Follow-Up Study Confirms Pneumonia Might Be More Common in Fuzeon Users

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The U.S. Food and Drug Administration (FDA) has announced that people taking the antiretroviral drug Fuzeon (enfuvirtide) might indeed be at a higher risk of developing serious bacterial pneumonia while taking the drug.

During the review of the two Phase III studies that led to the approval of Fuzeon, researchers found that the risk for developing bacterial pneumonia was nearly twelve-fold higher in those taking Fuzeon than in those who received a placebo. Approximately half of those who developed pneumonia while taking Fuzeon had to be hospitalized, and three people died.

People in the Phase III studies had very advanced HIV disease, however, and a number of other AIDS-related complications. This made it difficult to be certain whether the additional pneumonia cases were due to Fuzeon or if they were simply a fluke.

To test this, the FDA required Fuzeon's maker (then Roche and now Genentech) to conduct a large post-approval clinical trial involving 1,850 people—740 taking Fuzeon and 1,110 not taking the drug.

The recently completed study once again suggested an association between the use of Fuzeon and a higher risk for pneumonia, though to a lesser degree than in the original Phase III studies. The additional risk, after adjusting for other factors, was 34 percent.

For this reason, the new prescribing information for Fuzeon will now state: "It is unclear if the increased incidence of pneumonia is related to FUZEON use. However, because of these findings, patients with HIV-1 infection should be carefully monitored for signs and symptoms of pneumonia, especially if they have underlying conditions which may predispose them to pneumonia."