~~Dr. Curran~~

File — Lab studies

Date: June 11, 1984

To: Dr. Walter R. Dowdle

From: Frederick A. Murphy, D.V.M., Ph.D.

Subject: The Agreement with Dr. R. Gallo to Restrict CDC's Use of the HTLV-III(H9) Infected Cell Line

In keeping with your request, the following is my recollection of the agreement signed on 15 May 1984 by Jim Curran and myself in Dr. Gallo's office when we were given his HTLV-III infected cells (H9). As Jim and I have stated, it was a tense moment, fraught with the possibility of non-delivery. Our tack, stated orally in several different ways as we discussed the matter with Dr. Gallo, was that public health purposes were paramount. Dr. Gallo agreed. In our conversation, it became clear that comparison of his HTLV-III prototype with the French prototype LAV occupied a separate niche--the comparison was seen as having both academic and public health purposes. Because of the latter, I offered, using several tacks, to have certain comparative tests between his HTLV-III and the French LAV done at CDC; Dr. Gallo declined each time, stating that such work would be done in his lab. It was quite clear from our discussion that this was the only subject which engendered such difficulty--when we switched to other themes, such as "second generation test development," "technology transfer," "support for seroepidemiologic studies," there was no problem.

The agreement form was a standard one which Dr. Gallo stated was required of all recipients of his materials as part of the NIH patent/licensing arrangement. It comprised six items—all of which looked routine to me (rather like that which one might get from ATCC). I only remember the following (we did not get a copy):

a) Distribution to third parties was prohibited.

b) Use for commercial purposes was prohibited.

c) No responsibility for the status of the material was assumed, in regard to contamination, viability, etc.

d) Use of the material for research purposes was to be collaborative with Dr. Gallo's laboratory--with prior arrangement and preclearance of manuscripts. [Dr. Gallo orally stated that this item did not apply to CDC's public health purposes].

There was a seventh item typed in on the above form, for CDC only. This item is the entire basis for the ongoing controversy. Dr. Gallo stated that his HTLV-III (H9) infected cells had otherwise been distributed to collaborators doing work complimentary to the work ongoing in his lab, but that since CDC had lab competency which could become competitive, a restriction would have to be placed on the use made of his infected cells.

He stated that this was being done to protect the people in his lab who had not yet had a chance to capitalize on their basic discoveries. He stated that in usual circumstances this sort of protection would have been provided by delaying initial announcements. The item stated that CDC was prohibited from using the material from NIH [the HTLV-III (H9) infected cells] for comparison with other viruses (taken to mean LAV or surrogate for it). Orally, Dr. Gallo said that this prohibition would be lifted as soon as the comparison work was done in his lab. (estimated June or July 84)

It needs to be stated that this prohibition would only be noteworthy in circumstances such as those presently ongoing--involving the public health in an epidemic timeframe. Similar prohibitions are common in science where emergency conditions do not exist. It also needs to be stated that this prohibition has not stopped CDC's AIDS laboratory program "dead in the water". The material from NIH will add greatly to our capacity to do serologic tests--most important in this regard is CDC's request for a share of the large volumes of virus/antigen produced for NIH by contract. Likewise, our separate request for uninfected cells is important--so that we might try several different viruses (from CDC, France, etc.) to test questions of antigenic variations, maximum antigen yields, and primary virus isolation as a diagnostic aid. We have talked with Dr. Gallo about this request, following up on a letter, but we do not yet have these cells.

All in all, we are very close to the time when Dr. Gallo was going to lift the prohibition anyway--it seems more important to me at this time that CDC focus in its dealings with NIH on the matter of <u>scale</u>--we need NIHs resource for generating the volumes of cells and virus necessary for a very large serologic testing/screening testing program--we need this more than we need seed volumes of virus and cells and more than we need release from this single prohibition.

FAM

Frederick A. Murphy