

New! FDA Approves Enfuvirtide (Fuzeon, ENF, T-20) [The Hopkins HIV Report, May 2003]

The cost of a year's supply of enfuvirtide is approximately \$20,000.



Fuzeon Approved - But Who Will Get It?

Limited Supply, Outrageous Price, AIDS Budget Cuts... Action Needed!

Walt Senterfitt

On March 13, 2003, the FDA (federal Food and Drug Administration) approved Fuzeon (also known as T-20 or enfuvirtide) for use in combination anti-HIV therapy. Fuzeon is



the first in a new class of anti-HIV medications, called fusion inhibitors. Fusion inhibitors stop HIV from "fusing" with the membrane of T-cells and other targets in the body, thus preventing HIV's entry into these cells. They act at a point in the life cycle of the virus different from "nukes," "non-nukes" and protease inhibitors, and thus ? in combinations ? offer a way to overcome and perhaps prevent resistance to older drug regimens. Fuzeon represents the first drug of a new class to be introduced since 1996.

Even though we do not know exactly who will benefit most from Fuzeon and though there are serious problems with its route of administration (injections under the skin twice a day), its approval ought to be a cause for celebration. Why is that not so? Because the companies marketing it plan to price it at a level two to three times the next most expensive anti-HIV drug. This could cause a sharp escalation in the overall annual drug costs for thousands of PWAs, at a time when funding for ADAP and Medicaid (Medi-Cal) is under heavy pressure and likely net reductions. ADAP and Medicaid pay for drugs for more than 70% of all people with HIV who are in treatment.

What's Behind the Outrageous Price?

Fuzeon or T-20 was developed by a new biotech company in North Carolina, Trimeris, Inc., in cooperation with the pharmaceutical giant Roche, headquartered in Basel, Switzerland with its chief US office in Nutley, New Jersey. Roche has not yet announced its US price, but has said that it will be about what the company charges in Europe, about \$20,500 for a year's supply.

Roche says the reason for the high price is a combination of its need to recoup the \$600 million it says it invested in the drug's development and the fact that the drug is unusually complicated and therefore costly to manufacture. Whereas five or six steps are required in manufacturing the earlier anti-HIV drugs, Roche says Fuzeon requires 106 steps. The Fuzeon molecule is indeed very large and complex. Trimeris/Roche scientists had hoped by now to figure out a way to simplify its production and hopefully make a stable and absorbable form one can take by mouth, but to date they have not managed to do so.

There is more dispute about the \$600 million rationalization. For one thing, one must take Roche's word for this figure, with a grain or more of salt ? they have refused to open their books for independent assessment of the true cost. [Aside: Drug companies always justify their high prices on the basis of the large investment needed for development of new drugs. This explanation grows a bit tired however given the investment of as much or more money in marketing of their drugs and the fact that with all that, the companies make an average annual return on investment of 18%, the highest long-term profit rate of any industry!]

Many observers think Roche knows Fuzeon will not have a prominent place in the market for long, perhaps as little as two years. Other drugs in the pipeline may well be better and/or easier to take, and Roche itself already has fast track status from the FDA for testing of its second-generation fusion inhibitor, t1249. According to these activists, Roche thus figures it has to get back as much of its investment as fast as it can with as high a price as it can get away with.

Some activists point out that the initial basic research to define and outline fusion inhibitors was paid for by the federal government (though most of the costs were actually incurred after this, in the long slog to actually develop and test a usable formulation). More

importantly, Roche has let it be known privately to investors and other scientists that it is committed over the long-haul to the development of "large peptide molecule" drugs requiring similar manufacturing processes as Fuzeon ... for uses in treatment of other diseases and with markets far larger than the HIV one. In other words, a good part of the \$600 million Roche claims it invested in Fuzeon in fact will support other future drugs of Roche ? and arguably should be partly amortized by those drugs as well.

In Any Event: The Effect of the High Cost

Will those who need Fuzeon be able to get it? That's a good question. Even though active lobbying led Congress to add about \$80 million in new funding for ADAP this year (California's share is about \$9 million), the demands by new patients and annual rises in the prices of older drugs mean this modest increase is not enough to keep up with demand. A number of states have waiting lists to get onto ADAP and some have restricted the list of drugs they will pay for, known as the "formulary." Medicaid pays for an even larger share of HIV medications than ADAP, and both Congress and strapped state governments are making plans to cut Medicaid budgets significantly. And that was before the addition of Fuzeon.

At least two states, Maryland and Texas, have announced they will not add Fuzeon to their ADAP formularies because they simply cannot afford it. Other states are considering what to do. The ADAP directors of the six largest states met in Washington in late March to negotiate larger discounts with Roche and other pharmaceutical suppliers. They announced Roche has cut some sort of a deal (it almost had to given the negative publicity its price has garnered), but details had not been announced at time of this writing.

The dilemma ADAP, Medicaid and HMO's face is simple: Shall we buy Fuzeon for the several thousand patients whose lives it may save or extend, even if it means possibly damaging or shortening the lives of an even larger number of patients by cutting their access to other drugs that still work for them?

This is an inhumane choice that no one should have to make. It raises larger issues of who should pay for and who should profit from development of life saving therapies and how to strike balances. However, in the short run, pressure must be placed on Roche to lower the prices. If necessary, this huge and wealthy company should take a loss, as every indication is that it will more than make it back on other drugs. "Profits-as-usual" should not be the mantra for denying life to PWAs whose other options have run out.

Action

[Click here to read the letter](#) Being Alive signed with many other community organizations and sent to the head of Roche in Switzerland. Why don't you sit down, copy it or write your own, and send it off to Roche also?

We need other forms of action, too, from lobbying to good old-fashioned direct action and media-savvy protest. Being Alive's Advocacy Committee is waging an ongoing fight for access to Fuzeon as part of fighting for all the needs of all people living with HIV. We need you! We meet the **second Monday of every month at 7pm (next meetings are on June 9 and July 14, 2003)** at the office: 621 N. San Vicente Blvd, West Hollywood, across the street from the Pacific Design Center. Food is provided. Join us, please. For more information, call the Being Alive office at 310.289.2551 or call me at 213.481.2423.

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