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**NIH OFFICE OF TECHNOLOGY TRANSFER**

**OPEN MEETING ON BAYH-DOLE PETITION**

**REMARKS OF BENJAMIN YOUNG, MD PhD**

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Good morning. My name is Benjamin Young. I am a HIV specialist physician in from Denver, Colorado. I am also a clinical instructor of medicine at the University of Colorado Health Sciences Center.

I would like to thank the National Institutes of Health for giving me the opportunity to speak at this meeting.

I represent the Organization of HIV Healthcare Providers, a newly formed coalition of the nation's leading HIV doctors. OHHP organized as a completely self-funded organization, dedicated to improving care for people living with HIV. We operate independently, without financial support from the pharmaceutical industry or government. We organized because the actions of Abbott Laboratories threaten our patients and their communities; Abbott's actions threaten the very financial nature of paying for medications in this country.

I am neither an attorney nor a professional lobbyist. I am a doctor that has seen the worse and the best of the HIV epidemic. I am a doctor that has seen the worse and the best of pharmaceutical company citizenship.

I am here today to discuss Abbott Laboratory's 400 percent increase in the price of Norvir, a life-saving HIV medication. Others today have spoken about the history of the development of Norvir and the legal aspects of the Bayh-Dole act. I am here to speak from the perspective of a doctor involved in drug discovery and a doctor involved in life-saving patient care.

In the mid-1990's, as a physician in training, I cared for hundreds of young men with AIDS. Nearly all of them are now dead, because of effective HIV therapies were not yet discovered.

In the winter of 1995-6, the first HIV protease inhibitors were approved for use in the United States. The discovery of protease inhibitors capped an incredibly productive collaboration between government and industry. Ritonavir was developed in this public-private setting. In this period, NIH-funded studies such

as AIDS Clinical Trials Group studies 315 and 320 were among the first to demonstrate that combination therapies could stop HIV and restore immune system health. I was a research fellow assigned to the ACTG 315 study. Across the country and the developed world, the death rate from HIV/AIDS plummeted; the rates of AIDS complications fell as well. This means that HIV medications improved both quantity and quality of life for persons with HIV infection—for those who had access to these drugs. Countless thousands of American lives have been saved since that time; it is now rare to see death among the patients that I currently care for. The contribution of this governmental-pharmaceutical collaboration and investment in drug discovery is measured, every day, in the faces and productive lives of the hundreds of persons for which I currently care.

Norvir, like many of the early HIV protease inhibitors or PIs, were bitter pills to swallow. Side effects, such as relentless nausea and vomiting and high pill counts made these life-saving drugs difficult to take. Side effects so difficult, that in one survey, patients would rather die prematurely than to suffer from drug side effects. The market share for such difficult-to-take medications declined as soon as easier options became available.

Fortunately for Abbott Laboratories, Norvir found new life, not as a HIV protease inhibitor, but as a pharmacologic “boosting” agent. This means that Norvir can increase the levels and effectiveness of other protease inhibitors. There is no practical drug substitute for Norvir. The active compound of Norvir, ritonavir is now an essential component of nearly all protease inhibitor-containing HIV regimens, including Abbott’s own Kaletra. Ritonavir-boosted PI-containing regimens are the standard of care for initial HIV treatment, as endorsed by the Department of Health and Human Services March 2004 Treatment Guidelines.

Norvir’s role extends far past that for initial HIV therapy. It is estimated that approximately 50% of American HIV patients under care have some degree of drug resistance. This means that conventional, unboosted medications would have limited or no effectiveness. Ritonavir-boosted protease inhibitor-containing regimens have shown remarkable efficacy in regaining control of many of these drug resistant strains of HIV.

Taken together, these points dictate that through Norvir, Abbott Laboratory holds a virtual monopoly stake in the life expectancy of the majority of Americans living with HIV.

Not coincidentally, the newest HIV protease inhibitors, atazanavir and fosamprenavir, are optimally prescribed using Norvir boosting. These new drugs promise improved side effect and toxicity profiles for our patients. Bristol MyersSquibb and GlaxoSmithKline, the makers of these drugs purchased Norvir at full cost during their development phase and will by necessity, market Norvir to sell their products. Furthermore, all three of the next generation of HIV protease inhibitors will require Norvir boosting. For the consumer, the increase in Norvir

price effectively raises the daily cost of therapy from $6 to $48 per day. In essence, other pharmaceutical companies have provided free research, development and marketing support to Abbott. Abbott holds a virtual monopoly stake in future HIV protease inhibitor development.

Abbott has successfully developed its own boosted HIV protease inhibitor, lopinavir. Since Abbott coformulated lopinavir with ritonavir into a single product called Kaletra, facilitated a lower pill burden and fewer copayments to consumers. The fact that there are no other co-formulated PIs bears testimony to the monopoly that Abbott holds with Norvir.

A study by Dr. John Bartlett of Johns Hopkins University showed that HIV treatments with lower pill counts are associated with improved adherence and clinical effectiveness of HIV therapies. The failure to achieve coformulation of other boosted PIs is proof of Abbott's monopoly position with Norvir boosting. The lack of other co-formulated boosted PIs suggests that Abbott's monopoly may jeopardize the health of patients who must take other boosted PIs.

Furthermore, the fact that Kaletra's price did not rise in concert with Norvir means that American HIV consumers pay more for other boosted protease inhibitors. This discrepancy has not gone unnoticed— consumer groups, state attorneys general and members of both houses of the United States Congress have alleged that Abbott is in violation of federal antitrust law.

The 400% increase in the price of Norvir is unprecedented in the history of the pharmaceutical industry. Previous attempts by Burroughs Wellcome to raise the price of another HIV drug by 40% were met with objection and the company rescinded the increase. That this price increase comes at a time of unprecedented company profit does not go unnoticed. That the price increase comes at a time of skyrocketing healthcare costs does not go unnoticed.

The Canadian price for Norvir is approximately 10% of the price that American consumers pay. Abbott shareholders can rest assured that the drug is not sold at a loss in the Canadian or European marketplace. But the nearly 10-fold difference between the Canadian and American price for Norvir has not gone unnoticed, either. This singular price differential provides the strongest support for those who favor importation of medications from Canada and the European Union.

Abbott has attempted to reduce the impact of the price increase to the public sector—emblematic of corporate recognition of the unprecedented nature of the Norvir price increase. Yet, despite promises that no publicly funded agency would see price increases, state ADAP programs have been affected.

My home state Colorado is home to 1% of the American HIV-infected population, but 25% of the country's 1,300 persons waiting to receive the promise of life-

saving medications. That the Norvir price increase comes at a time when more and more American HIV patients cannot afford life-saving medications or are on such waiting lists to receive life-saving medications is nothing short of outrageous. Abbott's price increase is an egregious example of unmitigated corporate greed and monopolistic behavior.

Abbott's unprecedented price increase has been met with unprecedented physician response. Indeed, never before in the history of HIV medicine has the actions of one pharmaceutical company angered so many doctors. Across the country, doctors have resigned their consultant's relationship with the Abbott and refuse to permit Abbott representatives in their offices. Last week, the 1,800 member-strong American Academy of HIV Medicine sent a letter stating that Abbott's attempts to mitigate the impact of the price increase are not enough, and that the American HIV/AIDS care system may be "egregiously compromised". Abbott's leadership has attempted to marginalize OHHP physician protest, calling doctors who oppose the Norvir price increase an insignificant "lunatic" voice. But highly respected physicians from University, community and private practice, from all over America have joined in voicing strong opposition to the price increase. Many OHHP members have signed a petition in support of implementation of the march-in provisions of the Bayh-Dole Act.

Last week, in a remarkable bipartisan effort, the chairman and ranking member of the Senate Commerce Committee asked the Federal Trade Commission to investigate Abbott's market practices. The Senate Commerce Committee has a history of monitoring and investigating unfair market practices, including its recent investigation of Enron. Chairman John McCain said that Abbott's actions are "unconscionable" and that "taking such unscrupulous actions to maximize their bottom line, at the expense of patients suffering with AIDS. It is appropriate to investigate any potentially questionable anticompetitive behavior". Ranking member Ernest Hollings said that the Norvir price increase "appears to be monopolistic profiteering on a drug developed with taxpayer money" and has "put the marketplace at risk". In separate commentary, Colorado Senator Ben Nighthorse Campbell said: "[A] profitable pharmaceutical industry is essential to improve lives and health. Whatever the reason, Abbott Laboratories' 400 per cent price increase of Norvir threatens access to life-saving medications."

In supporting Essential Inventions' petition to implement the march-in provisions of the Bayh-Dole Act, it is critical to recognize our support of pharmaceutical industry profit. Pharmaceutical profits are the engine of drug discovery; drug discovery has improved the lives of everyone. The principle of an unregulated pharmaceutical industry requires adherence to an unwritten rule of corporate citizenship. Corporate citizenship does not start with corporate donations to the developing world or to non-profit organizations, but rather begins with corporate policies that are sensitive both to the needs of shareholder and consumer alike.

A 400% in the price of a publicly-supported, life-saving product eight years after initial FDA approval, in my view, is patently unethical and violates any semblance of corporate citizenship.

The most sinister aspect to Abbott's increase in the price of Novir is the precedent that this sets for the entire pharmaceutical industry. I've alluded to the impact that the 10-fold price difference between the American and Canadian consumer means for those who support Canadian product importation. But even within the United States, Abbott has created a two-tiered price structure for Norvir: privately-insured and private-paying American taxpayers pay 5-times more than those who receive their medications through publicly-funded drug assistance programs. Abbott says that this situation is "unique" and does not have implications to other drugs or other aspects of the pharmaceutical industry. We are not so naïve to think that other pharmaceutical companies are not already monitoring how the Norvir pricing situation is resolved, as there are those who would like to see a 400% increase in revenue for their products too. Imagine the price of your essential product increasing 5-fold overnight; imagine the price of gasoline increasing from $2 to $10 per gallon. So today, it's a HIV medication. Perhaps tomorrow it will be a life-saving drug for breast cancer or Alzheimer's disease.

Abbott Laboratories' price increase of Norvir is unprecedented and unethical. Without remediation, the entirety of the pharmaceutical industry will likely see regulated prices or importation. I believe that the Essential Inventions petition before you is a rational and justifiable remedy that protects both the pharmaceutical industry and the taxpaying, prescription medication-consumer public from egregious corporate actions.