

# CHICAGO HEALTH RESEARCH FOUNDATION

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January 26, 1971

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Dear Henry:

This is again a hasty reply to some aspects of your latest communications, including your telegram of January 19, which arrived here in somewhat garbled form. First, let me state that I am gratified with the feeling expressed in one of your letters that my efforts through Curt have led to some positive accomplishment in regard to the situation around Tomi. It is not yet clear to me whether the whole matter has indeed been fully resolved, and your telegram indicates that it has not. I will be in Baltimore this coming Tuesday evening and Wednesday in connection with a Heart Association function. I talked with Tomi on the phone the other day, chiefly about some information I needed concerning the ECG runs, and I took advantage of the occasion to make a date with him for a relaxed private chat on Tuesday evening. I also continue to be in touch with Curt, and will have a chance to spend some time with him on Wednesday, as well as with Chris, in addition to a meeting they have planned for me for most of the afternoon with the whole Coordinating Center staff. I will use that occasion to attempt to enhance esprit de corps, with special emphasis on the great value of the natural history study. I do this not only because I think there is a need, but because I do indeed feel that this is certainly second to no aspect of the study in importance.

You will be receiving soon a letter from me with reproductions of all of the graphs and tables from our work during the summer and since in the natural history study. I have been meaning to circulate this set of data among everyone for quite a while, and only the press of other activities has led to the delay. Once again, I will utilize this opportunity to emphasize the importance of the natural history work.

I had a long discussion on all these matters with Curt in San Juan, in a very relaxed and satisfactory fashion, including the matter of personnel. It was our joint conclusion that one approach to overcoming

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what seems to be one inadequacy -- i.e. the situation around Bill Krol -- is to give him a very specific assignment. The natural history task was viewed by both of us as an appropriate one. We did not in any sense regard this as in competition with Tomi, or instead of Tomi, but rather in order to meet the sizeable needs of the work generally, and to relieve Paul of the pressures from this work, so that he could give the attention he must to the huge current job of monitoring findings in the drug groups. Obviously, as long as there is any reason for uneasiness with respect to possible adverse effects in any one or more groups, the task of monitoring these groups must be the first priority, and as a matter of fact the Data and Safety Monitoring Committee has given huge chores to the Coordinating Center -- over and above the extensive routine analyses -- in connection with the possible problems in the DT4 group. This was all the more necessary, since the meeting of the Data and Safety Monitoring Committee prior to the San Juan meetings was divided in interpreting the complex set of data on the DT4 group and its subgroups.

I am convinced that there is general agreement on the importance of the natural history study, and keen interest in it on the part of the leaders of the Coordinating Center. I am also convinced that those of us most interested in it must appreciate a distinction at all times. There are in an ongoing big study needs that always are perforce immediate. Thus, when the decision is made that there may be a problem in a given group, and more extensive runs are needed to assess more thoroughly, that is an immediate need. When a decision is made, as was made in San Juan, that we missed the boat in our original forms with respect to an item of information (in this case, cigarette smoking), and we should go back and get an expanded set of data, this becomes an immediate task, since any delay makes it more difficult (particularly in relation to deceased patients). On the other hand, there are data in our files available for extended analyses at any time. Once in the record, the exact time at which the analyses are done cannot be viewed as critical. Of course, every effort should be made to do them as soon as possible, so that the findings can be evaluated, further thoughts be developed on additional analyses, and any inadequacies in the data spotted -- just in case we should want to go back and get more information. However, from the very nature of the case, work of this kind -- analyses of data already collected -- must take second place to urgent and pressing ongoing work, especially when it is related to safety considerations.

I am convinced that we have firmly established the importance of the natural history study, and that there is every possibility to do it in as great depth as we wish. I am further convinced that there ~~need~~ **never** arise a situation such as in the Pooling Project, in which considerable pressure to obtain a data tape had to be mounted, so that runs could be done elsewhere than in the center originally assigned to that task. I hope that Tomi will remain for another year, but long experience has taught me that only a certain amount of pressure

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should be mounted on an individual with respect to his career perspective. Moreover, long experience has also taught me that no one is indispensable.

I think it may be useful to develop a more systematic way to generate the proposals for the natural history study. I deliberately used the word may. The feeling is that we have not done badly at all so far in this regard. After all, we have now had two extensive data analyses, the one accomplished by Paul during the summer in preparation for the meetings in Europe, and the more recent one focussing on the ECG -- all of this in the midst of maintaining effective supervision of the on-going work, solving the problems with ESG2 etc. and trying to keep on top of the possible problems with DT4. I know it is very easy to get deeply concerned about matters when one is far away. I do not think there really is a critical situation. This does not mean that we should relax and let matters slide in this area. It does mean, I feel, that we should proceed on the basis that we have done pretty well so far in the natural history work, and can continue to do so with cooperation from our friends at the Coordinating Center, and attention from us, particularly the two of us in concert.

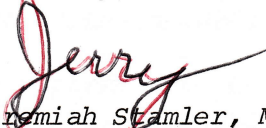
Specifically with respect to Bill Krol, I believe our approach should be to give him every opportunity to prove his abilities in this work, now that he has that specific clear assignment, be it with Tomi's remaining or no. If Tomi does elect to stay, we should see to it that a close effective working relationship is developed between them, with every effort to minimize friction, insecurity, offense, etc.

I remain a bit puzzled about the proposal in your telegram to have the results of the natural history study reported regularly to a subgroup of the Data Monitoring Committee. We are already reporting these results to that committee, although it obviously has had to be pre-occupied with possible adverse drug effects. In life, you and I will remain the principal ones concerned with and pushing forward that aspect of the work -- and that is really as it should be. Our task is in close cooperation with the Coordinating Center staff to make proposals, get the work done, evaluate the findings and participate with the Data and Safety Monitoring Committee.

I hope all these ruminations are useful. I will probably write to you again after I see our friends in Baltimore.

Warm good wishes to Nelly and yourself from Rose and me.

Cordially,



Jeremiah Stamler, M.D.  
Executive Director

JS/nd