented the fact that L.C. intended to use a directed donor, but did not document the significance of using a directed donor. Respondent also did not describe the ovarian stimulation protocol used, or that he discussed the number of embryos to be transferred with L.C.; however, Fujimoto was unpersuasive that the absence of that information constituted inadequate records, when considering Respondent's overall notations in each patient's records and Steinberg's and Achar's opinions. It was not established by clear and convincing evidence that Respondent's documentary omissions in L.C.'s records constituted inadequate records, sufficient to justify license discipline.

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[3] Achar's opinions regarding Respondent's record keeping was given less weight than that of Fujimoto's, as Achar established no background in IVF, endocrinology, or reproductive science. However, as a physician whose work is affiliated with the PACE program, his opinions were nevertheless given some weight.

55. Fujimoto's opinion that Respondent should have documented the FDA infectious disease assessment was also unpersuasive. Complainant provided no conclusive evidence establishing the FDA requirement Fujimoto asserted. Fujimoto's assertion alone was insufficient to establish what the FDA requires, especially given the ill-defined nature of the documentation requirement that Fujimoto described as only "implicit" in the requirements.

56. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2266, for maintaining inadequate or inaccurate records, as to patient L.C., as set forth in Factual Findings 1, 5, 99, 104, 108, 126-130, and Legal Conclusions 1-3, 10-12, 47, 48, and 52-55.

H.L.'s Medical Records

57. The consent forms in H.L.'s records indicate that Respondent informed H.L. about all IVF-related procedures, including embryo transfer, and that she consented to the procedures. The consent forms documented that Respondent discussed the IVF-related processes with L.C. sufficiently to establish adequate IVF-related records.

58. As H.L. signed the pertinent consent forms, Respondent's failure to sign treatment-related consent forms is not below the standard of care for the same reasons set forth in Legal Conclusion 49 regarding N.S.

59. H.L.'s records lacked documentation of Respondent's plans for artificial insemination and IVF therapies, when the plans for those therapies was made, what stimulation protocol was used, and the number of IVF cycles undergone. However, assessing Respondent's existing notations and documentation in H.L.'s records, and considering all three expert opinions (despite the lesser weight of Achar's opinions), the evidence failed to establish that these deficiencies merited license discipline, pursuant to Business and Professions Code section 2266.

60. Respondent failed to document any discussion with H.L. regarding her ovarian cystic masses or the abnormal cytology report, since it was that Respondent never had any such discussions with her. There is no documentation regarding H.L.'s consent to the cyst aspiration procedure. Distinct from the other records above, H.L.'s records are completely absent of any discussions with H.L. or actions Respondent took related to the cystic masses or the abnormal cytology report (except for the aspiration procedure). Respondent's failure to document any discussions on these topics constitutes inadequate records.

61. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2266, for maintaining inadequate or inaccurate records as to patient H.L., as set forth in Factual Findings 1, 5, 115, 123, 126-130, and Legal Conclusions 1-3, 10-12, 47, 48, and 57-61.

The Proper Level of License Discipline

62. A. Respondent committed acts of gross negligence and repeated negligent acts in his care and treatment of N.S. and L.C., and repeated negligent acts in his care and treatment of H.L. Respondent maintained inadequate records in the case of H.L.

B. However, to a great degree, Respondent succeeded in presenting a defense to the majority of the allegations, including other acts of gross negligence and repeated negligent acts, inadequate records, and all allegations of incompetence, and inadequate consents regarding HEED/DEED/SEED and clinical studies. This partially successfully defense does not lessen or diminish the gravity of Respondent's actions described in subparagraph A.

63. A. The evidence established that, overall, and with the noted exception of failing to inform H.L. of her abnormal cytology report, Respondent made IVF treatment decisions with regard for the patients' well-being, considering each patient's circumstances. On the issue of deciding on the number of embryos to transfer in N.S. and L.C., the evidence did not show that Respondent practiced carelessly in disregard of the patients, but that instead, he was aware of each patient's circumstances and used his professional judgment (albeit very poor judgment in a portion of the cases of N.S. and L.C., as concluded ante) and considered each patient's wishes to determine the number of embryos to transfer. While the evidence did not establish Respondent as a maverick or deviant physician, oblivious to standards of care in IVF practice, it certainly demonstrated that he did not exercise sound judgment in the transfer of twelve embryos to patient N.S, as Respondent admitted. (Reporter's Transcript (RT) 10/25/10, 74: 20-25, cont'd 75: 1-8.) Respondent also admitted that he was wrong to transfer seven embryos to patient H.L. (RT 10/21/10 131:10-16.)

B. In his written argument and at oral argument, Respondent suggested that the patients who agreed to fetal reduction but failed to follow through with this procedure somehow bear some responsibility in this matter. The Board does not accept this premise, as one must not forget the purpose for which these patients sought out Respondent: to create life and carry it into the world. A fetal reduction procedure has risks, including the loss of all pregnancy, and to assign even a scintilla of responsibility to a patient who becomes pregnant and then elects not to follow through with a procedure that may jeopardize her (and possibly her family's) prized objective is troubling and telling. In fact, Respondent admitted that he had counted on his patients N.S. and L.C. undergoing fetal reduction if higher gestation occurred as a result of embryonic transfer. (RT 10/25/10 80:8-12.)

64. Respondent has practiced medicine as a California licensed physician since 1979, never having suffered license discipline by the Board. He has a good reputation in the professional community.

65. A. In his proposed decision that placed Respondent's license on probation, the Administrative Law Judge concluded that the publicity regarding N.S.'s case would serve as a deterrent to Respondent's transferring an excessive number of embryos to a patient in the future. The Board adamantly disagrees with this suggestion for several critically important reasons. First, the Board is unwilling to cede its responsibility of public protection to any other party (See Bus. & Prof. Code, §§ 2001.1, 2004, & 2220.5.) and to do so would be a dereliction of its duty. Second, when respondent encountered public outcry regarding N.S.'s case, he admitted that bad press was a reason that he failed to follow up patient H.L.'s abnormal test results. (Reporter Transcript (RT) 10/,25/10, 83: 11-21, 95:19-24.) Accordingly, the Board is not persuaded that relying on the public or the media to fulfill or supplement the Board's public protection role is sound policy.

B. Moreover, the Administrative Law Judge (ALJ) found that Respondent might still deviate from the ASRM guidelines after testifying that he would strictly adhere to them. This inconsistency led the ALJ to conclude that Respondent's practice needed oversight (through probation) and specifically a practice monitor. The Board agrees with the ALJ's critical finding of inconsistency but disagrees that imposition of a probationary term and a practice monitor are sufficient to protect the public.

65. In determining the appropriate level of discipline, the Board is guided by its Disciplinary Guidelines, incorporated by reference in regulation at section 1361 of title 16 of the California Code of Regulations. The maximum level of discipline for a violation of subdivision (b) [gross negligence] or (c) [repeated negligent acts] of section 2234 of the Business and Professions Code is revocation; the minimum is stayed revocation with five years probation with attendant terms and conditions. The same level of discipline is applicable to a violation of section 2266 [failure to maintain adequate and accurate records] of the Business and Professions Code.

66. This is not a one patient case or a two patient case; it is a three patient case, and the established causes of discipline include repeated negligent acts (all three patients), gross negligence (two patients) and inadequate records (one patient). The Board is cognizant of Respondent's changes in his practice and his completion of professionalism and recordkeeping courses. However, whenever the Board exercises its disciplinary functions, public protection is paramount. (See Bus. & Prof. Code, § 2001.1.) The Board is not assured that oversight through probation is enough, and having weighed the above, has determined that revocation of Respondent's certificate is necessary to protect the public.

ORDER

Physician and Surgeon Certificate No. G 41227, issued to Respondent Michael Kamrava, is revoked.

This Decision shall become effective at 5:00 p.m. on July 1, 2011.

IT IS SO ORDERED this 1st day of June, 2011.

Shelton Duruisseau, Ph.D, Chair
Panel A

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

In the Matter of the First Amended Accusation Against:	)	
MICHAEL KAMRAVA, M.D.	)	Case No.: 06-2009-197098
Physician's & Surgeon's Certificate No: G-41227	)	OAH No.: 2010010877
Respondent.	)	

ORDER OF NON-ADOPTION
OF PROPOSED DECISION

The Proposed Decision of the Administrative Law Judge in the above-entitled matter has been **non-adopted.** A panel of the Medical Board of California (Board) will decide the case upon the record, including the transcript and exhibits of the hearing, and upon such written argument as the parties may wish to submit, including any argument directed to the question of whether the proposed Order should be modified. The parties will be notified of the date for submission of such argument when the transcript of the above-mentioned hearing becomes available.

To order a copy of the transcript, please contact Frances Taijeron, Transcript Coordinator, Star Reporting Service, Inc., 703 Market Street, Suite 1005, San Francisco, CA 94103. The telephone number is (415) 348-0050

To order a copy of the exhibits, please submit a written request to this Board.

In addition to written argument, oral argument will be scheduled if any party files with the Board within 20 days from the date of this notice a written request for oral argument. If a timely request is filed, the Board will serve all parties with written notice of the time, date and place for oral argument. Oral argument shall be directed only to the question of whether the proposed penalty should be modified. Please do not attach to your written argument any documents that are not part of the record as they cannot be considered by the Panel. The Board directs the parties attention to Title 16 of the California Code of Regulations, sections 1364.30 and 1364.32 for additional requirements regarding the submission of oral and written argument.

Please remember to serve the opposing party with a copy of your written argument and any other papers you might file with the Board. The mailing address of the Board is as follows:

MEDICAL BOARD OF CALIFORNIA
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815-3831
(916) 263-8906
Attention: Richard M. Acosta

Date: February 9, 2011

Shelton Duruisseau

Shelton Duruisseau, Ph.D., Chair
Panel A

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

In the Matter of the First Amended Accusation Against: MICHAEL KAMRAVA, M.D., Physician's and Surgeon's Certificate No. G 41227, Respondent.	Agency Case No. 06-2009-197098 OAH Case No. 2010010877

PROPOSED DECISION

Daniel Juárez, Administrative Law Judge (ALJ), Office of Administrative Hearings, heard this matter on October 18, 19, 20, 21, 25, 26, and November 17 and 18, 2010, in Los Angeles, California.

Judith T. Alvarado, Deputy Attorney General, represented Linda K. Whitney (Complainant), Executive Director of the California Medical Board.

Fenton & Nelson, and Henry Fenton, represented Michael Kamrava, M.D. (Respondent). Respondent was present on each day of hearing.

At hearing, Complainant amended the Accusation. On page 5, line 4, "December 10, 2005" was deleted and replaced with "December 31, 2005." On page 5, lines 20 and 25, and page 6, line 9, "embryo" was deleted and replaced with "oocyte." On page 11, line 24, "using known a directed donor" was deleted and replaced with "using a known directed donor."

Complainant also amended the Accusation at hearing by adding three causes for discipline, each to conform to proof at hearing. An eighth cause for discipline was added, alleging that Respondent committed acts of incompetence by the acts already asserted within the Accusation. A ninth cause for discipline was added, alleging that Respondent committed negligence by using a procedure known as "HEED," "DEED," and "SEED" (defined *post*) without the informed consent of the involved patients. A tenth cause for discipline was added, alleging that Respondent committed dishonest and corrupt acts when he performed clinical studies on patients without obtaining those patients' informed consent. Respondent opposed all three amendments, claiming a violation of due process. In accordance with Government Code section 11507, the ALJ noted and accepted Complainant's amendments, but also allowed Respondent the opportunity to request additional time to prepare a further

defense to the amendments. At no time during the hearing, however, did Respondent request additional time to prepare a further defense to the additional causes for discipline.

The parties submitted the matter for decision on November 18, 2010.

STATEMENT OF THE CASE

Respondent is a physician who practices gynecology and infertility treatment. This case involves Respondent's care and treatment of three patients identified herein by their initials, N.S., L.C., and H.L. Complainant contends Respondent's medical license should be revoked.

Regarding N.S., Complainant specifically contends Respondent committed gross negligence, repeated negligent acts, and incompetence when he transferred what is alleged to be an excessive number of embryos into N.S. in multiple attempts to achieve pregnancy through in vitro fertilization (IVF) between December 2002 and July 2008. Complainant further contends the following acts by Respondent also constituted acts of gross negligence and repeated negligent acts: the "systematic transfer" of embryos that exceeded the recommended number for the patient's age and history; his failure to recommend the use of, and his failure to use, N.S.'s frozen embryos between October 2002 and July 2008; and his failure to recognize that N.S.'s overall behavior was "outside the norm" and to refer N.S. to a mental health professional. Complainant also alleges that Respondent's administration of high doses of hormones, known as gonadotropins, constituted repeated negligent acts.

Complainant contends Respondent's written records of N.S.'s care and treatment were inadequate because Respondent failed to sign the treatment consent forms, and failed to document that he discussed with N.S. the following: the risks and benefits of IVF transfers, the risks of multiple gestations, whether to use frozen embryos, and the disposition of N.S.'s frozen embryos. Additionally, Complainant contends Respondent's records were inadequate because they failed to set forth N.S.'s "social situation."

Regarding L.C., similar to N.S.'s case, Complainant contends Respondent committed gross negligence, repeated negligent acts, and incompetence when he transferred what is alleged to be an excessive number of embryos into L.C. in one attempt to achieve pregnancy through IVF in September 2008. Complainant further contends Respondent's failure to refer L.C. and her family to a mental health professional also constituted gross negligence and repeated negligent acts.

Complainant contends Respondent's written records of L.C.'s care and treatment were inadequate because Respondent's records did not appropriately document the IVF process at the initial consultation, did not document the significance of using a directed donor (in this case, the patient's daughter), did not clearly describe the stimulation protocol used, and did not document that he discussed with L.C. the number of embryos Respondent intended to transfer and L.C.'s consent to that transfer.

Regarding H.L., Complainant contends Respondent committed repeated negligent acts when, after becoming aware of an abnormal cytology report, he failed to perform testing to rule out ovarian cancer and failed to refer H.L. to a specialist to rule out cancer.

Complainant also contends that Respondent's written records of H.L.'s care and treatment were inadequate for the following reasons: Respondent did not document discussions regarding infertility treatment options; he did not document the plans for artificial insemination and IVF therapies or when the plans for these therapies was made; the records were unclear as to what stimulation protocol was used or the number of IVF cycles undergone by H.L.; Respondent failed to sign the consent forms; the documents are unclear as to whether Respondent discussed the existence of cystic masses on H.L.'s ovaries at any time; there was no documentation as to H.L.'s consent to the aspiration of her ovaries in January 2009; and there is no documentation that Respondent discussed the results of an abnormal cytology report with H.L., including that she might have cancer.

Respondent contends he acted within the standard of care in his treatment of all three patients and produced adequate medical records that met the standard of care. He conceded that in hindsight, his transfer of numerous embryos into N.S. was erroneous, but argued that such an error was only appreciable after N.S gave birth to octuplets. He further argued that any error in judgment that he made in transferring numerous embryos into N.S. and L.C. did not rise to the level of gross negligence, repeated negligent acts, or incompetence. As such, he contends his medical license should not be revoked.

This matter solely assesses whether Respondent's care and treatment of each of the three patients, and his documentation for each patient, was within or below the standard of care for a physician practicing gynecology and infertility treatments. The serious and weighty bio-medical ethical issues inherent in the transfer of numerous embryos involve separate analyses that cannot and should not be assessed here, as the evidence and argument in this matter relate solely to the question of the standard of care.

FACTUAL FINDINGS

1. On June 30, 2010, Complainant, in her official capacity, filed the First Amended Accusation. On or about July 16, 2010, Respondent signed the Notice of Defense. The three causes for discipline added at hearing, were deemed controverted by Respondent, pursuant to Government Code section 11507.

Respondent's Background and Certification

2. Respondent received his Bachelor of Science from the University of Illinois in 1972, and his medical degree from Case Western Reserve University School of Medicine in 1976. He completed an internship in obstetrics and gynecology at the University Hospitals of Cleveland in Ohio, in 1977, and his residency, also in obstetrics and gynecology, at the Mount Sinai Hospital of Cleveland in 1980. In 1982, Respondent completed a fellowship in reproductive endocrinology and infertility at Beth Israel Hospital through Harvard Medical

School. He is a Diplomate of the National Board of Medical Examiners. He holds medical licenses in Ohio (1976), California (1979), and Massachusetts (1980).

3. Since 1982, Respondent has been in private practice in endocrinology and infertility in Los Angeles; he is currently the Director of West Coast IVF Clinic, Inc. in Beverly Hills, California. Currently, his practice is 25-30 percent gynecology and the remainder is IVF. Since 1986, he has been an attending physician in obstetrics and gynecology at Cedars Sinai Medical Center (Cedars Sinai) in Los Angeles.

4. From 1982 through the present, Respondent has published several articles and presented lectures on obstetrics and reproductive science nationally and internationally. Since 2004, Respondent has been an ad hoc reviewer for the "Fertility and Sterility" medical journal.

5. The California Medical Board (the Board) issued physician and surgeon certificate number G 41227 to Respondent on November 26, 1979. The license expires on November 30, 2011, unless renewed.

6. The Board has never disciplined Respondent's medical license.

Patient N.S.

N.S.'s Pre-IVF Care and Treatment

7. Respondent first met N.S. in April 1997; N.S. was 21 years old at that time. N.S. met with Respondent to discuss sex selection of her intended future pregnancy, a pregnancy she expected to create through artificial insemination. N.S. told Respondent she had had a first trimester miscarriage in approximately 1995, and was having difficulty becoming pregnant. N.S. had been taking clomiphene citrate, a medication used to stimulate ovulation, with no pregnancy success.

8. N.S. was single but had a male partner who, at later appointments with Respondent, would sometimes accompany N.S. Respondent documented the existence of N.S.'s partner as well as his presence at various appointments.

9. Respondent initially recommended to N.S. that she attempt pregnancy through artificial insemination, as he explained to N.S. that this was a less expensive and less invasive procedure than IVF. Respondent performed artificial insemination procedures on N.S. in April 1997, and November 1998, but those attempts at pregnancy were unsuccessful.

10. In October 1998, Respondent documented in N.S.'s medical records, among other things, that N.S. had been trying to get pregnant for four years with no success. Based on this information, Respondent considered N.S. infertile. At hearing, Respondent explained that he defines infertility as an inability to become pregnant after engaging in unprotected sex for at least one year. The parties did not dispute this general definition of infertility. In

discussing her pregnancy wishes, N.S. immediately informed Respondent that she intended to have a very large family, approximately 10 children. That intention by N.S. never changed throughout the entirety of her doctor/patient relationship with Respondent. Respondent did not react positively or negatively to N.S.'s desire to want a large family. He believed he could assist her to have children and agreed to treat her. Respondent described N.S. during these initial appointments as "intelligent" and "knowledgeable"; he did not observe anything that would have made him believe N.S. was psychologically unsound.

11. Respondent suggested N.S. return to Kaiser Permanente, where N.S. was receiving regular health care, to proceed with the examination of her fallopian tubes. After diagnostic testing, Kaiser Permanente found "bilateral tubal patency" but also "pelvic adhesions." In December 1998, N.S. underwent surgery to address the adhesions, specifically "[h]ysteroscopy, laparoscopy, hydrochromotubation, and lysis of pelvic adhesions." N.S. continued seeing and consulting Respondent thereafter.

12. In January 1999, Respondent prescribed N.S. clomiphene citrate and suggested that she attempt to become pregnant naturally. In that same month, he diagnosed N.S. with mild endometriosis.

13. Respondent saw N.S. in April 1999, and noted that she was still not pregnant.

N.S.'s IVF Care and Treatment

14. In April 1999, N.S. agreed to undergo an IVF procedure. Respondent explained IVF to N.S., describing it as an inexact science and recommending that she limit the number of embryos transferred. He explained that in the IVF process, there is a need to balance the number of embryos transferred with the potential outcome in babies. He informed N.S. about the risk of developing a multiple pregnancy. Respondent explained to N.S. the process of a multi-fetal reduction as a means to control the number of embryos that develop into babies. Multi-fetal reduction is a process whereby multiple embryos that properly attach and begin to develop into fetuses are terminated early to reduce the eventual number of babies to be born. Respondent explained to N.S. that if she was willing to agree to multi-fetal reduction, a greater number of embryos could be transferred; however if she was not so willing, then he would recommend that less embryos be transferred. N.S. agreed to multi-fetal reduction at the outset and thereafter at each embryonic transfer performed by Respondent.

15. In overly simple terms, to begin an IVF cycle, Respondent would administer gonadotropins (hormones) to the patient to stimulate the production of eggs, known as "ooctyes." Respondent would then retrieve the oocytes and fertilize them. Thereafter, Respondent would implant, otherwise referred to as "transfer," the fertilized oocyte (embryo) into the patient. The embryos are classified, based on their maturation. A less mature embryo is known as a "cleavage stage" embryo; a more mature embryo is known as a "blastocyst" embryo.

16. Respondent performed 14 ovarian stimulation cycles and 10 embryo transfers on N.S. between April 1999 and June 2008. Some of the transfers were successful, while others resulted in no pregnancy. Each stimulation cycle and embryo transfer is described in Factual Findings 20-22, 24, 25, 28-32, 35, and 37. Before each of these cycles and transfers, N.S. approached Respondent, requested Respondent's assistance, and asserted her agreement to the stimulation cycles and embryo transfers. In general, N.S. wanted the maximum chance to become pregnant, and informed Respondent of this desire.

17. Throughout his treatment of N.S., Respondent would determine each embryo's development, noting that some blastocyst embryos were of better quality than other embryos, and the better quality embryos would have a better chance of developing into a fetus. At each embryonic transfer, Respondent discussed with N.S. how many embryos should be transferred. Respondent's overall clinical success in IVF had been poor in 1999, and Respondent took his clinic's low pregnancy rate into consideration when opining as to the number of embryos that should be transferred in N.S.'s case. Respondent's understanding, then and now, based on his experience and professional judgment, is that greater quality embryos are more likely to result in a pregnancy than lesser quality embryos. Respondent did not think he could refuse to transfer less embryos than those to which N.S. would agree because he believed at the time that the ultimate decision should be largely driven by the patient's wishes.

18. N.S.'s stimulation cycles were unusual in that she required a greater dose of gonadotropins over more days than other patients her age to render oocytes. Respondent took this fact into consideration when determining the number of embryos to transfer into N.S. Respondent further considered each oocyte's development, the condition of the embryo on the day of each transfer, N.S.'s stated desire for a large family, the length of time N.S. had attempted to become pregnant before the first stimulation cycle began and the fact that N.S. had agreed to multi-fetal reduction.

19. Respondent informed and advised N.S. regarding the risks, benefits, alternatives, and side effects of the IVF and related procedures throughout his treatment and care of N.S. Respondent documented these consultations on N.S.'s medical records, using his own abbreviations. For example, on May 2, 1999, N.S.'s medical records contain the following notation, "Discussed alt's [alternatives], benefit, risks & SE'x [side effects]." On May 6, 1999, N.S.'s medical records read, "Discussed Findings—A's [alternatives] B's [benefits] R's [risks] SE'x . . . tx [treatment]." Respondent documented similar notations throughout N.S.'s medical records, including on the following dates: May 9, 1999; June 10, 1999; August 16, 1999; October 25, 1999; July 24, 2000; October 13, 2001; October 16, 2002; November 27, 2002; December 2, 2002; December 3, 2002; January 7, 2004; June 17, 2004; July 13, 2004; July 18, 2004; October 27, 2005; January 13, 2006; January 20, 2006; February 12, 2007; March 17, 2007; March 21, 2007; April 9, 2007; August 13, 2007; January 15, 2008; January 26, 2008; and July 19, 2008. Throughout his care and treatment of N.S., Respondent properly advised N.S. regarding the alternatives, risks, benefits, and side effects of the oocyte retrievals and embryo transfers, including information on multiple gestations and multi-fetal reduction. While he used abbreviations that were objectively

difficult to decipher, once explained by Respondent, those abbreviations were understandable.

20. On April 18, 1999, N.S. underwent the first ovarian stimulation cycle with gonadotropins. In May 1999, Respondent transferred six blastocyst embryos; however, this procedure resulted in an ectopic pregnancy. In an ectopic pregnancy, the pregnancy occurs in the fallopian tubes and must be terminated.

21. In September 1999, and July 2000, N.S. underwent a second and third ovarian stimulation cycle, but each of those cycles was cancelled.

22. In August 2000, N.S. underwent a fourth ovarian stimulation cycle and in September 2000, Respondent transferred five blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s first baby.

23. Respondent described determining the number of embryos to transfer in 2000 as "complex." Based on his experience treating her, Respondent opined that N.S. had low quality embryos and that her uterus was in what he described as "less than optimal condition." Earlier tests, and N.S.'s historic difficulty in the stimulation cycle, requiring greater doses of gonadotropins for longer periods of time, led Respondent to further opine that N.S. might be experiencing premature menopause. It is unclear whether Respondent continues to believe N.S. was experiencing premature menopause; however, he credibly established that his opinion in 2000 was that he believed she was experiencing such a condition. Respondent considered these factors, in addition to those set forth in Factual Findings 18 and 33, to suggest and ultimately determine the number of embryos to transfer in 2000 and every embryo transfer thereafter.

24. In September 2001, N.S. underwent a fifth ovarian stimulation cycle and in October 2001, Respondent transferred five blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s second baby.

25. In October 2002, at the age of 27, N.S. underwent a sixth ovarian stimulation cycle and in December 2002, Respondent transferred four blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s third baby.

26. In June 2004, N.S. met with Respondent and informed him that she wanted to have twin babies. Respondent documented N.S.'s desire; he recommended against N.S. attempting to have twin babies, and wrote in N.S.'s medical records, "Not recommended." Thereafter, N.S. agreed to attempt a single baby. Respondent further advised N.S. to wait a longer period of time before beginning a new stimulation cycle. N.S. complied.

27. In approximately January 2004, N.S. met with Respondent and informed him that she wanted to pursue another pregnancy, but this time with a surrogate. Respondent spoke with N.S. about this and in a note he drafted in her medical records, dated January 7, 2004, Respondent wrote that he advised N.S. "extensively against surrogacy." He explained

at hearing that he had counseled N.S. against using a surrogate because, in his opinion, that process was complicated, expensive, could develop its own legal problems, and generally was a process that she should not take lightly. N.S. did not pursue surrogacy thereafter.

28. In June 2004, N.S. underwent a seventh ovarian stimulation cycle and in July 2004, Respondent transferred four blastocyst embryos. This procedure resulted in a single pregnancy and N.S.'s fourth baby.

29. In October 2005, N.S. underwent an eighth ovarian stimulation cycle and in that same month, Respondent transferred three blastocyst embryos. This procedure resulted in a biochemical pregnancy. A biochemical pregnancy is one where the pregnancy hormone is detected in the blood, but the pregnancy terminates early on its own.

30. In November 2005, N.S. underwent a ninth ovarian stimulation cycle, however that cycle was cancelled.

31. In December 2005, N.S. underwent a tenth ovarian stimulation cycle and in January 2006, Respondent transferred six blastocyst embryos. This procedure resulted in a twin pregnancy, her fifth and sixth babies. Neither Respondent nor N.S. intended a twin pregnancy.

32. In February 2007, N.S. underwent an eleventh ovarian stimulation cycle and in March 2007, Respondent transferred six blastocyst embryos. This procedure did not result in a pregnancy.

33. In February 2007, based on earlier laboratory results, the failed IVF procedures in 1999, 2005, and 2007, and her difficulty responding to the gonadotropin hormones, in Respondent's on-going opinion, N.S. appeared pre-menopausal although she was only 31 years old at the time. Respondent considered this information, in addition to the factors set forth in Factual Findings 18 and 23, in suggesting and ultimately determining the number of embryos to transfer in February 2007 and thereafter.

34. In February 2007, Respondent was concerned that she would have significant difficulty having any more children, and as he was aware she continued to want more babies, he informed N.S. of his opinion as to her problematic fertility. Respondent described N.S. as "alarmed" upon hearing his opinion.

35. In October 2007, N.S. underwent a twelfth ovarian stimulation cycle but Respondent did not transfer any embryos. Instead, upon N.S.'s direction, Respondent froze all (in this instance, eight) embryos.

36. Over the time of all of her IVF treatments through 2008, N.S. directed Respondent to freeze a total of 29 embryos. They remain frozen to date. Respondent felt obligated to freeze them, as he believed he did not have the authority to dispose of them otherwise, as N.S. signed consent forms to authorize the freezing of her embryos and their

disposition in certain specified circumstances, but N.S. did not authorize Respondent to ultimately dispose of the embryos. According to Respondent at hearing, on January 4, 2008, Respondent suggested to N.S. that she use frozen embryos instead of fresh embryos, and further informed her that frozen embryos are generally much less successful in resulting in a pregnancy. Respondent did not document his asserted suggestion in N.S.'s medical records. N.S. chose to use fresh embryos throughout all of her embryo transfers.

37. In January 2008, N.S. underwent a thirteenth ovarian stimulation cycle and in that same month, Respondent transferred eight blastocyst embryos. This procedure did not result in a pregnancy.

38. When transferring what Respondent acknowledged was a great number of embryos in January 2008, he considered what he opined was N.S.'s debilitating ovaries, N.S.'s history of failed IVF over the years, including the failed attempt in February 2007, the fact that N.S. had given birth to only one set of twins before, despite the number of embryos transferred in each IVF attempt (that is, all previous successful transfers had resulted in a single baby with the exception of one set of twins), and the factors set forth in Factual Findings 18, 23, and 33.

39. At all embryonic transfers for N.S., beginning in 2004, Respondent considered the guidelines on the number of embryos to transfer in IVF procedures set forth by the American Society for Reproductive Medicine (ASRM), but understood those guidelines to be flexible depending on the factual circumstances presented in each patient's case. The Practice Committee of the Society for Assisted Reproductive Technology (SART) and the ASRM have published these embryo transfer guidelines in the journal of "Fertility and Sterility." These guidelines are referred to herein as the "ASRM guidelines." (The pertinent portions of the 2004, 2006, and 2008 ASRM guidelines are set forth in Factual Findings 85-93.)[1]

40. In June 2008, N.S. underwent a fourteenth ovarian stimulation cycle and in July 2008, Respondent transferred twelve blastocyst embryos, utilizing the HEED procedure. (HEED is described in Factual Finding 43.) This procedure resulted in an octuplet pregnancy.

41. In July 2008, N.S. insisted on transferring all 12 fresh embryos and she would not accept anything less. Respondent suggested that he only transfer four embryos, but felt bound to honor her wishes, after considering her insistent direction and the factors set forth in Factual Findings 18, 23, 33, and 38. Respondent wrote the following note in N.S.'s medical records on July 19, 2008: "[h]ave explained, [d]iscussed—A's [alternatives], B's [benefits] R's [risks] SE'x [side effects] of embryo transfer by implantation or HEED, alt's

[1] A 2010 "Fertility and Sterility" article, described further in Factual Finding 94, notes that, as early as 1998, the ASRM and SART published the first recommended guidelines on the transfer of embryos in IVF; however, the earliest guidelines offered into evidence by Complainant are those of 2004.

[alternatives], B's, R's, SE'x of freezing & [r]eduction (fetal)—Pt. [patient] insists and wants all embryos transferred by HEED . . . consequences to the babies of un-compliance [*sic*] were explained & Pt. understands and wishes to proceed with the HEED Tx [transfer] of all embryos—. . .–own recommendation—4 [a]dvanced embryos by HEED." This notation was signed by N.S. and a witness.

42. Respondent did not see N.S. thereafter and only heard from her briefly after her octuplet delivery. N.S. did not testify.

43. At hearing, Respondent defined HEED as "hysteroscopic endometrial embryo delivery" and explained it as the mechanical insertion of embryos into the endometrium under direct visualization. That is, Respondent would use a hysteroscope to see where to implant the embryos during an IVF transfer. The evidence also established two other similar acronyms: SEED ("sub-endometrial embryo delivery") and DEED ("direct endometrial embryo delivery"). The evidence failed to distinguish the three acronyms, and the parties largely used all three acronyms interchangeably. Consequently, HEED, DEED, and SEED are considered substantially similar for purposes of this matter and are referred to together throughout this Proposed Decision.

44. Respondent explained at hearing that he developed HEED/DEED/SEED, and believes it is an appropriate embryo transfer method. He concedes he is the only physician he knows who has used HEED/DEED/SEED, but argued that it is not an experimental process and only a distinct method of embryo implantation.

45. Respondent felt compelled to transfer all 12 embryos in July 2008, because he believed that the patient's wishes should largely dictate the number of embryos to transfer, even if he opined differently. Respondent pointed to his July 2008 note showing that he recommended to N.S. that only four embryos be transferred. As part of his consultation with her, Respondent told N.S. that there was no guarantee she would become pregnant, however, there was a significant risk of having a multiple pregnancy. N.S. agreed in no uncertain terms to multi-fetal reduction, and based on this, he figured that if a multiple pregnancy resulted, the multi-fetal reduction procedure would limit the number of babies to be born.

46. Respondent explained at hearing that while he had referred other patients to psychologists in the past, he did not observe N.S. to be in such a condition as to warrant a referral to a mental health professional. When asked at hearing about N.S.'s overall pregnancy-seeking behaviors, Respondent stated that he refused to pass judgment on N.S.'s familial desires. For this reason, as N.S. continued to consistently return to him after each cycle and transfer, whether successful or unsuccessful, he did not consider her returning to him to seek additional IVF procedures as behavior that warranted a mental health referral. He did not think N.S.'s desire to have a large family of approximately 10 children, her request for twins, or her request to use a surrogate were behaviors that warranted a mental health referral.

47. Respondent asserted that at each embryonic transfer, despite the number of embryos transferred, it was always his goal and intention to have his actions result in a single, healthy baby. This was his intention with the 2008 transfer of 12 embryos, and Respondent believed that given her failed pregnancies in March 2007, with six embryos transferred, and January 2008, with eight embryos transferred, that 12 embryos appeared reasonable to him at that time. Looking back now, Respondent agreed that transferring the 12 embryos was "wrong." He is sorry that the IVF process resulted in octuplets and he wishes he had never done the procedure. At the time in 2008, he thought it was the right thing to do, but at hearing, he readily conceded that, in hindsight, it was not.

48. Respondent testified with emotion, but also in an unhesitating manner, with factual consistency, and providing each counsel and the ALJ with direct eye contact. Consequently, Respondent's overall testimony was deemed credible.

49. Respondent documented his discussions with N.S. regarding the use of HEED/DEED/SEED as the embryonic transfer method. For example, on May 7, 2008, Respondent wrote, "Option of regular ET [embryo transfer] vs. DEED, vs. SEED was given. Possible scratch/bleeding of endometrium with possible impact on non implantation was explained." Respondent documented similar notations on July 19, 2008. Respondent discussed the use of HEED/DEED/SEED procedures with N.S. before using those procedures throughout his care and treatment, and those discussions are encompassed in his notations showing his discussions of embryo transfers generally. For example, on October 27, 2005, Respondent wrote in a note in N.S.'s medical records, "ET done by hysteroscopic embryo implantation. Alternative of regular embryo transfer given prior to preparation. . . Option of regular ET was given. Possible scratch/bleeding of endometrium with possible impact on non implantation [*sic*] was explained." Similar notations are found in N.S.'s records in 2007, 2006, 2004, 2002, and 1999. Furthermore, Respondent reviewed a video with N.S. regarding HEED/DEED/SEED. N.S. signed two consent forms that included HEED procedures. On July 14, 2008, N.S. signed a "Consent to Medical or Surgical Care and Treatment" that included "[h]ysteroscopic Embryo Transfer" and a consent form authorizing Respondent to perform a "[h]ysteroscopic transuterine fallopian tube transfer," in May 1999.

Dr. V.Y. Fujimoto's Opinions regarding N.S.'s case

50. Complainant presented the opinions of Victor Yutaka Fujimoto, M.D. (Fujimoto). Fujimoto is an Associate Clinical Professor in obstetrics, gynecology, and reproductive sciences at the University of California at San Francisco. He received his Bachelor of Science in bioengineering from the University of California at San Diego in 1982, and his medical degree from the University of California at San Diego, School of Medicine in 1986. He completed his residency in obstetrics and gynecology at the Mayo Graduate School in Rochester, Minnesota in 1990, and a postdoctoral fellowship in reproductive endocrinology and infertility at the University of California at San Francisco in 1993.

51. Fujimoto is a Diplomate of the National Board of Medical Examiners (1987), and Diplomate of the American Board of Obstetrics and Gynecology, in general OB/GYN (1994), and in reproductive endocrinology (1996). The American Board of Obstetrics and Gynecology recertified Fujimoto in 2005 and 2009.

52. Fujimoto has hospital privileges at Chinese Hospital in San Francisco, and the University of California at San Francisco Medical Center. He was the Director of the UCSF In Vitro Fertilization Program from 2000 through 2009, and was heavily involved in the development and growth of IVF practice. Since the early 1990s, Fujimoto has received numerous awards and honors, including from the ASRM, and presented lectures, and published in the areas of obstetrics, gynecology, and reproductive sciences. He has been an ad hoc reviewer for "Fertility and Sterility," among other professional journals. He has been a member of the ASRM since 1993, and a member of SART since 1995.

53. From 1993 to the present, he has held various professorships in obstetrics and gynecology, reproductive endocrinology, and reproductive sciences at the University of California at San Francisco and the University of Washington in Seattle.

54. Fujimoto reviewed the patient cases in this matter, including each patient's medical records. In the case of N.S., he opined that the number of embryos Respondent transferred exceeded the number recommended for patients like N.S., considering her age and history. He asserted that the recommended number of embryos and the overall standard of care in embryonic transfers are set by the ASRM. According to these guidelines, Respondent should have transferred no more than two embryos from 2004 to 2008. In his report, dated October 14, 2009, he described Respondent's transfers with regard to N.S. as a "systematic pattern of excessive number of blastocyst embryos." He stated that his greatest concern was the "systematic transfer of blastocyst embryos over the course of 10 fresh IVF stimulation embryo transfer cycles." He found that "[a] total of 60 blastocyst embryos were transferred over the 10 fresh embryo transfers, representing an average number of embryos transferred to be 6. As a result, every embryo transfer performed carried significant risk for higher-order multiple gestation."

55. Fujimoto concluded that Respondent transferred into N.S. an excessive number of embryos and those acts constituted an extreme departure from the standard of care.

56. As to the 2008 transfer of 12 embryos, Fujimoto wrote, "[t]here is no question that transferring 12 fresh blastocyst embryos in any woman regardless of age is a violation of ASRM guidelines and beyond the reasonable judgment of any treating physician especially in light of the social circumstances surrounding this case and prior pregnancies achieved."

57. Fujimoto further opined that Respondent should have referred N.S. to a mental health professional, given what he found to be "out of the norm" behavior in seeking the many embryo transfers, in relatively quick order, and insisting on the 12 embryo transfers in 2008. Fujimoto specifically opined that a referral to a mental health professional was

warranted and "necessary" once N.S. had four children in 2005, and that his failure to do so was an extreme departure from the standard of care. Fujimoto described N.S.'s desire for additional IVF as, "unusual requests from a single woman with multiple children already conceived from prior IVF treatment." He opined that he "found it quite abnormal and outside the norm for a single woman with 4 children conceived from IVF to request further IVF treatment for more children as this patient did in 2005. It is particularly worrisome that the patient requested conceiving shortly after delivery of her children without any period of delay."

58. Fujimoto conceded that the ASRM does not have standard of care guidelines for when to refer patients for mental health evaluations, but noted that in a 2009 reissue of a 2004 article, the ASRM wrote that the "well-being of offspring is an overriding ethical concern" that a physician should take into account "in determining whether to provide infertility services." According to Fujimoto, Respondent should have referred N.S. to a mental health professional once N.S. returned to him for further IVF procedures in 2005. Fujimoto considered N.S.'s requests for further IVF procedures beginning in 2005, as "out of the norm" and unsound. Throughout his testimony, Fujimoto emphatically asserted that a factor he took into consideration in reaching this opinion was that N.S. was unmarried and that it was unclear from N.S.'s medical records whether she in fact had a partner of any sort. By his assertions at hearing and the emphasis with which he made these assertions, it was apparent that Fujimoto was greatly impacted by his uncertainty of whether N.S. had a life partner. He noted this concern in his report. Fujimoto wrote, "after she [N.S.] delivered twins resulting in six children, appropriate judgment should be been [*sic*] used to question why this woman wanted more children as a single parent with concerns raised regarding potential harm to her offspring and future children." He also wrote that "concerns should have been raised with [N.S.] regarding her persistent desire to have more children despite being single and having four children," and he criticized Respondent for failing to consider the "social context associated with her [N.S.'s] family situation." (See also Factual Finding 57.) According to Fujimoto, N.S.'s social situation included her economic/employment status, her household, the number of children in her family, and her marital or partner status.

59. Regarding Respondent's transfer of only fresh embryos into N.S., Fujimoto opined that Respondent should have used N.S.'s frozen embryos to avoid greater costs to the patient and the risks of ovarian stimulation from using fresh embryos. It remained unclear why none of the 29 frozen embryos were ever used and Fujimoto questioned Respondent's judgment in recommending only fresh IVF stimulation treatment plans for N.S. in light of the frozen embryos.

60. However, Fujimoto could not articulate a clear standard of care in regard to using frozen embryos. In his report, he wrote, "[w]hile there is no standard of care nor guidelines for the utilization of human embryos that have been frozen, the apparent stockpiling of embryos totaling 29 embryos serves no clinical purpose with added medical risk to the patient with each successive fresh IVF stimulation cycle in which more embryos are generated." He concluded that the "non-utilization of any frozen embryos during the entire course of treatments" was an extreme departure from the standard of care.

61. Regarding Respondent's medical record keeping for N.S., Fujimoto opined that Respondent did not document having informed N.S. about the risks of bleeding, pain, infection, and anesthesia from the procedures in May 1999. Fujimoto noted that Respondent had not signed the embryo cryopreservation consent, although N.S. did. The absence of Respondent's signature on other consent forms, while containing N.S.'s signature, was also noted in July 2000, December 2003, July 2004, and Respondent's multiple IVF and embryo transfer consents and embryo disposition consents. Fujimoto found that there was "a lack of documentation with respect to [N.S.'s] willingness to undergo multi-fetal reduction if faced with a higher order multiple pregnancy," and also noted that it was unclear from the records "whether a discussion regarding the risk of multiple gestation occurred despite the transfer of 4-12 blastocyst embryos with any given embryo transfer from 1999-2008. At the very least, the documentation of such discussions was extremely poor." Fujimoto opined that these documentary problems and the lack of documentation regarding N.S.'s "social situation" and "unusual behavior" constituted an extreme departure from the standard of care.

62. Fujimoto's opinions as to Respondent's medical record keeping was given less weight because, at hearing, when asked to read Respondent's notes, similar to the ones quoted in Factual Findings 19 and 41, Fujimoto appeared overly confused by Respondent's abbreviations, even after being told, for example, to what the "A's" and "B's" notations referred. Fujimoto's inability to decipher Respondent's abbreviations appeared to the ALJ to be exaggerated in an effort to highlight their idiosyncratic nature.

63. Fujimoto also opined that Respondent engaged in a simple departure from the standard of care by using high doses of gonadotropins to stimulate the production of oocytes in N.S and thus risked causing what is known as ovarian hyperstimulation syndrome, the excessive stimulation of the ovaries. However, in his report Fujimoto conceded that it was "difficult to conclude that the stimulation practice [was] clearly outside the standard of care since there remains controversy on the 'optimal' dosing used in IVF cycles."

64. Although he did not so opine in his written report, at hearing, Fujimoto opined that Respondent acted incompetently in his overall care and treatment of N.S. However, Fujimoto failed to define incompetence, as he used the term. He did not refer, for example, to Business and Professions Code section 2234, subdivision (d) (see Legal Conclusion 2), nor did he explain why or how he reached his opinion.

Dr. J. Steinberg's Opinions regarding N.S.'s Case

65. Respondent presented the opinions of Jeffrey Steinberg, M.D. (Steinberg). Steinberg received his undergraduate degree from the University of California at Los Angeles and his medical degree from the Autonomous University of Guadalajara, in Guadalajara, Mexico. He completed an internship in obstetrics and gynecology at the Regina General Hospital through the University of Saskatchewan, School of Medicine in 1978, and a residency in obstetrics and gynecology at St. Luke's Hospital in Chicago, Illinois, through the Rush Medical College. Steinberg completed a fellowship in reproductive endocrinology and infertility at the University of California at San Diego, School of Medicine, and a

fellowship in IVF at Cambridge University in Cambridge, England. He is board certified by the American Board of Obstetrics and Gynecology (1983).

66. Steinberg is currently the Medical Director, Laboratory Director, and Tissue Bank Director of his two practice clinics: the Fertility Institutes in Encino, California, and New York, New York. He is the attending gynecologist for the Student Health Center at California State University, Northridge, in Northridge, California. He has practiced IVF for the past 35 years, since its approximate inception. His current practice includes approximately 200 to 480 IVF cases per year.

67. Steinberg reviewed the medical records of N.S., L.C., and H.L., and met with Respondent to discuss his treatment and care of all three patients.

68. Steinberg did not agree with Fujimoto that the ASRM guidelines establish the standard of care for the number of embryos to implant in an IVF procedure. Steinberg opined that there is no standard of care as to the number of embryos to implant, as there is a "long-standing dictum" in the practicing community that the number of embryos to implant is a decision that a physician must make, while considering the medical circumstances of the patient and importantly, in Steinberg's opinion, the patient's wishes. In support of his opinion, Steinberg highlighted the wording in the ASRM guidelines that indeed state the guidelines are not rigid limits. (See Factual Findings 85, 86, 88, and 90.)

69. Steinberg noted a number of N.S.'s circumstances: her miscarriage two years before she first met Respondent, the fact that in 1999, she had been trying unsuccessfully to get pregnant while on clomiphene citrate, that she had not gotten pregnant after four years of trying, her pelvic adhesions, what he considered an appropriate diagnosis of endometriosis, very low estrogen levels overall, low egg quality, a system that was difficult to stimulate with gonadotropins, and low embryo quality. Steinberg opined that all of these factors would lead him to accurately describe N.S. as infertile and made N.S.'s case an "unusual" case, given her younger age, wherein "aggressive" IVF treatment was warranted.

70. Steinberg opined that the number of embryos Respondent transferred into N.S. were all within the standard of care, with the exception of the 2008 transfers of eight and 12 embryos. He did not specifically state that the 2008 transfers were outside the standard of care, but asserted that he could not say those transfers were within the standard of care. He further asserted that it was clear to him that in those two instances, Respondent was undoubtedly "trying very hard" to help N.S. get pregnant and defined those instances and all of Respondent's IVF procedures with N.S. as "aggressive management." Despite this, on cross-examination, Steinberg agreed that Respondent's transfer of 12 embryos was wrong and an error or lapse in judgment, although he was adamant that the 2008 transfers did not constitute incompetence or gross negligence, given the existent factors and circumstances at issue, as delineated in Factual Finding 69.

71. Steinberg explained further that in all IVF procedures, a reasonable physician's goal is the birth of a single healthy baby and that infertility physicians must use

their good, professional judgment in determining the use of hormones, the retrieval of oocytes, and the transfer of embryos. Steinberg opined that, generally, Respondent used good judgment in his care and treatment of N.S., noting that Respondent was originally concerned with N.S.'s desire to have him implant all 12 embryos in July 2008, as set forth in Respondent's written notation (Factual Finding 41), and that Respondent recommended to N.S. that he only transfer four embryos. However, Steinberg conceded that the ultimate transfer of 12 embryos was not good judgment.

72. Despite his concessions regarding the 2008 transfers, Steinberg opined that it was reasonable for Respondent to rely on N.S.'s original agreement to a multi-fetal reduction procedure. In Steinberg's opinion, it is "extraordinarily unusual" for a patient to refuse that procedure. In Steinberg's 35 years of practice, a patient has only refused multi-fetal reduction once after agreeing to it.

73. In regard to Fujimoto's opinions that the standard of care required Respondent to consider N.S.'s social/familial situation, Steinberg did not agree. In contrast to Fujimoto, Steinberg opined that an IVF physician has no particular responsibility to the patient's existing children. He believes that responsibility lies squarely with the children's mother. In that same vein, he does not believe an IVF physician has a particular responsibility to the patient's future children. Instead, Steinberg opines than an IVF physician must primarily take responsibility to protect the best interests of the patient.

74. Steinberg did not agree with Fujimoto that Respondent was required to refer N.S. to a mental health professional. Steinberg agreed that in hindsight, it appears that N.S. would have benefited from counseling, but that at the time Respondent was treating her, there were no signs that would have required a reasonable IVF physician to refer her, as Complainant contends. Steinberg considered the number of babies N.S. wanted and did not think that this was sufficient reason to make a referral, noting that a portion of society considers large families appropriate and desirable and that patients seeking large families through IVF treatment are not uncommon. He considered N.S.'s desire for twins, and noted first, that Respondent had successfully counseled against twins, and second, that in his own practice between approximately 30 to 50 percent of his patients desire twins. Steinberg opined that N.S.'s proposal to use a surrogate was not uncommon and he saw nothing inherently suspect or "out of the norm" by her proposal. He also noted that Respondent had successfully counseled N.S. against surrogacy. Additionally, Steinberg explained that 10-16 IVF cycles for a patient are not uncommon in the practice. As Steinberg found that N.S.'s overall behavior was not uncommon in IVF patients, he described the viewpoint that Respondent should have referred N.S. to a mental health professional as an "ivory tower" opinion that is "out-of-touch" with what happens in the community.

75. When explaining how he would have dealt with N.S., Steinberg agreed that by February 2007, he would have been concerned about N.S.'s repeated requests for IVF, as she was focused on IVF treatments in short order. Steinberg asserted that he would have been "irked" by the number of babies she sought to have, but he nonetheless would not have

referred her to a mental health professional, had he had the same information Respondent did.

76. Steinberg opined that Respondent's use of gonadotropins on N.S. was appropriate and within the standard of care, given N.S.'s sluggish responses to the hormones.

77. Steinberg opined that IVF physicians prefer to use fresh embryos in transfers because fresh embryos are more likely to result in a pregnancy, and an IVF physician should attempt to give the patient the best chance to become pregnant. He explained that the rate of pregnancy using frozen embryos is very low. Therefore, it was reasonable for Respondent to advise N.S. that the using fresh embryos increased her chance of pregnancy and to ultimately use fresh embryos at each transfer. Steinberg took exception with Fujimoto's assertion and Complainant's allegation that there is an increased medical risk in using fresh embryos, especially with young women. Steinberg further opined that embryos, as fertilized oocytes, belong to the patient and that N.S. was therefore able to do with them as she pleased. This included freezing the embryos upon her direction.

78. As to the criticisms of Respondent's record keeping, Steinberg noted that Respondent repeatedly documented his consultations and advice to N.S., including the numerous notations where he documented his informing N.S. of the alternatives, risks, benefits, and side effects of the IVF procedures. He further noted that N.S. had signed all of the consent forms, and opined that this was sufficient to meet the standard of care, as in his opinion, the standard of care does not require a physician to sign the consent form. Steinberg explained that the consent form is meant to inform the patient of the procedure at issue, the risks, and side effects, among other things, and that the importance of the consent forms is that the patient understand the procedure or treatment and consent knowingly; the physician's signature is not nearly as important, in his opinion. Steinberg was able to read and understand Respondent's salient notations and opined that Respondent's documentation in N.S.'s medical records was within the standard of care.

79. Steinberg further opined that Respondent's failure to document N.S.'s "social situation" was not below the standard of care, as it was not required in Steinberg's opinion. He explained that such things as a patient's marital status, economic health, household membership, or whether the patient has a life partner of some kind is not information that must be recorded. Steinberg asserted that an IVF physician cannot withhold IVF treatment based on a patient's marital status, or disability status, and thus, such personal information need not be recorded, as it would be irrelevant to the patient's IVF care and treatment.

80. Steinberg conceded that Respondent's operative note did not mention use of a hysteroscope. Steinberg agreed an operative note should include the number of embryos transferred and how the patient tolerated the procedure, but his testimony was unclear whether the standard of care required it. He did not find any consent form that provided for N.S. to be in any research or clinical study by Respondent.

81. Regarding HEED/DEED/SEED, Steinberg conceded that he did not know of any physician in the community that uses HEED/DEED/SEED as an embryonic implantation method, but opined that that fact alone did not mean HEED/DEED/SEED was experimental.

82. Steinberg opined that Respondent was not incompetent by any of his care and treatment of N.S., explaining that incompetence would mean generally that Respondent did not have the knowledge to execute the IVF tasks necessary to properly care and treat N.S. In Steinberg's opinion, Respondent had that knowledge and largely cared and treated N.S. appropriately (excepting his statements regarding the 2008 transfers).

The ASRM Guidelines on Embryo Transfers

83. Complainant argued at hearing that the standard of care regarding the number of embryos a physician could transfer into an IVF patient is set by the ASRM guidelines in "Fertility and Sterility."

84. To the contrary, Respondent argued that the ASRM guidelines are solely recommended guidelines and do not establish definitive limits on the number of embryos a physician may transfer.

The 2004 ASRM Guidelines

85. In a September 2004 "Fertility and Sterility" article, entitled "Guidelines on the number of embryos transferred," the ASRM recommends that in patients under the age of 35, no more than two embryos should be transferred "in the absence of extraordinary circumstances." In setting forth these and all transfer guidelines, the article begins with the following qualification: "[i]n the absence of data generated by the individual program and based on data generated by all clinics providing ART [assisted reproductive technology] services, the following guidelines are recommended." For patients with the most favorable prognosis, the ASRM recommends that, "consideration should be given to transferring only a single embryo." It defines the most favorable prognosis as including factors such as good quality embryos, excess embryos of sufficient quality to warrant cryopreservation, and previous success with IVF. For women between the ages of 35 and 37 with favorable prognoses, the ASRM recommends that a physician transfer no more than two embryos, and for all other women between the ages of 35 and 37, no more than three embryos. For women ages 38 through 40 with favorable prognoses, the ASRM recommends that a physician transfer no more than three embryos, and for all other women, no more than four embryos. For women over 40, the ASRM recommends that a physician transfer no more than five embryos.

86. The 2004 ASRM guidelines further provide that for patients with two or more previous failed IVF cycles, and those having a less favorable prognosis, regardless of age, "additional embryos may be transferred according to individual circumstances after appropriate consultation." The article reads, "[t]hese guidelines are intended to assist ART programs and patients in determining the appropriate number of cleavage stage . . . embryos

to transfer. Strict limitations on the number of embryos transferred, as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient's own unique circumstances. Accordingly, these guidelines may be modified, according to individual clinical conditions, including patient age, embryo quality, and the opportunity for cryopreservation, and as clinical experience with newer technologies accumulates."

87. The ASRM provided that the 2004 guidelines "should be modified to replace fewer embryos when transferring embryos at a more advanced stage of development (i.e., blastocyst)."

88. On the issue of determining the doctor and patient mutually determining the number of embryos to transfer, the ASRM wrote, "[t]he number of embryos transferred should be agreed upon by the physician and the treated patient(s), informed consent documents completed, and the information recorded in the clinical record."

89. Regarding the issue of multiple gestation, the ASRM noted that a multiple gestation (three or more babies) is an "undesirable consequence" because it leads to the "increased risk of complications in both the fetuses and the mother." The ASRM further noted that multi-fetal reduction does not completely eliminate the risks, as a multi-fetal reduction procedure can lead to losing all the fetuses and emotional issues.

90. Salient to the issues assessed in this matter, the ASRM wrote in 2004, "[w]hile this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations."

The 2006 ASRM Guidelines

91. The November 2006 ASRM guidelines include all of the same statements, as quoted in Factual Findings 85-90, with the exception of the quotation in Factual Finding 87. For 2006, the recommended number of embryos for transfer are the same as the numbers set forth in the 2004 guidelines. The 2006 guidelines, however, further define embryos as either cleavage or blastocyst stage.

92. The 2006 ASRM guidelines provide that a physician should transfer no more than one embryo into women less than 35 years of age with favorable prognoses, and for all other women less than 35, no more than two embryos (cleavage or blastocyst). For women between the ages of 35 and 37 with favorable prognoses, a physician should transfer no more than two cleavage embryos, and for all other women between the ages of 35 and 37, no more than three cleavage embryos or two blastocyst embryos. For women ages 38 through 40 with favorable prognoses, a physician should transfer no more than three cleavage embryos or two blastocyst embryos, and for all other women, no more than four cleavage embryos or three

blastocyst embryos. For women over 40, a physician should transfer no more than five cleavage embryos or three blastocyst embryos.

The 2008 ASRM Guidelines

93. The November 2008 ASRM guidelines set forth all of the same statements contained in the 2004 and 2006 guidelines, as delineated in Factual Findings 85-90, with the exception of the quotation in Factual Finding 87, and contain the same number of recommended embryos that should be transferred as contained in the 2006 guidelines.

The 2010 "Fertility and Sterility" Article regarding Survey of Transfer Guideline Compliance by IVF Practitioners

94. In a September 2010 "Fertility and Sterility" article entitled, "Embryo transfer practices in the United States: a survey of clinics registered with the Society for Assisted Reproductive Technology,"[2] the authors conducted a national survey of clinicians practicing IVF who were registered with SART. The survey was conducted in 2008 and 2009. The authors described the ASRM guidelines as "voluntary guidelines" and found that only nine percent of responding physicians strictly adhered to the guidelines, while 55 percent of responding physicians would deviate from the guidelines "at patient request"; 55 percent would deviate from the guidelines if using frozen embryos; and 75 percent would deviate from the guidelines for patients with previously failed IVF cycles. The authors concluded, however, that while the majority of physicians deviate from the guidelines, the authors were supportive of the transfer guidelines, and agreed that "strong medical justification" should be required to deviate from those guidelines.

Patient L.C.

95. In May 2008, L.C. was a 48-year-old woman in a second marriage who sought IVF, using eggs donated by her daughter, a 28-year-old woman. Respondent discussed IVF with her and noted thereafter that L.C. intended to use her daughter as the oocyte donor. In July 2008, Respondent discussed with L.C. the risks associated with the IVF process, including ovarian hyperstimulation syndrome, multiple gestation, and multi-fetal reduction. Respondent generally described these discussions with L.C. in her medical records, dated May 1, 2008.

96. Respondent met L.C., L.C.'s daughter and L.C.'s husband and concluded that there were no emotional or psychological issues that required him to refer L.C. or her family to a mental health professional or other type of counseling. At hearing, Respondent explained that he did not react positively or negatively to L.C.'s decision to use oocytes donated by her daughter.

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[2] The authors are E.S. Jungheim, M.D.; G.L. Ryan, M.D.; E.D. Levens, M.D.; A.F. Cunningham, M.P.H.; G.A. Macones, M.D., M.S.C.E.; K.R. Carson, M.D.; A.N. Beltsos, M.D.; and R.A. Odem, M.D.

97. As a result of Respondent's treatment, L.C. produced seven embryos. Respondent recommended to L.C., that he transfer only four embryos and she agree to freeze the remaining three. Respondent informed L.C. that three of the embryos were of poor quality and the sperm used was of low quality. However, Respondent maintained that for L.C., transferring four embryos and freezing the remainder was appropriate. L.C. told Respondent she wished him to transfer all seven embryos. L.C. explained that due in part to her age, she intended to proceed with IVF only once, and so wanted all seven embryos transferred to increase her chances of becoming pregnant. L.C. agreed to a multi-fetal reduction procedure, understanding that such a procedure could result in losing all fetuses.

98. Respondent performed an oocyte retrieval on September 22, 2008, and on September 27, 2008, he transferred seven embryos into L.C. using the HEED procedure. Respondent explained that due to L.C.'s age, it appeared reasonable to transfer all seven embryos. Respondent asserted that his intention at all times with L.C. was to produce a single, healthy baby.

99. Respondent documented his discussion with L.C. regarding the risks, including multiple gestation, the benefits, and limitations of the IVF procedure, the embryo transfer process, including HEED, and multi-fetal reduction, in L.C.'s medical records, dated September 25 and 27, 2008.

100. In October 2008, Respondent determined that L.C. had quadruplet fetuses. Thereafter, Respondent recommended multi-fetal reduction and referred L.C. to a specialist in that procedure.

101. However, in November 2008, L.C.'s son was in a serious motorcycle accident and remained in a hospital intensive care unit for four weeks. L.C. became worried that her son might die. She did not want to risk losing all four of the proposed embryos due to multi-fetal reduction. L.C. subsequently refused multi-fetal reduction.

Dr. Fujimoto's Opinions regarding L.C.'s Case

102. Like with N.S., Fujimoto opined that Respondent transferred an excessive number of embryos and that the transfer of all seven embryos was an extreme departure from the standard of care. Fujimoto noted that according to the 2008 ASRM guidelines, the age of the donor should be used to determine the appropriate number of embryos to transfer, and as the donor in L.C.'s case was 28, the appropriate number of embryos to transfer was only two blastocyst embryos.

103. Fujimoto further opined that Respondent should have referred L.C. and her husband and daughter to a mental health professional. In his view, a physician should always refer the patient and involved family members for mental health counseling when family members are donors or surrogates. He cited no direct authority for his opinion, conceding that his opinion comes from his professional judgment, but pointed to a 2003 ASRM article that suggests such referrals in situations like L.C.'s. (See Factual Findings

109-111.) In his written opinion, dated July 23, 2010, Fujimoto noted the concerns in cases like L.C.'s include coercion. That is, a family member may feel coerced into donating oocytes by virtue of the relationship. Fujimoto further noted the unusual relationship that develops from the use of a family member donor and a successful pregnancy; he wrote, "the recipient patient is both the mother and 'genetic grandmother' of these children while her daughter is the sister and 'genetic mother' of these children." Fujimoto concluded, "the failure to recognize and recommend mental health referral [*sic*] for the unusual circumstances and request of [L.C.] to use her daughter as an egg donor is an extreme departure from the standard of care."

104. As to Respondent's medical record keeping in L.C.'s case, Fujimoto explained that by law, the United States Food and Drug Administration (FDA) requires an infectious disease risk assessment for donors like L.C.'s daughter. According to Fujimoto, a physician screens donors via a questionnaire, a physical assessment, and blood testing. Fujimoto noted that there was a lack of documentation regarding whether L.C.'s daughter was so screened. Fujimoto did not clearly define the requirement to document the assessment. In his report, Fujimoto wrote, "*[i]mplicit* in their [FDA] requirements was the importance of documenting this evaluation for every egg donor cycle performed by all clinics." (Italics added.) Fujimoto opined that the lack of documentation in the patient's records regarding L.C.'s daughter's FDA eligibility status was an "extreme departure from the standard of care." There was no evidence other than Fujimoto's opinion regarding such a requirement and no citation to legal authority requiring such screening.

105. Like with N.S., Fujimoto opined that Respondent acted incompetently in his care and treatment of L.C. However, also as with N.S., Fujimoto failed to define incompetence, as he used the term, or explain why or how he reached his opinion.

Dr. Steinberg's Opinions regarding L.C.'s Case

106. Steinberg opined that Respondent's failure to refer L.C. to a mental health professional was not below the standard of care. Steinberg explained that there was nothing particular about L.C.'s desire for IVF or her intention to use her daughter's eggs that would require an IVF physician to refer L.C. for counseling. Steinberg explained further that the decision to refer a patient to a mental health professional in the case of a family member donor should depend on particular behaviors noted or concerns that arise as the physician observes or hears the patient or involved family members during examinations and consultations. The familial ties between donor and patient, according to Steinberg, should not prompt a referral in and of themselves. Steinberg further explained that the decision to make a referral is solely based on the physician's professional judgment and he saw no reason, based on L.C.'s records, to believe a referral was necessary.

107. Having defined incompetence, as set forth in Factual Finding 82, Steinberg opined that none of Respondent's actions in his care and treatment of L.C. constituted incompetence.

108. Similar to his analysis in N.S.'s case, Steinberg explained that since L.C. initially agreed to a multi-fetal reduction procedure, the transfer of seven embryos was understandable given L.C.'s age and Respondent's understanding that the IVF procedure would likely be her only attempt at pregnancy. Like in N.S.'s case, Steinberg found it extremely unusual that L.C. refused multi-fetal reduction. He described Respondent's treatment as "aggressive treatment," but would not specifically state that the transfer of seven embryos was below the standard of care. He also did not agree that the transfer constituted gross negligence. However, also like with N.S.'s 2008 transfers, Steinberg would not opine that the transfer of seven embryos into L.C. was within the standard of care. He noted that Respondent recommended the transfer of only four embryos, but agreed at hearing that the transfer of seven embryos was "probably" wrong. Steinberg also opined that Respondent's documentation of L.C.'s medical records was adequate.

The ASRM on Family Member Surrogacy

109. In a 2003 "Fertility and Sterility" article, entitled "Family members as gamete donors and surrogates," the ASRM, described unique problems arising from family members as "ovum donors," such as "undue influence" (meaning donors feel coerced to donate) and "confused parentage" for the resulting children.

110. The ASRM affirms that the use of family members is "ethically acceptable," but notes that in circumstances, like in the case of L.C., where the patient is a mother in her second marriage, and the patient's daughter is the intended ovum donor, concern regarding the donor's coercion is significant, and a physician should also examine the relationship between the daughter and the stepfather. The ASRM states, "providers should be prepared to spend more time screening and counseling participants" and further notes that "the involvement of multiple professionals, including . . . counselors may be necessary for a thorough assessment." The ASRM suggests, "[IVF] [p]rograms should encourage prospective participants, including partners of donors and surrogates, to undergo psychological counseling by a professional experienced in surrogacy or gamete donation."

111. Additionally, the ASRM notes that there are potential emotional consequences to the children and families involved in IVF. The ASRM suggests that involved physicians should obtain informed consents from all family participants and ensure there is no undue influence. It further suggests that if a physician finds undue pressures on the donor or surrogate or an unhealthy family dynamic, IVF programs should "feel free to deny these procedures."

Patient H.L.

112. H.L. is a woman who began seeing Respondent for regular gynecological check-ups in approximately October 1995.

113. In 2009, at the age of 43, H.L. sought pregnancy by IVF and discussed the process with Respondent. H.L. had a history of melanoma.

114. A transvaginal ultrasound performed in November 2008, found a right ovarian cyst measuring 3.8 centimeters, confirmed by a second ultrasound in December 2008, and a left ovarian cyst measuring 2.1 centimeters. Respondent initially presumed the cystic masses were benign and further presumed endometrioma.

115. In January 2009, Respondent performed a transvaginal cyst aspiration. The cyst drainage was examined. The cytologic report, dated January 15, 2009, found the aspirated fluid from the left ovarian cyst to contain "hemosiderin-laden macrophages and scattered clusters of atypical epithelial cells." Despite these findings, Respondent explained at hearing that he continued to opine that H.L. had endometriosis and he was not concerned that she had cancer. Respondent proceeded with an oocyte retrieval on January 27, 2009, noting H.L.'s "endometriotic cysts." Respondent proceeded with an embryo transfer, using the HEED procedure, on January 29, 2009. On that same day, Respondent wrote the following note in H.L.'s medical record, "ET [embryo transfer] done by hysteroscopic embryo transfer (HEED). Alternative of regular embryo transfer given prior to preparation and embryo transfer intrauterine," and "[o]ption of regular embryo transfer was given and discussed . . . Implantation vs. [h]ysteroscopic endometrial embryo delivery (HEED) was also discussed; [b]enefits and risks involved with each procedure were also discussed."

116. On January 27, 2009, H.L. signed consent forms indicating that she was advised regarding IVF and the embryo transfer process, among other things, and that she agreed to the procedures. Respondent did not sign these consent forms.

117. Respondent saw H.L. again on February 12, 2009, for a pregnancy test.

118. In April 2009, H.L. underwent laparoscopic surgery by another physician, who found stage three ovarian cancer. H.L. underwent cancer surgery in May 2009.

119. On June 23, 2009, Respondent placed a telephone call to H.L. to follow up with her; he left her a message. Respondent never spoke to H.L. again after approximately February 2009.

120. At hearing, Respondent explained that, by his June 2009 telephone call to H.L., he intended to speak with her to discuss, among other things, the cytology findings and see how she was doing. He conceded, however, that he could have discussed the cytology findings with H.L. and referred her to another physician to rule out ovarian cancer on January 27, 29, or February 12, 2009, but did not. Respondent explained that, due to the intense media publicity he encountered regarding N.S.'s octuplets, he became overwhelmed and preoccupied and failed to follow up with H.L. He conceded that he should have referred H.L. to a gynecological oncologist and pursued blood and other diagnostic tests to confirm or rule out the possibility of ovarian cancer.

Dr. Fujimoto's Opinions regarding H.L.'s Case

121. Fujimoto opined that failing to follow-up for a suspicious ovarian cyst was a simple departure from the standard of care. Fujimoto agreed that the standard of care in screening for ovarian cancer has not been established and routine screening has not been recommended by any society. However, he noted that the American College of Obstetrics and Gynecology states "a woman with a suspicious or persistent complex adnexal mass requires surgical evaluation by a physician trained to appropriately stage and debulk ovarian cancer." According to Fujimoto, the cytology findings should have been a "red flag" indicating a potential malignancy with at least one ovarian cyst, and Respondent should have stopped the IVF process until he further evaluated the risks, and considered surgery to remove H.L.'s left ovarian cyst. The standard of care, according to Fujimoto required Respondent to refer H.L. to an oncologist and move forward aggressively to remove the cyst. Fujimoto explained at hearing that the aspiration that H.L. underwent was not enough because the source of the cyst remained.

122. Fujimoto opined that the use of gonadotropins in H.L. did not worsen the severity of H.L.'s preexisting ovarian pathology. In his report, dated July 23, 2010, he wrote that "[w]hile the use of gonadotropins in the presence of malignant ovarian neoplasm would be considered a simple departure, there is little evidence that the use of these drugs worsened the condition for this patient [H.L.]."

123. Despite the absence of any written opinions by Fujimoto regarding Respondent's medical record keeping for H.L., Fujimoto opined at hearing that H.L.'s medical records were unclear about whether Respondent discussed the cytology findings with H.L. and the records failed to document whether Respondent ever followed up with H.L. regarding the cysts.

124. Like with N.S. and L.C., Fujimoto opined that Respondent acted incompetently in his care and treatment of H.L. Fujimoto failed to explain how or why he reached his opinion and failed to define incompetence, as he used the term.

Dr. Steinberg's Opinions regarding H.L.'s Case

125. Steinberg opined that the color of the fluid collected from the aspirated cyst was consistent with endometriosis, and therefore Respondent's opinion of endometrioma was appropriate. Steinberg agreed that the cytology report contained abnormal findings, but he did not agree that the findings alone suggested cancer. From the cytology report's findings alone, Steinberg opined that it was not obvious that H.L. was likely to have cancer. As such, there was nothing inappropriate in Respondent continuing the IVF procedure in light of the cytology report. Steinberg opined that the standard of care requires a physician to inform a patient of any abnormal test results as soon as possible. However, he opined that it was best described, not as incompetence, but as an "oversight" on Respondent's part not to make further referrals, although Respondent should have immediately informed H.L. of the abnormal cytology results, at the latest, on any of H.L.'s three later appointments in January

and February 2009. Steinberg opined that Respondent's attempt to reach H.L. by telephone constituted follow up on Respondent's part, albeit belated. He opined that the publicity pressures brought forth in the case of N.S. did not excuse Respondent's failure to follow up with L.C.

Dr. S.A. Achar's Opinions regarding Respondent's Overall Record-Keeping

126. Respondent offered the opinions of Suraj Arthur Achar, M.D. (Achar). Achar is Associate Clinical Professor at the University of California at San Diego (UCSD), School of Medicine and Medical Director at the UCSD La Jolla Family and Sports Medicine Department, where he is currently a member of the risk management committee (since 2009) and the clinical quality assurance committee (since 2007). His work is affiliated with the Physician Assessment and Clinical Education (PACE) program at the UCSD, a nationally regarded remedial program for physicians.

127. Achar received his Bachelor of Arts in French Literature from the University of California at Santa Cruz and University of Poitiers, in France. He received his medical degree from the State University of New York at Buffalo, School of Medicine in 1993. He completed his internship and residency in family and preventative medicine at the UCSD in 1996, and a fellowship in sports medicine at the UCSD School of Medicine in 2001.

128. Achar is a Fellow of the American Academy of Family Physicians. He is a Diplomate of the American Board of Family Practice (1996; recertified in 2003). He has published a number of articles in numerous journals and textbooks on sports medicine. Achar was an expert reviewer for the Board from 2004 through 2009.

129. Achar reviewed the pertinent medical records of N.S., L.C., and H.L and opined that Respondent had appropriately documented all three patient's medical records, and consequently, all of those records were within the standard of care.

130. In the case of N.S.'s records, Achar saw sufficient documentation of N.S.'s social circumstances, and found that Respondent adequately documented his consultations and other discussions with N.S. He explained that all physicians use their own abbreviations within their notes, so that for example, Respondent's use of "A's" and "B's" to refer to alternatives and benefits was appropriate and within the standard of care, as long as Respondent could accurately decipher his notations. Achar acknowledged that while he teaches physicians and medical students to use complete words in their notes, and not abbreviations, the majority of physician notes he reviews contain abbreviations.

Respondent's Clinical Studies

131. Complainant proffered the testimony of Donna Tartagliano Besone (Tartagliano), an investigator for the FDA. Tartagliano conducted a five-day inspection of Respondent's clinic in August and September 2010, and concluded, based in part on Respondent's responses to Tartagliano's inspection-related questions, that N.S. was part of a

clinical study conducted by Respondent. During the inspection, Tartagliano asked Respondent for a copy of the consent form N.S. signed to participate in the study, but failed to receive an appropriate form.

132. Respondent argued that N.S., L.C., and H.L. were not human test subjects for his IVF work, and that none of his actions in his IVF care and treatment of N.S., L.C. or H.L. were part of any clinical study. Respondent further argued that the consent forms in N.S.'s, L.C.'s, and H.L.'s medical records were appropriate and contained each patient's agreement to all of his IVF-related actions, including HEED/DEED/SEED.

Evidence of Respondent's Character and Reputation

133. Respondent proffered Parviz Daniels, M.D. (Daniels) as a character witness. Daniels is board certified in general surgery. He completed medical school in Belgium and his residency in New York in approximately 1981. He has known Respondent professionally for approximately 25 years, having had contact with him at Cedars Sinai Medical Center, and having treated mutual patients. He is aware that, in the past, Respondent has referred patients to mental health professionals when necessary. Daniels described Respondent as a caring and professional physician with an excellent reputation for providing quality care to patients at Cedars Sinai.

134. Respondent also proffered Lawrence Platt, M.D. (Platt) as a character witness. Platt received his medical degree from Wayne State University, School of Medicine in 1972. He is a Diplomate of the National Board of Medical Examiners (1976), and a Diplomate of the American Board of Obstetrics and Gynecology (1979). He has a sub-specialty certification in Maternal-Fetal Medicine from the American Board of Obstetrics and Gynecology. Platt acts as reviewer for a number of medical journals, including "Fertility and Sterility," the American Journal of Obstetrics and Gynecology, and the International Journal of Gynecology and Obstetrics. His practice includes high-risk obstetrics. He is on the staff at Cedars Sinai and was Chair of obstetrics and gynecology at Cedars Sinai from 1990 to 2001. He has known Respondent professionally for approximately 20 years. He regards Respondent highly as a physician and a person, and knows that Respondent is highly respected by colleagues and patients alike at Cedars Sinai.

Respondent's Recent Activity

135. The ASRM revoked Respondent's ASRM membership in 2009; the evidence did not establish the specific reasons.

136. Respondent changed several aspects of his practice in January 2010, as a result of the N.S. case. He changed his office personnel, including his clinic embryologist and the staff in his front and back offices. He has also changed some of his IVF practices. For example, if a patient insists on the transfer of an excessive number of embryos, as N.S. did, he would now refuse to treat that patient.

137. In his direct examination, Respondent asserted that he now strictly follows the ASRM guidelines (since January 2010); however, on cross-examination, he asserted that he would still deviate from the guidelines, based on patient circumstances.

138. Respondent has upgraded his record-keeping, having taken the medical record keeping course through PACE at UCSD, on October 28 and 29, 2010, for 17 continuing medical education credits.

139. Respondent has completed a number of other continuing medical education credits: the Institute for Medical Qualify "Professionalism" course, for 22 credits, on August 21-22, 2010, in El Segundo, California; the Women's Health Annual Visit, by Omnia Education in Pasadena, California, on June 11, 2010 (6.25 credits); Luteal support in reproduction, by the ASRM (1 credit); the City of Hope's 4th Annual Conference on Breast and Gynecologic Cancers: Advances in Prevention, Diagnosis and Treatment, on June 13, 2009 (8 credits); Operative Hysteroscopy System, by Smith and Nephew, in Marina Del Rey, California, on August 20, 2009; the Role of RANK/RANK-Ligand/OPG Pathway in Bone Loss and Associated Diseases, by Education Outcomes Science, on April 24, 2007 (1 credit); Irvine Scientific Vitrification System—Hands-on Workshop; Achieving Success Using Ultra-Rapid Cryo, by the American Board of Bioanalysis Professional Enrichment Educational Renewal, on January 3, 2007, May 20, 2006, and January 23, 2005 (1.8 credits); Preservation of Fertility Through Advances in Cryobiology, by the American Board of Bioanalysis Professional Enrichment Educational Renewal, on January 22, 2005 (0.6 credits); Use of Progesterone in Management of Secondary Amenorrhea, by the ASRM, on January 8, 2009 (0.5 credits); Progesterone Use in Assisted Reproductive Technology by the ASRM (0.5 credits); Practical Considerations for Office-Based Endometrial Ablation, by CME Consultants, on June 21, 2008 (2 credits); 15th World Congress on In Vitro Fertilization, in Geneva, Switzerland, by the International Society for In Vitro Fertilization, from April 19-22, 2009; the Royan International Twin Congress, 10th Congress on Reproductive Biomedicine, 5th Congress on Stem Cells Biology and Technology, on September 23-25, 2009, in Tehran, Iran.

140. Respondent continues to have privileges at, and practices at, Cedars Sinai. Cedars Sinai's Credentialing Committee re-credentialed Respondent in 2007, and commended him for 25 years of "distinguished service" in 2009.

LEGAL CONCLUSIONS

Statutory Law

1. Business and Professions Code section 2227 states in pertinent part:

(a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code . . . and is found guilty . . . may, in accordance with the provisions of this chapter:

(1) Have his . . . license revoked upon order of the division.

(2) Have his . . . right to practice suspended for a period not to exceed one year upon order of the division.

(3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the division.

(4) Be publicly reprimanded by the division.

(5) Have any other action taken in relation to discipline as part of an order of probation, as the division or an administrative law judge may deem proper.

2. Business and Professions Code section 2234 states in pertinent part:

The Division 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:

[¶] . . . [¶]

(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.

[¶] . . . [¶]

(d) Incompetence.

(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.

Case Law

The Standard of Proof

3. Complainant must prove her case by clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) Clear and convincing evidence means the evidence is "so clear as to leave no substantial doubt" and is "sufficiently strong to command the unhesitating assent of every reasonable mind." (*Mathieu v. Norrell Corporation* (2004) 115 Cal.App.4th 1174, 1190 [citing *Mock v. Michigan Millers Mutual Ins. Co.* (1992) 4 Cal.App.4th 306, 332-333].)

Negligence

4. "[A] physician is required to possess and exercise, in both diagnosis and treatment, that reasonable degree of knowledge and skill which is ordinarily possessed and exercised by other members of his profession in similar circumstances." (*Landeros v. Flood* (1976) 17 Cal.3d 399, 408; see also, *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 997-998.)

5. "'Negligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.' [Citation.] Thus, as a general proposition one 'is required to exercise the care that a person of ordinary prudence would exercise under the circumstances.' [Citations.] Because application of this principle is inherently situational, the amount of care deemed reasonable in any particular case will vary, while at the same time the standard of conduct itself remains constant, i.e., due care commensurate with the risk posed by the conduct taking into consideration all relevant circumstances. [Citations.]" (*Flowers v. Torrance Memorial Hospital Medical Center*, *supra*, 8 Cal.4th at 997.) "Since the standard of care remains constant in terms of 'ordinary prudence,' it is clear that denominating a cause of action as one for 'professional negligence' does not transmute its underlying character. For substantive purposes, it merely serves to establish the basis by which 'ordinary prudence' will be calculated and [Respondent's] conduct evaluated." (*Id.*, at 998.)

6. "The fact that another physician or surgeon might have elected to treat the case differently or use methods other than those employed by [Respondent] does not of itself establish negligence." (*Williamson v. Prida* (1999) 75 Cal.App.4th 1417, 1425-1426.)

Gross Negligence

7. Gross negligence is defined as "the want of even scant care or an extreme departure from the ordinary standard of conduct." (*Eastburn v. Regional Fire Protection Authority* (2003) 31 Cal.4th 1175, 1185-1186.)

Incompetence

8. Incompetence means "an absence of qualification, ability or fitness to perform a prescribed duty or function." (*Pollack v. Kinder* (1978) 85 Cal.App.3d 833, 837.) Incompetence is distinguishable from negligence, in that one may be competent or capable of performing a given duty but negligent in performing that duty. (*Id.*, at 837-838.) Thus, "a single act of negligence . . . may be attributable to remissness in discharging known duties, rather than . . . incompetency respecting the proper performance." (*Id.*, at 838 [citing *Peters v. Southern Pacific Co.* (1911) 160 Cal. 48, 62].)

9. "It [incompetence] is commonly defined to mean a general lack of present ability to perform a given duty as distinguished from inability to perform such duty as a result of mere neglect or omission. (Footnote omitted.) Such an interpretation is totally consistent with the declared legislative objective of public protection by requiring a minimum standard of professional conduct on the part of those licensed to engage in regulated activities." (*Pollack v. Kinder*, *supra*, 85 Cal.App.3d at 837-838.) "[T]he terms negligence and incompetency are not synonymous; a licensee may be competent or capable of performing a given duty but negligent in performing that duty." (*Id.*, at 838.)

Expert Testimony

10. "The standard of care against which the acts of a physician are to be measured is a matter peculiarly within the knowledge of experts . . . and can only be proved by their testimony [citations], unless the conduct required by the particular circumstances is within the common knowledge of the layman." (*Landeros v. Flood*, *supra*, 17 Cal.3d at 410.)

11. The trier of fact may "accept part of the testimony of a witness and reject another part even though the latter contradicts the part accepted." (*Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 67.) The trier of fact may also "reject part of the testimony of a witness, though not directly contradicted, and combine the accepted portions with bits of testimony or inferences from the testimony of other witnesses thus weaving a cloth of truth out of selected available material." (*Id.* at 67-68 [citing *Nevarov v. Caldwell* (1958) 161 Cal.App.2d 762, 767].) Further, the fact finder may reject the testimony of any witness, even an expert, although uncontradicted. (*Foreman & Clark Corp. v. Fallon* (1971) 3 Cal.3d 875, 890.)

12. The fact that a trier of fact "may disbelieve the testimony of a witness who testifies to the negative of an issue does not of itself furnish any evidence in support of the affirmative of that issue and does not warrant a finding in the affirmative thereof unless there

is other [supportive evidence]." (*Hutchinson v. Contractors' State License Board* (1956) 143 Cal.App. 2d 628, 632 [citing *Marovich v. Central California Traction Co.* (1923) 191 Cal. 295, 304].)

Patient N.S.

Gross Negligence and Repeated Negligent Acts

13. As to the embryo transfers in January and July 2008, Fujimoto opined that they were extreme departures from the standard of care due to the excessive number of embryos transferred. Saliently, Steinberg could not say the transfers were within the standard of care. Further, Steinberg described those two embryo transfers as wrong and a lapse in judgment. With no expert testimony to the contrary, the evidence was clear and convincing that N.S.'s embryo transfers, in January and July 2008, were below the standard of care, and as Fujimoto opined, extreme departures from the standard of care. As such, the transfers constituted gross negligence, and as two acts, the transfers constituted repeated negligent acts.

14. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for an excessive number of embryo transfers in the case of N.S. on two occasions in January and June 2008, as set forth in Factual Findings 1-94, and Legal Conclusions 1-3, 7, and 10-13.

15. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for an excessive number of embryo transfers in the case of N.S. on two occasions in January and June 2008, as set forth in Factual Findings 1-94, and Legal Conclusions 1-6, and 10-13.

16. As to all the other embryo transfers, Steinberg opined contrary to Fujimoto. Whereas Fujimoto opined that the embryo transfers between December 2002 and 2007 were all below the standard of care, by sheer number, Steinberg explained that when an IVF physician considers, as Respondent did, the factors delineated in Factual Findings 17, 18, 23, 33, and 38, the number of embryos transferred is less pertinent than the analysis used by the IVF physician in considering the circumstantial patient data. Additionally, the ASRM guidelines do not set forth rigid limitations, as Fujimoto implicitly opined. In the ASRM's own wording, the guidelines are "recommended," "may be modified," and are "not intended to be the only approved standard of practice or to dictate an exclusive course of treatment." (Factual Findings 85, 86 and 90.) Furthermore, pursuant to a 2008/2009 national survey the majority of IVF practitioners nationwide deviate from the ASRM guidelines. (Factual Finding 94.) This survey corroborated Steinberg's similar assertions at hearing.

17. The evidence established, as to the embryo transfers between December 2002 and 2007, that Respondent considered the various factors set forth in Factual Findings 18, 23,

33, and 38, and consulted with N.S. to determine the number of embryos to transfer on each occasion. N.S.'s continuous and successive requests for IVF treatment were in objectively short order, but there was no evidence that the standard of care limits an IVF physician's ability to treat a patient who seeks IVF treatment in as continuous and as successive an order as N.S. did. As the ASRM guidelines provide for flexibility in determining the appropriate number of embryos to transfer, and with evidence that Respondent considered the appropriate factors and used his professional judgment to ultimately determine the number of embryos to transfer on each occasion between December 2002 and 2007, Respondent's embryo transfers between those dates were not extreme departures from the standard of care and thus did not constitute gross negligence or repeated negligent acts.

18. Fujimoto opined that Respondent should have referred N.S. to a mental health professional as soon as 2005, when she had four children and wanted further IVF treatment. However, nothing in the evidence, other than Fujimoto's opinion, supported that position. Fujimoto could point to nothing other than his own professional opinion as to why obtaining four children via IVF was the rational limit of children for N.S. to bear through IVF, without then requiring psychological counseling. Steinberg was persuasive that it is not up to the physician to decide how many children an IVF patient may have. Steinberg noted that, in hindsight, N.S. might have benefited from psychological counseling, but further noted that that viewpoint was not readily apparent in 2005. Whether N.S.'s behavior was abnormal in 2005, is an arguable matter that is not objectively established by the standard of care for an IVF physician. Respondent's failure to refer N.S. to a mental health professional, therefore, was not an extreme departure from the standard of care or otherwise negligence.

19. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for failing to refer N.S. to a mental health professional, as set forth in Factual Findings 1-94, and Legal Conclusions 1-3, 7, 10-12, and 18.

20. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for failing to refer N.S. to a mental health professional, as set forth in Factual Findings 1-94, and Legal Conclusions 1-6, 10-12, and 16-18.

21. Respondent's failure to recommend that N.S. use her frozen embryos was not a departure from the standard of care. Fujimoto's opinion on this was based solely on his professional judgment and he could not point to any standard in IVF practice. Steinberg credibly opined to the contrary, noting that the embryos belong to the patient, who may direct the physician to do with them as the patient sees fit. Moreover, the evidence established that Respondent advised N.S. regarding the use of frozen embryos, advising her, in concert with Steinberg's opinion, that frozen embryos are less successful than fresh embryos.

22. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for

gross negligence, for failing to recommend and use N.S.'s frozen embryos, as set forth in Factual Findings 1-36, 59, 60, 77, and Legal Conclusions 1-3, 7, 10-12, and 21.

23. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for failing to recommend and use N.S.'s frozen embryos, as set forth in Factual Findings 1-36, 59, 60, 77, and Legal Conclusions 1-6, 10-12, and 21.

24. While Fujimoto ultimately concluded that Respondent's use of high doses of gonadotropins was below the standard of care, he could not identify the standard of care. Moreover, Fujimoto conceded that the optimal dosing of gonadotropins remains unclear. Steinberg opined that the use of hormones was appropriate, given N.S.'s delayed responses to hormonal stimulation. Therefore the evidence was not clear and convincing that Respondent's use of gonadotropins on N.S. was below the standard of care.

25. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for the excessive dosing of gonadotropins in the case of N.S., as set forth in Factual Findings 1-40, 50-53, 63, 65-66, 76, and Legal Conclusions 1-3, 7, 10-12, and 24.

26. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for the excessive dosing of gonadotropins in the case of N.S., as set forth in Factual Findings 1-40, 50-53, 63, 65-66, 76, and Legal Conclusions 1-6, 10-12, and 24.

Incompetence

27. Respondent's overall care and treatment of N.S. was not established to be incompetent. Fujimoto's opinion that Respondent was incompetent merited little weight, as he failed to define incompetence and failed to set forth the analyses he used to reach his opinion. In contrast, Steinberg defined incompetence similar to the case law. (*Pollack v. Kinder*, *supra*, 85 Cal.App.3d at 837-838.), and opined that Respondent had the knowledge and skill to practice IVF and was therefore, not incompetent.

28. Even when considering the portions of Respondent's care and treatment of N.S. that constituted gross negligence and repeated negligent acts, the evidence did not establish that Respondent's IVF care and treatment showed an absence of qualification, ability, or fitness. (*Pollack v. Kinder*, *supra*, 85 Cal.App.3d at 837.) Thus, Respondent did not act incompetently in his care and treatment of N.S.

29. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (d), for incompetence, in his care and treatment of N.S., as set forth in Factual Findings 1-94, and Legal Conclusions 1-3, 8-12, 27, and 28.

Patient L.C.

Gross Negligence and Repeated Negligent Acts

30. For similar reasons as explained in Legal Conclusion 13, the number of embryos Respondent transferred into L.C. was below the standard of care, as Fujimoto opined. Like in the case of N.S., Steinberg failed to opine that the transfer of seven embryos was within the standard of care. The flexible nature of the ASRM guidelines does not, in this patient's case also, mean that the seven-embryo transfer into L.C. was appropriate. Steinberg's opinions neither discredited nor weakened Fujimoto's opinion. Thus, there was clear and convincing evidence that the Respondent's seven-embryo transfer into L.C. was an extreme departure from the standard of care, and consequently, gross negligence.

31. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for gross negligence, for an excessive number of embryo transfers in the case of L.C., as set forth in Factual Findings 1, 5, 95, 97, 98, 100-102, 108, and Legal Conclusions 1-3, 7, 10-12, and 30.

32. The embryo transfer, when considered with Respondent's negligent acts in the case of N.S., constitutes repeated negligent acts.

33. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for an excessive number of embryo transfers in the case of L.C., as set forth in Factual Findings 1, 5, 95, 97, 98, 100-102, 108, and Legal Conclusions 1-6, 10-12, and 32.

34. Respondent's failure to refer L.C. to a psychological professional was not a departure from the standard of care, as Steinberg persuasively opined that the standard of care did not absolutely require it. On this issue, Steinberg and the ASRM contradicted Fujimoto's opinion. The 2003 "Fertility and Sterility" article affirms the acceptability of family member ovum donation, and while it suggests that IVF physicians examine the family dynamics of involved family members, and suggests counseling for those participants, it does not mandate a mental health referral. While Fujimoto asserted that it was his practice to always refer patients and involved family members to counseling in situations like L.C.'s, and while such a practice may be optimal, the ASRM's language in the article is not compulsory. A reading of the ASRM article in whole renders the reasonable conclusion that the decision whether to refer a patient and her involved family members to a mental health professional is in the professional judgment of the physician. L.C.'s case provided no evidence that L.C. or her daughter required such a referral. Respondent credibly asserted that he observed and otherwise perceived no such issues. Therefore, the absence of a referral to a mental health professional, in the case of L.C., was not gross negligence or repeated negligent acts.

35. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (b), for

gross negligence, for his failure to refer L.C. or her family to a mental health professional, as set forth in Factual Findings 1, 5, 95-101, 103, 106, 109-111, and Legal Conclusions 1-3, 7, 10-12, and 34.

36. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for his failure to refer L.C. or her family to a mental health professional, as set forth in Factual Findings 1, 5, 95-101, 103, 106, 109-111, and Legal Conclusions 1-6, 10-12, and 34.

Incompetence

37. The analysis and conclusions reached regarding the allegation of incompetence in the case of N.S. are equally applicable to the case of L.C. Therefore, Respondent did not act incompetently in his care and treatment of L.C. for the reasons set forth in Legal Conclusions 27 and 28.

38. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (d), for incompetence, for his care and treatment of L.C., as set forth in Factual Findings 1, 5, 95-101, 105, 107, and Legal Conclusions 1-3, 8, 9, 10-12, and 37.

Patient H.L.

Repeated Negligent Acts

39. Respondent's failures to perform testing on H.L. and refer her to a specialist to rule out cancer were repeated negligent acts, two simple departures from the standard of care, as opined by Fujimoto. Fujimoto persuasively opined that the abnormal cytology report should have prompted Respondent to perform further testing and refer H.L. to a specialist. Steinberg's opinion, that the abnormal cytology report did not of itself establish H.L.'s cancer, was credible, but the important factor to consider in H.L.'s case, as opined by Fujimoto, was that the cytology report was abnormal. Whether the findings in that report pointed to conditions as serious as cancer, or other less serious conditions, it was Respondent's duty to pursue the abnormalities in the cytology report by testing and referral. Even Respondent conceded he should have, but neglected to do so because of the publicity pressures he experienced in N.S.'s case. Respondent further conceded, similar to Steinberg's opinion, that those pressures should not have deterred Respondent from his professional obligations.

40. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (c), for repeated negligent acts, for failing to perform testing on H.L. and failing to refer her to a specialist to rule out cancer after obtaining abnormal cytology report findings, as set forth in Factual Findings 1, 5, 112-122, 125, and Legal Conclusions 1-3, 4-6, 10-12, and 39.

Incompetence

41. The analysis and conclusions reached regarding the allegation of incompetence in the cases of N.S. and L.C. are equally applicable to the case of H.L. Therefore, Respondent did not act incompetently in his care and treatment of H.L. for the reasons set forth in Legal Conclusions 27 and 28.

42. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (d), for incompetence, in his care and treatment of H.L., as set forth in Factual Findings 1, 5, 112-125, and Legal Conclusions 1-3, 8-9, 10-12, and 41.

The Patients' Informed Consent to Respondent's Use of HEED/DEED/SEED

43. Respondent obtained the informed consent of N.S., L.C., and H.L., with respect to the use of HEED/DEED/SEED and documented that consent in the patients' records. (Factual Findings 41, 49, 99, and 115.)

44. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivisions (b) or (c), for gross negligence or repeated negligent acts, for using HEED/DEED/SEED without the informed consent of patients N.S., L.C., and H.L., as set forth in Factual Findings 1, 5, 41, 49, 99, 115, and Legal Conclusions 1-7, 10-12, and 43.

Respondent's Alleged Clinical Studies

45. The evidence established Respondent engaged in IVF clinical studies, and that N.S. participated in at least one such study. However, there was no persuasive expert opinion establishing the standard of care with regard to patient consent in clinical studies. There was no evidence conclusively establishing the legal requirement for consent forms within clinical studies and, for example, whether any exemptions, exclusions, or alternatives to consent forms exist. Further there was insufficient evidence establishing that any portion of the IVF care and treatment of N.S., L.C., or H.L. at issue in this case was a part of, or otherwise constituted, a clinical study.

46. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2234, subdivision (e), for dishonest and corrupt acts, for performing clinical studies on patients without their informed consent, as set forth in Factual Findings 1, 5, 80, 131, 132, and Legal Conclusions 1-3, 10-12, and 45.

Respondent's Record-Keeping

47. Business and Professions Code section 2266 states in pertinent part:

> 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.

48. Respondent maintained adequate records in the cases of N.S., L.C., and partially in the case of H.L.

N.S.'s Medical Records

49. N.S.'s records contain Respondent's numerous notations documenting his discussions and consultations with her, discussing the alternatives, benefits, risks, and side effects of the IVF process and related procedures. According to his notations, these discussions included the topics of multiple gestation and multi-fetal reduction. Based on the consent forms on the freezing and disposition of N.S.'s embryos, and Respondent's credible testimony, Respondent spoke with N.S. regarding those topics and obtained N.S.'s authorization and direction. Although as to the disposition of her frozen embryos, N.S.'s consents were limited to certain specified circumstances, Respondent's documentation adequately memorializes the pertinent IVF-related topics. The fact that Respondent did not sign the consent forms is of limited consequence, as Steinberg opined. The patient's signature is the primary concern. Fujimoto failed to set forth any valid reason why Respondent's signature would be so important as to make its absence a departure from the standard of care.

50. There was little, if any documentation regarding N.S.'s "social situation," which was understood to mean facts that would describe her personal and social circumstances. However, the evidence did not establish that the standard of care required the documentation of such information. On this, Steinberg's opinion was persuasive. Fujimoto's point that an IVF physician should consider the patient's children when treating an IVF patient is reasonable. But Steinberg's opinion, that an IVF physician's primary responsibility is to protect the best interests of the patient, is also reasonable. Steinberg further opined that it is the IVF patient who bears the responsibility to care for and consider her children and future children when pursuing IVF, and that the patient's other social circumstances are irrelevant to the physician's IVF care and treatment. This opinion has merit. Furthermore, to find as Fujimoto opined would risk placing IVF physicians in the role of those who would pass moral judgment on the social circumstances of patients, including for example whether a patient who is single, divorced, rich, poor, or has a disability should have children, or only a specified number of children, via IVF. As Steinberg more convincingly opined, the patient's social situation is not relevant to the patient's care, and thus need not be documented in the patient's medical record. Taken as a whole, the expert evidence did not establish, by clear and convincing evidence, that the standard of care for an

IVF physician requires him or her to document the social aspects of the patient's life. Respondent's documentation of N.S.'s records was therefore adequate.

51. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2266, for maintaining inadequate or inaccurate records as to patient N.S., as set forth in Factual Findings 1, 5, 8, 19, 26, 27, 41, 49, 50-53, 61, 62, 65, 66, 78-80, 126-130, and Legal Conclusions 1-3, 10-12, and 47-50.

L.C.'s Medical Records

52. Respondent documented L.C.'s records, showing that he discussed all IVF-related procedures with her on September 25 and 27, 2008. However, Respondent performed an oocyte retrieval on September 22, 2008. Respondent failed to document any IVF-related discussions at the initial consultation or otherwise before the oocyte retrieval.

53. However, Fujimoto's opinion, in light of the subsequent documentation on September 25 and 27, 2008, and the contrary opinions of Steinberg and Achar, and giving Achar's opinions less weight[3], Fujimoto's opinion alone did not establish by clear and convincing evidence that Respondent's omission constituted inadequate records that merited license discipline, pursuant to Business and Professions Code section 2266.

54. Respondent documented the fact that L.C. intended to use a directed donor, but did not document the significance of using a directed donor. Respondent also did not describe the ovarian stimulation protocol used, or that he discussed the number of embryos to be transferred with L.C.; however, Fujimoto was unpersuasive that the absence of that information constituted inadequate records, when considering Respondent's overall notations in each patient's records and Steinberg's and Achar's opinions. It was not established by clear and convincing evidence that Respondent's documentary omissions in L.C.'s records constituted inadequate records, sufficient to justify license discipline.

55. Fujimoto's opinion that Respondent should have documented the FDA infectious disease assessment was also unpersuasive. Complainant provided no conclusive evidence establishing the FDA requirement Fujimoto asserted. Fujimoto's assertion alone was insufficient to establish what the FDA requires, especially given the ill-defined nature of the documentation requirement that Fujimoto described as only "implicit" in the requirements.

56. Cause does not exist to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2266, for maintaining

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[3] Achar's opinions regarding Respondent's record keeping was given less weight than that of Fujimoto's, as Achar established no background in IVF, endocrinology, or reproductive science. However, as a physician whose work is affiliated with the PACE program, his opinions were nevertheless given some weight.

inadequate or inaccurate records, as to patient L.C., as set forth in Factual Findings 1, 5, 99, 104, 108, 126-130, and Legal Conclusions 1-3, 10-12, 47, 48, and 52-55.

H.L.'s Medical Records

57. The consent forms in H.L.'s records indicate that Respondent informed H.L. about all IVF-related procedures, including embryo transfer, and that she consented to the procedures. The consent forms documented that Respondent discussed the IVF-related processes with L.C. sufficiently to establish adequate IVF-related records.

58. As H.L. signed the pertinent consent forms, Respondent's failure to sign treatment-related consent forms is not below the standard of care for the same reasons set forth in Legal Conclusion 49 regarding N.S.

59. H.L.'s records lacked documentation of Respondent's plans for artificial insemination and IVF therapies, when the plans for those therapies was made, what stimulation protocol was used, and the number of IVF cycles undergone. However, assessing Respondent's existing notations and documentation in H.L.'s records, and considering all three expert opinions (despite the lesser weight of Achar's opinions), the evidence failed to establish that these deficiencies merited license discipline, pursuant to Business and Professions Code section 2266.

60. Respondent failed to document any discussion with H.L. regarding her ovarian cystic masses or the abnormal cytology report, since it was that Respondent never had any such discussions with her. There is no documentation regarding H.L.'s consent to the cyst aspiration procedure. Distinct from the other records above, H.L.'s records are completely absent of any discussions with H.L. or actions Respondent took related to the cystic masses or the abnormal cytology report (except for the aspiration procedure). Respondent's failure to document any discussions on these topics constitutes inadequate records.

61. Cause exists to discipline Respondent's physician and surgeon certificate, pursuant to Business and Professions Code section 2266, for maintaining inadequate or inaccurate records as to patient H.L., as set forth in Factual Findings 1, 5, 115, 123, 126-130, and Legal Conclusions 1-3, 10-12, 47, 48, and 57-61.

The Proper License Discipline

62. Respondent committed acts of gross negligence and repeated negligent acts in his care and treatment of N.S. and L.C., and repeated negligent acts in his care and treatment of H.L. Respondent maintained inadequate records in the case of H.L. However, to a great degree, Respondent succeeded in presenting a defense to the majority of the allegations, including other acts of gross negligence and repeated negligent acts, inadequate records, and all allegations of incompetence, and inadequate consents regarding HEED/DEED/SEED and clinical studies.

63. The evidence established that, overall, and with the noted exception of failing to inform H.L. of her abnormal cytology report, Respondent made IVF treatment decisions with regard for the patients' well-being, considering each patient's circumstances. On the issue of deciding on the number of embryos to transfer in N.S. and L.C., the evidence did not show that Respondent practiced carelessly in disregard of the patients, but that instead, he was aware of each patient's circumstances and used his professional judgment (albeit poor judgment in a portion of the cases of N.S. and L.C., as concluded *ante*) and considered each patient's wishes to determine the number of embryos to transfer. The evidence did not establish Respondent as a maverick or deviant physician, oblivious to standards of care in IVF practice.

64. Respondent has practiced medicine as a California licensed physician since 1979, never having suffered license discipline by the Board. He has a good reputation in the professional community.

65. For all of these reasons above, license revocation, as sought by Complainant, is too severe. The public would be adequately protected by a period of probation that includes, among other things, terms and conditions requiring Respondent to complete an ethics course. It does not appear likely that Respondent will repeat acts like transferring an excessive number of embryos as he did in the cases of N.S. and L.C., especially given the national publicity surrounding N.S.'s case. However, during his testimony, Respondent asserted he might still deviate from the ASRM guidelines, after initially asserting that he would strictly adhere to them. This inconsistency warrants oversight of Respondent's practice to ensure he properly assesses individual patients and uses good judgment in practice. The probationary terms and conditions should therefore include practice monitoring.

ORDER

Physician and Surgeon Certificate No. G 41227 issued to Respondent Michael Kamrava is revoked, however, revocation is stayed and Respondent is placed on probation for five years upon the following terms and conditions.

Enrollment in an Ethics Course

1(a) Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a course in ethics, at Respondent's expense, approved in advance by the Board or its designee. Failure to successfully complete the course during the first year of probation is a violation of probation.

1(b) An ethics course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Board or its designee had the course been taken after the effective date of this Decision.

1(c) Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

Monitoring - Practice

2(a). Within 30 calendar days of the effective date of this Decision, Respondent shall submit to the Board or its designee for prior approval as a practice monitor, the name and qualifications of one or more licensed physicians and surgeons whose licenses are valid and in good standing, and who are preferably American Board of Medical Specialties (ABMS) certified. A monitor shall have no prior or current business or personal relationship with Respondent, or other relationship that could reasonably be expected to compromise the ability of the monitor to render fair and unbiased reports to the Board, including but not limited to any form of bartering, shall be in Respondent's field of practice, and must agree to serve as Respondent's monitor. Respondent shall pay all monitoring costs.

2(b). The Board or its designee shall provide the approved monitor with copies of the Decision and Accusation, and a proposed monitoring plan. Within 15 calendar days of receipt of the Decision, Accusation, and proposed monitoring plan, the monitor shall submit a signed statement that the monitor has read the Decision and Accusation, fully understands the role of a monitor, and agrees or disagrees with the proposed monitoring plan. If the monitor disagrees with the proposed monitoring plan, the monitor shall submit a revised monitoring plan with the signed statement.

2(c). Within 60 calendar days of the effective date of this Decision, and continuing throughout probation, Respondent's practice shall be monitored by the approved monitor. Respondent shall make all records available for immediate inspection and copying on the premises by the monitor at all times during business hours and shall retain the records for the entire term of probation.

2(d). The monitor(s) shall submit a quarterly written report to the Board or its designee which includes an evaluation of Respondent's performance, indicating whether Respondent's practices are within the standards of practice of medicine, and whether Respondent is practicing medicine safely.

2(e). It shall be the sole responsibility of Respondent to ensure that the monitor submits the quarterly written reports to the Board or its designee within 10 calendar days after the end of the preceding quarter.

2(f). If the monitor resigns or is no longer available, Respondent shall, within five calendar days of such resignation or unavailability, submit to the Board or its designee, for prior approval, the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If Respondent fails to obtain approval of a replacement monitor within 60 days of the resignation or unavailability of the monitor, Respondent shall be suspended from the practice of medicine until a replacement monitor is approved and prepared to assume immediate monitoring responsibility. Respondent shall

cease the practice of medicine within three calendar days after being so notified by the Board or designee.

2(g). In lieu of a monitor, Respondent may participate in a professional enhancement program equivalent to the one offered by the Physician Assessment and Clinical Education Program at the University of California, San Diego School of Medicine, that includes, at minimum, quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at Respondent's expense during the term of probation.

2(h). Failure to maintain all records, or to make all appropriate records available for immediate inspection and copying on the premises, or to comply with this condition as outlined above is a violation of probation.

Probation Monitoring Costs

3. Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year. Failure to pay costs within 30 calendar days of the due date is a violation of probation.

Notification

4(a). Prior to engaging in the practice of medicine Respondent shall provide a true copy of the Decision and Accusation to the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to Respondent, at any other facility where Respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which extends malpractice insurance coverage to Respondent. Respondent shall submit proof of compliance to the Board or its designee within 15 calendar days of the effective date of this Decision.

4(b). This condition shall apply to any change(s) in hospitals, other facilities, or insurance carrier.

Supervision of Physician Assistants

5. During probation, Respondent is prohibited from supervising physician assistants.

Obey All Laws

6. Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California, and remain in full compliance with any court-ordered criminal probation, payments, and other orders.

Quarterly Declarations

7. Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all the conditions of probation. Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

Probation Unit Compliance

8(a). Respondent shall comply with the Board's probation unit. Respondent shall, at all times, keep the Board informed of Respondent's business and residence addresses. Changes of such addresses shall be immediately communicated in writing to the Board or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021, subdivision (b).

8(b). Respondent shall not engage in the practice of medicine in Respondent's place of residence. Respondent shall maintain a current and renewed California physician and surgeon license.

8(c). Respondent shall immediately inform the Board or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than 30 calendar days.

Interview with the Board or its Designee

9. Respondent shall be available in person for interviews either at Respondent's place of business or at the probation unit office, with the Board or its designee upon request at various intervals, and either with or without prior notice throughout the term of probation.

Residing or Practicing Out-of-State

10(a). In the event Respondent should leave the State of California to reside or to practice, Respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of departure and return. Non-practice is defined as any period of time exceeding 30 calendar days in which Respondent is not engaging in any activities defined in Business and Professions Code sections 2051 and 2052.

10(b). All time spent in an intensive training program outside the State of California which has been approved by the Board or its designee shall be considered as time spent in the practice of medicine within the State. A Board-ordered suspension of practice shall not be considered as a period of non-practice. Periods of temporary or permanent residence or

practice outside California will not apply to the reduction of the probationary term. Periods of temporary or permanent residence or practice outside California will relieve Respondent of the responsibility to comply with the probationary terms and conditions, with the exception of this condition and the following terms and conditions of probation: Obey All Laws and Probation Unit Compliance.

10(c). Respondent's license shall be automatically cancelled if Respondent's periods of temporary or permanent residence or practice outside California totals two years. However, Respondent's license shall not be cancelled as long as Respondent is residing and practicing medicine in another state of the United States and is on active probation with the medical licensing authority of that state, in which case the two year period shall begin on the date probation is completed or terminated in that state.

Failure to Practice Medicine - California Resident

11(a). In the event Respondent resides in the State of California and for any reason Respondent stops practicing medicine in California, Respondent shall notify the Board or its designee in writing within 30 calendar days prior to the dates of non-practice and return to practice. Any period of non-practice within California, as defined in this condition, will not apply to the reduction of the probationary term and does not relieve Respondent of the responsibility to comply with the terms and conditions of probation. Non-practice is defined as any period of time exceeding 30 calendar days in which Respondent is not engaging in any activities defined in Business and Professions Code sections 2051 and 2052.

11(b). All time spent in an intensive training program which has been approved by the Board or its designee shall be considered time spent in the practice of medicine. For purposes of this condition, non-practice due to a Board-ordered suspension or in compliance with any other condition of probation, shall not be considered a period of non-practice.

11(c). Respondent's license shall be automatically cancelled if Respondent resides in California and for a total of two years, fails to engage in California in any of the activities described in Business and Professions Code sections 2051 and 2052.

Violation of Probation

12. Failure to fully comply with any term or condition of probation is a violation of probation. If Respondent violates probation in any respect, the Board, after giving Respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation or Petition to Revoke Probation, or an Interim Suspension Order is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

License Surrender

13. Following the effective date of this Decision, if Respondent ceases practicing due to retirement, health reasons or is otherwise unable to satisfy the terms and conditions of

probation, Respondent may request the voluntary surrender of Respondent's license. The Division reserves the right to evaluate Respondent's request and to exercise its discretion whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, Respondent shall, within 15 calendar days, deliver Respondent's wallet and wall certificate to the Board or its designee and Respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation and the surrender of Respondent's license shall be deemed disciplinary action. If Respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

Completion of Probation

14. Respondent shall comply with all financial obligations (e.g., probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, Respondent's certificate shall be fully restored.

Dated: December 20, 2010

DANIEL JUAREZ
Administrative Law Judge
Office of Administrative Hearings