ORDER OF EMERGENCY RESTRICTION OF LICENSE

Douglas M. Cook, Director of the Agency for Health Care Administration, hereby orders the Emergency Restriction of the license to practice medicine of Richard Clair Davis, Jr., M.D. (hereinafter referred to as "Dr. Davis"). Dr. Davis holds license number ME 0041203 and his last known address is 4820 Longwater Way, Tampa, Florida 33615. The Emergency Restriction of Dr. Davis' license to practice medicine is supported by the following Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. Effective July 1, 1997, the Department of Health is the state agency charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes (1997) and Chapters 455 and 458, Florida Statutes (1997).

2. Section 455.621(8), Florida Statutes (1997), empowers the Secretary of the Department of Health (hereinafter referred to as "the Department") to summarily restrict Dr. Davis' license to practice as a physician in the State of Florida, in accordance with Section 120.60(6), Florida Statutes (1997).

3. Pursuant to the authority of Section 20.43(3)(g), Florida Statutes (1997), the Department has contracted with the Agency for Health Care Administration (hereinafter referred to as "the Agency") to provide consumer complaint, investigative, and prosecutorial services
required by the Division of Medical Quality Assurance, councils, or boards, as appropriate, including the issuance of emergency orders of suspension or restriction.

4. Dr. Davis is and has been at all times pertinent to this Order a duly licensed physician, licensed pursuant to Chapter 458, Florida Statutes.

5. Dr. Davis' medical background is in emergency medicine. He is not board certified in any specialty. Dr. Davis is the President and Chief Executive Officer of Rheotherapy Centers of Tampa Bay.

6. Age-related Macular Degeneration (AMD) is a disease wherein pathologic changes of the macula result in a loss or reduction in central vision. The vision of patients is characterized by spots of pigmentation, a moth-eaten appearance, or other alterations in central vision. AMD is a leading cause of vision loss in the elderly and is generally considered incurable. Laser coagulation is the only treatment proven to be effective in slowing the progression of the disease.

7. "Apheresis," also known as "pheresis," is a procedure involving the removal from a donor's blood of one or more of its components, followed by a return of the remainder to the donor.

8. On or about July 14, 1997, Dr. Davis disseminated or caused to be disseminated an advertisement letter from "RheoTherapy Centers of Tampa Bay." The advertisement began with the following announcement: "ANNOUNCING: A Breakthrough for Macular Degeneration!" The advertisement describes a "revolutionary new Therapeutic Apheresis modality used in the management of Age-related Macular Degeneration." Additional claims made in the advertisement include a description of the treatment as "a safe and effective treatment alternative, where before,
few options were available and little hope existed," and that "[a]lthough less than 400 maculopathy patients have undergone RheoTherapy, long-term follow-up results are encouraging and have repeatedly and consistently demonstrated the safety and effectiveness of RheoTherapy in the management of AMD and other perfusion-related ophthalmologic diseases."

9. Additional advertisements make further claims regarding the use of RheoTherapy. These include: the description of RheoTherapy as "a new blood filtration and purification process for patients with Age-Related Macular Degeneration," and that Rheotherapy removes "toxic proteins and fatty substances," thereby allowing for increased blood flow, "especially into the part of the eye called the macula." The advertisements state further, "[a]s oxygen and nutrient delivery is restored by this fresh blood flow, living cells which have been dormant or deteriorating revive, beginning the healing process. If enough cells are revived in the macula, patients notice this revival as improved vision."

10. Readers are advised that most patients will require 7 to 10 treatments at a cost of between $1800 and $2200 per treatment, and that a "booster treatment" may be needed every 6 to 10 months "to maintain the best therapeutic results."

11. Dr. Davis has also disseminated or caused to be disseminated a videotape which states in part that Rheotherapy has been shown to be effective in the "vast majority" of patients with Macular Degeneration who have undergone the treatment.

12. On or about September 11, 1997, the Agency began an investigation regarding the claims made in Dr. Davis' advertising and notified Dr. Davis.
13. Shortly after the Agency investigation began, Dr. Davis added or caused the addition of the following to the aforementioned advertisements for Rheotherapy:

> PLEASE BE ADVISED THAT ALTHOUGH THERAPEUTIC APHARESIS HAS BEEN AN ACCEPTED AND PROVEN MEDICAL THERAPY FOR VARIOUS DISEASES FOR MANY DECADES, RHEOTHERAPY (OUR PROPRIETARY FORM OF THERAPEUTIC APHARESIS) IS STILL CONSIDERED "EXPERIMENTAL" IN THE UNITED STATES FOR THE TREATMENT OF AMD.

14. Dr. Davis further advises patients that, because it is an experimental procedure, no third party payment is available to reimburse patients for the treatments.

15. Dr. Davis asserts that Rheotherapy has been demonstrated to be successful in the treatment of AMD, citing two separate articles, both written by Richard Brunner, Professor of Ophthalmology, University of Cologne, Germany, with others. Dr. Davis asserts that the evidence produced by this study established the efficacy of Rheotherapy in the treatment of AMD.

16. When asked about additional studies to establish the efficacy of Rheotherapy in AMD patients, Dr. Davis indicates that results of further study at the University of Cologne are pending. He references a study being conducted by Mano Swartz, M.D., at the University of Utah, and indicates that an additional study, the so-called "R-20 study," is examining the results of Rheotherapy in AMD patients treated at his Rheotherapy clinic in Largo.

17. The Utah study being conducted by Dr. Swartz is not designed to determine the efficacy of Rheotherapy in AMD patients, but is being performed pursuant to gaining FDA approval for a new filter, the Rheofilter, for use in therapeutic apheresis. Neither the process nor products being tested in the Swartz study are currently in use at the Rheotherapy Center.
18. Dr. Davis' R-20 study involves 17 patients, 11 or 12 of which have completed their treatments. Dr. Davis identifies Dana Deupree, M.D., as the lead investigator in the R-20 study.

19. An Institutional Review Board (IRB) is a board established in conjunction with an experimental study, most often associated with research funded by federal research grants. The main responsibility of the IRB is to protect the interests of the human subjects involved in the research. The IRB is not generally directly involved in a determination of the efficacy of the device or procedure being studied. No IRB has been established in relation to the R-20 study.

20. An Ophthalmologist is a physician who specializes in the science of the anatomy, physiology, diseases, and treatment of the eye. The Rheotherapy Center employs no Ophthalmologist. Advertisements reflect that the staff includes one physician, a "Board-eligible Nephrologist." A nephrologist is a physician who specializes in the science and the treatment of the diseases of the kidney.

21. As of January 6, 1998, the Center has treated or is treating approximately 50 patients. Of these 50 patients, 17 are enrolled in the R-20 study and are, according to Respondent, monitored through the study. The progress of patients not enrolled in the study, which currently number 33, is not monitored by the Rheotherapy Center. The Rheotherapy Center has no established method for determining these patients' progress, but relies on voluntary feedback from each patient's treating physician.

22. Dr. Davis, acknowledging that standard plasmapheresis filters and machinery are used at the Rheotherapy Center, refuses to divulge the details of the Rheotherapy process as
involving trade secrets. Dr. Davis also refuses to provide the research protocol developed in conjunction with the R-20 study, again indicating that it involves trade secrets.

23. Dr. Davis consulted a nationally known ophthalmologist, J. Donald M. Gass, M.D., at Vanderbilt University Medical Center, regarding the use of Rheotherapy for various eye ailments, including AMD, prior to opening the Rheotherapy Clinic in Largo. Dr. Gass advised him in a letter dated July 30, 1997, that before Rheotherapy could be considered a useful therapy in patients with AMD, further study in a controlled trial is needed. Dr. Gass further opined that until such studies are done, the procedure must be considered experimental with regard to patients with macular degeneration, and that he would be “reluctant to recommend the treatment to patients outside the scope of a controlled trial.”

24. Dr. Gass responded to an Agency inquiry, advising that he has personally corresponded with the authors of the aforementioned German study, specifically Richard Brunner, Professor of Ophthalmology at the University of Cologne, and Randolf A. Widder, M.D. Dr. Gass indicates that he received a letter dated December 4, 1997, in response to inquiries he made regarding the study. Dr. Gass asserts that, “I think it is fair to say that at this stage of our knowledge concerning the use of plasmapheresis for age-related macular degeneration, that it is an experimental therapy that should be used only in the context of a controlled clinical trial.” Dr. Gass further asserts that, “There is no excuse for not first performing a controlled study to determine the effectiveness of Rheotherapy on AMD patients,” and that reliance on the German study to support the use of Rheotherapy is inappropriate.
25. Dr. Davis provided a list of physicians who believe Rheotherapy is a viable treatment for patients who suffer from AMD. Several who were listed did not respond to attempts to elicit their comments regarding Rheotherapy.

26. Dana Deupree, M.D., is a Board Certified Ophthalmologist at St. Lukes Eye Center, Tampa. Dr. Deupree is identified by Dr. Davis as a physician who believes Rheotherapy has been shown to be a viable treatment for patients with AMD and as the lead investigator in the aforementioned R-20 study.

27. Dr. Deupree, during a telephone conversation on January 7, 1998, asserted the following regarding Rheotherapy and its use in patients with AMD:

- Rheotherapy is not proven as a viable treatment in patients with AMD. The current data is not sufficient to demonstrate that patients will improve.

- Rheotherapy has not yet undergone any rigorous studies to determine its efficacy.

- The data from the aforementioned German studies, while encouraging, is "limited."

- Rheotherapy is not a cure for AMD but perhaps can arrest the progression of the disease.

- Dr. Davis is funding the R-20 study.

- The R-20 study utilizes no IRB, has no controls, has no stringent statistical analysis, and should not be considered a "definitive study."

- He is unsure whether all the patients in the R-20 study have AMD.

- He is unsure whether there is any difference between standard plasmapheresis and Rheotherapy.
28. Robert Urban, M.D., is an ophthalmologist named by Dr. Davis as a supporter of Rheotherapy. Dr. Urban denies that he supports Rheotherapy for patients with AMD, advising that he does not believe it has been shown to be a viable treatment. Dr. Urban advises that he has reviewed the German study and finds the data to be "very soft." He advises that he is familiar with the R-20 study because Dr. Davis solicited area eye care specialists to provide patients for the study. Dr. Urban denies recommending the treatment to any patient, but that he did make several aware of Dr. Davis' offer to perform the treatments free of charge, and that one of his patients did enroll. He advises that, in his opinion, Dr. Davis' R-20 study is "not good science."

29. Also named by Dr. Davis as a supporter of Rheotherapy was Dr. A.H. Rodriguez, O.D., an optometrist. Dr. Rodriguez advises that he is not an actively practicing optometrist and has referred no patients for Rheotherapy. He did travel to Germany to meet with researchers there and claimed he was "astonished" at the results. After returning from Germany, he made a small investment in the Rheotherapy Corporation, and indicates he is a current stockholder and board member for the Rheotherapy Corporation.

30. Roy Beck, M.D., Ph.D., is an ophthalmologist and Medical Director of the Jae Center for Health Research, Tampa. Dr. Beck met with Dr. Davis during the summer of 1997 and discussed the possibility of performing a study to determine the efficacy of Rheotherapy in patients with AMD. Dr. Beck reviewed the information supplied by Dr. Davis, including the
aforementioned studies conducted at the University of Cologne in Germany. Dr. Beck informed Dr. Davis that the data was not the least bit convincing, that there was no rationale to believe Rheotherapy would work, and that he would not be interested in conducting any study until additional information supporting its use could be supplied.

31. Dr. Beck asserts that any study utilizing 17 patients with no control group, such as Dr. Davis' R-20 study, would have a "very remote chance" of yielding reliable results.

32. Harvey Klein, M.D., is the Chairman of the Department of Transfusion Medicine at the National Institute of Health, Bethesda, MD. Dr. Klein is familiar with apheresis procedures and their use as treatment for various medical conditions. He is also familiar with the study in Germany and the published data from that study. Dr. Klein is personally acquainted with one of the researchers involved in the study, Helmut Borberg, M.D., and has spoken with Dr. Borberg regarding the study.

33. Dr. Klein states that there is "absolutely no data" to support the contention that any form of apheresis procedure is beneficial in the treatment of AMD. He opined that the use of Rheotherapy in the treatment of AMD is "very much experimental." Dr. Klein asserted that he is aware of no other clinic in the country performing this procedure for the treatment of AMD. He further denied that the procedure is an accepted treatment for AMD in any country.

34. Bruce Lenes, M.D., is the Medical Director for the South Florida Division of the American Red Cross, Miami. He is Board Certified in Internal Medicine and Hematology, is an Associate Professor of Pathology and Medicine at the University of Miami, and has 16 years of experience in blood banking.
35. Dr. Lenes advises that he is very familiar with the process of therapeutic apheresis and its use in treating various ailments. He opines that Rheotherapy, however, is not an established procedure in the treatment of AMD, and that until its efficacy has been demonstrated in a controlled clinical trial, which includes as a component the involvement of an IRB to protect patients involved in the study, it should not be employed as a general therapeutic treatment for AMD.

36. Dr. Lenes asserts that apheresis is not a benign procedure. Complications may arise, including, but not limited to: angina or possible myocardial infarction in patients with pre-existing coronary problems, development of air emboli, cardiac arrhythmia, and bacterial contamination.

37. Philip J. Rosenfeld, M.D., Ph.D., and Mary Lou Lewis, M.D., are Board Certified Ophthalmologists at Bascom Palmer Eye Institute, Miami. Bascom Palmer Eye Institute is a national and international referral center for patients with AMD. Both Dr. Rosenfeld and Dr. Lewis treat patients in clinically approved experimental trials. Dr. Rosenfeld and Dr. Lewis are experts in the area of Ophthalmology and are specialists in the diagnosis and treatment of patients with AMD.

38. At the request of the Agency, Dr. Rosenfeld and Dr. Lewis reviewed the materials contained within the investigative report in this matter, including witness interviews, advertisements, patient testimonials, correspondence, reprints of the aforementioned studies conducted in Cologne, Germany, as well as other information gathered during the investigation.
On January 8, 1998, Dr. Rosenfeld and Dr. Lewis issued a joint opinion to the Agency regarding the practice of Rheotherapy for patients with AMD. That opinion includes the following assertions:

a) Patients should be treated with an experimental unproved method only within the context of an approved clinical study.

b) No well-controlled studies have established that Rheotherapy is beneficial in the treatment of AMD. Further, no studies have established that Rheotherapy is not detrimental to patients. Rheotherapy is an experimental procedure.

c) Rheotherapy is not being offered to patients with AMD within an approved clinical study protocol.

d) The practice of Rheotherapy as a treatment for patients with AMD does not comport with the appropriate standard of care.

e) Respondent's advertisements for Rheotherapy are deceptive and misleading in that the public has been led to believe that studies have shown the treatment to be beneficial when in fact there have been no well controlled studies showing any benefit of Rheotherapy in macular degeneration.

f) Rheotherapy could be a serious threat to the health of the elderly population as the effects of repeated plasmapheresis are unknown and could lead to cardiovascular instability, edema, complications of existing heart or kidney disease, and/or severe protein deficiencies.

g) Rheotherapy is a serious threat to the financial welfare of the elderly population who are most susceptible to being taken advantage of when offered a therapy which claims to slow down their vision loss.
h) The following studies must be performed in order to establish the safety and efficacy of Rheotherapy as a treatment for patients with AMD:

1. A Phase I study to determine the safety of repeated treatments in the elderly.

2. Phase II study must then determine whether Rheotherapy can prevent vision loss in patients with AMD.

3. A Phase III randomized, double-masked, placebo-controlled trial is then necessary to prove that Rheotherapy is better than the current standard of care for patients with AMD.

40. Dr. Davis poses an immediate serious danger to the health, safety, and welfare of the public in that he is currently advertising the procedure known as Rheotherapy as having been clinically proven as an effective treatment in patients who suffer from AMD, when Rheotherapy is an experimental treatment whose safety and effectiveness as a treatment for patients who suffer from AMD has not been established in a controlled clinical study.

41. Dr. Davis poses an immediate serious danger to the health, safety, and welfare of the public in that he is currently performing Rheotherapy as a treatment for AMD when Rheotherapy is an experimental treatment whose safety and effectiveness as a treatment for patients who suffer from AMD has not been established in a controlled clinical study.

42. Dr. Davis poses an immediate serious danger to the health, safety, and welfare of the public in that he is currently advertising Rheotherapy as an effective and proven treatment for patients who suffer from AMD and performing Rheotherapy on patients who suffer from AMD for a fee of between $1800 and $2200 per treatment for a total of up to ten treatments, with an additional treatment every 6 to 10 months, when there is no third party payment available to pay
for Rheotherapy treatment because it is an experimental therapy whose safety and effectiveness as a treatment for patients who suffer from AMD has not been established in a controlled clinical study, and when the AMD patient population, whose treatment options are limited and prognosis poor, is particularly susceptible to Dr. Davis’ claims that Rheotherapy is clinically proven to be an effective treatment.

43. Dr. Davis has committed acts in violation of the statutes governing the practice of medicine. Dr. Davis’ continued unrestricted practice presents an immediate serious danger to the health, safety, and welfare of the public.

CONCLUSIONS OF LAW

1. The Director of the Agency for Health Care Administration has jurisdiction over this matter pursuant to Section 455.621(8), Florida Statutes (1997) and Section 20.43(3)(g), Florida Statutes (1997), as set forth above.

2. Based on the foregoing Findings of Fact, the Director concludes that the procedure or therapy herein referred to as Rheotherapy, when performed as a treatment for the condition known as Age-Related Macular Degeneration, constitutes an experimental procedure or treatment.

3. Based on the foregoing Findings of Fact, the Director concludes that Dr. Davis has violated Section 458.331(1)(d), Florida Statutes, by engaging in false, deceptive, or misleading advertising; Section 458.331(1)(k), Florida Statutes, by making deceptive, untrue, or fraudulent representations in or related to the practice of medicine or employing a trick or scheme in the practice
of medicine; and Section 458.331(1)(t), Florida Statutes, by committing or causing to be committed gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.

4. The Director finds that Dr. Davis' continued unrestricted practice of medicine constitutes an immediate and serious danger to the health, safety and welfare of the public and that this summary restriction procedure is fair under the circumstances described above.

WHEREFORE, in accordance with Sections 120.54(4) and 120.60(6), Florida Statutes (1997), it is

THEREUPON ORDERED THAT:

1. The license of Richard Clair Davis, M.D., license number ME 0041203, is hereby immediately restricted as follows:

a. Dr. Davis shall not perform, or cause the performance of, the procedure known as Rheotherapy in any patient when said procedure is performed, either explicitly or implicitly, as a treatment for the condition known as Age-Related Macular Degeneration, except under the following conditions:

1) Rheotherapy may be performed on patients as a treatment for AMD within the context of a controlled clinical study approved by an independent medical research firm or academic institution which has been approved by the Board of Medicine or its designate prior to the beginning of the study.
2) Rheotherapy may be performed as a general therapy for the treatment of patients with AMD upon a determination by an independent medical research firm or academic institution, approved by the Board of Medicine or its designate, that the use of Rheotherapy in patients for the treatment of AMD is proven to be beneficial by objective criteria and is determined not to be experimental.

3) Respondent must petition the Board of Medicine for its approval prior to initiating Rheotherapy treatment, under the restrictions imposed herein, as a general therapy for the treatment of patients with AMD.

2. A proceeding seeking formal suspension or revocation of the license to practice as a physician of Richard Clair Davis, M.D., has been instituted and will be acted on in compliance with Section 120.60(6), Florida Statutes (1997), and this order shall be filed in accordance with Section 120.54(4), Florida Statutes (1997).

DONE and ORDERED this 26th day of January, 1998.

[Signature]

DOUGLAS M. COOK
DIRECTOR
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, FL 32308-5403
NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Section 120.54(4)(a)(3), Florida Statutes (1997), the Agency's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Petition for Review in accordance with Rule 9.100, Florida Rules of Appellate Procedure, with the Agency for Health Care Administration and a second copy of the petition accompanied by a filing fee prescribed by law with the District Court of Appeal within thirty (30) days of the date this Order is filed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Order of Emergency Restriction has been served on Elizabeth K. Davis, Esquire, Attorney for the Respondent, Waterford Plaza, 7650 Courtney Campbell Causeway, Suite 1120, Tampa, Florida 33607, this 21st day of January, 1998.

[Signature]
Britt Thomas
Senior Attorney