AIDS Treatment Activists Coalition (ATAC) Pharmaceutical Company HIV/AIDS Report Card

Issued by the ATAC Drug Development Committee

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Abbott Laboratories

Drug Development Portfolio and Plan: Abbott has no HIV drugs in development other than a reformulated, heat-stable version of Norvir (ritonavir). The company has three hepatitis C compounds in early development.	**D-**
Access to Drugs: Abbott has a patient assistance program and a co-pay assistance program, though the co-pay program currently excludes Norvir.	**D**
Pricing: Abbott has still not rescinded a 400% price increase on Norvir that came in 2003. Though the company's Kaletra (lopinavir/ritonavir) is the lowest-priced HIV protease inhibitor, critics charged that keeping a low price for Kaletra (which contains Norvir) while raising the price of Norvir--which all other competing protease inhibitors depend upon--was intended to spur sales of Kaletra.	**F**
Community Relations: Abbott's community relations efforts with HIV treatment activists have been predominantly focused on marketing concerns and not on gaining input on trial design issues. ATAC has officially refused to meet with Abbott until the price of Norvir is reduced.	**F**
Marketing Practices: Abbott was cited by the FDA for misleading marketing materials regarding the Norvir price increase.	**F**
Average Grade:	**F**

Suggestions for Improvement: Abbott needs to reduce the cost of Norvir to the pre-2003 price and collaborate with other HIV companies to coformulate Norvir at optimum doses with other protease inhibitors. The company should also provide free Norvir for all studies by the NIH's AIDS Clinical Trials Group (ACTG) and other HIV clinical trials networks. The HIV treatment activist community would like Abbott to cover 100% of co-pays for both of its drugs.

Boehringer Ingelheim

Drug Development Portfolio and Plan: Boehringer Ingelheim (BI) has two HIV drugs in its very early product pipeline, and at least two drugs for hepatitis C are in early development. The company was initially slow to respond to concerns about potentially fatal side effects of Viramune (nevirapine) in women though it subsequently conducted a thorough investigation of the problem. Women were not adequately represented in FDA-approval trials for Aptivus.	**D+**
Access: BI has a patient assistance program, but only recently announced plans to help cover co-pays for its drugs.	**C-**
Pricing: Though Viramune is not the highest priced drug in its class, BI has taken the second highest rate of post launch annual price increases among HIV drugs on the market. Its Aptivus was priced higher than all other protease inhibitors at the time of its launch and remains the third most expensive protease inhibitor.	**D-**
Community Relations: BI has refused to meet with ATAC. The company holds at least one community advisory board meeting per year by invitation only, but such meetings are almost solely devoted to talking about its existing drugs and related issues. Activist advice and concerns about BI studies have generally not been heeded by the company.	**D**
Marketing: BI's advertising and marketing practices are among the more conservative in the industry and the company has received no FDA warning letters. Information about its patient assistance program, however, is not prominently placed on the BI product websites.	**C-**
Average Grade:	**D+**

Suggestions for Improvement: BI needs to consult with the HIV treatment activist community in a meaningful way, institute a co-pay assistance program, and prominently place information about its patient assistance program on its websites.

Bristol-Myers Squibb

Drug Development Portfolio and Plan: Bristol-Myers Squibb (BMS) has two HIV and three HCV drugs in very early development. It was the first company to collaborate with another drug maker (Gilead) on a fixed-dose combination pill, Atripla (efavirenz/tenofovir/emtricitabine). Recruitment of women and people of color in BMS's clinical trials has ranged from average to slightly above average, though not sufficient to allow statistically meaningful comparisons of efficacy and safety among these groups.	**C**
Access: BMS has a patient assistance program and a co-pay assistance program, though the co-pay program requires a larger out-of-pocket expense than most. BMS has provided free drugs for studies conducted outside of the company.	**C+**
Pricing: BMS's Sustiva was priced higher than other drugs in its class. The company set a new record for protease inhibitor pricing with the launch of Reyataz (atazanavir). The price of Atripla is equivalent to the price of its three component drugs. BMS has taken price increases of approximately 6% per year on its products.	**D+**
Community Relations: BMS has a mixed history of engagement with the treatment activist community. The company consulted with the community during the development of Reyataz nine years ago, but then stopped meeting with ATAC altogether for several years. BMS recently met with ATAC and indicated that it was open to—but would not promise—consultation at a stage early enough in the development process to allow influence on research plans and protocols. It has met regularly with the community on public policy issues.	**D**
Marketing: BMS had not engaged in negative or fear-based advertising until recent ads for Reyataz implicated a competing drug for causing diarrhea.	**D+**
Average Grade:	**C-**

Suggestions for Improvement: BMS needs to consult openly, honestly, and in a timely manner with the community on trial design and development that will allow for community input to be incorporated. Company ads should be honest and realistic. The community would like BMS to cover 100% of co-pays.

Gilead Sciences

Drug Development Portfolio and Plan: Gilead has HIV, hepatitis C, and drug-blood-level boosting agents in development. It has a record of collaborating with other companies in the development of fixed-dose combination pills. Recruitment of women and people of color in its trials has been about average.	**B-**
Access: Gilead has a patient assistance program and a co-pay assistance program. Though it began working on its co-pay program earlier than most other companies, it is among the least generous. Gilead provides free drugs for research outside of the company.	**C+**
Pricing: Gilead has met with the treatment activist community on pricing issues and has kept the price of its coformulated drugs equal to the price of its component drugs. Gilead has also agreed to a price freeze through 2010. However it took a steep price increase in 2008 before the price freeze took effect, and the price of Viread (tenofovir) has increased more since launch than any other HIV drug.	**C+**
Community Relations: Gilead generally seeks input from the community on its trial designs, though not always early enough to allow for protocol changes. The company responds in a timely manner to written correspondence.	**B-**
Marketing: Gilead has generally not engaged in negative or fear-based advertising. It did receive an FDA warning letter about promotional practices that overstated the benefits and underplayed the risks of its drugs.	**C+**
Average Grade:	**C+**

Suggestions for Improvement: Gilead needs to consult with the treatment activist community on trial design and development in a timely manner that will allow for input to be incorporated into research plans. The company should not offer reimbursement and price concessions with one hand and take price increases with the other. The community would like Gilead to cover 100% of co-pays.

GlaxoSmithKline (GSK)

Drug Development Portfolio and Plan: GSK has HIV drugs in active development, but at the time grades were assigned the company had not yet sought community input on its development plans. GSK primarily communicates with the treatment activist community via an annual meeting among selected community members, usually to discuss topics other than drug development. GSK trials at one time recruited more women and people of color than did those of other companies, though still not in numbers that adequately reflected the demographics of the epidemic.	**D+**
Access: GSK has one of the oldest patient assistance programs and was the first company to publicly announce a co-pay program.	**B-**
Pricing: GSK's corporate predecessor, Burroughs Wellcome, marketed Retrovir (zidovudine, or AZT), the first anti-HIV drug, in 1987. Retrovir was introduced at an extremely high price and this sparked activist demonstrations. More recently, GSK's Ziagen (abacavir) and Lexiva (fosamprenavir) were introduced at prices more than one-third higher than those of similar drugs from its competitors. Yearly price increases subsequent to launch are among the highest taken by HIV drug makers.	**D**
Community Relations: GSK has not formally met with ATAC in more than five years nor consulted with the community on early drug development in a timely enough manner to allow for adjustments to its protocols. Most interactions have not regarded drug development plans, but there has been some focus on timely responses to emerging data on GSK's products. GSK funded some early and innovative programs for women and people of color.	**D+**
Marketing: GSK has extensively used negative and fear-based advertising against its competitors—something that ATAC strongly opposes. GSK received two warning letters from the FDA in 1999 about its marketing to medical providers.	**D-**
Average Grade:	**C-**

Suggestions for Improvement: GSK needs to consult with the community on trial design and development in a timely manner that will allow for community input to be incorporated into trial design. The company should stop instituting high price increases and refrain from using negative, fear-based advertising.

Merck

Drug Development Portfolio and Plan: Merck made a significant long-term investment in scientific research during the development of Isentress (raltegravir), although women were underrepresented in its clinical trials. Merck consulted the treatment activist community throughout the drug's development and is fulfilling its postmarketing commitments.	**B+**
Access: Merck has a patient assistance program and recently announced a co-pay assistance program.	**C+**
Pricing: Merck does not have a history of taking excessive price increases and has agreed to a price freeze through 2010.	**B**
Community Relations: Merck meets regularly with the treatment activist community. Input on trial design was sought early enough to allow changes to clinical trial protocols. Merck did not have a community member on its data safety monitoring board for Isentress.	**B-**
Marketing: Merck has not used negative or fear-based advertising for Isentress. It has received no warning letters from the FDA for its HIV products, though during the marketing of Crixivan (indinavir) there were community complaints about unrealistic advertising images.	**B-**
Average Grade:	**B**

Suggestions for Improvement:
Merck needs to improve recruitment of women and people of color in future trials, and include community members on its data safety monitoring boards and at its investigator meetings. The community would like Merck to cover 100% of co-pays.

Pfizer

Drug Development Portfolio and Plan: Pfizer is developing several drugs for HIV and hepatitis. Recruitment of women and people of color for studies of Selzentry (maraviroc) in treatment-experienced patients was inadequate, though equivalent to that of other companies.	**C+**
Access: Pfizer has a patient assistance program, but no co-pay assistance program. It provides royalty-free access to maraviroc, the active ingredient in Selzentry, for development as a microbicide.	**C**
Pricing: Pfizer set the price of Selzentry near the price of the most expensive protease inhibitors.	**C+**
Community Relations: Pfizer meets regularly with U.S. and European treatment activists. Correspondence is acknowledged in writing in a timely manner. Community members have served and are serving on safety monitoring boards and as reviewers of protocols and educational materials.	**B-**
Marketing: Pfizer's marketing of Selzentry has been relatively low key. The company has received no warning letters from the FDA. It does not prominently advertise its patient assistance programs. Advertising for its older drug Viracept (nelfinavir) has ceased.	**C+**
Average Grade:	**C+**

Suggestions for Improvement: Pfizer needs to improve recruitment of women and people of color in future trials, heed community concerns about pricing, and initiate a Selzentry co-pay assistance program.

Roche

Drug Development Portfolio and Plan: Roche has formally withdrawn from development of HIV drugs. It has an active hepatitis C research program.	**D+**
Access: Though Roche offered a patient assistance program for Fuzeon (enfuvirtide) and Invirase (saquinavir), it refused to expand the Fuzeon program for patients in states whose AIDS drug assistance programs had not added the drug to their formularies. Thus, Roche used some of the sickest, most desperate patients as hostages in its negotiations with these states.	**D-**
Pricing: Roche's Fuzeon is the most expensive HIV drug on the market by a wide margin. The excessive price initially kept some states' AIDS drug assistance programs from offering it to needy patients.	**D-**
Community Relations: At one time Roche offered a program to provide support from nurses for people taking Fuzeon, a twice-daily injectable drug that can cause injection-site reactions. However, community attempts to get Roche to adequately promote the program went unheeded. Roche no longer offers the program.	**D+**
Marketing: Roche ran an ad campaign for Fuzeon that many in the community felt was insensitive to people who had run out of treatment options and that underplayed challenges with injecting the drug. Training materials for self-administration of the drug were created in consultation with the community, but marketing materials were not.	**D**
Average Grade:	**D**

Suggestions for Improvement: Roche needs to lower the cost of Fuzeon and widen access to its patient assistance and co-pay programs.

Tibotec Therapeutics

Drug Development Portfolio and Plan: Tibotec currently has drugs in the pipeline for HIV, hepatitis C, and tuberculosis. Responding to FDA requests for more data in women and people of color due to underenrollment in its FDA approval trials, Tibotec conducted a large, innovative study that achieved greater enrollment diversity in gender, race, and age than any previous HIV trial.	**B+**
Access: Tibotec has both a patient assistance and a co-pay program, and it prominently displays information about these programs on its product web pages. Tibotec has provided HIV drugs for clinical research outside of the company and recently provided free cancer drugs for a trial in Africa.	**B**
Pricing: Tibotec has priced its drugs somewhat lower or equivalent to those from respective classes. It has consented to price-freeze agreements, and its price increases have not exceeded average rates for all HIV drugs. Tibotec meets regularly with the Fair Pricing Coalition and has honored its commitments on restrained pricing.	**B**
Community Relations: Tibotec has sought extensive consultation with HIV treatment activist community members on drug development issues. The company has not always followed the community's advice, but its representatives have generally communicated the reasoning behind their decisions.	**B+**
Marketing Practices: Tibotec's advertising and marketing practices have been fair and balanced, though an FDA warning letter was issued in 2009 concerning incomplete information in a search engine advertisement for Prezista.	**B-**
Average Grade:	**B**

Suggestions for Improvement: Tibotec needs to cover 100% of out-of-pocket costs in its co-pay program and disclose the number of patients served in its patient assistance program.

Appendix

Research Methodology

ATAC's Drug Development Committee completed its independent review of the pharmaceutical industry in June 2009. The information in the HIV/AIDS Report Card was gathered from interviews with pharmaceutical companies and data taken from publicly available sources. Each company was assigned an ATAC representative who led the data collection and reporting for that company. All voting ATAC Drug Development Committee members then suggested a grade for each company in each of the five areas (drug development portfolio and plans, access to drugs, pricing, community relations, and marketing practices), all of which were averaged.

Criteria Used for Scoring Each Report Card Category

Drug Development Portfolios and Plans

- has active development pipeline for HIV—including new targets
- has active development of treatments for viral hepatitis
- treatment development plan is rational, ethical, and expeditious
- drug development plans include both treatment-naive and treatment-experienced patients
- provides access to researchers who clearly describe the company's development plans
- complies with all FDA-required postmarketing studies
- initiates and supports wide range of company-sponsored and investigator-led postmarketing studies that increase knowledge about its drugs as used in clinical practice
- makes efforts to accrue and retain women, people of color, and people with common comorbid conditions (such as coinfection with viral hepatitis) in all phases of research and in numbers representative of the U.S. epidemic
- has an active pediatric R&D program
- includes community representatives on safety monitoring boards for clinical trials, in investigator meetings, and in reviewing informed consent documents, etc.

Access to Drugs

- has effective patient drug assistance program; inclusive co-pay and relevant patient support programs
- expanded access program(s) initiated in a timely manner
- has worked to improve formulations of existing treatments
- has shown willingness to cooperate with other drug manufacturers in combination drug trials and in developing co-formulations
- has provided free drugs to the ACTG and other networks for research purposes

Pricing

- has not broken industry precedents for pricing within a drug class
- has not priced new drugs substantially higher than other drugs in the same class
- has not used price hikes or other predatory practices to protect market share of its drugs
- does not increases drug prices frequently (e.g., more than once per year)

Community Relations

- provides access to scientists, marketing executives, community liaisons
- seeks input from a diverse range of opinions and voices in the U.S. HIV community
- seeks timely community input and implements community recommendations
- responds to correspondence in writing
- supports unrestricted educational grants for AIDS service organizations without specifying or providing branded content

Marketing Practices

- does not use scare tactics in advertising
- models used in advertising are representative of individuals living with HIV in the United States
- has not received warnings about improper advertising practices from the FDA
- advertises and actively informs communities about patient assistance and co-pay programs

Definitions for Each Letter Grade

A = Excellent; performance demonstrates corporate leadership in this area.

B = Very good; performance demonstrates actions beyond the expected.

C = Acceptable; performance within expectations.

D = Poor; performance subpar when compared to that of peers.

F = Failure; falls significantly below minimal expectations for corporate performance.