IN THE MATTER OF	*	**BEFORE THE**
	*	
PETER WIERNIK, M.D.	*	**STATE BOARD OF PHYSICIAN**
	*	
RESPONDENT	*	**QUALITY ASSURANCE**
	*	
LICENSE NUMBER: D13260	*	**CASE NUMBER: 95-0376**
	*	
	*	

****

CONSENT ORDER

BACKGROUND

Based on information received, the Maryland State Board of Physician Quality Assurance (the "Board") charged **PETER WIERNIK, M.D.**, (the "Respondent"), **D.O.B. 06/16/1939, LICENSE NUMBER D13260, CASE NUMBER 95-0376,** under the Maryland Medical Practice Act (the "Act"), MD CODE ANN., HEALTH OCC. ("H.O.") §14-401 et. seq. (1993 Repl. Vol.).

The pertinent provision of the Act under H.O. §14-404 provides:

> (a) Subject to the hearing provisions of Section 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:
>
> > (21) Is disciplined by a licensing or disciplinary authority or convicted or disciplined by a court of any state or country or disciplined by any branch of the United States uniformed services or the Veteran's Administration for an act that would be grounds for disciplinary action under this section;

The ground for disciplinary action under H.O. §14-

404(a)(21) is the following:

> (11) Willfully makes or files a false report or record in the practice of medicine.

FINDINGS OF FACT

The Board makes the following findings by clear and convincing evidence:

1. At all times relevant to these charges the Respondent was and is licensed to practice medicine in the State of Maryland.

2. The Respondent was granted a license to practice medicine and surgery in the State of New York on December 17, 1982, license number 152777.

3. In October 1987, investigations and inquiries were conducted by the Food and Drug Administration, the Department of Health and Human Services, and Montefiore Medical Center seeking, inter alia, to identify the source of supply of quantities of recombinant Interleukin 2 ("rIL-2") utilized by certain members of the Montefiore Medical Center Department of Neurosurgery.

4. Despite Respondent's knowledge that prior to October 7, 1987, the Department of Oncology had, with his consent, been the source of the rIL-2, he intentionally failed to disclose this knowledge falsely reported that the rIL-2 had been supplied without his consent. Said intentional failure to disclose and false reporting occurred on occasions including but not limited to:

1. a letter dated October 7, 1987 to the National Institute of Health;

2. communications with investigators from the Department of Health and Human Services in or about September 1988; and

3. in response to an internal inquiry by Montefiore Medical Center during 1988.

5. On April 21, 1994, the Respondent entered into a Consent Order with the New York State Board for Professional Medical Conduct (the "NY Board") as a result of the Respondent's failure to identify the source of supply of quantities of rIL-2 and falsely reporting that the rIL-2 had been supplied without his consent. The Respondent was charged with committing professional misconduct by willfully filing a false report within the meaning of N.Y. Educ. Law Section 6530 (21) (McKinney Supp. 1994). A copy of the Statement of Charges is attached hereto as Exhibit A.

6. On March 28, 1994, the Respondent filed with the NY Board an Application for Consent Order, attached hereto as Exhibit B. The Respondent admitted to willfully filing a false report within the meaning of N.Y. Educ. Law and agreed to the penalty that he be subject to a censure and reprimand.

7. On or about April 21, 1994, the application of the Respondent for Consent Order and provisions were adopted and so ordered, attached hereto as Exhibit C.

8. The disciplinary action taken by the NY Board constitutes disciplinary action by a licensing or disciplinary authority under for acts which are grounds for disciplinary action under H.O. §14-404.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, there is clear and convincing evidence for a majority of the full authorized membership of the Board to conclude as a matter of law that the Respondent committed prohibited acts under §14-404 of the Act by being disciplined by a licensing or disciplinary authority for an act that would be grounds for disciplinary action under this section.

The underlying ground for this determination is:

Willfully makes or files a false report or record in the practice of medicine [H.O. §14-404(a)(11)(1993)].

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 22 day of August, 1995, by an affirmative vote of a majority of the full authorized membership of the Board considering this case

ORDERED that the Respondent is REPRIMANDED; and it is further

ORDERED that this is a Final Order of the Board of Physician Quality Assurance and as such is a PUBLIC DOCUMENT pursuant to MD CODE ANN., STATE GOV'T §§ 10-611 et.seq. (1993 Repl. Vol.).

8/22/95
Date

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

CONSENT

I, PETER WIERNIK, M.D., acknowledge that I am represented by legal counsel, and I have had the opportunity to consult with counsel before entering into signing this document. By signing this Consent, I hereby accept and agree to be bound by the foregoing Consent Order and its conditions and restrictions consisting of seven (7) pages.

Further, by this Consent, I hereby admit the Findings of Fact and Conclusions of Law and, accordingly, I accept and submit to the foregoing Consent Order.

I acknowledge that by signing this Consent Order, I am waiving my right to appeal the Findings of Fact, the Conclusions of Law, and the Order contained in this Consent Order. I also acknowledge that I am waiving my right to a hearing on the charges against me, as well as any appeal from the findings of fact and conclusions of law which would result from such a hearing.

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

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 as my voluntary act and deed without reservation, and I acknowledge that I fully understand and comprehend the language, meaning and effect of this Consent Order.

7/28/95
Date

Peter Wiernik, M.D.
Respondent

Read and Approved:

8/14/95
Date

Ty Cobb, Esquire
Attorney for Respondent

STATE OF ~~MARYLAND~~ New York

CITY/COUNTY OF Bronx

I HEREBY CERTIFY that on this 28 day of July, 1995, before me, Notary Public of the State and City/County aforesaid, personally appeared Peter Wiernik, M.D., and made oath in due form of law that the foregoing Consent was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

Notary Public

My Commission Expires:

RALPH P. BELLOISE
Notary Public, State of New York
No. 03-4649801
Qualified in Bronx County
Commission Expires March 30, 1997

EXHIBIT A

EXHIBIT A

STATE OF NEW YORK : DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

----------X

IN THE MATTER	:	STATEMENT
OF	:	OF
PETER WIERNIK, M.D.	:	CHARGES

----------X

PETER WIERNIK, M.D., the Respondent, was authorized to practice medicine in New York State on December 17, 1982 by the issuance of license number 152777 by the New York State Education Department. The Respondent is currently registered with the New York State Education Department to practice medicine for the period January 1, 1993 through December 31, 1994.

FACTUAL ALLEGATIONS

A. Beginning in or about October, 1987, investigations and inquiries were conducted by the Food and Drug Administration, the Department of Health and Human Services, and Montefiore Medical Center seeking, inter alia, to identify the source of supply of quantities of recombinant Interlukin-2 ("rIL-2") utilized by certain members of the Montefiore Medical Center Department of Neuro[redacted]surgery

Despite Respondent's knowledge, prior to October 7, 1987, that the Department of Oncology had, with his consent, been the source of the rIL-2, he intentionally failed to disclose this knowledge and intentionally, falsely reported that the rIL-2 had been supplied without his consent. Said intentional failure to disclose and false reporting occurred on occasions including but not limited to:

1) a letter dated October 7, 1987 to the National Institute of Health;

2) communications with investigators from the Department of Health and Human Services in or about September, 1988; and

3) in response to an internal inquiry by Montefiore Medical Center during 1988.

SPECIFICATION OF CHARGES

FILING A FALSE REPORT

Respondent is charged with committing professional misconduct in that he has willfully filed a false report within the meaning of N.Y. Educ. Law Section 6530 (21) (McKinney Supp. 1994) as Petitioner alleges in:

1) Paragraphs A, A(1), A(2), and A(3).

DATED: New York, New York

CHRIS STERN HYMAN
Counsel
Bureau of Professional
Medical Conduct

ATTACHMENT I

PETER H. WIERNIK, M.D. ALLOCUTION

My name is Peter H. Wiernik. Among other positions I currently hold as a result of almost thirty years of uninterrupted cancer research which has resulted in the publication of 550 articles and 9 medical texts, I am the Director of the Oncology Department at Montefiore Medical Center. My entire professional life has been devoted to cancer research, the treatment of cancer and the training of others around the world.

In early 1987 the Oncology Department was asked by two doctors who had recently joined the Department of Neurosurgery to assist the Department of Neurosurgery in its experimental treatment of terminally ill cancer patients by allowing those physicians to utilize small amounts of recombinant Interleukin-2 ("rIL-2") which the Department of Oncology had left over from its own then ongoing studies. This residual rIL-2 otherwise would have been discarded. The neurosurgeons claimed that the Department of Neurosurgery would be receiving its own supply of rIL-2 for its clinical trial very shortly. Although I knew at the time that there were regulatory restrictions on the use of the residual rIL-2, I agreed.

It was agreed that the Cellular Immunology laboratory at Montefiore and our technicians would assist in preparing the rIL-2 for use by the Department of Neurosurgery. The primary reason for agreeing to assist the Department of Neurosurgery on the basis requested was because my principal assistant, Dr. Elisabeth Paietta, and I recognized the medical value of rIL-2, knew that these

terminally ill patients would die soon without treatment, and that this promising experimental treatment was their last hope.

Consistent with the Department of Neurosurgery's requests, we supplied left-over rIL-2 for the next several months. Although the original request was for one or two patients, the Department of Neurosurgery actually treated sixteen patients. Neither I, Dr. Paietta, nor the Department of Oncology received any financial or professional benefits of any sort from the arrangement.

Following the treatments in question, on October 5, 1987, the two doctors from the Department of Neurosurgery came to my office and explained that the FDA had asked the Department of Neurosurgery to identify the source of rIL-2 it had used to treat its patients at Montefiore. After much discussion, we all agreed not to disclose that the Oncology Department had consented to the Department of Neurosurgery's use of the residual rIL-2 from our laboratory, because that usage violated FDA regulations. I was afraid that if I acknowledged that I had permitted the Department of Neurosurgery's use of the residual rIL-2, I and the Department of Oncology would be severely penalized, and our contributions to the treatment of current and future patients and to the important cancer research to which we have been devoted every day since I first arrived would be jeopardized. I was also concerned about the unintended consequences to the staff of top-rate physicians and clinicians I had attracted to Montefiore. Following the meeting, I advised Dr. Paietta that I had agreed to tell a story, if asked, that was not true: that a technician in the Oncology Laboratory supplied the residual rIL-2 to the Department of Neurosurgery without either my knowledge or Dr. Paietta's.

I asked Dr. Paietta if she was willing to join in this untrue story and she agreed, motivated, in my view, by her dedication to our patients and the

importance of our ongoing research. For the next five years, on the occasions I was asked to explain what happened I told the untrue story. This occurred in a letter dated October 7, 1987 to NIH which was signed by me and one of the neurosurgeons and during communications with investigators from the Department of Health and Human Services on or about September 1988. In addition, I told this story during an internal inquiry by Montefiore Medical Center in 1988. I was also aware that Dr. Paietta continued to tell the false story. I also learned that our lab technicians had agreed to tell the false story on our behalf, and did so; I did nothing to stop them.

I was never comfortable or enthusiastic about telling these lies or about participating with others in what amounted to a cover-up. I became increasingly uncomfortable as the FDA and institutional investigations proceeded producing a host of surprising revelations about the qualifications, conduct and misrepresentations of others involved which magnified the gravity of the falsehoods to which I had agreed and thereafter sponsored. Dr. Paietta and I spoke repeatedly about telling the truth, but every time we concluded that the things we were afraid in 1987 would happen to our patients, our research, our laboratory and ourselves indeed would happen if we told the truth. Upon first consulting the attorney representing me in connection with this matter in May of 1992, I immediately told him the truth, and authorized him to tell it to the United States Attorney's Office. Although humiliated, I was greatly relieved.

There is no question that what I did was wrong. I am fully responsible for my actions and extremely sorry for my conduct. I have not, in this statement, set out all of the facts, understandings, events and motivations that led me to allow the Department of Neurosurgery to use the residual rIL-2 and thereafter to participate in promoting a prolonged fabrication. Nor have I discussed other

factors and information I learned subsequent to the events in 1987 that, had I known at the time, would have convinced me that we should not supply the rIL-2 to the Department of Neurosurgery or participate in the cover up. 1/ I have, however, shared all such information with the United States Attorney's Office.

Notwithstanding the existence of additional facts and circumstances which I believe to be mitigating and explanatory, I should not have done what I did. It was wrong and I am deeply sorry.

Peter H. Wiernik, M.D.

1/ For example, my initial decision to accommodate the neurosurgeons' request was influenced in large part by (1) my understanding at that time of their qualifications, reputations and experience; (2) my belief that only one or two patients would be involved; and (3) my desire to further institutional interests by being a team player and temporarily facilitating this new and important priority of the Department of Neurosurgery.

EXHIBIT B

STATE OF NEW YORK : DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF PETER WIERNIK, M.D.	APPLICATION FOR CONSENT ORDER

STATE OF NEW YORK)
ss.:
COUNTY OF NEW YORK)

PETER WIERNIK, M.D., being duly sworn, deposes and says:

That on or about December 17, 1982 I was licensed to practice as a physician in the State of New York, having been issued License No. 152777 by the New York State Education Department.

I am currently registered with the New York State Education Department to practice as a physician in the State of New York for the period January 1, 1993 through December 31, 1994.

I understand that the New York State Board of Professional Medical Conduct has charged me with One Specification of professional misconduct.

A copy of the Statement of Charges is annexed hereto, made a part hereof, and marked as Exhibit "A".

I admit guilt to that Specification in full satisfaction of the charges against me (See Attachment "I").

I hereby agree to the penalty that I be subject to a censure and reprimand.

I hereby make this Application to the State Board for Professional Medical Conduct (the Board) and request that it be granted.

I understand that, in the event that this Application is not granted by the Board, nothing contained herein shall be binding upon me or construed to be an admission of any act of misconduct alleged or charged against me, such Application shall not be used against me in any way and shall be kept in strict confidence during the pendency of the professional misconduct disciplinary proceeding; and such denial by the Board shall be made without prejudice to the continuance of any disciplinary proceeding and the final determination by the Board pursuant to the provisions of the Public Health Law.

I agree that, in the event the Board grants my Application, as set forth herein, an order of the Chairperson of the Board shall be issued in accordance with same.

I am making this Application of my own free will and accord and not under duress, compulsion or restraint of any kind or manner.

PETER WIERNIK, M.D.
RESPONDENT

Sworn to before me this
28th day of March, 1994.

NOTARY PUBLIC

RALPH P. BELLOISE
Notary Public, State of New York
No. 01-4[illegible]
Qualified in Bronx County
[illegible]

STATE OF NEW YORK : DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF PETER WIERNIK, M.D.	APPLICATION FOR CONSENT ORDER

The undersigned agree to the attached application of the Respondent and to the proposed penalty based on the terms and conditions thereof.

Date: 3/28/94

PETER WIERNIK, M.D.
RESPONDENT

Date: 3/29/94

WILLIAM WOOD, ESQ.
ATTORNEY FOR RESPONDENT

Date: 4/5/94

ROY NEMERSON
DEPUTY COUNSEL
BUREAU OF PROFESSIONAL
MEDICAL CONDUCT

Date: 27 April 1994

Anne F. Saile
for KATHLEEN M. TANNER
DIRECTOR
OFFICE OF PROFESSIONAL
MEDICAL CONDUCT

Date: 21 April 1994

Charles J. Vacanti
CHARLES J. VACANTI, M.D.
CHAIRPERSON
STATE BOARD FOR
PROFESSIONAL MEDICAL CONDUCT

EXHIBIT C

STATE OF NEW YORK : DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER :

OF : ORDER
BPMC #94-60

PETER WIERNIK, M.D. :

Upon the application of Peter Wiernick, M.D. (Respondent) for Consent Order, which application is made a part hereof, it is

ORDERED, that the application and the provisions thereof are hereby adopted and so ORDERED, and it is further

ORDERED, that this order shall take effect as of the date of the personal service of this order upon Respondent, upon receipt by Respondent of this order via certified mail, or seven days after mailing of this order by certified mail, whichever is earliest.

SO ORDERED,

DATED: 21 April 1994

Charles J. Vacanti

Charles J. Vacanti, M.D.
Chairperson
State Board for Professional
Medical Conduct