

## FDA "reform" bill threatens PLWAs

by Steve Fisher  
Special to Q-Notes

WASHINGTON, DC—AIDS Action denounced US Senate passage of S830, the so-called FDA "reform" bill. The Senate approved the bill by a vote of 98-2 and the House of Representatives consideration of a companion bill, HR1411, is expected before the end of the year.

"There are few constituencies who support the concept of FDA reform as strongly as the one million people living with HIV/AIDS in America; but few constituencies will be harmed as greatly by this bill," said Daniel Zingale, executive director of AIDS Action, the nation's leading AIDS advocacy organization representing more than 2000 community-based agencies. "Gradual improvements in the approval process have achieved a balance between increased approval time and the protection of consumer safety; the Senate bill breaks this delicate balance."

For those affected by HIV/AIDS, the most egregious and detrimental provision in the bill allows off-label drug marketing. Under the bill,

drugs approved for certain uses but also prescribed for unapproved purposes could be marketed for those unapproved uses. The promotion of off-label use would undercut the high efficacy standards at the FDA and would threaten the health and safety of people on certain HIV drug therapies.

"Enactment of off-label promotion could lead to an explosion in unapproved drug uses, dangerously diluting the drug safety process," added Zingale. "FDA reform must be enacted for the benefit of health care consumers, not the health care industry."

AIDS Action has called for an immediate long-term reauthorization of the Prescription Drug User Fee Act, the non-controversial backbone of an improved and more efficient FDA. In the meantime, AIDS Action will be working to ensure that the House version of the bill is enacted without provisions that threaten the important regulatory authority of the FDA.

Zingale added that "wholesale FDA reform must proceed with greater prudence. The lives of nearly a million HIV-affected people depend on it." ▼

## Festivals

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a potluck dinner and talent show at the Unitarian Universalist Church of Charlotte at 6:30. Fling together something delicious and come giggle at members of the local GLBT community on stage.

On October 9, there will be screenings of two films at the Mint Museum of Art. *The Watermelon Woman* is at 7pm and *Delta* is at 9pm. Then the pace picks up. The Artists-in-Residence for the 1997 festival are the Root Wymn Theatre Company out of Austin, Texas. This ensemble has been causing quite a stir, and you can be sure to be challenged by what they present. *No Mo Blues* plays on Friday and *Dyke Warrior/Prayers* Saturday, both at Theatre Charlotte. Also on Friday and Saturday is David Drake's comedy *The Night Larry Kramer Kissed Me*. This one-man show, performed by Kevin Fabian, performed Off-Broadway for an almost endless run and is sure to be a highlight of the

festival.

The Eggplant Faerie Players are a little hard to describe...it's sort of like Liberace, Tammy Faye and The Village People taking over an episode of *Designing Women*. But then, that could actually happen, couldn't it? They will perform *Next Year in Sodom* to the delight of all. Don't miss it, or you'll feel awfully left out when everybody else is talking about it! Friday at 10:45 at Theatre Charlotte. Dos Fallopa is a comedy duo that specializes in all things feminine. They perform twice on Sunday at Theatre Charlotte. Don't feel left out if you're a boy, because deep down, we're all girls. You'll think they are hilarious.

These are only the major performances of the weekend; there are dozens of other activities planned including workshops, a gallery exhibition at The Blue Pony, the NC Pride Marching Band, and of course, the Emerald City Ball. So put on your ruby pumps and click three times. Because we may not be in Kansas, but we *are* home! ▼

## Leaders

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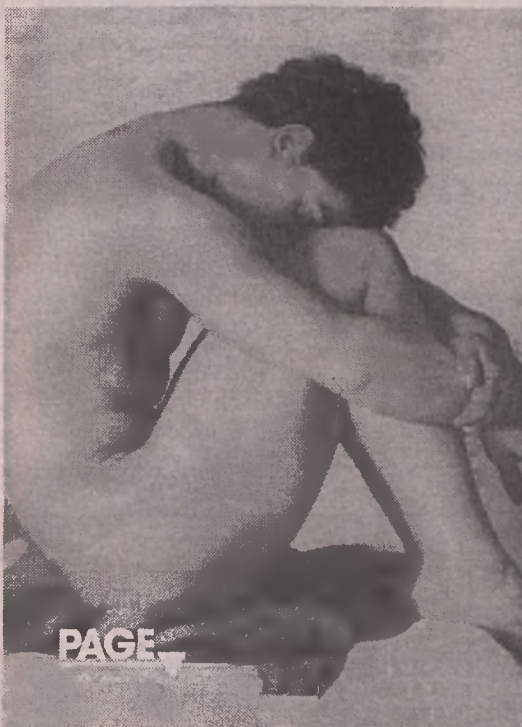
gay/lesbian service organization — ranked by their own peers, include: 1) Los Angeles Gay & Lesbian Center; 2) New York Lesbian & Gay Community Center; 3) Human Rights Campaign, headquartered in Washington, DC; and 4) Lambda Legal Defense Fund, headquartered in New York.

According to Joseph McCormack, the survey creator, "Our outcomes are not startling to us. They reveal an emerging network of social service agencies that are successfully making the transition — over the past 15 years — from grassroots activism to stable leadership and professional management. These responses are a 'snapshot' that enable us to measure how well we are matching resources and human capital to the needs of a large segment of the American people."

McCormack concluded that, "The AIDS

crisis has trained a new generation of leaders — many of them gay and lesbian — who are using this training to advance a broader agenda of social justice issues. We've seen the flourishing of an intricate, professional and cost-effective network of talent that has responded to HIV and AIDS — often against great odds, professional stigma and precarious funding. It is clearly a cause that has attracted many experienced and competent professionals who have taken substantial pay cuts and sacrificed personal time in service to the community. They have prevailed and achieved meaningful progress with limited resources."

The McCormack survey was conducted nationally on a confidential basis, and offered all respondents anonymity in completing and returning a written questionnaire. According to the firm, the response rate of 44 percent, combined with the anonymity of responses, provides a very high degree of confidence in the results. ▼



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