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

In the Matter of the Accusation Against:	)	
STEVEN L. KATZ, M.D. Certificate No. G-71332	)	No: 03-2001-122617
Respondent	)	

DECISION

The attached Proposed Decision is hereby adopted by the Division of Medical Quality as its Decision in the above-entitled matter.

This Decision shall become effective at 5:00 p.m. on April 27, 2005.

IT IS SO ORDERED March 28, 2005

By: _____
RONALD L. MOY, M.D.
Chair - Panel B
Division of Medical Quality

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MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: STEVEN L. KATZ, M.D. 1700 California Street, Suite 570 San Francisco, California 94109 Physician's and Surgeon's Certificate No. G-71332 Respondent.	Case No. 03-2001-122617 OAH No. N2004080093

PROPOSED DECISION

This matter was heard before Administrative Law Judge Jonathan Lew, State of California, Office of Administrative Hearings on January 3 through 13, 2005, in Oakland, California.

Lawrence A. Mercer and Jane Zack Simon, Deputy Attorneys General, represented complainant.

Brock D. Phillips, Esq., represented Steven L. Katz, M.D., who was present.

Submission of the matter was deferred pending receipt of written closing argument. The parties simultaneously submitted Closing and Reply Briefs, respectively, on January 24, 2005, and February 11, 2005. Complainant's briefs were marked as Exhibits 46 and 47 for identification and respondent's briefs were marked as Exhibits R and S for identification. The case was submitted for decision on February 11, 2005.[1]

[1] Complainant also submitted a February 15, 2005 letter requesting that documents submitted with respondent's brief not be considered, and should be stricken from any public record of this proceeding. Respondent submitted a response dated February 16, 2005. Complainant's objection to pages of the Medical Board's Enforcement Operations Manual being considered is sustained. It is a privileged document that tends to reveal law enforcement investigative techniques or sources. (*Fox v. Kramer* (2000) 22 Cal.4th 531.) These pages shall not be made part of the public record of this proceeding. Respondent notes that his objection to Dr. Schriock's testimony is otherwise

FACTUAL FINDINGS

1. David T. Thornton (complainant) brought the First Amended Accusation solely in his official capacity as the Executive Director of the Medical Board of California (Board).[2]

2. On May 13, 1991, the Board issued Steven L. Katz, M.D. (respondent) Physician's and Surgeon's Certificate No. G-71332. The certificate was current at all times pertinent to this matter. It will expire on November 30, 2006, if not renewed. There has been no prior disciplinary action taken against this certificate.

3. Respondent specializes in the area of reproductive endocrinology and fertility. He is the Medical Director of Fertility Associates of the Bay Area, with offices in San Francisco. The allegations against him arise from his involvement in the mistaken transfer on June 15, 2000, of three embryos intended for one of his patients (D.B.) into a second patient (S.B.), and his subsequent failure to disclose to either of the patients that this error had occurred. The more serious allegations relate to his failure to disclose the mistake. Specifically, complainant contends that respondent embarked upon a course of deception, dishonesty and cover-up that lasted for a year and a half. And that during this time medical records were falsified and altered, a patient (S.B.) was given a medication under false pretenses, office staff were lied to and then enlisted into the cover-up, fraudulent billings were submitted to a patient and her insurance company, and respondent lied to both his patients and to the Board's investigator.

Respondent admits the mistaken transfer of embryos. He also admits to his failure to take appropriate action to inform the patients and to his failure to properly document the mistake in the patients' charts. However, he denies giving S.B. medication in an attempt to terminate her pregnancy and he denies lying to the Board's investigator. While now acknowledging that he should have informed the patients of the mistaken transfer of embryos, respondent also notes that the problem with which he was confronted "was a novel, rare and complex one, the ramifications of which were so unusual and profound that his mistake is one that others might have made as well, and that his actions arose from a genuine desire to act in the best interests of the patients and the potential lives they carried." He suggests that he acted as he did because there were insufficient standards in place at that time to guide him. Through various changes in his practice, along with additional training and education, he believes he practices medicine safely and effectively, and urges that he be allowed to continue doing so. Complainant contends that the only resolution of this case which will protect and assure the safety of the public is license revocation.

4. Professional Background. Respondent attended Cornell University Medical College, graduating in 1989. He completed postgraduate residency training through the

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supported by the Report of the Enforcement Monitor, a public document posted to the Board's web site. However, such does not warrant striking Dr. Schriock's testimony in its entirety. Rather, it is a matter that was considered in evaluating the weight that should be attached to his testimony.

[2] Joyce Hadnot, Acting Executive Director of the Board, brought the original Accusation on February 18, 2004.

School of Medicine, University of California, San Francisco (UCSF), Department of Obstetrics, Gynecology and Reproductive Sciences. He was Chief Resident there in 1993, and between 1993 and 1995, he trained as a UCSF Fellow in reproductive endocrinology and infertility. Respondent is board certified in both obstetrics/gynecology and reproductive endocrinology and infertility.

Between July 1995, and November 1996, respondent served as Director of the Oregon Health Sciences University In Vitro Fertilization Satellite Program in Eugene, Oregon. He also served as Clinical Assistant Professor with Oregon Health Sciences University School of Medicine. In December 1996, respondent joined California North Bay Fertility Associates as its Co-Medical Director. He set up and operated offices for the practice in San Francisco and Marin County for two years. By January 1999, he opened his own practice, Fertility Associates of the Bay Area, essentially taking over the San Francisco and Marin offices in which he had been practicing. Respondent is currently an assistant clinical professor at UCSF School of Medicine, Department of Obstetrics, Gynecology and Reproductive Sciences, a position he has held since June 1997. He holds professional memberships in the American Society for Reproductive Medicine (ASRM), Society for Reproductive Endocrinology and Infertility, Pacific Coast Fertility Society, San Francisco GYN Society and RESOLVE. Respondent is also a fellow with the American College of Obstetricians and Gynecologists. He has authored a number of peer-reviewed publications and abstracts, and has presented numerous lectures and seminars in the western United States.

5. California Reproductive Laboratories. When respondent opened Fertility Associates of the Bay Area, he made arrangements for Imam El Danasouri, Ph.D., to establish and operate an embryology laboratory, known as California Reproductive Laboratories (CRL). The laboratory was located within respondent's San Francisco office suite and under the terms of an agreement executed between respondent and Dr. El Danasouri, respondent's patients were all referred to CRL. CRL was owned and operated by Dr. El Danasouri, who was not a licensed medical professional. CRL was required to hold a current tissue bank license. (Health & Saf. Code, § 1641.) CRL did not have a tissue bank license and no application for such a license was made until September 2000. In that September 2000 application, CRL disclosed that respondent was a person responsible for collection, processing, storage or distribution of tissue by the tissue bank and a copy of respondent's curriculum vitae was provided to the Department of Health Services, Laboratory Field Services, with the application.

Respondent had an absolute responsibility to verify that CRL was appropriately licensed and his failure to do so was a departure from the standard of care, or negligence. However, this failure did not rise to the level of gross negligence. The criticism in this case is that respondent neglected to physically check certificates or other records to confirm that CRL was fully and currently licensed. He relied instead upon representations made to him by Dr. El Danasouri that all necessary licensure was in place. Such reliance was not unreasonable for the following reasons. Dr. El Danasouri was recommended to respondent by his peers at Stanford University where Dr. El Danasouri ran the in vitro fertilization (IVF) laboratory. He had previously run successful IVF laboratories for the State of New Jersey

and also in Germany. Respondent had reviewed Dr. El Danasouri's curriculum vitae and was satisfied that he knew how to run large, complex and successful laboratories. He had no reason to question Dr. El Danasouri's qualifications and respondent believed he was well qualified and fully capable of setting up and running CRL. Under these circumstances, having been assured by a well credentialed and highly regarded colleague that all necessary licensure was in place, respondent was entitled to rely upon such assurances. His failure to take additional steps to review license documentation was not so extreme a departure from the standard of care as to constitute gross negligence.

Mistaken Transfer

6. Patient S.B. came under respondent's care in late 1999. She was age 47 and had been trying for many years to become pregnant. After four unsuccessful cycles of IVF, she desired to try having a child using a donor egg and donor sperm. She wished to raise the child as hers, and hers alone. An embryo transfer was attempted unsuccessfully in April 2000. She had seven remaining embryos that were cryo-preserved and a second embryo transfer was scheduled for June 15, 2000. The plan was to use S.B.'s frozen embryos at that time.

Patient D.B. was also under respondent's care and supervision for embryo transfer. She and her husband (R.B.) desired to have a child using R.B.'s sperm and donor eggs, so that R.B. would be the natural father of any child resulting from the transfer and implantation of the embryos. The plan was to have three fresh embryos transferred on June 15, 2000.[3] Patient S.B. was scheduled for frozen embryo transfer at 1:00 p.m., and Patient D.B. was scheduled for fresh embryo transfer at 1:30 p.m. The two patients go by the same first name. It is undisputed that on June 15, 2000, respondent transferred three fresh embryos that were intended for Patient D.B to Patient S.B. The implantation was successful and Patient S.B. became pregnant and delivered a boy.

At the time of this error, the following procedures were in place and followed by respondent during the course of all embryo transfer procedures:

a. A schedule of all procedures was prepared and reviewed the day before the procedures so that respondent and Dr. El Danasouri would know the order of patients to be seen the following day.

b. Respondent and Dr. El Danasouri would review the schedule a second time the morning of the day that the procedures were to be performed.

[3] For fresh embryo transfers, the donor and recipient are given hormones to synchronize their cycles. The donor also goes on fertility hormones to stimulate oocytes (eggs) in ovaries. The eggs are "harvested" from the donor near the time of the scheduled transfer. For frozen embryo transfers, the eggs are usually thawed two to three hours before the transfer.

c. An embryo report was prepared for each patient. This report contained the full name of each patient, age and date of birth. It also contained information regarding the number and quality of embryos. This report was prepared by Dr. El Danasouri.

d. Respondent reviewed the embryo report with each patient. He went over information with the patient relating to the number of embryos, grade and number of cells per embryo in reaching a decision on the number of, and which embryos were to be implanted. This information was recorded on a form. Respondent and Dr. El Danasouri would then have a separate discussion to confirm the number and which embryos were to be transferred to the patient. Dr. El Danasouri was given the form containing this information. The patient was then brought to a transfer room located directly across the hall and within 10 – 20 feet of Dr. El Danasouri's laboratory.

e. The patient disrobes and is prepped in the transfer room. Respondent and an assistant remain with the patient in that room. Respondent will state: "Almost ready for patient [Jane Doe]," stating the patient's first and last name. This is then repeated verbatim by the assistant in a voice loud enough for Dr. El Danasouri to hear. Respondent will then insert a catheter and hold it in place near a favorable implantation site. He will then state: "Please load [Jane Doe]" and this is repeated by the assistant loud enough for Dr. El Danasouri to hear. Dr. El Danasouri will then walk across the hall from his laboratory with the embryos. A smaller catheter containing the embryos is inserted in the larger catheter held by respondent, and on respondent's order, Dr. El Danasouri will depress a plunger and transfer the embryos to the implantation site. Dr. El Danasouri will then examine the catheter under a microscope for any residual embryo and after he yells "clear" respondent will remove the speculum and have the patient rest in place for up to an hour.

7. Within ten minutes of the June 15, 2000 embryo transfer to Patient S.B., respondent was notified by Dr. El Danasouri that an error had occurred. The two went into respondent's office to discuss the situation. Respondent was shocked. He notes that his reaction was such that he almost fainted. He had never encountered this situation before and he asked Dr. El Danasouri for advice on what to do. Dr. El Danasouri told respondent that he had a number of choices. One was that respondent could tell Patient S.B. what had just occurred and then lavage out her uterus. However, Dr. El Danasouri thought this would cause too emotional a response and he advised against it. Dr. El Danasouri recommended instead that respondent state that there had been an infection in the laboratory, and that Patient S.B. be given birth control pills. The latter would be comparable to a morning after pill and would terminate her pregnancy. Respondent gave the matter some thought before reaching a decision not to tell patient S.B. what had happened. He decided to personally handle Patient S.B's discharge, a highly unusual step for him as this was normally performed by Laura Grad, the clinical coordinator, or by Linda Keiser, a registered nurse.

Birth Control Pills

8. Respondent left his office, walked down the office hall to a closet and retrieved some birth control pills. The pills go by the trade name Levlen® and are small pink tablets that come in a bubble packet.[4] He opened the packet, removed the tablets and discarded the aluminum/bubble packet in a trash can. He gave four or five of these pills to Patient S.B.

Respondent denies doing so. He acknowledges taking the Levlen® from the closet and opening the packet, putting the tablets into his lab coat pocket and discarding the container. However, he avers that he did not go through with it. He notes that although he originally intended to follow Dr. El Danasouri's advice, he later "came to his senses" and changed his mind. Respondent has no recall of giving any pills to Patient S.B., but suggests that had he done so it would have been Prometrium®, a form of oral progesterone. Progesterone acts to thicken the uterine lining and enhance implantation. Prometrium® is also pink, but compared to Levlen® it is larger in size and globular in shape. Levlen® tablets are relatively flat.

Linda Keiser testified credibly that respondent gave Levlen® to Patient S.B. Ms. Keiser and other staff first suspected that something had gone wrong the afternoon of June 15, after respondent and Dr. El Danasouri expressed surprise and then met behind closed doors for an unusually long period of time. Her suspicions were heightened after a modified embryo report for Patient D.B. came out of the office printer showing a reduced number of available eggs from what had been earlier reported on Patient D.B.s embryo report. When Ms. Keiser learned that respondent had retrieved a sample box of birth control pills from the closet she felt something was clearly not right. She also thought it highly unusual that respondent, and not one of the staff, was handling Patient S.B.'s discharge. Ms. Keiser went into the treatment room where Patient S.B. was being discharged to see for herself what was happening. She observed respondent give Patient S.B. a handful of pinkish orange pills and she overheard him explaining to Patient S.B. that the pills would give an "extra boost" to help her implant. Ms. Keiser recognized the pills to be birth control pills.[5] At the time of the incident, Ms. Keiser looked in the trash receptacle and retrieved an empty Levelen® container. She later returned it to the trash out of concern that respondent might want to cover his trail and discover that she was on to him.

9. It is unlikely that respondent gave Patient S.B. Prometrium® as he now suggests. He avers that he did not give her birth control pills because he had a change of mind and that he determined to let nature take its course. Yet by giving her Prometrium® he would have enhanced Patient S.B.'s chances of becoming pregnant and this runs counter to his purported desire to let matters progress naturally. His actions were also inconsistent with treatment records indicating that he planned to switch her to Crinone®, a form of progesterone to be applied vaginally. There would have been no additional need for oral progesterone had

[4] Levlen® is a combination of levonorgestrel and ethinyl estradiol tablets

[5] At hearing, Ms. Keiser was shown Prometrium® samples and she is certain that respondent did not give Patient S.B. Prometrium®.

Patient S.B. been prescribed Crinone® and there was nothing in Patient S.B.'s records to suggest that it was his plan to supplement the Crinone® with oral progesterone. More importantly, if a physician were to augment progesterone with Prometrium®, the medication would be prescribed daily over a period of weeks. It would not consist of a single dose of four to five pills. One medical expert, Eldon Dean Schriock, M.D., opines that it would have made no medical sense for respondent to give Patient S.B. a handful of Prometrium®.

Respondent suggests that because Patient S.B. actually became pregnant she could not have been given birth control pills that day. Typically, a "morning after" contraceptive using Levlen® would consist of two separate doses of four pills, the second dose occurring 12 hours after the first. There is no evidence that Patient S.B. took a second dose. Dr. Schriock offers another theory why Patient S.B. became pregnant, notwithstanding being given Levlen®. Because Patient S.B. was on a controlled hormonal cycle her ovarian and pituitary functions had essentially been turned off. Dr. Schriock believes that under these circumstances Levlen® would have had no effect on her pregnancy. [6]

10. In determining that respondent gave Patient S.B. Levelen® the testimony of Ms. Keiser was most compelling. She was an eyewitness to this event. As a registered nurse, she recognized the tablets being given by respondent to Patient S.B. as being birth control pills. She readily distinguished these tablets from the Prometrium® pills. She was so concerned that respondent had retrieved birth control pills from the closet that she followed him into the treatment room and she later retrieved the open bubble packet from the trash to confirm that Levlen® had in fact been taken from the closet. In subsequent meetings and conversations that are described below, Ms. Keiser confronted respondent with the day's events and received very unsatisfactory responses causing her to resign out of principle shortly thereafter. In a staff meeting held on the morning of June 16, 2000, one day after the incident, respondent and Dr. El Danasouri were openly asked why Patient S.B. was given pills and Dr. El Danasouri responded that a baby must not be allowed to be born to the wrong parents. Respondent said or did nothing to correct or deny this statement.

Ms. Keiser's account is also corroborated by Jeanne Ricci, the office receptionist. Ms. Ricci testified that she asked respondent how he got Patient S.B. to take the pills and he explained that he told her that the pills were extra progesterone that she needed because she was heavy. Ms. Ricci also heard respondent state "that's impossible" at the time he received the results of Patient S.B.'s pregnancy test.

11. Respondent believes Ms. Keiser's testimony is suspect and unreliable because she has provided differing accounts of the events of June 15, 2000. He points to differences in an earlier declaration executed by her indicating that respondent had admitted during a staff meeting to "causing one of the patients to abort" and her more recent statements that

[6] There is a difference in medical opinion on whether the Levlen® would have acted instead to prevent implantation. Bernard Z. Gore, M.D., testified as a medical expert on behalf of respondent and he opines that Levlen® would have the same effect on women undergoing IVF because its effect is to prevent the endometrium from accepting implantation.

respondent was present at the staff meeting but said nothing. There were also statements she made earlier about having a more active role in Patient S.B.'s discharge and her not being sure whether she witnessed respondent taking the birth control pills from the closet, or was simply told about it. These differences in recollection are relatively minor. What stands out is that Linda Keiser was the one licensed professional in the office who immediately recognized what was happening and who acted and did what she could to stop it. She confronted respondent and pled with him to disclose to the patients everything that had occurred. When respondent did not act as requested, she quit her job rather than have any part in respondent's decision to conceal matters from the patients. Ms. Keiser acted on principle. She quit at a time when she believed she was placing herself somewhat at financial and personal peril. She explains that she was afraid and intimidated by respondent, that this occurred during a vulnerable time in her life and that respondent knew all her weak spots. Respondent made brief mention to Ms. Keiser that he hoped that she would not talk about the incident with anyone else. To avoid a face to face confrontation with respondent, Ms. Keiser sent him a letter detailing the reasons why she felt she needed to leave. Within a month of leaving she called the office and was told that Patient D.B. was pregnant, but office staff misrepresented to her that Patient S.B. had not become pregnant. Ms. Keiser made a courageous decision to stand up to respondent and then quit her position. Her testimony was forthright and persuasive. She was a credible witness.

Concealment of Error

12. Respondent also decided not to tell Patient D.B. or her husband that three of her and her husband's embryos had been mistakenly transferred to another patient. By reason of the fact that the three fresh embryos had already been transferred to Patient S.B., respondent transferred three others, which were obtained from Patient D.B.'s stored embryos, to her. Patient D.B. and her husband left respondent's offices believing that only D.B. had received a transfer of fresh embryos as intended.

Ms. Keiser asked respondent to meet with staff on June 15, 2000. After the patients were gone, the entire office met in respondent's office. Respondent appeared uncomfortable. Staff asked whether something unusual had happened that afternoon. Respondent stated that they had discovered an infection in the laboratory. He was asked if that was the case, why was Patient S.B., and not other patients, the only concern. No response was given. Ms. Keiser felt respondent was largely attempting to placate staff. Respondent also stated during that meeting that he had given Patient S.B. progesterone. He was non-committal and put off to the following day questions relating to the laboratory infection.

Ms. Keiser carpooled home with respondent on June 15. He told her that something had obviously gone wrong that day and he asked her what he should do. Ms. Keiser told him to tell the patient what had happened. Ms. Keiser told respondent that she had worked before in operating rooms when things had gone wrong and that it was always important to come clean with the patient. She told him that is why physicians carry malpractice insurance. She also told him to sit down with staff the next morning and come clean with them if he

expected them to have respect for him. Respondent listened but was non-committal. He did indicate that he would speak overnight with Dr. El Danasouri about the matter.

A staff meeting was held the following morning. Dr. El Danasouri took the lead during the meeting and respondent said little or nothing. Dr. El Danasouri stated that it was obvious what had happened the previous day. When asked why the patient could not be told, Dr. El Danasouri explained that it would unleash an unreal sequence of malpractice lawsuits and that it would hurt their medical/professional reputation. Dr. El Danasouri explained that he had seen this happen in a number of laboratories where he had worked and "You never allow a baby to be born to the wrong patient." This was the specific rationale offered for giving Patient SB the pills. Respondent was present during the entire meeting and he did not voice any disagreement with what Dr. El Danasouri said.

13. Respondent's medical records for Patient S.B. do not disclose the true facts regarding the transfer procedure or respondent's attempt to prevent her pregnancy. The standard of practice requires that a physician maintain a complete and accurate record of medical treatment provided to patients, including documentation of medical errors. In the event it is necessary to correct a chart entry, the standard of practice requires the physician to cross out the incorrect information, add the correct information and initial and date the changes. Respondent's medical records for Patient S.B. make no mention of the fact that she did not received the frozen embryos intended for her. Neither his June 15 progress note nor his June 15 procedure report indicates the medical error. The June 15 procedure report affirmatively represents that Patient S.B. received four frozen embryos and respondent knew this to be untrue. The freeze and thaw form, created by Dr. El Danasouri, was placed in Patient S.B.'s chart. It indicated that four frozen embryos were transferred to her on June 15. Her frozen embryos were in fact discarded. Respondent billed Patient S.B. and her insurance company as if he had performed the transfer of Patient S.B.'s frozen embryos even though he knew that he had not performed the transfer contemplated.

Respondent's medical records for Patient D.B. do not disclose the erroneous transfer of her embryos to Patient S.B. The Embryo Transfer Form for Patient D.B. does not disclose what became of the three erroneously transferred embryos. Respondent and Dr. El Danasouri produced altered records which purported to show that D.B. was intended to receive three embryos different than the fresh embryos contemplated.

14. Respondent received pregnancy test results for Patient S.B. and Patient D.B. He followed both patients for a short period until their care was assumed by their personal obstetricians. In February 2001, Patient S.B. delivered a baby boy and Patient D.B. delivered a baby girl. At no time up to delivery did respondent disclose to them the error. Neither woman was aware of the erroneous transfer of D.B.'s embryos nor that S.B.'s child was the natural child of D.B.'s husband, R.B.

15. In June 2001, the Board received information pertaining to the above and commenced an investigation. In December 2001, patient S.B. was contacted by Board investigator Ted Maurino. She then called respondent with her concerns and he determined

for the first time that he needed to disclose what had happened. Respondent got in touch with Dr. El Danasouri and the two arranged to personally meet with Patients S.B. and D.B. in their respective homes to tell them what had happened. They met first with Patient D.B. and her husband, R.B. Respondent explained to them that three of their embryos had been transferred to another patient by mistake and he apologized. When asked how this could have occurred, Dr. El Danasouri noted that the patients' names were similar. Respondent was careful to maintain patient confidentiality, but he did share with them that the boy was 10 months old, healthy and with a prominent lady living in a nice area. When asked why he took so long to tell them, respondent said that he was waiting for the right time. He also told them that Patient S.B.'s embryos were "no good" and that it was probably her last chance to get pregnant. Respondent urged the couple not to tell anybody as it could hurt everyone. Respondent promised to help them in any way he could.

Respondent and Dr. El Danasouri next met with Patient S.B. Respondent told her that there had been a terrible mix-up and that she had received embryos intended for another couple. She was in complete shock. Patient S.B. was told that this had never happened in thousands of transfers but, in this case, the patients' names were similar and normally the fresh embryo transfers would occur earlier in the day and the frozen transfers would be scheduled later. She was told that her frozen embryos had been discarded. Respondent told her that after thinking long and hard about the matter he thought he might disclose the error to her after the children reached age two.

Patient S.B. showed respondent a letter from the Board which included information about her possibly being given birth control pills. Respondent told her that this was incorrect. Respondent told Patient S.B. that the embryos she had received were from a Northern California couple, that the couple was religious and that they had had a girl. Respondent also told Patient S.B. that she should not talk about the incident because the careers of both respondent and Dr. El Danasouri would be ruined. She told him that she was not planning on having more contact with the Board and he was in agreement with this. Over the following days, respondent encouraged Patient S.B. to meet with the couple to help diffuse the situation. They agreed and respondent facilitated their eventual meeting.

16. Patient D.B. and R.B. regard the boy as their own son and they are presently engaged in a costly legal dispute with Patient S.B. to resolve their mutual claims on the child born to S.B. R.B. currently has visitation rights with the boy. There have also been civil actions filed against respondent. Patient S.B. notes that she never envisioned this happening in her wildest dreams. She intended to be a single parent and she never wanted a child to go through a "divorce situation." She fully trusted respondent and she now feels betrayed. She believes respondent was not truthful with her and that he was deceptive. She avers that she would have wanted the matter to have been disclosed to her on June 15, 2000, and have all her options explained to her at that time. She filed civil suit against respondent and that action has since been resolved. She notes that over the course of that civil suit she had occasion to be physically present with respondent and that he has not apologized to her or acknowledged that he betrayed, or lied to her.

Patient D.B. wanted as many pregnancies as the embryos would allow. She and her husband viewed the embryos as their "potential children." She placed her full trust and confidence in respondent. When the couple learned that they had a son, they moved from Del Norte County to the Bay Area because they wanted their daughter to be closer to her sibling. The move has created financial and other hardships because they left a lot of family and friends behind. Respondent's mistake has affected Patient D.B.'s confidence in the medical profession. She also feels that respondent betrayed her confidence by not disclosing the mistake and she would have wanted to have been told earlier.[7]

17. Complainant contends that when respondent was interviewed about the events in July 2002, by Board investigator Ted Maurino, respondent advised the Board that Patient S.B. had not become pregnant. This is reflected in a final investigation report authored by Mr. Maurino. It does appear that Mr. Maurino, at the time he interviewed respondent in July 2002, did not realized that Patient SB became pregnant and had a child from her IVF procedure. However, as early as May 2002, he was told by DB that she and her husband were trying to establish paternity but apparently Mr. Maurino did not understand that this reference to paternity meant that Patient SB had a child.

Respondent recalls cooperating totally with Mr. Maurino. He discussed both children being born, and how he spent time acting as liaison between the two families. Robert Slattery, counsel for respondent, was present when Mr. Maurino interviewed respondent and he confirms that there was specific reference Patient S.B. having a child.[8] Mr. Maurino recalls that respondent was cooperative during questioning. He also confirms that there were discussions generally about respondent arranging a meeting between the families and a child custody action. Mr. Maurino could not harmonize his recollections of discussions of these topics with his statement that respondent had not told him Patient S.B. had become pregnant and had a child. When Mr. Maurino eventually came to a correct understanding that patient S.B. had become pregnant he sent respondent an e-mail to confirm this information. It does appear that there was a miscommunication or misunderstanding of information shared between respondent and Ted Maurino. Respondent recalls calling Mr. Maurino and having a brief conversation confirming this fact. For these reasons it was not established that respondent misled the Board into believing that Patient S.B. had not become pregnant.

Standard of Practice – Embryo Transfers

18. Stephen P. Boyers, M.D., testified along with Dr. Schriock as medical experts on behalf of complainant. They agree that the relationship between the infertility physician and the laboratory director is a close one – a team effort. Both must exercise high levels of diligence in patient identification procedures which must include careful labeling and

[7] Although Patient D.B. would have wished to participate earlier in the decision making process, she notes that if she had no legal right to control what Patient S.B. did with the embryo implanted in her, she does not know in that case whether she would have wanted to be told right away.

[8] Respondent did tell Mr. Maurino that earlier in time, when he did not know whether Patient S.B. was pregnant, he determined to tell the parties about the error only if she did have a child. Respondent suggests that Mr. Maurino misunderstood this to mean that Patient S.B. had not become pregnant.

tracking of embryos. Written protocols for patient identification should be in place, and the procedures must be followed in meticulous detail.[9] William Keye, Jr., M.D., testified as a medical expert on behalf of respondent. He acknowledges that where the process is complex or errors are possible, written guidelines should be in place, and a double check system must be in place so that a formal identification of the patient is made to communicate the patient's identity to the embryologist. The physician must take the lead in this regard because it is the physician who has the relationship with and who knows the patient, not the embryologist. The physician bears ultimate responsibility for making certain that the patient is properly identified. Respondent acknowledges that an error occurred but believes that the procedures in place still fell within the standard of care.[10]

The procedures employed by respondent on June 15, 2000, were not unreasonable and they fell within the standard of care. Respondent and Dr. El Danasouri reviewed the patient schedule both the day before and the day of the embryo transfer procedure. The patients were correctly identified and scheduled. The schedule did not change. It was correctly documented that Patient S.B. was to receive four frozen embryos. The embryos were thawed and graded by Dr. El Danasouri on the morning of June 15 prior to the transfer. Respondent and Dr. El Danasouri conferred about Patient S.B.'s embryo report, and after respondent conferred with Patient S.B., respondent and Dr. El Danasouri spoke again about which embryos were to be transferred to Patient S.B. During the actual procedure, the usual practice was to call out the patient's first and last name at least twice. This was done in this case. Patient S.B. confirmed that her name, first and last, was called out during the procedure. Human error somehow came into play after this point. Dr. El Danasouri loaded three fresh embryos belonging to Patient DB and RB into the catheter for Patient S.B. Respondent had to remain with the patient the entire time, holding the catheter in place near the implantation site. It was not his practice to enter the laboratory, a sterile setting, to observe Dr. El Danasori during this phase of the transfer. Although respondent bears overall responsibility for the error, he did not depart procedurally in any way from established protocols on his end.

Dr. Keye notes that the system used by respondent was virtually identical to the system that he used in his own practice for many years, only recently slightly modified to add patient wrist bands as required by hospitals. The procedures followed by respondent were outlined in detail at hearing and considered by Board expert Dr. Boyers. Dr. Boyers concedes that it "sounds like a fairly reliable system" and he would not fault respondent for having this system in place. He opines that if all those procedures were followed and the embryologist made a mistake, respondent would be justified in relying upon all the

[9] ASRM guidelines and minimum standards provide: "Written procedures should be established for the double-checking and verification of patient identity and the identification of gametes and embryo samples. These procedures should be performed before insemination, embryo thawing, or embryo transfer procedures." (Revised Minimum Standards for In Vitro Fertilization, Gamete Intrafallopian Transfer, and Related Procedures, A Practice Committee Report, February 1998.)

[10] The procedures followed by respondent are those outlined in Factual Finding 6.

information he received from his embryologist.[11] For these reasons it was not established that the mistaken transfer constituted gross negligence on respondent's part.

19. Respondent has sought to improve identification protocols following this incident. He has a different embryologist, Charles Cornwell, who has instituted additional laboratory safeguards. For example, Mr. Cornwell assigns a unique identifier (number) for each patient and labels are generated, along with an additional stripe of color coding, for all sample containers. A nurse or staff person in the clinic will now witness the mixing of eggs and sperm, and then sign documentation verifying this. On the day of transfers, samples are placed in additional labeled containers. A photograph of each patient is maintained in the chart and Mr. Cornwell personally meets with each patient before commencing transfer procedures.

All these steps are memorialized in writing. Complainant faults respondent for not having written protocols for patient identification at the time of the incident. Written procedures are recommended, not required, and are more critical in situations where multiple physicians and multiple laboratory personnel are involved in embryo transfers. Where there are only two individuals, and they have a regular practice and routine working together on transfer procedures, having written procedures is less critical and respondent's failure to have them in place did not constitute gross negligence.

Standard of Practice – Informed Consent and Conflicts of Interest

20. Respondent suggests that because there were no specific standards or guidelines dealing with the precise circumstances of this case, his course of action was unclear when "confronted with a crisis unprecedented and virtually unique" within his specialty. Physicians cannot reasonably expect a guideline or standard to be in place for every conceivable error. Medical mistakes happen and when they do the only course open to the physician is to advise the patient of the medical error. In this respect, the situation facing respondent was not complex at all. The decision to tell the truth is foundational, as is the basic principle that the patient, not the physician, has the right to make complex choices and decisions relating to her medical planning and care. The standard of practice requires physicians to promptly and fully disclose errors to their patients. Patients have a right to be fully informed of errors and to have their medical options fully disclosed and discussed. Physicians are to be honest in their interactions with their patients, to respect the rights of their patients, and in particular, to respect the right of their patients to make choices about their healthcare. Physicians are required to recognize potential and actual conflicts of interest, and to place their patients' interest about their own. These are the longstanding and commonly understood principles guiding every physician confronted with a medical error.

[11] Complainant argues that respondent had a "near miss" in 1999 that prompted him to tighten patient identification procedures, and that he later reverted back to more lax procedures that remained in place through the time of this incident. But Dr. Boyers' testimony that reasonable procedures were in place make irrelevant whether respondent should have retained the more meticulous procedures which included having two individuals identify the embryos that were to be transferred.

The duty to inform is universal and respondent failed to honor his obligation to do so to Patients S.B. and D.B.

21. The American College of Obstetricians and Gynecologists (ACOG) has adopted a Code of Professional Ethics. ACOG's statement of Ethical Foundations notes: "The respect for the right of individual patients to make their own choices about their health care (autonomy) is fundamental." The Code of Conduct adopted by ACOG further requires:

> The obstetrician-gynecologist has an obligation to obtain the informed consent of each patient. In obtaining informed consent for any course of medical or surgical treatment, the obstetrician-gynecologist must present to the patient, or to the person legally responsible for the patient, pertinent medical facts and recommendations consistent with good medical practice.

The Committee on Ethics of ACOG explains that informed consent is more than a signature on a form. It is a process that includes "ongoing shared information and developing choices as long as one is seeking medical assistance."[12] It is a freedom from being acted on by others when they have not taken account of and respected the individual's own preference and choice.[13] And it is "an ethically unacceptable violation of who and what persons are to coerce their actions or to refuse their participation in important decision that affect their lives."[14]

ACOG's Code of Professional Ethics also addresses conflicts of interest. It recognizes that conflicts of interest are inherent in the practice of medicine and that they should be resolved "in accordance with the best interest of the patient, respecting a woman's autonomy to make health care decisions." (ACOG Code of Professional Ethics, Section III, Conflicts of Interest.) Physicians are required to disclose the conflict to the patient if it could reasonably be construed to affect significantly the patient's care. ACOG advises physicians to seek consultation with colleagues or an institutional ethics committee to determine whether there is an actual or potential conflict of interest and how to address it.

Finally, the Code of Professional Ethics confirms that the physician-patient relationship is built on trust and honesty. The Code also addresses physician interactions with nurses and health care professionals, noting that such relationships "should reflect fairness, honesty, and integrity, sharing a mutual respect and concern for the patient."

22. Respondent generally acknowledges these principles and admits that he made a wrong decision by failing to tell the patients of the mistake and to document the mistake in their patient records. But he has also presented evidence that the decision facing him was

[12] Ethics in Obstetrics and Gynecology, Second Edition, The American College of Obstetricians and Gynecologists, Revised January 2004, page 9.
[13] *Id.* at p. 13.
[14] *Id.* at p. 11.

much more complex than this and that his actions were more a result of poor judgment than deliberate misconduct. Two medical experts for respondent, William Keye, Jr., M.D. and Bernard Z. Gore, M.D., go even further, suggesting that telling the patients in this case about the mistake caused more harm than good and was not required by any standard of care. Such matters warrant additional discussion, particularly given the strength of Dr. Keye's credentials.

Dr. Keye serves as Director of the Division of Reproductive Endocrinology and IVF Programs at William Beaumont Hospital in Royal Oak, Michigan. He oversees an infertility practice of five physicians and an IVF program with seven physicians. He has been a Fellow with ACOG since 1982. Dr. Keye is quite active with ASRM. He was on its Board of Directors between 1995 – 1997, and 1999 – 2004. He served on its Ethics Committee in 2004. He was ASRM President Elect in 2001 and ASRM President in 2001 – 2002. Dr. Keye lectures extensively. He has edited four or five textbooks in a variety of areas, he is a reviewer for a number of journals, he has contributed to some 55 different textbook chapters, he has authored some 86 abstracts and he has made nearly 500 presentations at international, national, regional and local conferences.

Dr. Keye indicates that he found nothing in ASRM, ACOG or AMA guidelines that specifically addressed the situation faced by respondent. He believes that the appropriate course of action was not clear and that there were both pros and cons in disclosing or not disclosing information to the parties. Dr. Keye suggests that it was complicated by the fact that multiple interests were involved – the interests of the couple, the single woman and the embryos themselves. He believes the "central figure" of IVF is the embryo with interests that must be protected. Based upon his own review of AMA and ACOG guidelines, Dr. Keye believes the complexity of the situation presented an opportunity for a physician to not disclose if the physician felt disclosure would cause more harm than good. He does not believe that physicians have a paramount duty to disclose mistakes in patient care, pointing to an exception allowing physicians not to disclose if such would cause harm. In essence, Dr. Keye believes that where there is a conflict between informed consent and doing no harm, avoiding patient harm supersedes the patient's right to be informed. Dr. Keye also does not advocate seeking consultation from physician colleagues. He suggests that where uncertainty arises, the physician's main source of information derives from the physician-patient interaction and that an outside physician is not positioned to help in making those judgments.

23. Dr. Keye's testimony is not persuasive. There is a "therapeutic privilege" exception to the principle of informed consent but Dr. Keye overstates its application here. A physician may be excused from disclosing information to a patient in situations where the patient is unconscious or otherwise incapable of consenting and harm from the failure to treat is imminent, or where disclosure "poses such a serious psychological threat of detriment to the patient as to be medically contraindicated."[15] The rationale for withholding information from a patient should be carefully documented and exercise of the therapeutic privilege is

[15] American Medical Association Informed Consent Guideline. (Ex. 35.)

almost never a basis for permanently overriding the obligation of informed consent. It is ordinarily viewed as a temporary situation. There was no evidence in this case that would place either patient within this exception. Respondent presented no evidence that disclosure of this information would have impacted either Patient S.B.'s or Patient D.B.'s chances of becoming pregnant, or that either patient was in any way emotionally compromised or in such a fragile physical or mental state that they could not have been duly informed. And had respondent any concerns about either patient being in a fragile state; for example, Patient D.B. bleeding during her pregnancy, information could have been withheld until she improved. Dr. Keye conceded that this exception is almost never a basis for permanent withholding of information. He also conceded that he had no information to suggest that either patient was anything other than a competent adult, capable of making her own medical decisions.

The issues presented by the error were no doubt complex. But Dr. Keye appears not to appreciate that the complex choices and decisions faced the patients, not respondent. Dr. Schriock's testimony on this point is particularly persuasive – the situation facing respondent was not difficult at all, the decision to tell the truth is not complex and the obligation to inform is universal. Dr. Schriock also confirms that the standard of practice, consistent with published ethical standards, encourages any physician who is unclear regarding his/her obligations to consult with colleagues. That Dr. Keye would suggest otherwise is rather surprising.

24. Dr. Gore also testified as a medical expert on behalf of respondent. He is a Certified Diplomate, American Board of Obstetrics and Gynecology and he is in private practice with Obstetrics and Gynecology Associates of San Francisco. He serves as Associate Clinical Professor at UCSF School of Medicine, Department of Obstetrics and Gynecology. In this case he believes respondent was guided by what respondent believed to be in the best interests of both patients. Dr. Gore suggests that ultimately it was in the best interests of both women not to have been told of the mistake. Dr. Gore reasons that "do no harm" is the hallmark of medicine and that respondent's actions in this case were not detrimental to the patients' welfare, but rather it was his disclosures that created conflict and controversy. Dr. Gore even contends that respondent's passing on information to the patients constituted his only bad judgment.

Dr. Gore has not considered the AMA principles of medical ethics or the ACOG guidelines. The "do no harm" standard is apparently all he relies upon. He does not believe that informed consent requires that physicians disclose medical errors, noting that physicians are typically advised in our legal system, "Don't say anything." He believes that as long as physicians make decisions that they believe are in their patients' best interests, no conflict of interest arises and no duty necessarily arises to disclose medical errors. Dr. Gore believes it is the physician, not the patient, who determines what is in the patient's best interest. He even cites the "don't ask, don't tell" philosophy as support for qualifying a physician's duty of disclosure if a physician thinks it would be for the best. Dr. Gore clings to an historic and almost singular focus on the benefit of the patient as the governing ethical principle of medical care. And in his view it is the physician, not the patient, who determines what is in

the patient's best interest, even if it means covering up medical errors. Dr. Gore's opinions so deviate from well established principles of medical ethics that he is unqualified to offer any opinion on informed consent, conflicts of interest or other medical/ethical issues presented in this case.

Discussion

25. Respondent concedes that the patient's right to know ultimately should have "trumped his anxiety over the harm disclosure would unleash." However, he asks that such countervailing forces be recognized, along with the medical opinions of experts such as Dr. Keye and Dr. Gore, so that his failure to disclose might be judged within that context. Complainant contends that such thinking demonstrates that respondent does not appreciate the enormity of his misconduct and that he continues to "straddle the fence" regarding his responsibility and to rationalize his bad behavior. This does appear to be the case here. Respondent engaged in very serious misconduct. The evidence strongly points to an elaborate cover-up of wrongdoing and a physician acting to protect his own interests above those of his patients. It does not appear to be a case of a physician honestly struggling with and pondering what course of action would be in the best interests of his patients. The following matters were considered in making this determination.

Respondent was initially stunned by news of the mistaken embryo transfer. He was given very poor advice by Dr. El Danasouri that he commenced to follow. He attempted to terminate Patient S.B.'s pregnancy, and then later concocted the story about changing his mind and giving her Prometrium® instead to enhance the prospects of her becoming pregnant. He lied to staff about the laboratory being infected. Yet, even at that early stage respondent had an opportunity to correct course. That same day Ms. Keiser, the only licensed professional on staff, urged him to "come clean" with both patients and staff and to fully disclose all that had occurred. Hers was a strong, principled and ethically sound voice. He had a full evening to consider and act upon her counsel. Instead, he stood quietly before staff the following morning while Dr. El Danasouri explained why it was important that a baby not be allowed to be born to the wrong patient and how disclosing the mistake would unleash an unreal sequence of malpractice lawsuits that would hurt their medical/professional reputations. The protection of respondent's medical/professional reputation, and not the patients' best interests, became a recurring theme. Office staff, including Linda Keiser and Jeanne Ricci, were specifically asked not to discuss the incident with anyone. When Ms. Keiser advised respondent that she was leaving, he told her that he hoped that she would not talk about the incident with anyone else. And 18 months later, when respondent finally met with Patients S.B. and D.B., he told them that they should not talk about the incident because the careers of both respondent and Dr. El Danasouri would be ruined. When Patient S.B. told him that she was not intending to have further contact with the Medical Board he expressed agreement with this.

Respondent's failure to maintain a complete and accurate record of medical treatments on June 15, 2000, was also in furtherance and protective of his own interests. He took action to cover-up all records of what happened that day. He allowed an altered

(falsified) embryo report to be generated for Patient D.B. and placed into her medical chart. The medical records of Patients S.B. and D.B. contain no mention of the medical error. Respondent's claim that he did not know that he could correct mistakes in the medical record and/or that he was too upset to make any changes is not believable. Late chart entry procedures are common knowledge and respondent's own medical records demonstrate that he was aware of how to correct a charting error. The June 15 progress note, procedure report, freeze and thaw form either indicate no medical error or make affirmative representations that are false. Insurance billing records were also false. Respondent billed Patient S.B. and her insurance company for frozen embryo transfers knowing that he had not transferred frozen embryos. Respondent did nothing to correct these false records and such inaction demonstrates that he wished to conceal the medical error.

Respondent made other false statements in furtherance of the cover-up. His actions and statements regarding giving birth control pills to Patient S.B. have already been discussed. (See Findings 8 – 11.) He attempts to portray both patients in a way that was inconsistent with their own testimony and with his own records, in an attempt to make them appear more psychologically or physically fragile than they were, and to thus provide some justification for not telling them. For example, he has suggested that Patient D.B.'s bleeding during her pregnancy was a factor in not disclosing the error to her earlier. Yet he has not explained how his purported plan to make full disclosure some time years after the birth of the children could be construed as a medical decision and his suggestion that he planned to disclose the error at some point in time, either on the first or second birthdays of the children, simply does not ring true. He disclosed the mistake to the patients only after he learned that the Board was investigating the incident. Even then he encouraged them not to talk about the incident lest it ruin him professionally. He made additional statements to Patient D.B. and R.B. about Patient S.B. having eggs that were "no good." Patient D.B. and R.B. provided consistent and persuasive testimony on this point and respondent's statement to the contrary is not credible.

26. Respondent, by his actions and words above detailed, engaged in a prolonged course of dishonest and corrupt behavior. It was not a mere lapse in medical judgment. It was a deliberate decision to deceive and lie to his patients. Given this backdrop, his claims that he acted as he did because there were insufficient standards in place to guide him, or that he was too upset to think clearly, are viewed as disingenuous and after the fact rationalizations intended to portray his actions in a more positive light. The error was surely a shock to respondent and his initial state of mind may well have been as he described – specifically, that he was "a mental mess," on "autopilot," and had "so many thoughts on my mind." Yet he still managed to perform two additional complex embryo transfers that same afternoon and to conduct a staff meeting. More important, he had a full evening to contemplate Ms. Keiser's advice to "come clean." And long after his self-described state of sleepwalking panic had subsided he had multiple opportunities to disclose. He had repeated contact with both patients over the ensuing weeks and months but never said a word to them. Respondent had time and opportunity to correct course. Any continued reliance he had upon Dr. El Danasouri's advice was certainly misplaced. Dr. El Danasouri is neither a physician nor a licensed professional. Dr. El Danasouri committed the error and it should have been

apparent that any advice proffered by him was intended to further his own interests and not those of the patients. Dr. El Danasouri expressed the rationale for his advice so his motives were transparent – his foremost concerns being malpractice lawsuits and damage to their professional/medical reputations. If respondent was honestly struggling with what standards of care governed this situation, or what actions were in furtherance of the patients' best interests, consulting with physician colleagues was an option available to him.

For all these reasons it was established that respondent engaged in multiple acts of unprofessional and unethical conduct. Honesty is an essential and integral part of every physician's obligation, perhaps even more so in the area of infertility medicine where patients are particularly vulnerable and desperate. Respondent betrayed the trust and confidence placed in him by Patients S.B. and D.B. and his decision to deceive them constituted gross negligence, dishonesty and corruption.

27. Respondent asserts that despite the mistake he made in not disclosing to the patients or documenting the error, the totality of evidence demonstrates that he is a safe, effective and valuable physician providing an essential and deeply appreciated service to infertile patients in Northern California. He avers that he has learned bitter and hard lessons from this experience and carried on as best he could, made amends to the patients as best he could, and redoubled his efforts to offer safe and effective care as best he could. Respondent seeks a disposition of this matter that will permit him to continue to practice medicine while memorializing the mistake he made by way of public letter of reprimand.

Respondent was self-referred to the Physician Assessment and Clinical Education (PACE) program for a comprehensive physician assessment between November 30 and December 1, 2004. A review of respondent's performance during both the assessment and oral clinical portions of the PACE program indicated no deficiencies in his ability to perform obstetrics and gynecology safely. Joseph Scherger, M.D. is the PACE Associate Director. He notes that respondent acknowledged that he had made a mistake, that he expressed regret and that he demonstrated a high level of awareness of the consequences of what he had done. He believes respondent is a very caring person who speaks from the heart and who is trying to resolve issues so that he can go on with his practice. Dr. Scherger suggests that respondent was largely motivated to act in his patients' best interests. Dr. Scherger concedes that he did not consider the patients' point of view, that he did not have either the patients' medical records or deposition transcripts and that he was unaware of allegations relating to Patient S.B. being given the birth control pills.

Respondent enjoys an excellent reputation among patients he has helped over the years. There was testimony that he acted towards them with the highest ethical standards, that he was conscientious, attentive, caring and worked with them to get the best possible results. This included referring them to other clinicians when their chances of success might best be met through techniques not offered by him. Referring physicians testified that they send patients to respondent despite their knowledge of the mistake because they continue to hold respondent in very high regard. Respondent has a reputation for being highly

knowledgeable and accessible and for his willingness to share his knowledge with others. He is described as one who provides superb, caring and thoughtful assistance to his patients.

Respondent believes that his handling of a laboratory error in summer of 2003 is more indicative of how he now manages mistakes. At that time Dr. El Danasouri thawed a patient's embryos four days too early. When respondent learned of this mistake he immediately advised the patient of the error, apologized and explained all options to her. This particular patient appeared as a witness and testified that respondent was honest, straightforward and disclosed all the information needed for her to make choices after this mistake occurred.

Respondent also notes that he has strengthened the integrity of the embryo transfer process in his IVF practice, severing ties with Dr. El Danasouri and teaming with Charles Cornwell, whose training and experience are particularly strong with regard to patient identity and proper management of laboratory tissues and specimens. (See Finding 19.)

28. The above notwithstanding, respondent's conduct and his continued failure to acknowledge the full extent of his wrongdoing warrants license revocation. The enormity of respondent's misconduct cannot be overstated. Patients S.B. and D.B. had every right to know what had happened, if not immediately, sometime soon after the mistaken transfer had occurred. Concerns about respondent have less to do with the fact that a mistaken embryo transfer occurred, or even with his medical knowledge or technical skills as an IVF physician. They have everything to do with his professional ethics. Infertility medicine is a specialty where patients are particularly vulnerable, even desperate, and so honesty and trust are essential in all patient dealings. It is also an area of medicine inherently fraught with ethical issues. Respondent's actions undermined public confidence and the integrity of the medical profession, particularly the area of infertility medicine.

This case cannot be viewed as a physician honestly struggling with and pondering what course of action would be in the best interests of his patients. And so respondent's failure to acknowledge that his actions reflected anything more than mistaken judgment is particularly troubling. Respondent made more than a mistake, he made deliberate decisions that he knew to be unethical and dishonest. He persists in rationalizing his misconduct, he denies the more alarming allegations relating to giving Patient S.B. birth control pills,[16] and he has failed to fully acknowledge his ethical obligations and responsibilities to patients S.B. and D.B. His actions were largely guided by his own best interests, not the patients'. The public interest demands that patients must be able to rely upon the integrity and honesty of physicians licensed to practice in the State of California. When a physician betrays his fiduciary duty to patients to the extent found in this case, the only resolution that will protect and assure the safety of the public is license revocation.

[16] Although these serious allegations are referenced in the accusation pleading, they are not also specified as separate bases for discipline under paragraph 11, First Amended Accusation. They are considered here as matters in aggravation, considered along with other relevant factors, in determining the appropriate discipline to be imposed.

Cost Recovery.

29. The Board's costs of investigation of this case over the four year period 2001 – 2004 are $26,979.58.[17] An additional $1200 was incurred for record review/opinion by Board medical experts. The Board also requests the costs of prosecution by the Department of Justice and incurred by the Board. These total $63,102.[18] Total costs incurred by the Board in connection with the investigation and prosecution of this case are $91,281.58. Respondent urges that the majority of costs incurred after July 2002, be found unreasonable and unrecoverable. He contends that he cooperated fully with the Board at that time and that costs incurred after July 2002 were largely unnecessary. In fact, substantive issues were contested at hearing by respondent and respondent's case was not simply one of mitigation with admissions of mistake as he has suggested. The costs incurred by the Board in connection with its investigation and prosecution of this case are not unreasonable.

LEGAL CONCLUSIONS

1. Under Business and Professions Code section 2234, the Division of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. Unprofessional conduct includes gross negligence. (Bus. & Prof. Code, § 2234, subd. (b).)

2. Complainant contends that respondent was grossly negligent when he utilized an unlicensed laboratory in his infertility practice and failed to disclose this information to his patients. Respondent had reviewed Dr. El Danasouri's curriculum vitae and was satisfied that he knew how to run large, complex and successful laboratories. He believed he was well qualified and fully capable of setting up and running CRL and he reasonably relied upon Dr. El Danasouri's assurances that the laboratory was licensed. His failure to take additional steps to review license documentation was not so extreme a departure from the standard of care as to constitute gross negligence. Accordingly, no cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (b), by reason of the matters set forth in Finding 5. Respondent's utilization of an unlicensed laboratory in his infertility practice and his failure to disclose this information to his patients did not constitute gross negligence.

Complainant also contends that the erroneous embryo transfer constituted gross negligence. No cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (b), by reason of the matters set forth in Findings 6, 18 and 19. The Board's expert agreed that respondent's embryo transfer procedures were "fairly reliable" and that if all those procedures were followed and the embryologist made a mistake, respondent would be justified in relying upon all the information he received from his

[17] Of these costs, approximately 21.25 hours were spent conducting interviews; 81 hours on records review; 18.25 hours on travel; 101 hours on report, letter, memo and subpoena writing; and 21.25 hours in meetings with the Department of Justice and other agencies, phone calls, pickup and delivery of evidence, and research.

[18] Separate cost certifications were submitted for Deputy Attorneys General Lawrence A. Mercer and Jane Zack Simon, totaling $39,611 and $23,491, respectively.

embryologist. For this reason it was not established that the mistaken transfer constituted gross negligence on respondent's part.

3. Respondent's failure to promptly take appropriate action to advise the patients of the error and to obtain their informed consent to his continued medical care constituted gross negligence. Cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (b), by reason of the matters set forth in Findings 12 through 14, and 20 through 24.

Respondent's active concealment of the error from the patients also constituted gross negligence. Cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (b), by reason of the matters set forth in Findings 12 through 14, and 25 through 26. However, it was not established that respondent actively concealed the error from the Board's investigator by reason of the matters set forth in Finding 17.

4. Under Business and Professions Code section 2234, subdivision (e), unprofessional conduct includes "The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon."

Business and Professions Code sections 2261 and 2262 address false representations and alteration of medical records. Business and Professions Code section 2261 provides: "Knowingly making or signing any certificate or other document directly or indirectly related to the practice of medicine or podiatry which falsely represents the existence or nonexistence of a state of facts, constitutes unprofessional conduct." And Business and Professions Code section 2262 specifies: "Altering or modifying the medical record of any person, with fraudulent intent, or creating any false medical record, with fraudulent intent, constitutes unprofessional conduct."

5. Cause for disciplinary action exists under Business and Professions Code section 2234, subdivision (e), by reason of the matters set forth in Findings 12 through 16, 25 and 26. Respondent committed acts involving dishonesty and corruption which are substantially related to the qualifications, functions, or duties of a physician and surgeon.

6. Cause for disciplinary action exists under Business and Professions Code sections 2261 and 2262, by reason of the matters set forth in Findings 6, 13, 25 and 26. Respondent knowingly made or signed documents related to the practice of medicine which falsely represented the existence or nonexistence of a state of facts. He also altered or modified patient medical records, with fraudulent intent, or created false medical records, with fraudulent intent. Such actions constitute unprofessional conduct.

7. Under Business and Professions Code section 125.3, the Board may request the administrative law judge to direct any licentiate found to have committed a violation of the licensing act to pay the Board a sum not to exceed the reasonable costs of investigation and enforcement of the case. The Board has incurred $91,281.58 in connection with its

investigation and enforcement of this case. (Finding 29.) Certifications for Board investigative services and Department of Justice prosecution costs were considered in determining that such amount is not unreasonable.

8. The matters set forth in Findings 25 through 28 were considered in making the following Order. It would be contrary to the public interest to place respondent on probation at this time. No probationary terms can instill ethical judgment in a physician who demonstrates little insight into his misconduct, and there is no mechanism by which the Board can adequately monitor a physician who has demonstrated this degree of dishonesty. This case involves some of the most serious physician misconduct imaginable and nothing short of revocation will restore to the public confidence that this type of behavior will not be tolerated by the medical profession.

ORDER

Physician's and Surgeon's Certificate No. G-71332 issued to Steven L. Katz, M.D. is revoked pursuant to Legal Conclusions 3, 5 and 6, jointly and individually.

Respondent shall pay $91,281.58 to the Board for its costs in connection with the investigation and prosecution of this case.

DATED: March 8, 2005

JONATHAN LEW
Administrative Law Judge
Office of Administrative Hearings

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

In the Matter of the Accusation Against: **STEVEN L. KATZ, M.D.** **1700 California Street, Suite 570** **San Francisco, CA 94109** **Physician's and Surgeon's Certificate No. G-71332** **Respondent.**	**Case No. 03-2001-122617** **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. David T. Thornton (Complainant) brings this Accusation solely in his official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs.

2. On or about May 13, 1991, the Medical Board of California issued Physician's and Surgeon's Certificate Number G-71332 to STEVEN L. KATZ, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2006, unless renewed.

JURISDICTION

3. This Accusation is brought before the Division of Medical Quality (Division) for

the Medical Board of California, Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

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

5. Section 2234 of the Code states:

"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:

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

"(b) Gross negligence.

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

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

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

"(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.

"(f) Any action or conduct which would have warranted the denial of a certificate."

6. Section 2261 of the Code provides, in pertinent part, that it is unprofessional conduct for a physician to make statements which falsely represent the existence or non-existence of a state of facts directly or indirectly related to the practice of medicine.

7. Section 2262 of the Code provides, in pertinent part, that it is unprofessional conduct for a physician to alter or modify any medical record with fraudulent intent or to create any false medical record.

8. Section 125.3 of the Code provides, in pertinent part, that the Division may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

9. Section 14124.12 of the Welfare and Institutions Code states, in pertinent part:

"(a) Upon receipt of written notice from the Medical Board of California, the Osteopathic Medical Board of California, or the Board of Dental Examiners of California, that a licensee's license has been placed on probation as a result of a disciplinary action, the department may not reimburse any Medi-Cal claim for the type of surgical service or invasive procedure that gave rise to the probation, including any dental surgery or invasive procedure, that was performed by the licensee on or after the effective date of probation and until the termination of all probationary terms and conditions or until the probationary period has ended, whichever occurs first. This section shall apply except in any case in which the relevant licensing board determines that compelling circumstances warrant the continued reimbursement during the probationary period of any Medi-Cal claim, including any claim for dental services, as so described. In such a case, the department shall continue to reimburse the licensee for all procedures, except for

those invasive or surgical procedures for which the licensee was placed on probation."

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

10. Respondent is subject to disciplinary action under section 2234, subsection (b), of the Code in that respondent was grossly negligent in the practice of medicine. The circumstances are as follows:

A. On and before June 15, 2000, respondent was doing business as Fertility Associates of the Bay Area, with offices located at 1700 California Street, San Francisco California, and respondent held himself out to the public as a specialist in reproductive endocrinology and infertility.

B. On and before June 15, 2000, respondent was affiliated with California Reproductive Laboratories ("CRL"), which laboratories were also located at 1700 California Street, San Francisco, California. CRL was owned and operated by Imam El-Danasouri, who was not a licensed medical professional. At all relevant times, CRL was required to hold a current tissue bank license. Despite the law requiring licensure, CRL did not have a tissue bank license and did not apply for such a license until on or about September 5, 2000. In that September 2000 application, CRL disclosed that respondent Steven L. Katz, M.D., was a person responsible for collection, processing, storage or distribution of tissue by the tissue bank and a copy of respondent's curriculum vitae was provided to the Department of Health Services, Laboratory Field Services, with the application.

C. On June 15, 2000 and continuing thereafter, Patient S.B.[1] was under respondent's care and treatment at respondent's facility in San Francisco, California. Patient S.B. desired to have a child, using donor sperm and donor eggs, and to raise that child as hers and hers alone. At all relevant times, respondent was aware of the purpose of S.B.'s consultation and of her desires regarding the planned pregnancy and child.

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1. Patient's identities are withheld to protect their privacy.

D. On June 15, 2000, Patient S.B. was under respondent's care and supervision for transfer of frozen embryos. Said embryos were in the custody of CRL and Imam El-Danasouri. At said time, respondent's employees advised El-Danasouri that Patient S.B. was ready to receive the transfer of embryos. El-Dansouri brought three embryos to the treatment room where respondent Steven L. Katz, M.D., was waiting with the patient to effect the transfer. Three embryos were transferred to Patient S.B. by respondent with the assistance of El-Danasouri.

E. Within a very short time after the transfer, El-Danasouri learned that he had mistakenly transferred three fresh (i.e., not frozen) embryos to Patient S.B. These fresh embryos were known to El-Danasouri and to respondent to be in fact the property of another patient, D.B., who was a married woman, and her spouse, R.B. The fresh embryos were known by El-Dansouri and respondent to be the result of R.B.'s sperm and donor eggs, so that R.B. would be the natural father of any fetus resulting from the transfer and implantation of the embryos.

F. Upon discovery of his error, and while Patient S.B. was still on the premises of respondent's medical offices, El-Danasouri advised respondent of his error and that S.B. had mistakenly received the embryos belonging to D.B. and R.B.

G. After being advised of the error as mentioned above, respondent did not tell Patient S.B. that she had received a transfer of another patient's embryos. Instead, respondent gave S.B. birth control pills in an attempt to prevent her pregnancy. Respondent did not tell S.B. the true nature of the pills; Instead, respondent allowed S.B. to go home believing that she had received a transfer of her own embryos which might result in a successful pregnancy as she had planned. Respondent's medical records for S.B. do not disclose the true facts regarding the transfer procedure or respondent's attempt to prevent S.B.'s pregnancy. S.B.'s frozen embryos were later discarded.

H. On June 15, 2000, Patient D.B. was under respondent's care and supervision for transfer of those certain fresh embryos described above. At that time, respondent was aware that Patient S.B. and her husband desired to have a child using the fresh embryos and

to raise that child as theirs and theirs alone. By reason of the fact that the three fresh embryos had already been transferred to Patient S.B., respondent transferred three others, which were obtained from Patient D.B.'s stored embryos, to her. Respondent did not advise D.B. or her husband that three of her and her husband's embryos had been mistakenly transferred to another patient, nor did he advise D.B. and her husband that the other patient was still carrying the transferred embryos, nor did he advise D.B. and her husband that, as a consequence of the erroneous transfer, D.B. received three embryos of lesser quality in her own transfer. Patient D.B. and her husband left respondent's offices believing that only D.B. had received a transfer of the fresh embryos as intended. Respondent's medical records for D.B. do not disclose the erroneous transfer of her embryos. D.B.'s Embryo Transfer Form does not disclose what became of the three erroneously transferred embryos. Respondent and El-Danasouri produced altered records which purported to show that D.B. was intended to receive the three embryos of lesser quality.

I. After the erroneous transfer of fresh embryos to S.B., the staff of Fertility Associates noticed that a new embryo transfer records was created when it appeared in the office printer. The staff questioned respondent regarding what they suspected was a mistaken transfer of D.B.'s embryos to S.B. In response to their direct inquiry, respondent denied that an error had occurred. Respondent falsely advised his staff that there had been an "infection" in the lab, which might have affected S.B.'s embryos, and that this was the cause of the apparent turmoil in the office.

J. After the mistaken transfer of June 15, 2000, respondent had the opportunity to advise the patients of the error and to allow them to make a decision how each wanted to proceed given the circumstances. Respondent did not advise the patients and they were thereby deprived of their right to make informed decisions regarding their medical situations.

K. After the mistaken transfer of June 15, 2000, respondent billed S.B. and her insurance company as if he had performed the transfer of S.B.'s frozen embryos, albeit respondent knew that he had not performed the transfer that S.B. had contracted for.

L. After the mistaken transfer of June 15, 2000, respondent received the pregnancy test results and also performed two ultrasound procedures on Patient S.B. Consequently, respondent knew that S.B. was pregnant, that the pregnancy was the result of the erroneous transfer and that R.B. was the natural father of the fetus. Respondent did not reveal this information to Patient S.B.

M. After the mistaken transfer of June 15, 2000, respondent also received the pregnancy test results for D.B. and he knew that Patient D.B. became pregnant. Respondent did not advise D.B. and her husband of the mistaken transfer or that another patient was carrying a child as a result of that transfer.

N. Patient S.B. delivered a baby boy on February 16, 2001 and Patient D.B. delivered a baby girl on February 26, 2001. By reason of respondent's concealment, neither woman was aware of the erroneous transfer of D.B.'s embryos or that S.B.'s child was the natural child of D.B.'s husband, R.B.

O. On or about June 21, 2001, the Medical Board received information pertaining to the above-described events. An investigator for the Medical Board interviewed Dr. Katz about the events and, in that interview, respondent advised the Board that S.B. had not become pregnant.

P. The Medical Board investigation continued and, in December 2001, when it was apparent that Board had contacted S.B. and that the patients might independently learn of the erroneous transfer, respondent advised S.B., D.B. and R.B. of the mistake that had been made in his medical office 18 months earlier.

Q. As a consequence of respondent's misconduct in concealing the erroneous transfer, S.B. and R.B. have been required to turn to the courts to resolve their mutual claims on the child born to S.B.

11. Respondent's conduct, as set forth above, constitutes unprofessional conduct and respondent's license is subject to disciplinary action by reason of his gross negligence in the care and supervision of Patient S.B. and Patient D.B., including but not limited to the following:

A. Respondent utilized an unlicensed laboratory in his infertility practice and

respondent did not disclose this information to his patients;

B. Respondent erroneously transferred Patient D.B.'s embryos to Patient S.B.;

C. Respondent learned that he had mistakenly given S.B. another patient's embryos but failed to promptly take appropriate action to advise the patients and obtain their informed consent to his continued medical care under the circumstances;

D. Respondent actively concealed the error made in his medical offices from the patients and the Medical Board for his own protection and at the expense of his patients.

SECOND CAUSE FOR DISCIPLINE

(Dishonest Acts/False Statements/False Records)

12. Respondent is subject to disciplinary action under section 2234, subsection (e), and/or Section 2261 and/or 2262 of the Code, in that respondent engaged in a course of concealment and deception as regards his care and supervision of Patient S.B. and Patient D.B. The circumstances are as follows:

A. On June 15, 2000, respondent learned that an error had occurred at his medical offices and that Patient S.B. had received embryos belonging to and intended for another patient, D.B. Although he was urged by others to advise the patients what had transpired, respondent did not advise the patients that an error had occurred. Instead Dr. Katz engaged in an approximately 18 month course of misconduct to conceal the error from his patients. Respondent's medical records for the patients set forth facts which respondent knew were untrue regarding the disposition of Patient S.B.'s frozen embryos, the number and transfer of Patient D.B.'s fresh embryos and other matters relating to his patients' care. When respondent was directly questioned by staff regarding the mistaken transfer, he lied and stated that no error had occurred and that there had been an infection in the lab. Respondent billed S.B. and her insurer as if he had performed the transfer of her frozen embryos. Respondent did not disclose the error to his patients until he learned that the Medical Board investigation was proceeding, that Patient S.B. had been contacted by the Board and that his patients might

independently discover what had transpired. Even after his compelled disclosure, respondent continued to rationalize and minimize his misconduct and to state that it was always his intent to make full disclosure to his patients at a later date. Even after making disclosure to his patients, when questioned by the Medical Board's investigator, respondent again lied and stated that Patient S.B. had not become pregnant.

B. Respondent's course of conduct in concealing and lying about the error that had been made deprived his patients of their right to be informed of every aspect of their medical care, to make their own decisions how to proceed and to participate in a plan for corrective action.

13. Respondent's conduct, as set forth above, constitutes unprofessional conduct and respondent's license is subject to disciplinary action in that respondent engaged in dishonest and corrupt acts, including but not limited to the following:

A. Respondent failed to promptly advise Patient S.B. of the erroneous transfer and deprived her of the opportunity to make an informed decision how to proceed under the circumstances;

B. Respondent participated in deceiving Patient D.B. and her husband, R.B., about the mistaken disposition of their embryos by concealing the information from them and by maintaining false and inaccurate records regarding D.B. and R.B.'s embryos;

C. Respondent maintained false and inaccurate records regarding Patient S.B. and Patient D.B. to conceal his erroneous transfer of D.B.'s embryos;

D. Respondent continued to conceal his error from S.B., D.B. and R.B. long after any corrective action could be taken and to their detriment;

E. Respondent lied when questioned about the matter of S.B. and D.B.;

F. Respondent continued to rationalize and minimize his misconduct after it was discovered.

PRAYER

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

1. Revoking or suspending Physician's and Surgeon's Certificate Number G-71332, issued to STEVEN L. KATZ, M.D.;

2. Revoking, suspending or denying approval of STEVEN L. KATZ, M.D.'s authority to supervise physician's assistants;

3. Ordering STEVEN L. KATZ, M.D. to pay the Division of Medical Quality the reasonable costs of the investigation and enforcement of this case, and, if placed on probation, the costs of probation monitoring;

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

DATED: September 21, 2004

DAVID T. THORNTON
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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