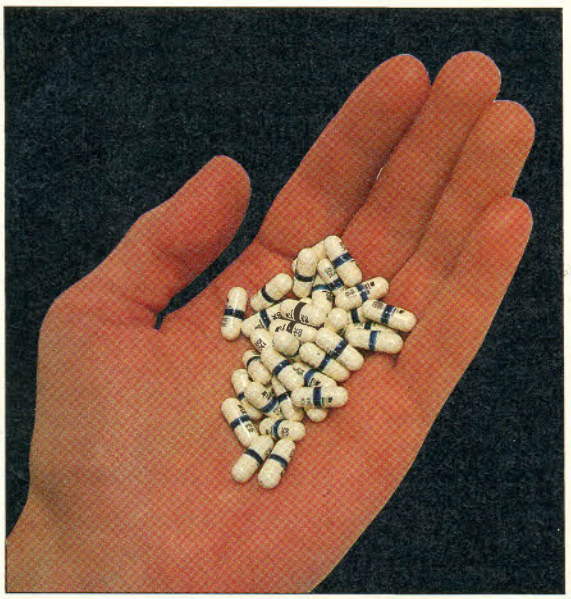
NEW STATESMAN
SOCIETY
24 June 198
US $1.75 A
IR £1.4
UK £

The AIDS scam



As if having Aids weren't enough . . . the big drugs companies are moving in for a killing. Duncan Campbell reports on the scramble to exploit the biggest pharmaceutical market in history: suspect drugs trials, quack remedies, overpriced drugs, toxic "cures" . . .

Bernard Crick on the KMG (Kinnock Must Go) movement

Breaking into new arias: the opera boom explained

The amazing Aids scam

As if Aids weren't enough... the big drugs companies are moving in for financial killings in the largest new pharmaceutical market in history. Duncan Campbell reports on the scramble for profits which leaves promising treatments out in the cold and creates disturbing alignments between leading researchers and the drugs industry.

At one press conference last week at the international Aids congress in Stockholm, the hardest, most complex questions on the recondite molecular biology of viral protein structures came from the reporter from the *Wall Street Journal*.

The implications weren't missed by those she was questioning. The present world total of about 100,000 Aids cases is expected to double every year for the next five years. Many millions of people, who are well for the moment, are already infected with the Human Immunodeficiency Virus (HIV) which leads on through increasingly severe disease to full-blown Aids within two to 16 years. When an effective cure for HIV disease does turn up, anyone infected will need treatment for life. That makes Aids and HIV the greatest new pharmaceutical market in history.

Meanwhile, the fears and vulnerabilities of people who are HIV-positive or have Aids are being exploited by drug companies and opportunists. Drug companies have kept the results of drugs trials confidential, have released information selectively, or have even delayed trials, in the interests of profitability. Some haven't bothered with trials at all before peddling cures or palliatives of no value.

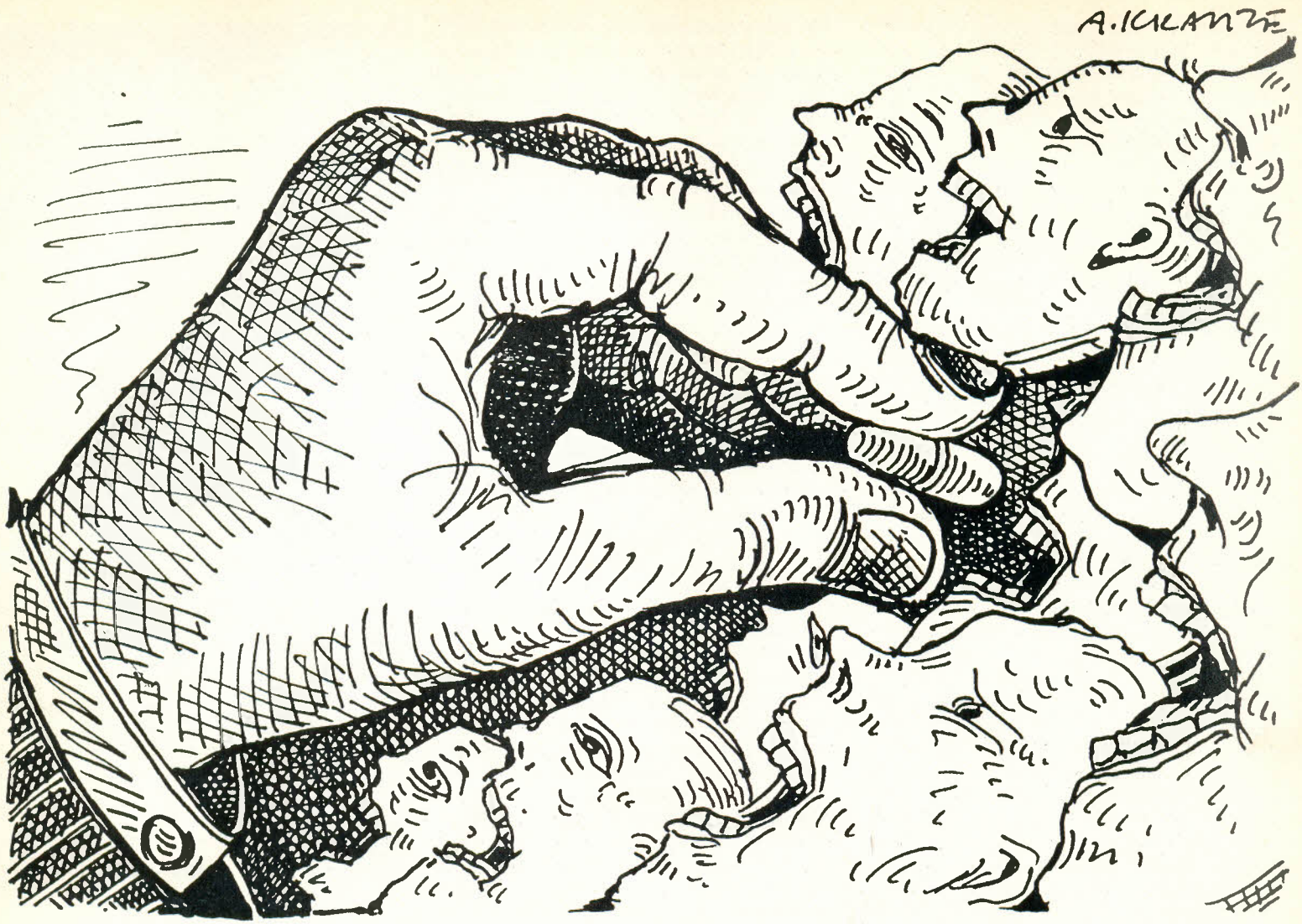
Manufacturers who do have useful drugs for fighting Aids have raised the prices to the maximum the market of terrified people will stand. Many of these drugs are still experimental and not yet officially approved for treatment. Until they are, people with Aids — who often quickly lose their jobs — pay for drugs with what little wealth they have. Many of them, particularly in the US, have been driven into destitution.

The commercial importance of developing a *new*, and therefore *patentable*, drug which provides exclusive profits, means that existing drugs and therapies which show potential for treating Aids aren't being researched; and other promising drugs or treatments are locked up and not used until the manufacturers can get patents or exclusive licences sewn up.

Many medical researchers are demonstrably aligned through financial support with the drugs companies whose efforts they are supposed to police. At the same time, red tape and lack of research funds or staff have delayed important drug trials for months or years. As the epidemic sweeps on to take the lives of up to a million and a half Americans, Aids specialists there denounce the delays in conducting human trials as "genocidal".

The stock market sees the millions facing Aids in cash terms. Huge sums of money can be — and have been — won and lost as the market moves in response to leaks and rumours about drug trials.

One of many drugs that Aids patients can't get because of commercial interests is AL721, a cheap and natural anti-viral agent made from substances as commonplace as egg yolks. It is



believed to spoil the Aids virus's ability to continue infecting human cells. But the Ethigen Corporation of Los Angeles, which holds the AL721 patent licence, has applied for US government approval to sell AL721 as an Aids treatment and is refusing to market it for now. But dying people can't wait while the wheels of bureaucracy turn. Since AL721 consists entirely of processed normal food substances, Ethigen could legally sell it now as a foodstuff, while waiting for its medical claims to be allowed. They have refused to do so, perhaps because it would be difficult later to charge high prices for the compound if it is approved as an anti-HIV drug.

So people with Aids and their helpers, as well as rival companies, have been busy at kitchen sinks and in labs, trying to imitate the secret mixture. Throughout the US, "buyers' clubs" and "guerilla clinics" make and distribute alternative "workalikes". In Britain, too, AL721 is probably the most popular "underground" drug among Aids and HIV-positive patients. Last summer, members of Frontliners, the self-help Aids group, threw other ethical considerations aside and flew to South Africa to procure supplies of a recommended alternative version.

AL721 might be a lifesaver — and many Aids patients in London and in the United States, believing it is just that, have been eagerly consuming the "workalikes", spread on bread or toast. But until profits are assured, Ethigen won't release the real thing, while alleging that the alternative formulas are "deficient". No clinical trials of Ethigen's formula have been done, but until they are no one can know if AL721 is any more than a harmless placebo.

Many companies have been equally tight-fisted about providing information. The early results of trials on Imuthiol, a French-made immune system booster which could help prevent the development of Aids, are said to be promising. But the company making Imuthiol, Institut Merieux of Lyon, has refused to release the results of trials held a year ago in San Francisco. Even though some of the men who took part may sicken or die, the company has refused to tell them or their doctors whether they had been receiving Imuthiol or just a placebo (on the grounds that other trials are still going on).

If a simple drug like aspirin were the answer to Aids, the drugs industry wouldn't want to know

The company has also made patients pay for their trials. To get supplies, one British man with Aids and his lover drove to France a few months ago, and had to pay cash for a six months supply, and further agree to send the manufacturers all the clinical information about the further development of his Aids illnesses.

If a simple generic drug like aspirin were to turn out to be the answer to Aids, the pharmaceutical industry wouldn't want to know, or to test it. The industry is permanently biased towards making new drugs, even if they work no better, or even worse, than existing drugs. If you can't patent and control a drug, you can't make an exclusive profit out of it.

Take the case of dextran sulphate — an unpatentable drug which has been widely used for 20 years in Japan for blood clotting problems. There is strong evidence that it can cripple the HIV virus in various ways and one researcher at Stockholm praised its "low toxicity and low cost". But dextran sulphate is cheap because it's been around for years. A special meeting of researchers called for a rapid start to international trials, but the big drugs companies do not seem to be interested.

The most effective — and money-spinning — drug so far available to fight Aids is Retrovir (formerly known as AZT). The first clinical trials of the drug in 1986 found that significantly fewer Aids patients died on Retrovir than on a placebo.

Retrovir is made by Burroughs Wellcome Corporation, a subsidiary of British-based Wellcome PLC. A California legal group — National Gay Rights Advocates — are currently sueing the US government for alleged collusion with Burroughs Wellcome.

Burroughs Wellcome does work closely with government agencies. The most eye-catching information from detailed US government correspondence obtained under the Freedom of Information Act is about $55,000 donations made by the company to pay for extra staff for a leading US government scientist, Dr Sam Broder, of the National Cancer Institute.

But at the same time that the company was demonstrating its appreciation, it was seeking a US government licence to sell ATZ as an "orphan drug". Approval for the sale of ATZ for use in Aids cases and "orphan drug" status were granted on the same day that Wellcome's cheque was delivered. Broder denies that his work for the US government's National Institute of Health had anything to do with the FDA's procedures for approving drugs.

"Orphan drug" status can be a licence to print money, if a drug is found to work. Such licences are granted when a company wants to investigate a particularly costly or complex new drug, and one for which the ultimate market is thought to be less than 200,000 people (which will soon no longer be the case with Aids). The company is given special tax benefits and has exclusive control of the drug for seven years. With market forces pushed aside, such drugs can become very expensive. AZT, relabelled Retrovir after its first trials, is no exception. A year at the recommended dosage for Aids patients costs about £5,000. US Aids activists believe that this price is five to ten times the actual cost of manufacturing the drug. Wellcome, they allege, is attempting to make as much money as it can out of AZT before another and less toxic drug arrives on the Aids scene.

The NGRA law suit claims that Burroughs Wellcome made huge profits from Aids as a direct result of the alleged collusion with the government. They say that there was "unethical and illegal conduct resulting in serious delays of promising new Aids medications" other than AZT. A judge recently refused the US government's application to strike out the NGRA case.

Because of the high cost of the drug, there were a string of incidents last year in which British patients with Aids were refused Retrovir treatment by regional health authorities. For the moment, this problem appears to be over and everyone with Aids gets the drugs required. But top British Aids specialists are, perversely, worrried about what will happen if new trials show that Retrovir will stop anyone infected with HIV from declining towards Aids. The bill for supplying Retrovir to every "HIV positive" person in Britain would, at current prices, lie between £200 and £500 million. Would health ministers authorise the high charges for permanent Retrovir therapy?

Retrovir, and other Aids-related products such as blood tests for antibodies to the HIV virus, have sent Wellcome PLC's stock booming. Sales are growing dramatically, and with it the company's wealth.

Last year's profits for the Wellcome Foundation were £169 million, with most of that coming from Burroughs Wellcome. By August 1987, sales of Retrovir in the four months since its final US approval as an Aids drug amounted to £16 million. With over 20,000 Aids patients on the drug, the real profits on Retrovir this year may well be over £100 million. Unsurprisingly, the company's stock exchange valuation has quadrupled since work on Retrovir began.

Wellcome PLC is sensitive about its profits from Retrovir, a significant part of which has funded extensive publicity campaigns, special conferences, lectures and videos, and its frequently criticised "lavish" and aggressive marketing. Critical journalists have been unwelcome at Wellcome. One leading Aids scientific journalist in Britain who has been critical of the pricing of AZT has been left in the dark about company research and news events.

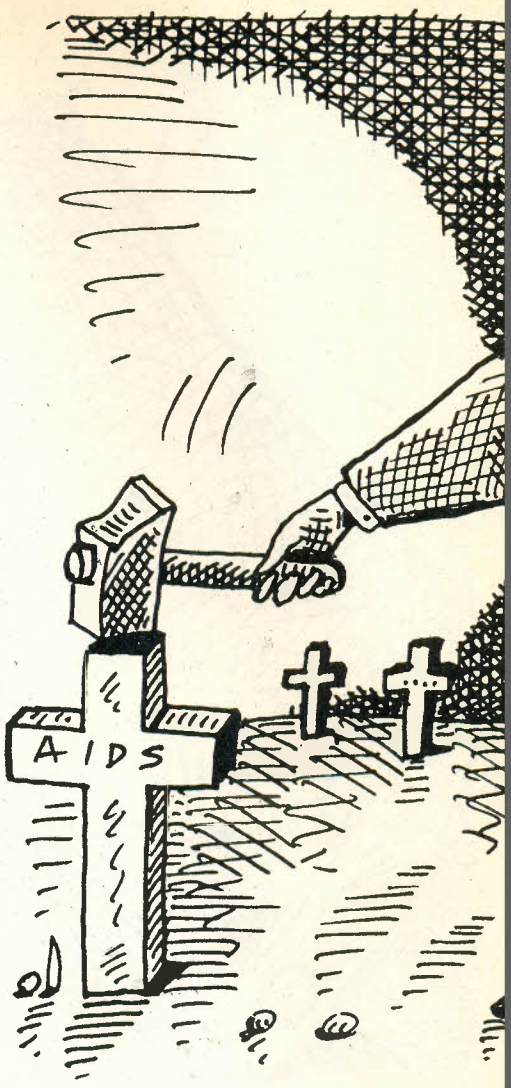
Dr Matthew Helbert, a British Aids doctor, may have affected the stock market valuation of Wellcome when, biting hard on the hand that had paid his air fare, he placed heavy emphasis on new, debilitating and sometimes deadly side-effects of Retrovir on some of his Aids patients. Some men's muscles had degenerated dramatically after long-term use of the drug. Others had rapidly developed a serious brain disease, encephalitis, soon after being taken off the drug.

Given the company's duty to keep a new drug under active surveillance, Dr Helbert asked why the company had not picked up similar cases among the thousands of people treated with Retrovir for a year or more in the United States. At first, senior Wellcome staff treated him to a ample dinner and tried to suggest that all the patients concerned were secretly treating themselves with Imuthiol or Ribavirin (a US made anti-viral drug) — which, Helbert was assured, could be "scored" by Aids patients on the streets of London as freely as cannabis or cocaine.

The suggestion is complete nonsense. When Dr Helbert's superior, British Aids expert Dr Tony Pinching, of St Mary's Hospital, London, backed up his view in a major discussion at the Stockholm conference — commenting that "serious problems of toxicity are compounded by those of dose reduction" — Wellcome chiefs became agitated. They tried to recruit an academic lynching party from among US researchers to counter Pinching's views.

Top executives made personal fortunes selling their shares before the news of poor trial results got out

Until news of this controversy got out, Wellcome shares, still buoyant on Retrovir's prospects, had been rising consistently for the three weeks before and during the conference to reach their highest-ever post-crash level of £5.59 early on Thursday. As the news from Stockholm got about, the price fell by 22p by Tuesday this week, wiping £180 million off the company's value. Wellcome said this week that they will review past patient histories to check on these newly-reported side-effects.



The next major Aids drugs battle will feature a British contender. The UK drugs giant, Fisons, and an American corporation, Lyphomed, have entered rival claims to "orphan drug" status for a new form of treatment that seems to curb one of the most lethal infections someone with Aids can get — a rare parasitic pneumonia called PCP. This may be yet another billion dollar Aids market, if the new treatment is effective.

The drug used to stop PCP, pentamidine, has long been known and is not patented. It was rarely used before Aids. In 1984 Lyphomed won an "orphan drug" licence to make and sell it for intravenous use (only) in fighting PCP. The licence expires in 1991, when Lyphomed's profits holiday would end. Then, two years ago, doctors in San Francisco found that pentamidine, if sprayed directly into the lungs, could often prevent PCP pneumonia altogether.

Fisons, spotting that early trials of inhaled pentamidine seemed very effective, applied for "orphan drug" status for the new application of the drug. This was "terrible arrogance", said Dr Bruce Montgomery, a leading San Francisco specialist now working on a major trial funded by Lyphomed. Fisons's action has set off a price escalation, in which, said Montgomery, you could say that Lyphomed had "just let the patients get screwed".

Indeed, you could. To pay for its trials, Ly-

phomed has gradually quadrupled the price of the drug from $24 to $99 a dose— even though manufacturing costs have fallen significantly and sales have swollen in volume (they're probably now worth well over $50 million). As Lyphomed still has its exclusive licence, there is no competition, except from the manufacturers of totally different drugs. Doctors in California say that Lyphomed has probably priced its "Pentam 300" pentamidine to cost just slightly less than either of the two other drugs commonly used to treat PCP pneumonia.

Meanwhile, patients once again seem to be at the bottom of the pile. To take inhaled or "nebulised" pentamidine means using a special respirator, costing £100 to £200. The respirator is normally used at home. Aids patients in Britain and America have been told that if they want this treatment to stop them getting PCP, they will have to buy their own respirators — even if they have no money. Film producer George Cant was diagnosed with Aids last year and is now on the dole. A few months ago, doctors at St Stephens Hospital, London, told him "regretfully" that he'd have to buy or borrow a respirator as the hospital would not supply it.

DHSS sources say that this shouldn't happen, as doctors can prescribe any equipment or drugs they think a particular patient needs — and GPs are increasingly frequently being asked to prescribe drugs to transfer costs from cash-limited hospital drugs budgets. Nevertheless, George's experience was one common to a number of British Aids patients. "People with Aids are having to survive on £30 a week, like me" said Danny Hare of the Frontliners Aids group. "We simply cannot afford to buy our own respirators".

Montgomery said Lyphomed could justify its massive price increases because the company is paying $12 million for him and others to conduct the trials needed to pip Fisons at the post in the orphan drug licence race. Yes, patients not in the trials (who get the drugs free) must now pay four times as much — or go untreated. But very few aren't on health insurance, he said. He is confident that Lyphomed will come first, but whichever company wins, he said, "it's all profiteering for the next seven years".

"I'm not used to offers that are so ethically and scientifically unfounded, and unjust" — Aids doctor Donald Abrams

The most remarkable of the Aids drug hypes has been Ribavarin. Speculation that this antiviral drug might prove to be a good Aids treatment pushed up the prices of the stocks of the manufacturers, ICN Pharmaceuticals, and its subsidiaries, for more than a year. ICN held back poor trial results and organised a press conference to say that one trial had shown the drug to be effective for people with Aids even though the US Food and Drugs Administration has informed ICN that it had proved inconclusive. In fact, Ribavirin appears to have no effect at all on Aids. In one trial, more people with Aids related illnesses taking the drug died than a similar group left untreated.

Yet some of ICN's top executives made personal fortunes, totalling more than $10 million, out of selling shares in 1986 and 1987, just before the US Food and Drug administration finally refused to licence the drug. For example, they disposed of shares in one subsidiary at artificially high prices of $60 to $70 a share before the findings finally leaked out last April. The shares thereafter fell to $15 each. ICN says the sales were not insider dealing, but were required for tax purposes.

No significant new research on Ribavirin was reported at Stockholm. But it was widely hyped at last year's Aids conference in Washington. Dr Charles Mansell, a Texas researcher, presented the results from Ribavirin trials held in 1986, and was quickly challenged as to whether he had a financial interest in the company. He refused to answer, but later admitted to being a paid consultant to ICN. Two leading British experts, Dr Tony Pinching and Dr Charles Farthing, each pointed out that many of the patients selected to go into the placebo (untreated) group had developed Aids far more quickly than was typical. This looked extremely suspicious to many people in the audience.

During the discussion, an FDA official intervened to point out that when six out of seven patients who looked likely quickly to develop Aids were excluded, Ribavirin lacked "any evidence of effectiveness". Indeed, an internal FDA report three months before had found that the placebo group of patients "did better immunologically" than those taking the drug.

The FDA's refusal of a licence for Ribavirin meant that it could not legally be sold in the US for Aids treatment. Even so ICN president Milan Panic suggested to one of San Francisco's leading Aids doctors, Dr Donald Abrams, that he buy the drug from them and sell it to his patients. Abrams said he was flabbergasted: "I'm not used to ... offers that are so ethically and scientifically unfounded, and unjust."

Nevertheless, ICN is still selling Ribavirin to Aids patients. The company exports it to Mexico where drugs control is very lax and has financed an alternative Aids health project in California, Project Inform, which explains to Aids patients and their friends how to cross the border and smuggle Ribavirin back in. Project Inform, has received $72,000 from ICN. Its 18–page advice document for people with Aids and HIV infection explains exactly how and where to cross the Mexican border and from which pharmacies in Tijuana they can buy Ribavirin and other drugs which aren't licenced in the US. (Martin Delaney, of Project Inform, says that they take a "positive" view of Ribavirin, and that the one-off grant was for collecting data about patients, and had no influence on their other work.)

ICN Pharmaceuticals is now under investigation both by the FDA and the US Securities and Exchange Commission, a special report by NBC television revealed earlier this year. The FDA has asked the US Justice Department to hold a grand jury investigation into whether ICN officials are guilty of criminal misconduct.

Professor Robin Weiss, a leading British Aids researcher and director of the Institute of Cancer Research, said that a fundamental problem in getting drugs evaluated was the extent to which much of the medical profession was now thoroughly in the debt of the pharmaceutical industry. "It's rather difficult to avoid a conflict of interest," he said. "I frankly don't understand how most of my colleagues do it." Few drug trials and research are funded by the government, and many doctors had consultancies from or shareholdings in the companies whose very products they were testing.

The pharmaceutical industry's well-established response to this criticism is that were it not for them, there would be few drugs or drugs trials originated in the public sector. This isn't true, and it isn't tried. Indeed, said Professor Weiss, "People are rushing off to privatise discoveries made on public funds. And if you're doing that, it's difficult to take a dispassionate view." Many leading Aids researchers have been trying to build up private research corporations based on their work for the government. However ethical and conscientious a researcher was, it was usually difficult then to bite the hand that fed him. "There is too much money around", said Professor Weiss. "Our judgment is wholly coloured by the stock market."

Additional research by Lyn Barlow.