

How surgeon's probe led to vinyl hazard findings

Earl was 58—getting close to retirement. He'd worked 27 years at the B.F. Goodrich plant in Louisville, making polyvinyl chloride (PVC) for plastics.

But he had these pains. His belly was swollen. His skin looked yellowish.

So he went to see his doctor, last July, who sent him to surgeon John L. Creech, MD, for a liver biopsy. Dr. Creech was also the part-time plant physician at Goodrich, so he and Earl knew each other. Dr. Creech performed two biopsies, and both times the lab reports indicated severe cirrhosis.

Earl died on Dec. 19, 1973. An autopsy found cirrhosis, all right, but it found something else, too: angiosarcoma in the liver.

DR. CREECH knew something about angiosarcoma. He had seen a case of it once, in 1954 as a resident at Houston's M.D. Anderson Hospital. He knew it was fatal and incurable. He also knew it was extremely rare—less than 25 cases reported annually in the U.S.

Interesting. Dr. Creech seemed to recall that another Goodrich worker had died of liver angiosarcoma in 1968. He went back to the plant's dispensary and

pulled the health records of every deceased employee, and called a few pathologists around town.

He came up with a total of four cases of angiosarcoma of the liver in the past six years—all among the 270 workers in the vinyl chloride polymerization section of the plant.

A morbidity rate 100,000 times the national average was no coincidence—it didn't take an epidemiologist to see that.

"I'm not a researcher, I don't read any of that literature," Dr. Creech told AMN. "I'm a damn good surgeon, but not even a very good medical man. But I tend to notice things like this—it's just a quirk of mine."

"I REMEMBERED that first boy, the one who died in '68. At the time I didn't realize the significance of it. After the second case, I began to get curious." A Louisville pathologist had also diagnosed two angiosarcomas among Goodrich workers, "but he didn't make the connection."

Dr. Creech did. He quickly called Maurice N. Johnson, MD, director of environmental health for B.F. Goodrich.

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Surgeons investigation launched worldwide probe of vinyl chloride

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Over Christmas, they worked up a report of the Louisville findings, and in January met with officials of the National Institute for Occupational Safety and Health (NIOSH).

When the report was made public, it sent shock waves through the plastics industry, government, labor, and the press.

Vinyl chloride, a pleasant-smelling gas, and PVC, a powdery white crystal, are the basis of a vast plastics industry. Some 6,500 workers, in 37 plants in the U.S., are directly involved in the polymerization of vinyl chloride. Some 4.8 billion pounds of vinyl chloride, and 4.4 billion pounds of PVC, are produced each year in this country—and an equivalent amount in Europe.

IN ADDITION, vinyl chloride is a common propellant for many household aerosols, such as hair spray, and PVC is the main ingredient in thousands of plastic products.

NIOSH and the Center for Disease Control (CDC) in Atlanta immediately began the immense detective job of digging out records on all the vinyl chloride polymerization workers in the country, and analyzing them for angiosarcoma figures—and anything else they might run across.

Gradually, a grim trend was revealed: to date, there are 14 verified cases of angiosarcoma, in four plants—Niagara Falls, N.Y. (Goodyear); Wheeling, W. Va. (Union Carbide); Pottstown, Pa., and Louisville (B.F. Goodrich).

In addition to angiosarcoma, unusually high morbidity rates were found for variously diagnosed ailments of liver, spleen, pancreas, and gall bladder.

THE PARTIAL results of the investigation—not yet completed—showed a sketchy pattern. The Louisville plant accounted for half the recorded angiosarcoma deaths, reported NIOSH investigator Joseph K. Wagoner, MD, possibly because it was the first PVC plant in the U.S., open since 1940.

Clark W. Heath, MD, of the CDC Bureau of Epidemiology, found that 12 years was the average time spent handling vinyl chloride by workers who died of angiosarcoma; the shortest time was six years. The earliest case was diagnosed in 1961, two decades after PVC was first produced industrially.

Complicating the problem is the fact that angiosarcoma may not always have been correctly diagnosed. "Any competent pathologist could readily diagnose it," said Hans Popper, MD, of the NIOSH group, "but you would have to be looking for it."

More than one researcher has commented that 14 deaths since 1961 is hardly a crisis—but angiosarcoma might well turn out to be only one piece in a big toxicological puzzle.

In February, NIOSH passed its tentative findings on to the U.S. Dept. of Labor's Occupational Safety and Health Administration (OSHA), which announced it was immediately lowering the federal maximum on airborne vinyl chloride in PVC plants from 500 ppm (parts per million) to 50 ppm.

The standard had been set at 500 ppm ten years ago, for two reasons: first, a Dow Chemical Co. scientist had found liver damage in some rats exposed to 500 ppm or better of vinyl chloride; and second, the gas was also suspected of causing a bone-eroding disease called acroosteolysis.

But plastics manufacturers responded to the OSHA edict by pointing out near-

ly all plants had set their own limits at 50 ppm a decade ago. (Dr. Creech had been instrumental in the acroosteolysis findings, too.) Yet most of the angiosarcomas cropped up after that.

OSHA THEN declared an "alert" and told the plants to take immediate steps to reduce vinyl chloride concentrations as much as possible—using better ventilation, respirators, or whatever means were feasible.

At the same time, the U.S. Consumer Products Safety Commission announced it intended to ban the use of vinyl chloride gas as a propellant for household aerosol products. Manufacturers were told to submit to the government any data they had on the gas—and to

find a substitute for vinyl chloride.

Marcus M. Key, MD, director of NIOSH, announced that vinyl chloride research was now number one priority at the institute. He used the occasion to complain that NIOSH, due to substantial budget cuts, was severely limited in research funds, and could not do as effective a job as it should in keeping tabs on the entire field of occupational health. The institute had to drop nearly every other project on the boards to pursue the vinyl chloride investigation.

The vinyl chloride mini-crisis culminated in a hastily convened meeting of scientists in New York on May 10-11, under the auspices of the New York Academy of Sciences. A "working group" of scientists in several nations

had been quickly formed six weeks before, and in New York they presented their confusing and half-completed data before an audience of 800 physicians, scientists, and labor and industry representatives from all over the world.

There was tension behind the scenes at the conference, as scientists confronted each other with charges of plagiarism and poor methodology, and of "publicity-grabbing" in a hot new research field.

There also was a large and clamoring contingent of newsmen there, persistently questioning scientists to prove that either NIOSH or the PVC manufacturers had been negligent in not heeding early research that warned of dangers in vinyl chloride. "If you ask me, they did prove it," admitted one scientist who participated in a raucous press conference.

AS EARLY AS 1945, in the infancy of PVC production, a team of Soviet sci-

tists reported in a Russian journal that PVC workers were found to have very high morbidity rates for liver diseases, but nobody paid any attention to it at the time—not even the Russians.

In 1960, the Dow Chemical Co. report on liver damage in rats exposed to vinyl chloride was made public; that led to the federal limit of 500 ppm. The acroosteolysis among men who cleaned out vinyl chloride vats was discovered next—by Dr. Creech—and by that time, the plants decided to voluntarily lower the gas concentrations with better ventilating systems to about 50 ppm. Vat cleaning procedures were changed, and workers required to wear rubber gloves. That had seemed, at the time, to be an adequate solution.

But in 1970, Italian scientist P.L. Viola reported that vinyl chloride in extremely high concentrations (up to 30,000 ppm) caused tumors in rats. Cesare Maltoni, MD, of Italy's U. of Bologna, reaffirmed

Viola's work in 1972 with comprehensive studies producing a wide variety of carcinomas in rats exposed to various amounts of the gas, from 30,000 ppm to 50 ppm; three very old rats had developed tumors in a relatively short time v
posure to 50 ppm.

Representatives of NIOSH and the Manufacturing Chemists Assn. (MCA) had by chance visited Dr. Maltoni's labs a year ago, and were told of the findings (which were also published in Italian and French medical journals). But nothing happened.

Much of this research had also been discussed at an international cancer symposium in 1972 in Dallas. Yet somehow, neither government nor industry did or said anything related to vinyl chloride until Dr. Creech informed B.F. Goodrich officials of his findings in December, 1973.

It is ironic, Dr. Creech said, that an ordinary practicing surgeon (he works only one day a week at Good-

rich, and is also on the clinical faculty of the U. of Louisville School of Medicine) should make two such epidemiological discoveries in a row.

When his friend, Earl, the Goodrich worker, died on Dec. 19, Dr. Creech notes, he had never heard of either Viola or Maltoni, and knew nothing of their work. "I don't have time for all that, to tell you the truth."

EVENTUALLY, the New York conference gradually brought out a vague picture of vinyl chloride toxicology that is more ominous than it first appeared to be.

German scientists at the U. of Bonn, headed by W. K. Leibach, MD, identified in German PVC workers a syndrome they called "vinyl chloride disease." Characterized by an increasing reticulated fibrosis generally through the liver, it was found to some degree in 25% of all German PVC workers examined.

Based on a variety of findings pieced together, the fibrosis was tentatively identified as a probable precursor of cancer. And, it was discovered, workers who had developed the fibrosis and then left the PVC plants continued to get worse instead of better.

In addition, Leibach said that the German team found six workers with "vinyl chloride disease" who had never worked in the vinyl chloride polymerization process—instead, they made floor tiles from raw PVC. Apparently, there were enough traces of vinyl chloride in the raw PVC to cause illness; yet it was an indication that it certainly didn't take high prolonged concentrations to produce the syndrome.

THERE WAS some discussion at the conference about whether the PVC plants should be closed down until the safety of the workers could be guaranteed—but many of the "working group" members strongly opposed the idea.

"You're all asking questions as if we had done our homework," snapped an irritated Irving J. Selikoff, MD, at news reporters present. "Well, we haven't done our homework. You want us to make guesses—but we need more hard data."

Yet Dr. Selikoff later declared that "we have a multi-system disease here. It's been demonstrated that wherever the arteries go, disease shows up." Dr. Selikoff, of New York's Mount Sinai Medical Center, led a team of 14 researchers to Goodyear's Niagara plant last month to conduct a full-scale screening of the 240 employees in the PVC-producing sections there.

Another complication added to the studies is the difficulty of diagnosing any of the vinyl chloride-linked diseases in living workers. "Liver biopsy is not a very good method of detecting either angiosarcoma or the general lesion," said Dr. Popper.

"We have a rather pessimistic outlook on conventional liver screening," agreed CDC's Dr. Heath. "We urgently need some new method."

For the time being, nobody knows quite what to do. OSHA has proposed to chemical and plastics makers for discussion a possible plant standard of "less than one" ppm—but the major manufacturers almost immediately rejected it as impossible.

MEANWHILE, NIOSH and others have separated out a cohort of PVC workers for what Dr. Selikoff called a "retrospective-prospective" study. These workers were able to provide accurate health records going back many years; they were carefully screened, and their smoking and drinking habits, etc., were noted, and now they will be followed for as long as it takes to identify causal factors.

Dr. Creech, after presenting his paper to the conference, went home disgusted. He called the conference "nothing but a political move—they've got no damn business publicizing some of these things."

And he was unimpressed by the august scientific types who attended the meeting. "They're dealing with rats, but I'm dealing with people."

"We don't have mice in Louisville, but we do have test animals. Unfortunately, they're the two-legged kind. I could have stayed home and done a hell of a lot more work here."

The work Dr. Creech intends to do, between office hours, operating time, and screening exams for Goodrich workers, is to start his own vinyl chloride research project at the U. of Louisville. □