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DUKE UNIVERSITY MEDICAL CENTER

SEP 11 1990 REC'D DEAN'S OFFICE

Department of Pediatrics
Division of Infectious Diseases

August 31, 1990

Dr. June Osborne
Dean, School of Public Health
University of Michigan
109 Observatory Street
Ann Arbor, Michigan 48109

Dear June,

The Third Report of the National Commission on Acquired Immune Deficiency Syndrome was sent to me on August 20, 1990. It is a comprehensive summary of a great deal of testimony presented to the commission. Our first hand experience in North Carolina substantiates the rural spread of this infection. In fact, that is one of the issues which interests us and we plan to investigate the mechanism of such spread.

The portion of the report which concerns me and prompts this letter relates to HIV Research and Drug Development. The personal opinion expressed in this letter is not at the request or instigation of any of the ACTU associated committees, groups, or leadership. It may be possible to dismiss my comments as biased on the basis of my role as an investigator in the ACTU. However, as one who is dedicated both to the care of HIV infected persons and to clinical trials. I must speak on behalf of our infected patients because the report may jeopardize their care.

The very strong criticism that there is a lack of information from the ACTU can be responded to with ample documentation of scientific accomplishments. The trial demonstrating the efficacy of AZT in asymptomatic patients was conducted through the ACTU. The ACTU also demonstrated the efficacy of AZT at all stages of a disease at a dose level which was half of that indicated at the time of initial approval of the drug. These two accomplishments alone are important to the hundreds of thousands of people with infection. The ACTU has done all the work in children with AZT resulting in approval of the drug. It is unnecessary to reiterate the entire list of accomplishments but I enclose a document dated May 16 with a cover letter by Dr. Fauci.

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The allegations of under-representation of people of color, women and children imply that this occurs through exclusion of these persons from protocols. This is not correct but rather is related to problems with the health care system in the United States. Some of the behaviors which place persons at risk for HIV infection define persons who have not had access to our existing health care system. This requires expenditure of funds to provide health services for these people. It is not easy to consider enrolling drug users if facilities for support systems including assistance in rehabilitation are unavailable. In order to obtain data from the clinical trials persons must be able to comply with the taking of medications and attendance in clinics. The commission has merely identified the disproportionately high representation in health care and in clinical trials of those persons with health insurance and education. The problem is the delivery of health care in this country and it is reflected in access to clinical trials. This is not the fault of the ACTU Clinical Trial system.

As you know, I have been an advocate for every aspect of care for children with HIV infection. It needs to be stated clearly that children are 1-2% of the total population with AIDS and therefore would be "under-represented" in clinical trials if absolute numbers are used for comparison. For the past four years the ACTU has worked very hard to conduct pediatric clinical trials. The number of ACTUs has expanded, the units supported by NICHD have been included, and the National Hemophiliac Foundation which cares for children has been incorporated into the trial system. Access of children to clinical trials has greatly improved and the design and implementation of trials is excellent. All trials have accrued patients at anticipated rates. The protocols are carefully coordinated to assure that the most important questions are asked first and that the patient population (a precious resource) is accessible to provide the answers in a timely fashion. I would suggest that the commission avail themselves of the research agenda, the priorities, and learn the means by which such decision making occurs. I am concerned that all the progress we've made could be destroyed by the commission's report. The withdrawal of funding would end the clinical trials.

An important issue is the allegation or perception of conflict of interest from investigators. Many of the investigators have multiple conflict of interest statements on record for various committees on which we serve. This allegation was made in person to the members of the executive committee within the last several months. I believe the allegation is totally unfounded. The ACTU is organizing formal conflict of interest statements so that even the perception of such conflict of interest can be avoided. Each one of us who has served on any Federal Advisory Committee or in the Institute of Medicine has multiple such documents on file. These are available for review. Responding to such allegations does take time away from investigative responsibilities and requires additional paper work.

A review of the AIDS publications and the preceding dissemination of information from the ACTU should serve to respond to the criticism of delays in the publication of clinical trial information. It is of primary importance to produce accurate scientific data. It is also important to disseminate information rapidly. It would be instructive for the commission to review a time line of one of the studies, the announcement of the data, and the publication dates. There are already in existence avenues to disseminate information prior to publication and the commission report does not refer to these existing mechanisms.

In summary I am disappointed that despite the many valid points made by the commission's report it seems to me that many allegations have not been critically reviewed prior to their publication in this report. I would encourage you and the commission to discuss these allegations with the AIDS Clinical Trial Unit. There are data to consider in addition to expressed opinions. You could certainly attend the meetings or discuss the issues with the leadership.

I hope that you will accept these comments as a personal response to the commission's report. I would be happy if they were shared with the other members of the commission. I feel strongly that the statements in the commission's report concerning the ACTU are inaccurate, incomplete and lack substantive documentation. The report could harm the clinical trials effort.

With warm personal regards.

Sincerely,

Catherine M. Wilfert, M.D.
Professor of Pediatrics
and Microbiology

CMW:jb

Enclosure