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Committee Meeting with Attachments

AMERICAN PETROLEUM INSTITUTE

MEDICAL ADVISORY COMMITTEE

31ST MEETING

9:00 A. M.

Saturday, April 8, 1961

Denver Hilton Hotel, Denver, Colorado

MEMBERS PRESENT:

J. W. Osborn, M. D., Chairman  
Leo J. Wade, M. D., Vice Chairman  
(Represented by N. J. Roberts, M. D.)  
L. E. Renes, Secretary

O. Armstrong, M. D.  
C. Baird, M. D.  
(Represented by R. W. Pipkin, M. D.)  
H. Baylor, M. D.  
F. Boys, M. D.  
H. Collings, M. D.  
E. Curtis, M. D.  
E. Eckardt, M. D.  
(Represented by T. G. Rigney, M. D.)  
M. Frank, M. D.  
D. Gassaway, M. D.  
V. Henson, M. D.

E. K. Linder, M. D.  
C. R. Miller, M. D.  
T. H. Mitchell, M. D.  
M. R. Plancey, M. D.  
J. C. Ruddock, M. D.  
C. L. Samuelson, M. D.  
G. M. Saunders, M. D.  
Ralph Schneider, M. D.  
(Represented by N. J. Roberts, M. D.)  
G. A. Sinclair, M. D.  
W. Wayne Stewart, M. D.

TECHNICAL ADVISORS PRESENT:

W. Adams  
H. Barcus  
A. Burhouse  
E. Chalfant  
K. Daniels  
E. Entwistle  
W. Gerarde, M. D.  
(Represented by T. G. Rigney, M. D.)

P. D. Halley  
N. V. Hendricks  
P. K. Kuhne  
C. A. Neilson  
J. B. Rather, Jr.  
J. A. Spence

MEMBERS ABSENT:

M. Adams, M. D.  
E. Allen, M. D.  
W. Crookshank, M. D.  
Jeffery Davis, M. D.  
L. R. Fourcher, M. D.

R. Emmet Kelly, M. D.  
T. J. Kelly, M. D.  
E. P. Luongo, M. D.  
B. S. Miller, M. D.  
R. J. Potts, M. D.

MEMBERS PRESENT:

Prof. Philip Drinker, Consultant  
R. Dugan, M. D.  
O. Mattocks  
van Raalte, M. D.  
B. Simon, M. D.

- Harvard University
- Continental Oil Company
- American Petroleum Institute
- Royal Dutch Shell, Netherlands
- Esso Standard, Paris

2. OPENING REMARKS

J. W. Osborn, M. D., Chairman of the Medical Advisory Committee, welcomed all members present. He thanked each one for his effort in attending the meeting.

3. INTRODUCTION OF NEW MEMBERS AND GUESTS

G. A. Sinclair, M. D. and E. V. Henson, M. D. were appointed new members of the Medical Advisory Committee.

The following new technical advisors have been appointed since the last meeting: J. A. Burhouse, W. E. Chalfant, A. W. Lindert, and T. J. Smith, M. D.

The following guests were introduced: R. R. Dugan, M. D., assistant to J. O. Armstrong, M. D.; R. W. Pipkin, M. D. representing V. C. Baird, M. D.; T. G. Rigney, M. D. representing R. E. Eckardt, M. D. and H. W. Gerarde, M. D.; N. J. Roberts, M. D. representing R. F. Schneider, M. D. and Leo J. Wade, M. D.; K. B. Simon, M. D., from Esso Standard of Paris; and H. van Raalte, M. D., from Royal Dutch Shell, Netherlands.

4. APPROVAL OF NOVEMBER 14, 1960 MINUTES

ACTION: It was regularly moved, seconded, and unanimously passed that the minutes of the 30th Meeting of the Medical Advisory Committee, held November 14, 1960, in the Conrad Hilton Hotel, Chicago, Illinois, be approved as distributed.

5. SUBCOMMITTEE REPORTS

5.1. Operating Subcommittee

The minutes of the Operating Subcommittee are attached as Appendix A.

The following recommendations of the Operating Subcommittee were considered and acted upon by the Medical Advisory Committee:

(1) Hazleton Laboratories wrote R. E. Eckardt, M. D. requesting that he determine if the API would be interested in contributing to a program, costing about \$37,000, to prepare a monograph of data on control rats used in long-term studies.

ACTION: It was regularly moved, seconded, and unanimously passed that the request from the Hazleton Laboratories for financial assistance to prepare a monograph on data on control rats used in long-term studies be denied.

(2) R. E. Eckardt, M. D., Chairman of the Subcommittee on Carcinogenicity, recommended previously that the subcommittee be discontinued and that no subcommittee dealing entirely with cancer matters be set up.

ACTION: It was regularly moved, seconded, and unanimously passed that no subcommittee of the Medical Advisory Committee be set up solely to handle matters relating to carcinogenicity and if any subcommittee has a problem dealing with carcinogenicity, it obtains such assistance as is needed or they request the Medical Advisory Committee to help them.

ACTION: The report of the Operating Subcommittee was accepted.

B. Atmospheric Pollutants

Mr. Herman Barcus, Secretary of the Subcommittee on Atmospheric Pollutants, gave the report of this group. The recommendations of the subcommittee that copies of Dr. Goldblatt's Summary be sent to the U. S. Public Health Service, to the API Air and Water Conservation Committee, and that Dr. Goldblatt's data be sent to the American Documentation Institute, Washington, D. C., the Medical Advisory Committee raised considerable objections.

ACTION: It was regularly moved, seconded, and unanimously passed that the references C., D., and E., relating to the Goldblatt report, be deleted from the subcommittee's report.

Likewise, several editorial and clarification changes to the subcommittee's report were approved.

ACTION: It was regularly moved, seconded, and unanimously passed that the amended report of the Subcommittee on Atmospheric Pollutants be approved. The amended report is shown in Appendix B.

C. C<sub>9</sub> - C<sub>12</sub> Aromatics

T. M. Frank, M. D. gave the report of this subcommittee. His report appears as Appendix C.

ACTION: It was regularly moved, seconded, and unanimously passed that the report of the Subcommittee on C<sub>9</sub> - C<sub>12</sub> Aromatics be adopted.

D. Certificates of Appreciation

J. W. Osborn, M. D. reported that the Subcommittee on Certificates of Appreciation met with three members present. They have several suggestions which will be processed through the Operating Subcommittee and, with its approval, to the Medical and Health Committee with a request for approval to issue Certificates of Appreciation at the November meeting of the Medical Advisory Committee.

ACTION: It was regularly moved, seconded, and unanimously passed that the report of the Subcommittee on Certificates of Appreciation be approved.

E. Dermatology

C. H. Baylor, M. D. gave the report of this subcommittee for Leo J. Wade, M. D., Chairman. A copy of his report is attached as Appendix D.

ACTION: It was regularly moved, seconded, and unanimously passed that the report of the Subcommittee on Dermatology be adopted.

F. Epidemiology

G. M. Saunders, M. D. reported that his group is working on a proposed pilot study of truck drivers. It is hoped that this will be available by the November meeting.

ACTION: It was regularly moved, seconded, and unanimously passed that this report be accepted.

G. Medical Policies and Administrative Practices

N. J. Roberts, M. D. reported for R. F. Schneider, M. D., the Chairman of the Subcommittee. There was no new or old business to be considered by the subcommittee at this meeting.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

H. Physical Agents

G. H. Collings, M. D., Chairman, reported on the activity of his subcommittee. His report is given as Appendix E.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

I. Specialty Petroleum Products

C. H. Baylor, M. D., Chairman, reported on the activity of this group. His report is attached as Appendix F.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be adopted.

J. Toxicological Reviews

T. G. Rigney, M. D. reported for H. W. Gerarde, M. D., Chairman, on the activities of the Subcommittee on Toxicological Reviews. Dr. Gerarde's report is attached as Appendix G.

ACTION: It was regularly moved, seconded, and unanimously passed that the report be accepted.

K. Industrial Hygiene

Dr. Jack Spence reported on the activities of the Subcommittee on Industrial Hygiene. His report is attached as Appendix H.

ACTION: It was regularly moved, seconded, and unanimously passed that the report of the Subcommittee on Industrial Hygiene be accepted.

V. REPORT OF LIAISON MEMBERS

A. Air and Water Conservation Committee

C. L. Samuelson, M. D. reported that since he has just taken over the chairmanship of the Subcommittee on Atmospheric Pollutants, he has had no direct contact, as yet, with the Division of Refining's Air and Water Conservation Committee.

B. First Aid Training

T. M. Frank, M. D. reported that there was considerable study being given to the various methods of resuscitation. Three methods have been listed by the Central Committee on Accident Prevention in its First Aid Manual.

Interdivisional Committee on Labeling

C. H. Baylor, M. D. reported for Mr. A. E. Dooley, Chairman of the Interdivisional Committee on Labeling. A copy of Mr. Dooley's report is attached as Appendix I.

D. Oil Mist Advisory Committee

N. V. Hendricks' report is attached as Appendix J.

E. Petroleum Food Additives

L. E. Curtis, M. D. reported that petitions had been filed for white oil, technical white oil, and odorless light petroleum hydrocarbons. An extension has been asked for petrolatum. Dr. Curtis explained that Congress had passed a new law permitting the use of food additives, under an extension, to June 30, 1964.

F. Quarantine Service

G. M. Saunders, M. D. presented a report of his activities. His report is given as Appendix K. The group indicated that they appreciated very much the information which Dr. Saunders was distributing to them.

G. Wax Committee

Kieffer Davis, M. D., one of the liaison members from the Medical Advisory Committee to the Advisory Committee to the Wax Research Project, prepared a report on the activities of the Wax Committee. The report was given for Dr. Davis by G. M. Saunders, M. D. The report is attached as Appendix L.

H. Asphalt Study Committee

J. W. Osborn, M. D. reported that Mr. Charles E. Spahr, Chairman of the Medical and Health Committee, had appointed a Special Asphalt Study Committee, composed of seven members, of which Dr. J. A. Spence was chairman. In addition to Dr. Spence, E. V. Henson, M. D. and C. H. Baylor, M. D., members of the MAC, are also on the study committee. Chairman Osborn explained that this special study committee reports directly to the Medical and Health Committee. He pointed out, however, that Mr. Spahr had asked the Medical Advisory Committee for an opinion as to whether such a study committee was desirable. The Medical Advisory Committee had answered him in the affirmative last November.

VI. 1962 BUDGET

A proposed budget for 1962, as compared with the approved 1961 budget, is as follows:

<u>BUDGET</u>	<u>Proposed 1962</u>	<u>Approved 1961</u>	<u>Change from 1961</u>
C9 - C12 Aromatics	\$10,000	\$10,000	-0-
Physical Agents	2,500	2,500	-0-
Specialty Petroleum Products	-	15,000	-15,000
Toxicological Reviews	-	5,000	- 5,000
Consultant	2,000	3,000	- 1,000
Atmospheric Pollutants	55,000	5,000	+50,000
Lead Survey	15,000		+15,000
	<u>\$84,500</u>	<u>\$40,500</u>	<u>+44,000</u>

The various items for the proposed expenditures of the subcommittees were presented in the appropriate subcommittee report.

ACTION: It was regularly moved, seconded, and unanimously passed that the \$84,500 proposed budget for 1962 be presented to the Medical and Health Committee for its approval.

## VI. NEW BUSINESS

### 1. Invitation to James G. Telfer, M. D.

In the report on liaison with the Quarantine Service, given by G. M. Saunders, M. D., it was recommended that the Medical Advisory Committee approve inviting Dr. James G. Telfer, of the U. S. Public Health Service, Quarantine Division, to attend a future meeting of the Medical Advisory Committee.

ACTION: It was regularly moved, seconded, and unanimously passed that the Chairman of the Medical Advisory Committee invite James G. Telfer, M. D. to the next Medical Advisory Committee meeting, or some future one which would be mutually agreeable.

### 2. Federal Hazardous Substances Labeling Law

G. H. Collings, M. D. presented to the Operating Subcommittee the need for consideration of necessary toxicological studies by API to comply with the recently enacted Federal Hazardous Substances Labeling Law. The Operating Subcommittee requested that Dr. Collings present his recommendations to the Medical Advisory Committee.

ACTION: It was regularly moved, seconded, and unanimously passed that the Chairman of the Medical Advisory Committee contact the Interdivisional Committee on Labeling to determine whether it has considered the possible merit of action on the part of the API to conduct toxicological investigations on standard types of petroleum products for the purpose of clearing such products with the Food and Drug Administration, with reference to the requirements of the Federal Hazardous Substances Labeling Act. If the Interdivisional Committee on Labeling has not done this and is not interested in this aspect of the problem, it is further moved that the chairman of the Medical Advisory Committee appoint a study group, within the Medical Advisory Committee, to consider appropriate action by the Medical Advisory Committee.

## VIII. NEXT MEETING

The question of when to have the next Medical Advisory Committee meeting and its subcommittees was discussed quite extensively. The question of whether to have the subcommittee meetings on Friday and Saturday, with the Medical Advisory Committee meeting on Monday, as against possibly having the subcommittee meetings on Thursday and Friday and the Medical Advisory Committee meeting on Saturday, was discussed at length.

ACTION: It was regularly moved, seconded, and unanimously passed that the Medical Advisory Committee subcommittees meet on Friday and Saturday, November 10 and 11, at the Conrad Hilton Hotel in Chicago, the Operating Subcommittee to meet on Saturday evening, November 11th, and the Medical Advisory Committee to meet on Monday morning, November 13th.

ADJOURNMENT

The meeting was adjourned at 11:00 A. M.

L. E. Renes, Secretary

Reported by E. O. Mattocks

Approved:  
W. Osborn, M. D., Chairman  
April 26, 1961

recommendations relative to the Goldblatt report which they planned to present to the Medical Advisory Committee for action. They, likewise, were planning to recommend the hiring of a technical consultant to assist the Atmospheric Pollutants Subcommittee in order to keep abreast of current literature.

Dr. Samuelson stated that his group was going to propose the initiation of a research proposal on the determination of the medical aspects of nitrogen oxides and sulfur oxides and particulate matter which occur in atmospheric pollution. They had three possible laboratories under consideration and expected to have a final recommendation as to the place by the November meeting. Considerable discussion resulted from the recommendations which were to be presented to the Medical Advisory Committee.

3. C<sub>9</sub> - C<sub>12</sub> Aromatics

T. M. Frank, M. D. reported on the activities of this subcommittee for Jeffrey Davis, M. D., Chairman, who was unable to be present. Dr. Frank indicated that they planned to ask for \$10,000 for the year 1962 to continue the work on C<sub>9</sub> - C<sub>12</sub> aromatic toxicity being conducted currently at The University of Texas. He indicated, however, that there was some uncertainty as to the future of the project. A study committee is to be appointed to review the findings of this project. Definite recommendations will be made at the November meeting.

4. Certificates of Appreciation

Chairman Osborn stated that only four Certificates of Appreciation had been awarded by the Medical and Health Committee to members of the Medical Advisory Committee up to date. This subcommittee had met and was planning to make recommendations to the Operating Subcommittee at a later date.

5. Dermatology

C. H. Baylor, M. D. reported for Leo J. Wade, M. D., Chairman. Dr. Baylor indicated that there were no further developments in the problem of dermatitis in the Detroit Area.

6. Epidemiology

George M. Saunders, M. D. indicated they were endeavoring to find practical means to implement the recommendation made last November concerning the making of a study of truck drivers.

7. Medical Policies and Administrative Practices

N. J. Roberts, M. D. reported for Ralph Schneider, M. D. It was indicated that there were no current problems.

8. Physical Agents

G. H. Collings, M. D., Chairman of this subcommittee, reported that they were going to request \$2,500 for 1962 for continuing the contribution to the Noise Committee, under Dr. Glorig. He indicated further that the group thought that there should be some criteria of noise. They were developing a uniform standard which would be suggested to the Medical Advisory Committee for use by the petroleum industry.

9. Specialty Petroleum Products

API 07681

C. H. Baylor, M. D. reported on the activity on kerosine poisoning at the University of Vermont and at Baylor University. Because of the inability to successfully

## AMERICAN PETROLEUM INSTITUTE

MINUTES OF THE MEDICAL ADVISORY COMMITTEE'SOPERATING SUBCOMMITTEE

Friday, April 7, 1961

Denver Hilton Hotel

Denver, Colorado

MEMBERS PRESENT:

J. W. Osborn, M. D., Chairman	
Leo J. Wade, M. D., Vice Chairman	
(Represented by N. J. Roberts, M. D.)	
L. E. Renes, Secretary	
V. C. Baird, M. D., Past Chairman	
(Represented by R. W. Pipkin, M. D.)	
C. H. Baylor, M. D.	H. W. Gerarde, M. D.
G. H. Collings, M. D.	(Represented by T. G. Rigney, M. D.)
L. E. Curtis, M. D. (PFA)	N. V. Hendricks (Oil Mist)
Kieffer Davis, M. D.	E. O. Mattocks (ex-officio)
(Represented by T. M. Frank, M. D.)	C. L. Samuelson, M. D.
A. E. Dooley (ICL)	G. M. Saunders, M. D.
(Represented by C. H. Baylor, M. D.)	Ralph Schneider, M. D.
R. E. Eckardt, M. D. (Wax)	(Represented by N. J. Roberts, M. D.)
(Represented by T. G. Rigney, M. D.)	J. A. Spence

I. INTRODUCTORY REMARKS

J. W. Osborn, M. D., Chairman of the Operating Subcommittee, welcomed all present. He introduced the following: R. W. Pipkin, M. D. who was representing V. C. Baird, M. D.; T. G. Rigney, M. D. representing R. E. Eckardt, M. D. and H. W. Gerarde, M. D.; N. J. Roberts, M. D. representing R. F. Schneider, M. D. and Leo J. Wade, M. D.; T. M. Frank, M. D. representing Kieffer Davis, M. D.

The chairman explained that Mr. Charles E. Spahr, Chairman of the Medical and Health Committee, had appointed a Special Asphalt Study Committee composed of seven members, with Dr. J. A. Spence, Chairman, and with two other Medical Advisory Committee members - C. H. Baylor, M. D. and E. V. Henson, M. D. The Chairman explained that this committee reports directly to the Medical and Health Committee. It was appointed following a request for a recommendation from the Medical Advisory Committee, which was given to Mr. Spahr, recommending the appointment of such a group.

II. APPROVAL OF MINUTES

ACTION: It was regularly moved, seconded, and unanimously passed that the minutes of the Operating Subcommittee meeting, held Sunday, November 13, 1960, in the Conrad Hilton Hotel, Chicago, Illinois, be approved as distributed.

III. REPORT OF SUBCOMMITTEE CHAIRMANA. Atmospheric Pollutants

API 07680

C. L. Samuelson, M. D., Chairman of the Subcommittee on 'Atmospheric Pollutants, reported that this subcommittee had met several times in Denver. They had a series of

analyze for hydrocarbons in human blood, very little had been done during the past year. H. W. Gerarde, M. D. has agreed to run the blood analyses in his laboratory. The possibility of C. A. Nau, M. D. using the same analysis as he has employed on his C<sub>9</sub> - C<sub>12</sub> aromatic for blood analysis was discussed. It was reported that the money currently appropriated through 1961 will be sufficient to carry through the year 1962.

6. Toxicological Reviews

T. G. Rigney, M. D. reporting for H. W. Gerarde, M. D., Chairman, stated there was no activity to be brought to the attention of the Operating Subcommittee.

7. Industrial Hygiene

Dr. J. A. Spence reported that last November his subcommittee recommended to the Medical Advisory Committee, which approved, contributing \$25,000 to assist the Department of Public Health in making a lead survey. It was agreed subsequently that this request should be channeled through the Division of Refining's Air and Water Conservation Committee. The Division of Refining did not report whether they agreed or disagreed with this suggestion. The industrial hygienists feel very strongly that the API should cooperate with the U. S. Public Health Department insofar as possible. By cooperating, the Public Health people are willing to listen to industry people's suggestions and tell them what their plans are. Failing to cooperate in this manner results in the API being labeled as uncooperative not only in this venture but other ventures. The industrial hygienists are recommending that \$15,000 be placed in the 1962 budget to assist in the lead survey.

8. Oil Mist Liaison Group

Chairman Osborn explained that following the report from the Oil Mist Task Group of the industrial hygienists, he had set this group up as a special liaison task force since they were primarily to act as liaison with other groups who are conducting research work on oil mists.

9. 1962 BUDGET

A proposed budget for 1962 is as follows:

C <sub>9</sub> - C <sub>12</sub> Aromatics	\$10,000
Physical Agents	2,500
Consultant	2,000
Atmospheric Pollutants	55,000
Lead Survey	15,000
	<u>\$84,500</u>

ACTION: It was regularly moved, seconded, and unanimously passed that the proposed budget of \$84,500 for 1962 be recommended to the Medical Advisory Committee for approval.

10. INVESTIGATION OF AUTOMOBILE EXHAUSTS

C. L. Samuelson, M. D., Chairman of the Subcommittee on Atmospheric Pollutants, reported that a conference is to be arranged with the Automobile Manufacturers Association and medical people to explore possible mutual problems.

11. CARCINOGENICITY

API 07682

R. E. Eckardt, M. D., Chairman of the former Subcommittee on Carcinogenicity,

recommended upon the completion of the work at Kettering Laboratory at The University of Cincinnati, that this subcommittee be discharged. He further recommended that no subcommittee be given the charge of handling the broad subject of carcinogenicity. He recommended that each subcommittee should handle its own carcinogenicity problems and if they are unable to do so, to request assistance from the Medical Advisory Committee.

ACTION: It was regularly moved, seconded, and unanimously passed that the recommendation of R. E. Eckardt, M. D. be presented to the Medical Advisory Committee.

#### VII. HAZLETON LABORATORIES' REQUEST

R. E. Eckardt, M. D. received a request from the Hazleton Laboratories to assist in defraying a proposed budget of \$37,000 to prepare a monograph of data on control rats used in long-term studies. The request is attached as Exhibit A. The question was raised as to whether any useful information for the future would be provided by such a study. It was indicated that perhaps this would be a proper project for the U. S. Public Health Service.

ACTION: It was regularly moved, seconded, and unanimously passed that the request from Hazleton Laboratories for financial assistance be disapproved.

#### VIII. NOVEMBER 1961 MEETING

Considerable discussion took place as to whether the Medical Advisory Committee and its subcommittees should meet on Friday, Saturday, and Monday in the Conrad Hilton Hotel in Chicago, in November 1961, during the Annual API Meeting, or whether they should meet on Thursday, Friday, and Saturday.

ACTION: It was regularly moved, seconded, and unanimously passed that the Operating Subcommittee recommend to the Medical Advisory Committee that the Medical Advisory Committee subcommittees meet on Friday and Saturday, November 10th and 11th, 1961, in the Conrad Hilton Hotel, Chicago, Illinois, the Operating Subcommittee to meet Saturday night, November 11th, and that the Medical Advisory Committee meet Monday morning, November 13th.

#### IX. NEW BUSINESS

1. Chairman Osborn reported that the Division of Refining had decided not to have an air pollution session at their midyear meeting this year and, therefore, the request for a paper from the Medical Advisory Committee did not materialize.

2. The Air Pollution Control Association had requested a paper on air pollution, to be given at its June 1961 meeting. The chairman declined this invitation since he was unable to comply with the requirement that the paper must be completed and furnished to them by March 15th.

3. Sometime ago, R. E. Eckardt, M. D. was appointed the API representative to the Liaison Panel of the Food Protection Committee of the National Academy of Science, National Research Council. Dr. Eckardt had requested to be relieved of this assignment. While he was an API representative, he reported to the Medical Advisory Committee.

Upon his resignation, it was the suggestion of J. W. Osborn, M. D., Chairman of the Medical Advisory Committee, that the responsibility be given to the Inter-Divisional Committee on Petroleum Food Additives which appeared to be more reasonable than assigning it to the Medical Advisory Committee. This suggestion was transmitted

cc L. E. Curtis, M. D. by J. W. Osborn, M. D. Dr. Curtis, Chairman of the Interdivisional Committee on Petroleum Food Additives, suggested that Mr. Charles M. Shaw, of the Standard Oil Company of California, who currently represents this company on the Liaison Panel, also represent API Interdivisional Committee on Petroleum Food Additives. A question was raised as to whether the representative on the Food Protection Committee should be a physician. It was generally agreed that the current arrangement appeared to be satisfactory.

D. Federal Hazardous Substances Labeling Act. - G. H. Collings, M. D. wished the API to consider the advisability of undertaking a joint toxicological study of common petroleum products which are required to be labeled. He indicated that requests were being received from customers to certify that the material being sold was in compliance with the Federal Hazardous Substances Labeling Act, for subsequent labeling. The work of the Interdivisional Committee on Labeling was discussed. While it was recognized that a large number of products are definitely an individual company problem, nevertheless, there appeared to be places where a joint activity by the API might be highly desirable. The Operating Subcommittee suggested that Dr. Collings present this to the Medical Advisory Committee at its meeting on the following day.

X. ADJOURNMENT

The meeting adjourned at 11:15 P. M.

L. E. Renes, Secretary

Reported by E. O. Mattocks

Approved:  
J. W. Osborn, M. D., Chairman

COPY

EXHIBIT A

A-5

HAZLETON LABORATORIES  
Incorporated

P. O. Box 30  
Falls Church  
Virginia

Falls Church  
January 20, 1961

Dr. R. E. Eckardt  
Director, Medical Research Division  
Esso Research and Engineering Co.  
P. O. Box 45  
Linden, New Jersey

Dear Bob:

The staff at Hazleton Laboratories is planning a program in which we hope you will be interested. This is the preparation of a monograph of data on control rats used in long-term studies. Our data cover a period of 14 years and we feel this is an untapped, rich source of information useful to our clients and colleagues in toxicology.

A systematic survey and analysis will be made of the following criteria which have been used in the classical evaluation of stress in toxicological investigations:

- Survival
- Body Weight Gains (Growth)
- Food Consumption and Utilization
- Water Consumption
- Clinical Values
  - Hematology
  - Biochemistry
  - Urine Analyses
- Organ Weights and Organ/Body Weight Ratios
- Reproduction
- Pathology
  - Gross and Microscopic
  - Tumor Incidence and Disposition
- Behavioral Characteristics

Data as outlined above will not be complete on all rats but will be typical of the era of toxicology in which it was obtained.

API 07685

Dr. R. E. Eckardt

- 2 -

January 20, 1961

Data will be taken from the records of our 2300 control rats of the following strains:

<u>STRAIN</u>	<u>NO. OF RATS</u>
Carworth Farms Wistar	1200
Charles River Wistar	400
Charles River Sprague-Dawley	350
Holtzman Sprague-Dawley	<u>350</u>
	2300

According to type and duration of the study, data are available as follows:

Dietary Feeding	Six Months	1450
	One Year	1000
	Two Years	700
Oral Administration	Three Months	500
	Six Months	400
	One Year	150
Reproduction Studies		350

The estimated cost for the entire program is approximately \$37,000. The Procter and Gamble Company has generously made an initial subscription to the support of this program. We are writing you in the chemical industry to ask your support in this undertaking. It is, of course, our intention to acknowledge each subscription in the publication of the data. Please be assured that no monetary profit to either Hazleton Laboratories or the contributors is to be realized from this project. We hope you will agree with us that dissemination of a monograph containing standard laboratory values on the rat would be a significant contribution to the science of toxicology.

If you have any questions, please contact me personally, or in my absence, either Tom Tusing or John Keller. In any event, we would like to hear from you concerning this program. As usual, your comments will be appreciated.

With best personal regards.

Sincerely yours,

L. W. HAZLETON, Ph.D.

LWH:dh

API 07686

REQUESTS FOR SUPPORT OF PUBLICATION OF MONOGRAPH ON CONTROL RAT  
SENT TO FOLLOWING PERSONS

Leon Z. Saunders  
Pathology and Toxicology Section  
Kline and French Laboratories  
Spring Garden Street  
Philadelphia 1, Pennsylvania

E. S. Feenstra  
Department of Pathology  
Upjohn Company  
Henrietta Street  
Lansing, Michigan

Elmer P. Wheeler  
Assistant Director, Medical Department  
Santo Chemical Company  
North Lindbergh Boulevard  
St. Louis 66, Missouri

Bernard F. Daubert  
Director of Scientific Research  
General Foods Corporation  
South Broadway  
Harrystown, New York

Robert L. Gates  
Director, Research and Development  
Food Machinery and Chemical Corporation  
Niagara Chemical Division  
Middleport, New York

John P. Frawley  
Chief Toxicologist  
Arcules Powder Company, Inc.  
Wilmington 99, Delaware

Floyd P. Hallett  
Assistant Director  
Product Development - Medicinal  
Melinckrodt Chemical Works  
St. Louis 7, Missouri

John A. Zapp  
Director  
Easkell Laboratory  
E. I. duPont de Nemours & Co., Inc.  
Wilmington 98, Delaware

John W. Ward  
H. Robins Co., Inc.  
407 Cummings Drive  
Richmond, Virginia

Mr. V. K. Rowe  
Biochemical Research Department  
12-634 Building  
The Dow Chemical Company  
Midland, Michigan

Dr. C. Boyd Shaffer  
Director of Environmental Health  
Central Medical Department  
American Cyanamid Company  
30 Rockefeller Plaza  
New York 20, New York

Dr. David W. Fassett  
Eastman Kodak Company  
Kodak Park Works  
Rochester 4, New York

Mr. William G. Whitehouse  
Philips Roxane, Incorporated  
2400 Frederick Avenue  
St. Joseph, Missouri

Mr. Donald H. Kirby  
Research and Development Laboratory  
John H. Breck, Inc.  
115 Dwight Street  
Springfield 3, Massachusetts

Dr. Frank M. Berger  
President  
Wallace Laboratories  
Half Acre Road  
Cranbury, New Jersey

Mr. Hobart O. Thomas  
Assistant to Vice President, Research  
Stauffer Chemical Company  
380 Madison Avenue  
New York 17, New York

Dr. Louis Lykken  
Manager, Technical Service Department  
Shell Chemical Company  
110 West 51st Street  
New York 20, New York

Dr. Fred Coulston  
Sterling-Winthrop Research Institute  
Rensselaer, New York

Joseph F. Treon  
Manager, Toxicology Section  
Research Department  
Gas Powder Company  
Wilmington 99, Delaware

Joseph Marrus  
Medical Department  
Pharmaceutical Company  
P. O. Box 430  
New York

George R. Boyd, Jr.  
Section Leader, Inorganic  
Research and Development Department  
Virginia-Carolina Chemical Corporation  
Richmond, Virginia

Leo R. Gardner  
Manager, Research and Development  
California Spray-Chemical Corporation  
Gas Street & Ortho Way  
Richmond, California

Ralph C. Wands  
Applied Research Section  
Minnesota Mining & Manufacturing Co.  
61 Hudson Road  
St. Paul 19, Minnesota

R. C. Anderson  
Head, Department of Toxicology  
Lilly Research Laboratories  
Lilly and Company  
Indianapolis 6, Indiana

Henry F. Smyth  
Elion Institute  
100 Fifth Avenue  
Pittsburgh 13, Pennsylvania

R. E. Eckardt  
Director, Medical Research Division  
Research and Engineering Co.  
P. O. Box 45  
New Jersey

George F. Rugar  
Associate Director  
Research Department  
Diamond Alkali Company  
P. O. Box 348  
Circleville, Ohio

Dr. Edward Eagle  
Head, Division of Physiology and Toxicology  
Swift & Company  
Union Stock Yards  
Chicago 9, Illinois

Dr. John F. Mahoney  
Manager, Technical Service  
Chemical Division  
Merck Sharp & Dohme, Inc.  
Rahway, New Jersey

Dr. Charles S. Delahunt  
Chas. Pfizer & Co., Inc.  
Research Division  
Groton, Connecticut

Dr. Douglas V. Frost  
Head, Nutrition Research Department  
Abbott Laboratories  
North Chicago, Illinois

Dr. Harold Wittcoff  
Director of Chemical Research  
General Mills, Inc.  
9200 Wayzata Boulevard  
Minneapolis 26, Minnesota

Dr. J. P. Dailey  
Director of Research  
Armour Pharmaceutical Company  
Kankakee, Illinois

Mr. Kenneth B. Nash  
Insecticide Products Department  
Olin Mathieson Chemical Corporation  
Mathieson Building  
Baltimore 3, Maryland

Dr. H. Douglas Tate  
Manager, Agricultural Chemicals  
Research and Development  
Naugatuck Chemical  
Naugatuck, Connecticut

Dr. Theodore King  
Ortho Research Foundation  
Division of Ortho Pharmaceuticals  
Raritan, New Jersey

COPY

A-10

THE STANDARD OIL COMPANY  
(An Ohio Corporation)  
Midland Building  
Cleveland, Ohio

February 17, 1961

Mr. Elmer O. Mattocks, Director  
Department of Technical Services  
American Petroleum Institute  
1271 Avenue of the Americas  
New York 20, New York

Subject: Hazleton Laboratories  
Proposed Monograph of  
Data on Controlled Rats

Dear Elmer:

Confirming our telephone conversation of today, I have reviewed Dr. Eckardt's letter of February 3, 1961, to Dr. L. W. Hazleton in reply to Dr. Hazleton's letter of January 20 to Dr. Eckardt.

I agree with Dr. Eckardt that the Public Health Service ought to give a substantial contribution to this project and perhaps support the project in total. On the other hand, the API Medical Advisory Committee would have a definite interest in the results of this proposed study. Thinking in terms of the entire program approximately \$37,000 in cost, the Medical Advisory Committee might do well to consider an amount in the neighborhood of \$1,000 or perhaps \$2,000 at the most.

Will you please reproduce Dr. Eckardt's and Dr. Hazleton's letters for distribution to the Members of the Operating Subcommittee. Each member should come to the Operating Meeting in December prepared to express his opinion. In the meantime, those who are chairman of subcommittees or liaison committees may put this matter before their respective committee members as each chairman sees fit.

Sincerely yours,

/s/ J. W. Osborn

J. W. OSBORN, M. D.  
Chairman, API - MAC

JWO/sjf

cc: Dr. R. E. Eckardt

API 07689

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A-11

ESSO RESEARCH AND ENGINEERING COMPANY  
P. O. Box 45, Linden, N. J.

Medical Research Division

February 3, 1961

Dr L. W. Hazleton  
Hazleton Laboratories, Inc.  
P. O. Box 30  
Falls Church, Virginia

Dear Lloyd:

We have your letter of January 20, 1961 concerning the contribution to a publication which will bring together the data on a group of normal animals maintained in your laboratories. Rest assured that I believe this is an extremely important project and one which ought to be supported. However, in looking through the group of individuals to whom you have written, asking for support, it occurs to me that with the exception of the Shell Chemical Company, we are the only oil company that you have approached. In view of this, and the fact that I believe such information would be of value to any of the oil companies, I would feel that the contribution toward your publication ought to come from the American Petroleum Institute. In view of this, I am sending a carbon copy of my letter to you, and also a copy of your letter to me, to both Jim Osborn, who is Chairman of the Medical Advisory Committee of the API, and to Mr. Elmer Mattocks, who is head of the Technical Services Division of the API, and serves as Executive Secretary of our Medical Advisory Committee.

Rest assured, that I believe your project is an excellent one and one that very much needs to be done and is very deserving of support. I would certainly feel that you ought to be able to get a substantial Public Health Service grant in support of such a project, since such a project is of extreme importance to the Public Health Service, and in particular, the Food and Drug Administration whose responsibility it is under the law to interpret the significance of biological data. Lacking good data on normal controls, I find it extremely difficult to understand how they can adequately interpret what may be developing in the experimental animals. I simply propose that they ought to give a substantial contribution to this project, and in all likelihood, ought to support the project in toto. It seems to me that this is an excellent expenditure of public funds which after all are made up of

API 07690

Dr. L. W. Hazleton

- 2 -

February 3, 1961

the taxes of all of the corporations that are represented and might be interested in this information.

I presume that you will probably hear either from Dr. Osborn or Mr. Mattocks, although it may be that you will not hear from them until after the next meeting of the Medical Advisory Committee which is scheduled for April 8th, I believe, in Denver, Colorado. In any event, this information will be in their hands in time for their coming meeting. In the event, that they do not support you, I hope you will contact me again, and because it may be that we would support you ourselves even though they might not choose to do so.

Sincerely yours,

R. E. ECKARDT, M. D.  
Director

REE:WK

cc: Mr. E.O. Mattocks - w/atts. - L.W.Hazleton ltr. of 1/20/61  
Dr. J.W. Osborn - " " " "

REPORT OF THE SUBCOMMITTEE ON ATMOSPHERIC POLLUTANTS  
J. L. Samuelson, M. D., Chairman

The subcommittee, in addition to closed sessions on Wednesday evening, Thursday morning, and Thursday afternoon, convened formally at 9:00 A. M. on Thursday morning, April 5, 1961. Seven of the nine members were present.

Since other meetings scheduled for the same time were cancelled, we were fortunate in having a large delegation of visitors who took an active part in the discussion.

The recommendations being presented reflect the thinking of the subcommittee, the discussion at the meeting, and verbal and written suggestions presented.

With regard to Dr. Goldblatt's work, the subcommittee makes the following recommendations:

- A. That Goldblatt's reports I, II, III, and Summary be accepted.
- B. That the Goldblatt project be terminated; that Dr. Goldblatt be notified; that the MAC express its appreciation to Dr. Goldblatt for his work.
- C. That consideration for publication of Goldblatt's Summary, as it was received or after editing, be tabled.
- D. That Dr. Goldblatt's Summary be studied further in an effort to make it publishable.

The last recommendation is being made as it did not appear practical nor feasible, at this time, to attempt to make any recommendations as to editing the Summary which would result in a manuscript acceptable to the MAC. This does not preclude the possibility of some such attempt being made by the subcommittee for consideration at some future date.

As to the matter of research in the field of air pollution and its effect on health, the subcommittee feels that this is a proper and timely undertaking for the MAC.

The subcommittee recommends:

- A. That the MAC request \$50,000 for 1962, and possibly to continue for a period of from three to five years, for investigating any possible relationship between pulmonary carcinoma and exposure to petroleum and petroleum products resulting from their use. Particular reference to be made to the roles of polycyclic aromatics, oxides of nitrogen, sulfur and its compounds, and particulate matter as they may arise from the use of petroleum and petroleum products.
- B. That the MAC authorize the subcommittee to contact various individuals, groups, or laboratories to develop a research program along the lines mentioned in A above. (Exhibit 1)
- C. That the subcommittee develop a specific study and select the proper personnel and facilities to carry out such a study and present these to the MAC for final approval and permission to proceed.

The nature of the study reflects the general feeling of those making suggestions and also reflects the opinion of the subcommittee.

Investigation as to facilities available and costs have been very limited because of the time the subcommittee has had. The subcommittee has not wished to proceed too far without some specific approval by the MAC. Based on the limited information at hand, we feel that a program which will be acceptable to the MAC can be developed for the amount requested.

While we have recommended that the Goldblatt project be terminated, the subcommittee believes that the work should be continued and that a review of current literature be made. In order to accomplish this, to be of help to this subcommittee and to the MAC, the following recommendations are presented for MAC consideration:

- A. That \$5,000 be budgeted for the services of a technical consultant.
- B. That the \$5,000 available for the year 1961 be used for the services of a technical consultant, for the year July 1, 1961 to June 30, 1962.
- C. That, pursuant to adoption of A above, Dr. Philip Drinker be engaged as this technical consultant.

As a matter of information, agreement has been reached for the subcommittee to meet with a comparable group of the Automobile Manufacturers Association. The subcommittee will report on this meeting in November.

C. L. Samuelson, M. D., Chairman

A PROPOSAL FOR THE RESEARCH AND EDUCATIONAL PROGRAM RELATING TO  
PETROLEUM PRODUCTS AND AIR POLLUTION

from

Charles Hines, M. D., Hine Laboratories, San Francisco, California

In August, 1960, a report of the surgeon general's ad hoc task group on air pollution research goals was published. Recommendations were to the effect that research is needed in some ten different fields of endeavor relative to the general problem of air pollution, in order to solve on a national basis the problems confronting the country regarding air pollution. Goal number one was concerned with the effects of air pollution on man, and was stated to embrace determination of the effects of air pollution on human health, the establishment of the identity of agents and mechanisms involved in the production of these effects, and the identification of pollutants which produced undesirable sensory response in human beings together with mechanism of their reaction. The joint role and responsibility for research was defined in this report, and it was indicated that in order to realize a maximum return both government and industrial resources should be directed towards the problem and information obtained by industry should be made available for integration with the general fund of knowledge. In addition to public funds which will probably exceed one million dollars, funds from other private sources such as research foundations and philanthropic organizations were indicated as necessary. The Public Health Service, at both national and at the State level, have moved ahead rapidly in this area, assuming the role not only as monitor of epidemiological effects and consultant to different administrative units, but also have assumed leadership in initiating research to an extent which has not heretofore been approached.

In 1957 the Subcommittee on Atmospheric Pollutants, in order to assess the direction in which medical research was needed, obtained the services of a consultant, Dr. Goldblatt (recommended by me), and have subsequently received suggestions regarding a suitable program.

Dr. Goldblatt's conclusions are known to you and need not be referred to further here. My group is in agreement with the general areas in which he has indicated that work could profitably be carried out, and believe that these can be well summarized into four general areas:

- I. Epidemiology
- II. Education
- III. Toxicological evaluations
- IV. Chemical research

I am proposing that you might wish to consider support of studies along these lines insofar as they seem to pertain to the problems of the petroleum industry.

I. Epidemiology

The objective of this phase of the study would be to determine what variations in morbidity and mortality may occur in specific geographic areas according to the use of specific fuel sources. We would propose that a professional epidemiologist be retained for purposes of working out a satisfactory experimental design and implementing a study which would be pertinent to geographic areas concerned with oil production and processing, and areas of heavy use of petroleum products in comparison with areas in which other sources of energy are utilized, and petroleum products are utilized to a lesser extent. We would also recommend that an evaluation be undertaken of all the current epidemiological studies now being carried out under U. S. Public Health Service support as an essential phase of the study in order to evaluate the data and conclusions extrapolated from it with special attention being given to preparation of a report critically assessing these studies.

### III. Education

The object of this phase of the activity would be to outline a broad scope educational program for the medical profession and the general public with regards to the relationship between the activities of the petroleum industry and the general air pollution problem. We would feel that it would be desirable to prepare a series of informative, documented articles which would be published in national scientific journals, in different local county medical society bulletins, and in state medical journals. We also feel a directed educational program should be carried out in critical areas such as Los Angeles and New Orleans, through personal contact of physicians, and repeated meetings with county medical society groups. Finally, a series of articles should be prepared for release to the newspapers and popular magazines relative to this problem indicating the exact extent of knowledge, and the extent to which speculation is engaged in regarding the long term effects on health.

### IV. Toxicological Studies

The objective of this plan of the study would be to obtain additional toxicologic information as regards a number of long term problems.

A. We propose first, a program relative to the long term effects of nitric oxide and its possible conversion in situ to NO<sub>2</sub> in the pulmonary tract in the presence of ozone or an oxidant atmosphere. While standard texts state that nitric oxide is of little importance because of its rapid conversion to nitrogen dioxide, the environmental data obtained in the Los Angeles basin indicates that the preponderant oxide of nitrogen is NO, and that the ratio may vary as much as ten to one in favor of this form. We would suggest setting up a series of experiments using air-way resistance measurements according to the Amdur technique, and/or the uptake of CO or nitrous oxide as a sensitive index of pulmonary exchange.

B. A second problem would have for its objective the determination of the effects of low levels of oxidants of oxides of nitrogen and/or SO<sub>2</sub> on absorption and retention of pulmonary carcinogens of the polyaromatic hydrocarbon type. We would suggest comparison of uptake from the respiratory tract of these compounds both in the intact animal and one from whom the trachae has been partially isolated, utilizing suitable tracer technique.

C. Finally we would propose a project to determine the effects of low levels of nitric oxide, nitrogen dioxide and sulfur dioxide on specific segments of the population with known deficit in pulmonary function. We would propose to expose suitable groups of subjects of up to 100 individuals to realistic air levels of these substances and determine pulmonary function by appropriate techniques.

### V. Chemical Research

Our goals in this area would be as follows:

A. Study of the formation of sulfuric acid mists from SO<sub>2</sub>. Several studies have been conducted in this area; however definitive answers are not yet available. The objective of these studies would be to evaluate factors which are important relative to conversion of sulfur dioxide to sulfuric acid mist to determine to what extent this conversion may occur.

B. Persistence of polycyclic carcinogens in the atmosphere. The objective of study would be to determine factors affecting the stability and disappearance of polycyclic hydrocarbons in the air; also to determine the half-life of these substances under various conditions.

We would be pleased to develop a comprehensive experimental design if your group is interested in any of these areas in which we have indicated that we believe further work is needed, or other problems. If there are other specific problems on which you would like a recommendation as to research, we would be happy to consider them and cooperate with you in any way possible.

ESTIMATED BUDGET REQUIREMENTS

- I. \$25,000 per annum
- II. \$25,000 per annum
- III. A. \$30,000  
B. \$15,000  
C. \$18,000
- IV. A. \$20,000  
B. \$25,000

REPORT OF THE SUBCOMMITTEE ON C<sub>9</sub> - C<sub>12</sub> AROMATICS

Kieffer Davis, M. D., Chairman

The Subcommittee on C<sub>9</sub> - C<sub>12</sub> Aromatics met in the Denver Hilton Hotel, Denver, Colorado, on Thursday, April 6, and Friday, April 7, with 15 members or representatives and 25 guests present.

A report was received from C. A. Nau, M. D. The work of the past six months has been chiefly on injection of the materials after techniques were worked out. Peripheral blood and bone marrow studies showed significant changes in general, similar to those produced by inhalation. The work was of limited duration and needs to be augmented somewhat, both in time and with respect to tests performed (e.g., pathology of body tissues).

Dr. Nau developed a blood test for detection of C<sub>9,10</sub> blood levels which shows great promise of practical value, both in future experiments and possibly in clinical application.

Action was taken to instruct Dr. Nau to extend the work by injection of C<sub>9,10</sub> in point of time and the use of at least one other species of animal, and that similar work be undertaken on the C<sub>11,12</sub> sample.

Budget requirements for 1962 seem adequate in the amount of \$10,000 which amount is requested from the MAC.

It was proposed that the chairman of the subcommittee appoint a study group to explore the possibility for more precise identification of the compounds in the C<sub>9</sub> - C<sub>12</sub> aromatic group and the preparation of smaller fractions of these mixtures for future study.

T. M. Frank, M. D., Acting Chairman

REPORT OF THE SUBCOMMITTEE ON DERMATOLOGY  
Leo J. Wade, M. D., Chairman

April 7, 1961  
9:00 A. M.

MEMBERS PRESENT:

W. O. Armstrong, M. D.  
C. H. Baylor, M. D.  
(Acting Chairman)

MEMBERS ABSENT:

Leo J. Wade, M. D., Chairman  
F. D. Gassaway, M. D.  
A. E. Dooley  
B. S. Miller, M. D.  
T. J. Smith, M. D.

- I. Prior to the Denver meeting the chairman, Leo J. Wade, M. D., requested Dr. Baylor to preside, in the chairman's absence, and reported to him that no important inquiries, developments, or information concerning subcommittee work had occurred since the subcommittee met in Chicago in November, 1960.
- II. There have been no further developments in the CIO-UAW matter discussed with Mr. Van Atta by Dr. Wade, Mr. M. D. Gjerde, and Mr. A. E. Dooley on October 3, 1960.
- III. No funds are requested by the subcommittee for 1962.
- IV. No new business was reported by the members present and, in the absence of a quorum, no action was taken.

C. H. Baylor, M. D.  
Acting Chairman

REPORT OF THE SUBCOMMITTEE ON PHYSICAL AGENTS  
G. H. Collings, M. D., Chairman

1. The subcommittee has reviewed a paper by Jones and Church, entitled "A Criterion for Evaluation of Noise Exposures," published in the American Industrial Hygiene Association Journal, 21:#6:481:1960. The subcommittee considers the method presented here for the evaluation of noise exposures to have possible merit as a guide for standardized practice in the petroleum industry. The subcommittee recognizes that this method has some inherent imperfections under certain conditions but these would be offset by advantages to be gained from more uniform practice in measuring and evaluating noise throughout the industry and no better method which might be used for this purpose is known to the subcommittee.

It is our plan, therefore, to recommend to the MAC in November 1961 the publication of this method for noise evaluation as a recommended guide for the petroleum industry. Prior to that time, members of the MAC will be requested to review and try out the method and comment upon its acceptability. The Industrial Hygiene Subcommittee will also be requested to furnish an opinion.

2. The subcommittee recommends that \$2,500 be budgeted in 1962 for continued support of Dr. Glorig's work on noise and deafness.

G. H. Collings, M. D., Chairman

REPORT OF THE SUBCOMMITTEE ON SPECIALTY PETROLEUM PRODUCTS  
C. H. Baylor, M. D., Chairman

P. M., April 6

MEMBERS PRESENT:

E. W. Adams  
G. Entwistle  
E. V. Henson, M. D.  
C. R. Miller, M. D.  
T. H. Mitchell, M. D.  
T. G. Rigney, M. D. (rep. H. W. Gerarde, M. D.)  
R. F. Schneider, M. D. (rep. by N.J. Roberts, M. D.)  
W. W. Stewart, M. D.  
C. H. Baylor, M. D., Chairman

MEMBERS ABSENT:

R. C. Cole  
J. W. Hammond

VISITORS:

J. W. Osborn, M. D.  
E. O. Mattocks  
K. B. Simon, M. D. (Guest of Standard Oil (N.J.) of Paris, France)  
R. W. Pipkin, M. D.

- I. The minutes of the meeting of November 12, 1960 were approved as submitted.
- II. In an effort to define more clearly the category of specialty petroleum products the Chairman reported replies from the Secretary, Mr. A. A. Mulliken, of the Chemical Specialties Manufacturers Association and the Chairman of the API Petroleum Products Committee, Mr. C. B. Gale - American Oil Company (formerly Standard Oil Company (Indiana)). The situation is not much clearer but apparently the API committee understands the term as a "marketing expression" and it does not include any petroleum product that sells in large quantities. Exactly what should be included is less well defined.
- III. In order to keep abreast of the knowledge accumulated by the American Association of Poison Control Centers the Subcommittee now has a member (the chairman) belonging to that organization.
- IV. The long-awaited report of Dr. Edward Press on cases of kerosine ingestion has not yet been published as far as the subcommittee can learn.
- V. Progress of the Medical Advisory Committee - API Kerosine Project  
(to determine the best method of treating patients who have ingested kerosine or products containing it with special emphasis on the wisdom of gastric lavage)  
The study was reactivated in early 1961 when Dr. Gerarde generously agreed to analyze the blood samples sent to him by Dr. Mintz and Dr. McKay from their clinical cases. Dr. Mintz has succeeded Dr. Daeschner as head of Pediatrics at Baylor University, Houston, Texas.  
Dr. McKay reports that he has observed only 2 cases of kerosine ingestion so far this year. He attributes the drop in the number of cases to publicity given the subject in his area. Dr. Mintz did not get his project started until March 1. To date, he has submitted no blood samples to Dr. Gerarde. Some are expected shortly.  
Dr. Nau plans further studies beginning in June and will have 2 or 3 research students working on one or more of the following projects under his supervision:
  1. Development of a satisfactory method for determining kerosine levels in blood. He has a method for measuring C9 compounds and hopes it can be adopted to kerosine.

2. Try to correlate blood levels with tissue changes in rats.
3. To determine the reversibility of these changes.
4. To test the ability of various household substances to delay the absorption of kerosine from the G.I. tract, e.g. olive oil, corn starch, egg white, etc.

Dr. Nau expects to work at Galveston (University of Texas) until September 1 and at Oklahoma City after that date.

- I. Budget - In view of the funds already available to the 3 investigators and the amount of clinical material which will likely be available for study within the next 18 months, the subcommittee requests no additional funds for 1962.
- II. No new business was presented and the subcommittee adjourned.

C. H. Baylor, M. D., Chairman

Adendum: Since the above meeting took place, the proposed regulations implementing the Federal Hazardous Substances Labeling Act were published in the Federal Register, April 29, 1961. The Food and Drug Administration proposes that kerosine be labeled as "highly toxic - Poison" with the skull and cross-bones included as part of the label.

REPORT OF THE SUBCOMMITTEE ON TOXICOLOGICAL REVIEWS

H. W. Gerarde, M. D., Chairman

Since the November meeting of the Medical Advisory Committee, second drafts of the Toxicological Reviews on Sulfur Dioxide and Sulfuric Acid have been circulated for comment and approval. For Sulfuric Acid, there were 20 approvals, 3 qualified approvals, and 4 disapprovals.

Also circulated were third drafts of Styrene and Cyclohexane. For Styrene there were 16 approvals, 12 qualified approvals, and 2 disapprovals; for Cyclohexane there were 15 approvals, 13 qualified approvals, and 2 disapprovals.

The review on Cumene has been rewritten by Professor Drinker and is currently being reviewed by members of the subcommittee.

The third draft on Sulfur Dioxide and Sulfuric Acid and the fourth draft on Styrene and Cyclohexane will soon be ready for duplication and re-circulation for approval for publication.

H. W. Gerarde, M. D.,  
Chairman

Presented by:  
T. G. Rigney, M. D.

REPORT OF THE SUBCOMMITTEE ON INDUSTRIAL HYGIENE  
Dr. J. A. Spence, Chairman

The subcommittee met on April 7, 1961, with six members, Prof. Drinker as consultant, and eight guests present.

Mr. Hendricks, as liaison member, reported no recent activity for the Z-62 Committee of the American Standards Association. Attached is Mr. Dooley's report on the Z-37 and Z-4 Committees' activities.

In Mr. Wilkening's absence, the chairman summarized the subcommittee's progress on the project "Industrial Hygiene Aspects of Petroleum Refining Processes." Mr. Wilkening is compiling the contributions of the subcommittee members and will distribute to them a composite draft in May. It is planned, as was done with the "Catalyst Project," that the final report will be submitted to the Medical Advisory Committee at the November 1961 meeting, with the recommendation that it be distributed only within the petroleum industry.

In Mr. Hammond's absence, the chairman reviewed the liaison activities with the Subcommittee on C<sub>9</sub> - C<sub>12</sub> Aromatics. As yet, no reports have been received from the industrial hygienists on environmental studies. The members were urged to investigate potential problem areas and follow the analytical techniques for air and blood analyses used by Dr. Nau. The results would supplement the research findings of the C<sub>9</sub> - C<sub>12</sub> subcommittee and so guide the Medical Advisory Committee on this important problem.

Mr. Hendricks reported that the Air and Water Conservation Committee has decided against the proposal that the API give financial support to the cooperative lead-in-air study being undertaken by the U. S. Public Health Service and participating industrial groups. In view of this development, the question was re-evaluated by the subcommittee. It is the subcommittee's unanimous recommendation that, in view of the Medical Advisory Committee's responsibility on health matters, they seek API participation in this program in the amount of \$15,000 total.

Next, the chairman mentioned that the Medical and Health Committee had appointed a Special Asphalt Study Committee to evaluate the need to study health problems associated with asphalt. The Industrial Hygiene Subcommittee was instructed to direct to the chairman any ideas or information which would be of value to the asphalt group in their assignment.

J. A. Spence, Chairman

AttachmentReport to the API Medical Advisory Committee

The Z-37 Committee on Maximum Allowable Concentrations of Toxic Dusts and Gases is sponsored by the American Industrial Hygiene Association. Standards have been published for 13 substances: carbon monoxide, hydrogen sulfide, carbon bisulfide, manganese, chromic acid and chromates, mercury, lead and certain inorganic compounds, nitrogen dioxide, methanol, formaldehyde, carbon tetrachloride, methyl chloride, and trichloroethylene. The standards for benzene, toluene, and xylene are being printed and will be available in early May. Drafts of standards for tetrachloroethylene (200 ppm), methylene chloride (500 ppm), methyl bromide (20 ppm), methyl chloroform (500 ppm), and paradichlorobenzene (75 ppm), chlorine (2 ppm), Styrene monomer (400 ppm), and ethylene dichloride (200 ppm) are in circulation among the sponsor and the various ASA committees which must act on them.

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The Z-4 Committee on Industrial Sanitation is being reactivated under its new sponsor, the American Conference of Governmental Industrial Hygienists. This committee published its American Standard on Minimum Requirements for Sanitation in Places of Employment in 1955.

A. E. Dooley

INTERDIVISIONAL COMMITTEE ON LABELING - LIAISON REPORT TO  
MEDICAL ADVISORY COMMITTEE

API Bulletin 2511 - Letter ballots have been returned from practically all members of the Interdivisional Committee on Labeling. Some members have suggested changes that are more than editorial ones and a second letter ballot will be necessary. This letter ballot will be sent to the committee members during the latter part of May.

Federal Labeling Law - Enforcement of the Act for hazardous substances other than "extremely flammable," "flammable," "highly toxic" has been deferred until August 1, 1961. Proposed regulations to implement the Act did not appear in the Federal Register on April 3 or 4 as expected but should be published within a day or so. Interested persons will be given 60 days to file comments. This time was a compromise between the 90-day period requested by industry and the 30-day period proposed by the Food and Drug Administration. The FDA leans toward an oral LD/50 of 5 grams per kilogram as the top figure for toxic substances rather than the 1 gram per kilogram suggested by industry. The FDA will probably insist that the precautionary label appear on the front panel of the package.

Inter-Industry Association Labeling Committee - Dr. Horace Gerarde has been made a member of the Toxicity Committee of the Chemical Specialties Manufacturers Association. The CSMA had previously asked the API to designate a toxicologist with knowledge of petroleum products to act as a consultant to this committee and Dr. Osborn selected Dr. Gerarde last November. The next meeting of the Inter-Industry Committee is tentatively set for the middle of May.

MCA Labeling Manual - The fifth revision of Manual L-1 will probably be ready for distribution sometime during this month.

State Labeling Legislation - Bills have been introduced in the legislature of several states this year. The Washington bill was not enacted and the passage of the Michigan bill appears doubtful at this time.

Leaded Gasoline Labels - Ethyl Corporation has made a sign for use on gasoline storage tanks. It is a 7-inch diamond shaped enameled sign with black letters on a yellow background. The wording is: "This tank has contained leaded gasoline - Warning - Do not enter without fresh air mask, special clothing, rubber gloves and rubber boots." These signs can be obtained from the Ethyl Corporation at twenty-four cents each.

Allan E. Dooley, Chairman  
Interdivisional Committee  
on Labeling

Presented by:  
C. H. Baylor, M. D.

OIL MIST LIAISON COMMITTEE

Acting on approval given by the MAC in November, the Oil Mist Committee is proceeding, as follows:

1. REPORT PUBLICATION

The committee report previously sent to you will be put in proper form for publication and submitted to an appropriate journal. Credit to API will be shown.

2. EPIDEMIOLOGICAL STUDY

In an effort to set up an epidemiological study of workers exposed to oil mist, the following approaches will be explored:

- (a) Selected industrial organizations will be contacted. These will be chosen on the basis of those having large groups of potentially exposed workers and having medical records available, and their willingness to cooperate in such a study.
- (b) Contact will be made with those labor unions whose members work in jobs offering exposure, such as the Machinists' Union, and where sickness or similar records may be available.
- (c) This will be discussed with the Public Health Service where considerable interest in the overall problem of oil mist exposure is evidenced by animal studies now being conducted by Dr. Stockinger.

3. CARCINOGENIC PROPERTIES OF OIL MIST

For the time being, this will be followed through epidemiological study that is set up and through the animal inhalation studies now under way by Dr. Stockinger and those planned by Dr. Vorwald and Prof. Urban. A meeting is to be arranged with Dr. Stockinger to discuss his study methods in terms of evaluating carcinogenic potency.

The Oil Mist Committee requests approval of this report.

Respectfully submitted,

N. V. Hendricks

REPORT ON LIAISON WITH QUARANTINE SERVICE TO  
MEDICAL ADVISORY COMMITTEE

Liaison with the Epidemiology and Domestic Operations Branch, Division of Foreign Quarantine of the U.S.P.H.S. has continued. Dr. James G. Telfer remains as Chief of the Branch, with Miss Regina Burns in charge of the epidemiology and immunization program.

Since the last report to the MAC, on 14 November 1960, there have been numerous communications from the Branch concerning disease occurrence, quarantine regulations and immunization requirements. Some of the information was felt to be of sufficient importance to the API members to pass on to MAC. Some was not.

A chronological listing of events is given below:

- 5 Jan. 1961 Telephone call from the Branch to inform that as of 15 Jan. 1961 any one entering U.S.A. from Cuba must be in possession of a valid Smallpox vaccination certificate. The MAC was notified through Mr. Mattocks' office.
- 5 Jan. 1961 Telephone call from the Branch informing about an outbreak of influenza (Type A) in England and reported cases in American Samoa and Hawaii (type undetermined). The MAC was informed by letter of 1 Feb. 1961 from Mr. Mattocks.
- 3 Feb. 1961 Information from the Branch concerning reported outbreak of mild Smallpox in Brasil in the Rio area and that quarantine officers were requested to apply "strick surveillance" rules to all arrivals in the U. S. from Brasil. The MAC was informed through Mr. Mattocks.
- 3 Feb. 1961 News articles and radio newscasts of previous few days reporting serious outbreak of human plague in Venezuela prompted a call to the Branch for clarification. The Branch investigated through their intelligence sources and reported back that there was no basis for the rumor which probably had been started as a political maneuver.
- 7 Mar. 1961 A memorandum of this date from Miss Regina Burns reporting an outbreak of Smallpox in Madrid and recommending that all travellers to Madrid have a successful smallpox vaccination within one year prior to departure was transmitted to Mr. Mattocks who, in turn, transmitted the information to the MAC.
- 23 Mar. 1961 Your liaison representative, while in Washington, had the opportunity to meet for discussions with Dr. Telfer, Miss Burns, and Dr. Holly, Quarantine Officer at Idlewild. Dr. Telfer would welcome an invitation to meet with the MAC members at some future date.
- 30 Mar. 1961 Miss Burns called to report that a case of smallpox had been imported into Frankfurt, Germany, on 11 March 1961 on a Pan American flight from Karachi. The patient was taken ill on 19 March, entered hospital on 25 March when the diagnosis was confirmed. No secondary cases had been reported in Germany. The Pan American flight continued on from Frankfurt and entered the U.S. on 11 March. The U.S.P.H.S. was to check the passenger list and investigate all contacts.

Recommendations

API 07707

It is recommended that: (1) This report be accepted by the MAC and (2) Dr. James G. Telfer be invited to meet with the MAC at some future date.

G. M. Saunders, M. D., MAC Liaison

ADVISORY COMMITTEE TO THE WAX RESEARCH PROJECT - LIAISON REPORT TO  
MEDICAL ADVISORY COMMITTEE

In the absence of Dr. Eckardt, Chairman, I am happy to submit a brief report of the activities of the API Wax Research Project.

In accordance with the new Food Additives Law, a petition was filed in February this year with the Food and Drug Administration for a regulation which would permit the use of certain waxes in connection with food. In a sense, the petition was incomplete because (1) some of the two-year animal studies have not been completed and the data submitted on this portion of the work, although factual, undoubtedly will not be accepted before the two-year period is up; and (2) a very short and proper analytical method for testing waxes has not yet been devised. The method submitted as a part of the petition is a lengthy one requiring days for completion. From past experience, the Food and Drug people will desire to have an analytical method that will require only a few hours for completion.

On the basis of a letter from the Food and Drug Administration, petroleum waxes are now eligible for an extension of time, since the enactment of the transitional amendment to the Food Additives Law. We are confident that the data already developed, plus that which will result from the long-term animal experimental work and a concise analytical method for testing waxes which will be resolved before long, will allow this research group to present a completed petition that will be accepted by the Food and Drug Administration, to the end that a regulation will be written for the use of certain waxes in connection with food.

Presented by:  
George Saunders, M. D.  
MAC Liaison Member