DRAFT

Health Studies at Springfield; Good and Bad Epidemiology

Recently there was a flurry of allegations regarding health problems, specifically cancer, at the Springfield plant. These allegations arose from several "epidemiologic" studies of mortality at the plant carried out by graduate students at the University of Massachusetts. Early in January, one of these studies was picked up by a major news service and circulated nationally. It may have come to the attention of Monitor readers.

Although the management at Springfield has kept its employees fully informed about all health studies of the plant, from whatever source, most of the rest of the Monsanto family is not aware of the somewhat involved series of events that led to the recent news story. To really appreciate it one needs a flow diagram, possibly in three dimensions, so the following account may leave you wondering from time to time just who did what with which and to whom.

For those of you who do not want to wade through what follows, the bottom line is this. If one takes a charitable view of what constitutes an epidemiologic study, there have been seven major studies of the Springfield plant since the mid 1970s. The first was done by a local activist group, the second by NIOSH, the next four by Monsanto or by the University of Pittsburgh under contract from Monsanto, and the most recent by a University of Massachusetts graduate class under the supervision

of a Dr. Kenneth Rosenman. The studies by NIOSH, Monsanto and Pittsburgh in toto conclude that (a) there is an excess of digestive and prostatic cancer at Springfield, (b) there is no assignable workplace exposure to which they can be attributed, and (c) surveillance of the work force should be continued. The studies pretty flatly contradict the University of Massachusetts study.

Now, some general background. Since 1977 Monsanto has had an Epidemiology Section which has been concerned with surveillance of the health of its employees. The most urgent questions are usually about possible occupational cancers, which typically arise several decades after exposure has occurred. The easiest way to study such questions is by looking at mortality, since it is, for technical reasons, much more feasible to find out whether a former employee has died than it is to find out if he had any illness after leaving Monsanto. With the advent of MEHI we are able also to study illnesses and other abnormalities, but in the case of occupational cancer MEHI will not be fully useful for several years because of the latency periods involved.

There are two ways to carry out a study of mortality from all causes. The first is a quick and dirty method called a proportional mortality study. In such a study we get hold of all the death certificates that we can find for, say, the Springfield plant, and look to see whether the proportion of deaths due to each cause is about the same as it would be in a similar collection of death certificates from the general population.

("Similar" here means deceased people of the same race and sex whose ages and dates of death were the same as those in our study sample.) This method is quick because you don't have to find the large living population out of which these deaths arose. It is dirty for several reasons. First, because you rarely know out of what population the deaths arose, you never know whether you have found all the deaths. Second, if you find an excess proportion of deaths from, say, cancer, you never know whether this is due to a real excess risk from cancer or whether it is due to a lower risk from other causes. In fact, most employed populations have a low risk of death from heart disease, the leading cause of death, so that proportional mortality studies of employed populations usually show an excess proportion of cancer deaths.

The second way to study mortality is hard and relatively clean. It is called a cohort study. In such a study we identify everyone who worked in a given department or location in the past, even if they subsequently left Monsanto, we find out whether they are still living, and if not, determine the cause of death. Then we in effect calculate mortality rates by cause and look to see if any of these rates exceed what one would expect in the same time period in a similar living population which was not exposed.

We have had an in-house capability to conduct proportional mortality studies since 1977, and to conduct cohort studies since 1979. We do both, but we regard proportional mortality studies with uneasiness and consider them at best as a screening

technique to identify areas where cohort studies should be done. Both kinds of studies have been done at Springfield. The chronology follows.

1. 1975. A local activist group found 86 death certificates of former employees and did a proportional mortality study. They found an overall cancer excess (see above) and an excess of pancreatic cancer. No one knows how the death certificates were found or selected, but two of them appeared to be for persons who had not worked at Springfield.

2. 1978. NIOSH arrived as a result of the above. Using 441 death certificates provided by Monsanto, NIOSH did a proportional mortality study, finding an excess of digestive and genito-urinary cancers. The excess pancreatic cancer mentioned above was not confirmed, and the excesses that were found were not statistically significant compared to the county (Hampden) in which the plant was located.

3. 1978. Monsanto identified additional death certificates and did a proportional mortality study using 564 death certificates. Results essentially agreed with the NIOSH study.

4. 1978. Monsanto worried about the biases in all of the above studies because they were proportional mortality and used only deaths that came to attention in the ordinary course of business, and did not include deaths among former employees. Monsanto contracted with the University of Pittsburgh to do a

cohort mortality study of every hourly employee who ever worked for Monsanto for a year or more between 1949 and 1966, inclusive (2490 men). NIOSH reviewed the study design and approved it.

5. Late 1979. The Pittsburgh study was completed, having traced all but seven of the cohort. Excess mortality from digestive and genito-urinary cancer was found, but could not be related to work history because work histories for the cohort were not computerized. Monsanto decided to commission a further study of the work histories of whose who died from these two causes.

6. 1980. Concern arose about formaldehyde exposure at Springfield. Further investigation of the above cancers was deferred, and Pittsburgh was asked to determine whether the proportional mortality was the same in those deceased who were exposed to formaldehyde as it was in those deceased who were not exposed. Massive assistance was provided by Springfield and DMEH industrial hygienists in identifying which of the deceased were exposed.

7. Mid 1981. Pittsburgh reported no difference in mortality patterns associated with formaldehyde, and resumed the work history analysis of the digestive and genito-urinary cancers. Again, the plant provided detailed data to group jobs and departments into usable exposure categories.

8. Late 1981. At this stage, what had gone on before, starting with the first University of Pittsburgh study, was a systematic series of highly professional epidemiologic studies designed to determine if there was a problem and, if so, to unscramble the relationship of the problem to work exposure. The Epidemiology Section was by this time involved in in-house cohort studies at Decatur, Krummrich, Nitro and Texas City, but worked closely with Pittsburgh on various details of the studies. By this time we had verified the existence of excess mortality from two causes at Springfield, established that it was not associated with formaldehyde exposure, and were awaiting the final Pittsburgh study of the detailed work histories of those who had died of digestive and genito-urinary cancers. We had gotten much more sophisticated (no more casual proportional mortality studies) and were sure that the Pittsburgh study would resolve matters one way or another.

Then, (and here is where the 3-D flow chart would be useful) -

9. Early October, 1981. We received a report of a cohort mortality study of former vinyl chloride and polyvinyl chloride workers at Springfield done by an anonymous group of University of Massachusetts graduate students, purporting to find large excesses of cancers of many sites, especially digestive cancer. Monsanto was never approached for data in connection with this study. A haphazard collection of bid

sheets was obtained from the union to identify some (not all) VC and PVC workers, who were followed and analyzed using techniques that probably make the study unacceptable to any scientific review group.

10. October 16, 1981. I received a call from someone identifying himself as a reporter from the Boston Globe, asking my opinion of the above study. I replied with some criticisms of the study design, and pointed out that the Pittsburgh study, which we expected to receive very shortly, would answer the question since it dealt with digestive cancers and work exposures. The reporter agreed to get back to me in a couple of weeks.

11. October 29, 1981. The University of Pittsburgh study arrived. The results were as summarized at the beginning of this article. In particular, there was no indication that VC or PVC exposure had any connection whatsoever with the digestive cancers. This study was later reviewed by NIOSH personnel who stated that it "uses well accepted methodology and appears to have been performed in a highly professional manner."

I never heard from the reporter again. That was that, so we thought. But -

12. Early January, 1982. It turned out that the "Boston Globe reporter" was in fact a free-lancer who also wrote for a

local activist newspaper. He wrote up the University of Massachusetts study and my reply of October 16, which essentially said that we didn't have any response at that time, and sat on it over the year-end holidays. In early January 1982 he sold it to the Globe, and either told them or allowed them to believe that it was hot news. United Press picked it up, and my phone began to ring. The story implied that no other studies of the Springfield plant had ever been done, and of course omitted the Pittsburgh findings because the story was in fact three months old.

Like many great dramas, this one ends on a mixed note. We wrote a letter to the Globe telling them the facts, and they produced a second well balanced story including an interview with our University of Pittsburgh researcher. (This was not picked up by United Press.) On the other hand, a Boston TV station picked up the earlier version and got in touch with the local activist newspaper. Several of us ended up being videotaped by the station, with a pretty good idea of how our comments were going to be edited before they went on the air.

Perhaps the real lesson to be learned is, don't raise your child to be an epidemiologist.