IN THE MATTE	ER OF			*	BI	EFORE 1	THE		
PAUL V. BEAI	.s, m.d.			*	SI	TATE BO	ARD OI	F PHYSIC	CIAN
Responden	ıt			*	QU	JALITY	ASSUR	ANCE	
License Numb	er: D2592	2		*	Ca	se Nun	ber:	85-008	81
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CONSENT ORDER

The State of Maryland Board of Physician Quality Assurance (the "Board") charged Paul V. Beals, M.D. (the Respondent) (D.O.B. 4/15/43), License Number D25922, with violation of the conditions of the Disposition Agreement/Consent Order of June 21, 1988, and with violations of the Maryland Medical Practice Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") §14-404 (1991 Repl. Vol.) on October 23, 1991.

The Board charged that the Respondent violated the following conditions of the Disposition Agreement/Consent Order which provide:

I. Cease and Desist Provisions

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(A) Respondent hereby agrees to the following permanent restrictions with respect to his medical practice in the State of Maryland:

(1) Respondent shall not prescribe or otherwise utilize the following tests, treatment, procedures or protocols:

- (a) Hair and diet analyses;
- (b) Indican tests;
- (c) Mauve urine factor;
- (d) Xanthine oxidose analysis (XOA).
- (e) Heidelberg capsule tests.

V. Additional Requirements

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(A) Respondent shall properly utilize and order standard diagnostic tests when medically indicated and shall document in the patients'

chart any refusal by the patient to submit to such test;

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(B) Respondent shall maintain legible and complete medical records which shall be typewritten if deemed necessary by any expert reviewing his practice on behalf of the Commission;

(C) Respondent shall practice medicine competently.

The Board further charged that the Respondent violated the following pertinent provisions of H.O. \$14-404 which provide:

(a) Subject to the hearing provisions of §14-405 of this subtitle, the Board, on the affirmative vote of a majority of its full authorized membership, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:

(22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State.

The Respondent was notified of these charges on March 1, 1993. On May 5, 1993, the Board held a case resolution conference (CRC). As a result of the CRC's recommendations and the negotiations entered into between the Office of the Attorney General and the Respondent, the Respondent agreed to enter into the following Consent Order according to the terms set forth below.

FINDINGS OF FACT

1. At all times relevant to these charges, the Respondent was and is licensed to practice medicine in the State of Maryland. He was initially licensed in Maryland on December 18, 1980.

2. On the basis of a complaint filed with and an investigation by the Maryland Commission on Medical Discipline,¹ now known as the Board of Physician Quality Assurance, (herein-after referred to as the "Board"), the Board issued a charge letter on or about February 17, 1987 alleging three violations of the Act, H.O. \$14-404(a)(4), (10), and (17).²

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3. As a resolution to the charges referred to in paragraph no. 2 above, the Respondent and the Board entered into a Disposition Agreement (the "Agreement") and Consent Order by which the Respondent agreed to certain restrictions, cease and desist provisions, practice limitations.

4. In Part III of the Consent Order, page 6, a provision for ongoing peer review of the Respondent's medical practice was set forth. Pursuant to this provision, the Peer Review Committee (PRC) of the Medical and Chirurgical Faculty of the State of Maryland (Med-Chi) conducted practice reviews of the Respondent's medical practice.

¹The 1988 General Assembly, by Senate Bill No. 508 and House Bill No. 855, merged the functions of the former Commission on Medical Discipline and the former Board of Medical Examiners into the new Board of Physician Quality Assurance.

 2 The above-referenced statute was codified as MD. HEALTH OCC. CODE ANN. §14-504(4), (11), and (18), with substantive language unchanged, for the period which formed the basis of the allegations against the Respondent, as referred to in paragraph no. 2 above.

5. On or about September 26, 1990, after conducting a practice review and interviewing the Respondent, the PRC reported to the Board its conclusion that the Respondent was committing certain violations, including overutilization of lab tests. The PRC members further concluded that various procedures/treatments used by the Respondent were outside the standard of care.

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6. On or about September 4, 1991, after conducting another practice review, consisting of a review of twenty-four (24) patient records, the PRC reported to the Board that it found deficiencies pertaining to patients,³ all as set forth below.

A. Indican tests performed on following patients:

1.	Patient	D	
2.	Patient	I	
з.	Patient	Ľ,	
4.	Patient	М	
5.	Patient	N	
б.	Patient	0	
7.	Patient	Q	
8.	Patient	S	
9.	Patient	U	

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None of the aforementioned patients required evaluation for intestinal integrity regarding absorption, protein, catabolism, high protein diets, increased bacterial growth in the G.I. tract, bacterial decomposition of tissue protein and purulent exudates as

 $^{3}\ensure$ confidentiality, patient names are not used in this document.

in gangrene, empyemas, or pulmonary suppuration. It is below the standard of care in violation of H.O. 14-404(a)(22) to utilize tests which are not medically indicated.

B. Thyroid testing and treatment for the following

patients:

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- Patient A thyroid medication treatment with (Cytomel)⁴ thyroid test (T-4)⁵ performed for monitoring.
- Patient C the records revealed no documentation to support diagnosis of "hypothyroidism; thyroid medication started despite normal thyroid function tests.
- Patient F thyroid medication (Cytomel) started despite normal thyroid function test.
- Patient H thyroid medication started despite the absence of any thyroid testing.
- Patient I treatment for hypothyroidism started despite normal or borderline elevated thyroid test.
- Patient J thyroid medication started despite normal tyroid function test.
- Patient L ~ hypothyroidism diagnosed and thyroid medication (Cytomel) started despite normal thyroid tests.
- Patient M hypothyroidism diagnosed and thyroid medication (Cytomel) started despite normal thyroid test (T-4).

'Cytomel is thyroid medication; a synthetic thyroid replacement hormone.

 ${}^{5}\mathrm{T4}$ is a medical diagnostic test which measures the level of thyroid hormone.

9. Patient N - thyroid medication started despite normal thyroid tests.

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- Patient P thyroid medication started. with no medical indications.
- 11. Patient Q thyroid medication started despite normal thyroid tests (T-4).
- 12. Patient S hypothyroidism diagnosed and thyroid medication (Cytomel) started despite normal thyroid tests.
- Patient X thyroid medication (Cytomel) started despite normal thyroid tests.

The Respondent breached the standard of care in violation of H.O. \$14-404(a)(22) when he instituted regimens of thyroid medication or diagnosed hypothyroidism when thyroid tests were normal. Furthermore, the Respondent's "use of Cytomel [the thyroid medication] for treatment of thyroid disorders is monitored by use of T-4 levels, which [use] is not the standard of care as [T-4] levels may be greatly reduced while on [Cytomel] therapy."

 C. <u>Cortisol tests and steroid treatment for following</u>
<u>patients:</u>

 Patient A - no medical indication for test; ordered as often as every three (3) months.

Patient B - no medical indication for test.

3.	Patient D -	no medical indication for test.
4.	Patient F -	no medical indication for test; yet daily hydrocortisone (steroids) started.
5.	Patient H -	no medical indication for test.
б.	Patient J -	no medical indication for test.
7.	Patient K -	no medical indication for test; yet hydrocortisone started.

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8.	Patient M -	no medical indication for test.
9.	Patient N -	no medical indication for test; yet hydrocortisone started.
10.	Patient P -	no medical indication for test.
11.	Patient R -	no medical indication for test.
12.	Patient S -	no medical indication for test.
13.	Patient X -	no medical indication for test.

It is below the standard of care in violation of H.O. 14-404(a)(22) to order tests or begin hormonal drug regimen with no medical indication.

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D. <u>Testosterone therapy for following patients:</u>

- Patient D a blood test was done on July 1, 1988 and testosterone was administered on the same date. Even though the test for testosterone was normal, the patient received injections of testosterone at regular intervals.
- Patient Q Testosterone treatment with no medical indication.
- Patient U ~ Testosterone treatment with no medical indication.

The Respondent violated H.O. \$14-404(a)(22) by failing to meet the standard of care by instituting hormonal treatment regimens without medical indication.

E. Follicle Stimulating Hormone (FSH) test for following patients: 1. Patient K - no medical indication.

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 Patient P - no medical indication; also treated with copper sulfate injection.

3. Patient Q - no medical indication.

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The standard of care is breached in violation of H.O. \$14-404(a)(22) when tests are ordered or any treatment initiated without documentation of medical indication.

F. Stress tests for following patients:

1. Patient D	•	Patient	D
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- 2. Patient Q
- 3. Patient I
- 4. Patient K
- 5. Patient L
- 6. Patient O
- 7. Patient P -
- 8. Patient W

These tests were administered to the aforementioned patients without medical indication and, except for patients D and Q, without indication as to the type (ACTH vs. cardiac) of stress test in violation of H.O. \$14-404(a)(22) as below the standard of care for utilization of tests without medical indication.

G. Other tests, procedures and medications:

The Respondent also utilized other tests, procedures and medications including, but not limited to: intramuscular estrogen given with oral estrogen (Patient W); megavitamins beyond the accepted and recommended dosages (Patients D, E, and Q); intravenous (IV) colchicine administered without reason (Patients F and K); copper sulfate injection without reason (Patient O); hyperlipidemia diagnosed despite normal lipid levels, folic acid

started without explanation (Patient K). It is a breach of the standard of care, (H.O. 14-404(a)(22)), to utilize or start any treatment or medication without medical indication, or if contrary to recommended dosages or laboratory results.

H. Medical Records:

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The Respondent's penmanship is poor and his records are difficult to read. There is no evidence in the records of diagnostic evaluation plans and/or therapy schedules, or communication of laboratory test results to patients. The records are incomplete, the types of tests, medications are not clearly documented; medical indications for ordering diagnostic tests are absent or not documented. It is a breach of the standard of care and a violation of H.O. \$14-404(a)(22) to fail to maintain complete, accurate, and legible medical records which include complaints, historical, physical, laboratory data, diagnosis, treatment plan, clear reasons for ordering diagnostic tests and prescribing medications.

7. The Respondent disputes some of the conclusions drawn by the peer reviewers in the foregoing Findings of Fact but will not contest them because the documentation for the tests and conclusions drawn therefrom were not self-evident from the office records.

CONCLUSIONS OF LAW

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Based on the foregoing Findings of Fact, the Board concludes, as a matter of law that the Respondent failed to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State in violation of MD. HEALTH OCC. CODE ANN. \$14-404(a)(22) (1991 Repl. Vol.).

The Board, pursuant to its authority under MD. HEALTH OCC. CODE ANN. §14-406, finds that it will not proceed with charges pursuant to a violation of the Disposition Agreement/Consent Order.

ORDER

Based upon the foregoing Findings of Facts and Conclusions of Law, it is this <u>10</u> day of <u>hormous</u>, 1993, by the State Board of Physician Quality Assurance:

ORDERED that Respondent'S LICENSE TO PRACTICE MEDICINE in the State of Maryland be and it is hereby SUSPENDED for a period of THREE YEARS; and it is further

ORDERED that the suspension of Respondent's license to practice medicine in the State of Maryland be and it is hereby STAYED; and it is further

ORDERED that Respondent be and he is hereby placed on PROBATION for a period of THREE YEARS from the effective date of

this Consent Order, that day being the date the Board executes this Consent Order; and it is further

ORDERED that Respondent is subject to the following terms and conditions of probation for a period of three (3) years from the date of this Consent Order:

1. The Respondent shall not perform, order, prescribe or utilize the following tests, treatments, procedures or protocols for or to any patients at any time:

a. Indican tests;

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b. Hair and diet analyses;

c. Heidelberg capsule tests

d. Mauve urine factor;

e. Xanthine oxidose analysis (XOA)

2. The Respondent shall not prescribe, order, utilize or otherwise make available Laetrile (Amygdalin) for or to any patients at any time.

3. The Respondent and all other persons employed by him and subject to his professional direction or control shall refrain from prescribing, administering, utilizing or otherwise engaging in the use of chelation therapy or treatments with respect to his practice of medicine in Maryland. The Respondent shall be permitted to petition the Board for a modification of this prohibitive aspect of the Consent Order and to seek authorization from the Board to resume use of chelation practices based upon new scientific evidence which may become available. The evaluation of the

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scientific evidence and the approval of any resumption of chelation practices is within the sole discretion of the Board.

4. The Respondent shall not utilize, prescribe, institute or administer folic acid, orally or through any vehicle, on, to or for any female patients for the treatment of abnormal pap smears (including Classes 2 and 3 and/or abnormal classifications under the Bethesda System of Reporting).

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a. The Respondent shall not utilize, prescribe, institute or administer folic acid, orally or through any vehicle, on, to, or for any female patients for the treatment of cervicitis without also referring such patient for gynecological treatment for cervicitis.

5. a. The Respondent shall not perform or order any diagnostic tests of any kind that are not medically indicated. The Respondent shall document in the patient's record the medical indication for any and all diagnostic tests. If the patient refuses any such tests, then Respondent shall document in the patient's record said refusal.

b. The Respondent shall not utilize, prescribe or institute any regimens of medication, or utilize, prescribe, administer or institute any drug treatment or therapy, if contrary to laboratory results and/or without medical indication.

c. The Respondent shall not utilize, prescribe or institute any regimens of medication, or utilize, prescribe, administer or institute any drug treatment or therapy, without documentation in the patient's record of medical indication.

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6. With respect to paragraph nos. 5a., b., and c. above, to the extent that Respondent employs "alternative medicine techniques," either in terms of the manner in which he diagnoses an ailment, or in terms of the manner in which he chooses to treat an ailment which he has diagnosed, and to the extent that Respondent utilizes standard testing techniques, but interprets them differently than what might be deemed "traditional," Respondent shall provide complete disclosure to each and every patient as to the nature and purpose of the treatment and/or testing, and/or interpretation of testing, and as to the Respondent's determination to employ continued testing upon patients whose results are normal by traditional standards.

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7. The "complete disclosure" to Respondent's patients of his non-traditional methods of treatment referred to in this Consent Order, as specified in paragraph no. 6 above, shall be in a written format and shall be submitted by the Respondent to the Board for the Board's approval prior to execution of this document and shall be as follows:

a. The complete disclosure to Respondent's patients shall be a written form which shall be entitled "Patient Disclosure," and shall be applicable to those patients described in paragraph 7b. below.

b. For patients that Respondent employs "alternative medicine techniques," either in terms of diagnosing or treating an ailment, and/or utilizing standard testing techniques, but interpreting them differently than what might be deemed

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"traditional," the Respondent shall submit a Patient Disclosure to each and every such patient, from the effective date of this Consent Order. Each and every such patient, or, in the event of a minor or incompetent, the legal guardian, shall sign the "Patient Disclosure" form, and be given a copy. The Patient Disclosure form shall be documented in, made a part of, and filed in the patient's office record.

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 c. For each such ailment or condition as described in
7b. above, the "Patient Disclosure" shall contain the following information:

(1) Documentation of traditional methods of treatment and/or medical management, including regimens of medication, drug treatment or therapy, and diagnostic tests; and

(2) Complete disclosure of the Respondent's proposed treatment plan utilizing alternative medicine (nontraditional) techniques, including:

 (a) Disclosure of Respondent's use/repeated use of standard testing techniques and/or diagnostic tests when such tests yield normal results/values by traditional standards; and

(b) Disclosure of Respondent's use of medication regimens and/or drug treatment or therapy for conditions or ailments for which standard testing techniques and/or diagnostic tests yield normal results/values by traditional standards; and

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(3) List of the risks associated with failing to follow the traditional methods of treatment as compared to adhering to the proposed alternative medicine (non-traditional) techniques.

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Ц Ца 8. The Respondent shall maintain complete and legible patient records, including in his charts a record of diagnostic evaluation plans and/or therapy schedules, communication of laboratory results to patients, types of tests, medications, and medical indications for ordering diagnostic tests. The Respondent shall retain and use the services of a medical records transcriber or transcription service for records transcription and shall submit proof of the retention to the Board in writing on or before the effective date of this Consent Order. The written proof shall be in the form of an Affidavit signed by the Respondent and shall consist of the name, address and telephone number of the transcriber or transcription service.

9. The Respondent shall be subject to periodic peer reviews during the period of probation as ordered by the Board, shall cooperate in order to facilitate peer review, and shall participate in peer review where and when requested. The first peer review shall commence six (6) months after the effective date of this Consent Order. Thereafter, the Respondent shall be subject to additional peer review on an annual basis. The Respondent will receive a copy of each peer review report. Pursuant to and in furtherance of this Consent Order, the periodic peer reviews of Respondent's practice shall not encompass any patient's records or materials pertaining to the treatment and care of patients prior to

the effective date of this Order. Such reviews shall only encompass treatment and care of patients seen by Respondent subsequent to the effective date of this Order, that being the date the Board executes the Order. However, nothing in this Consent Order shall be construed or interpreted as prohibiting or precluding the Board from investigating, reviewing, or charging Respondent, or otherwise proceeding against Respondent, for acts prior to the execution date of this Consent Order constituting violations of the Medical Practice Act.

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a. The Board through the Medical and Chirurgical Faculty of Maryland ("Med-Chi") Peer Review Management Committee has complete and sole discretion to select the peer review committee and peer reviewers.

b. If, after conducting appropriate peer review of any kind, the peer review committee reports to the Board that Respondent is not practicing within the standard of care, and if the peer review determination is approved and adopted by the Board, which has sole discretion in the matter, then this breach of standard of care shall be deemed a violation of probation under the terms of this Consent Order.

10. The Respondent shall practice competently. The Respondent shall practice within the standard of care as determined by appropriate peer review to be conducted as set forth in paragraph no. 9 above. If the Respondent is found to be practicing below the standard of care with respect to treatment rendered to his patients after the effective date of this Consent Order as

determined by the Board through appropriate peer review, then he is deemed to have breached and violated the terms of his probation and this Consent Order.

AND BE IT FURTHER ORDERED that if the Respondent violates any of the terms of his probation as set forth in this Consent Order, including a finding by the Board that the Respondent is not practicing medicine within the standard of care which breach of standard of care is deemed a violation of probation and this Consent Order as specified in paragraph no. 10 above, then the Board, after determination of violation and notice and a hearing, shall-lift the stay of suspension and reinstate the three (3) year suspension and/or impose any other disciplinary sanctions it deems appropriate, said violation of probation being proved by a preponderance of evidence; and be it further

ORDERED that if the Board has probable cause to believe that the Respondent presents a danger to the public health, safety or welfare, the Board, WITHOUT PRIOR NOTICE AND AN OPPORTUNITY FOR A HEARING, MAY VACATE THE STAY OF SUSPENSION AND REINSTATE THE SUSPENSION, and/or impose any other disciplinary sanctions it deems appropriate, provided that the Respondent is given notice of the Board's action and an opportunity for a hearing within thirty (30) days after requesting same in accordance with State Government Article, of the Annotated Code of Maryland, Section 10-405; and be it further

ORDERED that three (3) years after the effective date of this Consent Order, the Respondent may submit a petition for termination

of probation and reinstatement of his license without any conditions or restrictions to the Board; and be it further

ORDERED that the Respondent shall be responsible for all costs incurred under this Consent Order such as the copying of office records in the peer review process; and be it further

ORDERED that this Consent Order is considered a public document pursuant to MD. STATE GOV'T CODE ANN. \$10-611 <u>et seq</u>. (1993 Repl. Vol.).

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2 Israel H. Weiner, M.D., Chair

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Israel H. Weiner, M.D., Chair Board of Physician Quality Assurance

. CONSENT

I, PAUL V. BEALS, M.D., acknowledge that I am represented by legal counsel, and I have had an opportunity to consult with counsel before entering into and signing this document. By this consent, and in order to resolve this case, I agree to accept the Findings of Fact, Conclusions of Law, and accept and submit to the foregoing Consent Order, consisting of twenty (20) pages.

I acknowledge the validity of this Consent Order as if entered after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections provided by the laws of the State of Maryland.

I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order.

I also affirm that I am waiving my right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order, after having read and reviewed it and after having had an opportunity to consult with counsel, voluntarily and without reservation, and with full understanding and comprehension of the language, meaning, and terms of this

Consent Order

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M.D. V. Beals, Paul Respondent

Read and approved:

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25.1993 Date

Burt M. Kahn, Esquire Attorney for Respondent

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STATE OF Mandered CITY/COUNTY OF Acrice Harge's

I HEREBY CERTIFY that on this 25 day of <u>Juguet</u>, 1993, before me, a Notary Public of the State and City/County aforesaid, personally appeared Paul V. Beals, M.D. and made oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

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AS WITNESS my hand and notarial seal.

Ando Dancelose

My Commission expires: _________

PAUL V. BEALS, M.D. 9101 Cherry Lane, Suite 205 Laurel, Maryland 20708 (301) 490-9911

ADRENAL FUNCTION PATIENT DISCLOSURE FORM

The purpose of this form is to inform Dr. Beals' patients regarding his medical theories and methods of diagnosis and treatment for his patients in whom he has diagnosed low adrenal function.

Dr. Beals believes that some patients with some or all of the following symptoms and/or diseases may be suffering from mild to moderate adrenal insufficiency (low adrenal function): allergies; lethargy, arthritis; poor stamina; poor stress tolerance; vitiligo; low blood pressure; orthostatic hypotension; increased pigmentation; cold intolerance and dizziness. Dr. Beals believes that patients with the symptoms noted above may in fact be suffering from low adrenal function, despite the fact that their blood tests for adrenal function may be in the low normal or borderline range.

The adrenal gland is considered to be the anti-stress gland and is also involved in resisting inflammation, arthritis and allergies in the body. It is part of the body's immune system and is also involved in the body's ability to repair itself.

Hydrocortisone is a natural adrenal hormone. When taken orally in low doses (10mg, to 20mg, a day), Dr. Beals believes it to be a safe replacement dose which is designed to improve a patient's symptoms as set forth above. Dr. Beals believes that when given in such low doses, it is a safe replacement dose without significantly suppressing the body's adrenal gland or the gland's ability to produce natural hydrocortisone.

It is important to understand that Dr. Beals' theories and treatments with regard to low adrenal function, may be considered to be non-traditional medicine or "alternative medicine". Most traditional or conventional physicians would rely almost entirely on the blood test results in order to diagnose low adrenal function. Traditional or conventional physicians would probably consider adrenal function as measured by blood test results in the low normal or borderline range to be normal and therefore, they would not recommend any replacement therapy, since such a patient would not, by definition, have Addison's Disease, which is a more serious and to produce hydrocertisone naturally.

Hydrocortische taken orally may in some instances cause patients stomach pain or burning (if taken on a empty stomach) and it may cause fluid retention which is usually worse during hot, humid weather. Hydrocortische has also been known to cause uicers, diabetes, osteoporosis and vascular disease.

Dr. Beals proposes to treat this low adrenal function generally for a period of six to twenty-four months during which time the patient should notice improvement of the medical problem noted above.

Revised 10/25/93

It should be understood that once placed on this medication, Dr. Beals must monitor the patient's adrenal function and hormone levels periodically (two to three times a year) with additional laboratory tests in order to insure that the proper dosages of the medication are being given and absorbed by the body, and also in order to insure that the body's own natural ability to make and secrete the adrenal hormone is not suppressed.

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_, by signing this document, Ι, _ PRINT NAME

acknowledge that I have read this document, I have had an opportunity to ask any questions which I have regarding Dr. Beals' proposed treatment, and that I voluntarily agree to undergo this therapy. I understand that I am entitled to a copy of this document.

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Patient's Signature

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Date:_

9101 Cherry Lane, Suite 205

Laurel, Maryland 20708 (301) 490-9911

CANCER TREATMENT PATIENT DISCLOSURE FORM

The purpose of this document is to inform Dr. Beals' patients regarding his medical theories and methods of treatment for his patients who have been diagnosed as having some form of cancer. Once a patient has been diagnosed as having cancer, it is important to follow up with specialists in cancer treatment. It may also be beneficial for the patient to participate in a health program which may enhance the body's ability to fight the cancer and help the traditional cancer treatments to work effectively. The risk to the patient of not having the conventional cancer treatments prescribed by the cancer specialists is the possibility of death.

Dr. Beals believes that conventional cancer therapies can be enhanced by use of nutritional and metabolic support in the form of dietary suggestions, food concentrates, nutritional supplements, vitamin and mineral therapy (both by mouth and injection), herbal therapies, supplements for immune support, as well as some medications (non-chemotherapy) which have been shown to be helpful in treating some cancer patients.

These medications include, but are not limited to: Lanoxin: New England Journal of Medicine, February 1982, page 484; Coumadin - Journal of the American Medical Association, 1981, Volume 245, page 331; Lupron (LHRH analog drug), The Lancet, July 19, 1986; Nolvadex (Tamoxifen); Nizoral; Pont, "Ketoconazole (Nizoral) Therapy for Advanced Prostate Cancer," Lancet, August 25, 1984, page 433; Lithium: New England Journal of Medicine, 1980, Volume 302, page 257; DMSO: <u>DMSO Handbook</u> by Bruce Halstead, M.D., Golden Quill Pub., Colton, California; Hydrazine Sulfate, Syracuse Cancer Institute, Gold, Syracuse, New York; Parlodei (Bromocriptine), The Lancet, July 19, 1986, page 154.

It is important to understand that Dr. Beals' theories and treatments with regard to cancer therapy may be considered to be non-traditional medicine or 'alternative medicine." Traditional or conventional physicians would not elect to provide nutritional or metabolic support as is outlined in this document.

Dr. Beals will recommend certain medications or drugs when indicated as well as other modalities. Bio-feedback training and detoxification techniques may also be used along with B.C.G. (Bacillus Calmette-Guerin), S.P.L. (Staphage Lysate), and M.R.V. (mixed respiratory vaccine) in order to stimulate the body's immune responses.

Dr. Beals can make no specific claims for the cure, treatment or amelioration of cancer or other diseases by the use of nutrition or the other modalities mentioned in this document.

Dr. Beals' proposed treatment includes substances being injected or taken orally, including vitamins. The side effects from such treatment include anaphylactic reaction which may be fatal or life-threatening. The side effects from the nutritional and metabolic support therapy proposed by Dr. Beals include nausea, stomach pain, diarrhea, headache, and occasional dizziness. Side effects of detoxification include fatigue, headaches, nausea, diarrhea and insomnia.

Dr. Beals is not a specialist in the treatment of cancer and has little or no direct experience with the traditional or conventional cancer therapy modalities such as chemotherapy, radiation therapy or surgery. Accordingly, Dr. Beals cannot and will not advise his patients as to the relative benefits or risks of such conventional treatments. For this reason, all patients with cancer are urged if they have not already done so, to seek consultations with appropriate cancer specialists, such as surgeons, radiotherapists and oncologists in order to obtain information about the conventional cancer therapies which might be applicable to each patient's case.

All patients with cancer should seek information from such physicians regarding the following questions:

Revised 10/25/93

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(1) What kinds of treatment may reasonably be expected to benefit each patient's condition?

(2) What are the patient's chances of survival (over what period of time) if the patient undergoes such conventional treatments as opposed to if the patient does not have such treatments?

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(3) What can the patient expect in terms of quality of life if the patient has the traditional cancer therapy (i.e. what are the side effects during and after treatment)?

(4) To what extent will the patient experience damage to their immune defense system from any proposed conventional treatment which may then impair the patient's body from fighting the cancer?

(5) Does the conventional cancer specialist have any objection to the patient undergoing Dr. Beals' proposed treatment at the same time as they are receiving conventional therapy?

Dr. Beals' proposed treatment program requires evaluating the patient with routine lab work which may be required every 3-6 months to monitor the patient's response to therapy.

Dr. Beals believes that some patients may require therapy for several years.

I, ______, by signing this document, ZRNT NAME acknowledge that I have read this document, I have had an opportunity to ask any questions which I have regarding Dr. Beals' proposed treatment, and that I voluntarily agree to undergo this therapy. I understand that I am entitled to a copy of this document.

Witness

Patient's Signature

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Date:

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PAUL V. BEALS, M.D. 9101 Cherry Lane, Suite 205 Laurel, Maryland 20708 (501) 490-3911

CANDIDA TREATMENT PATIENT DISCLOSURE FORM

The purpose of this document is to inform Dr. Beals' patients regarding his medical theories and methods of diagnosis and treatment for his patients in whom he has diagnosed a 'candida syndrome'.

Candida is a yeast organism that is well known. Physicians commonly diagnose candida infections on the skin and in the vagina.

Dr. Beals, however, believes that the "candida syndrome" is less well understood and the concept is not accepted by many conventional or traditional physicians. It is important to understand that Dr. Beals' theories and treatments with regard to "candida syndrome" may be considered to be non-traditional medicine or "alternative medicine." Many traditional or conventional physicians would deny that there is such a syndrome, or that it can cause symptoms, or that it requires any specific treatment.

Dr. Beals believes that the candida syndrome is due to the release of toxic products from the candida organisms known as mycotoxins. He believes that these toxins cause many symptoms, many of which are allergic, intestinal, or 'emotional' in nature. These symptoms include: fatigue; food and respiratory allergies; digestive problems; recurrent vaginitis; chemical sensitivities; mood changes and skin problems.

Dr. Beals' treatment for this syndrome generally consists of restricted low-carbohydrate diet, nutritional supplements, vitamins and minerals (orally or intravenously), yeast-free diet, in combination with the drug Nystatin, or other antifungal medications. Nystatin is a non-toxic, anti-candida drug that is in wide use today. The risks of treatment with Nystatin include primarily nausea or stomach pain.

According to Dr. Beals, the length of treatment with Nystatin or other antifungal medications does vary and treatment may occasionally be prolonged, in some cases lasting for years.

As stated, the 'candida syndrome' is basically a new concept and accordingly, many more traditional or conventional physicians do not believe that it exists, and do not attempt to treat it. Several books have recently been written discussing this disorder include <u>The Yeast Connection</u> by William Crook, M.D. It should be understood that this syndrome and its treatment are relatively new and therefore is considered 'investigational.' The treatment by Dr. Beals is not presented as a 'miracle cure' and it should be understood that the treatment does not help all patients and thus success cannot be guaranteed.

I, _____, by signing this document, PRINT NAME

acknowledge that I have read this document, I have had an opportunity to ask any questions which I have regarding Dr. Beals' proposed treatment, and that I voluntarily agree to undergo this therapy. I understand that I am entitled to a copy of this document.

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CHRONIC FATIGUE SYNDROME (CFS) TREATMENT PATIENT DISCLOSURE FORM

The purpose of this document is to inform Dr. Beals' patients regarding his medical theories and methods of diagnosis and treatment for his patients in whom he has diagnosed as having CFS.

The concept of CFS is not accepted by many conventional or traditional physicians; however, Dr. Beals believes that CFS is an immune system dysfunction. It is important to understand that Dr. Beals' theories and treatments with regard to CFS may be considered to be non-traditional medicine or "alternative medicine". Many traditional or conventional physicians would deny that there is such a syndrome, or that it can cause symptoms, or that it requires any specific treatment.

Dr. Reals believes that patients who have CFS may experience symptoms daily or may have periods of illness followed by periods of remission. Oftentimes, this illness can be traced back to a bout with the flu or a case of mononucleosis. However, this cannot be counted as a prerequisite for contracting CFS. Many times patients have a difficult time being diagnosed and go from doctor to doctor for months, or even years. Many have been labeled hypochondriaes, chronic complainers or neurotic because all "standard" laboratory tests concluded that they had no actual known illness.

"National attention was brought to this illness in 1985 when an epidemic-type outbreak occurred in Incline Village, Nevada. It has been speculated that the condition is caused by a virus, but that remains unproven. The condition has been referred to by a number of names, but until it can be documented as to whether or not there are multiple causes, the name has been changed to Chronic Fatigue Syndrome. This is verified by the 'Working Case Definition' published in the Annals of Internal Medicine in March, 1988.

Clinical symptoms in patients with CFS include: severe fatigue; arthraigia; myalgia; recurrent nonexudative oropharyngitis; psychiatric disorders, i.e. depression, sleep disturbance, lack of concentration, lack of memory, confusion; neurologic disorders, i.e. neuralgias, peripheral neuropathy; recurrent lymphadenopathy; gastrointestinal complaints; recurrent low-grade fever; cardiac complaints, i.e. arrhythmias, tachycardias; recurrent headaches; recurrent skin eruptions and hypothyroidism.

Treatment consists of a nutritional dietary program along with vitamin and mineral therapy (oral and i.v.), Kutapressin (liver extract) injections, as well as when indicated symptomatic therapy including antidepressants, analgesics, muscle relaxants or anti-inflammatory (NSAIDS), also sometimes the anti-viral drug Acyclovir (Zovirax) is used. The risks of oral Zovirax therapy are nausea, vomiting, headaches and rash. Sometimes vaccines such as S.P.L. (Staphages Lysate) and M.R.V. (mixed respiratory vaccine) are used to stimulate the immune system. In more serious cases, there has been some success with i.v. gamma globulin therapy (6 grams per treatment; 1-2 times a month). The risks of i.v. gamma globulin therapy include headaches, flu-like symptoms, fatigue, fever, nausea and vomiting.

As stated, CFS is basically a new concept and accordingly, many more traditional or conventional physicians do not believe that it exists, and do not attempt to treat it. It should be understood that this syndrome and its treatment are relatively new and therefore is considered "investigational." The treatment by Dr. Beals is not presented as a "miracle cure" and it should be understood that the treatment does not help all individuals and thus success cannot be guaranteed.

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COLCHICINE PATIENT DISCLOSURE FORM

The purpose of this document is to inform Dr. Beals' patients regarding his medical theories and treatment for some of his patients with low back pain or other forms of chronic joint or spinal/neck pain.

Dr. Beals believes that some patients who have chronic low back problems due to herniated disks or other forms of chronic joint or spinal/neck pain may benefit from the use of a drug called Colchicine.

It is important to understand that Dr. Beals' treatment with Colchicine for low back pain, may be considered to be non-traditional medicine or "alternative medicine." Most traditional or conventional physicians would not use this drug regimen for this condition. Such physicians instead will attempt to treat low back pain due to herniated disks or muscle injuries in the low back with physical therapy, manipulations, acupuncture, relaxation, diets, exercise, medication and surgery. No one therapy approach is guaranteed to be effective.

Dr. Beals' treatment approach with respect to low back pain and the use of Colchicine is the result of work done by Michael R. Rask, M.D. over the past thirty years. Dr. Rask is physician who has treated 6,000 patients over 30 years, all with spinal disorders, 1,500 of whom had back surgery that failed. His work appeared in the December, 1989 issue of the Journal of Neurological and Orthopedic Medicine and Surgery, Volume 10. His success rate was approximately 92% with Colchicine therapy. Many of Dr. Rask's patients had previously had unsuccessful spinal surgery or other spinal procedures. Colchicine has been reported to be effective in relieving neck, back and limb pain, permitting patients to return to their former employment without complications.

Dr. Heals believes that Colchicine works by reducing the inflammation of the spinal nerve roots and disks as well as by eliminating deposits of natural body substances which result from irritation and increasing the endorphin producing neurons while at the same time shrinking the disk itself.

In severe cases, Dr. Beals uses Colchicine intravenously initially according to a specific protocol. Oral Colchicine is continued, sometimes for approximately three years until the disk heals. This treatment does not help all patients and successful treatment is not guaranteed.

Colchicine has little or no side effects as reported in Dr. Rask's patients when given intravenously. When used in the low dose regimen which Dr. Beals prescribes, the main complication from Colchicine is an occasional "burn" from extravasation when given in the intravenous form or delayed irritation of the vein. When given orally, Colchicine can cause nausea, stomach pain and diarrhea.

A possible risk of undergoing Dr. Beals' treatment with Colohicine to the exclusion of more traditional treatment is that, in severe cases, where there is disc herniation and pressure on a spinal nerve root, such pressure allowed to continue for a prolonged period without surgical decompression could cause permanent nerve damage. Accordingly, patients who have numbness or pain radiating down their legs, or bowel or bladder dysfunction are urged to also seek a consultation with a neurologist or orthopedist.

Colchicine is a substance derived from the autumn crocus plant which has been used for many years as an anti-inflammatory agent. Its most common indication in modern medicine is for the treatment of gout.

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OXIDATIVE THERAPY PATIENT DISCLOSURE FORM

The purpose of this document is to inform Dr. Beals' patients regarding his medical theories and methods of treatment for his patients who may be advised to undergo oxidative therapy.

Dr. Beals believes that the use of hydrogen peroxide intravenously in conjunction with other more conventional treatments can be of substantial benefit to patients who have certain symptoms or disease processes including heart and blood vessel diseases, pulmonary diseases, infectious diseases and immune disorders. The risk to the patient of using this treatment to the exclusion of other more conventional treatments for heart and blood vessel disease is heart attack, stroke, and/or death.

It is important to understand that Dr. Beals' theories and treatments with regard to oxidative therapy may be considered to be non-traditional medicine or 'alternative medicine.' Many traditional or conventional physicians would not elect to treat a patient with hydrogen peroxide therapy, and in many cases have never heard of it.

Hydrogen peroxide has been approved by the Food and Drug Administration (FDA) for use as a food preservative, and for use on the skin as an antiseptic solution. It has not been approved (nor disapproved) for intra-arterial or intravenous use, although its use in this manner has been documented in the medical literature since 1920, when T. H. Oliver, M.D. and others reported the treatment of influenzal pneumonia with i.v. hydrogen peroxide therapy in the Lancet Medical Journal, 1920, Volume 1, pages 432-33.

Dr. Beals uses a very dilute solution of hydrogen peroxide in doses of 0.0375% intravenously. In such cosages and concentrations, hydrogen peroxide has not been reported to be harmful. It has been studied in the treatment of arteriosclerosis of the heart, head and legs, and has been found to increase the effectiveness of treatment of cancer patients as reported in the following examples. Urschel, H.E., Jr.: Cardiovascular Effects of H₂O₂: "Current Status," Diseases of the Chest 1967; Volume 51, pages 18-192; Urschel, H.C., Finney, J.W., Dyll, L.M.: Treatment for Atherosclerotic Obstructive Cardiovascular Disease With H₂O₂: Vascular Surgery, 1967, Volume 1, pages 77-81; Gusak, V.K., Khoner, L.I., Belenski, V.E.: Possibilities of Using Weak Solutions of H₂O₂ in the Treatment of Experimental Ischemia of the Lower Extremities; KLIN LHIR, 1986; Volume 7, pages 31-33; Nathan, C.F., Cohn, Z.A.: Antitumor Effects of H₂O₂ in VIVO; Journal of Expert Medicine, 1981, Volume 154, pages 1539-1553.

A minority of 'alternative' physicians are increasingly using hydrogen peroxide for the treatment of immune dysfunction, pulmonary disease and cell and tissue hypoxia (low oxygen levels). The use of hydrogen peroxide is not generally approved by formal medical associations or other groups on the grounds that this substance has not yet been shown to be 'safe' or 'effective' or 'usual, customary and reasonable.' Because of the lack of such approval, and because a majority of physicians do not use this therapy, insurance companies ordinarily refuse to reimburse the patient for hydrogen peroxide therapy.

Whether hydrogen peroxide is "safe" or "effective" for a specific condition depends on the degree of likelihood of injury from the use of the procedure when properly administered as compared to the prognosis for the condition if left untreated, and upon the patient's cooperation in following dietary, metabolic nutrient recommendations and rest regimen which accompanies the therapy.

It is important to understand that Dr. Beals cannot guarantee or warrant the results of hydrogen peroxide therapy or any other therapy because its use is still regarded as experimental for the reasons previously stated.

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The risks of hydrogen peroxide therapy in general include death, gas embolus which can be fatal or life-threatening, acute hemolytic crisis secondary to i.v. injection, severe anemia, vasculitis which may result in permanent injury to vital organ structures such as the heart and brain or other serious injury, chest discomfort, infusion site pain, headache, nausea or chills, and rarely, muscle pain.

However, the risks of hydrogen peroxide therapy using very diluted solutions (0.07% or less) include vascuiitis, chest discomfort, infusion site pain, headache, nausea or chills; and rarely, muscle pain. In general, i.v. infusion of hydrogen peroxide given in the manner suggested by Dr. Beals is considered by most alternative physicians as extremely safe with a wide range of therapeutic applications, including cardiovascular disease, pulmonary disease, infectious disease, some viral diseases (herpes), as well as candidiasis and environmental altergies.

The risks of utilizing Dr. Beels' non-traditional approach of hydrogen peroxide therapy alone, without, or as opposed to, conventional therapy for the treatment of heart disease, blood vessel disease, hypertension, pulmonary disease, infectious diseases and immune disorders are that such therapy may result in death, heart attack, stroke or other serious, life-threatening conditions.

Dr. Beals' proposed oxidative therapy treatment initially consists of starting the patient on 0.0375% of hydrogen peroxide given intravenously in 250cc of intravenous fluids at the rate of one to two per week for one to three months. He will thereafter monitor the patient's progress by routine lab work and relief of symptoms.

Dr. Beals believes that some patients may require oxidative therapy for several weeks or months.

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opportunity to ask any questions which I have regarding Dr. Beals' proposed treatment, and that I voluntarily agree to undergo this therapy. I understand that I am entitled to a copy of this document.

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TESTOSTERONE TREATMENT PATIENT DISCLOSURE FORM

The purpose of this document is to inform Dr. Beals' patients regarding his medical theories and methods of diagnosis and treatment for his patients in whom he has diagnosed a low testosterone condition.

Dr. Beals believes that some patients who may have a blood test which shows blood testosterone levels in the low normal or borderline range may nevertheless be suffering from low testosterone levels, meaning that their testosterone levels are too low for their personal body chemistry which therefore causes them symptoms. It is Dr. Beals' belief that such patients may suffer symptoms including impotence, low libido, lethargy, poor stamina and depression.

It is important to understand that Dr. Beals' theories and treatments with regard to a low testosterone condition may be considered to be non-traditional medicine or 'alternative medicine.' Many traditional or conventional physicians would rely almost entirely on the blood test results in order to diagnose a low testosterone condition. Thus if a patient had clinical symptoms but a normal testosterone blood level based on the blood test results, such a physician would consider that patient's testosterone level to be normal, and no treatment would be offered. Dr. Beals, however, believes that patients who do test in the low normal range and who also have the symptoms noted above, may in fact have too little testosterone for their own system's ability to function properly, and he would diagnose a low testosterone condition.

Dr. Beals believes that patients such as described above may benefit from treatment which includes giving them doses of testosterone, usually intravenously, in the range of 100mg. - 200mg, one to four times a month, for periods of three months to three years. It should be understood that this is hormonal treatment, and that traditional or conventional physicians would not elect to treat a patient with low normal testosterone blood levels with any hormonal replacement.

The risk of receiving excessive testosterone therapy includes: in males - enlarged breasts, low sperm count, hypertension; in <u>females</u> - amenorrhea, facial hair, lowering of voice; in <u>both</u> - acce, fluid retention, headaches and nausea.

Dr. Beals will begin the patient on a relatively small dose of testosterone. Thereafter, it will be necessary for him to monitor the patient's dose with testosterone lab blood tests approximately 1-3 times a year in order to avoid over-medicating the patient and achieving the right dosage for each patient's body chemistry.

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acknowledge that I have read this document, I have had an opportunity to ask any questions which I have regarding Dr. Beais' proposed treatment, and that I voluntarily agree to undergo this therapy. I understand that I am entitled to a copy of this document.

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THYROID FUNCTION PATIENT DISCLOSURE FORM

The purpose of this document is to inform Dr. Beals' patients regarding his medical theories and methods of diagnosis and treatment for his patients in whom he has diagnosed a low thyroid condition.

Dr. Beals believes that in many instances, patients may be suffering from a condition in which the thyroid gland function is underactive (low). Dr. Beals believes that this diagnosis cannot necessarily be made simply on the basis of a thyroid hormone blood test (T3, T4, TSH), but rather, it must be based on the whole clinical picture which the patient presents, including the symptoms of cold intolerance, lethargy, cold extremities, memory problems, paresthesias (numbness of hands and feet), dysmenorrhea (heavy, painful periods) and most importantly, on morning axillary temperatures (core body temperature) less than 97.5°.

It is important to understand that Dr. Beals' theories and treatments with regard to low thyroid condition may be considered to be non-traditional medicine or "alternative medicine." Many traditional or conventional physicians would rely almost entirely on the blood test results in order to diagnose a low thyroid condition. Thus if a patient had clinical symptoms and low core body temperature, but a normal thyroid function based on the blood test results, such a physician would consider that patient's thyroid function to be normal, and no treatment would be offered for the thyroid.

The thyroid gland controls the body's metabolism and temperature and helps to regulate many instabolical functions. Dr. Beals believes that an untreated low thyroid condition contributes to low energy (fatigue), higher cholesterol levels, low body temperatures, dry skin, constipation, and when severe, cardiovascular disease.

Dr. Beals' proposed treatment for patients whom he diagnoses as having a low thyroid condition are designed to correct the patient's low thyroid function. In order to treat a low thyroid condition, Dr. Beals utilizes a synthetic or natural thyroid medication. It is important to understand that excessive thyroid medication can lead to hypertension (high blood pressure), heart palpitations, cardiac arrhythmias, insomnia, anxiety and death.

Dr. Beals' proposed treatment initially consists of starting the patient on low doses of thyroid medication. He will thereafter monitor the patient's dose by continuing to monitor the patient's thyroid (laboratory) blood tests, one to three times a year, in order to avoid giving the patient too much thyroid for their own body chemistry.

Dr. Beals believes that some patients may require thyroid replacement therapy for several years.

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IN THE MATTER OF * BEFORE THE PAUL V. BEALS, * STATE BOARD OF PHYSICIAN Respondent, * QUALITY ASSURANCE License Number: D25922 * Case Number: 85-0081

AFFIDAVIT

STATE OF MARYLAND COUNTY OF

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to wit:

COMES NOW your affiant, Paul V. Beals, M.D., and hereby swears and affirms under penalties of perjury that the following is true to the best of my knowledge, information and belief. 1. That I am over the age of 18 and otherwise competent.

2. That pursuant to the language of the Consent Order which I, through counsel, have been negotiating with the Assistant Attorney General's Office in this matter, I have retained and intend to utilize the services of a medical records transcriber.

3. The said transcriber is Betsy Craddock, 900 White Way, Laurel, Maryland 20707.

4. I intend to be using the services of Ms. Craddock at least as early as of the effective date of the Consent Order, namely the date upon which the Order is signed by the Board of Physician Quality Assurance.

5. I will use the services of Betsy Craddock and/or some other medical transcriptionist for all of my patient records at least as soon as the effective date of the Consent Order. I reserve the right to change the particular transcriptionist, although in doing so, there will be no lapse in my ability to have my medical records transcribed by a transcriptionist.

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6. In the event that I hire a transcriptionist to work directly for me, then I will obviously no longer be in need of an outside transcriptionist, but in any case, the intent is that I will have virtually all my medical records transcribed.

I HEREBY SWEAR AND AFFIRM UNDER THE PENALTIES OF PERJURY THAT THE FOREGOING FACTS ARE TRUE TO THE BEST OF MY KNOWLEDGE, INFORMATION AND BELIEF.

V. BEALS, M.D. PAUL 5/28/93