Down-and-Dirty Markups

High cost of combos is breaking the bank

December 1, 1998 By Dave Gilden

The FDA's mid-September approval of the 12th anti-HIV agent has sparked bitter disappointment as drug company economics once again hobble access to new treatments.

Sustiva (efavirenz), DuPont Pharma's brand-new NNRTI, has received much positive publicity for its apparent high potency and once-daily dosing schedule. Based on preliminary trial results, DuPont is even pitching the drug as a substitute for protease inhibitors in combination regimens. A major innovation, "protease-sparing" options would postpone until absolutely necessary the resistance and complicated toxicities and dosing associated with the protease class.

Unfortunately, DuPont has chosen not to help HIVers spare protease inhibitors' high price. Sustiva comes with an annual wholesale price tag of $5,000—a 60 percent and 80 percent increase, respectively, over its NNRTI competitors. Viramune (nevirapine) and Resciptor (delavirdine).

When the price was leaked to activists, DuPont's halo tarnished fast, as a prelaunch community meeting dissolved into a shouting match. Certain advocates may have been relatively silent about HIV-drug prices in recent years, hoping that higher prices encouraged more research, but the great leap upward that Sustiva's pricing represents is widely viewed as triggering a dangerous trend. Already Glaxo Wellcome is sending signals about charging an exceptionally high price for its new nucleoside analog, Ziagen (abacavir), and there are rumors of a price hike for Merck's Crixivan.

Public health programs, including state ADAPs for HIVers with moderate incomes, are reeling under the cost of combo therapy. The privately insured are hard-pressed to meet copayments, and some are bumping up against maximum reimbursement limits. Their insurance companies and HMO's, meanwhile, face their own financial meltdown. With pharmacies charging as much as $20,000-plus for Sustiva-containing regimens, no relief is in sight. One sign of the widespread alarm is the public letter (which I helped draft) signed by more than 100 AIDS organizations urging DuPont and Glaxo to price the new drugs no higher than others in their class.

DuPont justifies the high price by citing Sustiva's research and manufacturing costs, the standard excuse. But as activists are quick to note, the drug's development proceeded at record pace because of their pressure on the FDA, and the agency granted the drug accelerated approval on

the basis of results from treating fewer than 1,000 volunteers for six months. Questions about the side effects, toxicity and optimal use may never be answered.

It is hard to dispute claims about Sustiva's production costs because drug companies never open their books. But the fact is, costs are *never* a decisive factor in drug prices. Traditionally, less than a third of a drug's wholesale price pays for manufacture, 15 percent for research and development, and a quarter for marketing; the rest mostly goes to profits. Since cost recovery is rarely a problem, marketing concerns drive pricing decisions.

DuPont is no exception. In June, company consultants surveyed AIDS community "thought leaders" about an acceptable price. Then, at last summer's World AIDS Conference in Geneva, publicists swarmed out from DuPont's extravagant exhibition booth armed with press releases enthusiastically spinning the trial results, despite the fact that most researchers dismissed the "protease-sparing" claims as "premature."

Once Sustiva hits pharmacies, its high price is likely to kick off even-more-extensive marketing efforts to increase sales. HIVers need solid info to make the best treatment decisions. Instead, they are barraged by messages extolling the delights that anyone at any stage of disease can expect from taking fistfuls of pills.

In a familiar lament, ACT UP/Golden Gate's Mike Donnelly recently said, "What the adds should show isn't people mountain climbing but sitting on the toilet. We should demand that they stop those pretty, pricey ads." Donnelly can demand all he likes, but every time he goes to the drugstore, he pays for the very thing he detests.

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