ACT UP BOSTON

ATTITUDE!

December, 1991 No. 12

Treatment Notes

FDA Approves Treatment IND Status for 566c80

The Food & Drug Administration has approved a Treatment IND for 566c80 (now called "566") – a new drug to treat pneumocystis carinii pneumonia (PCP) in people with AIDS. The approval came after a series of actions and negotiations to speed up it's approval process were undertaken by members of the ACT UP/ Boston Treatment Issues Committee and other AIDS treatment activists.

A "Treatment IND" is a level of FDA approval that allows a drug to be made more widely available, in specific circumstances, before it is actually approved for sale. The "IND" stands for "investigational new drug". It allows the drug's manufacturer, in this case Burroughs-Wellcome, to advertise the drug's availability to people who have failed on or who are intolerant to Bactrim and Septra – two sulfa drugs that are the standard treatments for PCP. (Aerosolized Pentamadine [AP], which is much more expensive and invasive than Bactrim and Septra, is the other standard treatment for PCP.)

Unlike AP, Bactrim, and Septra, 566 is not used as a prophylaxis for PCP, only as a treatment. Research into the usefulness of 566 is continuing.

566 was previously available only on a case-by-case "compassionate use" basis. It is now available for everybody who has failed on Bactrim or Septra. Activists and doctors were happy to find that to receive 566 through the Treatment IND program requires filling out only three pages of paperwork. This is an important issue for overworked AIDS doctors, whose ability to get access to new drugs for their patients is sometimes thwarted by the ridiculous demands of pharmaceutical companies for mountains of paperwork. (See article about Abbott Pharmaceuticals.)

A concentrated campaign by treatment activists had an important impact

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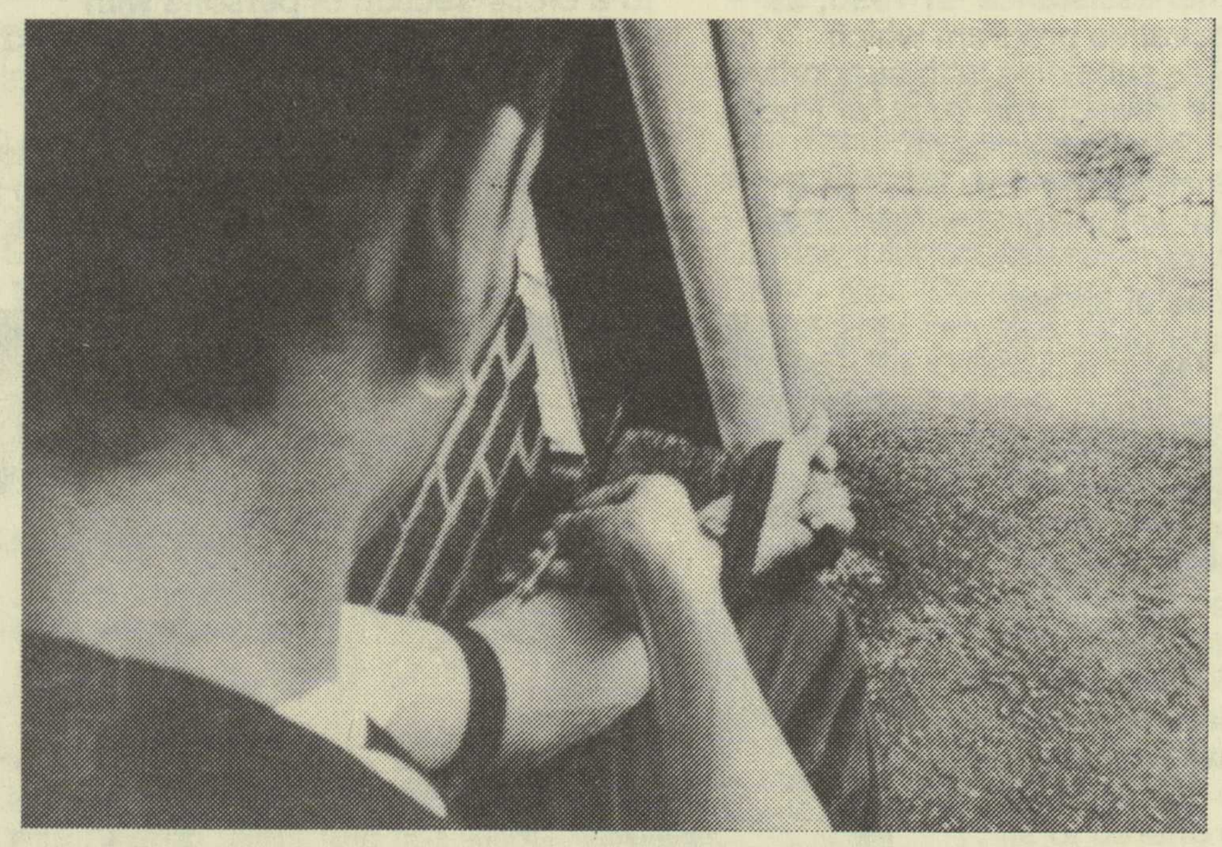

Photo by Benjamin Incerti for "A Phase I, Randomized Trial", an exhibit of pictures taken by people living with AIDS/HIV. See story on page 2. © Benjamin Incerti, 1991.

Stop the Bullshit! Legalize Needle Exchange Now!

When the National Commission on AIDS released its July 1991 report, "The Twin Epidemics of Substance Use and HIV", their first recommendation was to "expand drug abuse treatment so that all who apply for treatment can be accepted into treatment programs." Their second recommendation was that "legal barriers to the purchase and possession of injection equipment should be removed." Both of these points were reiterated in the Commission's comprehensive 1991 report to the President and Congress entitled "America Living With AIDS".

The "Twin Epidemics" report was issued at the same time that Yale University and the New Haven Department of Health released a study on the effectiveness of a city sponsored clean needle exchange program. The Yale/New Haven report showed that the clean needle program led to a significant reduction in the transmission of HIV. Like studies in other cities, it also concluded that the needle exchange program does not promote increased use of illicit substances. On the contrary, more addicts are seeking treatment as a result of the program.

So, how did our nation's foremost Yale graduate react to the news from his alma mater? And to the recommendation of the presidentially appointed AIDS commission? Mr. Bush quickly dispatched "drug czar" Bob Martinez to New Haven to condemn needle exchange programs as "promoting drug use". Mr. Martinez also bragged about how funding for treatment slots has gone up during the Bush administration. But he forgot to mention that this money only partly replaces the amount slashed during the Reagan years.

Meanwhile, more than a hundred people die of AIDS in the US every day. The cumulative deaths of the first ten years of AIDS will more than double in the next two: by the end of 1993, the toll will rise from 120,000 to over 350,000. Meanwhile, New York City is estimated to have 200,000 intravenous drug users, about half of whom are HIV positive. Yet New York has only 38,000 publicly funded drug treatment slots. Thirty-one percent of all AIDS cases (and 70 percent of heterosexual AIDS cases) can already be linked, either directly or indirectly, to IV drug use. In some cities, like Hartford, CT,

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