



Parallel Track: What It Is, Why We Need It, Where It Is and Why We Should Be Pissed That We Don't Have It Already

What It Is

Parallel Track is a proposed mechanism for the early release of drugs or treatments for life-threatening illnesses that have shown manageable toxicity and indications of efficacy (i.e., they seem reasonably safe and may actually do some good). Those people who would qualify and be able to take part in more definitive clinical trials of the drug would not be eligible under Parallel Track. Patients in reasonably good health with other treatment options (for example, patients with over 400 T-cells who can take AZT) would also not be eligible. While it would technically be applicable for other diseases, like cancer, for all practical purposes, it applies only to AIDS.

Why We Need It

Besides the obvious need to offer treatment options to people who have none, and consequently no hope, the need for Parallel Track is political. The FDA argues that mechanisms for such early release already exist. They point to the Treatment IND (Investigational New Drug) mechanism used for expanded access to ddI. While this has been a great victory, the Treatment IND process was not really designed for this kind of program in an international emergency like AIDS. The only way Treatment IND was allowed to be used this way for ddI was due to the tremendous political pressure and the cooperation of the drug company (which was also due to political pressure). We have too many other battles to fight to have to do this for every drug. What Parallel Track would do is to tell the FDA, the drug companies and the American people that early access was deemed appropriate and important by the powers that be. This would encourage bureaucrats and drug companies to take the inherent risks involved in the release of a drug that is only partially tested. Such risks are needed. Also, by introducing any new procedure into a bureaucracy like the FDA loosens the regulatory logjam that always exists in such agencies. This gives activists an opening to introduce even greater and more desperately needed changes!

STOP AIDS STOP AIDS STOP AIDS STOP AIDS STOP AIDS

Where It Is

Parallel Track was conceived and explained to Anthony Fauci, Director of the National Institute of Health (NIH), by AIDS advocates from New York, including ACT UP, in June of 1989. Dr. Fauci announced his support of the proposal the same month in San Francisco. A task force, including community activists, was set up and wrote a first draft of the proposal. Congressional hearings followed, at which Nancy Pelosi, the Congresswoman from San Francisco, was one of the few representatives to strongly advocate Parallel Track. Equivocation by some key Congressmen, especially Rep. Dingle from Michigan and Rep. Ted Weiss from Manhattan (who has the highest incidence of AIDS in the country), hurt the momentum of Parallel Track. They are known as consumer protection advocates and seemed unwilling to strongly support this, since it might put consumers at risk (As if people with AIDS weren't at risk already!). Another case of our elected officials trying to protect us to death! Another meeting of the Task force was held in November of 1989 and a second draft was sent to Louis Sullivan, Secretary of Health and Human Services (HHS) for approval and then appearance in the *Federal Register*, which is where the government announces such things. Since then it has been reviewed by all kinds of bureaucrats, attorneys, economists, etc., and it is currently lost somewhere between "upstairs and downstairs" in the National AIDS Program Office (headed by Jim Allen). All calls by us, congressional aides and everyone else yield the same response: that there is no problem, and it will be out soon.

Why We Should Be Pissed That We Don't Have It Already

Parallel Track is morally unquestionable. To deny dying individuals access to hope is outrageous!! Parallel Track was proposed 9 months ago, that represents over 25,000 deaths for AIDS in the US alone. A politically acceptable draft was given to Sullivan 4 months ago, that represents over 12,000 deaths. This last figure is particularly disgusting as the only thing holding it up is bureaucratic inefficiency, laziness and political cowardice. We cannot wait any longer. There are no more excuses!!! We demand parallel track now!!! We demand the release of ddC, a promising drug from Hoffman-Laroche that works like AZT and ddI that is the only hope for people who have failed both of these, and GMCSF, a drug from Schering that has been shown to effectively boost white blood cells, which would allow patients to continue on other toxic but effective treatments like gancyclovir for retinitis, AZT and chemotherapy for lymphoma, under the Parallel Track guidelines.

We have called for a demo at the old Federal Building at 4 PM on Monday, April 16. There is significant street theater and speakers planned. Help is needed, especially with artwork, putting up flyers and outreach to other groups. This is an issue that affects everyone impacted by HIV. The first planning meeting is at 2:30 PM, Sunday, April 1 (no fooling!) at 801 Corbett, #4. Call Jesse at 547-7414 for more info.