AIDS treatment ATAC activists coalition
Drug Development Committee

PRESS RELEASE

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AIDS Activists Respond to NIH Decision on Overriding HIV Drug Patent

(NEW YORK, August 5) — AIDS activists expressed disappointment with a recent decision of the National Institutes of Health (NIH) regarding the patent for Norvir, an HIV medication made by Abbott Laboratories, Inc. In an official statement released yesterday, Dr. Elias A. Zerhouni, NIH Director, stated the NIH's official decision not to override the patent on Norvir. The NIH held a public hearing regarding the Norvir patent on May 25, 2004, as a result of a petition claiming that a 400% increase in the drug's price in December 2003 adversely affected reasonable consumer access to the drug, which was developed in part with government funding.

The petition was filed under the Bayh-Dole Act, which allows the government to exercise "march-in" rights on a patented agent thereby allowing the drug to be produced by generic competitors. This authority has never been exercised since the Act was passed in 1980. The petition was filed by Essential Innovations, Inc., a nonprofit corporation, with the support of healthcare providers, some members of Congress, and patient advocacy groups such as the AIDS Treatment Activists Coalition (ATAC).

Robert Huff, of Gay Men's Health Crisis (GMHC) in New York said, "It's disappointing that the NIH rejected this petition without an on-the-record examination of the issues." Mr. Huff testified during the hearing last May in Bethesda, Maryland.

"ATAC's Drug Development Committee is entirely dissatisfied with the NIH's decision denying Essential Inventions' Bayh-Dole petition. This is a perfect example of the pro-industry climate fostered under the current presidential administration," remarked Lynda Dee, of AIDS Action Baltimore and co-chair of ATAC's Drug Development Committee. "Pharmaceutical company influence, as well as

increased scrutiny and criticism of research and funding at NIH, helped cement this outcome. Meanwhile consumers with a life-threatening illness are shuffled from one government bureau to the next with no help in sight." Ms. Dee also testified at the Bayh-Dole hearing.

Norvir is a protease inhibitor used to treat HIV but more commonly used now in small doses as a key agent to help make other HIV drugs more potent. The price of Abbott's other protease inhibitor, Kaletra, did not change, despite containing Norvir in its formulation. HIV therapies that require Norvir as a component are now significantly more expensive than Abbott's Kaletra option, leading some to accuse Abbott Laboratories of anticompetitive pricing activities.

Abbott's price hike has sparked a furor among healthcare providers, most notably members of the American Academy of HIV Medicine (AAHIVM) and the HIV Medicine Association (HIVMA), as well as the HIV activist community. Congressional leaders from both parties have taken interest in this issue and have issued letters requesting further investigation of the Norvir price increase. Currently, probes against the company by Attorneys General in New York and Illinois are still pending as are a class action filed in California and a complaint filed with the Federal Trade Commission (FTC).

"While the NIH decision is disappointing, it is not surprising. The Norvir price hike is an unprecedented departure from historical pharmaceutical industry pricing practices. Why is a Kaletra-based regimen now the cheapest Norvir-containing option on the market? As Dr. Zerhouni noted, these issues must be addressed by Congress, the FTC, or the courts. In any case, the American consumer cannot afford to let Abbott's action stand," stated Dr. Benjamin Young, a Denver physician who treats HIV and a co-founder of Organized HIV Healthcare Providers (OHHP), which formed soon after Abbott raised the price of Norvir.

The AIDS Treatment Activists Coalition (www.atac-usa.org) is a national coalition of AIDS activists, many living with HIV/AIDS, working together to end the AIDS epidemic by advancing research on HIV/AIDS.

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