# FDA Looks to Speed Up Drug Approval Process

*Bush wants the FDA to accelerate approval for drugs to treat life-threatening illnesses; more risks are okay, given the alternative; some clinical trials may be eliminated*

TO APPEASE AIDS PATIENTS and others clamoring for access to experimental drugs, Vice President George Bush recently asked the Food and Drug Administration to look for ways to cut some corners and to speed approval for drugs to treat life-threatening illnesses for which there are no alternative therapies.

FDA Commissioner Frank Young responded to Bush's charge with a proposal that would allow the FDA to approve a drug without knowing everything there is to know about the agent's long-term toxicity or long-term effectiveness. To answer these lingering questions, Young's proposal states that the agency may require additional studies on drugs after they have been approved. Whether the FDA can demand the additional studies without new legislation is uncertain. How the agency would yank drugs after it approved them is also problematic.

To hurry up the process for drug approval, Young sees the FDA taking a far more active role in helping drug companies design their early clinical trials. The FDA might even offer to do some of the research itself, especially in cases where the company sponsoring the drug is either too small or too inexperienced to do the job alone.

In the past few weeks, Young has been briefing interested parties on his proposal, which is winning mixed results, even within the FDA. Most everyone agrees that getting truly promising drugs into very sick patients as quickly as possible is a noble goal. But critics contend that the proposal is only a public relations gesture. Says Jeff Levi of the National Gay and Lesbian Task Force in Washington: "I suspect the whole thing is just a political exercise to boost the vice president's popularity."

Levi's dislike of the proposal comes from a basic disagreement between the regulatory agency and AIDS patients and their advocates concerning access to experimental or alternative treatments. Many AIDS patients want to be able to get their hands on drugs immediately after they've shown the slightest hint of efficacy, if only in a test tube. The FDA, however, maintains that drugs must not only prove to be relatively safe, but effective according to rigid scientific criteria. And it is here, over the government's insistence that it protect desperately ill patients from drugs that might not work, that the battle lines have been drawn.

"We believe that there are adequate provisions for protection, but not for access to drugs . . . The FDA is deeply rooted in consumer protection, not saving lives," says Martin Delaney of Project Inform, an AIDS information group in San Francisco.

Even some members of the Administration would like to see new regulations that give patients and their physicians greater access to drugs that might ultimately prove ineffective.

**Frank Young:** *A more active role*

"Historically, the FDA has felt that it's better to deny approval to a drug than approve one too quickly. But in this case, you're not talking about headache remedies or cosmetics, you're talking about a drug for someone who is threatened with imminent death," says Jay Plager, executive director of the Presidential Task Force on Regulatory Relief, the group chaired by Bush which instigated the new proposal.

As the system currently operates, an investigational new drug is put through three phases of clinical trials in humans after first showing biological activity and safety in test tubes and lab animals. The first phase concerns the safe dosage range of the drug and examines how the drug is absorbed and metabolized. Only a handful of people are needed for the first trial. The second phase, which involves several hundred patients and may last 2 years, asks the more pressing question: does the drug work? The third phase involves thousands of patients and several more years, and is designed to further test efficacy and to search for adverse reactions that might occur in only a few patients.

Young's proposal for accelerated approval would eliminate the need to do the large Phase 3 study before approval. Instead, Young would call for a mandatory meeting between the drug sponsor and the FDA following the completion of the Phase 1 clinical trial. At this meeting, the company and the government would agree on the design of the Phase 2 trial, so as to answer as many questions as possible concerning efficacy and possible side effects. This would probably mean larger and more elaborate Phase 2 trials. But if the drug proves to be safe and effective after the completion of the Phase 2 trial, FDA would approve the drug at that time.

Some potential stumbling blocks remain. One concern is the so-called treatment protocol for investigational new drugs, or the treatment IND. In June 1987, under pressure from AIDS patients, the FDA decided to allow people greater access to experimental drugs outside of the carefully controlled clinical trials. Under the treatment IND system, a company can release an experimental drug to patients after it completes a Phase 2 clinical trial, but before it completes its Phase 3 trial. According to Young's proposal to accelerate approval for drugs, the treatment IND system could be used to make a drug available to patients during the window of time between the completion of the Phase 2 trial and approval by the FDA to market the drug.

Unfortunately, the treatment IND system has been a great disappointment to AIDS patients. To date, only one AIDS drug has been released under the new protocol. Plager believes that a manufacturer has no reason to offer his product through the treatment IND process because the company is not allowed to actively market the drug, nor is it allowed to reap profits only to recoup manufacturing costs.

But Deborah Katz of the AIDS Program at the National Institutes of Health thinks the problem is not the treatment IND system itself, but "the fact that we haven't had enough promising drugs."

The proposal by Young does not deal with producing promising drugs, only moving drugs through the system with greater speed. Producing promising drugs is another problem entirely. ■ WILLIAM BOOTH