

November 18, 1965

Messrs. Harrington
Old
Andersson
Moore

Re: Council for Tobacco Research - U.S.A.

Two meetings were held yesterday at the Council for Tobacco Research. In the morning session there was a discussion of a proposed budget for 1966 as well as a discussion of the practicability of screening and conducting industry-inspired ideas for specific research.

The proposed budget, which Mr. Harrington will receive in the mail, is much the same as last years with a total of \$2,020,000, \$1,500,000 of which is allocable to grants. I advised Mr. Harrington before attending the meeting that I did not intend to approve any budget and that I wished to get some clear idea as to what, if any, portion of the budget allocable to grants would be expended in projects thought up by Dr. Little and Dr. Hockett, which I shall outline below. The projects which Dr. Little and Dr. Hockett expect SAB approval of fall into the following specific areas:

1. Whole smoke. Apparently a relatively simple method of applying whole smoke, as compared with condensate, has been developed by Walton, who works with Homburger in Boston. Dr. Little is encouraged by this approach and says we will be on a road no one else is traveling. Although the experiments (equivalent of painting at the outset) will take several years, the method should be a better method of bioassay and Dr. Little believes the results will not give the same results as skin painting. Dr. Little stated that he will need the help and advice of industry research directors to determine whether the whole smoke to be used is the same as that delivered in the smoking of a cigarette.
2. Oral Cavity. The Council had a conference recently of experts in the oral cavity. The fact is that although the mouth receives smoke initially, cancer of the area is rare. The mouth is an accessible and quick vehicle for bioassay and studies of the effect of smoke upon it should be revealing. The fact is that to date the American Cancer Society has kept away from the oral cavity, possibly because it does not fit their thesis with respect to lung cancer. Furthermore scientists can study the oral

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cavity of humans without impairment of the patient by broncoscopy.

In addition there is evidence that if the liver of a test animal is damaged before testing, a greater percentage of cancers result in the test animal. Since most of the plaintiffs in the lung cancer cases were also heavy drinkers, this type of test might help resolve the question whether people who contract cancer do so because of damage to the liver or other nutritional deficiencies. The testing in this area also might have implications in the cardiovascular area.

3. Epidemiology. The Council with the approval of the Scientific Advisory Board wishes to enter this area, which it considers the most promising if we want answers rather quickly. Dr. Little would like to call an informal conference of epidemiologists and statisticians to find out what they think should be done and how to accomplish it. The area for discussion would include
 - A. What can be done to reanalyze the existing data to show its gaps and weaknesses and formulate new points of view.
 - B. What can be done to collect more direct, pertinent and accurate data. In this area most of the present statistics used mortality figures whereas the incidence data (morbidity data) really shows the magnitude of the problem.
 - C. Why is the gap in the incidence of lung cancer between men and women growing. Do the lungs of women show the same changes which Auerbach reports finding in men?
 - D. Is the rate of increase in the incidence of lung cancer a true increase?
 - E. What effect, if any, does previous respiratory infection have on the risk?
 - F. Is inhalation an important factor (Doll and Hill strangely found less risk with inhalation than without)?
 - G. Since none of the mortality statistics record the incidence of secondary lung cancer, what is the true data with respect to primary lung cancer. Also, the existing data does break out the type of lung cancer.

- H. The effect, if any, of host factors; i.e., the constitutional makeup of the individual smoker.
- I. The availability of further data in the area of genetics (twins).

We were advised that Dr. Little and Dr. Hockett met with the Ad Hoc Committee, which is planning to enlist the aid of certain statisticians to prepare a broad critique of the existing prospective statistical studies. As the Ad Hoc study progresses, Dr. Little will first convene a conference of experts in the field and then will proceed with studies along the lines of those outlined above.

Dr. Little stated that the \$1,500,000 grant budget includes continuing grants in aid with respect to projects already approved as well as those outlined above, which were inspired by the Council's staff. It was made plain that a supplemental budget may be necessary because of the scope and cost of the Council-inspired studies cannot be measured precisely.

Dr. Little stated that if the \$1,500,000 budgetary figure for grants were to be decreased, it would cause emotional and psychological disturbances in the SAB, a panel of experts which has been of inestimable value to the industry.

I may say that I was encouraged with the thought that it is likely that the costs of Council-inspired studies as outlined above are intended to be included in the budget and I have since talked with Dr. Bates who gives his wholehearted approval of the budgetary figure.

As a result of a conference held by the General Counsel, we broached another subject with the Council staff. In view of the present posture of the industry with the Congress, Federal Trade Commission, etc., it was suggested that the organization of the Council be further implemented by creating an Industry Projects Advisory Board, which could feed suggestions for research to the staff. The Industry Projects Advisory Board would consist of General Counsel with the aid and advice of the Ad Hoc Committee and at least, in our instance, Dr. Bates. As projects of particular interest to the industry are devised, these are submitted to the staff of the Council, which would evaluate whether the project would be likely to obtain SAB approval. If, however, such approval were unlikely, or the element of time necessitated prompt action, or in a particular instance if the SAB received the suggestions and declined to go forward with it, the project would be handled independently.

This, of course, means that in addition to the budget proposed by the Council for 1966, there would be additional expenditures for special industry projects. The Ad Hoc Committee has been commissioned to come up with ideas, which will be discussed at a meeting on December 7. I will, of course, ask Dr. Bates for his comments and I have already asked him to give me any ideas he may have for worthwhile research.

I might also mention that with the stepped up activity it may be necessary to have additional staff at the Council although this should not be a substantial item.

At the afternoon session, which was attended by the research directors of each company, I was present with Dr. Bates. Dr. Little and Dr. Hockett explained the Council-inspired projects, which I have listed above, and they met with hearty acceptance by the research directors.

Dr. Little also stated that he and Dr. Hockett were very anxious to have a closer liaison with the research directors and would like to have one of their number attend SAB meetings so as to answer questions which may arise.

The upshot of all the foregoing is that the two "arms" of the Council in the future may expect to cost the industry additional monies but that the total impact should be of more value to the industry.

Attached hereto is a memo from Dr. Little which recapitulates the thought that has gone into the study in the oral cavity field.

F. P. H.