BEFORE THE DIVISION OF MEDICAL QUALITY MEDICAL BOARD OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:))	
Chaim Vanek, M.D.)	File No. 06-2002-141688
Physician's and Surgeon's Certificate No. A 77368)	
Respondent)))	

DECISION

The attached Stipulated Settlement and Disciplinary Order is hereby adopted as the Decision and Order of the Division of Medical Quality of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on October 10, 2006

IT IS SO ORDERED September 8, 2006

MEDICAL BOARD OF CALIFORNIA

Cesar A. Aristeiguieta, M.D., Chair

Consolidated Panel

Division of Medical Quality

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1 2 3 4 5 6	BILL LOCKYER, Attorney General of the State of California JOHN E. RITTMAYER, State Bar No. 67291 Deputy Attorney General California Department of Justice 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 897-7485 Facsimile: (213) 897-9395	·
.	Attorneys for Complainant	
7 8 9 10	BEFORE T DIVISION OF MEDIC MEDICAL BOARD OI DEPARTMENT OF CON STATE OF CAL	AL QUALITY F CALIFORNIA SUMER AFFAIRS
11		Case No. 06-2002-141688
12	In the Matter of the Accusation Against:	OAH No. L2005100647
13 14	CHAIM VANEK, M.D. Physician's and Surgeon's Certificate No.: A 77368,	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER
15	Respondent.	
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17	IT IS HEREBY STIPULATED AND	AGREED by and between the parties in this
18	proceedings that the following matters are true:	
19	PARTIE	<u>s</u>
20	1. David T. Thornton (Complain	ant) is the Executive Director of the Medical
21	Board of California. He brought this action solely in	his official capacity and is represented in
22	this matter by Bill Lockyer, Attorney General of the	State of California, by John E. Rittmayer,
23	Deputy Attorney General	
24	2. Respondent Chaim Vanek, M	D. (Respondent) is represented in this
25	proceeding by attorney Peter R. Osinoff, whose addr	ess is 3699 Wilshire Boulevard, 10th Floor
26	Los Angeles, CA 90010-2719.	
27	. 3. On or about December 12, 20	01, the Medical Board of California issued
28	Physician's and Surgeon's Certificate No. A 77368 to	Chaim Vanek, M.D. (Respondent). The
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27 28 Certificate was in full force and effect at all times relevant to the charges brought in Accusation No. 06-2002-141688 (the Accusation) and will expire on July 31, 2007, unless renewed.

JURISDICTION

4. The Accusation was filed before the Division of Medical Quality (Division) for the Medical Board of California, Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on November 12, 2004. Respondent timely filed his Notice of Defense contesting the Accusation. A copy of the Accusation is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 5 Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Accusation. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- Respondent understands that the charges and allegations in the 8. Accusation, if proved at a hearing, would constitute cause for imposing discipline upon his Physician's and Surgeon's certificate.
 - 9. For the purpose of resolving the Accusation without the expense and

uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could present a prima facie case for one or more of the charges contained therein, and Respondent hereby gives up his right to present a defense thereto and to contest that cause for discipline exists based on those charges.

CONTINGENCY

- Quality. Respondent understands and agrees that counsel for Complainant and the staff of the Medical Board of California may communicate directly with the Division regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Division considers and acts upon it. If the Division fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Division shall not be disqualified from further action by having considered this matter.
- 11. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.
- 12. In consideration of the foregoing admissions and stipulations, the parties agree that the (Division) may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

<u>ORDER</u>

A. PACE CLINICAL TRAINING PROGRAM Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a clinical training or educational program equivalent to the Physician Assessment and Clinical Education Program (PACE) offered at the University of California - San Diego School of Medicine ("Program").

The Program shall consist of a Comprehensive Assessment program comprised of a two-day assessment of respondent's physical and mental health; basic clinical and

communication skills common to all clinicians; and medical knowledge, skill and judgment pertaining to respondent's speciality or sub-speciality, and at minimum, a 40 hour program of clinical education in the area of practice in which respondent was alleged to be deficient and which takes into account data obtained from the assessment, Decision(s), Accusation(s), and any other information that the Division or its designee deems relevant. Respondent shall pay all expenses associated with the clinical training program.

Based on respondent's performance and test results in the assessment and clinical education, the Program will advise the Division or its designee of its recommendation(s) for the scope and length of any additional educational or clinical training, treatment for any medical condition, treatment for any psychological condition, or anything else affecting respondent's practice of medicine. Respondent shall comply with Program recommendations.

At the completion of any additional educational or clinical training, respondent shall submit to and pass an examination. The Program's determination whether or not respondent passed the examination or successfully completed the Program shall be binding.

Respondent shall complete the Program not later than six months after respondent's initial enrollment unless the Division or its designee agrees in writing to a later time for completion.

Failure to participate in and complete successfully all phases of the clinical training program outlined above is a violation of this agreement.

- B. <u>COMPLIANCE</u> If respondent timely and successfully completes the terms and conditions set forth above, a public letter of reprimand shall be issued to respondent pursuant to Business and Professions Code section 2233, in the form of the public letter of reprimand that is attached hereto as Exhibit B and, by this reference, is incorporated herein as though fully set forth.
- C. FAILURE TO COMPLY If respondent fails to timely and successfully complete each term and condition set forth above, then the Accusation may be amended to allege these matters as additional grounds for discipline, and the case will be returned to the Office of Administration Hearing for trial.

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Peter R. Osinoff. I understand the stipulation and the effect it will have on my Physician's and Surgeon's Certificate. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Division of Medical Quality, Medical Board of California.

DATED:

OHAIM VANEK, M.D.

Respondent

DATED: 8/3/06

PETER R. OSINOFF Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Division of Medical Quality, Medical Board of California of the Department of Consumer Affairs.

DATED: August 16, 2006

BILL LOCKYER, Artorney General

of the State of California

JOHN E. RITTMAYER
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 06-2002-141688

FILED STATE OF CALIFORNIA

MEDICAL BOARD OF CALIFORNIA

SACRAMENTO Devember 122004

Case No. 06-2002-141688

ACCUSATION

BILL LOCKYER, Attorney General of the State of California RICHARD D. MARINO, State Bar No. 90471

Deputy Attorney General

California Department of Justice 300 S. Spring St., Suite 1702

4 Los Angeles, CA 90013

Telephone: (213) 897-8644 Facsimile: (213) 897-9395

E-mail: richard.marino@doj.ca.gov

Attorneys for Complainant

BEFORE THE
DIVISION OF MEDICAL QUALITY
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

12 CHAIM VANEK, M.D. 100 UCLA Medical Plaza

13 | Los Angeles, CA **9**0095

Physician and Surgeon's Certificate No. A77368,

Respondent.

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Complainant alleges:

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1. David T. Thornton (Complainant) brings this Accusation solely in his

PARTIES

official capacity as the Executive Director of the Medical Board of California, Department of

21 | Consumer Affairs.

2. On or about December 12, 2001, the Medical Board of California issued

23 Physician and Surgeon's Certificate Number A77368 to Chaim Vanek, M.D. (Respondent). The

Physician and Surgeon's Certificate was in full force and effect at all times relevant to the charges

25 | brought herein and will expire on July 31, 2005, unless renewed.

<u>JURISDICTION</u>

27 3. This Accusation is brought before the Division of Medical Quality

(Division) for the Medical Board of California, Department of Consumer Affairs, under the

authority of the following statutes and regulations. All references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 651 of the Code provides:

- "(a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A 'public communication' as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.
- "(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:
 - "(1) Contains a misrepresentation of fact.
- "(2) Is likely to mislead or deceive because of a failure to disclose material facts.
- "(3) (A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been altered in any manner from the image of the actual subject depicted in the photograph or image.

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- "5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.
 - "6) Makes a claim either of professional superiority or of performing

services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

- "7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.
- "8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

. . . .

"g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action.

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5. Section 725 of the Code, in pertinent part, provides:

"Repeated acts of clearly excessive prescribing or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist."

6. Section 2220 of the Code provides:

"Except as otherwise provided by law, the Division of Medical Quality may take action against all persons guilty of violating this chapter [Chapter 5, the Medical Practice Act]. The division shall enforce and administer this article as to physician and surgeon certificate holders, and the division shall have all the powers granted in this chapter for these purposes including, but not limited to:

"(a) Investigating complaints from the public, from other licensees, from health care facilities, or from a division of the board that a physician and surgeon may be guilty of unprofessional conduct. The board shall investigate the circumstances underlying any report received pursuant to Section 805 within 30 days to determine if an interim

suspension order or temporary restraining order should be issued. The board shall otherwise provide timely disposition of the reports received pursuant to Section 805.

- "(b) Investigating the circumstances of practice of any physician and surgeon where there have been any judgments, settlements, or arbitration awards requiring the physician and surgeon or his or her professional liability insurer to pay an amount in damages in excess of a cumulative total of thirty thousand dollars (\$30,000) with respect to any claim that injury or damage was proximately caused by the physician's and surgeon's error, negligence, or omission.
- "©) Investigating the nature and causes of injuries from cases which shall be reported of a high number of judgments, settlements, or arbitration awards against a physician and surgeon."
 - 7. Section 2227 of the Code, in pertinent part, provides:
- "(a) Protection of the public shall be the highest priority for the Division of Medical Quality . . . and administrative law judges of the Medical Quality Hearing Panel in exercising their disciplinary authority."
 - 8. Section 2234 of the Code provides:

"The Division of Medical Quality shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

- "(a) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter [Chapter 5, the Medical Practice Act].
 - "(b) Gross negligence.
- "(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts. (1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act. (2) When the

standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

- "(d) Incompetence.
- "(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.
- "(f) Any action or conduct which would have warranted the denial of a certificate."
 - 9. Section 2238 of the Code provides:

"A violation of any federal statute or federal regulation or any of the statutes or regulations of this state regulating dangerous drugs or controlled substances constitutes unprofessional conduct."

- 10. Section 2239 of the Code, in pertinent part, provides:
- "(a) The use or prescribing for or administering to himself or herself, of any controlled substance; or the use of any of the dangerous drugs specified in Section 4022, or of alcoholic beverages, to the extent, or in such a manner as to be dangerous or injurious to the licensee, or to any other person or to the public, or to the extent that such use impairs the ability of the licensee to practice medicine safely or more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of the substances referred to in this section, or any combination thereof, constitutes unprofessional conduct. The record of the conviction is conclusive evidence of such unprofessional conduct.

11. Section 2241 of the Code provides:

"Unless otherwise provided by this section, the prescribing, selling, furnishing, giving away, or administering or offering to prescribe, sell, furnish,

give away, or administer any of the drugs or compounds mentioned in Section 2239 to an addict or habituè constitutes unprofessional conduct."

- 12. Section 2241.5 of the Code provides:
- "(a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain.
- "(b) 'Intractable pain,' as used in this section, means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.
- "(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.
- "(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.
- "(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for nontherapeutic purposes.
- "(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:
- "(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a

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nontherapeutic manner.

- "(2) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Controlled Substances Act, or of controlled substances scheduled in, or pursuant to, the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person and shall otherwise comply with all state recordkeeping requirements for controlled substances.
- "(3) Writes false or fictitious prescriptions for controlled substances listed in the California Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.
- "(4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substance Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.
- "(5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.
- "(g) Nothing in this section shall be construed to prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon, as authorized pursuant to Sections 809.05, 809.4, and 809.5.
 - 13. Section 2242 of the Code, in pertinent part, provides:
- "(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without a good faith prior examination and medical indication therefor, constitutes unprofessional conduct.

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14. Section 2261 of the Code provides:

"Knowingly making or signing any certificate or other document directly or indirectly related to the practice of medicine or podiatry which falsely represents the existence or nonexistence of a state of facts, constitutes unprofessional conduct."

15. Section 2262 of the Code provides:

"Altering or modifying the medical record of any person, with fraudulent intent, or creating any false medical record, with fraudulent intent, constitutes unprofessional conduct.

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16. Section 2266 of the Code provides:

"The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

17. Section 2285 of the Code provides:

"The use of any fictitious, false, or assumed name, or any name other than his or her own by a licensee either alone, in conjunction with a partnership or group, or as the name of a professional corporation, in any public communication, advertisement, sign, or announcement of his or her practice without a fictitious-name permit obtained pursuant to Section 2415 constitutes unprofessional conduct. This section shall not apply to the following:

- "(a) Licensees who are employed by a partnership, a group, or a professional corporation that holds a fictitious name permit.
- "(b) Licensees who contract with, are employed by, or are on the staff of, any clinic licensed by the State Department of Health Services under Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code.
- "(c) An outpatient surgery setting granted a certificate of accreditation from an accreditation agency approved by the medical board.

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"(d) Any medical school approved by the division or a faculty practice plan connected with the medical school."

18. Section 17500 of the Code provides:

"It is unlawful for any person, firm, corporation or association, or any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services, professional or otherwise, or anything of any nature whatsoever or to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated before the public in this state, or to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatever, including over the Internet, any statement, concerning that real or personal property or those services, professional or otherwise, or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading, or for any person, firm, or corporation to so make or disseminate or cause to be so made or disseminated any such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, so advertised at the price stated therein, or as so advertised. Any violation of the provisions of this section is a misdemeanor punishable by imprisonment in the county jail not exceeding six months, or by a fine not exceeding two thousand five hundred dollars (\$2,500), or by both that imprisonment and fine."

- 19. Section 17508 of the Code, in relevant part, provides:
- "a) It shall be unlawful for any person doing business in California and advertising to consumers in California to make any false or misleading advertising claim, including claims that (1) purport to be based on factual, objective, or clinical

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evidence, that (2) compare the product's effectiveness or safety to that of other brands or products, or that (3) purport to be based on any fact.

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HEALTH AND SAFETY CODE

- 20. Section 11153 of the Health and Safety Code provides:
- "(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

- 21. Section 11154 of the Health and Safety Code provides:
- "(a) Except in the regular practice of his or her profession, no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person or animal which is not under his or her treatment for a pathology or condition other than addiction to a controlled substance, except as provided in this division.
- "(b) No person shall knowingly solicit, direct, induce, aid, or encourage a practitioner authorized to write a prescription to unlawfully prescribe, administer, dispense, or furnish a controlled substance."
 - 22. Section 11157 of the Health and Safety Code provides:

"No person shall issue a prescription that is false or fictitious in any respect." without first obtaining a current valid license issued pursuant to this chapter."

23. Section 110390 of the Health and Safety Code provides:

"It is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular."

24. Section 110395 0f the Health and Safety Code provides:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food, drug, device, or cosmetic that is falsely advertised."

25. Section 110403 of the Health and Safety Code, in relevant part, provides:

"Except as otherwise provided in Section 110405, it is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

··. .

"(c) Bone or joint diseases.

" ,,

26. Section 110405 of the Health and Safety Code provides:

"An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is either one of the following:

- "(a) Disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.
- "(b) An advertisement that a drug or device has a specific curative or therapeutic effect on a condition, disorder, or disease listed in Section 110403 if the drug or device is approved or cleared for marketing for that specific curative or

1	therapeutic effect through any of the following means:
2	"(1) A new drug application approved pursuant to Section 111500, or
3	Section 505 of the federal act (21 U.S.C. Sec. 355).
4	"(2) An abbreviated new drug application approved pursuant to Section 505
5	of the federal act (21 U.S.C. Sec. 355).
6	"(3) A licensed biological product pursuant to Section 351 of the Public
7	Health Service Act (42 U.S.C. Sec. 262).
8	"(4) A nonprescription drug that meets the requirements of Part 330 of Title
9	21 of the Code of Federal Regulations.
10	"(5) A new animal drug application approved under Section 512 of the
11	federal act (21 U.S.C. Sec. 360b).
12	"(6) An abbreviated new animal drug application approved pursuant to
13	Section 512 of the federal act (21 U.S.C. Sec. 360b).
14	"(7) A new device application approved pursuant to Section 111550.
15	"(8) A device premarket approval application approved under Section 515
16	of the federal act (21 U.S.C. Sec. 360e).
17	"(9) A determination of substantial equivalence for a device pursuant to
18	Section 513(f)(1) of the federal act (21 U.S.C. Sec. 360c (i))."
19	<u>DANGEROUS DRUGS</u>
20	27. The following medications are dangerous drugs within the meaning of
21	Business and Professions Code section 4211, nee 4022:1
22	A. Enbrel (Etanercept) - used to treat rheumatoid arthritis ²
23	B. Methotextrate - an antimetabolite used control severe psoriasis,
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25	1. Business and Professions Code section 4211 has been renumbered 4022
26	(1996, ch. 890) and, in relevant part, defines a 'dangerous drug' as any drug or device which by federal or state law can be lawfully dispensed only on a prescription.

2. Approved by the Food and Drug Administration (FDA) on November 2, 1998, for the

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treatment of rheumatoid arthritis (RA).

rheumatoid arthritis, and certain types of cancer by interfering with cell growth and by suppressing the immune system

C. Remicade (Infliximab) - used to treat Crohn's Disease and rheumatoid arthritis by blocking the body's immune system's overproduction of the TNF-alpha³ protein

COST RECOVERY

28. Section 125.3 of the Code provides, in pertinent part, that the Division may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

MEDI-CAL REIMBURSEMENT

- 29. Section14124.12 of the Welfare and Institutions Code, in pertinent part, provides:
 - "(a) Upon receipt of written notice from the Medical Board of California, the Osteopathic Medical Board of California, or the Board of Dental Examiners of California, that a licensee's license has been placed on probation as a result of a disciplinary action, the department may not reimburse any Medi-Cal claim for the type of surgical service or invasive procedure that gave rise to the probation, including any dental surgery or invasive procedure, that was performed by the licensee on or after the effective date of probation and until the termination of all probationary terms and conditions or until the probationary period has ended, whichever occurs first. This section shall apply except in any case in which the relevant licensing board determines that compelling circumstances warrant the continued reimbursement during the probationary period of any Medi-Cal claim, including any claim for dental services, as so described. In such a case, the department shall continue to reimburse the licensee for all procedures, except for those invasive or surgical

^{3.} TNF-alpha is an immune system protein that controls tuberculosis infection. TNF is the acronym for tumor necrosis factor.

procedures for which the licensee was placed on probation."

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

- 30. Respondent is subject to disciplinary action pursuant to Business and Professions Code section 2234, subdivision (b), in that she committed gross negligence during his care, treatment and management of Patients O.C. and I.F., and others, as follows:
 - A. After graduating medical school, obtaining his California physician and surgeon's certificate, and completing a residency program, Respondent began working for Edward Lewis Tobinick, M.D. (Tobinick), at Tobinick's Institute for Neurological Research (INR) medical office located near the UCLA Medical Center. Respondent had no experience or training in neurology or in performing medical research apart from that which he learned in medical school and during his internship and residency program.

Patient O.C.

- B. On or about August 30, 2002, O.C., a female, then 83 years old, presented at the INR with back pain from disc disease.⁴ When making the appointment, O.C. confirmed that there would be no charge for the consultation.
- C. Upon her arrival at INR, O.C. did not meet a physician but, rather, a sales associate who showed O.C. a promotional video for DiskCure. For two years, Tobinick had been promoting "DiskCure," through the print and electronic media, as a revolutionary non-surgical treatment for back, neck, leg, and arm paint due to degenerative disc disease developed by, and available only at, INR. The promotional materials were false or misleading in that DiskCure was not a "cure" for degenerative disc disease but rather a subcutaneous injection of etanercept (Enbrel) which was developed by the Immunex Corporation, not Tobinick, and at Immunex' facilities, not at INR. Enbrel was FDA approved for

^{4.} According to the report of a magnetic resonance imaging test (MRI) which O.C. had undergone in July 2002, she had moderate disc protrusion at L4-5, moderate disc degeneration at L3-4, and moderate disc bulging at L2-3 and L-5/S-1.

treating various forms of arthritis. It was not FDA approved for treating pain associated with degenerative disc disease.⁵ Enbrel was available, by prescription, at any pharmacy for approximately \$145 per dose.

- D. Respondent knew that prospective patients scheduled initial appointments at INR believing that the consultation for Tobinick's widely publicized DiskCure was free. Respondent knew that patients could not receive DiskCure unless the patient agree to pay \$300 to 450 for a physician consultation and an additional fee, as high as \$2,200, for one treatment.
- E. With the assistance of an INR employee, O.C. completed a number of forms, including a legal disclaimer and "Informed Consent." After being advised that she would be charged \$300 to meet and consult with a physician to determine if she was an acceptable candidate for the DiskCure treatment and another \$2,200 for the treatment itself, O.C. agreed and then spoke with Respondent. At the time, O.C. had "had back pain for several years" and was "willing to try [and pay] anything."
- F. Respondent reviewed the results of the MRI which O.C. had undergone earlier at another facility. Respondent told O.C. that she was a good candidate for DiskCure and that the treatment would eliminate her pain.
- G. Respondent did not perform a complete physical examination. Respondent did not discuss the potential side effects and risks of Enbrel use. Respondent did not advise Patient O.C. that there was no scientific evidence to support the claims that Enbrel was effective in treating back pain. However, Respondent later prepared a medical record for the patient which indicates that he performed a complete physical examination and fully advised the patient of the risk of Enbrel before administering the drug.

^{5.} At the time, there was no scientifically acceptable evidence to support the effectiveness of etanercept (Enbrel) in relieving pain due to degenerative disc disease.

H. Patient O.C. paid \$2,500 for the August 30th visit, including the fee charged for the single etanercept (Enbrel) injection. The pain relief that O.C. experienced, if any, was short lived..

I. On or about December 31, 2002, O.C. filed a written consumer complaint with the Medical Board of California.

Patient I.F.

- J. Prompted by repeated media advertisements and the promise of a free consultation, I.V. scheduled his consultation for December 31, 2002. On that day, I.F. presented to INR. His free consultation, O.C.'s, was with a sales associate, not a physician. I.F. was shown a promotional video which testimonials by reported DiskCure users who were now pain free. I.F. was told that while he was likely candidate for the treatment, he would have to have to pay \$300.00 for a physician to make the final decision.
- K. Willing to do almost anything to be pain free, I.F. agreed to pay the \$300.00 whereupon he was met by Respondent. Respondent spent about 15 minutes with I.F. During this time, Respondent told I.F. that the treatment results for DiskCure were remarkable and that he was a good candidate for the "cure." I.F. then agreed to pay \$2,200 for the treatment and was administered an injection of etanercept (Enbrel) 25 mg. The charges were placed on the patient's credit card.
- L. Later, after being advised that his medical insurance may cover the DiskCure treatment, I.F. called Respondent to enlist his assistance in the filing the necessary paperwork as well as crediting I.F. credit card account.

 Respondent refused to take I.F.'s calls.
- M. The following acts and omissions of Respondent during his care, treatment and management of patients constitute departures from the standard of care:
 - 1) Respondent, intentionally or negligently, misled

the public to believe he was engaged in neurological research for, or on behalf of, the UCLA Medical Center.

- 2) Respondent falsely and fraudulently promoted and touted DiskCure as having been invented at INR when it was little more than a subcutaneous injection of etanercept (Enbrel), a drug developed by the Immunex Corporation.
- 3) Respondent falsely and fraudulently represented Tobinick's DiskCure as a revolutionary treatment only available at Respondent's Institute for Neurological Research when it was little more than a subcutaneous injection of etanercept (Enbrel).
- 4) Respondent took advantage of charged as much as \$1,500 \$2,000 for each injection even though Enbrel was available by prescription for around \$145 for each dose administered by Respondent.
- 5) Respondent failed to disclose the lack of scientifically acceptable evidence to support his public claim that DiskCure was a safe and effective alternative method to alleviate back, neck, arm and leg pain due to degenerative disc disease.
- 6) Respondent exposed patients to well documented potential risk and harm by administering etamercept (Enbrel) to treat back, neck, arm and leg pain due to degenerative disc disease where there was no known or available scientifically acceptable evidence to support etamercept (Enbrel)'s use for back, neck, arm and leg pain due to degenerative disc disease.
- 7) Respondent failed to obtain a valid informed consent before commencing treatment in that the document with the heading "Informed Consent" and which purported to advise the patient that the principle drug comprising DiskCure was not

approved for the treatment of back, neck, arm or leg pain due to degenerative disc disease compromised by statements made to the patient, specifically, and to the public, generally, by Respondent and Tobinick.

- 8) Respondent falsely claimed that DiskCure had shown to be 95% effective in the treatment of back, neck, arm and leg pain due to degenerative disc disease, even though there was no known scientifically acceptable data, findings, studies or other evidence supporting such claims.
- 9) Respondent failed to follow the professional standards of practice applicable for using a dangerous drug to treat disease and other medical condition for which the dangerous drug has not received approval.
- otherwise intentionally misrepresenting the medical condition of patients and others for the purpose of obtaining etanercept (Enbrel); or, in the alternative, enabling and allowing Edward Lewis Tobinick to provide false and fraudulent information and otherwise misrepresent the medical condition of patient for the purpose of obtaining etanercept (Enbrel).
- 11) Prescribed dangerous drugs without medical indication for the drug and without first performing an adequate physical examination.
- Refusing to return calls from patient concerning billing and other issues related to the treatment received.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

31. Respondent is subject to disciplinary action pursuant to Business and

Professions Code section 2234, subdivision (c), in that Respondent committed repeated acts of negligence during his care, treatment and management of Patients O.C. and I.F., and others, as follows:

- A. Complainant refers to and, by this reference, incorporates herein, Paragraph 30, subparagraphs A through L, inclusive, above, as though fully set forth.
- B. The following acts and omissions of Respondent during his care, treatment and management of patients constitute departures from the standard of care:
 - 1) Respondent, intentionally or negligently, misled the public to believe he was engaged in neurological research for, or on behalf of, the UCLA Medical Center.
 - 2) Respondent falsely and fraudulently promoted and touted DiskCure as having been invented at INR when it was little more than a subcutaneous injection of etanercept (Enbrel), a drug developed by the Immunex Corporation.
 - 3) Respondent falsely and fraudulently represented DiskCure as a revolutionary treatment only available at Respondent's Institute for Neurological Research when it was little more than a subcutaneous injection of etanercept (Enbrel).
 - 4) Respondent took advantage of charged as much as \$1,500 \$2,000 for each injection even though Enbrel was available by prescription for around \$145 for each dose administered by Respondent.
 - 5) Respondent failed to disclose the lack of scientifically acceptable evidence to support his public claim that DiskCure was a safe and effective alternative method to alleviate back, neck, arm and leg pain due to degenerative disc disease.

- 6) Respondent exposed patients to well documented potential risk and harm by administering etanercept (Enbrel) to treat back, neck, arm and leg pain due to degenerative disc disease where there was no known or available scientifically acceptable evidence to support etanercept (Enbrel)'s use for back, neck, arm and leg pain due to degenerative disc disease.
- 7) Respondent failed to obtain a valid informed consent before commencing treatment in that the document with the heading "Informed Consent" and which purported to advise the patient that the principle drug comprising DiskCure was not approved for the treatment of back, neck, arm or leg pain due to degenerative disc disease compromised by statements made to the patient, specifically, and to the public, generally, by Respondent Tobinick.
- 8) Respondent falsely claimed that DiskCure had shown to be 95% effective in the treatment of back, neck, arm and leg pain due to degenerative disc disease, even though there was no known scientifically acceptable data, findings, studies or other evidence supporting such claims.
- 9) Respondent failed to follow the professional standards of practice applicable for using a dangerous drug to treat disease and other medical condition for which the dangerous drug has not received approval.
- 10) Providing false and fraudulent information and otherwise intentionally misrepresenting the medical condition of patients and others for the purpose of obtaining etanercept (Enbrel); or, in the alternative, enabling and allowing Edward Lewis Tobinick to provide false and fraudulent information and otherwise

1	misrepresent the medical condition of patient for the purpose of
2	obtaining etanercept (Enbrel).
3	11) Prescribed dangerous drugs without medical
4	indication for the drug and without first performing an adequate
5	physical examination.
6	12) Refusing to return calls from patient
7	concerning billing and other issues related to the treatment received.
8	THIRD CAUSE FOR DISCIPLINE
9	(Incompetence)
10	32. Respondent is subject to disciplinary action pursuant to Business and
11	Professions Code section 2234, subdivision (d), for incompetence, in that Respondent has
12	demonstrated the inability to discharge the duties and responsibilities of a licensed physician and
13	surgeon, as follows:
14	A. Complainant refers to and, by this reference, incorporates
15	herein Paragraphs 30, subparagraphs A through L, inclusive, above, as though fully
16	set forth.
17	FOURTH CAUSE FOR DISCIPLINE
18	(Dishonest or Corrupt Acts)
19	33. Respondent is subject to disciplinary action pursuant to Business and
20	Professions Code section 2234, subdivision (e), in that Respondent has committed dishonest or
21	corrupt acts as a licensed physician and surgeon, as follows:
22	A. Complainant refers to and, by this reference, incorporates
23	herein Paragraph 30, subparagraphs A through L, inclusive, above, as though fully
24	set forth.
25	FIFTH CAUSE FOR DISCIPLINE
26	(Prescribing Without Good Faith Examination or Medical Indication))
27	34. Respondent is subject to disciplinary action pursuant to Business and

28 Professions Code section 2242 in that Respondent prescribed or administered dangerous drugs,

1	without a good faith examination and without acceptable medical indication, to Patients O.C. and
2	I.F., as follows:
3	A. Complainant refers to and, by this reference, incorporates
4	herein Paragraph 30, subparagraphs A through L, inclusive, above, as though fully
5	set forth.
6	SIXTH CAUSE FOR DISCIPLINE
7	(False Documents)
8	35. Respondent is subject to disciplinary action pursuant to Business and
9	Professions Code section 2261 in that Respondent knowingly made or signed a certificate or other
10	document directly or indirectly related to the practice of medicine which falsely represents the
11	existence or nonexistence of a state of facts, as follows:
12	A. Complainant refers to and, by this reference, incorporates
13	herein Paragraph 30, subparagraphs A through L., inclusive, above, as though
14	fully set forth.L-5/S-1.
15	SEVENTH CAUSE FOR DISCIPLINE
16	(Creating False Medical Records)
17	36. Respondent is subject to disciplinary action pursuant to Business and
18	Professions Code section 2262 in that Respondent altered, modified, or created a false, medical
19	record, with fraudulent intent, as follows:
20	A. Complainant refers to and, by this reference, incorporates
21	herein Paragraph 30, subparagraphs A through L, inclusive, above, as though fully
22	set forth.
23	EIGHTH CAUSE FOR DISCIPLINE
24	(Violation Of Drug Laws)
25	37. Respondent is subject to disciplinary action for unprofessional conduct,
26	pursuant to Business and Professions Code section 2238 in that Respondent violated the following
27	drug laws: Health and Safety Code sections 11153, subdivision (a) ["A prescription for a
28	controlled substance shall only be issued for a legitimate medical purpose by an individual

1	practitioner acting in the usual course of his or her professional practice Except as
2	authorized by this division, the following are not legal prescriptions: (1) an order purporting to be
3	a prescription which is issued not in the usual course of professional treatment or in legitimate and
4	authorized research"] and 11157 ["No person shall issue a prescription that is false or
5	fictitious in any respect."], during his care, treatment and management of patients, as follows:
6	A. Complainant refers to and, by this reference, incorporates
7	herein Paragraph 30, subparagraphs A through L, inclusive, above, as though fully
8	set forth.
9	NINTH CAUSE FOR DISCIPLINE
10	(Failure To Maintain Adequate and Accurate Medical Records)
11	38. Respondent is subject to disciplinary action for unprofessional conduct,
12	pursuant to Business and Professions Code section 2266, in that he failed to maintain adequate
13	and accurate records relating to the provision of medical services to Patients O.C. and I.F., as
14	follows:
15	A. Complainant refers to and, by this reference, incorporates
16	herein Paragraph 30, subparagraphs A through L, inclusive, above, as though fully
17	set forth.
18	TENTH CAUSE FOR DISCIPLINE
19	(Unprofessional Conduct)
20	39. Respondent is subject to disciplinary action for unprofessional conduct,
21	pursuant to Business and Professions Code section 2234, generally, in that Respondent breeched
22	the canons of ethics applicable to members of the medical profession ⁶ and violated the provisions
23	
24	6. The canons of ethics applicable to California physicians and surgeons, are set forth in
25	the Declaration of Professional Responsibility, adopted by the House of Delegates of the American Medical Association, December 4, 2001, and the American Medical Association
26	(AMA) Code of Ethics, adopted by the AMA's House of Delegates, June 17, 2001, which provide:
27	
28	Declaration of Professional Responsibility Medicine's Social Contract with Humanity
	II

Preamble

"Never in the history of human civilization has the well being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to:

- I. Respect human life and the dignity of every individual.
- II. Refrain from supporting or committing crimes against humanity and condemn all such acts.
- III. Treat the sick and injured with competence and compassion and without prejudice.
- IV. Apply our knowledge and skills when needed, though doing so may put us at risk.
- V. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.
- VI. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.
- VII. Educate the public and polity about present and future threats to the health of humanity.
- VIII. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.
- IX. Teach and mentor those who follow us for they are the future of our caring profession.

of the Medical Practice Act as alleged in the causes for discipline, set forth in paragraph 30, subparagraphs A through L, inclusive, above, during his care, treatment and management of

We make these promises solemnly, freely, and upon our personal and professional honor."

AMA Code of Medical Ethics

Preamble

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

Principles of Medical Ethics

A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.

A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

A physician shall support access to medical care for all people.

Patients O.C. and I.F., as follows:

A. Complainant refers to and, by this reference, incorporates herein Paragraph 30, subparagraphs A through L, inclusive, above, as though fully set forth.

PRAYER

1	IKALEK
2	WHEREFORE, Complainant requests that a hearing be held on the matters herein
3	alleged, and that following the hearing, the Division of Medical Quality issue a decision;
4	1. Revoking or suspending Physician and Surgeon's Certificate Number G,
5	issued to Chaim Vanek, M.D.;
6	2. Revoking, suspending or denying approval of Chaim Vanek's, M.D.,
7	authority to supervise physician's assistants, pursuant to section 3527 of the Code;
8	3. Ordering Chaim Vanek, M.D., to pay the Division of Medical Quality the
9	reasonable costs of the investigation and enforcement of this case, and, if placed on probation, the
10	costs of probation monitoring; and,
11	4. Taking such other and further action as deemed necessary and proper.
12	DATED: November 12, 2004.
13	
14	Dladd Marian Ba
15	DAVID T. THORNTON
16	Interim Executive Director Medical Board of California
17	Department of Consumer Affairs State of California
18	Complainant
19	
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22	
23	
24	
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26	03573160-LA03AD0761

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VanekAccusationFinalDraftl.wpd

27 rdm:11.25.03

Exhibit B
Public Letter of Reprimand



MEDICAL BOARD OF CALIFORNIA
EXECUTIVE OFFICE
1434 Howe Avenue, Suite 92
Sacramento, CA 95825-3236
(916) 263-2389 FAX (916) 263-2387
www.medbd.ca.gov



April 11, 2007

Chaim Vanek, M.D. P.O. Box 8485 Portland, OR 97207

RE:

Physician's and Surgeon's Certificate No. A-77368

Case No. 06-2002-141688

Public Letter of Reprimand

On November 12, 2004, an Accusation was filed against you regarding your care and treatment of two patients who were seen in 2002, while you were employed by Edward L. Tobinick, M.D., Inc. at the Institute for Neurological Research. You gave these two patients one injection each of etanercept (a tumor necrosis factor- α inhibitor that has been approved by the United States Food and Drug Administration for several uses, including in cases of rheumatoid arthritis and other autoimmune diseases) to relieve pain resulting from disk injury. The use of etanercept required that a physician and surgeon take particular care with patients who may have infections or who are at high risk of developing infections. Although no medical harm came to either of these two patients as a result of your care and treatment, you did not exercise that extra degree of care by:

- (1) Failing to measure the body temperature or to perform a skin test for tuberculosis in either patient before injecting them with etanercept, although neither patient had active tuberculosis.
- (2) Failing to assure that diabetes mellitus of patient I.F. was under control by measuring Hemoglobin A₁C.

Pursuant to the authority of the California Business and Professions Code section 2233, you are hereby issued this Public Letter of Reprimand by the Medical Board of California with the expectation that you have addressed the causes for this conduct, and that you have taken steps to ensure that this conduct will not be repeated.

Cesar A. Aristeiguieta, M.D.

President

Division of Medical Quality