Public Citizen

NEWS RELEASE

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DOZENS OF THAI INFANTS NEEDLESSLY INFECTED WITH HIV IN UNETHICAL U.S. GOVERNMENT-FUNDED STUDY

CDC STUDY IN THAILAND CONFIRMS SHORT COURSE AZT IS BETTER THAN PLACEBO IN PREVENTING HIV TRANSMISSION FROM MOTHER TO INFANT

Washington, D.C., Feb. 18, 1998 -- The Centers for Disease Control and Prevention (CDC) today released results of a study in Thailand confirming what the U.S. government knew four years ago: short courses of the drug AZT are highly effective in reducing the transmission of HIV from pregnant women to infants. The study, conducted in Bangkok, demonstrated that while 19% of infants whose mothers got a placebo became infected, only 9.2% of those whose mothers received AZT beginning 3 to 6 weeks before delivery and by mouth during labor were infected, a reduction in infant infections of 51%.

For almost a year, Public Citizen has been waging a campaign against over a dozen studies in developing countries, most funded by the CDC and National Institutes of Health (NIH), that denied HIV-positive pregnant women access to AZT, a drug that, when given for somewhat longer periods during pregnancy and intravenously during delivery, reduces mother-to-infant HIV transmission by two-thirds. Public Citizen, joined by several medical ethicists and the New England Journal of Medicine, argued that researchers were obligated to provide patients with the best proven therapy.

"We have been telling them this would happen for almost a year now," said Public Citizen Research Associate Peter Lurie, MD, MPH, "and now we've been proved right. The tragedy is that precious time and money have been wasted, dozens of infants in the CDC trial alone are now unnecessarily HIV-positive and we still aren't sure if the shorter regimens are as good as the longer ones."

Since April 1997, Public Citizen has recommended that the studies be redesigned to compare the shorter regimens to the longer ones (rather than to placebos), a design called an equivalency study. Such a study has been funded by the NIH in Thailand. This design was endorsed recently

by Dr. Hiroshi Nakajima, Director of the World Health Organization, which through the UNAIDS Program is sponsoring one of the placebo-controlled trials. In an interview at the African AIDS Conference in early December in Abidjan, Cote d'Ivoire, Dr. Nakajima stated that the placebo-controlled trials were "unjustifiable ... even in Asia, even in Africa." (See attached official translation of Agence France Presse story quoting Dr. Nakajima and also Dr. Luc Montagnier, discoverer of the AIDS virus as also saying the placebo studies are unethical.)

The results of the CDC study announced today are similar to a pre-planned subgroup analysis of the data from the placebo-controlled trial that first demonstrated the dramatic superiority of a regimen including a longer duration of pre-delivery AZT compared to placebo. In that subgroup analysis, the data from which we obtained recently, women receiving an average of seven weeks of AZT prior to delivery transmitted HIV to their infants only 7.7% of the time, compared to 22.9% of those given placebo (see attached graph). We have learned that, although these data were presented at a closed NIH meeting in February, 1994, they were not presented or discussed at a crucial June, 1994 World Health Organization-sponsored meeting at which placebo-controlled studies were recommended as the best choice for testing short-course AZT therapy. "Had they only paid attention to the results of their own earlier studies, this disgraceful loss of life would have been avoided," said Dr. Sidney M. Wolfe, Director of Public Citizen's Health Research Group.

Public Citizen added that any remaining study in which a group of women does not receive AZT or equivalent drugs must be immediately redesigned. In October, we announced that an NIH-funded trial in Ethiopia eliminated its placebo group. At that time, Dr. Joseph Saba of the UNAIDS Program indicated that if one of the placebo-controlled trials was positive, all of the trials would have to stop prematurely in their current design. Dr. Jack Killen of the NIH agreed that all placebo-controlled trials would have to be redesigned if the CDC's Thailand study was positive. "Like a stack of dominoes, everything will be rethought," he told the *Baltimore Sun.*

"It is time for the researchers to admit they erred, for us all to commit to studies that do not unnecessarily leave patients in danger, and get on with the business of getting this proven effective therapy to patients in the developing world," said Dr. Lurie.

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"Africa-AIDS-placebo

WHO chief condemns use of placebos in AZT tests

ABIDJAN, Dec 11 1997 (AFP) - The use of placebos to test new regimens of the drug AZT on pregnant women in developing countries is "unjustifiable," the head of the World Health Organisation said during a conference on AIDS in Africa here.

"I believe, on a personal level and as a pharmacologist, that these trials using placebos on women to reduce mother-to-child transmission of HIV are not justified," WHO Director General Hiroshi Nakajima told AFP during the 10th International Conference on AIDS and Sexually Transmitted Diseases in Africa, which ends Thursday.

Nakajima insisted his opposition applied "even in Asia, even in Africa."

Such tests using placebos "are to be proscribed ethically and scientifically because the efficacy of AZT has already been proved," inisisted Pierre M'Pele, head of the African Anti-Aids Society, pointing out a thousand infected babies are born every day in Africa.

"All the arguments advanced to justify placebo tests are false," said Abdourahmane Sow, who resigned from the WHO's Global Programme on AIDS (since evolved into UNAIDS) over the issue.

"AZT-placebo tests are no longer necessary," said Luc Montagner, the French Professor who first discovered the HIV virus.

In the West, AZT has been shown to reduce mother-to-child HIV transmission by two thirds.

But the placebo debate raging at CISMA is fuelled by the knowledge that the AZT regimen used in the developed world is wholly unsuited to poor countries because of the cost of the high doses used, the long duration of the treatment, and the sophisticated medical facilities required to administer it.

"It is important to know if shorter, lighter treatments are effective," explained Jean-Paul Levy, who heads the National Agency of Research into AIDS in France, which uses placebos in its trials.

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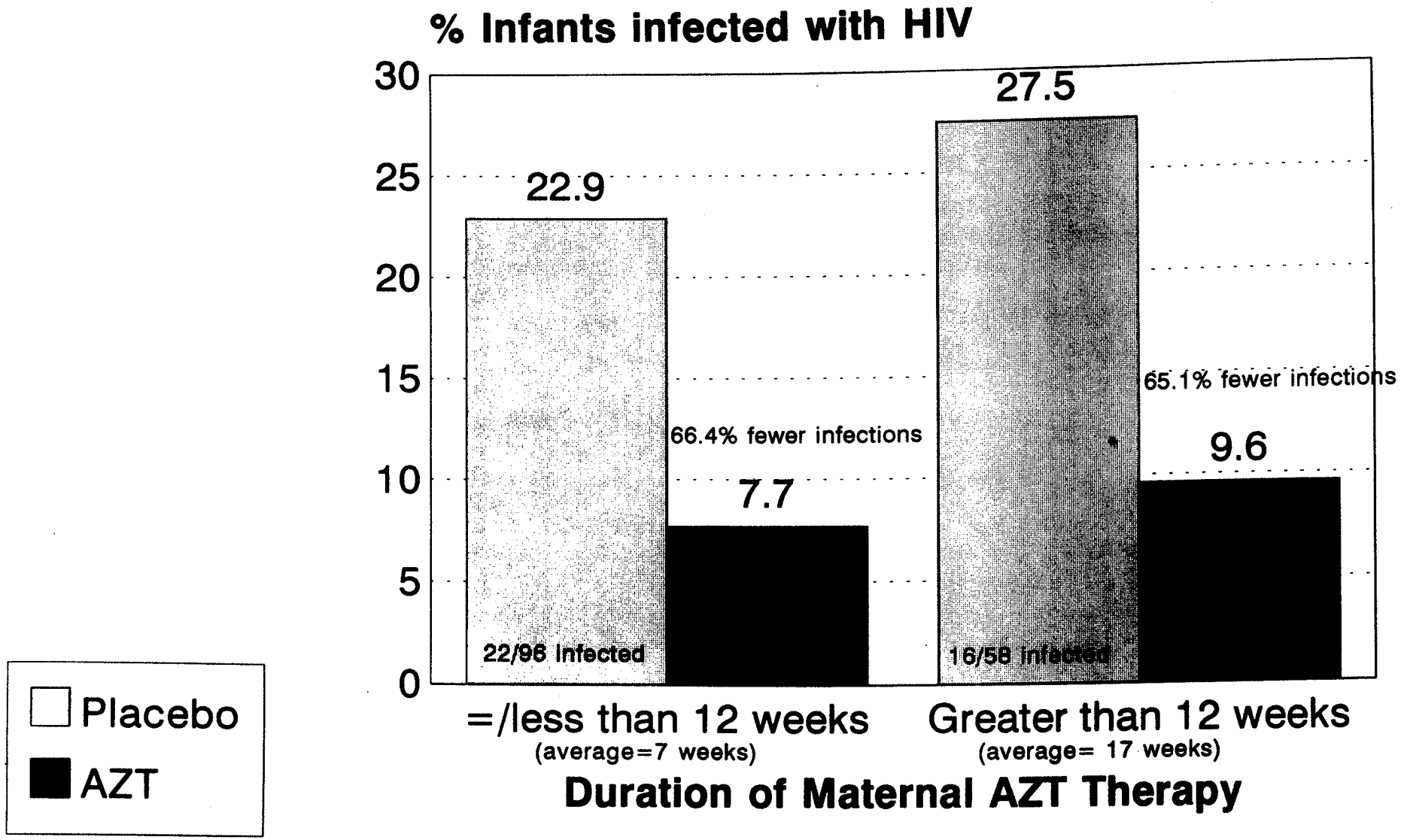
Effect of Duration of AZT Therapy on Infant Infections *

Data from ACTG 076



* Data Presented by ACTG 076 researchers to Data Safety Monitoring Board, February, 1994