BURZYNSKI
RESEARCH INSTITUTE, INC.

May 16, 1995

Michael A. Friedman, M.D.
Associate Director, CTEP
Division of Cancer Treatment, NCI
National Institutes of Health
Bldg. EPN Room 742
Bethesda MD 20892

Dear Dr. Friedman:

Thank you for your letter of May 12, 1995. You are correct in asserting that I raise issues of ethical misconduct, failure to obtain adequate informed consent and scientific misjudgment.

To be exact, my letter points out specific violations of the clinical trial protocol made by the current investigators. I provided careful documentation of some of the most egregious violations, including the removal of a patient from the study who had had no increase in tumor size and the inclusion of a patient with tumor pathology that did not meet the entry criteria. It seems possible that, in at least one of these cases, failure to follow the protocol resulted in the patient's unnecessary death.

In this case, the patient was removed from the study following an MRI dated 5/2/94. The conclusion of neuroradiologist Jim Cain, MD, is that this MRI shows that the tumor had not grown, and no new tumors are present. As you know, the protocol calls for patients to be taken off treatment if the tumor grows 50% or more, or a new tumor is present.

This is, as you point out, a most serious matter, and I was hoping that you could allay my concerns by showing me where they are unfounded. However, your letter conspicuously fails to address them. You also make reference to "numerous factual misstatements" but fail to identify any of them, much less provide documentation to show they are false.

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Contrary to another of your statements, I did provide "specific clinical data which support" my contention that patients with large tumors do not respond well to the current protocol. Let me repeat them here. In the 1991 NCI review of seven brain tumor cases, the only two patients with tumor size greater than 5.1cm were also the only two patients to have less than 50% reduction of their tumor. The correlation between large tumor size and failure to respond is obvious.

I am happy to learn that the trials have been put on hold. I must insist that they not be re-activated until I am satisfied that new investigators have been found who are capable of following the protocol -- the *original* protocol on which we both agreed. As you know, that protocol was changed without anyone bothering to seek my advice, and certainly without my consent.

I am glad to learn that you plan to "thoroughly examine the accusations" I have made. However, this review must not be done by the people responsible for the violations being investigated. This would amount to a whitewash of the whole affair, and is unacceptable. The review must be done by an independent body of experts acceptable to both of us. Otherwise it will be meaningless.

I still have not received the complete data on the first five patients, which was promised in your letter of April 3, 1995. I hope to receive the data soon. I also eagerly await a substantive response to the points raised in my letter of April 20, 1995.

Sincerely,

S.R. Burzynski, M.D., Ph.D.
President

cc:

Senator Joseph Biden
Senator Barbara Boxer
Senator Dianne Feinstein
Senator Tom Harkin
Senator Barbara Mikulski
Congressman Berkley Bedell
Congresswoman Nancy Pelosi
Dr. Jan Buckner
Dr. Jay Greenblatt
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