

Lynda Dee is a Drug Development Committee member and founder of the [AIDS Treatment Activist Coalition](#) (ATAC). In 2003, ATAC joined forces with a coalition of other AIDS treatment advocates, scientists, doctors, and government officials to create the Norvir Pricing Campaign. Abbott Laboratories had recently announced a more than 500% increase in the price of Norvir, an essential component of combination protease inhibitor therapies for HIV/AIDS. The campaign argued that increasing the price of Norvir, would have a negative impact on AIDS patient care as well as the competitive market for the research and development of new HIV/AIDS therapies.

In March 2004, the nonprofit organization [Essential Inventions](#) petitioned the NIH to permit competition to produce a generic, low-cost version of Norvir. The NIH subsequently held a hearing on the matter. Lynda Dee gave testimony at this hearing. While the FDA ruled that it did not have the authority to intervene, Congress subsequently began an [investigation](#) into the price increase.

Several months ago, Corporations and Health Watch staff member Sarah Bradley spoke with Ms. Dee about her AIDS activism, ATAC, and the general political context around the Norvir campaign. Excerpts are included here.

CHW: When did you start doing treatment activism? Was it with ACT UP?

DEE: I started twenty years ago with “AIDS Action Baltimore,” where I’m from. We started AIDS Action Baltimore down here before there even was an ACT UP.

CHW: As an activist, how have you worked with big pharmaceutical companies?

DEE: Well, we often work with drug companies to initiate expanded access programs so that they can make their drugs available to people who desperately need them before it’s actually FDA approved, which means before they get paid for the drug.

CHW: Can you explain the meaning of phases one, two and three in drug trials and how you worked to change this process in order to expand treatment options?

DEE: Phase one is when they make sure it doesn’t kill you. Phase two is when patients get the maximum tolerated dose. That’s the old way of doing it. And what researchers figure out is whether the drug is excreted more in your liver or the kidneys, or whatever system is involved with that. Because certain systems mean that a drug will have drug interactions or, require that the dose be adjusted because of those interactions.

CHW: Right.

DEE: And companies used to do Phase one. Do that. Finish. Phase two. Do that. Finish. And, you didn’t start the one until you finished the other completely. And what we tried to do was to say, “Look, let’s change the designs of these trials.” Sequential learning is not always the best way to do things when people are dropping dead. So

they now have Phase 2-B drugs wherein while they're doing the dose and looking at the interactions, also at the efficacy, and they use that data to help build better Phase 3 programs. The Phase 3 programs are about getting the drugs into a larger population, between 500 and 2,000 people (in AIDS anyway) to see what affects the drug will have and what other side effects turn up. So the more people you have in the trials, for the longer periods, the more you'll see of the efficacy or non-efficacy and the side effects.

CHW: So expanded access is mostly about making the trials bigger?

DEE: Well, no. Expanded access comes after Phase 3. We try to get them to start it in conjunction with Phase 3 now. In those testing phases they're very much trying to rule out different things that might really make the results confounded. So they try to be very scientific and not very patient friendly.

We've even pushed for things called OLSS's, which are open label safety trials, where you give expanded access to the even sicker patients. The FDA wants to see more safety data before they'll allow this expanded access program. Usually, because they want to make sure you're really not going to do more harm than good.

I'll never forget, when AZT was first approved, my husband died from complications of AIDS in 1987 and [it] was only for people that had had [pneumocystis](#). Well, he had two AIDS-defining conditions but neither one was pneumocystis, so he couldn't have access to AZT.

CHW: Why were they limiting its use to the treatment of pneumocystis?

DEE: Because that's the only place they had ever tried. We're about changing the old paradigms: years ago when you first tried AZT, they wouldn't let you take it in combination with one of the drugs for [cytomeglavirus](#) that caused people to have blindness. So either you had a choice of going blind or trying this new medication. It's very nice to have pristine trial results where you're in a little jar somewhere, but you're talking about real people.

CHW: Has the impact of the FDA and the pharmaceutical companies on human rights for people with HIV and access or health changed over the last twenty years?

DEE: To get the pharmaceutical industry to change any of these paradigms was like pulling teeth. These guys are conservative: a lot of money is riding on how they proceed. They're afraid their drugs won't get approved and they don't want to take any chances with the bottom line. You can imagine what lawyers were telling them, or even other scientists.

So they were very afraid to change how they did business. But then they had these crazy activists that would show up and cause a stink and bad press and they had to do something with us. After years of meeting with them, they've really come around. They know that they have to deal with us, and it's just part of the price of doing business.

CHW: How do the pharmaceutical companies react to you in these meetings?

DEE: They don't know what to expect. They come in, they see a reasonable bunch of people, and they see that these people really have good ideas, they're smart, they've been around sometimes longer than they have, and they're like, "Oh, wow, this has been a very constructive process."

CHW: What has it been like to work with academics?

DEE: If the pharmaceutical companies were afraid to change the paradigms for reasons of money and power, the academic investigators were very condescending and acted like, what could we possibly teach them? It was really kind of funny.

CHW: And what is your perception of their relationship to the pharmaceutical companies?

DEE: They all worked for pharmaceutical companies. What usually happens is, when you have a new drug, you want to get the foremost researcher or physician that you can find to experiment with your drug [in order] to believe your results. So they get paid for it. That doesn't mean the pharmaceutical company's bad, or the investigator is bad. Now there are a lot of researchers who have a conflict of interest. They own the company's stocks. The thing of it is, as long as I know that you're getting that money, maybe I'll look differently at what you say and how you say it.

CHW: In what capacity did you work with the National Institutes of Health?

DEE: I used to be on the Executive Committee of the AIDS Clinical Trial Group at the NIH, which is the national and now international network of the government's drug trials for HIV. The NIH is very byzantine — there [are] 22 different institutes; they don't speak to each other at all. So the people that dealt with this — [the] branch that deals with innovations and new inventions — had never dealt with any community people before. They treated us like it was day one of the movement instead of 20 years later. They were used to dealing with the universities and the patent issues and all that.

CHW: Tell me more about the announcement regarding the Norvir price increase in 2003.

DEE: They announced this increase over the Christmas holidays because they thought [it] would just pass through without a lot of fanfare. But instead, people were shocked and appalled. It was one of the most egregious increases.

There were a lot of people that had their \$300 insurance co-payment increased to a \$1,000 copay. And there are a lot of people whose insurance permits them only a certain number of dollars every year for drugs. So if Norvir uses it all up, then what about other necessary prescriptions? They'd have you believe that this 700% price

increase had no impact anywhere. I can't imagine that somebody would think they would be able to get away with this without raising some hackles. I don't think they ever expected to get the outcry that they got from us.

CHW: And in response, didn't Abbott announce they were giving Norvir for free to anyone who didn't have drug coverage?

DEE: Right. That's the Patient Assistance Program. Of course, we could never get them to say how many people were on their Patient Assistance Program.

CHW: Didn't Aetna actually sue Abbott and then withdraw the lawsuit two days later?

DEE: Yes, there's still another lawsuit pending. [John Doe vs. Abbott Labs](#) is still alive and well. They actually just won their motion for summary judgment against Abbott. So they may end up in court over this if they don't settle it.

CHW: How did the decision of the NIH not to allow competition to produce a generic version of Norvir affect the campaign?

DEE: I don't think we ever thought the petition was going to be granted. It was a way to get PR because that's what you have to do to get anything noticed. I think that really helped us to get the concessions that we did.

CHW: So was your goal more that Abbott would roll back the price because of the pressure?

DEE: We really thought we'd be more successful in getting them to do that. That's what we hoped for. And obviously we were extremely disappointed when we weren't able to do that. We're still disappointed.

CHW: So from your perspective at ATAC, what do you think was the primary obstacle in getting Abbott to lower the price of Norvir?

DEE: It was money, plain and simple. They were in it to make money, and we didn't have the power to do anything about it. At the time, ATAC had ten volunteers compared to a pharmaceutical giant — one doing press releases, one doing the actions, and me doing the coordination and getting the testimony together, and it was all we did for months. That we accomplished what we did was unbelievable.

CHW: What were some of your biggest successes?

DEE: We got some Congressional support and one of the Congressional people got the NIH to hold this hearing [which] really put the issue on the map as far as the press is concerned. And if it ain't in the press, it didn't happen. It doesn't affect anybody's bottom line or market share. The other thing was that we were able to get the docs fired up. I think that made a big difference too because these companies sell their drugs

through the sales force that visit[s] each doctor. And to have some doctors say, “Don’t bother coming back,” had a big impact.

CHW: In the Norvir campaign, your organization used different strategies: such as protests, petitions, and marches so you had all kinds of strategy going on. Do you think one was better than the other?

DEE: Who knows? We tried everything we could think of. We have a lot of good minds, just not a lot of money and not a lot of volunteers. We even had stockholders involved in our actions such as religious groups that held large stock portfolios. We’d ask them to go in and vote against certain things.

CHW: Do you think the demographic makeup of people with HIV/AIDs affected the Norvir campaign at all?

DEE: No. I don’t think it affected this particular campaign. I think it affected the government’s response. Reagan’s response was lacking from the beginning. My impression, and [that] of others at that time, was that the Reagan Administration didn’t care about homosexuals and was probably glad it was happening to that community. They did nothing. I think they felt gays were a throw-a-way population. Same for people of color, drug users, urban populations. That’s my honest opinion.

CHW: So you think that’s pretty much remained unchanged?

DEE: Yes. It’s the syphilis of old, just a lot worse. They just have a problem in knowing how to discuss these kinds of issues. If you take a look at England and Western Europe, the minute there is an idea of an epidemic — they react. In England they sent brochures and pamphlets door-to-door that were very graphic, talked about how to prevent it, and nothing happened in Western Europe like it did here. It was like dynamite here how it spread through certain populations.

I think the devastation could have been avoided if everyone were able to: 1. discuss it clearly and in an adult manner, and 2. cared about the people that were actually getting it. I mean look at that Legionnaires disease outbreak. Two or three people died of it and look at how much money and how crazy they were over that. Or look at this Avian Flu: we’ve never even gotten [it] here. I mean, they just go crazy. But how come they didn’t go crazy over [HIV/AIDs]? I mean millions of people have died because of this. Same in Africa. Do you think many Americans care what happens to people in Africa? I don’t think they really do.

CHW: What has your relationship been with Abbott Pharmaceuticals [maker of Norvir] since the campaign began?

DEE: They’ve been trying to give money away ever since this happened.

CHW: What do they want to give you money for?

DEE: Whatever we want it for. And you know, we didn't even ask them for it.

CHW: So they can put it on their corporate response?

DEE: To show how well they get along with community. I don't care what anyone says, when you take money from somebody, you're then beholden to them. It's just that simple.

CHW: So I take it you're opposed.

DEE: Yes.

CHW: Do you see similarities between the kind of work that you do and campaigns against, say, like the Brady campaign against guns, or campaigns against tobacco companies?

DEE: Those are huge issues to the American public. I think that we've been able to accomplish probably just as much if not more as those campaigns with an infinitesimal proportion of the resources that those campaigns have.

CHW: Do you think that the general lack of response regarding the increasing prices of HIV medication has to do with people not relating to it?

DEE: Yes, I think so.

CHW: Some observers have made the argument that the AIDS movement proved that the pharmaceutical companies *will* work with Non Governmental Organizations. What do you make of that?

DEE: Well, I think that the AIDS movement proves that the pharmaceutical companies can be forced into changing their ways. But, it's absolutely a battle, from both sides. I think the fact that we were a disenfranchised population that knew how to get a little PR and how to call our Congress people and knew how to make some noise [made] a huge difference.

CHW: So you don't see a rosy future where the industry changes?

DEE: I see a future where they know they have to deal with us, and we're part of the landscape now. Like I said, the drug industry wouldn't think of doing something without inviting the community. I just wish that our government would be as receptive. The FDA [was] not what it is today; they are a lot less willing to work with people, and [to] think about new ways of doing things. Under Clinton they were great. But this [the Bush] Administration has been unbelievable. Had it been another Administration in power, we could have had a much more welcome audience. I mean, it's a very precarious situation we find ourselves in with Big Pharma. Nowhere else in the world

do they get away with this. Their prices are fixed everywhere else in the world but here. And it's just really unconscionable what they get away with. You know, I'm not sure that if Clinton had been President we could have gotten that petition for margin rights. I'm not sure what Administration would change that.

CHW: Do you find the work harder or easier than you used to?

DEE: I think it's much easier. What's harder now is that a lot of the old people are doing different things and there are a lot of new people and it's just awfully hard to listen to some of old issues come up over and over again. But it's easier to deal with the companies and it's easier to deal with the government now. We're just part of the fabric of things now. They wouldn't think of having a forum without involving the affected community.

CHW: So, what's next for the Drug Development Committee?

DEE: Well, we're very excited about [integrase inhibitors](#). Merck [has] been a pleasure to deal with. The issues around Vioxx are unfortunate for them because they've always been one of the most progressive companies. They're known among the investigators as the "Prince of Drug Companies" because, when they develop a drug, they spend a lot of money on research and a great development program. They keep records of side effects in patients for years and years.

We've also been working with the Senate with regard to FDA reform, and I'm the ATAC person for that. We're looking forward to changing paradigms, as always, and, as far as drug development, the way protocols are designed, the way they're approved, and the authority the FDA has over some of these companies. So that's what I'm doing.

CHW: Thank you. I appreciate your talking to me.

DEE: You're welcome. I appreciate your looking into this. I'm sure that it will help somewhere.