

Start Making Sense

Stop placing short-term individual need over long-term benefit for all

BY PETER STALEY

AM YOUR TYPICAL SELF-EMPOWERED

person living with HIV. I'm a gay, white male with a personal physician who has a large AIDS practice. I subscribe to all the AIDS treatment newsletters. I know and frequently talk with other people living with HIV. I even have a support group. And when Project Inform's Martin Delaney comes to town to speak about the latest

treatments, I'm there. I'm aggressive. I've bought drugs from the underground. And since AIDS clinical trials have heretofore failed to provide clear-cut answers to my treatment questions, I've made best-guesses, relying on anecdotal information and vague clinical data. And I've been lucky: I'm still alive and relatively well.

In this light, the notion that every citizen with HIV should have the right to access any new drug that shows some promise of efficacy (however meager or ambiguous) is certainly appealing. Given the cult of individuality that American culture has so efficiently enshrined, it seems almost patriotic to demand universal access to such untested drugs. But should new and perhaps more informative clinical trials be held hostage to this demand? Should long-term improvements to an inadequate clinical trial system be sacrificed for this short-term individualistic need?

Unfortunately, the AIDS self-empowerment movement seems to be moving away from the goal of prolonging life for as many people as possible. Instead, the self-empowered seek only to save themselves. The moral shift became clear this past summer, when preliminary results from a small phase II study of saquinavir, Hoffmann-La Roche's protease inhibitor, were released. The study—a 24-week, 302-patient, three-arm trial comparing a triple combination of AZT, ddC and saquinavir against double combinations of AZT and saquinavir and AZT and ddC—showed the three-drug combo increased CD4 counts more than the two-drug regimens and that the suppressive effect of the triple combo on viral load was also better than the double combos. Given the short duration and small size of this trial, statistical differences between the arms in disease progression or survival could not be detected.

Shortly after these results were released, the Treatment Action Group (TAG, which I cofounded) got word that Roche was planning to ask the Food and Drug Administration (FDA) if it could

immediately file for accelerated approval of the triple-drug combo based on their experience with 99 patients. In a letter to FDA Commissioner Dr. David Kessler, TAG wrote the following: "We urge you not to invite Hoffmann-La Roche to apply for accelerated approval of saquinavir until we can complete further discussion between FDA, its Advisory Committee, the company and people with AIDS/HIV." This was the first time any AIDS activists had said "not so fast" concerning a drug's approval.

Needless to say, the proverbial shit hit the fan. Adding fuel to this fire, TAG's letter went on to suggest a novel approach to further testing of saquinavir. Instead

of a traditional expanded access program, we suggested that Roche initiate a large, simple trial (LST) comparing two doses of saquinavir to a placebo in all HIV positive patients with CD4 counts less than 500. Unlike traditional AIDS studies, there would be no restrictions on the use of other antiretrovirals. Very important, this study would be accompanied by a salvage protocol providing saquinavir to patients who have failed on all standard therapies or who have less than 50 CD4s. If the LST were further stratified using high and low CD4 ranges, we originally estimated a trial size of 18,000 patients.

Community reaction to our letter and suggestions was initially one of shock. How could we ask the FDA to delay a drug's

approval and suggest instead a giant study using a placebo? The answer, simply put, is: If you accept the premise that our goal with antiretroviral research is to prolong life for as many people as possible, then our desire for early access to a promising treatment must be balanced with a desire for reliable information on the treatment's ability to prolong life.

Maybe you believe that you can prolong your life by custom-tailoring a treatment regimen with early-access drugs and your doctor's close monitoring. But where does that leave the majority of people with HIV who aren't self-empowered? What

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ART: KENNY SCHAFF, "BLIND," OIL ON CANVAS, 3'8" X 3'7 1/2", 1986

The Perez Family

Charles and Rosie deliver HIV test results on TV—muy differently

BY DOUG IRELAND

Charles Perez is a semi-cute twink with empty, untroubled eyes who, after stints producing daytime TV talk for Montel, Ricki and Jenny and a taste of airtime as Norm Korpi's boyfriend on MTV's *The Real World I*, launched his own syndicated version of tabchat. One of his June Sweeps Week offerings: A show in which T.J., a 21-year-old gay student, received his HIV test results on the air.

A few days before, Rosie Perez, the effervescent Nuyorican actress and AIDS activist, had hosted ABC's *In a New Light: Sex Unplugged*, the fourth in a series of annual specials on (as the network's press release fastidiously put it) "the health risks young people are facing in today's sexual climate." In the course of the hour-long doc, a heterosexual girl named Chrissy is shown receiving her test results.

There, the similarity between the two broadcasts ends.

On Charles' show, T.J., a dark-haired Irish lad, is presented with his boyfriend Scott, a thirtysomething blonde yuppie. The couple had unsafe sex on their first date; Scott, who had previously been tested but "didn't stick around for my results," proclaimed that T.J. should have known about Scott's promiscuity because they met in a small-town gay bar where "everybody knows everybody else's business" (as if only the promiscuous can get or transmit HIV). T.J. seemed at somewhat of a loss to explain why he willingly agreed to unsafe sex, commenting that many depressed kids are having unsafe sex as "a '90s form of suicide."

A host of fascinating and important questions were raised by this intro, but they were quickly skirted by

Charles, who couldn't wait to give his audience a chance to have at the two queers, with Scott emerging as the enemy of choice. A certain Dr. Blau, who administered T.J.'s test for the show, was shown intermittently on camera but never given the floor; none of the counseling that should normally accompany an HIV consultation was shown. The word "condom" never passed

By contrast, *Sex Unplugged* had to be one of the most effective sex-ed shows ever aired by the commercial grids in prime time. Rosie Perez hammered home the importance of latex condoms, and the question of how difficult it is for young people to interrupt a moment of passion, intimacy and love to negotiate safer sex was at the center of the discussion. The possibili-



Charles' lips: The host preferred the formulation "unprotected sex."

After a commercial vaunting the sexual attractiveness one can manufacture at Jack LaLanne's, T.J. was finally given his test results. They were negative, thankfully, and T.J. collapsed sobbing into Scott's arms. Asked what he's going to do now, T.J. whimpered, "I'm going to St. Pat's." He'd have been better off taking Scott to a drug store to shop for condoms.

Charles at one point disingenuously insisted that he had "reservations" about telecasting an HIV test "live." During Sweeps Weeks? Sure, Charles. If T.J.'s results had been positive, in the absence of any real education context about treatment and survival, this show would have had the feel of a live-on-TV execution.

ties of fulfilling relationships between seropositive and seronegative persons were sensitively portrayed.

Dotted with cameo appearances by Melissa Etheridge, Jon Stewart and Jared (My So-Called Life) Leto, the ABC special was the first prime-timer on the Big Three networks that I know of to make a strong case for the sexual education of children before they begin active sex lives. A mother is shown discussing with her 11-year-old daughter how safer-sex talks brought them closer together, and a sex class with the child and her peers that include play with condoms was hearteningly sensible. ABC deserves credit for airing this smart, life-saving, intelligent documentary produced by Joseph F. Lovett. Too bad that this series comes only once a year.

RANDOM HITS

- On NBC's June 16 edition of *Dateline*, Maria Shriver's Nerfball questions allowed Magic Johnson to avoid real discussion of the AIDS crisis. Except for Magic's complaint that rumors he was gay in the wake of his disclosure had "hurt" him (why? Maria didn't ask), the focus was almost exclusively on whether he should be allowed to play on the U.S. Olympic basketball team. In another segment, Mickey Mantle—who was infinitely more self-analytical and educational about his alcoholism than Magic was about unsafe safe—reminded the audience that sports figures are the wrong folks to have as role models. Point taken.

- Three useful articles in the June 5 *The New Republic*: Ann Louise Bardach's first-rate exploration of how machismo and religion make fighting AIDS in the Latino community a losing battle thus far; Hanna Rosin's readable rehash of the nefarious role played by the Nation of Islam with its Kemron cure scam; and a discussion by Dante Ramos of the difficulties in statistical reporting on the second wave of infections.

- Focus on the Family is a \$100 million-plus operation with ties to the Christian Right and led by rabid homophobe Dr. James S. Dobson. The June issue of the group's eponymous magazine had a pleasant surprise: A cover story on "Living with HIV: Three Stories of Challenge and Hope," in which the subjects recount the rejection their seropositivity brought them from Christian evangelical churches and plead for more acceptance and support. Makes a surprising contrast to the rhetoric of the Falwells and Sheldons.■

ART: KENNY SCHARF, "LIPIORITE," ACRYLIC AND OIL ON CANVAS, 36" X 48", 1995