

National AIDS Treatment Advocacy Project

DELAVIRDINE FDA HEARING

TIE VOTE OF 4-4 PREVENTS APPROVAL RECOMMENDATION

November 22
Gaithersburg, Md.

This is an initial brief report of yesterday's FDA Antiviral Drug Advisory Committee meeting entertaining the discussion of whether or not to recommend accelerated approval for this NNRTI. I will follow up this report with another detailing the data. Nevirapine was the first NNRTI to gain FDA approval this past summer. DMP-266 is also a NNRTI in earlier stage of development.

There are 9 voting committee members. The chairman Scott Hammer MD, was unable to vote due to a technicality; but, the other 8 voters split evenly at 4-4. Therefore, the committee issued no recommendation. David Feigel MD, of the FDA, it appeared to me, tried to coax a recommendation out of the committee but they ended with the tie.

The FDA is not required to adhere to committee recommendations. The committee of 9 agreed that they would wait for RNA data (viral load) from ACTG 261 and if the data is convincing, they would recommend approval. The data is not expected to be available until mid-January. Unconfirmed sources revealed that the FDA will have to make a decision by early December because of user fee regulations. That is, the FDA is required to decide on a drug's approval application within 6 months after drug user's fees have been submitted to the FDA. That 6-month deadline expires in early December for Upjohn, the manufacturer of delavirdine.

Overall, the data was not impressive. Nor, was the presentation well coordinated by Upjohn. Three studies' results were presented but with mixed results. ACTG 261 supplied CD4 results but the viral load data will not be available until mid-January. Although there were CD4 benefits, the data was not convincing enough. As well, the overall results of two other studies protocols #0017 and #0021 were not convincing enough for the committee.

Scott Hammer MD, the new committee chairman, agreed the data could be better, but he expressed support for the approval of this drug. He and Gary Blick MD, a committee guest serving for the first time, but without voting privileges, supported the effort for approval. These two progressive voices were opposed by conservative opposition.

Admittedly, the data wasn't that good, but I felt that the drug should've received approval; the design of the studies may have masked the efficacy of the data. It appeared to me and others that the data was adequate for approval. I testified to the committee in support of its approval.

The data appears adequate enough that delavirdine is an antiviral that has some efficacy for which a certain group of people can benefit. Currently, there are many individuals who have exhausted all available NRTIs and need additional options. Delavirdine can

offer an option to these individuals now. As well, preliminary results Upjohn's protease interaction studies (detailed on NATAP web site) indicate delavirdine can increase saquinavir blood levels 5-fold; it can be combined with indinavir: it increases indinavir blood levels; the study indicated it may not affect ritonavir blood levels. The drug has an important role for a certain group of individuals. At least for them, it should be available.

A few other community advocacy organizations also spoke addressed the committee, all except one group supported approval. That one group remained neutral on the position.