Superior Court of New Jersey, Appellate Division

Matter of Cole

194 N.J. Super. 237 (N.J. Super. 1984) · 476 A.2d 836
Decided May 4, 1984

Argued April 9, 1984 —

Decided May 4, 1984.

Appeal from State Board of Medical Examiners

Before Judges BISCHOFF, PETRELLA and BRODY.

Steven I. Kern argued the cause for appellant

Peter A. Greene, Deputy Attorney General, argued the cause for respondent (*Irwin I. Kimmelman,* Attorney General of New Jersey, attorney for respondent State Board of Medical Examiners; *Andrea M. Silkowitz,* Deputy Attorney General, of counsel).

The opinion of the court was delivered by BISCHOFF, P.J.A.D.

Appellant Donald R. Cole, M.D. appeals from the final order of the Board of Medical Examiners revoking his license to practice medicine and surgery in New Jersey.

On March 3, 1983 a complaint was filed with the Board of Medical Examiners (Board) charging that the license of Donald R. Cole to practice medicine in New York was revoked by the Commissioner of Education in that State because he had been found "guilty of the fraudulent practice of medicine, and negligence and incompetence in the practice of medicine in the treatment of seven cancer patients; and wilfully or grossly negligent failure to comply with federal and state law in the administration of unapproved drugs, and failure to keep accurate records of two of these cancer patients." The complaint charged this revocation was for reasons consistent with N.J.S.A. 45:1-21 and, as such, constituted grounds for disciplinary action against appellant pursuant to N.J.S.A. 45:1-21(g). The complaint sought an order suspending or revoking the license of Dr. Donald R. Cole.

Appellant filed an answer to the complaint admitting his license to practice medicine and surgery had been revoked in New York but denied the violation of any of the laws of the State of New Jersey.

A hearing was held on the complaint before the Board on April 13, 1983, at which time evidence of the New York revocation was received. The Board ruled the New York order of revocation was sufficient on its face to establish grounds for sanction under N.J.S.A. 45:1-21(g) and that such New York action was based on conduct which was grounds for sanction in New Jersey under N.J.S.A. 45:9-16(h), (i), N.J.S.A. 45:9-6 and N.J.S.A. 45:1-21(b) through (e). The hearing continued with respect to a determination of the penalty to be levied. At

this hearing appellant testified and he produced the testimony of two physicians as character witnesses, as well as five of his current patients. After consideration of the record in executive session, the Board announced the revocation of Dr. Cole's license to practice medicine and surgery in New Jersey.

On this appeal Dr. Cole argues that N.J.S.A. 45:1-21, the statute relied upon by the Board, is inapplicable since N.J.S.A. 45:1-15 *et seq.* became effective on July 13, 1978 while the objectionable conduct which was the basis for the New York revocation occurred between 1976 and 1978. He argues that the proper statute for the Board's proceeding would be N.J.S.A. 45:9-16.

N.J.S.A. 45:9-16, in pertinent part, reads:

> 45:9-16. Refusal to grant, suspension or revocation of license, or registration of certificate or diploma; grounds; procedure; relicense.
>
> The board may refuse to grant or may suspend or revoke a license or the registration of a certificate or diploma to practice medicine and surgery or chiropractic filed in the office of any county clerk in this State under any act of the Legislature, upon proof to the satisfaction of the board that the holder of such license . . . (h) has been guilty of gross malpractice or gross neglect in the practice of medicine which has endangered the health or life of any person, . . .

That statute pertains to a situation where a physician licensed in New Jersey is charged with conduct sufficient to warrant revocation of his license irrespective of similar action taken in a sister state. Proceedings under that statute require a *de novo* hearing at which the State must establish by a preponderance of the evidence the charges against the physician. *In re Matter of Polk, 90 N.J. 550* , 560 (1982). However, N.J.S.A. 45:1-21 addresses a different situation. That statute provides in pertinent part:

> 45:1-21. Grounds for refusal to admit to examination, refusal to issue or to suspend or revoke any certificate, registration or license.
>
> A board . . . may suspend or revoke any certificate, registration or license . . . upon proof that the applicant . . .

. . . . . .

> c. Has engaged in gross negligence, gross malpractice or gross incompetence;
>
> d. Has engaged in repeated acts of negligence, malpractice or incompetence;

. . . . . .

> g. Has had his authority to engage in the activity regulated by the board revoked or suspended by any other state, . . . for reasons consistent with this section;

. . . . . .

This statute creates an entirely different ground for sanction. It allows revocation in New Jersey upon proof of the fact of revocation elsewhere. This section does not require the State to prove anew the facts which formed the basis of the out-of-state sanction.

An analogous situation exists in the rules governing attorney disciplinary proceedings. *R.* 1:20-3(h) provides in pertinent part:

> (h) Criminal or Disciplinary Determination in Another Jurisdiction. If a final determination has been made in a criminal or disciplinary proceeding in another jurisdiction that an attorney of this State has engaged in conduct warranting disciplinary action in this State, such determination shall be deemed to have established the facts upon which it rests . . .

The court in *In re Kaufman, 81 N.J. 300* (1979) said:

> When a New Jersey attorney who is also admitted to practice in another jurisdiction is disciplined in that jurisdiction, the findings as to misconduct will be adopted by this Court in proceedings commenced under our *R.* 1:20-3(h). Furthermore, unless good reason to the contrary is shown, the discipline accorded in New Jersey will ordinarily correspond with that imposed in the other jurisdiction. *Id.* at 302-303.

Appellant further contends the application of N.J.S.A. 45:1-21 to him constitutes impermissible retroactive enforcement. This is not so. N.J.S.A. 45:1-21(g) is triggered by the act of revocation in another state, not by the underlying conduct which caused the sanction to be imposed. Here the revocation in New York occurred after the effective date of N.J.S.A. 45:1-21. In the *Kaufman* case the court applied *R.* 1:20-3(h) which was effective April 1, 1978 to suspend an attorney's license based upon a New York order of suspension dated May 8, 1978, which, in turn, was based on conduct in New York prior to June of 1977. The Supreme Court found no issue of retroactive enforcement. See also *In re Friedland, 92 N.J. 107* (1983).

Moreover, N.J.S.A. 45:1-21 is part of a uniform enforcement act and the opening section, N.J.S.A. 45:1-14 et seq., declares the act to be remedial and calls for a liberal construction. A strong implication of a legislative intent toward the validity of retroactive application exists. *Gibbons v. Gibbons,* 86 N.J. 515, 522 (1981).

We have carefully examined the record of the New York proceedings furnished us and find that the revocation in New York was based upon conduct and for reasons consistent with N.J.S.A. 45:1-21.

Appellant further argues that in large part the revocation in New York was based upon the experimental use of the drug Laetrile which, while illegal in New York, is legal in New Jersey, N.J.S.A. 24:6F-1 *et seq.,* and cannot be the basis for a valid revocation in New Jersey. The argument is flawed. The New York panel action was based upon its findings of Dr. Cole's fraudulent practice and gross negligence in connection with false claims of success; his engaging in experimental therapy in the absence of protocol; his failure to keep accurate and proper records and to obtain an informed consent for treatment as it related to the use of Laetrile. This and not the use of Laetrile, is what provided the basis for the revocation. In fact, the New York panel specifically stated:

> "This Panel does not take a position either for or against the use of Laetrile for terminal cancer patients in the proper clinical setting, providing that the patients of their own violation seek such a substance and knowing that it has not been approved for humans by the Food and Drug Administration and that all other regimens have failed."

It was not the use of Laetrile per se that caused Dr. Cole's downfall, it was the manner in which he used it and generally conducted his practice as a result of that use.

Appellant further contends that N.J.S.A. 45:9-16(h) [1] cannot apply to him since his negligence, if any, could not have endangered the health or life of patients already terminally ill. The contention lacks merit. We have already demonstrated that the proceeding against Dr. Cole was instituted under N.J.S.A. 45:1-21 and not under

245 N.J.S.A. 45:9-16. Moreover, *245 the same argument has been implicitly rejected in prosecutions under the Federal Food, Drug and Cosmetic Act. *21 U.S.C.A. § 321(p)(1).* See *U.S. v. Rutherford,* 442 U.S. 544, 554, 99 S.Ct. 2470, 2476, 61 L.Ed.2d 68, 78-79 (1979).

[1] 45:9-16. Refusal to grant, suspension or revocation of license, or registration of certificate or diploma; grounds; procedure; relicense.

> . . . . (h) has been guilty of gross malpractice or gross neglect in the practice of medicine which has endangered the health or life of any person, or . . .

Appellant further argues that the New York revocation cannot form a basis for New Jersey action because New York uses a lower standard of proof to "judge the validity of administrative proceedings." The argument lacks merit. A comparison of the standard for appellate review of the two states shows them to be virtually identical. Compare *In re Suspension of Heller,* 73 N.J. 292, 309 (1977) with *Pell v. Bd. of Education,* 34 N.Y.2d 222, 231, 356 *N.Y.S.2d* 833, 839, 313 N.E.2d 321 (1974).

Appellant claims he was denied his right to a fair hearing and to due process in the proceeding before the Board. Since the charges and the proceedings were based solely on N.J.S.A. 45:1-21(g) the scope of the hearing was, of necessity, limited and appellant was quite properly not permitted to go behind the New York determination. See *In re Coruzzi, 95 N.J. 557* , 567-568 (1984). The appellant sought to introduce evidence for the stated purpose of showing that the Board should take no action since his continued practice was in the public interest. He argues the Board has discretion to ignore misconduct, gross negligence or revocation in a sister state since N.J.S.A. 45:1-21 commences with the statement "A board may . . ." revoke. However we read the statute to vest the Board with discretion only to modify the penalty imposed once there is proof of a violation of the statute. The Board found a violation of the statute and provided appellant an opportunity to be heard in mitigation. We see no due process violation. Appellant received a formal complaint, was provided with an adequate opportunity to prepare his defense, he was represented by counsel and was permitted to testify and present witnesses and documentary evidence on his own behalf. A verbatim transcript was made and the determination of the Board to hear the case rather than transfer it to the Office of Administrative Law was within the discretion of the Board. N.J.S.A. 52:14F-8.

The appellant's claim that he was improperly limited in calling witnesses is without merit. All eight mitigation witnesses were permitted to testify. His request that all 70 patients present be permitted to testify was unreasonable and the Board allowed the appellant to have the patients sign a list stating they supported Dr. Cole. Such a limitation is consistent with established law. *State v. Carter, 91 N.J. 86* , 106 (1982); *State v. Mucci,* 25 N.J. 423 (1957); N.J.A.C. 1:1-15.2(a).

Appellant's arguments that the exclusion of certain items of evidence, the poisoning of the mind of the Board by the prosecutor's questions of the character witnesses and cross-examination denied him a fair trial are all without merit.

Appellant also argues the Board improperly considered documents which were not introduced into evidence and, in fact, had been excluded from evidence. He contends this deprived him of a fair trial. While we agree the Board did improperly consider such evidence, we are satisfied that in the context of the entire proceeding consideration of these extraneous documents could not have led to an improper result and constituted, at most, harmless error.

Appellant charges that the final written order did not conform to the oral order of April 13th. However, we detect no significant deviation. Appellant also urges that an improper merger of the prosecutorial and advisory functions in the Office of the Attorney General deprived him of his constitutional right. The Supreme Court has recently held that a similar dual role assumed by a single deputy attorney general standing alone does not constitute a due process violation. *In re Matter of Polk,* 90 N.J. at 576-577. No evidence of taint appears in the record and the bare assertion of improper conduct falls short of proof of actual bias, prejudice or violation of due process in a hearing required by our case law. *In re Blum,* 109 N.J. Super. 125, 129 (App.Div. 1970); *In re Larson, 17 N.J. Super. 564* , 574-579 (App.Div. 1952) (Brennan concurring); Accord *Withrow v. Larkin,* 421 U.S. 35, 47, 95 S.Ct. 1456, 1464, 43 L.Ed.2d 712 (1975).

Appellant's contention that the Board's proceedings were conducted in violation of the Open Public Meetings Act in taking a "straw vote" behind closed doors and after reaching a consensus voting a second time in public was in violation of N.J.S.A. 10:4-12(a). The record is to the contrary. The Board properly entered executive session to consider whether the New York order was sufficient on its fact to establish grounds for sanction under N.J.S.A. 45:1-21(g); N.J.S.A. 10:4-12(b)(9). The Board deliberated and reached a consensus on the issue. It, of necessity, had to take a vote or "straw poll" to identify a consensus since without sufficient votes the deliberations could not have been concluded. These straw votes were obviously not illegal, secret votes. After reaching a consensus the Board reentered the public session and publicly voted on the motion and summarized its findings and conclusions.

The sanction of license revocation corresponds to the sanction imposed in New York and we affirm that disposition. *In re Kaufman, 81 N.J. 302*-303; 92 N.J. at 113.

Affirmed.

The University of the State of New York

IN THE MATTER

OF

Proceedings by the State Board for Professional Medical Conduct to determine the action to be taken with respect to the revocation or suspension of the license heretofore granted to DONALD ROBERT COLE, M.D. to practice medicine in the State of New York, or such other penalty as is warranted, pursuant to Article 2, Title II-A of the Public Health Law of the State of New York.

No. 2476

Report of the Regents Review Committee

DONALD ROBERT COLE, hereinafter referred to as respondent, was licensed to practice as a physician in the State of New York by the New York State Education Department by the issuance to him of license No. 073581.

The statement of charges charged respondent with practicing the profession fraudulently (first specification), with practicing the profession with gross incompetence (second specification), with practicing the profession with gross negligence on a particular occasion (third specification), with practicing the profession with negligence or incompetence on more than one occasion (fourth specification), and with

unprofessional conduct (fifth and sixth specifications). A copy of the charges is annexed hereto, made a part hereof, and marked as exhibit "A".

From February 21, 1979 through May 13, 1981, inclusive, hearings were held before a Hearing Committee of the State Board for Professional Medical Conduct.

Respondent appeared at the hearings and was represented by an attorney.

The Hearing Committee rendered a report of its findings, conclusions, recommendation, a copy of which is annexed hereto, made a part hereof, and marked as exhibit "B".

The Hearing Committee found and concluded that respondent was not guilty of the second and third specifications of the charges, and guilty of the first, fourth, fifth, and sixth specifications of the charges, and recommended that respondent's license to practice as a physician in the State of New York be revoked.

The Commissioner of Health recommended to the Board of Regents that the findings, conclusions, and recommendation of the Hearing Committee be accepted in full, that respondent's post-hearing motions be denied, and that the Board of Regents issue an order adopting and incorporating said findings and conclusions and further adopting as its determination said

recommendation. A copy of the recommendation of the Commissioner of Health is annexed hereto, made a part hereof, and marked as exhibit "C".

On July 28, 1982 respondent appeared before us in person and was represented by his attorneys, Algis K. Augustine, Esq. and Steven I. Kern, Esq. The Department of Health was represented by John Shea, Esq.

We have carefully reviewed and considered the entire record in this matter, the briefs submitted by respondent and by petitioner, and the statements made before us.

With respect to patient "A", it is our unanimous opinion that the charges have not been proven by substantial legal evidence. Accordingly, we unanimously recommend to the Board of Regents that, with respect to patient "A", the findings of fact of the Hearing Committee and the recommendation of the Commissioner of Health with respect thereto not be accepted, that the conclusions of the Hearing Committee and the recommendation of the Commissioner of Health with respect thereto be modified, and that respondent be found not guilty of the first through fourth specifications of the charges to the extent that they relate to patient "A".

With respect to the remaining charges relating to the other patients, except patient "G" as to whom the charges were withdrawn, we unanimously recommend to the Board of Regents that the findings of fact of the Hearing Committee as well as the recommendation of the Commissioner of Health with respect

thereto be accepted, that the conclusions of the Hearing Committee as well as the recommendation of the Commissioner of Health with respect thereto be modified, that the recommendation of the Hearing Committee as to the measure of discipline as well as the recommendation of the Commissioner of Health with respect thereto be accepted, that the Board of Regents accept the recommendation of the Commissioner of Health as to the post-hearing motions, that respondent be found guilty of each specification of the charges, and that respondent's license to practice as a physician in the State of New York be revoked upon each specification of the charges of which respondent was found guilty, as aforesaid.

Respectfully submitted,

MARTIN C. BARELL

DANIEL GUTMAN

PATRICK J. PICARIELLO

Martin C. Barell

Chairperson

Dated: September 16, 1982

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

IN THE MATTER

OF

Proceedings by The State Board For Professional Medical Conduct to determine the action to be taken with respect to the revocation or suspension of license heretofore granted to DONALD ROBERT COLE, M.D. to practice medicine in the State of New York, or such other penalty as is warranted, pursuant to Article 2, Title II-A, of the Public Health Law of the State of New York.

STATEMENT OF CHARGES

The State Board for Professional Medical Conduct, upon information and belief, charges and alleges as follows;

1. DONALD ROBERT COLE, M.D., hereinafter referred to as the Respondent, was authorized to engage in the practice of medicine in the State of New York on March 26, 1953 by the issuance of license Number 073581 by the State Education Department.

2. Respondent is currently registered with the New York State Education Department to practice medicine for the period 1979-1980 from 8 South Tyson Avenue, Floral Park, New York 11001 and 2702 Third Avenue, Bronx, New York 10454.

3. Respondent herein is charged with professional misconduct within the purview of Section 6509, of the Education Law of the State of New York, as set forth in the Specifications attached hereto and made a part hereof.

Executive Secretary
State Board for Professional
Medical Conduct

Dated: January 26, 1979

EXHIBIT "A"

STATEMENT OF CHARGES

I. Respondent is charged with practicing the profession fraudulently within the purview and meaning of Section 6509, Subdivision 2, of the Education Law, with respect to the following persons, all now deceased, who were cancer patients of respondent at Whitestone General Hospital, 10-01 166th Street, Whitestone, New York:

1. Patient A (the identification of Patient A, as well as other patients, is found in the attached appendix) a 58-year old female with a history of cancer of the breast and a chief complaint of cancer of the liver, entered Whitestone General Hospital on May 27, 1976, and was placed upon a course of treatment which included the "Mariyama" treatment, (more correctly known as "Maruyama vaccine"), Laetrile, BCG vaccine and Vitamin A dosages, which course of treatment respondent knew would not effect a remission or cure of cancer of the liver, and, despite his knowledge of an enlarged liver, abnormal liver chemistries, and an abnormal liver scan, respondent urged the husband to place a telephone call in order for respondent to announce to a cancer convention in Los Angeles, on July 4, 1976, that respondent had produced the first remission of liver cancer in the United States, and, despite the subsequent claim by respondent that Patient A had been cured of cancer, when, in fact, she had not been, Patient A's condition deteriorated and she died on July 10, 1976, with the final diagnosis being adenocarcinoma of the right breast with metastases and cardiac arrest along with a secondary diagnosis of anemia and hematoma and cellulitis of the left thigh.

I. (continued)

2. Patient B, a 48-year old female with a history of extensive inflammatory carcinoma of the left breast, with a large mass under the left arm, after a telephone conversation with the husband, on, or about, July 8, 1976, wherein respondent stated that

> Inflammatory doesn't make any difference. I think I can knock it out. She might have to have her ovaries removed. But that's no big thing; it's as simple as removing the appendix. If that's successful, she would have a 75 percent chance for a complete remission.

entered Whitestone General Hospital on July 9, 1976, and, on July 12, 1976, after having removed the ovaries and performed an exploratory laparotomy, respondent stated to the husband that

> No complications whatever. One added problem though -- it's into the liver ...we did a liver scan, and it's definitely into the liver....I would say that her points have slipped some; but I would still say she has at least a 65 percent chance for a complete remission.

and such statement gave false hope to Patient B and her husband, when respondent knew there was no such chance, and the condition of Patient B worsened, despite assurances of respondent that she was in "better shape" on August 1, 1976, than when she was admitte and respondent said that, "We've pulled off miracles here before," and Patient B's condition deteriorated until she died on August 6, 1976, as a result of cardio-respiratory arrest due to extensive inflammatory carcinoma with diffuse metastases from the left brea

I. (continued)

3. Patient C, a 39-year old female with a history of headaches for at least five years with increasing frequency and a recent diagnosis of two tumors in the brain, entered Whitestone General Hospital on November 3, 1976, with a presumptive diagnosis of metastatic carcinoma of the brain, after respondent stated that, "I never lost a patient with this type of problem," which statement gave false hope to Patient C and her husband, and, further, respondent referred to an article in Esquire magazine, dated April, 1976, about the Janker Clinic in Bonn, Germany, for cancer patients, stating, "I am the doctor mentioned in that article who went to Germany," thereby causing Patient C and her husband to believe that he would use the "Janker treatment" and that he could cure cancer, and respondent placed Patient C upon a course of treatment which respondent knew would not cure metastatic carcinoma of the brain, and despite respondent's claim that loss of sight, as a result of chemotherapy, meant that the drugs were reaching the brain and was a positive sign, Patient C's condition so deteriorated that the husband was going to transfer Patient C to New York University Medical Center but the respondent, on November 18, 1976, dissuaded the husband and Patient C continued to deteriorate, and she died on November 25, 1976, after cardiac arrest due to metastatic brain tumor(s).

I. (continued)

4. Patient D, a 58-year old female with a history of metastatic carcinoma into the liver and a pelvic mass, and the recommendation being made that there be no further surgery and no chemotherapy but to make her as comfortable as possible with the appropriate medication, entered Whitestone General Hospital on April 7, 1977, as a patient of respondent, and, on that day, respondent gave the husband of Patient D a telephone number to call to obtain Laetrile, referred to as "candy", as well as tablets which respondent called "Laetrile B17" which substances the husband purchased on April 8, 1977, at a telephone booth on the corner of 12th Street and Sixth Avenue, Manhattan, for $270, in cash for thirty (30) ampules of Laetrile and $75.00 for 100 tablets of Laetrile B17, and respondent placed Patient D on a course of treatment, which included said Laetrile and also BCG vaccine, which respondent knew were worthless for metastatic carcinoma to the liver, and, despite the husband's refusal to permit surgery since his wife was in "rundown condition", respondent caused husband to give such permission, and an exploratory laparotomy, liver biopsy and bilateral oopherectomy were performed on April 14, 1977, and pathology findings of cancer into the ovaries and the liver, Patient D was discharged on May 25, 1977, and re-admitted on May 28, 1977, and Patient D's condition "slowly but progressively" deteriorated and, although she died on June 13, 1977, due to cardio-respiratory arrest as a consequence of cancer and anemia, respondent told the husband that, "She did not want to live, that was why she died."

I. (continued)

5. Patient E, a 48-year old female with a history of carcinoma of the ovaries with widespread abdominal metastases and massive ascites, entered Whitestone General Hospital on February 20, 1977, after respondent, having been advised of her medical and surgical history, told Patient E and her husband that she had "at least a 50-50 chance with his treatment," which, according to respondent, would consist of the administration of drugs, which gave them false hope, and despite assurances of no further surgery, respondent did perform elective surgery, namely, an exploratory laparotomy and lysis of adhesions, on March 4, 1977, without notice to the husband and without informed consent from Patient E, whose condition was "fair," and, during said surgery, respondent encountered "a tremendous amount of difficulty ... because of the amount of metastatic lesions ... and difficulty in the identification of the anatomic structures," and respondent later did place Patient E upon a course of treatment, which included Laetrile and BCG vaccine, which respondent knew were worthless, and Patient E was discharged on March 25, 1977, followed in respondent's office and re-admitted on April 23, 1977, with abdominal pains, and Patient E's condition so deteriorated that, on June 29, 1977, the husband refused any further treatment but for relief of pain and discomfort, and she continued to deteriorate until, after an onset of Cheyne-Stokes respiration, Patient E died on August 10, 1977, due to carcinoma of the ovary (ovaries).

I. (continued)

6. Patient F, a 57-year old female with a history of oat cell carcinoma of the right lung, with metastases to the left lung, entered Whitestone General Hospital, on July 19, 1977, after respondent caused Patient F and her husband to believe that a cure was imminent within six months, and Patient F was discharged on July 29, 1977 and re-admitted on August 8, 1977, after respondent caused the husband to remove her from Nassau County Medical Center, when he said, "She's gonna die if you don't get her right down here," and respondent on, or about, August 28, 1977, placed Patient F upon a course of treatment which respondent knew was worthless for Patient F's condition, which treatment, in addition to BCG vaccine, included the administration of Wobe-mugos enzyme pills and A-mulsin, unapproved German medicines which respondent, through his representative "Alice", sold to the husband for $1.50 per Wobe pill and $50 for tube of A-mulsin, and Patient F was discharged on September 17, 1977 and given a week's supply of enzymes and some A-mulsin and despite respondent's claim, on September 19, 1977 that "she is doing fine, that her lung cancer is under control and her cardiovascular is under control," the condition of Patient F so deteriorated that, on September 21, 1977, the husband, after attempting to reach respondent, admitted his wife to Nassau County Medical Center, where Patient F continued to deteriorate until she died on September 2 1977, as a result of metastatic carcinoma of the lung, small cell type

I. (continued)

7. Patient G, a 39-year old male with a known diagnosis of metastatic carcinoma of the pancreas and a chief complaint of abdominal pain, entered Whitestone General Hospital, on September 27, 1977, as a patient of respondent, and, approximately two days later, respondent held a "seminar" for patients in the basement of the hospital and Patient G learned of the availability of Laetrile and the next morning respondent caused Patient G to contact Mrs. Alice Soto, respondent's representative, for the purchase of Laetrile or "candy," the code word used by respondent and his representatives for Laetrile, and respondent did sell to Patient G, through his representatives, said Laetrile for $280.00 in cash, with no receipt, for fourteen (14) days of treatment, and Patient G did receive injections of Laetrile or "candy," for at least thirteen (13) days, which substance respondent knew was worthless for the carcinoma of Patient G, and which substance gave false hope to Patient G, and, BCG vaccine was also administered to Patient G which respondent knew was worthless for carcinoma of the pancreas, and the condition of Patient G did so deteriorate that, on October 17, 1977, his family caused him to be removed from Whitestone General Hospital and from the treatment of respondent and to be admitted to another hospital. Patient G died on January 6, 1978, and the final diagnosis was carcinoma of the pancreas with widespread metastases.

I. (continued)

S. Patient H, a 10-year old male with a known diagnosis of carcinoma of the brain, with metastases, entered Whitestone General Hospital on November 13, 1977, after respondent caused the parents of Patient H to remove him from Sloan-Kettering Memorial Hospital, where, respondent said, the boy does not have a chance because the treatment will definitely fail and that there was a chance with him because he had a similar case where the patient walked out of the hospital, which words and conduct gave false hope to the parents, and subsequent to the admission of Patient H, respondent's representative, "Alice," said to the mother that, "We decided to start Richard on 'candy'," the code word used by respondent and his representatives for Laetrile and/or amygdalin, and the parents purchased Laetrile from respondent's representative(s), and respondent knew that Laetrile and/or amygdalin were worthless for cancer of the brain, as was the BCG vaccine given to him, and Patient H was discharged on December 22, 1977, re-admitted on December 27, 1977, discharged on December 29, 1977, and re-admitted on January 3, 1978, with increasing paralysis, and despite the fact that respondent had kept telling the parents that Patient H "was not hopeless, that tomorrow we'll have something new to try," on or about January 7, 1978, respondent told the parents that their son's case was desperate, and his condition deteriorated until Patient H, after cardio-respiratory failure, died on January 24, 1978, as a consequence of metastatic carcinoma.

I. (continued)

9. Patient I, a 61-year old male with a neglected carcinoma of the lung and recent weight loss, hemoptysis, dysphagia and orthopnea, was admitted to Whitestone General Hospital on December 22, 1977, after Patient I asked respondent for Laetrile and respondent said, "All right, so you get it," which gave Patient I and his wife false hope and respondent subsequently sold, through his representative "Alice," a twenty-one day supply of "candy," the code word for Laetrile, for $760.00 in cash, with no receipt, and thereafter sold Laetrile at the price of $680.00 in cash, with no receipt, for a twenty-one day supply and thereafter sold said Laetrile, or "candy," for $630.00, which respondent knew was worthless for the condition of Patient I, and injections of said Laetrile caused great pain for Patient I, and, when the wife told "Alice" that Laetrile was worthless, she replied, "We don't want anyone to know that we give it," and, on February 27, 1978, in response to the wife's request for "Doctor Burton's blood serum" from the Bahamas, respondent stated that "your husband is getting the equivalent," which blood serum or equivalent respondent knew was worthless, and the condition of Patient I continued to deteriorate, until, after an onset of respiratory distress, Patient I died on March 15, 1978, due to metastatic carcinoma.

II. Further, respondent is charged with practicing the profession with gross incompetence, and the allegations set forth at Roman numeral I, numbers 1 through 9, supra, regarding Patient A, Patient B, Patient C, Patient D, Patient E, Patient F, Patient G, Patient H and Patient I, are hereby repeated, restated and realleged as if fully set forth herein.

III. Further, respondent is charged with practicing the profession with gross negligence on a particular occasion, and the allegations set forth at Roman numeral I, numbers 1 through 9, supra, regarding Patient A, Patient B, Patient C, Patient D, Patient E, Patient F, Patient G, Patient H and Patient I, are hereby repeated, restated and realleged as if fully set forth herein.

IV. Further, respondent is charged with practicing the profession with negligence or incompetence on more than one occasion and the allegations set forth at Roman numeral I, numbers 1 through 9, supra, regarding Patient A, Patient B, Patient C, Patient D, Patient E, Patient F, Patient G, Patient H and Patient I, are hereby repeated, restated and realleged as if fully set forth herein.

V. Further, respondent is charged with willful or grossly negligent failure to comply with substantial provisions of federal and state laws in that he did possess and/or sell and did administer and/or cause to administer to human beings unapproved drugs, medications and substances in violation of 8 NYCRR 29.1 (b)(1). The allegations set forth at Roman numeral I, numbers 7, 8 and 9, supra, are hereby repeated, restated and realleged as if fully set forth herein.

VI. Further, respondent is charged with failing to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient in that he did not enter, or cause to be entered, all drugs and medications given to each patient in violation of 8 NYCRR 29.2 (a)(3). The allegations set forth at Roman numeral I, numbers 7, 8, and 9, supra, are hereby repeated, restated and realleged as if fully set forth herein.

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

IN THE MATTER OF Proceedings by the State Board for Professional Medical Conduct to determine the action to be taken with respect to the revocation or suspension of the license heretofore granted to DONALD ROBERT COLE, M.D. to practice medicine in the State of New York, or such other penalty as is warranted; pursuant to Article 2, Title II-A of the Public Health Law of the State of New York	REPORT OF FINDINGS, CONCLUSIONS AND RECOMMENDATION

TO: DAVID AXELROD, M.D., Commissioner
New York State Department of Health

The undersigned, Hearing Committee on Professional Conduct of the State Board for Professional Medical Conduct, duly designated to hear the charges against DONALD ROBERT COLE, M.D., hereinafter referred to as Respondent, pursuant to Article 2, Title II-A of the Public Health Law of the State of New York, and to report its findings, conclusions and recommendations in respect to the said charges, do hereby, after due deliberation, unanimously report its findings, conclusions and recommendation as follows:

EXHIBIT "B"

RECORD OF PROCEEDINGS

Notice of Hearing and Statement of Charges dated: January 26, 1979

Place of Hearing: New York City

Answer of Respondent verified: March 12, 1979

Petitioner appears by: Robert Abrams
Attorney General of the State of New York
622 Third Avenue
New York, New York 10017

By: John Shea, Esq.
Designee of the Attorney General
New York State Department of Health
Rockefeller Plaza
Albany, New York 12237

Respondent appears in person and by his attorneys:

Raphael P. Koenig, Esq.
Jerome J. Londin, Esq.
350 Madison Avenue
New York, New York 10017

Respondent's present address: Holistic Center
8 South Tyson Avenue
Floral Park, New York 11001

Hearing Dates:

February 21, 1979	January 9, 1980	November 6, 1980
April 3, 1979	January 24, 1980	December 3, 1980
May 2, 1979	February 21, 1980	December 23, 1980
July 11, 1979	April 10, 1980	February 4, 1981
August 15, 1979	April 30, 1980	March 5, 1981
October 11, 1979	May 22, 1980	April 11, 1981
October 31, 1979	June 26, 1980	May 13, 1981
November 29, 1979	September 4, 1980	
December 19, 1979	October 3, 1980	

Introduction.

At issue in this proceeding, for the most part, is the credibility of the Respondent, Donald Robert Cole, M.D., concerning his practice of medicine at the now-defunct Whitestone General Hospital, in Queens, New York, for the period May 27, 1976, through March 15, 1978. The issue of credibility places the testimony of the physicians and nurses at Whitestone General Hospital against the testimony of the Respondent. For the reasons which follow, we conclude that fraudulent representations were indeed made by the Respondent that he could effect remissions or cures of cancer which previously had been diagnosed as terminal. We also conclude that, notwithstanding his education and training, Respondent, after having lured the patients into Whitestone General Hospital with his fraudulent representations, then proceeded to render treatment which was both negligent and incompetent. We also find that he willfully maintained incomplete medical records, employed a code book for medications administered, and used experimental drugs without the prior knowledge and approval of the Food and Drug Administration or Whitestone General Hospital. Respondent's conduct so deviated from the standards of the medical profession that, at times, it was tantamount to quackery. It is our unanimous and emphatic recommendation that the Respondent's license to practice the profession of medicine be forthwith revoked.

Exhibits for Petitioner

Exhibit #1, Notice of Hearing and Statement of Charges; Exhibit #2, the Reply; Exhibit #3, letter, dated April 12, 1978, from John T. McGee to Dr. John Jacoby, New York State Department of Health; Exhibit #4, pamphlet, The Janker Clinic, by Patrick M. McGrady, Jr.; Exhibit #5 medical record of Patient A; Exhibit #6, Esquire magazine article of April, 1976, entitled "American Cancer Society Means Well, but the Janker Clinic Means Better," by Patrick M. McGrady Jr.; Exhibit #7, report of Elihu A. Gorelik to Dr. Plavin concerning a complaint alleging investigational drugs at Whitestone General Hospital; Exhibit #8, list of patients on experimental drugs at Whitestone General Hospital for the last 90 days; Exhibit #9, representative sample of vials of Isophosphamide; Exhibit #10, document, "Metabolic Cancer Therapy-Orientation Packet," prepared in cooperation with Dr. Juanito Pung, M.D. and Dr. Donald Cole, M.D., F.A.C.S.; Exhibit #11, composition notebook, dated 6/14/76, entitled, "Dr. Cole Chemo,"; Exhibit #12, negative certificate of the Food and Drug Administration for Wobe Mugos or Wobenzyn; Exhibit #13, two letters of Dr. Donald R. Cole, dated June 28, 1975, to persons in Germany, and tablets of Wobe-Mugos and a tube of A-Mulsin; Exhibit #14

letter, dated August 5, 1975 from Dr. C. Gordon Zubrod to Donald R. Cole, M.D.; Exhibit #15, letter, dated October 17, 1975, from Mead Johnson to Donald Cole, M.D., and letter from Mead Johnson dated January 2, 1979; Exhibit #16, four photographs, A, B,C, and D of cancer of Patient B; Exhibit #17, curriculum vitae of C. William Aungst, M.D.; Exhibit #18, medical record of Patient B; Exhibit #19 letter from Food and Drug Administration, dated April 30, 1979, to Mr. Thomas Flavin, New York State Department of Health; Exhibit #20, newspaper article, dated June 3, 1976, entitled "Successes Bringing Down the Walls of Resistance,"; Exhibit #21 and 21-A, medical record of Patient C; Exhibit #22, minutes of Lay Advisory Committee Meeting, Whitestone General Hospital on 5/23/76; Exhibit #23, Committee minutes, Whitestone General Hospital, Medical Board/Board of Governors, dated February 22, 1978; Exhibit #24, Committee minutes, Whitestone General Hospital, Medical Board-Board of Governors, dated March 1, 1978; Exhibit #25, a prescription of Donald R. Cole, M.D., for Patient E; Exhibit #26, marked for Identification; Exhibit #27, pages of a diary of Patient E while at Whitestone General Hospital; Exhibit #28, 3 vials Cyto Pharma Laetrile; Exhibit #29, medical record of Patient D; Exhibit #30 and 30-A, medical record of Patient F; Exhibit

#31, letter, dated October 4, 1979, from Food and Drug Administration to John Shea, Designee; Exhibit #32, certified copy of death certificate for Patient F; Exhibit #33, University Hospital summary for Patient H; Exhibit #34, Memorial Hospital discharge summary for Patient H; Exhibit #35, letter dated November 16, 1977, from Dr. Jeffrey C. Allen concerning Patient H; Exhibit #36, medical record of Patient I; Exhibit #37, curriculum vitae of Victor Herbert, M.D., JD.; Exhibit #38, negative certificate of Food and Drug Administration for Isophosphamide; Exhibit #39 and 39-A, medical record of Patient E; Exhibit #40, certified copy of death certificate for Patient A; Exhibit #41, certified copy of death certificate for Patient B; Exhibit #42, certified copy of death certificate for Patient C; Exhibit #43, certified copy of death certificate for Patient D; Exhibit #44, certified copy of death certificate for Patient E; Exhibit #45, certified copy of death certificate for Patient H; Exhibit #46, certified copy of death certificate for Patient I; Exhibit #47, letter, dated January 18, 1980, from Food and Drug Administration to Mr. Thomas Flavin; Exhibit #48, marked for Identification; Exhibit #49, poster concerning Harold

W. Manner, Phd.; Exhibit #50, poster entitled "Laetrile Warning," signed by Donald Kennedy, Commissioner of Food and Drugs; Exhibit #51, marked for Identification; Exhibit #52-1, letter from Jane E. Henney, M.D., dated December 8, 1980, to John Shea, Designee; Exhibit #52-2, protocol for clinical trials of Laetrile; Exhibit #52-3, statement by Jane E. Henney, M.D., dated October 1, 1980; Exhibit #53, letter from Medicare to Donald Cole, M.D., dated April 15, 1974; Exhibit #54, marked for Identification; Exhibit #55, marked for Identification; Exhibit #56, letter in the New England Journal of Medicine, dated December 15, 1975; Exhibit #57, article; "A Pharmacologic and Toxicological Study of Amygdalin,"; Exhibit #58, tape recording, "NHF 25th Annual Convention-'80 Holistic Clinical Oncology."

Exhibits for Respondent

Exhibit A, verified Answer; Exhibit B, excerpt from Memorandum of Law in the matter of Mary Doe et al. v. State Board for Professional Medical Conduct, et al.; Exhibit C, Two opinions of Supreme Court, Rockland County, in the matter of

Mary Doe et al., against the State Board for Professional Medical Conduct, et al.; Exhibit D, 5/26/76 memo & form from H.E.W.; Exhibit E, letter, dated March 30, 1979, from Food and Drug Administration to Mr. Thomas Flavin; Exhibit F, letter, dated December 22, 1978, from Food and Drug Administration to Mr. Tom Flavin; Exhibit G, report of Dr. Ueno on Patient B; Exhibit H, document, "Whitestone General Hospital authorization for medical and surgical treatment"; Exhibit I, letter of David Eisenberg, M.D., dated August 30, 1976; Exhibit J, letter of Myles Desner, M.D., dated February 21, 1977; Exhibit K, Cyto Pharma U.S.A. affidavit; Exhibit L, order sheet for Patient H; Exhibit M, and M_1, medical record for Patient H; Exhibit N, Two-page document signed by Patient I; Exhibit O, curriculum vitae of Donald R. Cole, M.D., F.A.C.S.; Exhibit P, minutes of Whitestone General Hospital Research Committee, dated November 30, 1977; Exhibit Q, minutes of Whitestone General Hospital Research Committee, dated December 28, 1977; Exhibit R, document, "Systemic Thermotherapy for Cancer"; Exhibit S, curriculum vitae of Bruce W. Halstead, M.D.; Exhibit T, curriculum vitae of Harold W. Manner, Phd.; Exhibit U, curriculum vitae of Dean Burk, Phd.; Exhibit V, curriculum vitae of William G. Tucker, M.D.; Exhibit W-1, W-2, W-3 and

W-4, four photographs of "Pamela"; Exhibit X, curriculum vitae of Allan Cott, M.D.; Exhibit Y, letter, dated June 4, 1980, from Raphael P. Koenig, Esq.; Exhibit Y (sic), curriculum vitae of Robert A. Berman, M.D.; Exhibit Z, curriculum vitae of Nancy Dixon; Exhibit AA, curriculum vitae of Sol Roy Rosenthal, M.D.; Exhibit BB, corrected curriculum vitae of Donald R. Cole, M.D., F.A.C.S.; Exhibit CC, COG on-study form; Exhibit DD-1, article, "An Effective Low-Dose Intermittent Cyclophosphamide, Methotrexate, and 5-Fluorouracil Treatment Regimen for Metastic Breast Cancer,"; Exhibit DD-2, article, "Nontoxic, Low Dose Chemotherapy,"; Exhibit DD-3, article, "Low Dose Chemotherapy of Metastic Breast Cancer with Cyclophosphamide, Adriamycin, Methotrexate, 5-Fluorouracil (CAMF) versus Sequential Cyclophosphamide, Methotrexate, 5-Fluorouracil (CMF) and Adriamycin,"; Exhibit EE, article, "Chemoprevention of Cancer with Retinoids,"; Exhibit FF, documents relating to Fe A. Pung, M.D.,; Exhibit GG, pathology and operative report on Patient P; Exhibit HH, marked for Identification; Exhibit II, Editorial, "Ca: The First 30 Years, " and article, "Annual Discourse: on caring for the patient with Cancer,"; Exhibit JJ, articles, "Moderate

Versus Intensive Chemotherapy of Prognostically Favorable Non-Hodgkin's Lymphoma" and "Chemotherapy for Advanced and Recurrent Squamous Cell Carcinoma of the Head and Neck with High and Low Dose Cis-Diamminedichloroplatinum"; Exhibit KK, article, "An Aggressive Multimodality Approach to Locally Advanced Carcinoma of the Breast,"; Exhibit LL, article, "Combination Chemoimmunotherapy of Metastic Breast Cancer with 5-Fluorouracil, Adriamycin, Cyclophosphamide, and BCG,"; Exhibit MM, article, "Adrenalectomy with Chemotherapy in the Treatment of Advanced Breast Cancer: Objective and subjective response rates; duration and quality of life,"; Exhibit NN, article, "Extended Survival and Remission Rates in Metastatic Breast Cancer,"; Exhibit OO, article, "Adrenalectomy and Oophorectomy Plus Limited-Term Chemotherapy in the Treatment of Breast Cancer,"; Exhibit PP, article, "Thrombocytopenia from Metastatic Carcinoma of the Breast,"; Exhibit QQ, article, "An Evaluation of Early or Delayed Adjuvant Chemotherapy in Premenopausal Patients with Advanced Breast Cancer Undergoing Oophorectomy,"; Exhibit RR, article, "Inflammatory Carcinoma of the Breast,"; Exhibit SS, chart with regard to Patient D; Exhibit TT, article, "Inappropriate Anti-Diuretic

Hormone Secretion"; Exhibit UU, article, "The Syndrome of Inappropriate Secretion of Antidiuretic Hormone"; Exhibit VV, article, "BCG as Adjuvant Immunotherapy for Neoplasia"; Exhibit WW, article, "Bone Marrow Involvement in Breast Cancer"; Exhibit VV (sic), table from New York Times.

Exhibits for Panel*

Exhibit I, medical record of Mr. L.S.; Exhibit II, additional medical documents concerning Mr. L.S.; Exhibit III, medical record of Mrs. M.E.; Exhibit IV, medical record of Mrs. D.O'N.; Exhibit V, medical record of Mrs. V.G.; Exhibit VI, medical record of Mrs. E.W.; Exhibit VII, medical record of Mr. P.B.; Exhibit VIII, medical record of Mrs. E.P.; Exhibit IX, medical record of Mrs. S. D'E.; Exhibit X, medical record of Mr. D.F.; Exhibit XI, medical record of Mr. J.A..

*All of these medical records concern patients of the Respondent who are not the subject of the instant charges.

Amendments to Statement of Charges (Exhibit 1)

1. Patient D: page 7, line 8, "tablets" should be "candy." Transcript p. 851.

2. Patient F: page 9, line 14, "$1.50" should be "$1.00." Transcript p. 895.

3. Patient G: Charges withdrawn.

4. Patient H: page 11, lines 13-14, should be "respondent knew or should have known that Laetrile and/or amygdalin were worthless for cancer of the brain." Transcript p. 1175. Also see corrections which appear at end of November 29, 1979, transcript.

5. Patient I: page 12, line 10, should be "knew or should have known;" p. 12 line 17, should be "knew or should have known." Transcript pp. 1323-1324.

Official and Administrative Notices

1. Balance of drugs (Ifosfamid/Isophosphamide) in carton from which Exhibit 9 is a sample. p. 315.

2. Letter, "Contaminated Laetrile: A Health Hazard," New England Journal of Medicine, Vol. 297, No. 24, p. 1355, December 15, 1977. (Identical to Petitioner's Exhibit 56). p. 828.

3. Federal statutory scheme and formal process required by the Food and Drug Administration for investigational new drugs (IND). p. 1521.

4. Public Health Law Article 24-A. "Protection of Human Subjects." p. 1848.

5. Education Law Section 6802(15), definition of "new drug." p. 1849.

6. Education Law Section 6817, "New Drugs," p. 1849.

7. "Statement of the National Cancer Institute on Laetrile Tests with Patients." p. 4034.

8. "Clinical Study of Laetrile in Cancer Patients. Investigators' Report: A Summary." p. 4034

9. Minutes of the Americal Society of Clinical Oncology, 17th Annual Meeting, Washington, D.C., April 30-May 2, 1981. p. 4034.

FINDINGS

We make the following findings with respect to the now-deceased patients of Respondent treated at Whitestone General Hospital, 10-01 166th Street, Whitestone, New York:

Whitestone General Hospital Whitestone General Hospital was a small, proprietary hospital of approximately 100 beds. It went into bankruptcy and closed in December, 1978. At times, Respondent's cancer patients occupied 50% to 60% of the beds. Whitestone was not a research hospital, and there was no proper research committee for human experimentation (cf. Monroe Broad, M.D., pp 1731-1732). We believe that the references of Exhibit P and Q to a "Research Committee" are not convincing. It is our opinion that such a committee was, for the most part, bogus. It is also our opinion that the "Lay Advisory Committee," mentioned in Exhibit 22, was not a proper committee to oversee medical research. Contrary to the self-serving declaration of Exhibit 22, we find that Respondent was, in fact, "experimenting on human beings...who have been considered hopeless elsewhere." We credit the testimony of Edith Lawrence, R.N., and Jean McKenna, R.N., who testified that the regular nursing staff at Whitestone did not know what medications were given to Doctor Cole's patients and acknowledged that the substances administered were not charted (e.g. Transcript pp. 190 and 463).

Laetrile This Panel does not take a position either for or against the use of Laetrile for terminal cancer patients in the proper clinical setting, providing that the patients of

their own volition seek such a substance and knowing that it has not been approved for humans by the Food and Drug Administration and that all other regimens have failed. However, the administration of Laetrile in a hospital like Whitestone General Hospital, during the period May 27, 1976 through March 15, 1978, required certain minimal safeguards for the protection of patients. First, there must be the specific approval of the governing authority and the medical board of the hospital for the use of Laetrile. Next there should be the voluntary informed consent of the patient without undue inducement, fraud or deceit upon the physician's part. Lastly, the Laetrile must be free of impurities and contaminants. Whitestone General Hospital never granted permission to Doctor Cole, or to anyone, to use Laetrile. See Exhibits 23 and 24. Respondent knew, or should have known that Cyto Pharma of Mexico Laetrile which he used (Exhibit 28) had been found by the Food and Drug Administration to be impure. See Exhibits 50 and 56. Testing of Respondent's own vial of Cyto Pharma Laetrile showed an impurity. Exhibit 31.

In our opinion, the record of this proceeding convinces this Panel that Patients A, D, E, H and I received Laetrile while under the treatment of Respondent at Whitestone General Hospital. We are also convinced that Laetrile was worthless for their conditions. Further, it must be noted--and Respondent

concedes--that no recordation of the administration of the Laetrile appears in the medical records of any of these patients. There is no written informed consent in any chart. Exhibits K and N do not appear in the medical records and, under the circumstances obtained, we find them not to constitute informed consent. There is no indication that Respondent fulfilled his professional obligation to disclose the attendant discomforts and risks reasonably expected as he himself acknowledged in Exhibit 10, "Metabolic Cancer Therapy--Orientation Packet." Finally, while we are judging Respondent's conduct by the standards of medical conduct and medical information available for the period in question, we are aware that the National Cancer Institute has recently concluded that Laetrile is not effective for cancer. It is the position of this Panel that the manner in which Doctor Cole utilized Laetrile for these desperate people was tantamount to, as Victor Herbert, M.D testified (transcript p. 1416), quackery.

The Patients

Patient A: We credit the testimony of John Jacoby, M.D., and C. William Aungst, M.D.. We also credit the testimony of Ms. Carol Lee. Respondent administered experimental and unappro drugs to Patient A, yet failed to obtain an informed consent fro the patient or the patient's relatives. He also failed to obtai from the United States Food and Drug Administration permission t administer these experimental drugs to Patient A. He failed to

obtain permission of the medical board of the hospital to use these experimental drugs. He failed to develop a protocol and nothing approaching one can be found in any of the medical charts. We do not believe that Respondent ever used Exhibit CC, the COG on-study form for these patients. The Panel finds, with respect to Exhibit CC and the alleged flow sheets for experimental drugs, that Respondent's testimony is not credible.

Only Doctor Cole's personal associates and the resident physician assigned to him knew of the experimental drugs (testimony of Francisco Mora, M.D., pp 1037-1173). In order to attempt to record the experimental drugs administered, information was placed in a privately held composition book (Petitioner's Exhibit 11). Entries for the unapproved, experimental drugs were made in a secret and personal code. Many times the Respondent and his associates did not even bother to record these substances at all (pp 1084-1085). The fraudulent nature of this practice lies in the fact that the patient and the patient's family were not given specific information concerning the experimental nature of the therapy. Even Respondent could not say with certainty what drugs or substances his own patient received. See, for example, pp 3842-3844. If the treating physician does not know what substances his own patient received, it is clear that a physician who may succeed him can never know. We find that Respondent did make claims that he could achieve remissions or cures of cancer which had previously been diagnosed as terminal. While Respondent did deny the allegation, his own words claiming successes with cancer, recorded on tape at the NHF 25th Annual Convention (Exhibit 58 and transcript pp 3914-

3949), exposed the falsity of his denial and his prevarication before this Panel.

Patient B: We credit the testimony of the husband of Patient B. Further we find that the photographs of Patient B taken by her husband, Exhibits 16-A, 16-B, 16-C, 16-D, reflect a patently advanced state of inflammatory carcinoma of the breast. We credit the testimony of C. William Aungst, M.D.. Further, the Panel is persuaded that the statements of the husband of Patient B and the relatives of all the other patients are indeed, and in fact, true in light of the following circumstances:

1. The similarity of history and experience in all of the dealings with Respondent of the families and the patients listed in the Statement of Charges. Indeed we find Respondent's conduct toward these patients to actually be a common scheme of fraud.
2. The nature of the literature in the Doctor's waiting room. See, for example, Exhibit 6 and Exhibit 10.
3. The Respondent's use of statistics dealing with remissions and prognosis during his testimony before this Panel in discussions with the families of cancer patients and in the taped speech which is Exhibit 58.

Patient C: We credit the testimony of the husband of Patient C. We also credit the testimony of the prior treating physician, Edward Schlesinger, M.D., and the testimony of

C. William Aungst, M.D.. The Panel find the Respondent's conduct toward Patient C. is similar if not identical, to his treatment of Patient A. and Patient B. We find that he did promise Patient C that he could cure her cancer.

Patient D: We credit the testimony of the husband of Patient D, and the testimony of C. William Aungst, M.D.. We find Respondent's conduct toward Patient D. to be similar in his treatment of Patient A, Patient B and Patient C. We find that the method by which Doctor Cole directed the husband to obtain Laetrile from lay persons to be contradictory to the proper practice of medicine.

Patient E: We credit the testimony of the husband of Patient E. We credit the testimony of C. William Aungst, M.D. We do find the Respondent promised "at least a 50-50 chance with his treatment" for her terminal condition.

Patient F: We credit the testimony of her husband of Patient F. We credit the testimony of C. William Aungst, M.D. We do find that Respondent did cause Patient F. and her husband to believe that a cure was imminent for her terminal condition.

Patient G: Charges were withdrawn.

Patient H: We credit the testimony of both parents of Patient H. We also credit the testimony of Richard Reuben, M.D., and C. William Aungst, M.D.. We find that Doctor Cole did cause, by holding out false hope, the parents to remove their child

from an excellent institution to Whitestone General Hospital. However, once there, the child inevitably degenerated from paralysis to death. The Laetrile, BCG vaccine and the foreign, exotic (and unknown) medicines administered were useless for his terminal condition. We find that the conduct of Respondent, in this case, to be especially reprehensible.

Patient I: We credit the testimony of the wife of Patient I and the testimony of C. William Aungst, M.D.. We also find that this patient did receive "Doctor Burton's blood serum" or the equivalent and Laetrile at Whitestone. We note that Doctor Aungst's testimony here, as with the other patients, was based upon a review of the medical record. He never had knowledge of the unapproved drugs given to the patient because they were not charted. Our findings are herein based upon a review of all the medical records, exhibits and testimony in this proceeding.

Concerning Witnesses for Respondent

The primary, professional witness for the Respondent, other than Doctor Cole himself, was William G. Tucker, M.D., a physician from Michigan who would not disclose his present activities. (Transcript pp 2989-2991). We find that his testimony, especially that concerning missing consent forms for experimental drugs, is devoid of credibility. In any event, we will disregard this witness' testimony because he, like the other witnesses for Respondent, had not reviewed the medical records of the patients who are the subject of this proceeding. See Transcript pp. 3035-3037.

We do not consider the extensive use of testimonials of cancer patients, who are, for the most part, current patients of Respondent at the Holistic Center, 8 South Tyson Avenue, Floral Park, New York, to be of value in our deliberations. Even if their lay opinions are correct, our professional judgment of Respondent's conduct at Whitestone General Hospital is limited to those patients who are the subject of the Statement of Charges. Nevertheless, the transcript will reflect that Respondent's treatment of even these patients was not without criticism from the Panel. In one instance, the patient may never have had cancer.

Conclusions

The Panel unanimously makes the following conclusions as to the Statement of Charges:

I. Respondent practiced the profession fraudulently within the purview and meaning of Section 6509, Subdivision 2, of the Education Law

1.	Patient A	Guilty
2.	Patient B	Guilty
3.	Patient C	Guilty
4.	Patient D	Guilty
5.	Patient E	Guilty
6.	Patient F	Guilty
7.	Patient H	Guilty
8.	Patient I	Guilty

II. Respondent practiced the profession with gross incompetence This Panel cannot agree on the meaning of the expression "gross incompetence" and must, accordingly, find the Respondent not guilty.

III. Respondent practiced the profession with gross negligence on a particular occasion. This Panel cannot agree on the meani

of the expression "gross negligence" and must, accordingly, find the Respondent not guilty.

IV. Respondent practiced the profession with negligence or incompetence on more than one occasion.

1.	Patient A	Guilty of both negligence and incompetence
2.	Patient B	Guilty of both negligence and incompetence
3.	Patient C	Guilty of both negligence and incompetence
4.	Patient D	Guilty of both negligence and incompetence
5.	Patient E	Guilty of both negligence and incompetence
6.	Patient F	Guilty of both negligence and incompetence
7.	Patient H	Guilty of both negligence and incompetence
8.	Patient I	Guilty of both negligence and incompetence

V. Respondent with willful or grossly negligent failure did not comply with substantial provisions of federal and state laws in that he did possess and/or sell and did administer and/or cause to administer to human beings unapproved drugs, medications and substances in violation of 8 NYCRR 29.1(b)(1).

1. Patient H. Guilty, in that Respondent, with willful failure, did not comply with substantial provisions of federal and state laws in that he did possess and did cause to administe to this child unapproved drugs, medications and substances nanel

Laetrile, BCG vaccine and foreign, exotic medicines as reflected in the testimony of the patients, and Respondent did, in effect, subject this child to what is tantamount to abusive human experimentation without the protection of even elementary protocols which resulted in the child's treatment approaching quackery.

2. Patient I. Guilty, in that Respondent, with willful failure, did not comply with substantial provisions of federal and state laws in that he did possess and did cause to administer to Patient I unapproved drugs, medications and substances, namely Laetrile and "Doctor Burton's blood serum" or the equivalent.

VI. Respondent failed to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient in that he did not enter, or cause to be entered, all drugs and medications given to each patient in violation of 8 NYCRR 29.2(a)(3).

1. Patient H. Guilty, because the Laetrile and exotic, foreign medicines administered do not appear in the chart. (Exhibits M and M_1).

2. Patient I. Guilty, because the Laetrile and the "Doctor Burton's blood serum" or the equivalent, do not appear in the medical chart (Exhibit 36).

Recommendation

The recommendation of the Panel, which is unanimous, is that Donald Robert Cole, M.D., suffer the revocation of licensure to practice the profession of medicine in the State of New York. The Panel unanimously recommends that, in the event of litigation, no administrative body or Court grant a stay of revocation. Desperate cancer patients and their families, as well as the general public, must be protected from the practices of this Respondent.

Irwin J. Cohen, M.D.
CHAIRMAN

Stanley Gitlow, M.D.

Rev. Edward Hayes

George Hyams, M.D.

Cyril J. Jones, M.D.

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

IN THE MATTER	
OF	: COMMISSIONER'S
Proceedings by the State Board for Professional Medical Conduct to determine the action to be taken with respect to the revocation or suspension of the license heretofore granted to:	: RECOMMENDATION
DONALD ROBERT COLE, M.D.	
to practice medicine in the State of New York, or such other penalty as is warranted, pursuant to Article 2, Title II-A of the Public Health Law of the State of New York.	

TO: Board of Regents

New York State Education Department

State Education Building

Albany, New York

A hearing in the above-entitled proceeding having been held on February 21, 1979, April 3, 1979, May 2, 1979, July 11, 1979, August 15, 1979, October 11, 1979, October 31, 1979, November 29, 1979, December 19, 1979, January 9, 1980, January 24, 1980, February 21, 1980, April 10, 1980, April 30, 1980, May 22, 1980, June 26, 1980, September 4, 1980, October 8, 1980, November 6, 1980, December 3, 1980, December 23,

EXHIBIT "C"

1980, February 4, 1981, March 5, 1981, April 11, 1981, and May 13, 1981; and the Respondent, Donald Robert Cole, M.D., having appeared personally and represented by Raphael Koenig, Esq., and Jerome J. Londin, Esq., counsel, and the evidence in support of the charges against the Respondent having been presented by Robert Abrams, Attorney General of the State of New York by John Shea, Esq., Designee of the Attorney General,

NOW, upon reading and filing the transcript of said hearing, the exhibits and the findings, conclusions and recommendation of the Hearing Committee, and upon reading the various post-hearing motions made by Respondent which were denied by the Hearing Committee and renewed before this office, and upon reading the Respondent's proposed findings and conclusions of law and Respondent's brief in opposition to the findings of the Hearing Panel, submitted by letter dated April 2, 1982,

I hereby make the following recommendation to the Board of Regents.

A. that the findings, conclusions and recommendation of the Hearing Committee be accepted in full; and

B. that the post-hearing motions of Respondent be denied; and

C. that the Board of Regents issue an order adopting and incorporating the said findings and conclusions and further adopting as its determination the said recommendation.

The entire record of the within proceeding is herewith transmitted.

DATED: Albany, New York
1982

DAVID AXELROD, M.D.
Commissioner of Health
State of New York

REPORT OF THE
REGENTS REVIEW COMMITTEE

DONALD ROBERT COLE

CALENDAR NO. 2476

Approved September 24, 1982

No. 2476

Upon the report of the Regents Review Committee, under Calendar No. 2476, the record herein, the prior proceedings had herein pursuant to Article 2, Title II-A of the Public Health Law, and in accordance with the provisions of Title VIII of the Education Law, it was

Voted: That, with respect to patient "A", the findings of fact of the Hearing Committee and the recommendation of the Commissioner of Health with respect thereto not be accepted and the conclusions of the Hearing Committee and the recommendation of the Commissioner of Health with respect thereto be modified; that, with respect to the remaining patients, except patient "G" as to whom the charges were withdrawn, the findings of fact of the Hearing Committee as well as the recommendation of the Commissioner of Health with respect thereto be accepted, the conclusions of the Hearing Committee as well as the recommendation of the Commissioner of Health with respect thereto be modified, and the recommendation of the Hearing Committee as to the measure of discipline as well as the recommendation of the Commissioner of Health with respect thereto be accepted; that the recommendation of the Commissioner of Health as to the post-hearing motions be accepted; that respondent is not guilty of the first through fourth specifications of the charges to the extent that they relate to patient "A"; that respondent is guilty of each specification of the charges, except as to patient "A" as

aforesaid and patient "G" as to whom the charges were withdrawn as aforesaid; that respondent's license to practice as a physician in the State of New York be revoked upon each specification of the charges of which respondent was found guilty, as aforesaid; and that the Commissioner of Education be empowered to execute, for and on behalf of the Board of Regents, all orders necessary to carry out the terms of this vote.