FRED
HUTCHINSON
CANCER
RESEARCH
CENTER

Clinical Research Division
1124 Columbia Street
Seattle, WA 98104

CONFIDENTIAL

September 19, 1996

Bill N. Crowell
Health Care Investigator
Medical Investigations Unit
Department of Health
1300 SE Quince Street
PO Box 47866
Olympia, Washington 98504-7866

Dear Mr. Crowell:

This letter is in response to your letter to me of August 27, 1996. You have asked me to provide a written statement in response to your preliminary inquiry into claims by that somehow my involvement as a member of the Scientific Advisory Board of Genetic Systems Corporation lead to the allegedly improper continuation of two protocols at Fred Hutchinson Cancer Research Center thereby resulting in the deaths of certain patients. These events allegedly took place approximately thirteen years ago during 1983 - 1984.

The history of the two protocols involved and a response to these allegations are detailed in a letter dated October 18, 1993 from Dr. Robert W. Day, the President and Director of the Center, to the Office for Protection from Research Risks ("OPRR") of the National Institutes of Health. I understand you have a copy of this letter. As you know, OPRR reviewed the same allegations and determined that all federal regulations for the protection of human subjects were complied with in regard to these protocols.

First, let me state that I have never and would never allow any financial interest to influence a decision that I made concerning the treatment of a patient. In addition, the allegations made by wrongly assume 1) that the protocols should not have been continued from a medical standpoint and 2) that I was responsible for determining whether or not they would continue.

As indicated in the October 18 letter and as you have discussed with Dr. Frederick Appelbaum, the current clinical division director of the Center, the protocols in question were continued for valid medical and scientific reasons. As Dr. Appelbaum advised you, similar research is still being conducted at the Center and other institutions.

Concerning the second assumption, I was not responsible for saying whether or not the studies continued. Although I was the head of the clinical division during the time period

in question, I was not the principal investigator for either of these protocols and was not primarily responsible for conducting the research with respect to them. Furthermore, the protocols in question went through several independent reviews. Both protocols were peer-reviewed and approved in connection with FHCRC's ALC grant. These protocols were also reviewed by working committees of clinical investigators and ultimately by the entire clinical staff at a weekly meeting before they were sent to the Institutional Review Board. Finally, the FHCRC Institutional Review Board reviewed these protocols throughout the time period in question. As described in detail in the October 18 letter, the review followed by the IRB in this case was appropriate and in compliance with the applicable government regulations, as OPRR later determined. Neither of these protocols was allowed to commence or continue without the approval of the IRB. At the request of the IRB, Dr. Day also established a separate scientific review committee to review these protocols and other protocols using monoclonal antibodies. Accordingly, the decision as to whether or not these studies should or should not continue was not made by me, and in any event, had substantial independent review.

I also want to say a brief word about my relationship with Genetic Systems Corporation. I was asked to be on the Genetic Systems Advisory Board in approximately 1981 when the company was organized. As a member of the Scientific Advisory Board, I received 100,000 shares of founder's stock valued at one cent per share. This represented a very small percentage of the total shares outstanding. Eventually, Genetic Systems merged into Bristol-Myers and shareholders received Bristol-Myers stock in exchange for their Genetic Systems stock. The consulting which I did for Genetic Systems did not relate to the work that was being done on the protocols in question, but rather to the basic science involved in the development of monoclonal antibodies. In fact, Genetic Systems' primary emphasis was never in the area involved in the protocols in question. The Center chose to use the antibodies selected because they had been made originally at the Center and Center researchers were familiar with their characteristics. Also, the Center could obtain them at no cost.

In conclusion, I have never exposed any patient to treatment risks for reasons which were not ethically and medically appropriate, and I did not do so in the matter into which you are inquiring. If you need any additional information from me, please contact me through the Center's general counsel, Doug Shaeffer, and I will try to provide it.

Very truly yours,

E. Donnall Thomas

E. Donnall Thomas, M.D.
Member, Fred Hutchinson Cancer Research Center
Professor Emeritus, University of Washington

cc: Dr. Frederick Appelbaum
Dr. Robert W. Day