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AMERICAN PETROLEUM INSTITUTE

MINUTES OF THE MEDICAL ADVISORY COMMITTEE'S
OPERATING SUBCOMMITTEE

Sunday, November 13, 1960
Private Dining Room 8
Conrad Hilton Hotel, Chicago, Illinois

THOSE PRESENT:

J. W. Osborn, M. D., Chairman
Leo J. Wade, M. D., Vice Chairman
L. E. Renes, Secretary
V. C. Baird, M. D., Past Chairman
(Represented by J. W. Hammond)

C. H. Baylor, M. D.
Kieffer Davis, M. D.
R. E. Eckardt, M. D.
G. H. Collings, M. D.
E. O. Mattocks

J. C. Ruddock, M. D.
(Represented by C. R. Miller, M. D.)
G. M. Saunders, M. D.
Ralph Schneider, M. D.
Jack Spence

MEMBERS ABSENT:

H. W. Gerarde, M. D.

VISITORS:

L. E. Curtis, M. D.

- Standard Oil Company of California

I. INTRODUCTORY REMARKS

The chairman welcomed all members present.

II. APPROVAL OF MINUTES

ACTION: It was regularly moved, seconded, and unanimously passed that the minutes of the April 24, 1960 meeting of the Operating Subcommittee be approved as distributed.

III. REPORT ON POLICY QUESTIONS BY SUBCOMMITTEE CHAIRMENA. Atmospheric Pollutants

J. W. Osborn, M. D. explained that J. C. Ruddock, M. D. had recently lost his wife and was unable to be present at this meeting. It was agreed that the following telegram should be read to the Medical Advisory Committee and their approval obtained to transmit it to J. C. Ruddock, M. D.: "The Medical Advisory Committee at its meeting November 14 were deeply grieved when they learned at this time of your wife's passing. Your associates share your sorrow and wish you to know of their sympathies. We sincerely missed you and hope you will be with us at our Spring meeting."

J. C. Ruddock, M. D. received a letter from Dr. G. A. Lloyd, Coordinator of Public Affairs, Esso Standard, Division of Humble Oil & Refining Company, requesting that he consider making a speech, under the auspices of the API, at the next annual meeting of the Air Pollution Control Association. There is also the possibility that the Division of Refining will request the Medical Advisory Committee to present a paper at a proposed atmospheric pollution session, which they are tentatively considering for their May 8 - 11, 1961 midyear meeting in Houston. The Program Committee of the Division of Refining is considering a paper by the Surgeon General of the Department of Health, Education, and Welfare, a paper by a member of the Medical Advisory Committee to explain this group's opinion of the medical aspects of air pollution, and a possible third paper by a member of the Division of Refining on the chemical aspects of air pollution.

It appeared that perhaps the same paper, with slight modifications could be given both to the Air Pollution Control Association and the Division of Refining midyear meeting.

ACTION: It was regularly moved, seconded, and unanimously passed that the Operating Subcommittee of the Medical Advisory Committee accept the invitation to give a talk at the Division of Refining midyear meeting in Houston, May 8 - 11, 1961, and the Medical Advisory Committee chairman present this paper, if possible, or if he finds he cannot, that he get together with the officers of the Medical Advisory Committee and select someone else to present the paper.

ACTION: It was regularly moved, seconded, and unanimously passed that if an invitation is received from the Air Pollution Control Association to give a paper that such invitation should be accepted and the paper which will be prepared for the Division of Refining May meeting should be used as the basis of the talk before the Air Pollution Control Association.

An item of \$5,000 is in the 1961 budget for use on air pollution. The subcommittee is recommending that \$2,500 be earmarked to continue the work being done by Dr. Goldblatt. The expenditure of the additional \$2,500 will be presented to the Medical Advisory Committee at their Spring meeting.

ACTION: It was regularly moved, with eight approvals and two disapprovals, that the budgetary requirements of the Subcommittee on Atmospheric Pollutants be supported.

B. C₉ - C₁₂ Aromatics

Kieffer Davis, M. D., chairman of this subcommittee, explained that the subcommittee originally thought the work being done by C. A. Nau, M. D. at the University of Texas would be completed in 1961. Based on the information which has been presented to the subcommittee from the experimental work up to date, the subcommittee doubts that the work can be terminated in the immediate future. Therefore, the subcommittee wishes to reaffirm the request for \$10,000 which is now in the 1961 budget and wishes to go on record indicating that there may be additional requests for money later.

ACTION: It was regularly moved, seconded, and unanimously passed that the budgetary requirements of the Subcommittee on C₉ - C₁₂ Aromatics, for 1961, be supported.

C. Carcinogenicity

R. E. Eckardt, M. D., chairman of the Subcommittee on Carcinogenicity, reported on the activity of this group. The final report from Kettering Laboratory has been received and will be distributed to all members of the Medical Advisory Committee and Technical Advisors. Dr. Eckardt stated that he believed the subcommittee should now be dissolved since they have been operating primarily as a research advisory committee to the work being done at Kettering. Since this work is finished now, there is need no longer for the subcommittee. It appears that in the future, all problems on carcinogenicity should be referred to existing subcommittees or special subcommittees appointed for a specific task rather than to have one subcommittee concerned with the broad subject of carcinogenicity.

ACTION: It was regularly moved, seconded, and unanimously passed that the Subcommittee on Carcinogenicity be abolished when the report from Kettering Laboratory is accepted.

D. Certificate of Appreciation

J. W. Osborn, M. D. stated that the Medical and Health Committee of the Board of Directors approved presenting a Certificate of Appreciation to Dr. John Ruddock. In his absence, Dr. Plancey, Dr. Ruddock's assistant, will accept the Certificate for him. Mr. C. E. Spahr, chairman of the Medical and Health Committee, is planning to present the Certificate at the Medical Advisory Committee meeting on Monday morning.

E. Dermatology

No request for funds.

F. Epidemiology

No request for funds.

G. Medical Policies and Administrative Practices

No request for funds.

H. Physical Agents

No request for funds.

I. Specialty Petroleum Products

No request for funds.

J. Toxicological Reviews

No request for funds.

K. Industrial Hygiene

API 07639

Mr. Jack Spence presented a proposal adopted by the subcommittee to request the Medical Advisory Committee's support of the urban lead-in-air study to be conducted by the Public Health Service. The proposal urged the technical support of the study jointly by the Medical Advisory Committee and the Smoke and Fumes Committee by an expenditure of \$25,000 to be used in paying for consultants

employed in the study.

ACTION: It was regularly moved, seconded, and unanimously passed that the recommendation of the Industrial Hygiene Subcommittee be approved.

The report on oil mist had been transmitted to the Medical Advisory Committee and Technical Advisors.

IV. 1961 BUDGET

The chairman explained that the 1961 budget had been approved by the Budget and Review Committee and the Executive Committee and was now awaiting approval by the Board of Directors. In this budget is an item of \$40,500 to cover the various projects sponsored by the Medical Advisory Committee.

V. INVESTIGATION OF AUTOMOBILE EXHAUSTS

Chairman Osborn read a suggested report to the Medical and Health Committee to the effect that the Medical Advisory Committee had no recommendations to make at this time as to possible research activities to determine the carcinogenic properties of atmospheric pollution, especially automobile exhausts. Several disagreed with the proposed report. They indicated that there were at least three areas of research work which would be worthwhile and should be initiated by the API. These were: (1) Repeat some of the analytical and physiological studies reported by Drs. Kotin and Falk on auto exhaust gases; (2) Support epidemiological studies of effects of air pollution on humans; and (3) Support further investigations into the effect of sulfur dioxide on health.

It was generally agreed that this subject would need further study and that the report to the Medical and Health Committee should read that no recommendations as to possible research studies could be made at this time.

VI. POSSIBLE INVESTIGATION OF PETROLEUM ASPHALTS

Chairman Osborn explained the activity of the Medical and Health Committee in determining from its members the need to investigate the possible toxicity and carcinogenicity of petroleum asphalts. The chairman of the Medical and Health Committee had requested Dr. Osborn to secure the opinion of the Medical Advisory Committee as to the need for such work.

R. E. Eckardt, M. D. indicated that he did not believe it was necessary to spend any money for research to determine the possible use of petroleum asphalts as food additives. He expressed extreme doubt that petroleum asphalts would ever be approved by the FDA as direct or indirect food additives.

ACTION: It was regularly moved, seconded, and unanimously passed that the problem of asphalts needs to be studied and such recommendation should be made to the Medical Advisory Committee for transmittal to the Medical and Health Committee.

VII. MIDYEAR MEETING

The chairman explained that the Medical Advisory Committee meeting will be held April 6 - 8, 1961 in the new Denver-Hilton Hotel in Denver, Colorado. The subcommittees will meet on Thursday and Friday, April 6 and 7. The Operating Subcommittee will meet on Friday evening, April 7. The Medical Advisory Committee will meet on Saturday, April 8th.

VIII. NEW BUSINESS

Because of the increased activity in petroleum asphalts, air pollution, oil mists, and several other items, the need for a full-time staff man to work on medical problems was reviewed carefully. Because of failure to have a full-time staff man, a few members of the Medical Advisory Committee are being overworked.

The desirability of having identification badges, something like those used by service clubs such as the Rotary and Kiwanis for Medical Advisory Committee and Technical Advisors to wear at meetings was considered. No action was taken on this suggestion.

The past practice of having posters at the door of all of the meeting rooms during the annual November meeting was discussed. This practice has resulted in a few people not directly associated with the Medical Advisory Committee activities visiting subcommittee meetings although the meetings were not listed nor scheduled. It was generally agreed that each subcommittee chairman should be able to control this situation without changing the practice.

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

REPORT OF SUBCOMMITTEE ON ATMOSPHERIC POLLUTANTS

J. C. Ruddock, M. D., Chairman

The meeting was called to order by Acting Chairman, Clark R. Miller, M. D., at 9:05 A. M. on Saturday, November 12, 1960, at the Conrad Hilton Hotel, Chicago, Illinois.

All members of the Subcommittee were present except one. There were, in addition, sixteen visitors.

The Subcommittee has held one meeting since the spring meeting, the minutes of which have been circulated.

The following are the recommendations of the Subcommittee:

1. Goldblatt Report

A. The report in its present form be sent to the American Documentation Institute, Washington, D. C.

B. Dr. Goldblatt's recommendations as circularized are attached.

2. Mr. Porter be requested to contact the Automotive Manufacturers' Association and offer the cooperation of the MAC with a comparable committee in the AMA in regard to air pollution.

3. That the MAC consider collecting any available papers, reports, articles, etc., on medical aspects of air pollution for an information packet, such as we have recently received from the API on the technical aspects of air pollution. We request that in the next six months that members of the MAC forward to the chairman of the Subcommittee on Atmospheric Pollutants any such articles or papers concerning medical aspects of air pollution. If the above action is approved, the subcommittee will report at the Spring meeting as to the sufficiency and adequacy of the papers to make a worthwhile packet. This proposed packet would be distributed to air pollution committees and information officers of medical associations and societies.

4. The MAC take no action on the suggested E. C. Hammond Project.

5. The MAC not recommend any project at this time in conformance with Mr. Porter's request as to medical research.

6. That we continue with Dr. Goldblatt in the same manner as we have in 1960, with financial support in the same amount (\$2,500). We will make further recommendations concerning the remaining \$2,500 at the Spring meeting.

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

C. R. Miller, M. D., Acting Chairman

SUBCOMMITTEE'S ACTION ON DR. GOLDBLATT'S RECOMMENDATIONS

1. The peroxy-acyl-nitrites are believed present in the Los Angeles atmosphere. This group of compounds possesses suggestive properties. In view of recent publicity on its explosive nature, it is believed that further study of this group and their physiologic properties, with special reference to the size of the alkyl group, is indicated. Both classic and Dahlgren technique, where the effects on ciliary activity of the trachea of live animals is observed, should be used.

In view of our present lack of knowledge concerning this group of compounds and of facilities, personnel, and method of study, we should not undertake any research at this time. However, the Subcommittee will endeavor to follow developments in this field and if facilities become available, the Subcommittee might recommend certain projects at that time.

2. There is considerable difference of opinion concerning the effect of inhaled particulates of various sizes on the toxic action of respired gas and vapors as stated in Part I of the Goldblatt Report. It seems likely that the nature of the particles, as well as their size, is involved in any effect. There is evidence that potent carcinogenic compounds can be rendered almost inactive by simple adsorption of carbon particles.

We believe that a comprehensive study should be made to decide this question, however, this is not a problem specific to the petroleum industry and the API should not sponsor research on this project.

3. Claims have also been made that the presence of a low concentration of SO₂ in an oxidizing polluted atmosphere may be beneficial.

This also needs to be tested with modern methods and measuring instruments. We believe that this is being included as part of U. S. Public Health Service research. Smoke and Fumes should review this topic.

4. It would be desirable to study the circumstances in which catalytic oxidation of SO₂ takes place in the concentrations met with both at the source and later in the highly diluted state. The increase in toxicity resulting from such oxidations needs to be expressed numerically, having regard especially to the influence of humidity and to changes in size of the liquid droplets as they pass down the respiratory tract.

The API has already supported this type of research by Johnstone. It is believed he has since changed some of his ideas in this field and Smoke and Fumes should determine if the field is covered adequately and is of interest to API.

5. There is frequent reference to many reports of the composition of Los Angeles smog to the presence of chlorinated hydrocarbons, but no experiments have been described on the effect of these on the toxic effects of sulfur and nitrogen oxides and ozone or other oxidants. Since chlorinated hydrocarbons are a group of compounds manufactured from products of petroleum, it may be proper for industry to sponsor research in this field.

This is not a petroleum industry problem.

API 07643

6. There is a possibility that nitrogen oxides may be shown to be promoters of tumors of which the initiators are polycyclic hydrocarbons. We do know that oxides

of nitrogen injure the lungs. What the nature of injuries are at low concentrations we do not know. This might be studied further.

This is not specifically a petroleum industry problem. This area is one in which we could cooperate with other industries and the U. S. Public Health Service.

7. a) Reliable analytical methods for aromatic polycyclics and their oxidation products should be developed. These should be applied to calculate the polycyclic content of gasoline, the motor exhaust, and the refinery stack effluent.
- b) The movement of polycyclics in the atmosphere should be plotted.
- c) An attempt might be made to determine the total emission of polycyclics attributable to the petroleum industry.
- d) To study the relationship of particle size and adsorbed polycyclic concentrations.

These recommendations should be referred to Smoke and Fumes Committee for study and their comments returned to the MAC if it is felt any action is needed.

8. The low benzpyrene values in California are currently being re-evaluated by USPES and the API should take no action at this time.

The remainder of the recommendations made in Dr. Goldblatt's report were not considered to be a problem to the petroleum industry or were already under study by the USPES.

REPORT OF SUBCOMMITTEE ON C₉ - C₁₂ AROMATICS

Kieffer Davis, M. D., Chairman

A meeting of the API MAC Subcommittee on C₉ - C₁₂ Aromatics convened at 2:00 P. M., November 12, 1960, at the Conrad Hilton Hotel, Chicago, Illinois. Eight members of the subcommittee and 29 visitors were in attendance.

The minutes of the last meeting were approved.

Dr. Carl Nau, chief investigator, summarized work to date. Pictures revealing cataracts in some test animals were passed around for examination. Important findings emphasized by Dr. Nau are as follows:

1. Exposure to any of the materials at 50 ppm or 200 ppm interferes with expected weight gain of the test animals. This also includes exposure to 3.2 mgs per liter benzene, C₉ - C₁₀, and C₁₁ - C₁₂.
2. Blood and bone marrow changes occurred from exposure to each of the materials and varied in degree and type in accordance to concentration and type of materials.
3. In mice and rats, the positive findings on inhalation are identical to those previously determined by the skin application method.
4. Human exposures have been directed toward determining threshold tolerances.
5. In monkeys, the hematological changes observed are consistent with those found in rats. In addition, some monkeys showed evidence of central nervous system involvement on exposure to 200 ppm C₉ - C₁₀ and C₁₁ - C₁₂. Monkeys exposed to 50 ppm of C₉ - C₁₀ and C₁₁ - C₁₂ showed no significant changes from the normal in any tests performed.

Suggestions for continuation of program are:

1. Determination of the chronic toxicity of C₉ - C₁₀ and C₁₁ - C₁₂ by injection technique. Possibly the same work is to be carried out by another investigator provided that sufficient amount of the test materials is available.
2. Evaluation of any microscopic changes in organs and tissues.

At this time no additional supporting funds are being requested for the year 1961 to January, 1962. Nevertheless, should early results warrant, the subcommittee will ask for funds necessary for program expansion.

The meeting adjourned at 5:00 P. M.

Kieffer Davis, M. D., Chairman

REPORT OF THE SUBCOMMITTEE ON CARCINOGENICITY

R. E. Eckardt, M. D., Chairman

The subcommittee met at 9:00 A. M. in Private Dining Room 9 of the Conrad Hilton Hotel in Chicago, on November 12, 1960, with the following members and guests present:

A. C. Pabst	-	Socony Mobil Oil Co., Inc.
W. O. Armstrong, M. D.	-	Continental Oil Company
Neill K. Weaver, M. D.	-	Esso Div., Humble Oil & Refining Co.
A. E. Dooley	-	Texaco Incorporated
E. K. Linder, M. D.	-	The Atlantic Refining Company
F. F. Boys, M. D.	-	Sinclair Refining Company
Fred S. Venable	-	Esso Div., Humble Oil & Refining Co.
J. W. Hammond	-	Humble Oil & Refining Company
R. G. Birrell, M. D.	-	Imperial Oil Limited
T. M. Frank, M. D.	-	American Oil Company
E. V. Henson, M. D.	-	Standard Oil Company (Indiana)
J. C. Calandra, M. D.	-	The Pure Oil Company
G. H. Collings, M. D.	-	Standard Oil Company (Indiana)
Leo J. Wade, M. D.	-	Esso Standard
R. E. Eckardt, M. D.	-	Esso Research & Engineering Company

The revised final report of the research work of the Kettering Laboratory has been received. After reviewing this report, the subcommittee makes the following recommendations:

1. The complete report, totalling 171 pages plus appendices and summary, should be made available to all the medical directors of the API for their study and appropriate individual action within their own companies.
2. The "Condensed Summary of the Objectives and Findings of an Experimental Program for the Appraisal of the Potential Carcinogenic Characteristics of Certain Petroleum Products" should be forwarded to the Medical and Health Committee as the final report of this research activity, with the notation that the complete report is available to them, should they desire to see it.
3. Since, in fact, the Subcommittee on Carcinogenicity has served as a research advisory committee, and since the research is now complete, the Subcommittee on Carcinogenicity should be dissolved. Any problems of carcinogenesis now before or presented in the future to the Medical Advisory Committee should be referred to appropriate existing subcommittees, specially created subcommittees, or appropriate study groups for their consideration, study, and recommendations.

R. E. Eckardt, M. D., Chairman

CONDENSED SUMMARY OF THE OBJECTIVES AND FINDINGS
OF AN EXPERIMENTAL PROGRAM FOR THE APPRAISAL OF
THE POTENTIAL CARCINOGENIC CHARACTERISTICS OF
CERTAIN PETROLEUM PRODUCTS

I. INTRODUCTION

Experiments were initiated in 1947 in order to develop more information concerning the carcinogenic characteristics of certain petroleum oils, some of which had been found by other investigators to be surprisingly active in this respect, when applied upon the skin of experimental animals. The initial work was exploratory in type, but it succeeded in heightening the interest of representatives of both the Laboratory and the Sponsors in an investigation of broader scope. Accordingly, in 1949, a program was designed and embarked upon which had as its ultimate purpose the determination of the degree of the potential hazard of cutaneous cancer which might be associated with contact of the human skin with a wide variety of petroleum oils. In the course of the investigation some attention was given to an examination of the potential usefulness of certain preventive procedures.

II. OBJECTIVES

The attack upon the primary problem was directed toward three primary objectives:-

1. That of testing representative samples of intermediate and finished petroleum products for their ability to induce cancer of the skin of mice, by methods which would demonstrate their relative activities in this regard in as nearly quantitative and reproducible terms as might

be possible.

2. That of comparing the "carcinogenic potencies" of the various test materials with the chemical or physical characteristics of their components, so as to develop, if possible, out of consistent correlations, technical means for detecting the carcinogenic properties of petroleum products and determining their relative potencies.

3. That of surveying as large and as representative a segment of the population of the American petroleum industry as might be relevant and available in temporal, spacial, and occupational terms, in an effort to establish, by appropriate epidemiological and biostatistical methods, the existence or non-existence of the occupational hazard of cancer, generally, in the recent past or at the present time.

III. RESULTS

1. Biological Estimation of Carcinogenic Properties

More than one hundred representative samples of intermediates or products of refining operations were collected, and their relative carcinogenic potency for the skin of inbred mice were determined and so expressed as to denote both the rate of development of tumors and the proportion of experimental mice affected thereby.

(a) Tumors of the skin of mice, at the site of multiple applications, were induced most rapidly by the residual products of catalytic cracking or reforming, and by the cycle gas oils from delayed coking. They developed somewhat less rapidly at the site of contact with the residual products of thermal cracking or reforming. Almost all of the cracked residual oils selected for examination produced a

high frequency of occurrence of tumors of the skin of the mice, when applied thereon three times each week.

(b) The results of tests on uncracked oils covered a very broad spectrum of potency, from the high level of certain "lube" distillates and solvent extracts (which produced tumors about as rapidly as the catalytically cracked residua), to the completely negative behavior of certain other highly refined oils.

(c) Limited numbers of data indicate that extraction with phenol, as commonly applied to lubricating distillates, removes almost all of the polycyclic aromatic carcinogens. Similarly, treatment with fuming sulfuric acid, commonly employed in the manufacture of white oil, appears to render the raffinate free of carcinogenic compounds.

2. Chemical Characteristics of Carcinogenic Oils

Relationships were established between the chemical components of certain oils and the carcinogenic potency of the latter when applied upon the skin of mice:-

(a) Benzo(a)pyrene and its alkyl derivatives were found to be important contributors to the potency of cracked residua, and a fairly rapid method for their determination in the oils was developed.

(b) There being no benzopyrenes in the catalytically cracked fractions in the 700° to 750° range, the development and application of a method of liquid partition chromatography revealed the presence of alkyl derivatives of benzo(c)phenanthrene as important contributors to the carcinogenic potency of these fractions.

(c) There is no general physico-chemical method, as yet, whereby the carcinogenic potency of refinery streams generally can be estimated. However, a fairly satisfactory classification of residua (fractionator bottoms) of catalytically cracked oils can be made through chemical measurements of their polycyclic aromatic components by means of the combined techniques of chromatography and spectrometry (mass and ultraviolet), in correlation with their potency for the skin of mice.

(d) The potency of an oil containing a minute proportion of aromatic components in the molecular range of 220 to 320, depends greatly upon the extent to which other constituents of the oil exert an indirect influence upon the carcinogenic process (see below in (d1) a brief account of "acceleration"). The available data are insufficient for the estimation of such activity by physico-chemical methods. Therefore, while a limited number of uncracked oils and cracked distillates may be classified as carcinogenic on the sole basis of their content of polycyclic aromatic hydrocarbons, the majority of such oils can now be so classified only in terms of the responses elicited by their application upon the skin of suitable test animals.

(d1) The carcinogenic potency of certain oils for the skin of mice was found to vary with the nature of their non-carcinogenic components. Some completely saturated fractions containing no polycyclic aromatic compounds were found to be capable of accelerating, three- or four-fold, the rate at which a given carcinogenic agent, introduced therein in a known concentration, induced tumors of the skin of mice. The investigation of the "accelerating activity" of various pure compounds indicated that this property was shared by a wide variety of

hydrocarbons containing 10 to 20 carbon atoms, including such examples as n-dodecane, dodecylbenzene, anylnaphthalene, and triisopropylbenzene. Experiments with various distilled fractions of petroleum oils indicated that the accelerating compounds occurred mainly in the fraction distilling between 450 and 700°F., whereas the compounds that were truly carcinogenic for the skin of mice occurred predominately in the higher boiling fractions.

(d2) A limited group of results indicated that certain sulfur compounds in catalytic cycle gas oils were also contributing to the carcinogenic potency of these oils. Further experiments with a pure sulfur compound, benzyldisulfide, indicated that this contribution was probably that of a special type of accelerator rather than that of a carcinogenic agent. The nature of this activity is being investigated further.

(d3) White oils employed as diluents have been found to be disproportionately effective in reducing the accelerating activity of n-dodecane and dodecylbenzene, as compared with the similar affect (apparently simple dilution) of more common solvents such as benzene and decahydronaphthalene.

3. Experimental Reduction of Carcinogenic Action by Washing Skin.

Removal of an oil from the skin of mice shortly after its application, by washing with a typical aqueous detergent, lengthened the time required for the production of cutaneous tumors. Such washing also reduced the frequency of the occurrence of tumors on the skin of the mice within groups subjected to multiple applications of the oils (with the exception of the more potent of those produced by catalytic cracking).

4. Epidemiological Information

The results of the epidemiological survey have been reported in detail and are not dealt with in this summary, except to indicate that, while they were unsatisfactory in several respects and therefore inconclusive, they yielded no evidence of the occurrence of occupational cancer within the population surveyed. This summary has dealt with the potential hazard of occupational cancer, therefore, in relation to the products investigated, as revealed by the responses of mice to carcinogenic stimuli, rather than to a present and demonstrable danger within the industry. To the extent that this dubiously negative evidence is reassuring, it may well be accepted as a favorable condition for the further development and maintenance of a technologic surveillance of petroleum products, and an hygienic and medical supervision of occupational conditions and personnel.

IV.

PUBLICATIONS

In addition to the regular interim reports to the Subcommittee on Carcinogenicity of the Medical Advisory Committee of the American Petroleum Institute, certain of the results of these investigations have been published in scientific journals as follows:

1. Tye, R., Graf, M.J., and Horton, A.W.: Determination of Benzo(a)pyrene in complex mixtures; use of catalytic iodination on activated alumina. Anal. Chem. 27, 248-53 (1955).
2. Horton, A.W. and Denman, D.T.: Carcinogenesis of the skin. A re-examination of methods for the quantitative measurement of the potencies of complex materials. Cancer Research 15, 701-8 (1955)
3. Horton, A.W., Denman, D.T. and Trosset, R.P.: Carcinogenesis of the skin. II. The accelerating properties of aliphatic and related hydrocarbons. Cancer Research 17, 758-66 (1957).

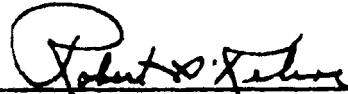
An oral presentation of additional data was made as part of the Symposium on Polycyclic Aromatic Hydrocarbons at the meeting of the American Chemical Society, September 1956, under the title "Relationships Between the Composition and Carcinogenic Properties of Various Refinery Streams."

Other publications will follow in due course.

From The Kettering Laboratory, Department of Preventive Medicine and Industrial Health, College of Medicine University of Cincinnati, Cincinnati, Ohio.

Report by:

A. Wesley Horton, Ph.D.
Robert A. Kehoe, M.D.

Approved: 

Robert A. Kehoe, M. D.
Director

Date: November 4, 1960

REPORT OF THE SUBCOMMITTEE ON DERMATOLOGY

Leo J. Wade, M. D., Chairman

The subcommittee met in Chicago on November 11, 1960 with four members present and two absent. Eighteen visitors were present. The following items were considered:

1. "Creeping eruption" is not limited solely to oil workers, but occurs among many other occupations. None of those present knew of any cases among its employees this past year. Since the subcommittee does not consider this to be a major problem peculiar to the petroleum industry, no further activity on this matter is recommended.
2. The Industrial Hygiene Foundation brochure and placard on dermatitis have not been distributed as widely as is desirable. The subcommittee recommends to the member companies that these materials be distributed and utilized to their maximum advantage.
3. The API Lubrication Committee in September requested the Medical Advisory Committee to discuss an alleged skin cancer problem associated with the use of cutting oils with the United Auto Workers - which had been raised earlier with individual petroleum industrial hygienists. Representatives of this subcommittee and the Lubrication Committee met in Detroit on October 3 with Mr. Floyd Van Atta, the UAW industrial hygienist. Mr. Van Atta's position can be summarized as follows:
 - a. He believes that there is a definite skin cancer hazard associated with prolonged contact with cutting oils. He has no information on the magnitude of the problem. He hopes that some information can be obtained on this point. He is also concerned about the possibility that inhalation of cutting oil mists may contribute to the occurrence of lung cancer.
 - b. He agrees that good personal cleanliness and proper education of employees in personal hygiene is necessary.
 - c. He feels, however, that manufacturers of cutting oils should remove all carcinogenic materials from their cutting oils because even the best hygiene programs will not insure complete protection. If this is impossible, he believes that dry machining may be necessary.

The UAW conducts a series of training schools for its shop stewards each summer and discussions of health and safety are included. Mr. Van Atta would like to use Industrial Hygiene Foundation brochures and placards in these schools as well as to distribute them to those on the UAW staff mailing list. (The API Division of Marketing has already arranged to furnish copies to Mr. Van Atta.)

On the basis of the discussion with Mr. Van Atta, the subcommittee recommends that:

1. The MAC of the API cooperate with the UAW in its educational program for UAW members by
 - a. supplying, as requested, the Industrial Hygiene Foundation brochures and placards on dermatitis and
 - b. "lending" on a voluntary and rotating basis the services of the petroleum industrial hygienists to lecture at the UAW training schools, if asked to do so.

1. The MAC of the API remain available for further consultation with the UAW if they find any potentially feasible way to engage in epidemiological studies on skin and lung cancer as they relate to cutting oils.

2. Each manufacturer of cutting oils review the properties of his own oils being sold for cutting purposes to identify potentially hazardous products, if any, and to give consideration to replacement of any such products where feasible with non-hazardous ones.

3. Continued liaison with the Hygiene Panel of the Lubrication Committee be maintained in carrying on the above recommendations.

The subcommittee feels that no changes are necessary in the statement of its functions and responsibilities nor in the makeup of the subcommittee.

Leo J. Wade, M. D., Chairman

REPORT OF SUBCOMMITTEE ON EPIDEMIOLOGY

G. M. Saunders, M. D., Chairman

A meeting of the full subcommittee was held on November 12, 1960. The scope and purpose, methods of procedure and possible results of epidemiologic studies were outlined. One specific and relatively simple study was agreed upon for recommendation to the MAC.

SCOPE

1. To initiate epidemiological studies relative to the health of employees within the petroleum industry with especial regard to occupation.
2. To act as a consulting group to other subcommittees on the MAC regarding matters of epidemiology which are of interest to the petroleum industry.
3. To collaborate with other groups outside the petroleum industry on the epidemiological aspects of the use of petroleum products.

METHODS

The subcommittee will apply epidemiological techniques to data which are made available by member companies and other sources with the objective of appraising their health significance.

RESULTS

It is expected that epidemiological studies will provide information which will:

1. Permit the evaluation of the health effects, if any, of selected environmental exposures on defined population groups.
2. Enable the API to inform the industry and the general public as to the relationship, if any, between petroleum processes and products, and the health of people.
3. Indicate to the petroleum industry the needs for modification of processes or products in order to promote better health.
4. Develop information which may be used as a guide for indicated changes or improvements.

PROPOSED INITIAL STUDY

A survey will be made of the health status of motor vehicle operators, with emphasis on drivers of heavy trucks. Details of methods and procedures will be stated in a memorandum to be prepared in the near future. Data will be collected on selected samples from medical units of member companies which agree to participate in the study. The data will be analyzed and the results will be summarized for presentation to the MAC.

The subcommittee does not at this time request any funds to carry on its activities.

G. M. Saunders, M. D., Chairman

REPORT OF THE SUBCOMMITTEE ON MEDICAL POLICIES AND ADMINISTRATIVE PRACTICES

Ralph F. Schneider, M. D., Chairman

The subcommittee met on November 11, 1960 with four members and five guests present and participating.

The chairman reported that all of the members of the Medical Advisory Committee responded to the request made at the last meeting, that they review the last draft of the "Guiding Principles in Regard to the Scope, Objectives and Function of Occupational Health Programs in Petroleum Operations" and that they vote their approval or disapproval.

Of the thirty members, one voted disapproval, twenty-three voted approval and six voted approval with recommendations for minor changes. The members of the subcommittee have now prepared the attached final statement with due consideration to the proposals made.

The subcommittee recommends:

1. The Medical Advisory Committee approve this final statement.
2. The subcommittee also draws to the attention of the members of the Medical Advisory Committee the revised statement of the Council on Occupational Health of the American Medical Association on the "Scope, Objectives and Functions of Occupational Health Programs" which was approved by the Board of Trustees and adopted by the House of Delegates in June, 1960.

The subcommittee recommends this statement, which was published in the Journal of the American Medical Association on October 1, 1960 and which is available in reprint form, as an authoritative reference and a useful piece of educative literature available for dissemination to physicians, technicians and management personnel.

Ralph F. Schneider, M. D., Chairman

GUIDING PRINCIPLES IN REGARD TO THE SCOPE, OBJECTIVES, AND FUNCTIONS
OF OCCUPATIONAL HEALTH PROGRAMS IN PETROLEUM OPERATIONS

Introduction

The term "occupational health program" means a program provided by management to deal constructively with the health requirements of employees and employers in relationship to employment.

The term "occupational medicine" is that branch of medicine which deals with the relationship of man to his occupation, for the purpose of the prevention of disease and injury and the promotion of optimal health, productivity, and social adjustment.

Occupational Health Programs

Although a person's health is primarily the responsibility of the individual himself, an occupational health program represents management's recognition of its obligation to provide a safe work environment and its opportunity to assist in promoting optimum health among its employees. While circumstances may affect the extent of certain services which may enter into a health program, a high quality of professional service must be preserved at all times.

Cooperation between physicians, industrial hygienists, nurses, technicians and other personnel of the occupational health program and management personnel responsible for the employment, safety and well-being of employees is essential. Occupational health personnel should cooperate also with private and official community agencies providing health, safety, employment and welfare services.

Through the years many forms of occupational health programs have been developed from which has emerged an acceptable basic pattern. Experience indicates that success can best be assured when:

1. The program
 - a. Observes the basic principles of medical service to the individual and conforms to medical customs in the community.
 - b. Complies with existing laws.
 - c. Emphasizes prevention and health maintenance rather than the treatment of injury and disease, which is left to the employee's personal physician except for emergencies on the job.
 - d. Utilizes community medical resources when adequate or when they can be developed reasonably.
2. The professional personnel participating in the program
 - a. Maintain high standards of professional service and conduct for the benefit of employee and employer alike.
 - b. Cooperate and maintain proper liaison with other professional colleagues in the community and with the appropriate professional associations.
 - c. Are engaged and compensated, and carry on their activities, with accepted ethical principles.

From time to time, problems arise out of a misunderstanding of the proper scope of occupational health programs as contrasted with medical programs for personal (non-occupational) illness of employees. It is, therefore, essential that employers, employees, and physicians recognize the fundamental distinction between these two types of programs.

The occupational health program providing medical care for personal illnesses and injuries must be oriented to the work environment and to the health of the employee in relation to his job. On the other hand, when service rendered under occupational health programs exceeds the limits described hereafter, the occupational health program becomes to that extent a medical care program for personal illness and should be so recognized by all concerned.

Objectives of Occupational Health Programs

The objectives of an occupational health program are:

1. To promote the healthful nature or the greatest possible freedom from health hazards in the industry's operation, environment, and products.
2. To facilitate the placement of individuals according to their physical capacities and their emotional make-up in work which they can reasonably perform with an acceptable degree of efficiency and without endangering their own health and safety or that of their fellow employees, and
3. To encourage personal health maintenance.

The achievement of these objectives benefits both employers and employees in terms of improved employee health, morale, and productivity.

Activities to Attain Objectives

In order to attain these objectives the following activities (and the maintenance of appropriate records) are essential:

1. A survey and knowledge of the work environment from a health standpoint. This requires periodic inspections of the entire premises used by employees, including provision for, and appropriate participation in, the procedures and tests required to detect and appraise health hazards. Such inspections and appraisals provide current information on health aspects of work conditions, processes and substances used, which is essential in evaluating symptoms, signs, and clinical laboratory data related to the differential diagnosis of disease. This information, including those relating to stress and mental health, will aid in evaluating any health hazards that may exist and in making appropriate recommendations for preventive or corrective measures.
2. Health examinations. Unrealistic and needlessly stringent standards of medical fitness defeat the purposes of health examinations and of maximum utilization of the available work force.

Health examinations should consist of:

- a. An initial examination to determine the health status of the individual in order to facilitate suitable placement in employment. This examination should include (1) his family and personal medical history; (2) his occupational history; (3) a health evaluation, and (4) other procedures to help determine the individual's employability and his capacity for work.

- b. Subsequent examinations carried out at suitable intervals on a voluntary basis and designed to detect any sign or symptom of ill health related to employment conditions, to evaluate the health status of the individual in order to determine whether his health is compatible with his job assignment, and to forestall long-term disability by early detection of disease.

All examinations must be conducted by physicians with such assistance from associated personnel as may be required. Prior to each examination, the individual should be advised as to its constructive purpose and value. At the conclusion of an examination, the physician should discuss his findings meaningfully with the individual. When health defects are found, the physician should explain to the individual the importance of obtaining further medical attention, and encourage him to consult his personal physician.

- 3. Medical records. The maintenance of accurate and complete medical records of every individual from the time of his first examination or treatment is a basic requirement. Except when otherwise required by law, the confidential character of these records, including the results of health examinations, must be rigidly observed by all members of the occupational health staff, and such records must remain in the exclusive custody and control of the medical personnel. The patient should be informed of all pertinent health findings except when such disclosure would have an adverse effect on his health and well-being. A private physician or other agency may be provided with a report of health findings when the patient so designates. Disclosure of health information should not be made without the approval of the patient except when essential to fulfill the legal obligations, and then, only to the extent necessary to fulfill such obligations.

- 4. Medical treatment. Every employee should be encouraged to have a personal physician.

- a. Medical care required by workmen's compensation laws for occupational injury or illness should be directed toward optimum rehabilitation of the employee. The attending physician may be a member of the occupational health staff or any physician in the community willing and qualified to perform the essential services.
- b. Medical care in case of non-occupational injury or illness is not a function of an occupational health program, with the limited exceptions noted below.

Emergency cases should be given the attention required to prevent loss of life or limb or to relieve suffering until the patient is placed under the care of a personal physician.

For minor disorders, first aid or palliative treatment may be given if the condition is one for which the individual would not reasonably be expected to seek the attention of a personal physician, or to enable the individual to complete his current work before consulting a personal physician.

In occupational health programs, requests for repetitive treatment of even minor personal disorders should be discouraged, and such individuals should be referred to their personal physicians.

- c. The best interests of a patient are served by cooperation and communication between their personal physician and physicians in charge of occupational health programs. In this way, prompt restoration of employees to suitable employment is encouraged.

Health and safety education. A high standard of occupational health cannot be achieved without familiarity with, and the observance of, fundamental health principles. The development of an understanding of these rules and the promotion of their observance is an essential task in which an occupational health staff can render very valuable assistance.

An occupational health program should promote the education of employees in matters of personal hygiene and health and encourage the use of safeguards provided to protect against any hazards to health which may be inherent in their jobs. The most favorable opportunities for carrying on health education and counselling will be afforded during visits of employees to health facilities and through periodic inspections of the employee's place of work.

Health and safety education involves the cooperative efforts of health, safety, and operating personnel. Such education should include not only the encouragement of habits of cleanliness and orderliness but also instruction, in collaboration with the employee's immediate supervisor, in safe work practices and in the use and maintenance of available personal protective clothing and equipment.

Experience has shown that health education is unlikely to be successful unless the employer demonstrates his sincere and continuing interest in the health of his employees. Likewise, employees should be encouraged to participate in the planning and conduct of health education activities and make full and effective use of occupational health services and facilities available to them.

An occupational health program to be effective and acceptable to the employee, must be staffed by objective and competent personnel who create an atmosphere of warm, sincere, and positive personal helpfulness.

Personnel

All phases of an occupational health program should be under medical supervision. This requires the appointment of a medical director, full or part-time, who is a qualified doctor of medicine. Training and/or experience in occupational medicine is desirable. The medical director should have a responsible role in the development and interpretation of medical policy. He should administer the health program and be directly responsible to a designated official at the policy-making level of management. Additional physicians, as consultants or associates, may be required for an effective program. The duties of these physicians should be clearly defined by the medical director.

Qualified associated personnel, selected and directed by the physician in charge, are essential to the proper functioning of an occupational health program. According to program needs, these may include industrial hygienists, nurses, first-aid attendants, and laboratory and clerical personnel.

The industrial hygienist should have the knowledge and training necessary to survey and evaluate the work environment as well as the processes and products of the operation in order to make necessary recommendations to correct and control any existing or potential hazards to health.

A nurse should be a graduate of an accredited school of nursing, registered and legally qualified to practice nursing where employed. Training and/or experience in occupational health is desirable. She should assist the physician in the supervision of the health of employees while at work and in their health education. Her professional duties and nursing procedures should be clearly defined in writing by the physician to whom she is responsible.

One or more qualified first-aid attendants, known to all employees, should always be available during working hours. They should receive periodic refresher instruction and be provided with specific written instructions by the physician in charge.

Facilities

The facilities of an occupational health program may be available at the place of employment or in the community. When provided on the employment premises, facilities should:

1. Be located in a quiet area, readily accessible to employees;
2. Be sufficiently spacious, well lighted, ventilated and heated;
3. Include waiting, consultation, examining and treatment rooms, and toilet facilities, to insure adequate privacy and comfort; and
4. Have appropriate medical and laboratory equipment.

It may also be desirable to provide a rest or recovery room, dressing rooms and facilities for laboratory and radiological examinations.

Conclusions

Specific and detailed recommendations as to personnel facilities, and other aspects of individual occupational health programs obviously are beyond the scope of this statement. It is recommended that the local medical society be consulted to assure that a given program is in agreement with the objectives of this statement and with established community practices.

REPORT OF THE SUBCOMMITTEE ON PHYSICAL AGENTS

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

The Subcommittee on Physical Agents met at the Conrad Hilton Hotel in Chicago, at 2:00 P. M., on Friday, November 11, 1960. It was suggested that we reestablish the practice of assigning individual members of the subcommittee to cover certain aspects of the physical agents' field in order to keep up with new developments. Assignments for this purpose will be made by the chairman of the subcommittee shortly.

The subcommittee again recommends that the API support Dr. Aram Glorig's work in the amount of \$2,500 for the next year.

It was suggested and the subcommittee agreed to develop a tabular summary of state laws with respect to noise and deafness. For this purpose we intend to contact Dr. Glorig to make use of any summaries which he may already have prepared.

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

REPORT OF SUBCOMMITTEE ON SPECIALTY PETROLEUM PRODUCTS

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

MEMBERS PRESENT:

C. H. Baylor, M. D.
George Entwistle

J. W. Hammond
Ralph Schneider, M. D.

MEMBERS ABSENT:

R. C. Cole
E. W. Gerarde, M. D.

W. W. Stewart, M. D.

GUESTS:

W. L. Avrett
T. H. Mitchell, M. D.
A. E. Dooley
A. C. Pabst

N. V. Hendricks
J. H. Johnson
E. K. Daniels

1. The kerosine study is still under supervision of the subcommittee. The primary aim of this project is to determine the best treatment of patients who have ingested kerosine or liquids containing it with special emphasis on the wisdom of gastric lavage.

Little progress has been made in the last year due to difficulties encountered in developing a simple method of detecting minute quantities of kerosine in human blood. However, Dr. Horace Gerarde, a member of the subcommittee, has offered to do these determinations by the ultraviolet method on blood specimens sent to his laboratory by Drs. McKay, Daeschner, and Nau who have been doing these studies. Plans are now underway to initiate the renewal of this work.

2. The chairman was requested to communicate with Dr. Edward Press (Public Health Director, Evanston, Ill.) in order to obtain a report of the information collected by him from patients who have ingested kerosine and acquaint him with our kerosine program.

3. At the request of this subcommittee, Mr. George Entwistle attended in Chicago on 10/18/60 the 3rd Annual Meeting of the American Association of Poison Control Centers. Mr. Entwistle submitted an excellent report of the proceedings and supplied tabulated data of some of the papers presented. This material was distributed to the subcommittee.

4. It was decided that a member of the subcommittee should apply for membership in the American Association of Poison Control Centers since they are collecting data on intoxication by kerosine as well as other materials.

5. There was considerable discussion as to what materials were properly classified as specialty petroleum products. Among those mentioned were kerosine, asphalt, spray oils, weed-killers, insecticides, solvents, paint constituents, fungicides, ethylene, and its derivatives and possibly certain additives and petrochemicals.

It was decided that no attempt should be made to consider this vast number of materials unless there was some definite indication of health hazards.

The subcommittee would like to request all members of the MAC and the technical advisors to pass on to the subcommittee any information they might acquire concerning the health hazards of these materials and also any problems they encounter concerning them.

The chairman was requested to communicate with the Petroleum Products Committee of the API and request from it an up-to-date list or classification of the principal specialty petroleum products as understood by that committee.

No further appropriation is requested by the subcommittee at the present time.

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

REPORT OF THE SUBCOMMITTEE ON TOXICOLOGICAL REVIEWS

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

Since the April meeting of the Medical Advisory Committee, the second edition of the Toxicological Reviews have been published on Benzene, Toluene and Xylene. Circulating currently for comment from members of the Medical Advisory Committee are first drafts of the Toxicological Reviews on Sulfur Dioxide and Sulfuric Acid prepared personally by Professor Philip Drinker.

Second drafts on Styrene and Cyclohexane containing comments and suggestions received from members of the Medical Advisory Committee will soon be ready for duplication and re-circulation for approval for publication.

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

REPORT OF THE SUBCOMMITTEE ON INDUSTRIAL HYGIENE

J. A. Spence, Chairman

The subcommittee met on November 11, 1960 with fourteen members and sixteen guests present.

Liaison members reported on the activities of the American Standards Association Z37, Toxic Dusts and Gases; Z4, Industrial Sanitation, and Z62, Industrial Hygiene Standards. The Z4 committee sponsorship has been assumed by the American Conference of Governmental Industrial Hygienists. It is expected that work will begin shortly on revisions of sanitation standards. The Z37 committee is presently active in revising standards for certain chemicals. The committee has recently issued final drafts on benzene, toluene, and xylene. The Z62 committee is currently writing a guide on good industrial hygiene practices. The section on Sanitation, Housekeeping and Personnel facilities as well as the section on Noise are near completion. The sections on Temperature, Humidity, and Ventilation and Chemical Agents are in first draft form. The membership for the four writing groups on biological agents, microwaves, ionizing radiation and illumination has not as yet been selected. It is expected that completion of the various sections of the Z62 committee will take another two years.

Progress continues on the subcommittee's project "Industrial Hygiene Aspects of Petroleum Refining Processes." It is expected that a final draft of this material will be circulated to subcommittee in about three months.

Because of the apparent toxicity of the C₉ - C₁₂ fractions uncovered by the work of Dr. Nau, the members of the Subcommittee on Industrial Hygiene have agreed to obtain quantitative data on exposures to C₉ - C₁₂ concentrations within petroleum operations. Mr. J. Hammond is to serve as liaison to the C₉ - C₁₂ subcommittee.

Mr. N. V. Hendricks' special study group on oil mists presented its report revealing a lack of reported cases of illness due to the inhalation of oil mist. There also appears to be a paucity of information on the physiological response to the inhalation of oil particles in concentrations experienced in the work environment. The subcommittee unanimously accepted the recommendations given in the report that:

1. The API develop liaison with Dr. Herbert Stokinger of the U. S. Public Health service in his long-range study of the effects of oil mist exposure in animals.
2. The API in cooperation with an appropriate group undertake the epidemiological study of groups of workers exposed to oil mists. This should be broad enough to cover lung cancer as well as other lung ailments. The assistance of a pathologist would be helpful by studying lung sections of individuals brought to autopsy who had history of exposure to oil mist.
3. The important question of lung cancer in relation to the inhalation of oil mist should be referred to the chairman of the Medical Advisory Committee.

The subcommittee unanimously endorsed Mr. Hendricks' amended proposal that the Medical Advisory Committee, in cooperation with the Smoke and Fumes Committee, review the desirability of giving financial support in the amount of \$25,000 to the cooperative lead-in-air study being undertaken by the U. S. Public Health Service along with certain participating industry groups. This lead study is being made in compliance with a recommendation from the U. S. Surgeon

General's Advisory Committee on Tetraethyl Lead. The study will seek to establish the present lead burden in representative U. S. cities and determine the trends in atmospheric lead concentrations.

J. A. Spence, Chairman

INTERDIVISIONAL COMMITTEE ON LABELING - REPORT TO THE MEDICAL ADVISORY COMMITTEE

The revision of API Bulletin 2511 has been completed by the Interdivisional Committee on Labeling. Labels for the following products have been added:

Ethylene Glycol Antifreeze
Methanol Antifreeze
Aromatic Petroleum Oils
Cut-Back Petroleum Asphalts
Gasoline Containing Lead Alkyl Compounds

The statement "If swallowed, call a physician immediately" will be added to the label for kerosine.

The Federal Hazardous Substances Labeling Act becomes fully effective on February 1, 1961. The Food and Drug Administration is now preparing regulations to implement the law. An Inter-Industry Trade Association group, of which the API is a part, is now drafting suggested regulations covering certain household products which contain petroleum fractions. The Chemical Specialties Manufacturers' Association has asked the API Committee on Labeling to have a toxicologist from the petroleum industry meet with and advise its Committee on Toxicology so that any suggested regulations will exclude those petroleum fractions and products that are not hazardous within the meaning of the Federal law. Accordingly, the API Labeling Committee requests that the MAC select one of its members or Technical Advisors for this assignment. This should be done promptly because the FDA is expected to start publishing labeling regulations very shortly.

Two more states, Kentucky and Massachusetts, now have labeling laws. These laws follow closely the model law prepared by the Inter-Industry Trade Association Group. North Carolina now has labeling requirements by virtue of its earlier enacted legislation which stated that when a federal labeling law was enacted, the same requirements would constitute the North Carolina law.

This report is submitted for the MAC representatives on the Interdivisional Committee on Labeling, R. D. Bent, W. W. Stewart, M. D., and A. E. Dooley.

1960 REPORT OF THE ADVISORY COMMITTEE TO THE WAX RESEARCH PROJECT TO THE MEDICAL & HEALTH COMMITTEE

R. E. Eckardt, M. D., Chairman

Because little reliable information was available on the possible toxicity of petroleum waxes, the Board of Directors authorized, in 1957, the establishment of an investigation on the toxicity of petroleum waxes. The research project was initiated at the beginning of 1958. This far-sighted move proved exceedingly helpful when, in September 1958, the President of the United States signed into law the Food Additives Amendment. This amendment requires that the producer or marketer of a food additive must show to the full satisfaction of the U. S. Department of Health, Education, and Welfare that the food additive under question is not harmful to man or animals.

The investigation of possible toxicity of petroleum waxes has been under study continuously at The Chicago Medical School, under the direction of an internationally known expert on cancer, Dr. Philippe Shubik.

Based on the findings at The Chicago Medical School, sufficient information was obtained to permit the Department of Health, Education, and Welfare to grant a year's extension to the use of two groups of petroleum waxes: type 1, which is essentially paraffin wax, and type 2, which is essentially microcrystalline wax. This extension expires March 6, 1961. It will be necessary for the industry to petition the Department of Health, Education, and Welfare before this time and request an approval of petroleum waxes.

The investigational work at The Chicago Medical School has not yet been completed, nor is it expected that it will be completed by March 6, 1961. The findings to date indicate that there should be no difficulty in obtaining an outright approval for the use of petroleum waxes as an incidental food additive. While the use of waxes as a food additive was justified from the experimental results, nevertheless, additional experimental investigations have been necessary to clarify beyond any doubt certain unexplained conditions which appeared during the biological testing. The experimental work is proceeding well and should be essentially completed in about one year.

The committee is planning to formally request, before March 6, 1961, approval for the use of petroleum waxes after that date.

The cooperation of the petroleum analysts has been obtained in the development of a satisfactory analytical method for use with petroleum waxes. The one developed by The Chicago Medical School, while highly satisfactory and extremely accurate, is time consuming. The use of such a method in plant control work or by the Food and Drug Administration people in their inspection work is extremely doubtful. Great effort is being made by various petroleum industry laboratories to develop a control type of analysis which will still have incorporated within it the desired accuracy, but which can be performed in a reasonable length of time.

In anticipation of the financial requirement of the wax investigation, the 1961 budget of the API contains an item of \$150,000 to continue the wax research project for another year. However, a careful review of future requirements indicates that only \$100,000 will be needed. Therefore, the budget can be reduced by \$50,000.

R. E. Eckardt, M. D., Chairman

REPORT ON LIAISON WITH QUARANTINE SERVICE

Since the last report in April 1960, contact has been maintained with the U. S. Public Health Service quarantine activities. The Epidemiology and Domestic Operations Branch, Division of Foreign Quarantine, Department of Health, Education, and Welfare, is the office with which liaison is accomplished.

On 6 September 1960, Dr. James G. Telfer was appointed Medical Director and Chief of that office, replacing Dr. Ralph McComas who had been Chief. Miss Regina Burns is in charge of the epidemiology and immunization program within the Branch.

Since last April, a few noteworthy incidents have occurred:

On 10 June 1960, a request was received from one of the members of the Medical Advisory Committee for information regarding an epidemic of meningitis in Tahiti. A telegram was sent stating that we had no information, nor did the U. S. Public Health Service, concerning meningitis in Tahiti.

On 9 September 1960, a cable was received from Dr. W. H. J. Weston, of Iranian Oil Services Limited, concerning cholera cases near the eastern border of Iran and advising cholera vaccination be given to visitors to Iran. The U. S. Public Health Service verified an outbreak of cholera in Afghanistan. This information was passed on to Mr. Mattocks' office from which a memorandum was sent to members of the Medical Advisory Committee.

On 7 October 1960, a telephone call from Miss Regina Burns reported a case of smallpox in London in a passenger on a B.O.A.C. plane which had arrived three days earlier from Singapore in Ceylon. The U. S. Public Health Service was enforcing the rule that anyone arriving in the U. S. A. from the United Kingdom must be in possession of a valid vaccination certificate. This information was passed on to Mr. Mattocks' office which, in turn, informed the members of the Medical Advisory Committee. A follow-up report from Dr. Telfer's office was received on 13 October 1960. This gave an account of a number of the passengers who subsequently came to the U. S.:

"Two Americans who were on the plane were vaccinated before departure from England and were placed under surveillance on their arrival in the United States. An infant was vaccinated at the time of arrival in the United States and placed in isolation at Staten Island. This infant had been in the clinic in England at the time that the smallpox case was examined.

"Two Christian Scientists who were in London before the time that the smallpox case was clinically diagnosed are in isolation in Boston."

G. M. Saunders, M. D.

1960 REPORT OF THE INTERDIVISIONAL COMMITTEE ON PETROLEUM FOOD
ADDITIVES TO THE MEDICAL AND HEALTH COMMITTEE

L. E. Curtis, M. D., Chairman

The Interdivisional Committee on Petroleum Food Additives was established to determine if action should be taken by the API to obtain approval for the use of petroleum products which are used as food additives. If action is needed, the Petroleum Food Additives Committee provides the framework for such action.

The White Oil Council, which consists of manufacturers of white oil, was formed many years ago. This group raised money and initiated necessary experimental work which is necessary to secure approval for the use of white mineral oil as a food additive. The White Oil Council requested that their members be made a subcommittee of the Interdivisional Committee on Petroleum Food Additives. This was done. The experimental work on white oil is progressing satisfactorily and it is the hope that approval may be obtained for the use of white oil as food additives after March 6, 1961.

Refiners, marketers, and raw material suppliers of petrolatum formed the Petrolatum Council in order to raise money and initiate biological test work to obtain approval for the use of petrolatum as a direct or indirect food additive. The biological test work is progressing nicely. However, since this is a two-year program, final results will not be available by March 6, 1961. It is, however, expected that based on the results obtained by that time, the Petrolatum Council will be able to secure, before that time, an extension until their biological test work is completed.

The committee is following closely the use of other petroleum products that might be classified as a food additive. At this moment, there appears to be no petroleum product which requires separate action.

L. E. Curtis, M. D., Chairman