Call To Arms: Expended Access

Stop the rollbacks in expanded access to experimental drugs for optionless PWAs

October 1, 1997 By Matt Sharp

Expanded-access programs -- which offer free experimental treatments to PWAs out of options -- are disappearing, and that's a disaster. Drug companies have constantly postponed their launch dates, drastically limited the numbers allowed to enroll, and outrageously narrowed the criteria for patient inclusion. It's time to join the growing community chorus demanding treatments for the many people at the end of their antiretroviral rope.

Expanded-access began with great promise. In 1989, after much activist sound and fury -- including many ACT UP demonstrations and civil-disobedience arrests -- the Food and Drug Administration (FDA) instituted this revolutionary change in the drug-development process: Manufacturers were allowed to provide drugs with early signs of efficacy and clearly established safety, before FDA approval, to people with serious or life-threatening conditions for whom approved drugs had failed.

After AIDS activists poured energy into generating pressure on the manufacturers, expanded-access quickly got drugs into the bodies of sick and dying PWAs -- while accumulating efficacy data faster than clinical trials alone could have, thereby helping bring drugs to market faster. Examples of the numbers of PWAs served by past programs: ddI, 23,000; d4T, 12,000; and 3TC, 32,000. These programs probably saved thousands of lives.

But since 1992, the FDA's "accelerated approval" process has required less and less data from AIDS-drug studies. So why should the companies bother with cumbersome drug giveaways that no longer even help speed the start of their profit-making? And until this year, in-your-face activist pressure had sharply declined.

The result: In 1995-96, manufacturers of the first three protease inhibitors shamefully limited drug access to small numbers of PWAs through "lotteries" in only the last few months before approval: Roche's saquinavir, 4,000; Abbott's ritonavir, 1,480; and Merck's indinavir, 1,500. A lottery for life-saving drugs is immoral -- you can't gamble with people's lives.

Over the past year, though there have been no more lotteries, the miserly pattern has continued in the allocation of expanded-access slots: Boehringer/Ingelheim's nevirapine, 300; Pharmacia & Upjohn's delavirdine, 1,500; and Agouron's nelfinavir, 3,100 (most of them granted just before FDA approval).

Repeatedly, pharmaceutical PR flaks trot out the same phoney excuses for limiting the programs: “We need time to ramp up production capacity,” or “This drug is difficult to make; it requires sophisticated factories.” If these problems indeed exist, why can’t the manufacturers subcontract with other companies to increase supply? And if they can provide drugs for all their clinical trials, why can’t they plan ahead for large-scale access programs that might -- if the drug works -- save a few thousand lives?

The fact is the companies usually drag their feet as long as possible until FDA approval allows them to charge whatever the market will bear -- and then voila! Unlimited supplies appear on every pharmacy shelf in the country, sometimes within 72 hours.

The bottom-line corporate motivation is clear: They don’t want to forgo lucrative sales -- almost always at exorbitant prices -- to thousands of PWAs. So now these multibillion-dollar corporations with extraordinarily high profit margins seek the best of both worlds: Sharply limiting the quantities of free drugs provided while turning expanded-access into a marketing tool to publicize new drugs before approval. This subverts the original purpose of these programs.

Today, antiretrovirals have failed for an estimated 10,000 U.S. PWAs. I’m one of those. For a decade, my survival strategy has been to treat aggressively and buy time with the best drugs I could get my hands on. Over the years I enrolled in four expanded-access programs (for d4T, 3TC, delavirdine and nelfinavir) that enabled me to stay ahead of the mutated virus replicating wildly in my body. Each drug came along when my CD4 count was dropping, my viral load rising or my overall health declining. And each drug delayed my disease progression -- for a while.

But now, I’ve again exhausted my options. My viral load is rising and I need to move to the next expanded-access program. Only none are open to me -- despite the existence of several promising experimental drugs.

Perhaps the worst case of corporate foot-dragging is Glaxo Wellcome’s behavior with 1592 (abacavir), its easy-to-produce nucleoside antiretroviral creeping through its ninth year of development. Last year, clinical-trial data showed that 1592 appears reasonably safe and somewhat effective. Yet at presstime, despite months of activist pressure, Glaxo is only offering access to 2,400 people worldwide, and says it won’t apply for FDA approval until mid-1998. The go-slow policy is no surprise for a promising alternative to that company’s hot sellers (and the most profitable anti-HIV drugs ever), AZT and 3TC, patents on which still have several years to run.

Meanwhile, Glaxo’s experimental protease inhibitor, 141W94, is nowhere near expanded access. Gilead’s PMEA (adefovir), another anti-HIV drug, is not much further along. DuPont-Merck is already claiming supply problems with its antiretroviral DMP-266. Some corporate officials say they’re considering a combined expanded-access program for 1592, PMEA and DMP-266, but this strategy will require cooperation from three competing companies and even then, will take a while to implement.

For months, a broad range of AIDS advocacy groups has applied many forms of pressure to the various offenders. This has included not only letter-writing, meetings and product boycotts

(backed by the San Francisco and New York city councils), but also ACT UP protests at the *POZ* Life Expo and civil disobedience at corporate offices (See Gazette, “Wellcome to My Nightmare,” [files not available]) Some companies have made concessions, but we’ve got a long way to go.

Join the fight. Support the boycott of Glaxo’s antacid Zantac (rantidine) and anti-herpes drug Zovirax (acyclovir) -- use generic versions instead. Confront drug company representatives wherever they go. Tell them you won’t accept converting expanded access from the life-saving program it was meant to be into a mere marketing campaign. Greed = Death. Demand that PWAs get all the options that could save their lives.

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