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AIDS ACTION NEWS!

AIDS ACTION NOW! Statement on the Ribavirin Trial

A national trial of a proposed anti-HIV treatment, Ribavirin, has been announced in the media. Subjects are being enrolled in Toronto, and in more than a dozen other centres across the country. If you are thinking of participating in this trial there are two important things you should consider: first, the way the trial has been arranged; and second, some recent political developments around the issue of placebo-controlled trials.

The Ribavirin Trial

- I. This is a placebo-controlled trial. This means that half of those participating will receive no active treatment for their HIV infection during the course of the trial which may last as long as three years. Subjects enrolled in the trial will not be allowed to take other promising treatments that might come along. Moreover, untreated HIV infection may result in damage to your immune system. Other experimental treatments are available.
- 2. This means that subjects who enroll in this trial should do so in the spirit of wanting to contribute to scientific research, not because they hope to get the treatment benefits of Ribavirin. There is an important distinction here between research and treatment. For this reason it is also unethical, for example, for researchers to offer any kind of treatments to you as an inducement to enroll in the trial (e.g., better monitoring of your health, or access to new, experimental treatments after the trial is over).
- 3. The choice of Ribavirin from the range of drugs awaiting testing, and the planning of this trial did not involve people representing HIV-positive individuals or their physicians. AAN! believes that these people should be included in the planning stages of a trial, and that drugs should be selected based on probable effectiveness rather than on commercial considerations. Ribavirin is being tested primarily because the firm that manufactures it wants it tested, not because it shows great promise as a treatment. The AIDS Resource Centre at ACT (AIDS Committee of Toronto, 464 Yonge St.) has more medical-scientific information on Ribavirin if you are interested in reading more on this issue.

Placebo-controlled Trials

AAN! agrees with the Medical Research Council of Canada that placebo-controlled trials are only ethical when treatment and research are completely divorced. The use of placebo-controlled trials to provide treatment to people who have HIV illness, consequently, is unethical. This means, first, that it is also unethical to deny a person treatment because he will not enroll in a placebo-controlled trial. And secondly, that placebo-controlled trials are only for those people who are simply interested in contributing to medical research.

At both the recent conference in London, Ontario and the Consensus Conference held in Scarborough, government officials, representatives from the pharmaceutical industry, medical researchers, and representatives of HIV-positive individuals and PLWAs agreed that the basic protocols for drug trials have to be redesigned because of the ethical problems of placebo-controlled trials. At both conferences, there was also a proposal to add a third arm to treatment trials where patients could get the treatment, if they needed it, without enrolling in the placebo-controlled branch of the trial. As far as can be determined, nothing has been done to implement these suggestions. AAN! believes that if the government, the industry, and the researchers are serious about this proposal that current and imminent treatment trials should be temporarily withdrawn and redesigned to include an open treatment arm.

Lastly, one argument being put forward for using a placebocontrolled trial with HIV-positive individuals is that you are not sick. There is an important difficulty with this argument. Just because a person does not have an opportunistic infection does not mean that he is not sick—especially when he is HIV-positive and his T4 count is below normal. There is a strong current of medical opinion in the United States that supports early intervention in cases of HIV infection. This means beginning the management of your HIV infection as early as possible, long before you come down with an opportunistic infection like PCP.