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Paul K. Bronston, MD, FACEP 1 Jib Street, #202 Marina del Ray, CA 90292

Dear Dr. Bronston: ()

I wish to join you in your condemnation of the fund-raising efforts of the Heimlich Institute to study induced malaria therapy (IMT) of AIDS. As a reviewer of research grants for the National Institutes of Health, I am qualified to comment on the Institute's proposal for solicitation of private funds.

The proposal fails to meet even the most basic standards for an acceptable research proposal. The background section of the proposal contains not even a single specific reference to published literature and misstates the conclusions of many of the studies. There are several outright falsehoods in this background section. The proposal states that HIV kills by destroying the body's production of immune substances. The primary defect in AIDS is, in fact, a defect in cell-mediated immunity. Production of "immune substances", e.g. gamma globulins, is often increased in patients with AIDS. To my knowledge, there is no specific immune substance that is known to be capable of destroying HIV. If Dr. Heimlich is aware of data showing such an effect, he has an obligation to cite it in the proposal. The example of smallpox is a distortion in two respects. First, smallpox vaccination is a preventive measure, not a therapeutic one. Second, in smallpox vaccination, the induced disease is immunologically similar to the disease being prevented. IMT is not analogous in either respect. In summary, the rationale for IMT in AIDS is pure speculation on the part of Dr. Heimlich.

It is understandable that the Heimlich institute would make much of the fact that Dr. Wagner-Jauregg was awarded the Nobel Prize in 1927 for his use of IMT in treatment of neurosyphilis. However, a critical review of Wagner-Jauregg's work [1], concludes that his studies, which used historical controls, failed to meet modern criteria for clinical trials and, based on Wagner-Jauregg's own data, one cannot conclude that IMT benefited patients.

The proposal claims prior success in using IMT in treatment of Lyme disease and cancer. No reference is given to this prior work and the design of these prior studies was not described. No data was presented on the safety of malaria therapy except to state that there has never been a failure to cure a patient with the induced infection. Even if this were true, it is ludicrous to extrapolate this claim of safety to

patients with AIDS who not only are immunologically compromised, but often have severe anemia and hepatic dysfunction which might render them more susceptible to the effects of malaria infection and, possibly, to the effects of drugs used to treat it.

The study design is woefully inadequate. There is no description of the selection criteria for patients or exclusion criteria. There is no description of the "laboratory studies" that will be used to evaluate these patients, nor is there any mention of the outcome measures to be used to determine the effects of IMT. There is no control group, so the results of the treatment cannot be evaluated. The type of antimalarial therapy to be used is not specified. Finally, the sample size of 10 patients is so small, that any observed effect would likely be statistically insignificant. In summary, the research proposal is monumentally flawed and the proposed study cannot answer the question of efficacy of IMT in AIDS. This proposal would be resoundingly rejected by any credible grant review committee.

The ethical defects in the proposed study are even more egregious. One serious failing is the lack of review by a human subjects protection committee. If consent is obtained from subjects based on Dr. Heimlich's flawed interpretation of previous data, the subjects will have been misled. Because no data are available on the safety of IMT in patients with AIDS, it is irresponsible to subject human patients to this treatment. I think there is a significant chance that the proposed study would result in harm to the subjects. There would, of course, be no need to perform the study in Mexico if the proposal met ethical standards acceptable in the United States. The sensationalistic way in which Dr. Heimlich and his colleagues promote themselves and the misleading way in which prior research is presented in the proposal, are inappropriate and unprofessional. I share your concern that this effort will attract donations of money that would be far better used in legitimate research on AIDS. I join you in strongly condemning the Heimlich institute's proposal and their misleading method of soliciting funds. Groups targeted by the institute for donations should be made aware of the inadequacies and the potential dangers of the proposal and urged not to support it.

Sincerely,

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Frank A. Sonnenberg, M.D. Assistant Professor of Medicine General Internal Medicine

## Reference:

Austin SC, Stolley PD, Lasky T. The History of Malariotherapy for Neurosyphilis, Modern Parallels. JAMA 1992;268:516.