

FDA Documents Show Fraud In AZT Trials

The following chapter is from *The AIDS War* (1993) by John Lauritsen. It is still in-print.

CHAPTER XXIX

*FDA Documents Show Fraud In AZT Trials*¹

After an arduous three-month battle with the Food and Drug Administration (FDA), I have finally obtained documents which describe in detail many acts of fraud committed in the conduct of the Phase II AZT Trials. It was on the basis of the Phase II Trials that AZT was approved for marketing by the FDA in 1987.

Anyone who requests government documents under the Freedom of Information Act should be aware that he's in for a hard time. If the requested documents are completely innocuous, then the government will probably lose them through incompetence. If the documents are not innocuous, then dilatory tactics of every kind will be employed, on top of the usual incompetence. If the documents should eventually be found and released, they will be heavily censored.

On 12 December 1991 I filed my request with the FDA's Freedom of Information Staff, asking for various documents pertaining to the multi-center Phase II AZT trials conducted in 1986. My requests comprised the "Establishment Inspection Report" on the Boston center, written by FDA investigator Patricia Spitzig, and two sets of minutes, written by Jackie Knight and Mary Gross. Three weeks after filing my request I got an acknowledgment. When I called the woman who sent it to me, she said that all three of my requests had been found, and I would get them soon. A few days later a form letter arrived from a different woman, stating that *none* of my requests could be found, and my search had been completed. I began calling around until finally I got a Freedom of Information specialist within the FDA, Liz Berbakos, who went to bat for me. With her help, the people in Boston were able to re-find the Establishment Inspection Report by Patricia Spitzig, and the

¹Published in the *New York Native*, 30 March 1992.

people in Maryland (the FDA's headquarters) were able to re-find the Jackie Knight minutes, though not those by Mary Gross. Berbakos said I should receive them in a few days.

Weeks went by, and nothing arrived. I called Berbakos again, and she investigated. She called back to explain that the Jackie Knight minutes would be sent immediately, and that Barbara Recupero in Boston had had the Spitzig report on her desk for two weeks, and was waiting for her supervisor to give the OK before sending it. The next morning I got a conference call, with Liz Berbakos and Barbara Recupero on the other end. Berbakos said she wanted me to hear what Recupero had to say. Recupero said that she had no idea what document I was referring to. I then called Patricia Spitzig, the author of the Boston Inspection Report, who called Liz Berbakos and told her exactly what the document was. This put an end to the stonewalling, and I received the 76-page report. Almost every page was heavily censored. Obviously my difficulty in obtaining the document had nothing to do with problems in finding it; they had it all the time. Rather, the difficulty derived from the FDA's unwillingness to let the document see the light of day, and the various censorship decisions that needed to be made once they realized that further stonewalling would be counterproductive.

The Mary Gross minutes are another story. On the first four times I called her, she was always "away from her desk", and my calls were not returned. On the fifth try I finally got her, and expressed my disbelief that she should be unable to find her own minutes of a very important meeting. The next day she called to say that something I said had "triggered her memory", and she had found the minutes. She faxed them to me, and I found that they consisted of a half page of nothing. For reasons I'll explain later in this article, I do not believe the minutes she sent me are genuine. Indeed, I regard the phoney minutes I received as one more form of censorship, one more way the FDA has of circumventing the spirit and the letter of the Freedom of Information Act.

Background: The Fraudulent Phase II Trials

A bit of background is in order. In the approval process for a new drug, the most important tests are the Phase II trials, which are supposed to determine whether or not the new drug is safe and

effective. (The Phase I trials are concerned solely with toxicity — whether or not it is possible to administer the drug to human beings, and if so, to estimate what a proper dose might be.) The Phase II AZT trials were conducted in 1986, in 12 centers around the country. They were designed as a “double-blind, placebo-controlled” study, though in practice they were nothing of the kind.

The Phase II AZT trials were prematurely terminated in the fall of 1986, owing to what appeared to be a spectacular difference in death rates between the AZT and the placebo group. Allegedly only one person in the AZT group died, as compared to 19 in the placebo group. The trials were terminated “for ethical reasons”, so that everyone in the study would have the opportunity to take the “life-extending” wonder drug. As I have argued repeatedly since 1987, these mortality data cannot possibly be correct; not only are they in conflict with mortality data from other AZT studies, but from the standpoint of common sense, one cannot expect dramatic health benefits from a drug that is manifestly injurious to health.

On the basis of hundreds of pages of FDA documents that were released under the Freedom of Information Act, I wrote an analysis of the Phase II trials in 1987, concluding that the study was not only appallingly sloppy, but manifestly fraudulent.² For my accusation of fraud (which I, as the son of a lawyer, do not make lightly), I relied on the fact that the investigators had deliberately used bad data, and that they had covered up the premature unblinding of the study. The Phase II trials are still relevant today, even though they took place six years ago. Since these fraudulent trials were the basis for the FDA’s approval of AZT for marketing, the approval itself was improper and illegal. Consequently, AZT is being marketed illegally at this very moment.

A document written by Ellen Cooper, the FDA Medical Officer who reviewed the New Drug Application for AZT, indicated that many serious violations of the “protocols” of the study had occurred in all of the centers. (Since protocols represent the rules of the game, so to speak, to violate them constitutes cheating.) The Boston center, whose principal investigator was Robert Schooley, was

²John Lauritsen, Chapter II: “AZT on Trial”, in *Poison By Prescription: The AZT Story*, New York 1990.

especially bad. It was so bad that an FDA investigator recommended that all data from the Boston center "be excluded from the analysis of the multicenter trial."³

A series of FDA meetings were held in order to decide what to do about the numerous violations of protocol, and in particular, about the delinquent Boston center. The decision was made to exclude nothing, to throw in all of the garbage along with the good data. The rationale for this appalling decision was two-fold: *one*, if all of the patients with protocol violations were excluded, there would be almost nobody left in the study; and *two*, including the bad data didn't really change the results very much. Needless to say, these are the excuses of crooks and idiots. No ethical scientist would ever knowingly use bad data. Period.

This, then, is the background for my keen interest in obtaining the Establishment Inspection Report on the Boston center. After nine years of research and writing on "AIDS", I'm not easily shocked anymore. But this report succeeded in making my mind reel, from time to time, as it described innumerable, brazen acts of fraud committed by the investigators in the conduct of the trial. Even more shocking is the fact that the FDA, at the very highest level, chose to excuse and cover up these acts of fraud. For the rest of this article I'll describe the crimes and blunders that were committed in Boston in 1986.

The Delinquent Boston Center

In October and November 1986 FDA Inspector Patricia Spitzig made a "For Cause Inspection" of the Massachusetts General Hospital clinical center, which was used in the Phase II multi-center AZT trials. Her findings are contained in her 76-page "Establishment Inspection Report" (EIR). The principal investigator at this center was Robert Schooley, MD, who was assisted by co-investigator Martin Hirsch, MD; Dr. (no first name cited) Ho, and Teri Flynn, Research Nurse. The "Monitor" — the man who appeared to be calling the shots — was Ron Beitman, an employee of Burroughs Wellcome, the manufacturer of AZT. (Although the censors

³Ellen Cooper, "Addendum #1 to Medical Officer Review of NDA 19,655", 16 March 1987.

attempted to prevent me from knowing Beitman's name, they slipped up a couple of times.)

(In recent scandals involving the FDA's acceptance of fraudulent data on silicone breast implants and the drugs Halcion and Versed, it was disclosed that the FDA basically works on the Honor System.⁴ Drug manufacturers do their tests, all by themselves, and then present their "data" to the FDA, who assumes that everything was done honestly and competently. The FDA has no subpoena power, so even if it found something fishy, it would be unable to investigate any further. And even if acts of fraud should be clearly documented, as they were in the Boston case, it is still likely that the FDA would cover them up.)

The record-keeping at the Boston center was incredibly sloppy. Often there no indications of when, by whom, or why entries had been made, erased or changed. The "monitor", Ron Beitman, appears to have taken the lead in most of the misdeeds that were committed, though this by no means absolves Schooley, Hirsch, Ho, and Flynn from culpability. Certainly Schooley, as principal investigator, ought to have known what was happening. And co-investigator Martin Hirsch had previously gotten in trouble over a drug trial:

Dr. Schooley has not been inspected previously; Dr. Hirsch has, in 1979, covering an Interferon Study. That EIR revealed errors in the Protocol; no notification of the IRB re Protocol changes or other Study medications used; subjects were given each other's drugs; and some of the label color was visible, thereby breaking the code.

Among others, Spitzig found the following forms of improprieties in the Boston center:

The current EI revealed numerous deviations, many of them similar to those cited above in the 1979 EI. The observations listed on the FD-483 included: Deaths (two, so far) and adverse reactions have not been reported to the IRB; undocumented

⁴Gina Kolata, "Questions Raised on Ability of FDA to Protect Public", *The New York Times*, 26 January 1992.

Protocol deviations including: concomitant meds, subjects not meeting entrance criteria admitted (two); tests not performed as frequently as required by the Protocol; adverse reactions not reported as such on Case Report Forms ("CRF's"). There were changes made on photocopied CRF's usually with no explanation, date, or initials; significant observations were not addressed on CRF's by clinical investigator; some raw records could not be located and were explained to have been discarded. Accountability of the Study medication is inadequate; 87 bottles/containers shipped cannot be accounted for; Pharmacy kept the inventory and it does not correlate with shipping records; Study medication returned by subjects was not counted, stored properly, or signed off by the clinical investigator.⁵

In addition, Spitzig found that Schooley and his accomplices frequently indicated on Case Report Forms that patients were in the study much longer than they really were. Amazingly, Spitzig missed the single most serious act of fraud, apparently because she was unaware that AZT is the abbreviation for the full chemical name of the drug, "azidothymidine": *Patient #1009, who was already taking AZT, was illegally entered in the study as a placebo patient. After being in the study for only four weeks, he dropped out. When he died two months later, he was counted as a death in the placebo group!* More about this later.

It should be explained that the Case Report Forms (CRFs) were the official recording forms for the study. What was written on the CRFs became "data" for the study. However, medical information on patients was also contained in medical records kept by private physicians, hospitals, and the clinical center at Massachusetts General Hospital, as well as in patients' diaries. For virtually every patient in the Boston center, FDA Investigator Spitzig found serious discrepancies between the medical records and what was entered on the CRFs.

A note about censorship: Virtually every page of the report I received was covered with black splotches. The censors attempted

⁵Patricia Spitzig, FDA Investigator, "For Cause Establishment Inspection Report of Massachusetts General Hospital and Robert Schooley, MD", October and November 1986.

to prevent me from even knowing what the name of the study was, or that it concerned AIDS and ARC patients, or that it was testing the drug AZT. There can be no legal justification for this kind of censorship, and it is clearly in violation of the principles of the Freedom of Information Act. I have sent a letter of protest to the FDA, demanding to be given the complete and uncensored report.⁶

I shall now describe, by category, the major violations that were uncovered by Spitzig in her investigation of the Boston center.

Lies about length of time in study

Comparing the CRFs with medical records, FDA investigator Spitzig found that the CRFs often falsely indicated that patients had been in the study longer than they really were:

Another general issue applying to a number of subjects in the Study is that a cursory review of their Case Report Forms would indicate that they had been on the Study longer than actually happened. Generally this is due to the fact that Study records continued to be generated even when the subject had been dropped from the Study for a period of two weeks to a month. Examples include: number 1053, [CENSORED] dropped out of the Study for two weeks from June 19th to July 3rd, and he was off the Study again on August 11 for a final time due to decreased white blood cell count. CRF were generated as though he were on the study through 9-8-86. Number 1057, [CENSORED] was on the Study for 13 to 14 weeks but the Monitor's Accountability Sheet indicates that he was on the Study for 16 weeks. The Case Report Forms showed that he last came to the Clinic during Week 14 and nothing was returned thereafter. Subject Number 1008, [CENSORED] was off the Study for a month even though the Accountability Record indicates that he never left it. He was off the Study during the Week 6 visit. It is unclear if the Week 8th's medication was dispensed. In fact during Week 4 the Case Report Form states that he had pneumonia beginning July 7th and ending August 7th. And during

⁶15 April 1993: the FDA has neither acknowledged the letter nor met the demand.

the week four visit he was not dispensed any medication. In fact it appears that he was hospitalized then or soon after although the Case Report Forms do not state that he wa hospitalized. So he was off the Study medication for at least a month, but to view the Record of Dispensing of Medication to him, as an example, D-2 it appears that he was on the Study pretty regularly for 12 weeks.⁷

This sort of thing is not merely a form of sloppiness. It is cheating, and it is serious. For one thing, survival rates were an important issue in the study. Falsely extending the length of time that a patient was in the study would affect the statistical projections that were made regarding survival rates.

In addition, falsely extending the length of time patients were in the study made the final results look more plausible than they really were. The Phase II trials were designed so that each patient would be treated for 24 weeks. In practice, when the study was prematurely terminated, some patients had been treated for only three or four weeks, and arcane statistical projection techniques were used to compensate for this violation of the study design. The official "data" on the Phase II trials, which were derived from the CRFs, indicated that patients were treated for an average of only 17 weeks. However, if the same kind of cheating took place in the other 11 centers, as did in Boston, the average may well have been even less than 17 weeks.

Finally, Schooley and his accomplices profited by lying about the length of time patients were in the study. It is stated in Spitzig's report, "The Investigator [Schooley] would be paid [CENSORED] per patient.... For patients who drop out of the Study the cost would be 'pro-rated based on the amount of time the patient was in the Study.'"⁸ That is to say, the longer a patient was in the study, the more money Schooley got. While this may not amount to grand larceny, it is nevertheless a form of theft.

⁷Spitzig, p. 26.

⁸Spitzig, p. 7.

Concealment of adverse reactions

The rules of the study indicated clearly that all adverse reactions were to be recorded on the CRFs and reported immediately. Schooley et al. often failed to do so, especially if the patient was on AZT. In theory, the investigators were not supposed to know who was on AZT and who was on placebo, but there are many indications in Spitzig's report that they did know, and that they referred openly to patients' being on AZT. It would have been easy to determine which medication a patient was on by having a chemist test the capsules (which in fact many patients did) or by glancing at blood test results: marked blood abnormalities could be found in nearly all of the AZT patients.

Spitzig wrote that the study rules stated, "ANY ADVERSE EXPERIENCE BY A STUDY SUBJECT IS TO BE REPORTED IMMEDIATELY BY TELEPHONE, FOLLOWED BY A WRITTEN REPORT." She added, "The IRB requirement that *all* adverse reactions be reported was not met. None of them were reported."⁹

From the standpoint of the study's "data", many serious adverse reactions were concealed by not recording them on the CRFs, even though they were mentioned in the patient's medical records. And this appeared to be tendentious — that is, favoring AZT — as all except one of the eight cases where serious adverse reactions were concealed involved patients on AZT.

For example, patient #1008, on AZT, was hospitalized during the study, suffering from anemia, headache, dizziness, nausea, shortness of breath, fever, fatigue, abdominal cramps, chills, odynophagia, and severe anemia. None of these were listed as "adverse reactions" on the CRF. This patient later experienced "extreme postural lightheadedness and felt close to syncope" and was then transferred to the Emergency Ward, where he received a blood transfusion. "There was no mention of having received blood in the Case Report forms for this individual."¹⁰

Patient #1012, who was on AZT, developed a severe rash. Although nurse Flynn "agreed that it should have been called an

⁹Spitzig, p. 12.

¹⁰Spitzig, pp. 49-53.

adverse reaction", it was not recorded on the CRF.¹¹ Patient #1053, on AZT, experienced high temperature, nausea, marked fatigue, paresthesia in the toes, and severe anemia; he received multiple transfusions; none of these were recorded on the CRF as being "adverse reactions".¹² Patient #1055, on AZT, suffered fatigue, nausea, and loss of appetite, and was hospitalized with a fever of 105 degrees; his CRF said he had experienced no adverse reactions.¹³

Patient #1009: from AZT to placebo

The real bombshell in Patricia Spitzig's Establishment Inspection Report concerns patient #1009. Before entering the study this patient was suffering from severe anemia and headaches, for which he "was taking Tylenol every four hours without relief of symptoms." He had received a number of transfusions, the last one only a week before being entered in the study as a placebo patient on 29 May 1986. However, the record for his Week 1 visit on 5 June 1986 states that the patient "was still taking Azidothymidine as of this visit"!

In other words, patient #1009, who was already taking AZT and who was suffering from typical AZT toxicities (severe headaches and anemia), was illegally entered into a study for which he was ineligible. Patient #1009 was then assigned to the placebo group, although he continued to take AZT. He dropped out of the study after being in it for less than a month, and died on 20 August 1986, two months after leaving the study. He was then counted as a death in the placebo group.¹⁴

Further comment would be superfluous. If this is not fraud, the word has no meaning.

¹¹Spitzig, p. 59.

¹²Spitzig, pp. 61-62.

¹³Spitzig, p. 64.

¹⁴Spitzig, pp. 53-55.

Disappearing test product

Drug accountability was a major problem at the Boston center. The test products were not recorded, counted, or stored properly. Some records, such as the running inventory kept by the pharmacy, were destroyed. After trying valiantly to make sense out of total chaos, FDA Investigator Patricia Spitzig gave up, and stated:

It is not possible from these records to compare the test article usage against the amount shipped to the C.I., and as compared to the amount returned to the Sponsor. (FD-483, No. 9) In fact, the number of bottles (or amount of capsules) used or unaccounted for varies with the system checked.¹⁵

It was apparent, at any rate, that a lot of product was missing. Comparing the number of bottles shipped to the number that were recorded as received by the pharmacy, Spitzig found that 87 bottles were missing. Some of the product was undoubtedly stolen, the code broken, and the AZT sold on the black market where, as one of the most expensive medications of all time, it was probably worth its weight in gold. Spitzig states:

Exhibit C-15 is a July 22, 1986 letter from [CENSORED] saying that some of the Study Drug, [CENSORED], had been purchased "on the street". Clemons asked them to be sure that the Study medications be kept under a "double-lock system".¹⁶

As a consequence of the sloppiness with which the test medications were handled, for two weeks patients #1056 and #1057 received each other's medication. Patient #1056, assigned to placebo, received AZT for two weeks, and patient #1057, assigned to AZT, received placebo for two weeks. This is not mentioned on their CRFs.¹⁷

¹⁵Spitzig, p. 16.

¹⁶Spitzig, p. 9.

¹⁷Spitzig, p. 70.

There may have been some funny business regarding the labels of the Study medications, but the Burroughs Wellcome monitor, Ron Beitman, prevented inquiry in this direction:

It was not possible to review the label of the Study medication since we were told the monitor had picked up all the empty and full bottles the week before we arrived and he had subsequently destroyed them all since. Ex H-6 is a copy of what the label would have looked like according to R. [CENSORED]... A seven digit code was written on two records and crossed out but not explained (1003 [an AZT patient] and 1005 [a placebo patient]). T. Flynn explained it may be a product code. On 1003's CRF (p. 82) the code was "1017401"; on 1005's CRF, p. 199, wk. 6, the number is "1118401".¹⁸

Violations of protocol

Investigator Spitzig listed numerous violations of protocol for every patient in the Boston center, and it would be tedious to go into them all. In general, tests were not performed that should have been, ineligible patients were entered into the study, records were kept badly, and patients took many concomitant medications.

In a drug trial it is obviously important to avoid confounding the results by allowing patients to take drugs other than the study medications. This is the rationale for study protocols forbidding the use of particular drugs. Spitzig made the following observation regarding the Boston center:

Other deviations from the Protocol included undocumented approval by the Sponsor for concurrent medication used for 11 subjects.... Deviations from the Protocol were allegedly approved per telcons. These calls were not documented, or noted in the Case Report Forms. These deviations from the Protocols were not reported to the IRB.¹⁹

¹⁸Spitzig, p. 18.

¹⁹Spitzig, p. 19.

Patients in the study took the following drugs in addition to their test medications: Cefadroxil, Erythromycin, Acyclovir, Wacomil, Ranitidine (Zantac), Hydrocortisone Cream (topical), Benadryl, Dilantin, Stelazine, Xanax, Halcion, Colace, Compazine, Tylenol, Lomotil, Excedrin, Keflex, Streptomycin, INH (isoniazid), Ethambutol, Pyridoxine, and Lithium.

In going through the correspondence file, Spitzig uncovered an unusual incident, in which the 18-month daughter of patient #1006 swallowed some of his test product, which happened to be AZT. The incident, which was not mentioned in the Case Report Forms or any other records, is described by Spitzig as follows:

Dr. Schooley had told us verbally that the subject had kept the vial of medication at home. He had walked into a room and seen his daughter sitting on the floor with capsules in her hand. He had received a call about the incident from a [CENSORED] hospital. She had taken an unknown number of capsules. Further followup indicated that between 1 and 3 capsules were missing. Dr. Schooley meanwhile had called the sponsor firm and had determined that his subject was on the drug [CENSORED]. Dr. Schooley mentioned verbally speaking with [CENSORED]. However, there is no mention of his name in the memo of telephone conversation. He made some comment about calling the Poison Center but the memo of telephone conversation indicates that the assessment of the toxicity of the drug was made by [CENSORED]. He said it was "below the acute toxic dose". He made a comment about the hospital planning to draw blood for samples and, in fact, the memo makes reference to that as well. T. Flynn mentioned that the child was taken back (apparently to the hospital) one more time. There is no additional followup to indicate the results of the blood sample or checks on the condition of the child's health. There was no copy of any hospital treatment record from the [CENSORED] hospital in the study records.²⁰

Obviously, for patient #1006, the trial was no longer blind, as he was told that his test medication was AZT. It is hard to think of an

²⁰Spitzig, p. 47.

innocent explanation for Schooley's neglecting to mention this incident in the Case Report Forms.

The Coverup

On 30 January 1987 an in-house FDA meeting was held "to consider whether or not to exclude the data from the Boston center, (Robert Schooley, P.I.) from the analysis of the AZT multi-center trial."²¹ For some reason Patricia Spitzig was not present at the meeting.

The meeting was not just a whitewash, it was a total farce. The eight MDs and three PhDs present appeared to have not the slightest grasp of the techniques and ethical standards of professional research. Rather pathetically they posed the questions:

1. How did the conduct of the study at this center compare with the other centers and
2. did the recording and record changing irregularities occur at the two other centers for which Mr Beitman was clinical monitor?

In other words, deplorable as the work at the Boston center was, might it not be possible that the other centers were just as bad, or even worse? Mr. El-Hage, apparently a co-investigator with Patricia Spitzig, said he was unable to answer these questions, "since written reports of the inspections have not been received."

No consensus was reached on whether or not to drop out the Boston center or drop out individual patients. "It was finally decided that the situation would be presented to Dr. Young [Commissioner of the FDA] for his input. It was also agreed that a second meeting would be scheduled to discuss issues common to all the study centers e.g. prophylactic medication for OIs, dose reductions and discontinuations not recorded on the CRFs, poor screening of patients, etc."²²

²¹Jackie Knight, minutes of meeting of 30 January 1987.

²²Jackie Knight, work cited.

The second meeting was held on 11 February 1987. A number of big shots were present, including FDA Commissioner Frank Young and David Barry, vice president in charge of research at Burroughs Wellcome. The alleged minutes of this meeting, as supplied by Mary Gross, are as follows, in their entirety:

A meeting was held to discuss FDA's investigation of Dr. Schooley's facilities.

Dr. Young summarized the meeting by saying that it was clear from the inspection report that there were some problems in recordkeeping in the study and he impressed upon Dr. Schooley the importance of maintaining good records during these trials in order to help FDA inspectors verify clinical trial activities. However, these procedural discrepancies were judged not to have influenced the validity of the data or the ability to draw conclusions and FDA will include Dr. Schooley's data in the overall analysis of the zidovudine multicenter trial.

Dr. Young thanked everyone for attending the meeting and Dr. Schooley expressed appreciation to FDA for the expeditious review given his data.²³

It is inconceivable that these three brief, meaningless paragraphs could be the minutes of such an important meeting. These minutes cannot be genuine for the following reasons: they are on FDA letterhead, whereas all other FDA minutes are on plain paper; they do not address the issues common to all the test centers; and their innocuousness is at odds with the difficulties I had in obtaining them. I had to fight for three months to get them. If these are the real thing, then there would have been no need for stonewalling.

In 1989 Sidney Wolfe, director of the non-profit Public Citizen Health Research Group, charged that under Commissioner Frank Young, the FDA "is implicitly inviting all of the industries it regulates to join in the lawlessness."²⁴ Young was later forced to resign, in disgrace over the generic drugs scandal and others.

²³Mary Gross, alleged minutes of meeting of 11 February 1987.

²⁴Morton Mintz, "Anatomy of a Tragedy", *New York Newsday*, 3 October 1989.

Conclusion

In England, Wellcome PLC, the parent company of Burroughs Wellcome, recently made the claim that 4000 studies demonstrated the benefits of AZT. This is ridiculous. If one devoted a mere ten minutes to studying each of the 4000 alleged studies, it would take him 667 hours to do so, or, assuming he worked for 7 hours a day and 5 days a week, a total of 19 weeks, more than a third of a year.

The fact remains that the Phase II trials are still the single most important test of AZT. They were the main basis for the drug's approval by the FDA; they were one of the "historical controls" upon which approval of ddI was based; and they are still cited as proving that AZT "extends life". And they are fraudulent. Fraud in drug testing may be common, but it should not be tolerated.

If there were justice in the world, the crooks in the FDA, NIAID, Burroughs Wellcome, and their accomplices in the medical profession would pay for their crimes. But it is more important now to save lives. At present well over 150,000 people are being poisoned by the nucleoside analogues, AZT, ddI, and ddC. We must all help sound the tocsin. We must stop the genocide.

ROBERT T. SCHOOLEY, MD., MASSACHUSETTS GENERAL HOSPITAL, BOSTON, MASS.
 10/14-17, 20-24, 27-30 & 11/10,12/1986 PAS 6

he came to the site on March 20, April 23, May 15, June 5, 23 and 24th. Other dates were July 8th and 30th, September 4th and 23th, and October 7th and 8th. We know in addition that after the investigator was notified of this inspection and prior to our arrival that the monitor also visited apparently for a few days and did work on the Study including Accountability Records and return of Study medication records (see below).

5. When I asked about additional meetings with the monitor during the Study, Dr. Schooley mentioned the meeting at [REDACTED]. This [REDACTED] that Mr. Byington, Lab Supervisor, attended. He also (repeated) a meeting in [REDACTED], "several Saturdays ago" where [REDACTED] presented data prior to the Press Conference explaining the results of the Study.

(Also in response to this question, Dr. Schooley said that one of the problems in organizing or running the Study was that the [REDACTED] all overlap with each other and with the Study. The [REDACTED] are runned wholly by [REDACTED]. Drs. Hirsch and Schooley are in charge of these Units in Boston. Dr. Schooley said they are not doing anything with these groups yet. It will be six weeks to two months before they begin. It was my understanding that what he meant by a conflict was that these Units, once established, will be a more organized way of dealing with new substances to treat [REDACTED]. Dr. Schooley and Ms. Flynn mentioned several times that the subject Study was organized quickly and it's my understanding that they felt that some of the disorganization, both theirs and [REDACTED] was due to the fact the the Units were not in place and there is no standard way of dealing with all these Studies. As an example, personnel have not been put in place to perform clerical functions for the [REDACTED] and since the units have not yet been established, the commitment to hiring additional people prior to that time has not yet been made.

(Correspondence regarding the Study is attached as Exhibit C to this report. In this section we will mention briefly the review made of the correspondence. It appears that this correspondence file was incomplete. In one case (Ex E-2) only page one of a two page letter was made available to me.

Exhibit C-1 - Is a letter to Dr. Schooley from L. [REDACTED] dated November 22, 1985. [REDACTED] explained that a Tentative Outline for the Double Blind Study is enclosed and he asked for Dr. Schooley's comments. He also recommends that the outline be submitted to the IRB for their consideration and Dr. Schooley "start screening patients based on the entry and exclusion criteria of this Outline".

Exhibit C-2 - Is a January 23, 1986 letter from Dr. Schooley [REDACTED]. Dr. Schooley discusses the Safety Monitoring Board and recommends that they be in a position to terminate the Study "if clearcut clinical benefit or significant toxicity is observed in the

Censored page from Spitzig document



Wellcome headquarters in London
photo by John Lauritsen