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December 31, 1990

William L. Roper, M.D., M.P.H. Director Centers for Disease Control Atlanta, GA 30333

Dear Dr. Roper:

A CDC report of two late-stage Lyme disease patients treated with malariatherapy appeared in the December 7, 1990 MMWR. These patients and their physicians presented the patients' case histories at the Midwest Lyme Disease Conference, November 10, 1990. The patients, 29 and 33 year-old women, disabled with arthritic and neurologic had been manifestations, one for nine years, and had received intravenous antibiotics for up to three years with progressive disability. One of the patients said that the cost of her antibiotic therapy was \$300,000. The other patient, a twentynine year old woman, had been confined in the fetal position for three years due to exquisitely painful, swollen joints, despite 40-1/2 weeks of antibiotics. Both patients demonstrated remission of symptoms after malariatherapy and regained normal body function. The duration of remission cannot be predicted at this time; it is feasible, however, to repeat courses of malariatherapy, and there is no other successful means of treatment for these antibiotic failures.

An accompanying editorial note in the MMWR, by Dr. Roy Campbell of the CDC, is described in a newspaper report as being the official opinion of the CDC, as are his published comments to the press. The editorial is replete with inaccuracies and misleading statements attempting to negate and erase 60 years of scientific studies and clinical experience that proved the success of malariatherapy in treating neurosyphilis, raising serious questions about Campbell's credibility.

The errors in the MMWR editorial are evident from a 1984 paper on malariatherapy by the eminent authority on tropical diseases, Dr. Eli Chernin, Professor of Tropical Medicine, Harvard School of Public Health. Chernin's comprehensive historical review, "The Malariatherapy of Syphilis," published in The Journal of Parasitology, October, 1984, from the Harvard School of Public Health, received support from the U.S. Public Health Service. Chernin's article lists thirty-nine references, which refer to hundreds of other publications describing animal and clinical research confirming the effectiveness of malariatherapy for treating neurosyphilis.

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To demonstrate the inaccuracies of Campbell's statements in the MMWR editorial, please compare them with Chernin's documented, referenced data.

Campbell: "Controlled studies of malariotherapy for neurosyphilis never were done." (Campbell cites one obscure 1936 reference entitled, "A review of selected papers contributing to the progress of malariatherapy during the past year.")

Chernin: Prior to malariatherapy, "1,559 paretics were admitted to St. Elizabeth's in Washington, DC, and 77% soon died." In two other studies, "80% of 1,500 untreated paretics died within four years of onset, as did 60-70% of paretics treated with arsphenanine and heavy metals. Among malaria-treated paretics, however, the case fatality rate usually did not exceed 5-10%." Johns Hopkins Hospital, two U.S. Public Health Laboratories, and the Horton Laboratory in Epsom, England, where 10,000 patients received malariatherapy, were the best known research centers. (Their studies were controlled, and the decision to grant Wagner-Jauregg the Nobel Prize for his discovery of malariatherapy was based on sound scientific studies.)

Campbell: "Published results (cites the same 1936 reference) suggested that the response to treatment was unpredictable and primarily clinical and that the duration of remission was variable." (When did "primarily clinical" results become unimportant?)

Chernin: "The strongest data on malariatherapy were reported or cited by Moore (1941) who emphasized, as had Wagner-Jauregg in 1922, that 'The probability of complete remission stands in direct relationship to the duration of paretic symptoms before treatment. The earlier treatment is given, the more likelihood of a favorable outcome.' Thus, malaria given within two months of symptoms produced 90% remissions, within six months about 80%, and within six to twelve months, only 20%; after two years, fever therapy resulted in 10-20% remission. 'This is a convincing demonstration', wrote Moore (1941), ' of what is after all no more than is to be anticipated. Treatment of any nature cannot be expected to revivify dead brain cells'."

Boyd's Malariology states that of untreated syphilitic optic atrophy patients, 65% were blind in three years, and 10% more went blind thereafter. Of the malaria-treated patients, only Centers for Disease Control December 31, 1990 Page Three

18% were blind at the end of three years, and subsequent observation revealed that no decrease in normal visual acuity was observed in these patients following this treatment and an observation period of three years. In addition, malariatherapy benefitted 50% of syphilitics with eighth nerve deafness. (The above provides predictability of both response and duration of remission.)

Campbell: "Changes in serologic status generally did not correlate with clinical improvement, suggesting that malariotherapy had minimal, if any, effect on the underlying spirochetal infection." (Campbell cites the same 1936 reference.)

Chernin: "Still other experts opined that malaria parasites and spirochaetes must somehow be related since nearly all non-syphilitics who contracted malaria developed positive serologies for syphilis (Wasserman or Kahn 'false positives'); the explanations for those well-known sero-conversions are not clear to this date." Others report that serology is negative in paresis, but the spinal fluid is positive. Campbell's statement concerning serology, therefore, is meaningless other than to erroneously denigrate malariatherapy.

Boyd (1949) reports, "Many years of treatment (of tabes) can usually be shortened a great deal by the early use of malariatherapy. In an analysis of 396 cases of tabes, the Cooperative Clinic Group (1938) found that of seventy-five patients who failed to obtain serologic improvement from intensive (drug) therapy, 35% were further improved after malaria treatment."

<u>Campbell</u>: "Malariotherapy for syphilis was discontinued when penicillin and other effective antibiotics became available."

Chernin: "The advent of penicillin in the mid-1940's ineluctably signalled the end of malariatherapy for syphilis, but, as suggested by the title of an editorial on that subject (Anon., 1975), the 'final curtain' did not come down on malariatherapy in Britain until the 1970's and combined therapy with penicillin and malaria, once common in the United States (Crawford, 1948; Becker, 1949), ceased in the mid-1960's."

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Antibiotics frequently could not traverse the blood-brain barrier. Malariatherapy enhanced penetration of drugs into the brain by producing hyperemia of the meninges, and is still recommended for neurosyphilis resistant to antibiotics (Bruce-Chwatt, L.J. Essential Malariology. 2nd Ed. New York. John Wiley, 1985.)

Campbell: "malariotherapy causes iatrogenic morbidity and carries a direct risk for death from complications of P. vivax infection or from infection with other, undetected blood-borne pathogens."

Chernin: "Several related points on the historical landscape of malariatherapy deserve mention: (i) on average, malariatherapy was less expensive and produced clinical improvement more frequently and more rapidly than did the best drug treatment. (ii) the contraindications to malariatherapy, and there were some, must have been carefully observed because records of treatment-related deaths or extreme debility are few relative to the thousands of patients treated . . ."

Obviously, donor blood for malariatherapy must be screened as for a transfusion. A statement issued by the Department of Health and Human Services (HHS) on December 5, 1990, based on present screening methods, said that the blood supply "is safer now than at any other time in the history of transfusion medicine."

<u>Campbell</u>: "A small but definite risk exists of local transmission of malaria when parasitemic persons enter the United States."

That statement is, at best, a scare tactic designed to deter malariatherapy. In almost 60 years of malariatherapy given to tens of thousands of patients in this country and throughout the world, there was no known instance of it resulting in local malaria transmission, and much of that period was prior to air conditioning. Campbell's cited reference is not related to malariatherapy.

Malariatherapy is well established and scientifically proven to be effective and safe for the treatment of neurosyphilis. Chernin wrote: "It is not hard to imagine the almost certain fate of the thousands of paretics who would have sickened horribly and died but for malariatherapy." The MMWR editorial Centers for Disease Control December 31, 1990 Page Five

of December 7 as well as Campbell's statement that "induced malaria is not recommended for the treatment of Lyme disease" are based on the false premise that malariatherapy was not effective for treating neurosyphilis. Both should be retracted by the CDC. In addition, the CDC should recommend that malariatherapy for Lyme disease be continued and evaluated.

Malariatherapy is the only method that has resulted in remission of disabling arthritic and neurologic manifestations of Lyme disease after prolonged intravenous antibiotic Thirty-seven percent of Lyme disease treatment failed. patients suffering from neurological disease do not respond to I.V. antibiotics or have recurrence of Lyme disease in less than six months after antibiotic treatment (Logigian, Kaplan, Steere, New England Journal of Medicine, November 22, 1990). These patients, along with countless others with incurable disabling, painful arthritis, should not be denied the option of malariatherapy. In addition, the recent report that there were 50,000 syphilis cases last year, the largest number since 1949, many in advanced stages, will surely yield antibiotic failures that will require reactivation of malariatherapy. I have already received pleas for help from such patients.

In 1987, the CDC invited me to your Centers in Atlanta to meet with CDC physicians and researchers to present data on malariatherapy for neurosyphilis as a cancer treatment. Consequently, after this committee expressed confidence in the value of malariatherapy, the CDC, in a letter of May 29, 1987, offered to find a donor and obtain P. vivax for our use in patients in the United States. No new data has appeared in the past three years demonstrating any reason for the CDC to change its positive attitude toward malariatherapy. It seems unlikely, therefore, that Dr. Campbell's editorial represents CDC opinion.

Are the views expressed in Dr. Roy Campbell's editorial in the MMWR, those of the CDC? What is the current opinion of the CDC concerning the use of malariatherapy for Lyme disease and syphilis?

I would appreciate hearing from you as scen as possible. If you wish further information, I would be delighted to meet with you.

Sincerely,

Henry J. Heimlich, M.D., Sc.D. President, Heimlich Institute