

IN THE MATTER OF

VEIN CLINICS OF AMERICA, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3501. Complaint, June 24, 1994--Decision, June 24, 1994*

This consent order prohibits, among other things, an Illinois-based corporation and its officer from misrepresenting the rate of likely recurrence for any venous disease following treatment, or misrepresenting the newness, past availability, safety, risks or potential side-effects of any cosmetic or plastic surgery procedure. In addition, the consent order requires the respondents to have scientific evidence to substantiate any representations it makes about any cosmetic or plastic surgery procedure it markets or sells in the future.

Appearances

For the Commission: *Richard F. Kelly, Sondra Mills and Melissa Feinberg.*

For the respondents: *Robert E. Kehoe and Daniel S. Kaplan, Wildman, Harrold, Allen & Dixon, Chicago, IL.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Vein Clinics of America, Inc., a corporation, and D. Brian McDonagh, M.D., individually and as an officer of said corporation (hereinafter "respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Vein Clinics of America ("VCA") is a Delaware corporation, with its corporate headquarters at 1101 Perimeter Drive, Suite 615, Schaumburg, Illinois. Respondent has offices in fifteen cities located in the states of California, Georgia, Illinois, Maryland, Kansas, and Michigan.

Respondent D. Brian McDonagh, M.D., is the Chairman of the Board and National Medical Director of Vein Clinics of America. His address is 1535 Lake Cook Road, Northbrook, IL.

PAR. 2. Respondents are engaged, and have been engaged, in the sale and offering for sale of sclerotherapy treatments for venous disease, including varicose veins and spider veins. Sclerotherapy involves the injection of a solution with a fine needle directly into the vein. The solution irritates the lining of the vein, causing it to swell and stick together and the blood to clot. The vein turns into scar tissue that fades from view. A variety of solutions, called sclerosing agents, may be used for this procedure. These include, but are not limited to, hypertonic saline, Sotradecol (sodium tetradecyl sulfate), Polidocanol (Aethoxysklerol), and sodium morrhuate. In addition to sclerotherapy, other methods are used to treat varicose and spider veins. These include, but are not limited to, surgical procedures, laser treatments and electro-cautery treatments.

Respondents use the terms "MicroCure Process" or "refined compression sclerotherapy" to refer to the procedure used at their clinics. Doctors at respondents' clinics limit their practice to the treatment of varicose and spider veins. Respondents' procedure involves the injection of solutions of Sotradecol into the blood vessel using an empty vein technique, followed by compression of the area with bandages and wraps and post-procedure ambulation by the patient. This procedure is generally referred to by the medical profession as "compression sclerotherapy."

PAR. 3. In the course and conduct of VCA's business, respondents have disseminated or caused to be disseminated advertisements and promotional material for the purpose of promoting the sale of sclerotherapy services which include the use of the drug Sotradecol. Sotradecol is a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. Respondents have placed, or caused to be placed advertisements in various periodicals that are in general circulation to the public to promote their treatments of varicose and spider veins to prospective patients. Respondents further advertise and promote their sclerotherapy services through the use of brochures, videos, and pamphlets which are provided to patients and prospective patients.

PAR. 4. The acts and practices of respondents alleged in this complaint are, and have been, in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PAR. 5. Respondents' advertisements and promotional materials include, but are not necessarily limited to, the advertisements and promotional materials attached hereto as Exhibits A through H.

PAR. 6. Respondents' advertising contains the following statements:

(a) The recurrence rate for surgical treatment of varicose veins is "approximately 65% in 5 years" (Exhibit A); and

(b) "With surgery.... the recurrence rate is about 85% in five years. Quite unsatisfactory." (Exhibit B).

PAR. 7. Through the use of the statements contained in the advertisements referred to in paragraph six, including but not necessarily limited to the advertisements attached as Exhibits A and B, respondents represent, and have represented, directly or by implication, that the rate at which venous disease recurs following surgical treatment is approximately 65% to 85% in 5 years.

PAR. 8. In truth and in fact, the rate at which venous disease recurs following surgical treatment is not approximately 65% to 85% in five years but is substantially lower than 65 percent.

Therefore, the representation set forth in paragraph seven was, and is, false and misleading.

PAR. 9. Respondents' advertising contains the following statements and depictions:

(a) In a chart captioned "A Comparison of the Available Options for Treatment of Venous Disease," contained in the brochure "New Solutions to an Age Old Problem" attached hereto as Exhibit A, in the column identifying the "Recurrence rate" of venous disease following "Surgery-(Ligation and Stripping)," "Hypertonic Saline Injections" and "VCA-MicroCure Process":

(1) The rate at which venous disease recurs following treatment by surgery (ligation and stripping) is "approximately 65% in five years;"

(2) The rate at which venous disease recurs following treatment by hypertonic saline injections is "high;" and

(3) The rate at which venous disease recurs following treatment by VCA's MicroCure Process is "less than 3% in five years;"

(b) "This procedure [the MicroCure Process] . . . produc[es] results not presently available with other treatment methods.

The MicroCure Process, performed only at Vein Clinics of America, produces more cosmetically appealing results with a higher success rate [and] lower recurrence rate

... [T]he treatment [of spider veins by the MicroCure Process] produces more cosmetically appealing (and symptom relieving) results, with a lower recurrence rate than any other method of treatment." (Exhibit D); and

(c) "The MicroCure Process has been used to successfully treat these patients [those who have had previous surgery or other modes of treatment] with virtually no recurrences." (Exhibit E).

PAR. 10. Through the use of the statements contained in the advertisements referred to in paragraphs six and nine, including but not necessarily limited to the advertisements attached as Exhibits A, D and E, respondents represent, and have represented, directly or by implication, that:

(a) The rate at which venous disease recurs within five years following treatment by VCA is less than 3%;

(b) The rate at which venous disease recurs following treatment by hypertonic saline injections is high;

(c) There is virtually no recurrence of venous disease among patients who have undergone treatment by VCA after having previously undergone surgery or other modes of treatment; and

(d) The rate at which venous disease, including spider veins, recurs following treatment by VCA is lower than that following any other method of treatment.

PAR. 11. Through the use of the statements contained in the advertisements referred to in paragraphs six and nine, including but not necessarily limited to the advertisements attached as Exhibits A, B, D and E, respondents represent, and have represented, directly or by implication, that at the time they made the representations set forth in paragraphs seven and ten, respondents possessed and relied upon a reasonable basis that substantiated such representations.

PAR. 12. In truth and in fact, at the time respondents made the representations referred to in paragraphs seven and ten, respondents did not possess and rely upon a reasonable basis that substantiated such representations. Therefore, the representation contained in paragraph eleven was, and is, false and misleading.

PAR. 13. Respondents' advertising contains the following statements:

(a) "The Vein Clinics of America uses an exclusive injection treatment called MicroCure." (Exhibit B);

(b) "With the development of the MicroCure Process, Vein Clinics of America (VCA) has achieved a major breakthrough in the treatment of spider veins." (Exhibit D);

(c) "This procedure [MicroCure] . . . produc[es] results not presently available with other treatment methods." (Exhibit D);

(d) "Until recently, satisfactory treatment of spider veins and other small vessel disease was not possible because of an inability to successfully eradicate a majority of the veins, a high recurrence [sic] rate, side effects and complications such as cramping, ulcerations, and staining of the skin. However, now with the MicroCure Process, unlike saline injections, tiny spider veins on the legs or face can disappear." (Exhibit D);

(e) "The MicroCure Process, performed only at Vein Clinics of America, produces more cosmetically appealing results with a higher success rate, lower recurrence rate, and virtually no side-effects or complications." (Exhibit D);

(f) "The development of the MicroCure Process by Vein Clinics of America (VCA) has resulted in a major breakthrough in the treatment of varicose veins and small vessel disease." (Exhibit E);

(g) "Until the success of Vein Clinics of America, surgery was the only treatment for large varicose veins." (Exhibit E); and

(h) "Painful procedures that leave surgical scars are no longer your only options. Vein Clinics of America offers a safe, non-surgical injection treatment administered by licensed M.D.'s." (Exhibit F).

PAR. 14. Through the use of the statements contained in the advertisements referred to in paragraph thirteen, including but not necessarily limited to the advertisements attached as Exhibits B, D, E and F, respondents represent, and have represented, directly or by implication, that:

(a) The procedure respondents employ for treating varicose and spider veins, which they sometimes refer to as the "MicroCure Process," is a unique mode of treatment that is exclusively available from VCA and that differs materially from the procedures generally used by other physicians to treat varicose and spider veins;

(b) The procedure respondents employ for treating varicose and spider veins, which they sometimes refer to as the "MicroCure Process," is a newly discovered and previously unavailable method of treating varicose and spider veins; and

(c) Prior to the opening of Vein Clinics of America, surgery was the only available treatment for large varicose veins.

PAR. 15. In truth and in fact:

(a) The procedure respondents employ for treating varicose and spider veins, which they sometimes refer to as the “MicroCure Process,” is not a unique mode of treatment, is not exclusively available from VCA and does not differ materially from the procedures used by physicians to treat varicose and spider veins. The procedure used by respondents, known within the medical community as compression sclerotherapy, can be, has been, and is regularly performed by other physicians;

(b) The procedure respondents employ for treating varicose and spider veins, which they sometimes refer to as the “MicroCure Process,” is not a newly discovered or previously unavailable method of treating varicose and spider veins; and

(c) Prior to Vein Clinics of America, surgery was not the only available treatment for large varicose veins.

Therefore, the representations set forth in paragraph fourteen were, and are, false and misleading.

PAR. 16. Respondents’ advertising contains the following statements and depictions:

(a) In a chart captioned “A Comparison of the Available Options for Treatment of Venous Disease,” contained in the brochure “New Solutions to an Age Old Problem” attached hereto as Exhibit A, in the column identifying the “Risks/Complications” of “Surgery-(Ligation and Stripping),” “Hypertonic Saline Injections” and “VCA-MicroCure Process”:

(1) “Surgery (ligation and stripping)” presents the “[a]ssociated risks of anesthesia, post-op complications with infections and multiple scars;”

(2) “Hypertonic saline injections” present the “[p]ossibility of burns on the skin - unsuitable for extensive disease;” and

(3) “VCA-MicroCure Process” presents the risk of a “[m]ild allergic reaction in approximately 1 in 1000 patients.”

(b) “There are other options besides surgery. These include electrocautery, laser and various saline based injections. Problem is, these methods can burn the skin and leave marks. There is a better way.” (Exhibit B);

PAR. 17. Through the use of the statements contained in the advertisements referred to in paragraph sixteen, including but not necessarily limited to the advertisements attached as Exhibits A and

B, respondents represent, and have represented, directly or by implication, that:

(a) Respondents' method of sclerotherapy does not result in burning, marking or scarring the skin;

(b) The only significant risk to health presented by respondents' method of sclerotherapy is that of a mild allergic reaction in 1 in 1,000 patients; and

(c) The only significant risk of allergic reaction presented by respondents' method of sclerotherapy is that of a mild allergic reaction in 1 in 1,000 patients.

PAR. 18. In truth and in fact:

(a) Respondents' method of sclerotherapy can result in burning, marking and scarring the skin. As described in paragraph eighteen (b), injections of Sotradecol may cause ulcers to form, leaving scars on the skin. Moreover, potentially permanent post-sclerosis pigmentation may occur following injections of Sotradecol;

(b) The risk of a mild allergic reaction in 1 in 1,000 patients is not the only significant risk to health posed by respondents' method of sclerotherapy. In addition to the possibility of severe allergic reactions described below in paragraph eighteen (c), Sotradecol may cause ulcers, or open sores, to form if it extrudes onto the surface of the skin when it is injected; and

(c) The risk of a mild allergic reaction in 1 in 1,000 patients is not the only significant risk of allergic reaction presented by respondents, method of sclerotherapy. Sotradecol, the drug respondents inject, can cause severe allergic reactions, including anaphylactic shock.

Therefore, the representations set forth in paragraph seventeen were, and are, false and misleading.

PAR. 19. Respondents' advertising contains the following statements and depictions:

(a) In a chart captioned "A Comparison of the Available Options for Treatment of Venous Disease," contained in the brochure "New Solutions to an Age Old Problem" attached hereto as Exhibit A, in

the column identifying the “Risks/Complications” of “Hypertonic Saline Injections” and “VCA-MicroCure Process”:

(1) Hypertonic saline injections present the “[p]ossibility of burns on the skin - unsuitable for extensive disease;” and

(2) VCA-MicroCure Process presents the risk of a “[m]ild allergic reaction in approximately 1 in 1000 patients.”

(b) “There are other options besides surgery. These include electrocautery, laser and various saline based injections. Problem is, these methods can burn the skin and leave marks. There is a better way.” (Exhibit B); and

(c) “The MicroCure Process produces the most complete symptomatic relief of pain and discomfort and superior cosmetic results compared to other modes of treatment such as saline injections, laser, electrocautery or surgery.” (Exhibit C);

(d) “The MicroCure Process, performed only at Veins Clinics of America, produces more cosmetically appealing results with a higher success rate, lower recurrence rate, and virtually no side-effects or complications.” (Exhibit D).

PAR. 20. Through the use of the statements contained in the advertisements referred to in paragraph nineteen, including but not necessarily limited to the advertisements attached as Exhibits A, B, C and D, respondents represent, and have represented, directly or by implication, that:

(a) Respondents’ method of sclerotherapy presents fewer significant risks to health than other non-surgical methods of treating venous disease;

(b) Respondents’ method of sclerotherapy produces fewer risks of adverse cosmetic side-effects than other methods of treating venous disease.

PAR. 21. Through the use of the statements contained in the advertisements referred to in paragraphs sixteen and nineteen, including but not necessarily limited to the advertisements attached as Exhibits A, B, C and D, respondents represent, and have represented, directly or by implication, that at the time they made the representations set forth in paragraphs seventeen and twenty, respondents possessed and relied upon a reasonable basis that substantiated such representations.

PAR. 22. In truth and in fact, at the time respondents made the representations referred to in paragraphs seventeen and twenty,

respondents did not possess and rely upon a reasonable basis that substantiated such representations.

Therefore, the representation contained in paragraph twenty-one was, and is, false and misleading.

PAR. 23. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices and the making of "false advertisements" in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

Complaint

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EXHIBIT A

*New
Solutions*
to an Age Old
Problem

Varicose,
Spider Veins
and Leg Ulcers

Vein Clinics of America

EXHIBIT A

What are varicose veins?

Varicose veins are abnormally enlarged veins containing stagnant blood caused by the breakdown and leakage of valves and/or the dilation or loss of elasticity of the vein walls. They may appear as bulging, bluish and noddy looking.

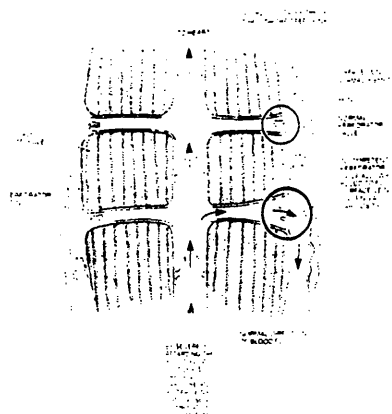
What are spider veins?

These are bluish-red intrusive veins which can occur in a cluster or may be isolated and may develop on the legs or face.

Who suffers from venous disease?

At least 17% of Americans suffer from venous disease. Women are afflicted much more frequently than men at a ratio of 11 to 1. Causes include hereditary factors, the naturally occurring female hormone estrogen, pregnancy, and trauma. Standing occupations and weight gain can aggravate the disease.

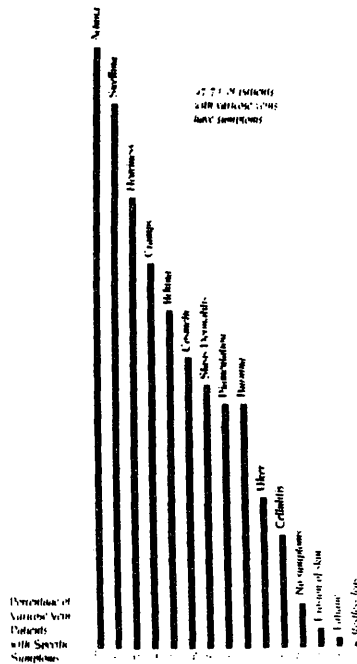
How Venous Disease Occurs



What are the symptoms associated with this disease?

Most people with varicose veins complain of aching, swollen, heavy and tired legs. They often complain of cramping, especially at night. Other patients complain of blood dermatitis from the varicose veins which consists of itching or burning skin pigmentation and darkening of the skin. This can lead to ulceration, an open sore or breakdown of the skin caused by the intense pressure resulting from venous disease.

Symptoms



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EXHIBIT A

A Comparison of the Available Options for Treatment of Venous Disease

Venous Disease	Surgery— (Ligation and Stripping)	Hypertonic Sodium Injections	VCA—MicroCure Process
Who treats this?	General or Vascular Surgeons	Primary Dermatologists & Plastic Surgeons	Licensed M.D.'s—Practice is limited to Venous Disease on the MicroCure Process
Able to treat the following?			
■ Telangiectases (Spider Veins)	Yes	No	Yes
■ Truncal veins (Lower Stem Veins)	No	Yes	Yes
■ Fetal Veins	No	No	Yes
■ Leg Ulcers	Surgical skin grafting—Low success rate	No	Yes
Pain/Discomfort?	Yes	Prolonged Lying/Muscle Cramping	Slight Soreness on occasion during treatment
Disruption of Daily Activities?	Yes—May require 4-6 wks. recovery	No	No
Recurrence rate:	Approximately 65% recurrence in 5 years	High	Less than 3% in 5 years
Cost:	Approximately \$8000 and up for in-hospital surgery	Wide range of fees	Approximately 25% of surgery
Risks/Complications	Associated risks of anesthesia, post-op complications, with infections and multiple scars.	Possibility of burns on the skin— unsuitable for extensive disease	Mild allergic reaction in approxi- mately 1 in 1000 patients

How VCA treats Venous disease?

VCA has developed an advanced and refined sclerotherapy technique called the MicroCure Process. It consists of an injection of an FDA approved medication into "points of control" followed by compression and prescribed walking.

What can I expect to experience during the MicroCure treatment?

An individualized plan of treatment in specific steps are followed for each patient. An appropriate history and physical is performed.

The doctor identifies the veins to be treated. From the total evaluation of diseased veins, a series of micro-injections are given, proportioned to the size of the vessel. Compression strips or dressings are applied to the leg. The patient is then encouraged to take a short walk immediately after each treatment session. Treatment sessions are short and you can return to work immediately. The number of sessions required depends on the severity of the problem. Our needles are very tiny and generally feel like pulling a hair. Most patients who are afraid of injections, gladly go to the treatment when they see their varicose spider veins disappear.

EXHIBIT A

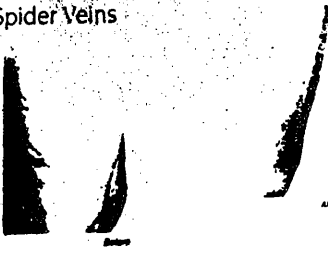
Facial Veins



What are the advantages of the MicroCure Process?

- The MicroCure Process offers many benefits from both health and economic perspectives.
- The Procedure is performed by well-trained, licensed physicians at Vein Clinics of America who specialize and whose full-time practices are devoted exclusively to phlebology (the treatment of vein disease).
- Although a newer technology than surgery, the MicroCure Process of the Vein Clinics of America has a proven track record of over 100,000 successful treatment sessions. The most important advantages of the MicroCure technique are that it is safe, effective and economical.
- With the MicroCure Process, all sizes of varicose veins and spider veins can be treated. The need for traditional vein surgery (ligation and stripping) is eliminated.
- The MicroCure Process avoids surgery and general anesthesia with its associated complications and risks which include pain, scars and the loss of time (and income) from work.
- Treatment occurs in our comfortable offices on an out-patient basis, with little or no interruption to the patient's work or activity schedule.
- Where your vein disorder permits, we have an accelerated treatment program. This is especially valuable for our out-of-town patients.
- Only the diseased veins are treated so your normal veins are preserved for possible future by-pass surgery.

Spider Veins



Who Recommends the MicroCure Process?

Many doctors from diverse medical and surgical specialties, including cardiovascular surgeons, routinely refer not only their patients, but also, their own family members to Vein Clinics of America for treatment of varicose veins. VCA physicians speak to medical groups about the unique and effective MicroCure treatment program. Vein Clinics of America physicians are often interviewed on radio and television and quoted in both newspaper and magazine articles as among the authorities in the treatment of varicose veins.

Does Health Insurance cover the cost of the Treatment?

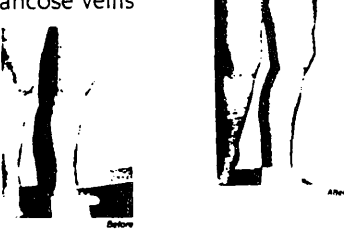
Medical attention is necessary to alleviate both the pain and potential degeneration caused by untreated varicose veins. Vein disease is a pathological disorder and needs to be treated. For these reasons, most health insurance policies cover the cost of treatment. However, individual policies may vary in their exact coverage.

Vein Clinics of America invites you to see examples of our treatment results so you can compare them with other vein clinics.

Vein Clinics of America

Schaumburg, IL (708) 619-5100
 Chicago, IL (Michigan Avenue) (312) 642-8340
 Oak Brook, IL (708) 571-0955
 Northbrook, IL (708) 295-9700
 Kansas City, KS (913) 345-3622
 Detroit/Ann Arbor, MI (313) 642-0210
 Arcadio, CA (619) 465-8668
 Beverly Hills, CA (310) 652-0601
 Irvine, CA (714) 553-4284
 Encino, CA (818) 784-1818
 San Bernardino, CA (714) 899-0102
 Walnut Creek, CA (915) 945-8656
 Atlanta, GA (404) 435-4441
 Chevy Chase, MD/Washington D.C. (301) 654-6611
 Salt Lake, UT (801) 359-1131

Varicose Veins



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EXHIBIT A

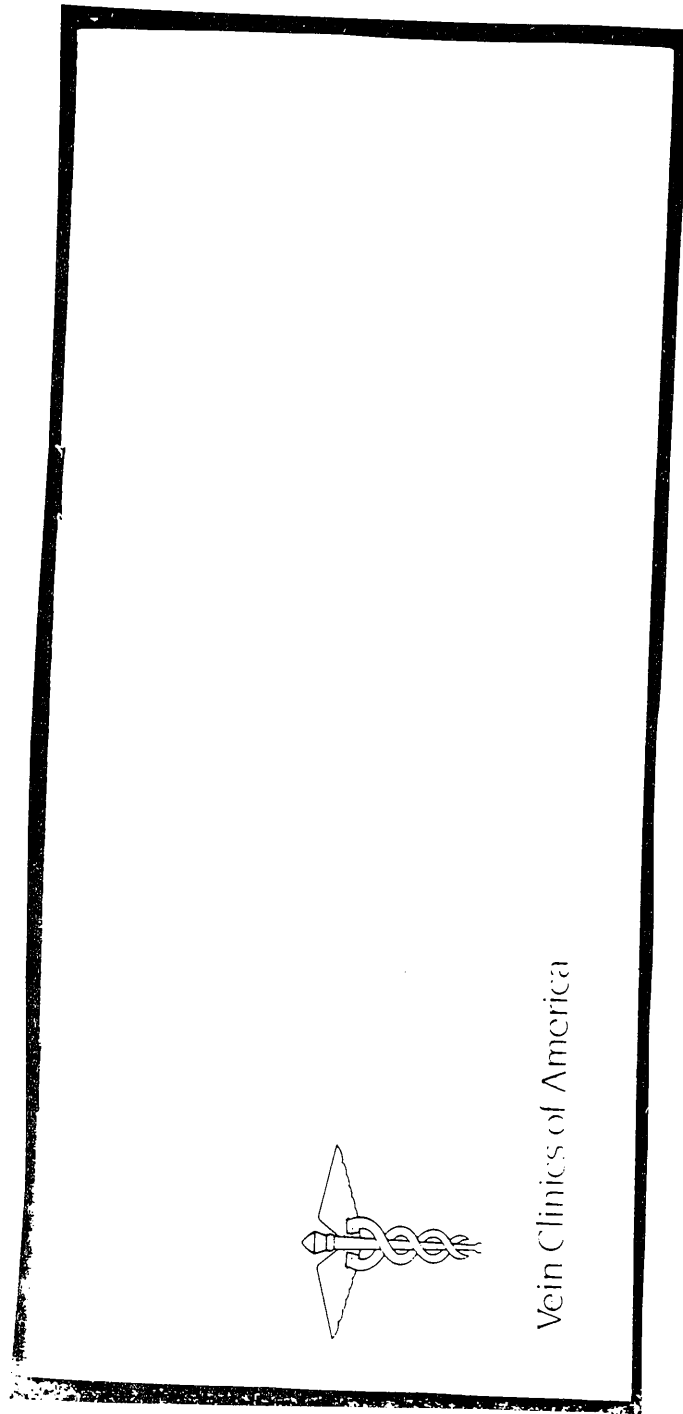


EXHIBIT B

BEFORE YOU HAVE YOUR VARICOSE VEINS TREATED, KNOW THESE IMPORTANT FACTS

1. POTENTIAL DANGERS

Varicose veins are not just unsightly, they're unhealthy. Without treatment they will continue to grow, causing aches, pains, cramping and reduced circulation... and can even develop into leg ulcers.

2. SURGERY OBSOLETE

With surgery, damaged veins are pulled out of the leg altogether. This is a painful, rather mutilating procedure always leaving scars. It's also very costly, involving hospitalization and time off from work. And the recurrence rate is about 85% in five years. Quite unsatisfactory.

3. HIGH SURGICAL METHODS DIFFER

There are other options besides surgery. These include electrocautery, laser and various saline based injections. Problem is, these methods can burn the skin and leave marks. There is a better way.

4. MICROCURE IS THE MOST EFFECTIVE TREATMENT

The Vein Clinics of America uses an exclusive injection treatment called MicroCure. The treatment safely eliminates vein disorders of all sizes without the scars associated with surgical techniques. It is administered only by licensed M.D.'s who specialize in vein disease. It's also covered by most insurance plans. Find out more.

Call for a physician consultation

(301) 654-6633

IT'S TIME TO DO SOMETHING ABOUT YOUR VARICOSE VEINS.

Vein Clinics of America

EXHIBIT C

The MicroCure Process

The development and introduction of the **MicroCure Process** by Vein Clinics of America in the early 1980's marked a major breakthrough in the treatment of vein disorders.

The MicroCure Process involves a series of micro-injections which are administered over several treatment sessions. There are three important steps in the treatment program: injection, compression, and ambulation. After injection of the varicose veins, individualized therapeutic compression is applied with dressings custom made in Europe. Walking for a prescribed period of time concludes the treatment session.

The MicroCure Process produces the most complete symptomatic relief of pain and discomfort and superior cosmetic results compared to other modes of treatment such as saline injections, laser, electrocautery or surgery. Even among patients who have undergone previous alternative methods of treatment, the MicroCure Process has an extraordinary level of patient acceptance and preference. In addition, VCA accomplishes these results without disruption of daily activities or time lost from work.

The MicroCure Process produces cosmetically appealing results in the treatment of spider veins. Dramatic changes are noticed on even the largest rope-like varicose veins within a few days. Both spider and varicose vein treatments are administered on an out-patient basis, allowing patients to return immediately to their normal activities. The significant advantages over surgery include no incisions or scars, no pain, no risk of infection, no immobilization, and no recuperation time or lost income from work. The MicroCure Process is safe, effective and less expensive than surgery. One of the major advantages of the MicroCure Process over alternative treatments is the attention to detail. Successful concentration on even the smallest abnormal veins is the key to obtaining the lowest recurrence rate, the most normal or psychologic return of circulation, the most symptomatic relief and the best looking finish.

Varicose veins require treatment. Successful treatment relieves associated painful symptoms by improving the circulation in the legs. Even patients who have had previous surgery or other treatment methods for varicose veins greatly benefit from the MicroCure Process, which is available only at Vein Clinics of America.

EXHIBIT D

Treatment of Spider Veins by the Microcure Process

With the development of the **MicroCure Process**, Vein Clinics of America (VCA) has achieved a major breakthrough in the treatment of spider veins. This procedure, a series of micro-injections, focuses careful attention to the details of the diseased veins, thereby producing results not presently available with other treatment methods.

What are Spider Veins?

■ Spider veins or telangiectasia are either clustered or isolated, threadlike red-to-purplish veins that stem from a network of small veins just below the skin's surface. They develop predominantly on the legs and face. More commonly found in women, most find that they have at least a few of these spider veins which are usually caused by the female hormone estrogen. Other causes of these unsightly and often uncomfortable veins may include hereditary factors, and injury or trauma to the area.

■ Even though many people consider spider veins to be only a cosmetic nuisance, in actuality, many patients with spider veins suffer from symptoms including night cramps, dry skin, aching, tired legs, and a "heaviness" of their legs.



Before



After

Until recently, satisfactory treatment of spider veins and other small vessel disease was not possible because of an inability to successfully eradicate a majority of the veins, a high recurrence rate, side-effects and complications such as cramping, ulcerations, and staining of the skin. However, now with the MicroCure Process, unlike saline injections, tiny spider veins on the legs or face can disappear. The MicroCure Process, performed only at Vein Clinics of America, produces more cosmetically appealing results with a higher success rate, lower recurrence rate, and virtually no side-effects or complications. Vein Clinics of America's success in treating spider veins is partially due to the fact that the MicroCure Process is suitable for the entire leg or face and can treat extensive, diffuse small vessel disease.

Furthermore, by treating both the spider veins and the venules from which the spider veins originate, the treatment produces more cosmetically appealing (and symptom relieving) results, with a lower recurrence rate than any other method of treatment.

Treatment of spider veins is conducted under the direction of highly qualified, professionally trained and licensed physicians in a pleasant, comfortable out-patient setting. Since the procedure is non-surgical in nature, patients can return to normal activities immediately following treatment. A brief walk following each treatment session is recommended to improve circulation and to promote healing.

EXHIBIT E

Treatment of Varicose Veins by the Microcure Process

The development of the **MicroCure Process** by Vein Clinics of America (VCA) has resulted in a major breakthrough in the treatment of varicose veins and small vessel disease.

What are Varicose Veins?

■ When discussing varicose veins, it is best to break these abnormal veins into two categories: spider veins (telangiectasia) and varicose veins. They vary in size from very small to very large, tortuous, ropelike varicose veins.

■ Varicose veins are abnormally enlarged veins, engorged with blood due to the breakdown and leakage of some of the valves in the communicating veins. Varicose veins are usually recognized as the large, often unsightly and symptomatic component of vein disease. As you know, oxygenated blood is carried throughout the body from the lungs and heart by arteries. Veins transport the deoxygenated blood back to the heart and lungs. The venous system of the legs works against gravity when it carries blood from the legs back up to the heart. The veins are successful in this task due to the interaction between muscular contractions of the leg and a system of one-way valves in the veins. The valves when operating properly, provide uni-directional blood flow by allowing the blood to flow only toward the heart. If the valves of the veins malfunction, the force of gravity predominates and the blood will pool and collect in the superficial veins, causing them to widen, bulge, elongate and become tortuous. Valvular failure is usually located in one or more of the approximately two hundred communicating veins.

■ Varicose veins can cause painful, swollen, heavy, aching legs by severely retarding the flow of blood as it leaves the legs. An estimated 17 percent of Americans suffer from large varicose veins. More women are afflicted than men, probably due to the interaction of factors caused by pregnancy.



Until the success of Vein Clinics of America, surgery was the only treatment for large varicose veins. Now with the MicroCure Process, there is no need to consider conventional surgery. In comparison with the MicroCure Process, surgery is less effective, more painful, more expensive, requires a lengthy recovery period, and leaves permanent scars. Treatment at Vein Clinics of America, on the other hand, is performed on an out-patient basis. There are no surgical incisions or scars. Furthermore, patients can return to most normal activities immediately following treatment. A brief walk is recommended to improve circulation and to promote more rapid healing.

Ten to twenty percent of the patients who come to Vein Clinics of America have had previous surgery or other modes of treatment as an attempt to treat their varicose veins. The MicroCure Process has been used to successfully treat these patients with virtually no recurrences. These patients, as well as all of our patients, have been delighted with the symptomatic relief among other advantages of our micro-injection treatment.

HAVEN'T YOU SUFFERED LONG ENOUGH WITH VARICOSE VEINS?

**Proven, non-surgical treatment has
worked for thousands.**

Make the decision today to finally get rid of your uncomfortable varicose veins. Painful procedures that leave surgical scars are no longer your only options. Vein Clinics of America offers a safe, non-surgical injection treatment administered by licensed M.D.'s. It eliminates varicose veins of all sizes as well as the smallest spider veins without hospitalization. Normal treatment takes four to six weeks and will not interfere with your busy schedule.

Covered by most insurance plans.

Limited time offer: Free physician consultation

(213) 852-0605
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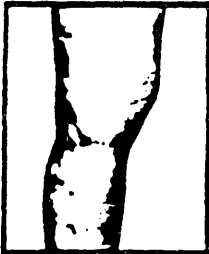
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SAN BERNARDINO

IT'S TIME TO DO SOMETHING ABOUT YOUR VARICOSE VEINS.

Vein Clinics of America

Chicago • Los Angeles • Atlanta • Detroit • Washington D.C. • Baltimore

EXHIBIT G



BEFORE



AFTER

GET RID OF VARICOSE VEINS WITHOUT SURGERY OR HOSPITALIZATION.

No matter how bad you think your varicose veins are, Vein Clinics of America has successfully treated thousands of cases that may have been much worse. We offer a proven, safe and effective injection method that eliminates varicose veins of all sizes including the smallest spider veins—without hospitalization and without the limitations of saline. And we offer the latest ultrasound techniques.

The nation's largest group of licensed M.D.s specializing in vein disease. Covered by most insurance plans.

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Vein Clinics Of America

Los Angeles • San Francisco • Chicago
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1049

Complaint

EXHIBIT H



**THERE IS
STILL TIME
TO PUT YOUR
LEGS HERE
THIS
SUMMER.**

**IMMEDIATE
APPOINTMENTS AVAILABLE**

Have varicose veins been making you hide your legs? Our safe, proven MicroCure injection treatment is fast, easy and won't interfere with your busy summer schedule. In fact, the more active you are, the better. We'll eliminate varicose veins and spider veins—both large and small—without the ugly scars associated with surgery. Normal treatment is 4-6 weeks, so if you call today your legs can feel better and look better this summer.

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NORTH BROS

**IT'S TIME TO DO SOMETHING
ABOUT YOUR VARICOSE VEINS.**

**Vein Clinics
of America**

CLINICS IN: AUSTIN • BOSTON • CHICAGO • DALLAS • DENVER • HOUSTON • LOS ANGELES • MIAMI • MINNEAPOLIS • NEW YORK • OAKLAND • PHOENIX • SAN ANTONIO • SAN DIEGO • SEATTLE • TAMPA • WASHINGTON, D.C.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such an agreement on the public record for a period of sixty (60) days, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Vein Clinics of America, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 1101 Perimeter Drive, (#615), Schaumburg, Illinois.

Respondent D. Brian McDonagh, M.D. is the Chairman of the Board and National Medical Director of Vein Clinics of America, Inc. He formulates, directs and controls the policies, acts and practices of said corporation. His address is 1535 Lake Cook Road, Northbrook, Illinois.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. “*Sclerotherapy*” means the treatment of venous disease by injecting a solution into a vein with a needle.
2. “*Compression sclerotherapy*” means the treatment of venous disease by injecting a solution, including but not limited to Sotradecol (sodium tetradecyl sulfate), into a vein with a needle, followed by compression of the injected area with bandages or wraps and post-procedure ambulation by the patient.
3. “*Any substantially similar service*” means compression sclerotherapy in which a solution of Sotradecol (sodium tetradecyl sulfate) is injected into a vein.
4. “*Venous disease treatment procedure*” includes, but is not limited to, sclerotherapy, compression sclerotherapy, laser treatments, electrocautery and surgery.
5. “*Competent and reliable scientific evidence*” means tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

I.

It is ordered, That respondents Vein Clinics of America, Inc., a corporation, its successors and assigns, and its officers, and D. Brian McDonagh, M.D., individually and as an officer and medical director of said corporation, and respondents’ agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, promotion, offering for sale or sale of any venous disease treatment procedure or any other cosmetic or plastic surgery procedure in or affecting

commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from, in any manner, directly or by implication:

A. Representing that the rate at which varicose veins recur following surgery is approximately 65% to 85% in five years, or otherwise misrepresenting the rate at which venous disease is likely to recur or return following treatment by any venous disease treatment procedure;

B. Representing that prior to the opening of Vein Clinics of America, surgery was the only available treatment for large varicose veins;

C. Representing that the sclerotherapy practiced at respondents' clinics as of the date respondents sign this order, sometimes referred to as the "MicroCure Process," or any substantially similar service, is a newly discovered and/or previously unavailable method of treating varicose and spider veins;

D. Misrepresenting that the sclerotherapy practiced at respondents' clinics as of the date respondents sign this order, sometimes referred to as the "MicroCure Process," or any substantially similar service, is exclusively available at respondents clinics;

E. Misrepresenting the newness of, or the past or present availability of, any cosmetic or plastic surgery procedure, including any venous disease treatment procedure;

F. Representing that the sclerotherapy practiced at respondents' clinics as of the date respondents sign this order, sometimes referred to as the "MicroCure Process," or any substantially similar service:

- 1) Does not present the risk of burning, marking, or scarring the skin; or
- 2) Presents no possibility of significant risks to health;

G. Misrepresenting the safety, risks, or potential side-effects of any cosmetic or plastic surgery procedure, including any venous disease treatment procedure.

II.

It is further ordered, That respondents Vein Clinics of America, Inc., a corporation, its successors and assigns, and its officers, and D.

Brian McDonagh, M.D., individually and as an officer and medical director of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, promotion, offering for sale or sale of any venous disease treatment procedure or any other cosmetic or plastic surgery procedure, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication, regarding:

A. The success rate or the rate at which a condition is likely to recur or return following treatment by any cosmetic or plastic surgery procedure, including any venous disease treatment procedure; or

B. The rate or nature of risks to health or of adverse cosmetic side-effects presented by any cosmetic or plastic surgery procedure, including any venous disease treatment procedure;

unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

It is further ordered, That for five (5) years after the last date of dissemination of any representation covered by this order, respondents, or their successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials that were relied upon in disseminating such representation; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

IV.

It is further ordered, That respondents shall distribute a copy of this order to each of their operating divisions, to each of their

managerial employees, and to each of their officers, agents, representatives, or employees engaged in the preparation or placement of advertising or other material covered by this order and shall secure from such person a signed statement acknowledging receipt of this order.

V.

It is further ordered, That respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of this order.

VI.

It is further ordered, That, for a period of ten (10) years from the date of entry of this order, the individual respondent named herein shall promptly notify the Commission of the discontinuance of his present business or employment, with each such notice to include the respondent's new business address and a statement of the nature of the business or employment in which the respondent is newly engaged as well as a description of respondent's duties and responsibilities in connection with the business or employment.

VII.

It is further ordered, That respondents shall, within sixty (60) days after service upon them of this order and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with the requirements of this order.