Peter Engelhard, a Miami Beach physician specializing in HIV, received training in administering New-Fill in Paris and later organized a compassionate use, 100-patient, open-label trial of the product in Florida. HIV physician Douglas Mest organized a parallel trial for patients in the Los Angeles area. Both found similar patterns of ease of administration, safety and patient satisfaction as were seen in the European trials.

Engelhard said about half of his patients require a "touch up treatment" within a year, though some have gone two to three years without additional treatment. He believes patients who need the touch up are continuing to experience fat redistribution as they show continued signs of lipodystrophy in other parts of their body. Many patients who go the longest without needing additional injections have switched HIV regimens, and their lipodystrophy has either stopped or reversed.

The FDA panel was concerned by formation of what were described as micro-nodules or irregularities where the injections were made. But the doctors said these formations seldom were visible or even noticed by the patients; only a trained physician could tell they were there by gently massaging the skin. The problem was most noticeable around the eyes, where the skin is thinnest and directly over bone.

Mest said the nodules tend to occur within the first two months of treatment and slowly abate over time; he assumes they are excess product. The way to minimize their formation is to inject less of the product and add more later, if needed.

While the FDA panelists were frustrated with limitations of the data presented to them, there was little doubt that the product is safe. The committee unanimously recommended approval of Sculptra, but with several caveats. Among them is a training and certification program for doctors who administer it; trials in women and people of color to make sure the effects are no different (most trial participants have been white men); and longer-term safety data. The FDA is expected to follow the panel's advice and approve Sculptra within the next month or so.

The next hurdle for people with AIDS who want the benefits of Sculptra is getting insurers to pay for it. That is why the AIDS Treatment Activists Coalition pressed for "the strongest possible labeling language, indicating the reconstructive/corrective nature" of the product, as most insurers do not pay for cosmetic procedures. The FDA agreed with the stronger labeling.

Conant said his Conant Foundation, which conducted a trial of Sculptra, would push private insurers and MediCal in California to cover the procedure. The foundation will take administrative and legal action as necessary to see that people have access to it.

> *"Facial lipoatrophy has become the scarlet letter of AIDS. It is the thing that is bothering our patients the most...even doctors wait to start their medication."*
>
> —Marcus Conant

Whether financially hard-pressed state AIDS Drug Assistance Programs agree to add Sculptra to their formulary is unclear. But given the FDA label indication and the often severe psychological burdens that can accompany facial lipoatrophy, a strong case for inclusion can be made.

Dermik Laboratories, the U.S. dermatology arm of the international pharmaceutical company Aventis, recently acquired rights to Sculptra and submitted it to the FDA. It has begun discussing creation of a patient assistance program with AIDS advocates.

BOB ROEHR *is a free-lance reporter based in Washington, D.C.*

FDA Approves Rapid HIV Test

The Food and Drug Administration announced March 26 that the first oral rapid HIV test, which can deliver results in 20 minutes, has been approved for use.

About 40,000 people are infected each year with HIV, and approximately 300,000 men, women and children are unknowingly infected, according to the Centers for Disease Control and Prevention. The Human Rights Campaign called the newly approved rapid HIV test is a leap forward for prevention efforts.

"This is a vital new tool for preventing new HIV infections and getting life-prolonging treatment to those already infected," president Cheryl Jacques said. "Everyone should know their status to protect their own health and the health of their loved ones.

"HIV testing should be rapid, accurate and confidential," Jacques continued. "By offering a pain-free testing mechanism and reducing wait time for results, this new test could increase testing rates.

"In addition to testing advances, it is critical that Congress and the administration fund strategic prevention programs at the CDC," Jacques added. "Infection rates of gay and bisexual men are rising, and we need well-funded science-based approaches to halt this alarming trend."

—*Jim Radosta*