tabershaw/cooper associates inc.
2180 Milvia Street, Berkeley, California 94704. Telephone (415) 845-3355

W. CLARK COOPER, M.D.
Vice President and Scientific Director

28 February 1974

RECEIVED
MAR 4 1974
H. A. SINCLAIRE, M.D.

H. A. Sinclaire, M.D.
Associate Medical Director
Mobil Oil Corporation
150 East 42nd Street
New York, New York 10017

Dear Dr. Sinclaire:

This is in reply to your letter of 5 February 1974 to Dr. Tabershaw, which you and I discussed by telephone last week. While I think it is desirable and necessary to determine to what extent refinery workers may have been affected by asbestos, I am not sure that the present protocol is the best way to go about it. I think that one could learn more at less cost.

First, as you know, asbestosis (asbestos pneumoconiosis) develops rather slowly and does not usually manifest itself in diagnosable form until 15, 20 or more years after exposure. It may sometimes appear years after exposure has ceased. In our experience, changes are not very rapid from year to year.

The prevalence of diagnosable asbestosis in any group, however, is a good indicator of how many have had fairly heavy exposures at some time in the past. The asbestos-related diseases that are our major concern these days are lung cancers and mesothelial tumors of the pleura and peritoneum, which characteristically do not appear until 20 or 40 years after exposures begin. The latter are rarely picked up by periodic physical examinations even in high risk groups, and may occur without diagnosable asbestosis, even though examination of the tissues may show that there is evidence of subclinical disease.

I recommend that you not commit yourself to a 5 year study until the situation has been appraised by a single cross-sectional survey. This should include the elements you mentioned, i.e. history, chest roentgenography and pulmonary ventilatory tests. Blind film reading would be desirable and we would suggest two readers, one regarded as conservative and one as liberal. We have found that the early changes of asbestosis are so non-specific that readers are strongly influenced by their knowledge of work histories.

PLAINTIFF'S EXHIBIT
MBL-111

The population selected for study should include all individuals who can be identified as having worked with asbestos, either in the application or tear-out of insulation, and others who have worked nearby. Again, in our experience it would be unusual to find that the indirect exposures would be sufficient to cause asbestosis, but they might be found to entail a measurable tumor risk. Workers over 55 years of age should not be excluded, as they would provide much useful information.

I would not regard the followup examinations as really part of the study but instead part of the clinical management that plant medical departments provide. Asbestosis is not likely to develop rapidly enough for annual examinations to be necessary in younger employees but, would be desirable in older workers with long work histories. Some people are recommending chest films every 4 or 6 months in people known to have had exposures beginning 20 or more years ago and who smoke cigarettes. This would not be expected to produce much of a yield but would be good occupational medicine on an individual plant basis. They should be done whether or not a man had disgnosable asbestosis.

The mortality study that we are currently doing for API should be looked at to see what information it can provide regarding asbestos. Certainly we should check out lung cancers and mesotheliomas (if any) that turn up in our death record search. As you know, we are also working on a data system for medical and environmental records for API which would lend itself to use in the study you have proposed.

If you are receptive to our developing a more detailed and specific protocol for managing a cross-sectional study along the lines I have suggested above, we would be glad to do so. We could also cost it out, based on the assumption that actual roentgenograms, histories, and pulmonary function test results would be provided by the individual refinery participants under the contractor's supervision. We could do the examinations ourselves in special situations.

We look forward to hearing from you. Best wishes.

Sincerely,

W Clark Cooper /RFB

W. Clark Cooper, M.D.

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6 Mar. '74 - Talked c̄ C Cooper. Will send $ cost for study.

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DRAFT

PROTOCOL FOR A FIVE YEAR STUDY OF THE PROBLEM OF ASBESTOSIS AMONGST OIL REFINERY WORKERS IN FIVE REFINERIES OWNED BY FIVE DIFFERENT CORPORATIONS

1. For purposes of this study all prospective participants should be studied yearly for a minimum of 5 years, a minimum of 3,000 persons are needed.

2. The participants should be all refinery workers under age 55 at the onset of the study in the participating oil refineries. (This assumes a usual retirement age of 60 or 62 years.)

3. The proposed study will include:

   a) a multiple choice history completed by the participant to include questions concerning:

      1. exertional dyspnea
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The history is to be reviewed by a physician. A complete physical examination will then be performed with special emphasis on the chest. Standardized pulmonary function studies on a Pulmonor Vital Capacity FEV, and a 14" x 17" chest x-ray; AP + Lateral will be done.

Any person found to have an abnormal chest x-ray and/or a vital capacity less than 85% of the predicted maximum expiratory flow rate, should be examined by a pulmonary specialist for diagnosis and possible recommended care. All chest x-rays will be reviewed by two radiologists, centrally located, doing blind

readings and reviewing each other's reports.

All subjects having a diagnosis of asbestosis should have an x-ray every four months instead of yearly, to observe the progression of the disease.

The overall study will be monitored by a university-connected pulmonary specialist, data collected, tabulated and a report written. The study's cost will be underwritten by the participating refineries' parent organization.

N. B.. 1. Controls would be refinery office workers and other non-manual workers in a refinery population.

2. Refinery participants would be geographically dispersed.

3. Data collection systems will conform with computer programs.

HAS/maw

2/5/74

tabershaw/cooper associates inc.
2180 Milvia Street, Berkeley, California 94704. Telephone (415) 845-3355

W. CLARK COOPER, M.D.
Vice President and Scientific Director

April 5, 1974

H. A. Sinclaire, M.D.
Associate Medical Director
Mobil Oil Corporation
150 East 42nd Street
New York, New York 10017

Dear Dr. Sinclaire:

Enclosed is TCA's proposal for A Study of Refinery Workers Exposed to Asbestos. I believe it is in line with our telephone discussion and your letter of 5 February, 1974. We would like very much to be associated with Mobil in this undertaking.

I will be out of the country for the next two weeks, but if you have any questions or need additional information, please do not hesitate to call Mr. Robert Boggus or Mr. Richard Davis. Either will respond to your needs.

We will eagerly await your reply.

Sincerely,

W. Clark Cooper, M.D.

Enclosures

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PROPOSAL FOR A STUDY

OF REFINERY WORKERS EXPOSED TO ASBESTOS

INTRODUCTION

There is ample documentation to show that many workers exposed to insulating materials develop pneumoconiosis and that they have a high incidence of lung cancer and other neoplasms associated with the inhalation of asbestos (Leathart et al; Selikoff; Cooper and Balzer; Tabershaw, Cooper and Balzer). Balzer and Cooper included workers engaged in refinery construction in their studies of the levels of exposure to asbestos. Both asbestosis and malignancies may not appear until many years after brief but heavy exposures.

For these and other reasons, we think it is prudent for refineries to define their worker populations who are potentially exposed to asbestos and to determine whether or not there is any evidence of asbestos-related disease in those who have been exposed. Useful information may be forthcoming to some extent from the American Petroleum Institute (API) long-term mortality study. Negative information from the mortality study may not be conclusive, however, in view of the dilution of asbestos-exposed workers by a large population that was not exposed, i.e., those actually exposed to asbestos are not identifiable.

TABERSHAW/COOPER METHODOLOGY

We feel that a practical approach would be to perform a cross-sectional survey of individuals who are directly exposed to asbestos, and others indirectly exposed (i.e., in jobs that require them to work in areas near those where asbestos work is going on), to determine the prevalence of changes indicative or suggestive of asbestosis. Our review of chest films of insulating workers in the San Francisco areas shows clearly (See Table) that many exhibit positive findings.

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Table Analysis of Chest X-ray Films

Period of Entering Trade	No. Available for X-ray Films	No. Having X-ray Film(s)	No. with Definite Changes Consistent with Asbestosis	
			No.	%
1906-1910	0	0	0	0
1911-1915	2	2	2	100
1916-1920	8	5	5	100
1921-1925	7	3	2	67
1926-1930	19	13	8	62
1931-1935	17	13	6	46
1936-1940	49	41	17	41
1941-1945	117	101	33	33
1946-1950	61	47	12	26
1951-1955	69	57	5	9
1956-1960	74	55	2	4
1961-1965	57	49	1	2
Total	480	386	93	24

The absence of such findings would be very reassuring to the individual firm as well as to the industry. A cross-sectional survey would provide information which would indicate whether or not a problem exists, and would also define a population which could be the subject of ongoing follow-up, without the need of plant identification. The plan for such a study is detailed in the following paragraphs.

STUDY PLANT

The survey logically falls into five phases:

I. Definition of the population to be studied;

II. Development of detailed instructions and forms for use by participants;

III. Performance of examinations and tests;

IV. Interpretation of tests and analysis of data; and,

V. Preparation of final report.

PHASE I. DEFINITION OF THE POPULATION TO BE STUDIED

A. Planning Meeting

After authorization to proceed, members of the Tabershaw/Cooper Associates, Inc. (TCA) project team would meet in a mutually agreed upon location with representatives of participating plants. We anticipate that five (5) plants will be involved, representing approximately 3,000 employees. The purpose of the planning meeting will be to:

(1) Establish lines of communication and coordination;

(2) Discuss the format and content of a questionnaire to be completed at each plant.

(3) Agree upon a schedule for information flow, plant visits by TCA personnel and all other major milestones.

B. Environmental Information

As part of the information required for the study, each participating plant would inform TCA (in a prescribed format) of those plant areas regarded as potentially hazardous; provide quantitative measurements of airborne asbestos (if available); describe the use of materials containing chrysotile and amosite; and, estimate the degree to which there has been recent substitution of fibrous glass or mineral wool for asbestos insulation. Other environmental data, as appropriate, also may be requested from the plants.

C. Listing of Population

In addition to the environmental data, each plant would provide TCA with:

1. The names of all employees currently engaged in the application, repair or removal of insulating materials including sprayed asbestos materials; and,

2. The names of all employees who work in areas where the above cited operations are performed.

3. For all employees identified above, a brief history including date of birth, date of hire, date(s) when possible exposure to asbestos began or ended.

PHASE II. DEVELOPMENT OF INSTRUCTIONS AND FORMS

Given the complete and accurate listing of personnel, TCA will develop standard forms for medical history, physical examination, and laboratory reports on each person. This will assure comparable data and results for the populations at each refinery. The forms will include:

(1) Detailed occupational history;

(2) Standardized smoking history;

(3) Standardized history for dyspnea;

(4) Examination of lungs with special attention to evidence of rales and thickening of pleura;

(5) Uniform examination for clubbing of fingers;

(6) Pulmonary ventilatory tests to determine forced vital capacity and forced expiratory ventilation;

(7) Chest roentgenograms by techniques designed for maximum detection of early pneumoconiosis; and,

(8) Use of UICC/Cincinnati classification system films.

So as to assure further the uniformity and comparability of results, staff members of TCA will visit each plant site to discuss methodologies with the medical department. This will include, for instance, instructions on the use of the forms, discussions about the quality of radiography, preview of examinations procedures and the like.

PHASE III. PERFORMANCE OF EXAMINATIONS AND TESTS

There are two logical alternative methods for performing the actual physical examinations and tests on the population. The first, and the one we recommend, would be for each local refinery, in its own medical department, or by arrangement with local physicians and laboratories,

to accomplish the tasks. The use of TCA forms and instructions would provide uniformity of results. The medical data would then be forwarded to TCA medical personnel for interpretation and inclusion in the final report. The second method would be for staff members of TCA to visit each refinery and carry out part or all of the examination. This method might increase somewhat the uniformity of results but would be considerably more costly. In our schedule and cost section, we have assumed the first method as being acceptable to all parties.

PHASE IV. INTERPRETATIONS OF TESTS AND ANALYSIS OF DATA

Tabershaw/Cooper Associates, Inc. would interpret all chest films. As part of this service, interpretations (without knowledge of exposures) would be made by a radiologist identified with the development of the UICC/Cincinnati classification and major consultant to NIOSH.

All information would then be analyzed and employees would be grouped by age, length, and intensity of potential exposures to asbestos. These characteristics would be correlated with x-ray classifications and pulmonary function results, as well as physical findings and symptoms. From these results it would be possible to determine how the groups compare internally and how they compare with other populations who have had asbestos exposures.

PHASE V. PREPARATION OF FINAL REPORT

At the conclusion of the study, a first draft of a report would be prepared for review by representatives of the participating plants. Following such review, the report will be finalized and thirty copies made available to the review committee. The report will include the following:

(1) Background discussion;

(2) Copies of procedures, instructions, the questionnaire, forms etc.;

(3) Tables summarizing the data;

(4) Discussion of conclusions reached by the analysis; and

(5) Recommendations as to the number of individuals needing specialized periodic followup and the nature of such followup action.

TCA PERSONNEL

This project would be under the direction of Dr. W. Clark Cooper and would include the support of our professional staff such as board certified physicians, registered nurse, statistician and epidemiologists. Resumes of all personnel, and the background of TCA, are included for your information.

SCHEDULE AND COST

We think the study can be completed within twelve (12) months from the data of authorization to proceed. Our estimate for the timing of each phase is as follows:

Phase I	3 months
Phase II	2 months
Phase III	4 months
Phase IV	1.5 months
Phase V	1.5 months

This requires timely action on the part of TCA and the participating plants. To assure milestone definition, a detailed schedule will be established at the Phase I planning meeting.

Our price for the complete study is $71,325. This includes professional labor, travel, x-ray interpretation and all other costs associated with the completion of the project.

Memorandum from H. A. SINCLAIRE, M. D.
NEW YORK, N. Y.

Date 16 Jan. 74

To T.E. Allen, M.D.

Ted

Attached is the draft of asbestosis study. If you have suggested corrections, pls. feel free to "blue pencil". It is then to be finalized for P.C.K. ~~IAS~~ presented.

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DATE 23 January 1974

TO

Dr. H.A. Sinclaire

C. C.

This memorandum is in reply to your request for the protocol for an asbestosis study. The undersigned feels that the protocol that you submitted is most adequate if purely for basis for discussions with Mobil management. However, if this same protocol is one to be presented to other cooperating oil companies, I think considerable material needs to be added to it. Essentially, these materials at least should include:

1) A very detailed explanation of what the proposed study would include - including details on the content of the physical examination, types of pulmonary studies and type of examination, including what standards should be utilized in judging and reading x-rays in terms of specific exposures.

2) The exclusion of the utilization of a nurse in reviewing the history proposed by this protocol. As you know, many of our colleagues in other oil companies are not as kindly disposed to nurses reviewing history forms as we are in Mobil. I think the nurse involvement might also be interpreted by union representatives as an evidence of placing less importance on the study.

3) A study of this nature would probably, in my opinion, lose much of its creditability if done by a joint committee made up only of the medical advisers of each of the participating companies. Although the actual medical examination and clinical studies could be done within the respective participating company, the agency doing the study and collecting the data should, in my opinion, be an outside agency such as TCA, Univ. of Michigan, Harvard, or possibly a clinical group such as the Cornell group.

4) The cooperating committee or the single outside agency directing the study should establish in advance what represents the criteria for an exact diagnosis of asbestosis, otherwise this aspect of the study could be seriously challenged by the union medical advisers.

5) I think a protocol such as this should involve estimates of cost since I am sure that each cooperating company as well as our management would want to know what is involved as far as investment.

These are some of the items that I think should be included, if this does represent, as I stated earlier, a protocol for general review inside and outside of Mobil.

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Theodore E. Allen, M.D.

TEA:jd

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HAS/maw

2/5/74

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