Occupational Cancer: Government Challenged in Beryllium Proceeding

The beryllium industry and the government have been locked for months in an intense struggle over the question of whether beryllium should be declared a carcinogen. At issue are not only the merits of an epidemiological study conducted by the chief government agency involved, the National Institute for Occupational Safety and Health (NIOSH), but questions of fair play in government regulation. Even the conduct of the director of NIOSH, John F. Finklea, a respected but controversial federal official, has come under question, because he engaged in a telephone conversation that industry says was a naked threat to intimidate industry witnesses.

The focus of the controversy is a study done by NIOSH which concludes that, among the beryllium workers employed since the 1940's at a plant in Reading, Pennsylvania, the incidence of fatal lung cancer was unusually high. Industry has accused NIOSH of "gerrymandering" its data to produce this result. Joseph K. Wagoner, who is a principal author of the study and is now a special assistant to the director of the Occupational Safety and Health Administration (OSHA), which must decide on beryllium's carcinogenicity, defends the study, saying the deficiencies are due to industry's poor records.

"There is absolutely no doubt in my mind that beryllium is a human carcinogen," Wagoner told *Science*. But Wagoner and other officials stress that sound epidemiology is hard to do because industry may be tampering with or destorying worker records. The beryllium companies deny doing any improper meddling. They would like to see the study redone, or another study made of a separate cohort of beryllium workers. Wagoner, however, says another study "will mean more delay and increased risk to the health of the American worker."

The study, known as Bayliss III because it is the third study of beryllium workers by NIOSH bench scientist David L. Bayliss, is crucial to the determination of a new standard for beryllium. NIOSH proposed a new standard on the basis of animal data in 1975. The industry has argued that the animal data are an insufficient base for the new standard because the animal data are negative for beryllium copper, the form to which some 70 percent of all the industry's workers are exposed. The government's case, based only on animal data, therefore looks iffy.

But Bayliss III, claiming on epidemiological grounds that human beings exposed to beryllium incur a lung cancer risk, has strengthened the government's case. If the study is considered acceptable, it will increase the likelihood that the Administrator of OSHA, which is part of the Department of Labor, will approve a new, stricter standard and that the courts would uphold a subsequent appeal. But by the same token the study has caused the industry great alarm.

Aside from the questions of scientific merit and fair play, the NIOSH beryllium controversy also involves the issue of when animal data alone can be the basis of federal standard setting, and what level of human epidemiological evidence should serve as allowable in federal regulation. These questions are all the more important now because the OSHA's new director, Eula Bingham, is a former cancer scientist, who has announced a new, get-tough stance on regulating carcinogens in the workplace (*Science*, 21 October).

Toxicity of Beryllium

The beryllium industry came of age in the 1940's, when there was increased demand for the tough, lightweight, heat-resistant metal during the Second World War. Since then, beryllium has been widely used in electronics and missile parts, and in other applications. But from the start it was known that beryllium is toxic to humans; it causes a disease known as berylliosis. Since the 1940's then, the industry has had to limit exposures to 2 micrograms per cubic meter for workers.

Although animal data linking beryllium to tumors in some animals have been around for years, NIOSH only recently (in 1972) issued a "criteria" document laying out the case against the metal as carcinogenic. In 1975, NIOSH proposed that the 2 microgram per cubic meter standard be lowered to 0.5 microgram per cubic meter. Industry has responded that such a change is unwarranted by the scientific evidence and that the lower standard is technically impossible.

It seems that in the early 1970's few people paid much attention to the possible carcinogenic potential of beryllium to humans, particularly since the only two well-known studies of the subject, known as Bayliss I and Bayliss II (published in 1971 and 1972) examined large cohorts of beryllium workers at several plants and found no unusual incidence of lung cancer. But at some point, Bayliss and Wagoner decided to restudy the life histories of workers at a single plant. They picked one at Reading, owned by Kawecki Berylco Industries, Inc. (KBI). In early 1977, OSHA scheduled a hearing on the proposed new standard; the two major producers of beryllium, KBI and Brush Wellman, Inc., who knew of the existence of a new study partly because it had been reported in a Cleveland, Ohio, newspaper, began asking NIOSH for the data it was examining. In March, Brush hired a Washington consulting firm, Equitable Environmental Health Corp., to handle the human epidemiological issues relating to the proposed standard.

At this time, there began a series of events through which each side has become embittered, with each accusing the other of harassment, obstructionism, and bad faith. The entire controversy, and many of the associated emotions, were aired on the public record in August and September during the hearing.

The industry charges, first, that NIOSH did not make a good faith effort to turn over its data on the more than 3000 Reading workers it was using as the basis of Bayliss III, so that industry could check NIOSH's calculations and conclusions. Brush's Vice President, Martin B. Powers, testified that "throughout 1976" the company made both informal and formal Freedom of Information Act requests to obtain the data. Although NIOSH kept giving the industry other information and documents, it did not hand over the Bayliss II paper or accompanying backup until 1 July 1977, shortly after officials met with OSHA's Bingham, and threatened to sue if the material was not forthcoming. Indeed, it seems that, throughout the hearing NIOSH continued to hand over information at the last minute, and then only in response to formal, freedom of information act requests—in some instances 72 hours, or 48 hours, before industry was to present expert testimony on the material.

NIOSH's version of these events is that the repeated freedom of information

requests were intended to paralyze NIOSH's attempts to get its beryllium study finished for the hearing. Said Peter Infante of the NIOSH Cincinnati staff, where he and Bayliss were working on it, "They strap you down with all those requests. They had the whole staff battened down to the point where we couldn't get our own work done . . . We could have met the [hearing] deadline easily if we hadn't had those requests."

In any event, industry received a copy of the Bayliss III paper—which turned out to be a first version, a second was submitted at the hearing—on 1 July, and turned it over to Equitable, when another incident occurred. Industry charges that Finklea, through a telephone threat, caused Equitable to cease working with Brush and to prevent one of its scientists, Michael Utidjian, from testifying on the deficiencies in the NIOSH study.

According to the hearing transcript, on 12 August, 4 days before the hearing was to begin, Finklea telephoned William Malloy, the executive vice president of Equitable, and "suggested that there might be a conflict of interest on Dr. Utidjian's part if he participated in the hearing on Brush's behalf." Finklea was referring to the fact that Utidjian was also working on Equitable's NIOSH contracts to prepare criteria documents on other substances. The following day Malloy ordered Utidjian off the Brush contract and told Brush that Equitable would not participate further.

Brush officials say the call was tantamount to a threat of the loss of NIOSH business if Equitable did not stop working for the beryllium industry. Brush may sue Equitable for breach of contract, while another Equitable official, a beryllium expert, who objected to Malloy's decision is leaving the company.

Finklea was abroad for several weeks and could not be reached for comment on this incident. Both Wagoner and Howard Walderman, a lawyer who works on NIOSH matters, declined to comment on Finklea's actions and what he really intended to accomplish. At the hearing, Finklea defended himself by saying that he wanted "Mr. Malloy to look at the contract he had with the Federal government, which had a clause in which people were seeking to avoid the appearance as well as any actual conflict of interest. I expressed concern about that and . . . just called that to his attention."

But Edward J. Baier, deputy director of NIOSH, told *Science* that Finklea had been under the impression that Utidjian was working full time on NIOSH work, and became alarmed when he saw Utidjian's name on the industry witness list. But in Finklea's absence, Baier declined comment on why Finklea made his concern known by a phone call to Utidjian's boss, instead of by a more conventional route.

Industry is also charging foul play because NIOSH did not produce the principal author of the paper, Bayliss, at the hearing. By all accounts, on 16 August when the hearing began, Bayliss was on leave from his NIOSH job in Cincinnati and was registering as a doctoral student in the department of epidemiology at the University of North Carolina.

Industry believes that Bayliss was deliberately kept away because his testimony would have admitted the weaknesses in the case against beryllium.

NIOSH's Wagoner, who was Bayliss' superior at the time, told *Science*, "Bayliss didn't want to testify. We asked him and he said he didn't want to come."

Science located Bayliss in North Carolina, where he gave his version of these events. Bayliss says he received a phone call from his boss's boss, Finklea, the Friday before he was to register. "He said he wanted it to be known that an invitation stands if I cared to testify. He indicated that Wagoner could handle the whole thing though, so I said I didn't see any need for me to go." He says NIOSH has barely contacted him since, and that he learned of the "Where's Bayliss" controversy through "a third party who had access to an OSHA newsletter."

Study Under Fire

Besides the fair play issues, the Bayliss II study has become the major focus of the controversy. Brush's president and chief executive officer, Robert W. Biggs, claims that the study is "slanted" and that the cohort of workers has been "gerrymandered" to come to the conclusion that beryllium workers have an increased risk of getting lung cancer. NIOSH counters that any errors that have been found in the paper are "insignificant." Wagoner told *Science* that the Bayliss study, and another one produced by Thomas Mancuso on the first day of the hearings showing an increased risk, "converges" with the animal data presenting a total case that is "irrefutable."

Bayliss III examined the histories of 3070 workers, who worked at the Reading KBI plant, between January 1942 and December, 1967. The study calculated the expected number of deaths from lung cancer for the group at 33. The conclusion that beryllium is linked to lung cancer hinged on the fact that the observed number of lung cancer deaths was larger, namely 46.

At the hearing, Brush's statistical consultant H. Daniel Roth, testified that the results were impossible to verify because the tables that he received in July on 3070 individuals showed no birth dates for 70 percent of the cohort, or everyone listed as alive. Since the ages of the majority of the cohort were unknown, it was impossible to replicate NIOSH's life table analysis or verify its expected lung cancer death rates.

The NIOSH paper presented blocks showing that the largest number of lung cancer deaths occurred among workers employed at the Reading plant 5 years or less. But examining the 46 cases of lung cancer death, name by name, Roth found that 4 who had been classified as being there for approximately 20 years actually worked there a year or less. Moreover, Roth found of the 46, some 30 had been there fewer than 1 year, 24 had worked there fewer than 6 months, and 17 had worked there fewer than 3 months. Both Roth and other expert witnesses testified they knew of no theory of cancer where the risk increased as the length of time of exposure shortened. (In an interview, Wagoner admitted he knew that a large number of the deaths were among people who had been employed less than a year. Asked why this fact was not mentioned in the paper, Wagoner replied, "I don't know what it would have meant.")

Roth claimed that the "excess" of 46 lung cancer deaths as compared to the expected 33 is explained by correcting for smoking and the plant's location. The Bayliss III paper used the assumption that smoking habits of the cohort were similar to those of U.S. males in 1964. Although the paper acknowledged that a 1968 plant survey showed smoking at the plant to be higher than this figure, it was discounted on the grounds that the county in which the plant is located was below national average.

Factoring in the actual 1968 smoking data instead of assumed 1964 data, Roth calculated the expected lung cancer deaths among the cohort to be 38 to 44—numbers which eliminate the statistical significance of the observed value of 46.

But Roth pointed out that the lung cancer death rate in Reading itself—an old industrial town—was much higher than both the surrounding county and the U.S. as a whole. In fact, applying the Reading rate to the KBI plant population, Roth says, the expected lung cancer deaths became even more than those actually observed.

Wagoner, interviewed about the specifics of the study, admitted that there were deficiencies in the information available on the cohort of workers. "We

had some people whom we weren't sure whether they were alive or dead," he said, "so we assumed they were alive." He explained the shifting size of the cohort, which at different times numbered 3070, 3201, and 3055, was because NIOSH was trying to square its information with that offered by Mancuso in his study, which included some Reading workers. Industry's position on the Mancuso study is that it should be stricken from the record, since the paper seems not to mention smoking at all, and since Mancuso has said he would give his backup data to the industry but has failed to do so.

Interestingly, the authors of the Bayliss study differ on how strong a case their paper makes. Bayliss told *Science*, "I thought there was a pretty, reasonably strong case, but of course that's a judgmental matter." Wagoner, in a separate interview, maintained that the evidence was all "converging" and the case "irrefutable." Infante said: "The results and the interpretation don't change. We had to keep stating, defining, who the cohort was . . . We know what the meal is, but we have to go out and buy the meat and vegetables."

The hearing ended in September, but the administrative judge before whom it was held, has allowed until mid-December for posthearing submissions. On the NIOSH side, these include a fourth Bayliss paper. Industry will submit the most comprehensive rebuttal yet to the Bayliss and Mancuso studies.

Warfare Continues

But the warfare continues. Brush's vice president, Powers, questions whether the hearing record will make any difference, since Wagoner, one of the most ardent supporters of a new beryllium standard, recently moved to OSHA to be Eula Bingham's special assistant. Industry believes that Wagoner should not participate in Bingham's decision-making on beryllium, and is seeking a written reply from Bingham on Wagoner's role.

Brian MacMahon, professor of epidemiology at Harvard, has gone over the latest cohort tape which has 3055 workers and 47 lung cancer deaths. The added lung cancer death is that of a man who was hired and terminated on the same day. *Science* asked Wagoner whether he knew of the man's brief employment. "I guess we didn't have that information" he replied.

So the parties to the controversy seem locked in an epidemiological treadmill, with NIOSH blaming the problems in its cohort data on industry, and industry blaming the "slanted" data on NIOSH.

In the long run, the controversy's importance lies not so much in whatever the beryllium industry ultimately knuckles under to a new tighter, standard. It is more important as a precedent, for beryllium is among the first of many alleged carcinogens on which OSHA's Bingham will have to rule.

These decisions will have their political element; that is, Bingham will want to not only protect American workers but to give the appearance of protecting American workers. But she will also have to judge whether the scientific evidence in each case ultimately supports or erodes those political decisions.

—DEBORAH SHAPLEY

National Laboratories: Focused Goals and Field Work Hinted Under DOE

Even before the federal energy agency underwent two face-liftings, people were saying that the national laboratories were declining in importance and were in need of new missions. Their old roles—as practitioners of basic research, nuclear reactor development and weapons design—proved to be embarrassingly narrow when the Energy Research and Development Administration (ERDA) inherited the labs from the Atomic Energy Commission in 1975. Although ERDA expanded the breadth of energy research at many of the individual laboratories, it never quite determined what should be the laboratories' role in the national energy program.

In the 2 months since the Department of Energy inherited all of ERDA's former programs, officials of the new energy agency have been crisscrossing the airways to inspect some of their 25 laboratories and research centers. The new undersecretary of the department has visited three laboratories in the west, Sandia, Los Alamos, and Livermore. The man who had primary responsibility for getting the new department running, Tom Reed, has visited a number of east coast labs. The major laboratory directors have also met with the undersecretary as a group. The message in these meetings has been that no abrupt changes will occur, but the past roles of the labs are being analyzed carefully and their future roles may gradually change.

Soundings taken in Washington when the energy department was inaugurated in early fall raised a number of problems. The laboratories had accumulated a multitude of new programs to spearhead ERDA's acceleration of energy research. Some critics said that the labs spend too much money on projects that are not put up for bids and that their expenditures would be more productive if brought under zero-based budgeting. The various laboratories have enjoyed considerable autonomy during most of their history.

On paper there are reasons for the laboratories to worry about losing their independence. The reorganization that accompanied the formation of the energy department created two new vehicles for monitoring the work of the various laboratories at the highest levels of the agency. For their institutional needs, the laboratories will no longer report to regional operations offices but will report to an administrator at the rank of assistant secretary in the department. In addition, the laboratories will be regularly scrutinized by a newly created council composed of all the line administrators of the department. The council will be chaired by the same man who has responsibility for day-to-day coordination of all the department's energy research activities, Undersecretary Dale D. Meyers, and that may be an indication of how closely the laboratories' efforts will eventually be interwoven into the whole research and development fabric.

Whatever develops in the new department's relations with the field, the possibility that the changes pose a threat to the traditional independence of the laboratories is taken seriously in some quarters. Two weeks ago the House Science and Technology Committee called in the directors of eight major labs to testify in a hastily arranged hearing that had no apparent routine purpose. Some observers thought that the committee, which has