Cautious optimism

October meeting of Clinton's AIDS drug task force an improvement over others

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by Bob Roehr

Cautious optimism is perhaps the best way to describe the aura surrounding the National Task Force on AIDS Drug Development meeting which took place Oct. 27 and 28 near Washington, D.C. The group is a major initiative by the Clinton administration, through Health and Human Services Secretary Donna Shalala, to facilitate development and approval of AIDS-related therapies.

"I think the last two days were definitely better than our July meeting," said Peter Staley, a member of the task force and of the Treatment Action Group in New York City. "Up until now I have been very frustrated with the task force's work, because we have kind of been all over the map and not come up with any hard recommendation on specific issues, with the exception of gene therapy and the regulatory process."

ness and analysis in order to gain approval of new drugs.

AIDS and women's advocates want more. ACT UP demonstrated outside the FDA in September and several dozen members from around the country were back for this hearing. They held up posters reading "Guidelines are not enough. Access now," and "Killing time is killing women."

Dr. Maxine Wolfe, a researcher and member of ACT UP, was invited to speak from the audience. She called the current policy "totally unwarranted paternalism." She pushed the government to move beyond simply dropping restrictions, to formulate an affirmative mandate to include women in all phases of clinical trials, and to put resources into enforcement of those guidelines.

Theresa McGovern, attorney with the HIV Law Project and a member of the task force, was encouraged by the direction in which the panel was

President Bill Clinton

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Discussion of protease inhibitors, the most promising family of next generation anti-viral medications, highlighted the first day's activities. Staley is encouraged that the next full meeting of the task force, in February, will be dedicated to "looking comprehensively at development of protease inhibitors."

"We are going to haul in all of the top executives of all of the companies who are developing protease and try to knock some heads together and get everybody working together. We don't want to repeat the mistakes that we made with the nukes [nucleoside analogs such as AZT]."

Women and clinical trials opened the second day and extended into twice its allotted time. A 1977 Food and Drug Administration regulation had barred women of child-bearing potential from early Phase I and II clinical trials of experimental drugs.

That was challenged in December 1992 by the HIV Law Project. Both the FDA and National Institutes of Health subsequently lifted their gender-biased restrictions on enrollment for clinical trials of drugs for life-threatening illnesses, except where there is "medical justification." They have also issued guidelines calling for gender inclusive-moving. However, she noted there were "no teeth" in monitoring and enforcement provisions, those need to be built into the system. She called upon the FDA to "use its regulatory power." Both women pushed for "by gender analysis" of drug effects in trials, something which is only now being implemented.

Staley called the FDA response "unfortunate," as they knew the debate was coming. He wants them to mandate and enforce nonexclusionary policies in all phases of drug trials. "That puts the burden of responsibility on the trial participant, where it always is anyway on these issues."

That burden can include death, as it did with FIAU. Last year the experimental hepatitis B drug killed five of the first 10 people enrolled in the Phase II trial at NIH. Most were gay men.

The FDA published new regulations Oct. 27, designed to shift the most basic presumptions in all clinical trials. "The data needs to be seen with as much skepticism as optimism," said FDA spokesman Jim O'Hara.

It was a stark reminder that clinical trials are just that—experiments, not treatment. They often do not work and sometimes have unanticipated, even disastrous effects.