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(INTERDEPARTMENTAL CORRESPONDENCE SHEET)

To Dr. Edward Gall, Chairman
Clinical Research Committee

From Dr. Thomas E. Gaffney Date 4/17/67

I cannot recommend approval of the proposed study entitled "The Therapeutic Effect of Total Body Irradiation Followed by Infusion of Stored Autologous Marrow in Humans" for several reasons.

The stated goal of the study is to test the hypothesis that total body irradiation at a dose of 200 rad followed by infusion of stored autologous marrow is effective, palliative therapy for metastatic malignancy in human beings. I don't understand the rationale for this study. The applicants have apparently already administered 150-200 rad to some 18 patients with a variety of malignancies and to their satisfaction have not found a beneficial effect. In fact, as I understand it, they found considerable morbidity associated with this high dose radiation. Why is it now logical to expand this study?

Even if the study is expanded, its current design will not yield meaningful data. For instance, the applicants indicate their intention to evaluate the influence of 200 rad total body radiation on survival in patients with a variety of neoplasms. This "variety" or heterogeneity will be present in a sample size of only 16 individuals. It will be difficult if not impossible to observe a beneficial effect in such a small sample containing a variety of diseases all of which share only CANCER in common.

This gross deficiency in design will almost certainly prevent making meaningful observations. When this deficiency in experimental method is placed next to their previously observed poor result and high morbidity with this type of treatment in a "variety of neoplasms" I think it is clear that the study as proposed should not be done.

I have the uneasy suspicion, shored up by the revised statement of objectives, that this revised protocol is a subterfuge to allow the investigators to achieve the purpose described in their original application; namely, to test the ability of autologous marrow to "take" in patients who have received high doses of total body radiation. This latter question may be an important one to answer but I can't justify 200 rad total body radiation simply for this purpose, "even in terminal case material" (italics are mine).

I think there is sufficient question as to the propriety of these studies to warrant consideration by the entire Research Committee. I recommend therefore that this protocol and the previous one be circulated to all members of the Committee and that a meeting of the entire Committee be held to review this protocol prior to submitting a recommendation to the Dean.

Sincerely,

Thomas E. Gaffney, M.D.

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