ABBOTT LABORATORIES COMMENTS AT NIH PUBLIC MEETING REGARDING NORVIR® AND BAYH-DOLE MARCH-IN PROVISIONS

Following are remarks Jeffrey M. Leiden, M.D., Ph.D., president and chief operating officer, Pharmaceutical Products Group, Abbott Laboratories, delivered today at the National Institutes of Health public meeting regarding the Bayh-Dole march-in provisions for Norvir, Abbott's HIV/AIDS drug.

Bethesda, Maryland May 25, 2004 — Good morning. I am Dr. Jeffrey Leiden, president and chief operating officer of Abbott Laboratories' Pharmaceutical Products Group. I hold a medical degree as well as a PhD in virology, both from the University of Chicago. Before joining Abbott in August 2000 as chief scientific officer, I practiced and taught medicine – at Harvard Medical School and the Harvard School of Public Health, and before that at the University of Chicago. I am a member of the American Society of Clinical Investigation and the American Association of Physicians, a fellow of the American Academy of Arts and Sciences, and a member of the Institute of Medicine of the National Academy of Sciences.

I'd like to begin by saying that all of us at Abbott are very proud of the contribution that Abbott – and our scientists – have made to the treatment of HIV.

Abbott's pioneering science and investment of hundreds of millions of dollars in the research and development of our two HIV medicines, Norvir and Kaletra, have contributed to saving hundreds of thousands of lives and helped to make HIV a disease people can live with today as opposed to the death sentence that it was just a decade ago.

We care very much about the patients we serve. We understand that our decision to re–price Norvir in December of last year has caused concern and even anger in the HIV community – this was certainly never our intention.

While we respect the right of others to disagree with our decision, unfortunately, many of the concerns we've heard are the result of confusion and misinformation. So, we're grateful for the opportunity offered by this meeting to provide the facts about Norvir and our repricing action.

These are the facts:

1. Norvir was invented by Abbott scientists–no one else;
2. Abbott developed and brought Norvir to market where it has helped hundreds of thousands of patients as a result of Abbott's investment of more than 300 million dollars;
3. Abbott has taken extraordinary steps to ensure Norvir will not cost more for patients or government AIDS Drug Assistance Programs - called ADAPs - or for Medicaid programs as a result of the Norvir re-pricing;
4. Abbott has made Norvir widely available to patients therefore Bayh–Dole march–in rights do not apply to Norvir.

This morning I'd like to walk you through the facts supporting each of these statements—and to explain to you and most importantly to our patients what we did, why we did it and the steps we have taken to ensure that the drug will not cost more for patients or for ADAP and Medicaid programs.

Let me begin by giving you some background on the discovery and development of Norvir at Abbott and on the different roles that Norvir plays in HIV therapy. I want to specifically address the respective roles of Abbott and the government in the discovery and development of Norvir.

Norvir was solely the invention of Abbott and Abbott scientists – the drug was discovered in the laboratories of Abbott in Chicago by Dale Kempf, Hing Sham, Chen Zhao and Dan Norbeck. In fact, Dan Norbeck is here today, now head of our pharmaceutical discovery group as is John Leonard, who headed up Norvir clinical development. John now runs our global pharmaceutical development programs.

In 1988, Abbott received a small discovery grant from the NIH. The grant was part of an effort by the NIH to encourage collaborative research among pharmaceutical manufacturers and university research centers on protease inhibitors and to explore their potential to treat HIV, a then uncontrollable and fatal disease.

The NIH grant we received was approximately $694,000 a year for a period of five years, from 1988 to 1993, totaling $3.474 million, a fraction of Abbott's investment in HIV research during that same period. These funds were used to pay for expenses related to pre–clinical research for Abbott's early protease inhibitor research program.

In contrast, Abbott spent well over $300 million to discover and develop Norvir—over 100 times the entire amount of the NIH grant that supported our early HIV research program.

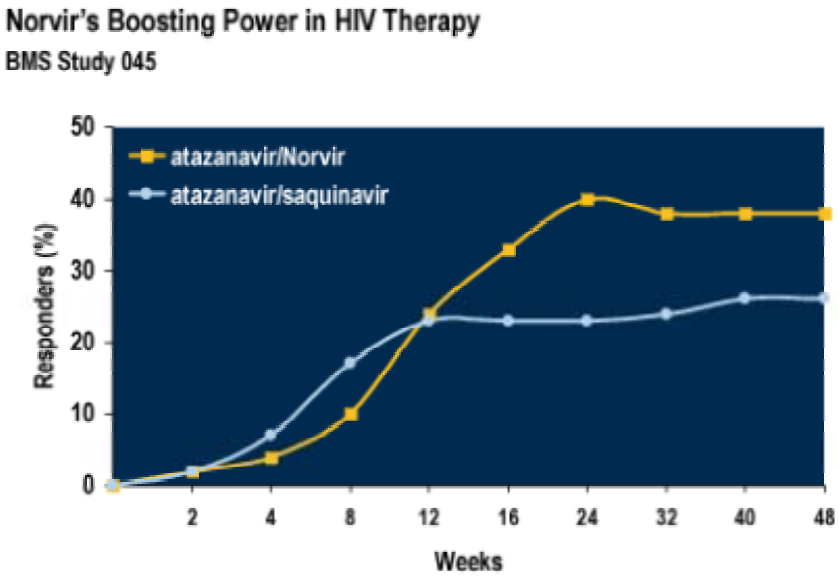
Let me be clear — we are certainly grateful for the NIH grant that supported our early HIV research, but it was Abbott scientists who charted the scientific path that led to the discovery of the Norvir molecule and Abbott funds — in excess of 300 million dollars — that supported the development of the drug. Indeed, Abbott has accomplished with Norvir precisely what the NIH grant was intended to do: support Abbott scientists in the discovery of a medicine that, through Abbott's subsequent research, development and commercialization, has improved, and contributed to saving the lives of hundreds of thousands of patients with HIV. In fact, Abbott's commercialization of Norvir is a perfect example of what the Bayh–Dole Act was intended to accomplish.

Norvir was originally launched in 1996 as a stand–alone HIV medicine to be taken at relatively high doses—approximately 1200 mg per day .

However, in the mid–to–late 1990s, Abbott scientists discovered that Norvir had a second, equally important role in HIV therapy — that it could be used at much lower doses – most commonly at 100 mg or 200 mg — as a boosting agent—that is that low doses of Norvir could increase the blood levels of many other HIV drugs and thereby make those other drugs more powerful in fighting the virus.

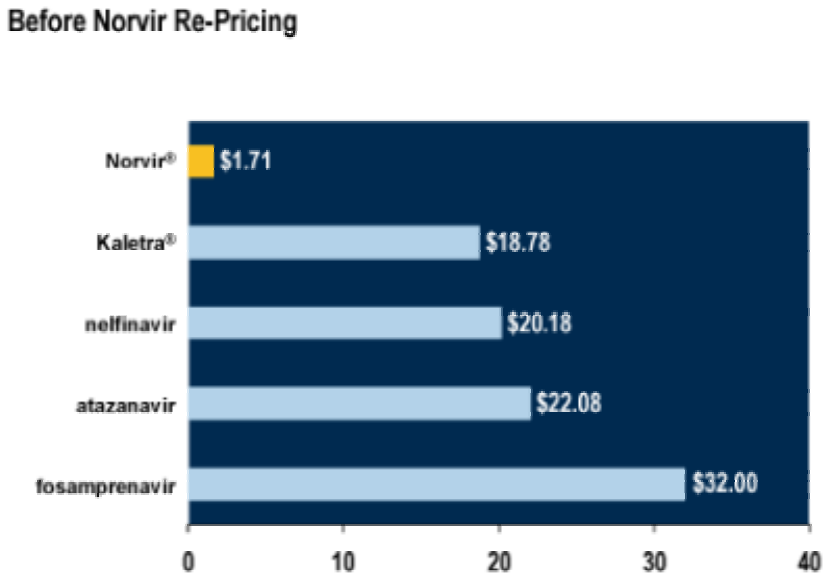
Essentially combining Norvir with other less effective HIV drugs makes those drugs better at fighting HIV, thereby extending and improving the lives of many thousands of additional HIV patients.

Let me provide you with an example of what I mean. The results of a recent clinical study carried out by one of our competitors compared the effectiveness of their newly launched protease inhibitor atazanavir either with or without typical low–dose Norvir booster therapy. The study was designed to show what percentage of patients essentially went into complete remission with total suppression of their viral load. Twenty-six percent of patients taking atazanavir without Norvir went into remission. However, the addition of low–dose Norvir booster therapy increased the effectiveness of atazanavir by almost 50 percent, allowing 38 percent of patients to go into remission.



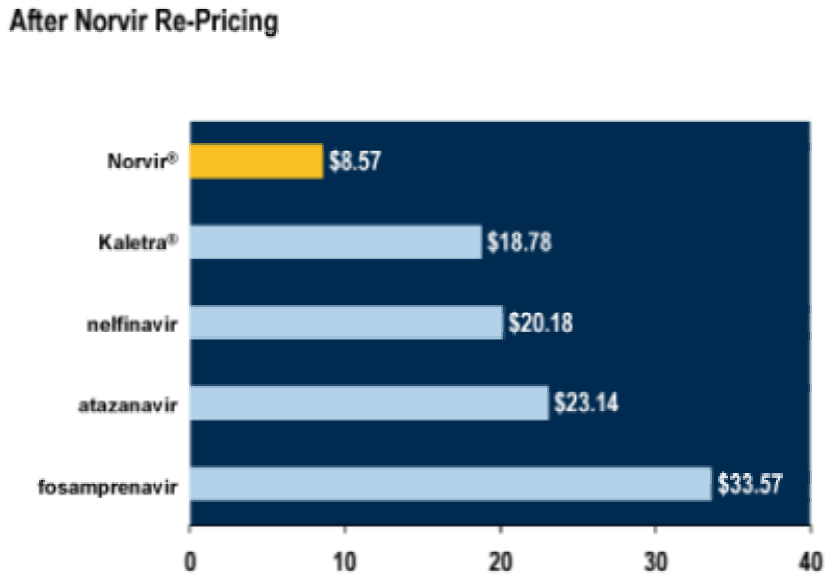
This is a dramatic example of the power of low–dose Norvir as a booster therapy. Similar data have been produced on the effectiveness of low–dose Norvir with many other protease inhibitors.

As we reviewed this data, what was striking to us was the disparity in the value of these different components of protease inhibitor therapy. Norvir at its most common boosting dose of 100 mg was priced at $1.71 per day. In contrast, the other protease inhibitors at their most common doses, were priced at between 500 percent and 1,800 percent higher than Norvir, that is at $10 to $32 per day.



So clearly the value of Norvir as booster therapy was not being properly recognized.

With these considerations in mind, we carefully re–evaluated the important role of low–dose Norvir as a booster therapy and re–priced low–dose Norvir from $1.71 per day to $8.57 per day. I should emphasize that even after the repricing, Norvir remains the lowest priced drug in its class at its most common dose and remains the lowest cost component of a typical HIV regimen. Other drugs in the class still cost up to 300 percent more than Norvir on a daily basis.



Next, I'd like to discuss why this re–pricing action was warranted. Today the Abbott pipeline is filled with promising new products that have the potential to diagnose, treat and cure many important and prevalent diseases – not only HIV, but cancer, diabetes, coronary artery disease, Alzheimer's Disease and rheumatoid arthritis, to name a few. As you know, new medicines cost hundreds of millions of dollars to develop. So it's critical that we capture the value of today's drugs to allow development of these new therapies in our pipeline as quickly as possible.

Turning research into new medicines for the benefit of patients is precisely what we are about at Abbott. And creating a climate that supports and encourages this process is exactly what Bayh–Dole is intended to do.

Many press releases and news reports have focused on the percentage of the Norvir re–pricing and unfortunately, what has been lost in that discussion has been the actions Abbott has taken for the benefit of Norvir patients.

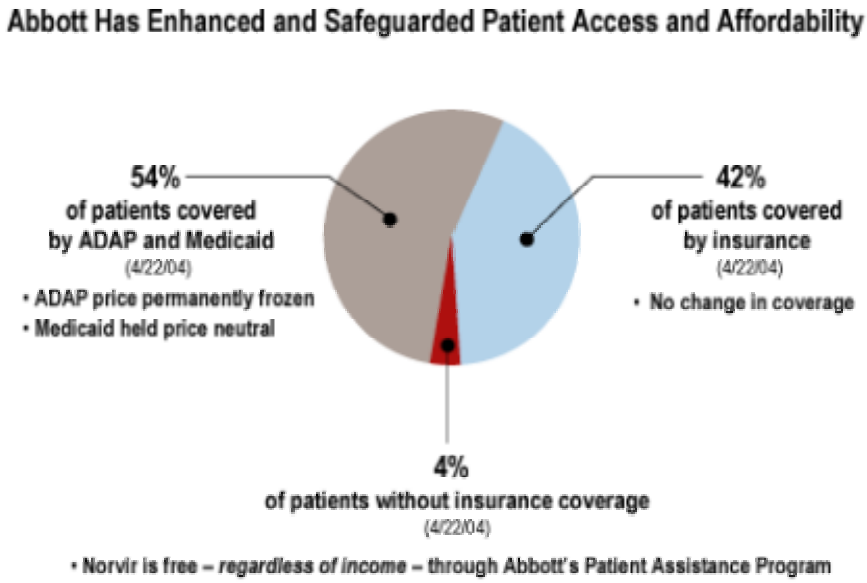
So, next and most importantly, I want to talk with you about what we did to ensure continued access and affordability for patients taking Norvir. Abbott is absolutely committed to ensuring that:

- First, not a single patient goes without Norvir because of the re–pricing.
- Patients will not pay more. We have eliminated income requirements for our patient assistance program such that if there are patients who are having difficulty getting Norvir, or paying for it we are ensuring that they get Norvir for free. Our patient assistance program number is 1–800–222–6885. In fact, Mary McAndrews, head of our Patient

Assistance Program, is here with us today to address any concerns that patients may have.
- And finally, Medicaid and ADAPs do not pay more due to the Norvir re-pricing.

In order to explain these programs, I need to give you a bit of background on how HIV medicines are paid for in the U.S.

- Approximately 54 percent of all HIV patients in the U.S. have their medicines paid for by two government programs: ADAP or Medicaid. Abbott has taken unprecedented steps to ensure that these programs and patients are not adversely impacted by the re–pricing of Norvir. In fact, we have permanently frozen the price of Norvir, at its former price, for ADAPs. We are the only company to permanently freeze the price of an HIV drug for this government program. In most instances, state Medicaid programs will end up paying less today than they did before the re–pricing. Further, we have contacted state Medicaid programs to address their questions and explain the steps we have taken to ensure that they will not pay more than they were before the re-pricing.
- For the approximately 4 percent of patients who do not have insurance and therefore need to pay cash for Norvir, we eliminated all income requirements or means testing for our Norvir Patient Assistance Program so that regardless of their income, these patients can receive free Norvir. We've already processed hundreds of applications this year. So, the fact is that today more patients have access to free Norvir than before the price increase.
- For the approximately 42 percent of patients who do have private insurance, those patients continue to have drug coverage. However, if for any reason a patient's insurance coverage runs out, our Patience Assistance Program will provide them with free Norvir.



Let me also address another aspect of the access question: the effect of our re–pricing on the protease inhibitor market.

In HIV, as in most diseases, physicians prescribe medicines based on what is best for their patients, not on the basis of price. So it's not surprising that Norvir's re–pricing has not affected

the market share for protease inhibitors. Since the re–pricing, the protease inhibitor market has grown slightly. Newer protease inhibitors continue to gain share, just as they were doing before the re–pricing, and Norvir's share itself has actually grown, likely due to its use in combination with newer protease inhibitors.

Much has been said and written about how the Norvir re–pricing would impact the sales of Abbott's other protease inhibitor, Kaletra. The accusation is that Kaletra would gain market share as a result of the re–pricing. In fact, Kaletra's market share has experienced no gain over the past two quarters and Kaletra has not benefited from the re–pricing of Norvir.

Given these facts, I'd like to conclude by considering whether Bayh–Dole is applicable to the Norvir situation, which is the central question to be addressed by today's meeting.

As we've heard from several speakers today, including Senator Bayh himself, the primary purpose of the Bayh–Dole Act is to foster public–private collaboration and to ensure that the public has access to the discoveries that flow from that collaboration and receives the benefits of innovative science sooner. The government can exercise its march–in rights only when the private industry collaborator has not successfully commercialized the invention as a product. Bayh–Dole was never intended to be a mechanism to determine prices.

Given what I've told you this morning, the Bayh–Dole march–in rights are clearly not applicable to Norvir.

Abbott has commercialized Norvir, made it available to the public and guaranteed access – free Norvir — to any patient who needs it and does not have adequate coverage, through our Patient Assistance Program. To the limited extent that NIH funding supported the research that led to the discovery of Norvir, this medicine can be viewed as a Bayh–Dole success story.

The authors of the Bayh–Dole Act understood that true advances in medicine and technology come from private sector investment. They understood that by providing selective financial incentives for further investment by the private sector, the public would end up being the true beneficiaries of the resulting advances.

Norvir, which has helped save the lives of hundreds of thousands of HIV patients, fully meets both the spirit and the letter of the Bayh–Dole Act. We believe there is no need for the NIH to proceed further in this matter. Thank you.