



Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

Embargoed for release:
5 p.m. Wednesday, August 11

Contact: Dr. Peter Lurie (202) 588-7781
Dr. Sidney M. Wolfe (202) 588-1000

Scientists Seek to Justify and Continue Unethical Research by Gutting International Ethical Guidelines

WASHINGTON, D.C. -- Public Citizen, reacting to two articles in this week's *New England Journal of Medicine*, today criticized attempts to rewrite the World Medical Association's Declaration of Helsinki, which governs international research ethics. As Dr. Robert Levine, the author of one of the articles, admits, the Declaration's requirements are routinely violated.

"The research industry's solution to these flagrant violations of the Declaration is to water down the Declaration until it meets the low ethical standards many researchers currently practice," said Dr. Peter Lurie of Public Citizen's Health Research Group. "Our solution is to step up enforcement of the Declaration."

This debate results in substantial part from Public Citizen's 1997 exposure of unethical research funded by the National Institutes of Health (NIH) and the Centers for Disease Control (CDC) in Africa and Asia. In these studies, thousands of HIV-positive pregnant women were provided placebos instead of the known effective medication AZT. The debate over those studies is described by Dr. Levine as "the most acrimonious controversy over the ethics of clinical trials in recent memory."

Much of the drive to revise the Declaration of Helsinki comes from the NIH and CDC, but the rapidly growing human experimentation corporations (HECs) would also benefit from the proposed changes.

"The NIH is trying to do for research ethics what Nike has done for wages and working conditions in developing countries," said Dr. Lurie. "As elsewhere in the globalizing economy, we are witnessing a race to the ethical bottom."

Moreover, the changes to the Declaration of Helsinki are just part of a coordinated assault on long-held ethical principles. Similar changes are proposed for the Council for International Organizations of Medical Sciences (CIOMS) ethics documents. The most recent version of a

Ralph Nader, Founder

1600 20th Street NW • Washington, DC 20009-1001 • (202) 588-1000

United Nations AIDS Programs HIV vaccine trials ethics document includes similar proposals. All three of these documents have been written primarily by Dr. Levine.

“These changes would formalize double standards based on economics, convenience and efficiency that should be anathema to any physician or patient,” said Dr. Sidney M. Wolfe, Director of Public Citizen’s Health Research Group.

###

A detailed critique of some proposed changes to the Declaration of Helsinki, including a table summarizing these changes, can be found on Public Citizen’s website at <http://www.citizen.org/hrg/PUBLICATIONS/1477.htm>

Public Citizen’s comments on the UNAIDS vaccine guidelines can be found at <http://www.citizen.org/hrg/PUBLICATIONS/1471.htm>