DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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Dr. Gaston Naessens
President,
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Dear Dr. Naessans:

I am writing at the request of Dr. Faye Austin of the Dana Farber Cancer Center to inform you of a process for the independent review of clinical data of cancer patients who have been successfully treated with alternative medicine practices and to encourage you to participate in this program. The National Cancer Institute's (NCI's) Best Case Series program (BCS) was developed to provide an opportunity for practitioners of complementary and alternative medicine (CAM) to demonstrate the evidence for the clinical effectiveness of alternative medicine therapies. Completed BCS are presented to the Cancer Advisory Panel for Complementary and Alternative Medicine. This panel comments on the quality and significance of the findings and makes recommendations about what, if any, further research is warranted.

This program is administered through the NCI's Office of Cancer Complementary and Alternative Medicine. The information we need is very basic:

1) A summary of the patient's disease course

2) A copy of the pathology report documenting the cancer for which the patient was treated. Ideally this pathologic specimen should have been obtained prior to the 714-X treatment and after any conventional cancer therapy. If that was not done then we will consider a report from some other time point.

3) Documentation that the patient received 714-X and information about any other therapies the patient received before, during or after the 714-X.

4) Documentation of response. For solid tumors this would generally be pre- and post-therapy radiographic reports. For hematologic malignancies (e.g. leukemias, multiple myeloma) we would need laboratory reports documenting decreases in the disease indicators (e.g. leukemic cell counts or paraprotein level) and post-therapy bone marrow biopsy reports.

The optimal patient for this type of review is one that has, at some point in his/her disease course, been treated with 714-X alone, rather than in combination with some conventional therapy or some other alternative therapy. If data on such patients is not available then we will consider evaluating data on patients that had progressive disease on some other therapy and then had a response after 714-X was added to the treatment regimen.

We do not need information on a large number of patients. The quality of the cases is really what matters. Five or ten fully documented cases would be fine. If your company does not have this data then I would appreciate if you would forward this request to physicians you know have used 714-X for the treatment of cancer and encourage them to participate. Alternatively, you could supply us with the names and addresses of these physicians and we will contact them directly.

We prefer to receive all the paper documentation for all patients from any one site at one time. Once this documentation is obtained and determined to be complete, we will request the actual pathology slides and the radiographic films for review by physicians at the NIH's Clinical Center.

I would be glad to discuss this program with you at your convenience. Please feel free to contact me with any other questions.

Sincerely,

Jeffrey D. White, M.D.

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Enclosures:

cc: Faye C. Austin, Ph.D.