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

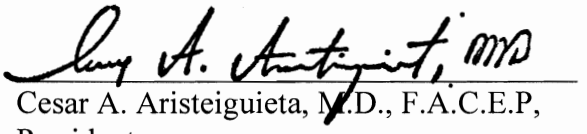
In the Matter of the Accusation Against:	)	
	)	OAH No. N2002050521
	)	
JOSEPH F. BASILE, M.D.	)	MBC Case No. 03-2000-108170
	)	
Physician's and Surgeon's	)	PRECEDENTIAL DECISION
Certificate No. G 74601	)	No. MBC-2007-01-Q
	)	
Respondent.	)	
	)	

DESIGNATION AS A PRECEDENTIAL DECISION

Pursuant to Government Code section 11425.60 and Title 16 CCR 1364.40, the Division of Medical Quality, Medical Board of California, hereby designates as precedential Decision No. MBC-2007-01-Q those sections listed below of the decision in the Matter of the Accusation Against Joseph F. Basile, M.D.

1) Factual Findings 1 and 2; the first sentence of Factual Finding 3; Factual Findings 4 and 5; and Factual Finding 6 except for the last two sentences.; and
2) Legal Conclusions 1 through 5.

This precedential designation shall be effective July 27, 2007.



Cesar A. Aristeiguieta, M.D., F.A.C.E.P,
President
Division of Medical Quality
Medical Board of California

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

In the Matter of the Accusation Against: JOSEPH F. BASILE, M.D. 130 Coffee Road, Suite 7 Modesto, California 95355 Physician and Surgeon's Certificate No. G 74601 Respondent.	Case No. 03-2000-108170 OAH No. N2002050521

PROPOSED DECISION

This matter was heard before Administrative Law Judge Jonathan Lew, State of California, Office of Administrative Hearings on May 24 through 27, and June 16, 2004, in Oakland, California.

Jose R. Guerrero, Deputy Attorney General, represented complainant.

Robert B. Zaro, Esq., represented Joseph F. Basile, M.D., who was present.

The case was submitted for decision on June 16, 2004.

FACTUAL FINDINGS

1. Complainant Ronald Joseph was formerly the Executive Director of the Medical Board of California (Board). The Accusation and First and Second Amended Accusations were issued by him in his official capacity.

2. On July 9, 1992, the Board issued Joseph F. Basile, M.D. (respondent) Physician and Surgeon's Certificate No. G 74601. The certificate was current at all times pertinent to this matter. It was due to expire on May 31, 2004, if not renewed. There has been no prior disciplinary action taken against this certificate.

3. The allegations against respondent arise from his involvement in and operation of a medical office called "The Vein & Cosmetic Enhancement Center" (VCEC).

* * * * * * *

4. Professional Background. Respondent attended Georgetown University School of Medicine, graduating in 1987. He completed a portion of his residency at Georgetown University before transferring to St. Francis Hospital, affiliated with the University of Connecticut. Respondent became board certified in general surgery in April 1996. Between 1992 and 1999 he was on the medical staff of Salinas Surgery Center in Salinas, California. He also associated with the Monterey Peninsula Surgery Center. He describes his work in Salinas as a "bread and butter general surgery practice" involving hernia repairs, gall bladder, blunt trauma, cancers of all sorts and gastrointestinal surgery. Respondent also served as the medical director of VCEC, a business wholly owned by his wife, Vina Basile. She is neither a physician nor a nurse and she holds no other health profession licenses. VCEC was located in Carmel. Respondent relocated his medical practice to Modesto, where he worked for a short time with the Stanislaus County Health Services Agency. Vina Basile remained behind and continued to work in the Carmel VCEC office for a period before that office was closed in March 2001. VCEC moved to Modesto and respondent continued there in his position as its medical director.

5. PhotoDerm Vasculight Machine. Much of this case revolves around the use of a medical device known as a PhotoDerm Vasculight machine. In 1998, respondent became interested in new equipment that could be used for certain cosmetic procedures in a medical office setting. He leased a PhotoDerm Vasculight machine from a company called ESC Medical Systems, and this machine was delivered to his Salinas office in September or October 1998. The PhotoDerm Vasculight machine was designed for the treatment/removal of pigmented lesions, varicose veins, spider veins, reticular veins, age spots and hair. It works on the principle of light selectively being absorbed into pigment and then being converted into heat energy. The heat induces photocoagulation of blood vessels, a mild thermal destruction, without actually bursting the vessels. The body apparently repairs this damage and absorbs the damaged vein. This process causes the vein or cosmetic blemishes to fade. The concept and technology were developed and tested through the early 1990s, and approved by the Food and Drug Administration in early 1994. It is viewed as a relatively safe and non-invasive alternative to previous modes of removing blemishes. For example, one alternative, sclerotherapy, requires injection of an irritating solution to destroy the inner lining of veins, causing clotting and spasm. The new technology eliminated the need for sclerotherapy for most patients.

There are other light emitting devices on the market similar to the one manufactured by ESC Medical Systems. However, the PhotoDerm Vasculight machine is unique in that it combines two light components into a single unit. The PhotoDerm component emits intense pulse light (IPL) through a hand piece, 5 to 15 mm wide. Filters are used to vary the wavelength of light emitted and this will affect the degree of skin penetration. For example, shorter wavelengths (550 nanometers (nm)) will penetrate 1 – 2 mm, and longer wavelengths (near the infrared spectrum) will penetrate 4 – 6 mm. The amount or dose of light delivered per surface unit area is called fluence, and it is measured in joules per square centimeter (J/cm^2). The duration and number of pulses can also be varied. The operator may input these several parameters into a computer software program that allows for individualized settings. Patients are typically categorized according to a Fitzpatrick skin type scale that

incorporates their responses to a questionnaire on genetic disposition, reaction to sun exposure and tanning habits. The resulting Fitzpatrick scaled score (Skin Types I – VI) will guide the operator in making appropriate settings. The PhotoDerm or IPL component is particularly effective for treating the small varicose and "spider veins."

The second component (Vasculight) is essentially a laser. It is a single very long wavelength (1064 nm) of light amplified by reflecting mirrors. The beam from the laser hand piece is relatively small (4 mm circle) and because it emits a stronger and more coherent light beam it can be used effectively to treat larger veins. The Photoderm Vasculight machine operator can alternate between IPL or laser settings. The machine itself can also provide the operator with recommended settings based on the patient's skin type and the type of lesion (small, medium or deep) that is being treated. The operator may accept these settings or enter different ones. When the treatment is completed, information about each patient's treatment is stored in the machine's computer and can be retrieved later and printed at any time. These records contain patient identifying information, skin type, date and site of treatment, and the settings/figures for wavelength, fluence, pulse duration and number. The operator can also type narrative information under sections describing "Immediate response" and "Note."

6. Respondent and Vina Basile both received training on the operation and use of the PhotoDerm Vasculight from the manufacturer. Both operated the machine. Vina Basile was VCEC's only officer and sole shareholder. Respondent was a non-salaried employee of VCEC. His duties as the corporation's medical director were to obtain patient histories, conduct physical examinations and determine whether individuals were viable candidates for cosmetic procedures. After obtaining the patient's Fitzpatrick skin typing he would determine the appropriate IPL or laser settings for patients. Respondent also had sole responsibility for preparing and submitting patient medical evaluations and for setting fees. There were times when Vina Basile used the machine on patients without respondent also being present.

* * * * * * *

LEGAL CONCLUSIONS

Unlicensed Medical Practice

1. Respondent is charged with aiding and/or abetting the unlicensed practice of medicine. The primary issue is whether unlicensed individuals can administer IPL or laser treatments to patients.

The scope of medical practice is defined by statute. It cannot be expanded by consideration of practitioners' knowledge, skill, experience or what is taught to practitioners in schools and colleges. (See *People v. Mangiagli* (1950) 97 Cal.App.2d Supp. 935, 939; *Crees v. California State Board of Medical Examiners* (1963) 213 Cal.App.2d 195, 204;

Magit v. Board of Medical Examiners (1961) 57 Cal.2d 74, 85.) Neither can the scope of medical practice be determined by the practices which have developed in the medical profession and are allegedly common. (*Crees v. California State Board of Medical Examiners*, *supra*, 213 Cal.App.2d at pp. 207-208; *Magit v. Board of Medical Examiners*, *supra*, 57 Cal.2d at pp. 85-86.) The custom and practice of a particular industry or profession is not controlling in determining the intent of the legislature. (*Jacobsen v. Board of Chiropractic Examiners* (1959) 169 Cal.App.2d 389, 395; *Bendix Forest Products Corp. v. Division of Occupational Safety and Health* (1979) 25 Cal.3d 465, 471.) Thus, statutory interpretation is purely a question of law.

The fundamental rule of statutory construction is that a court should ascertain the intent of the legislature so as to effectuate the purpose of the law. (*T.M. Cobb Co. v. Superior Court* (1984) 36 cal.3d 273, 277.) Reference is first made to the words of the statute. They are to be construed in context of the nature and obvious purpose of the statute where they appear. An attempt is to be made to give effect to the usual and ordinary import of the language and to avoid making any language mere surplusage. (*Palos Verdes Faculty Assn. v. Palos Verdes Peninsula Unified School District* (1978) 21 Cal.3d 650, 658-659.) Ordinarily, if the statutory language is clear and unambiguous, there is no need for judicial construction. (*California School Employees Assn. v. Governing Board* (1994) 8 Cal.4th 333, 340.)

2. The relevant statute in this case is Business and Professions Code section 2052, subdivision (a), which provides as follows:

> …[A]ny person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person, without having at the time of doing a valid, unrevoked, or unsuspended certificate as provided in this chapter or without being authorized to perform the act pursuant to a certificate obtained in accordance with some other provision of law is guilty of a public offense, …

Companion section 2051 of the Business and Professions Code authorizes a physician certificate holder "to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions."

It is clear that the legislature intended to allow only those holding certain certificates to treat blemishes, or other physical conditions. (Bus. & Prof. Code, § 2052, subd. (a).) It is also clear that included within the scope of medical practice is the physician's authority "to penetrate the tissues of human beings and to use any and all other methods" in the treatment of physical conditions. (Bus. & Prof. Code, § 2051.) IPL and laser treatment fall within the

ambit of these statutes. These medical devices are designed to treat blemishes or physical conditions involving the veins and skin. Human tissue is penetrated anywhere from 1 to 6 mm depending upon the machine setting. And such tissue penetration is not without attendant risks. The informed consent form warned the patient of the possibility of rare side effects such as scarring and permanent discoloration, as well as short term effects such as reddening, mild burning, temporary unsightly bruising, and temporary discoloration of skin. These negative outcomes were confirmed by medical expert John Stuart Nelson, M.D., and also by the experience of patient S.S. In short, the use of IPL and laser clearly involves penetration of human tissue and therefore falls within the scope of medical practice.

3. Respondent agrees that Business and Professions Code section 2052 is the governing statute. He contends rather that medical "practice" is a term of art and that unlicensed medical assistants are permitted to provide adjunctive and technical supportive services to physicians under authority of Business and Professions Code section 2069. Subdivision (a)(1) of Business and Professions Code section 2069 provides: "Notwithstanding any other provision of law, a medical assistant may administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical supportive services upon the specific authorization and supervision of a licensed physician and surgeon or a licensed podiatrist." "Specific authorization" means a specific written order prepared by the supervising physician authorizing the procedures to be performed and placed in the patient's medical record. (Bus. & Prof. Code, § 2069, subd. (b)(2).) "Supervision" must be by one "who shall be physically present in the treatment facility during the performance of those procedures." (Bus. & Prof. Code, § 2069, subd. (b)(3).) "Technical supportive services" is defined as "simple routine medical tasks and procedures that may be safely performed by a medical assistant who has limited training and who functions under the supervision of a license physician and surgeon…." (Bus. & Prof. Code, § 2069, subd. (b)(4).) Regulations set forth specific technical supportive services that can be performed by medical assistants, including administration of medications orally, sublingually, topically, vaginally or rectally; performing electrocardiogram, electroencephalogram or plethysmography tests; application and removal of bandages and dressings and certain orthopedic appliances; removal of sutures or staples from superficial incisions or lacerations, performing ear lavage; and collection by non-invasive techniques specimens for testing. (Cal. Code Regs., tit. 16, § 1366, subd. (b).)

Respondent notes that medical assistants are allowed by law to perform procedures at least as invasive as IPL or laser treatments, including administration of medication by intramuscular injections. He contends that medical assistants who are merely providing adjunctive services to a physician's medical practice and who are not practicing a particular profession – that is to say, they are not independently exercising discretion and specialized training to prescribe and implement a course of action – are not practicing medicine. (*PM & R Associates v. Workers Comp. Appeals Bd.* (2000) 80 Cal.App.4th 357.) Respondent believes Vina Basile's administration of IPL and laser treatment should be viewed in this same light.

4. Business and Professions Code section 2069 carefully limits the type of, and manner by which medical assistants perform certain procedures. In all cases the procedures must be performed while certain approved supervisors are physically present in the treatment facility. Respondent was not always physically present when Vina Basile administered IPL and laser treatments to patients. The tasks performed by medical assistants are to be "simple routine medical tasks and medical procedures" that may be performed by one who has limited training. In some respects, Vina Basile performed in a strictly adjunctive capacity to respondent. Respondent, and not Vina Basile, was responsible for making overall treatment decisions. For example, it was respondent who obtained patient histories, performed physical examinations, determined whether patients were appropriate candidates for treatment and who determined appropriate machine settings. Vina Basile exercised no independent discretion and she had not authority in these areas. Yet it was Vina Basile who was 100 percent shareholder and sole corporate officer for VCEC. It was her business. Importantly, the treatment was not ancillary to respondent's workup or diagnosis of a patient's condition. Instead, it was the primary treatment mode sought by patients seeking removal of unsightly varicose veins or other cosmetic blemishes. In that regard it differs from most, if not all, of the "technical supportive services" routinely performed by medical assistants. (Cal. Code Regs., tit. 16, § 1366, subd. (b).) When Vina Basile provided IPL/laser treatment to patients, particularly when respondent was absent from the facility, she was not performing adjunctive services for respondent. She engaged in the unlicensed practice of medicine.

Respondent points out that intradermal, subcutaneous or intramuscular injections performed by medical assistants involve more penetration of human tissue than IPL or laser. However, these are limited exceptions, set forth in statute, to the general rule limiting those who are authorized to penetrate tissue for medical purposes. And even before medical assistants can perform intramuscular, subcutaneous and intradermal injections, or venipuncture for the purposes of withdrawing blood, they are required to complete minimum training (10 hours for each of the different procedures) and to demonstrate proficiency to their supervising physicians. (Cal. Code Regs., tit. 16, § 1366.1.) No such regulations are in place to ensure that medical assistants operating IPL/laser machines are adequately trained. The training received by Vina Basile from ESC Medical Systems may have been adequate, but it is irrelevant to the question of whether there is a legislative intent to include procedures such as IPL/laser within the definition of "technical supportive services" that can be performed by medical assistants. That simply does not appear to be the case at this time. Absent further legislative authority and/or regulatory action, medical assistants cannot legally perform IPL/laser treatments on patients.

5. Respondent aided and/or abetted the unlicensed practice of medicine by allowing Vina Basile to use the IPL/laser to treat patients. Business and Professions Code section 2264 provides: "The employing, directly or indirectly, the aiding, or the abetting of any unlicensed person … to engage in the practice of medicine or any other mode of treating the sick or afflicted which requires a license to practice constitutes unprofessional conduct." A violation of section 2264 does not require a showing of either knowledge or intent on the part of the practitioner. (*Khan v. Medical Board* (1993) 12 Cal.App.4th 1834, 1844-1845.) The

objective of section 2264 is the protection of the public from certain forms of treatment by unlicensed and presumably unqualified persons. (*Newhouse v. Board of Osteopathic Examiners* (1958) 159 Cal.App.2d 728, 734.)

For these reasons, cause for disciplinary actions exists under Business and Professions Code section 2264. Respondent engaged in unprofessional conduct by aiding and/or abetting the unlicensed practice of medicine by Vina Basile.

* * * * * * *

DATED: July 16, 2004

JONATHAN LEW
Administrative Law Judge
Office of Administrative Hearings