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ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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April 11, 2005

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The Honorable Elias Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

On April 29, 2004, the Committee on Energy and Commerce sent the National Institutes of Health (NIH) a confidential request concerning questions raised about the findings of the HIVNET 012 study. In 1997, the Division of Acquired Immunodeficiency Syndrome, National Institute for Allergies and Infectious Diseases, sponsored HIVNET 012, a trial comparing two drugs, nevirapine and zidovudine (AZT), and their efficacy in the prevention of transmission of Human Immunodeficiency Virus from mother to child. The findings of this landmark study have been relied upon in the establishment of global strategies for addressing the AIDS crisis. We asked the NIH to answer the following question:

After a comprehensive review of all records and information relating to HIVNET 012, does NIH stand behind the findings of HIVNET 012?

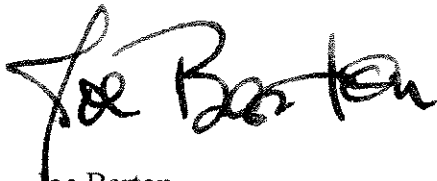
In response to the Committee's request, you asked several of your staff to review the records and information relating to the HIVNET 012 study and other related studies. On July 12, 2004, you informed the Committee that you had decided to ask the Institute of Medicine (IOM) to conduct a more detailed independent review of the HIVNET 012 study process.

The IOM released its report on the HIVNET 012 study on April 7, 2005. The Committee staff also received a briefing by members and staff of the IOM on the IOM's review of the HIVNET 012 study. Based on that briefing and on that IOM committee report, we are now satisfied that the data and findings presented in the published papers can, as the report says, "be relied upon for scientific and policy-making purposes." We believe that the NIH's request of the IOM for this review has proven useful and has served to clarify the public health and medical case for the use of nevirapine for the prevention of mother-to-child transmission of HIV. We appreciate your assistance in this matter.

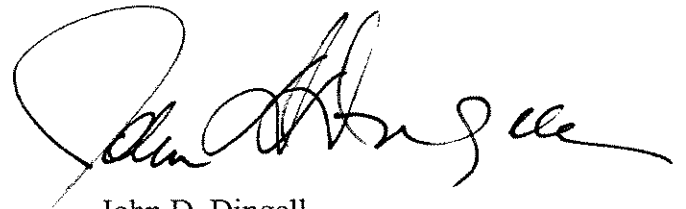
Having said that, and acknowledging the consensus that the drug is useful and the published reports valid, the Committee still remains interested in the NIH's review of the research trial itself and of the concerns raised about it. As you know, the IOM explicitly did not "examine either NIH's handling of the HIVNET 012 trial or the process of research oversight at NIH." Questions remain about both of these issues. Committee staff will be in touch with your office about these additional matters.

Thank you again for your assistance. If you have any questions, please contact Alan Slobodin, Majority Committee staff, at (202) 225-2927, or David Nelson, Minority Committee staff, at (202) 226-3400.

Sincerely,



Joe Barton
Chairman



John D. Dingell
Ranking Member