626 South Staunton Drive
Tucson, Arizona 85710
September 9, 1974

Richard A. Lemen
Chief, Biometry Branch, DFSCI
NIOSH
U.S. Post Office Building
5th and Walnut Streets
Cincinnati, Ohio 45202

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Dear Dick:

Enclosed is my report of our recent trip to the Texas Asbestos Workers Program in Tyler.

Please let me know what happens with the findings and recommendations. If you have any questions, please call me.

Thank you.

Sincerely yours,

William M. Johnson, M.D.

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TEXAS ASBESTOS WORKERS PROGRAM

TYLER, TEXAS

AUGUST 26-27, 1974

TRIP REPORT: WILLIAM M. JOHNSON, M.D.

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Purpose:

On August 26 and 27, 1974, Richard Lemen of NIOSH and I reviewed many of the medical, epidemiological, and procedural aspects of the Tyler Asbestos Workers Program. This review was considered a function of NIOSH's responsibility to assist the National Cancer Institute in the monitoring of the contract with the Texas Chest Foundation in view of NIOSH's experience and expertise in asbestos epidemiology and field programs.

Findings:

A former asbestos worker of the Pittsburgh Corning Corporation plant was first seen on June 24, 1974. A total of 138 patients have been examined as of August 26, 1974, an average of three to four patients per working day. Reports on 64 patients have been sent to the patients and their private physicians as of August 26, 1974. The 64th patient was examined on July 18, 1974. This represents a delay in reporting of approximately five weeks; however, we were told most of the remaining patient reports would be completed during the week of August 26, 1974.

The acting Program Director and chief physician is Dr. John Miller, former Clinical Director of the East Texas Chest Hospital. This is a part time job for Dr. Miller, who recently left his full-time position with the East Texas Chest Hospital to enter the private practice of internal medicine and chest diseases in Tyler. Dr. Miller reportedly spends his largest block of continuous time at the Program on Wednesday afternoons, although he is available for a limited time on most other days. Dr. Hurst expressed concern about the need for a full time medical director and emphasized that Dr. Miller has extraordinary time demands in just establishing his private practice.

Dr. J.T. Lu has been recently assigned to the Program as a full time physician and has been seeing all the patents since August 15, 1974. Dr. Miller is reviewing chest X-rays and reviewing and signing patient summaries, after the clinical data has been assembled by the nurse.

Clinical data sheets including respiratory symptoms, smoking histories, pertinent physical findings, pulmonary function data, chest X-ray features, and sputum cytology findings are sent to each patient's private physician.

Following a brief review of a limited number of medical records, it is apparent that the diagnosis of asbestosis or "findings consistent with asbestosis" are not entered in the patient charts and

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letters. Two out of two individuals who were diagnosed as asbestosis in the NIOSH survey of October, 1971, by multiple criteria are not currently diagnosed as having asbestosis, despite the fact that these individuals meet multiple criteria for the diagnosis and have essentially the same findings as in 1971. The reluctance to include asbestosis in the charts is interpreted as a way to avoid involvement in compensation and legal actions. Consequently, the patient's private physician does not even receive benefit of the interpretation of whether his patient has asbestosis or "findings consistent with asbestosis".

Only a small fraction of the total number of chest X-rays have been interpreted by a radiologist and have a dictated report for the patient record. Examples were noted where the examining physician made handwritten interpretations on small sheets of paper, which did not even include the name of the patient. Also, the chest X-rays have not been interpreted according to either the U.I.C.C./Cincinnati or ILO-U/C Classification of Radiographs of Pneumoconiosis.

Also, the few charts we reviewed did not include a mounted 12-lead EKG with an interpretation by a cardiologist.

The sputum cytology laboratory is staffed by three technicians. The senior technician indicated she was pleased with the quality of specimens. Aerosol induction by an ultrasonic nebulizer is used for the collection of one specimen at the hospital. In addition, three first morning specimens are examined for the presence or absence of asbestos or ferruginous bodies using Papanicalou stain. Iron stain has not been used. The presence or absence of asbestos bodies or ferruginous particles is then reported to the patient and his physician without interpretation of their significance. The senior technician said she counts and records the number of particles in some specimens but not in relation to any specific unit area or volume.

Forced expirograms are obtained with an Ohio 842 spirometer with a graph recording. We did not observe an actual patient situation and the recording and calculation of spirometric values. Also, a twelve lead EKG is obtained in addition to blood samples for a hematocrit, hemoglobin, and carcinoembryonic antigen (CEA). The CEA test is provided by by Hoffman-La Roche. A urinalysis is performed without an apparent microscopic exam. Three technicians are budgeted for the pulmonary function, and blood and urine specimens

Each patient has four chest radiographs in the Radiology Department including a P-A and lateral with grid and a P-A and lateral without grid. A two minute processor is used, and total time in the Radiology Department is considered less than thirty minutes per patient.

Also, a questionnaire apparently pertaining to the patient by the nurse or social worker was submitted with the contract application to the National Cancer Institute and was never submitted for approval. It has not

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been formatted for keypunch coding purposes. It has been assumed that the "government" will provide the final questionnaire and obtain OMB approval. Consequently, the Program has been limiting the number of patients, awaiting a final questionnaire. NIOSH and NCI have been confused about their specific roles and responsibilities in developing a final questionaire. According to Dr. Michael Sporn, the NCI Project Officer, NCI is waiting for NIOSH and Dr. Irving Selikoff to develop a final questionnaire. Also, according to Dr. Sporn, NCI has responsibility for obtaining OMB approval. In addition, Dr. Sporn says that NCI expects NIOSH and Dr. Selikoff, with their experience in asbestos field investigations, to provide medical-epidiological and data control guidance to the Program. Dr. Selikoff apparently has a $40,000 contract with NCI to follow up the Patterson workers and provide guidance to the Tyler Program.

No meaningful provisions appear to have been made at this time for data handling including coding and reduction of medical information. Also, it appears that no decision has been made regarding where and who will do the computer storage and analysis of the data.

Patients are entered into a master log book and assigned a Program number as they are seen. When summary letters and data are sent to individual patients, the date of correspondence and a check mark are inserted in the patient name column in the log book.

Richard Lemen and I learned that in November 1973, chest X-rays and pulmonary function studies were obtained by the East Texas Chest Hospital, at the expense of the Pittsburgh Corning Company, on many workers included in the August 1971 medical studies. According to Herman Yandle, the former local union chairman, the workers and their physicians have never received the results of the November 1973 medical studies.

Richard Lemen and I visited Dr. Haskell Muntz in his office in Tyler. Dr. Muntz is in the practice of general internal medicine and has referred approximately 70 former Tyler asbestos workers to a Tyler thoracic surgion for closed lung biopsy at the Mother Frances Hospital. Dr. Muntz said that as many as two to three men have been biopsied on some days and that no biopsies have been done in recent weeks. A local pathologist has read the biopsies and microscopic evidence of asbestosis reportedly has been found in individuals with no other objective clinical evidence of asbestosis and in individuals with very brief employment at the asbestos plant. Individuals reportedly are admitted to Mother Frances Hospital for one day, and the closed lung biopsies are done under a local anesthetic in the operating room. Dr. Muntz expressed to us the opinion that the procedure entails a low risk and that a tissue diagnosis of asbestosis is essential for purposes of litigation and compensation, particularly in patients with a negative chest X-ray. I expressed my reservations to Dr. Muntz about using

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an invasive procedure with a low but definite risk to make the diagnosis of asbestosis. I expressed my opinion that one must look at the entire clinical picture and the exposure history.

Dr. Muntz said that he personally had delivered frozen lung tissue to Dr. Selikoff in New York and that he had not received any interpretations from Dr. Selikoff.

Dr. Muntz expressed concern about the psychological health of the former asbestos workers in his practice and said that they were as a group bitter and depressed about their prognosis. Dr. Muntz said many of the former workers have shown marked improvement in the forced expirograms over the past several months following symptomatic treatment in addition to allery shots for pollenosis.

Richard Lemen and I talked briefly by telephone with Mr. Fred Baron, a Dallas attorney who is representing many of the former workers. I again expressed my reservations about doing closed lung biopsies for litigation and compensation purposes.

During a two week period ending June 3, 1974, a total of eleven educational meetings were held within a 50 mile radius of Tyler. A total of 689 letters were mailed inviting former workers to attend, and a total of 198 individuals attended these evening meetings. In addition, 60 individuals contacted the Program for an appointment.. Summaries of the educational meetings were sent to those unable to attend, including approximately 180 individuals out of state and in the Dallas and Houston metropolitan areas. Approximately 130 individuals are lost to follow up as confirmed by returned Program correspondence.

Four sessions were held at the East Texas Chest Hospital (three for former workers and one for hospital staff). In addition, meetings wer held in Athens, Longview, Kilgore, Hawkins, Jacksonville Lindale, and Gilmer, Texas. The meetings consisted of a slide presentation followed by a question and answer period. These meetings were largely the responsibility of Mrs. Fielding, the Program nurse, and Mrs. Klein, a social worker.

Richard Lemen and I paid a visit to the Imperial American Company, the current owner of the building in the Owentown Industrial Park formerly occupied by the Pittsburgh Corning Corporation asbestos operations. We discussed the asbestos problem with Mr. Dennis M. McInnis, the Plant Manager of Imperial American.. For the past year the building formerly housing the asbestos operations has been leased to International Metals for storage of electrical appliances such as evaporative coolers. Richard Lemen and I toured the building with permission and could find no visual evidence of residual asbestos dust. The NIOSH regional office in Dallas reportedly did an industrial hygiene evaluation for residual asbestos dust several months ago, and reportedly neither the Imperial American Company nor the Division of Field Studies and Clinical Investigations received a report.

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Conclusions, Recommendations, and Questions:

1.) A medical director is needed who can devote all or a significant proportion of his professional time to the Program. Dr. Miller has the pressing demands of a private practice. The problem of recruiting a qualified and experienced chest physician for the position has no easy solution.

2.) All chest X-rays should be read by a radiologist, hopefully with some training, interest, and experience in occupational lung disease. All chest X-rays should be read with a comprehensive radiological interpretation and according to the U.I.C.C./Cincinnati or ILO-U/C Classification of Pneumoconiosis. A dictated report by a radiologist should become a part of each patient's medical record, a copy of the report should be placed in the X-ray envelope, and an additional copy should be sent to the patient's private physician.

3.) Each sheet of paper in the medical record should include the patient's name for medical-legal reasons and for good record keeping. Also, an identification number should be on each sheet. Perhaps each patient should have an identification plate for stamping of medical record sheets, as used in a hospital or clinic setting.

4.) The master log book used to enter patient names and identification numbers is not adequately organized. For example, there are no separate columns for recording only disposition data and when summary medical data has been forwarded to the private physicians. Consequently, the log does not fulfill any control or scheduling function. Also, the secretary has made data entries in the patient name column which only she or a limited number of people can understand.

5.) All addresses on envelopes are individually typed. Mailing address labels should be made up in advance using modern data processing or computer methods. Many of these addresses already have been key punched by NIOSH.

6.) A medical records consultant should review the entire method of record keeping and data flow in view of the current inadequacies. Also, no provisions have yet been made for formatting the medical data for computer storage and eventual analysis. No decisions or concrete plans have been made about who will do the data processing and control.

7.) The National Cancer Institute apparently has not yet even applied for preliminary OMB clearance on a questionnaire. Also a final questionnaire has not been drafted, and final clearance has not been requested. The exact roles of NIOSH, [illegible], and Mt. Sinai in the development, approval, and [illegible] organization of the questionnaire has not been defined adequately. Also, the Program in Texas has limited the number of scheduled appointments, while awaiting a final questionnaire from the "government".

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8.) A final questionnaire should be put into finished form quickly, and OMB approval should be requested without delay. Meanwhile, at least 10 patients should be scheduled daily in view of the number of professional and technical staff and the availability of sputum cytology and radiological services. The present questionaire should continue to be used until a final form is available.

9.) Asbestosis or "findings consistent with asbestosis" should be used in the medical record. The patient may request that his data be released to his legal representatives for purposes of litigation or compensation. The medical record should include an accurate clinical assessment including the diagnosis of asbestosis based on sound criteria; moreover, an interpretation regarding the presence of asbestosis or "findings consistent with asbestosis" should be forwarded to the patient's private physician, not just fragments of clinical data which the average physician has no way of interpreting as asbestosis.

10.) Carcinoembryonic antigen (CEA) testing is being provided by a major pharmaceutical company. This is a controversial test is view of the problems of false-positive and false-negative results. Who will provide sigmoidoscopic and barium enema procedures? Has this phase of the Program, which is essentially clinical research, been reviewed by a human subjects research committee. There is already some epidemiological data pointing toward an increased risk of colon cancer in asbestos workers according to Dr. Selikoff. The current questionaire does not assess change in bowel habits which may be the first hint of colon cancer. Also, the physical exam does not include apparently a rectal examination and test for occult blood, particularly in those individuals who are over age 50.

11.) Have the research and clinical aspects of the Program been reviewed in total by an NCI human subjects review committee. It is my understanding that at this time not one full time U.S. Public Health Service physician has made a site visit to the Program, despite the fact that the Program exists basically for the medical surveillance and the early clinical detection of lung cancer in a high risk group.

12.) Although I have serious reservations about the closed lung biopsies reportedly performed on 70 former asbestos workers, the slides should be reviewed by a pathologist experienced in occupational lung diseases and asbestosis. For example, the confirmation of asbestosis in a number of workers with short exposures would have scientific and medical value, particularly in those individuals with no radiological or other clinical evidence of disease.

13.) Why were the results of the November 1973 medical studies performed at the East Texas Chest Hospital not forwarded to the former workers and their physicians?

14.) Most of the education meetings were held in a two week period beginning in late May. Apparently there has been minimal

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initial publicity and no continuing publicity of the Program in local newspapers, radio, and television. Should the Program maintain a low profile with the local media?

15.) No educational meetings reportedly have been held with local physician groups. The clinical and procedural aspects and Program goals should be explained at clinical conferences at local hospitals.

16.) Many of the workers reportedly are very depressed and anxious about the projected increased incidence of cancer and disabling lung disease. Should not a social psychiatrist or behavioral scientist be consulted about the problem in order to maximize the total health benefit of the Program?

17.) Two social workers are currently employed, and a third social worker is budgeted. Comprehensive social and economic information apparently is not being vigorously obtained from those patients and their families with employment, financial, and health complications associated with past occupational exposures to asbestos. Working relationships apparently have not been established with local social agencies to assure maximization of benefits and public services. Also, the number of home visits have been minimal.

18.) Many workers reportedly are very suspicious of the Program objectives and integrity. If these attitudes appear to endanger the success of the Program, perhaps the staff should undergo sensitivity training directed toward the warranted confidence and needs of their patients. Many of the former asbestos workers see the East Texas Chest Hospital as an agent of the Pittsburgh Corning Corporation, because the workers were initially told there were no cases of asbestosis in the medical survey of August 1971 performed by the hospital at the expense of the company.

19.) The identification and reporting of asbestos or ferruginous bodies in the sputum of former asbestos workers appears to be a meaningless endeavor with no diagnostic or prognostic significance. What is the research objective of this procedure?

20.) Apparently part time workers including college students and individuals obtained from Manpower were employed at the Pittsburgh Corning Corporation plant in such activities as unloading bags of asbestos from railroads cars. These individuals should be identified and offerred the services of the Program.

21.) Some Program staff members expressed concern and confusion about the selection of a control group. How would a control group be utilized at the present time. Would a control group be important in interpreting the prevalence and incidence of sputum cytology findings of atypical [illegible], NIOSH and NCI should reach an agreement on the indications for and selection methods of a control group. A control group seems academic at this time, because top Program priority should be devoted to health screening of the highest risk former asbestos workers.

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22.) The NIOSH Regional Office in Dallas should send a report of their industrial hygiene findings about the building formerly occupied by the asbestos operations to all concerned parties.

23.) The roles and expectations of NIOSH, NCI, and Mt. Sinai in the Program need further discussion and possibly formal agreement. Perhaps, the time has come for a meeting of all concerned parties to evaluate the current status and progress of the Program and their respective roles. Prior to such a meeting, the Program personnel should prepare a progress report and activities summary.

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Respectfully submitted,

William M. Johnson

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