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Joan Claybrook, President

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Harold Varmus, MD
Director
National Institutes of Health
Building 1, Room 126
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Varmus:

We are writing to seek clarification of the National Institutes of Health's position on future studies of HIV-infected pregnant women. As you know, the drug nevirapine was recently shown in an NIH-funded trial to significantly reduce the transmission of HIV from mother to infant. The cost of this regimen has been estimated to be as low as $4 per course.

One might think that the development of this extremely cost-effective regimen ($40 per infant life saved) would result in an immediate change in NIH policy. But testimony delivered by Jack Killen of the National Institute of Allergy and Infectious Diseases before the National Bioethics Advisory Commission on September 16, 1999 suggests otherwise. Below are excerpts from an interchange following Dr. Killen's presentation between Dr. Killen and Dr. Ruth Macklin, a consultant to the Commission. Dr. Macklin asked whether, given present knowledge, it would be acceptable in certain countries to enroll HIV-positive pregnant women in observational studies in which the women were followed during their pregnancies and the HIV transmission rate to their offspring determined, without providing these women with known effective medications such as nevirapine.

Ruth Macklin: "There are some who are arguing that it is ethically acceptable to do natural history studies [of mother-to-infant HIV transmission] in precisely those [poor] areas where there is no intervention and people do not get the care and it is not available, et cetera, since you are not making them worse off. I mean that is the argument so could you address [that]?"

Jack Killen: "... I think you have got to know what the -- what is the purpose of the study. If the purpose of the study is to inform health or health policy in the context in which the study is being done there is more justification for doing it than if the purpose is to go in and do natural history to exploit it for the purpose of bringing it home and using it for other purposes than the health of the setting where the study is being done."

It is clear from the transcript that Dr. Killen is equivocating and not willing to categorically preclude these studies, in which the researchers observe and count HIV transmissions but do not intervene, despite the practicality and cost-effectiveness of available regimens. This failure to act would be particularly unacceptable in the setting of multimillion dollar clinical studies. Can this really be the position of NIH? If NIH-funded researchers fail to provide even so inexpensive and effective a regimen as nevirapine after all the NIH's prior work on this issue, real questions will be raised about the true intent of the prior research.

By 1993, prior to the proof that antiretrovirals can prevent perinatal HIV transmission, at least 13 observational studies had been conducted.[1] Now that effective drugs are available, there is neither the need nor the ethical justification for studies that will needlessly leave infants at risk. Your previous comments on this issue suggest that you would concur with us. In your New England Journal of Medicine article on the perinatal trials,[2] you describe the so-called standard of care argument (that researchers are obligated to provide no more treatment than what is locally available) as "too simple."

Dr. Killen suggested that one can distinguish between acceptable and unacceptable observational studies based on whether the purpose of the research was "to inform health or health policy in the context in which the study is being done." Of course, any researcher conducting an observational study would insist that the purpose of the research was to benefit local citizens, so this does not seem like a helpful distinction, nor should it be used to justify unethical studies.

We urge you to immediately and publicly dissociate yourself from Dr. Killen's comments and clearly state that NIH is now opposed to all observational studies of perinatal HIV transmission and will not fund any such studies. Implementing effective antiretroviral regimens in NIH-funded studies is a very small step in expanding access to lifesaving anti-HIV drugs in developing countries. But we doubt you would like part of your legacy at NIH to be that, even after a positive NIH-funded study, some NIH-funded researchers sat around and watched while infants needlessly contracted a fatal illness.

Yours sincerely,

Peter Lurie, MD, MPH
Deputy Director

Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group

cc: Tony Fauci
Jack Killen

1. The Working Group on Mother-To-Child Transmission of HIV. Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology 1995;8:506-10.

2. Varmus H, Satcher D. Ethical complexities of conducting research in developing countries. New England Journal of Medicine 1997;337:1003-5.