

MONSANTO

From William R. Gaffey, A3NK, 4-8811
(Name-Location-Phone)

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G. Roush

Subject : G.E. Pittsfield, Mass. Study

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TO : T.M. Bistline
J.H. Craddock
R.G. Kaley
W.J. McCarville
P.R. Michael

On Friday, October 16 I met with Dr. Steven Hamilton and Mr. Teevee Barbela at General Electric's Fairfield office to hear what they had to say about the above study. (Barbela is G.E.'s epidemiologist.) I learned that some of my previous impressions, which I had communicated particularly to Dr. McCarville, were not exactly true. This communication can be regarded as coming from the horse's mouth, or at least from the correct end of the animal.

First a general impression. In the past G.E. has regarded PCBs as a business problem. At the two previous meetings between G.E. and Monsanto Barbela was not present. The studies that G.E. had done in-house were done independently of Barbela, and the contact person for reacting to outside studies was Steve Hamilton. I note that in his communications to those outside authors he does not copy in Barbela.

All of this may be because of G.E.'s decentralized organization. Individual units are free to go outside for their epidemiology, and it may be a matter of principal for those units not to admit that they are dependent on a corporate resource. In any case Barbela, who is quite competent, is now actively involved in G.E.'s reaction to the Pittsfield studies.

The sequence of events leading up to the present state of affairs appears to be as follows. I got this from my conversation with Hamilton, my reading of one of Dr. Wegman's reports, and some newspaper clippings that G.E. gave me. Incidentally, I believe G.E. told me everything that there was to tell about the current situation, except for the politics that I deduced from the newspaper articles.

1. In the late 1970s Dr. David H. Wegman, then with the Massachusetts Division of Occupational Hygiene, looked at mortality in a series of New England towns where one or a few industries dominated employment. In Pittsfield he found too much leukemia and colon cancer among deaths

October 23, 1987
Page 2

occurring in the town among people for whom the death certificate indicated employment at G.E. It's not known how he concluded that there was "too much".

2. On the strength of this, Wegman approached G.E. in 1978 and got a list of all their deaths from 1969 to 1977 that resulted in death claims. He did a proportional mortality study that he says confirmed the original findings above, but did not relate them to any particular job type or exposure.

3. In January 1981, G.E. funded Wegman, now at the Harvard School of Public Health, to enlarge the study by getting two additional years of deaths and complete work histories for all pension eligible workers who died. A preliminary analysis was done in May, 1982, but was not released. This p.o.'d State Representative Sherwood Guernsey and one-time mayor Remo Del Gallo, who apparently have pressed, from that point until now, for release of the data. This analysis may have been a case-control study.

The facts seem to be that work histories were not available for a considerable number of the deaths that were collected.

4. It was then decided that, to increase the sample size, deaths up through 1981, and later through 1984 should be added. In addition, the work histories were to be translated into exposure histories by Dr. Thomas Smith of Harvard. Just to complicate matters Wegman moved from Harvard to UCLA, and brought Sandor Greenland, a biostatistician from UCLA, on board. Since the intention was to use all deaths up through the end of 1984, this incarnation of the study must have begun in 1985 or later. The end results of this incarnation are what the current ruckus is all about. Also, sometime after 1985 Wegman moved from UCLA back to Massachusetts, to the University of Lowell.

The current status of the study is as follows. The study is restricted to deaths occurring between 1969 and 1984 to pension eligible employees for whom work history records are available. About one third (some 800 or 900) of the pension eligible deaths were discarded because no work histories were available. An unknown number of deaths

October 23, 1987
Page 3

terminated or non-eligible employees was also not included. Among the remainder, a death was considered a cancer death if cancer was mentioned on the death certificate. It was considered a control if there was no mention of cancer and no mention of some selected other causes.

The study has three defects. In decreasing order of importance they are:

a. The exposure measures have apparently been proved to be invalid. Dr. Smith of Harvard apparently established exposures by interviewing people at the plant who allegedly knew what jobs entailed what exposures. This process ended up assigning high PCB exposures to places where PCBs were never used. This led G.E. to question the whole exposure scheme, and led Wegman to concede that there were some unresolved questions. However, Dr. Smith apparently stands by his original estimates.

b. A large percentage of deaths was excluded from study. This includes both deaths among non-eligible employees and deaths among eligible employees for whom no work histories were available. Barbela is going to look at the latter group to see if they die at about the same ages and from the same causes as the group that was studied. If not, this creates a real problem with the study as it has been done. As far as the other deaths are concerned, there is nothing that can be done at the moment. However, Wegman had almost three years to track down terminated employees. It's unfortunate that he didn't do so.

c. Case ascertainment is from death certificates. Pancreatic cancer is more susceptible to misdiagnosis than many other kinds of cancer, and a case-control study usually looks for the true cause of death rather than the death certificate cause. It would be prudent to at least do a pathology review of the pancreatic cancer deaths.

Nevertheless, G.E. sent in an "FYI" notice about pancreatic cancer and (maybe) dielectric fluids. (The early excesses of leukemia and colon cancer at Pittsfield vanished as the studies progressed.)

October 23, 1987

Page 4

There was one final minor complication. Remember State Representative Guernsey from Item (3) above? He got together with a former G.E. employee and they have been pressuring both G.E. and Wegman to provide a report right now on which buildings are dangerous. Therefore, Wegman did a case control study using as an exposure measure employment in one or both of two buildings in which there might have been PCB exposure. The study was inconclusive.

G.E. put out a press release on October 1 to accompany the release of Wegman's two-building study. This also happened to be the day that G.E. sent their FYI notice to EPA. The press release spent about half a page on the Wegman two-building study and about a page and a half on the larger study about which they had informed EPA.

Those of you with more experience than I may feel paranoid about this. However, having notified EPA, G.E. pretty much had to make a public announcement. By combining the two, they threw Mr. Guernsey a bone without releasing any of the details of the original study.

It's not clear how much time they have bought. In the Berkshire Eagle of October 2, Wegman is quoted as promising a draft of the complete study by next June.

In any case, G.E. feels that they may have problems resolving the difficulties in the larger study, at least partly because Wegman and some of his coinvestigators are going to be reluctant to back down on the exposure estimates and because Wegman chooses to interpret data in such a way as to maximize the number of positive results. G.E. is planning to set up an advisory committee containing a couple of prestigious epidemiologists, plus representatives from NIOSH (Robert Rinsky?) and a sprinkling of other people, whose opinions they hope Wegman will heed. At the same time they are going to hire an outside consultant to help them with their exposure estimates. They welcome any bright ideas we might have, which would be presented to the committee through G.E.

October 23, 1987
Page 5

I am going to keep in touch with Hamilton and Barbela, and in fact will write Hamilton today with some reactions to the study. I didn't say much at the meeting because of information overload and because I don't think fast on my feet.


William R. Gaffey

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