

Press Release  
19 Dec. 2006

## **New AIDS Study is Flawed and Biased Scientists Say There's No Proof Taking AIDS Drugs is Better Than Taking Nothing**

Responding to a study on AIDS drugs published in the Nov. 30, 2006 issue of the *New England Journal of Medicine (NEJM)*, scientists from the non-profit public interest group Rethinking AIDS\* (RA) state the trial's conclusions are flawed and that the idea that AIDS drug interruptions are dangerous is based on unproven assumptions. According to Dr. Etienne de Harven, a pioneer in virology research and electron microscopy and President of RA, "The *NEJM* study does not provide evidence that taking AIDS drugs is better than not taking them. Unfortunately, incorrect conclusions drawn by the study's authors, 14 of whom receive some form of monetary compensation from manufacturers of AIDS drugs, have been repeated in the media and touted by a number of AIDS organizations."

In the *NEJM* paper, about half of the participants were assigned to take antiretroviral drugs continuously, while the others stopped taking drugs when the number of CD4 immune cells in their blood rose above a certain level (350 per cubic millimeter), and resumed taking drugs when CD4 counts dropped below 250. The study's authors concluded that people interrupting antiretroviral therapy were 2.5 times more likely to die or become ill from AIDS diseases and were also 70 per cent more likely to develop "non-AIDS-related" events such as heart, kidney or liver problems. Based on these findings, Dr. Anthony Fauci, head of the U.S. National Institute for Allergy and Infectious Diseases which funded the study, concluded that "doctors should no longer offer treatment breaks without at least monitoring the amount of virus circulating in a patient's blood. "I think for practical purposes, it is the end" of treatment interruptions.

"But a closer look at the trial reveals that it is misleading and the conclusions drawn by the authors are unfounded and biased," says Dr. de Harven of RA, an international watchdog group of medical doctors and scientists ([www.rethinkaids.net](http://www.rethinkaids.net)). Among RA's criticisms:

- The study used no control group of HIV-positives with CD4 helper cell counts over 350 who were not taking any medication in order to provide a baseline measure for health.
- The experiment was unblinded – both doctors and patients knew which group engaged in treatment interruptions – affecting expectations and interpretations.
- There was no "measure of adherence" which raises questions about which group took more drugs. People on continuous therapy may have stopped taking drugs due to side effects and stayed off while failing to report this to doctors, a common occurrence when drugs are administered in clinical settings.
- The study did not consider withdrawal symptoms from stopping these drugs quickly. People on intermittent therapy may have gone back on drugs due to symptoms (or low CD4 counts), making their treatment appear continuous.
- The study claims "only 8% of deaths were due to opportunistic disease." However, there were 65 cases of adverse events known to be caused by AIDS drugs – major renal, cardiovascular or hepatic disease – in the interrupted group but only 39 in the continuous group. Since these diseases are common side effects of AIDS drugs, it may indicate that the interrupted group actually took more drugs than the group on continuous therapy.
- The AIDS drugs used during the study varied from person to person, introducing unaccounted for variables into the study.

- Although the study shows that episodic use of antiretroviral drugs is inferior to continuous use, it does not provide evidence that taking antiretrovirals is better than not taking them.
- CD4 helper cell counting was the primary lab marker used in the study despite questions of its reliability as a marker for clinical health. For example, the 1994 Concorde Study questioned the use of helper cell counts as a diagnostic method for AIDS – and the 1996 paper, “Surrogate endpoints in clinical studies: are we being misled?,” published in *Annals of Internal Medicine* concluded that CD4 count in the HIV setting is as uninformative as “a toss of a coin.” A 2006 study by the World Health Organization published in the *Journal of Infectious Diseases* concludes that CD4 counts may be “less reliable” measures of immune competence than previously believed.
- While Dr. Anthony Fauci concludes the study shows that “doctors should monitor the amount of virus circulating in a patient’s blood,” the latest studies confirm that PCR viral load tests – the standard used since 1996 to assess patient health, predict progression to disease, and grant approval to new AIDS drugs – are not reliable indicators or predictors of illness. A Sept. 2006 study published in the *Journal of the American Medical Association* of more than 22,000 HIV positives showed viral load measures failed in more than 90% of cases to predict or explain immune status, showing little correlation between viral load (supposedly a measure of the amount of virus) and CD4 cell counts (supposedly a measure of the damage done by the virus).
- Among the *NEJM* study’s authors, 14 reported receiving consultancy fees, advisory fees and other payments from pharmaceutical companies that make HIV medications. RA commends the media outlets, including CBC News and Associated Press, that reported this important conflict of interest.

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**\*About Rethinking AIDS** ([www.rethinoids.net](http://www.rethinoids.net)):

In 1991, an international group of renowned scientists and medical doctors joined under the name “Rethinking AIDS” with the following mission statement: “It is widely believed by the general public that a retrovirus called HIV causes the group of diseases called AIDS. Many biochemical scientists now question this hypothesis. We propose that a thorough reappraisal of the existing evidence for and against this hypothesis be conducted by a suitable independent group. We further propose that critical epidemiological studies be devised and undertaken.” (*Science*, 1995, vol. 267, pp. 945-946). Among RA’s founders: Harvard microbiologist Dr. Charles Thomas; 1993 Nobel Laureate for Chemistry Dr. Kary Mullis; co-founder of *Nature Biotechnology* Dr. Harvey Bialy; Yale mathematician Dr. Serge Lang and UC Berkeley molecular biologist Dr. Peter Duesberg, both members of the National Academy of Sciences; Professor of medical physics at the Royal Perth Hospital in Western Australia Eleni Papadopulos; and professor emeritus of public health at Glasgow University and WHO consultant Dr. Gordon Stewart. RA’s current president, Etienne de Harven, is a professor emeritus of Pathology at the University of Toronto and a former cancer researcher at Sloan Kettering Institute, New York (1956-1981). De Harven produced the first electron microscopic studies of a retrovirus (the murine Friend leukemia virus) and was co-director of the Electron Microscopy Laboratory at the Banting Institute, Department of Pathology, University of Toronto.