



University of Medicine & Dentistry of New Jersey
Robert Wood Johnson Medical School

Department of Medicine
Division of Rheumatology
Telephone: (908) 937-7702
Fax: (908) 418-8238

One Robert Wood Johnson Place - CN 19
New Brunswick, NJ 08903-0019

March 15, 1993

Paul K. Bronston, M.D.
1 Jib Street, #202
Marina del Rey, CA 90292

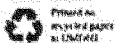
Dear Dr. Bronston;

I have had the opportunity to review the proposal from the Heimlich Institute Foundation sent to me by FAX earlier today. My comments follow:

On page 2, the ignorance of immunology implicit in stating that AIDS "HIV...kills by destroying the body's production of immune substances..." is appalling. HIV destroys T cell in number and function. Although the precise mechanism is unclear, this fact is established, for the writer(s) of this proposal to not know this and state this makes the entire document suspect. Having trained in immunology at the start of the AIDS outbreak and cared for some of the first cases of AIDS to occur in New Haven, I am amazed that such an incomplete statement could be made in 1993.

The assertion that vaccinia or attenuated poliovirus gives disease to the patient is another incorrect statement; neither give disease, "a morbid process having a characteristic train of symptoms" (as defined in Dorland's medical dictionary), although there may be a local reaction in vaccinia - both induce immunity to a real pathogen. The Sabin strain is incapable of making disease in the immunocompetent individual - that is the whole point of using it. In both cases, the virus used resembles the pathogen; malaria bears no resemblance to HIV.

No scientific proof of the efficacy of malariotherapy in syphilis can be offered, as no proper studies of this effect were ever done. The mere fact that a high fever and a systemic reaction causes the elaboration of various immune substances does not prove that malariotherapy has any worthwhile effect - it simply shows that an immune response is evoked.



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The document goes on to discuss the fact that in one anecdotal report children with malaria did better.

What other factors were involved?

Other parasitic infections?

What was the duration of HIV infection?

What evidence is there that malaria actually altered the natural course of HIV infection?

Why is it that AIDS is so rampant in Africa, where there is also still much malaria? All of these questions should be settled before GIVING patients malaria.

T cells are part of the immune response to malaria. what evidence is there that malaria, even "benign malaria", will not be deadly to these patients?

I defy the writer(s) to give proof of efficacy of malariotherapy in Lyme disease. At least one of the patients treated for Lyme disease has stated to the media in NJ that she would not suggest malariotherapy for Lyme disease since it did not work in her. In the absence of proof of efficacy in Lyme disease, the writer(s) should not be allowed to glibly claim efficacy. Finally, no studies of malariotherapy in Lyme disease have ever been done; all that exist are individual testimonials, hardly concrete proof of efficacy.

Where is the proof of efficacy in cancer?

What is the source of the "benign form" of malaria? Is this to be human blood? If so, what assurances can be given that the patient is not harboring another virus or parasite? Or for that matter another strain of HIV?

In the Question and Answers section, the writer(e) essentially say that they know the truth and don't want to be bothered by taking the arduous route of doing the scientific studies necessary to prove that their premise is correct. The reason for doing this in Mexico is that there has been no approval by an Institutional Review Board and that this purely experimental protocol would be impossible to do under U.S. laws.

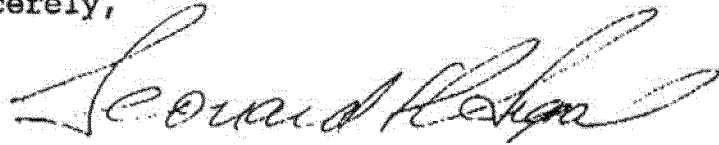
Under A Brief History - Dr. Heimlich's contribution to the New England Journal of Medicine was a LETTER not a PAPER; he suggested that malariotherapy MIGHT be a reasonable notion, but offered no proof for this promise. The number of references in a letter does not add to the nil weight of a suggestion without any relevant precedents or any experimental proof.

Perhaps as the least important note: what is the legal responsibility of a donor to such an endeavor if IMT proves to be deleterious or fatal? Before anyone donates to this dangerous and flawed therapeutic adventured he or she had best assess personal culpability as well as conscience. The work proposed is fraught with peril and ill-conceived and the presentation in the proposal is at the least incomplete if not truly intellectually

dishonest in its omissions and overstatements, No informed consent from patients is noted in any explicit statement in the document. Thus, the patients will be told that this is an effective modality, which represents an untruth. Untruths have a way of translating into lawsuits in our culture. whatever is the proper analogy for "caveat emptor", referring to donors rather than purchasers, should be applied here.

In summary, this proposal represents a very superficial and flawed attempt at playing on the current concern about AIDS. No proof of efficacy in AIDS is offered and the prior successes of IMT, aside from whatever was done with neurosyphilis, in Lyme disease and cancer are not delineated; certainly, no such success in Lyme disease has been documented and I have serious doubts as to the existence of any such successes. This study is to be condemned as ill-planned, poorly presented with statements that are not true, and fatally flawed, a disservice to the patients and donors alike. If there is anything else I can do to make sure that this study never receives funding to proceed, please let me know.

Sincerely,

A handwritten signature in black ink, appearing to read "Leonard H. Sigal". The signature is fluid and cursive, with a large initial "L" and "H".

Leonard H. Sigal, MD, FACP, FACR
Associate Professor
Department of Medicine
Adjunct Assistant Professor
Department of Molecular Genetics &
Microbiology
Chief, Division of Rheumatology and
Connective Tissue Research
Director, Lyme Disease Center