NIH OFFICE OF TECHNOLOGY TRANSFER
OPEN MEETING ON BAYH-DOLE PETITION
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REMARKS OF LYNDA DEE, J.D.
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CO-CHAIR DRUG DEVELOPMENT COMMITTEE

Good morning. My name is Lynda Dee. I am Co-Chair of the Drug Development Committee of the AIDS Treatment Activist Coalition.

I am became an AIDS activist when my husband was diagnosed with AIDS in 1986. In those days, there were absolutely no anti-HIV medications available to people with AIDS. Garey Lambert and I co-founded AIDS Action Baltimore in 1986. Garey Lambert died in 1996, about two weeks before Norvir was approved. Abbott Laboratories (Abbott) did not bother to initiate the customary expanded access program for Norvir. Garey might still be here today if Abbott would have spent the money necessary to make Norvir available to patients pre-approval like every other HIV drug company does.

The Drug Development Committee wanted my Co-chair Matt Sharp to speak here today. Unfortunately, Matt is recuperating from a hospitalization and is unavailable. He would have told you that he is currently receiving Norvir via a tipranivir clinical trial, but does not know how he will access Norvir once that trial is completed.

Abbott would have you believe that no patients have been adversely affected by this unprecedented 400% price increase. I'm here to tell you that this is patently false. Abbott claims that Norvir prices to ADAPs (AIDS Drug Assistance Programs) have not been increased. What they have not told you is that ADAPs are as many and varied as the 50 states. There is not one set formula across the country. For example, NASTAD (National AIDS State & Territories AIDS Directors) informs us that as of June 2003, 24 states pay insurance co-pays. When co-pays are increased, state payments are increased. The picture is even more complicated in states like Minnesota where once a patient reaches a maximum amount of ADAP co-pay coverage, Minnesota Medical Assistance begins to pick up the tab. The point is that budgets of state governments are being affected even with Abbott's current Norvir pricing policy.

What about patients whose Medicaid and Medicare plans are administered by managed care insurance companies? For example, Arizona and other states with these arrangements are paying full price for Norvir.

What about the patients that pay co-insurance payments, like 80/20 percentages? I

received this e-mail from a Norvir patient that illustrates this issue. “My daily dosage of Norvir is 8 100mg capsules. The price for a 30-day supply from CVS Drugs increased from $299.04 at the beginning of 2003 to $431.60 in December (2003). Imagine my shock when I picked up my first 2004 refill last month and saw that the price was now $2,179.50!” Abbott’s claim to offer free Norvir to patients without insurance won’t help this person. Abbott also tells us that this person represents 5% of privately insured patients. This represents thousands of people who will not get relief from the 30-pill count bottle remedy instituted by Abbott.

Abbott also claims that it will provide free Norvir to patients who have insurance that provides maximum limits of insurance coverage. This policy fails to address the fact that this unconscionable increase will serve to bring people to their maximum coverage much more quickly. Who will pay for the other drugs that must be taken in combination with Norvir? (A full treatment 1200mg dose will now cost over $45,000 per year, and a 200mg boosting dose will cost nearly $800 per year. Remember, this must also be combined with the cost of two, three of even more other anti-viral drugs.)

We received information from a patient about an alarming prescription drug coverage change from Regence Blue Cross/Blue Shield of Oregon. His old benefit covered 50% of all prescription drug costs, with a $5,000 out-of-pocket maximum to be paid by the patient annually. The new coverage pays only 50% up to $10,000, with a maximum of $5,000 to be paid by Regence annually. Prescription coverage is already changing as a result of high drug costs. In both co-insurance instances, patients will eventually revert back to government assistance programs.

What about private insurance? In a letter to physicians, Abbott has claimed that private insurance will cover the entire cost of this enormous increase and that premiums will not be affected. Dr. Jeffrey Leiden has stated that insurers have continued to cover Norvir and that co-pays haven’t increased. Maybe he can explain to us how insurance companies can provide increased coverage without increasing premiums and co-pays.

I ask you, are your insurance premiums increasing or decreasing? Are your insurance companies covering more or less services and drug costs? Abbott would have you believe that private insurance is an endless money pit. We all know that nothing in life comes free. We pay for things one way or the other!

Using Abbott’s own facts and figures, we can calculate the approximate cost this astronomical price increase has levied on private insurance. The average annual 200 mg booster dosage cost rose from $1500 to $7800. Dr. Leiden has stated that 42% of Norvir patients have private insurance. The company has also stated that 22,000 US patients take Norvir. Thus, (22,000 x .42) x ($7,800 - $1,500) = $58,212,000.00. Abbott’s price increase for one drug, only one drug is costing private insurers approximately 58 million dollars per year!

Abbott received a NIAID grant for Norvir preclinical development. Do we want the our government to stop conducting or contributing to drug research? Of course not! The

idea that the government contributed to Norvir's development costs only serves to illustrate how Abbott is attempting to work the system both coming and going. Abbott's public relations machine is using fear tactics calculated to alarm scientists and universities, erroneously suggesting that granting this petition will halt government research support to both academia and Industry. This is not our intention and couldn't be further from the truth.

Essential Innovations, Inc. estimates that Abbott's contribution at the clinical stage was a modest $15 million. FDA approval was based on a three clinical trials in a mere 1,583 patients, less than 30% of the usual number of patients generally utilized for big pharma drug approvals according to Tufts University. Moreover, Norvir's development was extremely short in relation to other approved drugs. It was marketed only four years after Abbott received the NIAID pre-clinical grant and one year after key patents were filed. No pivotal trials lasted more than 48 weeks.

FDA Approval was expedited and granted within 70 days of its New Drug Application (NDA) filing. All these factors support the notation that Norvir was relatively inexpensive to development compared to other approved drugs. To illustrate this point, let me share a personal story with you. My friend Spencer Cox was the community representative on the Norvir FDA Antiviral Advisory Panel. Spencer's Norvir FDA package consisted of a booklet he read on the shuttle from New York's LaGuardia to National Airport. I was the community representative on the Crixivan hearing which occurred the next day. My crixivan FDA package consisted of boxes of data and trial summaries. My first comment was what a difference a day makes when it comes to the supporting data.

Abbott uses the tired old argument that price increases are needed to cover the cost of new HIV research and development. But what new HIV drugs is Abbott developing? Newer, more stable formulations are not next generation HIV medications, but will serve only to extend Abbott's Norvir patent rights.

As luck would have it, Norvir was able to overcome the ramifications of both its horrific full dose side effect profile and the pitfalls of HIV drug resistance because it is now primarily used as a protease inhibitor booster. As such, Norvir dosing is greatly reduced in most instances, resulting in significantly reduced side effects. It is also used as a boosting agent in conjunction with all but one currently marketed protease inhibitor, serving to also combat resistance. Thus, Norvir has been able to maintain its market share, unlike many older HIV antivirals that usually enjoy only a limited window of opportunity in this market.

Norvir has generated cumulative sales of more than $1 billion by 2001. Even without a price increase, reasonable estimates indicate that Norvir will generate more than $2 billion in sales over the next ten years as a result of its boosting properties. Instead of losing its initial market edge like other HIV drugs, Norvir continues to generate profits for Abbott. This is to say nothing of what Norvir's price increase will do to Abbott's competitors that need Norvir to boost their products for salvage regimens for patients

who need these drugs the most. Both Bristol-Myers Squibb (BMS) and GlaxoSmithKline (GSK) have recently approved protease inhibitors that require Norvir boosting for optimal efficacy. Boehringer-Ingelheim (BI) is extremely close to filing an NDA for its new protease inhibitor. The price of these new combinations just increased by at least $12,500.00. But the price of Kaletra, Abbott's own combination protease inhibitor has remained untouched. We believe that this is nothing less than pharma terrorism designed to steer insurance formularies toward Abbott's Kaletra.

Granting this petition would allow any drug company an open license to make generic Norvir available for combination with other PIs. Other companies could also co-formulate Norvir with their antivirals. Co-formulation requests to Abbott from other drug companies have consistently been denied. Think of the millions of dollars that could be saved and the increased Norvir access to US HIV patients that could be achieved!

For better or worse, a free market and fair competition has made the United States pharmaceutical Industry the worldwide giant it is today. Is it now the American way for taxpayers to foot the bill and incur all the risk associated with drug development while Abbott reaps all the benefit with no risks and also freezes competitors from the market place?

Abbott's 2003 fourth-quarter net income jumped 51% with US pharmaceutical sales continuing to drive growth. Net income increased from $627.1 million to $944.4 million. US pharmaceutical sales grew 28%. When is enough profit enough? Instead of being grateful that Abbott has maintained its market share over the years, Abbott executives have stated that the price increase reflects the fact that less Norvir is now sold and the price should reflect the importance of the drug. In other words, they're going to charge as much as they can get their greedy little hands on! They will charge whatever the market will bear, even if Norvir, and as a result of its increased price other anti-HIV medicines, are no longer available to some people in the United States. Just imagine these drugs being unavailable in the country responsible for their discovery to many of the people who actually volunteered their very bodies to ensure that they received FDA approval. It's unimaginable to us and we hope to you too!