

Minutes:

August 30, 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)**

**Holiday Inn
2726 S. Grand Avenue
Santa Ana, CA 92705**

Members Present:

Mary Moran, M.D., Medical Board of California
LaFrancine Tate, R.N., President, Board of Registered Nursing
Susanne Phillips, R.N., Board of Registered Nursing

Staff Present:

Barb Johnston, Executive Director, MBC
Kimberly Kirchmeyer, Deputy Director, MBC
Renee Threadgill, Enforcement Chief, MBC
Janie Cordray, Research Director, MBC
Kelly Nelson, Analyst, MBC
Heidi Goodman, Assistant Executive Officer, BRN
Louise Baily, Supervising Nursing Education Consultant, BRN
Elliot Hochberg, Enforcement Manager, BRN
Janette Wackerly, Nursing Education Consultant, BRN
Kurt Heppler, Attorney, Department of Consumer Affairs
Harry Gibbons, Attorney, Department of Consumer Affairs

Audience Present:

Nora Wang, Palo Alto Medical Foundation
Melanie Balestia, R.N., N.P., California Association of Nurse Practitioners
Julie Petters, Medical Aesthetic Training of California
Sasha Parker, R.N., Association of Medical Esthetic Nurses
Sana Remillard, Metropolitan Oasis Medical Aesthetic Center
Roseanne Boffia
Margaret Montgomery, Kaiser Permanente
Jane Paul-Hutson, ASPSN
Connie Hoy, Cytera, Inc.
Danielle Waters
Marylyn Hagerty, Aesthetic Trends Institute
Susan Tiso, NP, NP Aesthetics Anton Aesthetics
Janet Peterson, R.N.

Donna Hays, R.N., Skintastic Laser Retreat
Michelle Buttler, Center for Public Interest Law, USD
Linda Simonian, R.N.,N.P, Kate Somerville Skin Health Experts
Melissa Haloossim, R.N., N.P., Kate Somerville Skin Health Experts
Teresa Frohny
Michael Scott, CNA Insurance
Gail Dunlop, R.N., Lumenis
Lisle Poulsen, American Society for Dermatologic Surgery
Diana Breister Ghosh, M.D., Private practice plastic surgeon
Julie Che, R.N., Dermatology
Beth Grivett, P.A., PAC, California Academy of Physician Assistants
Joseph P. Furman, Curtis, Green, and Furman, LLP
Daniel Gross, M.D.
Ljiljana Vasil, Healthcare Partner
Michael Lum, D.O., Lumier Medical, Inc.
Jim Parrot, Solano Med Spas
Connie Cruz, R.N., Immoull
Dawn Carl, Calidora Skin Clinic
Janet Petterson
Eden Leyanna, R.N., N.P.
Cynthia Furnsberg, N.P.
Linell Wagers, R.N.
Norm Davis, attorney specializing in healthcare law
Alan Voss, A.L. Voss Associates
Jim Newman, M.D.
Beth Haney, R.N., N.P., California Association of Nurse Practitioners
Trisha Hunter, R.N., California Nursing Association
Donna Fox, R.N., California Nursing Association
Jennifer A. Fagginato, PA, California Academy of Physician Assistants
Ann Davis, P.A., American Academy of Physician Assistants
Jerry Potazkin, M.D., California Society of Dermatologists
Christopher Zachary, M.D., American Society of Dermatologic Surgery.
Brian Kinney, M.D., California Society of Plastic Surgeons.
Tom Simorson, M.D.
Nancy Pelagrino, R.N., N.P.
Dan Gross, M.D.
Thomas Shelton Powers, M.D.
Erin Olsonso, R.N., N.P.
Others in the audience were present, but were not identified.

The meeting was called to order at 9:00.

1. Welcome - Introductions

Dr. Mary Moran, member of the Medical Board of California, welcomed everyone for attending the meeting, and explained that it was the first in a series to be held jointly by the Medical and Nursing Boards. The forums' purpose is to gather information about the current practice environment that utilizes lasers and intense light pulse devices for cosmetic procedures.

Dr. Moran introduced those who would be participating in the meeting and sitting at the main table:

LaFrancine Tate, R.N., President of the Board of Registered Nursing,
Susanne Phillips, R.N., Member of the Nursing Board,
Kurt Heppler and Harry Gibbons, legal counsels, Department of Consumer Affairs
Kim Kirchmeyer, Deputy Director of the Medical Board,
Louis Bailey, Supervising Nursing Education Consultant, and
Heidi Goodman, Assistant Executive Officer of the Nursing Board.

Dr. Moran introduced some members of the audience, including Barb Johnston, Executive Director of the Medical Board, Renee Threadgill, Medical Board Chief of Enforcement, and Elliot Hochberg, the Nursing Board's Enforcement manager. Dr. Moran introduced Janie Cordray, Research Director of the Medical Board, and Janette Wakerly, Nursing Education Consultant for the Nursing Board, and explained that they were coordinating the forums, and that they should be contacted for information or scheduling of presentations for future meetings.

2. Overview of Charge - Business & Professions Code Section 2023.5

LaFrancine Tate, President of the Nursing Board, explained that Business & Professions Code section 2023.5 charges the Medical and Nursing Boards to study the safety of lasers and intense pulse light devices for cosmetic procedures. The law enumerates a number of things that are to be examined, including appropriate level of physician supervision, the appropriate level of training, and guidelines for standardized procedures. The law directs the boards to examine the use of topical agents, patient informed consent, follow-up care, among other things. If, after the Boards complete their fact finding, regulations are deemed to be necessary, they must be promulgated by January 1, 2009. By that date, the Boards will also report their findings to the Legislature.

3. Statement of Purpose of the Meetings - Public Health & Safety

Dr. Moran explained that the purpose of the forum was to gather information. She stated that the forums were not official Board meetings, and the group conducting them was not authorized to take any action. Their focus would be on public safety.

Dr. Moran stated that the day's meeting, as well as the two scheduled in the future, would gather information. Following the meetings, the staff would prepare a summary of findings to be presented to the Medical Board of California (MBC) and Board of

Registered Nursing (BRN). The Boards' members would decide on the next course of action. She stated that all of the meetings would be public and any materials presented to the members would be public. Before any action could be taken, interested parties would be given the opportunity to weigh-in with their comments. If regulations are to be promulgated, they would be subject to the formal rulemaking process, which provides for a public comment period and a public regulatory hearing.

Dr. Moran stated they had asked a number of groups and individuals to present testimony, and offered anyone else to make a presentation at the end of the meeting in "Public Comment." She stated that if anyone wished to be given time to make a full, formal presentation at future meetings, they should contact Janie Cordray or Janette Wackerly, and they would be scheduled to speak in September or October.

Dr. Moran stated the group would hear testimony from those who were scheduled to make formal presentations, and asked those testifying to be as brief as possible. She asked that presenters provide copies of their written materials to Janie Cordray, so that they could be included into the official record.

4. Testimony:

- Representatives of the Laser Industry

Norm Davis thanked the members for the opportunity to speak. He explained that he came from a hospital administrative background, had several years of healthcare consulting, and has been practicing healthcare law for about 14 years. Over the past 6 or 7 years, he's been heavily involved in the field of aesthetic medicine. He was asked to present on healthcare law and how it relates to this field.

The growth of the aesthetic field has been staggering --- a \$250 billion a year industry. It started in a few medical offices with very few procedures, and has grown to include many procedures in medical spas, dental spas, and even veterinary medical spas. It is his opinion that this growth has been caused by a number of factors, including consumer acceptance and demand for a better and more youthful appearance. In addition, the medical technology has advanced tremendously. Cosmetic injections such as Botox and fillers, demacare, laser hair removal, intense pulse light devices, skin tightening, lipodissolve, and all the other procedures have evolved to meet the demand.

Mr. Davis added that economic factors also contribute to the growth of aesthetic medicine. Physicians are trying to compensate for the managed-care squeeze, and find other sources of income outside of insurance reimbursements. Nurses, nurse practitioners, physician assistants, technicians, and estheticians throughout the country also want to get into the field. Lay investors have the funds to provide the working capital for these types of ventures, largely contributing to the industry's growth.

There also is a lack of definition in practice regulations. Problems have evolved, including those relating to public safety. There have been problem cases of hyper and hypo pigmentation, however, there have been very few deaths or permanent disfigurements, and, statistically, they are not very significant. While there have been cases of unlicensed practice of medicine, those also are very few. Most procedures are performed by licensed healthcare professionals, if not physicians. Of great importance is liability between lay entities and medical providers and groups in the spa-type operations. There are also turf wars that develop between certain specialties. Physicians that have a number of settings with staff performing the procedures compete with those that perform their procedures in their single offices.

Mr. Davis proposed that the following should be addressed and may provide solutions:

1. Increased definition of medical practice and ownership responsibilities. There needs to be a definition of practice and medical offices.
2. A better defined span of control over sites, whether based on location or number of sites. There needs to be some kind of control so that one doctor is not controlling 30 offices.
3. Increased M.D. supervision for R.N.s, much like the P.A.s in California. In addition N.P.s could have their scope expanded.
4. Increased R.N. and N.P. training, with possible requirements of certification for specific treatments and devices.
5. Redefining Standardized Procedure guidelines to close loopholes.
6. Defining regulations to address lay-involvement and corporate practice.

Mr. Davis then provided the group with a list of laws relating to medical practice and corporate practice issues. (Attached.)

Alan Voss, of A.L. Voss Associates, a business and regulatory consultant who has been in medicine for over 35 years, addressed the panel. He stated that about eight years ago he went into consultancy on issues relating to medical devices, specifically those to be used by individuals other than physicians. Historically, companies developed prescriptive medical devices for use by physicians. The emergence of devices designed for non-physicians has changed the practice environment.

According to Mr. Voss, the business of medicine has changed dramatically, with reimbursement going down, and doctors' hours and overhead going up. With revenue going down, non-procedural specialties are looking for ways to financially survive. To increase revenue, physicians may see more patients,

which may not be possible, or raise fees, which is rarely possible. As non-procedural care does not pay as well as procedures, one way of increasing revenue is to offer additional services. Most importantly, they can add procedures that their staff can perform. The desire is to add services that can raise revenue.

In his consulting, Mr. Voss deals with physicians, licensed medical professionals, and regulators nationwide. One of the issues that continuously arises is the misassumption of FDA regulation. The FDA does not have a hand in regulating devices, other than to approve them for what they may be used. It is up to the individual states to regulate the profession, including who may use the device. Many states assume that the control of the device will be performed by the FDA, which is not true. In talking with nationwide regulatory boards, most were unprepared to address the use of the devices. It has been a nagging problem -- creating concerns with little solutions. Some states have taken knee-jerk actions that they have found do not address the problems.

States have tried to regulate the devices in various ways. They've chosen to regulate procedures, medical device classifications, and tried various things that have not worked. In the past, there were two regulatory schemes to control the devices; the Bureau of Radiological Health, which regulated all light-emitting devices with a classification scheme of numbers 1 through 4, depending upon the power and light output; and the Office of Device Evaluation, which controlled the device for commercialization, with a classification of devices from 1 through 3.

Another problem that arises is multiple boards claiming ownership of the devices. Boards generally operate independently, and only regulate their own licensees with little or no communication or coordination of efforts. As an example, a medical board, a nursing board, and a cosmetology board may all have differing opinions about the use of a device.

Some states have regulated these devices legislatively, which tend to cause problems because they are politically driven rather than safety driven. Some address use by regulation, which is done through a process of public comment and testimony, which has worked best. Others have addressed the problems through policies, which does not generally work well.

In closing, Mr. Voss stated that most of the laser treatments being performed are being done by licensed healthcare staff, not physicians. Physician presence has shown very little to do with the safety of the procedures. Since the many devices and treatments are very new to the market, most physicians have had no training to do the procedures, other than that provided by the device manufacturer. The majority of adverse effects are a result of inadequate training. State regulatory boards want more control and better provider training, and insurance companies are requiring more training. The most important element to ensure patient safety is training, and training programs should be certified by the state. If states require

training, but have no oversight over its quality, there's little value to the regulation.

- Representatives of the Nursing Associations

Beth Haney, representing the California Association of Nurse Practitioners, said that she was a family nurse practitioner for over 7 years, has been practicing in aesthetic laser procedures for the last 5 years, and in the last three years, she has been a trainer for a global laser company. She is now VP of training for Medical Aesthetics. Their focus is on patient safety, procedural complications and their remedies. The aesthetic industry is growing at too fast a rate to provide comprehensive safe and effective treatments. Reduction of insurance reimbursement rates has caused an explosion of physicians providing aesthetic treatments to supplement their income.

Ms. Haney stated that many practitioners were not adequately trained to ensure patient safety. As an educator, she sees under-trained persons doing these procedures, and in some states, even estheticians providing treatments. Some are getting only about 4 hours of training by a device manufacturer before treating patients. As Alan Voss and Norm Davis had testified, lay entities with no medical background are entering the business and hiring under-qualified persons to perform the treatments, with monetary gain their priority, not patient safety. Typically, this corporate practice is misleading the public in their advertising, implying that physicians are involved in the procedure, when in fact, they are not. There have been increases in injuries, and most are caused by inadequate training of physicians and their staff.

Ms. Haney stated that on behalf of the California Association of Nurse Practitioners, she was testifying to remind the Boards that N.P.s are masters prepared practitioners, educated to provide quality primary care. With additional and thorough training in aesthetics, N.P.s are able to provide safe and effective treatment. On-site, direct supervision is not necessary for adequately trained N.P.s. Compared with other duties they perform in urgent care clinics and primary care settings, without direct physician supervision, lasers are not as complicated or demanding.

Based on her experience as an educator, 12 hours of concise, thorough, and intense didactic sessions, including basic laser physics, pre and post treatments, safety and complications, and especially patient expectations, in addition to 12 hours of hands-on, supervised clinical training, appears to be an appropriate amount to ensure competency. A proctored examination should also be required.

Trisha Hunter, representing the California Nursing Association, spoke. She stated that it would appear that there are sufficient laws and regulations to address public safety, but they need to be enforced. Rather than look to regulate individual practitioners, it might be wise to look to the facilities, much like what was done to

address the problems in outpatient surgery. In addition, requiring certification might be best, as medical practice changes constantly, and regulations will become obsolete.

Ms. Hunter stated Standardized Procedures and law and regulation appear to address many of the safety concerns, if enforced. Under current law and regulations, physicians should not be delegating procedures to those not adequately trained, and the safety elements addressed on the agenda are already addressed. Passing new laws or regulations without enforcing current law will have no value. Under standardized procedures, physicians and nurses are signing-off that they have the qualifications and ability to do what is being delegated, and supervision is defined.

In summary, it is the CNA's position that the current laws address all of the issues of patient safety concerns, and they should be enforced. In addition, if it is deemed necessary to seek new laws or regulations, facilities should be addressed.

Donna Fox, of the California Nurses Association, thanked the members for the opportunity to address both boards. Public safety is their organization's priority, whether procedures are necessary or elective. The use of lasers is relatively new, and may need specific regulation. When addressing training, the BRN rules relating to CME may be a model that may be used for aesthetic training. Physicians are not automatically qualified to perform all procedures, nor are nurses. For the safe use of lasers, additional training is necessary. She stated that she agreed with Ms. Hunter's comments about standardized procedures, as they address clinical and system issues.

In addressing facilities, she noted that under current law, most physicians' offices are exempt from any regulation. In the absence of regulatory oversight, perhaps facilities should be addressed, including physician offices.

- Representatives from Physician Assistant Organizations

Jennifer A. Faggionato, physician assistant and past president of the California Academy of Physician Assistants (CAPA), spoke on behalf of CAPA. Ms. Faggionato thanked the members for an opportunity to speak. As a P.A. with clinical experience in emergency medicine, dermatology and plastic surgery, she attested to the need for consumer protection.

CAPA provided technical assistance to Senator Figueroa and her staff in the drafting of SB 1423, and suggested that the current laws addressing P.A. supervision should serve as the model for any future laws or regulations relating to physician supervision. It is the position of CAPA that the MBC and the Physician Assistant Committee already have the necessary laws and regulations to oversee the practice of cosmetic laser procedures. The practice of laser

procedures should not be treated any differently than any other medical procedure. (Testimony attached.)

Ann Davis, physician assistant and Director of State Government Affairs of the American Academy of Physician Assistants spoke. She stated that physician assistant practice is always dependent upon supervision and their practice is by delegation from physicians. Physician assistants' scope of practice is derived from delegation. She explained the concepts of the P.A. practice, and the California regulations, which require:

- supervision by a physician who must be available either in-person or via telecommunications at all times while providing patient care;
- delegation of only tasks or procedures consistent with the supervisor's specialty or usual and customary practice;
- the physician to observe or review evidence of the P.A.'s performance of all delegated tasks to ensure competency;
- the P.A. and physician to establish transport and back-up procedures for immediate care of patients in an emergency when physician is not on-site;
- the physician and P.A. to establish guidelines for adequate supervision, which may include same day examination by the physician or protocols;
- the supervising physician to have continuing responsibility to follow the progress of the patient to assure that the P.A. practices with supervision, and the physician is responsible for all of the services provided by the PA.

All of the requirements address patient safety, and it would appear that no further regulations would be required. New technology will be developed, and the current laws and regulations are adequate to ensure proper supervision and patient safety.

She also cautioned the Boards in using the term "non-physicians" as that could mean unlicensed practice. She would encourage the boards to use more specific terms to define exactly what is meant. She thanked the members for the opportunity to speak and offered the services of CAPA to assist the Boards in their work. (Full testimony attached.)

Robert C. Higman, PA and President of the Society of Dermatology Physician Assistants, was unable to attend but sent his written comments. (Attached.)

- Representatives from Physician Organizations

Dr. Jerry Potazkin, representing the California Society of Dermatologists (CSD), spoke. He thanked the members for the opportunity to speak. He stated that he is a dermatologist that has experience with lasers. His first experience with lasers began in 1989, during his residency in New York. In 1989, there were about two or three lasers available, and presently there are at least 92 rejuvenation devices.

He said that his testimony would focus on patient safety. He presented data from a brief study performed by four of his colleagues throughout the United States, one in California, one in North Carolina, one in Massachusetts and one in Colorado, which focused on complications from laser and pulse light procedures. The study also focused on injectables, but he would not be addressing that subject.

There is an increased in the use of these devices by non-physicians, and the rules for supervision and training in the states are inconsistent. The cases in the study were a result of 18 months of data gathered on patients seen for complications after undergoing laser procedures. Complications included changes in pigmentation, hypotrophic scars, atrophic scars, infections processes, and skin atrophy. (Slides provided, showing the complications, attached.) Some complications correct or improve over time, and some are permanent.

The types of complications were categorized by indication, starting with laser hair removal, light vein treatments, photo rejuvenation, tattoo removal, and treatment of melasma.

As an example, recently he saw a patient who had been seen by a non-physician who had recommended a \$5,000 laser treatment for melasma. Instead, he provided the patient with an \$80 cream, which, after 6 weeks had corrected 90% of the problem. He owns the same device as was recommended, but it was not indicated for her problems, which posed significant risk for a dark-skinned Asian patient.

Complications done by inappropriate indication is significant, and is a reflection of inadequate training. Complications are also a result of over-utilization of devices. The use of a device when something else, usually with less risk, would have worked more effectively.

Complications due to inadequate physician supervision accounted for 82 percent of the complications. Of these, medical directors with little or no training in the procedure resulted in 57 percent of the complications.

Non-traditional medical facilities, such as storefronts, salons or shopping malls accounted for 78 percent of the complications.

Complications also were related to core vs. non-core physicians and direct versus non-direct supervision. (Core physicians are defined by the study as dermatologists, plastic surgeons, etc.) Seventy-two percent of complications resulted from non-core physicians without on-site supervision. He stated, however, that it was not the position of the CSD that only core physicians be allowed to perform or supervise laser procedures, but that all supervision should be adequate and on-site.

Dr. Potazkin showed a number of slides showing the complications, including burns and scarring. (Attached.)

The conclusion of the study was that the majority of serious complications were a result of inappropriate or over utilization of a device, the greatest incidence of complications occurred where there was no direct supervision, and more occurred in non-core physician sites. He said that the variety of slides he showed were to demonstrate that complications were not device-specific.

The position of the CSD is to require direct and on-site supervision in facilities where procedures are performed. There is no medical necessity for these treatments --- they are all elective. It is their position that wherever the procedures are performed, patients must be fully informed, and, at minimum, need to be told the name of the physician and their specialty.

In addition, there may only be a need to enforce current laws, and no new laws or regulations may be necessary. There needs to be enforcement of the current statutes relating to corporate practice. With the limited resources of the Boards, there needs to be additional funding. The CSD would recommend that enforcement efforts be funded by establishing substantial fines.

Dr. Potazkin concluded his presentation and thanked the members for the opportunity to speak.

Dr. Christopher Zachary, professor and chairman for the UC Irvine Department of Dermatology, spoke on behalf of the American Society of Dermatologic Surgery (ASDS). He thanked the members for the opportunity to address the Boards.

ASDS performed a patient safety survey. Of those who responded, 65% of their members had treated complications caused by treatments performed by non-physicians. A significant number had treated patients with skin cancer, some of which resulted in patient mortality, which was either overlooked or misdiagnosed by a non-physician.

He stated that it is important to not trivialize skin disease, and showed a picture of a patient who, 11 months after undergoing an esthetic procedure to remove a facial spot, went to a dermatologist with a subcutaneous mass and was diagnosed with amelanotic melanoma, locally metastatic. (Slide show attached.) This case demonstrates the need for an appropriate exam by a trained physician that can identify skin conditions before treating the symptoms.

The top complications from laser procedures performed by non-physicians were burns and scarring and misdiagnosis of skin cancer.

The problems being addressed by the Forum are national problems. Dr. Zachary presented a number of slides of patients who have been burned and scared. (Slide show attached.)

Dr. Zachary stated that none of the procedures being discussed are non-invasive, and they should not be dismissed as inconsequential. Another issue of importance is lidocaine toxicity, which has caused death. Anesthetics should only be individually prescribed by physicians with on-site supervision.

While many procedures can be delegated to non-physicians, only physicians are trained to diagnose skin disease, evaluate the causes, types and symptoms of skin conditions related to aging and sun-damage, and equipped to treat disorders.

It is the position of the ASDS that:

- Under appropriate circumstances, certain cosmetic medical procedures can be delegated;
- Procedures must only be delegated to trained and licensed medical staff with direct, on-site supervision by a physician; and
- On-site physician supervision ensures the necessary responsiveness to questions and the avoidance of complications as well as treatment of complications, if they arise.

Dr. Zachary thanked the members, and said he agreed with the California Society of Dermatology recommendations.

Dr. Brian Kinney, spoke on behalf of the California Society of Plastic Surgeons (CSPS). Dr. Kinney is a plastic surgeon in Los Angeles, past president of the Plastic Surgery Educational Foundation of the U.S. and currently a member of the Board of Directors of the American Society for Plastic Surgeons and the American Society for Aesthetic Plastic Surgery.

Dr. Kinney provided the members with a prepared, written statement. He stated that he would not read the entire statement, but he wanted to address a few issues. (Written statement attached.)

The American College of Surgeons (ACS) issued a statement on surgery using lasers, pulse light, radiofrequency devices, or other techniques. All of these procedures are invasive and can cause great harm to patients. There are substantial risks with the use of these devices, especially when used incorrectly, as Dr. Zachary's slide show demonstrated.

The CSPS agrees with the ACS statement, in that the use of the devices in non-medical settings is inappropriate. Although many of the procedures may be safely delegated to licensed healthcare staff with adequate supervision and training, they should be done in appropriate settings. Physicians should be responsible for the initial patient review before delegation, and it should be noted in the patients'

records. When delegated to a non-physician, there should be appropriate licensing and credentialing, including documented training and certification. The supervising physician should also be trained in the procedure, and should not delegate functions for which they themselves are unqualified to perform. In addition, the supervising physician should be on-site or reachable by phone, and available to see the patient within 24 hour, in the event complications arise.

The CSPS also believes that there should be vigilant enforcement of advertising laws, as the current environment of misleading and shameless marketing has implications to patient health and safety. Supervising physicians should be required to be named in all advertising, as well as the names of those performing the procedure.

Dr. Kinney thanked the boards for an opportunity to speak, and offered the CSPS's continued support and assistance with future patient safety efforts.

Dr. Jim Newman spoke on behalf of the California Society of Facial Plastic and Reconstructive Surgery. Dr. Newman presented a slide show. (Attached.)

Dr. Newman said that many of the views expressed by previous organizations were similar to that of the California Society's. He said that the reason for the law, and this project, is due to the vast explosion of the medical spa business. The spas blur the line between medical and non-medical procedures and the line between clients and patients. These spas provide treatments under the scope of cosmetology, but also provide medical treatments. Patients are offered a menu of services that fall under both categories, and therefore patients are not always aware that some of the procedures offered are medical.

Dr. Newman stated the corporate practice of medicine bar is violated daily in some of the spas, and physicians are not always involved in the patients' care. These types of operations often open and close, and there are no medical records to be accessed after their closure. Patients often are pre-sold procedure packages, and often have nowhere to go for refunds or treatments after the closure of the business, and treatment of complications is left to physicians in the community. Medical spas are also problematic as they have medical directors who are actually only ghost physicians who are not properly trained in core specialties.

The issue of core specialties had been introduced by previous speakers, which deals with specialties that are trained to deal with skin diseases and conditions, burns, the use of lasers, treatment of skin cancers. These physicians work very well with nurses and physician assistants to provide these types of treatments. Physicians may be licensed M.D.s, but they are not adequately trained. While it is not practical to legislate the type of training, as the treatments and technologies are constantly changing, issues relating to training will need to be addressed in some way. There can, however, be enforcement of current laws relating to supervision, delegation and competence.

Dr. Newman stated that in his community, there are medical spas that have employed medical directors who are pathologists, psychiatrists, anesthesiologists and other specialties that do not have the requisite training to treat skin conditions or diseases, or to perform cosmetic treatments. The problem, according to his colleagues who were polled, is statewide.

Their organization polled 30 patients in the Northern California area who have received treatments at medical spas. Eighty percent of those polled reported that they have received treatment from different nurses or technicians and that they had never seen a physician. Their organization agrees with the other groups that are of the opinion that patients should be first seen by a doctor, and treatment plans should be developed before treatments are delegated to nurses and physician assistants.

The complications can be very severe. A patient who was treated in May by a nurse in a medical spa with state-of-the-art equipment in San Mateo with no physician contact resulted in 3rd degree burns on her face. Scar revision is in her future. These types of problems are happening not only in remote areas, but in major cities where quality care is accessible.

The Society would like to see the MBC increase the enforcement of all of the current laws. In addition, they would propose a patient bill of rights in medical spas, which would require, among other things, that patients be told that the procedure they are about to receive is a medical procedure, the identity of the attending physician, and that medical records will be protected in the same manner as any other medical office. If a nurse or physician is going to perform the procedure, patients should be fully informed, and should be under the supervision of a physician. Procedures should only be delegated to those nurses and physician assistants with adequate training and certification in the core specialty.

The technology is excellent, and harm done to patients is not due to the technology, but to operator error. Avoidable complications will continue to occur with inadequate training and little or no supervision.

Dr. Newman thanked the members for the opportunity to address the boards jointly, and offered the Society of Facial Plastic and Reconstructive Surgeons continued support.

Dr. Moran thanked all of those representing the organizations for their presentations.

- Consumers

Dr. Moran stated that letters had been written to eight patients who had filed complaints with the MBC, but for confidentiality reasons, no names would be used. She stated that the letters had said that they would be given an opportunity to address the group at any of the three meetings scheduled. Dr. Moran asked if any of the patients were in the audience, and there was no response.

6. Public Comment (taken out-of-order)

Dr. Moran stated that she would take public comment before addressing issues for the next meetings. She asked speakers to confine their comments to five minutes.

Sasha Parker thanked the Boards for initiating the forums, and thanked Senator Figueroa for authoring the legislation. Ms. Parker is a Registered Nurse who has been doing medical aesthetics for the past 10 years, as well as a licensed esthetician in Florida and an electrologist. She had just recently been informed of the forum, and apologized for not having prepared a presentation. Ms. Parker founded the Association of Medical Aesthetic Nurses (AMAN). AMAN is in the process of administering their first certification examination in conjunction with the American Academy of Medical Aesthetic Professionals. Their organization will certify physicians, nurses, nurse practitioners, and physician assistants.

Ms. Parker is also a trainer, and owns the Aesthetic Skin Institute. Nurses tend to work in isolation, as the boards don't understand what they do. AMAN's position is to call for patient safety in the industry, and that training is essential.

In the presentations made earlier, the use of the term "non-physician" was used, which may be confusing. The term could mean an esthetician, a nurse, or anyone. To make the data useful, it should be more specific as to who performed the treatment, in what setting, and the level of training. In addition, she would like to know where some of the statistics quoted originated.

Her organization is in agreement that supervision is needed, however, they do not believe that on-site supervision is necessary. Adverse events may be discovered up to three days following the treatment, and therefore on-site supervision isn't helpful. Training and experience is the key to patient safety, whether for nurses or physicians.

She stated that she agreed with the CNA representative who said that most of the problems are already addressed in current laws and regulations, and that California's standardized procedures were used as a model in Arizona.

Dr. Moran stated that Ms. Parker had extensive experience, and due to limited time, she would suggest that she be given more time at a future meeting to make a formal presentation.

Melanie Balestia stated that she had been a registered nurse for 40 years and a nurse practitioner for 30. She is past president of the California Association of Nurse Practitioners and American College of Nurse Practitioners. For 15 years, she has been an attorney primarily practicing in healthcare law. The practice environment for nurse practitioners in the last 30 years has dramatically changed. 30 years ago, N.P.s were only practicing in pediatrics. Currently there are N.P.s in cardiology, emergency rooms, oncology, orthopedics, and just about every other specialty imaginable. As a result of this change, there are now national certifying examinations.

There is no need to regulate every specialty and procedure. What is needed is certification. There needs to be a certification program for aesthetic procedures for physicians and nurses.

Dr. Tom Simorson stated that he is board-certified in internal medicine. In his residency he had a rotation in dermatology, and in 20 years of office practice he saw lots of skin conditions, including skin cancer. He practiced internal medicine for about 17 years, and after he left the military, he worked as an emergency physician for about 15 years. About 6 years ago, he developed a heart condition and could no longer keep up with the pace of an ER. Since then, he discovered aesthetic medicine, such as Botox, fillers and laser treatments. He is associated with a number of well-qualified R.N.s. Cumulatively, they have treated thousands of patients.

He agreed with previous speakers, in that he would like to seek standards established for training. With proper training, he thinks nurses and nurse practitioners can safely perform treatments.

Nancy Pelagrino, a nurse practitioner, stated that she has been a nurse for 18 years and a nurse practitioner for 16. She has a masters degree, practiced in internal medicine for 9 years, and for the last 7 years, she has been practicing aesthetic medicine. She stated that she received her original aesthetic training from two cosmetic dermatologists under whom she worked, and has spent thousands of dollars being trained throughout the world. Her priority is patient safety, and she has a successful practice in the office of a plastic surgeon. Two years ago, she was approached by two major cosmetic companies to do training in injectables. She was then approached by a number of specialties for training, as well as dentists and others who are not qualified or licensed to perform these types of procedures. In addition, many are seeking inadequate training – only four hours in some cases.

She stated that she agreed that there should be some minimum training requirement, but that standards for that training should also be addressed. As part of her N.P. training, she was educated in skin conditions, and frequently diagnoses these conditions in her practice.

Susan Tiso, a Family Nurse Practitioner said that she agreed that the "non-physician" label needs to be clarified. As it could mean anyone, including non-licensed, non-trained persons, it would be more helpful to be more specific. Additionally, Nurse practitioners and R.N.s have different training. Nurse Practitioners are trained in diagnosing skin diseases and are tested in their competence. As extensive as their training, it does not make them competent in laser procedures. It is her opinion that there should be standards and requirements established for training.

She stated that there is probably a wealth of training provided by the dermatology and plastic surgery societies, and the nurses would like to attend some of their training.

Dr. Dan Gross, professor emeritus of dermatology from University of California, Los Angeles, and practicing dermatologist, spoke. He noted that he had heard the term "the industry" used several times during the meeting. He never thought of the practice of medicine as an industry, but thought of it as a profession. He treats patients, not clients. For 35 years he has done medical legal consultation, and when he first began, the most common problem was a missed diagnosis of cancer. Now, the most common problem seen is laser damage performed by a host of different persons. He has a large group practice with other dermatologists in the San Fernando Valley, and they have been approached by a medical spa to be medical directors. These businesses were not interested in physicians seeing patients, only lending their license, in name only, to their operations. They have also been approached by a non-core physician who asked if their group would treat his complications.

When his office does laser procedures, they are either performed by a physician, or delegated to trained, licensed staff after seeing a physician. Appropriate physicals and histories are performed, and patients are fully informed about the procedure. Physicians are on-site when treatments are done, even if delegated. Physicians also see patients to follow-up the patients' progress.

Patients are patients, not consumers. These treatments are invasive procedures, and are all elective. Every effort should be made to deliver safe and quality medical care.

Dr. Thomas Shelton Powers said he was an emergency physician for 25 years, and five years ago he became an aesthetic physician. About a year ago, he contracted with a management practice firm to run his laser hair removal practice. In February, he stated that the firm took the lasers and left his practice. In March,

the firm returned and set-up a practice in competition with his. For seven months, the firm has refused to disclose the name of the medical director. He wrote a complaint to the MBC, but he was told they could do nothing without the name of the doctor. He then said that for 7 months there has been a lay person in his clinic competing with him for his own patients. He has not found any legal remedy for this problem, and then he said that the case will go to court in February for practicing medicine without a license. He said that there was no need for new laws, but there is a need to enforce current laws.

Erin Olonso, a nurse practitioner, said she had been practicing aesthetic medicine for about 7 or 8 years. She said she believes that with proper training, most nurses can perform in any specialty under standardized procedures. Physicians need to include nurses and nurse practitioners in their training. If they are truly concerned about public safety, then they need to provide education. Most training she has received is from her supervising physicians. Turf wars between the professions do not help patient safety.

Dr. Moran thanked everyone for their comments, and said that the Boards would consider all of them.

5. Issues for discussion at future meetings, to be held September 13 in Sacramento and October 31 in San Diego

Dr. Moran stated there would be another forum held on September 13 in Sacramento. That meeting will again provide an opportunity for interested parties to speak. She stated that California already has a number of laws that could be used to address the problems expressed in the testimony presented. Presently, however, the laws may not be fully enforced or utilized. The Boards will need to hear from staff to determine how they may become more proactive. She directed staff to prepare an issue paper on current laws and their enforcement, as well as how patients are being misled and what can be done to better educate the public.

Dr. Moran adjourned the meeting at approximately 12:30 p.m.