TAG, ACT UP in Hot Fax War

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Which is more important: The right of a person with AIDS to have quick access to a reasonably safe drug or the right of the same person to know just how well an expensive drug works?

The question is at the heart of a furious volley of sometimes hyperbolic consensus statements, calls-to-action and outright diatribes that jammed the fax machines of major AIDS treatment-advocacy groups recently. The faxes were mobilizing opposition to a recently announced proposal for a clinical trial of protease inhibitors. “This is the worst set of feelings I’ve seen in years,” said Dr. Donald Kotler at an ACT UP/New York meeting.

The fury was not aimed at a pharmaceutical giant or a government agency but at New York City-based Treatment Action Group (TAG). The fuss, brewing since ddC was approved last year, exploded after the financial weekly *Barron’s* quoted TAG member Spencer Cox as favoring a slowdown in the rapid pace of drug approval.

The man leading the charge against TAG’s proposal is Martin Delaney, founder of the San Francisco-based advocacy and information group Project Inform. Delaney says that protease inhibitors, a new class of anti-HIV drugs with an encouraging street reputation, should be approved as quickly as possible -- even if that means no one will really know how effective they are. “Our point is that the community needs to say that we still believe in the accelerated approval process,” he says.

TAG doesn’t want researchers to make the same research mistakes made when the marginally effective nucleoside analog drugs AZT, ddI, ddC and d4T were tested. “When do you start AZT? When do you switch to ddI? When do you stop?” asks TAG member Gregg Gonsalves. “No one can answer any of these questions. We shouldn’t make the same mistakes with protease inhibitors.”

To avoid that, TAG discouraged the Food and Drug Administration (FDA) from inviting Hoffman-La Roche to submit an accelerated approval application for its protease inhibitor, saquinavir. Instead, TAG proposed a “large, simple trial” (LST). Rather than asking a very specific question based on arcane immunological values, like most clinical trials, the LST would test whether adding a protease inhibitor to a regular treatment regimen delays death or AIDS.

TAG’s action provoked widespread fear that access to a promising new treatment was being taken away. But Gonsalves claims that Project Inform and ACT UP are misrepresenting the LST concept and the extent to which approval would be slowed. “You don’t have to choose between access and

information," he says.

Because TAG has the ear of the FDA, Project Inform began circulating a consensus statement to show the agency that there is, in fact, broad-based support for the status quo. "It would be a major step backward to use the concerns about 'how best to use drugs' as a lever to slow accelerated approval," the statement says.

TAG insists its proposal will not dramatically diminish access. "This proposal is not about taking anything away," says TAG member Derek Link. "It's about adding something. We don't just need drugs, we need information."

This is a slow pot that has just come to a boil. The fire was lit when the FDA approved ddC on the condition that Hoffman-La Roche conduct post-approval studies to determine how to use the drug. Tens of millions in sales later, Hoffman-La Roche has not conducted the studies. TAG's LST proposal would force drug companies to spend the money for full FDA approval.

So AIDS activists opposing the TAG proposal have found themselves in the unfamiliar position of defending multi-national drug companies. Perhaps uneasiness about this is one of the reasons the rhetoric has gotten so heated. One unsigned circular passed around an ACT UP/New York meeting in mid-August -- that quickly made its way across the country -- accused TAG members of being a "genocidal, patriarchal elite." Spencer Cox was not amused. "They're either too dumb to discuss the issues or it's a conscious political move. If you hype people into a frenzy over personalities, they never stop to think whether these drugs work."

Many activists are searching for a middle ground in time for a mid-September FDA hearing on the subject.

Meanwhile, Jeff Getty of ACT UP/Golden Gate is angry. "There's a space in my medicine cabinet I thought would be filled by a protease inhibitor by November," he says.

Whether that's good or bad is largely in the eye of the beholder.
