



# THEBODY PRO

The HIV/AIDS Resource for Healthcare Professionals

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BI-WEEKLY PROFESSIONALS UPDATE • April 25, 2006  
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TO:

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## IN THE NEWS

Medical Reviewer: Benjamin Young, M.D.

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### Mixed Results for Investigational Enfuvirtide Administrations

New research suggests dimmed hopes for a once-daily dose of enfuvirtide (T-20, Fuzeon), but continued promise for a needle-free administration device. A randomized, open-label, crossover study by AIDS Research Consortium of Atlanta researchers found that administering enfuvirtide as two 90-mg injections once daily appeared to result in a sub-optimal antiretroviral effect compared to the standard twice-daily dosing of the drug. Thirty-three patients spent seven days receiving one dosage level, then another seven days receiving the other. Although researchers found that the two dosages were bioequivalent and had similar adverse event profiles, trough levels and viral load reduction were found to be lower among once-daily dose recipients. The study was published in the Feb. 14 issue of *AIDS*. Meanwhile, in a 32-patient study published in the March 21 issue of *AIDS*, researchers from the British Columbia Centre for Excellence in HIV/AIDS reported that the needle-free, gas-powered device Biojector B2000 was regarded by patients as significantly easier to use than the standard syringes used to inject enfuvirtide. The device also significantly reduced, but did not eliminate, the occurrence of injection site reactions, while achieving similar plasma levels of enfuvirtide to that observed with needle administration.

### DFC, an Investigational NRTI, Is Pulled From Drug Pipeline

The development of an investigational NRTI, DFC (dextelvucitabine, formerly D-D4FC or Reverset), has been discontinued due to concerns that the drug may cause pancreatic inflammation, according to an announcement by Incyte, the company that had been developing the drug. Incyte said that researchers conducting a phase 2b study of DFC found that an “unacceptably high” number of patients—quantified as “well above ... 10% to 15%”—developed severe hyperlipasemia when switching to DFC from lamivudine (3TC, Epivir) or emtricitabine (FTC, Emtriva). Although signs of DFC-related hyperlipasemia had been seen in earlier trials, Incyte said that the rates of severe hyperlipasemia in the new phase 2b study were so high that it was no longer worthwhile to continue developing the drug.

### Interaction Reported: Buprenorphine, Atazanavir + Ritonavir

Buprenorphine (Subutex), which is increasingly being utilized as a step-down drug for patients recovering from opiate addiction, may interact with ritonavir (Norvir)-boosted atazanavir (Reyataz), according to a trio of case reports published in the March 21 edition of *AIDS*. Connecticut physicians R. Douglas Bruce and Frederick L. Altice reported sedative-like adverse events such as grogginess, dizziness and reduced mental function in three patients who had been concurrently prescribed ritonavir-boosted atazanavir and buprenorphine. In two of the three cases, a reduction in the buprenorphine dose was associated with an improvement in symptoms. In the third, opiate cravings made a dose reduction

undesirable, but the patient reportedly developed a tolerance to the neuropsychological effects after receiving support and counseling.

### FDA Allows Indian Firm to Sell Generic AZT Capsules in U.S.

The U.S. Food and Drug Administration (FDA) has granted Indian drug manufacturer Aurobindo Pharma approval to sell and market in the United States a capsule dosage of the generic antiretroviral zidovudine (AZT, Retrovir). The treatment is the first generic capsule form of zidovudine to be approved by the FDA for the U.S. market. The FDA approved generic tablet and oral solution forms of zidovudine for U.S. sale in September 2005, following the expiration of GlaxoSmithKline’s patent on the drug.

### Race Impacts Lipid Effects of HIV Treatment, Study Finds

Race and ethnicity may help predict which HIV-infected patients receiving antiretroviral therapy are at risk for protease inhibitor (PI)-related dyslipidemia, according to a cross-sectional analysis by U.S. researchers of data from 626 AIDS Clinical Trials Group (ACTG) studies. The study found that a patient’s race or ethnicity had a highly significant impact ( $P < .001$ ) on triglycerides, HDL cholesterol and non-HDL cholesterol levels while the patient was on HIV treatment. Specifically, African-American patients on treatment appeared to have a less-atherogenic lipid profile than white or Hispanic patients on treatment. The study, published in the March 2006 issue of *PLoS Medicine*, also examined the impact of PI-containing regimens on triglycerides: It found that regimens containing ritonavir (Norvir) tended to increase triglycerides for all races/ethnicities, but that regimens *not* containing ritonavir were associated with a triglyceride increase only in African-American and Hispanic patients. Additionally, researchers noted racial/ethnic differences in the role that apolipoprotein C-III gene variants may play in the effects of PIs on plasma lipid levels. In a related perspective piece, Patrick Mallon of the National Centre in HIV Epidemiology and Clinical Research at the University of New South Wales wrote that the ACTG cross-sectional analysis highlights how pivotal it is that researchers conducting pharmacogenetic studies ensure adequate diversity in their patient populations.

### Experimental Candidiasis Pill May Cut Relapse Rate

The most common treatments for oral candidiasis are the antifungals fluconazole (Diflucan) and itraconazole (Sporanox), but these medications have been so widely used that concern has grown about the spread of antifungal resistance. A new oral candidiasis treatment called posaconazole may provide some help: An international, randomized, single-blind study published in the April 15 issue of *Clinical Infectious Diseases* has found that posaconazole is as safe and effective as fluconazole through 14 days of treatment—and may have a lower post-treatment relapse rate. Twenty-eight days after treatment ceased, continued mycological success was noted for a significantly larger percentage of patients on posaconazole than patients on fluconazole (40.6% vs. 26.4%;  $P = .038$ ), and a smaller proportion of patients experienced a clinical relapse of candidiasis (31.5% on posaconazole vs. 38.2% on fluconazole).



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