

December 15, 1967

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Dear Tom:

I want to thank you and the members of your group for cooperating in the review held here on October 6. I feel that the presentations were well done and that the review committee did their job well.

Comments from the reviewers have been received and were practically unanimous in their recommendations. We have had time now to digest them and I write to you to express their comments and to register our concurrence with them.

It was the unanimous opinion that your study is unlikely to demonstrate late effects because of the relatively small population involved, rarity of such effects and the low levels of exposure. I will quote freely from several letters.

"I hope it will be evident that my criticism is aimed at the overall concept of such a study and not at the way the study is being conducted. Nobody has had more experience than Dr. Mancuso with the practical aspects of a study such as this, and it is clear that he is pursuing this study with energy and ability. While I disagree with Dr. Mancuso on the recommendation to continue and expand the study, I have nothing but admiration for the way he has handled it to date.

"I realize that the Atomic Energy Commission can have interests in this study which may transcend its immediate scientific rewards, and I respect these interests. Clearly, the AEC must confront real, day-to-day operational issues the impact of which we can only dimly perceive such as the effect of radiation hazards, real or imagined, upon personnel employment and recruitment practices, the image which the AEC projects vis-a-vis its employees, etc.

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"I recognize that much of the motivation for starting this study arose from the 'political' need for assurance that AEC employees are not suffering harmful effects. Such assurance will derive from the five-year study as already planned. One of the major contributions of the study to date has been the extensive documentation of the levels of radiation exposure received in various segments of the industry. This is a collection of information that should be of great value in assuring whoever needs to be assured regarding harmful effects to employees."

They did feel that some estimate of the statistical power of the study should be carried out:

"I should think that, at the least, they should have approached the following question: Suppose the leukemogenic effect of radiation is really two cases per million per year per rad, linearly on dose, with what probability will we be able to conclude, at the end of 25, 35, 50 years of observation that the effect is less than 5, or 10, or 20 or whatever. I believe that the answer to this question would be very discouraging!"

In view of the statistical limitations of the study imposed by low numbers, it was urged that the study be limited in scope, at least for the time being.

"I would not expand this project beyond the Hanford and Oak Ridge Installations, at this time. I would insist that the data from Hanford be tabulated and evaluated; that they be implemented, without delay, with corresponding information from the Social Security Administration; and that death certificate information be sought wherever necessary.

"I would try to expedite the retrieval of Oak Ridge data so that the additional pertinent information may be pursued in the same manner as indicated for the Hanford data. The analysis of the one should not be delayed until the completion of the other.

"It is most important that analyses of the methods used and of data already collected be undertaken promptly. This will assure an early return on the substantial investment which has been made by both the investigator and the AEC in this project."

Furthermore, as suggested above, it was proposed that analysis of the Hanford data be started at once.

"I should also point out that, while a great deal of material has been 'put on tape' we have not tested in any way the accessibility of the material in forms appropriate for epidemiologic study. The best type of test would, of course, be an actual utilization of part of the data. I would, therefore, urge Dr. Mancuso to proceed with the whole program on those parts of the industry experience that have already been abstracted (e.g. Hanford), rather than waiting until all the industry experience has been abstracted. Such a procedure would also test the willingness and ability of Social Security to carry out their part of the plan. I cannot imagine that Social Security would object to having the material submitted in three or four blocks, rather than all at once, and they could be working on the Hanford data while the industry abstracting continues."

Comments of the reviewers during the meeting with respect to the marginal utility of the studies of synergistic effects were repeated in written comments.

"On the question of synergism between radiation and chemical agents, the data are not yet assembled in such a way that one can pick out opportunities for study. It may be that within this tremendous variety of experience there are specific situations that could be studied with profit. I would hope that these would be identified within the context of the present data collection plans. However, such situations are likely to be few.

"It seems to me that the prospects of being able to detect synergistic effects of radiation at these exposure levels are forlorn, and fraught with so many pitfalls as to make accurate estimation almost impossible even at highest exposures."

To summarize these opinions, several recommendations can be stated. They are:

- (1) That the study not be expanded at present.
- (2) That studies of synergism be pursued only in those exceptional cases when what appears to be a radiation effect needs clarification, and not as an end in itself.
- (3) That tracing of mortality at Hanford and analysis be begun at Hanford with all possible speed.

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(4) That the effort at Oak Ridge be further expedited if possible.

These recommendations, to some extent, are also dictated by financial constraints, which, as you know, are not inconsiderable.

In implementing the above recommendations, the effort in industrial hygiene both at Richland and at Oak Ridge should be curtailed during the next few months, with result that some savings might be realized which would be available to expedite the radiation studies. Further, it is expected that the budgets for this work can be drastically reduced for FY 1969.

All of us in the Division who are interested in your work feel that the directions indicated above will strengthen rather than weaken the program and that early Hanford data analysis will provide firm basis for further program planning.

If you should like to discuss this either with myself or others in the Division, let me know and we will get together.

Sincerely yours,

Leonard A. Sagan, M. D.
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