

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of)	DOCKET NO. C-3589
)	
DAVID GREEN, M.D.,)	
an individual doing business)	
as The Varicose Vein Center,)	
a sole proprietorship.)	

COMPLAINT

The Federal Trade Commission, having reason to believe that David Green, M.D., an individual doing business as The Varicose Vein Center, a sole proprietorship (hereinafter "respondent"), has 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 ONE: Respondent David Green, M.D. ("Dr. Green") is an individual doing business as The Varicose Vein Center, a sole proprietorship ("VVC"). Respondent operates a VVC clinic located at 4800 Montgomery Lane, Suite M50, Bethesda, MD 20814.

PARAGRAPH TWO: Respondent is engaged, and has 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 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 electrocautery treatments.

Respondent's regimen for treating venous disease involves the injection of solutions of Sotradecol into the veins followed by compression of the surrounding tissue with bandages and wraps and post-procedure ambulation by the patient. In the past,

respondent has also used hypertonic saline and Polidocanol as sclerosing agents when administering his sclerotherapy treatments.

As part, of his treatment regimen, respondent refers certain patients with varicose veins to surgeons to perform a surgical procedure prior to injecting the veins with a sclerosing agent. These include patients whom respondent has diagnosed as having truncal varicosities with incompetence at the saphenofemoral or saphenopopliteal junction. Respondent refers such patients to a surgeon for surgical division and ligation of these veins before performing his sclerotherapy treatments.

PARAGRAPH THREE: In the course and conduct of Dr. Green's business, respondent has disseminated or caused to be disseminated advertisements and promotional materials 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. Respondent has placed, or caused to be placed, advertisements in various periodicals that are in general circulation to the public to promote VVC's treatments of varicose and spider veins to prospective patients. Respondent further advertises and promotes VVC's sclerotherapy services through the use of brochures and pamphlets that are provided to patients and prospective patients.

PARAGRAPH FOUR: The acts and practices of respondent 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.

PARAGRAPH FIVE: Respondent's advertisements and promotional materials include, but are not necessarily limited to, the advertisements and promotional materials attached hereto as Exhibits A through D.

PARAGRAPH SIX: Respondent's advertisements and promotional materials contain the following statements:

(a) My only mistake was not coming to The Varicose Vein Center first."

...

-Spider and Varicose Veins Permanently Eliminated

-Painless, Safe, Non-Surgical

(Exhibit A);

(b) ****The Varicose Vein Center Presents****

Great Legs for Summer

...

If varicose or spider veins are the problem, these unsightly veins can be permanently removed by a simple, non-surgical procedure.

(Exhibit B);

(c) "My only mistake was not coming to The Varicose Vein Center first."

...

Don't let the disappointment of other vein treatments keep you from discovering the one that works. With a success rate greater than 95%, our non-surgical, inoffice procedure is safe, painless Find out how easy and affordable it is to get rid of spider or varicose veins, often with just one treatment.

(Exhibit C) ; and

(d) The Varicose Vein Center

...

What You Should Know About Varicose Veins, Spider Veins and Sclerotherapy

...

WHAT IS SCLEROTHERAPY?

Sclerotherapy is the non-surgical procedure used to permanently remove spider and varicose veins from the legs and thighs.

...

IF I HAVE MY VEINS TREATED, CAN THEY REAPPEAR ?

Once these spider or varicose veins are treated successfully they disappear permanently. However, this treatment does not prevent new veins, that would otherwise have developed, from appearing.

(Exhibit D).

PARAGRAPH SEVEN: Through the use of the statements contained in the advertisements referred to in PARAGRAPH SIX, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A, B, C and D, respondent has represented, directly or by implication, that

- (a) spider veins and varicose veins treated by respondent are permanently eliminated;
- (b) greater than 95% of the spider veins and varicose veins treated by respondent are eliminated for at least a significant period of time.

PARAGRAPH EIGHT: Through the use of the statements contained in the advertisements and promotional materials referred to in PARAGRAPH SIX, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A, B, C and D, respondent has represented, directly or by implication, that at the time he made the representations set forth in PARAGRAPH SEVEN, respondent possessed and relied upon a reasonable basis that substantiated such representations.

PARAGRAPH NINE: In truth and in fact, at the time respondent made the representations referred to in PARAGRAPH SEVEN, respondent did not possess and rely upon a reasonable basis that substantiated such representations. Therefore, the representation contained in PARAGRAPH EIGHT was, and is, false and misleading.

PARAGRAPH TEN: 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 C, respondent has represented, directly or by implication, that patients do not experience any pain in connection with respondent's regimen for treating their varicose and spider veins.

PARAGRAPH ELEVEN: 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 C, respondent has represented, directly or by implication, that at the time he made the representation set forth in PARAGRAPH TEN, respondent possessed and relied upon a reasonable basis that substantiated such representation.

PARAGRAPH TWELVE: In truth and in fact, at the time respondent made the representation referred to in PARAGRAPH TEN, respondent did not possess and rely upon a reasonable basis that substantiated such representation. Therefore, the representation contained in PARAGRAPH ELEVEN was, and is, false and misleading.

PARAGRAPH THIRTEEN: The acts and practices of respondent 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.

Therefore, the Federal Trade Commission this twenty-third day of June, 1995, has issued this complaint against respondent.

By the Commission, Chairman Pitofsky not participating.

Donald S. Clark
Secretary

SEAL:

"My only mistake was not
coming to The Varicose Vein
Center first."

EXHIBIT A - SEE IMAGE [IMAGE NOT AVAILABLE]

****The Varicose Vein Center Presents****

ADVERTISEMENT - SEE IMAGE [IMAGE NOT AVAILABLE]

EXHIBIT B

“My only was not Coming to The Varicoce Vein Center First.”

ADVERTISEMENT - SEE IMAGE [IMAGE NOT AVAILABLE]

EXHIBIT C

The Varicose Vein Center

ADVERTISEMENT - SEE IMAGE

[IMAGE NOT AVAILABLE]

EXHIBIT D

WHAT ARE VARICOSE VEINS?

Varicose veins are dilated blood vessels that become enlarged because of a weakness in the wall of the vein. They are most common in the legs and thighs. Spider veins refers to smaller varicose veins that usually appear in patches close to the skin surface.

WHY DO PEOPLE DEVELOP VARICOSE VEINS?

The tendency for having varicose veins is usually hereditary and can begin in adolescence or early adulthood. However, pregnancy, oral contraceptives, and injuries often contribute to the problem. In addition, large varicose veins can give rise to smaller ones. Once formed, these dilated vessels do not disappear without treatment

WHAT IS SCLEROTHERAPY?

Sclerotherapy is the non-surgical procedure used to permanently remove spider and varicose veins from the legs and thighs.

PHOTOGRAPH - SEE IMAGE [IMAGE NOT AVAILABLE]

HOW LONG HAS THIS PROCEDURE BEEN USED BY PHYSICIANS?

Sclerotherapy for varicose veins has been performed for more than 100 years. Spider veins have been treated for more than 50 years. But the smallest spider veins have been effectively treated for only the past 10 years, when needles were developed that were small enough to inject them.

HOW IS THE PROCEDURE DONE?

A sterile salt solution (a saline solution, or sodium chloride in water) is injected into the veins to be removed. This solution is called the sclerosing solution. injecting directly into the vein insures that only the vein is removed.

HOW DOES THE PROCEDURE WORK?

The saline solution, being very concentrated, irritates the injected veins. This irritation damages the veins and closes them off. The body recognizes that the veins are no longer working and dissolves them the same way it would dissolve a bruise in the skin.

IS THE PROCEDURE SAFE?

The procedure is safe and effective. Complications were more common in the past. But with the use of safer sclerosing agents and the availability of very fine sterile needles, complications today are quite uncommon.

PHOTOGRAPH - SEE IMAGE [IMAGE NOT AVAILABLE]

HOW EFFECTIVE IS THIS PROCEDURE?

Sclerotherapy is effective in at least 90% of patients at improving the veins that are treated. Some veins may require more than one treatment.

IS THERE DISCOMFORT ASSOCIATED WITH SCLEROTHERAPY?

There may be mild discomfort at the site of injection when the procedure is performed. This is caused by the solution and may feel like a stinging or burning sensation. The needle itself is small so there is minimal, if any, discomfort. Some people develop a muscle cramp in the leg or thigh near the veins that are being treated. This is due to the sodium in the saline solution. If a cramp develops, it subsides within minutes after the injection.

IS IT NECESSARY TO TREAT EVERY VEIN IF I HAVE HUNDREDS OF VEINS?

Usually in any area where there are multiple spider veins or varicose veins, these veins are interconnected. When one vein is injected, the solution gets into the adjacent veins and helps eliminate them. Therefore, it is unnecessary to inject each vein in order to have complete clearing.

WHERE IS SCLEROTHERAPY PERFORMED?

The procedure is done in the doctor's office. After a treatment session you may go back to work or resume normal activities. There is no recuperation period and no need for bed rest.

PHOTOGRAPH - SEE IMAGE [IMAGE NOT AVAILABLE]

HOW MANY TREATMENT VISITS ARE REQUIRED?

The number of visits depends upon the number of varicose and spider veins that you have. Sometimes only one treatment is needed. However, if there are a great number of veins, several treatment sessions may be required. This can be determined during the first consultation. You should be seen one month after your first treatment to assess the degree of improvement. At that time, if additional veins are present another treatment may be done.

HOW LONG DOES THE PROCEDURE TAKE?

Each session lasts 20 to 30 minutes.

WHAT WILL MY LEGS LOOK LIKE AFTER TREATMENT?

Immediately after a treatment, the skin may be red and there may be some bruising. This color usually disappears within a few days. The treated veins may be firm to the touch until they are absorbed by the body. This process of absorption can take several weeks to several months depending upon the vein size. Before leaving the office, the treated leg or thigh is wrapped with an elastic bandage.

PHOTOGRAPH - SEE IMAGE [IMAGE NOT AVAILABLE]

WILL I HAVE DISCOMFORT AFTER THE PROCEDURE?

Once you leave the office, there is usually no discomfort. However the elastic bandage may be bothersome because it fits tightly. It remains on for 3 to 7 days, depending on the vein size and location.

ARE THERE ANY LIMITATIONS AFTER THE PROCEDURE OR ANY SPECIAL CARE I MUST PROVIDE?

The elastic bandages may be removed to take a bath or shower but should otherwise be kept on, including at bedtime. Hosiery may be worn over the bandage during the daytime. Some women are prone to swelling of the legs due to fluid retention. If this is a problem the elastic bandage may cause this to be somewhat worse. However, swelling may be seen below the bandages in anyone. This swelling disappears about one day after the bandages are removed. For the first 24 hours after the treatment, it is recommended that no strenuous activity take place, such as running or aerobic exercise. After the first day you may resume all types of activity. Immediately after sclerotherapy you may perform your usual non-strenuous activity, such as going to work.

DO I NEED SOMEONE TO DRIVE ME HOME AFTER A TREATMENT ?

No. You should be able to get along well and can even drive yourself.

AFTER A TREATMENT, HOW LONG WILL IT TAKE BEFORE THE VEINS DISAPPEAR?

Spider veins slowly disappear several weeks after the treatment. Large varicose veins may take longer to disappear, sometimes several months. While the veins are fading, there may be some faint redness.

CAN MY LEGS BE EXPOSED TO SUNLIGHT AFTER TREATMENT?

It is recommended that you avoid getting much sunlight to the treated site. If you plan on being outdoors within the first month after the elastic bandage is removed, you should apply at least a #25 SPF sunscreen on the skin over the treated veins.

IF I HAVE MY VEINS TREATED, CAN THEY REAPPEAR?

Once these spider or varicose veins are treated successfully they disappear permanently. However, this treatment does not prevent new veins, that would otherwise have developed, from appearing.

IS THERE ANY HARM DONE IN REMOVING THESE UNSIGHTLY VEINS?

No. These veins are just abnormal veins which have no useful purpose. Their removal is not dangerous since your body doesn't rely on these veins for any useful circulation. By removing them, we don't cause new ones to appear elsewhere on your legs.

WILL TREATING THE VEINS THAT I ALREADY HAVE MAKE IT LESS LIKELY NEW VEINS WILL APPEAR?

Yes. Most spider veins occur in patches connected to one another. These patches slowly enlarge by new veins sprouting out from the original patch. If a patch is treated, then new branches cannot develop. Therefore, treating a site can prevent new veins from developing.

IS THERE ANY TIME OF THE YEAR THAT IS BEST TO HAVE THIS PROCEDURE?

This procedure can be performed any time of the year. However, since there may be a slight bruising and redness to the treated site for a few days to a couple of weeks, you may not want to begin treatment just before taking a vacation or going to the beach.

ARE THERE ANY MEDICAL CONDITIONS WHICH WOULD MAKE ME A POOR CANDIDATE FOR SCLEROTHERAPY?

If you have a history of phlebitis, or blood clot of the legs, this procedure may not be recommended. Before beginning therapy you should inform Dr. Green of any medical problems that you have and all of the medications that you take. Although there is no harmful chemical injected with this procedure, we prefer not to treat women who are pregnant or nursing, since varicose and spider veins that worsen during pregnancy often become smaller or resolve after delivery.

HOW DOES THIS PROCEDURE COMPARE WITH TREATMENT USING A LASER OR AN ELECTRIC NEEDLE ?

Laser and electric needle treatments for spider veins scar the overlying skin. The advantage of sclerotherapy is that the needle is placed under the skin directly into the vein. Thus, the likelihood of damaging the skin is greatly reduced.

HOW ABOUT VEIN STRIPPING FOR VARICOSE VEINS?

Only in rare cases is the stripping of large varicose veins, an extensive surgical procedure, required. However, sclerotherapy will usually remove large varicose veins without resorting to surgery. Vein stripping always causes scarring of the legs and thighs.

WHAT OTHER ADVANTAGES DOES SCLEROTHERAPY HAVE OVER SURGERY ?

Sclerotherapy is an outpatient procedure done in the office. It doesn't require hospitalization, anesthesia, or loss of time away from work. It costs a fraction of what surgery would cost with less risk of complications. It is the safest method for vein removal available.

ARE THERE ANY RISKS OR SIDE EFFECTS OF SCLEROTHERAPY ?

Temporary or permanent discoloration may result from sclerotherapy after the veins have disappeared. This discoloration may parallel the course of the treated vein. However, such discoloration is usually less unsightly than the veins. Scarring of the skin, although rare, is a potential complication. This results from leakage of the saline solution from the vein into the overlying skin. Such scars are usually very small and are much less obvious than scars that invariably result from surgical vein stripping.

HOW SHOULD I PREPARE FOR MY SCLEROTHERAPY OFFICE VISITS?

On the day of your procedure, you should not apply any moisturizer or use any bath oil on your legs or thighs. It would also be helpful if you bring along a pair of shorts to put on in the office since most women find this more comfortable than a gown.

WHO IS QUALIFIED TO PERFORM SCLEROTHERAPY ?

Since this technique is a medical procedure it should only be performed by a qualified physician. In particular, the physician should be one who has a great deal of experience in sclerotherapy.

WHAT QUALIFICATIONS DOES DR. GREEN HAVE?

Dr. Green specializes in sclerotherapy and has been performing it for ten years. He lectures nationally and has written scientific articles about sclerotherapy in well recognized medical books and journals. Dr. Green is recognized by his peers as an authority on sclerotherapy. Also, Dr. Green is Certified by the American Board of Dermatology: a Fellow of the American Academy of Dermatology: a Fellow of the American Academy of Facial Plastic and Reconstructive Surgery: a Fellow of the American Society for Dermatologic Surgery: and a Member of the North American Society of Phlebology.

DO INSURANCE COMPANIES PAY FOR SCLEROTHERAPY ?.

Since health insurance plans vary in their benefits, consult your insurance carrier to determine whether sclerotherapy is covered by your policy.