Rights stakes may be highest in '98

by Peg Byron
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NEW YORK—Lambda Legal Defense and Education Fund staff are predicting that the coming year will bring a record number of gay and AIDS-related concerns to the country's highest courts.

"The United States Supreme Court and other high-level courts are expected to address employment, the military, disability protections, family and other fundamental constitutional issues for lesbians, gay men and people with HIV in 1998," said Lambda Legal Director Beatrice Dohrn.

"Never have the stakes been so high for the civil rights of our community. We expect an unprecedented number of decisions from top-level state as well as federal courts, and they are likely to affect the way lesbians and gay men are treated across the country for many years to come," she added.

Last fall, a three-judge federal panel disregarded the Supreme Court's ruling against Colorado's Amendment 2 and upheld Cincinnati's Issue 3.

In 1998, among more than 50 cases on its docket, Lambda expects a ruling from Hawaii's highest court that may make civil marriage available to lesbian and gay couples for the first time in this country. State by state, Lambda also is fighting child custody and adoption rulings that discriminate against lesbian and gay families. In one such case, being fought in North Carolina, the state's highest court is expected to rule on whether Fred Smith, who is gay, can have his two sons returned to his care, since his ex-wife won custody because of his sexual orientation.

In the US Supreme Court this spring, Lambda is coordinating *amicus* briefs challenging a Maine dentist's refusal to treat a woman with asymptomatic HIV. The case, *Bragdon v. Abbott* brought by the Gay and Lesbian Advocates and Defenders, could determine whether the Americans with Disabilities Act covers hundreds of thousands of people who are infected with HIV but show no sign of illness.

Lambda awaits a Supreme Court ruling in another employment-related case, *Oncale v. Sundowner Offshore Services, Inc.*, for which it authored an *amicus* brief joined by the leading women's organizations as well as gay and other civil rights groups. In this same-sex sexual harassment case, heard by the Court December 3, Lambda argued that the federal law against sexual harassment at work should be applied without regard to the sex or sexual orientation of the harasser or victim.

Another challenge to the widespread problem of anti-gay employment discrimination is one of the first cases to test California's protection for lesbian and gay workers. Argument against California Causality Management's firing of salesman Dan Kovatch is expected before a state court of appeals this spring.

In the only active federal appeal of "Don't Ask, Don't Tell," Lambda, with the ACLU, has just filed its brief in *Able v. USA*. A district-level court rejected the policy as unconstitutional in July; the US Court of Appeals for the Second Circuit is expected to hear the government's appeal early in 1998.

In a renegade decision last fall, a three-judge federal panel disregarded the Supreme Court's ruling against Colorado's Amendment 2 and upheld Cincinnati's nearly identical Issue 3, which would prohibit legislators from approving discrimination protections for lesbians, gay men and bisexuals. Determined to put an end to the nation's last remaining anti-gay ballot initiative, Lambda and co-council have appealed for a hearing by the entire Sixth Circuit Court.

Lambda, which celebrates its 25th anniversary this year, itself was born of a court battle. It incorporated in 1973 after defeating a New York state court judgment that found there was "no demonstrated need" for a non-profit group defending lesbian and gay civil rights. ▼

Two groups propose live HIV vaccine trials

by Dan Van Mourik
Q-Notes Staff

NEW YORK—The media has recently focused a great deal of attention on volunteers who have stepped forward to submit themselves to live attenuated (weakened) HIV vaccine tests. However, researchers warned of the risks posed by the studies and a US company said it could be two years before a product was even ready for testing. At the same time, an Australian research team said human studies could begin within 18 months.

The flurry of activity surrounding live attenuated HIV vaccines began when the Chicago-based International Association of Physicians in AIDS Care (IAPAC) announced that more than 50 individuals had volunteered to participate in a study of a live attenuated vaccine, first described by Ronald Desrosiers of the Harvard Medical School.

Desrosiers and other research teams have shown that live attenuated SIV (Simian Immunodeficiency Virus) vaccines could provide impressive protection in monkeys. But concerns began to mount with reports that some newborn and adult monkeys developed simian AIDS from the vaccines.

These reports led some researchers, including Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), and Barry Bloom, chair of the UNAIDS Vaccine Advisory Committee, to publicly suggest that human studies should not begin at this time.

"Further delays are unethical." — Dr. Charles Farthing

To date, at least four research groups report monkeys that show signs of immune suppression after receiving a live attenuated SIV vaccine.

Proponents of the live attenuated trials met with officials at the US National Institutes of Health (NIH) to explore ways of "moving the live attenuated approach forward." According to participants, a number of key questions, beyond safety concerns, were identified. These questions included: 1) whether any company would be willing to produce a live attenuated HIV vaccine; 2) whether the US Food and Drug Administration (FDA) would approve a manufacturing plan and clinical trial protocol for such a vaccine; 3) how an informed consent process might be developed that would accurately describe the potential risks from the trial; and 4) what party would be responsible for adverse events caused by the vaccine.

IAPAC proposed a trial that would use a live vaccine designed by Desrosiers that contains HIV with at least four genes deleted. Initially, five individuals would be vaccinated. If these individuals maintain low levels of HIV after six months, the trial would be expanded. John Sullivan, a researcher at the University of Massachusetts Medical School, has proposed that the first study should be in terminal cancer patients. The study would last 6-12 months and only patients with solid tumors for which there is no therapy would be enrolled. According to Sullivan, since many terminal cancer patients have competent immune systems, important information could be obtained from the trial.

But no matter what trial plan might be adopted, producing a suitable vaccine could take several years. Even then, there is no guarantee of FDA approval for testing in humans. In the past, the FDA has been reluctant to approve the use of transformed T-cell lines (one proposed method of producing the vaccine). However, this policy is currently under review.

While IAPAC officials suggested they would go ahead with a trial, even without FDA approval, Dennis Panicali, president of Therion Biologics, said his company "would not, under any circumstances, produce a product for human testing without full FDA approval."

Researchers at Macfarlane Burnet Centre in Australia may be farther along in preparing for a human study. The Australian team, led by John Mills, is pursuing a different strategy than the US researchers. It is attempting to produce a live vaccine that mimics an apparently weakened HIV strain found in a group of long-term non-progressors. The vaccine will be produced from infectious DNA clones capable of causing infection rather than the live virus that IAPAC is proposing. Mills believes that infectious DNA will be less expensive to produce, store and administer than live attenuated HIV. If all goes well, Mills suggests that human trials would begin within 18 months.

Although most AIDS researchers have expressed admiration for the potential courage of the IAPAC volunteers, many appear to agree with Fauci and Bloom that it is too early to test a live attenuated HIV vaccine in humans.

Safety concerns are unquestionably the greatest hurdle to human studies. While not dismissing the need for safety, Desrosiers explained that "it is unrealistic to expect any live attenuated vaccine to be absolutely, 100 percent safe. Every live vaccine used in people has some adverse events associated with it. For example, the live polio vaccine is associated with a very small number of paralytic poliomyelitis cases. But society accepts this risk because of the overall benefits of the vaccine. Similarly, the likelihood of adverse events from an HIV vaccine must be weighed against the frequency of new infections and disease in a target population."

Charles Farthing, a Los Angeles physician and IAPAC member who has volunteered for the trial, says "it is wrong to require an AIDS vaccine to meet US safety and efficacy standards when 8500 individuals are infected with HIV every day around the world." Given the enormity of the crisis, says Farthing, "further delays are unethical." He does recognize, however, that "our willingness to test the vaccine on ourselves is useless without the support of the decision makers in the US, the UN, the scientific community and the biotechnology companies." ▼