THE WALL STREET JOURNAL.

JANUARY 3, 2007

New Regimen: Inside Abbott's Tactics To Protect AIDS Drug

Older Pill's Price Hike Helps Sales of Flagship; A Probe in Illinois

By JOHN CARREYROU

In the fall of 2003, Abbott Laboratories grew worried about new competition to its flagship AIDS drug, Kaletra. Then it seized on an unusual weapon that helped Kaletra's global sales top $1 billion a year, even as it exposed Abbott to criticism that it was endangering patients.

The weapon was an older Abbott AIDS drug called Norvir. It is a key part of drug regimens that include rival companies' pills. Previously undisclosed documents and emails reviewed by The Wall Street Journal show how Abbott executives discussed ways to diminish the attraction of Norvir, with the goal of forcing patients to drop the rival drugs and turn to Kaletra.

At one point the executives debated removing Norvir pills from the U.S. market and selling the medicine only in a liquid formulation that one executive admitted tasted like vomit. The taste would discourage use of Norvir and competitors' drugs, the executives reasoned, and Abbott could claim it needed Norvir pills for a humanitarian effort in Africa. Another proposal was to stop selling Norvir altogether.

A third proposal carried the day: quintupling the price of Norvir. One internal document warned the move would make Abbott look like a "big, bad, greedy pharmaceutical company." But the executives expected a Norvir price hike would help Kaletra sales, and they bet any controversy would eventually die down.

They were right. Kaletra sales in the U.S. rose 10% over the next two years. Some objected that the price hike made it harder for patients who needed drug combinations pairing Norvir with non-Abbott pills to get their medicine. After an initial burst, the criticism faded, partly because Abbott exempted government health plans and AIDS drug-assistance programs from the Norvir price increase.

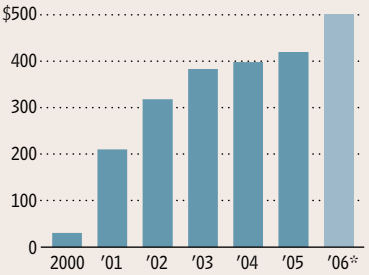
The debate at Abbott over Norvir provides a rare inside look at a pharmaceutical company's efforts to maximize profits and thwart competitors. The industry has come under fire in recent years for tactics such as heavy marketing of drugs that offer little advantage over older products and paying generic-drug makers to delay the introduction of cheap copycats. Norvir represents a twist in which a company took advantage of its monopoly over one drug to protect sales of another, more profitable one.

An Abbott spokeswoman, Melissa Brotz, says the company never seriously considered pulling Norvir from the global market or withdrawing the pill version in the U.S. Abbott denies raising Norvir's price to protect Kaletra and says the increase didn't hurt its competitors since their drugs continued to gain market share and they later raised their own prices. It says the price increase was intended to better reflect Norvir's medical value after years of being underestimated.

Illinois Attorney General Lisa Madigan has been investigating Abbott's price hike for three years, saying it may be an example of unfair pricing that violates the state's consumer-fraud law. A lawsuit filed in U.S. district court in Oakland, Calif., by two AIDS patients and the Service Employees International Union Health and Welfare Fund alleges that Abbott broke antitrust law by using its market power to boost Kaletra sales. The case is scheduled to go to trial in early 2008.

Prescription Boost

U.S. sales of Abbott Laboratories' AIDS drug, Kaletra, in millions:



Source: Abbott Laboratories *Estimate

In the 1990s, a new class of drugs called protease inhibitors revolutionized the treatment of AIDS. By impeding the human immunodeficiency virus's ability to reproduce itself, these drugs turned the disease from a death sentence into a chronic, manageable illness for many patients.

Norvir, which received Food and Drug Administration approval in 1996, is a protease inhibitor. Serious side effects prevented it from being used as a stand-alone drug. But Abbott found that at small doses Norvir boosted the effectiveness of other protease inhibitors. Norvir soon received wide use in the drug combinations taken by AIDS patients.

In 2000, Abbott introduced Kaletra, which combined a new Abbott-made protease inhibitor with Norvir in a single pill. Kaletra's effectiveness and convenience quickly made it the most popular AIDS drug, with 35% of the protease-inhibitor market by 2003 and annual U.S. sales nearing $400 million. By contrast, Norvir, when sold as a stand-alone drug, was bringing in less than $50 million a year in the U.S.

Then, in June 2003, Bristol-Myers Squibb Co. introduced a new protease inhibitor called Reyataz. Bristol-Myers presented a study it funded suggesting that Reyataz, boosted with Norvir, was as effective as Kaletra at holding HIV in check and had a better effect on cholesterol levels. Reyataz was also more convenient because it required fewer pills a day.

As Reyataz began gaining market share, Abbott executives considered ways to protect Kaletra sales. On Sept. 6, 2003, Jeffrey Devlin, Abbott's HIV marketing director, emailed a slide presentation to a colleague that discussed two options: quintupling Norvir's price, or withdrawing Norvir

pills from the U.S. market and leaving only the liquid version of the drug.

The pill withdrawal option would dramatically improve Kaletra's sales and cripple Reyataz, the presentation predicted, because the drug regimen that included Reyataz would suddenly become more expensive. It forecast that U.S. sales of Kaletra would grow by 20% to 30% between 2004 and 2006, while U.S. prescriptions of Reyataz would fall by 28% to 54% over the same period under the scenario. Anticipating that people would wonder why the Norvir pills were suddenly unavailable, the document recommended telling the American public that they needed to be sent "to the developing world (i.e. Africa)" as part of a humanitarian effort.

But Mr. Devlin fretted that forcing Americans to swallow Norvir in liquid form "will always be a tough sell." Abbott was keenly aware of the liquid's unpleasant taste. In a deposition the following year with investigators from the Illinois attorney general's office, John Leonard, Abbott's vice president of global pharmaceutical research and development, referred to liquid Norvir as "this fluid that has been—I'll just say it—characterized as tasting like someone else's vomit."

When Abbott briefly halted the production of Norvir pills in 1998 because of manufacturing problems, patients resorted to creative methods to block the liquid's foul taste. These included using a straw to shoot it to the back of their throats, coating their mouths with peanut butter or chocolate, and numbing their taste buds with ice or popsicles.

Foreseeing a backlash over the taste, Mr. Devlin recommended the price increase. But the liquid option stayed alive. On Sept. 12, 2003, Jesus Leal, then vice president of Abbott's virology franchise, recommended it in an email to a colleague. "Please don't be stunned by the outcome of the thought process," Mr. Leal wrote to her.

Mr. Leal's concern: A price hike on Norvir would be hard to justify. Abbott might claim it couldn't afford to produce the drug at the lower price, but it would face exposure "if forced to open books," he wrote. The liquid switch, on the other hand, would "minimize any federal investigations regarding price increases" he argued. Mr. Leal, who has since left the company, says today the email "was part of a long and vigorous debate within Abbott, and should not be taken out of context."

A slide presentation titled "HIV Communications Plan" and dated Sept. 24, 2003, reviewed the two options and added a third: pulling all formulations of Norvir from the global market. This radical step, the presentation said, would remove "pricing from public debate" and render moot any discussion of the liquid's taste. However, it noted that Abbott's "corporate reputation" would suffer.

As for the price-increase scenario, the document listed as a "Pro" that health insurers might stop covering Norvir, which would hurt sales of other protease inhibitors and force patients to use Kaletra. Among the cons, it cautioned that the move would "tarnish" Abbott Chief Executive Officer Miles White's debut as chairman of the Pharmaceutical Research and Manufacturers of America, the industry's trade group, and "position" Abbott as a "big, bad, greedy pharmaceutical company." Abbott says this slide presentation was made by a public-relations firm working for the company at the time.

In early October, as a second new protease inhibitor from GlaxoSmithKline PLC neared FDA approval, another internal document recommended the price increase. It warned that if Norvir's price wasn't raised, "the Abbott franchise will be severely threatened by the competitor's ability to 'piggy back' on Norvir's uniqueness." If Abbott took no action, it predicted, Kaletra prescriptions would fall 10% in 2004.

Price Check

Key events surrounding Abbott Laboratories' increase in the price of AIDS drug Norvir:

1996: Abbott introduces Norvir.

2000: Abbott introduces AIDS drug Kaletra, which includes Norvir.

June 2003: Bristol-Myers Squibb introduces Reyataz, a rival to Kaletra that is taken with Norvir.

September 2003: In internal documents, Abbott executives discuss pulling Norvir from global market, quintupling the drug's price, or withdrawing Norvir pills from the U.S. market and leaving only its foul-tasting liquid form.

October 2003: Company document warns Kaletra prescriptions will fall if Norvir's price isn't raised.

December 2003: Abbott quintuples Norvir's price.

February 2004: Illinois attorney general opens investigation into price increase.

Abbott declined to make Messrs. Devlin, Leonard and White available for comment. Ms. Brotz, the Abbott spokeswoman, says Mr. White, who remains chief executive, didn't know that lower-ranking executives discussed forcing Americans to take Norvir as a liquid or ending its sale altogether. She says the executives were just brainstorming and quickly discarded some of the options. These executives weren't decision makers, she adds.

However, in a court brief filed in the California case last year opposing a plaintiffs' motion to unseal the documents, Abbott said they "were prepared by and for some of the most senior officers at the company as part of an enormously important strategic discussion about Norvir."

In December 2003, Abbott implemented its final decision: a 400% price increase. Norvir's U.S. wholesale price rose to $257.10 from $51.30 for 30 100-milligram capsules. The move made Kaletra a cheaper option for American AIDS patients. It raised the cost of using a Reyataz/Norvir regimen by $2,504 to $11,187 a year. In the case of regimens requiring more than once-daily Norvir boosting, the cost rose by $5,000 or more a year. Kaletra at the time cost about $7,000 a year.

As Abbott had foreseen, the price hike triggered an uproar. AIDS activists protested in front of the company's suburban Chicago headquarters and at its annual meeting of shareholders. Three hundred doctors banded together to boycott Abbott products and barred company sales representatives from entering their offices.

Abbott exempted Medicaid, Medicare and state AIDS drug-assistance programs from the price increase. It also announced that it would expand its own patient-assistance program. This enabled the company to argue that the increase was being shouldered by private health insurers, not patients.

Hollis Salzman, a partner with Labaton Sucharow & Rudoff, one of the law firms that brought the California case, says the Norvir price hike still made it harder for some patients to get drugs they needed. "Abbott single-handedly turned back the clock on the treatment of AIDS," she says.

Allen Thornell, an AIDS patient and plaintiff in the California case, says the 20% co-payment required by his insurance plan at the time jumped to $1,000 a month from $400 when Abbott raised Norvir's price. The new co-payment represented a third of his take-home salary. As a result, Mr. Thornell, 36, says he had to quit his job as head of Georgia Equality, a gay and lesbian organization. His current insurance has a low fixed co-payment.

Ms. Brotz of Abbott says Mr. Thornell is not typical because most private health plans cap co-payments at a much lower level. She adds that people in his position are eligible for Abbott's patient- assistance program. "Our intention was that no patient be denied access to Norvir," she says.

The Norvir price increase also affected institutions that weren't ex-

empted, such as state prisons. The North Carolina Department of Corrections, which counts about 800 HIV-infected inmates, saw its Norvir costs rise to $95,000 in the first quarter of 2004 from $28,000 the previous quarter.

Abbott's move "created a huge price discrepancy" between Kaletra and rival drugs, says David Wohl, an associate professor at the University of North Carolina who works part-time treating infected inmates. Dr. Wohl resisted shifting patients to Kaletra unless he thought it was the best drug for them. He says resulting budget difficulties forced prisons to cut back on testing inmates for virus resistance.

In May 2004, the National Institutes of Health held a public hearing to consider a request by a consumer advocacy group that it authorize cheaper generic copies of Norvir to be made before the drug's patent expired. The NIH has legal authority to do that in cases where it has helped fund research into a drug, but it has never used this power.

John Erickson, a former Abbott scientist who did much of the research work on Norvir, spoke in favor of the request. He testified that it was unlikely Abbott would have funded Norvir's early development without a $3.5 million grant it received from the NIH in 1988. Abbott doesn't dispute the grant was important but says it also invested its own money in HIV research, including $300 million on clinical trials of Norvir. The NIH decided in Abbott's favor, saying it wasn't empowered to determine whether a drug's price was too high.

To justify the price increase, Abbott posted a cost-comparison chart on its Norvir Web site, showing that Norvir remained cheaper than other protease inhibitors. However, the chart implied that Norvir could be taken on its own at a 100-milligram dose when in fact it is approved at that dose only in combination with other protease inhibitors. The FDA ordered Abbott to remove the chart in June 2004, calling it "false and misleading," and Abbott complied.

Over time, the outcry faded. Private health insurers took a bigger blow but had little leverage, because they could hardly deny patients a lifesaving drug. Insurer Aetna Inc. sued Abbott but dropped the suit within days. Abbott also settled a suit brought by the AIDS Healthcare Foundation. The company agreed to support programs at the foundation, which provides free medicine to poor and uninsured AIDS patients. Financial terms weren't disclosed.

Dr. Wohl says Abbott has been "winning back some community goodwill, including from me" with new initiatives, such as a partnership with basketball Hall of Famer Magic Johnson to fight AIDS among African- Americans. Dr. Wohl says he has resumed making paid speaking appearances on behalf of the company.

U.S. sales of Reyataz, the Bristol-Myers drug, have grown despite Norvir's higher price. They reached $370 million in the first nine months of last year, up 25% from the same period of 2005. Kaletra too has been selling well, thanks in part to a new formulation that improves convenience. U.S. sales of Kaletra grew 27% in the first three quarters of 2006 and are on track to reach $500 million for the year.