DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

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NATIONAL CANCER INSTITUTE

Mr. Anthony Mazzocchi
Legislative Representative
Oil, Chemical and Atomic Workers
International Union
1126 Sixteenth Street, N.W.
Washington, D. C. 20036

Dear Tony:

When we met with you on February 13 you asked that we outline the plan for the possible preventive trial of a vitamin-like material for the men who had been occupationally exposed to asbestos in Tyler, Texas. Here, in rough outline is the plan:

Research on animals exposed to carcinogenic chemicals appears to demonstrate that a class of drugs, not previously used in cancer prevention, can abort the development of cancer which would otherwise be observed.

1. We would do a controlled trial in which some men will get the drug and some will get a placebo -- the selection being done randomly.

2. Anti-smoking clinics will be set up for all men who wish to use them, independent of their participation in the trial.

3. The analysis of the data will allow for rapid ending or modification of the trial as soon as either a favorable effect or excessive toxicity is seen.

4. The study will have a supervisory committee consisting of at least:

   (a) a representative of the men, chosen through their union;

   (b) a biological scientist and a statistician from the National Cancer Institute;

   (c) a person designated by the West Texas Chest Hospital; and

   (d) an expert in the design and conduct of prophylactic trials.

5. Men with cancer will not be included in the trial, but will be treated in the best possible way.

6. Each person will be free to decide to participate or not and to withdraw. His decisions will not affect any other treatment.

7. In estimation of what proportion of men exposed will develop some form of cancer, we shall use as a first approximation the experience of amosite factory workers exposed during 1941-45 and followed by Dr. Selikoff. Within a thirty-year period (to 1971) of 877 men traced, 484 have died, with six times the lung cancer and two times the gastrointestinal cancer rates expected. The probable contributions of age and duration of exposure will be computed and applied during the planning phase in order to estimate feasibility, and the probable duration of study. The preliminary arithmetic seems to show that in thirty years, other things being equal, about one man in five to about one man in ten is likely to die of cancer, nearly half being due to lung cancer.

In order to come to a dependable answer as to the preventive value (if any) of these drugs, we may need to continue the observations on the man at risk for many years, possibly even twenty years, though we shall attempt to answer the critical questions as promptly as we can.

The class of drugs under consideration are related to vitamins, and are not related to drugs used to treat cancer. The dosage and type of drugs intended for use will carry a hazard of toxicity, which, based on present knowledge, is reversible. However, we have not yet had the opportunity to observe long-term effects of such agents.

We must therefore understand, from our experience with other drugs, that even if one form of cancer is prevented, there might be a risk of developing another long-term, possibly fatal disease.

We intend to proceed, once all parties have agreed, to set up a group to plan the study, and one to supervise the hazard detection aspects, and to evaluate it from time to time. The latter group will be independent of the staff actually administering drugs, doing tests and examinations.

Every potential participant must be told what the hazards are, what we intend to do, and must be free at any time to withdraw. Once the trial is under way, we would then set up a reaction monitoring system, so that the effects of any toxic hazards will be minimized, and would make periodic reports to all interested. The supervisory group would be able, under agreed-upon criteria, to end the study or portions of it, or to withdraw from the study a person or group when continuing would be harmful.

We want to have your views on two questions. First, as a group, do the men wish to have us proceed with the detailed development and presentation of a proposal for a prophylactic or preventive trial?

Second, if the answer to the first question is yes, will you or some other person designated by the men affected work with us in planning and carrying out the study, and in supervision and analysis of results?

Preventing cancer by chemicals is a new type of research which may have beneficial effects for many persons. However, the risks are possibly great. We must include you or some other representative of the men as a full partner in the planning, supervision and evaluation process.

The risks fall into three categories, of which the most obvious is the risk of the underlying disease processes which may either not be favorably influenced, or may even be aggravated or accelerated. The second category of risk consists of the toxicity hazard of this class of drugs; the third hazard is of the anxiety, inconvenience, and other health risks associated with the procedures involved in informed consent, diagnosis, and monitoring. We must exert every effort to minimize these risks, (and maximize the possible benefits) but we cannot avoid them and we will not disguise them.

Please let me know your thoughts, suggestions, advice, etc.

It was good to see you and talk with you.

Very truly yours,

Marvin A. Schneiderman, Ph.D.
Associate Director for Field
Studies and Statistics, DCCP

cc: Dr. Goldsmith
Mr. Corle
Dr. Sporn
Dr. Fox
Dr. Woolridge