

MEMORANDUM

CONFIDENTIAL

TO: Dr. Richard Clapp
cc: Dr. Peter Montague

FROM: Paul Merrell

RE: Gaffey v. Montague PRIVILEGED AND CONFIDENTIAL
COMMUNICATION

DATE: November 16, 1993

I have asked Peter Montague to use his scientific skills to review Dr. Gaffey's study and see if he might be able to identify some leads for you to further develop, in order to hold his expenses down and reduce the demands on your time. Enclosed please find his first cut.

It would be extremely helpful if you might look this over and let me know when you might be available for a conference call among yourself, Peter, and me, hopefully tomorrow. If not tomorrow, Friday would be the next day I am able to do it because of my need to travel to Eugene on Thursday.

I caution that I or one of Peter's other attorneys need to be part of any communications between him and you in regard to the issues of this lawsuit, both to ensure that the communications remain privileged and to get the trial lawyers up to speed.

I'd appreciate it if you could call me in the morning to set a time for the telephone conference, which we will initiate.

Best regards from me and from Carol.

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November 16, 1993

Mr. Paul Merrell
7493 East Five Rivers Road
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Dear Paul,

In preparing my defense in Gaffey v. Environmental Research Foundation et al., I have been reviewing the basis for some of the statements in my newsletter #171, which Mr. Gaffey found defamatory.

One of the offending statements occurs at the bottom of column 1, pg. 1: "In fact, excess cancers *have* occurred, but it appears that the data have been manipulated to hide the facts." [Emphasis in the original.]

The statement has two parts: (a) excess cancers have occurred; and (b) it appears that the data have been manipulated to hide the facts.

At the moment, I am focused entirely on lung cancer in the Nitro cohort, as reported by Zack/Gaffey. I will refer to two studies, Zack/Gaffey¹ and Zack/Suskind.²

Regarding the first part of the statement, I am attaching two short analyses I have done, based on Zack/Gaffey's data. I merely calculated the probability that the apparently-increased lung cancers in the Nitro cohort were due to chance. Gaffey tested for significance at the 0.05 level; if he had selected 0.20 as his level of significance, as one might justifiably do in an exploratory analysis,³ he would have found significantly-elevated increases in lung cancer in the period 1970-1977.

¹ Judith A. Zack and William R. Gaffey, "A Mortality Study of Workers Employed at the Monsanto Company Plant in Nitro, West Virginia," In Richard E. Tucker, Alvin L. Young, and Allan P. Gray, editors, *Human and Environmental Health Risks of Chlorinated Dioxins and Related Compounds* (New York: Plenum Press, 1983), pgs. 575-591.

² Judith A. Zack and Raymond R. Suskind, "The Mortality Experience of Workers Exposed to Tetrachlorodibenzodioxin in a Trichlorophenol Process Accident," *Journal of Occupational Medicine* Vol. 22 No. 1 (January, 1980), pgs. 11-14.

³ John T. Roscoe, *Fundamental Research Statistics for the Behavioral Sciences* (Second Edition) (Fort Worth: Holt, Rinehart and Winston, 1975), pg. 182, says most research is conducted at the .01 and .05 levels of significance but "...in exploratory research, the .10 and .20 levels may be more appropriate."

Since Gaffey's selection of 0.05 is an arbitrary choice, I think my two analyses strengthen my case for saying that cancers have increased.

The second part of the offending phrase, about the data being manipulated, is somewhat more complicated. In Table 9 of the Zack/Gaffey study, we see the heart of the matter: he conducted PMR analyses for the "exposed" workers and the "non-exposed" workers.

In the "exposed" workers, Zack/Gaffey found a PMR of 168 (3.57 expected and 6 observed). Among the "non-exposed" workers, Zack/Gaffey reported a PMR of 125 (6.42 expected, 8 observed).

However, we know from Table 11 of Zack/Gaffey and Table 10 of Zack/Suskind that four workers listed as "exposed" in Zack/Suskind's Table 10 are listed as "Not Exposed" in Zack/Gaffey's Table 11. In Zack/Suskind's Table 10 these workers are (counting from the top of the table), Nos. 1, 2, 5, and 7. In Zack/Gaffey's table 11, these same workers appear as (counting from the top), Nos. 5, 6, 9, and 22.

I will refer to these 4 workers as "misclassified."

If we re-classify the misclassified workers, Zack/Gaffey's Table 8 changes accordingly. The number of deaths among the "exposed" becomes 62 (not 58) and the number of deaths among the non-exposed becomes 100 (not 104). These changes cause additional changes in the "Percent" column of Table 8; the percent of deaths among the "exposed" becomes 38.0 (not 35.6), and the percent of deaths among the "non-exposed" becomes 61.4 (not 63.8).

I note that 3 of these misclassified workers died of lung cancer. If we re-classify these 4 workers in Zack/Gaffey's Table 9, moving them from the "non-exposed" column to the "exposed" column, then the lung cancer figures in Table 9 would change. The new numbers would be 9 (not 6) lung cancers observed among the "exposed" workers, causing the PMR to change from 168 to 252. Among the non-exposed, we would now have 5 (not 8) lung cancers observed among the "non-exposed" workers, causing the PMR to change from 125 to 78.

I am unable to go further with this analysis. Having re-classified these workers and calculated new PMRs, I would like to calculate the probability that the new PMRs were due to chance.

Unfortunately, I can't understand Gaffey's method for calculating the 95% confidence interval for any given PMR; he describes his method at the top of pg. 579 but I don't see where one gets the basic data he calls "confidence limits for the % of observed deaths" and I don't understand the denominator, which Gaffey

gives as

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$\exp_x$

To me, $\exp$ means "e raised to the power of," but power of what? Or does Mr. Gaffey intend $\exp$ to mean "expected deaths?"

I need to talk to Dick Clapp about this. Could you please set up a conference call with Dick and you and me?

I want to discuss how to calculate confidence intervals for the revised PMRs or, perhaps, how to calculate the standard error of a PMR. My goal is to calculate various confidence intervals and/or standard errors that will help me understand quantitatively what the revised PMRs tell us about the likelihood of real lung cancer increases having occurred among the Nitro cohort. (The direction of the change induced by Mr. Gaffey's misclassification is already clear.) By this means, I hope to learn something quantitative about the effect of Mr. Gaffey's misclassification of 4 exposed workers.

I also need Dick to check my methods and arithmetic in the two attached analyses of SMRs among the entire Nitro cohort.

Thanks very much for your help with this.

Sincerely,

A handwritten signature in dark ink, appearing to be 'P. Montague'.

Peter Montague

SMR FOR LUNG CANCER, 1955-1977, IN THE ENTIRE NITRO WORKER COHORT

In their study of Nitro workers, Zack/Gaffey conducted an analysis of cause-specific standardized mortality ratios (SMRs) for 15 selected cancer sites among the entire Nitro worker cohort during the period 1955-1977.⁴

This paper focuses on their analysis of lung cancer.

With 9.91 lung cancers expected and 14 observed, they reported that the SMR for lung cancer was 141 [Zack/Gaffey Table 4].

Zack/Gaffey highlighted this finding by saying, "Although not statistically significant, the SMR for lung cancer appears to be elevated."

What is the likelihood that this apparently-elevated lung cancer mortality was due to chance?

Zack/Gaffey suggest that the proper way to calculate the standard error is:

$$\text{standard error} = \frac{100 * \text{sqrt}(\text{no. of observed deaths})}{\text{no. of expected deaths}}$$

By this formula, the standard error for lung cancer is:

$$(100 * 3.74)/9.91 = 37.8$$

The SMR, which is 141, differs from 100 by 41, which is $41/37.8 = 1.09$ standard errors.

In the table of areas under the standard normal distribution, we find the probability that a lung cancer SMR of 141 is due to chance is 0.276.

In other words, the chance that the SMR of 141 is due to an actual increase in lung cancer among Nitro workers (and not due to chance) is 72.4 percent.

Thus Zack/Gaffey's analysis of the entire Nitro cohort reveals that the chances are better than 2-out-of-3 that an actual increase of lung cancer occurred among the Nitro workers during the period 1955-1977 (compared to the normal occurrence of lung cancer among the American public).

--Peter Montague, 11-15-93

⁴ Judith A. Zack and William R. Gaffey, "A Mortality Study of Workers Employed at the Monsanto Company Plant in Nitro, West Virginia," in Richard E. Tucker, Alvin L. Young, and Allan P. Gray, editors, *Human and Environmental Health Risks of Chlorinated Dioxins and Related Compounds* (New York: Plenum Press, 1983), pgs. 575-591.

SMR FOR LUNG CANCER, 1970-1977, IN THE ENTIRE NITRO WORKER COHORT

Zack/Gaffey⁵ calculated cause-specific standardized mortality ratios (SMRs) for 15 selected cancer sites among the entire Nitro cohort during the period 1970-1977.

Here we examine lung cancer.

With 5.52 lung cancers expected and 10 observed, Zack/Gaffey reported that the SMR is 181 [their Table 5].

What is the likelihood that this apparent increase was due to chance, and not due to a real increase in lung cancer among the Nitro workers?

Zack/Gaffey calculate the standard error of the SMR as:

$$\text{standard error} = \frac{100 * \text{sqrt}(\text{no. of observed deaths})}{\text{no. of expected deaths}}$$

By this formula, the standard error for lung cancer is:

$$(100 * 3.16)/5.52 = 57.3$$

The SMR, which is 181, differs from 100 by 81, which is $81/57.3 = 1.42$ standard errors.

In the table of areas under the standard normal distribution, we find the probability that a lung cancer SMR of 181 is due to chance is 0.168.

In other words, the chance that the SMR of 141 is due to an actual increase in lung cancer among Nitro workers (and not due to chance) is 83.2 percent.

Thus Zack/Gaffey's analysis of the entire Nitro cohort reveals that the chances are better than 4-out-of-5 that an actual increase of lung cancer occurred among the Nitro workers during the period 1970-1977 (compared to the normal occurrence of lung cancer among the American public).

--Peter Montague, 11-15-93

⁵ Judith A. Zack and William R. Gaffey, "A Mortality Study of Workers Employed at the Monsanto Company Plant in Nitro, West Virginia," in Richard E. Tucker, Alvin L. Young, and Allan P. Gray, editors, *Human and Environmental Health Risks of Chlorinated Dioxins and Related Compounds* (New York: Plenum Press, 1983), pgs. 575-591.

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FAX TRANSMITTAL SHEET

To: Dr. Richard Clapp No. 617-482-0617
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Pages (including this sheet) 8
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