Time Trials

Former CEO Linda Grinberg fights to speed-up drug approval

August 1, 1995 By Evan Forster

Four years ago, if you could have pinned down the CEO of the Grinberg Film Library for coffee, you might have brainstormed an idea for a television project or discussed her upcoming documentary series for the Discovery Channel. Today, you might ask Linda Grinberg to discuss her public testimony before the Food and Drug Administration (FDA). In April of last year, Grinberg sold the world's largest independent news and film library, and left her career of 19 years to become a full-time soldier in the war on AIDS.

She may have sold one library, but she's amassing another. Her Brentwood, L.A., home has become a computerized command post. Armed with a Pentium and 14.4 modem, Grinberg navigates the World Wide Web, hunting, searching, reading and posting bulletins, rallying the HIV positive cybercommunity and downloading article after article on AIDS. You name it: If it's about AIDS, she's logged it. "I have decided to devote my time, energy and resources toward treatment advocacy and, hopefully, finding a cure," says Grinberg.

In August of '91, in the midst of developing a television series and doing her daily two to three hours of cardio, Grinberg found herself at her dermatologist's office testing for HIV due to a sudden outbreak of shingles. After her divorce from a physician in 1987, she'd been dating, but for the most part was sexually inactive. She recalls laughing off her dermatologist's suggestion: "AIDS? Through what? Immaculate conception?" Diagnosed with a mere 73 T-cells, given a prognosis of one year to live and later receiving the half-expected phone call bearing the news that her ex-husband had AIDS, Grinberg quietly began treatment and receded into a carefully constructed closet open to only a few of her closest friends.

She ran the gamut of all the approved antiviral drugs, exhausting their benefit, and began to helplessly watch her T-cells tumble. There simply weren't any approved drugs left to try. Rather than become a victim, Grinberg went to work, searching for experimental therapies. "I do believe that those who live the longest are the people who are most resourceful and proactive with their treatment.

As she grew more informed, Grinberg became aware of a new class of drugs, protease inhibitors, which had already clinically demonstrated less toxicity and more potent antiviral activity than the approved drugs. As her knowledge increased, so did her frustration. "I could not get my hands on

any of them," she says. She was continuously rejected at trial sites. "My T-cells were either too high or too low, or my viral load was too high or not high enough, or I wasn't a virgin to the right antiviral drugs." Grinberg realized there was something wrong with the drug approval process. "I was shocked to learn that it took a decade to bring a drug to market and that it cost in excess of $100 million dollars. Even the accelerated approval process is not fast enough, especially for those of us in late-stage."

An activist was finding her voice.

Then a bomb blew the door off Grinberg's closet: An article in the August '94 issue of *Barron's* described how AIDS activists who had formerly fought for accelerated approval were now pressuring the FDA to slow down the drug approval process, jeopardizing the approval of the first protease drug, saquinavir. "I was absolutely shocked, horrified, that activists who I'd had a great deal of respect for and who'd chained themselves in front of the FDA in the '80s, were now crying that we needed to slow down. I felt betrayed." Grinberg threw herself directly into the trenches of this conflict.

Unable to attend a special two-day session of the FDA last September due to illness, Grinberg collected signatures for a consensus statement on accelerated approval. She wrote in her initial call to arms on the Prodigy AIDS bulletin board, "I get so angry at this Big Brother attitude: That we need *more* protection from potential, long-term side effects. When are they going to wake up? The side effect of AIDS is death." The support from the cybercommunity was overwhelming. Letters poured into the FDA and the accelerated approval process was upheld at the September meeting.

When another FDA Task Force meeting was scheduled to specifically address protease inhibitors, Grinberg testified: "I come before you, out of the shadows, to plead for my life and the lives of thousands of others in late stage disease.... Please, let's not spend another three to five years literally studying this drug to death, prior to accelerated approval." The public exposure was new for Grinberg. "I've never been comfortable in the limelight. But I thought, as a woman, perhaps I might be able to get through in a way others haven't." A week later, saquinavir maker Hoffmann-La Roche, which had previously committed to supplying only 150 patients under compassionate use, agreed in writing to supply enough drugs for 1,400 patients.

With some of these battles behind her and surely many more battles to come, Grinberg continues to fight for her life and the lives of many others. "There's a bigger battle than what rages within my own body. There are battles to be fought in research and on the political front," she says and then looks away, speaking almost to herself. "I intend to fight with every ounce of my passion and energy. I am not ready to leave the party yet."

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.poz.com/article/Time-Trials-1846-1787