

ADDENDUM TO PAT'S REPORT

(Unless otherwise noted, all references are to page and exhibit numbers in Pat's report.)

CHANGE IN STUDY DESIGN: THE MISSING COHORT

The Zack/Suskind mortality study of 1949 explosion workers with chloracne states (p. 11): "The results of this study will be incorporated with those of a larger study which will include plant workers exposed in the course of 2,4,5-trichlorophenoxyacetic acid production during the period 1948-1969," and (p. 12) "An analysis of the chloracne cases and exposures not associated with this accident but rather with the normal TCP/2,4,5-T production processes will be the subject of a future paper." (2,4,5-T was produced at Nitro from 1948 through 1969.)

The Zack/Suskind study announcing the above future study of TCP production workers with chloracne was published in January, 1980. Ten months later, in October 1980, Monsanto issued a press release proclaiming completion of the second study, identifying it as authored also by Zack and Suskind. (Monsanto medical director George Roush has identified this second study as the one subsequently published as the Zack/Gaffey study. pp. 437-438.) By the time of the October 1980 press release (pp. 347-350), however, the study described in the Zack/Suskind study was no longer a study of TCP workers with chloracne, and indeed did not address chloracne at all; instead, it had become a study of mortality in the entire Nitro plant, compared with mortality in a subset of TCP workers identified solely from employment records without any reference to medical condition (i.e., chloracne). The study differed from the study described in the Zack/Suskind study in several significant areas:

1. It did not address chloracne at all;
2. It eliminated from the study altogether all workers who died or ended employment at Nitro from 1948 [first year of 2,4,5-T production at Nitro] to the end of 1954, and from the end of 1977 to the end of 1978 [the cut-off for the Zack/Suskind study], and thus does not include "plant workers exposed in the course of 2,4,5-trichlorophenoxyacetic acid production during the period 1948 to 1969" as described in the Zack/Suskind study.
3. It included only hourly payroll employees within the above time limits and excluded from study all salaried employees (thus excluding 14 deaths of men with chloracne, according to Monsanto's own records, p. 339).
4. "Exposure" to TCDD was determined with no reference to

plant medical or safety records but solely by plant employment records (i.e., only workers in the actual TCP process), excluding all others (such as maintenance workers) who had potential exposure and leading to blatant misclassification of four workers classified as exposed in Zack/Suskind but as unexposed in Zack/Gaffey.

5. "Exposure" was determined only for a subset of dead workers, not for all TCP process workers (even by the limited employment criteria).

Thus, at some point between publication of the Zack/Suskind study and Monsanto's press release, the study design for the second mortality study had changed radically. No explanation has ever been given for this extreme change; the only reason given -- that no work history records existed prior to 1955 -- in no way explains why the study planned as a chloracne study was changed to a "work history" study in the first place. Dr. Roush testified that the two studies were begun and conducted at the same time (1978-1979, p. 443); at the time of publication of Zack/Suskind the second study was still a chloracne study, yet ten months later it had been transformed totally. What happened to the chloracne study?

A series of memos from Jan Yung, the person who collected the data for both studies, shows that the data for the second chloracne study (of production process exposure) was indeed collected. A December 5, 1978 memo from Yung (Tab 15 * to be numbered) summarizes sources for the 114 "dermatitis cases" in "Group I" (the accident exposures), and refers to the need for further work "to determine total dermatitis cases for Group II" (normal process exposures). (Tab 15 *)

[VERY INTERESTING NOTE: Yung refers to "the S.R.I. visit to computerize work histories at Nitro." I believe "S.R.I." is the Stanford Research Institute. Gaffey worked at SRI from 1976-1979: is it possible he was involved in SRI's visit to Nitro and/or the computerization effort during 1978? Good question for discovery/deposition. If he was, then he could actually have been working on the "work history" study before he came to Monsanto, which would explain how the study design could have gotten changed so radically in so short a time.]

A December 28, 1981 memo from Jan Yung to Gaffey establishes that a second cohort (Group II) was in fact identified from plant records ("safety, personnel, and medical records") and Workmen's Compensation records for the years 1950-1954. (Tab 16*) From this period, "a total of 135 white males were identified as having reported dermatitis or chloracne associated with TCDD exposure during normal TCP operations at the plant." Yung notes that "All of the individuals in the cohort were traced for vital status." As of the date of the memo (12/28/81), "we have a total of 56 known deceased with death certificates on file." Attached to her memo is the list of persons with chloracne associated with

normal TCP operations, and a table of "Chloracne Cases 1950-1954 Deceased" listing names, date of death, age, and cause of death. (Of these, roughly 42 died of heart/circulatory disease, and 11 of cancer; of the heart and cancer deaths, 20 were at or before age 50; of these 20, 6 were cancers. These are rough numbers, but do suggest that men with chloracne were dying of heart disease before the opportunity for cancers to develop.)

Significantly, this 1981 memo identifies a TCP-process chloracne cohort exposed only from 1950-1954 (although the vital status is given as of Dec. 1981). The Zack/Suskind study promised a cohort of process workers exposed from 1948 through 1969. Was a cohort for this entire period identified? Testimony in the Nitro case was that there were chloracne cases occurring during every year of this period (Nitro transcript, pp. ____*). Apparently Yung wrote the memo in response to a request from Gaffey for data only on 1950-1954. If the data for the entire period (through 1969) reflect the trends in the 1950-1954 period, that is probably why Monsanto chose to change the study design to a work history study!

DR. SUSKIND'S RETREAT

Why Dr. Suskind refused to be named as author of the second study is still unanswered. Given his career-long dedication to chloracne as the hallmark of TCDD exposure, he may simply have been angry at his study design being changed. He may also have recognized the misclassifications in the changed study and would not put his name to a study that classified as unexposed the very people he had classified as exposed in the first, already published study. In addition, however, between 1949 and 1953 Suskind himself had examined and diagnosed with chloracne some of the very workers listed as unexposed in the Zack/Gaffey study.

Dr. Suskind is identified by Monsanto in its October 9, 1980 press release as the co-author of both the Zack/Suskind "accident" study, and what was later published as the Zack/Gaffey study. Dr. George Roush, Monsanto Medical Director, confirmed that the second "Zack/Suskind" study referred to in the press release and in the first Zack/Suskind is the Zack/Gaffey study (p. 437-438).

The question never answered by Dr. Roush or Suskind in the Kemner record is why Dr. Suskind took his name off the study. A clue may be found in the misclassifications and omissions of the Zack/Gaffey study. Among the individuals either misclassified as "unexposed" or excluded altogether from the Zack/Gaffey study are a number of men whom Dr. Suskind examined in 1953 and unequivocally diagnosed as exposed, based on his clinical exams and on Monsanto's own records.

The list of deaths in workers examined in 1953 (plaintiff's exhibit 1748) is at page 14 of text.

Monsanto's own record of misclassifications and exclusions from the Zack/Gaffey study is in Marcie Strauss's memo (pp. 336-341).

Of the four men classified as exposed in the Zack/Suskind study but as unexposed in the Zack/Gaffey study, one (Ralph Westfall, p. 336) was diagnosed by Suskind in 1953 (p. 14 text); of 14 men included as exposed in the Zack/Suskind study but excluded altogether from the Zack/Gaffey study, three (John E. Blackwell, Rarry Hudnall, and Lawrence L. Shank, p. 339) were diagnosed as exposed in 1953 (p. 14 text); and of three men (p. 341) listed as "unexposed" in Zack/Gaffey who should have been exposed, one (William Simmons) was diagnosed as exposed in 1953 (p. 14 text).

Thus, Suskind was unquestionably aware that the change in study design for the second study, from a chloracne study to an "hourly worker" study, not only resulted in misclassifying workers clearly classified as exposed in Zack/Suskind, but also excluded workers he had diagnosed -- and Monsanto had identified -- as exposed in 1953. This perhaps was too much even for Dr. Suskind to put his name to.

Suskind testified that Monsanto did not want to include citations to his 1949, 1950, and 1953 unpublished studies in the Zack/Suskind study (NITRO transcript 28590). Monsanto's motives in wanting to keep those citations out may have been to prevent readers from discovering what Suskind knew. (Judith Zack's argument that the Journal of Occupational Medicine had a policy of not citing unpublished data [NITRO P. 28593] is pretty weak.) The actual records cited on these NITRO transcripts would be important to obtain. We don't have them.

AUTHORSHIP OF ZACK/GAFFEY STUDY

1. Gaffey states in his answers to interrogatories that:
 - A. He came to work at Monsanto in 1979 [p. 3]
 - B. He initiated the Zack/Gaffey study and it was approved by his superior Dr. Roush [p. 8]
 - C. Dr. Roush was his immediate supervisor [p.3]
 - D. The present custodian of the data and documents used in preparing the Zack/Gaffey study is James J. Collins, Epidemiology Director, Monsanto Company.

2. There are strong indications, however, that Gaffey in fact was not involved in the actual conduct of the Zack/Gaffey study at all, and was not named as an author until after the study was completed.

A. Dr. Roush testified that the work for the Zack/Gaffey study was begun in 1978, "about the same time" as the work for the Zack/Suskind study [p. 69].

B. Jan Yung was in Nitro, W. Va., in November, 1978, collecting data for both Group I (1949 accident cases) and Group II (non-accident exposure). [pp. 99-89] Marcie Strauss confirms that Yung developed two lists: "the 'Nitro TCP Accident' list with 122 people on it and the list of 'Chloracne Cases Not Related to 1949 TCP Accident' containing 228 people." [p. 18]

C. Gaffey did not come to work for Monsanto until 1979 [p.3], and therefore could not have either "initiated" the study nor participated in the work done on it prior to his arrival at Monsanto. Gaffey is not listed as an attendee of the meeting of the Nitro Health Study Task Force on July 20, 1979 [pp. 80-82], but was a recipient of the minutes of that meeting [p. 80], at which the plan to issue a Monsanto press release on the Zack/Suskind study was discussed.

D. Monsanto's October 9, 1980 press release on the two Nitro mortality studies identifies both as being authored by Zack and Suskind [pp. 84-87]. Dr. Roush, testifying in the Kemner case, confirmed that the second study referred to in the press release is the Zack/Gaffey study. [p. 36] Dr. Roush acknowledged that the study originally identified by the press release as a Zack/Suskind study ultimately was published as the Zack/Gaffey study [p. 36] and testified that he didn't know why Suskind had removed his name from the study [pp. 36-38]

3. A copy of what was subsequently published as the Zack/Gaffey study was entered in the record of the 2,4,5-T cancellation proceedings on February 9, 1981. The study, dated August 14, 1980, and labeled "Draft," has only one author named, Judith Zack. Gaffey's name appears nowhere on it. Otherwise, it is the same study as was eventually published as Zack/Gaffey. Note that the date on this draft was only two months before the Monsanto October 9, 1980 press release.

4. If Gaffey in fact did not do the actual work on the Zack/Gaffey study, and is not in possession of the actual records used to conduct it, he has no basis for asserting its validity or the absence of fraud.

5. The only indication that Gaffey may indeed have been involved with the study is Jan Yung's reference to SRI's (Stanford Re-

search Institute) visit to Nitro to computerize work history records in 1978. (p. *____) Gaffey was head of SRI's epidemiology division at that time, and as a statistician would more than likely have been involved in the Nitro work history computerization effort. The dramatic and unexplained change from the planned chloracne study to a work history study, and its short-order completion, could have been Gaffey's work: having seen the horrific data on chloracne cases, Monsanto hired Gaffey away from SRI specifically to manipulate the computerized work history data (i.e., eliminating salaried workers, shortening time period, eliminating maintenance workers, etc.) to come up with an "acceptable" result. This could have been accomplished very quickly with the software available at that time. (This issue need not be explored yet, however, because the unanswered questions about Gaffey's authorship, as well as his admitted lack of any records, raise a sufficient question for summary judgment.)

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particularly
and if he doesn't respond to SJ
with SRI records.

OTHER ISSUES

1. Dr. Roush testified that the Zack Gaffey study is the study identified in the Zack/Suskind study as a forthcoming study of TCP process workers exposed to dioxin [pp. 63-64], and acknowledges that the two studies are "tied together." [p. 31] Monsanto's October 9, 1980 press release characterizes the Zack/Gaffey study as a "larger, follow-up effort" to the Zack/Suskind study. [p. 85]
2. The forthcoming study described in Zack/Suskind is described as a chloracne study [p. 63], however, while the Zack/Gaffey study did not involve chloracne at all [p. 69].
3. Dr. Roush (Gaffey's boss) admits that the Zack/Gaffey study deliberately classified workers exposed to dioxin as "unexposed", and that this was done "on purpose" because "of the design of that study" [p. 40]
4. How the design of the Zack/Gaffey study, described in the Zack/Suskind study as a chloracne study, changed into a study designed "on purpose" to classify workers with chloracne as unexposed to dioxin, is a critically important question in determining whether the Zack/Gaffey study was fraudulent.