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December 1, 1995

The Honorable Donna E. Shalala Ph.D.
Secretary of Health and Human Services
National Institutes of Health
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Humphrey Building
200 Independence Avenue SW
Washington, D.C. 20201
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SHEPHERD EXECUTIVE SECRETARIAT

Dear Madame Secretary:

The current NIH policy of murder for profit must stop. In 11/93 I wrote you to report murderous misconduct for financial gain at the Fred Hutchinson Cancer Center, a problem which dramatically illustrates the inadequacy of protocol reviews by Institutional Review Boards. The enclosed response from the Research Compliance Office of the NIH to my complaint of 5/93 is arrogant, chilling, and totally unacceptable. It does, however, explain why rogue clinical researchers exist and will continue to do so.

In late 20th century America prominent physicians at a major cancer center knowingly risked the lives of unsuspecting patients in pursuit of financial gain, successfully bypassed regulatory bodies, and repeatedly silenced opposition. The FHCRC Institutional Review Board on which I served was repeatedly lied to about the existence of financial conflict of interest and kept uninformed about protocol death rates in a general atmosphere of fear and intimidation. After a 2+ year delay, the RCO report accepts these facts but concludes that the FHCRC is not at fault since it successfully prevented its own IRB from stopping it!! The RCO fails to recommend any changes to prevent more such a tragedies, such as the independent outside reviewers desperately requested of FHCRC Director Dr. Robert Day 10+ years ago .

Not once in the more than 2 years of the RCO investigation was I contacted for additional information, clarification, or supporting documents. My own attempts to contact the RCO were rebuffed. However, the RCO did succeed in broadcasting my name as a trouble maker.

Like most people, I have long been aware of sobering tales of the price paid by "Whistle Blowers" and their kin. This price also applies to the wanton sacrifice of human life for personal gain within the medical profession. The NIH has made this problem worse by establishing local IRBs to protect patients from unethical medical behavior by their treating physicians. These local review boards are totally dependent upon the institutions

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which they regulate for the information which they need, and their members are at the mercy of the Institutions which employ them. This problem of self-regulation is particularly acute in small institutions where power is highly concentrated. In the wrong hands, self-regulation is a license to kill. With hundreds of profit-driven biotechnology companies now conducting clinical trials at NIH-supported medical centers, the current NIH policy of "shoot the messenger and bury the dead" all but guarantees more abuse.

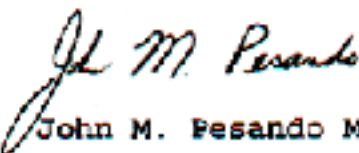
As a people we want desperately to believe in the integrity of our institutions and of those who run them. To do otherwise threatens our very social fabric. Thus we refuse to accept reports that they are anything less than the perfection that we require. In their infinite wisdom, our leaders gratify this basic need, not by the difficult route of correcting very real problems, but by the expedient process of discouraging and suppressing reports of misconduct, thereby ensuring that such reports are few in number.

Murder for profit is wrong, regardless of the power and status of the perpetrators. More than 20 patients were killed at the FHCRC by their NIH-sponsored physicians in pursuit of profit, yet there could hardly be less concern if laboratory rats had died instead. At the FHCRC, economic and professional self-interests were clearly best served by silence or complicity, but the NIH's silence appears to arise either because it is unable to accept the fact that leading medical researchers are capable of such behavior or because it is unwilling to face the consequences of accepting the truth.

If the wealth and power of those accused of wrong-doing prevent taking effective action on behalf of those who have died, then at least eliminate the travesty of self-regulation for the sake of future patients. Those who stand by and do nothing while innocent people are sacrificed for personal gain share the responsibility.

I hope that you will not bury this problem.

Sincerely,



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