

STATE OF FLORIDA
BOARD OF MEDICINE

IN RE: PETITION FOR DECLARATORY STATEMENT OF
JACK DAUBERT, M.D., F.A.C.S.

FINAL ORDER

This matter came before the Board of Medicine (hereinafter the Board) on June 7, 2013, in Tampa, Florida, for consideration of the above-referenced Petition for Declaratory Statement. The Notice of Petition for Declaratory Statement was published on May 7, 2013, in Vol. 39, No. 89, in the Florida Administrative Register. Petitioner made a personal appearance before the Board and was represented by Alexis Gilroy Esq., who appeared on behalf of the Petitioner as his qualified representative.

Dr. Daubert, a Florida licensed physician and ophthalmologist, inquires as to whether his proposed usage of technology to conduct remote eye exams to increase access to refractions and eye exams for Florida residents would be in compliance with Section 458.3485, Florida Statutes, Rule 64B8-9.014, Florida Administrative Code, and Rule 64B8-9.003, Florida Administrative Code.

FINDINGS OF FACTS

1. The facts set forth in Petitioner Daubert's petition and attachments are hereby adopted and incorporated herein by reference as the findings of fact by the Board.

CONCLUSIONS OF LAW

1. The Board of Medicine has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

2. The Petition filed in this cause is in substantial compliance with the provisions of 120.565, Florida Statutes, and Rule 28-105.002, Florida Administrative Code.

3. Section 120.565, Florida Statutes, reads as follows:

120.565. Declaratory statement by agencies

(1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3) The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Weekly and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action

4. Rule 28-105.001, Florida Administrative Code, reads as follows:

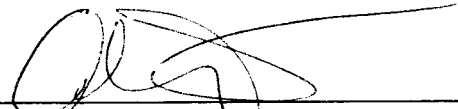
A declaratory statement is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority. A petition for declaratory statement may be used only to resolve questions or doubts as to how the statutes, rules, or orders may apply to the petitioner's particular circumstances. A declaratory statement is not the appropriate means for determining the conduct of another person or for obtaining a policy statement of general applicability from an agency.

5. The Board declines to issue a declaratory statement in response to Dr. Daubert's petition on the basis that the Board was presented with insufficient information to make an informed determination.

6. The issuance of this order does not preclude the Petitioner from filing an amended or new petition providing additional or more detailed data and information.

DONE AND ORDERED this 12th day of August, 2013.

BOARD OF MEDICINE



Allison M. Dudley, J.D., Executive Director
For Zachariah P. Zachariah, M.D., Chair

NOTICE OF APPEAL RIGHTS

Pursuant to Section 120.569, Florida Statutes, Respondents are hereby notified that they may appeal this Final Order by filing one copy of a notice of appeal with the Clerk of the Department of Health and the filing fee and one copy of a notice of appeal with the District Court of Appeal within 30 days of the date this Final Order is filed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail to: Jack Daubert, M.D., 1050 SE Monterey Road, Suite 104, Stuart, Florida 34994; by email to: Edward A. Tellechea, Chief Assistant Attorney General, PL-01 The Capitol, Tallahassee, Florida 3239-1050, ed.tellechea@myfloridalegal.com; Jennifer Tschetter, General Counsel, Department of Health, 4052 Bald Cypress Way, BIN A02, Tallahassee, Florida 32399-1703, Jennifer_Tschetter@doh.state.fl.us; and Alexis Gilroy, Esq., Nelson Mullins Riley & Scarborough LLP, 101 Constitution Avenue, NW, Suite 900, Washington, DC, 20001, Alexis.Gilroy@nelsonmullins.com on this 13th day of August, 2013.

Angel Sanders

Deputy Agency Clerk

7012 3050 0002 3881 5001

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK

CLERK *Angel Sanders*
DATE MAY 06 2013

PETITION FOR DECLARATORY STATEMENT
BEFORE FLORIDA DEPARTMENT OF HEALTH BOARD OF MEDICINE

April 22, 2013

VIA OVERNIGHT CARRIER

Florida Department of Health
Office of Agency Clerk
ATTN: Crystal Sanford
4052 Bald Cypress Way
Bin# A02
Tallahassee, FL 32399-1703

**IN RE: PETITION FOR DECLARATORY STATEMENT
OF JACK DAUBERT, M.D., F.A.C.S.**

1. Petitioner Jack Daubert, M.D., F.A.C.S., a Florida-licensed ophthalmologist with an address of 1050 SE Monterey Rd. Suite 104, Stuart, FL 34994, (772) 283-2020 (telephone), plans, as a method of increasing access to refractions and eye exams for Florida residents, to perform examinations (A) from a location remote to an eye patient located in Florida, (B) using automated refraction and eye imaging technology operated by a technician specially trained in the use of the automated technology (each an "Automated Technology Technician"), (C) deployed in a real-time (synchronous) manner, while the eye patient located in Florida receives on-site disclosures, consent materials, and general assistance from an attendant trained in the use of the automated technology (the "Remote Exams").
2. The Petitioner is assisted in the preparation of this Petition for Declaratory Statement by Nelson Mullins Riley & Scarborough LLP, ATTN: Alexis Slagle Gilroy, 101 Constitution Ave, NW, Suite 900, Washington, DC 20001, (202) 712-2893 (telephone), (202) 712-2849 (facsimile). Kindly copy Ms. Gilroy on all correspondence related to this Petition for Declaratory Statement.
3. Petitioner seeks a declaratory statement from the Florida Department of Health, Board of Medicine, with regard to Section 458.3485 of the Florida Statutes and Section 64B8-9.014 of the Florida Administrative Code, as they pertain to the proposed Remote Exams. The term "Petitioner," as used below to describe the Remote Exams includes Petitioner, Jack Daubert, M.D., F.A.C.S., individually, and/or, as applicable, Petitioner's employed or contracted ophthalmologists working in collaboration with or at the direction of Petitioner regarding the Remote Exams.
4. Petitioner intends to conduct the Remote Exams using technology specially designed for refractions and eye health examinations, including (1) for the refraction portion of the Remote Exam, an automated objective and subjective refraction technology developed by Eyelogic System, Inc. and (2) as to the eye health evaluation, applicable FDA-approved instruments such as Optovue's anterior and posterior ocular coherence tomography instruments paired with fundus photography for the real-time capture of digital images.

5. Each Remote Exam will include a vision test to determine optical or refractive eye aberrations for evaluating the refraction error of the eye and to provide for a prescription (power formula specifications) of refractive lenses, as applicable, to adjust for the refractive error given applicable results. As requested by the patient, certain Remote Exams would also involve a non-invasive (e.g. no use of eye drops) comprehensive eye health exam whereby state of the art auto-focus, auto-tracking, auto-imaging and other FDA approved technology and instruments are used to test eye tissue health, intraocular pressure, depth perception, color vision, pupil reflexes, muscle balance, and visual fields of the patient's eyes. The results of all tests will be transmitted instantaneously to Petitioner for immediate review. The patient then receives the results of the assessments in real-time.
6. Petitioner plans to implement the Remote Exams by placing equipment for conducting the Remote Exams, in a separately designated and exclusive exam area, within other health care and medical related facilities such as optical dispensaries, primary care offices, and ophthalmology practices. The exam area will contain the equipment described above for the Remote Exams and will include real-time audio and video technology enabling simultaneous connection with the Petitioner and the Automated Technology Technicians.
7. The exam room will be attended by an onsite attendant trained and supervised by Petitioner in the use, function, and patient care practices related to the Remote Exams. Such on-site attendant will obtain signed forms such as HIPAA authorizations and informed patient consents for inclusion in the medical chart of the patient, direct the patient to the equipment and clean the equipment after each use.
8. Upon entering the exam room, the patient will view an instructional and informational video developed by Petitioner explaining the Remote Exams, including the risks and benefits of such exams and related prescriptions for refractive lenses. This video will be pre-recorded by Petitioner.
9. Following the video, the patient will be greeted by the Automated Technology Technician via real-time audio and video technology in order to obtain appropriate patient history data and guide and instruct the patient through the Remote Exam. The video and audio in the exam room will be transmitted between the patient and the Automated Technology Technician through synchronous video and audio feed. In the event that the Remote Exam also involves a comprehensive eye health exam, the captured measurements and images will be transmitted and reviewed in real-time by Petitioner. The results of that assessment (i.e. whether the eyes are healthy, clear and normal or require further evaluation by an in-person ophthalmologist or other professional) will be conveyed to the patient via pre-recorded real-time audio and video messages from Petitioner. In the event a patient has any questions or other concerns to address with Petitioner, at any time, before, during, and after the Remote Exam, the Petitioner will be made available for a live, synchronous, audio and/or video conversation.
10. The Petitioner intends to maintain an office in the State of Florida that will house the Automated Technology Technicians, as well as a call center to facilitate the performance of the Remote Exams, thus the Petitioner and the Automated Technology Technicians will be physically located in the same facility (the "Petitioner Location"). As such, Petitioner will provide real-time direct supervision of the Automated Technology Technicians during the performance of each Remote Exam.
11. Petitioner will only issue prescriptions for refractive lenses, as needed, based on the results of the Remote Exam. Petitioner would not dispense or fit eyeglasses or contact lenses. No prescriptions would be issued for any treatments, legend drugs or devices based on the eye health portion of the Remote Exam. Should the eye health portion of the Remote Exam result in a finding that is adverse for the patient, the Petitioner will refer such patient to the applicable local ophthalmologist, primary care physician or other local physician of their choice for further evaluation.

12. Under F.S. §458.3485, medical assistants may perform certain duties under the direct supervision of a licensed physician, including, for example, assisting with patient care management, executing administrative and clinical procedures, and performing managerial and supervisory functions. Direct supervision is defined as requiring "the physical presence of the supervising licensee on the premises so that the supervising licensee is reasonably available as needed ..." See, Florida Administrative Code §64B8-2.001. Petitioner believes that the proposed model for the Remote Exams meets the direct supervision requirement because all of the functions performed by the Automated Technology Technician will be taken under the direct supervision of Petitioner while the Automated Technology Technician is located on the same premises as Petitioner.

13. Because the attendant on-site with the patient undergoing the Remote Exam will not be a licensee and will not act as a medical assistant, Petitioner believes that such individual would not be subject to the "direct supervision" of Petitioner. Notwithstanding, Petitioner will provide a general level of supervision as Petitioner will be available via real-time technology to answer any questions that the on-site attendant may have and to direct the duties and tasks performed by the on-site attendant, as necessary.

14. The Florida Department of Health has issued standards for prescribing in connection with the provision of remote care (telemedicine), but no specific guidelines or standards for the general use of technology in connection with the remote provision of healthcare services. See, Florida Administrative Code §64B8-9.014(2). The subject guidance only appears to contemplate the prescribing of legend drugs via electronic means, which Petitioner believes to be inapplicable to the proposed activities conducted in connection with the Remote Exams. Notwithstanding, contemporaneous with the performance of the Remote Exams, Petitioner plans to ensure that: (1) a documented patient evaluation, including history and physical examination necessary for the Remote Exam will be performed by the Automated Technology Technician under the direct supervision of the Petitioner, (2) Petitioner will be available for direct patient questions at all times throughout the Remote Exam; and (3) contemporaneous medical records are maintained in compliance with 64B8-9.003 F.A.C. Further, Petitioner expects that the equipment for the performance of the Remote Exams will be proximately located within other healthcare facilities such as optical dispensaries, primary care offices, and ophthalmology practices to provide overall ease of access to additional on-site professionals and licensees as needed.

15. Petitioner believes that the proposed Remote Exams are appropriately and narrowly structured to comply with applicable Florida laws and regulations. Given the innovative and novel use of technology to provide access to refractive and eye health examinations, Petitioner seeks the guidance of the Board of Medicine in connection with the implementation of the proposed business model.

16. Petitioner would be happy to further discuss or make available a demonstration of the proposed Remote Exams to the Board of Medicine at its next available meeting should the Board so desire. A copy of Petitioner's Curriculum Vitae is also attached for the Board's reference.

PETITIONER



Jack Dauber, M.D., F.A.C.S.

Jack Steven Daubert, M.D., F.A.C.S.

Curriculum Vitae



Medical Offices

1050 SE Monterey Rd. Suite 104 Stuart, FL 34994 (772) 283-2020	550 Heritage Drive Suite 105 Jupiter, FL 33458 (561) 839-2780	1515 N. Flagler Drive Suite 500 West Palm Beach, FL 33401 (561) 659-9700	1715 SE Tiffany Ave. Port St, Lucie FL 33458 (561) 839-2780
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Board Certifications

July 1991	Diplomat, American Board of Ophthalmology
July 1986	Diplomat, National Board of Medical Examiners

Education

1981 – 1985	Jefferson Medical College Philadelphia, PA Degree: M.D.
1977 – 1981	Pennsylvania State University, Pennsylvania Graduate: Summa Cum Laude Phi Beta Kappa Degree: Bachelor of Science

Post Doctoral Training

1991 – 1992	Vitreo-Retinal Fellow Retina Associates Boston, Massachusetts	1985 – 1986	Surgical Internship Washington Hospital Center Washington, D.C.
1986 – 1989	Ophthalmology Residency Washington Hospital Center Washington National Eye Center Washington, D.C.	1989 – 1990	Palm Beach Eye Clinic 130 Butler Street West Palm Beach, FL
1988 – 1989	Chief Ophthalmology Resident Washington Hospital Center Washington National Eye Center Washington, D.C.	1992 – Present	Florida Vision Institute Self-employed

Awards and Honors

- 2012 Top Doctor Award – Castle Connolly Medical, Ltd.
2011 Top Doctor Award – Castle Connolly Medical, Ltd.
2010 Top Doctor Award – Castle Connolly Medical, Ltd.
2009 Top Doctor Award – Castle Connolly Medical, Ltd.
2008 Top Doctor Award – Castle Connolly Medical, Ltd.
2007 Top Doctor Award – Castle Connolly Medical, Ltd.
1989 Davis Cup Recipient for outstanding Scientific Research & Presentation
Washington National Eye Center
1988 Davis Cup Recipient for outstanding Scientific Research and Presentation
Washington National Eye Center
+ Muller Memorial Award in Ophthalmology + Phi Beta Kappa
+ Graduated Summa Cum Laude + Who's Who Among Students in American Universities?

Professional Membership

Fellow American Academy of Ophthalmology
Fellow American College of Surgeons
American College of Surgeons
Florida Society of Ophthalmology
Florida Medical Society
Palm Beach Ophthalmology Society
Palm Beach Medical Society
American Society of Cataract & Refractive Surgery

Medical Licensure

Florida
Pennsylvania

Appointments

Attending Staff Good Samaritan Hospital
West Palm Beach, FL.
Attending Staff Martin Memorial Medical Center
Stuart, FL.
Attending Staff Palm Beach Gardens Medical Center
Palm Beach Gardens, FL.
Attending Staff Jupiter Medical Center
Jupiter, FL.

Publications and Original Reports

Daubert, J; E1-choufi, L; Stephens, R:
Laser Treatment of Subfoveal Choroidal
Neovascular Membranes
Ophthalmic Surgery 1991; 22: 665-669

Stephens, R; Daubert, J; E1-choufi, L:
Visual Improvement after Four Laser Treatments
To Foveola for Choroidal Neovascular Membrane
Ophthalmic Surgery 1991; 22: 470-474

Daubert, J; Nik, N; Chandeyssoun, PA; E1-choufi, L:
Tear Flow Analysis Through the Upper and Lower Systems
Ophthalmic Plastic Reconstructive Surgery 1990; 6(3): 193-196

Daubert, J; Bernanrdino, V
Conjunctival Nev, Review of 350 cases
Wills Eye Hospital 1985

Clinical Trials

- 2009/10 Sub-Investigator, Genentech, FVF4168g, A Phase III, Double-Masked, Multi-Center, Randomized, Sham-Controlled Study of the Efficacy and Safety of Ranibizumab Injection in Subjects with Clinically Significant Macular Edema with Center Involvement Secondary to Diabetes Mellitus
- 2009/10 Sub-Investigator, Regeneron Pharmaceuticals, Study VGFT-OD-0605 Version VGFT-OD-0605.1 A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of repeated Doses of Intravitreal VEGF Trap in Subjects with Neovascular Age-Related Macular Degeneration.
- 2008/09 Sub-Investigator, Genentech, FVF4165g, A Phase III, Double-Masked, Multi-Center, Randomized, Sham-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared with Sham in Subjects with Macular Edema Secondary to Branch Retinal Vein Occlusion.
- 2008/09 Sub-Investigator, Genentech, FVF4166g, A Phase III, Double-Masked, Multi-Center, Randomized, Sham-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared with Sham in Subjects with Macular Edema Secondary to Central Retinal Vein Occlusion.
- 2008 Sub-Investigator, Allergan Protocol 206207-016: A 6-Month, Single-Masked, Multicenter, Randomized, Controlled Study to Assess the Safety and Efficacy of 700 µg Dexamethasone Posterior Segment Drug Delivery System Applicator System as Adjunctive Therapy to Lucentis[®] Compared with Lucentis[®] Alone in the Treatment of Patients with Choroidal Neovascularization.