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NIH EXECUTIVE SECRETARIAT

Dr. Harold Varmus
Director, NIH
Building 1, Room 126
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Varmus:

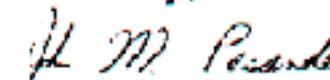
The NIH has a long and distinguished record of bungling investigations of scientific misconduct. This is also true of its probe into activities at the Fred Hutchinson Cancer Center.

Dr. Puglisi's report on this matter repeatedly and wrongly states that the IRB could have stopped any dangerous FHCRC clinical protocols. That is the problem. Our IRB simply did not have the power to do so. Ignoring other issues, who would have carried out IRB decisions? The IRB had no executive arm, and the two most powerful people at the FHCRC were opposed to its recommendations: Dr. Thomas' memo of 10/14/83 recorded but one of his many strong objections to IRB interference while FHCRC Director Dr. Robert Day repeatedly refused to act on IRB requests. At a 1/17/84 meeting with Dr. Day, Dr. Kaplan and I tried to stop the worst of these protocols, but were overruled. When Dr. Kaplan contacted the NIH for advice, they had none.

The FHCRC IRB was charged with protecting patients involved in medical research, yet it lacked an executive arm, lacked the support of the FHCRC, lacked access to necessary information, and lacked protection for its members. FHCRC management successfully engaged in a multitude of self-serving activities to prevent its IRB from performing its function. The result was the avoidable deaths of 20+ patients. As an IRB committee member and an attending physician on the transplant service, I saw this happen. Patient deaths and the multimillion dollar conflict of interest problem which I cited are merely symptoms of the bigger problem of failure to protect patients involved in clinical research.

The NIH's handling of this matter suggests that it was afraid of finding something, and the profound apathy of those at the top to misconduct in the field helps to explain why such problems exist. I leave you with the words of Albert Einstein: "The world is a dangerous place to live in not because of those who do evil but because of those who watch and let it happen." Thank you.

Sincerely,



John M. Pesando M.D., Ph.D.

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