

IN THESE TIMES MAY 11-17, 1983 3

IN THESE TIMES

IBT Labs' trial reveals faked data

By Keith Schneider

THE TRIAL OF FOUR TOP OFFICIALS of Industrial Bio-Test Laboratories (IBT), at one time the nation's largest independent chemical testing firm, is underway here, seven years after federal investigators uncovered what they allege is the most massive scientific fraud in U.S. history.

IBT, headquartered in Northbrook, Ill., 25 miles north of Chicago, conducted thousands of research projects during the '70s for almost every major American chemical and drug manufacturer as well as dozens of foreign firms and several federal agencies. Established in 1953, IBT employed 350 people, collected annual revenues close to \$10 million and performed more than 1,500 studies a year in its main Northbrook facility and its two satellite labs. Almost half of IBT's studies were used by the U.S. Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) to register a wide array of products, ranging from insecticides and herbicides to pharmaceuticals and food additives.

In May 1981, after a five-year joint FDA/U.S. Justice Department probe, IBT President Dr. Joseph C. Calandra and three of his associates were indicted in Chicago by a special federal grand jury. The four are each charged with eight counts of conducting and distributing fake scientific research and then of attempting to cover up the scheme.

After several postponements, the IBT trial began here on April 4. If convicted on all counts, the officials face up to 40 years in prison and fines totaling more than \$40,000. Federal prosecutors predict the trial may last up to three months.

The four officials claim they are innocent and have hired some of the Midwest's top trial attorneys to defend them. In the months following the indictment, the defendants filed stacks of legal motions seeking dismissal of the charges. They insist that FDA and Justice Department agents "harassed, abused, misled, bullied, intimidated and coerced" key witnesses in order to make their case. Chief FDA investigator Carlton Sharp is accused of "abuse of the grand jury" because he knowingly presented "false, misleading and inflammatory" statements during his two grand jury appearances.

Similar tactics were employed by defense attorneys in two previous cases prosecuted several years ago by U.S. attorneys here. In the first case in 1977, an 11-count indictment was returned against the Velsicol Chemical Company on charges of concealing the fact that two insecticides, chlordane and heptachlor, were proven carcinogens. The case was dismissed in 1979 on procedural grounds.

U.S. attorneys were frustrated once again in 1980 in a case against the G.D. Searle Company, a major pharmaceutical manufacturer. In that case, Chicago prosecutors couldn't gain an indictment. But in the IBT case, the prosecutors successfully answered each motion.

During the trial, prosecutors not only hope to prove the defendants' guilt, but also will outline what they claim is a pattern of chemical company knowledge of the fraudulent research taking place at IBT and in some cases, promotion of those practices by chemical company executives in order to secure the kind of results they knew would pass registration standards at FDA and EPA. Said one Justice Department investigator, "IBT became the largest testing lab in the country because

companies knew this was the place to get the results they wanted."

A primary example, the prosecutors allege, is the case of defendant Paul Wright. Before he joined IBT in March 1971, Wright was employed as a toxicologist by Monsanto Corp. in St. Louis. FDA investigators say Wright went to IBT to manage Monsanto's contract with IBT to test the safety of the company's antibacterial agent TCC, which is widely used in popular deodorant soaps.

TCC was under investigation by the FDA for causing lesions in laboratory rats fed the compound. At that time, Monsanto was counting on TCC as a major product to replace hexachlorophene, another antibacterial that had just been withdrawn from the American market. Monsanto needed a "clean" IBT study to convince the FDA that TCC was safe so the agency would allow increases in the levels of TCC in some deodorant soaps. Wright stayed on IBT's payroll for 18 months, long enough to supervise most of the TCC research. He then returned to Monsanto where he was named manager of toxicology for the department of medicine and environmental health.

While at Monsanto, according to prosecutors and witnesses, Wright wrote

several critical sections of the final TCC summary report and pressured a key IBT scientist into reversing his finding that TCC did, in fact, cause lesions in laboratory rats. The sections Wright authored were included in the IBT summary report mailed to the FDA in 1976. The agency eventually approved raising the levels of TCC in some soaps.

IBT's test of TCC was only one of 22,000 toxicology studies the lab performed in the quarter century it operated. It has been estimated that between 35 to 40 percent of all toxicology tests in the country were conducted by IBT.

Until recently, the details of the joint investigation were untouchable as prosecuting attorneys, defendants and witnesses declined to comment pending the outcome of the case. In December, however, as part of a motion to dismiss the case made by Calandra's attorneys, almost 1,000 pages of secret grand jury testimony and related documents were made public in U.S. District Court. These documents, reinforced by the first days of trial testimony, reveal a disturbing pattern of scientific ethics giving way to business greed. The pages of grand jury testimony are filled with descriptions of employees working in cramped and filthy facilities while massive rodent

deaths went unreported and summary tables were filled with phony numbers. The Justice Department prosecution covers the period between 1970-76 and involves fraudulent research alleged to have been conducted on four compounds: the insecticide Nemacur and the herbicide Sencor produced by Chemagro Corp., now owned by Mobay Chemical Co.; the drug Naprosyn, manufactured by Syntex Corp., to treat arthritis swelling; and Monsanto Corp.'s antibacterial agent TCC.

The government charges: Chemagro paid for two 18-month mice studies that IBT actually conducted for only 14 months. Throughout the study, large numbers of mice died and were replaced without being properly documented. The final mortality summary tables for the Nemacur and Sencor reports were faked. Moreover, IBT never fed a known animal carcinogen to a control group of mice in order to make comparisons with the study group. So the results from this study were also faked. Syntex Corp. contracted with IBT

Continued on page 6

The rise and fall of IBT

When Joseph Calandra founded IBT in 1953, the 35-year-old graduate of the Northwestern University School of Medicine was a man of high scientific standards who also knew how to make a dollar, according to his colleagues. He knew that a toxicology lab that contracted its services was a growth business for the future since the federal government was gradually increasing the standards required for registration. Manufacturers, pressed to account for the safety of their products, needed firms to prepare the scientific research.

From the start, Calandra had a prize client: the Pentagon. Between 1953 and 1977, in an effort to discover better ways to preserve food for troops during the war, the Pentagon paid IBT more than \$8 million to carry out a long-term study in which irradiated beef was fed to mice and rats.

Throughout the '50s and early '60s, IBT's growth lagged far behind the demand for its services. The lab's reputation circulated quickly through the science and development areas of corporate America: IBT's work was good. It was moderately priced. Most important, it passed examination in Washington.

While its finances were closely guarded, several estimates put IBT's revenues in the mid-'60s at close to \$2 million an-

nually, enough to attract the attention of the officers of Nalco Chemical Co. (1981 revenues: \$666.3 million), a specialty chemicals manufacturer based in Oak Brook. In 1966 Nalco bought IBT from Calandra for a reported \$4.3 million. Calandra remained as president. Backed by Nalco's millions, Calandra began a program of expansion to turn his pioneering lab into America's largest chemical testing firm. Two smaller labs were built. In 1968, construction began on a \$2 million, four-story research building.

During the same period, events in Washington turned a river of business IBT's way. By the end of the '60s, the environmental movement was a powerful force, compelling President Richard Nixon to establish the EPA in 1970. With the agency came publication of dramatically more stringent regulations for pesticide registration and use, requiring a broad range of scientific studies.

IBT thought it was ready for the new business, welcoming its new clients with open arms. But it soon found itself in the position of having much more work than it could handle. Things started to get out of hand.

Take the "mouse hunts." According to Manny Reyna, an animal technician at IBT, the first time he was ordered out on a mouse hunt he thought it was a joke. But it wasn't. Armed with a plastic squeeze bottle filled with chloroform and outfitted in thick gloves and a white lab coat, Reyna found himself joining a squad of technicians in a search-and-destroy mission for rats and mice run-

ning wild at IBT.

Soon after he was hired at IBT in May 1971, Reyna realized that not all the rodents he tended finished their lives in cages. Every week dozens of research mice and rats squeezed through the bent wires of IBT's mangled cages, raced across the long wooden racks and dropped to the grimy floor to breed with rodents living behind tall stacks of animal bedding piled in the corners of the lab's feeding rooms. During the night mice climbed back up on the racks to feed on spilled food and feces, and they persisted in poking their snouts through the bottoms of cages. "For some reason they would cannibalize the toes of animals that were standing on the wire," Reyna testified in his grand jury appearance. "In the morning we would see that the toes had been chewed off. We were at a loss as to what to do. ... It was a never-ending battle."

So the temporary solution was a mouse hunt. For hours the armed squadron would flush rodents from cover and douse them with chloroform as they skittered past.

Reyna had other stories for federal investigators. For example, he said, more than once rats on two-year feeding studies were fed the wrong compound, something IBT never reported to its sponsors.

"We did a large volume of studies," Reyna told the grand jury. "No sooner would one study end than another would start. It seemed that the conditions were just so stressed—doing studies and finishing studies and starting new studies." —K.S.



905653

PLAINTIFF'S
EXHIBIT
1136

IBT

In These Times

Continued from page 3

for an 18-month rat study that IBT allowed to continue for four extra months. A critical section of the final report listing detailed blood and urine figures was faked. IBT also included an appendix to the report that listed complete autopsy and microscopic tissue analysis results. IBT scientists and technicians never conducted the examinations.

• Monsanto Corp. contracted with IBT for a 24-month rat feeding study on TCC. During the course of the study, hundreds of rats died without being properly documented. Yet IBT reported in its summary report that these rats finished their natural life spans and had been autopsied and microscopically examined. So many rats died during the study that IBT was forced to establish an extra set of animals to use as replacements. IBT called these animals the "research study group." Dr. Donovan Gordan, IBT's pathologist, was repeatedly pressured by Paul Wright and by IBT president Dr. Joseph Calandra to change his diagnosis that TCC caused dangerous lesions in rats fed the compound.

No matter the outcome of the trial, the IBT scandal leaves a legacy of falsified records and botched experiments. Each day most Americans contact chemicals, chiefly from pesticide residues contained in their food and water. IBT tested and found "non-hazardous." Since the IBT scandal was first reported, some chemicals have been declared by federal agencies to be harmful to human health and the environment. Many others are accused by researchers across the country of causing serious illnesses and environmental contamination.

In 1979, pathologists at the FDA, the EPA and in Canada and Sweden began an immense and complex program of auditing IBT studies. They have determined that more than 10,000 IBT studies were used to register products for the American market, and they consider 2,000 of these primary research; without these studies, the products would not have been registered. Most of these were for 325 insecticides and herbicides. American and Canadian scientists have called the vast majority of these studies "invalid." The manufacturers of the chemicals have been asked to repeat the studies, and the results for most will not be ready for review until 1985.

On this continent and in Europe, health authorities have begun to take regulatory action against chemicals registered with IBT data. Sweden recently outlawed eight IBT pesticides. Last year, after studying data on 113 pesticides, Canada outlawed six and severely restricted application of the fungicide captan.

The EPA's final report on 212 more pesticides registered with IBT data is due to be released this month or in June, according to Kevin Keany, an official with the Office of Pesticide Programs. And the EPA has suspended the use of the herbicide silvex (1979) and cancelled most uses of the insecticides DBCP (1979) and toxaphene (1982), which have been shown to be dangerous to human health and the environment. All three were registered with extensive IBT data that found them "safe."

■ *Keth Schneider is editor of SC Featured, an independent news service based in Charleston, S.C. This article is excerpted from the spring issue of The Amicus Journal. Research was funded by a grant from the Fund for Investigative Journalism.*

905654