

DDI episode demonstrates Ottawa's impotence on drug release

## US agency controls Canadian AIDS treatment

Story by Ken Blott  
Photo by Jeffrey Woods

At the end of September, Health and Welfare Canada announced that Bristol Myers would make DDI available under the Emergency Drug Release Program (EDRP).

But the release was accompanied by extensive restrictions on who could get DDI. And its release by Bristol Myers long after government approval demonstrated how the medical treatment of HIV-positive Canadians is controlled, not by Health and Welfare Canada, but by a hostile US government agency.

With the announcement of the drug's release came a copy of a draft which Ottawa had released to doctors six days earlier. It includes "Bristol Myers' criteria for EDRP use of DDI by AZT intolerant patients." The list is three pages long: to qualify for DDI, you must have a totalled immune system but otherwise normal blood, you must have a history of horror involving AZT, you must be over 12, you

must not be pregnant, you must not be breast-feeding and you must be using "an acceptable contraceptive method."

So, there will be a lot of people falling through the cracks. But, if you are HIV-positive and you want either AZT or DDI, you should be able to get one or the other.

If you have a T4 count of less than 500, you can get AZT (with strings attached) for free. If you have a T4 count above 500, you can get AZT through the EDRP, but it's not free. If you cannot get AZT paid for through a drug plan, try local AIDS organizations. In Toronto, some financial assistance is available from the Toronto PWA Foundation.

If you are AZT-intolerant, ask your doctor to get you DDI.

So, why did Bristol Myers not release DDI immediately upon EDRP approval? The Sep 22 letter to doctors stated: "The actual date of availability of DDI is not yet finalized. This information will be communicated to you as soon as it becomes available to (Bristol Myers)." Whose permission was

Bristol Myers waiting for? Well, Health and Welfare Canada announced the release of DDI on the same day as the US Federal Drug Administration.

Like it or not, HIV treatment in Canada is linked to HIV treatment in the United States. If our community is to survive, we must understand how the FDA is effectively preventing treatment of HIV illness in Canada.

Why was Bristol Myers so stingy in its release of DDI? John S James spelled it out in San Francisco's AIDS Treatment News: "Providing access to experimental drugs before (FDA approval) ... is an expense and bother to companies. They must pay not only for the drug, but also for associated research and administrative expenses, and they can seldom be reimbursed, let alone profit from this activity."

Putting pressure on US drug companies to release a drug to everyone prior to FDA approval means that the company cannot charge for the drug.

Why wouldn't the FDA allow



early access to DDI? James again: "Apparently these researchers fear that early access will deprive them of subjects for their trials, and as a result they are pressing to restrict such access."

It is important to understand that the rules by which drugs are evaluated are chosen by the FDA. In the case of anti-HIV drugs, the

**EVA:** This Toronto woman, whose son has AIDS, stood in front of Bristol Myers offices for weeks to force the release of DDI.

rules are simple. Take a bunch of people with AIDS. Divide them into two groups. Treat one group, but not the other. Wait until a statistically significant number of people die. Then count heads.

James suggests a better way. "The FDA should waive the requirement to prove reduced death or opportunistic infections. Instead, it could work with Bristol Myers to design much faster trials using p24 antigens (and) T-helper counts." (These are early indicators of HIV activity.)

"Why hasn't such an approach been used already? ... Fantastic scenarios can be concocted in which drugs could look good after the trials suggested above, but really not give any benefit to patients. But the small chance of mistakenly approving such a drug must be balanced by the built-in, two-year delay of the kinds of trials currently required."

Health and Welfare Canada has announced clinical trials to start in November in Halifax, Montreal, Toronto, Calgary and Vancouver. If the protocols for trying other anti-AIDS drugs are any indication, the DDI trial will be unethical. Often the protocols have been designed to maximize the amount of product information obtained rather than the number of lives saved.

For example, the study might put one group on AZT and another on DDI. This would give a direct comparison of the two drugs and would be the best product-testing protocol they could choose. But it probably would not provide the best treatment to either group. That's because both of these drugs may have serious side-effects. Scientists have suggested that the best way to minimize side-effects would be to alternate between the two. But there is no way to know for sure until it's tried.

So, what is the most ethical treatment protocol possible? Let people choose what they want for themselves. The scientists will surely still get their data.

### FOCUS

Dale Oxford & friends sewed Canada's AIDS quilt together

## Stitches in time

Story & photo  
by Robin Metcalfe

The day the Names Project opened in Halifax, Dale Oxford got a call from his sister. As the production coordinator for the Canadian national tour, he was frantically absorbed in preparations. Now his sister was having a baby — three weeks early — and he had promised to help with the delivery. "You can't be in labour now," he protested — but she was. Twenty-five minutes later, baby Dale was born, in the presence of his uncle. Dale the elder rushed from the hospital back to the Saint Mary's University Field House, where the Quilt was soon, for the first time in Canada, to be unfolded.

"Within 12 hours," remembers Oxford, "life began, and we also identified the end of so many lives." You can hear emotion in the voice of this quiet, handsome man with the striking features and the clear hazel-grey eyes. Oxford was born in Springdale, in central Newfoundland. It was "a small town, 300 people," he says. "Use your imagination." Dale did. He ran a design business, Oxford & Jones, with a friend, and completed a fashion show before moving to Nova Scotia four years ago. There, Oxford, who was self-taught, took courses in pattern-making and design. He was hired

a production assistant to a small factory, a sewing contractor making "everything from flags to clothing to parachutes." In August of 1987, he was diagnosed with AIDS.



Oxford's involvement with the Names Project allowed him to combine his "career/professional side" with "the intense emotional side of dealing with my own diagnosis. I felt I had something professional to offer, and it was emotional therapy for me, too. Once I heard about the possibility of a Canadian quilt being put together, I got in contact with Paul McNair and let him know I'd like to help in any way I could."

McNair had done the groundwork for establishing the Names

Project Foundation — Canada, which he serves as chairman. With the addition of Oxford's skills, the group had the administrative and production capabilities necessary for staging a national

produced a panel with three friends and helped with three others, including one for the Nova Scotia Persons With AIDS Coalition, of which he is an active member. The work "took about 26 hours a day for three weeks straight." Oxford insists on equal billing for his partners on the production team, Annie Walsh, Wendy Woodruff and Bruce Davidson. The four "literally moved in together," working, eating and sleeping in shifts. The team's Herculean efforts were recognized during Halifax's 1989 Lesbian and Gay Pride Week with a special citation for Outstanding Cultural Contribution, sponsored by the Gay and Lesbian Alliance (GALA) of Nova Scotia.

The Quilt started in Halifax with 100 Canadian panels, and ended in Vancouver with about 250. Permanent storage is in Halifax, but Oxford would "rather see it travel than sit in a museum as a monument." A second tour is planned for next year, including a stop in Newfoundland that has special meaning for Oxford. He particularly looks forward to showing the Quilt again in Ottawa. Although the Names Project is nonpolitical, Oxford says of the Quilt that "without even trying to be, it is political." He challenged politicians to "look at this and tell me there isn't a problem in Canada."

**DALE OXFORD:** He challenged politicians to say that AIDS isn't a problem.

tour, and Halifax became the Canadian base for the Quilt.

Oxford was responsible for joining together quilt panels from across Canada. He organized a system to catalogue them, and coordinated volunteers to repair and, in some cases, complete, the panels received. He himself pro-

Metcalf, Robin. "Stitches in Time." Xtra! Toronto's Gay and Lesbian News, no. 136-2, 10 Nov. 1989, p. 14. Archives of Sexuality and Gender, [link.gale.com/apps/doc/OYEUTY146878728/AHSI?u=crepuq\\_mcgill&sid=bookmark-AHSI](https://link.gale.com/apps/doc/OYEUTY146878728/AHSI?u=crepuq_mcgill&sid=bookmark-AHSI). Accessed 4 July 2023.