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TWIN CITIES

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June 2, 1989

**CONFIDENTIAL**

(Dictated Memorial Day weekend. Very outdated)

TO: Richard Grimm, Jerry Stamler, Ron Prineas

FROM: Henry Blackburn

RE: Advisory Council and TOMHS

**LOBBYING!**

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You will have gotten the "straight dope" from Bill Harlan, I hope. I was not privy to the manner in which he presented the grant or the nature of the very long discussion, well over an hour, that the Advisory Council gave to the application for TOMHS Phase II. I have reported to you by phone what I saw and what I said, which is represented as follows:

Among the first in orders of business in Dr. Lenfant's report to the Council was his indication that the Institute, he personally, and Congress had been extensively lobbied in direct support of the TOMHS grant. He then went through several computations to arrive at a bottom line of approximately 70 R01 grants that would be displaced if this grant were awarded.

He addressed none of the scientific issues which led to the application. He addressed none of the socio-economic issues that led to the lobbying effort. He indicated his great discomfort at being so lobbied. To my recollection (and I suppose we will have "reduced" minutes), only two comments were made to his introduction of this matter. The first was by Tony Gotto, who asked, "Was this lobbying effort unusual in your experience?" and he replied something like: "A half a dozen letters is unusual. The many dozens in this case and the effort with Congress are quite unique in the experience of the Institute." This left a distinct flavor of inappropriate lobbying on the part of the investigators and set the grant up for being in major competition for resources in an already constricting NIH budget. The only other comment I believe was mine, which, almost word-for-word was as follows: "I will be in conflict for the discussion of the grant so I would like to make a brief comment now. I think there are several aspects to the issue, the first being the scientific one in which the most appropriate strategies for treatment of this widespread condition, mild hypertension, remain a central question in medicine. The second is a major socio-economic issue in that the clinical community is already moving in the direction of replacing tested, inexpensive medications with ACE inhibitors and calcium channel blockers that are 3-5 times more expensive. This would roughly be the equivalent of a shift from over \$1 billion to over \$4 billion cost to the American people annually. The third issue,

in reference to the lobbying, is that because there is a level of NIH policy review established for large grants, there needs to be a level of public policy consideration. It is my understanding that the intent of the investigators was to lobby generically for increased awards to NIH for studies in the area of mild hypertension. It is possible that these efforts in some cases became focused on this application because it was at hand, but that was not the intent of the investigators."

Lenfant was as skillful as any politician I have ever seen in choosing the comment he wanted to choose, ignoring the others and he said immediately "the most important thing you have said, Dr. Blackburn, has to do with the policy review and that's what this Council must consider in an application of this magnitude that will significantly displace already limited opportunities for new grants", or something along that line. At any rate, he did not take up at all on the issues of medical and economic need and failed to mention any concern or plan of NHLBI to take this area generally under consideration.

Thus, from the opening gun, he set the situation up for the recommendation we will have to hear about in detail in the letter to you and in the minutes.

In his hallway comments to me he said the lobbying had been "a real pain" for him. He also said to me that he had "met with those guys and advised them not to do this", and that as far as he could see, "they shot themselves in the foot." These are pretty direct quotes and indicate his reaction and strategy. Based on Harlan's more knowledgeable evaluation of this, I am sure you will develop your new strategy.

I think we must clearly acknowledge and accept the errors made. We assumed the lobbying was being done with the "utmost" strategy and shared communication and common understandings how it would be pursued. Based on what we heard about our University administrators, it was clear that the generic lobbying was hardly taking place and that we were engaging in direct pressure activities for which we have actively criticized others. I can find in the letters little justification for a claim that the lobbying was for increased generic support for NHLBI or increased generic support even for this area of research when the particular initials of TOMHS were used, rather than the generic term, etc.

I assumed that you were all in good communication on this and had carefully instructed your colleagues on the nature of their lobbying. It turns out that the model letters had not been seen by all.

My view is that we should get all the information from Harlan, which you would do anyway, and we should pursue vigorously TOMHS I and that you should meet on your own and that we should meet to discuss strategies. After having decided on the strategy, whether to "cool it", or to move ahead with a different type of lobbying or to abandon lobbying, which I would much prefer, and to submit a proposal that would be regarded more realistically and fight it through in the usual process (as is our custom). A redesign so that you are likely to get more industry support might also be helpful in that regard.

I think we must decide relatively soon, though not precipitously, whether there should be a reply of the investigators in a coordinated way, rather than the individual reporting of

initiatives that is now going on in response to the "shot in the foot" situation. I think you might consider a deliberative editorial released to the press and/or through a rapid journal editorial in JAMA in which you focus on the scientific and economic issues and in which you indicate your intent in regard to necessary influencing of public policy.

Though it would be possible to drop words that would make Dr. Lenfant look pretty bad in this situation (certainly he has gone to considerable efforts to make you look bad), it would not be healthy in the long-run. On the other hand, once you've formulated strategy you should meet with him again and inform him about it and indicate where there was an initial misunderstanding or where he may be misrepresenting you, but also admit mistakes not rationalize them.

Clearly, one of the most powerful people on the panel, who understands most about the issues, is Tony Gotto. You should get his view of the situation because he's certainly aware of how to lobby skillfully for research. I can help with this but I think your directly contacting him would be useful. Beyond that Fran Klocke is a very understanding and level-headed person. He confided to me personally, after my little spiel about the intent of the investigators, that he was concerned that there had been "inappropriate lobbying" for this grant, including his institution. So, we want to bring him around. I think that if we had those two voices, Klocke and Gotto on the next round, we might fare better.

I think if you also had a couple of good Congresspersons who understand the issues and who also understand the issue of an individual grant versus NHLBI lobbying, it would be worthwhile to get them on your side now rather than in the way that provokes an exaggerated "pork barrel" concept.

The remarkable reductions in the number of new grant initiatives possible, due to the rising average grant cost, made this a not propitious time to submit such a massive undertaking. But there is never such a time! I look forward to a "cooling off" and a resolution of these issues and a concerted policy that is shared by all concerned (including me). I admire your courage and determination in putting this matter through and I will support your courage and undertakings in trying to beat the "bum rap", heal the wounds and get this issue on track.

/jrh

p.s. I also look forward to see your individual replies in press, which should help matters.

Sample letter

-- SAMPLE --

Confidential to R.G.  
Richard: Sorry but  
This is wholly improper!  
& should have been  
reviewed by your  
colleagues in TOMS,  
2) Dr. Hood or Dean Kane.  
Sorry! No one  
could have  
imagined you  
would have  
proposed such  
a strategy!

January 13, 1989

Claude Lenfant, M.D., Director  
National Heart, Lung and Blood Institute  
National Institutes of Health  
Room 5A52, Building 31  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Lenfant:

I have been impressed with the results I have seen from the Treatment of Mild Hypertension Study Phase I that is being coordinated by the University of Minnesota. The data obtained to date are so compelling that it is imperative that the nationwide follow-up Phase II study be funded at the earliest possible time.

Out!

The health risks of mild hypertension are indeed serious and of concern for a number of reasons. First, the expense associated with treating hypertension, both from financial and man-hours spent on physician visits is tremendous (76 million physician office visits in 1987 with drug costs alone in excess of \$1.5 billion). Second, hypertension affects a major percentage of the adult U.S. population. This percentage is expected to grow as the majority of the population reaches the 'senior ages.' Thirdly, I understand hypertension contributes to heart disease which is the leading cause of death in the adult population of the U.S.

OK

I am aware of the many serious health concerns in our society. I support comprehensive hypertension research such as the Treatment of Mild Hypertension Study. This effort and others being undertaken by the National Heart, Lung and Blood Institute are indeed laudable.

Change wording to remove TOMS

Sincerely yours,

R. GRIMM

Sorry but  
This departure  
from proper  
language (+  
unnecessary procedure)  
belies all other  
claims of  
generic  
lobbying.  
Neither Kane nor  
I (nor Skunkie?)  
would have  
approved this  
letter. So please  
reword/revise your  
note &  
to be generic of  
lobbying.