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PHILIP MORRIS

U. S. A.

OPERATIONS CENTER, RICHMOND, VIRGINIA

THOMAS S. OSDENE, PH. D.
DIRECTOR OF SCIENCE
AND TECHNOLOGY

April 25, 1988

Dr. Samuel D. Chilcote, Jr.
President
The Tobacco Institute
1875 I Street, NW
Washington, DC 20006

Dear Sam:

Thank you very much for your letter which I received on April 19 regarding the ETS issues. As you well know, we have been concerned with the scientific aspects of the ETS issue for sometime. I think many of us have conceptualized the ETS issue as a battlefield in which the arena is dominated by public relations and legal issues while the ammunition which is used happens to be science. It has been the purpose of CIAR as well as its precursor, the ETS Advisory Committee, to provide ammunition in this fight. I believe the most important issue one needs to examine is the role that science can play in this major controversy. As you well know, on a number of occasions over the years, we have generated data by measuring particulates as well as nicotine and other gases in smoking versus nonsmoking situations. In every case we have seen the following phenomenon: namely, that the amount of particulate as well as nicotine in a space in which smoking is permitted or is taking place, has a very slight increase over that of the controlled (nonsmoking) space. The increase is really quite minuscule. In addition, most of the studies done by others have often been conducted poorly thus yielding questionable results. I am totally

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Dr. S. D. Chilcote

2

April 25, 1988

convinced, as I am sure my scientific colleagues are, that the values obtained have absolutely no biological consequence; however, the key issue is that any increase (in nicotine and/or particulates) is being now used in a political sense to beat us over the head as well as being used as a "scientific" basis for making policy decisions. Thus, I am afraid that unless we can counter the above claim and state that the very small increase of particulates and/or nicotine has no significance either biologically or to human health, we will not move far. It is my opinion that one requires a well known or, preferably, a number of well known people who would have medical qualifications to make that kind of a statement. This person or persons would make the statement, after reviewing the experimental results obtained from the literature, that exposure to the levels measured, even over an extended period of time (e.g., in aircraft--the Piedmont study as well as the JAL study and also the restaurant and workplace studies), will not affect human health. The difficulty, I believe, is finding a suitably qualified person or persons who would be willing to make meaningful statements based on the results of our studies in the United States. Perhaps the answer is that we might be able to move towards this goal more easily in Canada or overseas. The thought occurs to me whether the former Medical Directors of T.I., who used to be on your staff, would be willing to make such factual statements on results obtained. I strongly believe this is key to the whole ETS issue, since the only thing that the science can provide us with is actual (or real life) measurements, while it is the interpretation thereof, whether rightly or wrongly, that is now being used in the legislative and political processes. Having stated that, which I believe is basic to the issue, I would point out to you that CIAR and its precursors have addressed a number of the questions which you pose in your letter to me.

The analysis of research critical of ETS: As you are aware, we have once again revisited Hirayama and we will pursue this with great vigor. The reason for the importance of relooking at Hirayama is because it is this database which I believe forms the pseudo-scientific basis for the push against ETS. As you know, the results of several studies, I believe 11 or 13, were subject to "meta analysis" by the National Academy of Sciences (NAS) panel. This is the addition of all of these studies regardless of their merits and then pretending there is a scientific trend.

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Dr. S. D. Chilcote

3

April 25, 1988

Since Hirayama contributed the majority of the total database, if we could show that Hirayama's data is not correct, this certainly might change the scientific environment. However, even if we show that Hirayama's results are inappropriate or misused, the major question still arises, how is this going to be used to defend our position? I believe once again we will be depending on a spokesperson who has suitable qualifications to do this.

There have been additional analyses done over the period of time and I would remind you that recently a study by Dr. J. Kilpatrick, which was presented in Japan, reanalyzed some of the Hirayama data. In addition, we have had Dr. L. Husting undertake a study which looks at the epidemiology of low risk associations as determined by the case-control method. As I am sure you have heard Dr. Ernst Wynder at the ETS Meeting in Tokyo also gave some cautionary comments about this type of epidemiology. I might, however, say that Barbara Hulka, who was the Chairman of the NAS panel, seemed to be totally impervious at the Tokyo meeting to any suggestions made by Dr. Wynder. Therefore, I would think it would be very difficult to get her or members of her group to change their minds because, frankly, I do believe that the attitude is "please, don't bother me with facts."

In terms of the second issue, Sponsorship of research into alleged health effects of ETS, with the exception of some work by Dr. Salvaggio we have avoided this issue. I would remind you that there were restrictions placed upon us over the period of time regarding any determinations of any smoke components in body fluids. This, I believe led to discouragement of doing specific experimentation of this area.

The next subject, Sponsorship of research into overall air quality, was and continues to be a major thrust of CIAR's work, and I would remind you that we have undertaken a number of studies in aircraft (mentioned above) as well as workplace and restaurant studies undertaken in New York, Dallas, and now to be done in Washington. In all of these, the levels of particulates and nicotine, and to some extent carbon monoxide, were determined. Philip Morris has undertaken some studies in railways in the New York City area. In addition, CIAR has sponsored work with Dr. S. DiNardi in which he has looked at the overall air quality (with emphasis on respirable suspended

2046594611

Dr. S. D. Chilcote

4

April 25, 1988

particulates) in shopping malls and offices, as well as studies undertaken at the Oak Ridge National Laboratory evaluating personal nicotine monitors. The project with Dr. D. Eatough is directed at trying to understand the relationship between a nonsmoker's exposure to ETS and the dose actually received, as well as to investigate additional chemical markers for ETS in indoor environments. I am quite sure if you wish, we could give you greater details about these, but I think for the purpose of this letter this summation is sufficient.

I believe that if we continue down this line, and we must, then it is vital that there be a unified position and an appreciation of the role that science and therefore CIAR can play in this controversy. I believe further that the frustration which is felt by all of us is uppermost in the minds of members of CIAR. You are aware that we have had problems regarding the selection of an Executive Director and in addition, it has been difficult to plan a program which will give rapid results in a short time span. It is my opinion that CIAR originally was not intended for providing short-term results; nevertheless, we are vigorously pursuing the avenues open to us and we will certainly seek any input from you and your groups regarding this.

In terms of Communication with the scientific community related to ETS and overall indoor air quality, there are two points. 1) It has been our wish and intention that we establish: a) a newsletter; and b) perhaps more importantly, get access to or form a new journal for the entire question of overall air quality. This of course would be a peer review journal. I do believe that the time to establish this and to get material published with due speed is however still a long way off. Unfortunately, I cannot think of an effective way to cut the time in conducting good studies and in turn getting their results rapidly published in a scientific journal. 2) I believe it is very important that we recruit other industries which have interest in the question of indoor air quality, and I believe that this is another function which CIAR must undertake. However, this can only be done if we broaden our areas of research to include studies not solely related to ETS. The CIAR board plans to meet in early May and spend two days reviewing what has been achieved, and more importantly agree upon what needs to be done in the future.

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Dr. S. D. Chilcote

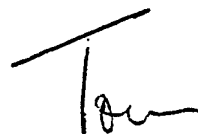
5

April 25, 1988

I trust that these comments will be of some assistance to you in the context of the overall ETS program.

Please be advised that my need to appear in New Jersey sometime in the very near future may well prevent me from joining you at the meeting of the Institute's Communication and State Activities Policy Committee. Nevertheless, feel free to call on me or any members of the CIAR board if we can be of any help.

Sincerely yours,



bc: F. Resnik
M. Serrano

xc: R. Pages

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