



Minutes:

October 31, 2007

**Medical Board of California and Board of Registered Nursing
Forum on Public Safety and the Use of Lasers for Cosmetic Procedures
(Business & Professions Code Section 2023.5)**

**Hilton San Diego Mission Valley
901 Camino del Rio South
San Diego, CA 92108**

Members Present:

Mary Moran, M.D., Medical Board
Janet Salomonson, M.D., Medical Board
LaFrancine Tate, R.N., Nursing Board
Carmen Morales, Nursing Board

Staff Present:

Heidi Goodman, Assistant Executive Officer, BRN
Louise Bailey, Supervising Nursing Education Consultant, BRN
Janette Wackerly, Nursing Education Consultant, BRN
Elliot Hochberg, Enforcement Manager, BRN
Barb Johnston, Executive Director, MBC
Kimberly Kirchmeyer, Deputy Director, MBC
Renee Threadgill, Chief of Enforcement, MBC
Janie Cordray, Research Director, MBC
Kurt Heppler, Legal Counsel, DCA
Harry Gibons, Legal Counsel, DCA
Jose Guerro, Deputy Attorney General

Members of the Audience:

Tina Keshishian, Belle Visage Medical Corp.
Jamie Sherrill, R.N.
Melanie Balestra, California Association of Nurse Practitioners
Richard Baxter, M.D., Calidora Skin Clinics
Don Fagen, Syneron Medical
Colette Courtim
Gaye Breyman, California Association of Physician Assistants
Jennifer Faggionato, California Association of Physician Assistants
Dawn Carl, Calidora Skin Clinic

Shannon Gunderson, All About Me
Norman Davis, Attorney
Terri Thomas, Thomas Advocacy Inc.
Connie Cruz, R.N.
Allan Cruz, R.N.
Connie Hoy, Cutera, Inc.
Robert Kearney, M.D., All About Me
Harrison Robbins, M.D., California Academy of Cosmetic Surgery
Carl A. Powell, California Academy of Cosmetic Surgery
Trisha Hunter, American Nurses Association, California
Mitchell Goldman, American Academy of Cosmetic Surgery
Susan Kaweski, M.D., California Society of Plastic Surgeons
Mariana Arnold, R.N., Lumenis
Lisle Poulsen, American Society for Dermatologic Surgery
April Gaoat
Vic Narurkar, M.D., ASCDAS
Thomas Simelson, M.D.
Jamie Warner, R.N.
Sasha Parker, R.N., Association of Medical Esthetic Nurses
Michel Lum, D.O., Lumier Medical Inc.
Jerry Potaskin, M.D., California society of Dermatology
Kimberly Butterwick, M.D., California Society of Dermatologic Surgery
John Valencia, Wilke, Fleury, Hoffelt, Gould & Birney

1. Welcome – Introductions:

Nursing Board President, LaFrancine Tate, welcomed the audience to the third jointly held Forum of the Medical and Nursing Boards to gather information about the current practice environment utilizing lasers and intense light pulse devices for cosmetic procedures.

She introduced herself, and introduced her co-chair, Dr. Janet Salomonson of the Medical Board. In addition, she introduced, Dr. Mary Moran, member of the Medical Board, and legal counsels from DCA, Kurt Heppler and Harry Gibbons, Louise Bailey, supervising Nursing Education Consultant for the Nursing Board, Janette Wackerly, Nursing Education Consultant, Heidi Goodman, Assistant Executive Office of the Nursing Board, Elliot Hochberg, Enforcement Manager for the Nursing Board, Barb Johnston, Executive Director of the Medical Board, Kimberly Kirchmeyer, Deputy Director of the Medical Board, and Renee Threadgill, Chief of Enforcement of the Medical Board. She explained that Janie Cordray, Research Director for the Medical Board, was coordinating the meetings, and asked that those scheduled to speak at the meeting check-in with her. In addition, she asked that Ms. Cordray be given copies of all written material distributed, so they may be included into the official record.

2. Overview of Business & Professions Code Section 2023.5 and purpose of Forum:

Dr. Janet Salomonson thanked everyone for attending, and reviewed the purpose of the meeting. She explained B&P Code Section 2023.5 charged the Boards to study the safety of lasers and intense pulse light devices for cosmetic procedures. The law directs the Boards to examine the appropriate level of physician supervision, the level of training, guidelines for standardized procedures, among other things. If, after studying the issues, the Boards deem it necessary to promulgate regulations, they must be promulgated by January 1, 2009.

Dr. Salomonson reminded the audience the forums were not official board meetings and panel members had no authority to take action. Any actions taken would have to be done by the separate boards at a publicly noticed meeting. For that reason, there would probably be no more jointly-held forums scheduled.

Dr. Salomonson stated there were a number of speakers scheduled and the meeting was scheduled for only 3 hours. She asked speakers to be brief and not duplicate previous testimony. She said if there was any new information to be presented after the meeting to send it to Janie Cordray, who would distribute materials to the members of the boards. She said she hoped presenters would keep their presentations to 10 minutes. Those not on the agenda to speak would be given a time to speak in "public comment" at the end of the meeting.

3. Report on the August 30 and September 13 Forum discussions:

Ms. Tate announced the August 30 meeting minutes were posted on the Medical Board's website, and the September 13 minutes had been posted on the Nursing Board's website.

She stated the forums have heard testimony from a number of organizations representing nurses, physicians, patients and the laser industry. While no actions can be taken at the forum, the testimony presented has been helpful. The recurring theme of the testimony has been that the laws and regulations may be sufficient to protect the public if they are enforced. The Medical and Nursing Boards are working to analyze the laws and regulations as they relate to their licensees, and staff will also be looking at enforcement procedures. Both Boards will be scheduling the matter for presentation at their future committee or board meetings.

4. Testimony of Interested Parties:

Dr. Salomonson introduced Dr. Susan Kaweski:

Dr. Kaweski said she was a board-certified plastic surgeon practicing in the community for over 24 years. She's a member of the California Society of Plastic Surgeons and the American Society of Plastic Surgery. She said the issue of laser safety is very important, and she has personally cared for patients that have been burned at laser clinics that have had insufficient supervision. It is her opinion that persons using lasers must be adequately trained and licensed, and they must be adequately supervised by physicians. She further believes the training should be demonstrated by certificates or graduation from certified CME providers. While she believes practitioners should have certification, she does not believe that the Boards should issue a separate form of license.

Supervising physicians must ensure the training of the non-physicians practitioners is adequate. Physicians should be genuine supervisors, not "name-only" supervisors of clinics, should have a working knowledge of all practitioners in their clinics, and must be available when complications arise. Advertising also needs to be transparent, disclosing who is actually performing the procedures. Patients are better protected if they are fully informed of their practitioners' credentials and degrees.

In closing, she said patient safety should be the utmost priority in determining how lasers are used in California. To guarantee safety, adequate credentials and education, physician supervision, and truth in advertising are all necessary and should be mandated.

Dr. Salomonson introduced Norm Davis:

Mr. Davis, an attorney specializing in healthcare law, thanked the members for the opportunity to speak. He said he has been practicing healthcare law for fourteen years, after working as a hospital administrator and consultant for many years. In the past 6 years, his work has been focused on the aesthetic medical field.

He explained everyone has witnessed the emerging growth of the aesthetic medical industry, the enormous revenue generated, and the emergence of medi-spas, mall spas, and dental spas, among others. The primary factor driving this growth is consumer demand for improved appearance and youthfulness at all costs. That, coupled with medical technological advances, including all types of class-two FDA devices, has been combined to address the consumer demand. Advances in injections, such as fillers and Botox, have also contributed to the growth.

The desire for additional income not based on insurance reimbursement has greatly promoted an interest of physicians, and an interest in delegated procedures. Delegated procedures allow physicians to bill patients for activities for which they are not personally involved. This has produced a growth of nurses and others to go into this field to practice outside of an MD office environment. All of these factors, coupled with the willingness of law investors to provide capital, produced the present industry.

According to Mr. Davis, one of the problems created has been a lack of definition in practice regulations. The problems are manifest in patient safety, corporate practice and allowing lay-entities to control the practice of medicine. While all agree the practice of medicine should be driven by physicians, the lack of definition complicates the issues of concern. "Aiding and abetting the unlicensed practice of medicine" is often used relating to corporate practice, and yet unlicensed persons are rarely performing the procedures.

Another problem area is the issue of liability. In addition, there are turf-issues that are driven by physicians who argue for on-site supervision, which has little impact on patient safety.

Mr. Davis suggested the following solutions to the problems:

- Increase the definition of medicine, including issues of ownership, and the responsibility for the practice;
- Define the expansion of control of the MD over the sites, including the location and numbers, as well as the qualifications of the physician to oversee the procedures;
- Increase the required training for nurses and physician assistants;
- Nurse Practitioners practice should be recognized, expanded, and defined;
- Increased supervision requirements for nurses, much like the regulations of PAs;
- Promulgate defining regulations to address lay-involvement.

Mr. Davis said he hoped the forums would provide the Boards with the needed information to develop meaningful solutions to the problems.

Dr. Salomonson introduced Shasha Parker, R.N, president of the Association of Medical Esthetic Nurses, and member of the American Academy of Medical Esthetic Professionals:

Ms. Parker thanked the members for the opportunity to speak, and said her organizations recognized there are unlicensed and untrained individuals providing laser treatments. She receives e-mails and messages frequently from nurses and physicians asking her what to do. She tells them to file a complaint with their state medical or nursing board. Her organization's number one goal is patient safety, and it supports extensive training and strict compliance with up-to-date, scientifically based protocols to ensure patient safety. On site supervision, in their opinion, however, is not necessary or cost-effective to promote safety. Services performed by properly trained staff under the supervision of Medical Directors is superior to on-site supervision.

Further, Ms. Parker stated physicians supervising nurses should be fully trained and competent in the procedures for which they are supervising. Physicians cannot supervise procedures about which they know

nothing. The laser and light-based technology has evolved over the years, and the devices are designed for non-physician use. The companies provide the protocols and instructions for the use by non-physicians.

In previous presentations, there are photos of burned patients by "non-physicians." She noted that "non-physician" can mean a lay-person, an esthetician, or untrained nurse. The pictures are presented, but she would like more information about the practitioner responsible for the injury. Burns can be produced by any non-physician or physician if the procedures are not performed properly.

Ms. Parker stated she would give the Boards a paper produced by Dr. Stephen Finder, of a dermatology organization, that showed on-site supervision had little impact on injury or safety. Standardized procedure rules should be strictly enforced, and that tool, if properly enforced, should provide the needed assurances of patient safety. She provided a model for laser procedures to the Nursing Board.

In addition, she noted physicians go on vacation or go to conferences, and nurses are trained to proceed with the procedures, and she does not believe physicians close their practices while out-of-town.

She stated it is unrealistic to expect no complications from the procedures, just as it is unrealistic to expect no complications from surgery performed by physicians. There is no data to support that on-site supervision will ensure no complications or injury.

Ms. Parker stated medical esthetics is a \$5 billion industry. She stated the reason that those testifying are saying that they are seeing more burns is due to the great increase in the procedures.

Ms. Parker stated there had been testimony at previous forums that stated there is a greater risk for patient abuse in non-reimbursed procedures, and she disagreed with those statements. In her opinion there is greater patient abuse by Insurance Companies, Medicare, and Managed Care plans than there could be in the esthetic field.

Ms. Parker stated there is no evidence to support the need for on-site supervision, while there is evidence proper training does provide for greater patient safety. The surveys relating to patient injury provided by the physicians do not evaluate the type of practitioner providing the treatment, the type of device, or the setting where it was performed.

Practicing physicians and nurses are generally not trained in new procedures in their formal education. As new procedures are developed, practitioners must seek additional training through courses, proctorships, and so forth.

Ms. Parker stated advertising should be proper, and should not use terms that cannot be substantiated such as "painless," and the use of models and statements should be regulated. The medical director's name should appear in all advertising. Facilities could be required to report, as required by Florida, to notify the Board when a laser is purchased, and to have a dedicated laser safety officer. It is not her opinion, however, facilities should be regulated like surgery centers. Training, in Ms. Parker's opinion, is the key to public protection.

Ms. Parker stated at a previous forum, a physician testified about "weekend courses." Dermatologists and others go to "weekend courses" to perform procedures like liposuction. Laser training is not brain surgery, and does not kill patients as can liposuction. With proper training, safe equipment, and proper protocols, the procedures are safe.

Ms. Parker offered to assist the Nursing Board with writing model procedure guidelines and training guidelines to assure public safety. In her opinion, requiring the Board to issue certification is unnecessary

and costly. It is her opinion that 30 hours of training, including 15 hours didactic and 15 hours clinical, plus an examination, is sufficient.

Dr. Salomonson introduced Dr. Michael Lum, of Lumier Medical, Inc.

Dr. Lum thanked the Boards for holding the forums and for giving him an opportunity to speak. He stated he became board-certified in 1994, and owns an esthetic medical practice in Torrance, California. He specializes in laser and light-based treatments, and performs them on an almost daily basis. He said he also provides training to physicians and nurses. He's also a member of the Association of Medical Esthetic Nurses, and a faculty member of the American Skin Institute.

Dr. Lum stated there has been great improvement in laser technology. In the changing environment, medical or nursing training does not prepare practitioners for the updated equipment or procedures. The laser companies hire physicists to train and provide training, as well as nurses, and he rarely sees physicians being trained. Nurses are more likely to be fully trained in laser treatments.

It is Dr. Lum's opinion that the reason dermatologists are seeing more burns from the procedures is due to the increase in procedures being performed, as well as non-medical personnel performing the treatments. All procedures certainly carry risks, and there may be burns by physicians or nurses, but, in his opinion, those complications are rare in medical settings.

Dr. Lum stated the physician must be responsible for knowing the technology, providing informed consent to patients, for the nurses training and protocols, and ultimately the patient's safety. Physicians must be trained in the procedures being delegated in order to provide supervision, although physicians will rarely perform the treatment, and nurses will likely be the more experienced practitioner.

There is a problem in the businesses where nurses does not even know who the supervisors are, and neither do patients. They are unaware of who is liable or responsible for the patients. Physicians must always be available, not necessarily on site all the time, but reachable and involved. They should also be able to be physically present, should the need arise. That should be required not only for laser procedures, but for all delegated procedures. The need for the presence of a physician 100% of the time has not been demonstrated, if there is adequate physician involvement in the practice.

Dr. Lum stated it is important for physicians to be responsible for all patients, and they should have protocols for follow-up and appropriate aftercare. Physicians should be well-educated in skin, knowledgeable of the procedures, and be available when procedures are performed. Without proper involvement and knowledge of the physician, procedures should not be delegated.

Dr. Salomonson introduced Dr. Baxter, Medical Director for Calidora Skin Clinics.

Dr. Baxter said he is a board-certified plastic surgeon that has been practicing for 17 years, owner of Calidora Skin Clinics in Washington and California, and he is licensed in Washington and California. He said he is past president of the Washington Society of Plastic Surgeons, past president of the Northwest Society of Plastic Surgeons, an inspector for AAAASF, and spokesperson for the American Society of Plastic Surgeons (although he is not speaking for any of the organizations).

He stated he thought the Boards' discussions should be based in evidence-based medicine, not arbitrary decisions that could be perceived as politically or economically motivated. There are a range of business models outside of the physician office model, and any regulations considered should acknowledge the various business models. He said he had provided his testimony to the members in writing.

He addresses the issue of patient safety in his practice by using appropriately trained and licensed personnel, all of whom undergo training on average of 120 hours before treating patients, and they are given on-going training as well. All personnel work under the supervision of a physician, and they disclose the name of the doctor, including putting the name on the front door. It is his belief this practice is required by current regulation.

In his opinion, any new rules should focus on patient safety in a demonstrateable way, and requiring on-site supervision has not been demonstrated to improve patient safety. There must be, however, a clear chain of responsibility to the supervising physician. The dramatic reports of complications presented are anecdotal and are not a substitution for verifiable data.

Dr. Baxter stated the standardized procedure guidelines, if followed, provide for adequate supervision and patient safety. These guidelines provide the needed safeguard for patients receiving much more perilous medical treatment than esthetic lasers, and there is no data questioning their adequacy. To require more for laser treatments is not needed.

He said he would support requiring more training and education for healthcare professionals, as that would have greater impact on patient safety. Under current regulations, it is his belief nurses and other healthcare professionals should be able to evaluate and treat patients without a physician being present. He does not support the use of lasers by medical assistants or estheticians.

If it is the decision of the Boards that more regulations are needed, he would support the requirement that physicians prescribing or supervising laser treatments should be educated in the delegated treatments, and proper training and protocols for the non-physicians. They do not support broad-based restrictions or requiring on-site supervision. He would hope any regulation would:

- Authorize qualified non-physician practitioners to prescribe laser treatments;
- In complex cases involving treatment of a disease, or surgical procedure, physicians should be involved in the assessment;
- For less complex cases, non-physicians should be allowed to perform the evaluation;
- Limit the supervision requirement, and not require on-site supervision.

Dr. Salomonson introduced Melanie Balestra representing the California Nurse Practitioners Association (CNPA).

Ms. Balestra said she has been a member of the CNPA for 20 years, and has been an attorney for 15 years. For 5 years, she has worked on medical malpractice defense, and currently she works in administrative law and transactional law.

Ms. Balestra noted the NP was established in the 1960s. The NP was established to address the need for health care providers. The program was a masters program requiring a nursing license and experience in patient care. The CNPA has grown to 21 regions with 2500 members, the voice of the profession to ensure the protection of the healthcare consumer. NPs function in a variety of healthcare settings, including acute care, adult healthcare, pediatric care, women's health, oncology, family practice, ophthalmology, rheumatology, neonatology, dermatology, neurology and trauma. In all of these areas, NPs are able to function without direct, on-site supervision.

According to Ms. Balestra, NP practice is grounded in the nursing model that emphasizes treatment and education of the patient in the context of the patients' total well-being. This model is also applicable to

aesthetic laser practice. NPs diagnose and treat patients, order, perform, and interpret laboratory tests and furnish and prescribe medications.

Ms. Balestra stated 23 out-of 50 states allow NPs to practice independently. In those states, there has not been any data that demonstrates that there are more cases of malpractice or burns than in states requiring more direct supervision. To require a physician on-site will not make any difference. The difference in care is due to the qualifications of the person performing the treatment.

Ms. Balestra noted a master degree is the minimum education of all NPs. In a recent *JAMA* article, it noted there was no difference in the quality of care of patients seen by NPs or physicians. An article in *Medical Research in Review* published in 2003, reported a follow-up study showed no difference in quality. A *Wall Street Journal* report in 2004 noted there was a growing shortage of medical providers, and there would be a need to increase the use of NPs.

NPs are acutely aware of their limitations, and are therefore much more likely to refer patients to specialists than primary care physicians, and often diagnose conditions previously gone unnoticed by the physician.

At previous forums, there was testimony noting there was not enough enforcement of current laws. In her experience, the RN Board's investigations were more professional and more thorough than the Medical Board's. In her opinion, the BRN is doing an excellent job. In her experience, the Medical Board's investigations are not thorough.

Ms. Balestra stated physicians have accepted the NPs role in treating patients. Physicians and NPs in aesthetics must be properly trained, and must collaborate on effective protocols. She does not believe there is a need for new laws or regulations. More education is of greater importance to public protection.

Dr. Salomonson introduced Dr. Mitch Goldman, representing the American Academy of Cosmetic Surgery.

Dr. Goldman thanked the members for giving him an opportunity to speak, and introduced Dr. Harrison Robbins. He thought the legislation requiring the Nursing and Medical Boards to work together is a good idea, as it will improve the safety of California patients.

Dr. Goldman said he went to medical school at Stanford, and has been practicing for 21 years. He's a board-certified dermatologist and is also a cosmetic surgeon. He's a clinical professor of dermatology at UCSD and medical director for the La Jolla Spa MD. He said he is partially responsible for the problems, as he helped develop the intense pulse light device, which 12 years ago became the Epi-Light. That was the beginning of the industry, and they opened one of the first Medi-Spas in San Diego. It became so profitable, and is so easy to perform, that virtually anyone can operate the devices safely. The problems voiced in the testimony, is not so much about how to perform the procedures, but how to handle complications.

He said while the treatments don't generally critically injure patients, a scar on the face can be devastating. Physicians need the knowledge of how to treat all kinds of skin types, and the lack of this knowledge is responsible for many of the complications. The problems that he and his colleagues have seen have to do with complications. While many of these complications will eventually go away, it is unacceptable for patients to be scarred for 6 to 9 months.

Dr. Goldman stated the current business practice is unacceptable. There is a current Med-spa that has a supervising physician who has been stationed in Iraq for the past 6 months. In his opinion, this is in violation of the law, and it should be enforced. While the physician in Iraq is a well-qualified plastic surgeon, Dr. Goldman does not believe the doctor can fly back to the states to handle complications. The

nurses at the spa have never met the supervising physician, and the physician has no way of knowing what is going on at the Spa. He strongly supports the recommendations of the American Academy of Cosmetic Surgery, American Society of Laser Medicine & Surgery, the American Academy of Dermatology, the American Society of Dermatologic Surgery, and the American Board of Surgeons, that all agree physicians either be on-staff or able to go to the facility. It's not appropriate for physicians to be overseas or out-of-reach. These types of supervision relationships are not in the best interest of patients. While the Forums are designed to only address lasers, the problems also relate to other procedures and treatments, such as fillers.

Dr. Goldman stated he has written a chapter for a medical textbook that will soon be published, entitled "Advances in Medical Spa Technology," which he will forward to the Boards.

He thanked the Boards for their efforts, and asked Dr. Harrison Robbins to speak.

Dr. Robbins said he represented the American Academy of Cosmetic Surgeons. To be certified, physicians must first be certified by an ABMS board, and then be certified in elective cosmetic procedures. The only physicians qualified to sit for the certification examination are those who have already been certified by an appropriate ABMS board. This process recognizes the need for additional training and certification.

Dr. Robbins directed the members' attention to the written statement of the Academy, which had been provided to the members and was also available to the public on the registration table. The reason for the statement is to protect patients, making sure that patients are fully informed of the nature of the treatment, and that physicians be held responsible and liable for their patients' treatment.

Dr. Robbins shared an anecdote that was applicable to the Boards' discussions. One of Dr. Robbin's surgical professors, who was head of the Burn Department at the University of Michigan, said, "I can teach Chimpanzees to do surgery, but I can't tech them who to do it on and when to do it, or who not to do it on or when not to do it." The professor's statement is relevant to the discussions on laser safety.

Dr. Robins stated future regulation of these procedures should not be determined by who has the best lobbyist, but the best answers for public safety. Physicians should be held responsible for the patients' care and be held liable. The treatments are medical, and should be treated as medical.

Dr. Robbins stated he also is of the opinion that there is a need for greater regulation of advertising. The advertising in many publications is often a study in misleading claims.

Dr. Goldman stated that currently a "laser liposuction" is being developed, and can be done in office settings under local anesthesia. For that reason, the Boards need to address issues of concern about the lesser laser treatments, as they will have application to this future procedure, which is more likely to be injurious.

Dr. Salomonson introduced April, a patient that had been injured by laser procedures

April stated she had laser treatment to address acne in August. A consultant stated the spa had a new blue light treatment that would help her problem. She asked what medical qualifications the consultant had, and he said he was not a medical person, but there would be a doctor on site to see her. She proceeded with the treatment, which would be 8 treatments over 2 to 3 months.

The first treatment, April was greeted by the manager, who told her they had a new treatment that would be better than blue light, and they proceeded to treat her. Later, after complications manifested, she was told by a doctor the treatment she received was an IPL procedure, and it was not appropriate for her acne

condition. She had found the Spa in San Jose through the Internet. She thought it was a doctor's office, but it was in a Mall. She was skeptical, so she asked to see the nurses' licenses, which they showed her, and that gave her more confidence. The first treatment was performed by a nurse that did not seem very confident. She asked the nurse if she had done the treatment before, and she responded that April was her second patient. The nurse was very nice, and April did not want to offend her, so she let her perform the treatment.

The next treatment was to be performed in 2 weeks, but the spa rescheduled it to 4 weeks. She was told it had to be rescheduled because the FDA had advised them the treatments should be at 4-week intervals. For the second appointment, they referred her to a different spa, as they said they did not have a necessary piece of equipment. At the Valley Fair Mall Spa, close to San Jose, a very confident nurse greeted her. Because of the nurse's confidence, April did not ask to see her nursing license. The second treatment was more intense, it was different, longer, and more painful. She noticed the nurse wiping her face, and she could see blood. At that point, she asked the nurse if everything was going OK. The nurse responded it was normal, as it was more intense and a little bleeding is expected. The nurse gave her anti-biotic cream, and directed April to apply it to the treatment site.

April's face was very purple and painful. On the third day, she went back to the spa, and the nurse told her the burning was normal and to continue applying the cream for another three days. After another three days, she could not stand the pain, and called them from her home in Stockton. She was told the treating nurse was unavailable, so she was referred to another nurse. That nurse stated April could either drive back to their spa, or seek treatment from a local dermatologist.

Before her treatment, she was told by the spa she could see the doctor if there were complications. She was never offered that when she had problems. She went to a local dermatologist, Dr. Bock, who took pictures and treated her.

She went to the spa for better skin. Her experience has been painful, and left her with scars. She sought treatment at the Spa because she thought the treatments would be cheaper than going to a dermatologist, but she now wished she had paid more and got proper treatment. For seven months she dealt with the pain and scarring. She had to drop out of school and quit her job and stayed in her house for 7 months with the fear that she would never be able to go out in public again. The treatment for recovery was painful as well, including a number of injections in her face. She was required to take medication, which also had side effects. In addition, it was emotionally very painful, making her suicidal.

She said she is very grateful to Dr. Bock for treating her, as she has made a full recovery. She feels strongly that there needs to be more protection from these types of operations.

Dr. Salomonson introduced Dr. Jerry Potaskin, representing the California Society of Dermatology.

Dr. Potaskin thanked the Boards for holding the forums. Before beginning his presentation, he said he would respond to some of the previous statements made.

Dr. Potaskin stated he took issue with the statements made about the safety of liposuction, and dermatologists taking weekend courses. Dermatologists perform liposuction under local anesthesia, and the deaths reported are from procedures done by non-dermatologists under general anesthesia.

Dr. Potaskin said on the BRN website they state their primary mission is to protect the public. The MBC site states it disciplines physicians. These are the two key boards that must come together to protect patients. He said he treats patients in his practice, and does not treat clients. He views what he does as medical practice, not an industry.

In reference to the testimony on training, he stated he does training for a major laser company, and about 8 years ago, he told the Company he would no longer train non-core physicians. The reason for his decision was not because he couldn't train physicians in the procedure, but because he thought non-core physicians, such as an anesthesiologist, could not learn in a day how to diagnose and treat skin disease. After completing training, students are given a certificate, which implies they have a higher level of competency.

For these reasons, the California Society of Dermatology is recommending:

- requiring on-site supervision for laser procedures;
- short of on-site-supervision, limit the number of sites physicians are allowed to supervise;
- enforcement of existing laws, such as those prohibiting nursing private practice, the corporate practice bar, and the employment of medical directors by lay entities;
- requiring full disclosure of the physician name in advertising and at the facility;
- enforcement of advertising laws relating to false claims, the use of photos, bait and switch promotions, false claims of superiority, etc.

Further, where there are violations relating to lasers, there are other violations, including injectable treatments. The newest treatment being promoted by these businesses are lipodissolve – an illegal substance.

Dr. Potaskin said the loophole in the advertising law is that physicians only need to reveal the board under which they are board certified if they advertise certification. Patients have a right to know the qualifications of the physicians, and if they are certified in an unrelated field. Patients might not be eager to undergo the treatment if they knew the physician supervising was a psychiatrist, rather than a dermatologist.

Dr. Potaskin stated he reads the MBC newsletter, particularly the back section which is basically a gossip column on disciplinary actions. Most of the actions are taken for violations relating to drugs and sex. While those are serious violations, there needs to be actions taken against physicians who are violating the law in other areas.

Current laws need to be enforced, and the Society appreciates the limited resources of the Board. Dr. Potaskin stated the Society recommends the establishment of substantial fines to pay for the enforcement.

Dr. Salomonson introduced Dr. Kimberly Butterwick, representing California Society of Dermatologic Surgery.

Dr. Butterwick thanked the members for the opportunity to speak. She stated she is a board-certified dermatologist, and has been practicing for 18 years.

The California Society of Dermatologic Surgery conducted a survey of its members last year on patient safety. According to the survey, in the past year, 65% of their members treated complications arising from the use of lasers by non-physicians. 92% of the members treated patients for skin cancer, which had either been overlooked or misdiagnosed by non-physicians. In some cases, they were melanomas, which resulted in fatalities. The top three complications seen by the members were burns and scars from laser hair removal, missed diagnosis of skin cancer, and burns and scars from chemical peels.

Dr. Butterwick stated everyone had seen the pictures of the burn patients. While dramatic, there is the question of frequency or rarity of the complications. In the past 10 years, there has been a great increase in cosmetic procedures, and invasive procedures have increased 100%. Non-invasive procedures have increased by 750%. The increase in the procedures is driving the increase in complications. In laser resurfacing procedures, there has been a 200% increase in complications. In 2005, over \$2 billion was spent

on aesthetic procedures, and that drives the interest of physicians in entering this lucrative field. In 2007, there will be over 10 million non-invasive procedures performed in the United States. With a 1-2% risk of complication, one can expect 100,000 to 200,000 complications per year. Since over half of these procedures are performed in California, our state can expect 50-100,000 patients harmed per year. Because of the increased popularity of these treatments, it is likely to get worse in future years.

As a dermatologist, Dr. Butterwick stated she sees a number of these types of complications. She stated it is important to not equate "non-invasive" with "complication free." Patients hear "non-invasive" and believe they are risk free. Dr. Butterwick recalled a patient that had five laser hair removal treatments without incident. At each treatment, she saw a different non-physician provider. The treatments were by an Alexandra laser, a good laser for her dark skin-type. On the sixth treatment, the patient noticed that it hurt, something she had not experienced at prior treatments, and told the operator several times. The nurse, however, continued the treatment. She developed blistering throughout her legs. The nurse probably followed her protocol, but injured the patient nonetheless. Dr. Butterworth suspected that the nurse believed that the cryogen wasn't working. There are a number of things that could have gone wrong. Dr. Butterwork showed pictures of the scarred legs, which eventually, after another 7 months of treatments to treat the complications, healed.

A common denominator of the patients who are burned is severe pain during treatment. Perhaps this fact isn't taught in the weekend courses, or perhaps one only learns this through experience. In her opinion, even if a nurse is not reckless, medical experience is necessary for patient safety. Nurses may be able to perform the treatment, but it takes a medically trained person to recognize complications.

While the Board is only addressing lasers at the Forums, it is Dr. Butterwick's opinion there will be further problems in the industry in the non-physician use of fillers, Botox, and other medical cosmetic treatments.

Infections and lidocaine toxicity are other complications that may occur, and are more dangerous than burns. Lack of diagnosis of skin cancer is also a risk. Non-physicians are not trained at the same level of physicians to diagnose the scope of skin diseases and medical complications.

Besides medical problems, there is the proper dilution and preparation of products. Storage and sterile technique may also be deficient in non-medical settings. Another concern of the future may be the ordering of products over the Internet. Many of these discounted products, some sold through E-Bay, may come from other countries, and may not be genuine or safe.

Dr. Butterwick is concerned about accessibility, accountability and responsibility. Patients having problems off-hours, should be able to contact the responsible physician for help. Medical supervision is vital to minimize errors and ensure patient safety.

Dr. Butterwick shared a photo of an advertisement for miso-therapy. The fine print states a nurse practitioner owns the practice, and she is performing a treatment not approved by the FDA. In the past week, she received a mail advertisement soliciting physicians to be medical directors for \$400 a month per spa. How could any physician adequately supervise a number of spas for \$400 per month?

It is the ASDS's position that some treatments may be delegated to trained nurses, however, there must be adequate supervision, and the physician must always be available. It is their position that there must be direct, on-site supervision of the physician. This will reduce complications, and result in prompt treatment when there are complications.

The ASDS asks that the Boards enforce current law, including violations of advertising and corporate practice, and promulgate regulations to require on-site physician supervision. In addition, they would ask that the Boards not wait until 2009 to take action.

Dr. Butterwick thanked the Board for the opportunity to speak.

Dr. Salomonson introduced Dr. Vic Narurkar, representing the American Society of Cosmetic Dermatology and Aesthetic Surgery.

Dr. Narurkar stated after reviewing previous discussions, the panel members had questions about data, and he was attending the meeting to present the data that presently exists. He would present a paper that was first presented at the American Society of Lasers and Medicine and Surgery, published, in abstract, in 2005, and presented to the ASDS in 2006. It was an analysis of complications from laser and light devices, as well as injectables.

Dr. Narurkar stated they performed an analysis of complications from procedures from only licensed healthcare workers, including RNs, NPs, and PAs. The complications were all reviewed by board-certified dermatologists. Complications ranged from pigmentation problems, scarring, burns, and others. The procedures with the most complications were first, laser hair removal, followed by leg vein treatment and tattoo removal.

The complication analysis looked at improper indication, faulty devices, over utilization of devices, improper use of devices, those performing the procedure and the nature of the supervision. The most common cause for complications was not due to the device, but the use of an improper device for an indication. Next, they found that over-utilization of devices when other modalities were better indicated for the treatment. 82% of the complications occurred when there was no on-site supervision of the physician. 57% occurred when the medical director had minimal training in lasers. 78% of complications occurred in non-traditional medical settings, such as shopping malls.

The study also looked at "core" versus "non-core" physicians. Regardless of whether the supervisor was "core" or "non-core" physicians, there was an increase in complications when there was not on-site supervision.

Dr. Narurkar showed an example of a patient treated by a non-physician with the wrong device, because that was the only device in the facility to remove a tattoo. Instead of removing the tattoo, it permanently branded the patient. (Scars are in the shape of the previous tattoo.)

Dr. Narurkar then showed an example of a patient who received laser treatment on a red vein with a device that is designed to treat blue veins. The treatment resulted in permanent scarring. The most egregious example of a patient treated with the incorrect device was a dark-skinned woman treated with a laser that caused permanent de-pigmentation. Dr. Narurkar showed a number of slides of burns, branding, and scarring from the improper use of lasers, as well as examples of improper injection treatments.

The conclusion of all of the data is that there are greater complications when there is inappropriate selection or use of devices, and that most complications occur in settings where there is no on-site supervision. Core specialists will also have complications; however, core specialists are best equipped to handle complications when they occur. The majority of the complications seen in their analysis were not addressed by the physicians supervising the non-physicians performing the treatments. Once a complication occurred, many patients were told to see a local dermatologist.

Dr. Narurkar stated the solution is to require better training, better supervision, and better reporting and analysis of adverse events. There needs to be greater responsibility of the industry, and there needs to be better integrity in the medical community.

Dr. Salomonson introduced Janie Cordray, Research Director for the Medical Board, who read a letter from an injured patient who was unable to attend the form.

Ms. Cordray read a letter from Kathleen (last name redacted for confidentiality), who wrote she had laser hair removal on her lip and chin that resulted in scarring. The supervising physician was an anesthesiologist who was unavailable and unable to treat her complications. The nurses misdiagnosed her complication, and provided no effective treatment for her burns, which, eventually, may need surgery to correct. She had to seek help from her personal physician, who referred her to a qualified specialist. Kathleen believed that she was misled, and that the Boards should require physicians supervising nurses to be qualified and available. (Letter attached.)

6. Public Comment:

Shannon Gunderson, R.N., of "All About Me" spoke. She stated she has been a nurse for 11 years and works at a spa owned by a plastic surgeon. The surgeon is always on call, and within a driving distance of 30 minutes. The nurses use strict protocols and must have 100 hours of training. In addition, the final approval and evaluation is done by the plastic surgeon. In her opinion, the present system works well, and they have very few complications, that, if they do occur, can be treated by the surgeon.

Jamie Sherrill, R.N., stated she has been a laser nurse for over 10 years, and also provides training. She asked that the panel not discriminate against cosmetic nurses, as other specialties work without on-site supervision, many specialties performing treatments and procedures that are more dangerous than the cosmetic procedures.

She stated she suffers from a number of complications from cosmetic procedures performed by board-certified plastic surgeons. In her opinion, on-site supervision is not necessary.

Shasha Parker, R.N., stated she appreciated that complications occur everywhere, including in doctors offices with direct supervision. She questioned the statistics presented by Dr. Narurkar, and stated there needs to be a distinction made between a "non-physician" and licensed nurses or physician assistants. In her opinion, on-site supervision is not needed, as nurses frequently perform much more difficult and life-threatening procedures than lasers without direct supervision. She stated the effort to require on-site supervision is more from an economic turf-war than from concern for patient safety.

Don Fagin, president of North American Laser Center, stated there is an extensive effort of the laser manufacturers to provide the best training possible. They train nurses, as well as physicians, of all specialties. He stated if testimonials and pictures of the pleased patients could be shown, they would far outnumber those who have been harmed.

He stated the previous day he had undergone an IPL treatment on his face by a technician, with no physician in the facility, and he felt completely safe. He thanked the Boards for their efforts, and offered their assistance.

Dr. Salomonson asked about the qualifications of the technician who performed his IPL treatment. Mr. Fagin stated the person was a trained technician, not a licensed nurse or other licensed health-care professional. He said the person is called a "clinician."

Cynthia Moore, RN, stated she had been practicing nursing for over 30 years, and frequently trains nurses in a number of fields, including oncology, outpatient blood banks, and others. In 2000, she became an

aesthetic nurse working under a Medical Director who is always available. She said she had seen some of the complications presented at the Forum, but very few, and none were permanent. In nursing, she has done many more serious and risky procedures than what she does as an aesthetic nurse, without direct supervision. In her opinion, on-site, direct supervision is not necessary for laser procedures, as long as the supervising physician is available. More important to patient safety, is adequate training.

5. Discussion of Information to be presented to the Medical and Nursing Boards

Ms. Tate stated any action taken must be done by the respective boards. Nursing practice is regulated by the Nursing Board, and physicians are regulated by the Medical Board. Staff will be presenting the information learned at these forums to the members of their respective boards, and any action must be taken at board meetings. The agendas of the meetings are posted on the boards' websites, and any discussion for action must be publicly noticed. Please reference the boards' websites for information for when discussions will be held.

7. Adjournment

Dr. Salomonson thanked everyone for their participation, and adjourned the meeting at approximately noon.