

IN THE MATTER OF
PAUL V. BEALS, M.D.

Respondent

License Number: D25922

* BEFORE THE
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* STATE BOARD OF PHYSICIAN
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* QUALITY ASSURANCE
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* Case Number: 85-0081
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MODIFIED ORDER

BACKGROUND

On June 21, 1988, the Commission on Medical Discipline (the "Commission") executed a non-public Disposition Agreement in which the Respondent was required to comply with terms and conditions imposed by a Consent Order attached to the Disposition Agreement. The Agreement served to resolve charges, against the Respondent, for alleged violations of the Maryland Medical Practice Act, Health Occupations Article §14-504(4)(11) and (18). The Agreement provided that the Board of Physician Quality Assurance (the "Board"), successor to the Commission, would entertain a petition to terminate any portion of the Agreement, with the exception of the cease and desist provisions contained in the Consent Order, four (4) years from the date of the Agreement, namely June 1992.

On October 23, 1991, the Board voted to charge the Respondent with a violation of the Disposition Agreement/Consent Order. The charge of a violation occurred prior to the Respondent's eligibility to petition for termination of the probationary conditions. As a result of the violation, a Consent Order was executed on November 10, 1993. In accordance with the Consent Order, the Respondent's license to practice medicine, in the State of Maryland, was suspended for a period of three (3) years, the suspension immediately stayed and a probationary period of three (3) years imposed. The Order further provided that the Respondent be subject to

terms and conditions during the period of probation.¹

On March 6, 1996, the Respondent appeared before the Board's Case Resolution Conference (the "CRC") with a request for modification of the Consent Order.

FINDINGS OF FACT

1. On June 21, 1988, the Commission executed a non-public Disposition Agreement in which the Respondent was required to comply with terms and conditions imposed by a Consent Order attached to the Disposition Agreement.

2. On October 23, 1991, the Board voted to charge the Respondent with a violation of the conditions of the Disposition Agreement/Consent Order.

3. The Respondent entered into a public Consent Order, dated November 10, 1993, as resolution of charges issued under the Maryland Medical Practice Act.

4. In accordance with the Consent Order, dated November 10, 1993, the Respondent's license to practice medicine in the State of Maryland was suspended for a period of three (3) years, the suspension immediately stayed and a three year period of probation imposed.

5. In accordance with the Consent Order, the Respondent was required to submit to certain terms and conditions during the three year period of probation.

6. On January 18, 1996, the Board received the Respondent's Petition for modification of the Consent Order, so as to permit the Respondent to perform chelation therapy.²

¹ The November 10, 1993 Consent Order is incorporated by reference and available upon request.

² Chelation therapy was prohibited under the 1993 Consent Order as a result of the cease and desist provisions of the 1988 Disposition Agreement having been incorporated into the 1993 Consent Order.

7. On March 6, 1996, the Respondent appeared before the Board's CRC with a request for modification of the Consent Order.

8. The CRC Committee recommended that the Consent Order be modified so as to permit the Respondent to perform chelation therapy, and that the Respondent be required to provide his patients with an informed consent and disclosure agreement, on a form approved by the Board, prior to the date on which chelation treatment is to begin.

9. On April 24, 1996, the Board voted to accept and in turn ratified the recommendations of the CRC.

CONCLUSION OF LAW

The Board incorporates by reference those Conclusions of Law set forth in the Consent Order dated November 10, 1993.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 26th day of July, 1996, by an affirmative vote of the majority of the full authorized membership of the members of the Board of Physician Quality Assurance, who considered this case, hereby

ORDERED that the Consent Order dated November 10, 1993 be **MODIFIED** so as to permit the Respondent to perform chelation therapy; and it is further

ORDERED that prior to the start of chelation therapy, the Respondent shall acquire

informed consent from the patient utilizing a form approved by the Board³; and it is further

ORDERED that all other conditions of the Consent Order dated November 10, 1993 shall remain unmodified and in full force and effect; and it is further

ORDERED that this **MODIFIED ORDER** is a **PUBLIC** document pursuant to Maryland State Gov't Code Ann. §10-611 et. seq.

Date 26 July 1996



J. Michael Compton
Executive Director

3. Attached is a copy of the Board approved chelation therapy patient disclosure form. Board approval of a form for purposes of informed consent does not constitute an endorsement of any medical treatment, regimen or practitioner.

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CHELATION THERAPY PATIENT DISCLOSURE FORM

The purpose of this document is to provide information to Dr. Beals' patients regarding his use of Chelation Therapy as a treatment for patients with occlusive vascular disease. This document outlines the potential benefits, risks and alternatives to this treatment.

By signing this document, you understand that you will become a patient in a program involving the controversial use of E.D.T.A. (Ethylenediamine Tetraacetic Acid) as a chelating agent in the treatment of Occlusive Vascular Disease. This treatment program is to be conducted and supervised by Dr. Paul Beals and his staff.

The treatment will begin on your second office visit (or if you have received this by mail, at your next office visit), after initial laboratory test results are available. You will be asked to take this document home with you and read it carefully. At the next scheduled visit, you will have an opportunity to ask Dr. Beals any questions you may have regarding your condition, the treatment program, its risks, its benefits, and all of the alternatives to this treatment. After you have fully discussed the program and the information in this document with Dr. Beals, you will be asked to sign this document, and permanent copy will be maintained in your medical chart.

Advocates of this form of treatment state the potential benefits and values of this treatment are primarily to attempt to improve the flow of blood in your body, particularly through certain critical and vital areas of the body where there is impaired flow of blood that may be due to Occlusive Vascular Disease. Chelation is approved by the Food and Drug Administration as safe and effective for the removal of lead and/or other heavy metals that may be toxic to the body as well as calcinosis (elevated blood calcium) and digitalis toxicity. It has not been specifically approved for the treatment of Occlusive Vascular Disease. The FDA need not specifically approve a drug for a particular use for it to be used. So long as the drug has been approved by the FDA for one use, doctors may lawfully use that drug for a different purpose even though use of the drug for that purpose has not been approved by FDA as safe and effective.

REASONS FOR TREATMENT

Dr. Beals has recommended that you participate in this treatment program because of your occlusive vascular disease which was determined by and based on your history, physical examination, and non-invasive vascular testing. Your diagnosis, therefore, may have been because you have already had a previous heart attack, stroke, gangrene, scleroderma, early senility, or even previous vascular surgery which demonstrated your problem or, you may have already undergone special x-rays with invasive procedures in the hospital with another physician (an angiogram or an arteriogram) which may have demonstrated your occlusive vascular disease process.

You may not yet have had these conditions or problems, but as a result of your examination and tests, it has been found that you have an impairment in circulation in one or more areas of your body which may cause you trouble in the future. This could be demonstrated on an examination such as your treadmill stress electrocardiogram, which may have disclosed that you had a significant or potentially dangerous abnormality, or it could have been demonstrated on your plethysmograph examination showing blood flow impairment to your leg or other extremities. In addition, this may have been supported by special doppler ultrasound studies or other studies regarding the adequacy of blood flow through your arteries to your brain, or your arms and legs.

A DESCRIPTION OF THE TREATMENT PROGRAM

A. Protocol: The chelation program you will be receiving will adhere to the guidelines of the protocols established and approved by the American College for Advancement in Medicine (ACAM), which is [describe group].

B. Type of Treatment: You will receive a series of intravenous treatments through a vein in your arm or leg. During each treatment you will receive from 500 to 1000 cc's of fluids consisting of a synthetic amino acid known as E.D.T.A. (Ethylenediamine Tetraacetic Acid)

C. EDTA: EDTA is a well accepted chelating agent which was approved by the FDA when used for lead poisoning but which is controversial and not FDA approved when used for occlusive vascular disease.

D. Additives: The intravenous treatment not only includes E.D.T.A. added to a bottle containing sterile water, dextrose, salt water or other similar diluting fluids, but it may also include liquid injectable forms of vitamin C, potassium, magnesium, heparin, hydrochloric acid and one or more of the vitamin B factors. In addition, some common anesthetic agents known as lidocaine, xylocaine, or procaine may be added if there should be any undue discomfort or burning as the infusions enter your arm or leg.

E. Rate of Infusion: Each time you receive this intravenous treatment, it should be at a rate not to exceed 250 cc's per hour.

F. Number of Treatments: You will receive approximately _____ treatments, although it may be necessary to have as many as fifty or more treatments depending on your response. The average number of treatments necessary for the first series is between 30 and 40. The number of additional treatments per series and the number of series necessary will depend on your response to the treatments.

G. Frequency of Treatment: You may generally expect to receive these treatments at least once but not more than five times per week.

H. Maintenance Therapy: After one or more series of treatments, it is advisable to continue chelation therapy either once per month or ten to twelve treatments per year.

I. Response Monitored: Your response to this treatment program will be monitored from time-to-time by whatever means Dr. Beals and his staff deem medically necessary and in accordance with good medical practice.

J. Diet: You are also expected to comply with the special dietary program recommended for you which includes the definite restriction of all refined sugars, starches, or other processed foods and beverages and dairy products.

K. Drugs: You are not to use coffee, tea, tobacco, alcohol, or illegal drugs in any form and that you will notify us immediately of all prescription drugs which you are taking and that they will be reduced to an absolute minimum.

L. Exercise: You are expected to embark on an active, planned and regular exercise program which we may recommend for you.

M. Supplements: The complete program includes regularly taking the prescribed vitamins and minerals, enzymes, amino acids and any other supplements that may be recommended for you this office.

N. Safety: It is necessary to follow the entire treatment program in order to insure the safety of the program and to prolong any benefits the treatment may provide.

HISTORY AND PHYSICAL: There is the necessity for a complete history and physical examination being performed and you agree to cooperate to the best of your ability. It may be necessary for Dr. Beals to seek consultations regarding your condition from other physicians.

LABORATORY TESTING:

A. **Blood:** You will be subject to certain laboratory tests in order to ascertain exactly what your health status may be. These tests may determine whether you have diabetes, elevated cholesterol, or other blood fats, hypoglycemia, liver disease, kidney disease, anemia, infection, clumping of blood cells, a condition of your immune system and such other problems that may have some bearing on whether or not you should undergo chelation therapy. Many of these tests will serve later as a source of additional useful information regarding the effectiveness of the total program in your case.

B. **Urine:** It will be necessary to submit many urine specimens. Some of these will be used for routine urinalysis and may be cultured for bacteria content to determine the possibility of infection or the condition of your immune system. Other specimens may be collected for an entire 24-hour period so that creatinine clearance, the total amount of calcium and possibly other minerals that are removed from your body with chelation may be determined. In addition, this urine test will see if any poisons that are supposed to be removed from your body efficiently, i.e. creatinine are in fact being removed. This information also helps to ascertain the basic health of your kidneys and retesting them during treatment helps assure Dr. Beals that no harm is occurring or has occurred to your kidneys as a result of either the treatment program or any prior health problem.

C. **Non-Invasive Studies:** Part of your laboratory evaluation may be directed to determining the location and extent of any reduction in blood flow in your body. These studies are painless and do not require hospitalization. Such studies may include some or all of the following:

1. **EKG:** The necessity for a resting EKG is to monitor the progress of the treatment as well as to determine the condition of your heart.

2. **Exercise Tolerance:** This study may be necessary to give more complete information than a resting EKG. If the test is performed, you will be asked to walk rapidly on a treadmill while your heart is continuously monitored and your blood pressure will be taken at frequent intervals. You will also be asked to sign an informed consent for this procedure because of the chance that your heart may react adversely to vigorous exercise.

3. **Plethysmograph:** That this is a special blood pressure cuff that can go on your wrist, thigh or even fingers and which has an electronic device which makes a graph from which the amount of occlusive vascular disease in your arms or legs, etc. may be inferred.

4. **Doppler Ultrasound:** This device works similarly to a microphone and it listens to the blood as it goes through a blood vessel. It also provides additional information regarding your circulation and records it on a graph.

5. **Cardiac Output:** This highly sensitive device uses twelve electrodes, computer and recorder to measure and determine your cardiac output, stroke volume, heart rate, cardiac ejection time and systemic vascular resistance.

6. **Pulmonary Function:** This test will determine if you have lung disease and if present, the severity of the lung disease. This test will probably be done if you have a history of smoking, asthma, emphysema, chronic bronchitis, occupational exposure to pollutants or a previous report of an abnormal lung condition.

ALTERNATIVES TO CHELATION

There are alternative treatments and/or procedures for occlusive vascular disease that might be beneficial to you. These alternatives or other treatment options include:

A. Drug Therapy:

You may choose to undergo long-term drug therapy which, if your basic health problem is an impairment of blood flow through your coronary arteries (heart), producing angina (chest pain) you might be placed on a drug program which could include the long-term use of long acting nitrates to dilate blood vessels and/or Propranolol (Inderal), to control the workload of your heart or "calcium blockers" or "calcium antagonists", other than E.D.T.A. as well as other more experimental and unproven drugs such as aspirin, or Persantine which are currently believed to help decrease platelet agglutination and serious complications of occlusive vascular disease.

If your occlusive vascular disease is primarily in your head, arms or legs, you might be placed on other blood vessel dilating drugs (vasodilators) such as Pavabid, Papaverine, Arlidin, Vasodilan, and/or even high doses of Niacin. These preparations have been reported by some patients to decrease symptoms associated with their impaired circulation of the head or legs. Also, you might be placed on cholesterol-lowering drugs.

B. Surgery:

1. By-pass: You may choose to undergo a vascular surgical procedure in the area where your disease is worse, for example, if the disease is primarily in your legs, this may be an aortal-femoral by-pass which may involve the placing of a graft in your lower abdomen and into your upper leg. Another surgical procedure known as a sympathectomy (cutting of a nerve) could be done in order to increase the blood flow to your leg (if successful) by relaxing the blood vessels. If your problem is blood flow to your head, you may undergo a procedure in the neck (known as endarterectomy) to hopefully clean out blocked areas in your neck vessels in order to improve the blood flow to your head. If your problem is blood flow to your heart blood vessels, you may undergo so-called by-pass surgery on the involved coronary arteries which supply the blood to your heart. This operation is especially recommended at most major heart centers when you have a significantly severe obstruction of your left main coronary artery and you suffer from disabling intractable (i.e. will not respond to drugs) angina or if you have more than a 70% obstruction in the blood flow to any of the three major coronary vessels.

2. Benefits of Surgery: At this time there is little evidence to demonstrate that if you undergo by-pass surgery on the coronary arteries of your heart, that it may extend your life span. There is a study which was recently reported by the National Institute of Health which demonstrated that the drug therapies listed above (i.e. nitrates and Inderal and/or digitalis) has apparently been at least as good if not better than by-pass surgery in attaining the long-term survival of five years or more in coronary heart disease patients.

C. Non-surgical Procedures:

1. Angioplasty: You may choose to undergo a procedure known as angioplasty whereby a catheter is passed into the affected arteries and a balloon is then expanded in order to widen the channel at the point of blockage. This is a procedure which is done by interventional cardiologists and can be done at a variety of area hospitals. This procedure involves only minimal surgery when a vein must be opened in order for a catheter to be threaded up through the body into the area where the blood vessel is narrowed by occlusive vascular disease.

D. No treatment at all:

You may choose to undertake no therapy whatsoever and simply go on living with your present condition for as long as you live.

E. Conservative life style changes only.

F. No E.D.T.A.: You may choose to follow the above treatment program but may leave out the intravenous E.D.T.A. part of the program. This means that you would follow the dietary changes, supplements, exercise program, cessation of smoking and even attempt to decrease excessive levels of stress in your life. These changes in life style should tend to decrease or delay to some degree the rate of development of occlusive vascular disease without even receiving the special chelation therapy with E.D.T.A. All of these changes in life style have been reported in different scientific articles as showing some benefit by themselves, either through delaying the otherwise inevitable development of occlusive vascular disease or by either preventing further progression or a demonstrable reversal of occlusive vascular disease in some patients.

G. Watchful Waiting: You can choose watchful waiting and simply report to a physician your choice periodically, waiting until your condition either improves or becomes worse at which time you may decide to then go into a more active therapy program such as any or all of those already discussed above. Some who have had surgery may later need to follow these programs and some who follow these programs may later require surgery.

YOUR RIGHTS AS A PATIENT

A. This a controversial treatment program. As with almost any treatment, you have the right not to participate in this treatment program for any reason whatsoever.

B. You will not lose any rights or benefits with Dr. Beals or his staff now or in the future if you decide not to participate.

C. You can ask any questions you wish about this treatment at any time. Dr. Beals and/or his staff will try to answer them as fully, fairly and understandably as possible.

D. You can withdraw from this treatment at any time for any reason and you do not have to explain your reasons to anyone. If you do withdraw, none of your other rights or privileges unrelated to the treatment program will be negatively affected or denied.

E. You will receive a copy of this disclosure form for future reference.

F. You will be told the status of your condition upon your request and you will be told of any change in your condition as it may have been affected by the treatment program by either Dr. Beals or his staff.

RISKS AND POTENTIAL SIDE EFFECTS

A. Kidney Damage:

1. The current statistics indicate that the potential for any serious renal (kidney) problem developing as a definite and direct result of your receiving E.D.T.A. therapy is approximately 1 in 50,000.

2. You must accept the remote possibility of potential kidney damage resulting from any decision to undertake E.D.T.A. therapy.

3. There are reports that state that E.D.T.A. may be toxic to your kidneys. This is particularly important to consider if you have ever had any previous ailment or disease. The total reported cases of "apparent" damage to kidneys definitely resulting from E.D.T.A. is less than 1 per 1000 and that apparently where damage did occur, a much higher and more rapidly administered dose of E.D.T.A. had been given than is used today.

4. Contrary to popular belief, E.D.T.A. is not damaging to the kidneys when properly administered. Actually, in most cases kidney function improves after a course of therapy.

B. Thrombophlebitis:

1. A soreness or a redness over a vein which may proceed to an actual inflamed red streak going up and down your vein is called thrombophlebitis or an inflammation of the vein. This usually appears in the area in which the intravenous treatment has been given, but it also might occur in any other part of your body, such as your leg. This inflamed area is a potential danger area where a blood clot could later develop and this might represent a significant threat to your health. Blood clots have been known to break off and go to the lung or even other parts of the body, and they could thus cause a serious medical condition which might require hospitalization or surgery.

2. Thrombophlebitis occurs in less than one percent of patients and that usually simple local treatment consistent of moist heat and elevation of the affected part of your body with complete rest is sufficient. However, because occasionally a blood clot does form, you must immediately bring any inflamed vein condition to the attention of Dr. Beals so that he may decide whether or not more aggressive therapy, including anticoagulants, antibiotics, hospitalization, or even surgery is warranted.

C. Low Blood Sugar: There is a definite likelihood that your blood sugar may drop during your intravenous chelation treatment so that you may have to receive a glass of orange juice or it may be necessary to have an intravenous feeding of glucose to elevate your blood sugar in order to eliminate a faint or weak feeling during your treatment.

In addition, if you have sugar diabetes, you must carefully watch your urine and get weekly blood sugar tests for the first few weeks and report immediately, any change in your condition to your physician so that he may advise any change in your insulin dose that may become necessary as a result of this potential change in your condition due to chelation.

D. Low Blood Pressure: Occasionally some people receiving chelation therapy may get a feeling of sudden generalized weakness or a feeling that they may faint, particularly if they were to stand up suddenly and especially during or after their intravenous treatment. This is apparently because blood pressure can become much lower during treatment and in fact, many people with high blood pressure will not need to continue their high blood pressure medication after chelation because of this effect. If you get this feeling that you may black out during treatment, you may have to stay in your chair for an extra period of time (an hour or so) in a resting position, which is particularly helpful if your feet are elevated and your head is kept low for fifteen minutes or even up to an hour, until your blood pressure is normalized. This severe drop in blood pressure happens in less than one percent of patients.

E. Nausea: It is possible during your therapy to get an upset stomach with nausea, and you might even have the desire to vomit. If you bring this problem to the attention of Dr. Beals or his staff, it is usually readily treated with medicine or more vitamin B-6. This affect, however, also occurs in less than one percent of patients.

F. Diarrhea: You may develop a loose stool (diarrhea) immediately after treatment or even the following day. If this occurs, simple antidiarrheal treatment will usually resolve this problem which has never been reported to be a major problem and which occurs in less than one percent of patients.

G. Numbness and Cramps: Because this treatment lowers your calcium during the time the intravenous treatment is going into your body, that you will have some strange feelings in your body. Most of these are due to the low calcium condition in your blood and these feelings may include a feeling like pins and needles around your mouth or even in other parts of your body. There may be leg cramps during treatment and

leg cramps or spasm have been reported as late as a day or two after intravenous treatments. These may require Dr. Beals to change your treatment by giving you treatments more slowly (over six to eight hours) or even decreasing the dose given at each treatment to a lower amount of E.D.T.A. Another choice is that you may have to take your treatments less frequently. You may require some supplemental minerals such as calcium, magnesium or even potassium which can be injected while you are still in the office when this problem arises or which can be taken by mouth if the problem occurs after you go home. Some cramps reportedly happen at one time or another in five percent of patients. Recently, the use of added magnesium in the intravenous treatment has markedly decreased the frequency and severity of this problem so that it is a minor problem.

H. Headache: Occasionally headaches may develop which usually respond to simple pain medication. Headaches have been reported in less than one percent of patients.

I. Fever: Rarely (1 in 5000 or less) you may develop an unexplained fever within the first twenty-four hours after a treatment which usually goes away without any treatment. I would handle this the same as a simple one-day flu, by taking additional aspirin. You should, nonetheless, bring this problem, should it occur to the attention of Dr. Beals or his staff.

J. Skin Rash: There has been some patients who develop a skin rash. This is apparently related to the body's increased loss of certain vitamins such as B-6 and minerals such as zinc during chelation. Since you are taking these substances in your supplements, this problem may not develop. This has only been reported in less than one percent of patients even before the addition of these supplements to the treatment program. Any rashes which occur at this point in time should be much less frequent. If you develop a skin problem, you should report it to Dr. Beals or his staff so that it may be evaluated and proper treatment recommended.

POTENTIAL BENEFITS

Although occasionally some patients have seen a dramatic improvement in their vascular problems such as angina or leg cramps, after only a few treatments, this is not the average or expected time frame for any potential benefits that you may obtain as a result of chelation to appear. Usually benefits may not be evident until thirty, sixty, or even ninety days after you have completed your course of therapy comprising at least thirty to forty treatments as determined by Dr. Beals. Your response will also depend on the severity of your problem, your individual response to treatment, and your compliance with all other treatment recommendations.

Any benefits which you may see as a result of this therapy may not be very long lasting and in one or two years, your problems could recur so that you might need additional chelation therapy. It is currently believed, however, that occlusive vascular disease takes years to develop and, therefore, life style changes which you are being encouraged to undertake include discontinuing smoking, decreasing intake of saturated fats, sugars and all processed foods, eliminating the intake of coffee, tea, milk and alcohol, establishing or increasing an exercise program, and continuing at least one chelation treatment per month after the desired response to this therapy has been achieved.

UNDERSTANDING

I understand that the above procedures involved in the chelation therapy program as they apply to me, and it is up to me to follow all of the recommended treatment programs faithfully if I am to obtain the maximum possible benefits for my time, money and effort in participating in this program.

I also understand that as a medicare or medicaid patient, these programs will not pay for my treatments or any of my vitamin or mineral supplements because this program is not considered to be the usual and customary treatment for my health problem.

I further understand that Dr. Beals' theories and treatments with regard to occlusive vascular disease and chelation therapy may be considered to be non-traditional medicine or "alternative medicine". Most conventional physicians would not entertain chelation therapy as a treatment option nor would they prescribe or provide chelation therapy to their patients. If a patient had serious health problems arising from occlusive vascular disease, such physicians would rely entirely on the surgical, medical or other procedures listed above rather than providing chelation therapy.

I have fully read this document which was provided to me on my previous visit. I have now had the opportunity to ask Dr. Beals any questions or concerns which I have regarding the treatment, its potential benefits, the risks of the treatment and the potential alternatives to this treatment as well as their risks and benefits.

I now wish to undergo this treatment.

PATIENT'S SIGNATURE

DATE

WITNESS

DATE

PHYSICIAN'S SIGNATURE

DATE