

Appendix D: Two Views on Drug Prices

M.J. Peterson

Version 1, June 2010

Fair Pricing Coalition Statement on Prices of New HIV Drugs
Posted by Paris-based group Actions Traitements, 6 June 2009
<http://www.actions-traitements.org/spip.php?breve2542>

Merck public policy statement: Charitable Product Donations, June 2010
From <http://www.merck.com/about/views-and-positions/charitable-product-donations.pdf>

This case was created by the International Dimensions of Ethics Education in Science and Engineering (IDEESE) Project at the University of Massachusetts Amherst with support from the National Science Foundation under grant number 0734887. Any opinions, findings, conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation. More information about the IDEESE and copies of its modules can be found at <http://www.umass.edu/sts/ethics>.

This case should be cited as: M.J. Peterson. 2010. "Access to HIV Treatments in Developing Countries." International Dimensions of Ethics Education in Science and Engineering. Available www.umass.edu/sts/ethics.



© 2010 IDEESE Project

Fair Pricing Coalition Statement on Prices of Newly-Developed AIDS Drugs

Posted by Paris-based group Actions Traitements, 6 June 2009
<http://www.actions-traitements.org/spip.php?breve2542>

TMC114/darunavir will soon become Tibotec's first licensed drug for the treatment of HIV disease. It is likely to be the first of several important anti-HIV drugs from Tibotec. To date, the HIV/AIDS community's relations with Tibotec have been exemplary as the company has shown an exceptional willingness to invite and listen to input from people affected by HIV disease. Based on everything we know now, the licensure of TMC-114/darunavir will be a worthy addition to our anti-HIV armamentarium, especially for people who have developed resistance to the existing protease inhibitors.

This good news, however, does not exist in a vacuum. Instead, it will be played out against a background of growing national and international crises in the cost of health care. The cost of a typical anti-HIV regimen in United States has risen to \$15,000 or more for initial therapy, while the cost of salvage therapy can easily reach three times that amount. This is just for cost of the drugs. These costs plus the cost of associated medical care must be supported for decades to come for every single person with HIV disease. Better drugs, like TMC114/darunavir, result in longer lives and thus even longer times on therapy. If the average duration of therapy is limited to no more than 50 years per person, the costs of HIV drugs over this period will easily exceed a trillion dollars in the US alone, not even counting future price increases. Add in a reasonable cost for the vast numbers needing therapy in developing nations and the overall cost of drug for treating HIV disease worldwide could easily equal the current US national debt. Clearly, the path we are on is not sustainable, at least not for anyone other than the pharmaceutical industry.

At a time when evidence of responsible citizenship is needed from the pharmaceutical industry, we have instead been treated to ever increasing prices with each new drug. Two recently approved protease inhibitors, Reyataz and Aptivus, leapfrogged each other in setting new pricing thresholds, quickly reaching a price nearly three times that charged for Crixivan when it offered the first real breakthrough in AIDS treatment in 1996. TMC114/darunavir is the next drug in line and all eyes will be on it the day its price is announced. Its net price must include the cost of a booster drug, Norvir from Abbott Labs, whose price was recently increased by 400% in another demonstration of reckless civic behavior by a pharmaceutical company. While Tibotec isn't responsible for the price increases taken by others, it is responsible for the decision to use the Norvir booster. Tibotec now has two choices. It can either follow in the footsteps its predecessors, defying the needs of patients and taxpayers, or it can make a bold statement that shows that the industry will do its part to restrain the cost of healthcare. Make the wrong choice and all of the company's efforts to maintain strong relationships with the government and the community will have been for

naught. The cycle of ever increasing costs, and ever higher profits, will once again be validated. Is this the legacy that Tibotec wishes to create ?

Since it was formed in 1998, the Fair Pricing Coalition has sought drug pricing that is cost neutral. We seek to avoid having each new drug push the cost of treatment upward. In the case of TMC114/darunavir, this leads to a very specific demand : we ask that the price charged for TMC114/darunavir should be less than or equal to the current price of Kaletra, which is presently the best selling protease inhibitor and the drug that TMC114/darunavir is most likely to replace in clinical practice. Since Tibotec has chosen to use a ritonavir booster to improve the bioavailability of TMC114/darunavir, the price must include its cost, just as the ritonavir booster is already included in the price of Kaletra.

We also expect substantial discounts over and above the minimum required by law for the AIDS Drug Assistance Program and other government payers. We trust that separate negotiations are underway with the appropriate representatives of those programs, but we hope to establish the baseline for those discussions with the pricing principles laid out here.

We urge the leadership of Tibotec Research, Tibotec Therapeutics, and parent companies Ortho and Johnson & Johnson to give this proposal the most serious possible consideration. We believe that the company will benefit greatly from agreeing to this request. It will establish the company both as a scientific leader and also as a civic leader. It will stand as evidence to the taxpayer and to the Congress that the pharmaceutical industry is capable of more than simply seeking the greatest possible profits without regard for the impact on society. Perhaps most importantly, it will be welcomed and appreciated by the people with HIV and the medical professionals who treat them. It will almost certainly generate positive press about a "new, more responsible attitude" by industry. And, we believe, it will encourage the fastest possible uptake of the drug into clinical practice. Tibotec is aware, no doubt, that recent Medicare Part D formulary guidance issued by the Centers for Medicaid and Medicare services, has changed the mechanism for adding newly FDA approved drugs in the six protected classes, including anti-retrovirals, as of April 17, 2006. Any drug approved by the FDA after April 17 must be approved for inclusion in the individual plan formulary by that plan's Pharmacy and Therapeutics (P & T) committee. Drugs included in a protected class will have an expedited approval time that can take up to 90 days or three months, but there is no guidance suggesting that newly approved drugs in the protected classes must automatically be added to the plan formulary. Each state will likely take price into account along with therapeutic value. Additionally the P& T committees will make decisions as to how to tier new drugs for co-payment amounts. Because of their price, most of the newer anti-retrovirals are tiered in the highest tiers making them unaffordable for many. Therefore, if Tibotec hopes to see a rapid inclusion in formularies, they must price it aggressively. How state authorities and the HIV affected public feel about the pricing of new drugs will contribute to the speed of

this process. At the state level, price will almost certainly be a key consideration. Meeting the goal described here will make it possible for the activist community to support the fastest possible acceptance on the formularies.

The payers, Congress, patients and providers are greatly frustrated with the pricing practices of the pharmaceutical industry. While patients and payers are struggling year after year to raise the money needed to obtain access for a growing patient population, the pharmaceutical industry has shown virtually no restraint in its quest for profits and shareholder benefits. Its profitability ranks among the highest of all industries while the percentage of revenues devoted to research and development are at best average. The pharmaceutical industry speaks proudly of the need for a "free market economy" and the benefits of competition, but in fact it behaves more like a group of monopolies. It accepts little or no pressure on prices as a result of competition, the cornerstone of a market driven economy. In the US, the industry funds massive political lobbying to prevent government from negotiating prices for the largest national payers. Unlike other industries, in which high profits are usually the result of the consumers' selection of outstanding products, the "buyers" of pharmaceutical products have little choice in the selection of products and product quality bears no relationship to the price charged. This coercive relationship between buyer and seller can no longer be tolerated. It must be challenged, whether through consumer protest, eventual price controls, or payer product selection, none of which are very attractive to industry. Make the right choice now and none of these approaches will be necessary.

Public Policy Position

Charitable Product Donations

- Merck is committed to enabling access to our medicines and vaccines to populations worldwide. In working towards this goal, the Company engages in a wide range of access initiatives, including programs and partnerships with a charitable product donation component. However, charitable product donations are only one component of Merck's comprehensive approach to enabling access to medicines and vaccines (which also includes initiatives involving differential pricing, product licensing, product registration and World Health Organization (WHO) pre-qualification.)
- Merck believes that donations can address specific health needs, whether in communities with a fundamental lack of access to care and services or in acute or protracted humanitarian crises.
- Merck acknowledges that donations are typically not a long-term solution to enabling access to medicines and vaccines, and, except in cases of open-ended donation commitments (e.g., the Mectizan Donation Program), Merck does not view charitable donations as sustainable, stand-alone initiatives.
- Donations can also help to support essential services such as national health care capacity by protecting the work force that provides these services (e.g., vaccinating first responders and key administrative personnel). Similarly, donations can provide opportunities for national institutions (e.g., Ministries of Health) and other approved organizations (e.g., NGOs endorsed by the Ministry of Health) to gain valuable operational experience designing and implementing small-scale treatment or vaccination projects using newly developed pharmaceuticals or vaccines.
- Merck is committed to conducting product donation activities in a thoughtful, responsible manner that is consistent with established, endorsed and widely accepted public health guidelines and practices (e.g., WHO Guidelines on Drug Donations).
- Merck is committed to continuing to improve and expand upon its exemplary product donation practices through membership in the Partnership for Quality Medical Donations (PQMD) and continued dialog with other important stakeholders such as WHO.
- Merck believes that product donations, when conducted in a responsible manner, do not detract from a country's ability to develop and/or introduce low-cost alternatives (e.g., generics or alternative products produced by local manufacturers) into their health systems since appropriate donations respond to a specific request, are endorsed by the host government, and are in place for a limited duration
- Although not the primary driver for Merck, the Company supports the continuation of the enhanced tax deduction granted by the United States Internal Revenue Service (IRS) as an appropriate incentive for qualified charitable product

donations. The Company also supports the elimination of import tariffs and taxes on charitable product donations.

- To facilitate charitable donations, Merck partners primarily with a limited number of qualified non-governmental organizations (NGOs) or private voluntary organizations (PVOs). Each of these organizations has a long-standing relationship with the Company, demonstrates integrity of purpose, provides assurance that Merck products will be securely warehoused and will not be diverted, mishandled or misappropriated, and has well-established programs for the ill and needy in developing countries. These qualifications provide the Company with the controls necessary for the proper distribution, handling and administration of donated Merck products.

Approved: January 2010