

## DDI Early Release Program A Partial Victory for AIDS Activism

DDI has become the first new AIDS treatment to be released to a significant number of people at the end of Phase I toxicity studies. This antiviral drug will be given to about 2500 people in Phase II drug trials to measure its effectiveness and (hopefully) given to several thousand more who meet special definitions of AZT intolerance or resistance.

The early release of AIDS treatments as soon as they are proven safe (but before the long process of measuring efficacy has been completed) has been a demand of the AIDS activist movement for years. It was a demand when 1500 of us shut down the Food and Drug Administration headquarters in October 1988. And it has been echoed in every meeting, phone call, and letter between AIDS activists and the FDA and drug companies.

In particular, ACT UP/New York, Project Inform, and ACT UP/San Francisco began a sustained campaign last spring to pressure for an institutionalized early release program for promising treatments with ddi as the first candidate for the program (see other side).

That is why Bristol-Meyers was forced to design a proposal for ddi early release and that is why the FDA was forced to approve it.

It is vitally important to acknowledge the role of AIDS activism in ddi's early release. Drug companies and government bureaucracies have shown very little willingness to recognize the crisis nature of the AIDS epidemic. They have only begun responding to the special needs of AIDS-affected communities in the last year, over eight years into the epidemic, in response to tremendous pressure and widespread criticism.

The early release program is a great step forward, however long overdue, but it is still seriously flawed.

The eligibility requirements for both the "treatment IND" (Investigational New Drug) program (for AZT intolerant people) and the "open label" program (for AZT resistant people) are incredibly restrictive. The definitions for AZT toxicity and failure are cruelly extreme and will exclude many whose experience with AZT, under a humane plan, would entitle them to try ddi.

Furthermore:

- all children are excluded
- pregnant women are excluded
- those without personal private doctors, or whose doctors won't do the extensive paperwork, are excluded
- those who cannot afford ongoing extensive lab work are excluded
- those who choose not to try AZT are excluded

In addition, it is important to note that this program is not the "parallel track" demanded by AIDS activists, despite incorrect media reporting.

Like the ddi programs, parallel track would make promising treatments available after safety testing. But parallel track would distribute these treatments not only through doctors' offices but through public health clinics and community-based research institutions. Unlike the ddi program, parallel track would not be contingent on supplying extensive lab data. It would make treatments available not only to those who don't meet the drug trial criteria but to those who live too far from the trials, are too sick for the trials, or cannot participate for a variety of other reasons.

We must all recognize the role AIDS activists can play in pressing for a *true* parallel track program and an expanded and truly fair system for early ddi release. Recognizing the need for such pressure should make many more of us into AIDS activists.

ACT UP/San Francisco  
2300 Market Street # 68 San Francisco, CA 94114 563-0724  
ACT UP/SF meets every Thursday night, 7:30 p.m. at the MCC Church, 150 Eureka St. (3 blocks West of Castro).  
Everyone is welcome.

## ddI and AIDS Activism: A Partial Chronology

1989

- May 22 ACT UP/NY had a letter writing campaign to Bristol-Meyers concerning ddI: one letter hand delivered to CEO.
- May 31 Project Inform warned that ddI would not be available until the end of the year, at earliest.
- June 8 ACT UP/NY presented treatment agenda at Montreal AIDS conference, including a call for immediate ddI availability.
- June 20 ACT UP/NY met with Anthony Fauci of the National Institute of Allergies and Infectious Diseases to discuss concept of wider access to drugs; a plan ACT UP/NY named "parallel track."
- June 21 ACT UP/NY met with Ellen Cooper, head of antiviral section of the Food and Drug Administration, to discuss parallel track and to focus on ddI.
- June 23 ACT UP/NY met with Bristol-Meyers in NY to develop preliminary ideas about inclusion for treatment IND and Compassionate Access to ddI. This is the earliest use of treatment IND ever, coming directly out of phase I trials; formerly efficacy data needed to be included. ACT UP/NY unsatisfied with Bristol-Meyers, sends letter of complaint.
- June 23 At San Francisco's Treatment Awareness Week sponsored by Project Inform Anthony Fauci publicly announced support for parallel track concept. ACT UP/SF met with Fauci to discuss ddI, parallel track and other issues.
- July 7 At the Community Research Initiative Conference ACT UP/NY met again with Fauci. He agrees parallel track should not be data driven but rather a system to get drugs to those that need them.
- July 13 Bristol-Meyers promised "widespread early access" to ddI (in conjunction with phase II trials) by September.
- July 17 ACT UP/NY met with Bristol-Meyers and presented list of who should receive ddI; particularly stressing community based trials (a concept which has received a great deal of resistance within the FDA).
- July 20 Representative Waxman holds Congressional Hearings for parallel track. Project Inform wanted to know if those who choose not to take AZT would be allowed to die without ddI therapy. Assistant Secretary of Health James Mason calls for advisory panel on parallel track since Fauci is only apparent supporter.
- Late July Toronto based AIDS Action Now protested Bristol-Meyers.
- August 1 ACT UP/SF met with local FDA officials to discuss ddI and to establish meeting with Stuart Nightingale from the FDA in D.C. concerning ddI while 250 demonstrate outside demanding ddI access for all who need it.
- All of August Meetings took place between community doctors, the FDA & Bristol-Meyers. FDA's Ellen Cooper listened to doctors' input.
- August ACT UP/SF met with Stuart Nightingale about inclusion criteria and other drug related issues.
- August 15 Bristol-Meyers applied for Treatment IND and Compassionate Use protocols. *This is not parallel track but pre-existing classifications. ddI is not an example of parallel track.*
- August 17 Consensus group statement about parallel track from many different AIDS organizations, including ACT UP/SF and ACT UP/NY, given to FDA.
- September Treatment IND and Compassionate Access to ddI delay due to 1) fear that other more regimented clinical trials may be in jeopardy through the wider access program and 2) toxicity of ddI; Dr. Paul Worrall of Bristol-Meyers changed protocols almost daily to incorporate toxicity data.  
Study centers started to receive ddI in last few weeks.  
ACT UP/LA holds 21 day hunger strike focusing on ddI early release.
- Mid-September AIDS activists including ACT UP/SF and ACT UP/NY obtained drafts of ddI protocols prior to official release. Intense negotiations between ACT UP/NY, Bristol-Meyers & FDA resulted in significant expansion of inclusion criteria.
- September 29 Bristol-Meyers released protocols for Treatment IND and Open Label Study Regiment. ddI became available.
- October 11 ACT UP/SF unsatisfied with narrow inclusion criteria sent point by point evaluation of concerns to Bristol-Meyers, the FDA and the National Institutes of Health.
- November 2 ACT UP/NY, the FDA and Bristol-Meyers met to discuss further expansion of inclusion criteria. FDA and Bristol-Meyers promise to expand significantly both protocols.

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