

Experimentation with Human Beings

*The Authority of the Investigator,
Subject, Professions, and State
in the Human Experimentation Process*

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with the assistance of
Alexander Morgan Capron
and Eleanor Swift Glass

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CHAPTER ONE

The Jewish Chronic Disease Hospital Case

In July 1963, three doctors, with approval from the director of medicine of the Jewish Chronic Disease Hospital in Brooklyn, New York, injected "live cancer cells" subcutaneously into twenty-two chronically ill and debilitated patients. The doctors did not inform the patients that live cancer cells were being used or that the experiment was designed to measure the patients' ability to reject foreign cells—a test unrelated to their normal therapeutic program.

The cancer experiment engendered a heated controversy among the hospital's doctors and led to an investigation by the hospital's grievance committee and board of directors. William A. Hyman, a member of the board who disapproved of the experiment, took the hospital to court to force disclosure of the hospital's records, claiming that the directors' approval of the experiment had not been properly obtained. As *Hyman v. Jewish Chronic Disease Hospital* wound its way up from the trial court through two appellate tribunals, it became clear that the legal issue involved in the suit, whether a hospital director is entitled to look at patients' medical records, only provided the backdrop for the questions really at issue which concerned the duties and obligations that the various participants in the human experimentation process should have toward one another.

Subsequently, these issues were confronted more directly when the Board of Regents of the University of the State of New York heard charges brought by the attorney general against two of the doctors involved. The board imposed sanctions, under the authority given it by New York Education Law § 6514(2) to revoke, suspend, or annul the license of a prac-

tioner of medicine upon determining "after due hearing . . . that a physician . . . is guilty of fraud or deceit in the practice of medicine [or] that a physician is or has been guilty of unprofessional conduct."

In examining these materials, consider the following questions:

1. What values does human experimentation seek to implement, and are they in conflict with other values?
2. How do the participants weigh these conflicting values, and what weight should be given to these values?
3. What values are preserved or undermined by delegating decisionmaking power to each participant respectively?
4. Under what circumstances should the extent of actual or potential harm and benefit to subjects or society affect the authority of each participant in the human experimentation process?

A.

How and by Whom Should Research Policy Be Formulated?*

**Letter from Chester M. Southam, M.D.
to Emanuel Mandel, M.D.—July 5, 1963**

I want to thank you for the courtesy shown to me and Dr. Levin on our recent visit and the interest that you showed in our proposed research collaboration. This letter is to record and perhaps clarify the principal points of that conversation.

The study we discussed would permit evaluation of the immunologic status of patients with chronic non-neoplastic diseases, as revealed by promptness of rejection of subcutaneous cancer cell homografts. My own interest in these studies stems from their importance to the understanding and possible treatment and diagnosis of cancer, but I am sure that you would have an equally great interest in their potential importance for the understanding of autoimmune and degenerative diseases and in the budding field of organ homotransplantation.

Clinical research on this phenomenon is quite new—my own work started only ten years ago—but is accelerating rapidly as would be expected from its importance and as attested by the recent entry of several hospitals and research

institutes into the fields of cancer, skin, and organ transplantation in man. To date the studies carried out by me, with numerous collaborators here and at the Ohio State University Medical School, have revealed that healthy persons reject the cancer cell homografts completely and promptly (in 4 to 6 weeks) as one would obviously predict, but many patients with widespread cancer have a delayed rejection (over 6 weeks and sometimes 3 months or more). In either group of recipients the usual reaction is development of a painless subcutaneous nodule up to 2 or 3 cm in diameter at the time of maximum development. The immunologic derangement responsible for the comparative slowness of rejection in patients with cancer is still unidentified, but the search is narrowing down and an impairment of cell-associated immune mechanisms now seems probable.

There is a gap in our data in that we have not yet studied this reaction in people who do not have cancer but who do have chronic and debilitating diseases of other kinds. I would expect that the homograft rejection reaction would be normal or near normal in such patients. This estimate is based on results of scattered studies of skin homografts by others and on our recent demonstration of intact macrophage mobilization (a non-specific cellular immunologic mechanism) in such patients, whereas in cancer patients macrophage mobilization is depressed and correlates with homograft rejection. But suppo-

* This is an actual record. Without indicating deletions we have edited the record primarily to reduce repetition. Some repetition was necessary, however, to allow each participant to present his own understanding of the events.

sitions are not direct evidence of you.

We do diseases other Ewing hospital collaboration of such disease Hospital which had interest in me mented by and by its County Hospital.

The process simply the of tissue-cultured prior thigh cancer at about we regression is more cancer were chosen growth capacity. It is, these are assigned to the only drawn phobia and cancer. It a process by less satisfactory difficult technique to your dermic injection the only other rum for study.

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sitions are not knowledge and it is the need for direct evidence on this point that brought me to you.

We do not have patients with debilitating diseases other than cancer at Memorial or James Ewing hospitals, and therefore we are seeking collaboration in some hospital with a large population of such patients. The Jewish Chronic Disease Hospital was suggested to me as a hospital which had not only the patients but also an interest in medical teaching and research, as evidenced by the Isaac Albert Research Institute and by its teaching arrangements with Kings County Hospital.

The procedure, as I explained, requires simply the hypodermic injection of a suspension of tissue-cultured cells at two sites on the anterior thigh or arm and observation of the sites at about weekly intervals for six weeks or until regression is complete. These cells are of two or more cancer cell lines. These cancer cell lines were chosen because they have the necessary growth capacity to produce a measurable reaction. It is, of course, inconsequential whether these are cancer cells or not, since they are foreign to the recipient and hence are rejected. The only drawback to the use of cancer cells is the phobia and ignorance that surrounds the word *cancer*. It would be possible to study the same process by experimental skin grafts, but this is less satisfactory for quantitation, is much more difficult technically, and is unacceptably annoying to your patients. Other than the two hypodermic injections and observation of the reaction, the only other procedure would be drawing serum for study of antibody reactions to the trans-

planted cells at approximately two-week intervals during the observation period.

I have no hesitation in suggesting these studies since our experience to date includes over 300 healthy recipients and over 300 cancer patients, and for two years we have been doing the tests routinely on all postoperative patients on our gynecology service as a measure of immunologic status, with the collaboration of Dr. Alexander Brunschwig, chief of the gynecology service. You asked me if I obtained (written) permissions from our patients before doing these studies. We do not do so at Memorial or James Ewing hospital since we now regard it as a routine study, much less dramatic and hazardous than other routine procedures such as bone marrow aspiration and lumbar puncture. We do get signed permits from our volunteers at the Ohio State Penitentiary but this is because of the law-oriented personalities of these men, rather than for any medical reason.

Collaboration in this research effort would involve no expense to the Jewish Chronic Disease Hospital or its patients since these studies are supported by a grant from the United States Public Health Service and the American Cancer Society, and I would supply all cultures and equipment from my laboratory. On the other hand, the Jewish Chronic Disease Hospital and collaborators there would be appropriately acknowledged in such scientific papers and lay publications as may ensue, subject of course to your prior approval.

I hope that this opportunity for research continues to interest you and that you will find it possible to participate in this program.

B.

How and by Whom Should the Research Process Be Administered?

1.

Petition of William A. Hyman— December 12, 1963

To the Supreme Court of the State of New York, Kings County:

The petitioner, William A. Hyman, respectfully states as follows:

That the said Jewish Chronic Disease Hospital is governed by a board of directors.

That your petitioner is still a member of said board of directors and continues to act as such director.

That in the month of September, 1963, your petitioner was informed that injections of live cancer cells had been made and were being made into non-cancerous patients at the hospital without their consent, either written or oral, and without their knowledge of the nature of the injections and that these injections were not for purposes of therapy or treatment of patients at the hospital but were done for the purpose of determining whether cancer can be induced by injection of live cancer cells and that, furthermore, some certain medical employees of the hospital were undertaking these experiments in

12 JEWISH CHRONIC DISEASE HOSPITAL CASE

cooperation and in concert with certain parties not affiliated with the said hospital and that all of this was being done without the approval, sanction, authorization and consent of the proper authorities of the said hospital.

That on September 30, 1963, a meeting of the board of directors of the hospital was held at which time and place Solomon Siegel, executive director of the hospital, read a report which purported to show that these injections of live cancer cells into non-cancerous patients were done with the oral consent of these patients. Furthermore, at this said meeting of the board of directors on September 30, 1963, Benjamin Saltzman, chairman of the executive committee of the said hospital, orally reported on a hearing held by him and certain associates and stated that the injection of live cancer cells into non-cancerous patients were harmless "tests" although he admitted before the board of directors that the patients who received such injections were never informed that live cancer cells were being injected into them but rather they were told that these were skin tests.

That your petitioner strenuously opposed the acceptance of the written report of the said Solomon Siegel, executive director of the hospital, and the oral report of said Benjamin Saltzman as a whitewash which imposed upon the board of directors serious civil and perhaps criminal responsibility if the facts as reported to your petitioner were correctly stated and, accordingly, petitioner made a motion that the said report of the said Solomon Siegel be rejected and that an independent committee be appointed to make a further investigation into the circumstances attending the injection of live cancer cells into non-cancerous patients.

Although to the best of my recollection there was a second to this motion by one of the directors present, there resulted considerable disorderly conduct and confusion, and a superseding motion was made to accept the report of said Solomon Siegel but, however, in the midst of the discussions and arguments back and forth at said meeting Mr. Herman W. Shane, chairman of the board of directors, suddenly declared the meeting adjourned.

At this meeting of the board of directors, he called attention to certain of the Nuremberg trials in which Nazi doctors were found guilty and some hanged and some otherwise punished for using human beings for experimental purposes without their informed consent to and knowledge of the experiments being conducted

on them and that such practices could not and should not be tolerated by any organization.

Likewise, when the attention of the directors present at this meeting was called to the fact of the responsibility devolved upon the board of directors, under the circumstances, the suggestions were disregarded and even ridiculed.

The question that he raises is whether those directors who voted to adopt that whitewash report of Mr. Siegel's would permit themselves to be used for experimental purposes. Will these directors who voted for this whitewash report consent to having injections of live cancer cells made into their bodies to see if cancer can be induced in their bodies?

That petitioner, in order to protect the integrity of the hospital and to terminate any possible abuses that may have arisen and to avoid injury to any patients and possible liability therefor on the part of the hospital and of the directors, requested the secretary of the hospital to furnish petitioner, at his expense, with a copy of the minutes of the meeting of the board of directors.

That petitioner's aforesaid request was ignored.

That petitioner wishes to be fully informed of all actions taken by the board of directors of the Jewish Chronic Disease Hospital and by all committees therein relative to the investigations of the complaints made and relative to the findings upon such investigations and to be fully informed of all the facts pertaining to the injection of live cancer cells into patients at the hospital, and petitioner, who has been associated with the said hospital for many years in various capacities, believes that it is his obligation as a director of said hospital to inquire into such happenings, and to ascertain all the facts, and to take adequate steps to protect the patients of the hospital and the good name and reputation of the hospital and of the directors and of the physicians connected with the hospital, and to avoid any possible liability on the part of the hospital and of the directors as a result of any injury that may be suffered by any patient as a result of said injections.

That the Jewish Chronic Disease Hospital, through its executive director and medical director, have contended that although the patients gave no written consent to the injections they gave their oral consent; but said contention is false and entirely without any basis in fact because some of the patients were in such mental and physical condition that they could neither

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know and understand the nature of the injections and the danger involved, nor consent to such injections, and other patients could speak only Yiddish, whereas Dr. Custodio could not speak one word of Yiddish, and, therefore, could neither ask for nor obtain oral consents.

That your petitioner has exhausted the remedy of requesting access to and examination and copies of the minutes of the meetings of the board of directors and the reports by Mr. Siegel and Dr. Abramson and the patients' charts and records and the other papers and documents pertaining to the experimental injection of cancer cells into non-cancerous patients, and by refusing petitioner's requests therefor the board of directors of said hospital have failed, neglected and refused to perform a duty enjoined upon them.

Wherefore, your petitioner respectfully prays that pursuant to Article 78, C.P.L.R., an order be made granting the inspection of the books, records, papers and documents sought by the petitioner herein, and granting such other and further relief as to the court may seem just and proper.

2.

Affidavits for Petitioner

a.

David Leichter, M.D.*— September 12, 1963

My name is David Leichter. I am a duly licensed physician in the State of New York having received my license in 1958 in New York State.

I have been associated with the Jewish Chronic Disease Hospital since July 1, 1959, first as chief resident in medicine and since 1960 as co-ordinator of medicine and in charge of cancer therapy and research. In this capacity all projects relating to the field of cancer were within my domain.

On or about July 3, 1963, I was approached by Dr. Emanuel Mandel, who was the director of medicine and medical education of the Jewish Chronic Disease Hospital, about a project which would involve the injection of live cancer cells

into non-cancer patients of our hospital. He stated that two doctors from Memorial Hospital who had done some prior experimental work in this field would supply the hospital with this cancer cell suspension and he asked me to see them and discuss taking over this project.

After this brief discussion I told Dr. Mandel that at first blush, such a project would certainly require the informed consent of the patients on whom it was to be done, and until such prior informed consent was obtained there was absolutely no reason for me to meet with these doctors from Memorial Hospital and, further, that I did not believe such consent could be obtained. By informed consent, I mean discussing the project with the patient, advising him of the dangers, if any, informing him of the agent to be used—in this case live cancer cells. It also means to me that the patient on whom the experiment is to be made must be mentally competent and aware of the full extent and dangers of such a project, and that such consent to be legal and proper would have to be obtained in writing.

On about July 31, 1963, Dr. Avir Kagan approached me and informed me that he had been requested by Dr. Mandel to conduct experiments on chronic patients of the Blumberg Building by injecting in them a suspension of live cancer cells. He told me that he had refused to become a part of this project because he could not see how the informed consent of any of these patients could be obtained once they were aware of the nature of the agent and the purpose of the project.

On or about August 15, 1963, I received a telephone call at my home from Mr. Sol Siegel, who is the executive director of our hospital and he told me that he wanted to see me at 9 o'clock the following morning on a matter of importance.

On August 16, 1963, in his office, Mr. Siegel asked me about this cancer project and what I knew of it. I told him in detail about my first encounter with Dr. Mandel and the fact that I had refused to become a party to it because I felt that it was immoral and illegal without the prior written informed consent of each and every informed patient.

I further told him that I had been informed by Dr. Samuel Rosenfeld, the co-ordinator of medicine of the Blumberg Building, that some 18 patients in his ward had received injections of this live cancer suspension, without his knowledge, without his consent and without the patients' knowledge and informed consent, and

* The affidavits of Drs. Avir Kagan and Perry M. Fersko, coordinators in the department of medicine of the Jewish Chronic Disease Hospital, are essentially similar to the above affidavit.

14 JEWISH CHRONIC DISEASE HOSPITAL CASE

under the auspices of Dr. Mandel and Dr. Custodio to whom he had assigned the project. He asked me some questions about the legality of Dr. Mandel's project and I told him that I had attended lectures given by Bryant L. Jones of the CCNSC (Cancer Chemo-Therapy National Service Center) whereby we were informed that it was illegal to administer experimental drugs to patients without their prior informed consent and knowledge and approval.

I also told him of the danger of rumors spreading in the hospital about giving these cancer cells to patients without their consent and the tremendous damage it could do to the reputation of the hospital and its standing in society. I also reminded him of the potential malpractice suits that might result from reactions in these patients who had received these injections. He asked me if Dr. Mandel could lose his license as a result of his action and I told him that I did not know but that it was a serious matter.

I repeated many times that I was against the project; that I had nothing to do with it; that I had not condoned it and that it was done without my knowledge and consent and against my express desires.

On or about August 26, 1963 I was informed that a meeting had been scheduled for the co-ordinators of the different divisions of the hospital to discuss this matter with Dr. Mandel and Mr. Siegel in an effort to hush it up. However, this meeting was cancelled.

On August 27, 1963 Dr. Avir Kagan, co-ordinator of the department of medicine, Dr. Perry M. Fersko, also a co-ordinator in the department of medicine, and I, in reviewing the project and our individual refusal to become a part of it and the fact that the parties responsible for it appeared to be passing the buck, thought it advisable to make our positions clear by resigning together and giving our reasons for such resignation. We realized that our position was untenable despite the fact that we had never become a party to this project and that the entire matter was unethical and immoral. Further, that if we remained, our silence or continued association with the hospital might be construed as condoning the actions of Dr. Mandel and Dr. Custodio and might be tantamount to our being co-conspirators. Therefore, on August 27, the three of us composed one letter of resignation, signed by all of us, wherein we stated the following:

We the undersigned co-ordinators in the department of medicine do hereby submit our resignations

as co-ordinators, effective immediately. The reasons for our decision are based upon disagreement and opposition to certain research practices in which the department of medicine has engaged.

Our position has been stated to you. Inaction on our part might be interpreted as condoning these acts which we feel, under the circumstances, would be morally wrong.

This letter was addressed to the executive director of the Jewish Chronic Disease Hospital and copies were sent to the president of the executive board, chairman of the medical board, administrator of welfare, and the chairman of the department of medicine.

On August 28, 1963, Mr. Siegel called me in his office, advised me that he had read the resignation and attempted to intimidate me by stating that I had improperly obtained the consent of the relatives of certain cancer patients in another project involving the administration of an anti-cancer drug in cancer patients, which drug was known as Thermonycin 401.

I reminded Mr. Siegel that these were cancer patients who were actually receiving anti-cancer treatment but that these patients did not know they had cancer and that under these circumstances the law permitted us to obtain the consent of the nearest relative in an effort to save the lives of these patients, and that this situation was not in any way similar to the improper project previously described.

Mr. Siegel then attempted to claim that our resignation amounted to an abandoning of the patients. Thereupon we informed Mr. Siegel that we would be at the disposal of the hospital and the patients for any necessary treatment, free of charge and whenever required.

To date we have never been asked by anybody connected with the hospital to service such patients.

On August 29, 1963 Dr. Mandel met me at the hospital and we discussed this problem at length wherein I reiterated the fact that in my opinion the entire project was unethical and immoral and against public good and violated the rights of the patients who had not been informed of the nature of the project (*i.e.*, the inherent dangers associated with an unknown experimental agent involving live cancer cells) and who had actually not given their informed consent. Dr. Mandel then informed me that he could not get their consent because these patients were incompetent.

I have read my statement and it is true to the best of my knowledge.

b.

Samuel
Siegel

My name is a duly licensed physician in New York since June, 1958.

I have been a member of the Jewish Chronic Disease Hospital for 15 years and have been a member of the Board of Directors of the Blum Pavilion since 1961.

On Thursday, August 29, 1963, at 10:30 A.M. while I was in the Blum Pavilion, senior resident Mr. Celi Stephens, M.D., called me and stated that he had a patient who was in pain, and that the patient's right leg was swollen. He said that he had received no further information from the patient's family and that he was in a difficult position for him.

I inquired of the patient's service, and he told me that the patient had been given a mental injection of Mandel. I was not at the time of the injection and I inquired of Dr. Mandel. He told me that the patient was delivered to the Hospital.

On Monday, August 30, 1963, I went to Dr. Custodio's office and the material for the project was to be given to these patients to be used.

On Tuesday, August 31, 1963, I was called by Dr. A. Kagan, M.D., of the department of medicine, and he asked me if I was aware of the fact that cancer cells had been injected into the Blum Pavilion. He also made him uncomfortable to resign. He said that he had requested "cancer cells" and that he had refused to do so.

Dr. Kagan, David Leichter, M.D., and I discussed the research at our hospital and he informed me that he had been approached by Dr. Mandel and Dr. Custodio.

b.

**Samuel Rosenfeld, M.D.—
September 12, 1963**

My name is Samuel Rosenfeld. I have been a duly licensed physician in the State of New York since June, 1923.

I have been associated with the Jewish Chronic Disease Hospital for the past thirty years and have been the co-ordinator of medicine of the Blumberg Pavilion since 1956 and a visiting physician since 1945.

On Thursday, August 8, 1963, at about 10:30 A.M. while making my usual rounds in the Blumberg Pavilion, accompanied by Dr. Custodio, senior resident physician, a ward patient, Mr. Celi Stephano, stopped me, complaining bitterly of pain, and told me that he was injected under the right thigh and that that area was now swollen. He said that he had not been sick at the time he received the injection and he stated further that he knew that I had not ordered anything for him.

I inquired of Dr. Custodio, a resident in my service, and he motioned me away from the patient and then told me that he was doing experimental injections on orders from Dr. Emanuel Mandel. I was unable to pursue this subject further at the time but on the following day I again inquired of Dr. Custodio what had transpired. He told me that he was injecting material which was delivered to him by the Cancer Memorial Hospital.

On Monday, August 12, 1963, I again spoke to Dr. Custodio and he confirmed the fact that the material consisted of "cancer cells" and the project was to test the immunologic response of these patients to this agent.

On Tuesday, August 13, 1963, I was accosted by Dr. Avir Kagan, the then co-ordinator of the department of medicine, and he asked me if I was aware that Dr. Mandel had injected cancer cells in patients in my care and in my pavilion. He also spoke of other matters which made him unhappy and he told me he wished to resign. He specifically stated that Dr. Mandel had requested that he, Dr. Kagan, inject these "cancer cells suspensions" but that he flatly refused to do same.

Dr. Kagan then asked that I speak to Dr. David Leichter, who is in charge of the cancer research at our hospital, which I did, and he informed me that there was no project going on under his direction but that he had been approached by Dr. Mandel to authorize the injection

of live cancer cells in chronically ill patients and that he did not consider this project feasible because of the potential danger attached to it and because the prior written consent of each patient would be required.

Dr. Kagan also told me that Dr. Perry Fersko had been requested by Dr. Mandel to give these injections but that he too had refused.

With this information on hand I felt it my duty to inform the administration of my findings as all new projects involving experimental drugs or agents, prior to their being used on patients, had to be approved by the research committee. This had not been done nor had the project received the approval of Dr. David Leichter even though this was a cancer project. In addition, it was being performed on patients for whom I am responsible in the Blumberg Pavilion, which patients had not been advised of the nature of the project nor told of its potential dangers nor had they given their prior written or oral consent. There were 18 patients in my ward who received these injections and many of them were mentally incapable of giving their consent. In my opinion this project was, therefore, both illegal and immoral and it has been conducted surreptitiously without my knowledge or consent.

In view of the fact that Mr. Sol Siegel, the executive director of the hospital, was on vacation, and Mr. Isaac Albert, the president, was seriously ill at the hospital, I contacted Mrs. Minnie Tulipan, the director of welfare and gave her all the facts and together we discussed matters further with Dr. Abraham Rabiner, patriarch of our hospital and former chief of neurology.

In the afternoon of August 14, 1963, Mrs. Tulipan told me that she had phoned Mr. Sol Siegel in Florida, had given him the facts and that he was scheduled to return on August 15, 1963.

On August 15, 1963, a patient in Ward P 6, Mr. Grossman, who had received the injection of these cancer cells was visited by three doctors from Memorial Hospital. In response to my questioning, Dr. Custodio told me that these were the doctors who were investigating the effects of the cancer cell suspension injections.

Shortly thereafter Mr. Siegel came to my home office and I informed him of the entire matter. He stated he would look into it.

On August 26, 1963, Mr. Siegel told me he was scheduling a meeting for the following day and upon inquiry as to the purpose of the meeting, I learned that in substance it was a meeting

16 JEWISH CHRONIC DISEASE HOSPITAL CASE

of the coordinators and his intention was to suppress this information and to take no action. I told him I would not attend this meeting as in my opinion the entire experimental project was dangerous and illegal and I would not condone what amounted to a crime. I told him that this situation was explosive, that it could result in malpractice actions and in the destruction of the reputation of the hospital. I told him in my opinion it should be handled by the board of directors and responsible physicians and that the president of the medical board and other true and loyal supporters of the hospital should be consulted.

The August 27th meeting was thereafter cancelled by Mr. Siegel.

On August 28, 1963, Mr. Siegel called me at 8:00 A.M. and told me he was going to see an important lawyer on this matter. I urged him again to make every effort to inform selective members of the board of directors of the situation since Dr. Joseph Abramson, the president of the medical board of the Jewish Chronic Disease Hospital, was not in the city.

Later the same morning, I learned that Drs. Leichter, Kagan and Fersko had resigned.

I was also told by Dr. Kagan that Dr. Mandel had called him into his office, had offered him an increase in salary and some private cases. The purpose of this effort was obvious. It was Dr. Mandel's attempt to keep Dr. Kagan and the others from talking about the project.

On August 29, 1963, I had a further discussion with Mr. Siegel who requested that I talk to Dr. Abramson who had just returned from abroad.

On August 30, 1963, at about 11:00 A.M. I discussed the matter with Dr. Joseph Abramson. After getting the entire report from me, he informed me that he would take this matter up before the grievance committee of the hospital for further evaluation.

To my knowledge no corrective action has been taken by any responsible committee or in-

the grievance committee or the medical board or any other responsible board of inquiry.

c. Hyman Strauss, M.D.—November 23, 1963

I am a physician and surgeon duly admitted to practice in the State of New York specializing in gynecology and I am an attending physi-

cian in gynecology in the Jewish Chronic Disease Hospital.

On October 28, 1963, I addressed a letter to the medical board of the hospital, attention of the secretary of the executive committee which was given to that board. This letter was prompted by the horrible news that had reached me to the effect that patients in our hospital where I had been an attending physician for approximately twenty-five years were now being used for experimental purposes not associated with their therapy or their ailments, and that these experiments comprised the injection of live cancer cells into these chronic invalids at the hospital who were not informed of the fact that they were being injected with live cancer cells. As I am informed and verily believe, they were told that these injections of live cancer cells were mere "skin tests."

I am informed that no action was taken on this letter of complaint of mine. Instead, a conspiracy of silence developed in which an effort to suppress the disclosure of these practices to the membership and to the proper authorities was quite apparent.

Since no report of any proper action to correct this deplorable and outrageous situation was given to me and various other members of the medical staff, and apparently no proper and thorough investigation was made of the situation to prevent this recurrence and to prevent the practice of and to prevent the commission of these acts which belong more properly in Dachau, where for similar acts there had been prosecutions against the Nazis, I sent a copy of my letter of complaint to the Division of Professional Conduct of the New York State Education Department enclosed in my letter of October 30, 1963.

NOTES

NOTE 1.

LETTER OF HYMAN STRAUSS, M.D. TO THE
MEDICAL BOARD OF THE JEWISH CHRONIC

Inasmuch as I am unable to attend meetings at the present time for reasons beyond my control, I am obliged to write this letter as an expression of my position.

While the executive director was vacationing, an abundance of rumors found their way into medical circles. My first knowledge of this affair about cancer experimentation upon pa-

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M.D. TO THE
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rients known to be free of malignant disease.
without their fully informed written consent,
came from conversations at two other hospitals
in this borough. I next heard from a professor at
the State University of New York, and finally
a top-ranking investigator from Sloan-Kettering,
a man with an international reputation, discussed
this with me on the phone. I have also been
questioned by laymen and clergymen not con-
nected with our hospital. The coordinators re-
fused to talk, indicating that they had been in-
structed not to say a word. Obviously, they had
been successfully frightened.

Upon Mr. Siegel's return, I went to his of-
fice and asked for the truth about the matter that
had already been rumored around quite a bit. He
refused to make any statement but asked in-
stead that I tell him what I had heard. Since I
informed him that I was willing to discuss it only
following his affirmation or denial, and since he
refused to make such a statement, I left his office
with the feeling that nothing could be gained
and that the conspiracy of silence was continu-
ing.

An effort to obtain an explanation from Dr.
Joseph Abramson was equally unsuccessful, al-
though instead of silence, I encountered con-
flicting comments. Within a period of 15 min-
utes, I was told first, that proper consent had
been obtained in advance and duly witnessed.
Next, I was told that the consent had been oral
and that only some of the patients understood
English. Finally, I was informed that consent
was not necessary, according to Mr. Harry Al-
bert, one of the attorneys for the hospital, and
that it was unlikely that Jewish patients would
agree to live cancer cell injections, especially
since they were free of cancer themselves.

Finally, at the last meeting, twice when Dr.
Mandel endeavored to inform the committee
during his report of the resignation of the co-
ordinators and when the question of consent
was raised following a report by Dr. Slepian,
the chairman arbitrarily utilized the privilege of
his office to defer the discussion until the end of
the meeting. The unfortunate sequence, how-
ever, was that the meeting was prolonged unduly
and then abruptly and, I believe, deliberately,
adjourned by the chair. This technique, I un-
derstand, was used by him at another hospital
whenever he wished to stifle discussion. It might
be suggested that the chairman acquaint himself
with the democratic foundation of parliamentary
procedure which entitles him to guide but not

to dictate or interfere with full and free deliber-
ation.

For three young coordinators to have re-
signed must have required some soul-searching
on their parts. If undue pressures had been ex-
erted to get them to act in ways inconsistent
with their consciences, their sense of medical
ethics, and in violation of the law, then their res-
ignations, under such duress, are unacceptable.
Further, men of such high ethical standards as
to jeopardize their security when morality is at
stake should not be lost to any hospital. Since
medical liability insurance does not cover ex-
perimentation, no one has the right to demand
that a physician perform any act for which he
has no insurance protection without providing
additional insurance which will cover him in the
event of suit.

The matters at issue here are of extreme
importance. A full and frank and complete hear-
ing is absolutely necessary in order that no in-
justice be done to anyone. Denial of the oppor-
tunity to speak is undemocratic and should not
be tolerated. All persons involved in this matter
are entitled to ample opportunity to state their
cases.

I therefore propose that the executive com-
mittee constitute a committee of the whole to
investigate all sides in this issue. A small com-
mittee may be susceptible to instruction to act as
a whitewash body. Unless we condemn what is
improper, we share the guilt.

This is a medical matter and must be dealt
with by medical persons. It is not within the
province of the lay board of any hospital to pass
upon medical ethics or to dictate what is or is
not ethical in medical practice.

I feel that this is a matter involving my
conscience and that no other solution can be
considered satisfactorily.

NOTE 2.

LETTER OF HYMAN STRAUSS, M.D. TO DIVI-
SION OF PROFESSIONAL CONDUCT, NEW
YORK STATE EDUCATION DEPARTMENT—
OCTOBER 30, 1963

The original of the previous letter was per-
sonally delivered to the secretary with the re-
quest that it be read and considered at the meet-
ing held on October 28. I have been informed
that the letter was not read and that no definitive
action of any type was taken with reference to
the matter described.

d.

**Mendel Jacobi, M.D.—
December 11, 1963**

I am a physician and surgeon duly licensed to practice medicine in the State of New York and have been practicing since 1925.

I am the consultant pathologist at the Jewish Chronic Disease Hospital.

On October 4, 1963, I examined the charts of five of the 26 patients who were subjected to the injection of live cancer cells.

In this affidavit I shall not reveal the names of the patients, but shall refer to each patient by his chart number, so as not to disclose any confidential information.

Chart No. K-14397 shows that the patient was admitted on June 8, 1962 at the age of 67. The patient had been in chronic congestive heart failure for a year and a half prior to admission. One year prior to admission he had had a cerebral vascular accident with a right hemiparesis and acute myocardial infarction. A note by the social service dated in April, 1962, describes his attitude as one of isolation, perversity and negativism with resistance to all forms of treatment. His blood urea nitrogen levels had been consistently high since admission indicating a state of chronic uremia, in which cerebation is generally poor. A psychiatric note in May, 1963, indicated that he had been in a depressive state for a year. A nurse's note dated July 16, 1963, states "Cell suspension injected into right thigh by Dr. Custodio and resident." A progress note of the same day signed by Dr. Custodio reads: "Cell suspension injected left thigh."

Chart No. 2290 shows that the patient was admitted May 21, 1941, at the age of 41, so that he is now 63 years old. The patient is a postencephalitic Parkinsonian of advanced grade who on February 19, 1963, fell while in the ward and fractured his left wrist. An undated note in the record made some ten years after his admission, when he was 52 years old, describes him as showing a marked speech defect, markedly irritable personality and one who cries steadily and in a shrieking manner when his requests are not instantly carried out and that persuasion or argument was of no avail "due to the patient's low mentality and lack of insight and judgment." A note by Dr. Custodio, dated July 16, 1963, reads: "Cell suspension injected right thigh." A progress note dated September 5, 1963, notes that for two or three days he has developed hematuria. After an operation of Sep-

tember 27, 1963, it was found that he had a transitional cell carcinoma of the bladder which was resected. A consent to be photographed for moving pictures had been given by him on July 31, 1957, at which time his signature was still decipherable. Consents for cystoscopy on September 5, 1963, and for the bladder operation on September 27, 1963, were also signed by him, but with a barely legible and very scrawl-like signature. All three consents were witnessed by a person designated as his sister. However, there is no indication in the chart of any consent for the injection of the cell suspension.

Chart No. 8183 shows that the patient was admitted January 2, 1958, at the age of 38 with a diagnosis of multiple sclerosis. A history showed that in 1954 and 1955 a craniotomy and Gasserian ganglion decompression was performed twice on the right side and once on the left side. In 1957 he had been a patient in the Brooklyn State Hospital with a depressive psychosis, at which time he was unaware of his surroundings and unmanageable and his condition was diagnosed as dementia praecox. The chart shows that when admitted to the Jewish Chronic Disease Hospital in 1958 he was deemed mentally unsound and in the subsequent years his neurological status had not improved. From the beginning of 1963 onward he had repeated bouts of bilateral pneumonia and these events are specifically indicated to have occurred about May 31, 1963, and again about September 17, 1963. The chart makes no mention of any cell suspension or cell injections.

Chart No. 3762 shows the patient was admitted on June 10, 1952, at the age of 44. The diagnosis was postencephalitic Parkinsons with speech so dysarthric as to be noted "hard to understand." The chart shows he had had several falls during 1961 and 1962 on which occasions he hit his head against the ground. On May 8, 1963, there is another notation of a fall from a chair and striking his forehead on the floor. A note by Dr. Rosenfeld, the attending physician in charge, dated August 13, 1963, indicated an attempted suicide and requested psychiatric consultation. There is also a note dated August 16, 1963, that he had threatened to kill himself. The patient has been on considerable sedation throughout the years. There is no mention of cell suspension injections into this patient.

Chart No. B-15918 shows that the patient was admitted May 20, 1963, at the age of 72. The diagnosis was arteriosclerotic heart disease, coronary insufficiency, emphysema, hiatus hernia

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and spinal compression due to osteoporosis, with X ray showing compression fractures of the 6th, 7th and 12th dorsal vertebrae. On September 24, 1963, blood tests indicated a marked anemia and the biochemical changes of malnutrition. There are no notes of any injections of cell suspension in the chart of this patient.

I was informed by Dr. Rosenfeld that another patient who had received the cell suspension injections and who had had tabes dorsalis, central nervous system syphilis and diabetes had died. I was not able to locate the chart and have not been able to determine whether an autopsy was performed on this patient.

From my examinations of the five charts above described it is clear that these patients who were subjected to cancer cell injections were in no condition, mentally and physically, to understand the nature of the injections being given to them and to consent to such experimental injections. There was, of course, no written consent—and there is no entry in the charts of any oral consent. In fact three of the five charts do not even note the injections that were made.

3.

Answer of the Jewish Chronic Disease Hospital—January 6, 1964

The Jewish Chronic Disease Hospital herein referred to as "the hospital," by its attorney, Morris Ploscowe, for its answer to the petition herein avers as follows:

Admits that the petitioner is a director of the hospital, which is a membership corporation, and that the hospital is governed by a board of directors which presently numbers sixty.

The hospital is an institution for the care and treatment of the chronically ill, without regard to race, color or creed. The Isaac Albert Research Institute is affiliated with the hospital and has done some of the outstanding research in this country in the area of chronic diseases.

Denies that petitioner was the sole attorney for the hospital and is still one of the attorneys of record. The petitioner has never been the sole attorney for the hospital, and is not now an attorney of record.

Denies the statement that patients of the hospital were injected with live cancer cells "for the purpose of determining whether cancer can be induced." This statement is unqualifiedly false. There was absolutely no danger that any patient

would contract cancer from the subcutaneous injection given to him. Nor has any patient in fact contracted cancer or in any way been harmed by the tests administered to him. The injection was not designed to induce cancer, but to test the patient's immunologic reaction to cancer cells. The said experiment was conducted in collaboration with doctors from the Sloan-Kettering Institute. It was part of a bona fide attempt to advance human knowledge in dealing with cancer and has been financed by grants from the United States Public Health Service and the American Cancer Institute.

Admits that a board of directors' meeting was held on September 30, 1963. There were more than enough directors present for a quorum for the transaction of business.

At the said meeting, the petitioner did characterize as "whitewash" the report of Solomon L. Siegel and of the grievance committee of the medical staffs of the hospital. The said report was read at the board of directors' meeting.

The petitioner, at this meeting, did make the scurrilous analogy between Nazi experimentation at places like Dachau and the work done at the Jewish Chronic Disease Hospital with the collaboration of doctors from the Sloan-Kettering Institute and financed by United States Public Health Service funds.

The petitioner, by his emotionally rhetorical questioning at this meeting, did falsely spread the notion that the purpose of the experimentation was to see whether cancer could be induced.

The 22 members of the board of directors unanimously voted to approve the report of the grievance committee of the medical staffs of the hospital, despite the scurrilous, false and emotional statements of the petitioner. Only the petitioner dissented from this vote.

There is no truth in the petitioner's allegation that no vote was taken on the medical grievance committee report.

The documents and records which the petitioner is legally entitled to see as a director of the hospital have been mailed to him. These include the minutes of meetings of the board of directors, the report of Solomon Siegel, executive director of the hospital, the report of Dr. Joseph Abramson, the affidavit of Dr. Custodio, which were requested in the notice of motion submitted by the petitioner.

The Jewish Chronic Disease Hospital cannot legally turn over charts and records of patients, since the petitioner has not obtained the

20 JEWISH CHRONIC DISEASE HOSPITAL CASE

consent of such patients. The turnover of such material to the petitioner without the patients' consent is prohibited by CPLR, Sec. 4504(a), and the cases decided thereunder.

There was no attempt on the part of Isaac Albert to maintain a veil of secrecy and prevent a full disclosure of the situation, as alleged in the petition.

The petitioner is fully informed concerning the experimental work done at the hospital by the report made to the board of directors' meeting, a copy of which has been sent to him.

The right to determine whether any physician in the hospital has committed an unprofessional, illegal, or immoral act is not entrusted to any single director of the hospital, but is entrusted to various committees provided by the constitution and by-laws of the hospital, as follows:

The executive committee of the board of directors, which has full power to act on any matter requiring immediate action.

The medical conference committee, consisting of physicians, members of the staff, and directors of the hospital, which makes recommendations to the executive committee concerning medical and surgical activities of the hospital.

The medical board, which enforces rules and regulations for the proper supervision and care of patients.

The grievance committee, which has the duty to investigate "all grievances arising between members of the staff as well as the actual or alleged transgression by members of the staff."

The research committee, which has the power to review all protocols of projects submitted to it by members of the staff.

The petitioner has sought unilaterally, by a process of innuendo and slander, to arrogate to himself powers which are in the scope of the aforementioned committees of the hospital. Although not a physician, the petitioner seeks to determine what is and what is not the proper practice of medicine.

There is no individual liability of directors of a hospital for matters within their knowledge.

The petition herein is not brought in good faith, but is the product of a long standing feud and vendetta which the petitioner has carried on for years against the president of the hospital, Isaac Albert.

The claim is made in these paragraphs, quoting the affidavits of various doctors, that the injections were made on patients without their

consent. None of the doctors quoted was present when the injections were made, and any statement made in their affidavits concerning lack of consent is pure hearsay. Moreover, the affidavits of Doctors Custodio, Mandel and Southam, attached hereto, show that each patient was asked whether he would consent to the injection which was to be made. The injections were, in fact, made with the oral consent of the patients involved. There is no requirement in the law for written consent.

It is charged in the petition that the patients were mentally incapable of giving their consent to any injections. The refutation of this allegation is found in the affidavits of Doctors Mandel, Custodio and Abramson attached hereto. Their affidavits clearly demonstrate that these patients were not mentally incompetent to give a consent to the injections. Dr. Abramson, a neurologist and psychiatrist, who examined the affidavit of Dr. Jacobi, came to the following conclusion: "In the light of the above examination, I do not believe that any conclusion can be drawn that the five patients whose charts were examined by Dr. Jacobi were mentally incompetent."

There are charges in the above paragraphs concerning a conspiracy of silence to suppress disclosures, and to suppress facts. There has never been any such conspiracy. Nor has there been any attempt to suppress facts (see affidavits of Solomon L. Siegel and Dr. Mandel attached hereto). The complaints of the doctors whose affidavits support the petition were heard in due course by the grievance committee of the medical staff, provided for by the constitution and by-laws of the hospital. The report of the latter committee was fully discussed at the September 30, 1963 board of directors' meeting, at which the petitioner was present. All the 22 directors present, with the exception of the petitioner, voted to accept the report absolving the medical staff of any blame for alleged professional misconduct.

The charge is made that three of the doctors at the hospital (Kagan, Fersko and Rosenfeld) were asked to participate in the project by Dr. Mandel, the director of medicine, and that they refused because of either ethical grounds or because proper consents could not be obtained from the patients. The affidavit attached hereto of Dr. Mandel flatly denies that any such requests were made to these doctors.

Complaint is made that the consent of Dr. Rosenfeld was not obtained to the injections made on patients (see Fersko and Rosenfeld affidavits). Dr. Mandel, as director of medicine

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at the hospital, was the superior of both of the aforementioned doctors. Under the constitution and by-laws of the hospital, he did not need the consent of his subordinates for a pilot study such as the one herein under consideration.

None of the affidavits of the doctors produced by the petitioner supports the charge in the petition, that the purpose of the tests conducted at the Jewish Chronic Disease Hospital was to see whether "cancer could be induced" in any of the patients. The latter notion is a figment of the petitioner's imagination. The affidavits of Doctors Mandel, Custodio, Korman and Southam, attached hereto, make it crystal clear that no harm resulted to the patients at the hospital from the injections made on them, and no harm was expected at the time the injections were made.

For a complete and affirmative defense to the petition herein, the Jewish Chronic Disease Hospital alleges:

Upon information and belief, the petitioner has made complaints similar to those contained in his petition, to the Kings County district attorney's office, which investigates and prosecutes the commission of crime in Kings County, and to the New York State Department of Education, which has the duty of investigating and prosecuting complaints concerning breaches of medical discipline and ethics by physicians. All the doctors involved in the research and experimentation complained of have been questioned by the said public agencies. These include, Dr. Chester Southam and Arthur J. Levin of the Sloan-Kettering Institute, and Dr. Emanuel E. Mandel and Dr. D. B. Custodio of the Jewish Chronic Disease Hospital. The hospital has cooperated fully with the aforementioned public agencies in making all data available to them. Upon information and belief, the petitioner's complaints are still under advisement in the said agencies.

Wherefore, the Jewish Chronic Disease Hospital prays that the petition herein be dismissed.

4.

Affidavits for Respondent

a.

Solomon L. Siegel—January 3, 1964

I am the executive director of Jewish Chronic Disease Hospital.

The petitioner states that the injections were made in the patients at the Jewish Chronic Disease Hospital for the purpose of determining

whether cancer can be induced by the injection of live cancer cells. This is an outrageous falsehood. The attached affidavits of Drs. Southam, Mandel, Korman and Custodio, and medical literature throughout the world, will support the fact that cancer cannot be induced by injection of cancer cells. It is a recognized natural phenomenon that any foreign cells injected into the human body from an outside source will be rejected. Cancer cells are no exception. The purpose of the test was to determine whether the chronically ill, debilitated patients would reject the foreign cells at the same rate as cancer patients, or at the rate associated with normal humans.

Cancer cells were used in the experiment at the hospital, because unlike other foreign cells, the resultant nodule could be measured and the rejection time could thus be determined.

It is of significance, scientifically, that the patients injected rejected the cancer cells the same as normal humans, despite the fact that these were chronically ill, debilitated patients. The problem remaining now is to isolate the immunity factor which distinguishes the normal human from the cancer victim. Such isolation would provide an important clue in the conquest of the dread disease.

It should be noted that none of the doctors who submitted supporting affidavits made the claim contained in the petition that the purpose of the tests at the hospital was to determine whether cancer could be induced. As a matter of fact, Dr. Leichter, who was familiar with problems of cancer, has admitted that the injection of the cell suspensions which were used in the project constituted no possibility whatsoever of producing cancer in the patients involved.

It is not true that the injections were made without the knowledge and consent of patients. As appears from the affidavit of Dr. Custodio, who actually administered the injections, the consent of each patient was asked for orally and obtained. Neither medical ethics nor the law require that a consent to an injection be in writing. Dr. Custodio's affidavit is better testimony as to what happened than the hearsay statements of the petition and the doctors who were not present when the injections were made. Dr. Custodio was familiar with the patients. He has been a resident physician for two years. He found no difficulty in communicating with the patients in English. Dr. Arthur Levin, from Sloan-Kettering Institute, who was present when the injections were made, is familiar with the Yiddish language and was available to talk to the patients,

22 JEWISH CHRONIC DISEASE HOSPITAL CASE

had this been necessary. Nor is the charge true that the patients were mentally incompetent to give their consent. Dr. Jacobi's statement concerning the mental condition of five patients, contained in his affidavit, and which is based only on an examination of their charts, is refuted by the affidavit of Dr. Joseph L. Abramson, who was president of the medical staff, and who is a consultant at the hospital in neurology and psychiatry. Dr. Abramson concluded that the charges of mental incompetence with respect to the five patients whose charts were examined by Dr. Jacobi were not justified. Dr. Jacobi did not know the number of patients involved. He stated that 26 patients were injected, whereas only 22 patients were involved in the tests at the hospital.

The fact is that neither the consent of Dr. Leichter nor Dr. Rosenfeld was required for the tests. Dr. Emanuel Mandel is the director of medicine of the hospital. He is the superior of both Dr. Leichter and Dr. Rosenfeld. Dr. Leichter was not in charge of cancer research, as claimed in Dr. Kagan's affidavit. Any project to do research required the approval of Dr. Mandel. Dr. Mandel approved the study and under the constitution and by-laws of the medical staff, he had the authority to give such approval. The said constitution and by-laws permit directors of services, without prior approval, to make pilot studies. The injection of 22 patients was such a pilot study. Dr. Mandel's only obligation was to submit a protocol to the research committee of the medical staff within 60 days.

The petitioner states that it is his obligation as a director to inquire into happenings and to ascertain all the facts and to take adequate steps to protect the patients and the good name of the hospital. Mr. Hyman is so obsessed with the notion that there has been wrongdoing at the hospital that he brushes aside the unanimous opinion of the directors who disagreed with him and of the medical grievance committee which found no wrongdoing. Moreover, he overlooks the fact that those who disagree with him are just as much interested in the welfare of the patients and the welfare of the hospital as he. One begins to wonder just how much Mr. Hyman has the interests of the hospital and patients at heart.

Mr. Hyman also overlooks an important fact: There is a basic distinction between the medical affairs of the hospital and the care of patients, on the one hand, and the administrative affairs of the hospital. It is accepted procedure in hospitals for the board of directors to detail its medical responsibilities to the medical staffs of the hospital. This is the case at the Jew-

ish Chronic Disease Hospital. The medical and dental staffs have their own constitution and by-laws. The by-laws provide for a grievance committee to handle matters of any questionable nature. A duly appointed grievance committee considered the problems raised by the tests on the 22 patients. The grievance committee report was approved by the board of directors. Mr. Hyman wishes to set himself up as a one man court of appeal from the judgment of the grievance committee and the board of directors.

There are statements in the affidavits that Doctors Kagan and Leichter had been requested by Dr. Mandel to make injections or to authorize injections and that these doctors had refused to do so. This is contrary to the information that I received from Dr. Mandel when I made an inquiry into the matter. He stated that no such requests were made. Moreover, as the superior of the doctors, he did not need their approval to make any appropriate studies or tests. Dr. Leichter has already repudiated the statement attributed to him (see affidavit of Dr. Samuel Korman attached hereto).

Dr. Rosenfeld alleges that the project was illegal and immoral and conducted surreptitiously without his knowledge and consent. The short answer is that his knowledge and consent were not required, and it is somewhat difficult to conceive that dedicated research workers of the Sloan-Kettering Institute would be engaged in illegal and immoral practices on our patients with the consent of our director of medicine. It should be noted that Dr. Rosenfeld has a personal animus against Dr. Mandel and on more than one occasion, when I discussed the problem with him, he insisted that Dr. Mandel be discharged immediately.

Petitioner as a lawyer should know that the hospital is prohibited by law from divulging the contents of patients records which are confidential, and which records he is demanding by court order.

The petitioner has embarked upon a reckless campaign to discredit the Jewish Chronic Disease Hospital unless he has his way. The court should not assist him in his campaign. May I therefore respectfully urge the court to deny the petition herein.

b.

**Emanuel E. Mandel, M.D.—
December 31, 1963**

I am a physician duly licensed to practice medicine in the State of New York since 1939.

I am the director and director of Chronic Diseases since November 1963. I am a clinical associate professor at Downstate Medical School, New York. I am an associate professor of Medical School education at the University of Illinois.

The petitioners' affidavits annexed, distorted, shall try to bring court.

The most of man's papers is and tests conducted purpose of determining induced by the. Similarly misleading in the p. berg trials, and inane argument voted against M. tests was being having injection their own bodies in their bodies.

It should be absolutely the hospital with of suspensions human cancer tions (which was 16, 1963) was rate of rejection recipients. This transplants, i.e., planted into an such as normal the same purpose because they had to produce a sequential when since they are are rejected. T cancer cells is surrounds the written by Dr. injections could cancer" in any concerning dan live cancer cell cians' affidavits

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I am the director of the department of medicine and director of medical education at the Jewish Chronic Disease Hospital, having held these positions since November 1961. In addition, I am a clinical associate professor of medicine at the Downstate Medical Center, State University of New York. Previously, from 1957 to 1962, I was associate professor of medicine at the Chicago Medical School and associate director of medical education at Mount Sinai Hospital of Chicago, Illinois.

The petition of William A. Hyman and the affidavits annexed thereto are replete with falsehoods, distortions, and misrepresentations. I shall try to bring these to the attention of the court.

The most shocking misstatement in Mr. Hyman's papers is the allegation that the experiment and tests conducted at the hospital were "for the purpose of determining whether cancer can be induced by the injection of live cancer cells." Similarly misleading and fallacious are references in the petition to Nazi doctors, Nuremberg trials, and Dachau methods, as well as the inane argument as to whether the directors, who voted against Mr. Hyman when the matter of the tests was being considered, would "consent to having injections of live cancer cells made into their own bodies to see if cancer can be induced in their bodies."

It should be clearly understood that there was absolutely no danger arising to patients of the hospital who received hypodermic injections of suspensions of cells obtained from cultures of human cancer tissue. The purpose of the injections (which were given to 22 patients on July 16, 1963) was to determine the mechanism and rate of rejection of the injected material by the recipients. This material represented homologous transplants, i.e., tissue of one human being transplanted into another person. While other tissue, such as normal skin muscle, could be used for the same purpose, cancer cell lines were chosen because they have the necessary growth capacity to produce a measurable reaction. "It is inconsequential whether these are cancer cells or not, since they are foreign to the recipient and hence are rejected. The only drawback to the use of cancer cells is the phobia and ignorance that surrounds the word cancer (quoted from a letter written by Dr. C. M. Southam)." Indeed, the injections could not possibly and did not "induce cancer" in any of the patients. The innuendos concerning danger to patients from "injections of live cancer cells" contained in some of the physicians' affidavits attached to the petition can be

explained only by their ignorance in the subject, unless ulterior motives were at play.

The project was undertaken because of its vital importance not only to the understanding and possible treatment and diagnosis of cancer, but also to the understanding of other diseases, particularly those of autoimmune and degenerative nature, and because of its possible contribution to our knowledge in the general field of organ homotransplantation. Tests of the nature described above had been carried on for several years on patients at Memorial Hospital in New York and on healthy prisoners at the Ohio State Penitentiary. For the past 2 years, these tests have been routinely applied to all postoperative patients on the gynecology service of Memorial Hospital as a measure of their immunologic status. These studies had revealed that healthy persons rejected cancer cell homografts completely and promptly (in 4 to 6 weeks), while patients with advanced cancer usually showed a delayed rejection (6 weeks to 3 months). The typical reaction consists in a painless subcutaneous nodule (lump) which attains a maximal size of 2 to 3 cm. in diameter and disappears within the periods noted above. The project at the hospital was designed by Dr. C. M. Southam of the Sloan-Kettering Institute to determine whether the immunologic response (rate of rejection) in chronically ill and debilitated non-cancer patients was similar to that of healthy persons or conformed to that of cancer patients. Results of the project conducted at the hospital by Drs. Southam and Arthur G. Levin of The Sloan-Kettering Institute and by Dr. D. B. Custodio of the hospital clearly indicated that chronically ill, debilitated non-cancer patients reacted like normal individuals in rejecting homologous tissue cells. Hence, the delayed immunologic response of cancer patients must be attributed to the disease itself (cancer), rather than to the attendant metabolic changes (weakness, debilitation). This finding furthermore suggests that the spread of cancer in the human body is associated with an impairment of the normal immunologic defense mechanisms. If this impairment could be prevented or remedied, the spread of cancer might be halted. This discovery may prove to be of great importance in the future control of cancer.

Mr. Hyman was fully aware that the above-named investigators were not trying to "induce cancer" but that they were testing the immunologic response of our patients. This information was available from Dr. Rosenfeld's affidavit attached to the petition stating that "the project

24 JEWISH CHRONIC DISEASE HOSPITAL CASE

was to test the immunologic response of these patients." This is a far cry from inducing cancer in the patients. Indeed, as I stated above, there was absolutely no danger of inducing cancer by these tests.

It is charged in the petition and affidavits that the patients' consent to the skin tests had not been obtained; that many of the patients were incompetent and incapable of giving a real consent; that some of the patients did not even speak English. Please note that Dr. D. B. Custodio, senior medical resident at the hospital, voluntarily, at my suggestion, undertook this research in collaboration with the two physicians from the Sloan-Kettering Institute, Dr. Chester M. Southam and Dr. Arthur G. Levin. Each of the patients was asked by Dr. Custodio for his consent to the injections, in the presence of those other 2 physicians. Dr. Custodio had known these patients for many months and was able to communicate with them in English, despite allegations in the petition to the contrary. Obviously, Dr. Custodio was in a better position to gauge the ability of patients to comprehend the requests which were being made of them than was Dr. Jacobi who drew his conclusions concerning the patients' mental status from charts. Moreover, when personally visiting on December 20, 1963, 4 of the 5 patients listed in Dr. Jacobi's affidavit, I found each to be in satisfactory condition for comprehending or giving consent to a diagnostic test or a surgical procedure. The fifth patient had died in October following a bladder operation.

The reference in the petition and affidavits to the requirement of written consent of patients for the tests is not consistent with my understanding of the law of New York. I believe that oral consent was adequate. Such consent was obtained in every instance, in accordance with the procedure which had been in vogue at Memorial Hospital for several years. There, these tests are used as routine studies and are being considered to be even less hazardous than such other routine diagnostic procedures as bone marrow aspiration and lumbar puncture.

The petition charges that the experiments on the patients were made without the "approval, sanction, authorization and consent" of the proper authorities at the hospital. This is untrue; Drs. Southam and Levin of the Sloan-Kettering Institute were initially referred to me by Mr. Sol Siegel, the executive director of the hospital, whom they had called over the telephone about this research project. As director of medicine

and of medical education of the hospital, I authorized the project after I had discussed it at great length with Drs. Southam and Levin; after I had ascertained Dr. Southam's reputation in the field of cancer research and reviewed his publication on the subject; and after I had become convinced that the proposed clinical study was likely to make a significant contribution to science without exposing our patients to any risk. Under the constitution, by-laws and rules and regulations governing the medical staff of the hospital, I had the right to engage in pilot studies and was under the obligation to inform the research committee of the hospital of such pilot studies within 60 days from the time when such project was undertaken. When complaints about the project came to the attention of the grievance committee of the medical staff at its meeting on September 7, 1963, my actions were upheld and, indeed, further studies of the same type were being encouraged by the committee. This is apparent from the annexed minutes of this meeting. Furthermore, the board of directors, at its meeting of September 30, 1963, expressed its approval, with only Mr. Hyman dissenting.

It is asserted that there may be liability on the part of the directors and the hospital because of "injuries that may be received by any patient" as a result of the injections that were made. It should be noted that no injury resulted to any patient from the injections. A small nodule (lump) formed within 2 weeks after the injection and disappeared completely not later than 2 months thereafter. This was the typical reaction which was being expected. As mentioned previously, the vital part of the project was measurement of the size of the nodule and of the time of its disappearance. With respect to the statement in Dr. Rosenfeld's affidavit that one patient complained bitterly of pain in connection with such an injection. I was advised by Dr. Custodio that this was incorrect; the patient did not complain of pain but merely inquired with respect to the lump which had formed on his thigh following the injection. This lump as well as the skin reactions in all the patients who received these tests have completely disappeared.

It is claimed that I asked three physicians at the hospital, namely, Drs. Fersko, Kagan and Leichter, to "undertake a project of injecting cancer cells" and that they all turned me down. The falsehood of this claim is, in part, proven by the affidavit concerning Dr. Leichter signed by Dr. S. Korman. The only one of those three

physicians ("c participation Kagan. How Dr. Kagan th such participa was no longer posed research two coordinat to acquaint th spectve opini the project. T physicians was

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the hospital, I had discussed it at a meeting with Dr. Southam and Dr. Levin; after Dr. Southam's reputation in the field was reviewed and after I had been assured of the important contribution to the medical staff of the hospital of such information. When complaints were made to the attention of the medical staff at its meeting on July 16, 1963, my actions were reviewed in the studies of the same by the committee. The annexed minutes of the board of directors, dated September 30, 1963, expressly Mr. Hyman dis-

may be liability on the hospital because induced by any patient" that were made. It was stated to any patient. A small nodule was seen after the injection, not later than 2 weeks after the typical reaction. As mentioned previously, the project was measured and of the time respect to the statement that one patient in connection with the project was measured by Dr. Custodio. The patient did not comply with respect to his thigh following as well as the patients who received the injection.

Dr. Southam, Dr. Kagan and Dr. Levin, in part, proven by Dr. Leichter signed by one of those three

physicians ("coordinators") to whom I suggested participation in the research project was Dr. Kagan. However, several days later, I informed Dr. Kagan that Dr. Custodio had consented to such participation so that Dr. Kagan's assistance was no longer needed. I also discussed the proposed research project with each of the other two coordinators on separate occasions in order to acquaint them with it and to obtain their respective opinions about the scientific value of the project. The opinion of each of the three physicians was indeed favorable.

The charges in Dr. Rosenfeld's affidavit that the experiment was conducted "surreptitiously" and in Dr. Jacobi's affidavit that proper notations on the patients' charts were not made are totally unwarranted and without foundation. There was no reason at all for secrecy concerning a bona fide research project which was being carried out in collaboration with one of the outstanding research institutions in the country. Dr. Custodio had been instructed by me to make appropriate entries in each of the patients' charts who received the test and, as far as I know, he complied with this instruction.

The claim contained on the last page of Dr. Rosenfeld's affidavit is completely unwarranted that I attempted to keep "Dr. Kagan and the others from talking about the project" by offering him an increase in salary and some private patients. The truth is that I reassured Dr. Kagan on August 27th that the request for an increase in salary which he had made repeatedly over the preceding 4 months would be granted. I also indicated that I would turn some of my private cases over to him and to other members of the staff in order to find more time for research. This discussion took place the day after my return from a two-week vacation, at which time I was unaware of Dr. Kagan's antagonistic attitude and of his intention to resign abruptly.

A report on this study is scheduled to be presented to the sixth Biennial International Transplantation Conference at the New York Academy of Sciences in February 1964.

c. **Deogracias B. Custodio, M.D.—**
January 3, 1964

I am a resident physician at the Jewish Chronic Disease Hospital. I have held this position since July 1, 1961 to June 30, 1962 and from July 1, 1963 up to date.

Some time in July of 1963 I was asked by

Dr. Mandel whether I would be interested in participating in a research project which would be done at Jewish Chronic Disease Hospital with doctors from Sloan-Kettering Institute. I was told that the project was financed by a grant from the U.S. Public Health Service and that the work was being carried on under the direction of Dr. Chester Southam of Sloan-Kettering Institute. The project involved injecting patients with cancer cell suspensions in order to determine what their rate of rejection of the injected material would be. I was told that similar tests had been made on cancer patients and on healthy prisoners at the Ohio State Penitentiary. The purpose of the project was to determine whether weak, debilitated, chronically sick patients would reject this material like normal individuals or whether the rate of rejection would resemble cancer patients. I knew from my medical experience and studies that there was no possibility of any patient developing cancer as a result of these injections. The material injected was a foreign body and must by the laws of biology and medicine be rejected by the human organism.

The charge in the petition that the purpose of the injections made at the Jewish Chronic Disease Hospital was to determine whether cancer could be induced by such injections just simply is not true. Cancer cannot be induced by such injections. The purpose of the test was to determine the patients' immunological reaction to the injection of cancer cells and not "to induce cancer."

On July 16, 1963, I met with Dr. Mandel, the director of medicine of the hospital, and Dr. Chester Southam and Dr. Arthur Levin of the Sloan-Kettering Institute. Dr. Southam demonstrated the techniques of injection on three patients. I injected the other 19 patients under his general supervision. The appropriate entry showing this injection was made on the chart of each patient in accordance with proper medical practice. Before any patient was injected, Dr. Mandel obtained the oral consent from the first 2 patients and I did from the next 20 patients. The patient was told that an injection of a cell suspension was planned as a skin test for immunity or resistance. The patient was also told that a lump would form which would last several weeks and gradually disappear. The patient was not told that the injection would contain cancer cells. The reason for this is that we did not wish to stir up any unnecessary anxieties, disturbances or phobias in our patients. There was no need to tell the

patients that the injected material contained cancer cells because it was of no consequence to the patients.

Drs. Southam and Levin were present when I asked for the oral consent of 20 patients. Dr. Mandel obtained the consent from the first 2 patients. Dr. Mandel was present when the first 2 patients were injected as well as Dr. Southam and Dr. Levin. I had no difficulty in communicating with the patients in English. The charge that some of the patients spoke only Yiddish is not correct. Dr. Levin, I am advised, speaks Yiddish, and he could have spoken to the patients in this language had it been necessary.

Nor is there any truth in the assertion made in the petition and in Dr. Jacobi's affidavit that some of the patients were mentally incompetent to give this consent. I have known some of these patients for at least 6 months and I have no difficulty in communicating with them. In my opinion, none of the patients was mentally incompetent so that they could not give their consents to the injections.

After the injections were made, I observed the patients with Dr. Southam and/or Dr. Levin twice a week during the first 3 or 4 weeks and weekly thereafter. As expected, the lump or nodule developed and disappeared within an average period from six to eight weeks. As expected, no harm or injury occurred, as a result of these injections, to any of the patients, with the exception of the transient lump mentioned.

For my services in connection with this project I was paid the sum of \$100.00 out of the research funds available to the Sloan-Kettering Institute from the U.S. Public Health Service grant.

d.

Chester M. Southam, M.D.—
January 5, 1964

I am a licensed physician in the State of New York. I am employed as a full-time staff member of the Sloan-Kettering Institute for Cancer Research where I am chief of the section of clinical virology of the division of clinical chemotherapy, and chief of the section of oncogenic virology of the division of virology and immunology. I am an associate attending physician of Memorial Hospital for Cancer and Allied Diseases and an associate visiting physician of the James Ewing Hospital of the City of New York, on the chemotherapy service of the department of medicine. I am an associate profes-

sor of medicine of the School of Medicine of Cornell University. I have been with these institutions for approximately 15 years engaged in the practice of clinical medicine (medical management of cancer), medical teaching, and research in various phases of clinical and laboratory oncology.

Since 1954 one of the major types of research in which I have been engaged is the study of the relationships between immunological responses and cancer. The studies in 1954 revealed for the first time evidence of a major immunological defect in patients with advanced cancer. This was evidenced by the delayed rejection of homotransplants of neoplastic tissue-cultured human cells by such patients, in contrast to the prompt rejection which would, of course, be expected to occur since these are homotransplants (that is, these cells are foreign to the individual into whom they are injected).

A major deficiency of these investigations until the present year was the lack of direct evidence that the immunological deficiency observed in cancer patients was specifically related to cancer. Recently it was possible to establish this important point by the demonstration that patients who are chronically ill and debilitated due to various diseases other than cancer have a normal or near normal capacity to reject this same type of tissue-cultured cell transplant. This work was made possible through the collaboration of Dr. Emanuel Mandel, chief of medicine of the Jewish Chronic Disease Hospital in Brooklyn, and the cooperation of patients in that hospital.

It was possible to arrange for this collaboration because my present clinical research fellow, Dr. Arthur Levin, through personal acquaintances was able to discuss this work and the need for similar studies in non-cancer patients with persons affiliated with the Jewish Chronic Disease Hospital. Through such persons we were referred to Mr. Siegel, executive director of that hospital, who referred us to Dr. Mandel, chief of medicine, to discuss the problem and the possibility of a collaborative research project. After thorough discussion of the purpose, importance, procedures, reactions, and previous scientific publications, Dr. Mandel indicated his interest in such studies and some time later arrangements for a preliminary study were made. He was, of course, aware that homologous cells (cells from a human other than the person in whom they are injected) could not long continue to persist unless immunological reactivity was

severely impaired, ability of inducing cancer reaction in his patient.

This study was at which time each of two injections under tissue-cultured cells. These represented lines known as HEp injections were made one thigh at two sites. Injections were made by me, as a demonstration of the instruction of Dr. Custod interest in assisting in all of the injections. After observing the and all of the tests were done by Dr. C. Dr. Arthur Levin arranged prepared the cell ready for the injection the procedure and date book. Explaining the consents, at the chart, as well as the activities of Dr. my knowledge each were done was informed would measure his reactions and further whenever the patient knowledge each patient to this test.

The test sites were and Dr. Levin at in four days for the next almost all reaction further checked for weeks until no persistence of reaction accompanied Drs. Custod follow-up visits (June August 20th).

I have seen the is charged that the Jewish Chronic Disease whether "cancer patients who were injected material which was categorically that the study and that cally impossible to The purpose was to

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reaction in his patients.

This study was initiated on July 16, 1963,
at which time each of the 22 patients was given
two injections under the skin of a suspension of
tissue-cultured cells of human neoplastic origin.
These represented three long-established cell
lines known as HEP 3, HEP 4, and K1 +1. The
injections were made on the anterior surface of
one thigh at two sites just beneath the skin. The
injections were made in the first three patients
by me, as a demonstration of the technique for
the instruction of Dr. Mandel and the medical
resident (Dr. Custodio) who had expressed an
interest in assisting in this project and who did
all of the injections after my demonstration.
After observing the technique, Dr. Mandel left
and all of the tests on the remaining patients
were done by Dr. Custodio in the presence of
Dr. Arthur Levin and myself. Dr. Levin and I
prepared the cell suspensions in the syringes
ready for the injections and recorded details of
the procedure and the patient's name in our
date book. Explanations to the patient, obtain-
ing the consents, and the writing of notes in
the chart, as well as the injection itself, were
the activities of Dr. Custodio. To the best of
my knowledge each patient on whom these tests
were done was informed that it was a test that
would measure his or her reactions or defense
reactions and further information was given
whenever the patient wished it. To the best of my
knowledge each patient did indicate his consent
to this test.

The test sites were checked by Dr. Custodio
and Dr. Levin at intervals of not longer than
four days for the next four weeks by which time
almost all reaction had disappeared. They were
further checked for an additional three or four
weeks until no person showed any further evi-
dence of reaction at the test site. I, too, accom-
panied Drs. Custodio and Levin on three of these
follow-up visits (July 19th, August 13th and
August 20th).

I have seen the petition herein, in which it
is charged that the purpose of the tests at the
Jewish Chronic Disease Hospital was to see
whether "cancer could be induced" in the pa-
tients who were injected with the cell-suspension
material which was used. I wish again to assert
categorically that this was not the intention of
the study and that it is biologically and medi-
cally impossible to induce cancer by this means.
The purpose was to test the immunological re-

sistance of these patients to cancer. No patient
who was injected was harmed in the slightest by
the test which was made on him, except for the
lump or nodule which formed at the test
site, and which disappeared within four to eight
weeks. During the past 10 years, as we have seen,
cancer cells have been implanted in almost 600
well persons and cancer patients. They have
caused no untoward effects and have not resulted
in the development of any cancers in either the
well persons or those already suffering from
their own cancers. The technique for measuring
immune reactions is now standardized and the
results are predictable. All the patients in the
study undertaken at the Jewish Chronic Disease
Hospital rejected the transplants as promptly as
did the healthy persons. Thus it has been dem-
onstrated that cancer patients lack an immune
mechanism present in other individuals, includ-
ing chronically diseased patients.

Thus the research done at the Jewish
Chronic Disease Hospital has enabled us to take
one more step forward in the continuing battle
against cancer.

e.

Joseph L. Abramson, M.D.—
January 3, 1964

I am a physician, duly licensed to practice
medicine in the State of New York since 1924. I
hold the rank of consultant at Jewish Chronic
Disease Hospital. I am a psychiatrist and neu-
rologist. I was president of the medical staff of
Jewish Chronic Disease Hospital from January
1, 1962 to December 31, 1963. I am consulting
neuro-psychiatrist at Brooklyn Jewish and Swed-
ish hospitals; I am a Diplomate in Neurology
and in Psychiatry. I am assistant clinical profes-
sor in neurology at Downstate Medical Center;
and a qualified psychiatrist in the State of New
York.

Dr. Mendel Jacobi has submitted an affi-
davit in which he comments on the charts of five
patients who allegedly were injected with cancer
cells. The conclusion has been drawn from his
analysis that these patients were mentally incom-
petent and could not give a rational consent to
any injections made on them. This conclusion is
not justified from the data used by Dr. Jacobi. I
have examined Dr. Jacobi's affidavit and wish to
make the following comments on the cases ex-
amined by him:

K14397: Does not say that he did or did
not have aphasia and no indication that he did

28 JEWISH CHRONIC DISEASE HOSPITAL CASE

not talk or fails to understand what was said to him. Even though "perverse, negative, resistant to therapy," does not indicate that he did not comprehend. No justification for statement that "a state of chronic uremia in which cerebration is generally poor" applied in this particular case.

#2990: At age 52 a note indicates that patient had "marked speech defect, marked irritable personality—who cries steadily and in a shrieking manner." The conclusion of the examiner at the time was that "this is due to the patient's low mentality, and lack of insight and judgment." There is nothing in the above statement to justify that the patient had a low mentality. Two months after the alleged injection, the patient signed consent which was acceptable to the surgeon, for an operation on the bladder. One can obviously say, that two months before, in July, he was just as well aware of his environment, and could give consent at that time.

#8183: Admitted to Jewish Chronic Disease Hospital 1958. He had been a patient at Brooklyn State Hospital in 1957 with diagnosis of "dementia praecox." There is nothing in the chart to indicate that he was incompetent, and a diagnosis of this condition, per se, does not indicate incompetence. There is a note to the effect that the "neurologic status had not improved." There is no note in the allegation as to his mental status when he was admitted.

#3762: There is absolutely nothing in the allegation to indicate that the patient was not competent mentally even though he made a suicidal attempt one month after the alleged injection.

B15918: There is absolutely nothing in the allegation of the patient's incompetency.

In the light of the above examination, I do not believe that any conclusion can be drawn that the five patients whose charts were examined by Dr. Jacobi were mentally incompetent.

f.

**Samuel Korman, M.D.—
December 19, 1963**

I am a physician duly licensed to practice medicine in the State of New York.

I am the associate director of the Department of Medicine of the Jewish Chronic Disease Hospital and chief of the division of neoplastic diseases in that department.

On Tuesday, December 17, 1963, between 9:30 and 10:30 A.M., I was present in the office

of Dr. E. E. Mandel, director of medicine of the Jewish Chronic Disease Hospital, when he talked with Dr. David Leichter who had come to see Dr. Mandel about his reappointment to the attending staff of the hospital.

In the course of this conversation, Dr. Mandel read aloud the summary of an affidavit which Dr. Leichter had signed on September 12, 1963 pertaining to a research project that had been undertaken by Dr. Mandel in collaboration with Drs. Southam and Levin of the Sloan-Kettering Institute.

Upon listening to the reading of this summary, Dr. Leichter admitted that certain statements mentioned in the summary were untrue; to wit, that he (Dr. Leichter) had never been asked by Dr. Mandel "to undertake the project of injecting live cancer cells into non-cancer patients." Dr. Leichter further stated that he had not used the expression attributed to him in the summary that "... efforts were made to hush-up the complaints about the project." In addition, Dr. Leichter indicated that he (and Drs. P. M. Fersko and A. Kagan) had been quite upset at the time of their abrupt resignations from their salaried positions in the hospital (about August 27, 1963), and he conceded that they may not have used their best judgment in taking that action. Dr. Leichter also informed Dr. Mandel that he and the two doctors mentioned had made their affidavits on September 12th largely because of rumors that the hospital was going to make formal charges against them for abandonment of patients. Finally, Dr. Leichter agreed with Dr. Mandel and the undersigned that injection of the cell suspensions which were used in the project constituted no hazard whatsoever to the patients involved with respect to production of cancer.

5.

Minutes of Grievance Committee of the Medical Staff, Jewish Chronic Disease Hospital—September 7, 1963

Attendance: Drs. David Kershner, Mayer E. Ross, Harry Weiner
Nathan A. Lewis (D.D.S.),
Joseph L. Abramson

By Invitation: Solomon L. Siegel, executive director
Benjamin Saltzman, chairman of executive committee of board of directors

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Harry B. Albert, director
and hospital counsel
Absent: Dr. Samuel Millman, chair-
man of grievance commit-
tee
Herman W. Shane, chair-
man of board of directors

In the absence of Dr. Millman, Dr. Abramson presided. He opened the meeting indicating that a complaint had been brought to his attention in regard to certain research activities which had been done under instructions of Dr. Mandel, director of medicine. He read a letter of resignation by three coordinators in medicine, signed jointly by Drs. Kagan, Fersko and Leichter. (A copy of the letter is made part of these minutes). He then called upon Mr. Siegel, executive director, to relate the sequence of events leading up to his meeting.

Testimony by Solomon L. Siegel, Executive Director

He arrived at Miami Beach on vacation on Wednesday, August 14, 1963. Within an hour after checking in at a hotel, he received an emotionally frantic call from Mrs. M. Tulipan urging him to return to the hospital immediately because "something terrible has happened, which cannot be discussed on the telephone." Alarmed, Mr. Siegel arranged to return by plane and called Mrs. Tulipan at her home that evening to make arrangements to be picked up at the airport. It was during this call that Mrs. Tulipan told Mr. Siegel that "some of our patients were injected with live cancer cells" and indicated that terrible consequences would result.

Mr. Siegel arrived at the hospital Thursday afternoon and immediately saw Mrs. Tulipan. She had learned through Dr. Rosenfeld that a number of patients had been injected with live cancer cells without knowledge of Dr. Rosenfeld; that Dr. Rosenfeld learned of these injections when one of the patients called him to ask why he had been given the injection; that he then investigated and traced the injections to Dr. Custodio (resident) who gave these injections for a certain Dr. Southam and another doctor, both from Memorial Hospital who are friends of Dr. Mandel.

Under obvious emotional strain, Mrs. Tulipan practically demanded that Mr. Siegel fire Dr. Mandel at once or get his resignation. She further advised Mr. Siegel that the patients were not advised on nature of or reason for

injection. She wanted to know if the medical board, research committee, or executive director knew of this project. Mr. Siegel told her he had no knowledge of this project and was quite sure neither of the other bodies had prior knowledge.

Mr. Siegel visited Dr. Rosenfeld at his private office that afternoon. He related the story substantially the same as had been presented by Mrs. Tulipan; while he had no personal reason for finding fault with Dr. Mandel, he was terribly hurt because Dr. Mandel had not discussed the project with him. He kept advising Mr. Siegel that Dr. Mandel should be fired, or that he should be forced to resign and he placed great emphasis on the fact that three coordinators had been approached by Dr. Mandel to participate in this project and each had turned it down because they told him written informed consent was required. He named Drs. Kagan, Fersko and Leichter as the individuals who had refused to participate. He also named Dr. Custodio, a resident, as the physician who had done the injections. Mr. Siegel told Dr. Rosenfeld he intended interviewing all the persons named and advised him that Dr. Mandel was on vacation and he did not feel any conclusions could be drawn without discussing the problem with Dr. Mandel. Dr. Rosenfeld kept warning Mr. Siegel that "the thing would blow up," that he'd "better get good legal advice," "that this was a terrible thing that had been done," "that he'd better fire Dr. Mandel at once," etc., etc.

The following morning, Friday, August 16, 1963, Mr. Siegel interviewed Dr. Leichter, Dr. Kagan and Dr. Custodio. Dr. Fersko was on vacation and was not available.

Dr. Leichter told him that early in July, Dr. Mandel had discussed the project with him and had advised Dr. Mandel that written informed consent was required, and that Dr. Mandel never again approached him on this matter. He was very resentful of Dr. Mandel, he did not know how many patients were injected, or who the patients were. Mr. Siegel felt the resentment and bitterness directed toward Dr. Mandel were really based on the fact that he was being superseded as chief of the cancer service by a new full-time physician (Dr. Korman) who was to join the staff as associate director of medicine. Dr. Leichter placed emphasis on his distrust of Dr. Mandel and also implied that the thing would blow up.

Mr. Siegel told Dr. Leichter that the matter of injecting the patients appeared to be in the province of the grievance committee of the

30 JEWISH CHRONIC DISEASE HOSPITAL CASE

medical staff and that it would be given to Dr. Abramson upon his return from vacation. He requested that Dr. Leichter not be hasty in his actions.

Mr. Siegel then met with Dr. Kagan who likewise was approached by Dr. Mandel on the proposed project. Dr. Kagan stated that he had advised him that written informed consent was required and that he did not think the patients would give such consent. Dr. Mandel never again discussed the matter with him. He had heard that injections had been given but did not know how many or to which patients. He felt this was done illegally. He appeared confused as to what course to take, feeling that knowledge that an illegal act was done implicated him and that he was morally bound to make it known. Further conversation revealed that he had other complaints against Dr. Mandel as follows:

1. He had been inveigled into using other experimental drugs without getting written consent and that he was fearful of possible damaging consequences;
2. That he wanted an appointment at the State University and did not feel Dr. Mandel was really trying to get him one.
3. That he thought he was entitled to an increase in salary and did not believe Dr. Mandel was trying to get him one.

Mr. Siegel stated he had learned that Dr. Mandel had spoken and written to Dr. Eichna at the university regarding Dr. Kagan's appointment, but that the latter had hurt his own cause when he wrote directly to Dr. Eichna without Dr. Mandel's knowledge. Dr. Eichna looked unfavorably upon such behavior.

In regard to an increase, Dr. Mandel had spoken and written to Mr. Siegel, requesting an increase for Dr. Kagan and was advised this was to be referred to the finance committee. Not believing that Dr. Mandel was trying, Dr. Kagan wrote directly to Mr. Siegel without Dr. Mandel's knowledge. Mr. Siegel looked upon this procedure with disfavor and so advised Dr. Kagan.

Mr. Siegel advised Dr. Kagan that the findings in regard to the injections would be turned over to Dr. Abramson upon his return from vacation and requested that Dr. Kagan take no hasty action. Dr. Kagan was extremely bitter toward Dr. Mandel.

Mr. Siegel then interviewed Dr. Custodio, a resident in the Blumberg Building. Dr. Custodio stated that he was engaged in a project to study the immunological response of chroni-

cally ill, debilitated patients to a cell suspension of tissue cultures taken from cancer patients. He stated he was interested in research and was glad to cooperate, since this appeared to be a worthwhile study, that he was assured by Dr. Mandel (Southam and Levin of Sloan-Kettering Institute) with absolute certainty that there could be no ill effects on the patients; that written consents were not really required because of the negative emotional impact of reference to "cancer"; that he had advised each patient and gotten their verbal consent, witnessed by Drs. Southam and Levin, that they would be given a skin test to determine their immunological reaction to foreign injections; that small nodules would develop and would then disappear after a few weeks; that on the advice of Dr. Mandel, he wrote into each patient's chart that a "cell injection had been given in either right or left thigh." He submitted the names of the patients who had been injected.

Mr. Siegel, after these interviews, called Mr. Samuel Bisgyer, hospital attorney, informing him of this problem and to seek his advice. Mr. Bisgyer pleaded not to get him involved, since he was not well and not really well-informed on such hospital problems.

He then called Mr. Harry Albert, an attorney on the board of directors and met with him that night. Mr. Albert thought there was no great urgency and that Mr. Siegel could return to Florida.

Mr. Siegel returned to Florida, but feeling ill-at-ease, returned the following Thursday, called Dr. Abramson's office with a message for Dr. Abramson to call Mr. Siegel immediately upon his arrival.

In frequent conversations with Mrs. Tulipan and Dr. Rosenfeld, Mr. Siegel stated he was constantly being reminded that he'd better get Dr. Mandel out of the hospital. He decided to visit Mr. Benjamin Saltzman, chairman of the executive committee, who was the next ranking officer in the absence of Mr. Isaac Albert, to acquaint him with the facts.

In the interim, Dr. Mandel returned from vacation. Mr. Siegel advised him of the nature of the problem and that he was planning to present the case to the medical staff. Dr. Mandel confidently stated that he had done nothing wrong and would gladly submit to evaluation by this body.

Dr. Abramson returned from vacation and Mr. Siegel met with him on Wednesday, August 28. Dr. Abramson already had on his desk a

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letter of resignation signed by Drs. Kagan, Fersko and Leichter. He readily accepted the matter as one within the province of the medical staff, felt that Mr. Siegel had handled the matter properly up to this point.

Testimony by Dr. Abramson, President of the Medical Staff

Dr. Abramson stated that he personally interviewed the doctors who had resigned. In regard to their attitude that written consent was required, he tried to allay their fears, since they had not participated in this project in any way and were in no way involved. He felt that none of the men, Drs. Kagan, Fersko and Leichter, had any substantial basis for their position, and were using this incident to support other personal complaints against Dr. Mandel. Dr. Abramson felt none of their reasons justified their actions and so advised these doctors.

Mr. Saltzman suggested that the committee consider the medical and legal aspects of the complaint, rather than the extraneous attitude of the coordinators.

Testimony by Dr. Southam

At this point, Dr. Southam of the Sloan-Kettering Institute arrived and was invited for questioning. The following facts were brought out in the questioning:

1. The work has been in progress for about 10 years, and various papers on the subject have been published in medical journals.
2. Cancer cells are used rather than other tissue cells because cancer cells are reproduced easier in measurable amounts and the rejection period is measurable.
3. In normal patients, a measurable nodule develops in about two weeks and disappears in four to six weeks. In cancer patients, the nodule might not disappear for a few months since the immunological rejection is impaired.
4. Purpose of using our patients was to determine whether the delayed rejection was unique for cancer patients only, or whether a similar reaction would be present in chronically ill patients suffering from debilitating diseases.
5. All patients injected showed the normal rejection associated with healthy individuals except one patient, and this one

had a prior history of rectal surgery, based on information subsequently taken from his chart.

6. Each patient was told in advance of the test and each one consented. The word "cancer" was not used because of emotional reaction to use of word in addition to the fact that the use of cancer cells was immaterial. There was absolute certainty that there would be no permanent side effects.
7. This hospital was approached because of its reputation as a progressive medical institution interested in research and teaching, coupled with the fact that we had large numbers of debilitated patients with diseases other than cancer.
8. The tests were extremely useful. Dr. Horsfall, director of Sloan-Kettering Institute, who was never overly enthused about this project, upon hearing of the test results at our hospital, called Dr. Southam to congratulate him on his successful findings.
9. Dr. Southam's concern was for scientific progress and he would be extremely pleased if the tests could continue at our hospital.

Dr. Abramson read a notarized affidavit signed by Dr. Custodio stating that each patient had given verbal consent for the injection and that the consent was witnessed by Drs. Southam and Levin. Dr. Southam indicated that he would willingly testify that he witnessed such consent.

Testimony by Dr. Abramson (continued)

Dr. Abramson learned from Mr. Siegel that a reporter from the *World-Telegram* had called for information regarding resignation of three doctors because of certain research work. Dr. Abramson stated he saw Dr. Kagan who also stated he was approached by a man from the *World-Telegram*. He swore he gave no information and referred the reporter to officials at the hospital.

Discussion

Dr. David Kershner was highly impressed by the facts as presented. He felt the reaction of the coordinators to the project was not at all their affair, since they did not participate in the project.

He felt that it is an obligation of an institu-

tion such as ours to encourage research. We have a wealth of patient material that had never been properly utilized.

While it is advisable, wherever possible, to get written consent, it is not required by law. He suggested that use of the word "cancer" should be avoided for purpose of advancing ease of doing research projects.

Dr. Kershner stated that he was fully aware, based on his readings and clinical work, that there could not possibly be any danger to the patient in the project in question. He offered a vote of thanks to Mr. Siegel for the calm and professional manner in which the problem was handled, under very trying, emotional circumstances. He suggested that Dr. Mandel explain why the project was not handled through the research committee.

Dr. Kershner recommended the prompt acceptance of the resignations of the three coordinators and continuation of the research project, and that any calls for information from any source be referred to proper channels—Mr. Siegel, Dr. Abramson and Dr. Mandel.

Further discussion revealed that under our medical staff constitution, pilot studies may be initiated by directors of services without prior review by the research committee. However, should the director desire to continue a project, he must submit a protocol to the research committee within 60 days after initiation of the pilot study.

Dr. Mandel was called in. He indicated that in addition to the fact that this was a pilot study with a very limited number of patients, he had every intention of referring a protocol to the research committee. He admitted an oversight in not advising Dr. Rosenfeld of the study, but it was the general consensus of opinion that the director of service is not really obligated to advise all his subordinates on such matters. This question could offer no basis for charges against Dr. Mandel.

Dr. Mandel stated that the coordinators were never asked to give the injections. The projects were merely discussed with them to get their opinions. Each one thought the project had merit. It was totally untrue that they advised him that written informed consent was necessary.

He stated that only Dr. Kagan was asked if he was interested in participating, but not having gotten an answer in three days, Dr. Mandel assumed that he was too busy studying for

his board examinations and didn't want to become involved.

Mr. Harry Albert indicated that Dr. Mandel's intent should be judged in association with the very reputable Memorial Hospital and with the outstanding work done by Dr. Southam who is also associate professor of medicine at Cornell Medical School. He also questioned the involvement of Mrs. Tulipan in a complicated medical matter and strongly urged that she be forbidden to be further involved in this matter.

Dr. Abramson stated that none of the coordinators interviewed could adequately explain why Mrs. Tulipan was involved in a medical matter and why they had sent a copy of the letter of resignation to her.

Dr. Harry Weiner drew the following conclusions:

1. Dr. Mandel did not violate the constitution.
2. Resignations should be accepted.
3. A special committee should seek out facts as to who was involved in disseminating misinformation.
4. Report should be presented to medical board.
5. Responsibility for report should be the executive director's and chairman of the executive committee.

Dr. Lewis felt that the coordinators deserved to be heard. However, it was stated that they resigned without notice after being advised as to proper procedure for disposing of said matter; and that they resigned without arranging for adequate coverage of patients.

Conclusions

1. Resignations by Drs. Kagan, Fersko and Leichter were irresponsible and should be accepted.
2. There were no reasonable complaints against Dr. Mandel under the medical staff constitution.
3. A report should be submitted to medical staff.
4. All public relations matters related to this incident be referred to executive director.
5. Any medical reports resulting from the tests should be referred to research committee.
6. The scientific information resulting from this study was of outstanding significance and we should lend our support in continuing this project.

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Reply Affidavits for Petitioner

a.

**Bernard J. Pisani, M.D.—
January 17, 1964**

I was admitted to the practice of medicine and surgery in the State of New York since 1933. I have been a past president of the Medical Society of the County of New York. From 1954 to date I have served as director of obstetrics and gynecology at St. Vincent's Hospital.

The question has been put to me as to the propriety of a nontherapeutic experiment consisting of injecting live cancer cells into non-cancerous patients who have not been told that this injection consists of live cancer cells and who have not given their informed consent to this experiment. (By *informed* consent is meant the voluntary agreement of a patient capable of normal comprehension, *after* this patient has been told in lay language, the nature of the experiment, its hazards, present and potential, its complications and sequelae).

In answer to this question I state unequivocally that such an experiment, without the informed consent of the patient, is improper, unethical and immoral. Under no circumstances as a physician would I participate in or condone this type of experiment on any human being. The *known hazards* of such experiments include growth of nodules and tumors and may result in a *metastases of cancer* if the patient does not reject these cells.

In my practice of medicine and surgery and under the rules and regulations of St. Vincent's Hospital the informed written consent of the patient is required for all unusual or major procedures, therapeutic and experimental.

b.

Mendel Jacobi, M.D.—January 16, 1964

I hereby reaffirm the correctness of the statements made by me in my affidavit dated December 11, 1963.

It is stated in various affidavits filed with the answer of the respondents that the injections of cancer cells into patients at the Jewish Chronic Disease Hospital were performed merely to test the patients' immunologic reaction to these cells, not in order to determine whether cancer could be produced by such injections.

It is further stated that Dr. Mandel "was, of course, aware that homologous cells (cells from a human other than the person in whom they are injected) could not long continue to persist unless immunological reactivity was severely impaired." Finally it is indicated that previously performed experiments had demonstrated that delayed reaction of neoplastic tissue-cultured human cell homotransplants had occurred in cancer patients "due to an impaired immunological capacity" and that "At present the only method of evaluating this type of immunologic capacity is to observe the efficiency with which homotransplants are rejected."

From these statements alone it follows that the very measure of the immunologic response the experiments performed at the Jewish Chronic Disease Hospital were to test was to be the rate of rejection of the cancerous nodule expected to develop at the injection site. If the patients' immunologic responsiveness were severely impaired—and this, from the above-quoted statement, could only have been determined after such rejection of the locally produced cancer—cancer development could have occurred. Obviously, then, saying that the injections were for the purpose of testing immunological responsiveness is merely a reverse manner of saying that it was for the purpose of establishing whether a cancer would be rejected by these debilitated patients and if so, at what rate or with what degree of completeness.

As a matter of fact, if these homotransplants were to behave as had those in cancerous patients, there was the real possibility that the locally produced cancerous nodule would grow progressively and even metastasize. In a paper published in *Science*, Dr. Southam and associates described the homotransplants of cancer cells into 14 cancer-bearing patients, noted the development of a cancer nodule at the implantation site in from 5 to 10 days after the injection, and that it attained a maximum diameter of $\frac{1}{2}$ to 2 centimeters, in 1 to 2 weeks, at which time the nodules were excised completely for histologic study.

It is urged in several of the affidavits that cancer was not produced by the injections and/or that no patient was harmed in the slightest.

From one with the specific experience in the cancer field such as Dr. Southam has, or even from one who has not so limited his experience but has been in practice as long as Dr. Mandel, such statements are quite surprising in view of

the fact that cancer, even when completely clinically eradicated by adequate and even intensive treatment, is known to recur after long periods of latency free of all evidence of cancer. It is precisely for this reason that, in the field of cancer, one speaks not of cure but of 5-year, 10-year, 15-year, 20-year, etc. cure, meaning only that the cancer has not reappeared during such intervals. In view of the recurrence of the homotransplanted cancer in the debilitated cancerous patients, and in view of the fact that this was deemed due to debility rather than to their intrinsic cancer per se, and that, even now after the instant experiments, the basis for injected tumor rejection remains unknown, all that is presently warranted is the statement that the homotransplants of July 16, 1963 have disappeared as determined by local inspection and/or palpation and that some 2 months after the injections (or possibly some 5 months thereafter if the patients were re-examined at or about the date of the affidavits) no cancer is apparently present, a statement by no means equivalent to the non-development of, or freedom from, cancer in the patient.

Actually the fact that one patient, clinically free from evidences of cancer for the many preceding years of his hospital stay, developed overt clinical cancer of the bladder some 2 months after the homotransplants is rather disquieting. There is animal experimental evidence to indicate that delicate tumor-host relationship balances exist and that the growth rate of implanted tumors may upset these balances in manner adverse to the animal host. In the present vague state of knowledge as to the nature of these relationships one wonders whether the very development of a tumor nodule at the site of the cancer cells injected into this patient and its subsequent rejection by the patient—presumably this rejection involved the patient's defense mechanisms against cancer—had, in fact, exhausted these defenses, and had so upset the patient's tumor-host balance to the end that the bladder cancer, previously latent (i.e. kept from growth activity by the patient's body defenses) had now attained active growth capability and overt clinical activity. If this is the patient who, according to Dr. Mandel's affidavit "died in October following a bladder operation," this sequence of events is even more possibly significant and disturbing.

From the above facts one must conclude that the statements anent the non-development of cancer in the patients injected on July 16,

1963 or that they were harmed in no way are presently premature and unwarranted. One patient in this series is certainly dead under circumstances possibly indicating at least an indirect influence of the injections; as to the others, the post-injection period will have to extend for many years before such statement can become unequivocally demonstrable. Parenthetically it should be noted that, to the best of my knowledge, no one other than the people involved in these injection experiments at the hospital has made an independent examination of these injected patients with respect to the presence of cancer or of other complications possibly sequential to the injection, and that, if the 5 charts examined by me on October 4, 1963, are indicative, the records in the charts of the patients injected are in such a state that no conclusions as to any such developments were, or will be, possible.

NOTE

CHESTER M. SOUTHAM, ALICE E. MOORE, AND
CORNELIUS P. RHOADS
HOMOTRANSPLANTATION OF HUMAN
CELL LINES*

The development of human neoplastic cell lines that can be grown serially in tissue cultures and in heterologous hosts has made necessary the investigation of the capacity of such cells to grow in a homologous (human) recipient. Such studies are of fundamental importance to our knowledge of tissue transplantation and host defense mechanisms. In addition, there is the possible danger of initiating neoplastic disease by accidental inoculation during laboratory investigation or by injection with such cells or cell products if they should be used for production of virus vaccine. This article is a preliminary report of a continuing study of (i) the persistence and growth of neoplastic human cell lines after homologous transplantation and (ii) host reactions to such implants.

All recipients were volunteers who were aware of the general purposes of the study and the nature of the implanted materials and who were agreeable to subsequent biopsies.

* * *

... Usually a single preparation was inoculated at one or two sites, but a few recipients

* 125 *Science* 158-160 (1957). Reprinted by permission.

received two to four c and one received a total two occasions. Comp were usually performed palpable nodule appears, excision was delay growth and the process

Initial studies were patients with advanced very short life expectancy and metabolic complications. None had received treatment, ACTH, marrow as nitrogen mustard, 6 months preceding the start of any of these treatment studies.

Slight local induration followed inoculation completely by the third day. Fibroblasts with normal nuclei in three patients. No neoplastic cells inoculated. The same patients did not were available for study of normal origin were patients, usually produced these recurred in one patient. It can be considered normal tissue neoplastic characteristic passage, and the nodules named as cancer.

Twenty-four human cancer cell lines (seven cancer cell lines) were received between February 1955 and March 1956. Lines multiplied in medium indicated by formation of nodules at implantation site and cancer cells with metastases. ... Usually 7-10 days after implantation diameter of 1/2 to 2 cm then excised completely.

If they were not implants usually regressed completely by 4 to 6 weeks. In 6 patients there was recurrence after biopsy at several sites. These recurrences were repeat excision on the same site respectively. In two patients nodules grew. Two patients died, 42 days after implantation. ... In

time in experimental therapeutic studies. Further studies designed to detect possible differences in cellular and humoral defense mechanisms are in progress.

* * *

We, as well as our collaborators, wish to express our appreciation of and admiration for these volunteers, both cancer patients and normal individuals, who, without expectation or possibility of personal gain, have made these studies possible.

* * *

c. **David Leichter, M.D.—January 16, 1964**

In reply to the false, unwarranted accusations made against me in the answering affidavits submitted by the respondent, I wish to state the following:

As to the affidavit verified by me on September 12, 1963, I reaffirm the correctness of all my statements contained therein. The respondent seeks to impeach my credibility and the correctness of my statements by alleging that I have repudiated certain statements therein contained. This is utterly false.

7.

Rebuttal Affidavits for Respondent

a. **Chester M. Southam, M.D.—
February 4, 1964**

I address myself first to the question of the measure of risk of bodily harm to the patients who were the subject of the procedures in question at the Jewish Chronic Disease Hospital. At the outset I should say that in clinical procedures neither I nor any scientist or doctor can deal in absolutes. We are always limited, at least when dealing with the human body, to speaking in terms of measurable risks. Thus while no doctor or scientist can say as to any clinical procedure, even the simplest, that there is *no possibility* of untoward results, we are constantly required, both in therapeutic and in investigative procedures, to make judgments as to whether there is any unusual risk of untoward results, and if so, the degree of that risk. In terms of this standard I unhesitatingly assert that on the basis of

present biological knowledge supplemented by clinical experience to date there was no practical possibility of untoward results to the patients who received injections of homotransplants in the form of tissue-cultured cells derived from other patients. The probability of any unforeseen deleterious consequences of this test is so extremely small as to be comparable to numerous other procedures used routinely in clinical medicine for therapeutic, diagnostic, or investigative purposes, e.g., blood transfusions, intravenous pyelograms (kidney x-rays), or tuberculin tests. The fact that these cells were tissue-cultured cancer cells did not measurably increase any risk inherent in the procedure because, being foreign to the recipient (the person injected), they bring about an immunologic reaction (defense reaction, rejection reaction) that ultimately causes their destruction and elimination.

It has been known for many years that a human being will reject cells transplanted from another human being unless both are of precisely the same genetic makeup (i.e., identical twins). In fact, intensive clinical studies are now being carried on at many research centers attempting to find methods (such as treatment with certain drugs or x-ray) to overcome this rejection reaction in the hope that diseased organs, such as kidneys, might be successfully replaced. While the precise mechanisms of cell rejection are not yet known, the fact that such mechanisms exist is beyond question. The efficiency of this type of immunological reaction can be measured in terms of the time required for complete rejection of homotransplanted cells. As yet no other method of measuring this reaction has been found, and tissue-cultured cancer cells are the only kind of cells which provide sufficient reproducibility for comparison of results in different individuals at different times.

The three lines of cells derived from human cancer which were used in the studies at the Jewish Chronic Disease Hospital were derived from tumor tissues of three patients, from 4 to 12 years ago. Since that time these cells have been cultivated in sterile bottles in the laboratory in a solution of nutrients which include salts, vitamins and blood serum. This is the process called tissue culture. After such years of growth under these artificial laboratory conditions each line of cultured cells has a high degree of uniformity and, consequently, the reaction which it will produce is highly predictable. I have had an extensive experience with each of these three cell lines in homotransplantation studies in cancer

patients and in heal several years.

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patients and in healthy volunteers during the past several years.

In the early 1950's it began to appear that the defense mechanisms (i.e., the mechanism of rejection of homotransplants) of those persons who develop cancer might be in some way impaired. The most striking indication of this was the result of clinical tests on a limited number of patients with terminal cancer as reported over the signatures of myself and Drs. Rhoads and Moore in *Science*. These were all patients suffering from advanced stages of widely disseminated cancer for whom there was no known method of treatment to either inhibit their disease or prolong their lives, each of whom died as the result of his own cancer within a relatively short time. In view of the then state of knowledge the precise details of the procedure were explained and the patients freely and readily consented.

The significant result of the test was that the rate of rejection of the foreign transplants was in all cases slower than would have been expected, indicating that there was some impairment of their immunological reaction. Because these patients had far advanced cancer before the homotransplants were injected, they did not survive for long after the tests were performed. Obviously this was not the result of the test, but rather was the reason that these particular patients were selected for these earliest tests. In no case was the patient deleteriously affected by the implants. Several patients in this initial group and in subsequent groups had not rejected their transplants in the brief interval between the start of the test and their death. In fact, at autopsy a lymph node from the armpit of one of these patients contained unrejected cancer cells of the type used for the test. (These lymph nodes are in the natural route of drainage from the forearm where the test was made in this patient.)

Prior to the publication of the article in question tests were made on a number of volunteer healthy human beings in the Ohio Penitentiary. In all such cases the foreign transplants were quickly and completely rejected, as would have been expected.

After the initial tests reported in *Science*, intensive studies were undertaken, designed to increase our body of knowledge as to the immunological reaction both of normal healthy persons and those with cancer, to homotransplants of tissue-cultured lines of human cells derived from normal and tumor tissues. Between the time of the initial tests and July 16, 1963 (the

date on which the injections were made in Jewish Chronic Disease Hospital) approximately 600 persons had been studied by means of the techniques employed at Jewish Chronic Disease Hospital, approximately 300 of whom were patients with cancer and 300 healthy, normal persons. In every healthy recipient of tissue-cultured cells, these foreign transplants were rejected with uniform promptness. Some patients with cancer rejected the cells less rapidly and after significantly varying intervals of time. Patients in the earlier stages of neoplastic disease showed normal or only slightly impaired rejection reaction. Patients in the terminal stages of cancer showed the greatest deficiency in these immunological defense mechanisms (as measured by the length of time to effect rejection) and in several such persons rejection had not been accomplished in the few weeks or months that elapsed between injection of the test cells and the patient's death from his own cancer. These patients died from the effects of their own cancer before the expected ultimate rejection of the implants. The studies also demonstrated a correlation between the rate of rejection of homotransplanted cancer cells and the patient's apparent ability to restrain his own disease, thus providing additional direct evidence that patients may have immunological (defense) mechanisms to restrain their own cancer. These results, of course, give hope that, through further clinical research, methods of stimulating such mechanisms to greater efficacy can be developed.

The studies of healthy, normal persons at the Ohio Penitentiary, aside from demonstrating that the normal body will reject cancer cell homotransplants with the same efficiency as other types of homotransplants, further indicated the potentially highly significant fact that the body's rate of rejection increased with successive implantations of foreign cancer cells, suggesting long-run possibilities of building up the immunological mechanisms where deficiencies now occur. At present, studies are being continued to verify these scientific observations and to investigate their possible applicability to the treatment and prevention of human cancer. Such studies of human cancer can be accomplished only through the cooperation of patients and healthy volunteers.

Until the investigation conducted at the Jewish Chronic Disease Hospital, there was no direct clinical evidence that the impairment of the immunologic responses in patients with advanced cancer (as measured by the slow rate at

which they rejected homotransplants) was associated with the fact that they had cancer rather than with the fact that they were in a debilitated state. This study provided direct clinical evidence that indeed the impairment was associated with the fact of cancer rather than general debilitation. The patients at Jewish Chronic Disease Hospital reacted in essentially the same manner as normal, healthy human beings. I want to make perfectly clear that the question in this investigation was not whether the patients would reject the tissue-cultured cancer cell homotransplants. The only question was how fast would the body mobilize its resources of rejection. Three patients known to have cancer were also included in these tests. It was expected that rejection in the three cancer patients might be delayed, consistent with our previous experience in cancer patients, but that rejection would occur after the predicted delay unless these patients succumbed very rapidly to their own cancer.

I next turn to the question of procedures. In the early stages of this clinical research and, indeed, until the last few years a full explanation was given to the patient or healthy volunteer, including the fact that the techniques employed were not designed for his own therapy, the nature of the cultured cells involved, the general purposes of the test and the expected reactions. More recently, as our body of knowledge has increased and the course of reaction to the injections became predictable, we have simply explained that the procedure was a test which had nothing to do with treatment, that it involved the injection of foreign material, described the expected course of reaction, and that its purpose was to determine the rate at which the expected nodules would develop and then regress. In all instances in which the test was done the patients have readily given their consent, and the tests were not performed if such consent was not readily given. Unless the patient inquired, we refrained from describing the precise nature of the human cells (i.e., that they had originally been derived from tumors and then grown in tissue culture) for the reason that in my own professional judgment as well as that of my professional colleagues who had followed the course of these experiments, the precise nature of the foreign cells was irrelevant to the bodily reactions which could be expected to occur.

This course was followed, I submit, not out of any disregard for the rights or best interests of the patient nor of my responsibilities as a practitioner of medicine. It was a sincere profes-

sional judgment, based upon extensive scientific and clinical experience, that the procedures involved only the same low degree of risk inherent in many routine clinical test procedures, the patient in all such cases being informed only of the facts which are important from his standpoint. I submit that but for the highly emotion-charged term "cancer cells," this conclusion would be unquestioned by those in the medical profession who are fully cognizant of the present stage of knowledge with respect to immunological reactions.

Furthermore, in my own clinical judgment—based on fifteen years of clinical management of advanced cancer patients—to use the dreaded word "cancer" in connection with any clinical procedure on an ill person is potentially deleterious to that patient's well-being because it may suggest to him (rightly or wrongly) that his diagnosis is cancer or that his prognosis is poor. Some cancer patients do not know that their diagnosis is cancer, and even those who have been informed rarely discuss it and may even deny it. It is seldom possible for the physician to be full cognizant of the cancer patient's extent of knowledge of and his attitude toward his disease. The doctor's choice of words in discussions with the patient has a great influence upon the patient's mental attitude. Since the initial neoplastic source of the test material employed was not germane to the reaction being studied and not, in my opinion, a cause of increased risk to the patient, I believe that such revelation is generally contraindicated in the best consideration of the patient's welfare and therefore to withhold such emotionally disturbing but medically non-pertinent details (unless requested by the patient) is in the best tradition of responsible clinical practice.

On these questions concerning procedure, I will readily submit to the judgment of my colleagues after they are fully informed.

b.

Frank L. Horsfall, Jr., M.D.—
February 4, 1964

I am now and have been since 1937 licensed to practice medicine in the State of New York. I am now and have been since April 1, 1960 president and director and chief executive officer of the Sloan-Kettering Institute for Cancer Research, New York, New York, as well as director, Sloan-Kettering Division, Graduate School of Medical Sciences, Cornell University Medical College.

I hold now 1960 the rank of University Medicine.

I have read Southam sworn and generally familiar with the facts described therein in complete accordance with the opinions expressed by

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Henry Th...
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I am now licensed to practice medicine in New York. I am vice president of Memorial Hospital and medical director and president for clinical research at the Sloan-Kettering Institute for Cancer Research, New York, New York, of surgery in Cornell University Medical College.

I have read Southam sworn and generally familiar with the facts described therein and their implications in accordance with the opinions expressed by Dr. Southam in

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The method of the Sloan-Kettering Institute in its papers, must be in accordance with basic medical principles and must be in accordance with the judgment of the medical profession. There are many physicians for the treatment of cancer which may be given to patients. Yet, it is not normally going explanation of oral consents (e.g., intravenous X-ray treatment, administration of and phosphorus).

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I hold now and have held since April 1, 1960 the rank of professor of medicine, Cornell University Medical College.

I have read the affidavit of Chester M. Southam sworn to February 4, 1964. I have been generally familiar with the clinical tests described therein and their results to date. I am in complete accord with the professional opinions expressed by Dr. Southam in his affidavit.

**Henry Thomas Randall, M.D.—
February 4, 1964**

I am now and have been since 1941 licensed to practice medicine in the State of New York. I am vice president for medical affairs of Memorial Hospital for Cancer and Allied Diseases and medical director of this hospital; also vice-president for clinical affairs of the Sloan-Kettering Institute for Cancer Research, and professor of surgery in Cornell University Medical College.

I have read the affidavit of Chester M. Southam sworn to on February 4, 1964. I am generally familiar with the clinical tests described therein and their results to date. I am in complete accord with the professional opinions expressed by Dr. Southam in his affidavit.

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**Emanuel E. Mandel, M.D.—
February 4, 1964**

The method of obtaining the consents to the Sloan-Kettering tests, outlined in the answering papers, must be evaluated in relation to the basic medical principle that the extent of information to be imparted to the patient must be left to the judgment of the responsible physician. There are many standard techniques used by physicians for the purpose of diagnosis and treatment which may result in injury, or even death, to patients. Yet, in the interest of the patient, they are not normally preceded by any thorough-going explanations, or even by any written or oral consents (e.g., penicillin injections, the obtaining of intravenous pyelograms, "BSP" tests, X-ray treatment for non-cancerous patients, the administration of radioactive substances (iodine and phosphorus), etc.).

It must be patent that the investigative team of Sloan-Kettering and JCDH acted in full compliance with conventional procedure accepted by the medical profession at large. The injections of cell suspensions in question here

were no more hazardous than any of the above named routine tests, and, indeed, far safer than most of them or perhaps all of them. In fact, consideration was being given at the outset of this study to the possibility of adopting those injections as routine tests to uncover hidden (sub-clinical) cancer, since it was regarded as a routine test at Memorial Hospital (see minutes of the hearing in the offices of the New York State Education Department on December 19, 1963). For even advanced (metastatic) cancer can escape the physician's attention in a patient suffering from other chronic and debilitating disease, and even advanced cancer can, at times, be treated with success. There is no basis for the argument of Dr. Strauss and other medical witnesses that the tests were "dissociated" from the "patient's ailment and condition."

NOTE

**EARL UBELL
INJECTING CANCER CELLS—THE CASE FOR
THE DEFENSE***

Would you take an injection of a million cancer cells in your arm? The thought of it will send shudders through any normal person unfamiliar with modern biology. He thinks: what if those cells took hold and grew into a full, deadly cancer?

Yet almost every cancer biologist knows that one of the hardest biological tricks to pull is to transplant a cancer from one animal to another. And nobody has ever transplanted a cancer from one human being to another.

At the same time such experiments on human beings—injecting cancer cells—have the possibility of an enormous pay-off: a vaccine against cancer or a technique for helping the body get rid of cancer.

Given this information, one wonders why cancer injection tests on patients at the Jewish Chronic Disease Hospital in Brooklyn raised such a brouhaha. It is entirely possible that the doctors involved made a tactical error in failing to describe fully to the patients or to their families every step of the experiment. But even if they omitted the deadly word: cancer, have they hurt their volunteering patients? The answer is no.

The experiments in this field began with a question: is there something wrong with the can-

* *New York Herald Tribune* 29, col. 5 (January 26, 1964). Reprinted by permission.

cer patient's defenses against cancer? The possibility had been raised by a whole series of tests on animals.

* * *

Dr. Southam induced 96 healthy men incarcerated at Ohio State Penitentiary at Columbus to volunteer with the full knowledge of what he was going to slip under their skin.

Since that time more than 300 prisoners have volunteered for the tests. In not one of them did the cancer cells become a full-blown cancer. Most of the cells died within days; in some volunteers it took a couple of weeks. When the same volunteers received additional injections, their bodies killed off the cells even more quickly.

* * *

But what about cancer patients? At about the same time Dr. Southam secured volunteers among the dying cancer victims at Memorial Hospital which is associated with Sloan-Kettering. Most of them were not only willing, but eager to help saying: "I know it is too late for me. Maybe this will help somebody else."

The cancer cells lived longer in the cancer victims than in the healthy volunteers. In one instance, a patient with an advanced cancer of his own died of his disease six months after receiving the injection of cancer cells. The injected cells were still alive and localized.

These tests indicated that in the cancer patient the defenses were down or at least weak. Similar results followed in almost 300 cancer patients. But none of the injected cells turned into full-blown cancers on their own.

Because of the results—namely that the injected cells never took over—Dr. Southam and his associates told their volunteers less about the nature of the injections to save them any possible anguish. Each patient was told that he was volunteering for a test, not a treatment.

Still, a basic biological issue remained open. Was the weakened defense a result of cancer or did it come simply from a person's being very sick and debilitated? Wasn't it possible that if somebody suffered a severe heart attack, say, and lost 60 pounds and was very weak, that the defenses against cancer might also be low?

It was this question which Dr. Southam tried to answer with the experiments carried out by the doctors at the Jewish Chronic Disease Hospital in Brooklyn. The results are in: these patients had the same response to the cancer cells as the healthy volunteers: the cells died in a few

days to two weeks, at most. The anti-cancer defenses were strong.

Here, then, we have a wide possibility: if there is such a biological mechanism as a defense against cancer, then it may be possible to stimulate it either before cancer strikes or perhaps even later when the cancer has taken hold.

This is the question which Dr. Southam is trying to pursue. It would be a shame if a squabble over who-told-what-to-whom should destroy a thrilling lead in cancer research.

* * *

8.

Sur-Reply Affidavit for Petitioner

Statements by Nathan Fink—
January 25 and February 1, 1964

[i] I, Mr. Nathan Fink, aged 73, make this statement, while a patient at the Brooklyn Chronic Disease Hospital.

Sometime in July or August of 1963, while a patient at the above hospital, two doctors visited me at my bedside and told me that I was to get an injection. This was supposedly a skin test, I was informed. They did not ask my approval nor consent.

A few days later, I detected a hardening under the top layer of my skin, in the area where I had previously been injected, my right thigh. This hardening enlarged about 2½" in length.

During the next six or seven weeks, I was visited by these two doctors, every second or third day, at which time, one would measure the area with a ruler, and the other one would make notations in a small book. I do not know the name of these two doctors but one of the doctors, the one who made the notations in the book, was a Filipino.

Within a period of seven weeks, the hardened area seemed to have subsided, and I was informed, by the two doctors that I had a good resistance, and that the skin injection, performed upon me, had been successful.

After reading the most recent newspaper articles, about the cancer injections, performed on patients at this hospital, I now have reason to believe that I was one of the patients used as a guinea pig, in conjunction with this cancer experiment.

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Hyman v. Jev
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CONE, J.

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portunity by the doctors at this hospital, to ac-
cept or refuse this injection, nor was I ever told
what was the actual purpose of this experiment.

[ii] I recently submitted a statement regard-
ing an injection which I was given while a pa-
tient at B.C.D. Hospital. In that statement, I ad-
vised that I believed that this injection was a
cancer experiment and that I had never given
any one my oral or written consent for this ex-
periment.

I now wish to amend this statement pre-
viously submitted. About 1 month after the in-
jection given me in July 1963, I was approached
by the same 2 doctors, at which time they sug-
gested that I sign a blank questionnaire.

I asked what this was all about and was in-
formed that they intended to give me a new ex-
perimental pill to pep up my appetite. They fur-
ther stated that my signature was necessary for
them to administer this pill. Naturally I signed
this questionnaire because at this time I was
actually suffering from lack of appetite.

I never was given this pill after they ob-
tained my signature, although I asked about the
pill on many occasions.

Now that I realize about the unauthorized
injection given me in July 1963 and the subse-
quent signature taken from me, I have more rea-
son to believe I was tricked into taking a cancer
experiment with subsequent authorization.

9.

Opinions of the Court

a. **Hyman v. Jewish Chronic Disease Hospital**
42 Misc.2d 427, 248 N.Y.S.2d 245
(Sup.Ct. 1964)

CONE, J.

In this article 78 proceeding the petitioner,
a member of the board of directors of the re-
spondent, seeks an order directing the respondent
to permit the inspection and the making of cop-
ies by the petitioner of the minutes of the board
of directors and the report of its executive direc-
tor made at such meeting held on September 30,
1963, the report of Dr. Abramson made by him
at the medical board meeting of October 28,
1963, the affidavit of Dr. Custodio, as well as the
charts and records of the patients who submitted
to the subject tests. In addition, by affidavit dated
February 6, 1964, the petitioner enumerates other
records that he demands access to.

It appears undisputed that the respondent,
as a result of this application, has furnished the
petitioner with the minutes of the board of
directors, the report of the executive director and
the report of Dr. Abramson, as well as the affi-
davit of Dr. Custodio, but refuses to turn over to
the petitioner the charts and records of the pa-
tients without the consent of such patients as
being precluded under section 4504(a), CPLR.

The court in making its present determina-
tion, is not passing upon the merits of the al-
leged improper acts or upon the technical as-
pects of the tests given to the patients of the
respondent. It is merely called upon to deter-
mine the narrow issue as to the right of a mem-
ber of the board of directors to obtain an order
permitting an inspection and the making of the
copies requested.

It is the well-established law of this state
that a director has an absolute and unqualified
right to the inspection of the corporate records
regardless of his motives (*Matter of Cohen v.*
Cocoline Products, 309 N.Y. 119; 127 N.E. 2d
906).

The basis for this premise taken by our
courts is aptly stated by the court in *Cohen v.*
Cocoline (*supra*): "In order properly to per-
form his directing duties, a corporate director
must, of course, keep himself informed as to the
policies, business and affairs of the corporation
and as to the acts of its officers. He owes a
stewardship obligation to the corporation and its
stockholders, *and he may be subjected to liabil-*
ity for improper management during his term of
office. Because of those positive duties and poten-
tial liability the courts of this state have accorded
to corporate directors an absolute, unqualified
right, having its roots in the common law, to in-
spect their corporate books." (Emphasis sup-
plied.)

* * *

Accordingly, the petition is granted . . .

b. **Hyman v. Jewish Chronic Disease Hospital**
21 App.Div.2d 495, 251 N.Y.S.2d 818 (1964)

PER CURIAM.

The question presented on this appeal is
whether a member of the board of directors or
of the board of trustees of a hospital membership
corporation is entitled as a matter of right to an
inspection of medical charts of patients at the
hospital. Special Term held that he is so entitled.
We are of the contrary opinion.

Special Term directed that the hospital also permit petitioner to inspect records of a financial and administrative nature (e.g., books of account, fiscal records, minutes of the meetings of the board of directors, of its medical boards and committees, and rules and regulations governing the handling of patients). The hospital has acceded to such direction and has allowed petitioner to inspect such records; and such records are not involved on this appeal.

The genesis of this controversy and the facts giving rise to it may be briefly stated:

As the result of approximately ten years of research, Dr. Chester M. Southam of the Sloan-Kettering Institute for Cancer Research found that cancer patients did not have as marked a defense against cancer as did non-cancer patients. It is a biological law that human beings will reject cells which are transplanted from another human being unless both persons are of precisely the same genetic constitution (e.g., identical twins). It was found that, when a healthy individual was injected with the cancer cells of another individual, the healthy person promptly rejected the transplant, whereas when a cancer patient was injected with such foreign cancer cells, rejection of the transplant was delayed. What was not known was whether the foreign cancer cells lived longer in cancer patients (as contrasted with non-cancer patients) as the result of the pre-existing cancer or as the result of the patient's general weakness and debilitation. It was this question which Dr. Southam attempted to answer by the experiments conducted at the Jewish Chronic Disease Hospital; and it is these experiments which are involved in the present appeal.

The experiments showed that the sick and debilitated non-cancer patients had the same response to foreign cancer cells as healthy volunteers, that is, there was a prompt rejection of the transplant. This in turn opened a wide possibility that, if there be such a biological mechanism as a defense against cancer, it may be possible to stimulate it either before cancer strikes or perhaps even later when the cancer has taken hold.

The project was financed by the United States Public Health Service and by the American Cancer Society. It was undertaken by Drs. Southam and Levin of the Sloan-Kettering Institute at the Jewish Chronic Disease Hospital, with the permission of Dr. Mandel, director of the department of medicine and director of medical education of the hospital.

On July 16, 1963, under the supervision of

Drs. Southam and Levin, 22 patients at the hospital were injected with foreign cancer cells on the anterior surface of one thigh at two sites just beneath the skin. The patients were not told that the injection was of cancer cells because the doctors did not wish to stir up any unnecessary anxieties in the patients. The doctors felt there was no need to tell the patients that the injected material contained cancer cells because: (a) it was of no consequence to the patients; (b) the precise nature of the foreign cells was irrelevant to the bodily reactions which could be expected to occur; (c) it was not germane to the reaction being studied; and (d) it was not a cause of increased risk to the patient.

However, the patients were told that an injection of a cell suspension was planned as a skin test for immunity or response. The patients were also told that within a few days a lump would form and would last for several weeks and gradually disappear. The patients were observed for several weeks after the injection of July 16, 1963. As expected, the lump developed and disappeared within an average period of from six to eight weeks.

The hospital and the doctors in charge of the experiment claim that each patient gave his oral consent. Petitioner, however, claims that the patients were either incompetent to give their consents or that they did not understand to what it was they were being asked to consent.

On December 2, 1963 this article 78 proceeding was instituted by petitioner to obtain the hospital records which are involved in this proceeding, as well as the hospital's financial and administrative records. The application was granted at Special Term on the ground: (a) that, regardless of his motives, a director of a membership corporation, as well as a director of a business corporation, has the absolute and unqualified right to inspect corporate records; and (b) that the disclosure of the patients' medical records to a member of the hospital's board of directors is not within the doctor-patient privilege because it is a disclosure to a member of the hospital's administration—one who has a legitimate interest in the contents of the patients' records.

In our opinion, the determination of the Special Term was improper for several reasons:

(1) Although the experiments were not conducted for the purpose of diagnosis or treatment of the patients, the results of such experiments nevertheless comprised part of the medical charts of the patients and, therefore, come

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(2) It has been held that a director of a stock exchange is not required to keep himself informed of the policies, business and affairs of the exchange. *Cohen v. Cocoline*, 100 N.Y.S.2d 915 (1951). This rule also applies to a member of the board of trustees of a hospital. *Terter of Davids v. Board of Trustees of Hospital for Chronic Diseases*, 41 N.Y.S.2d 915 (1951).

(3) A corporation is liable for an inspection of the premises if he may be subject to management during the inspection (*of Cohen v. Coca-Cola Co.*, 2d 906). However, liability is here not a Membership Corp. in the absence of fraud of a membership corporation liable for its debts is only when a director in a wrongful act (*Hinkle Iron Co. v. ...*) is no claim of bad participation on the

(4) The petitioner, in his capacity as the hospital's patient physician who cannot proceed by any party in question has been

(5) The hospital's policy, in accordance with previous experiments such as those to be done only with the approval of the patient's family after the patient has been informed, was approved on September 7, 1963 by the hospital's board of trustees. On March 30, 1963 its board of trustees approved a grievance committee. In 1964 the hospital's

* 31 N.E.2d 3

† 127 N.E.2d

‡ 79 N.E.2d 4.

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within the physician-patient privilege (*Matter of New York City Council v. Goldwater*).^{*} Since the patients have concededly not waived the privilege, petitioner is not entitled to an inspection of such records.

(2) It has become a well settled rule that a director of a stock corporation is entitled to an inspection of the corporate books in order to keep himself informed as to the corporation's policies, business and activities so that he may carry out his duty to direct its affairs (*Matter of Cohen v. Cocoline Products, Inc.*).[†] The rule also applies to a membership corporation (*Matter of Davids v. Sillcox*).[‡] However, by this rule it was never intended to permit a member of the board of directors or of the board of trustees of a hospital to inspect the medical charts of hospital patients (*Munzer v. State, Ct. Cl.*, 41 N.Y.S. 2d 98; *Munzer v. Blaisdell*, 49 N.Y.S.2d 915).

(3) A corporate director is also entitled to an inspection of the corporation's books because he may be subjected to liability for improper management during his term of office (*Matter of Cohen v. Cocoline Products, Inc.*, 127 N.E. 2d 906). However, the possibility of petitioner's liability is here non-existent. Section 46 of the Membership Corporations Law provides that, in the absence of fraud or bad faith, the directors of a membership corporation are not personally liable for its debts, obligations or liabilities. It is only when a director personally participates in a wrongful act that he is personally liable (*Hinkle Iron Co. v. Kohn*, 128 N.E. 113). There is no claim of bad faith or fraud or of personal participation on the petitioner's part.

(4) The petitioner does not have the right, in his capacity as trustee or director, to act for the hospital's patients. It is only the patient or his physician who can act for the patient. No proceeding by any patient to obtain the information in question has been instituted.

(5) The hospital's future policy will be in accordance with petitioner's contention that experiments such as the one here involved should be done only with the patient's written consent after the patient has been properly informed. On September 7, 1963 the hospital's grievance committee approved the experiment. On September 30, 1963 its board of directors approved its grievance committee's report. On January 27, 1964 the hospital's research committee approved

^{*} 31 N.E.2d 31.

[†] 127 N.E.2d 906.

[‡] 79 N.E.2d 440.

continuance of the cancer immunization studies, but only upon the written, informed consents of the patients. Therefore, no further need for the inspection exists. It should be noted that petitioner is now in possession of the facts as to the manner in which the experiment was conducted on July 22, 1963; as to what information was given to the patients; and as to what information was not given to them.

Accordingly, the order, insofar as appealed from, should be reversed on the law and the facts, with costs; and the petitioner's application should be denied insofar as petitioner seeks the disclosure of the: (a) charts and records of patients who had been subjected to the experimental injection of live cancer cells; (b) the death certificates of any such injected patients who later died; and (c) the pathological studies, slides and laboratory data relating to all of said injected patients.

The inspection under the order (insofar as the order has not been reversed) shall proceed on twenty days' written notice or on such other date as the parties may mutually fix by written stipulation.

* * *

C.
Hyman v. Jewish Chronic Disease Hospital
15 N.Y.2d 317, 206 N.E.2d 338 (1965)

DESMOND, CHIEF JUDGE.

Special Term was correct in its holding that petitioner, being a director of a hospital corporation, is entitled as matter of law to an inspection of the records of the hospital to investigate into the facts as to alleged illegal and improper experimentation on patients (*Matter of Cohen v. Cocoline Products*, 309 N.Y. 119, 127 N.E. 2d 906; *Matter of Martin v. Martin Foundation, Inc.*, 32 Misc. 2d 873, 224 N.Y.S. 2d 972).

It is argued that the data as to such experiments on patients are privileged (CPLR 4504 [a]) and that the patients have not waived the privilege. Any such confidentiality could be amply protected by inserting in the court's order a direction that the names of the particular patients be kept confidential. Actually, the supposed strict secrecy does not really exist as to qualified persons since these records have been seen, read and copied by numerous staff members and employees of the hospital and of the co-operating institution.

We are told that, since this petitioner direc-

tor would not be personally liable for the wrongdoing of the hospital, he does not need such an inspection. However, the possibility of liability of the corporation of which he is a director entitles him to learn the truth about the situation on which such alleged liability may be predicated. Again, it is said that a director should not be allowed to act on behalf of the patients without their authority. We do not understand the petitioner to claim any such right of representation. He is carrying out his own duties as a director—to direct the affairs of the corporation.

It is argued, again, that an inspection is unnecessary since newly enacted rules of the hospital now require that written and informed consents of the patients be obtained before experiment. This fact, however, cannot be an obstacle to this director's effort to learn the full truth as to what has been done in the past.

No one seriously questions the right and obligation of a membership corporation director to keep himself informed as to the corporation's policies and activities so that he may do his duties and carry his responsibilities. Any necessary safeguards and protections can, in the discretion

of the Special Term, be provided by its order, including appropriate arrangements for concealing the names of individual patients if that appears to be necessary or proper. The order appealed from should be reversed, without costs, and the matter remitted to Special Term for further proceedings not inconsistent with this opinion.

SCILEPPI, JUDGE (dissenting).

I would affirm especially on the unique facts of this case: (1) The State Department of Education is inquiring into the matter; (2) the Kings County district attorney has been alerted to the situation; (3) the petitioner already knows the facts underlying his contention that the injections were given without the informed consent of the subject patients; (4) the informed consent of the patients is now required; and (5) all administrative and financial records have been ordered turned over to the petitioner. Since petitioner is already in possession of the facts as to the manner in which the experiments were conducted, no further need for the inspection exists.

C.

How and by Whom Should the Consequences of Research Be Reviewed?

1.

Informing the Board of Regents Grievance Committee for Decision

a.

Louis J. Lefkowitz, Attorney General of the State of New York Petitioner's Post-Hearing Memorandum

IN THE MATTER of the

Application for the revocation of the authorization and license heretofore granted to EMANUEL MANDEL, M.D. and CHESTER SOUTHAM, M.D. to practice medicine in the State of New York, and for the cancellation of their registrations as such, and for such other relief as the premises warrant.

THE STATUTES

The applicable provisions of the Education Law are as follows:

Section 6514. Revocation of Certificates.

2. The license or registration of a practitioner of medicine . . . may be revoked, suspended or annulled or such practitioner reprimanded or disciplined in accordance with the provisions and procedure of this article upon decision after due hearing in any of the following cases:

2 (a) That a physician . . . is guilty of fraud or deceit in the practice of medicine. . .

2 (g) That a physician is or has been guilty of unprofessional conduct. As implemented and defined by the Rules of the Commissioner, filed pursuant to Statute in the Office of the Secretary of State under Title 8, part 60.1, subd. (d) 7 of the Official Compilation Codes, Rules and Regulations of the State of New York, i.e. "immoral conduct of a physician in his practice as a physician."

1. A VALID AND INFORMED CONSENT WAS NOT OBTAINED SINCE THE PATIENTS WERE NOT FULLY INFORMED OF THE NATURE AND DETAILS OF THE EXPERIMENT.

At the outset, it should be firmly understood that while we are dealing with 22 patients in a

hospital, what was mentation involved care or treatment of the patients they had; and

It should also be noted that the patients had a right to be informed from those charged with the hospital in its operations that only those patients who gave consent of drugs that were administered and treatment be given.

. . . An argument is made that they had not sufficient ability to comprehend or what was being done to them may have had the right to be given the full truth.

As to patient Rosenfeld, this patient had a physical handicap; was always in a wheelchair; had difficulty in walking; did not understand what was being explained and his symptoms had been treated from 1959 to 1964. His condition worsened and he was further stated as being unable to understand type performed with

Rosenfeld to a vegetative state after one year at the hospital without consent.

Southam testified that he had complete possession of the patient's agreement to participate in the experiment; that each patient was ambulatory and drooled considerably and was capable of understanding.

This testimony is contradicted by the observations made by the examining physician. An examination of the patient reveals Southam said that on August 13, 1964, the patient was in a vegetative state.

Further, when given to Southam for four visits—where Dr. Leichter or Rosenfeld was constantly in attendance for many years.

vided by its order, ements for conceal- patients if that ap- per. The order ap- sed, without costs, ecial Term for fur- tent with this opin-

lly on the unique State Department to the matter; (2) attorney has been e petitioner already his contention that hout the informed s; (4) the informed v required; and (5) ncial records have e petitioner. Since sion of the facts as e experiments were for the inspection

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of a practitioner of d, suspended or an- primanded or disci- provisions and pro- decision after due g cases:

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se firmly understood ith 22 patients in a

hospital, what was done to them, in the experi- mentation involved herein, was not done in the care or treatment of whatever illnesses or infirm- ities they had; and the respondents so admit.

It should also be remembered that, [all patients] had a right to expect and to demand from those charged with the administration of the hospital in its care and treatment of patients, that only those procedures and administrations of drugs that were a necessary part of their care and treatment be given and administered.

. . . An analysis of the patients selected amply illustrates that a substantial number of them had not sufficient mental or physical abil- ity to comprehend what was being told to them or what was being done to them; and those who may have had the capacity to understand were not given the full and true nature of the experi- ment.

As to patient #18: Leichter had testified this patient had Parkinsons; developed lung ab- scess; was always running and falling against wall; had difficulty in communicating; that pa- tient did not understand what was being ex- plained and his speech was unintelligible. Leich- ter had treated this patient during the years from 1959 to 1963 and stated the patient's con- dition worsened with respect to July 16th. He further stated as his opinion this patient was unable to understand what an experiment of the type performed would mean.

Rosenfeld testified this patient was in a vegetative state and incommunicative the last year at the hospital; and could not have given a consent.

Southam testified this patient was in com- plete possession of his senses to extent he nodded agreement to permit examination at site of in- jection; that each time Southam saw the patient he was ambulatory, had marked shuffling gait, drooled considerably; that he did not regard the patient to be in a vegetative state, but was fully capable of understanding.

This testimony of Southam's is based upon observations made *after* injections were given. An examination of the record of this patient re- veals Southam saw patient first time July 19th, then August 13, August 20 and finally October 1st.

Further, what probative weight should be given to Southam's testimony—based as it is on four visits—when it is compared to that of Leichter or Rosenfeld, doctors who have been constantly in attendance at Blumberg Building for many years prior to date of injections, and

who have seen this patient countless numbers of times, examined him and treated him?

Mandel testified he *did not* see this patient before July 16th: introduced report of psychia- trist made August 16th stating "patient is diffi- cult to understand." Mandel stated he did not consider this a psychiatric report and that the charts were very defective. Stated he saw patient on October 5th, 1964 when the patient walked slowly, needed support, drooled a lot; tried to avoid speaking; found him fully alert and aware of place, time and what was going on and an- swered intelligently whatever questions were asked. Mandel submitted another psychiatric re- port dated October 27th, 1964 which stated pa- tient was alert, oriented, denied hallucinations, illusions. It should be recalled that on cross- examination Mandel had testified he saw this patient *prior* to July 16th, but did not recall when; that patient drooled a lot; that patient's condition was essentially unchanged for last two or three years. Mandel could not state whether patient avoided speaking when he saw him prior to July 16th. Again, it should be re- called that Mandel, on direct examination, had testified he first saw the patient around Decem- ber, 1963 and then again October 5th, 1964, and a week before he was testifying on November 4th.

Custodio testified that he did not agree with Rosenfeld's testimony concerning this pa- tient that he was in a vegetative state and in- communicable. Custodio stated he knew patient since his service in 1961; that although patient had difficulty communicating with others who did not know him, he, Custodio, never had any difficulty and that patient understood him.

Mandel's testimony relative to this patient should be completely disregarded; he has con- tradicted himself as to when he first saw this patient. Even assuming he had seen the patient before July 16th, he gives no valid testimony concerning the patient's condition. As to Cus- todio, while he testified he disagreed with Rosen- feld's testimony he was silent as to his thoughts regarding Leichter's testimony, and it must therefore be assumed he agreed with Leichter.

It is respectfully urged, with respect to this patient, that Leichter and Rosenfeld, because of their length of service in Blumberg Building, were in a much better position to see, examine and observe this patient than were Southam (who never saw the patient before July 16th), Mandel and Custodio. Mandel's testimony is contradictory as to when he first saw the pa-

tient; at one time he testified it was October 5th, 1964; at another point in his testimony he fixed the time as at December, 1963; and still another point he stated it was *before* July 16th, but could not recall when. Custodio at least agreed the patient had difficulty communicating with others who did not know him.

It is submitted that the testimony of Leichter and Rosenfeld as to this patient should be accepted by the committee; and that a finding be made declaring this patient was incapable of understanding and thus could not have given a valid consent to participate in this experiment.

While only the records and testimony pertaining to a few patients have been shown to illustrate that the believable and probative proof established the absence of ability to understand fully the scope of the experimentation and thus give valid consent, it is by no means conceded that, in those patients not shown, there was present ability to understand and give consent.

The procedures adopted by the respondents in their conduct in pursuing the same give rise to certain compelling and important questions:

Was there any attempt on the part of Mandel, the director of medicine at JCDH, to in any way help or assist Custodio in the selection of the 19 patients in the Blumberg Building? And the answer, admittedly, was NO! Surely, this was a worth-while project—Mandel had been properly enthusiastic—but only to the extent of selecting the three cancer patients and actually being present when two of them were injected by Southam, and then Mandel left! But what of the patients in the Blumberg Building—should they have been placed at the beck and call of Custodio, or, more logically, should not this selection have been made by others more qualified, such as Rosenfeld, head of the Blumberg Building or Leichter who was not only familiar with the patients but was in charge of a cancer research project sponsored by the NIH. Was Custodio fully competent to participate in this project? On his own admission, he had never participated in such an experiment, nor had he read any literature relating to it. All he knew was what Mandel had told him. And what did Mandel know of this project? Only what Southam had told him, and the gist of what Southam told Mandel is that there was no risk to the test, that it was being done regularly at Memorial and that oral consent was sufficient with no knowledge to the patient that cancer cells were to be injected!

Why wasn't a careful screening done by both Mandel and Custodio, with a careful

scrutiny of the hospital records which were available to them prior to July 16th? Why wasn't, prior to July 16th, a detailed statement prepared concerning the test, detailing each and every step of the procedures, the purposes for which the test was to be given and the names of the patients to be selected to participate? And, most important of all, why wasn't each patient informed that the injectable material was cancer cells? Why all the secrecy concerning cancer cells being injected if Mandel and Southam were so sure no deleterious effect could befall the patients? Yet Mandel had the gall to state in an affidavit submitted to the Supreme Court that everything was open and above-board!

Where was consideration shown to the patients with respect to their comfort; their freedom from unnecessary molestation and their absolute right to expect only such procedures and administrations necessary to their care and treatment? How dared Mandel introduce strangers to his hospital and to his patients and to permit these strangers to go through the various wards of the hospital, in open view of other patients? Oh, yes, those strangers were dressed like doctors—they had the long white coat commonly worn by visiting doctors; this then perhaps justified the intrusion as far as Mandel was concerned!

The haphazard method of selecting patients; the almost complete disregard of their comfort; the slipshod manner in which the entire project was conceived and conducted, is evident throughout the record.

Southam was not concerned with whether Mandel had the right to proceed with this project without sanction or authority. Nor was he concerned with what patients were selected; whether they were informed, and whether they were capable of giving consent. Mandel was evidently flattered that his hospital had been selected; he made no independent investigation concerning Southam or the project; he took Southam's word that no risk was involved, *although this was the first time they were engaged in performing this test upon debilitated patients*; he failed or refused to select a more capable and experienced participator than Custodio; and failed to assist and supervise the selection of patients.

And the greatest sin of all was the deliberate and willful failure on the part of the respondents herein, to inform each of the 22 patients that they were going to be injected with live cancer cells.

We are dealing with a project which admit-

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tedly was in no way therapeutic. It was, rather,
an experiment relating to cancer research which
had as its ultimate intention the benefit of hu-
manity. This being the fact, it was then incum-
bent upon the respondents to have seen to it that
ALL information connected with the experiment
was given, since the patients at JCDH were be-
ing asked to become volunteers

Respondents both ~~are~~ they ~~sanctioned~~
and counselled the withholding from each pa-
tient the fact that the cell suspension to be used
was indeed "live cancer cells." Their reasoning?
They state that to release this information to
the patients would cause a phobia, make them
frightened, cause fear and anxiety—and this they
wanted to avoid!

Every human being has an inalienable right
to determine what shall be done with his own
body. These patients then had a right to know
what was being planned—not just the bald state-
ment that an injection was to be given, but also
the contents of the syringe: and if this knowledge
was to cause fear and anxiety or make them
frightened, they had a right to be fearful and
frightened and thus say NO to the experiment.

Petitioner's exhibit #19, an article en-
titled "Problems of Informed Consent May Be
Unsolvable" cites that Nuremberg Code—"the
voluntary consent of the human subject is abso-
lutely essential."

Petitioner's exhibit #6 and Resp. Southam's
exhibit AA are entitled "The Normal Volunteer
Program of the NIH Clinical Center" and is
published by the U.S. Department of Health,
Education and Welfare. Under the heading "Def-
initions" a distinction is made between the "nor-
mal volunteer"—a person who is judged to be
in excellent health, etc., and "volunteer"—one
who offers himself for a service of his own
free will. Concededly, the patients at JCDH
would come under the second classification. "In-
formed Consent" is defined as follows:

A formal, explicit, free expression of willingness to
serve as a subject for research after the values and
effects of such participation have been explained by
the investigator and are sufficiently understood for
the Volunteer to make a mature judgment.

At page 3 of the exhibit, under "Informed
Consent" appears the following language:

The principal investigator *personally* provides the
assigned volunteer, *in lay language* and at the level of
his comprehension, with information about the pro-
posed research project. He outlines its purpose,
method, demands, inconveniences and discomforts, to
enable the volunteer to make a *mature judgment* as

to his willingness and ability to participate. When he
is fully cognizant of all that is entailed, the volunteer
gives his *signed consent* to take part in it. (Emphasis
supplied.)

It should be remembered that one of the
sponsors for Southam's project and experimen-
tation was the NIH!

How then did Southam discharge his duties
and obligations to the volunteers as the principal
and chief investigator in this experiment? Again,
do we not see the careless and absolute disre-
gard for the rights of the patients who were cho-
sen to participate? While it may be argued that
Southam was a stranger to JCDH and its patients
and therefore relied upon Mandel, it neverthe-
less remains the undisputed fact that the 22
patients selected were volunteers in this project,
and as to them in that capacity, Southam owed
them every consideration and obligation as de-
scribed by the NIH (*supra*). His was the duty
personally to provide the volunteer *in lay lan-
guage* at the level of his comprehension with in-
formation about the proposed research project;
outlining its purpose; methods; demands; incon-
veniences and discomforts; so as to enable the
volunteer to make a mature judgment as to his
willingness and ability to participate; and only
when the volunteer is fully cognizant of *all that
is entailed*, does he give Southam his *signed*
consent. And how did Southam discharge this
duty and obligation? First, he said he left it to
Mandel to decide the question of "consent" and
the manner by which it was to be obtained, al-
beit he stressed to Mandel the method of ob-
taining oral consents at Memorial which, in
Southam's opinion, were sufficient although the
recipient of the injection was not told that can-
cer cells were being injected. Secondly, he said
he was satisfied to have Custodio as his col-
laborator, despite the fact that he saw Custodio
for the first time on the day of the experiment
and knew nothing whatever of the latter's abil-
ity, experience or knowledge in projects of this
kind. This, it is strongly urged, Southam had no
right to do. As a scientist engaged in research he
had the duty and responsibility for ascertaining
the quality of the consent, which may not be
delegated to another with impunity. This was
his project, and, if it was to serve any useful
purpose he should have taken and assumed full
and complete authority; by having carefully
screened, with Mandel, the patients that were to
be selected; by having, with Mandel, spoken, in
advance of the injections, to each patient, ex-
plaining in lay language at the level of the pa-
tient's comprehension, the purpose, methods,

demands, inconveniences and discomforts of the proposed project.

For the record is replete with contradictory statements as to the manner by which "consents" were obtained; Mandel wasn't sure whether he had obtained so-called oral consents from one or two patients; he wasn't sure of the language he used in speaking of the project. Custodio likewise is not sure of just what words were used when speaking to the patients stating that interchangeably he used words as "immunity," "resistance" or "immunological response."

But the salient factor remains that at *no time* and to *no volunteer patient* was information given that, in truth and in fact, the cell suspension mentioned contained *live cancer cells*.

This then is the nub of the entire case. These volunteers, the 22 debilitated patients at JCDH, were not each made "*fully cognizant of ALL that is entailed*" in the proposed project. There was *missing*, deliberately and wilfully so, any statement to the effect that the injectable material contained live cancer cells. As was stated in SCIENCE, petitioner's exhibit 9, in the article entitled "Medical Ethics" and that portion under the chapter heading "Procedures not of direct benefit to the individual" found on page 1025 of the exhibit:

The common feature of this type of investigation is that it is of no direct benefit to the particular individual and that, in consequence, if he is to submit to it he must volunteer in the full sense of the word. It should be clearly understood that the possibility or probability that a particular investigation will be of benefit to humanity or to posterity would afford no defense in the event of legal proceedings. The individual has rights that the law protects and nobody can infringe those rights for the public good. In investigations of this type it is, therefore, always necessary to ensure that the true consent of the subject is explicitly obtained.

It is therefore respectfully submitted that the respondents herein failed to secure a valid and informed consent from each of the 22 patient-volunteers to participate in the experimentation conducted at ICDH.

2. THE RESPONDENTS ARE EACH GUILTY OF EACH SPECIFICATION OF THE CHARGES.

The failure of each respondent to reveal ALL that was entailed in the experimentation to each of the volunteer debilitated patients that were selected to participate was fraudulent and deceitful. As illustrated supra, the licensees herein had no right, moral or legal, to with-

hold any information relating to the experimentation. By so doing they violated the absolute right of each patient to determine what shall be done with his own body. By withholding the fact that live cancer cells were to be injected in this experiment, they deprived each patient of their inalienable right to refuse such an injection. *No choice* was given to these volunteers.

The conduct of each respondent was unprofessional, immoral and shocking to one's sense of fairness. Mandel has testified that patients do not question procedures that are done to them in a hospital because they have confidence in the doctors and that patients tend to accept what doctors say to them. It is submitted this confidence was misplaced; that all of these patient-volunteers were duped and misled by Southam and Mandel. Surely, the image of the medical profession must be sullied in the eyes of the public, if the conduct of the respondents herein was to be sanctioned and blessed with innocence.

Again and again it must be repeated and emphasized that a human being has rights and privileges that may not be trespassed upon to any degree. How shocking indeed it would be if a person were to realize that he had no rights or privileges as to what should be done to his body, and that he was a mere "guinea pig" in the eyes of any doctor, whether scientist or researcher, who desired to perform some experimentation on him!

Such a fantastic and gruesome thought could never withstand the indignation and denial of the public.

Upon the entire case therefore it is respectfully submitted each licensee is guilty of each specification contained in the charges.

b.

Morris Ploscowe, Esq.
Brief on Behalf of Dr. Emanuel E. Mandel

THE CHARGE THAT DR. MANDEL IS GUILTY OF FRAUD AND DECEIT BECAUSE THE PATIENTS WERE NOT ADVISED "THAT LIVE CANCER CELLS WERE TO BE INJECTED IN THEIR BODIES" CANNOT BE SUSTAINED.

The reasons why the patients were not told that the injections contained tissue cultured cancer cells are not found in fraud or deceit. This is apparent from the following:

Dr. Southam was asked why he deliberately refrained from describing (the injected cells) as "cancer cells." He testified as follows:

For two reasons really. First, I saw no reason why we

should use such a word to describe the phenomenon without implying that we are not doing something. We are not going to cause them any harm. We are going to transplant cancer cells that will grow and reject.

The fact then that mean that there is a Now, the second power," has a tremor everybody, not only and me. What the medical person, and petence in clinical n edge of the basic not great—to them imply a risk that i and the fear that t and I don't think I the point. I think w like neoplastic; if w no problem.

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[*] CROSS-EXAMINATION
SOUTHAM BY MR.

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should use such a word because it is not pertinent to the phenomenon which is going to follow. We are not doing something which is going to induce cancer. We are not going to do something which is going to cause them any harm; it is not going to produce a transplanted cancer. We are going to observe the growth and rejection of these transplanted cancer cells.

The fact then that they are cancer cells does not mean that there is any risk of cancer to this patient.

Now, the second point is simply that the word, "cancer," has a tremendous emotive value, disvalue, to everybody, not only to the cancer patients but to you and me. What the ordinary patient, what the non-medical person, and even many doctors whose competence in clinical medicine is great but whose knowledge of the basic science behind transplantation is not great—to them the use of a cancer cell might imply a risk that it will grow and produce cancer, and the fear that this word strikes in people is great, and I don't think I have to argue the point to make the point. I think we all recognize it. If we use words like neoplastic; if we use words like tumor, we have no problem.

... Many of these patients undoubtedly know deep down that they have cancer, but the great majority of them have either suppressed this knowledge from the surface or at least they are not talking about it

[*] CROSS-EXAMINATION OF DR. CHESTER M. SOUTHAM BY MR. CALANESE.

Q: Doctor, in Vol. 143 of *Science* which is issued February 1964 at page 551 you wrote that there was no theoretical likelihood that the injections would produce cancer. Yet, in the same article, Doctor, you stated that you were unwilling to inject yourself or your colleagues, and you stated, and I quote, "But, let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk."

A: I deny the quote. I am sure I didn't say, "let's face it."

Q: Did you make any statement similar to that?

A: I think the philosophy is an accurate statement.

Q: What was your statement, do you recall?

A: What I am objecting to is the phrase, "let's face it." The statement that I see no reason why a doctor should necessarily serve as a recipient, this is valid, that is, this statement may validly be attributed to me.

Q: The statement, Doctor, was published by Elinor Langer in *Science* of February 7, 1964, Vol.

find out from you whether or not what she is quoting as coming from you is correct or not. "Southam, however, who ought to know, said in an interview with *Science* that, although there was no theoretical likelihood that the injections would produce cancer, he had nonetheless been unwilling to inject himself or

and they don't welcome conversation that brings it up. So, it is our firmly established and I feel very sound policy *not to use the word "cancer"* with the cancer patients. ...

The position taken by Dr. Mandel and Dr. Southam in not mentioning the fact that the injections contained cancer cells is justified by medical ethics and current medical practice. Medical ethics do not require the full disclosure to a patient of all conceivable risks and all relevant information as a basis for obtaining patients' consent to a medical procedure. The amount of information imparted to a patient must bear some relation to the risk of a particular procedure. Where there is no substantial risk of harm to a patient, the information imparted to him may be kept at a minimum. We submit that in the instant case it was not necessary to tell the patient that the injections involved tissue cultured cancer cells since there was no possibility that harm could come to the patients from the said cells.[*]

It should also be noted that the amount of information which should be imparted to a patient as a prerequisite for consent to a medical

his colleagues, when there was a group of normal volunteers at the Ohio Penitentiary fully informed about the experiment and its possible risks and nonetheless eager to take part in it. 'I would not have hesitated' Southam said, 'if it would have served a useful purpose. But,' he continued, 'to me it seemed like false heroism, like the old question whether the General should march behind or in front of his troops. I do not regard myself as indispensable—if I were not doing this work someone else would be—and I did not regard the experiments as dangerous. But, let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk.'

Did you make that statement?

A: As I said before, the philosophy is correct. I do not know if I made that statement. This is reported—I remember the interview very well. I am still saying that the quotes are not necessarily correct; the philosophy is correct.

Q: That part of the quoting concerning the, "stupid to take even the little risk," do you recall that?

A: No, I don't, and this is one of the reasons that I question whether it is a true quote.

Q: Do you recall the statement that you made ... would produce cancer?

A: This is, in other words, exactly what I have said earlier this afternoon. [From transcript of proceedings before a Subcommittee of the Committee on Grievances, Department of Education of the State of New York, September, 1964, pp. 636-638.]

or surgical procedure may be left to the sound discretion of a conscientious physician. [*] This is the import of the rules concerning the testing of drugs which is in evidence as respondent's Exhibit B, and which state that while consent should be obtained for testing of investigational drugs, the laws and the regulations make it clear

[*] EXAMINATION OF DR. EMANUEL E. MANDEL BY MR. RASHKIS, INVESTIGATOR, NEW YORK STATE DEPARTMENT OF EDUCATION.

Q: Each patient was told that an experiment to determine his immunity was to be conducted. Was each patient told that cell tissue was to be injected?

A: Yes, cell suspension was to be injected.

Q: Each patient was told this?

A: Yes, each patient was told.

Q: Did any patient ask you what a cell suspension is?

MR. PLOSCOWE: If you can recall.

A: I can't.

Q: No one asked you?

A: (No response.)

Q: Did you actually have a conversation with the patients that you spoke to them and they answered you?

A: Yes.

Q: Every patient?

A: Every patient. I asked them if they have—each and every one of them has any objection to us doing the test and they said no.

Q: Did any patient answer anything other than yes or no; that he would agree—

A: No.

Q: No patient questioned any of the terms that you used?

A: I don't remember. I don't think anyone asked.

DR. MANDEL: May I add to that?

MR. RASHKIS: Yes.

DR. MANDEL: I will say almost every day doctors come into situations where they have to ask a patient for permission to do a certain procedure, say a bone-marrow aspiration, a spinal tap, what not.

Most patients don't question these procedures; the patients have confidence in the doctors.

MR. RASHKIS: What is the purpose for the tests?

DR. MANDEL: Diagnostic nature.

MR. RASHKIS: For that particular patient?

DR. MANDEL: For that particular patient.

MR. RASHKIS: Would these patients have understood these tests were to be diagnostic in nature?

DR. MANDEL: No.

MR. RASHKIS: Is there any relevancy in the statement you made about the bone-marrow test?

DR. MANDEL: Only in terms of conversation with patients. Ordinarily they listen and tend to accept what the doctor says to them. [From transcript of proceedings before a Subcommittee of the Committee on Grievances, Department of Education of the State of New York, September, 1964, pp. 96-100.]

that if in the professional judgment of the investigator "it is not feasible or in the best interests of the subject to obtain permission, the investigational nature of the drug need not be disclosed." This concept of patient consent is not new but has been part of the Code of Ethics of the American Medical Association for many years.

If, in the judgment of a conscientious physician, the investigational nature of a drug need not be disclosed, when it is tested, then there appears to be no reason why the nature of the injected material should have been disclosed to the patients at JCDH, since there was no hazard to the patients from the injections.

The following statements made by distinguished physicians in affidavits submitted on behalf of Dr. Southam, support our contention that a proper consent was obtained from the patients at JCDH in the tests conducted at JCDH and that it was not fraud or deceit not to tell the patients that the injected material contained cancer cells:

Dr. Michael J. Brennan, physician in charge of the division of oncology, Henry Ford Hospital, Detroit, Michigan, stated as follows:

... The need to enter into detailed description of the source and nature of a test material cannot be shown to be a part of our moral and legal duty unless it would be objectively helpful to the patient in coming to a rational and knowledgeable conclusion about the real risks of the procedure to his health.

... He [Southam] did not speak to these patients of giving them a treatment. He asked permission to do a test of considerable scientific import. He then faithfully explained to them the sequence of reactions which they could expect and rightly and correctly assured them of their innocuous character. He hid nothing from the patients which would have been useful to them in making a rational decision regarding the real risks of the test.

He did not mention that the test solutions were made from tissue cultures of cancer cells. This now proves to have been imprudent because of the emotional character of the response which followed revelation of that fact and the opening it gave for accusations of dishonesty and duplicity on his part. There is a difference between withholding information and giving false information but it is often overlooked. However, the information he withheld was not needed by the patients for judging rightly that his test was safe.

The real test of the adequacy of his description to the patients of what would happen is whether it corresponded with what did in fact happen.

It was the compassion of the good physician, not the deceit of the charlatan or the calculation of the cold experimentalist, which has laid him open to his present troubles. ...

Dr. George E. M. surgery of Roswell F Buffalo, New York, st

... For the past 4 years similar type of project : stitute. My research inv to patients with cancer from human cancer tiss of vital importance in t it is my hope that, th knowledge of immunol cer, important strides sible immunization aga To the best of my know tical risk of any dele patients who served as by me.

The question of the t nished a patient incide participation in these t me in conjunction with It was our decision th that their consent was investigation involving rived from a tumor. T narily employed. In so tured cells from human

While our procedure: played by Dr. Southa was motivated solely of his patients; it is ch fully informed doctor: their patients may ar to the best approach tentially traumatic eff "cancer" may produ Dr. Southam's view ti in such studies since. general term "cancer" nature of the biologic

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judgment of the investigator in the best interests of the patient. The investigator need not be disinterested. Patient consent is not required by the Code of Ethics of the American Association for many

of a conscientious physician. The nature of a drug when it is tested, then the reason why the nature should have been disclosed, since there was no deception from the injections.

Decisions made by distinguished physicians submitted on behalf of our contention that informed consent from the patients induced at JCDH and the deception not to tell the patients that the material contained cancer

an, physician in charge of the Henry Ford Hospital, stated as follows:

A detailed description of the material cannot be shown and I have a duty unless it is to the patient in coming to a decision about the patient's health.

Speak to these patients of the need for permission to do the experiment. He then faithfully followed the sequence of reactions and correctly understood the character. He hid the truth which would have been a rational decision regarding

test solutions were made for cells. This now proves the cause of the emotional reaction which followed revelation and gave for accusations of deception on his part. There is a difference in information and giving information overlooked. However, the test was not needed by the patient at his test was safe.

of his description to the patient is whether it corresponds to what happened.

good physician, not the calculation of the cold and him open to his pres-

Dr. George E. Moore, director and chief of surgery of Roswell Park Memorial Institute of Buffalo, New York, stated as follows:

... For the past 4 years, I have been engaged in a similar type of project at Roswell Park Memorial Institute. My research involves the homotransplantation to patients with cancer of tissue-cultured cells derived from human cancer tissue. In my view these tests are of vital importance in the field of cancer research and it is my hope that, through the resulting increased knowledge of immunological factors relating to cancer, important strides may be made leading to possible immunization against, or treatments of, cancer. To the best of my knowledge, there has been no practical risk of any deleterious effects upon any of the patients who served as subjects in the tests performed by me.

The question of the type of information to be furnished a patient incident to obtaining his consent to participation in these tests was carefully explored by me in conjunction with other officials of my hospital. It was our decision that the patients would be told that their consent was sought to participation in an investigation involving the injection of live cells derived from a tumor. The word "cancer" was not ordinarily employed. In some instances the phrase "cultured cells from human tumors" was used.

While our procedures thus differ from those employed by Dr. Southam, I believe that Dr. Southam was motivated solely by his concern for the welfare of his patients; it is clear that this is an area in which fully informed doctors acting solely for the benefit of their patients may arrive at different conclusions as to the best approach to take. I am aware of the potentially traumatic effects which the use of the word "cancer" may produce, and for the most part, I share Dr. Southam's view that the word should be avoided in such studies since, from a scientific standpoint the general term "cancer" does not accurately reflect the nature of the biologic materials being used.

I do not believe that the differences in the procedures employed by Dr. Southam and by me cast any reflection upon the professional integrity or judgment of Dr. Southam. I believe that the factors which I know were weighed by Dr. Southam prior to making his decision make it preposterous to assert that there was any modicum of "fraud," "deceit" or "immorality" involved in his actions. . . .

Dr. Alvin L. Watne, associate professor of surgery and cancer coordinator at West Virginia Medical Center, stated as follows:

... In his affidavit, Dr. Southam describes the procedures which he has employed in his project relating to the study of the relationship between immunological research and cancer. I am engaged in a comparable research project. The information that we present to the patient is that this is a research project that we are conducting here in the department and that their participation is entirely voluntary. If there is any re-

luctance on their part, we do not press the issue. We do not use the words "cancer" or "tumor" in describing the possible transplantation. We do say that we will test the patient's ability to respond to the stimulation and that we are interested in knowing more about their particular tumor problem and that this will give us some information along that line.

... I believe that the procedures described by Dr. Southam in connection with the obtaining of consents are in accord with the highest standards of the medical profession and I subscribe to the reasons given by him for the adoption of such procedures.

Dr. I. S. Ravdin, professor of surgery and vice-president of medical affairs at the University of Pennsylvania, stated as follows:

... It is the considered opinion of many investigators that research in the field of host response and immune reactions is likely to provide the first important breakthrough in the treatment of malignant diseases. It is men like Dr. Southam who are best prepared to accomplish this highly desirable breakthrough.

Physicians are constantly concerned as to whether they should tell a patient that he is suffering from a malignant disease. Dr. William T. Fitts, Jr., and I studied this matter some years ago. We sent a questionnaire to members of the Philadelphia County Medical Society in order to ascertain what they did under these circumstances. Only the dermatologists did this with any frequency.

The question of whether a proper consent was obtained from the patients in the Southam research at JCDH was also presented to three distinguished physicians who appeared as witnesses on behalf of Dr. Mandel. Each of these physicians was asked a hypothetical question based on the facts brought out at the hearing herein which include the assumption that the patients were not told that the injections contained live cancer cells. Each of these physicians was asked the basic question, "In your opinion as an experienced and conscientious physician, do you believe that a proper consent was obtained to the aforementioned (tissue cultured cancer cells) injections?" Each of the physicians testified affirmatively that a proper consent was obtained to the injections herein.

Dr. David Kershner testified as follows:

Well, in my experience in handling surgery cases for about 40 years and the problems which we have to decide on the Malpractice and Defense Board of the State Society as well as the equal level of the county society, we talk in terms of informed consent and what is informed consent and much is made of it. I don't think any law can be laid down. I don't think we can strictly say this is informed consent and this is not informed consent and this is what you must not tell the patient. I think it has to be individualized. Pa-

52 JEWISH CHRONIC DISEASE HOSPITAL CASE

tients are not all the same; they don't react the same way. But by and large, I think we can safely say that if a patient is going to be operated upon or any work is going to be done involving malignancy, and we use the word "cancer," it throws a horrible fear into the patient. . . .

Dr. Charles E. Rogers testified as follows:

The reason I say that I believe informed consent was obtained was because I don't think there was any risk involved here. It is well known that we have been trying hard to transplant tissues for a number of years and we have been failing miserably. As far as I can see, what occurred here is they wanted to find out whether there was immune response or to what degree the immune response was engendered in patients who had debilitating diseases, and since we know that we can't transplant these tissues unless we have identical twins or unless we pretreat the patient with radiation or other toxic substances, I would feel that informed consent was obtained. There wasn't a risk involved.

I base that on literature and my knowledge of the immunology such as it may be and the general knowledge I have. I just don't think there is any doubt in my mind these tissues could have possibly survived in these patients. Obviously, they didn't.

On cross-examination, Dr. Rogers was asked the following questions and gave the following answers:

MR. CALANESE: All those volunteers at Jewish Chronic Disease Hospital were not told that cancer cells were being injected.

DR. ROGERS: That isn't germane to the problem, Sir.

MR. CALANESE: As far as you're concerned?

DR. ROGERS: Yes, Sir. That is my opinion.

MR. CALANESE: Further they were told there would be no risk involved with the test they were going to be subjected to at that time.

DR. ROGERS: I think that is true in my opinion.

MR. CALANESE: That is not important as far as the patient or the volunteer is concerned?

DR. ROGERS: No, Sir. I think that you would be causing the patient undue anxiety and undue concern over a procedure that doesn't have a risk.

* * *

MR. CALANESE: It has been established here, Doctor, by the testimony so far, that all that was told to these patients is that an injection was going to be given to determine their resistance to disease and that a lump would form within a few days which would disappear within

2 or 3 weeks; that is all that was told. In your opinion, is that sufficient?

DR. ROGERS: Yes, sir, in this particular case. But, I wish to emphasize every case must be decided on its own merits. In this particular case, there was no risk and there was no need to advise the patients unnecessarily and alarm them and say these are cancer cells, you could get cancer, because the volunteer in a situation like that would be worried.

Dr. Irving Hirshleifer testified as follows:

MR. PLOSCOWE: . . . Was a proper consent obtained from the patients to the cancer injections involved in the instant proceeding?

DR. HIRSHLEIFER: Yes, sir.

MR. PLOSCOWE: Would you tell the panel the reason why you came to that opinion.

DR. HIRSHLEIFER: Well, having been in clinical investigation for many years and also having served in a teaching and training capacity and a medical school affiliated institution for many years, and having helped train many interns and residents since 1946, these were the practices which were performed in no other manner in all my experience.

MR. PLOSCOWE: When you state these were the practices, Doctor, would you be more specific, the technique of obtaining consent. That's right.

DR. HIRSHLEIFER: Yes.

MR. PLOSCOWE: Well, does it make any difference that in this particular proceeding what was done here was for the purpose of experimentation, the making of a test rather than for the therapeutic benefit of the patient?

DR. HIRSHLEIFER: These are the usual practices in hospitals where interns and residents are trained.

MR. PLOSCOWE: Can you tell me, for example, in the hospitals with which you have been associated, . . . universities and teaching institutions, are frequent tests performed on patients which have nothing to do with the therapy or treatment of the patient?

DR. HIRSHLEIFER: Yes, sir.

MR. PLOSCOWE: And is the method of consent obtained in that framework any different from the method of consent obtained here?

DR. HIRSHLEIFER: Sometimes, not to the degree that was obtained here.

MR. PLOSCOWE: Does that mean that we were more formal here?

DR. HIRSHLEIFER: Yes.

* * *

MR. PLOSCOWE: cific project, there b: that the word "cance injection of these pa is a proper subject o framework?

DR. HIRSHLEIFER: never to use that te patient.

[*] CROSS-EXAMINATION
MANDEL BY MR. CALA

Q: Now, before Dr. Southam, did you of any of these three p

A: I believe I sp this is something I c been able to rememl Custodio who spoke to the objective was, whi Custodio thought it wa

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A: I remember leukemia. I think I m I mentioned this mor some resentment over a period of his hosp was really getting bett

Q: That is wha Mandel; . . . I want this record what was what if anything was.

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A: Well, I only call vaguely he indi happy over having s diagnostic procedures better. He showed n showed me he had what is called ascites I recall that I tried to

Q: As to what?

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A: I don't—

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A: Sometimes, not to the

Q: That mean that we

MR. PLOSCOWE: With respect to the specific project, there has been criticism of the fact that the word "cancer" was not used prior to the injection of these patients. Do you find that this is a proper subject of criticism in this particular framework?

DR. HIRSHLEIFER: No, I don't. I attempt never to use that term when conversing with a patient.

[*] CROSS-EXAMINATION OF DR. EMANUEL E. MANDEL BY MR. CALANESE.

Q: Now, before the injections were made by Dr. Southam, did you personally secure the consent of any of these three patients?

A: I believe I spoke to at least one of them and this is something I cannot remember and haven't been able to remember, whether it was I or Dr. Custodio who spoke to these patients explaining what the objective was, what we were planning to do. Dr. Custodio thought it was I. It may well be.

Q: Let's take your statement that you may have spoken to at least one. Can you tell this committee exactly, to the best of your recollection today, what you told that particular patient . . . concerning this experiment?

A: I remember talking to the one that had the leukemia. I think I mentioned that earlier today, and I mentioned this morning that the patient indicated some resentment over being stuck with needles over a period of his hospitalization without evidence he was really getting better.

Q: That is what I was trying to bring out, Dr. Mandel; . . . I want you to tell this committee and this record what was said by you to this patient and what if anything was said by the patient to you.

A: It is impossible for me to do that. I can't remember it.

Q: To the best of your recollection.

A: Well, I only know I spoke to him and I recall vaguely he indicated his—the fact he was unhappy over having so many forms of treatment and diagnostic procedures and didn't think he was getting better. He showed me how he had lost weight. He showed me he had an enlarged abdomen. He had what is called ascites, free fluid in the abdomen, and I recall that I tried to reassure him.

Q: As to what?

A: As to eventual improvement, that he was going—getting better; that various procedures that have been planned for him and that have been carried out will eventually bring about his ultimate recovery.

Q: Had he told you in any manner, shape or form as to the numbers of time that tests had been made on him over a short period of time before July 16th?

A: I don't—

Q: A number of tests had been made, he was sick and tired of it, he said?

It is apparent from the aforementioned discussion that the respondents, Dr. Mandel and Dr. Southam, by failing to disclose to the patients that the cell suspension injections were cancer cells, were not guilty of fraud or deceit, but were acting in the best interests of the patients and according to accepted standards in the field of medicine.[*]

A: I am sure he didn't use that expression. He was very well mannered and quite a quiet sort of fellow.

* * *

Q: When you spoke to him concerning this test, just exactly what did you tell him this test was and what it comprised, what the expectations were?

A: I cannot tell you exactly. I can only tell you what I told him, what has been stated a number of times; that the test was planned for the determination of his immune response or his resistance and that it would result in a lump which would disappear after a period of time, after some weeks.

* * *

Q: Did he ask you for any further particulars concerning the test?

A: I don't believe so.

Q: Despite the fact he made a complaint to you about too many tests having been made upon him before, you say he made no further complaint or asked you no information concerning this test?

A: He did this more in a way of general complaint and his complaint was directed primarily towards not getting better. In other words, he compared his lack of improvement with the number of procedures being applied.

Q: Was any statement made to him, Doctor, by you that this test might be of benefit to him?

A: Did I indicate that to him?

Q: Yes.

A: I am certain I didn't.

Q: Did you say anything to him, Doctor, that as part of this test, in addition to the injection and the lump that would form, that would disappear within a short period of time, that blood tests would also be taken and made?

A: I would think that I did.

Q: Don't you know?

A: I don't remember. I am quite certain this was done in every instance.

Q: You are quite sure.

A: Yes.

Q: We are speaking with respect to this specific instance, this leukemia patient. Did you tell him there would be blood tests taken?

A: I don't recall. [From transcript of proceedings before a Subcommittee of the Committee on Grievances, Department of Education of the State of New York, September, 1964, pp. 960-965.]

Even if it should be maintained that Dr. Mandel and Dr. Custodio should have told the patients that "live cancer cells" were being used in the injections despite their fear of instilling cancer phobias in the patients, there can be very little doubt that their failure to do so was an honest medical error. An honest medical error cannot be deemed fraud or deceit or "immoral conduct" of a physician.

2.

The Board of Regents Grievance Committee Makes Its Recommendations

a.

Report of the Subcommittee of the Committee on Grievances

To the Committee on Grievances:

The undersigned, subcommittee of the COMMITTEE ON GRIEVANCES duly designated to hear the charges against DR. CHESTER M. SOUTHAM and DR. EMANUEL E. MANDEL hereinafter referred to as respondents, pursuant to Section 6515 of the Education Law of the State of New York, and to report its findings and recommendation in respect to the said charges, do hereby, after due deliberation, unanimously report its findings and recommendations as provided by law as follows:

* * *

The findings and recommendation of Dr. Lawrence Ames, chairman of the subcommittee is as follows:

The above two physicians are charged with fraud or deceit, as well as unprofessional conduct, in the practice of medicine within the purview and meaning of the Education Law and as implemented and defined by the Rules of the Commissioner. . . .

* * *

Sitting as chairman of the subcommittee of the medical grievance committee hearing this case, I had full opportunity to hear all the testimony and evidence introduced by the attorneys for the respondents and by the attorney general for the petitioner.

Every opportunity was afforded both respondents and the petitioner to present their cases completely and thoroughly and there was no attempt on the part of the committee to impede or curtail the introduction of any evidence or testimony pertinent to the case. I have re-

viewed all the testimony and evidence and after a great deal of study I have come to the following conclusions:

This experiment or research project was not done for the care or treatment of any of these individuals, but rather as a non-therapeutic clinical research project.

All the patients chosen were in a very debilitated condition for that was a necessary prerequisite for this experiment.

Dr. Southam, the chief investigator, was working partly under a grant from the United States Department of Health, Education and Welfare of the Public Health Service and was governed by their rules and regulations regarding experimentation and research.

Dr. Southam was aware of the rules and regulations as set down by the Public Health Service for research and experimentation under these grants. It specifically states, "The principal investigator personally provides the assigned volunteer in lay language and at the level of his comprehension, with information about the proposed research project. He outlines its purposes, methods, demands, inconveniences and discomforts, to enable the volunteer to make a mature judgment as to his willingness and ability to participate. When he is fully cognizant of all that is entailed, the volunteer gives his signed consent to take part in it."

Dr. Southam as chief investigator and Dr. Mandel as chief of medicine of the Jewish Chronic Disease Hospital are both equally responsible for whatever took place and share equal responsibility for these acts.

The 19 patients who were chosen by Dr. Custodio were not given sufficient facts on which to base their judgment of whether or not to give consent. It is admitted that at no time were the words "cancer cell injection" ever used. Many of these 19 patients, in my opinion based on the evidence introduced, were not physically or mentally capable of understanding what was involved and therefore incapable of giving informed consent, even if such information were given to them by Dr. Custodio. The manner in which Dr. Custodio elected to choose the cases for the experiment, the very morning of the injections, and the total time consumed in giving all these injections, convinces me beyond reasonable doubt that proper informed consent could not have been obtained. It is my considered opinion that he was more interested in getting his name on a research project, than in protecting the interests of these debilitated people placed in his

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care and trust as senior resident at the Jewish Chronic Disease Hospital.

I find that Dr. Southam, as chief investigator, and Dr. Mandel, as chief of medicine at the Jewish Chronic Disease Hospital, did not fulfill their obligations to the people involved in this investigation, in that they did not obtain or see that the proper informed consent was obtained from these patients or those qualified to give the proper consent for them. [*]

Every human being has an inalienable right

[*] CROSS-EXAMINATION OF DR. CHESTER M. SOUTHAM BY MEMBERS OF THE COMMITTEE ON GRIEVANCES.

DR. HELLER: . . . the question in our minds, I believe, the committee's mind, is whether or not patients, whether they are terminal patients, patients who are socially adjusted and could be right here in a social gathering, would know the difference between a test or a treatment and whether or not they could construe, in a setting such as we have described, a test as a routine procedure within a hospital revolving about themselves and their betterment, their welfare, care and treatment?

In other words, the patients, as we have it, were not asked, "Do you know what research is? Do you know what an experiment consists of?" and we don't know what they might have answered to the question "Do you know what research is? Do you want to become a research subject?" These are the points, though they are points of semantics, yet relate to understanding of the patient. It would seem to us that cooperation depends upon the recognition of a doctor, his confidence, but not upon his understanding that this was a research project. What we are concerned with is the method of obtaining the consent, primarily. That is why I raise that question, and I would like your comment on it.

A: One of your key points, I think, is whether these patients in saying, all right, I will have a test, interpreted in this sense of something out of the ordinary, not a routine matter, test that might have been done, but a research project, an experiment.

Obviously, I cannot speak for the patients, but I think there is no question but—I am speaking now over the period of time that these tests were carried on rather than at the particular moment about which I was being questioned previously—certainly when doctors come in, two doctors known not to be associated with their hospital, it certainly was clear to most of these people, I would guess, that they know that this was something out of the routine; that this was a research, and I would not doubt at all that we used such words as research and experiment. Some patients were quite able to converse. As others, as you heard, had impaired ability to converse, but certainly those who were able to talk better, I feel confident, knew that not only that this was research involved, they probably knew that we were from a cancer re-

to determine what shall be done with his body. This, without regard as to whether he be confined to a penal institution, or free, or whether he be healthy or debilitated and confined in an institution or hospital. The same rights or priv-

search hospital. This is obviously opinion. This is not a statement of facts.

DR. HELLER: That is the point I am making. The ability to converse is no measure of understanding whatsoever. The most conversant patients can have the least understanding or the least competency to understand that they are being used for an experiment; that they are volunteering to do so; and that this is research; and certainly in the presence of a doctor whom they are familiar with and other doctors in white coats, confidence is automatically generated. They need no other.

My question is, isn't it an assumption on your part that these patients had understanding; they can communicate even by the visual observations of a syringe, doctor's bag, injection, they—this is part of hospital procedure. So, the communication is taken for granted. My question was, didn't you have to make an assumption that these patients understood, had understanding of the request that you were making, a request of them to volunteer as subjects for an experiment?

A: Yes. I certainly agree both in this specific instance that I was making an assumption—I think that Drs. Mandel and Custodio may be able to make a better answer to this particular point, because they know the patients better. I think it is true, also, as I think you have indicated, that we assume an understanding also when we communicate with patients, that is, I don't know if I said that clearly, but in any doctor-patient relationship there is this quality that you mentioned of the patient in a setting where he recognizes that the doctor is doing things to and for him. Undoubtedly, they associate this with what is proper. He accepts, essentially, things as being proper because they are being done under this total picture of medical doctor-patient relationship. I think that all we can do in such situations is to explain that what we are doing is not for your treatment, if necessary, to say that it makes no difference whether you have such a procedure or not. This will not influence your disease, and it will not influence your proper treatment.

DR. WIENER: Was there any deviation, as far as obtaining patients' consents here, was there any deviation from the long-standing practice of obtaining consents?

A: No, sir. There was—this was the reason that I believe that Dr. Mandel accepted this method. I had assured him that this was our established method of obtaining consents at Memorial and Ewing. [From transcript of proceedings before a Subcommittee of the Committee on Grievances, Department of Education of the State of New York, September, 1964, pp. 784-789.]

ileges must be accorded him. If they be so mentally or physically affected that they be incapable of making decisions, then the nearest of kin must be afforded the right to make this decision.

I therefore find the respondents, Dr. Southam and Dr. Mandel, both guilty beyond reasonable doubt of the charges and specifications as charged.

In considering the degree of punishment, I am considering the outstanding records of both these doctors, the high esteem by which they are held by the medical profession and scientists in general throughout the world. I also take into consideration the nature of the experiment and its purposes and I therefore recommend that they both be given a censure and reprimand.

The findings and recommendation of Dr. Saul I. Heller, member of the subcommittee is as follows:

It is my finding that Chester Southam, M.D. and Emanuel Mandel, M.D. are both guilty of each specification contained in the charges.

Just because such a project is worthy, and just because terminal patients were readily available, who were deteriorating anyhow, does not, in my opinion, warrant deceiving such patients into believing that they were submitting to ordinary and customary hospital procedure, intended to aid in the diagnosis of, or the alleviation of their particular illnesses.

This project was not even experimental therapy, although there are many inferences that it might be. In experimental therapy, patients and volunteers are selected who are able to clearly comprehend beforehand the full nature and details of the experiment, which generally are outlined on a printed form on which the patient or volunteer is asked to sign his consent. A volunteer consents after he is fully informed in lay language, that is, language that he can comprehend and this usually involves considerable thought and much discussion, with dozens of questions being asked, and fully answered over a period of time.

In my contacts with various investigators, especially during the past seven years, I was impressed by the fact that the National Institute of Health always advised the investigators to follow the above procedure in experimental therapy.

The project of Dr. Southam and Dr. Mandel at Jewish Chronic Disease Hospital was experimental research on a group of human beings, who were told that an injection was being given to them to test their immunity or resistance to

disease, and that a nodule would form and disappear. However, they were not asked to become volunteers and participate in an experiment on human beings for the purpose of furthering Dr. Southam's cancer research project. These patients and their relatives had the human right to decide what should be done with their bodies, except in a dire medical emergency.

These patients were entrusted to the care of the Jewish Chronic Disease Hospital by their relatives, who visited the patients and spoke to their doctors, and even the relatives were not informed of this research project. I cannot understand why the relatives of these patients were never informed of this experiment prior to the patients' having received the experimental injections of live cancer cells. This omission can only imply deceit, especially when one considers the procedure in any hospital, as, the unrefuted testimony of Dr. Leichter that in regard to patient No. 18, he had secured written consent from the patient's family to tap the patient's chest, and further that before administering the antibiotic drug, Terramycin 401 to patient No. 18, he also secured signed consent from the family. These procedures antedated the injections of live cancer cells.

It is only reasonable to conclude, if you must secure written consent from the family and disclose the true nature of an antibiotic, to give an antibiotic, you must disclose the true nature of the cellular material injected in this experiment, both to the patient and his family, in order to obtain informed consent, as was done by a competent resident in the case of the antibiotic, Terramycin 401. I am referring to Dr. Leichter, who in 1960 had been placed in charge of a research project sponsored by the National Institute of Health, by Dr. Goldner, the director of Jewish Chronic Disease Hospital, at that time. The competent residents at Jewish Chronic Disease Hospital were deliberately by-passed by Dr. Mandel, director at this time because he knew they would only adhere to the procedure of informed written consent.

Dr. Mandel asked Dr. Custodio, a resident who had just returned after a year's absence, if he were interested in participating in a research project which had been brought to Dr. Mandel's attention by Dr. Southam a week or so earlier. When Dr. Custodio indicated that he was interested, he was told by Dr. Mandel, "if we can get oral consents we can go ahead." He directed Dr. Custodio to prepare a list of non-cancer patients. It appears that there was no specific discussion between Dr. Mandel and Dr. Custodio

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of any need for their terminal patients nor their families to understand that the patients were to be used as volunteers in cancer research.

Dr. Custodio testified that he chose 19 non-cancer terminal patients, in his mind, at random, the night before the experiment; and the next morning led Dr. Southam and his assistant, Dr. Levin, to the rooms of these patients.

Dr. Southam says that an explanation of some kind was made by Dr. Custodio regarding a test to study the patient's immune reactions and that a nodule would form and later disappear.

Dr. Mandel, himself, chose three cancer patients and states he was familiar with these cases. One of these cases was scheduled for elective surgery on July 18, 1963, and such elective surgery, according to Dr. Mandel, is arranged about five days in advance, and written consent was obtained for this operation. Nonetheless, this patient was used for human experimentation just two days before this scheduled operation and died on July 19, 1963, the day after the operation.

It is obvious that this patient would never have been subjected to this experiment, had any of the 4 doctors involved in the experiment known, or cared about knowing, the status of this patient.

Another of the three cases selected by Dr. Mandel was suffering from leukemia. Dr. Mandel testified that he tried to reassure this patient that he was getting better, because the patient expressed resentment in "being stuck with needles without getting better," and compared his lack of improvement unfavorably with the number of tests. Moreover, Dr. Mandel does not remember if he explained to this leukemia patient that there would be follow-up blood tests. It does seem that this leukemia patient was led to assume that his part in this procedure was therapy for his own illness, or a diagnostic aid to help him.

I thought it necessary, in forming an opinion, to review the 19 non-cancer terminal patients, who were selected at random by Dr. Custodio in his mind the night of July 15, 1963.

The mental and physical condition of the patients renders it impossible for them to give informed consent, in terms of forming a mature judgment in a matter of one to five minutes, on a complex scientific subject. Actually they were subjected to an injection by doctors in hospital attire, and were deceived into believing that this injection was of direct therapeutic benefit to them, or was essential for their treatment. This

was evidenced by Dr. Mandel's statement that patients do not question procedures which are done in a hospital, because they have confidence in the doctors, and tend to accept what they are told. In this instance, I believe their confidence was misplaced.

I would like to re-emphasize the procedure of the experiment which illustrates that informed consents could not have been obtained, because the patients nor their families were never told the truth; in that they were being asked to submit themselves as volunteers for human experiment in the field of cancer research, on a purely research basis, and not for a direct benefit of their particular illnesses. Nor were they told the true nature of the material to be injected.

Dr. Custodio greeted the patient and in the few minutes that the doctors prepared the injections, he told the patient that this was an injection to test their immune reactions and that a nodule would form in a few days and disappear in a few weeks.

During this time, Dr. Southam was sterilizing the skin of the thigh with cotton and alcohol. If the patient appeared apprehensive, Dr. Southam would verbally reassure the patient by such remarks as, "this is cotton, this is alcohol, this is novocaine, it doesn't hurt, you've had it before." Then he would proceed with the subcutaneous injections of live cancer cells. This procedure was repeated with remaining patients, selected by Dr. Custodio. Neither Dr. Southam nor Dr. Mandel knew which patients were selected. Could this be construed as informed consent?

Dr. Mandel, medical director of Jewish Chronic Disease Hospital, was not even present at the experiment of these 19 patients, which indicates that he has shunned his responsibility to the patients entrusted to his care.

In arriving at my decision in this matter, I am extremely concerned with the fact that these chronic, debilitated, sick patients were hurriedly and unexpectedly confronted with a verbal description of a technical procedure, which, even to a normal, educated, intelligent and healthy person, would have been inadequate and untruthful. This is fraud and deceit. I also believe that the omission on the hospital charts that these patients were injected with cultured live human cancer cells constitutes fraud and deceit.

I further believe that the rights of these patients and their families were violated by the respondents in this matter; who resorted to

trickery, false statement, deliberate deception. The respondents by acting in such a manner as to omit and conceal the facts of this experiment involves a breach of duty, trust and confidence to these patients, their families, and their fellow-man.

The findings and recommendation of Dr. Morris F. Wiener, member of the subcommittee is as follows:

The allegation that fraud and deceit had been perpetrated upon a group of patients in the Jewish Chronic Disease Hospital by the respondents is based upon: (a). Inadequate consents having been obtained for clinical investigation in not fully disclosing the cancer-origin of the material used in certain immunologic tests, and (b). The assumption that these injections were harmful and may produce cancer.

Although no fact of personal greed on the part of either respondent was revealed, nor was any appreciable injury to any of the subject-patients clearly demonstrated, the respondents failed to obtain written or meaningful consent consistent with appropriate directive governing research projects.

The problems of informed consent are considered nebulous and insoluble by a large segment of competent medical authority. The emotional reaction to the word "cancer" very often justifies its concealment. The blind patient whose sight is restored is not informed that his or her new cornea was transplanted from a cancerous eye removed from another patient. There are other instances where significant facts are concealed from patients, concealment tolerated or condoned by both medical and civil authority.

The injection of material obtained from a culture of cancer cells is not known to cause human cancer. These diseases are the result of autonomous new-growths which develop from an unrestrained proliferation of the individual's own native body cells. Total clinical experience, notably that of surgeons and pathologists who have frequent direct physical contact with cancerous tumors, further supports the principle that cancer is not a disease that is transferable from one individual to another. The universal acceptance of pooled plasma and blood-transfusions since World War II has offered a wide experience for the possible development of cancer from one person to another, and yet not one single case has ever been recorded.

In a recent case of purported transplantation of cancer to a noncancerous patient from a

cancerous patient, no analogous inference can be made. This instance was published in the *Journal of the American Medical Association*, Vol. 192: 752, 1965, the article entitled "Cadaveric Renal Homotransplantation with Inadvertent Transplantation of Carcinoma."

This article refers to the recipient of a homotransplanted kidney obtained from a patient who died of cancer and which apparently was present in the grafted organ. In order to negate the usual homograft rejection and enable the grafted kidney to survive, the patient was treated with immunosuppressive drugs for 5 months from the time of operation: Azathioprine, 100 to 300 mg. doses and Prednisone, 30 to 100 mg. daily were administered, and in addition, the grafted kidney was treated with x-radiation.

A deliberate calculated effort was made by drugs and x-ray to depress the known immune response mechanism that causes the rejection reaction. The treatment was continued until two days before death. It is obvious, and not surprising, that the immune suppression resulting from the treatment to prevent the rejection of the homotransplanted kidney also prevented rejection of the occult cancer cells within the grafted kidney.

It should be noted that the cancer cells in this case were directly transmitted as a part of a vital organized active tumor tissue from the donor to the recipient. On the contrary, in the experiment at issue, the suspension of cells used had been derived from cancer tissue which had been grown in artificial culture media for a period of 5 to 12 years. Considerable experience has shown that this artificially cultured material represents a "standardized biological," and not a biologically active organized tumor with known aggressive determinants.

With regard to the one instance of axillary metastasis following an injection of suspended tissue cultured cancer cells into the arm of one of the patients, the following points may very well be considered. The finding of extrinsic cells in lymph nodes which are not cancer and do not behave as cancer is known. In the case at issue, the presence of cancer cells in the lymph nodes may actually be a result of their passive transportation from the point of inoculation to the node. This type of passive transportation is commonly found in cases of eczematoid skin conditions, tattoo and other pigmentation. In view of the comprehensive experience involving injections of tissue cultured cells, not one case

is known to be scientifically proven against sensitivity reactions in ill patients immunologically like patient in other words confidently that the aged no

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is known that resulted in cancer. The known scientific principles and abundant evidence militate against such a possibility. Delayed hypersensitivity response in healthy and in sick individuals indicates that both groups of non-cancer ill patients and healthy individuals respond immunologically like healthy patients and not like patients afflicted with advanced cancer. In other words, it was reasonable to assume confidently that prompt rejection of homographs in the aged non-cancer patients could be predictive.

This meaningful term, "practice of medicine," is well proven by the test of time since it was first mentioned by Hippocrates over 2000 years ago. It is within the profound concept of this particular specific designation that medical science has evolved. Without this functioning concept scientific medical research is imperiled. The practice of medicine throughout the centuries has been, to a great extent, a matter of trial and error, and thereby inevitably connoting clinical experimentation. The doctor-patient relationship, which is the core of the practice of medicine, is not altered by hospital practice.

If an error has, in fact, been committed, it is in an area of judgmental vagueness. "The reverse of error is not truth, but error still; truth may lie in between." The public interest may be better served by constructive suggestions aimed at greater clarification of more specific guidelines in clinical research.

However, in view of the apparent current unacceptable method of pursuing the highly laudable purpose of the research program, the respondents are found guilty of the charges herein.

I dissent from the majority opinion as to the measure of discipline. The record shows that both respondents are exceptionally well-trained and highly regarded clinical investigators, and strongly endorsed by the highest local and national medical authorities.

I, therefore, recommend no further action as to discipline be taken.

b.
Recommendations of the Medical Grievance Committee—June 10, 1965

To the Board of Regents:

I, the undersigned, secretary of the MEDICAL GRIEVANCE COMMITTEE duly appointed pursuant to the Education Law of the State of New York, do hereby certify:

1. That charges, in writing, were duly pre-

ferred and filed against Dr. CHESTER M. SOUTHAM and Dr. EMANUEL E. MANDEL, duly licensed physicians of the State of New York, hereinafter referred to as respondents, wherein each respondent was charged with fraud or deceit and unprofessional conduct in the practice of medicine within the purview and meaning of Section 6514, subdivisions 2(a) and 2(g) of the said Education Law; that a copy of the said charges with notice of hearing were duly served upon each respondent, and hearings duly held thereon before a subcommittee composed of Drs. Ames, (chairman) Heller and Wiener and its written report of findings and recommendations together with a transcript of the evidence were duly transmitted to me.

2. That the said report of findings and recommendations, with the transcript of evidence, wherein it was recommended that each of the respondents, CHESTER M. SOUTHAM, M.D. and EMANUEL E. MANDEL, M.D., be found guilty of each specification of the charges herein, and further, Drs. Ames and Heller recommended that each respondent shall receive a censure and reprimand, Dr. Wiener recommends that no further action be taken as to discipline, were duly submitted to the members of the committee at a regular meeting held on June 10, 1965.

3. That, after due consideration and discussion, the vote of each member of the committee present was duly recorded as follows:

RECORD OF VOTE

MEMBER	DETERMINATION	RECOMMENDATION
DR. LAWRENCE AMES	guilty— both charges	censure and reprimand
DR. SAUL I. HELLER	same	same
DR. MORRIS F. WIENER	same	no further action
DR. FRANCIS M. BENEDETTO	same	censure and reprimand
DR. PASQUALE CARONE	same	same
DR. IRVING L. ERSHLER	same	same
DR. HENRY I. FINEBERG	same	same
DR. FRANCIS O. HARBACH	same	same
DR. SYDNEY M. KANEV	same	same
DR. JAMES C. POTTER	same	no further action
DR. SAMUEL SANES	same	same
DR. ALFRED A. SCHENONE	same	censure and reprimand
DR. SOLOMON SCHUSSHEIM	same	same
DR. HERMAN B. SNOW	same	same
DR. MILTON S. WEINBERG	same	same
DR. WILLIAM L. WHEELER, JR.	same	same
DR. FREDERICK A. WURZBACH, JR.	same	same

4. That, as appears by the aforesaid tabulation of vote, the findings and recommendations

of the subcommittee as to GUILT was thereby adopted and made the findings, recommendation and determination of the committee; and it further appears by the said tabulation of vote as to the measure of discipline that the committee recommended to the Regents by a majority vote that each respondent be given a censure and reprimand on each specification of the charges.

I FURTHER CERTIFY that annexed hereto is a true copy of the record and proceedings taken herein as follows:

1. Transcript of the evidence
2. Report, findings and recommendation of the subcommittee
3. Report, findings, determination and recommendation of committee

All of which is respectfully submitted.

Henry I. Fineberg
SECRETARY

3.

The Board of Regents' Discipline Committee Reviews the Recommendations

We are of the opinion that there are certain basic ethical standards concerning consent to human experimentation which were involved in this experiment and which were violated by the respondents. When a patient engages a physician or enters a hospital he may reasonably be deemed to have consented to such treatment as his physician or the hospital staff, in the exercise of their professional judgment, deem proper. Consent to normal diagnostic tests might similarly be presumed. Even so, doctors and hospitals as a matter of routine obtain formal written consents before surgery, and in a number of other instances, and whether or not a specific consent is required for a specific act must be decided on the facts of the particular case.

No one contends that these 22 patients, by merely being in the hospital, had volunteered their bodies for any purpose other than treatment of their condition. These injections were made as a part of a cancer research project. The incidental and remote possibility, urged by Dr. Mandel, that the research might have been beneficial to a patient is clearly insufficient to bring these injections within the area of procedures for which a consent could be implied. Actual consent was required.

What form such an actual consent must take is a matter of applying common sense to the particular facts of the case. No consent is

valid unless it is made by a person with legal and mental capacity to make it and is based on a disclosure of all material facts. Any fact which might influence the giving or withholding of consent is material. A patient has the right to know he is being asked to volunteer and to refuse to participate in an experiment for any reason, intelligent or otherwise, well-informed or prejudiced. A physician has no right to withhold from a prospective volunteer any fact which he knows may influence the decision. It is the volunteer's decision to make, and the physician may not take it away from him by the manner in which he asks the question or explains or fails to explain the circumstances. There is evidenced in the record in this proceeding an attitude on the part of some physicians that they can go ahead and do anything which they conclude is good for the patient, or which is of benefit experimentally or educationally and is not harmful to the patient, and that the patient's consent is an empty formality. With this we cannot agree.

In his testimony before the subcommittee, Dr. Mandel took the position that he regards these experiments as beneficial to the patients both because the experiment might result in a diagnosis of an advanced cancer which had not been discovered by the hospital, and also because the participation in the experiment would result in extra medical attention to the patients involved and possibly other patients in the hospital. The record indicated that the only additional medical care any of these patients received as a result of this experiment was that the injections were made and they were occasionally checked thereafter as to the progress of the growth and disappearance of the nodule. The inference that participation in the experiment benefited the patients because of such additional medical care is without foundation in the record. Since the purpose of the experiment was to obtain verification of Dr. Southam's hypothesis that diseased patients would reject the implant in the same manner as healthy patients and that their rejection would not be delayed as was that of patients suffering from an advanced cancer, it is somewhat inconsistent for Dr. Mandel to say before the experiment was completed that he authorized it as a diagnostic measure. In any event, it was clearly not treatment, not experimental therapy, and not a diagnostic test which would reasonably be given to these particular patients. Nevertheless, from the manner in which they were asked for their consent and from

the statement to determine disease, the it was being treatment clearly and to volunteer research pro

There namely, the cells to be the respondent to be experiment not appreciate the patients cancer cells refrain from where t ment concluded harmful to fied that th the materi would upset consent. T far as this there was ship and, t their usual patient car volunteered understood matter whi withholding nondisclosure from delibe The respon hold the fa they thoug have refused cancer cell ever, a pos made by th ingly, the tained afte mation we for this rea Altho evidence in of these p mental co understand of giving with the d the report

the statement made to them that this was a test to determine their immunity or resistance to disease, the patients could naturally assume that it was being given to help in the diagnosis or treatment of their condition. They were not clearly and unequivocally asked if they wanted to volunteer to participate in an extraneous research project.

There is one point which is undisputed, namely, that the patients were not told that the cells to be injected were live cancer cells. From the respondents' standpoint this was not considered to be an important fact. They regarded the experiment as medically harmless. There was not appreciable danger of any harmful effects to the patients as a result of the injection of these cancer cells. It is not uncommon for a doctor to refrain from telling his patient that he had cancer where the physician in his professional judgment concludes that such a disclosure would be harmful to the patient. The respondents testified that they felt that telling these patients that the material did consist of live cancer cells would upset them and was immaterial to their consent. They overlooked the key fact that so far as this particular experiment was concerned, there was not the usual doctor-patient relationship and, therefore, no basis for the exercise of their usual professional judgment applicable to patient care. No person can be said to have volunteered for an experiment unless he has first understood what he was volunteering for. Any matter which might influence him in giving or withholding his consent is material. Deliberate nondisclosure of the material fact is no different from deliberate misrepresentation of such a fact. The respondents maintain that they did not withhold the fact that these were cancer cells because they thought that some of the patients might have refused to consent to the injection of live cancer cells into their bodies. This was, however, a possibility and a decision that had to be made by the patients and not for them. Accordingly, the alleged oral consents that they obtained after deliberately withholding this information were not informed consents and were, for this reason, fraudulently obtained.

Although there is conflicting testimony and evidence in this point, it is our opinion that some of these patients were in such a physical and mental condition that they were incapable of understanding the nature of this experiment or of giving an informed consent thereto. We agree with the discussion of this aspect of the case in the report of findings of Dr. Heller. We note that

in no case were any relatives of any of these patients told about the experiment nor were any of these patients asked if they wished to think the matter over or discuss it with their relatives. It is noteworthy that one of these same patients was operated on two days after the injections and that prior to making the operation, which was a part of the patient's treatment, the hospital obtained two separate written consents each signed by both the patient and a relative. If there was any doubt at all concerning a patient's ability to fully comprehend and consent to this experiment, it was the duty of the physicians involved to resolve that doubt before proceeding further. Even if we accept the testimony of Drs. Mandel and Custodio as to the condition of these patients, it is still clear that there was at least a doubt as to whether or not some of them fully understood what was going on and were mentally competent to consent. We do not say that it is necessary in all cases of human experimentation to obtain consents from relatives or to obtain written consents, but certainly upon the facts of this case and in view of the fact that the patients were debilitated, the performance of this experiment on the basis of alleged oral consents from those particular patients falls short of the ethical standards of the medical profession.

We now come to the question as to the ethical responsibility of Dr. Southam for the improper conduct of this experiment. In addition to his argument that the consent obtained was proper in all respects, Dr. Southam takes the position that he was not responsible for the internal practices at this hospital. He does not remember very well exactly what was said by Drs. Mandel and Custodio while they were obtaining the consents. He realized, however, that these patients were being approached for the first time. He also knew that they were all in a debilitated condition. As a physician in charge of the experiment, it was his duty to pay enough attention to what was going on to make sure that he was dealing with persons capable of being volunteers and sufficiently informed to consent to the use of their bodies for the experiment and not merely with people who were too confused or too sick or too resigned to object to the injection. He could not avoid responsibility for the procedure followed by Drs. Mandel and Custodio when he could see and hear what was going on. He accepts responsibility for the fact that the patients were not told the material to be injected consisted of live cancer cells. He

clearly indicates in his testimony that in such experiments he regards it as important to make it clear to the patients that what is being done is an experiment and is not for the treatment or diagnosis of their own condition, yet he was present, this was not adequately done, and he did not complain. A physician may not shirk his ethical responsibility or violate basic human rights so easily.

As the director of medicine at the hospital Dr. Mandel is directly responsible for the determination of the procedure followed in this experiment. His commendable desire to encourage research in the hospital cannot excuse his indifference to the rights of the patients. Although Dr. Mandel denied it, three of the physicians on his staff at the time testified that before this experiment was carried out he had discussed it with each of them and they had all individually told him that in their opinion he would be unable to obtain an informed consent from the patients. Dr. Mandel subsequently designated Dr. Custodio to carry out most of the details of the experiment and did not discuss it with those three physicians or with the staff physician who was responsible for making the normal rounds in the pavilion where the 19 non-cancer patients were housed. Dr. Mandel attempted to explain away the testimony of these four physicians by stating that they were all hostile to him. With respect to one physician who had been on the staff of the hospital for over 15 years and who held a responsible position under Dr. Mandel for over two years, and who had testified that many were physically or mentally incapable of giving an informed consent, Dr. Mandel testified that he never thought much of that doctor's ability. We believe the testimony of the other four physicians and agree with the statements of Dr. Heller in his report of findings that "the competent residents at Jewish Chronic Disease Hospital were deliberately bypassed by Dr. Mandel . . . because he knew they would only adhere to the procedure of informed written consent." Furthermore, Dr. Mandel was himself present while the first three patients were questioned and injected. The record indicates that the consents obtained from those three patients were defective in all of the respects discussed above except that they were apparently competent to have given an informed consent if they had been properly apprised of all the material facts. Dr. Mandel is equally responsible for failing to give adequate instructions to Dr. Custodio or to take any measures to assure that the other 19

patients were capable of giving an informed consent and in fact gave such consent.

An opportunity to appear before this committee was accorded to the respondents on October 5, 1965. Both respondents appeared in person. Dr. Southam was also represented by Philip Scott, John R. Hupper, and Gerald Oscar, his attorneys. Dr. Mandel was presented by Morris Ploscowe and by Irving Lattimer, his attorneys. John J. Calanese, assistant attorney general, appeared for the petitioner. This committee has given careful consideration to the entire record and to the briefs submitted to it and statements made before it.

After due deliberation and for all of the reasons discussed above it is the unanimous recommendation of this committee that the Board of Regents accept the findings of the medical committee on grievances that both of the respondents are guilty of fraud or deceit in the practice of medicine and of unprofessional conduct in the practice of medicine. It is also our unanimous recommendation that the Board of Regents modify the recommendation of said committee as to the measure of discipline, and that the medical license of each respondent be suspended for a period of one year on each specification, but that the execution of such suspensions be stayed, and each respondent be placed on probation for a period of one year upon the following terms and conditions:

1. That each respondent shall conduct himself in all ways in a manner befitting his professional status and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession.
2. That so long as there is no indication of any further misconduct, each respondent may continue to practice as a physician, but that the department, upon receipt of satisfactory evidence of any such further misconduct, may forthwith terminate the stay of execution and order that the stay be vacated and the medical license of the respondent or respondents involved be suspended for a period of one year from the date of said order.
3. That any such action by the department vacating the stay of the suspension as to either or both respondents shall in no way bar further disciplinary action based upon additional misconduct.
4. That each respondent shall notify the department of any change of address or employment.
5. That upon full compliance with these

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conditions for a period of one year each respondent may apply to the department for discharge from probation.

We trust that this measure of discipline will serve as a stern warning that zeal for research must not be carried to the point where it violates the basic rights and immunities of a human person.

Respectfully submitted,
JOSEPH W. MCGOVERN, CHAIRMAN
JOSEPH T. KING
CARL H. PFORZHEIMER, JR.

4.

The Board of Regents Decides

Board of Regents of the University of the State of New York Licenses Suspended, Suspensions Stayed, Respondents Placed on Probation*

Upon the report of the Regents Committee on Discipline, made in accordance with the provisions of section 211 of the Education Law, it was

Voted, That the determination of the Medical Committee on Grievances in the matter of Chester M. Southam . . . and Emanuel E. Mandel . . . be accepted, but that the recommendation of said Committee be modified and license No. 71055 and license No. 37359 respectively, issued under date of March 21, 1951, to said Dr. Southam and December 1, 1939, to said Dr. Mandel, and their registration or registrations as physicians, wherever they may appear, be suspended for a period of 1 year on each specification, said suspensions to run concurrently from the date of the service of the order effecting such suspensions, but that the execution of

* 34 *Journal of a Meeting of the Board of Regents of the University of the State of New York* 787 (1965). [The Board of Regents consists of 15 individuals elected by joint resolution of the two houses of New York's legislature for terms of 15 years. The Regents have jurisdiction over all education in the state, public and private, and over all licensed professions excluding the law. The three Regents most intimately involved in this decision were the three members of a special committee on discipline: Joseph W. McGovern, a lawyer; Joseph T. King, a lawyer; and Carl H. Pforzheimer, Jr., an investment banker. The remaining Regents, who concurred in the decision, are drawn from a variety of business and professional interests, including law, banking, education, and philanthropy.]

such suspensions be stayed, and each respondent be placed on probation for a period of 1 year upon the following terms and conditions:

1. That each respondent shall conduct himself in all ways in a manner befitting his professional status and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession;

2. That so long as there is no indication of any further misconduct, each respondent may continue to practice as a physician, but the Department, upon receipt of satisfactory evidence of any such further misconduct, may forthwith terminate the stay of execution and order that the stay be vacated and the medical license of the respondent or respondents involved be suspended for a period of 1 year from the date of said order.

3. That any such action by the Department vacating the stay of the suspension as to either or both respondents shall in no way bar further disciplinary action based upon additional misconduct;

4. That each respondent shall notify the Department of any change of address or employment;

5. That upon full compliance with these conditions for a period of 1 year each respondent may apply to the Department for discharge from probation; 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.

NOTES

NOTE 1.

ELINOR LANGER

HUMAN EXPERIMENTATION—NEW YORK
VERDICT AFFIRMS PATIENT'S RIGHTS*

* * *

[The] lawyers for Mandel and Southam raised two technical points of some interest. First, they claimed that, because "no clear-cut medical or professional standards were in force or were violated" by the two physicians, the attempt to find them guilty had an ex post facto quality. They also argued that the charges did

* 151 *Science* 663, 665-666 (1966). Reprinted by permission. Copyright 1966 by the American Association for the Advancement of Science.

not accurately fit the case. Testimony was introduced from well-known cancer and other professional researchers, including I. S. Ravdin, vice president for medical affairs of the University of Pennsylvania, and George E. Moore, director of Roswell Park Memorial Institute, to the effect that Southam's practices did not differ dramatically from those of other researchers. "If the whole profession is doing it," one of the lawyers remarked in an interview, "how can you call it 'unprofessional conduct'?" The lawyers also argued that the "fraud and deceit" charge was more appropriate to low-brow scoundrels, such as physicians who cheat on insurance, supply illegal narcotics, or practice medicine without a license, than to their respectable and well-intentioned clients.

To all arguments of humane motivations, extenuating circumstance, conflicting testimony, or legal ambiguities, the final answer of the Regents was very simple: It is no excuse. There was never any disagreement on the principle that patients should not be used in experiments unrelated to treatment unless they have given informed consent. But in the Regents' decision, two refinements of that principle are heavily stressed. The first is that it is the patient, and not the physician, who has the right to decide what factors are or are not relevant to his consent, regardless of the rationality of his assessment. "Any fact which might influence the giving or withholding of consent is material," the Regents said. . . .

The second principle stressed by the Regents is that the physician, when he is acting as experimenter, has no claim to the doctor-patient relationship that, in a therapeutic situation, would give him the generally acknowledged right to withhold information if he judged it in the best interest of the patient. In the absence of a doctor-patient relationship, the Regents said, "there is no basis for the exercise of their usual professional judgement applicable to patient care." Southam, in an interview, disagreed. "An experimental relation has some elements of a therapeutic relationship," he said last week. "The patients still think of you as a doctor, and I react to them as a doctor, and want to avoid frightening them unnecessarily." Mandel takes a similar position. In a letter to the editor of a medical affairs newspaper he stated: "In accordance with the age-old motto—*primum non nocere*—it would seem that consideration of the patient's well-being may, at times, supersede the requirement for disclosure of facts if such facts lack

pertinence and may cause psychologic harm." But on this point, the Regents are clear: "No person can be said to have volunteered for an experiment unless he had first understood what he was volunteering for. Any matter which might influence him in giving or withholding his consent is material. Deliberate nondisclosure of the material fact is no different from deliberate misrepresentation of such a fact."

In closing their case, and acknowledging that the penalties imposed were severe—they might have just authorized a censure and reprimand—the Regents were pointed and succinct: "We trust that this measure of discipline will serve as a stern warning that zeal for research must not be carried to the point where it violates the basic rights and immunities of a human person."

What the impact of the case will be is by no means clear. The Regents' decision outlines clear rules for a very narrow situation and attempts to set out some broad principles as well. But it is by no means binding, and it by no means covers the variety of situations with which researchers seeking to use human subjects are faced. The question is, What will cover these situations? Codes and declarations, of which there are already several, are too general to offer specific guidance. Researchers and patients alike are too vulnerable to await a slow case-by-case accretion of specific rulings. One alternative is the development within each hospital or research institution of "ethical review committees" that could define the consent-and-disclosure requirements for each proposed experiment and see that they were adhered to. In theory, this is already taking place. During the Southam-Mandel hearings, the state attempted to prove that Southam, a recipient of an NIH grant, had violated regulations of the Public Health Service. In fact, the regulations in question govern only the normal volunteer program of the NIH Clinical Center in Bethesda. The PHS response to an inquiry from New York's Attorney General made clear that the rules were not generally applicable and stated that, "in supporting extramural clinical investigations, it is the position of the Public Health Service that proper ethical and moral standards are more effectively safeguarded by the processes of review and criticism by an investigator's peers than by regulation."

That is the theory, but the trouble is it is not yet being done. And, given the tremendous growth and variety of medical research involving human beings, if it is not done by the sci-

entific community. The New beginning.

NOTE 2. AMERICAN ASSOCIATION MINUTES OF

The Annual Meeting was called to order at the Sheraton Hotel by President Kaplan. Two candidates for the recent Association, with Chester M. S. asked them to President.

Dr. Kaplan informed him

* 9 Proceedings for Cancer Research by Cancer Research

entific community, someone else will start to do it. The New York Regents may be only the beginning.

NOTE 2.
AMERICAN ASSOCIATION FOR CANCER RESEARCH
MINUTES OF THE 58TH ANNUAL MEETING*

The Annual Business Meeting of Members was called to order at 5:05 P.M., April 14, 1967, at the Sherman House, Chicago, Illinois by President Kaplan. . . . Dr. Kaplan said that the two candidates for Vice-President, as selected in the recent mail balloting by members of the Association, were Drs. Leon Dmochowski and Chester M. Southam; he appointed tellers and asked them to conduct the balloting for Vice-President.

* * *

Dr. Kaplan announced that the tellers had informed him that Dr. Chester M. Southam had

* 9 *Proceedings of the American Association for Cancer Research* 87-89 (1968). Copyright 1968 by Cancer Research, Inc. Reprinted by permission.

been selected as Vice-President of the Association for 1967-68. . . .

* * *

NOTE 3.
AMERICAN ASSOCIATION FOR CANCER RESEARCH
MINUTES OF THE 59TH ANNUAL MEETING†

The Annual Business Meeting of Members was called to order at 5:10 P.M., April 12, 1968, at Haddon Hall, Atlantic City, New Jersey by Vice-President Southam. . . .

* * *

Dr. Southam announced that the tellers had informed him that Dr. Abraham Cantarow had been selected as the Vice-President of the Association for 1968-69. The Secretary-Treasurer said that the Board recommended that Dr. Chester M. Southam be elected President for 1968-69. When no additional nominations were made from the floor, it was moved that these two officers be declared duly elected. . . .

* * *

† 10 *Proceedings of the American Association for Cancer Research* 110-111 (1969). Copyright 1969 by Cancer Research, Inc. Reprinted by permission.