

Patents before

ONE OF THE BEST – but most disturbing – explanations for the scale and urgency of the controversial new British AZT drug trial (*Capital Gay* last week) can be found in the stock market page of today's newspaper.

Since the Fourth International Aids Conference held in Stockholm this June, shares in Wellcome PLC – the manufacturers of AZT – have fallen by up to £1, wiping almost £600 million off the value of investors' holdings. That fall began on the afternoon that two London researchers from St Mary's Hospital, Dr Tony Pinching and Dr Matthew Helbert, described evidence of new, unreported, and sometimes lethal side-effects they had discovered while treating Aids patients with the drug.

Over the last few months, Wellcome has been pressuring Britain's Medical Research Council to support the £3 million new trials on 'asymptomatic' (clinically well) people who are HIV antibody-positive. But in Wellcome's secret document defining the proposed study, identified as 'Protocol H56-017', (a copy of which we have obtained) it is made clear that the company wants only to test HIV-positive patients who are

found by special laboratory tests to be 'at high risk of developing Aids.'

Scientifically, it does make sense to get quicker results by looking only at more advanced cases of HIV disease. But Wellcome's commercial objectives come first. Clause 4 of the 'Confidential' 'terms and conditions' every participating doctor must sign to take part says that they must 'obtain Wellcome's written consent before the publication of medical or scientific papers arising from (the trial)'. The doctors are specifically forbidden to object if Wellcome refuse permission to publish 'for the purpose of protecting an application for a patent'.

They also have to agree to keep the protocol itself confidential, and not to disclose it to patients or other researchers' without Wellcome's specific permission.

The 'trial objectives' spelt out in the protocol are to see how many patients 'progress' beyond Stage II or Stage III or HIV disease, and become seriously ill with Aids or Arc, or even die. At this point, according to the

Special meeting

BODY Positive and the Terrence Higgins Trust have called a special public meeting in Earl's Court this weekend to discuss the Anglo-French AZT trial which we reported last week.

The meeting, which will be addressed by members of both groups and by Dr Karen Gelmon, the Trail Physician, starts at 3pm on Sunday October 30th at the Body Positive Centre, 51 Philbeach Gardens, London SW5.

protocol, they can be given 'open label' Zidovudine (the official new name for AZT). But even then neither they nor their doctors will be allowed to know whether they had been having the real drug until then, even though this could in some cases be critical to their treatment.

For every person with Aids in Britain or the USA, there are ten to 100 people with HIV infection but few or no symptoms. There is grim and overwhelming scientific evidence that, without early use of drugs, that infection

will turn into Aids within a decade for all but a lucky few. Wellcome PLC is naturally anxious to be first into the lucrative field of treating that vastly larger, HIV-positive-only, market, probably for life.

But getting the trials now beginning under way has been, in the words of a leading American Aids specialist, Dr Paul Volberding of San Francisco General Hospital, 'like turning round an aircraft carrier'.

Part of the problem has been the scale, length, and complexity of the trials. The major obstacle, however, has been that HIV-positive gay men in the United States have not been willing to let drugs company computers play dice with their lives by taking part in so-called 'blind' trials, where half of those at risk of developing Aids or Arc get 'placebo' tablets and go untreated.

In these blind trials, neither patient nor doctor is supposed to know who is really getting the drug. But most gay Americans at risk of Aids have decided views about AZT – one way and the other. They either want AZT prescribed, or they definitely do not want to touch the stuff. As a result, the US trial which was hoped to involve over 1,500 patients by July 1987 was not even half way there eight months later.

Duncan Campbell examines whether the new AZT

It is not possible to conduct 'blind' trials

But some experimenters have fruitfully come to terms with patients' views. The experience of the gay community and some medical researchers in the United States and in the Netherlands has been that it is neither necessary nor possible to conduct 'blind trials' with AZT or other drugs.

Ironically, two small tests using AZT in Amsterdam and San Francisco which have already been conducted have shown promising results for both HIV positive people – and for Wellcome. Researchers in Amsterdam have found that the side-effects of AZT in healthy HIV positive men were 'mild, transient and infrequent'. According to information presented to the Stockholm Aids conference, only two out of 24 gay men needed blood transfusions, compared to 20 to 50 per cent of Aids patients. The drug worked better too. In almost all patients, use of AZT appeared rapidly and permanently to switch off or reduce activity by the HIV virus.

The Amsterdam trial, run by Joep Lange from the University

patients?

trial is intended to help ill people or company profits.

of Amsterdam found that, in contrast, patients who had decided that they didn't want AZT had continually rising levels of viral protein ('antigen') in their blood.

In San Francisco, a new and increasingly popular clinic specialising primarily in treating HIV-positive people has monitored a group of about 50 asymptomatic gay men using AZT for six months. It found an average 37 per cent increase in the men's T-helper cells, compared with an average 25 per cent fall in the previous, untreated six month period. The number of T-helper cells in someone's blood is widely used to indicate the strength of their immune system.

'It has become unethical to study a drug in this way'

The clinic director, Dr Levin of Positive Action Healthcare, is strongly opposed to 'normal' trials involving placebos instead of drugs. He said: "It has

CONFIDENTIAL

A RANDOMISED, DOUBLE BLIND, PLACEBO CONTROLLED TRIAL TO DETERMINE THE EFFICACY OF ZIDOVUDINE IN REDUCING DISEASE PROGRESSION AMONG THOSE PATIENTS, WITH CDC GROUP II AND III HIV INFECTIONS, WHO ARE AT HIGH RISK OF DEVELOPING AIDS

become unethical to study the effectiveness of an HIV treatment by comparing treated patients to others who are forcibly denied treatment and allowed to progress to well known life-threatening complications or death. Laboratory tests available to any physician make it abundantly clear when treatment is working or not".

Gay men on such drugs trials in America have also been fighting back against 'blinding'. At last month's Anglo-American Aids conference at the Royal Society of Medicine, Dr Volderbing described how groups of patients on such trials in the USA practise 'drug-sharing' - pooling their supplies so that everybody was getting some of the drug. It is also possible, in major US cities, to get chemical laboratories to analyse whether the capsules someone gets contains drug or placebo.

Wellcome's secret document

In fact, with AZT, it's easy for guinea pig patients to spot whether they're getting the real thing or not by asking for the results of their ordinary blood counts (or getting another physician such as a GP to do a count). 'If the volume of your red cells doesn't go up, you're on the placebo', said Dr Volderbing. The red cell volume, called MCV in blood counts, will rise from around 90 to over 100 after a few months on genuine AZT, and usually go on rising after that.

AZT is a wonderful drug'

Dr Levin of Positive Action Healthcare is scathing about the drugs companies, while nevertheless believing that their

products are the "best we have. AZT is a wonderful drug, it's our backstop. Use AZT like you use insulin in diabetes." He, like other practitioners has found that the standard advice to patients to take AZT every four hours (the current norm) is 'crazy' and unnecessary.

Gay San Francisco seems to like this approach. Within a few months, more than 500 gay men had beaten a path to Levin's door. In contrast, two blocks away in a shiny new \$1 million laboratory aimed instead at setting up immaculate clinical trials of new drugs, paid for by drugs companies, the waiting room was empty.

In New York, doctors and people with Aids have set up the Community Research Initiative, aimed at conducting formal drug trials with full scientific rigour - but with priorities set by the communities at risk from Aids, not Wall Street. The growing controversy about AZT and other drugs trials in Britain suggests that drugs companies here too may have to accept which way the wind is blowing.

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CAPITAL GAY

Major drugs test on HIV people who are well

2,000 guinea pigs for £3m AZT trial

RETROVIR Capsules (ZIDOVUDINE) 100 mg

Capital Gay - the pain what it's all about

An extreme health

Stars salute Russia's Harty

A huge £3 million trial of Aids drug AZT on 2,000 well people