DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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June 6, 1995

Dr. Stanislaw Burzynski
Burzynski Research Institute, Inc.
12000 Richmond Avenue
Houston, Texas 77082-2431

Dear Dr. Burzynski:

This letter is intended to respond to the major issues which have been raised in your recent correspondence of April 20 and May 16, 1995. Your accusations are serious and require comment.

I will first address the questions you raised about individual patients participating in the NCI-sponsored antineoplaston studies. Two patients were treated at the National Cancer Institute. Patient 26-77-03-9 had evidence of focal glioblastoma multiforme on the biopsy reviewed at the NCI. A different specimen submitted to Dr. Rorke may or may not be relevant. This patient, however, had a brain scan 3 weeks prior to study entry. Patient 27-53-76-5 had a tumor which was 0.8 cm larger than the eligibility criteria dictated. Although pharmacologic data were obtained on both, neither patient is counted in an assessment of response. Both patients had objective tumor progression and are now off study. With respect to the other patients, I am including specific patient summaries from the treating investigators which address your other concerns; in particular, a response to your serious and unfounded statement that patient #196370 was treated in an unethical manner. Also contrary to your statement, you have been sent monthly clinical summaries of these patients since July 1994 directly from Theradex (see March 9, 1994 letter).

Having provided this information, I must convey my deep pessimism about the potential for continued interactions with you regarding these trials. Given recent events and your clearly articulated bias that the Mayo Clinic, Memorial Sloan Kettering Hospital and even the National Cancer Institute could not fairly test your product (please see your letters of October 26, 1993 and April 20, 1995), I now see a diminishing chance for a productive dialogue with you. Historically, the NCI has demonstrated pragmatism and flexibility in working with a wide variety of individuals and organizations to explore diverse interventions of potential benefit to the cancer patient. However, such a fruitful collaboration may simply not be possible with you.

The decision to suspend the NCI antineoplaston studies was reached by the investigators and the NCI and was explained in our letter of May 12, 1995 (see enclosed). While we have frequently solicited your advice, we are in no way obligated to obtain your consent. Our interactions with you have been similar to those with pharmaceutical companies or other independent investigators. In the interest of testing antineoplastons, we have consistently considered your advice and recommendations but that in no way cedes control of these studies to you (please refer to our letters of July 15, October 20, and November 2, 1993). Your insistence on dictating the manner in which we conduct or review these clinical trials is both presumptuous and inappropriate. The future of these trials rests entirely with the investigators and the NCI, since our primary obligation is to the American public. Recognizing your potential conflict of interest as the developer and the most visible proponent of antineoplastons, we could not responsibly act in any other manner.

In contrast to the tenor of your unsupported statements, the NCI bases its position on scientific data. You have stated that you have a vast clinical experience with antineoplastons and we have generally been deferential to your demands despite the lack of substantive data. However, our scientific standards are broadly applied to all studies. The data and level of proof we require from you is much the same as that for other professional collaborators who make such claims. The 7 case records initially examined by the NCI hardly constitute a definitive scientific result. It is naive and misleading for you to suggest that the experience of 2 of those patients who had tumors in excess of 5 cm provides adequate proof for all your contentions about tumor size, dose, etc., unless these were the only 7 brain tumor patients from your entire experience who had any hint of benefit. To be precise, in order to responsibly and properly assess your claims and accusations (as per your April 20, 1995 letter), we request that you provide the following information:

1. Exactly how many adult patients with primary brain tumors have you evaluated and treated with antineoplastons?

2. When analyzed by histologic type, performance status, prior therapy, concurrent therapy (including chemotherapy), disease size and focality, how many adult brain tumor patients had objective responses? Please characterize the quality and magnitude and duration of these responses.

3. What dose, duration, schedule, and composition of antineoplastons did these patients receive? Which of these patients benefited objectively? What toxicities were encountered? Do you have pharmacokinetic or pharmacodynamic data to support your contention that certain types of brain tumor patients require specific regimens?

4. For these patients, what statistical analyses relate patient or tumor characteristics with exact treatment regimen and outcome?

If you provide such specific data, we can properly assess your claims. Lacking such information, we cannot. Moreover, your charges that patients received inappropriate care are not supportable without such detailed information.

If, after careful consideration, the investigators at Memorial Sloan Kettering and Mayo Clinic do not reopen their studies, it is unlikely that the NCI will attempt to conduct further antineoplaston trials. Any unused antineoplaston material will, of course, be returned to you. Since we can make no judgment about the benefit or toxicity of antineoplastons at this time, we will be interested in the published outcome of peer reviewed studies that you or others may perform. If the NCI investigators choose to continue these studies, you will be so informed. In either circumstance, we will continue to sponsor clinical research of small molecules that may have differentiating properties (such as pure phenylacetate and phenylbutyrate).

Sincerely yours,

MA Friedman

Michael A. Friedman, M.D.
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