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The Mali HIV+ AIDS Initiative

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Compelling clinical experience suggests there is an innovative way to markedly improve the HIV/AIDS picture in Africa with an integrated medical and social/cultural approach.

International health experts agree that gender inequality and men's culturally supported entitlement are primary factors in creating and continuing the AIDS catastrophe in many parts of Africa (and in other developing countries as well). Current data indicates that 55%-60% of those infected are girls or women, many with children who are then also infected. In an increasing number of villages there are only a few women left alive between the ages of 20 and 40. Recent studies indicate that the majority of HIV-positive women were infected by their husbands. Because of traditional social/gender mores, the vast majority of women do not have the capacity to refuse sex, cannot insist on condoms, and, therefore, cannot protect their own health. U.N. officials and others have stated that this epidemic will not abate until women are empowered to protect their own health and the health of their children. Of the thousands of babies born HIV-positive each week, most die without medical care before the age of two. In sub-Saharan Africa there are 14 million AIDS orphans 50% of whom are estimated to be HIV-positive. Although the standard HAART drugs for treating AIDS are being used more widely in Africa, it is estimated that they are available to less than 25% of the people who need them. Even where available, these drugs are expensive, complex to administer, have significant side effects and require regular medical testing to be used safely. In addition, the HAART drugs are usually too toxic for children who, even more than adults, require the kind of medical management that is often unavailable.

Besides the high priority of bringing treatment to the vast number already suffering with AIDS, what is clearly needed to meet the situation in Africa is an integrated approach that helps to reduce the rate of infection through changes in the traditional social/gender patterns and, simultaneously, strengthens the immune systems of the large HIV-positive population—children and adults alike—to prevent them from moving into full-blown AIDS. The long-term goal of the Mali Project is to demonstrate the efficacy of such a combined approach.

The Ojai Foundation, a 501(c) 3 organization devoted to education and research, is sponsoring an integrated, two-faceted HIV/AIDS initiative conducted by the University Hospital in Bamako, Mali that will:

- 1) Test the efficacy of a treatment protocol for those who are HIV positive that significantly reduces their chances of developing full-blown AIDS; and
- 2) Reduce the rate of HIV infection by encouraging changes in the ways men and women relate that will empower women to protect their health and the health of their children.

Mali has been chosen because their government officially supports this combined approach as the best way to combat the growing incidence of HIV/AIDS in their country and, although poverty is rampant, they are a relatively stable democratic nation. In addition, Mali women are among the least empowered of any country in Africa. In a recent UNESCO survey of African women's

ability to shape their own lives and those of their children, 85% of Mali women indicated they did not feel empowered to make decisions that affect their intimate life.

In regard to the primary medical goal of the proposed program, there are good reasons for believing that an effective medical treatment already exists for preventing the HIV positive state from developing into full-blown AIDS. Naltrexone is a generic, inexpensive U.S. FDA-approved opiate antagonist that has been used widely to combat drug addiction for more than 20 years. At less than one tenth the dose, “Low-Dose Naltrexone” (LDN) has been shown to be an effective immune system modulator that is non-toxic, non-addicting and requires administering a single capsule only once daily. *LDN is also now available as a transdermal cream that is particularly effective with children. This crème has been used successfully in the treatment of some 5000 immune-impaired autistic children over the past two years, principally under the direction of Dr. Jaquelyn McCandless, the medical coordinator for this project (See her book, “Children with Starving Brains: Third Edition”).* Before it can be used with HIV-positive children, the efficacy of LDN must be tested in a controlled study with HIV positive adults. *When this is accomplished this non-toxic, easily administered (once daily) medication can then be explored as an effective treatment in preventing HIV positive infants and children from ever developing full-blown AIDS as long as they use the medication daily.* If LDN were to be manufactured in Africa, (and there are interested parties who want to do this) it is estimated that the cost would be less than \$25 per year per person for the cream and probably less for capsules.

The safety as well as potential efficacy of LDN in preventing AIDS was first discovered by Bernard Bihari, M.D, a Harvard-trained New York physician, in 1985. Since that time Dr. Bihari has treated more than 350 patients, 94% of whom have remained HIV positive without progression into AIDS for up to 18 or more years. Many of these individuals received only LDN and some used LDN as an auxiliary to the evolving HAART medications. However, to this date no carefully designed controlled study has been done to prove the efficacy of LDN in HIV-positive individuals as a prevention from developing AIDS. To more deeply evaluate this hypothesis, Dr. Bihari, Dr. Abdel Kader Traoré (and other health officials at the University Hospital in Bamako), and more recently Dr. Jaquelyn McCandless, created a protocol for a controlled, non-placebo study involving 250 adult volunteers—all of whom are HIV positive but have not yet developed any AIDS symptoms. The protocol will test the efficacy of LDN alone compared to the current HAART medications, as well as the combination of the two. The Malian government is fully supportive of this study and will provide the HAART medications needed.

LDN has also been shown to be useful in the treatment of other autoimmune illnesses such as MS, ALS, diabetes, chronic fatigue syndrome, rheumatoid arthritis and Crohn’s Disease. Several new studies of such applications are currently being initiated in the US--for example, a crossover MS study at the University of California, San Francisco, and a clinical fibromyalgia study at Stanford University, both of which are planned for 2007.

As yet, there has not been support for a controlled LDN study for HIV+ AIDS in the United States, since those with AIDS in this country have ready access to the currently used HAART medications and are, therefore, less interested in participating in new treatment studies. In

addition, most US studies are designed by drug companies that are uniquely in a position to afford the huge cost of the required extensive trials. Drug companies are generally not interested in generic, low cost medications such as LDN. In regard to ethical issues, it is important to note that no one connected with the Mali study is associated with any drug company and both US consultants are working *pro bono*.

Concerning the second goal of the proposed program, the United Nations, the G8 countries, several large foundations and many smaller locally focused organizations have sponsored a variety of gender and health oriented educational programs in several African countries during the past 20 years. The primary thrust of these programs is based on educating individuals, particularly young women, about the nature and source of HIV infection. Although progress is being made, social mores change slowly and there remains a dishearteningly long way to go. In the proposed 56-week Mali Initiative we will accelerate this process by building on the educational programs and gender reconciliation initiatives that already exist in Mali using The Ojai Foundation's many years of experience in dealing with gender communication issues. This innovative program will include interviews as well as men's, women's and couples' "councils" with volunteers from the population of 250 individuals that will be involved in the 56-week controlled LDN medical study. These councils will focus on improving gender communication, women's empowerment and the reduction of violence in relationships.

This part of the program will be guided by Dr. Jack Zimmerman, council and communications specialist, longtime member of the Ojai Foundation's Board of Directors and co-author of "The Way of Council." Council has been a primary focus of The Ojai Foundation's training program in gender and group communication for adults and children since 1980. It has been successfully and widely used in schools such as Crossroads School in Santa Monica (where Dr. Zimmerman initiated their ongoing council program in 1983) and more recently (through the Los Angeles Unified School District's "Council Practitioners' Center") at a growing number of public schools in Los Angeles. Council is also being used widely in places of business, schools, communities and families in other parts of the US, Israel, Europe and South Africa.

A substantial portion of the \$250,000 required to fund the Mali initiative is being sought as grants from concerned foundations and international AIDS organizations. However, because such grants take time to manifest, we have decided to seek support from individual donors in the US and elsewhere in order to launch the program this spring. We will begin with a council training for University of Bamako graduate students and faculty and counselors from the Bamako AIDS Center on April 29, 30 and May 1, 2007. The need is great, the protocol is fully developed, and experienced council trainers from South Africa are available to conduct the training. In just a month we have raised almost half of the funds needed and are confident that the full amount will be pledged by the time of the council training.

The potential for an inexpensive, generic medication utilized in combination with encouraging change in gender mores that will significantly reduce the AIDS epidemic is enormous. A recent visit to Bamako by Drs. McCandless and Zimmerman (husband and wife team) to discuss the project with the staff of the University Hospital confirmed that the research laboratory there is excellently equipped to carry out the study, and that the Minister of HIV/AIDS, the Chairperson

of their medical ethics committee and other significant Malian officials are fully in support of the program (see attached letter). Once successfully completed, this project can be replicated in other countries that are facing similar challenges.

We ask anyone touched by the situation in Africa to consider making as substantial a contribution as possible. Please know that all of us involved with the project will be appreciative of any amount donors decide is appropriate. A few people have told us they are concerned the amount they can afford is too small. But many modest donations add up! We would also appreciate referrals to others (people and/or agencies) known personally by you who might be able and willing to contribute to this project. Additional information including further details of the medical, education/communications and financial portions of the program as well as resumes of the principal investigators are available for anyone interested.

With appreciation for your consideration and support,
Jaquelyn McCandless, M.D. and Jack Zimmerman, PhD

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